



Istituto di Ricerche Farmacologiche Mario Negri - IRCCS
Department of Cardiovascular Medicine

COVER PID 80

Codebook ▾

Data Dictionary Codebook

30/09/2021 14:22

[^ Collapse all instruments](#)

#	Variable / Field Name	Field Label <i>Field Note</i>	Field Attributes (Field Type, Validation, Choices, Calculations, etc.)
Instrument: RANDOMIZATION (randomization)			<div>⤴ Collapse</div>
1	record_id	Record ID	text
2	cov2_positive	Positive sample for SARS-CoV-2 Nasopharyngeal swab (to be stored at -80 °C after exam)	radio <div><div>1yes</div><div>2no</div></div> <div>Custom alignment: RH</div>
3	date_cov2_p <div>Show the field ONLY if: [cov2_positive]=1</div>	Date of nasopharyngeal swab	text (date_dmy)
4	infcons <div>Show the field ONLY if: [cov2_positive]=1</div>	Informed consent	radio <div><div>1yes</div><div>2no</div></div> <div>Custom alignment: RH</div>
5	date_ic <div>Show the field ONLY if: [infcons]=1</div>	Date of informed consent acquisition	text (date_dmy)
6	alert_infcons_mandatory <div>Show the field ONLY if: [infcons]=2</div>	The informed consent is mandatory	descriptive
7	ic_age <div>Show the field ONLY if: [infcons]=1</div>	Section Header: <i>Inclusion criteria</i> 1. Age (>=18 years)	radio <div><div>1yes</div><div>2no</div></div> <div>Custom alignment: RH</div>
8	ic_cov2 <div>Show the field ONLY if: [infcons]=1</div>	2. Positivity at RT-PCR per SARS_CoV2 (nasopharyngeal swab)	radio <div><div>1yes</div><div>2no</div></div> <div>Custom alignment: RH</div>
9	ic_severity <div>Show the field ONLY if: [infcons]=1</div>	3. COVID-19 Severity Score: (< 3)	dropdown <div><div>11 no limitation of activities</div><div>22 limitation of activities</div><div>33 hospitalized, no oxygen therapy</div><div>44 hospitalized, oxygen by mask or nasal prongs</div><div>55 non-invasive ventilation or high-flow oxygen</div><div>66 intubation and mechanical ventilation</div><div>77 ventilation + additional organ support - pressors, RRT (renal replacement therapy), ECMO (extracorporeal membrane oxygenation)</div><div>88 death</div></div> <div>Custom alignment: RH</div>

10	oral_drugs	4. Patient able to take oral drugs	radio <div>1 yes</div> <div>2 no</div> Custom alignment: RH
11	informed	5. Informed consent to study participation and personal data treatment	radio <div>1 yes</div> <div>2 no</div> Custom alignment: RH
12	inclusion_count	sum of inclusion	calc Calculation: $\text{sum}(\text{if}([\text{ic_age}]=1,1,0)+\text{if}([\text{ic_cov2}]=1,1,0)+\text{if}([\text{oral_drugs}]=1,1,0)+\text{if}(<3,1,0))$ Custom alignment: RH Field Annotation: @HIDDEN
13	ec_pregnant Show the field ONLY if: [infcons]=1	Section Header: <i>Exclusion criteria:</i> 1. Pregnant or lactating women (pregnancy test not required, if doubt patient is excluded)	radio (Matrix) <div>1 yes</div> <div>2 no</div>
14	ec_cns Show the field ONLY if: [infcons]=1	2. Subjects suffering from known CNS diseases	radio (Matrix) <div>1 yes</div> <div>2 no</div>
15	ec_informed Show the field ONLY if: [infcons]=1	3. Lack of (or inability to provide) informed consent	radio (Matrix) <div>1 yes</div> <div>2 no</div>
16	ec_dialysis Show the field ONLY if: [infcons]=1	4. Patient under dialysis	radio (Matrix) <div>1 yes</div> <div>2 no</div>
17	ec_6m_prognosis Show the field ONLY if: [infcons]=1	5. Any medical condition with prognosis < 6 months	radio (Matrix) <div>1 yes</div> <div>2 no</div>
18	ec_warfarin Show the field ONLY if: [infcons]=1	6. Patient under warfarin treatment	radio (Matrix) <div>1 yes</div> <div>2 no</div>
19	ec_antiviral Show the field ONLY if: [infcons]=1	7. Patient under antiviral treatment	radio (Matrix) <div>1 yes</div> <div>2 no</div>
20	ec_chloroquine Show the field ONLY if: [infcons]=1	8. Patient under chloroquine phosphate or hydroxychloroquine	radio (Matrix) <div>1 yes</div> <div>2 no</div>
21	exclusion_count	sum of exclusion	calc Calculation: $\text{sum}(\text{if}([\text{ec_pregnant}]=2,1,0)+\text{if}([\text{ec_cns}]=2,1,0)+\text{if}([\text{ec_informed}]=2,1,0))$ Custom alignment: RH Field Annotation: @HIDDEN
22	weight Show the field ONLY if: [inclusion_count]=5 AND [exclusion_count]=8	Weight: (Kg)	text (integer, Min: 40, Max: 200) Custom alignment: RH
23	height Show the field ONLY if: [inclusion_count]=5 AND [exclusion_count]=8	Height: (cm)	text (integer, Min: 80, Max: 230) Custom alignment: RH
24	alert_fill_inccxc Show the field ONLY if: ([ic_age]=" OR [ic_cov2]=" OR [oral_drugs]=" OR [informed]=" OR [ic_severity]=" OR [ec_pregnant]=" OR [ec_cns]=" OR [ec_informed]=" OR [ec_dialysis]=" OR [ec_6m_prognosis]=" OR [ec_warfarin]=" OR [ec_antiviral]=" OR [ec_chloroquine]=") AND [infcons]=1	The randomization is not available at this moment. Please, check all the inclusion/exclusion criteria	descriptive

25	<div>no_inc_alert</div> <div>Show the field ONLY if: [ic_age]=2 OR [ic_cov2]=2 OR [oral_drugs]=2 OR [informed]=2 OR ([ic_severity]>2 AND [ic_severity]<>") OR [ec_pregnant]=1 OR [ec_cns]=1 OR [ec_informed]=1 OR [ec_dialysis]=1 OR [ec_6m_prognosis]=1 OR [ec_warfarin]=1 OR [ec_antiviral]=1 OR [ec_chloroquine]=1</div>	The patient is not eligible for the randomization due to one or more inclusion/exclusion criteria	descriptive																																																																																														
26	<div>alert_positive_cov2</div> <div>Show the field ONLY if: [cov2_positive]=2</div>	There is no positive sample for SARS-CoV-2	descriptive Custom alignment: RH																																																																																														
27	<div>randomization</div> <div>Show the field ONLY if: [inclusion_count]=5 AND [exclusion_count]=8 AND [ic_severity]<>"</div>	<div>Section Header: <i>Randomization</i></div> <div>Randomization:</div>	<div>dropdown</div> <table><tr><td>CO-001</td><td>CO-001</td></tr><tr><td>CO-008</td><td>CO-008</td></tr><tr><td>CO-028</td><td>CO-028</td></tr><tr><td>CO-037</td><td>CO-037</td></tr><tr><td>CO-047</td><td>CO-047</td></tr><tr><td>CO-065</td><td>CO-065</td></tr><tr><td>CO-075</td><td>CO-075</td></tr><tr><td>CO-092</td><td>CO-092</td></tr><tr><td>CO-099</td><td>CO-099</td></tr><tr><td>CO-111</td><td>CO-111</td></tr><tr><td>CO-116</td><td>CO-116</td></tr><tr><td>CO-136</td><td>CO-136</td></tr><tr><td>CO-147</td><td>CO-147</td></tr><tr><td>CO-152</td><td>CO-152</td></tr><tr><td>CO-171</td><td>CO-171</td></tr><tr><td>CO-181</td><td>CO-181</td></tr><tr><td>CO-188</td><td>CO-188</td></tr><tr><td>CO-203</td><td>CO-203</td></tr><tr><td>CO-217</td><td>CO-217</td></tr><tr><td>CO-224</td><td>CO-224</td></tr><tr><td>CO-249</td><td>CO-249</td></tr><tr><td>CO-255</td><td>CO-255</td></tr><tr><td>CO-269</td><td>CO-269</td></tr><tr><td>CO-277</td><td>CO-277</td></tr><tr><td>CO-291</td><td>CO-291</td></tr><tr><td>CO-301</td><td>CO-301</td></tr><tr><td>CO-312</td><td>CO-312</td></tr><tr><td>CO-327</td><td>CO-327</td></tr><tr><td>CO-340</td><td>CO-340</td></tr><tr><td>CO-349</td><td>CO-349</td></tr><tr><td>CO-002</td><td>CO-002</td></tr><tr><td>CO-017</td><td>CO-017</td></tr><tr><td>CO-027</td><td>CO-027</td></tr><tr><td>CO-039</td><td>CO-039</td></tr><tr><td>CO-055</td><td>CO-055</td></tr><tr><td>CO-056</td><td>CO-056</td></tr><tr><td>CO-077</td><td>CO-077</td></tr><tr><td>CO-087</td><td>CO-087</td></tr><tr><td>CO-104</td><td>CO-104</td></tr><tr><td>CO-113</td><td>CO-113</td></tr><tr><td>CO-128</td><td>CO-128</td></tr><tr><td>CO-130</td><td>CO-130</td></tr><tr><td>CO-145</td><td>CO-145</td></tr><tr><td>CO-154</td><td>CO-154</td></tr><tr><td>CO-166</td><td>CO-166</td></tr><tr><td>CO-185</td><td>CO-185</td></tr><tr><td>CO-192</td><td>CO-192</td></tr></table>	CO-001	CO-001	CO-008	CO-008	CO-028	CO-028	CO-037	CO-037	CO-047	CO-047	CO-065	CO-065	CO-075	CO-075	CO-092	CO-092	CO-099	CO-099	CO-111	CO-111	CO-116	CO-116	CO-136	CO-136	CO-147	CO-147	CO-152	CO-152	CO-171	CO-171	CO-181	CO-181	CO-188	CO-188	CO-203	CO-203	CO-217	CO-217	CO-224	CO-224	CO-249	CO-249	CO-255	CO-255	CO-269	CO-269	CO-277	CO-277	CO-291	CO-291	CO-301	CO-301	CO-312	CO-312	CO-327	CO-327	CO-340	CO-340	CO-349	CO-349	CO-002	CO-002	CO-017	CO-017	CO-027	CO-027	CO-039	CO-039	CO-055	CO-055	CO-056	CO-056	CO-077	CO-077	CO-087	CO-087	CO-104	CO-104	CO-113	CO-113	CO-128	CO-128	CO-130	CO-130	CO-145	CO-145	CO-154	CO-154	CO-166	CO-166	CO-185	CO-185	CO-192	CO-192
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CO-393	CO-393																																								
CO-392	CO-392																																								
CO-407	CO-407																																								
CO-388	CO-388																																								
28	randomization_date	Randomization date	text (datetime_seconds_ymd) Field Annotation: @READONLY @HIDEBUTTON																																						
29	randomization_complete	Section Header: <i>Form Status</i> Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete																																
0	Incomplete																																								
1	Unverified																																								
2	Complete																																								
Instrument: BASELINE (baseline) <div>^ Collapse</div>																																									
30	alert_rnd Show the field ONLY if: [randomization]="	In order to fill this form, the patient must be randomized	descriptive																																						
31	bl_rnd Show the field ONLY if: [randomization]<"	Randomization code: [[randomization]]	descriptive																																						
32	bl_dov Show the field ONLY if: [randomization]<"	Date of visit	text (date_dmy), Required																																						
33	v1_setting Show the field ONLY if: [randomization]<"	Section Header: <i>DEMOGRAPHICS</i> Setting of first visit	radio, Required <table><tr><td>1</td><td>Home</td></tr><tr><td>2</td><td>Hospital emergency room</td></tr><tr><td>3</td><td>Hospital outpatient ambulatory care</td></tr><tr><td>4</td><td>Extra- Hospital outpatient ambulatory care</td></tr><tr><td>5</td><td>Other</td></tr></table>	1	Home	2	Hospital emergency room	3	Hospital outpatient ambulatory care	4	Extra- Hospital outpatient ambulatory care	5	Other																												
1	Home																																								
2	Hospital emergency room																																								
3	Hospital outpatient ambulatory care																																								
4	Extra- Hospital outpatient ambulatory care																																								
5	Other																																								
34	v1_setting_specify Show the field ONLY if: [v1_setting]=5	Specify	text, Required																																						
35	d_gender Show the field ONLY if: [randomization]<"	Gender	radio, Required <table><tr><td>1</td><td>M</td></tr><tr><td>2</td><td>F</td></tr><tr><td>3</td><td>Other</td></tr></table> <div>Custom alignment: RH</div>	1	M	2	F	3	Other																																
1	M																																								
2	F																																								
3	Other																																								
36	v1_age Show the field ONLY if: [randomization]<"	Age: (years)	text (integer, Min: 18, Max: 110), Required Custom alignment: RH																																						
37	v1_noo Show the field ONLY if: [randomization]<"	Nation of origin:	radio, Required <table><tr><td>1</td><td>European</td></tr><tr><td>2</td><td>Extra-European</td></tr></table> <div>Custom alignment: RH</div>	1	European	2	Extra-European																																		
1	European																																								
2	Extra-European																																								

38	v1_comorbidity Show the field ONLY if: [randomization]<>"	Section Header: <i>COMORBIDITY</i> Comorbidity	radio, Required 1 yes 2 no Custom alignment: RH
39	v1_c_respiratory Show the field ONLY if: [v1_comorbidity]=1	Respiratory	radio, Required 1 yes 2 no Custom alignment: RH
40	v1_c_cardiovascular Show the field ONLY if: [v1_comorbidity]=1	Cardiovascular	radio, Required 1 yes 2 no Custom alignment: RH
41	v1_c_hd Show the field ONLY if: [v1_comorbidity]=1	Hepatic disease	radio, Required 1 yes 2 no Custom alignment: RH
42	v1_c_diabetes Show the field ONLY if: [v1_comorbidity]=1	Diabetes	radio, Required 1 yes 2 no Custom alignment: RH
43	v1_c_st Show the field ONLY if: [v1_comorbidity]=1	Solid tumors	radio, Required 1 yes 2 no Custom alignment: RH
44	v1_c_ht Show the field ONLY if: [v1_comorbidity]=1	Hematologic tumors	radio, Required 1 yes 2 no Custom alignment: RH
45	v1_ccd_symptoms Show the field ONLY if: [randomization]<>"	Section Header: <i>Current clinical data</i> Symptoms?	radio, Required 1 yes 2 no Custom alignment: RH
46	v1_ccd_symptoms_days Show the field ONLY if: [v1_ccd_symptoms]=1	How many days?	text (integer, Min: 1), Required Custom alignment: RH
47	v1_ccd_fever Show the field ONLY if: [v1_ccd_symptoms]=1	Fever (>37.5°C)	radio, Required 1 yes 2 no Custom alignment: RH
48	v1_ccd_dyspnea Show the field ONLY if: [v1_ccd_symptoms]=1	Dyspnea	radio, Required 1 yes 2 no Custom alignment: RH
49	v1_ccd_cough Show the field ONLY if: [v1_ccd_symptoms]=1	Cough	radio, Required 1 yes 2 no Custom alignment: RH
50	v1_ccd_diarrhoea Show the field ONLY if: [v1_ccd_symptoms]=1	Diarrhoea	radio, Required 1 yes 2 no Custom alignment: RH

51	v1_ccd_anosmia Show the field ONLY if: [v1_ccd_symptoms]=1	Anosmia	radio, Required <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no						
1	yes												
2	no												
52	v1_ccd_other Show the field ONLY if: [v1_ccd_symptoms]=1	Other	dropdown, Required <table><tr><td>0</td><td>none</td></tr><tr><td>1</td><td>one</td></tr><tr><td>2</td><td>two</td></tr><tr><td>3</td><td>three</td></tr><tr><td>4</td><td>four or more</td></tr></table> Custom alignment: RH	0	none	1	one	2	two	3	three	4	four or more
0	none												
1	one												
2	two												
3	three												
4	four or more												
53	v1_s_specify_1 Show the field ONLY if: [v1_ccd_other]>0	Specify first other symptom	text, Required Custom alignment: RH										
54	v1_s_specify_2 Show the field ONLY if: [v1_ccd_other]>1	Specify second other symptom	text, Required Custom alignment: RH										
55	v1_s_specify_3 Show the field ONLY if: [v1_ccd_other]>2	Specify third other symptom	text, Required Custom alignment: RH										
56	v1_s_specify_4 Show the field ONLY if: [v1_ccd_other]>3	Specify fourth other symptom	text, Required Custom alignment: RH										
57	v1_symptoms_d15 Show the field ONLY if: [v1_ccd_symptoms]=2	Did you have symptoms in the last 15 days?	radio, Required <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no						
1	yes												
2	no												
58	v1_ccd_od Show the field ONLY if: [v1_symptoms_d15]=1	Onset date	text (date_dmy), Required Custom alignment: RH										
59	v1_ccd_rd Show the field ONLY if: [v1_symptoms_d15]=1	Recovery date	text (date_dmy), Required Custom alignment: RH										
60	alert_dates_v1_ccd Show the field ONLY if: [v1_ccd_rd]<[v1_ccd_od]	The recovery date must be later than the onset date. Please, verify.	descriptive										
61	v1_ccd_fever_d15 Show the field ONLY if: [v1_symptoms_d15]=1	Fever (>37.5°C)	radio, Required <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no						
1	yes												
2	no												
62	v1_ccd_dyspnea_d15 Show the field ONLY if: [v1_symptoms_d15]=1	Dyspnea	radio, Required <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no						
1	yes												
2	no												
63	v1_ccd_cough_d15 Show the field ONLY if: [v1_symptoms_d15]=1	Cough	radio, Required <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no						
1	yes												
2	no												
64	v1_ccd_diarrhoea_d15 Show the field ONLY if: [v1_symptoms_d15]=1	Diarrhoea	radio, Required <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no						
1	yes												
2	no												
65	v1_ccd_anosmia_d15 Show the field ONLY if: [v1_symptoms_d15]=1	Anosmia	radio, Required <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no						
1	yes												
2	no												

66	v1_ccd_other_d15 Show the field ONLY if: [v1_symptoms_d15]=1	Other	radio, Required <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no		
1	yes								
2	no								
67	v1_ccd_specify_d15 Show the field ONLY if: [v1_symptoms_d15]=1	Specify	text, Required Custom alignment: RH						
68	v1_fv_temperature Show the field ONLY if: [randomization]<>"	Section Header: <i>Findings at visit</i> Temperature: (C°)	text (number_1dp), Required Custom alignment: RH						
69	v1_fv_hr Show the field ONLY if: [randomization]<>"	Hearth rate: (/min)	text (integer, Min: 20, Max: 100), Required Custom alignment: RH						
70	v1_fv_rr Show the field ONLY if: [randomization]<>"	Respiratory Rate: (/min)	text (integer, Min: 6, Max: 80), Required Custom alignment: RH						
71	v1_fv_bps Show the field ONLY if: [randomization]<>"	Blood Pressure (systolic): (mmHg)	text (number), Required Custom alignment: RH						
72	v1_fv_bpd Show the field ONLY if: [randomization]<>"	Blood Pressure (diastolic): (mmHg)	text (integer), Required Custom alignment: RH						
73	v1_fv_sato2 Show the field ONLY if: [randomization]<>"	SatO2: (% in air)	text, Required Custom alignment: RH						
74	v1_ir_cxr Show the field ONLY if: [randomization]<>"	Section Header: <i>Imaging at recruitment</i> Chest X-Ray	radio, Required <table><tr><td>1</td><td>performed</td></tr><tr><td>2</td><td>not performed</td></tr></table> Custom alignment: RH	1	performed	2	not performed		
1	performed								
2	not performed								
75	v1_ir_lcts Show the field ONLY if: [randomization]<>"	Lung CT scan	radio, Required <table><tr><td>1</td><td>performed</td></tr><tr><td>2</td><td>not performed</td></tr></table> Custom alignment: RH	1	performed	2	not performed		
1	performed								
2	not performed								
76	v1_lfr_wbc Show the field ONLY if: [randomization]<>"	Section Header: <i>Laboratory findings at recruitment</i> WBC	radio, Required <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr><tr><td>3</td><td>N/A</td></tr></table> Custom alignment: RH	1	yes	2	no	3	N/A
1	yes								
2	no								
3	N/A								
77	v1_fv_wbc_v Show the field ONLY if: [v1_lfr_wbc]=1	WBC value : (N/μl)	text (integer), Required Custom alignment: RH						
78	v1_lfr_lympho Show the field ONLY if: [randomization]<>"	Lymphocytes	radio, Required <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr><tr><td>3</td><td>N/A</td></tr></table> Custom alignment: RH	1	yes	2	no	3	N/A
1	yes								
2	no								
3	N/A								
79	v1_lfr_lympho_2 Show the field ONLY if: [v1_lfr_lympho]=1	Lymphocytes value: (N/μl)	text (integer), Required Custom alignment: RH						
80	v1_fv_crp Show the field ONLY if: [randomization]<>"	C-reactive protein	radio, Required <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr><tr><td>3</td><td>N/A</td></tr></table> Custom alignment: RH	1	yes	2	no	3	N/A
1	yes								
2	no								
3	N/A								
81	v1fv_crp_v Show the field ONLY if: [v1_fv_crp]=1	C-reactive protein: (μg/l)	text (integer), Required Custom alignment: RH						

82	v1_fv_alt Show the field ONLY if: [randomization]<>"	ALT	radio, Required <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr><tr><td>3</td><td>N/A</td></tr></table> Custom alignment: RH	1	yes	2	no	3	N/A				
1	yes												
2	no												
3	N/A												
83	v1_fv_alt_v Show the field ONLY if: [v1_fv_alt]=1	ALT (U/I)	text (integer), Required Custom alignment: RH										
84	v1_fv_pao2 Show the field ONLY if: [randomization]<>"	PaO2	radio, Required <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr><tr><td>3</td><td>N/A</td></tr></table> Custom alignment: RH	1	yes	2	no	3	N/A				
1	yes												
2	no												
3	N/A												
85	v1_fv_pao2_v Show the field ONLY if: [v1_fv_pao2]=1	PaO2: (mmHg)	text, Required Custom alignment: RH										
86	v1_otantipyretic Show the field ONLY if: [randomization]<>"	Section Header: <i>THERAPIES RELATED TO COVID-19 DISEASE BEFORE RANDOMIZATION</i> Antipyretic	radio, Required <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no						
1	yes												
2	no												
87	v1_otanantipyretic_s Show the field ONLY if: [v1_otantipyretic]=1	Specify, please	text, Required										
88	v1_otantipyretic_sd Show the field ONLY if: [v1_otantipyretic]=1	Antipyretic therapy start date	text (date_dmy), Required										
89	v1_otnsaid Show the field ONLY if: [randomization]<>"	Nonsteroidal anti-inflammatory drugs	radio, Required <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no						
1	yes												
2	no												
90	v1_otnsaid_s Show the field ONLY if: [v1_otnsaid]=1	Specify, please	text, Required										
91	v1_otnsaid_sd Show the field ONLY if: [v1_otnsaid]=1	NASIDs therapy start date	text (date_dmy), Required										
92	v1_otantibiotic Show the field ONLY if: [randomization]<>"	Antibiotics	radio, Required <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no						
1	yes												
2	no												
93	v1_otantibiotic_s Show the field ONLY if: [v1_otantibiotic]=1	Specify, please	text, Required										
94	v1_otantibiotic_sd Show the field ONLY if: [v1_otantibiotic]=1	Antibiotic therapy start date	text (date_dmy), Required										
95	v1_ot_otcr Show the field ONLY if: [randomization]<>"	Other therapies related to COVID-19	dropdown <table><tr><td>0</td><td>none</td></tr><tr><td>1</td><td>one</td></tr><tr><td>2</td><td>two</td></tr><tr><td>3</td><td>three</td></tr><tr><td>4</td><td>four or more</td></tr></table>	0	none	1	one	2	two	3	three	4	four or more
0	none												
1	one												
2	two												
3	three												
4	four or more												
96	v1_ot_ot_spec_1 Show the field ONLY if: [v1_ot_otcr]>0	Specify first other therapy	text										

97	vt_ot_ot_sd_1 Show the field ONLY if: [v1_ot_ot_spec_1]<>"	[v1_ot_ot_spec_1]	radio <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>discontinued</td></tr></table> Custom alignment: RH	1	started	2	discontinued						
1	started												
2	discontinued												
98	v1_ot_ot_spec_2 Show the field ONLY if: [v1_ot_otcr]>1	Specify second other therapy	text										
99	vt_ot_ot_sd_2 Show the field ONLY if: [v1_ot_ot_spec_2]<>"	[v1_ot_ot_spec_2]	radio <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>discontinued</td></tr></table> Custom alignment: RH	1	started	2	discontinued						
1	started												
2	discontinued												
100	v1_ot_ot_spec_3 Show the field ONLY if: [v1_ot_otcr]>2	Specify third other therapy	text										
101	vt_ot_ot_sd_3 Show the field ONLY if: [v1_ot_ot_spec_3]<>"	[v1_ot_ot_spec_3]	radio <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>discontinued</td></tr></table> Custom alignment: RH	1	started	2	discontinued						
1	started												
2	discontinued												
102	v1_ot_ot_spec_4 Show the field ONLY if: [v1_ot_otcr]>3	Specify fourth other therapy	text										
103	vt_ot_ot_sd_4 Show the field ONLY if: [v1_ot_ot_spec_4]<>"	[v1_ot_ot_spec_4]	radio <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>discontinued</td></tr></table> Custom alignment: RH	1	started	2	discontinued						
1	started												
2	discontinued												
104	v1_otahd Show the field ONLY if: [randomization]<>"	Section Header: <i>Other chronic therapies before randomization</i> Any antihypertensive drug	dropdown, Required <table><tr><td>0</td><td>none</td></tr><tr><td>1</td><td>one</td></tr><tr><td>2</td><td>two</td></tr><tr><td>3</td><td>three</td></tr><tr><td>4</td><td>four or more</td></tr></table> Custom alignment: RH	0	none	1	one	2	two	3	three	4	four or more
0	none												
1	one												
2	two												
3	three												
4	four or more												
105	v1_otahd_s_1 Show the field ONLY if: [v1_otahd]>0	Specify the first antihypertensive drug	text, Required Custom alignment: RH										
106	v1_otahd_s_2 Show the field ONLY if: [v1_otahd]>1	Specify the second antihypertensive drug	text, Required Custom alignment: RH										
107	v1_otahd_s_3 Show the field ONLY if: [v1_otahd]>2	Specify the third antihypertensive drug	text, Required Custom alignment: RH										
108	v1_otahd_s_4 Show the field ONLY if: [v1_otahd]>3	Specify the fourth antihypertensive drug	text, Required Custom alignment: RH										
109	v1_otsteroids Show the field ONLY if: [randomization]<>"	Steroids	radio, Required <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no						
1	yes												
2	no												
110	v1_otsteroids_s Show the field ONLY if: [v1_otsteroids]=1	Specify, please	text, Required Custom alignment: RH										
111	v1_otantiblastics Show the field ONLY if: [randomization]<>"	Antiblastics	radio, Required <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no						
1	yes												
2	no												
112	v1_otantiblastics_s Show the field ONLY if: [v1_otantiblastics]=1	Specify, please	text, Required Custom alignment: RH										

113	v1_otisd Show the field ONLY if: [randomization]<>"	Immunosuppressive drugs	radio, Required 1 yes 2 no Custom alignment: RH
114	v1_otisd_s Show the field ONLY if: [v1_otisd]=1	Specify, please	text, Required Custom alignment: RH
115	v1_otbio Show the field ONLY if: [randomization]<>"	Biologicals	radio, Required 1 yes 2 no Custom alignment: RH
116	v1_otbio_s Show the field ONLY if: [v1_otbio]=1	Specify, please	text, Required Custom alignment: RH
117	v1_otot Show the field ONLY if: [randomization]<>"	Any other chronic therapy?	dropdown, Required 0 none 1 one 2 two 3 three 4 four or more Custom alignment: RH
118	v1_otot_s_1 Show the field ONLY if: [v1_otot]>0	Specify the first other chronic therapy	text, Required Custom alignment: RH
119	v1_otot_s_2 Show the field ONLY if: [v1_otot]>1	Specify the second other chronic therapy	text, Required Custom alignment: RH
120	v1_otot_s_3 Show the field ONLY if: [v1_otot]>2	Specify the third other chronic therapy	text, Required Custom alignment: RH
121	v1_otot_s_4 Show the field ONLY if: [v1_otot]>3	Specify the fourth other chronic therapy	text, Required Custom alignment: RH
122	related_therapy_bl Show the field ONLY if: [randomization]<>"	Section Header: THERAPIES RELATED TO COVID-19 DISEASE PRESCRIBED AT THE END OF BASELINE VISIT Has any covid-19 related therapy been changed since the enrollment?	radio, Required 1 yes 2 no Custom alignment: RH
123	ot_antipyretic_bl Show the field ONLY if: [related_therapy_bl]=1	Antipyretic	radio, Required 1 started 2 discontinued Custom alignment: RH
124	antipyretic_spec_bl Show the field ONLY if: [ot_antipyretic_bl]=1	Specify, please	text, Required
125	ot_nsaid_bl Show the field ONLY if: [related_therapy_bl]=1	Nonsteroidal anti-inflammatory drugs	radio, Required 1 started 2 discontinued Custom alignment: RH
126	antipyretic_spec_bl_2 Show the field ONLY if: [ot_nsaid_bl]=1	Specify, please	text, Required
127	ot_antibiotic_bl Show the field ONLY if: [related_therapy_bl]=1	Antibiotics	radio, Required 1 started 2 discontinued Custom alignment: RH
128	antipyretic_spec_bl_3 Show the field ONLY if: [ot_antibiotic_bl]=1	Specify, please	text, Required

129	bl_ot_otcr Show the field ONLY if: [related_therapy_bl]=1	Other therapies related to COVID-19	dropdown, Required <table><tr><td>0</td><td>none</td></tr><tr><td>1</td><td>one</td></tr><tr><td>2</td><td>two</td></tr><tr><td>3</td><td>three</td></tr><tr><td>4</td><td>four or more</td></tr></table>	0	none	1	one	2	two	3	three	4	four or more
0	none												
1	one												
2	two												
3	three												
4	four or more												
130	bl_ot_ot_spec_1 Show the field ONLY if: [bl_ot_otcr]>0	Specify first other therapy	text, Required										
131	bl_ot_ot_sd_1 Show the field ONLY if: [bl_ot_otcr]>0	[bl_ot_ot_spec_1]	radio, Required <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>discontinued</td></tr></table> Custom alignment: RH	1	started	2	discontinued						
1	started												
2	discontinued												
132	bl_ot_ot_spec_2 Show the field ONLY if: [bl_ot_otcr]>1	Specify second other therapy	text, Required										
133	bl_ot_ot_sd_2 Show the field ONLY if: [bl_ot_otcr]>1	[bl_ot_ot_spec_2]	radio, Required <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>discontinued</td></tr></table> Custom alignment: RH	1	started	2	discontinued						
1	started												
2	discontinued												
134	bl_ot_ot_spec_3 Show the field ONLY if: [bl_ot_otcr]>2	Specify third other therapy	text, Required										
135	bl_ot_ot_sd_3 Show the field ONLY if: [bl_ot_otcr]>2	[bl_ot_ot_spec_3]	radio, Required <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>discontinued</td></tr></table> Custom alignment: RH	1	started	2	discontinued						
1	started												
2	discontinued												
136	bl_ot_ot_spec_4 Show the field ONLY if: [bl_ot_otcr]>3	Specify fourth other therapy	text, Required										
137	bl_ot_ot_sd_4 Show the field ONLY if: [bl_ot_otcr]>3	[bl_ot_ot_spec_4]	radio, Required <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>discontinued</td></tr></table> Custom alignment: RH	1	started	2	discontinued						
1	started												
2	discontinued												
138	ct_changed_bl Show the field ONLY if: [randomization]<>"	Section Header: <i>OTHER CHRONIC THERAPIES PRESCRIBED AT THE END OF BASELINE VISIT</i> Has any chronic therapy been changed since the enrollment?	radio, Required <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no						
1	yes												
2	no												
139	ot_ahtd_bl Show the field ONLY if: [ct_changed_bl]=1	Antihypertensive drugs	radio, Required <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>discontinued</td></tr></table> Custom alignment: RH	1	started	2	discontinued						
1	started												
2	discontinued												
140	ot_ahtd_specify_bl Show the field ONLY if: [ot_ahtd_bl]=1	Specify new antihypertensive drug	text, Required Custom alignment: RH										
141	ot_ahtd_disc_bl Show the field ONLY if: [ot_ahtd_bl]=2	Specify discontinued antihypertensive drug	text, Required Custom alignment: RH										
142	ot_steroids_bl Show the field ONLY if: [ct_changed_bl]=1	Steroids	radio, Required <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>discontinued</td></tr></table> Custom alignment: RH	1	started	2	discontinued						
1	started												
2	discontinued												
143	ot_steroids_specify_bl Show the field ONLY if: [ot_steroids_bl]=1	Specify new steroid	text, Required Custom alignment: RH										

144	ot_ab_bl Show the field ONLY if: [ct_changed_bl]=1	Antiblastics	radio, Required 1 started 2 discontinued Custom alignment: RH
145	ot_ab_specify_bl Show the field ONLY if: [ot_ab_bl]=1	Specify new antiblastic	text, Required Custom alignment: RH
146	ot_isd_bl Show the field ONLY if: [ct_changed_bl]=1	Immunosuppressive drugs	radio, Required 1 started 2 discontinued Custom alignment: RH
147	ot_isd_specify_bl Show the field ONLY if: [ot_isd_bl]=1	Specify new immunosuppressive drug	text, Required Custom alignment: RH
148	ot_bio_bl Show the field ONLY if: [ct_changed_bl]=1	Biologicals	radio, Required 1 started 2 discontinued Custom alignment: RH
149	ot_bio_specify_bl Show the field ONLY if: [ot_isd_bl]=1	Specify new biological	text, Required Custom alignment: RH
150	otot_n_bl Show the field ONLY if: [ct_changed_bl]=1	Has any other chronic therapy changed since lat visit?	dropdown, Required 0 none 1 one 2 two 3 three 4 four or more
151	ot_ot1_bl Show the field ONLY if: [otot_n_bl]>0	First other therapy	radio, Required 1 started 2 interrupted Custom alignment: RH
152	ot_specify_ot1_bl Show the field ONLY if: [ot_ot1_bl]=1	Specify first new other therapy	text, Required Custom alignment: RH
153	ot_ot2_bl Show the field ONLY if: [otot_n_bl]>1	Second other therapy	radio, Required 1 started 2 discontinued Custom alignment: RH
154	ot_specify_ot2_bl Show the field ONLY if: [ot_ot2_bl]=1	Specify second new other therapy	text, Required Custom alignment: RH
155	ot_ot3_bl Show the field ONLY if: [otot_n_bl]>2	Third other therapy	radio, Required 1 started 2 discontinued Custom alignment: RH
156	ot_specify_ot3_bl Show the field ONLY if: [ot_ot3_bl]=1	Specify third new other therapy	text, Required Custom alignment: RH
157	ot_ot4_bl Show the field ONLY if: [otot_n_bl]>3	Fourth other therapy	radio, Required 1 started 2 discontinued Custom alignment: RH
158	ot_specify_ot4_bl Show the field ONLY if: [ot_ot4_bl]=1	Specify fourth new other therapy	text, Required Custom alignment: RH

159	covid_bl Show the field ONLY if: [randomization]<>"	COVID-19 Severity Score	dropdown, Required <table border="1"> <tr><td>1</td><td>1, no limitation of activities</td></tr> <tr><td>2</td><td>2, limitation of activities</td></tr> <tr><td>3</td><td>3, hospitalized, no oxygen therapy</td></tr> <tr><td>4</td><td>4, hospitalized, oxygen by mask or nasal prongs</td></tr> <tr><td>5</td><td>5, non-invasive ventilation or high-flow oxygen</td></tr> <tr><td>6</td><td>6, intubation and mechanical ventilation</td></tr> <tr><td>7</td><td>7, ventilation + additional organ support - pressors, RRT (renal replacement therapy), ECMO (extracorporeal membrane oxygenation)</td></tr> <tr><td>8</td><td>8, death</td></tr> </table>	1	1, no limitation of activities	2	2, limitation of activities	3	3, hospitalized, no oxygen therapy	4	4, hospitalized, oxygen by mask or nasal prongs	5	5, non-invasive ventilation or high-flow oxygen	6	6, intubation and mechanical ventilation	7	7, ventilation + additional organ support - pressors, RRT (renal replacement therapy), ECMO (extracorporeal membrane oxygenation)	8	8, death
1	1, no limitation of activities																		
2	2, limitation of activities																		
3	3, hospitalized, no oxygen therapy																		
4	4, hospitalized, oxygen by mask or nasal prongs																		
5	5, non-invasive ventilation or high-flow oxygen																		
6	6, intubation and mechanical ventilation																		
7	7, ventilation + additional organ support - pressors, RRT (renal replacement therapy), ECMO (extracorporeal membrane oxygenation)																		
8	8, death																		
160	sd_therapy Show the field ONLY if: [randomization]<>"	Starting date of therapy	text (date_dmy), Required																
161	how_many_pills Show the field ONLY if: [randomization]<>"	How many pills/day have been prescribed?	text (integer), Required																
162	stored_bl Show the field ONLY if: [randomization]<>"	Has the nasopharyngeal swab been stored at -80 °C after exam?	radio <table border="1"> <tr><td>1</td><td>yes</td></tr> <tr><td>2</td><td>no</td></tr> </table> Custom alignment: RH	1	yes	2	no												
1	yes																		
2	no																		
163	pharmak_bl Show the field ONLY if: [randomization]<>"	Section Header: <i>Pharmacokinetics study</i> Has the subject been recruited for the ancillary pharmacokinetics study?	radio <table border="1"> <tr><td>1</td><td>yes</td></tr> <tr><td>2</td><td>no</td></tr> </table> Custom alignment: RH	1	yes	2	no												
1	yes																		
2	no																		
164	baseline_complete	Section Header: <i>Form Status</i> Complete?	dropdown <table border="1"> <tr><td>0</td><td>Incomplete</td></tr> <tr><td>1</td><td>Unverified</td></tr> <tr><td>2</td><td>Complete</td></tr> </table>	0	Incomplete	1	Unverified	2	Complete										
0	Incomplete																		
1	Unverified																		
2	Complete																		
Instrument: PHONE VISIT (phone_visit) ^ Collapse																			
165	alert_random_dv Show the field ONLY if: [baseline_arm_1][randomization]="	In order to fill this form, the patient must be randomized	descriptive																
166	rnd_days Show the field ONLY if: [baseline_arm_1][randomization]<>"	Randomization code: [[baseline_arm_1][randomization]]	descriptive																
167	dov Show the field ONLY if: [baseline_arm_1][randomization]<>"	Day of visit	dropdown <table border="1"> <tr><td>1</td><td>first</td></tr> <tr><td>2</td><td>second</td></tr> <tr><td>3</td><td>third</td></tr> <tr><td>4</td><td>fourth</td></tr> <tr><td>5</td><td>fifth</td></tr> </table>	1	first	2	second	3	third	4	fourth	5	fifth						
1	first																		
2	second																		
3	third																		
4	fourth																		
5	fifth																		
168	dov_dv Show the field ONLY if: [baseline_arm_1][randomization]<>"	Date of visit	text (date_dmy)																
169	drug_assumption Show the field ONLY if: [baseline_arm_1][randomization]<>"	Section Header: <i>Study drugs</i> Has the drug taken according to medical indication?	radio <table border="1"> <tr><td>1</td><td>yes</td></tr> <tr><td>2</td><td>no</td></tr> </table> Custom alignment: RH	1	yes	2	no												
1	yes																		
2	no																		
170	dv_withdrawn Show the field ONLY if: [drug_assumption]=2	Has the drug been withdrawn?	radio <table border="1"> <tr><td>1</td><td>yes</td></tr> <tr><td>2</td><td>no</td></tr> </table> Custom alignment: RH	1	yes	2	no												
1	yes																		
2	no																		
171	dv_to_wdform Show the field ONLY if: [dv_withdrawn]=1	if the drug was withdrawn, please complete the withdrawal form	descriptive																

172	dv_pills_skpd Show the field ONLY if: [dv_withdrawn]=2	Have one or more pill(s) skipped?	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no						
1	yes												
2	no												
173	n_pills Show the field ONLY if: [dv_pills_skpd]=1	how many pills have been taken?	text (number) Custom alignment: RH										
174	dv_skpd_reason Show the field ONLY if: [dv_pills_skpd]=1	Reason for dose skipped	dropdown <table><tr><td>1</td><td>Toxicity*</td></tr><tr><td>2</td><td>Deterioration of clinical conditions or clinical decision</td></tr><tr><td>3</td><td>Patient decision**</td></tr><tr><td>4</td><td>Non compliance</td></tr><tr><td>5</td><td>Logistic organization</td></tr></table> Custom alignment: RH	1	Toxicity*	2	Deterioration of clinical conditions or clinical decision	3	Patient decision**	4	Non compliance	5	Logistic organization
1	Toxicity*												
2	Deterioration of clinical conditions or clinical decision												
3	Patient decision**												
4	Non compliance												
5	Logistic organization												
175	dv_skpd_p_dec Show the field ONLY if: [dv_skpd_reason]=3	** If patient decision, please specify	text										
176	if_tox Show the field ONLY if: [dv_skpd_reason]=1	if Toxicity, please complete the adverse reaction/adverse event form	descriptive										
177	dv_fever_t Show the field ONLY if: [baseline_arm_1][randomization] <>"	Section Header: <i>Symptoms?</i> Temperature: (°C)	text (number_1dp, Min: 34.0, Max: 43.0) Custom alignment: RH										
178	dv_hr Show the field ONLY if: [baseline_arm_1][randomization] <>"	Hearth rate: (/min)	text (integer) Custom alignment: RH										
179	dv_rr Show the field ONLY if: [baseline_arm_1][randomization] <>"	Respiratory Rate: (/min)	text Custom alignment: RH										
180	dv_dyspnea Show the field ONLY if: [baseline_arm_1][randomization] <>"	Dyspnea	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no						
1	yes												
2	no												
181	dv_cough Show the field ONLY if: [baseline_arm_1][randomization] <>"	Cough	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no						
1	yes												
2	no												
182	dv_diarrhoea Show the field ONLY if: [baseline_arm_1][randomization] <>"	Diarrhoea	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no						
1	yes												
2	no												
183	symp_other_pv Show the field ONLY if: [baseline_arm_1][randomization] <>"	Other	dropdown <table><tr><td>0</td><td>none</td></tr><tr><td>1</td><td>one</td></tr><tr><td>2</td><td>two</td></tr><tr><td>3</td><td>three</td></tr><tr><td>4</td><td>four or more</td></tr></table>	0	none	1	one	2	two	3	three	4	four or more
0	none												
1	one												
2	two												
3	three												
4	four or more												
184	symp_other_1 Show the field ONLY if: [symp_other_pv]>0	Specify first other symptom	text										
185	symp_other_2 Show the field ONLY if: [symp_other_pv]>1	Specify second other symptom	text										
186	symp_other_3 Show the field ONLY if: [symp_other_pv]>2	Specify third other symptom	text										

187	symp_other_4 Show the field ONLY if: [symp_other_pv]>3	Specify fourth other symptom	text												
188	dv_drowsiness Show the field ONLY if: [baseline_arm_1][randomization] <>"	<div>Section Header: Adverse reactions Please report each occurred adverse reaction also in the AE FORM, in order to provide major details Grading: 0 (none); 1 (mild: any symptoms possibly related to study drug, not necessitating medication); 2 (moderate: any symptoms resolved with medication, not requiring hospitalization); 3 (severe: necessity of hospitalization or prolongation of existing hospitalization); 4 (near fatal: necessity of intensive care); 5 (fatal). Please write "0" if the symptom was not present</div> <div>Drowsiness</div>	<div>dropdown</div> <table><tr><td>0</td><td>0</td></tr><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr><tr><td>4</td><td>4</td></tr><tr><td>5</td><td>5</td></tr></table> <div>Custom alignment: RH</div>	0	0	1	1	2	2	3	3	4	4	5	5
0	0														
1	1														
2	2														
3	3														
4	4														
5	5														
189	alert_sae1 Show the field ONLY if: [dv_drowsiness]>2	Please, go to the "Serious adverse event initial report" Form	descriptive												
190	dv_vomit Show the field ONLY if: [baseline_arm_1][randomization] <>"	Vomit	<div>dropdown</div> <table><tr><td>0</td><td>0</td></tr><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr><tr><td>4</td><td>4</td></tr><tr><td>5</td><td>5</td></tr></table> <div>Custom alignment: RH</div>	0	0	1	1	2	2	3	3	4	4	5	5
0	0														
1	1														
2	2														
3	3														
4	4														
5	5														
191	alert_sae2 Show the field ONLY if: [dv_vomit]>2	Please, go to the "Serious adverse event initial report" Form	descriptive												
192	dv_pruritus Show the field ONLY if: [baseline_arm_1][randomization] <>"	Pruritus	<div>dropdown</div> <table><tr><td>0</td><td>0</td></tr><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr><tr><td>4</td><td>4</td></tr><tr><td>5</td><td>5</td></tr></table> <div>Custom alignment: RH</div>	0	0	1	1	2	2	3	3	4	4	5	5
0	0														
1	1														
2	2														
3	3														
4	4														
5	5														
193	alert_sae3 Show the field ONLY if: [dv_pruritus]>2	Please, go to the "Serious adverse event initial report" Form	descriptive												
194	dv_ap Show the field ONLY if: [baseline_arm_1][randomization] <>"	Abdominal pain	<div>dropdown</div> <table><tr><td>0</td><td>0</td></tr><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr><tr><td>4</td><td>4</td></tr><tr><td>5</td><td>5</td></tr></table> <div>Custom alignment: RH</div>	0	0	1	1	2	2	3	3	4	4	5	5
0	0														
1	1														
2	2														
3	3														
4	4														
5	5														
195	alert_sae4 Show the field ONLY if: [dv_ap]>2	Please, go to the "Serious adverse event initial report" Form	descriptive												
196	dv_hypotension Show the field ONLY if: [baseline_arm_1][randomization] <>"	Hypotension	<div>dropdown</div> <table><tr><td>0</td><td>0</td></tr><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr><tr><td>4</td><td>4</td></tr><tr><td>5</td><td>5</td></tr></table> <div>Custom alignment: RH</div>	0	0	1	1	2	2	3	3	4	4	5	5
0	0														
1	1														
2	2														
3	3														
4	4														
5	5														
197	alert_sae5 Show the field ONLY if: [dv_hypotension]>2	Please, go to the "Serious adverse event initial report" Form	descriptive												

198	<div>dv_fatigue</div> <div>Show the field ONLY if: [baseline_arm_1][randomization] <>"</div>	Fatigue	<div>dropdown</div> <div><div>00</div><div>11</div><div>22</div><div>33</div><div>44</div><div>55</div></div> <div>Custom alignment: RH</div>
199	<div>alert_sae6</div> <div>Show the field ONLY if: [dv_fatigue]>2</div>	Please, go to the "Serious adverse event initial report" Form	descriptive
200	<div>dv_headache</div> <div>Show the field ONLY if: [baseline_arm_1][randomization] <>"</div>	Headache	<div>dropdown</div> <div><div>00</div><div>11</div><div>22</div><div>33</div><div>44</div><div>55</div></div> <div>Custom alignment: RH</div>
201	<div>alert_sae7</div> <div>Show the field ONLY if: [dv_headache]>2</div>	Please, go to the "Serious adverse event initial report" Form	descriptive
202	<div>dv_nausea</div> <div>Show the field ONLY if: [baseline_arm_1][randomization] <>"</div>	Nausea	<div>dropdown</div> <div><div>00</div><div>11</div><div>22</div><div>33</div><div>44</div><div>55</div></div> <div>Custom alignment: RH</div>
203	<div>alert_sae13</div> <div>Show the field ONLY if: [dv_nausea]>2</div>	Please, go to the "Serious adverse event initial report" Form	descriptive
204	<div>pv_aeo</div> <div>Show the field ONLY if: [baseline_arm_1][randomization] <>"</div>	<div>Section Header: <i>Adverse Events</i></div> <div>Other adverse event occurred?</div>	<div>dropdown</div> <div><div>1yes</div><div>2no</div></div> <div>Custom alignment: RH</div>
205	<div>dv_go_to_ae_form</div> <div>Show the field ONLY if: [pv_aeo]=1</div>	If yes, please complete the AE FORM	descriptive
206	<div>dv_related_therapy</div> <div>Show the field ONLY if: [baseline_arm_1][randomization] <>"</div>	<div>Section Header: <i>OTHER THERAPIES RELATED TO COVID-19 DISEASE</i></div> <div>Has any covid-19 related therapy been changed since the last visit?</div>	<div>radio</div> <div><div>1yes</div><div>2no</div></div> <div>Custom alignment: RH</div>
207	<div>dv_ot_hcq</div> <div>Show the field ONLY if: [dv_related_therapy]=1</div>	Hydroxychloroquine	<div>radio</div> <div><div>1started</div><div>2discontinued</div></div> <div>Custom alignment: RH</div>
208	<div>dv_ot_cqp</div> <div>Show the field ONLY if: [dv_related_therapy]=1</div>	Chloroquine Phosphate	<div>radio</div> <div><div>1started</div><div>2discontinued</div></div> <div>Custom alignment: RH</div>
209	<div>dv_ot_avd</div> <div>Show the field ONLY if: [dv_related_therapy]=1</div>	Antiviral drugs	<div>radio</div> <div><div>1started</div><div>2discontinued</div></div> <div>Custom alignment: RH</div>

210	dv_antipyretic Show the field ONLY if: [dv_related_therapy]=1	Antipyretic	radio 1 started 2 discontinued Custom alignment: RH
211	dv_nsaid Show the field ONLY if: [dv_related_therapy]=1	Nonsteroidal anti-inflammatory drugs	radio 1 started 2 discontinued Custom alignment: RH
212	dv_antibiotic Show the field ONLY if: [dv_related_therapy]=1	Antibiotics	radio 1 started 2 discontinued Custom alignment: RH
213	dv_ot_otcr Show the field ONLY if: [dv_related_therapy]=1	Other therapies related to COVID-19	dropdown 0 none 1 one 2 two 3 three 4 four or more
214	dv_ot_spec_1 Show the field ONLY if: [dv_ot_otcr]>0	Specify first other therapy	text
215	dv_ot_sd_1 Show the field ONLY if: [dv_ot_spec_1]<>"	[dv_ot_spec_1]	radio 1 started 2 discontinued Custom alignment: RH
216	dv_ot_spec_2 Show the field ONLY if: [dv_ot_otcr]>1	Specify second other therapy	text
217	dv_ot_sd_2 Show the field ONLY if: [dv_ot_spec_2]<>"	[dv_ot_spec_2]	radio 1 started 2 discontinued Custom alignment: RH
218	dv_ot_spec_3 Show the field ONLY if: [dv_ot_otcr]>2	Specify third other therapy	text
219	dv_ot_sd_3 Show the field ONLY if: [dv_ot_spec_3]<>"	[dv_ot_spec_3]	radio 1 started 2 discontinued Custom alignment: RH
220	dv_ot_spec_4 Show the field ONLY if: [dv_ot_otcr]>3	Specify fourth other therapy	text
221	dv_ot_sd_4 Show the field ONLY if: [dv_ot_spec_4]<>"	[dv_ot_spec_4]	radio 1 started 2 discontinued Custom alignment: RH
222	dv_prah Show the field ONLY if: [baseline_arm_1][randomization] <>"	Section Header: Patient required admission to hospital?	radio 1 yes 2 no Custom alignment: RH
223	dv_prah_why Show the field ONLY if: [dv_prah]=1	Why	text
224	dv_prah_date Show the field ONLY if: [dv_prah]=1	Date of hospitalization	text (date_ymd)

225	dv_prah_hospital Show the field ONLY if: [dv_prah]=1	Which Hospital	text																
226	dv_prah_ward Show the field ONLY if: [dv_prah]=1	Which ward	text																
227	d1_covid_ss Show the field ONLY if: [baseline_arm_1][randomization] <>"	COVID-19 Severity Score	dropdown <table><tr><td>1</td><td>1, no limitation of activities</td></tr><tr><td>2</td><td>2, limitation of activities</td></tr><tr><td>3</td><td>3, hospitalized, no oxygen therapy</td></tr><tr><td>4</td><td>4, hospitalized, oxygen by mask or nasal prongs</td></tr><tr><td>5</td><td>5, non-invasive ventilation or high-flow oxygen</td></tr><tr><td>6</td><td>6, intubation and mechanical ventilation</td></tr><tr><td>7</td><td>7, ventilation + additional organ support - pressors, RRT (renal replacement therapy), ECMO (extracorporeal membrane oxygenation)</td></tr><tr><td>8</td><td>8, death</td></tr></table>	1	1, no limitation of activities	2	2, limitation of activities	3	3, hospitalized, no oxygen therapy	4	4, hospitalized, oxygen by mask or nasal prongs	5	5, non-invasive ventilation or high-flow oxygen	6	6, intubation and mechanical ventilation	7	7, ventilation + additional organ support - pressors, RRT (renal replacement therapy), ECMO (extracorporeal membrane oxygenation)	8	8, death
1	1, no limitation of activities																		
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7	7, ventilation + additional organ support - pressors, RRT (renal replacement therapy), ECMO (extracorporeal membrane oxygenation)																		
8	8, death																		
228	phone_visit_complete	Section Header: <i>Form Status</i> Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete										
0	Incomplete																		
1	Unverified																		
2	Complete																		

Instrument: **RECRUITING CENTRE VISIT** (recruiting_centre_visit)

⤴ Collapse

229	alert_random_rc Show the field ONLY if: [baseline_arm_1][randomization] ="	In order to fill this form, the patient must be randomized	descriptive						
230	rnd_days_rc Show the field ONLY if: [baseline_arm_1][randomization] <>"	Randomization code: [[baseline_arm_1][randomization]]	descriptive						
231	dov_rc Show the field ONLY if: [baseline_arm_1][randomization] <>"	Day of visit	dropdown <table><tr><td>1</td><td>seventh</td></tr><tr><td>2</td><td>fourteenth</td></tr></table>	1	seventh	2	fourteenth		
1	seventh								
2	fourteenth								
232	dov_dv_rc Show the field ONLY if: [baseline_arm_1][randomization] <>"	Date of visit	text (date_dmy)						
233	rc_alive Show the field ONLY if: [baseline_arm_1][randomization] <>"	Section Header: <i>Patient status</i> Is the patient alive?	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no		
1	yes								
2	no								
234	rc_setting Show the field ONLY if: [rc_alive]=1	Current setting	dropdown <table><tr><td>1</td><td>Home</td></tr><tr><td>2</td><td>Hospitalization</td></tr><tr><td>3</td><td>Other</td></tr></table>	1	Home	2	Hospitalization	3	Other
1	Home								
2	Hospitalization								
3	Other								
235	rc_ps_specify Show the field ONLY if: [rc_setting]=3	Specify please	text						
236	rc_hosp_date Show the field ONLY if: [rc_setting]=2	Hospitalization date	text (date_dmy)						
237	rc_hosp_why Show the field ONLY if: [rc_setting]=2	Reason for hospitalization	text						
238	rc_icu Show the field ONLY if: [rc_setting]=2	Recovery in Intensive Care Unit?	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no		
1	yes								
2	no								

239	rc_death_date Show the field ONLY if: [rc_alive]=2	Death date	text (date_dmy) Custom alignment: RH										
240	rc_deat_cause Show the field ONLY if: [rc_alive]=2	Death cause	text Custom alignment: RH										
241	rc_curr_setting Show the field ONLY if: [rc_alive]=1	Setting of current visit	radio <table><tr><td>1</td><td>Home</td></tr><tr><td>2</td><td>Hospital emergency room</td></tr><tr><td>3</td><td>Hospital outpatient ambulatory care</td></tr><tr><td>4</td><td>Extra- Hospital outpatient ambulatory care</td></tr><tr><td>5</td><td>Other</td></tr></table>	1	Home	2	Hospital emergency room	3	Hospital outpatient ambulatory care	4	Extra- Hospital outpatient ambulatory care	5	Other
1	Home												
2	Hospital emergency room												
3	Hospital outpatient ambulatory care												
4	Extra- Hospital outpatient ambulatory care												
5	Other												
242	rc_currsett_spec Show the field ONLY if: [rc_curr_setting]=5	Specify, please	text Custom alignment: RH										
243	drug_assumption_rc Show the field ONLY if: [rc_alive]=1 AND [dov_rc]=1	Section Header: <i>Study drugs</i> Has the drug been taken according to medical indication?	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no						
1	yes												
2	no												
244	rc_withdrawn Show the field ONLY if: [drug_assumption_rc]=2	Has the drug been withdrawn?	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no						
1	yes												
2	no												
245	rc_with_alert Show the field ONLY if: [rc_withdrawn]=1	if the drug was withdrawn, please complete the withdrawal form	descriptive										
246	rc_pills_skpd Show the field ONLY if: [rc_withdrawn]=2	Have one or more pill(s) skipped?	dropdown <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>no</td></tr></table>	1	Yes	2	no						
1	Yes												
2	no												
247	n_pills_rc Show the field ONLY if: [rc_pills_skpd]=1	If yes, how many pills have been taken?	text (number) Custom alignment: RH										
248	rc_skpd_reason Show the field ONLY if: [rc_pills_skpd]=1	Reason for dose skipped:	dropdown <table><tr><td>1</td><td>Toxicity*</td></tr><tr><td>2</td><td>Deterioration of clinical conditions or clinical decision</td></tr><tr><td>3</td><td>Patient decision**</td></tr><tr><td>4</td><td>Non compliance</td></tr><tr><td>5</td><td>Logistic organization</td></tr></table> Custom alignment: RH	1	Toxicity*	2	Deterioration of clinical conditions or clinical decision	3	Patient decision**	4	Non compliance	5	Logistic organization
1	Toxicity*												
2	Deterioration of clinical conditions or clinical decision												
3	Patient decision**												
4	Non compliance												
5	Logistic organization												
249	rc_tox_alert Show the field ONLY if: [rc_skpd_reason]=1	*if Toxicity, please complete the adverse reaction/adverse event form	descriptive										
250	dv_specify_p_dec Show the field ONLY if: [rc_skpd_reason]=3	** If patient decision, please specify:	text Custom alignment: RH										
251	fever_t_rc Show the field ONLY if: [rc_alive]=1	Section Header: <i>Symptoms?</i> Temperature: (°C)	text (number_1dp, Min: 34.0, Max: 43.0) Custom alignment: RH										
252	hr_rc Show the field ONLY if: [rc_alive]=1	Hearth rate: (/min)	text (integer) Custom alignment: RH										
253	rr_rc Show the field ONLY if: [rc_alive]=1	Respiratory Rate: (/min)	text Custom alignment: RH										
254	dyspnea_rc Show the field ONLY if: [rc_alive]=1	Dyspnea	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no						
1	yes												
2	no												

255	cough_rc Show the field ONLY if: [rc_alive]=1	Cough	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no								
1	yes														
2	no														
256	diarrhoea_rc Show the field ONLY if: [rc_alive]=1	Diarrhoea	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no								
1	yes														
2	no														
257	symp_other_rc Show the field ONLY if: [baseline_arm_1][randomization] <>"	Other	dropdown <table><tr><td>0</td><td>none</td></tr><tr><td>1</td><td>one</td></tr><tr><td>2</td><td>two</td></tr><tr><td>3</td><td>three</td></tr><tr><td>4</td><td>four or more</td></tr></table>	0	none	1	one	2	two	3	three	4	four or more		
0	none														
1	one														
2	two														
3	three														
4	four or more														
258	rc_symp_other_1 Show the field ONLY if: [symp_other_rc]>0	Specify first other symptom	text												
259	rc_symp_other_2 Show the field ONLY if: [symp_other_rc]>1	Specify second other symptom	text												
260	rc_symp_other_3 Show the field ONLY if: [symp_other_rc]>2	Specify third other symptom	text												
261	rc_symp_other_4 Show the field ONLY if: [symp_other_rc]>3	Specify fourth other symptom	text												
262	rc_drowsiness Show the field ONLY if: [baseline_arm_1][randomization] <>"	Section Header: Adverse reactions Please report each occurred adverse reaction also in the AE FORM, in order to provide major details Grading: 0 (none); 1 (mild: any symptoms possibly related to study drug, not necessitating medication); 2 (moderate: any symptoms resolved with medication, not requiring hospitalization); 3 (severe: necessity of hospitalization or prolongation of existing hospitalization); 4 (near fatal: necessity of intensive care); 5 (fatal). Please write "0" if the symptom was not present Drowsiness	dropdown <table><tr><td>0</td><td>0</td></tr><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr><tr><td>4</td><td>4</td></tr><tr><td>5</td><td>5</td></tr></table> Custom alignment: RH	0	0	1	1	2	2	3	3	4	4	5	5
0	0														
1	1														
2	2														
3	3														
4	4														
5	5														
263	alert_sae15 Show the field ONLY if: [rc_drowsiness]>2	Please, go to the "Serious adverse event initial report" Form	descriptive												
264	rc_vomit Show the field ONLY if: [baseline_arm_1][randomization] <>"	Vomit	dropdown <table><tr><td>0</td><td>0</td></tr><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr><tr><td>4</td><td>4</td></tr><tr><td>5</td><td>5</td></tr></table> Custom alignment: RH	0	0	1	1	2	2	3	3	4	4	5	5
0	0														
1	1														
2	2														
3	3														
4	4														
5	5														
265	alert_sae16 Show the field ONLY if: [rc_vomit]>2	Please, go to the "Serious adverse event initial report" Form	descriptive												
266	rc_pruritus Show the field ONLY if: [baseline_arm_1][randomization] <>"	Pruritus	dropdown <table><tr><td>0</td><td>0</td></tr><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr><tr><td>4</td><td>4</td></tr><tr><td>5</td><td>5</td></tr></table> Custom alignment: RH	0	0	1	1	2	2	3	3	4	4	5	5
0	0														
1	1														
2	2														
3	3														
4	4														
5	5														

267	alert_sae17 Show the field ONLY if: [rc_pruritus]>2	Please, go to the "Serious adverse event initial report" Form	descriptive												
268	rc_ap Show the field ONLY if: [baseline_arm_1][randomization] <>"	Abdominal pain	dropdown <table><tr><td>0</td><td>0</td></tr><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr><tr><td>4</td><td>4</td></tr><tr><td>5</td><td>5</td></tr></table> Custom alignment: RH	0	0	1	1	2	2	3	3	4	4	5	5
0	0														
1	1														
2	2														
3	3														
4	4														
5	5														
269	alert_sae18 Show the field ONLY if: [rc_ap]>2	Please, go to the "Serious adverse event initial report" Form	descriptive												
270	rc_hypotension Show the field ONLY if: [baseline_arm_1][randomization] <>"	Hypotension	dropdown <table><tr><td>0</td><td>0</td></tr><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr><tr><td>4</td><td>4</td></tr><tr><td>5</td><td>5</td></tr></table> Custom alignment: RH	0	0	1	1	2	2	3	3	4	4	5	5
0	0														
1	1														
2	2														
3	3														
4	4														
5	5														
271	alert_sae19 Show the field ONLY if: [rc_hypotension]>2	Please, go to the "Serious adverse event initial report" Form	descriptive												
272	rc_fatigue Show the field ONLY if: [baseline_arm_1][randomization] <>"	Fatigue	dropdown <table><tr><td>0</td><td>0</td></tr><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr><tr><td>4</td><td>4</td></tr><tr><td>5</td><td>5</td></tr></table> Custom alignment: RH	0	0	1	1	2	2	3	3	4	4	5	5
0	0														
1	1														
2	2														
3	3														
4	4														
5	5														
273	alert_sae20 Show the field ONLY if: [rc_fatigue]>2	Please, go to the "Serious adverse event initial report" Form	descriptive												
274	rc_headache Show the field ONLY if: [baseline_arm_1][randomization] <>"	Headache	dropdown <table><tr><td>0</td><td>0</td></tr><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr><tr><td>4</td><td>4</td></tr><tr><td>5</td><td>5</td></tr></table> Custom alignment: RH	0	0	1	1	2	2	3	3	4	4	5	5
0	0														
1	1														
2	2														
3	3														
4	4														
5	5														
275	alert_sae21 Show the field ONLY if: [rc_headache]>2	Please, go to the "Serious adverse event initial report" Form	descriptive												
276	rc_nausea Show the field ONLY if: [baseline_arm_1][randomization] <>"	Nausea	dropdown <table><tr><td>0</td><td>0</td></tr><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr><tr><td>4</td><td>4</td></tr><tr><td>5</td><td>5</td></tr></table> Custom alignment: RH	0	0	1	1	2	2	3	3	4	4	5	5
0	0														
1	1														
2	2														
3	3														
4	4														
5	5														
277	alert_sae22 Show the field ONLY if: [rc_nausea]>2	Please, go to the "Serious adverse event initial report" Form	descriptive												

278	rc_aeo Show the field ONLY if: [baseline_arm_1][randomization] <>"	Section Header: <i>Adverse Events</i> Other adverse event occurred?	dropdown 1 yes 2 no Custom alignment: RH
279	rc_go_ae_form Show the field ONLY if: [rc_aeo]=1	If yes, please complete the AE FORM	descriptive
280	related_therapy_rc Show the field ONLY if: [rc_alive]=1	Section Header: <i>OTHER THERAPIES RELATED TO COVID-19 DISEASE</i> Has any covid-19 related therapy been changed since the last visit?	radio 1 yes 2 no Custom alignment: RH
281	ot_hcq_rc Show the field ONLY if: [related_therapy_rc]=1	Hydroxychloroquine	radio 1 started 2 discontinued Custom alignment: RH
282	ot_cqp_rc Show the field ONLY if: [related_therapy_rc]=1	Chloroquine Phosphate	radio 1 started 2 discontinued Custom alignment: RH
283	ot_avd_rc Show the field ONLY if: [related_therapy_rc]=1	Antiviral drugs	radio 1 started 2 discontinued Custom alignment: RH
284	ot_antipyretic_rc Show the field ONLY if: [related_therapy_rc]=1	Antipyretic	radio 1 started 2 discontinued Custom alignment: RH
285	ot_nsaid_rc Show the field ONLY if: [related_therapy_rc]=1	Nonsteroidal anti-inflammatory drugs	radio 1 started 2 discontinued Custom alignment: RH
286	ot_antibiotic_rc Show the field ONLY if: [related_therapy_rc]=1	Antibiotics	radio 1 started 2 discontinued Custom alignment: RH
287	rc_ot_otcr Show the field ONLY if: [related_therapy_rc]=1	Other therapies related to COVID-19	dropdown 0 none 1 one 2 two 3 three 4 four or more
288	rc_ot_ot_spec_1 Show the field ONLY if: [rc_ot_otcr]>0	Specify first other therapy	text
289	rc_ot_ot_sd_1 Show the field ONLY if: [rc_ot_otcr]>0	[rc_ot_ot_spec_1]	radio 1 started 2 discontinued Custom alignment: RH
290	rc_ot_ot_spec_2 Show the field ONLY if: [rc_ot_otcr]>1	Specify second other therapy	text
291	rc_ot_ot_sd_2 Show the field ONLY if: [rc_ot_otcr]>1	[rc_ot_ot_spec_2]	radio 1 started 2 discontinued Custom alignment: RH

292	rc_ot_ot_spec_3 Show the field ONLY if: [rc_ot_otcr]>2	Specify third other therapy	text				
293	rc_ot_ot_sd_3 Show the field ONLY if: [rc_ot_otcr]>2	[rc_ot_ot_spec_3]	radio <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>discontinued</td></tr></table> Custom alignment: RH	1	started	2	discontinued
1	started						
2	discontinued						
294	rc_ot_ot_spec_4 Show the field ONLY if: [rc_ot_otcr]>3	Specify fourth other therapy	text				
295	rc_ot_ot_sd_4 Show the field ONLY if: [rc_ot_otcr]>3	[rc_ot_ot_spec_4]	radio <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>discontinued</td></tr></table> Custom alignment: RH	1	started	2	discontinued
1	started						
2	discontinued						
296	ct_changed_rc Show the field ONLY if: [rc_alive]=1	Section Header: <i>Other chronic therapies</i> Has any chronic therapy been changed since the last visit?	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no
1	yes						
2	no						
297	ot_ahtd_rc Show the field ONLY if: [ct_changed_rc]=1	Antihypertensive drugs	radio <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>discontinued</td></tr></table> Custom alignment: RH	1	started	2	discontinued
1	started						
2	discontinued						
298	ot_ahtd_specify_rc Show the field ONLY if: [ot_ahtd_rc]=1	Specify new antihypertensive drug	text Custom alignment: RH				
299	ot_ahtd_disc Show the field ONLY if: [ot_ahtd_rc]=2	Specify discontinued antihypertensive drug	text Custom alignment: RH				
300	ot_steroids_rc Show the field ONLY if: [ct_changed_rc]=1	Steroids	radio <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>discontinued</td></tr></table> Custom alignment: RH	1	started	2	discontinued
1	started						
2	discontinued						
301	ot_steroids_specify_rc Show the field ONLY if: [ot_steroids_rc]=1	Specify new steroid	text Custom alignment: RH				
302	ot_ab_rc Show the field ONLY if: [ct_changed_rc]=1	Antiblastics	radio <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>discontinued</td></tr></table> Custom alignment: RH	1	started	2	discontinued
1	started						
2	discontinued						
303	ot_ab_specify_rc Show the field ONLY if: [ot_ab_rc]=1	Specify new antiblastic	text Custom alignment: RH				
304	ot_isd_rc Show the field ONLY if: [ct_changed_rc]=1	Immunosuppressive drugs	radio <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>discontinued</td></tr></table> Custom alignment: RH	1	started	2	discontinued
1	started						
2	discontinued						
305	ot_isd_specify_rc Show the field ONLY if: [ot_isd_rc]=1	Specify new immunosuppressive drug	text Custom alignment: RH				
306	ot_bio_rc Show the field ONLY if: [ct_changed_rc]=1	Biologicals	radio <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>discontinued</td></tr></table> Custom alignment: RH	1	started	2	discontinued
1	started						
2	discontinued						
307	ot_bio_specify_rc Show the field ONLY if: [ot_isd_rc]=1	Specify new biological	text Custom alignment: RH				

308	otot_n_rc Show the field ONLY if: [ct_changed_rc]=1	Has any other chronic therapy changed since last visit?	dropdown <table><tr><td>0</td><td>none</td></tr><tr><td>1</td><td>one</td></tr><tr><td>2</td><td>two</td></tr><tr><td>3</td><td>three</td></tr><tr><td>4</td><td>four or more</td></tr></table>	0	none	1	one	2	two	3	three	4	four or more
0	none												
1	one												
2	two												
3	three												
4	four or more												
309	ot_ot1_rc Show the field ONLY if: [otot_n_rc]>0	First other therapy	radio <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>interrupted</td></tr></table> Custom alignment: RH	1	started	2	interrupted						
1	started												
2	interrupted												
310	ot_specify_ot1_rc Show the field ONLY if: [ot_ot1_rc]=1	Specify first new other therapy	text Custom alignment: RH										
311	ot_ot2_rc Show the field ONLY if: [otot_n_rc]>1	Second other therapy	radio <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>interrupted</td></tr></table> Custom alignment: RH	1	started	2	interrupted						
1	started												
2	interrupted												
312	ot_specify_ot2_rc Show the field ONLY if: [ot_ot2_rc]=1	Specify second new other therapy	text Custom alignment: RH										
313	ot_ot3_rc Show the field ONLY if: [otot_n_rc]>2	Third other therapy	radio <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>interrupted</td></tr></table> Custom alignment: RH	1	started	2	interrupted						
1	started												
2	interrupted												
314	ot_specify_ot3_rc Show the field ONLY if: [ot_ot3_rc]=1	Specify third new other therapy	text Custom alignment: RH										
315	ot_ot4_rc Show the field ONLY if: [otot_n_rc]>3	Fourth other therapy	radio <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>interrupted</td></tr></table> Custom alignment: RH	1	started	2	interrupted						
1	started												
2	interrupted												
316	ot_specify_ot4_rc Show the field ONLY if: [ot_ot4_rc]=1	Specify fourth new other therapy	text Custom alignment: RH										
317	rc_sbp Show the field ONLY if: [rc_alive]=1	Section Header: <i>Laboratory findings</i> Systolic Blood Pressure: (mmHg)	text (integer)										
318	rc_dbp Show the field ONLY if: [rc_alive]=1	Diastolic Blood Pressure: (mmHg)	text (integer)										
319	rc_wbc Show the field ONLY if: [rc_alive]=1	WBC	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr><tr><td>3</td><td>N/A</td></tr></table> Custom alignment: RH	1	yes	2	no	3	N/A				
1	yes												
2	no												
3	N/A												
320	rc_wbc_v Show the field ONLY if: [rc_wbc]=1	WBC value: (N/ μ l)	text (integer) Custom alignment: RH										
321	rc_lymphocytes Show the field ONLY if: [rc_alive]=1	Lymphocytes	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr><tr><td>3</td><td>N/A</td></tr></table> Custom alignment: RH	1	yes	2	no	3	N/A				
1	yes												
2	no												
3	N/A												
322	rc_lymphocytes_v Show the field ONLY if: [rc_lymphocytes]=1	Lymphocytes value: (N/ μ l)	text (integer) Custom alignment: RH										

323	rc_crp Show the field ONLY if: [rc_alive]=1	C-reactive protein	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr><tr><td>3</td><td>N/A</td></tr></table> Custom alignment: RH	1	yes	2	no	3	N/A
1	yes								
2	no								
3	N/A								
324	rc_crp_v Show the field ONLY if: [rc_crp]=1	C-reactive protein value: (µg/l)	text (integer) Custom alignment: RH						
325	rc_alt Show the field ONLY if: [rc_alive]=1	ALT	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr><tr><td>3</td><td>N/A</td></tr></table> Custom alignment: RH	1	yes	2	no	3	N/A
1	yes								
2	no								
3	N/A								
326	rc_alt_v Show the field ONLY if: [rc_alt]=1	ALT value: (U/l)	text (integer) Custom alignment: RH						
327	rc_pao2 Show the field ONLY if: [rc_alive]=1	PaO2	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr><tr><td>3</td><td>N/A</td></tr></table> Custom alignment: RH	1	yes	2	no	3	N/A
1	yes								
2	no								
3	N/A								
328	rc_pao2_v Show the field ONLY if: [rc_pao2]=1	PaO2 value: (mmHg)	text (integer) Custom alignment: RH						
329	rc_cov2	SARS-CoV-2 Nasopharyngeal swab: (to be stored at -80 °C after exam)	radio <table><tr><td>1</td><td>positive</td></tr><tr><td>2</td><td>negative</td></tr><tr><td>3</td><td>N/A</td></tr></table> Custom alignment: RH	1	positive	2	negative	3	N/A
1	positive								
2	negative								
3	N/A								
330	rc_cxr Show the field ONLY if: [rc_alive]=1	Section Header: <i>Imaging</i> Chest X-Ray	radio <table><tr><td>1</td><td>performed</td></tr><tr><td>2</td><td>not performed</td></tr></table> Custom alignment: RH	1	performed	2	not performed		
1	performed								
2	not performed								
331	rc_lcts Show the field ONLY if: [rc_alive]=1	Lung CT scan	radio <table><tr><td>1</td><td>performed</td></tr><tr><td>2</td><td>not performed</td></tr></table> Custom alignment: RH	1	performed	2	not performed		
1	performed								
2	not performed								
332	prah_rc Show the field ONLY if: [rc_alive]=1	Section Header: Patient required admission to hospital?	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no		
1	yes								
2	no								
333	rc_prah_why Show the field ONLY if: [prah_rc]=1	Why	text						
334	rc_prah_date Show the field ONLY if: [prah_rc]=1	Date of hospitalization	text (date_ymd)						
335	rc_prah_hospital Show the field ONLY if: [prah_rc]=1	Which Hospital	text						
336	rc_prah_ward Show the field ONLY if: [prah_rc]=1	Which ward	text						

337	rc_covid_ss	COVID-19 Severity Score	<div>dropdown</div> <div><div>1</div><div>1, no limitation of activities</div></div> <div><div>2</div><div>2, limitation of activities</div></div> <div><div>3</div><div>3, hospitalized, no oxygen therapy</div></div> <div><div>4</div><div>4, hospitalized, oxygen by mask or nasal prongs</div></div> <div><div>5</div><div>5, non-invasive ventilation or high-flow oxygen</div></div> <div><div>6</div><div>6, intubation and mechanical ventilation</div></div> <div><div>7</div><div>7, ventilation + additional organ support - pressors, RRT (renal replacement therapy), ECMO (extracorporeal membrane oxygenation)</div></div> <div><div>8</div><div>8, death</div></div>
338	stored_d7 Show the field ONLY if: [dov_rc]=1	Has the nasopharyngeal swab been stored at -80 °C after exam?	<div>radio</div> <div><div>1</div><div>yes</div></div> <div><div>2</div><div>no</div></div> <div>Custom alignment: RH</div>
339	pharma_d7 Show the field ONLY if: [dov_rc]=1	<div>Section Header: <i>Pharmacokinetics study (Only for subjects been recruited for the ancillary pharmacokinetics study)</i></div> <div>Has the pharmacokinetics study been performed regularly?</div>	<div>dropdown</div> <div><div>1</div><div>yes</div></div> <div><div>2</div><div>no</div></div> <div>Custom alignment: RH</div>
340	serum_stored_d7 Show the field ONLY if: [dov_rc]=1	Have the serum samples been stored at -80? °C ?	<div>dropdown</div> <div><div>1</div><div>yes</div></div> <div><div>2</div><div>no</div></div> <div>Custom alignment: RH</div>
341	recruiting_centre_visit_complete	<div>Section Header: <i>Form Status</i></div> <div>Complete?</div>	<div>dropdown</div> <div><div>0</div><div>Incomplete</div></div> <div><div>1</div><div>Unverified</div></div> <div><div>2</div><div>Complete</div></div>
<div>Instrument: FOLLOW UP VISIT (follow_up_visit)</div> <div>⤴ Collapse</div>			
342	alert_random_d30 Show the field ONLY if: [baseline_arm_1][randomization] ="	In order to fill this form, the patient must be randomized	descriptive
343	alert_rc_alive Show the field ONLY if: [alive_d30]=2	Then patient si not alive	descriptive
344	rnd_days_d30 Show the field ONLY if: [alive_d30]<>2	Randomization code: [[baseline_arm_1][randomization]]	descriptive
345	dov_d30 Show the field ONLY if: [alive_d30]<>2	Date of visit	text (date_dmy)
346	alive_d30 Show the field ONLY if: [baseline_arm_1][randomization] <>"	<div>Section Header: <i>Patient status</i></div> <div>Is the patient alive?</div>	<div>radio</div> <div><div>1</div><div>yes</div></div> <div><div>2</div><div>no</div></div> <div>Custom alignment: RH</div>
347	setting_d30 Show the field ONLY if: [alive_d30]=1	Current setting	<div>dropdown</div> <div><div>1</div><div>home</div></div> <div><div>2</div><div>hospitalized</div></div> <div><div>3</div><div>other</div></div>
348	ps_specify_d30 Show the field ONLY if: [setting_d30]=3	Specify please	text
349	hosp_date_d30 Show the field ONLY if: [setting_d30]=2	Hospitalization date	text (date_dmy)
350	hosp_why_d30 Show the field ONLY if: [setting_d30]=2	Reason for hospitalization	text

351	icu_d30 Show the field ONLY if: [setting_d30]=2	Recovery in Intensive Care Unit?	radio 1 yes 2 no Custom alignment: RH
352	death_date_d30 Show the field ONLY if: [alive_d30]=2	Death date	text (date_dmy) Custom alignment: RH
353	deat_cause_d30 Show the field ONLY if: [alive_d30]=2	Death cause	text Custom alignment: RH
354	d30_currsetting	Setting of current visit	radio 1 Home 2 Hospital emergency room 3 Hospital outpatient ambulatory care 4 Extra- Hospital outpatient ambulatory care 5 Other
355	fever_t_d30 Show the field ONLY if: [alive_d30]=1	Section Header: <i>Symptoms?</i> Temperature: (°C)	text (number_1dp, Max: 43.0) Custom alignment: RH
356	hr_d30 Show the field ONLY if: [alive_d30]=1	Hearth rate: (/min)	text (integer) Custom alignment: RH
357	rr_d30 Show the field ONLY if: [alive_d30]=1	Respiratory Rate: (/min)	text Custom alignment: RH
358	dyspnea_d30 Show the field ONLY if: [alive_d30]=1	Dyspnea	radio 1 yes 2 no Custom alignment: RH
359	cough_d30 Show the field ONLY if: [alive_d30]=1	Cough	radio 1 yes 2 no Custom alignment: RH
360	diarrhoea_d30 Show the field ONLY if: [alive_d30]=1	Diarrhoea	radio 1 yes 2 no Custom alignment: RH
361	symp_other_d30 Show the field ONLY if: [alive_d30]=1	Other	dropdown 0 none 1 one 2 two 3 three 4 four or more
362	d30_symp_other_1 Show the field ONLY if: [symp_other_d30]>0	Specify first other symptom	text
363	d30_symp_other_2 Show the field ONLY if: [symp_other_d30]>1	Specify second other symptom	text
364	d30_symp_other_3 Show the field ONLY if: [symp_other_d30]>2	Specify third other symptom	text
365	d30_symp_other_4 Show the field ONLY if: [symp_other_d30]>3	Specify fourth other symptom	text

366	<div>d30_drowsiness</div> <div>Show the field ONLY if: [baseline_arm_1][randomization] <>"</div>	<div>Section Header: Adverse reactions Please report each occurred adverse reaction also in the AE FORM, in order to provide major details Grading: 0 (none); 1 (mild: any symptoms possibly related to study drug, not necessitating medication); 2 (moderate: any symptoms resolved with medication, not requiring hospitalization); 3 (severe: necessity of hospitalization or prolongation of existing hospitalization); 4 (near fatal: necessity of intensive care); 5 (fatal). Please write "0" if the symptom was not present</div> <div>Drowsiness</div>	<div>dropdown</div> <div><div>00</div><div>11</div><div>22</div><div>33</div><div>44</div><div>55</div></div> <div>Custom alignment: RH</div>
367	<div>alert_sae29</div> <div>Show the field ONLY if: [d30_drowsiness]>2</div>	<div>Please, go to the "Serious adverse event initial report" Form</div>	<div>descriptive</div>
368	<div>d30_vomit</div> <div>Show the field ONLY if: [baseline_arm_1][randomization] <>"</div>	<div>Vomit</div>	<div>dropdown</div> <div><div>00</div><div>11</div><div>22</div><div>33</div><div>44</div><div>55</div></div> <div>Custom alignment: RH</div>
369	<div>alert_sae30</div> <div>Show the field ONLY if: [d30_vomit]>2</div>	<div>Please, go to the "Serious adverse event initial report" Form</div>	<div>descriptive</div>
370	<div>d30_pruritus</div> <div>Show the field ONLY if: [baseline_arm_1][randomization] <>"</div>	<div>Pruritus</div>	<div>dropdown</div> <div><div>00</div><div>11</div><div>22</div><div>33</div><div>44</div><div>55</div></div> <div>Custom alignment: RH</div>
371	<div>alert_sae31</div> <div>Show the field ONLY if: [d30_pruritus]>2</div>	<div>Please, go to the "Serious adverse event initial report" Form</div>	<div>descriptive</div>
372	<div>d30_ap</div> <div>Show the field ONLY if: [baseline_arm_1][randomization] <>"</div>	<div>Abdominal pain</div>	<div>dropdown</div> <div><div>00</div><div>11</div><div>22</div><div>33</div><div>44</div><div>55</div></div> <div>Custom alignment: RH</div>
373	<div>alert_sae32</div> <div>Show the field ONLY if: [d30_ap]>2</div>	<div>Please, go to the "Serious adverse event initial report" Form</div>	<div>descriptive</div>
374	<div>d30_hypotension</div> <div>Show the field ONLY if: [baseline_arm_1][randomization] <>"</div>	<div>Hypotension</div>	<div>dropdown</div> <div><div>00</div><div>11</div><div>22</div><div>33</div><div>44</div><div>55</div></div> <div>Custom alignment: RH</div>
375	<div>alert_sae33</div> <div>Show the field ONLY if: [d30_hypotension]>2</div>	<div>Please, go to the "Serious adverse event initial report" Form</div>	<div>descriptive</div>

376	<div>d30_fatigue</div> <div>Show the field ONLY if: [baseline_arm_1][randomization] <>"</div>	Fatigue	<div>dropdown</div> <div><div>00</div><div>11</div><div>22</div><div>33</div><div>44</div><div>55</div></div> <div>Custom alignment: RH</div>
377	<div>alert_sae34</div> <div>Show the field ONLY if: [d30_fatigue]>2</div>	Please, go to the "Serious adverse event initial report" Form	descriptive
378	<div>d30_headache</div> <div>Show the field ONLY if: [baseline_arm_1][randomization] <>"</div>	Headache	<div>dropdown</div> <div><div>00</div><div>11</div><div>22</div><div>33</div><div>44</div><div>55</div></div> <div>Custom alignment: RH</div>
379	<div>alert_sae35</div> <div>Show the field ONLY if: [d30_headache]>2</div>	Please, go to the "Serious adverse event initial report" Form	descriptive
380	<div>d30_nausea</div> <div>Show the field ONLY if: [baseline_arm_1][randomization] <>"</div>	Nausea	<div>dropdown</div> <div><div>00</div><div>11</div><div>22</div><div>33</div><div>44</div><div>55</div></div> <div>Custom alignment: RH</div>
381	<div>alert_sae36</div> <div>Show the field ONLY if: [d30_nausea]>2</div>	Please, go to the "Serious adverse event initial report" Form	descriptive
382	<div>d30_aeo</div> <div>Show the field ONLY if: [baseline_arm_1][randomization] <>"</div>	<div>Section Header: <i>Adverse Events</i></div> <div>Adverse event</div>	<div>dropdown</div> <div><div>1yes</div><div>2no</div></div> <div>Custom alignment: RH</div>
383	<div>fu_alert_aeform</div> <div>Show the field ONLY if: [d30_aeo]=1</div>	If yes, please complete the AE FORM	descriptive
384	<div>related_therapy_d30</div> <div>Show the field ONLY if: [alive_d30]=1</div>	<div>Section Header: <i>OTHER THERAPIES RELATED TO COVID-19 DISEASE</i></div> <div>Has any covid-19 related therapy been changed since the last visit?</div>	<div>radio</div> <div><div>1yes</div><div>2no</div></div> <div>Custom alignment: RH</div>
385	<div>ot_hcq_d30</div> <div>Show the field ONLY if: [related_therapy_d30]=1</div>	Hydroxychloroquine	<div>radio</div> <div><div>1started</div><div>2discontinued</div></div> <div>Custom alignment: RH</div>
386	<div>ot_cqp_d30</div> <div>Show the field ONLY if: [related_therapy_d30]=1</div>	Chloroquine Phosphate	<div>radio</div> <div><div>1started</div><div>2discontinued</div></div> <div>Custom alignment: RH</div>
387	<div>ot_avd_d30</div> <div>Show the field ONLY if: [related_therapy_d30]=1</div>	Antiviral drugs	<div>radio</div> <div><div>1started</div><div>2discontinued</div></div> <div>Custom alignment: RH</div>

388	ot_antipyretic_d30 Show the field ONLY if: [related_therapy_d30]=1	Antipyretic	radio 1 started 2 discontinued Custom alignment: RH
389	ot_nsaid_d30 Show the field ONLY if: [related_therapy_d30]=1	Nonsteroidal anti-inflammatory drugs	radio 1 started 2 discontinued Custom alignment: RH
390	ot_antibiotic_d30 Show the field ONLY if: [related_therapy_d30]=1	Antibiotics	radio 1 started 2 discontinued Custom alignment: RH
391	d30_ot_otcr Show the field ONLY if: [related_therapy_rc]=1	Other therapies related to COVID-19	dropdown 0 none 1 one 2 two 3 three 4 four or more
392	d30_ot_ot_spec_1 Show the field ONLY if: [d30_ot_otcr]>0	Specify first other therapy	text
393	d30_ot_ot_sd_1 Show the field ONLY if: [d30_ot_otcr]>0	[d30_ot_ot_spec_1]	radio 1 started 2 discontinued Custom alignment: RH
394	d30_ot_ot_spec_2 Show the field ONLY if: [d30_ot_otcr]>1	Specify second other therapy	text
395	d30_ot_ot_sd_2 Show the field ONLY if: [d30_ot_otcr]>1	[d30_ot_ot_spec_2]	radio 1 started 2 discontinued Custom alignment: RH
396	d30_ot_ot_spec_3 Show the field ONLY if: [d30_ot_otcr]>2	Specify third other therapy	text
397	d30_ot_ot_sd_3 Show the field ONLY if: [d30_ot_otcr]>2	[d30_ot_ot_spec_3]	radio 1 started 2 discontinued Custom alignment: RH
398	d30_ot_ot_spec_4 Show the field ONLY if: [d30_ot_otcr]>3	Specify fourth other therapy	text
399	d30_ot_ot_sd_4 Show the field ONLY if: [d30_ot_otcr]>3	[d30_ot_ot_spec_4]	radio 1 started 2 discontinued Custom alignment: RH
400	ct_changed_d30 Show the field ONLY if: [alive_d30]=1	Section Header: <i>Other chronic therapies</i> Has any chronic therapy been changed since the last visit?	radio 1 yes 2 no Custom alignment: RH
401	ot_ahtd_d30 Show the field ONLY if: [ct_changed_d30]=1	Antihypertensive drugs	radio 1 started 2 discontinued Custom alignment: RH

402	ot_ahtd_specify_d30 Show the field ONLY if: [ot_ahtd_d30]=1	Specify new antihypertensive drug	text Custom alignment: RH										
403	ot_ahtd_disc_d31 Show the field ONLY if: [ot_ahtd_d30]=2	Specify discontinued antihypertensive drug	text Custom alignment: RH										
404	ot_steroids_d30 Show the field ONLY if: [ct_changed_d30]=1	Steroids	radio <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>discontinued</td></tr></table> Custom alignment: RH	1	started	2	discontinued						
1	started												
2	discontinued												
405	ot_steroids_specify_d30 Show the field ONLY if: [ot_steroids_d30]=1	Specify new steroid	text Custom alignment: RH										
406	ot_ab_d30 Show the field ONLY if: [ct_changed_d30]=1	Antiblastics	radio <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>discontinued</td></tr></table> Custom alignment: RH	1	started	2	discontinued						
1	started												
2	discontinued												
407	ot_ab_specify_d30 Show the field ONLY if: [ot_ab_d30]=1	Specify new antineoplastic	text Custom alignment: RH										
408	ot_isd_d30 Show the field ONLY if: [ct_changed_d30]=1	Immunosuppressive drugs	radio <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>discontinued</td></tr></table> Custom alignment: RH	1	started	2	discontinued						
1	started												
2	discontinued												
409	ot_isd_specify_d30 Show the field ONLY if: [ot_isd_d30]=1	Specify new immunosuppressive drug	text Custom alignment: RH										
410	ot_bio_d30 Show the field ONLY if: [ct_changed_d30]=1	Biologicals	radio <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>discontinued</td></tr></table> Custom alignment: RH	1	started	2	discontinued						
1	started												
2	discontinued												
411	ot_bio_specify_d30 Show the field ONLY if: [ot_isd_d30]=1	Specify new biological	text Custom alignment: RH										
412	otot_n_d30 Show the field ONLY if: [ct_changed_d30]=1	Has any other chronic therapy changed since last visit?	dropdown <table><tr><td>0</td><td>none</td></tr><tr><td>1</td><td>one</td></tr><tr><td>2</td><td>two</td></tr><tr><td>3</td><td>three</td></tr><tr><td>4</td><td>four or more</td></tr></table>	0	none	1	one	2	two	3	three	4	four or more
0	none												
1	one												
2	two												
3	three												
4	four or more												
413	ot_ot1_d30 Show the field ONLY if: [otot_n_d30]>0	First other therapy	radio <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>discontinued</td></tr></table> Custom alignment: RH	1	started	2	discontinued						
1	started												
2	discontinued												
414	ot_specify_ot1_d30 Show the field ONLY if: [ot_ot1_d30]=1	Specify first new other therapy	text Custom alignment: RH										
415	ot_ot2_d30 Show the field ONLY if: [otot_n_d30]>1	Second other therapy	radio <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>discontinued</td></tr></table> Custom alignment: RH	1	started	2	discontinued						
1	started												
2	discontinued												
416	ot_specify_ot2_d30 Show the field ONLY if: [ot_ot2_d30]=1	Specify second new other therapy	text Custom alignment: RH										

417	ot_ot3_d30 Show the field ONLY if: [otot_n_d30]>2	Third other therapy	radio <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>discontinued</td></tr></table> Custom alignment: RH	1	started	2	discontinued		
1	started								
2	discontinued								
418	ot_specify_ot3_d30 Show the field ONLY if: [ot_ot3_d30]=1	Specify third new other therapy	text Custom alignment: RH						
419	ot_ot4_d30 Show the field ONLY if: [otot_n_d30]>3	Fourth other therapy	radio <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>discontinued</td></tr></table> Custom alignment: RH	1	started	2	discontinued		
1	started								
2	discontinued								
420	ot_specify_ot4_d30 Show the field ONLY if: [ot_ot4_d30]=1	Specify fourth new other therapy	text Custom alignment: RH						
421	sbp_d30 Show the field ONLY if: [alive_d30]=1	Section Header: <i>Laboratory findings</i> Sistolic Blood Pressure: (mmHg)	text (integer)						
422	dbp_d30 Show the field ONLY if: [alive_d30]=1	Diastolic Blood Pressure: (mmHg)	text (integer)						
423	wbc_d30 Show the field ONLY if: [alive_d30]=1	WBC	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr><tr><td>3</td><td>N/A</td></tr></table> Custom alignment: RH	1	yes	2	no	3	N/A
1	yes								
2	no								
3	N/A								
424	wbc_v_d30 Show the field ONLY if: [wbc_d30]=1	WBC value: (N/ μ l)	text (integer) Custom alignment: RH						
425	lymphocytes_d30 Show the field ONLY if: [alive_d30]=1	Lymphocytes	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr><tr><td>3</td><td>N/A</td></tr></table> Custom alignment: RH	1	yes	2	no	3	N/A
1	yes								
2	no								
3	N/A								
426	lymphocytes_v_d30 Show the field ONLY if: [lymphocytes_d30]=1	Lymphocytes value: (N/ μ l)	text (integer) Custom alignment: RH						
427	crp_d30 Show the field ONLY if: [alive_d30]=1	C-reactive protein	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr><tr><td>3</td><td>N/A</td></tr></table> Custom alignment: RH	1	yes	2	no	3	N/A
1	yes								
2	no								
3	N/A								
428	crp_v_d30 Show the field ONLY if: [lymphocytes_d30]=1	C-reactive protein value: (μ g/l)	text (integer) Custom alignment: RH						
429	alt_d30 Show the field ONLY if: [alive_d30]=1	ALT	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr><tr><td>3</td><td>N/A</td></tr></table> Custom alignment: RH	1	yes	2	no	3	N/A
1	yes								
2	no								
3	N/A								
430	alt_v_d30 Show the field ONLY if: [lymphocytes_d30]=1	ALT value: (U/l)	text (integer) Custom alignment: RH						
431	pao2_d30 Show the field ONLY if: [alive_d30]=1	PaO2	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr><tr><td>3</td><td>N/A</td></tr></table> Custom alignment: RH	1	yes	2	no	3	N/A
1	yes								
2	no								
3	N/A								

432	pao2_v_d30 Show the field ONLY if: [lymphocytes_d30]=1	PaO2 value: (mmHg)	text (integer) Custom alignment: RH																
433	cov2_d30 Show the field ONLY if: [alive_d30]=1	SARS-CoV-2 Nasopharyngeal swab: (to be stored at -80 °C after exam)	radio <table><tr><td>1</td><td>positive</td></tr><tr><td>2</td><td>negative</td></tr><tr><td>3</td><td>N/A</td></tr></table> Custom alignment: RH	1	positive	2	negative	3	N/A										
1	positive																		
2	negative																		
3	N/A																		
434	cxr_d30 Show the field ONLY if: [alive_d30]=1	Section Header: <i>Imaging</i> Chest X-Ray	radio <table><tr><td>1</td><td>performed</td></tr><tr><td>2</td><td>not performed</td></tr></table> Custom alignment: RH	1	performed	2	not performed												
1	performed																		
2	not performed																		
435	lcts_d30 Show the field ONLY if: [alive_d30]=1	Lung CT scan	radio <table><tr><td>1</td><td>performed</td></tr><tr><td>2</td><td>not performed</td></tr></table> Custom alignment: RH	1	performed	2	not performed												
1	performed																		
2	not performed																		
436	prah_d30 Show the field ONLY if: [alive_d30]=1	Section Header: Patient required admission to hospital?	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no												
1	yes																		
2	no																		
437	prah_why Show the field ONLY if: [prah_d30]=1	Why	text																
438	prah_date Show the field ONLY if: [prah_d30]=1	Date of hospitalization	text (date_ymd)																
439	prah_hospital Show the field ONLY if: [prah_d30]=1	Which Hospital	text																
440	prah_ward Show the field ONLY if: [prah_d30]=1	Which ward	text																
441	covid_ss_d30 Show the field ONLY if: [alive_d30]=1	COVID-19 Severity Score	dropdown <table><tr><td>1</td><td>1, no limitation of activities</td></tr><tr><td>2</td><td>2, limitation of activities</td></tr><tr><td>3</td><td>3, hospitalized, no oxygen therapy</td></tr><tr><td>4</td><td>4, hospitalized, oxygen by mask or nasal prongs</td></tr><tr><td>5</td><td>5, non-invasive ventilation or high-flow oxygen</td></tr><tr><td>6</td><td>6, intubation and mechanical ventilation</td></tr><tr><td>7</td><td>7, ventilation + additional organ support - pressors, RRT (renal replacement therapy), ECMO (extracorporeal membrane oxygenation)</td></tr><tr><td>8</td><td>8, death</td></tr></table>	1	1, no limitation of activities	2	2, limitation of activities	3	3, hospitalized, no oxygen therapy	4	4, hospitalized, oxygen by mask or nasal prongs	5	5, non-invasive ventilation or high-flow oxygen	6	6, intubation and mechanical ventilation	7	7, ventilation + additional organ support - pressors, RRT (renal replacement therapy), ECMO (extracorporeal membrane oxygenation)	8	8, death
1	1, no limitation of activities																		
2	2, limitation of activities																		
3	3, hospitalized, no oxygen therapy																		
4	4, hospitalized, oxygen by mask or nasal prongs																		
5	5, non-invasive ventilation or high-flow oxygen																		
6	6, intubation and mechanical ventilation																		
7	7, ventilation + additional organ support - pressors, RRT (renal replacement therapy), ECMO (extracorporeal membrane oxygenation)																		
8	8, death																		
442	ic_obtained	Informed consent available as:	dropdown <table><tr><td>1</td><td>oral consensus</td></tr><tr><td>2</td><td>written and signed consensus</td></tr><tr><td>3</td><td>other</td></tr></table>	1	oral consensus	2	written and signed consensus	3	other										
1	oral consensus																		
2	written and signed consensus																		
3	other																		
443	ic_obtained_s Show the field ONLY if: [ic_obtained]=3	Please, specify	text																
444	alert_death Show the field ONLY if: [alive_d30]=2	Please, go to the "Death" Form	descriptive																
445	follow_up_visit_complete	Section Header: <i>Form Status</i> Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete										
0	Incomplete																		
1	Unverified																		
2	Complete																		

Instrument: **UNSCHEDULED PHONE VISIT** (unscheduled_phone_visit)

⬆ Collapse

Instrument: **UNSCHEDULED PHONE VISIT** (unscheduled_phone_visit)[^ Collapse](#)

446	alert_random_dv_u Show the field ONLY if: [baseline_arm_1][randomization] =>	In order to fill this form, the patient must be randomized	descriptive										
447	rnd_days_u Show the field ONLY if: [baseline_arm_1][randomization] <>	Randomization code: [[baseline_arm_1][randomization]]	descriptive										
448	dov_dv_u Show the field ONLY if: [baseline_arm_1][randomization] <>	Date of visit	text (date_dmy)										
449	drug_assumption_u Show the field ONLY if: [baseline_arm_1][randomization] <>	Section Header: <i>Study drugs</i> Has the drug taken according to medical indication?	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no						
1	yes												
2	no												
450	dv_withdrawn_u Show the field ONLY if: [drug_assumption_u]=2	Has the drug been withdrawn?	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no						
1	yes												
2	no												
451	dv_u_alert_wdform Show the field ONLY if: [dv_withdrawn_u]=1	if the drug was withdrawn, please complete the withdrawal form	descriptive										
452	dv_u_pills_skpd Show the field ONLY if: [dv_withdrawn_u]=2	Have one or more pill(s) skipped?	dropdown <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	Yes	2	no						
1	Yes												
2	no												
453	n_pills_u Show the field ONLY if: [dv_u_pills_skpd]=1	If yes, how many pills have been taken?	text (number) Custom alignment: RH										
454	dv_u_skpd_reason Show the field ONLY if: [dv_u_pills_skpd]=1	Reason for dose skipped:	dropdown <table><tr><td>1</td><td>Toxicity*</td></tr><tr><td>2</td><td>Deterioration of clinical conditions or clinical decision</td></tr><tr><td>3</td><td>Patient decision**</td></tr><tr><td>4</td><td>Non compliance</td></tr><tr><td>5</td><td>Logistic organization</td></tr></table> Custom alignment: RH	1	Toxicity*	2	Deterioration of clinical conditions or clinical decision	3	Patient decision**	4	Non compliance	5	Logistic organization
1	Toxicity*												
2	Deterioration of clinical conditions or clinical decision												
3	Patient decision**												
4	Non compliance												
5	Logistic organization												
455	dv_u_alert_aeform Show the field ONLY if: [dv_u_skpd_reason]=1	*if Toxicity, please complete the adverse reaction/adverse event form	descriptive										
456	dv_u_skpd_p_dec Show the field ONLY if: [dv_u_skpd_reason]=3	** If patient decision, please specify:	text Custom alignment: RH										
457	dv_fever_t_u Show the field ONLY if: [baseline_arm_1][randomization] <>	Section Header: <i>Symptoms?</i> Temperature: (°C)	text (number_1dp, Min: 34.0, Max: 43.0) Custom alignment: RH										
458	dv_hr_u Show the field ONLY if: [baseline_arm_1][randomization] <>	Hearth rate: (/min)	text (integer) Custom alignment: RH										
459	dv_rr_u Show the field ONLY if: [baseline_arm_1][randomization] <>	Respiratory Rate: (/min)	text Custom alignment: RH										
460	dv_dyspnea_u Show the field ONLY if: [baseline_arm_1][randomization] <>	Dyspnea	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no						
1	yes												
2	no												

461	dv_cough_u Show the field ONLY if: [baseline_arm_1][randomization] <>"	Cough	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no								
1	yes														
2	no														
462	dv_diarrhoea_u Show the field ONLY if: [baseline_arm_1][randomization] <>"	Diarrhoea	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no								
1	yes														
2	no														
463	symp_other_pv_u Show the field ONLY if: [baseline_arm_1][randomization] <>"	Other	dropdown <table><tr><td>0</td><td>none</td></tr><tr><td>1</td><td>one</td></tr><tr><td>2</td><td>two</td></tr><tr><td>3</td><td>three</td></tr><tr><td>4</td><td>four or more</td></tr></table>	0	none	1	one	2	two	3	three	4	four or more		
0	none														
1	one														
2	two														
3	three														
4	four or more														
464	symp_other_1_u Show the field ONLY if: [symp_other_pv_u]>0	Specify first other symptom	text												
465	symp_other_2_u Show the field ONLY if: [symp_other_pv_u]>1	Specify second other symptom	text												
466	symp_other_3_u Show the field ONLY if: [symp_other_pv_u]>2	Specify third other symptom	text												
467	symp_other_4_u Show the field ONLY if: [symp_other_pv_u]>3	Specify fourth other symptom	text												
468	dv_drowsiness_u Show the field ONLY if: [baseline_arm_1][randomization] <>"	Section Header: Adverse reactions Please report each occurred adverse reaction also in the AE FORM, in order to provide major details Grading: 0 (none); 1 (mild; any symptoms possibly related to study drug, not necessitating medication); 2 (moderate: any symptoms resolved with medication, not requiring hospitalization); 3 (severe: necessity of hospitalization or prolongation of existing hospitalization); 4 (near fatal: necessity of intensive care); 5 (fatal). Please write "0" if the symptom was not present Drowsiness	dropdown <table><tr><td>0</td><td>0</td></tr><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr><tr><td>4</td><td>4</td></tr><tr><td>5</td><td>5</td></tr></table> Custom alignment: RH	0	0	1	1	2	2	3	3	4	4	5	5
0	0														
1	1														
2	2														
3	3														
4	4														
5	5														
469	alert_sae1_u Show the field ONLY if: [dv_drowsiness_u]>2	Please, go to the "Serious adverse event initial report" Form	descriptive												
470	dv_vomit_u Show the field ONLY if: [baseline_arm_1][randomization] <>"	Vomit	dropdown <table><tr><td>0</td><td>0</td></tr><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr><tr><td>4</td><td>4</td></tr><tr><td>5</td><td>5</td></tr></table> Custom alignment: RH	0	0	1	1	2	2	3	3	4	4	5	5
0	0														
1	1														
2	2														
3	3														
4	4														
5	5														
471	alert_sae2_u Show the field ONLY if: [dv_vomit_u]>2	Please, go to the "Serious adverse event initial report" Form	descriptive												
472	dv_pruritus_u Show the field ONLY if: [baseline_arm_1][randomization] <>"	Pruritus	dropdown <table><tr><td>0</td><td>0</td></tr><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr><tr><td>4</td><td>4</td></tr><tr><td>5</td><td>5</td></tr></table> Custom alignment: RH	0	0	1	1	2	2	3	3	4	4	5	5
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3	3														
4	4														
5	5														

473	alert_sae3_u Show the field ONLY if: [dv_pruritus_u]>2	Please, go to the "Serious adverse event initial report" Form	descriptive												
474	dv_ap_u Show the field ONLY if: [baseline_arm_1][randomization] <>"	Abdominal pain	dropdown <table><tr><td>0</td><td>0</td></tr><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr><tr><td>4</td><td>4</td></tr><tr><td>5</td><td>5</td></tr></table> Custom alignment: RH	0	0	1	1	2	2	3	3	4	4	5	5
0	0														
1	1														
2	2														
3	3														
4	4														
5	5														
475	alert_sae4_u Show the field ONLY if: [dv_ap_u]>2	Please, go to the "Serious adverse event initial report" Form	descriptive												
476	dv_hypotension_u Show the field ONLY if: [baseline_arm_1][randomization] <>"	Hypotension	dropdown <table><tr><td>0</td><td>0</td></tr><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr><tr><td>4</td><td>4</td></tr><tr><td>5</td><td>5</td></tr></table> Custom alignment: RH	0	0	1	1	2	2	3	3	4	4	5	5
0	0														
1	1														
2	2														
3	3														
4	4														
5	5														
477	alert_sae5_u Show the field ONLY if: [dv_hypotension_u]>2	Please, go to the "Serious adverse event initial report" Form	descriptive												
478	dv_fatigue_u Show the field ONLY if: [baseline_arm_1][randomization] <>"	Fatigue	dropdown <table><tr><td>0</td><td>0</td></tr><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr><tr><td>4</td><td>4</td></tr><tr><td>5</td><td>5</td></tr></table> Custom alignment: RH	0	0	1	1	2	2	3	3	4	4	5	5
0	0														
1	1														
2	2														
3	3														
4	4														
5	5														
479	alert_sae6_u Show the field ONLY if: [dv_fatigue_u]>2	Please, go to the "Serious adverse event initial report" Form	descriptive												
480	dv_headache_u Show the field ONLY if: [baseline_arm_1][randomization] <>"	Headache	dropdown <table><tr><td>0</td><td>0</td></tr><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr><tr><td>4</td><td>4</td></tr><tr><td>5</td><td>5</td></tr></table> Custom alignment: RH	0	0	1	1	2	2	3	3	4	4	5	5
0	0														
1	1														
2	2														
3	3														
4	4														
5	5														
481	alert_sae7_u Show the field ONLY if: [dv_headache_u]>2	Please, go to the "Serious adverse event initial report" Form	descriptive												
482	dv_nausea_u Show the field ONLY if: [baseline_arm_1][randomization] <>"	Nausea	dropdown <table><tr><td>0</td><td>0</td></tr><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr><tr><td>4</td><td>4</td></tr><tr><td>5</td><td>5</td></tr></table> Custom alignment: RH	0	0	1	1	2	2	3	3	4	4	5	5
0	0														
1	1														
2	2														
3	3														
4	4														
5	5														
483	alert_sae7_u_2 Show the field ONLY if: [dv_nausea_u]>2	Please, go to the "Serious adverse event initial report" Form	descriptive												

484	pv_aeo_u Show the field ONLY if: [baseline_arm_1][randomization] <>"	Section Header: <i>Adverse Events</i> Adverse event	dropdown 1 yes 2 no Custom alignment: RH
485	dv_u_alert_aeform_2	If yes, please complete the AE FORM	descriptive
486	dv_related_therapy_u Show the field ONLY if: [baseline_arm_1][randomization] <>"	Section Header: <i>OTHER THERAPIES RELATED TO COVID-19 DISEASE</i> Has any covid-19 related therapy been changed since the last visit?	radio 1 yes 2 no Custom alignment: RH
487	dv_ot_hcq_u Show the field ONLY if: [dv_related_therapy_u]=1	Hydroxychloroquine	radio 1 started 2 discontinued Custom alignment: RH
488	dv_ot_cqp_u Show the field ONLY if: [dv_related_therapy_u]=1	Chloroquine Phosphate	radio 1 started 2 discontinued Custom alignment: RH
489	dv_ot_avd_u Show the field ONLY if: [dv_related_therapy_u]=1	Antiviral drugs	radio 1 started 2 discontinued Custom alignment: RH
490	dv_antipyretic_u Show the field ONLY if: [dv_related_therapy_u]=1	Antipyretic	radio 1 started 2 discontinued Custom alignment: RH
491	dv_nsaid_u Show the field ONLY if: [dv_related_therapy_u]=1	Nonsteroidal anti-inflammatory drugs	radio 1 started 2 discontinued Custom alignment: RH
492	dv_antibiotic_u Show the field ONLY if: [dv_related_therapy_u]=1	Antibiotics	radio 1 started 2 discontinued Custom alignment: RH
493	dv_prah_u Show the field ONLY if: [baseline_arm_1][randomization] <>"	Section Header: Patient required admission to hospital?	radio 1 yes 2 no Custom alignment: RH
494	dv_prah_why_u Show the field ONLY if: [dv_prah_u]=1	Why	text
495	dv_prah_date_u Show the field ONLY if: [dv_prah_u]=1	Date of hospitalization	text (date_ymd)
496	dv_prah_hospital_u Show the field ONLY if: [dv_prah_u]=1	Which Hospital	text
497	dv_prah_ward_u Show the field ONLY if: [dv_prah_u]=1	Which ward	text

498	d1_covid_ss_u Show the field ONLY if: [baseline_arm_1][randomization] <>"	COVID-19 Severity Score	dropdown <table><tr><td>1</td><td>1, no limitation of activities</td></tr><tr><td>2</td><td>2, limitation of activities</td></tr><tr><td>3</td><td>3, hospitalized, no oxygen therapy</td></tr><tr><td>4</td><td>4, hospitalized, oxygen by mask or nasal prongs</td></tr><tr><td>5</td><td>5, non-invasive ventilation or high-flow oxygen</td></tr><tr><td>6</td><td>6, intubation and mechanical ventilation</td></tr><tr><td>7</td><td>7, ventilation + additional organ support - pressors, RRT (renal replacement therapy), ECMO (extracorporeal membrane oxygenation)</td></tr><tr><td>8</td><td>8, death</td></tr></table>	1	1, no limitation of activities	2	2, limitation of activities	3	3, hospitalized, no oxygen therapy	4	4, hospitalized, oxygen by mask or nasal prongs	5	5, non-invasive ventilation or high-flow oxygen	6	6, intubation and mechanical ventilation	7	7, ventilation + additional organ support - pressors, RRT (renal replacement therapy), ECMO (extracorporeal membrane oxygenation)	8	8, death
1	1, no limitation of activities																		
2	2, limitation of activities																		
3	3, hospitalized, no oxygen therapy																		
4	4, hospitalized, oxygen by mask or nasal prongs																		
5	5, non-invasive ventilation or high-flow oxygen																		
6	6, intubation and mechanical ventilation																		
7	7, ventilation + additional organ support - pressors, RRT (renal replacement therapy), ECMO (extracorporeal membrane oxygenation)																		
8	8, death																		
499	unscheduled_phone_visit_complete	Section Header: <i>Form Status</i> Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete										
0	Incomplete																		
1	Unverified																		
2	Complete																		

Instrument: **UNSCHEDULED RECRUITING CENTRE VISIT** (unscheduled_recruiting_centre_visit)

^ Collapse

500	alert_random_rc_u Show the field ONLY if: [baseline_arm_1][randomization] ="	In order to fill this form, the patient must be randomized	descriptive						
501	rnd_days_rc_u Show the field ONLY if: [baseline_arm_1][randomization] <>"	Randomization code: [[baseline_arm_1][randomization]]	descriptive						
502	dov_dv_rc_u Show the field ONLY if: [baseline_arm_1][randomization] <>"	Date of visit	text (date_dmy)						
503	rc_alive_u Show the field ONLY if: [baseline_arm_1][randomization] <>"	Section Header: <i>Patient status</i> Is the patient alive?	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no		
1	yes								
2	no								
504	rc_setting_u Show the field ONLY if: [rc_alive_u]=1	Current setting	dropdown <table><tr><td>1</td><td>Home</td></tr><tr><td>2</td><td>Hospitalization</td></tr><tr><td>3</td><td>Other</td></tr></table>	1	Home	2	Hospitalization	3	Other
1	Home								
2	Hospitalization								
3	Other								
505	rc_ps_specify_u Show the field ONLY if: [rc_setting_u]=3	Specify please	text						
506	rc_hosp_date_u Show the field ONLY if: [rc_setting_u]=2	Hospitalization date	text (date_dmy)						
507	rc_hosp_why_u Show the field ONLY if: [rc_setting_u]=2	Reason for hospitalization	text						
508	rc_icu_u Show the field ONLY if: [rc_setting_u]=2	Recovery in Intensive Care Unit?	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no		
1	yes								
2	no								
509	rc_death_date_u Show the field ONLY if: [rc_alive_u]=2	Death date	text (date_dmy) Custom alignment: RH						
510	rc_deat_cause_u Show the field ONLY if: [rc_alive_u]=2	Death cause	text Custom alignment: RH						

511	rc_curr_setting_u Show the field ONLY if: [rc_alive_u]=1	Setting of current visit	radio 1 Home 2 Hospital emergency room 3 Hospital outpatient ambulatory care 4 Extra- Hospital outpatient ambulatory care 5 Other
512	rc_currsett_spec_u Show the field ONLY if: [rc_curr_setting_u]=5	Specify, please	text Custom alignment: RH
513	drug_assumption_rc_u Show the field ONLY if: [rc_alive_u]=1	Section Header: <i>Study drugs</i> Has the drug been taken according to medical indication?	radio 1 yes 2 no Custom alignment: RH
514	rc_withdrawn_u Show the field ONLY if: [drug_assumption_rc_u]=2	Has the drug been withdrawn?	radio 1 yes 2 no Custom alignment: RH
515	rc_u_alert_wdform Show the field ONLY if: [rc_withdrawn_u]=1	if the drug was withdrawn, please complete the withdrawal form	descriptive
516	rc_u_pills_skpd Show the field ONLY if: [rc_withdrawn_u]=2	Have one or more pill(s) skipped?	dropdown 1 Yes 2 no
517	n_pills_rc_u Show the field ONLY if: [rc_u_pills_skpd]=1	If yes, how many pills have been taken?	text (number) Custom alignment: RH
518	rc_u_skpd_reason Show the field ONLY if: [rc_u_pills_skpd]=1	Reason for dose skipped:	dropdown 1 Toxicity* 2 Deterioration of clinical conditions or clinical decision 3 Patient decision** 4 Non compliance 5 Logistic organization
519	rc_u_alert_aeform Show the field ONLY if: [rc_u_skpd_reason]=1	*if Toxicity, please complete the adverse reaction/adverse event form	descriptive
520	rc_u_skpd_p_dec Show the field ONLY if: [rc_u_skpd_reason]=3	** If patient decision, please specify:	text
521	fever_t_rc_u Show the field ONLY if: [rc_alive_u]=1	Section Header: <i>Symptoms?</i> Temperature: (°C)	text (number_1dp, Min: 34.0, Max: 43.0) Custom alignment: RH
522	hr_rc_u Show the field ONLY if: [rc_alive_u]=1	Hearth rate: (/min)	text (integer) Custom alignment: RH
523	rr_rc_u Show the field ONLY if: [rc_alive_u]=1	Respiratory Rate: (/min)	text Custom alignment: RH
524	dyspnea_rc_u Show the field ONLY if: [rc_alive_u]=1	Dyspnea	radio 1 yes 2 no Custom alignment: RH
525	cough_rc_u Show the field ONLY if: [rc_alive_u]=1	Cough	radio 1 yes 2 no Custom alignment: RH

526	diarrhoea_rc_u Show the field ONLY if: [rc_alive_u]=1	Diarrhoea	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no								
1	yes														
2	no														
527	symp_other_rc_u Show the field ONLY if: [baseline_arm_1][randomization] <>"	Other	dropdown <table><tr><td>0</td><td>none</td></tr><tr><td>1</td><td>one</td></tr><tr><td>2</td><td>two</td></tr><tr><td>3</td><td>three</td></tr><tr><td>4</td><td>four or more</td></tr></table>	0	none	1	one	2	two	3	three	4	four or more		
0	none														
1	one														
2	two														
3	three														
4	four or more														
528	rc_symp_other_1_u Show the field ONLY if: [symp_other_rc_u]>0	Specify first other symptom	text												
529	rc_symp_other_2_u Show the field ONLY if: [symp_other_rc_u]>1	Specify second other symptom	text												
530	rc_symp_other_3_u Show the field ONLY if: [symp_other_rc_u]>2	Specify third other symptom	text												
531	rc_symp_other_4_u Show the field ONLY if: [symp_other_rc_u]>3	Specify fourth other symptom	text												
532	rc_drowsiness_u Show the field ONLY if: [baseline_arm_1][randomization] <>"	Section Header: Adverse reactions Please report each occurred adverse reaction also in the AE FORM, in order to provide major details Grading: 0 (none); 1 (mild; any symptoms possibly related to study drug, not necessitating medication); 2 (moderate: any symptoms resolved with medication, not requiring hospitalization); 3 (severe: necessity of hospitalization or prolongation of existing hospitalization); 4 (near fatal: necessity of intensive care); 5 (fatal). Please write "0" if the symptom was not present Drowsiness	dropdown <table><tr><td>0</td><td>0</td></tr><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr><tr><td>4</td><td>4</td></tr><tr><td>5</td><td>5</td></tr></table> Custom alignment: RH	0	0	1	1	2	2	3	3	4	4	5	5
0	0														
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3	3														
4	4														
5	5														
533	alert_sae15_u Show the field ONLY if: [rc_drowsiness_u]>2	Please, go to the "Serious adverse event initial report" Form	descriptive												
534	rc_vomit_u Show the field ONLY if: [baseline_arm_1][randomization] <>"	Vomit	dropdown <table><tr><td>0</td><td>0</td></tr><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr><tr><td>4</td><td>4</td></tr><tr><td>5</td><td>5</td></tr></table> Custom alignment: RH	0	0	1	1	2	2	3	3	4	4	5	5
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3	3														
4	4														
5	5														
535	alert_sae16_u Show the field ONLY if: [rc_vomit_u]>2	Please, go to the "Serious adverse event initial report" Form	descriptive												
536	rc_pruritus_u Show the field ONLY if: [baseline_arm_1][randomization] <>"	Pruritus	dropdown <table><tr><td>0</td><td>0</td></tr><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr><tr><td>4</td><td>4</td></tr><tr><td>5</td><td>5</td></tr></table> Custom alignment: RH	0	0	1	1	2	2	3	3	4	4	5	5
0	0														
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3	3														
4	4														
5	5														
537	alert_sae17_u Show the field ONLY if: [rc_pruritus_u]>2	Please, go to the "Serious adverse event initial report" Form	descriptive												

538	rc_ap_u Show the field ONLY if: [baseline_arm_1][randomization] <>"	Abdominal pain	dropdown <table><tr><td>0</td><td>0</td></tr><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr><tr><td>4</td><td>4</td></tr><tr><td>5</td><td>5</td></tr></table> Custom alignment: RH	0	0	1	1	2	2	3	3	4	4	5	5
0	0														
1	1														
2	2														
3	3														
4	4														
5	5														
539	alert_sae18_u Show the field ONLY if: [rc_ap_u]>2	Please, go to the "Serious adverse event initial report" Form	descriptive												
540	rc_hypotension_u Show the field ONLY if: [baseline_arm_1][randomization] <>"	Hypotension	dropdown <table><tr><td>0</td><td>0</td></tr><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr><tr><td>4</td><td>4</td></tr><tr><td>5</td><td>5</td></tr></table> Custom alignment: RH	0	0	1	1	2	2	3	3	4	4	5	5
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1	1														
2	2														
3	3														
4	4														
5	5														
541	alert_sae19_u Show the field ONLY if: [rc_hypotension_u]>2	Please, go to the "Serious adverse event initial report" Form	descriptive												
542	rc_fatigue_u Show the field ONLY if: [baseline_arm_1][randomization] <>"	Fatigue	dropdown <table><tr><td>0</td><td>0</td></tr><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr><tr><td>4</td><td>4</td></tr><tr><td>5</td><td>5</td></tr></table> Custom alignment: RH	0	0	1	1	2	2	3	3	4	4	5	5
0	0														
1	1														
2	2														
3	3														
4	4														
5	5														
543	alert_sae20_u Show the field ONLY if: [rc_fatigue_u]>2	Please, go to the "Serious adverse event initial report" Form	descriptive												
544	rc_headache_u Show the field ONLY if: [baseline_arm_1][randomization] <>"	Headache	dropdown <table><tr><td>0</td><td>0</td></tr><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr><tr><td>4</td><td>4</td></tr><tr><td>5</td><td>5</td></tr></table> Custom alignment: RH	0	0	1	1	2	2	3	3	4	4	5	5
0	0														
1	1														
2	2														
3	3														
4	4														
5	5														
545	alert_sae21_u Show the field ONLY if: [rc_headache_u]>2	Please, go to the "Serious adverse event initial report" Form	descriptive												
546	rc_nausea_u Show the field ONLY if: [baseline_arm_1][randomization] <>"	Nausea	dropdown <table><tr><td>0</td><td>0</td></tr><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr><tr><td>4</td><td>4</td></tr><tr><td>5</td><td>5</td></tr></table> Custom alignment: RH	0	0	1	1	2	2	3	3	4	4	5	5
0	0														
1	1														
2	2														
3	3														
4	4														
5	5														
547	alert_sae22_u Show the field ONLY if: [rc_nausea_u]>2	Please, go to the "Serious adverse event initial report" Form	descriptive												

548	rc_aeo_u Show the field ONLY if: [baseline_arm_1][randomization] <>"	Section Header: <i>Adverse Events</i> Other adverse event occurred?	dropdown 1 yes 2 no Custom alignment: RH
549	rc_u_alert_2 Show the field ONLY if: [rc_aeo_u]=1	If yes, please complete the AE FORM	descriptive
550	related_therapy_rc_u Show the field ONLY if: [rc_alive_u]=1	Section Header: <i>OTHER THERAPIES RELATED TO COVID-19 DISEASE</i> Has any covid-19 related therapy been changed since the last visit?	radio 1 yes 2 no Custom alignment: RH
551	ot_hcq_rc_u Show the field ONLY if: [related_therapy_rc_u]=1	Hydroxychloroquine	radio 1 started 2 discontinued Custom alignment: RH
552	ot_cqp_rc_u Show the field ONLY if: [related_therapy_rc_u]=1	Chloroquine Phosphate	radio 1 started 2 discontinued Custom alignment: RH
553	ot_avd_rc_u Show the field ONLY if: [related_therapy_rc_u]=1	Antiviral drugs	radio 1 started 2 discontinued Custom alignment: RH
554	ot_antipyretic_rc_u Show the field ONLY if: [related_therapy_rc_u]=1	Antipyretic	radio 1 started 2 discontinued Custom alignment: RH
555	ot_nsaid_rc_u Show the field ONLY if: [related_therapy_rc_u]=1	Nonsteroidal anti-inflammatory drugs	radio 1 started 2 discontinued Custom alignment: RH
556	ot_antibiotic_rc_u Show the field ONLY if: [related_therapy_rc_u]=1	Antibiotics	radio 1 started 2 discontinued Custom alignment: RH
557	rc_ot_otcr_u Show the field ONLY if: [related_therapy_rc_u]=1	Other therapies related to COVID-19	dropdown 0 none 1 one 2 two 3 three 4 four or more
558	rc_ot_ot_spec_1_u Show the field ONLY if: [rc_ot_otcr_u]>0	Specify first other therapy	text
559	rc_ot_ot_sd_1_u Show the field ONLY if: [rc_ot_otcr_u]>0	[rc_ot_ot_spec_1]	radio 1 started 2 discontinued Custom alignment: RH
560	rc_ot_ot_spec_2_u Show the field ONLY if: [rc_ot_otcr_u]>1	Specify second other therapy	text
561	rc_ot_ot_sd_2_u Show the field ONLY if: [rc_ot_otcr_u]>1	[rc_ot_ot_spec_2]	radio 1 started 2 discontinued Custom alignment: RH

562	rc_ot_ot_spec_3_u Show the field ONLY if: [rc_ot_otcr_u]>2	Specify third other therapy	text				
563	rc_ot_ot_sd_3_u Show the field ONLY if: [rc_ot_otcr_u]>2	[rc_ot_ot_spec_3]	radio <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>discontinued</td></tr></table> Custom alignment: RH	1	started	2	discontinued
1	started						
2	discontinued						
564	rc_ot_ot_spec_4_u Show the field ONLY if: [rc_ot_otcr_u]>3	Specify fourth other therapy	text				
565	rc_ot_ot_sd_4_u Show the field ONLY if: [rc_ot_otcr_u]>3	[rc_ot_ot_spec_4]	radio <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>discontinued</td></tr></table> Custom alignment: RH	1	started	2	discontinued
1	started						
2	discontinued						
566	ct_changed_rc_u Show the field ONLY if: [rc_alive_u]=1	Section Header: <i>Other chronic therapies</i> Has any chronic therapy been changed since the last visit?	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no
1	yes						
2	no						
567	ot_ahtd_rc_u Show the field ONLY if: [ct_changed_rc_u]=1	Antihypertensive drugs	radio <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>discontinued</td></tr></table> Custom alignment: RH	1	started	2	discontinued
1	started						
2	discontinued						
568	ot_ahtd_specify_rc_u Show the field ONLY if: [ot_ahtd_rc_u]=1	Specify new antihypertensive drug	text Custom alignment: RH				
569	ot_ahtd_disc_u Show the field ONLY if: [ot_ahtd_rc_u]=2	Specify discontinued antihypertensive drug	text Custom alignment: RH				
570	ot_steroids_rc_u Show the field ONLY if: [ct_changed_rc_u]=1	Steroids	radio <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>discontinued</td></tr></table> Custom alignment: RH	1	started	2	discontinued
1	started						
2	discontinued						
571	ot_steroids_specify_rc_u Show the field ONLY if: [ot_steroids_rc_u]=1	Specify new steroid	text Custom alignment: RH				
572	ot_ab_rc_u Show the field ONLY if: [ct_changed_rc_u]=1	Antiblastics	radio <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>discontinued</td></tr></table> Custom alignment: RH	1	started	2	discontinued
1	started						
2	discontinued						
573	ot_ab_specify_rc_u Show the field ONLY if: [ot_ab_rc_u]=1	Specify new antineoplastic	text Custom alignment: RH				
574	ot_isd_rc_u Show the field ONLY if: [ct_changed_rc_u]=1	Immunosuppressive drugs	radio <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>discontinued</td></tr></table> Custom alignment: RH	1	started	2	discontinued
1	started						
2	discontinued						
575	ot_isd_specify_rc_u Show the field ONLY if: [ot_isd_rc_u]=1	Specify new immunosuppressive drug	text Custom alignment: RH				
576	ot_bio_rc_u Show the field ONLY if: [ct_changed_rc_u]=1	Biologicals	radio <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>discontinued</td></tr></table> Custom alignment: RH	1	started	2	discontinued
1	started						
2	discontinued						
577	ot_bio_specify_rc_u Show the field ONLY if: [ot_isd_rc_u]=1	Specify new biological	text Custom alignment: RH				

578	otot_n_rc_u Show the field ONLY if: [ct_changed_rc_u]=1	Has any other chronic therapy changed since lat visit?	dropdown <table><tr><td>0</td><td>none</td></tr><tr><td>1</td><td>one</td></tr><tr><td>2</td><td>two</td></tr><tr><td>3</td><td>three</td></tr><tr><td>4</td><td>four or more</td></tr></table>	0	none	1	one	2	two	3	three	4	four or more
0	none												
1	one												
2	two												
3	three												
4	four or more												
579	ot_ot1_rc_u Show the field ONLY if: [otot_n_rc_u]>0	First other therapy	radio <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>interrupted</td></tr></table> Custom alignment: RH	1	started	2	interrupted						
1	started												
2	interrupted												
580	ot_specify_ot1_rc_u Show the field ONLY if: [ot_ot1_rc_u]=1	Specify first new other therapy	text Custom alignment: RH										
581	ot_ot2_rc_u Show the field ONLY if: [otot_n_rc_u]>1	Second other therapy	radio <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>interrupted</td></tr></table> Custom alignment: RH	1	started	2	interrupted						
1	started												
2	interrupted												
582	ot_specify_ot2_rc_u Show the field ONLY if: [ot_ot2_rc_u]=1	Specify second new other therapy	text Custom alignment: RH										
583	ot_ot3_rc_u Show the field ONLY if: [otot_n_rc_u]>2	Third other therapy	radio <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>interrupted</td></tr></table> Custom alignment: RH	1	started	2	interrupted						
1	started												
2	interrupted												
584	ot_specify_ot3_rc_u Show the field ONLY if: [ot_ot3_rc_u]=1	Specify third new other therapy	text Custom alignment: RH										
585	ot_ot4_rc_u Show the field ONLY if: [otot_n_rc_u]>3	Fourth other therapy	radio <table><tr><td>1</td><td>started</td></tr><tr><td>2</td><td>interrupted</td></tr></table> Custom alignment: RH	1	started	2	interrupted						
1	started												
2	interrupted												
586	ot_specify_ot4_rc_u Show the field ONLY if: [ot_ot4_rc_u]=1	Specify fourth new other therapy	text Custom alignment: RH										
587	rc_sbp_u Show the field ONLY if: [rc_alive_u]=1	Section Header: <i>Laboratory findings</i> Systolic Blood Pressure: (mmHg)	text (integer)										
588	rc_dbp_u Show the field ONLY if: [rc_alive_u]=1	Diastolic Blood Pressure: (mmHg)	text (integer)										
589	rc_wbc_u Show the field ONLY if: [rc_alive_u]=1	WBC	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr><tr><td>3</td><td>N/A</td></tr></table> Custom alignment: RH	1	yes	2	no	3	N/A				
1	yes												
2	no												
3	N/A												
590	rc_wbc_v_u Show the field ONLY if: [rc_wbc_u]=1	WBC value: (N/ μ l)	text (integer) Custom alignment: RH										
591	rc_lymphocytes_u Show the field ONLY if: [rc_alive_u]=1	Lymphocytes	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr><tr><td>3</td><td>N/A</td></tr></table> Custom alignment: RH	1	yes	2	no	3	N/A				
1	yes												
2	no												
3	N/A												
592	rc_lymphocytes_v_u Show the field ONLY if: [rc_lymphocytes_u]=1	Lymphocytes value: (N/ μ l)	text (integer) Custom alignment: RH										

593	rc_crp_u Show the field ONLY if: [rc_alive_u]=1	C-reactive protein	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr><tr><td>3</td><td>N/A</td></tr></table> Custom alignment: RH	1	yes	2	no	3	N/A
1	yes								
2	no								
3	N/A								
594	rc_crp_v_u Show the field ONLY if: [rc_crp_u]=1	C-reactive protein value: (µg/l)	text (integer) Custom alignment: RH						
595	rc_alt_u Show the field ONLY if: [rc_alive_u]=1	ALT	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr><tr><td>3</td><td>N/A</td></tr></table> Custom alignment: RH	1	yes	2	no	3	N/A
1	yes								
2	no								
3	N/A								
596	rc_alt_v_u Show the field ONLY if: [rc_alt_u]=1	ALT value: (U/l)	text (integer) Custom alignment: RH						
597	rc_pao2_u Show the field ONLY if: [rc_alive_u]=1	PaO2	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr><tr><td>3</td><td>N/A</td></tr></table> Custom alignment: RH	1	yes	2	no	3	N/A
1	yes								
2	no								
3	N/A								
598	rc_pao2_v_u Show the field ONLY if: [rc_pao2_u]=1	PaO2 value: (mmHg)	text (integer) Custom alignment: RH						
599	rc_cov2_u	SARS-CoV-2 Nasopharyngeal swab: (to be stored at -80 °C after exam)	radio <table><tr><td>1</td><td>positive</td></tr><tr><td>2</td><td>negative</td></tr><tr><td>3</td><td>N/A</td></tr></table> Custom alignment: RH	1	positive	2	negative	3	N/A
1	positive								
2	negative								
3	N/A								
600	rc_cxr_u Show the field ONLY if: [rc_alive_u]=1	Section Header: <i>Imaging</i> Chest X-Ray	radio <table><tr><td>1</td><td>performed</td></tr><tr><td>2</td><td>not performed</td></tr></table> Custom alignment: RH	1	performed	2	not performed		
1	performed								
2	not performed								
601	rc_lcts_u Show the field ONLY if: [rc_alive_u]=1	Lung CT scan	radio <table><tr><td>1</td><td>performed</td></tr><tr><td>2</td><td>not performed</td></tr></table> Custom alignment: RH	1	performed	2	not performed		
1	performed								
2	not performed								
602	prah_rc_u Show the field ONLY if: [rc_alive_u]=1	Section Header: Patient required admission to hospital?	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no		
1	yes								
2	no								
603	rc_prah_why_u Show the field ONLY if: [prah_rc_u]=1	Why	text						
604	rc_prah_date_u Show the field ONLY if: [prah_rc_u]=1	Date of hospitalization	text (date_ymd)						
605	rc_prah_hospital_u Show the field ONLY if: [prah_rc_u]=1	Which Hospital	text						
606	rc_prah_ward_u Show the field ONLY if: [prah_rc_u]=1	Which ward	text						

607	rc_covid_ss_u	COVID-19 Severity Score	<div>dropdown</div> <div><div>1</div><div>1, no limitation of activities</div></div> <div><div>2</div><div>2, limitation of activities</div></div> <div><div>3</div><div>3, hospitalized, no oxygen therapy</div></div> <div><div>4</div><div>4, hospitalized, oxygen by mask or nasal prongs</div></div> <div><div>5</div><div>5, non-invasive ventilation or high-flow oxygen</div></div> <div><div>6</div><div>6, intubation and mechanical ventilation</div></div> <div><div>7</div><div>7, ventilation + additional organ support - pressors, RRT (renal replacement therapy), ECMO (extracorporeal membrane oxygenation)</div></div> <div><div>8</div><div>8, death</div></div>
608	unscheduled_recruiting_centre_visit_complete	Section Header: <i>Form Status</i> Complete?	<div>dropdown</div> <div><div>0</div><div>Incomplete</div></div> <div><div>1</div><div>Unverified</div></div> <div><div>2</div><div>Complete</div></div>

Instrument: **Death Form** (death_form)[^ Collapse](#)

609	ud_df	Section Header: Record ID/Patient [baseline_arm_1][record_id] - Treatment [randomization_arm_1][randomization] DEATH FORM Upload document	file										
610	dea_pat_dece	Patient Deceased	radio <table><tr><td>1</td><td>Yes</td></tr></table>	1	Yes								
1	Yes												
611	uf_df	upload Files	file										
612	dea_deat_date Show the field ONLY if: [dea_pat_dece] = '1'	Date of death (dd/mm/yyyy)	text (date_dmy)										
613	dea_caus_deat Show the field ONLY if: [dea_pat_dece] = '1'	Cause of death	dropdown <table><tr><td>1</td><td>COVID-19 infection</td></tr><tr><td>2</td><td>Adverse event unrelated to treatment (SAE)</td></tr><tr><td>3</td><td>Treatment related adverse event (SADR)</td></tr><tr><td>4</td><td>Unknown</td></tr><tr><td>5</td><td>Other cause</td></tr></table>	1	COVID-19 infection	2	Adverse event unrelated to treatment (SAE)	3	Treatment related adverse event (SADR)	4	Unknown	5	Other cause
1	COVID-19 infection												
2	Adverse event unrelated to treatment (SAE)												
3	Treatment related adverse event (SADR)												
4	Unknown												
5	Other cause												
614	dea_ae_spec Show the field ONLY if: [dea_caus_deat] = '4' or [dea_caus_deat] = '5'	If Adverse event, please specify the diagnosis	text										
615	dea_othe_spec Show the field ONLY if: [dea_caus_deat] = '6'	For post study deaths, unrelated to disease, please specify cause	text										
616	death_form_complete	Section Header: Form Status Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete				
0	Incomplete												
1	Unverified												
2	Complete												

Instrument: **Adverse Event Form** (adverse_event_form)[^ Collapse](#)

617	ud_ae	Section Header: Record ID/Patient [baseline_arm_1][record_id] - Treatment [baseline_arm_1][randomization] ADVERSE EVENT FORM Upload document	file		
618	ae_term1	AE Term (CTCAE - Common Terminology Criteria for Adverse Event)	text <table><tr><td>BIOPORTAL:CTCAE</td><td>BIOPORTAL:CTCAE</td></tr></table>	BIOPORTAL:CTCAE	BIOPORTAL:CTCAE
BIOPORTAL:CTCAE	BIOPORTAL:CTCAE				
619	ae_term_spec1 Show the field ONLY if: [ae_term1] <> " AND ends_with ([ae_term1],"other, specify")	if other specify	text		
620	ae_desc1 Show the field ONLY if: [ae_term1] <> "	Description	text		
621	ae_meddra1 Show the field ONLY if: [ae_term1] <> " and ([user-name] ='Icarlucci' or [user-name]='vgiuli ano' or [user-name]='fzollo')	MedDRA codification (for sponsor use only)	text <table><tr><td>BIOPORTAL:MEDDRA</td><td>BIOPORTAL:MEDDRA</td></tr></table> Custom alignment: RH	BIOPORTAL:MEDDRA	BIOPORTAL:MEDDRA
BIOPORTAL:MEDDRA	BIOPORTAL:MEDDRA				

622	ae_sdate1 Show the field ONLY if: [ae_term1] <> "	Start Date (dd/mm/yyyy)	text (date_dmy)												
623	ae_edate1 Show the field ONLY if: [ae_term1] <> "	End Date (dd/mm/yyyy)	text (date_dmy)												
624	ae_grade1 Show the field ONLY if: [ae_term1] <> "	AE Grade	dropdown <table><tr><td>1</td><td>1=Mild</td></tr><tr><td>2</td><td>2=Moderate</td></tr><tr><td>3</td><td>3=Severe</td></tr><tr><td>4</td><td>4=Life Threatening</td></tr><tr><td>5</td><td>5=Death</td></tr></table>	1	1=Mild	2	2=Moderate	3	3=Severe	4	4=Life Threatening	5	5=Death		
1	1=Mild														
2	2=Moderate														
3	3=Severe														
4	4=Life Threatening														
5	5=Death														
625	ae_ivermectincr Show the field ONLY if: [ae_term1] <> "	Causal relation to study drug	dropdown <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
1	Certain														
2	Probable														
3	Possible														
4	Unlikely														
5	Unrelated														
6	Unknown														
626	ae_ivermectina Show the field ONLY if: [ae_term1] <> "	Action Taken with study drug	dropdown <table><tr><td>6</td><td>None</td></tr><tr><td>1</td><td>Drug withdrawn</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr></table>	6	None	1	Drug withdrawn	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced		
6	None														
1	Drug withdrawn														
2	Dose delayed														
3	Dose reduced														
4	Dose delayed and reduced														
627	ae_crods Show the field ONLY if: [ae_term1] <> "	Causal relation to other drugs	dropdown <table><tr><td>0</td><td>none</td></tr><tr><td>1</td><td>one</td></tr><tr><td>2</td><td>two</td></tr><tr><td>3</td><td>three</td></tr><tr><td>4</td><td>four or more</td></tr></table>	0	none	1	one	2	two	3	three	4	four or more		
0	none														
1	one														
2	two														
3	three														
4	four or more														
628	ae_drug_1 Show the field ONLY if: [ae_crods]>0	Specify first drug	text												
629	ae_crod1 Show the field ONLY if: [ae_crods]>0	Causal relation to [ae_drug_1]	dropdown <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
1	Certain														
2	Probable														
3	Possible														
4	Unlikely														
5	Unrelated														
6	Unknown														
630	ae_actiona1 Show the field ONLY if: [ae_crods]>0	Action Taken with [ae_drug_1]	dropdown <table><tr><td>6</td><td>None</td></tr><tr><td>1</td><td>Drug withdrawn</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr></table>	6	None	1	Drug withdrawn	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced		
6	None														
1	Drug withdrawn														
2	Dose delayed														
3	Dose reduced														
4	Dose delayed and reduced														
631	ae_crod2 Show the field ONLY if: [ae_crods]>1	Causal relation to [ae_drug_2]	dropdown <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
1	Certain														
2	Probable														
3	Possible														
4	Unlikely														
5	Unrelated														
6	Unknown														

632	ae_actiona2 Show the field ONLY if: [ae_crods]>1	Action Taken with [ae_drug_2]	dropdown <table border="1"> <tr><td>6</td><td>None</td></tr> <tr><td>1</td><td>Drug withdrawn</td></tr> <tr><td>2</td><td>Dose delayed</td></tr> <tr><td>3</td><td>Dose reduced</td></tr> <tr><td>4</td><td>Dose delayed and reduced</td></tr> </table>	6	None	1	Drug withdrawn	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced		
6	None														
1	Drug withdrawn														
2	Dose delayed														
3	Dose reduced														
4	Dose delayed and reduced														
633	ae_crod3 Show the field ONLY if: [ae_crods]>2	Causal relation to [ae_drug_3]	dropdown <table border="1"> <tr><td>1</td><td>Certain</td></tr> <tr><td>2</td><td>Probable</td></tr> <tr><td>3</td><td>Possible</td></tr> <tr><td>4</td><td>Unlikely</td></tr> <tr><td>5</td><td>Unrelated</td></tr> <tr><td>6</td><td>Unknown</td></tr> </table>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
1	Certain														
2	Probable														
3	Possible														
4	Unlikely														
5	Unrelated														
6	Unknown														
634	ae_actiona3 Show the field ONLY if: [ae_crods]>2	Action Taken with [ae_drug_3]	dropdown <table border="1"> <tr><td>6</td><td>None</td></tr> <tr><td>1</td><td>Drug withdrawn</td></tr> <tr><td>2</td><td>Dose delayed</td></tr> <tr><td>3</td><td>Dose reduced</td></tr> <tr><td>4</td><td>Dose delayed and reduced</td></tr> </table>	6	None	1	Drug withdrawn	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced		
6	None														
1	Drug withdrawn														
2	Dose delayed														
3	Dose reduced														
4	Dose delayed and reduced														
635	ae_crod4 Show the field ONLY if: [ae_crods]>3	Causal relation to [ae_drug_4]	dropdown <table border="1"> <tr><td>1</td><td>Certain</td></tr> <tr><td>2</td><td>Probable</td></tr> <tr><td>3</td><td>Possible</td></tr> <tr><td>4</td><td>Unlikely</td></tr> <tr><td>5</td><td>Unrelated</td></tr> <tr><td>6</td><td>Unknown</td></tr> </table>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
1	Certain														
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636	ae_actiona4 Show the field ONLY if: [ae_crods]>3	Action Taken with [ae_drug_4]	dropdown <table border="1"> <tr><td>6</td><td>None</td></tr> <tr><td>1</td><td>Drug withdrawn</td></tr> <tr><td>2</td><td>Dose delayed</td></tr> <tr><td>3</td><td>Dose reduced</td></tr> <tr><td>4</td><td>Dose delayed and reduced</td></tr> </table>	6	None	1	Drug withdrawn	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced		
6	None														
1	Drug withdrawn														
2	Dose delayed														
3	Dose reduced														
4	Dose delayed and reduced														
637	ae_drug_2 Show the field ONLY if: [ae_crods]>1	Specify second drug	text												
638	ae_drug_3 Show the field ONLY if: [ae_crods]>2	Specify third drug	text												
639	ae_drug_4 Show the field ONLY if: [ae_crods]>3	Specify fourth drug	text												
640	ae_rela_dise1 Show the field ONLY if: [ae_term1] <> "	Causal relation to disease	dropdown <table border="1"> <tr><td>1</td><td>Certain</td></tr> <tr><td>2</td><td>Probable</td></tr> <tr><td>3</td><td>Possible</td></tr> <tr><td>4</td><td>Unlikely</td></tr> <tr><td>5</td><td>Unrelated</td></tr> <tr><td>6</td><td>Unknown</td></tr> </table>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
1	Certain														
2	Probable														
3	Possible														
4	Unlikely														
5	Unrelated														
6	Unknown														
641	ae_exp_report1 Show the field ONLY if: [ae_term1] <> "	Is this a Serious AE? <i>If Yes, please complete the SAE Form</i>	radio <table border="1"> <tr><td>0</td><td>No</td></tr> <tr><td>1</td><td>Yes</td></tr> </table> Custom alignment: RH	0	No	1	Yes								
0	No														
1	Yes														

642	ae_outcome1 Show the field ONLY if: [ae_term1] <> "	Outcome	dropdown <table border="1"> <tr><td>1</td><td>Resolved</td></tr> <tr><td>2</td><td>Resolving</td></tr> <tr><td>3</td><td>Resolved with sequelae</td></tr> <tr><td>4</td><td>Not resolved</td></tr> <tr><td>5</td><td>Fatal</td></tr> <tr><td>6</td><td>Unknown</td></tr> </table>	1	Resolved	2	Resolving	3	Resolved with sequelae	4	Not resolved	5	Fatal	6	Unknown
1	Resolved														
2	Resolving														
3	Resolved with sequelae														
4	Not resolved														
5	Fatal														
6	Unknown														
643	adverse_event_form_complete	Section Header: <i>Form Status</i> Complete?	dropdown <table border="1"> <tr><td>0</td><td>Incomplete</td></tr> <tr><td>1</td><td>Unverified</td></tr> <tr><td>2</td><td>Complete</td></tr> </table>	0	Incomplete	1	Unverified	2	Complete						
0	Incomplete														
1	Unverified														
2	Complete														
Instrument: Serious Averse Event Initial Report (serious_averse_event_initial_report)			^ Collapse												
644	ud_saeir	Section Header: <i>Record ID/Patient [baseline_arm_1][record_id] - Treatment [baseline_arm_1][randomization] SERIOUS ADVERSE EVENT FORM - INITIAL REPORT1. Patient Information</i> Upload document	file												
645	sae_birth	Year of birth (yyyy)	text (integer, Min: 1920, Max: 2020)												
646	sae_sex	Sex	dropdown <table border="1"> <tr><td>1</td><td>M</td></tr> <tr><td>2</td><td>F</td></tr> <tr><td>3</td><td>Other</td></tr> </table> Field Annotation: @DEFAULT=[baseline_arm_1][d_gender]	1	M	2	F	3	Other						
1	M														
2	F														
3	Other														
647	sae_height	Height (cm) (cm)	text (integer) Field Annotation: @DEFAULT="[baseline_arm_1][height]"												
648	sae_weight	Weight (Kg) (Kg)	text (integer, Min: 30, Max: 140) Field Annotation: @DEFAULT="[baseline_arm_1][weight]"												
649	sae_imp1_fadm_date	Section Header: <i>2. Investigational Medicinal Product (IMP)/Study drug</i> Date of first admin.	text (date_dmy) Custom alignment: RH												
650	sae_imp1_ladm_date	Date of last admin.	text (date_dmy) Custom alignment: RH												
651	sae_imp1_idose	Intended dose & unit	text Custom alignment: RH												
652	sae_imp1_adose	Administered dose & unit	text Custom alignment: RH												
653	sae_aware_date	Section Header: <i>SAE Details</i> Date of SAE awareness (dd/mm/yyyy)	text (date_dmy)												
654	sae_term1 Show the field ONLY if: [sae_aware_date] <> "	1. SAE Term/Diagnosis	text												
655	sae_grade1 Show the field ONLY if: [sae_term1] <> "	1. SAE NCI-CTC AE Grade	dropdown <table border="1"> <tr><td>1</td><td>Grade 1/Mild</td></tr> <tr><td>2</td><td>Grade 2/Moderate</td></tr> <tr><td>3</td><td>Grade 3/Severe</td></tr> <tr><td>4</td><td>Grade 4/Life Threatening</td></tr> <tr><td>5</td><td>Grade 5/Death</td></tr> </table>	1	Grade 1/Mild	2	Grade 2/Moderate	3	Grade 3/Severe	4	Grade 4/Life Threatening	5	Grade 5/Death		
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656	ctc_ae_link1 Show the field ONLY if: [sae_term1] <> "	Please click on file attachment to reference the CTCAE v 4.03:	descriptive												
657	sae_death1 Show the field ONLY if: [sae_term1] <> "	1. Death	radio <table border="1"> <tr><td>0</td><td>No</td></tr> <tr><td>1</td><td>Yes</td></tr> <tr><td>99</td><td>Unknown</td></tr> </table> Custom alignment: RH	0	No	1	Yes	99	Unknown						
0	No														
1	Yes														
99	Unknown														
658	sae_death_date1 Show the field ONLY if: [sae_death1] = '1' and [sae_term1] <> "	If Death, Date of Death:	text (date_dmy)												

659	<div>sae_death_due1</div> <div>Show the field ONLY if: [sae_death1] = '1' and [sae_term1] <> "</div>	Death due to the SAE	<div>radio</div> <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	0	No	1	Yes	99	Unknown						
0	No														
1	Yes														
99	Unknown														
660	<div>sae_auto_perf1</div> <div>Show the field ONLY if: [sae_death1] = '1' and [sae_term1] <> "</div>	Was an autopsy performed?	<div>radio</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr></table> <div>Custom alignment: RH</div>	1	Yes	2	No								
1	Yes														
2	No														
661	<div>sae_life_threa1</div> <div>Show the field ONLY if: [sae_term1] <> "</div>	Life-threatening	<div>radio (Matrix)</div> <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	0	No	1	Yes	99	Unknown						
0	No														
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662	<div>sae_hospi1</div> <div>Show the field ONLY if: [sae_term1] <> "</div>	Hospitalisation/Prolonged Hospitalisation	<div>radio (Matrix)</div> <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	0	No	1	Yes	99	Unknown						
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663	<div>sae_disabi1</div> <div>Show the field ONLY if: [sae_term1] <> "</div>	Persistent or significant Disability/Incapacity	<div>radio (Matrix)</div> <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	0	No	1	Yes	99	Unknown						
0	No														
1	Yes														
99	Unknown														
664	<div>sae_anoma1</div> <div>Show the field ONLY if: [sae_term1] <> "</div>	Congenital Anomaly/Birth defect	<div>radio (Matrix)</div> <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	0	No	1	Yes	99	Unknown						
0	No														
1	Yes														
99	Unknown														
665	<div>sae_med_even1</div> <div>Show the field ONLY if: [sae_term1] <> "</div>	Important Medical Event	<div>radio (Matrix)</div> <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	0	No	1	Yes	99	Unknown						
0	No														
1	Yes														
99	Unknown														
666	<div>sae_imp1_causa1</div> <div>Show the field ONLY if: [sae_term1] <> "</div>	1. Causal relation to Study drug	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
1	Certain														
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667	<div>sae_sdate1</div> <div>Show the field ONLY if: [sae_term1] <> "</div>	1. Start date <i>(dd/mm/yyyy hh:mm)</i>	text (datetime_dmy)												
668	<div>sae_edate1</div> <div>Show the field ONLY if: [sae_term1] <> "</div>	1. Stop date <i>(dd/mm/yyyy hh:mm)</i>	text (datetime_dmy)												
669	<div>sae_outcome_stat1</div> <div>Show the field ONLY if: [sae_term1] <> "</div>	1. Outcome	<div>dropdown</div> <table><tr><td>1</td><td>Resolved</td></tr><tr><td>2</td><td>Resolving</td></tr><tr><td>3</td><td>Resolved with sequelae</td></tr><tr><td>4</td><td>Not resolved</td></tr><tr><td>5</td><td>Fatal</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Resolved	2	Resolving	3	Resolved with sequelae	4	Not resolved	5	Fatal	6	Unknown
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6	Unknown														

670	<div>sae_imp1_action1</div> <div>Show the field ONLY if: [sae_term1] <> "</div>	1. Action taken with the Study drug	<div>dropdown</div> <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr><tr><td>5</td><td>IMP withdrawn</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	None	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced	5	IMP withdrawn	6	Unknown
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671	<div>sae_term2</div> <div>Show the field ONLY if: [sae_aware_date] <> "</div>	2. SAE Term/Diagnosis	text												
672	<div>sae_grade2</div> <div>Show the field ONLY if: [sae_term2] <> "</div>	2. SAE NCI-CTC AE Grade	<div>dropdown</div> <table><tr><td>1</td><td>Grade 1/Mild</td></tr><tr><td>2</td><td>Grade 2/Moderate</td></tr><tr><td>3</td><td>Grade 3/Severe</td></tr><tr><td>4</td><td>Grade 4/Life Threatening</td></tr><tr><td>5</td><td>Grade 5/Death</td></tr></table>	1	Grade 1/Mild	2	Grade 2/Moderate	3	Grade 3/Severe	4	Grade 4/Life Threatening	5	Grade 5/Death		
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673	<div>ctc_ae_link2</div> <div>Show the field ONLY if: [sae_term2] <> "</div>	Please click on file attachment to reference the CTCAE v 4.03:	descriptive												
674	<div>sae_death2</div> <div>Show the field ONLY if: [sae_term2] <> "</div>	2. Death	<div>radio</div> <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	0	No	1	Yes	99	Unknown						
0	No														
1	Yes														
99	Unknown														
675	<div>sae_death_date2</div> <div>Show the field ONLY if: [sae_death2] = '1' and [sae_term 2] <> "</div>	If Death, Date of Death:	text (date_dmy)												
676	<div>sae_death_due2</div> <div>Show the field ONLY if: [sae_death2] = '1' and [sae_term 2] <> "</div>	Death due to the SAE	<div>radio</div> <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	0	No	1	Yes	99	Unknown						
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677	<div>sae_auto_perf2</div> <div>Show the field ONLY if: [sae_death2] = '1' and [sae_term 2] <> "</div>	Was an autopsy performed?	<div>radio</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr></table> <div>Custom alignment: RH</div>	1	Yes	2	No								
1	Yes														
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678	<div>sae_life_threa2</div> <div>Show the field ONLY if: [sae_term2] <> "</div>	Life-threatening	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
1	No														
2	Yes														
99	Unknown														
679	<div>sae_hosp12</div> <div>Show the field ONLY if: [sae_term2] <> "</div>	Hospitalisation/Prolonged Hospitalisation	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
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680	<div>sae_disabi2</div> <div>Show the field ONLY if: [sae_term2] <> "</div>	Persistent or significant Disability/Prolonged Hospitalisation	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
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681	<div>sae_anoma2</div> <div>Show the field ONLY if: [sae_term2] <> "</div>	Congenital Anomaly/Birth defect	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
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2	Yes														
99	Unknown														

682	<div>sae_med_even2</div> <div>Show the field ONLY if: [sae_term2] <> "</div>	Important Medical Event	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
1	No														
2	Yes														
99	Unknown														
683	<div>sae_imp1_causa2</div> <div>Show the field ONLY if: [sae_term2] <> "</div>	2. Causal relation to Study drug	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
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684	<div>sae_sdate2</div> <div>Show the field ONLY if: [sae_term2] <> "</div>	2. Start date <i>(dd/mm/yyyy hh:mm)</i>	text (datetime_dmy)												
685	<div>sae_edate2</div> <div>Show the field ONLY if: [sae_term2] <> "</div>	2. Stop date <i>(dd/mm/yyyy hh:mm)</i>	text (datetime_dmy)												
686	<div>sae_outcome_stat2</div> <div>Show the field ONLY if: [sae_term2] <> "</div>	2. Outcome	<div>dropdown</div> <table><tr><td>1</td><td>Resolved</td></tr><tr><td>2</td><td>Resolving</td></tr><tr><td>3</td><td>Resolved with sequelae</td></tr><tr><td>4</td><td>Not resolved</td></tr><tr><td>5</td><td>Fatal</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Resolved	2	Resolving	3	Resolved with sequelae	4	Not resolved	5	Fatal	6	Unknown
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687	<div>sae_imp1_action2</div> <div>Show the field ONLY if: [sae_term2] <> "</div>	2. Action taken with the Study drug	<div>dropdown</div> <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr><tr><td>5</td><td>IMP withdrawn</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	None	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced	5	IMP withdrawn	6	Unknown
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688	<div>sae_term3</div> <div>Show the field ONLY if: [sae_aware_date] <> "</div>	3. SAE Term/Diagnosis	text												
689	<div>sae_grade3</div> <div>Show the field ONLY if: [sae_term3] <> "</div>	3. SAE NCI-CTC AE Grade	<div>dropdown</div> <table><tr><td>1</td><td>Grade 1/Mild</td></tr><tr><td>2</td><td>Grade 2/Moderate</td></tr><tr><td>3</td><td>Grade 3/Severe</td></tr><tr><td>4</td><td>Grade 4/Life Threatening</td></tr><tr><td>5</td><td>Grade 5/Death</td></tr></table>	1	Grade 1/Mild	2	Grade 2/Moderate	3	Grade 3/Severe	4	Grade 4/Life Threatening	5	Grade 5/Death		
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690	<div>ctc_ae_link3</div> <div>Show the field ONLY if: [sae_term3] <> "</div>	Please click on file attachment to reference the CTCAE v 4.03:	descriptive												
691	<div>sae_death3</div> <div>Show the field ONLY if: [sae_term3] <> "</div>	3. Death	<div>radio</div> <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	0	No	1	Yes	99	Unknown						
0	No														
1	Yes														
99	Unknown														
692	<div>sae_death_date3</div> <div>Show the field ONLY if: [sae_death3] = '1' and [sae_term3] <> "</div>	If Death, Date of Death:	text (date_dmy)												

693	<div>sae_death_due3</div> <div>Show the field ONLY if: [sae_death3] = '1' and [sae_term3] <> "</div>	Death due to the SAE	<div>radio</div> <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	0	No	1	Yes	99	Unknown						
0	No														
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694	<div>sae_auto_perf3</div> <div>Show the field ONLY if: [sae_death3] = '1' and [sae_term3] <> "</div>	Was an autopsy performed?	<div>radio</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr></table> <div>Custom alignment: RH</div>	1	Yes	2	No								
1	Yes														
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695	<div>sae_life_threa3</div> <div>Show the field ONLY if: [sae_term3] <> "</div>	Life-threatening	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
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696	<div>sae_hospi3</div> <div>Show the field ONLY if: [sae_term3] <> "</div>	Hospitalisation/Prolonged Hospitalisation	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
1	No														
2	Yes														
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697	<div>sae_disabi3</div> <div>Show the field ONLY if: [sae_term3] <> "</div>	Significant Disability	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
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698	<div>sae_anoma3</div> <div>Show the field ONLY if: [sae_term3] <> "</div>	Congenital Anomaly/ Birth defect	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
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699	<div>sae_med_even3</div> <div>Show the field ONLY if: [sae_term3] <> "</div>	Important Medical Event	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
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702	<div>sae_imp3_causa3</div> <div>Show the field ONLY if: [sae_term3] <> "</div>	3. Causal relation to IMP/Study drug (3)	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
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703	<div>sae_sdate3</div> <div>Show the field ONLY if: [sae_term3] <> "</div>	<div>3. Start date</div> <div>(dd/mm/yyyy hh:mm)</div>	<div>text (datetime_dmy)</div>												

704	<div>sae_edate3</div> <div>Show the field ONLY if: [sae_term3] <> "</div>	<div>3. Stop date</div> <div>(dd/mm/yyyy hh:mm)</div>	text (datetime_dmy)												
705	<div>sae_outcome_stat3</div> <div>Show the field ONLY if: [sae_term3] <> "</div>	3. Outcome	<div>dropdown</div> <table><tr><td>1</td><td>Resolved</td></tr><tr><td>2</td><td>Resolving</td></tr><tr><td>3</td><td>Resolved with sequelae</td></tr><tr><td>4</td><td>Not resolved</td></tr><tr><td>5</td><td>Fatal</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Resolved	2	Resolving	3	Resolved with sequelae	4	Not resolved	5	Fatal	6	Unknown
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706	<div>sae_imp1_action3</div> <div>Show the field ONLY if: [sae_term3] <> "</div>	3. Action taken with the IMP/s drug (1)	<div>dropdown</div> <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr><tr><td>5</td><td>IMP withdrawn</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	None	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced	5	IMP withdrawn	6	Unknown
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707	<div>sae_imp2_action3</div> <div>Show the field ONLY if: [sae_term3] <> "</div>	3. Action taken with the IMP/s drug (2)	<div>dropdown</div> <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr><tr><td>5</td><td>IMP withdrawn</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	None	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced	5	IMP withdrawn	6	Unknown
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709	<div>sae_term4</div> <div>Show the field ONLY if: [sae_aware_date] <> "</div>	4. SAE Term/Diagnosis	text												
710	<div>sae_grade4</div> <div>Show the field ONLY if: [sae_term4] <> "</div>	4. SAE NCI-CTC AE Grade	<div>dropdown</div> <table><tr><td>1</td><td>Grade 1/Mild</td></tr><tr><td>2</td><td>Grade 2/Moderate</td></tr><tr><td>3</td><td>Grade 3/Severe</td></tr><tr><td>4</td><td>Grade 4/Life Threatening</td></tr><tr><td>5</td><td>Grade 5/Death</td></tr></table>	1	Grade 1/Mild	2	Grade 2/Moderate	3	Grade 3/Severe	4	Grade 4/Life Threatening	5	Grade 5/Death		
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711	<div>ctc_ae_link4</div> <div>Show the field ONLY if: [sae_term4] <> "</div>	Please click on file attachment to reference the CTCAE v 4.03:	descriptive												
712	<div>sae_death4</div> <div>Show the field ONLY if: [sae_term4] <> "</div>	4. Death	<div>radio</div> <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	0	No	1	Yes	99	Unknown						
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713	<div>sae_death_date4</div> <div>Show the field ONLY if: [sae_death4] = '1' and [sae_term4] <> "</div>	If Death, Date of Death:	text (date_dmy)												

714	sae_death_due4 Show the field ONLY if: [sae_death4] = '1' and [sae_term4] <> "	Death due to the SAE	radio <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table> Custom alignment: RH	0	No	1	Yes	99	Unknown						
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722	sae_imp2_causa4 Show the field ONLY if: [sae_term4] <> "	4. Causal relation to IMP/Study drug (2)	dropdown <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Unknown</td></tr></table> Custom alignment: RH	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
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723	sae_imp3_causa4 Show the field ONLY if: [sae_term4] <> "	4. Causal relation to IMP/Study drug (3)	dropdown <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Unknown</td></tr></table> Custom alignment: RH	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
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724	sae_sdate4 Show the field ONLY if: [sae_term4] <> "	4. Start date (dd/mm/yyyy hh:mm)	text (datetime_dmy)												

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728	<div>sae_imp2_action4</div> <div>Show the field ONLY if: [sae_term4] <> "</div>	4. Action taken with the IMP/s drug (2)	<div>dropdown</div> <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr><tr><td>5</td><td>IMP withdrawn</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	None	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced	5	IMP withdrawn	6	Unknown
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731	<div>sae_grade5</div> <div>Show the field ONLY if: [sae_term5] <> "</div>	5. SAE NCI-CTC AE Grade	<div>dropdown</div> <table><tr><td>1</td><td>Grade 1/Mild</td></tr><tr><td>2</td><td>Grade 2/Moderate</td></tr><tr><td>3</td><td>Grade 3/Severe</td></tr><tr><td>4</td><td>Grade 4/Life Threatening</td></tr><tr><td>5</td><td>Grade 5/Death</td></tr></table>	1	Grade 1/Mild	2	Grade 2/Moderate	3	Grade 3/Severe	4	Grade 4/Life Threatening	5	Grade 5/Death		
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732	<div>ctc_ae_link5</div> <div>Show the field ONLY if: [sae_term5] <> "</div>	Please click on file attachment to reference the CTCAE v 4.03:	descriptive												
733	<div>sae_death5</div> <div>Show the field ONLY if: [sae_term5] <> "</div>	5. Death	<div>radio</div> <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	0	No	1	Yes	99	Unknown						
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734	<div>sae_death_date5</div> <div>Show the field ONLY if: [sae_death5] = '1' and [sae_term5] <> "</div>	If Death, Date of Death:	text (date_dmy)												

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743	sae_imp2_causa5 Show the field ONLY if: [sae_term5] <> "	5. Causal relation to IMP/Study drug (2)	dropdown <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Unknown</td></tr></table> Custom alignment: RH	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
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5	Fatal														
6	Unknown														
748	sae_imp1_action5 Show the field ONLY if: [sae_term5] <> "	5. Action taken with the IMP/s drug (1)	dropdown <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr><tr><td>5</td><td>IMP withdrawn</td></tr><tr><td>6</td><td>Unknown</td></tr></table> Custom alignment: RH	1	None	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced	5	IMP withdrawn	6	Unknown
1	None														
2	Dose delayed														
3	Dose reduced														
4	Dose delayed and reduced														
5	IMP withdrawn														
6	Unknown														
749	sae_imp2_action5 Show the field ONLY if: [sae_term5] <> "	5. Action taken with the IMP/s drug (2)	dropdown <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr><tr><td>5</td><td>IMP withdrawn</td></tr><tr><td>6</td><td>Unknown</td></tr></table> Custom alignment: RH	1	None	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced	5	IMP withdrawn	6	Unknown
1	None														
2	Dose delayed														
3	Dose reduced														
4	Dose delayed and reduced														
5	IMP withdrawn														
6	Unknown														
750	sae_imp3_action5 Show the field ONLY if: [sae_term5] <> "	5. Action taken with the IMP/s drug (3)	dropdown <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr><tr><td>5</td><td>IMP withdrawn</td></tr><tr><td>6</td><td>Unknown</td></tr></table> Custom alignment: RH	1	None	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced	5	IMP withdrawn	6	Unknown
1	None														
2	Dose delayed														
3	Dose reduced														
4	Dose delayed and reduced														
5	IMP withdrawn														
6	Unknown														
751	sae_afte_stop_drug1	Section Header: <i>STUDY DRUG DECHALLENGE</i> Did event abate after stopping drug(s)?	dropdown <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr><tr><td>3</td><td>NA</td></tr></table> Custom alignment: RH	1	Yes	2	No	3	NA						
1	Yes														
2	No														
3	NA														
752	sae_dech_num Show the field ONLY if: [sae_afte_stop_drug1] = '1'	Specify SAE number	text (integer) Custom alignment: RH												
753	sae_susp_readm1	Section Header: <i>STUDY DRUG RECHALLENGE</i> Was Study drug re-administered?	dropdown <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr><tr><td>3</td><td>NA</td></tr></table> Custom alignment: RH	1	Yes	2	No	3	NA						
1	Yes														
2	No														
3	NA														
754	sae_rech_date Show the field ONLY if: [sae_susp_readm1] = '1' and [sae_susp_readm1] = '1'	Specify the date	text (date_dmy) Custom alignment: RH												
755	sae_reap_reint1 Show the field ONLY if: [sae_susp_readm1] = '1'	Did event reappear after Study drug reintroduction?	dropdown <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr><tr><td>3</td><td>NA</td></tr></table> Custom alignment: RH	1	Yes	2	No	3	NA						
1	Yes														
2	No														
3	NA														

756	<div>sae_dech_num_2</div> <div>Show the field ONLY if: [sae_reap_reint1]='1' and [sae_susp_readm1] = '1'</div>	<div>Specify SAE number</div>	<div>text (integer)</div> <div>Custom alignment: RH</div>														
757	<div>sae_dise_under1</div>	<div>Section Header: <i>Disease under study</i></div> <div>Was the disease under study the primary cause of the SAE?</div>	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Conditional/Unclassified</td></tr><tr><td>7</td><td>Unassessable/Unclassifiable</td></tr></table>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Conditional/Unclassified	7	Unassessable/Unclassifiable
1	Certain																
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4	Unlikely																
5	Unrelated																
6	Conditional/Unclassified																
7	Unassessable/Unclassifiable																
758	<div>sae_dise_spec1</div>	<div>If disease primary cause, please specify which SAE</div>	<div>text</div>														
759	<div>sae_conc_stat</div>	<div>Section Header: <i>Concomitant treatments/Procedures(e.g. : prophylactic medications, procedures to obtain central venous access)</i></div>	<div>radio</div> <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Applicable</td></tr><tr><td>99</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	None	2	Applicable	99	Unknown								
1	None																
2	Applicable																
99	Unknown																
760	<div>sae_conc_name1</div> <div>Show the field ONLY if: [sae_conc_stat] = '2'</div>	<div>1. Name</div> <div><i>Do not list in this section drugs used to treat the SAE</i></div>	<div>text</div> <div>Custom alignment: RH</div>														
761	<div>sae_conc_dose1</div> <div>Show the field ONLY if: [sae_conc_name1] <> "</div>	<div>1. Total daily dose and unit</div>	<div>text</div> <div>Custom alignment: RH</div>														
762	<div>sae_conc_route1</div> <div>Show the field ONLY if: [sae_conc_name1] <> "</div>	<div>1. Route</div>	<div>dropdown</div> <table><tr><td>1</td><td>OS</td></tr><tr><td>2</td><td>Parenteral</td></tr><tr><td>3</td><td>Inhalation</td></tr><tr><td>4</td><td>Sublingual</td></tr><tr><td>5</td><td>Transdermic</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Other</td></tr></table> <div>Custom alignment: RH</div>	1	OS	2	Parenteral	3	Inhalation	4	Sublingual	5	Transdermic	6	Rectal	7	Other
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3	Inhalation																
4	Sublingual																
5	Transdermic																
6	Rectal																
7	Other																
763	<div>sae_conc_sdate1</div> <div>Show the field ONLY if: [sae_conc_name1] <> "</div>	<div>1. Start date</div> <div><i>(dd/mm/yyyy)</i></div>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
764	<div>sae_conc_edate1</div> <div>Show the field ONLY if: [sae_conc_name1] <> "</div>	<div>1. Stop date</div> <div><i>(dd/mm/yyyy)</i></div>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
765	<div>sae_conc_ong1</div> <div>Show the field ONLY if: [sae_conc_name1] <> "</div>		<div>radio</div> <table><tr><td>1</td><td>ongoing</td></tr></table> <div>Custom alignment: RH</div>	1	ongoing												
1	ongoing																
766	<div>sae_conc_prim1</div> <div>Show the field ONLY if: [sae_conc_name1] <> "</div>	<div>1. Primary cause of the SAE/s?</div>	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Conditional/Unclassified</td></tr><tr><td>7</td><td>Unassessable/Unclassifiable</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Conditional/Unclassified	7	Unassessable/Unclassifiable
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7	Unassessable/Unclassifiable																
767	<div>sae_conc_prim_num1</div> <div>Show the field ONLY if: [sae_conc_name1] <> "</div>	<div>2. If primary cause, specify which SAE number (i.e. 1,3)</div>	<div>text (integer)</div> <div>Custom alignment: RH</div>														
768	<div>sae_conc_name2</div> <div>Show the field ONLY if: [sae_conc_stat] = '2'</div>	<div>2. Name</div> <div><i>Do not list in this section drugs used to treat the SAE</i></div>	<div>text</div> <div>Custom alignment: RH</div>														

769	sae_conc_dose2 Show the field ONLY if: [sae_conc_name2] <> "	2. Total daily dose and unit	text Custom alignment: RH														
770	sae_conc_route2 Show the field ONLY if: [sae_conc_name2] <> "	2. Route	dropdown <table><tr><td>1</td><td>OS</td></tr><tr><td>2</td><td>Parenteral</td></tr><tr><td>3</td><td>Inhalation</td></tr><tr><td>4</td><td>Sublingual</td></tr><tr><td>5</td><td>Transdermic</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Other</td></tr></table> Custom alignment: RH	1	OS	2	Parenteral	3	Inhalation	4	Sublingual	5	Transdermic	6	Rectal	7	Other
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4	Sublingual																
5	Transdermic																
6	Rectal																
7	Other																
771	sae_conc_sdate2 Show the field ONLY if: [sae_conc_name2] <> "	2. Start date (dd/mm/yyyy)	text (date_dmy) Custom alignment: RH														
772	sae_conc_edate2 Show the field ONLY if: [sae_conc_name2] <> "	2. Stop date (dd/mm/yyyy)	text (date_dmy) Custom alignment: RH														
773	sae_conc_ong2 Show the field ONLY if: [sae_conc_name2] <> "		radio <table><tr><td>1</td><td>ongoing</td></tr></table> Custom alignment: RH	1	ongoing												
1	ongoing																
774	sae_conc_prim2 Show the field ONLY if: [sae_conc_name2] <> "	2. Primary cause of the SAE/s?	dropdown <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Conditional/Unclassified</td></tr><tr><td>7</td><td>Unassessable/Unclassifiable</td></tr></table> Custom alignment: RH	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Conditional/Unclassified	7	Unassessable/Unclassifiable
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2	Probable																
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4	Unlikely																
5	Unrelated																
6	Conditional/Unclassified																
7	Unassessable/Unclassifiable																
775	sae_conc_prim_num2 Show the field ONLY if: [sae_conc_name2] <> "	2. If primary cause, specify which SAE number (i.e. 1,3)	text (integer) Custom alignment: RH														
776	sae_conc_name3 Show the field ONLY if: [sae_conc_stat] = '2'	3. Name Do not list in this section drugs used to treat the SAE	text Custom alignment: RH														
777	sae_conc_dose3 Show the field ONLY if: [sae_conc_name3] <> "	3. Total daily dose and unit	text Custom alignment: RH														
778	sae_conc_route3 Show the field ONLY if: [sae_conc_name3] <> "	3. Route	dropdown <table><tr><td>1</td><td>OS</td></tr><tr><td>2</td><td>Parenteral</td></tr><tr><td>3</td><td>Inhalation</td></tr><tr><td>4</td><td>Sublingual</td></tr><tr><td>5</td><td>Transdermic</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Other</td></tr></table> Custom alignment: RH	1	OS	2	Parenteral	3	Inhalation	4	Sublingual	5	Transdermic	6	Rectal	7	Other
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2	Parenteral																
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4	Sublingual																
5	Transdermic																
6	Rectal																
7	Other																
779	sae_conc_sdate3 Show the field ONLY if: [sae_conc_name3] <> "	3. Start date (dd/mm/yyyy)	text (date_dmy) Custom alignment: RH														
780	sae_conc_edate3 Show the field ONLY if: [sae_conc_name3] <> "	3. Stop date (dd/mm/yyyy)	text (date_dmy) Custom alignment: RH														
781	sae_conc_ong3 Show the field ONLY if: [sae_conc_name3] <> "		radio <table><tr><td>1</td><td>ongoing</td></tr></table> Custom alignment: RH	1	ongoing												
1	ongoing																

782	<div>sae_conc_prim3</div> <div>Show the field ONLY if: [sae_conc_name3] <> "</div>	3. Primary cause of the SAE/s?	<div>dropdown</div> <div><div>1</div><div>Certain</div></div> <div><div>2</div><div>Probable</div></div> <div><div>3</div><div>Possible</div></div> <div><div>4</div><div>Unlikely</div></div> <div><div>5</div><div>Unrelated</div></div> <div><div>6</div><div>Conditional/Unclassified</div></div> <div><div>7</div><div>Unassessable/Unclassifiable</div></div> <div>Custom alignment: RH</div>
783	<div>sae_conc_prim_num3</div> <div>Show the field ONLY if: [sae_conc_name3] <> "</div>	3. If primary cause, specify which SAE number (i.e. 1,3)	<div>text (integer)</div> <div>Custom alignment: RH</div>
784	<div>sae_conc_name4</div> <div>Show the field ONLY if: [sae_conc_stat] = '2'</div>	<div>4. Name</div> <div>Do not list in this section drugs used to treat the SAE</div>	<div>text</div> <div>Custom alignment: RH</div>
785	<div>sae_conc_dose4</div> <div>Show the field ONLY if: [sae_conc_name4] <> "</div>	4. Total daily dose and unit	<div>text</div> <div>Custom alignment: RH</div>
786	<div>sae_conc_route4</div> <div>Show the field ONLY if: [sae_conc_name4] <> "</div>	4. Route	<div>dropdown</div> <div><div>1</div><div>OS</div></div> <div><div>2</div><div>Parenteral</div></div> <div><div>3</div><div>Inhalation</div></div> <div><div>4</div><div>Sublingual</div></div> <div><div>5</div><div>Transdermic</div></div> <div><div>6</div><div>Rectal</div></div> <div><div>7</div><div>Other</div></div> <div>Custom alignment: RH</div>
787	<div>sae_conc_sdate4</div> <div>Show the field ONLY if: [sae_conc_name4] <> "</div>	<div>4. Start date</div> <div>(dd/mm/yyyy)</div>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>
788	<div>sae_conc_edate4</div> <div>Show the field ONLY if: [sae_conc_name4] <> "</div>	<div>4. Stop date</div> <div>(dd/mm/yyyy)</div>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>
789	<div>sae_conc_ong4</div> <div>Show the field ONLY if: [sae_conc_name4] <> "</div>		<div>radio</div> <div><div>1</div><div>ongoing</div></div> <div>Custom alignment: RH</div>
790	<div>sae_conc_prim4</div> <div>Show the field ONLY if: [sae_conc_name4] <> "</div>	4. Primary cause of the SAE/s?	<div>dropdown</div> <div><div>1</div><div>Certain</div></div> <div><div>2</div><div>Probable</div></div> <div><div>3</div><div>Possible</div></div> <div><div>4</div><div>Unlikely</div></div> <div><div>5</div><div>Unrelated</div></div> <div><div>6</div><div>Conditional/Unclassified</div></div> <div><div>7</div><div>Unassessable/Unclassifiable</div></div> <div>Custom alignment: RH</div>
791	<div>sae_conc_prim_num4</div> <div>Show the field ONLY if: [sae_conc_name4] <> "</div>	4. If primary cause, specify which SAE number (i.e. 1,3)	<div>text (integer)</div> <div>Custom alignment: RH</div>
792	<div>sae_conc_name5</div> <div>Show the field ONLY if: [sae_conc_stat] = '2'</div>	<div>5. Name</div> <div>Do not list in this section drugs used to treat the SAE</div>	<div>text</div> <div>Custom alignment: RH</div>
793	<div>sae_conc_dose5</div> <div>Show the field ONLY if: [sae_conc_name5] <> "</div>	5. Total daily dose and unit	<div>text</div> <div>Custom alignment: RH</div>

794	<div>sae_conc_route5</div> <div>Show the field ONLY if: [sae_conc_name5] <> "</div>	5. Route	<div>dropdown</div> <table><tr><td>1</td><td>OS</td></tr><tr><td>2</td><td>Parenteral</td></tr><tr><td>3</td><td>Inhalation</td></tr><tr><td>4</td><td>Sublingual</td></tr><tr><td>5</td><td>Transdermic</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Other</td></tr></table> <div>Custom alignment: RH</div>	1	OS	2	Parenteral	3	Inhalation	4	Sublingual	5	Transdermic	6	Rectal	7	Other
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795	<div>sae_conc_sdate5</div> <div>Show the field ONLY if: [sae_conc_name5] <> "</div>	5. Start date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
796	<div>sae_conc_edate5</div> <div>Show the field ONLY if: [sae_conc_name5] <> "</div>	5. Stop date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
797	<div>sae_conc_ong5</div> <div>Show the field ONLY if: [sae_conc_name5] <> "</div>		<div>radio</div> <table><tr><td>1</td><td>ongoing</td></tr></table> <div>Custom alignment: RH</div>	1	ongoing												
1	ongoing																
798	<div>sae_conc_prim5</div> <div>Show the field ONLY if: [sae_conc_name5] <> "</div>	5. Primary cause of the SAE/s?	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Conditional/Unclassified</td></tr><tr><td>7</td><td>Unassessable/Unclassifiable</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Conditional/Unclassified	7	Unassessable/Unclassifiable
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799	<div>sae_conc_prim_num5</div> <div>Show the field ONLY if: [sae_conc_name5] <> "</div>	5. If primary cause, specify which SAE number (i.e. 1,3)	<div>text (integer)</div> <div>Custom alignment: RH</div>														
800	<div>sae_conc_name6</div> <div>Show the field ONLY if: [sae_conc_stat] = '2'</div>	6. Name <i>Do not list in this section drugs used to treat the SAE</i>	<div>text</div> <div>Custom alignment: RH</div>														
801	<div>sae_conc_dose6</div> <div>Show the field ONLY if: [sae_conc_name6] <> "</div>	6. Total daily dose and unit	<div>text</div> <div>Custom alignment: RH</div>														
802	<div>sae_conc_route6</div> <div>Show the field ONLY if: [sae_conc_name6] <> "</div>	6. Route	<div>dropdown</div> <table><tr><td>1</td><td>OS</td></tr><tr><td>2</td><td>Parenteral</td></tr><tr><td>3</td><td>Inhalation</td></tr><tr><td>4</td><td>Sublingual</td></tr><tr><td>5</td><td>Transdermic</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Other</td></tr></table> <div>Custom alignment: RH</div>	1	OS	2	Parenteral	3	Inhalation	4	Sublingual	5	Transdermic	6	Rectal	7	Other
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7	Other																
803	<div>sae_conc_sdate6</div> <div>Show the field ONLY if: [sae_conc_name6] <> "</div>	6. Start date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
804	<div>sae_conc_edate6</div> <div>Show the field ONLY if: [sae_conc_name6] <> "</div>	6. Stop date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
805	<div>sae_conc_ong6</div> <div>Show the field ONLY if: [sae_conc_name6] <> "</div>		<div>radio</div> <table><tr><td>1</td><td>ongoing</td></tr></table> <div>Custom alignment: RH</div>	1	ongoing												
1	ongoing																

806	<div>sae_conc_prim6</div> <div>Show the field ONLY if: [sae_conc_name6] <> "</div>	6. Primary cause of the SAE/s?	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Conditional/Unclassified</td></tr><tr><td>7</td><td>Unassessable/Unclassifiable</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Conditional/Unclassified	7	Unassessable/Unclassifiable
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7	Unassessable/Unclassifiable																
807	<div>sae_conc_prim_num6</div> <div>Show the field ONLY if: [sae_conc_name6] <> "</div>	6. If primary cause, specify which SAE number (i.e. 1,3)	<div>text (integer)</div> <div>Custom alignment: RH</div>														
808	<div>sae_relev_stat</div>	Section Header: 6. <i>Relevant Medical Conditions (pre-existing relevant medical conditions, family history)</i>	<div>radio</div> <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Applicable</td></tr><tr><td>99</td><td>UK</td></tr></table> <div>Custom alignment: RH</div>	1	None	2	Applicable	99	UK								
1	None																
2	Applicable																
99	UK																
809	<div>sae_dise1</div> <div>Show the field ONLY if: [sae_relev_stat] = '2'</div>	1. Disease/Allergy/Risk Factor	<div>text</div> <div>Custom alignment: RH</div>														
810	<div>sae_rele_sdate1</div> <div>Show the field ONLY if: [sae_dise1] <> "</div>	1. Start date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
811	<div>sae_rele_edate1</div> <div>Show the field ONLY if: [sae_dise1] <> "</div>	1. Stop date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
812	<div>sae_rele_ong1</div> <div>Show the field ONLY if: [sae_dise1] <> "</div>		<div>radio</div> <table><tr><td>1</td><td>ongoing</td></tr></table> <div>Custom alignment: RH</div>	1	ongoing												
1	ongoing																
813	<div>sae_rele_prim1</div> <div>Show the field ONLY if: [sae_dise1] <> "</div>	1. Primary cause of the SAE/s?	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Conditional/Unclassified</td></tr><tr><td>7</td><td>Unassessable/Unclassifiable</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Conditional/Unclassified	7	Unassessable/Unclassifiable
1	Certain																
2	Probable																
3	Possible																
4	Unlikely																
5	Unrelated																
6	Conditional/Unclassified																
7	Unassessable/Unclassifiable																
814	<div>sae_rele_prim_num1</div> <div>Show the field ONLY if: [sae_dise1] <> "</div>	1. If primary cause, specify which SAE number (i.e. 1,3)	<div>text (integer)</div> <div>Custom alignment: RH</div>														
815	<div>sae_dise2</div> <div>Show the field ONLY if: [sae_relev_stat] = '2'</div>	2. Disease/Allergy/Risk Factor	<div>text</div> <div>Custom alignment: RH</div>														
816	<div>sae_rele_sdate2</div> <div>Show the field ONLY if: [sae_dise2] <> "</div>	2. Start date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
817	<div>sae_rele_edate2</div> <div>Show the field ONLY if: [sae_dise2] <> "</div>	2. Stop date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
818	<div>sae_rele_ong2</div> <div>Show the field ONLY if: [sae_dise2] <> "</div>		<div>radio</div> <table><tr><td>1</td><td>ongoing</td></tr></table> <div>Custom alignment: RH</div>	1	ongoing												
1	ongoing																

819	<div>sae_rele_prim2</div> <div>Show the field ONLY if: [sae_dise2] <> "</div>	2. Primary cause of the SAE/s?	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Conditional/Unclassified</td></tr><tr><td>7</td><td>Unassessable/Unclassifiable</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Conditional/Unclassified	7	Unassessable/Unclassifiable
1	Certain																
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3	Possible																
4	Unlikely																
5	Unrelated																
6	Conditional/Unclassified																
7	Unassessable/Unclassifiable																
820	<div>sae_rele_prim_num2</div> <div>Show the field ONLY if: [sae_dise2] <> "</div>	2. If primary cause, specify which SAE number (i.e. 1,3)	<div>text (integer)</div> <div>Custom alignment: RH</div>														
821	<div>sae_dise3</div> <div>Show the field ONLY if: [sae_relev_stat] = '2'</div>	3. Disease/Allergy/Risk Factor	<div>text</div> <div>Custom alignment: RH</div>														
822	<div>sae_rele_sdate3</div> <div>Show the field ONLY if: [sae_dise3] <> "</div>	<div>3. Start date</div> <div>(dd/mm/yyyy)</div>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
823	<div>sae_rele_edate3</div> <div>Show the field ONLY if: [sae_dise3] <> "</div>	<div>3. Stop date</div> <div>(dd/mm/yyyy)</div>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
824	<div>sae_rele_ong3</div> <div>Show the field ONLY if: [sae_dise3] <> "</div>		<div>radio</div> <table><tr><td>1</td><td>ongoing</td></tr></table> <div>Custom alignment: RH</div>	1	ongoing												
1	ongoing																
825	<div>sae_rele_prim3</div> <div>Show the field ONLY if: [sae_dise3] <> "</div>	3. Primary cause of the SAE/s?	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Conditional/Unclassified</td></tr><tr><td>7</td><td>Unassessable/Unclassifiable</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Conditional/Unclassified	7	Unassessable/Unclassifiable
1	Certain																
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3	Possible																
4	Unlikely																
5	Unrelated																
6	Conditional/Unclassified																
7	Unassessable/Unclassifiable																
826	<div>sae_rele_prim_num3</div> <div>Show the field ONLY if: [sae_dise3] <> "</div>	3. If primary cause, specify which SAE number (i.e. 1,3)	<div>text (integer)</div> <div>Custom alignment: RH</div>														
827	<div>sae_dise4</div> <div>Show the field ONLY if: [sae_relev_stat] = '2'</div>	4. Disease/Allergy/Risk Factor	<div>text</div> <div>Custom alignment: RH</div>														
828	<div>sae_rele_sdate4</div> <div>Show the field ONLY if: [sae_dise4] <> "</div>	<div>4. Start date</div> <div>(dd/mm/yyyy)</div>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
829	<div>sae_rele_edate4</div> <div>Show the field ONLY if: [sae_dise4] <> "</div>	<div>4. Stop date</div> <div>(dd/mm/yyyy)</div>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
830	<div>sae_rele_ong4</div> <div>Show the field ONLY if: [sae_dise4] <> "</div>		<div>radio</div> <table><tr><td>1</td><td>ongoing</td></tr></table> <div>Custom alignment: RH</div>	1	ongoing												
1	ongoing																
831	<div>sae_rele_prim4</div> <div>Show the field ONLY if: [sae_dise4] <> "</div>	4. Primary cause of the SAE/s?	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Conditional/Unclassified</td></tr><tr><td>7</td><td>Unassessable/Unclassifiable</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Conditional/Unclassified	7	Unassessable/Unclassifiable
1	Certain																
2	Probable																
3	Possible																
4	Unlikely																
5	Unrelated																
6	Conditional/Unclassified																
7	Unassessable/Unclassifiable																

832	sae_rele_prim_num4 Show the field ONLY if: [sae_dise4] <> "	4. If primary cause, specify which SAE number (i.e. 1,3)	text (integer) Custom alignment: RH
833	sae_dise5 Show the field ONLY if: [sae_relev_stat] = '2'	5. Disease/Allergy/Risk Factor	text Custom alignment: RH
834	sae_rele_sdate5 Show the field ONLY if: [sae_dise5] <> "	5. Start date (dd/mm/yyyy)	text (date_dmy) Custom alignment: RH
835	sae_rele_edate5 Show the field ONLY if: [sae_dise5] <> "	5. Stop date (dd/mm/yyyy)	text (date_dmy) Custom alignment: RH
836	sae_rele_ong5 Show the field ONLY if: [sae_dise5] <> "		radio <div>1 ongoing</div> Custom alignment: RH
837	sae_rele_prim5 Show the field ONLY if: [sae_dise5] <> "	5. Primary cause of the SAE/s?	dropdown <div> <div>1 Certain</div> <div>2 Probable</div> <div>3 Possible</div> <div>4 Unlikely</div> <div>5 Unrelated</div> <div>6 Conditional/Unclassified</div> <div>7 Unassessable/Unclassifiable</div> </div> Custom alignment: RH
838	sae_rele_prim_num5 Show the field ONLY if: [sae_dise5] <> "	5. If primary cause, specify which SAE number (i.e. 1,3)	text (integer) Custom alignment: RH
839	sae_description	7. SAE narrative(Please describe chronologically the clinical sequence of the events, results of any confirmatory procedures, treatment of the event and outcome. Attach separately laboratory results and other relevant documents like hospital or post-mortem reports when available)	notes
840	sae_diag_stat	Section Header: 8. Relevant Diagnostic Tests(including laboratory values preceding the event)	radio <div> <div>1 None</div> <div>2 Applicable</div> </div> Custom alignment: RH
841	sae_test1 Show the field ONLY if: [sae_diag_stat] = '2'	1. Test	text
842	sae_test_date1 Show the field ONLY if: [sae_test1] <> "	1. Date (dd/mm/yyyy)	text (date_dmy)
843	sae_test_resu1 Show the field ONLY if: [sae_test1] <> "	1. Result	text
844	sae_test_refe1 Show the field ONLY if: [sae_test1] <> "	1. Reference range (if applicabile ULN-LLN)	text
845	sae_test2 Show the field ONLY if: [sae_diag_stat] = '2'	2. Test	text
846	sae_test_date2 Show the field ONLY if: [sae_test2] <> "	2. Date (dd/mm/yyyy)	text (date_dmy)
847	sae_test_resu2 Show the field ONLY if: [sae_test2] <> "	2. Result	text
848	sae_test_refe2 Show the field ONLY if: [sae_test2] <> "	2. Reference range (if applicabile ULN-LLN)	text

849	sae_test3 Show the field ONLY if: [sae_diag_stat] = '2'	3. Test	text														
850	sae_test_date3 Show the field ONLY if: [sae_test3] <> "	3. Date <i>(dd/mm/yyyy)</i>	text (date_dmy)														
851	sae_test_resu3 Show the field ONLY if: [sae_test3] <> "	3. Result	text														
852	sae_test_refe3 Show the field ONLY if: [sae_test3] <> "	3. Reference range <i>(if applicabile ULN-LLN)</i>	text														
853	sae_test4 Show the field ONLY if: [sae_diag_stat] = '2'	4. Test	text														
854	sae_test_date4 Show the field ONLY if: [sae_test4] <> "	4. Date <i>(dd/mm/yyyy)</i>	text (date_dmy)														
855	sae_test_resu4 Show the field ONLY if: [sae_test4] <> "	4. Result	text														
856	sae_test_refe4 Show the field ONLY if: [sae_test4] <> "	4. Reference range <i>(if applicabile ULN-LLN)</i>	text														
857	sae_test5 Show the field ONLY if: [sae_diag_stat] = '2'	5. Test	text														
858	sae_test_date5 Show the field ONLY if: [sae_test5] <> "	5. Date <i>(dd/mm/yyyy)</i>	text (date_dmy)														
859	sae_test_resu5 Show the field ONLY if: [sae_test5] <> "	5. Result	text														
860	sae_test_refe5 Show the field ONLY if: [sae_test5] <> "	5. Reference range <i>(if applicabile ULN-LLN)</i>	text														
861	sae_tre_stat	Section Header: 9. Treatments/Procedures for SAE	radio <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Applicable</td></tr></table> Custom alignment: RH	1	None	2	Applicable										
1	None																
2	Applicable																
862	sae_tre_name1 Show the field ONLY if: [sae_tre_stat] = '2'	1. Name	text Custom alignment: RH														
863	sae_tre_dose1 Show the field ONLY if: [sae_tre_name1] <> "	1. Daily dose and unit	text Custom alignment: RH														
864	sae_tre_route1 Show the field ONLY if: [sae_tre_name1] <> "	1. Route	dropdown <table><tr><td>1</td><td>OS</td></tr><tr><td>2</td><td>Parenteral</td></tr><tr><td>3</td><td>Inhalation</td></tr><tr><td>4</td><td>Sublingual</td></tr><tr><td>5</td><td>Transdermic</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Other</td></tr></table> Custom alignment: RH	1	OS	2	Parenteral	3	Inhalation	4	Sublingual	5	Transdermic	6	Rectal	7	Other
1	OS																
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3	Inhalation																
4	Sublingual																
5	Transdermic																
6	Rectal																
7	Other																
865	sae_tre_sdate1 Show the field ONLY if: [sae_tre_name1] <> "	1. Start date <i>(dd/mm/yyyy)</i>	text (date_dmy) Custom alignment: RH														
866	sae_tre_edate1 Show the field ONLY if: [sae_tre_name1] <> "	1. Stop date <i>(dd/mm/yyyy)</i>	text (date_dmy) Custom alignment: RH														

867	sae_tre_ong Show the field ONLY if: [sae_tre_name1] <> "		radio 1 ongoing Custom alignment: RH
868	sae_tre_name2 Show the field ONLY if: [sae_tre_stat] = '2'	2. Name	text Custom alignment: RH
869	sae_tre_dose2 Show the field ONLY if: [sae_tre_name2] <> "	2. Daily dose and unit	text Custom alignment: RH
870	sae_tre_route2 Show the field ONLY if: [sae_tre_name2] <> "	2. Route	dropdown 1 OS 2 Parenteral 3 Inhalation 4 Sublingual 5 Transdermic 6 Rectal 7 Other Custom alignment: RH
871	sae_tre_sdate2 Show the field ONLY if: [sae_tre_name2] <> "	2. Start date (dd/mm/yyyy)	text (date_dmy) Custom alignment: RH
872	sae_tre_edate2 Show the field ONLY if: [sae_tre_name2] <> "	2. Stop date (dd/mm/yyyy)	text (date_dmy) Custom alignment: RH
873	sae_tre_ong_2 Show the field ONLY if: [sae_tre_name2] <> "		radio 1 ongoing Custom alignment: RH
874	sae_tre_name3 Show the field ONLY if: [sae_tre_stat] = '2'	3. Name	text Custom alignment: RH
875	sae_tre_dose3 Show the field ONLY if: [sae_tre_name3] <> "	3. Daily dose and unit	text Custom alignment: RH
876	sae_tre_route3 Show the field ONLY if: [sae_tre_name3] <> "	3. Route	dropdown 1 OS 2 Parenteral 3 Inhalation 4 Sublingual 5 Transdermic 6 Rectal 7 Other Custom alignment: RH
877	sae_tre_sdate3 Show the field ONLY if: [sae_tre_name3] <> "	3. Start date (dd/mm/yyyy)	text (date_dmy) Custom alignment: RH
878	sae_tre_edate3 Show the field ONLY if: [sae_tre_name3] <> "	3. Stop date (dd/mm/yyyy)	text (date_dmy) Custom alignment: RH
879	sae_tre_ong_3 Show the field ONLY if: [sae_tre_name3] <> "		radio 1 ongoing Custom alignment: RH
880	sae_tre_name4 Show the field ONLY if: [sae_tre_stat] = '2'	4. Name	text Custom alignment: RH
881	sae_tre_dose4 Show the field ONLY if: [sae_tre_name4] <> "	4. Daily dose and unit	text Custom alignment: RH

882	<div>sae_tre_route4</div> <div>Show the field ONLY if: [sae_tre_name4] <> "</div>	4. Route	<div>dropdown</div> <div><div>1</div><div>OS</div></div> <div><div>2</div><div>Parenteral</div></div> <div><div>3</div><div>Inhalation</div></div> <div><div>4</div><div>Sublingual</div></div> <div><div>5</div><div>Transdermic</div></div> <div><div>6</div><div>Rectal</div></div> <div><div>7</div><div>Other</div></div> <div>Custom alignment: RH</div>
883	<div>sae_tre_sdate4</div> <div>Show the field ONLY if: [sae_tre_name4] <> "</div>	4. Start date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>
884	<div>sae_tre_ede4</div> <div>Show the field ONLY if: [sae_tre_name4] <> "</div>	4. Stop date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>
885	<div>sae_tre_ong_4</div> <div>Show the field ONLY if: [sae_tre_name4] <> "</div>		<div>radio</div> <div><div>1</div><div>ongoing</div></div> <div>Custom alignment: RH</div>
886	<div>sae_tre_name5</div> <div>Show the field ONLY if: [sae_tre_stat] = '2'</div>	5. Name	<div>text</div> <div>Custom alignment: RH</div>
887	<div>sae_tre_dose5</div> <div>Show the field ONLY if: [sae_tre_name5] <> "</div>	5. Daily dose and unit	<div>text</div> <div>Custom alignment: RH</div>
888	<div>sae_tre_route5</div> <div>Show the field ONLY if: [sae_tre_name5] <> "</div>	5. Route	<div>dropdown</div> <div><div>1</div><div>OS</div></div> <div><div>2</div><div>Parenteral</div></div> <div><div>3</div><div>Inhalation</div></div> <div><div>4</div><div>Sublingual</div></div> <div><div>5</div><div>Transdermic</div></div> <div><div>6</div><div>Rectal</div></div> <div><div>7</div><div>Other</div></div> <div>Custom alignment: RH</div>
889	<div>sae_tre_sdate5</div> <div>Show the field ONLY if: [sae_tre_name5] <> "</div>	5. Start date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>
890	<div>sae_tre_ede5</div> <div>Show the field ONLY if: [sae_tre_name5] <> "</div>	5. Stop date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>
891	<div>sae_tre_ong_5</div> <div>Show the field ONLY if: [sae_tre_name5] <> "</div>		<div>radio</div> <div><div>1</div><div>ongoing</div></div> <div>Custom alignment: RH</div>
892	<div>sae_tre_name6</div> <div>Show the field ONLY if: [sae_tre_stat] = '2'</div>	6. Name	<div>text</div> <div>Custom alignment: RH</div>
893	<div>sae_tre_dose6</div> <div>Show the field ONLY if: [sae_tre_name6] <> "</div>	6. Daily dose and unit	<div>text</div> <div>Custom alignment: RH</div>
894	<div>sae_tre_sdate6</div> <div>Show the field ONLY if: [sae_tre_name6] <> "</div>	6. Start date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>
895	<div>sae_tre_ede6</div> <div>Show the field ONLY if: [sae_tre_name5] <> "</div>	6. Stop date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>
896	<div>sae_tre_ong_6</div> <div>Show the field ONLY if: [sae_tre_name6] <> "</div>		<div>radio</div> <div><div>1</div><div>ongoing</div></div> <div>Custom alignment: RH</div>

897	sae_tre_name7 Show the field ONLY if: [sae_tre_stat] = '2'	7. Name	text Custom alignment: RH
898	sae_tre_dose7 Show the field ONLY if: [sae_tre_name7] <> "	7. Daily dose and unit	text Custom alignment: RH
899	sae_tre_sdate7 Show the field ONLY if: [sae_tre_name7] <> "	7. Start date (dd/mm/yyyy)	text (date_dmy) Custom alignment: RH
900	sae_tre_edate7 Show the field ONLY if: [sae_tre_name7] <> "	7. Stop date (dd/mm/yyyy)	text (date_dmy) Custom alignment: RH
901	sae_tre_ong_7 Show the field ONLY if: [sae_tre_name7] <> "		radio <div><div>1</div>ongoing</div> Custom alignment: RH
902	sae_tre_name8 Show the field ONLY if: [sae_tre_stat] = '2'	8. Name	text Custom alignment: RH
903	sae_tre_dose8 Show the field ONLY if: [sae_tre_name8] <> "	8. Daily dose and unit	text Custom alignment: RH
904	sae_tre_sdate8 Show the field ONLY if: [sae_tre_name8] <> "	8. Start date (dd/mm/yyyy)	text (date_dmy) Custom alignment: RH
905	sae_tre_edate8 Show the field ONLY if: [sae_tre_name8] <> "	8. Stop date (dd/mm/yyyy)	text (date_dmy) Custom alignment: RH
906	sae_tre_ong_8 Show the field ONLY if: [sae_tre_name8] <> "		radio <div><div>1</div>ongoing</div> Custom alignment: RH
907	sae_report_date	Section Header: _____ DATE OF REPORT (dd/mm/yyyy)	text (date_dmy) Custom alignment: RH
908	sae_report	REPORTED BY (full name)	text Custom alignment: RH
909	sae_invest	INVESTIGATOR (If different from reporter) (full name)	text
910	sae_signat	Signature (please, draw signature with mouse or finger)	file (signature) Custom alignment: RH
911	sae_indic_titolo_1	To send the notification of the SAE form to the Sponsor safety desk, click Save. Please, complete the SAE form with all information available before saving.	descriptive
912	serious_averse_event_initial_report_complete	Section Header: Form Status Complete?	dropdown <div><div>0</div>Incomplete</div> <div><div>1</div>Unverified</div> <div><div>2</div>Complete</div>

Instrument: **Serious Averse Event Follow Up Report 1** (serious_averse_event_follow_up_report_1)[^ Collapse](#)

913	ud_sae1	Section Header: Record ID/Patient [baseline_arm_1][record_id] - Treatment [enrollment_arm_1][randomization] SERIOUS ADVERSE EVENT FORM - FOLLOW UP REPORT 11. Patient Information Upload document	file				
914	sae_birth_f1	Year of birth (yyyy)	text (integer, Min: 1920, Max: 2020)				
915	sae_sex_f1	Sex	dropdown <table><tr><td>1</td><td>M</td></tr><tr><td>2</td><td>F</td></tr></table> Field Annotation: @DEFAULT=[baseline_arm_1][d_gender]	1	M	2	F
1	M						
2	F						
916	sae_height_f1	Height (cm) (cm)	text (integer) Field Annotation: @DEFAULT="[baseline_arm_1][height]"				
917	sae_weight_f1	Weight (Kg) (Kg)	text (number_1dp, Min: 30.0, Max: 100.0) Field Annotation: @DEFAULT= "[baseline_arm_1][weight]"				
918	sae_imp3_fadm_date_f1	Section Header: 2. Investigational Medicinal Product (IMP)/Study Drugs Date of first admin.	text (date_dmy) Custom alignment: RH				

919	sae_imp3_ladm_date_f1	Date of last admin.	text (date_dmy) Custom alignment: RH										
920	sae_imp3_idose_f1	Intended dose & unit	text Custom alignment: RH										
921	sae_imp3_adose_f1	Administered dose & unit	text Custom alignment: RH										
922	sae_aware_date_f1	Section Header: <i>SAE Details</i> Date of SAE awareness <i>(dd/mm/yyyy)</i>	text (date_dmy)										
923	sae_term1_f1 Show the field ONLY if: [sae_aware_date_f1] <> "	1. SAE Term/Diagnosis	text										
924	sae_grade1_f1 Show the field ONLY if: [sae_term1_f1] <> "	1. SAE NCI-CTC AE Grade	dropdown <table><tr><td>1</td><td>Grade 1/Mild</td></tr><tr><td>2</td><td>Grade 2/Moderate</td></tr><tr><td>3</td><td>Grade 3/Severe</td></tr><tr><td>4</td><td>Grade 4/Life Threatening</td></tr><tr><td>5</td><td>Grade 5/Death</td></tr></table>	1	Grade 1/Mild	2	Grade 2/Moderate	3	Grade 3/Severe	4	Grade 4/Life Threatening	5	Grade 5/Death
1	Grade 1/Mild												
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3	Grade 3/Severe												
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925	ctc_ae_link1_f1 Show the field ONLY if: [sae_term1_f1] <> "	Please right-click on this link to reference the CTC AE V 4.03	descriptive										
926	sae_death1_f1 Show the field ONLY if: [sae_term1_f1] <> "	1. Death	radio <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table> Custom alignment: RH	0	No	1	Yes	99	Unknown				
0	No												
1	Yes												
99	Unknown												
927	sae_death_date1_f1 Show the field ONLY if: [sae_death1_f1] = '1' and [sae_term1_f1] <> "	If Death, Date of Death:	text (date_dmy)										
928	sae_death_due1_f1 Show the field ONLY if: [sae_death1_f1] = '1' and [sae_term1_f1] <> "	Death due to the SAE	radio <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table> Custom alignment: RH	0	No	1	Yes	99	Unknown				
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1	Yes												
99	Unknown												
929	sae_auto_perf1_f1 Show the field ONLY if: [sae_death1_f1] = '1' and [sae_term1_f1] <> "	Was an autopsy performed?	radio <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr></table> Custom alignment: RH	1	Yes	2	No						
1	Yes												
2	No												
930	sae_life_threa1_f1 Show the field ONLY if: [sae_term1_f1] <> "	Life-threatening	radio (Matrix) <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	0	No	1	Yes	99	Unknown				
0	No												
1	Yes												
99	Unknown												
931	sae_hospi1_f1 Show the field ONLY if: [sae_term1_f1] <> "	Hospitalisation/Prolonged Hospitalisation	radio (Matrix) <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	0	No	1	Yes	99	Unknown				
0	No												
1	Yes												
99	Unknown												
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0	No												
1	Yes												
99	Unknown												
933	sae_anoma1_f1 Show the field ONLY if: [sae_term1_f1] <> "	Congenital Anomaly/Birth defect	radio (Matrix) <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	0	No	1	Yes	99	Unknown				
0	No												
1	Yes												
99	Unknown												
934	sae_med_even1_f1 Show the field ONLY if: [sae_term1_f1] <> "	Important Medical Event	radio (Matrix) <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	0	No	1	Yes	99	Unknown				
0	No												
1	Yes												
99	Unknown												

935	sae_imp1_causa1_f1 Show the field ONLY if: [sae_term1_f1] <> "	1. Causal relation to IMP/Study drug (1)	dropdown <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Unknown</td></tr></table> Custom alignment: RH	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
1	Certain														
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3	Possible														
4	Unlikely														
5	Unrelated														
6	Unknown														
936	sae_imp2_causa1_f1 Show the field ONLY if: [sae_term1_f1] <> "	1. Causal relation to IMP/Study drug (2)	dropdown <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Unknown</td></tr></table> Custom alignment: RH	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
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5	Unrelated														
6	Unknown														
937	sae_imp3_causa1_f1 Show the field ONLY if: [sae_term1_f1] <> "	1. Causal relation to IMP/Study drug (3)	dropdown <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Unknown</td></tr></table> Custom alignment: RH	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
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4	Unlikely														
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6	Unknown														
938	sae_sdate1_f1 Show the field ONLY if: [sae_term1_f1] <> "	1. Start date <i>(dd/mm/yyyy hh:mm)</i>	text (datetime_dmy)												
939	sae_edate1_f1 Show the field ONLY if: [sae_term1_f1] <> "	1. Stop date <i>(dd/mm/yyyy hh:mm)</i>	text (datetime_dmy)												
940	sae_outcome_stat1_f1 Show the field ONLY if: [sae_term1_f1] <> "	1. Outcome	dropdown <table><tr><td>1</td><td>Resolved</td></tr><tr><td>2</td><td>Resolving</td></tr><tr><td>3</td><td>Resolved with sequelae</td></tr><tr><td>4</td><td>Not resolved</td></tr><tr><td>5</td><td>Fatal</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Resolved	2	Resolving	3	Resolved with sequelae	4	Not resolved	5	Fatal	6	Unknown
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2	Resolving														
3	Resolved with sequelae														
4	Not resolved														
5	Fatal														
6	Unknown														
941	sae_imp1_action1_f1 Show the field ONLY if: [sae_term1_f1] <> "	1. Action taken with the IMP/s drug (1)	dropdown <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr><tr><td>5</td><td>IMP withdrawn</td></tr><tr><td>6</td><td>Unknown</td></tr></table> Custom alignment: RH	1	None	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced	5	IMP withdrawn	6	Unknown
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942	sae_imp2_action1_f1 Show the field ONLY if: [sae_term1_f1] <> "	1. Action taken with the IMP/s drug (2)	dropdown <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr><tr><td>5</td><td>IMP withdrawn</td></tr><tr><td>6</td><td>Unknown</td></tr></table> Custom alignment: RH	1	None	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced	5	IMP withdrawn	6	Unknown
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943	<div>sae_imp3_action1_f1</div> <div>Show the field ONLY if: [sae_term1_f1] <> "</div>	1. Action taken with the IMP/s drug (3)	<div>dropdown</div> <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr><tr><td>5</td><td>IMP withdrawn</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	None	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced	5	IMP withdrawn	6	Unknown
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944	<div>sae_term2_f1</div> <div>Show the field ONLY if: [sae_aware_date_f1] <> "</div>	2. SAE Term/Diagnosis	text												
945	<div>sae_grade2_f1</div> <div>Show the field ONLY if: [sae_term2_f1] <> "</div>	2. SAE NCI-CTC AE Grade	<div>dropdown</div> <table><tr><td>1</td><td>Grade 1/Mild</td></tr><tr><td>2</td><td>Grade 2/Moderate</td></tr><tr><td>3</td><td>Grade 3/Severe</td></tr><tr><td>4</td><td>Grade 4/Life Threatening</td></tr><tr><td>5</td><td>Grade 5/Death</td></tr></table>	1	Grade 1/Mild	2	Grade 2/Moderate	3	Grade 3/Severe	4	Grade 4/Life Threatening	5	Grade 5/Death		
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946	<div>ctc_ae_link2_f1</div> <div>Show the field ONLY if: [sae_term2_f1] <> "</div>	Please right-click on this link to reference the CTC AE V 4.03	descriptive												
947	<div>sae_death2_f1</div> <div>Show the field ONLY if: [sae_term2_f1] <> "</div>	2. Death	<div>radio</div> <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	0	No	1	Yes	99	Unknown						
0	No														
1	Yes														
99	Unknown														
948	<div>sae_death_date2_f1</div> <div>Show the field ONLY if: [sae_death2_f1] = '1' and [sae_term2_f1] <> "</div>	If Death, Date of Death:	text (date_dmy)												
949	<div>sae_death_due2_f1</div> <div>Show the field ONLY if: [sae_death2_f1] = '1' and [sae_term2_f1] <> "</div>	Death due to the SAE	<div>radio</div> <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	0	No	1	Yes	99	Unknown						
0	No														
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950	<div>sae_auto_perf2_f1</div> <div>Show the field ONLY if: [sae_death2_f1] = '1' and [sae_term2_f1] <> "</div>	Was an autopsy performed?	<div>radio</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr></table> <div>Custom alignment: RH</div>	1	Yes	2	No								
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951	<div>sae_life_threa2_f1</div> <div>Show the field ONLY if: [sae_term2_f1] <> "</div>	Life-threatening	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
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952	<div>sae_hospi2_f1</div> <div>Show the field ONLY if: [sae_term2_f1] <> "</div>	Hospitalisation/Prolonged Hospitalisation	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
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954	<div>sae_anoma2_f1</div> <div>Show the field ONLY if: [sae_term2_f1] <> "</div>	Congenital Anomaly/Birth defect	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
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955	<div>sae_med_even2_f1</div> <div>Show the field ONLY if: [sae_term2_f1] <> "</div>	Important Medical Event	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
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2	Yes														
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956	<div>sae_imp1_causa2_f1</div> <div>Show the field ONLY if: [sae_term2_f1] <> "</div>	2. Causal relation to IMP/Study drug (1)	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
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957	<div>sae_imp2_causa2_f1</div> <div>Show the field ONLY if: [sae_term2_f1] <> "</div>	2. Causal relation to IMP/Study drug (2)	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
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958	<div>sae_imp3_causa2_f1</div> <div>Show the field ONLY if: [sae_term2_f1] <> "</div>	2. Causal relation to IMP/Study drug (3)	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
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959	<div>sae_sdate2_f1</div> <div>Show the field ONLY if: [sae_term2_f1] <> "</div>	2. Start date <i>(dd/mm/yyyy hh:mm)</i>	text (datetime_dmy)												
960	<div>sae_edate2_f1</div> <div>Show the field ONLY if: [sae_term2_f1] <> "</div>	2. Stop date <i>(dd/mm/yyyy hh:mm)</i>	text (datetime_dmy)												
961	<div>sae_outcome_stat2_f1</div> <div>Show the field ONLY if: [sae_term2_f1] <> "</div>	2. Outcome	<div>dropdown</div> <table><tr><td>1</td><td>Resolved</td></tr><tr><td>2</td><td>Resolving</td></tr><tr><td>3</td><td>Resolved with sequelae</td></tr><tr><td>4</td><td>Not resolved</td></tr><tr><td>5</td><td>Fatal</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Resolved	2	Resolving	3	Resolved with sequelae	4	Not resolved	5	Fatal	6	Unknown
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962	<div>sae_imp1_action2_f1</div> <div>Show the field ONLY if: [sae_term2_f1] <> "</div>	2. Action taken with the IMP/s drug (1)	<div>dropdown</div> <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr><tr><td>5</td><td>IMP withdrawn</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	None	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced	5	IMP withdrawn	6	Unknown
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963	<div>sae_imp2_action2_f1</div> <div>Show the field ONLY if: [sae_term2_f1] <> "</div>	2. Action taken with the IMP/s drug (2)	<div>dropdown</div> <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr><tr><td>5</td><td>IMP withdrawn</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	None	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced	5	IMP withdrawn	6	Unknown
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964	<div>sae_imp3_action2_f1</div> <div>Show the field ONLY if: [sae_term2_f1] <> "</div>	2. Action taken with the IMP/s drug (3)	<div>dropdown</div> <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr><tr><td>5</td><td>IMP withdrawn</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	None	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced	5	IMP withdrawn	6	Unknown
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965	<div>sae_term3_f1</div> <div>Show the field ONLY if: [sae_awaar_date_f1] <> "</div>	3. SAE Term/Diagnosis	text												
966	<div>sae_grade3_f1</div> <div>Show the field ONLY if: [sae_term3_f1] <> "</div>	3. SAE NCI-CTC AE Grade	<div>dropdown</div> <table><tr><td>1</td><td>Grade 1/Mild</td></tr><tr><td>2</td><td>Grade 2/Moderate</td></tr><tr><td>3</td><td>Grade 3/Severe</td></tr><tr><td>4</td><td>Grade 4/Life Threatening</td></tr><tr><td>5</td><td>Grade 5/Death</td></tr></table>	1	Grade 1/Mild	2	Grade 2/Moderate	3	Grade 3/Severe	4	Grade 4/Life Threatening	5	Grade 5/Death		
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967	<div>ctc_ae_link3_f1</div> <div>Show the field ONLY if: [sae_term3_f1] <> "</div>	Please right-click on this link to reference the CTC AE V 4.03	descriptive												
968	<div>sae_death3_f1</div> <div>Show the field ONLY if: [sae_term3_f1] <> "</div>	3. Death	<div>radio</div> <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	0	No	1	Yes	99	Unknown						
0	No														
1	Yes														
99	Unknown														
969	<div>sae_death_date3_f1</div> <div>Show the field ONLY if: [sae_death3_f1] = '1' and [sae_term3_f1] <> "</div>	If Death, Date of Death:	text (date_dmy)												
970	<div>sae_death_due3_f1</div> <div>Show the field ONLY if: [sae_death3_f1] = '1' and [sae_term3_f1] <> "</div>	Death due to the SAE	<div>radio</div> <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	0	No	1	Yes	99	Unknown						
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971	<div>sae_auto_perf3_f1</div> <div>Show the field ONLY if: [sae_death3_f1] = '1' and [sae_term3_f1] <> "</div>	Was an autopsy performed?	<div>radio</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr></table> <div>Custom alignment: RH</div>	1	Yes	2	No								
1	Yes														
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972	<div>sae_life_threa3_f1</div> <div>Show the field ONLY if: [sae_term3_f1] <> "</div>	Life-threatening	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
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973	<div>sae_hospi3_f1</div> <div>Show the field ONLY if: [sae_term3_f1] <> "</div>	Hospitalisation/Prolonged Hospitalisation	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
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2	Yes														
99	Unknown														

974	<div>sae_disabi3_f1</div> <div>Show the field ONLY if: [sae_term3_f1] <> "</div>	Significant Disability	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
1	No														
2	Yes														
99	Unknown														
975	<div>sae_anoma3_f1</div> <div>Show the field ONLY if: [sae_term3_f1] <> "</div>	Congenital Anomaly/ Birth defect	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
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99	Unknown														
976	<div>sae_med_even3_f1</div> <div>Show the field ONLY if: [sae_term3_f1] <> "</div>	Important Medical Event	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
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977	<div>sae_imp1_causa3_f1</div> <div>Show the field ONLY if: [sae_term3_f1] <> "</div>	3. Causal relation to IMP/Study drug (1)	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
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978	<div>sae_imp2_causa3_f1</div> <div>Show the field ONLY if: [sae_term3_f1] <> "</div>	3. Causal relation to IMP/Study drug (2)	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
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979	<div>sae_imp3_causa3_f1</div> <div>Show the field ONLY if: [sae_term3_f1] <> "</div>	3. Causal relation to IMP/Study drug (3)	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
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980	<div>sae_sdate3_f1</div> <div>Show the field ONLY if: [sae_term3_f1] <> "</div>	<div>3. Start date</div> <div>(dd/mm/yyyy hh:mm)</div>	<div>text (datetime_dmy)</div>												
981	<div>sae_edate3_f1</div> <div>Show the field ONLY if: [sae_term3_f1] <> "</div>	<div>3. Stop date</div> <div>(dd/mm/yyyy hh:mm)</div>	<div>text (datetime_dmy)</div>												
982	<div>sae_outcome_stat3_f1</div> <div>Show the field ONLY if: [sae_term3_f1] <> "</div>	3. Outcome	<div>dropdown</div> <table><tr><td>1</td><td>Resolved</td></tr><tr><td>2</td><td>Resolving</td></tr><tr><td>3</td><td>Resolved with sequelae</td></tr><tr><td>4</td><td>Not resolved</td></tr><tr><td>5</td><td>Fatal</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Resolved	2	Resolving	3	Resolved with sequelae	4	Not resolved	5	Fatal	6	Unknown
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983	<div>sae_imp1_action3_f1</div> <div>Show the field ONLY if: [sae_term3_f1] <> "</div>	3. Action taken with the IMP/s drug (1)	<div>dropdown</div> <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr><tr><td>5</td><td>IMP withdrawn</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	None	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced	5	IMP withdrawn	6	Unknown
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984	<div>sae_imp2_action3_f1</div> <div>Show the field ONLY if: [sae_term3_f1] <> "</div>	3. Action taken with the IMP/s drug (2)	<div>dropdown</div> <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr><tr><td>5</td><td>IMP withdrawn</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	None	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced	5	IMP withdrawn	6	Unknown
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986	<div>sae_term4_f1</div> <div>Show the field ONLY if: [sae_awaar_date_f1] <> "</div>	4. SAE Term/Diagnosis	text												
987	<div>sae_grade4_f1</div> <div>Show the field ONLY if: [sae_term4_f1] <> "</div>	4. SAE NCI-CTC AE Grade	<div>dropdown</div> <table><tr><td>1</td><td>Grade 1/Mild</td></tr><tr><td>2</td><td>Grade 2/Moderate</td></tr><tr><td>3</td><td>Grade 3/Severe</td></tr><tr><td>4</td><td>Grade 4/Life Threatening</td></tr><tr><td>5</td><td>Grade 5/Death</td></tr></table>	1	Grade 1/Mild	2	Grade 2/Moderate	3	Grade 3/Severe	4	Grade 4/Life Threatening	5	Grade 5/Death		
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988	<div>ctc_ae_link4_f1</div> <div>Show the field ONLY if: [sae_term4_f1] <> "</div>	Please right-click on this link to reference the CTC AE V 4.03	descriptive												
989	<div>sae_death4_f1</div> <div>Show the field ONLY if: [sae_term4_f1] <> "</div>	4. Death	<div>radio</div> <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	0	No	1	Yes	99	Unknown						
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990	<div>sae_death_date4_f1</div> <div>Show the field ONLY if: [sae_death4_f1] = '1' and [sae_term4_f1] <> "</div>	If Death, Date of Death:	text (date_dmy)												
991	<div>sae_death_due4_f1</div> <div>Show the field ONLY if: [sae_death4_f1] = '1' and [sae_term4_f1] <> "</div>	Death due to the SAE	<div>radio</div> <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	0	No	1	Yes	99	Unknown						
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992	<div>sae_auto_perf4_f1</div> <div>Show the field ONLY if: [sae_death4_f1] = '1' and [sae_term4_f1] <> "</div>	Was an autopsy performed?	<div>radio</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr></table> <div>Custom alignment: RH</div>	1	Yes	2	No								
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993	<div>sae_life_threa4_f1</div> <div>Show the field ONLY if: [sae_term4_f1] <> "</div>	Life-threatening	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
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994	<div>sae_hospi4_f1</div> <div>Show the field ONLY if: [sae_term4_f1] <> "</div>	Hospitalisation/Prolonged Hospitalisation	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
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996	sae_anoma4_f1 Show the field ONLY if: [sae_term4_f1] <> "	Congenital Anomaly/Birth defect	radio (Matrix) <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
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997	sae_med_even4_f1 Show the field ONLY if: [sae_term4_f1] <> "	Important Medical Event	radio (Matrix) <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
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998	sae_imp1_causa4_f1 Show the field ONLY if: [sae_term4_f1] <> "	4. Causal relation to IMP/Study drug (1)	dropdown <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Unknown</td></tr></table> Custom alignment: RH	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
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999	sae_imp2_causa4_f1 Show the field ONLY if: [sae_term4_f1] <> "	4. Causal relation to IMP/Study drug (2)	dropdown <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Unknown</td></tr></table> Custom alignment: RH	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
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1000	sae_imp3_causa4_f1 Show the field ONLY if: [sae_term4_f1] <> "	4. Causal relation to IMP/Study drug (3)	dropdown <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Unknown</td></tr></table> Custom alignment: RH	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
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1002	sae_edate4_f1 Show the field ONLY if: [sae_term4_f1] <> "	4. Stop date <i>(dd/mm/yyyy hh:mm)</i>	text (datetime_dmy)												
1003	sae_outcome_stat4_f1 Show the field ONLY if: [sae_term4_f1] <> "	4. Outcome	dropdown <table><tr><td>1</td><td>Resolved</td></tr><tr><td>2</td><td>Resolving</td></tr><tr><td>3</td><td>Resolved with sequelae</td></tr><tr><td>4</td><td>Not resolved</td></tr><tr><td>5</td><td>Fatal</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Resolved	2	Resolving	3	Resolved with sequelae	4	Not resolved	5	Fatal	6	Unknown
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1004	sae_imp1_action4_f1 Show the field ONLY if: [sae_term4_f1] <> "	4. Action taken with the IMP/s drug (1)	dropdown <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr><tr><td>5</td><td>IMP withdrawn</td></tr><tr><td>6</td><td>Unknown</td></tr></table> Custom alignment: RH	1	None	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced	5	IMP withdrawn	6	Unknown
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1005	<div>sae_imp2_action4_f1</div> <div>Show the field ONLY if: [sae_term4_f1] <> "</div>	4. Action taken with the IMP/s drug (2)	<div>dropdown</div> <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr><tr><td>5</td><td>IMP withdrawn</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	None	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced	5	IMP withdrawn	6	Unknown
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1006	<div>sae_imp3_action4_f1</div> <div>Show the field ONLY if: [sae_term4_f1] <> "</div>	4. Action taken with the IMP/s drug (3)	<div>dropdown</div> <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr><tr><td>5</td><td>IMP withdrawn</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	None	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced	5	IMP withdrawn	6	Unknown
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1007	<div>sae_term5_f1</div> <div>Show the field ONLY if: [sae_awaar_date_f1] <> "</div>	5. SAE Term/Diagnosis	text												
1008	<div>sae_grade5_f1</div> <div>Show the field ONLY if: [sae_term5_f1] <> "</div>	5. SAE NCI-CTC AE Grade	<div>dropdown</div> <table><tr><td>1</td><td>Grade 1/Mild</td></tr><tr><td>2</td><td>Grade 2/Moderate</td></tr><tr><td>3</td><td>Grade 3/Severe</td></tr><tr><td>4</td><td>Grade 4/Life Threatening</td></tr><tr><td>5</td><td>Grade 5/Death</td></tr></table>	1	Grade 1/Mild	2	Grade 2/Moderate	3	Grade 3/Severe	4	Grade 4/Life Threatening	5	Grade 5/Death		
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1009	<div>ctc_ae_link5_f1</div> <div>Show the field ONLY if: [sae_term5_f1] <> "</div>	Please right-click on this link to reference the CTC AE V 4.03	descriptive												
1010	<div>sae_death5_f1</div> <div>Show the field ONLY if: [sae_term5_f1] <> "</div>	5. Death	<div>radio</div> <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	0	No	1	Yes	99	Unknown						
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1011	<div>sae_death_date5_f1</div> <div>Show the field ONLY if: [sae_death5_f1] = '1' and [sae_term5_f1] <> "</div>	If Death, Date of Death:	text (date_dmy)												
1012	<div>sae_death_due5_f1</div> <div>Show the field ONLY if: [sae_death5_f1] = '1' and [sae_term5_f1] <> "</div>	Death due to the SAE	<div>radio</div> <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	0	No	1	Yes	99	Unknown						
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1015	<div>sae_hospis5_f1</div> <div>Show the field ONLY if: [sae_term5_f1] <> "</div>	Hospitalisation/Prolonged Hospitalisation	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
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1016	sae_disabi5_f1 Show the field ONLY if: [sae_term5_f1] <> "	Significant Disability	radio (Matrix) 1 No 2 Yes 99 Unknown
1017	sae_anoma5_f1 Show the field ONLY if: [sae_term5_f1] <> "	Congenital Anomaly/Birth defect	radio (Matrix) 1 No 2 Yes 99 Unknown
1018	sae_med_even5_f1 Show the field ONLY if: [sae_term5_f1] <> "	Important Medical Event	radio (Matrix) 1 No 2 Yes 99 Unknown
1019	sae_imp1_causa5_f1 Show the field ONLY if: [sae_term5_f1] <> "	5. Causal relation to IMP/Study drug (1)	dropdown 1 Certain 2 Probable 3 Possible 4 Unlikely 5 Unrelated 6 Unknown Custom alignment: RH
1020	sae_imp2_causa5_f1 Show the field ONLY if: [sae_term5_f1] <> "	5. Causal relation to IMP/Study drug (2)	dropdown 1 Certain 2 Probable 3 Possible 4 Unlikely 5 Unrelated 6 Unknown Custom alignment: RH
1021	sae_imp3_causa5_f1 Show the field ONLY if: [sae_term5_f1] <> "	5. Causal relation to IMP/Study drug (3)	dropdown 1 Certain 2 Probable 3 Possible 4 Unlikely 5 Unrelated 6 Unknown Custom alignment: RH
1022	sae_sdate5_f1 Show the field ONLY if: [sae_term5_f1] <> "	5. Start date (mm/dd/yyyy hh:mm)	text (datetime_dmy)
1023	sae_edate5_f1 Show the field ONLY if: [sae_term5_f1] <> "	5. Stop date (mm/dd/yyyy hh:mm)	text (datetime_dmy)
1024	sae_outcome_stat5_f1 Show the field ONLY if: [sae_term5_f1] <> "	5. Outcome	dropdown 1 Resolved 2 Resolving 3 Resolved with sequelae 4 Not resolved 5 Fatal 6 Unknown
1025	sae_imp1_action5_f1 Show the field ONLY if: [sae_term5_f1] <> "	5. Action taken with the IMP/s drug (1)	dropdown 1 None 2 Dose delayed 3 Dose reduced 4 Dose delayed and reduced 5 IMP withdrawn 6 Unknown Custom alignment: RH

1026	<div>sae_imp2_action5_f1</div> <div>Show the field ONLY if: [sae_term5_f1] <> "</div>	5. Action taken with the IMP/s drug (2)	<div>dropdown</div> <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr><tr><td>5</td><td>IMP withdrawn</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	None	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced	5	IMP withdrawn	6	Unknown
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5	IMP withdrawn														
6	Unknown														
1027	<div>sae_imp3_action5_f1</div> <div>Show the field ONLY if: [sae_term5_f1] <> "</div>	5. Action taken with the IMP/s drug (3)	<div>dropdown</div> <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr><tr><td>5</td><td>IMP withdrawn</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	None	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced	5	IMP withdrawn	6	Unknown
1	None														
2	Dose delayed														
3	Dose reduced														
4	Dose delayed and reduced														
5	IMP withdrawn														
6	Unknown														
1028	<div>sae_afte_stop_drug1_f1</div>	<div>Section Header: <i>DECHALLENGE</i></div> <div>Did event abate after stopping drug(s)?</div>	<div>dropdown</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr><tr><td>3</td><td>NA</td></tr></table> <div>Custom alignment: RH</div>	1	Yes	2	No	3	NA						
1	Yes														
2	No														
3	NA														
1029	<div>sae_dech_spec1_f1</div> <div>Show the field ONLY if: [sae_afte_stop_drug1_f1] = '1'</div>	IMP1	<div>checkbox</div> <table><tr><td>1</td><td>sae_dech_spec1_f1__1</td><td>Yes</td></tr><tr><td>2</td><td>sae_dech_spec1_f1__2</td><td>No</td></tr></table>	1	sae_dech_spec1_f1__1	Yes	2	sae_dech_spec1_f1__2	No						
1	sae_dech_spec1_f1__1	Yes													
2	sae_dech_spec1_f1__2	No													
1030	<div>sae_dech_spec2_f1</div> <div>Show the field ONLY if: [sae_afte_stop_drug1_f1] = '1'</div>	IMP2	<div>checkbox</div> <table><tr><td>1</td><td>sae_dech_spec2_f1__1</td><td>Yes</td></tr><tr><td>2</td><td>sae_dech_spec2_f1__2</td><td>No</td></tr></table>	1	sae_dech_spec2_f1__1	Yes	2	sae_dech_spec2_f1__2	No						
1	sae_dech_spec2_f1__1	Yes													
2	sae_dech_spec2_f1__2	No													
1031	<div>sae_dech_spec3_f1</div> <div>Show the field ONLY if: [sae_afte_stop_drug1_f1] = '1'</div>	IMP3	<div>checkbox</div> <table><tr><td>1</td><td>sae_dech_spec3_f1__1</td><td>Yes</td></tr><tr><td>2</td><td>sae_dech_spec3_f1__2</td><td>No</td></tr></table>	1	sae_dech_spec3_f1__1	Yes	2	sae_dech_spec3_f1__2	No						
1	sae_dech_spec3_f1__1	Yes													
2	sae_dech_spec3_f1__2	No													
1032	<div>sae_dech_num_f1</div> <div>Show the field ONLY if: [sae_afte_stop_drug1_f1] = '1'</div>	Specify SAE number	<div>text (integer)</div> <div>Custom alignment: RH</div>												
1033	<div>sae_susp_readm1_f1</div>	<div>Section Header: <i>RECHALLENGE</i></div> <div>Was suspected drug(s) re-administered?</div>	<div>dropdown</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr><tr><td>3</td><td>NA</td></tr></table> <div>Custom alignment: RH</div>	1	Yes	2	No	3	NA						
1	Yes														
2	No														
3	NA														
1034	<div>sae_rech_spec1_f1</div> <div>Show the field ONLY if: [sae_susp_readm1_f1] = '1'</div>	IMP1	<div>radio (Matrix)</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr></table>	1	Yes	2	No								
1	Yes														
2	No														
1035	<div>sae_rech_spec2_f1</div> <div>Show the field ONLY if: [sae_susp_readm1_f1] = '1'</div>	IMP2	<div>radio (Matrix)</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr></table>	1	Yes	2	No								
1	Yes														
2	No														
1036	<div>sae_rech_spec3_f1</div> <div>Show the field ONLY if: [sae_susp_readm1_f1] = '1'</div>	IMP3	<div>radio (Matrix)</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr></table>	1	Yes	2	No								
1	Yes														
2	No														
1037	<div>sae_rech_date_f1</div> <div>Show the field ONLY if: [sae_susp_readm1_f1] = '1' and [sae_susp_readm1_f1] = '1'</div>	Specify the date	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>												
1038	<div>sae_reap_reint1_f1</div> <div>Show the field ONLY if: [sae_susp_readm1_f1] = '1'</div>	Did event reappear after drug(s) reintroduction?	<div>dropdown</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr><tr><td>3</td><td>NA</td></tr></table> <div>Custom alignment: RH</div>	1	Yes	2	No	3	NA						
1	Yes														
2	No														
3	NA														

1039	<div>sae_dech_num_2_f1</div> <div>Show the field ONLY if: [sae_reap_reint1_f1]= '1' and [sae_susp_readm1_f1] = '1'</div>	Specify SAE number	text (integer) Custom alignment: RH
1040	<div>sae_dise_under1_f1</div>	<div>Section Header: <i>Disease under study</i></div> <div>Was the disease under study the primary cause of the SAE?</div>	<div>dropdown</div> <div><div>1</div><div>Certain</div></div> <div><div>2</div><div>Probable</div></div> <div><div>3</div><div>Possible</div></div> <div><div>4</div><div>Unlikely</div></div> <div><div>5</div><div>Unrelated</div></div> <div><div>6</div><div>Conditional/Unclassified</div></div> <div><div>7</div><div>Unassessable/Unclassifiable</div></div>
1041	<div>sae_dise_spec1_f1</div>	If disease primary cause, please specify which SAE	text
1042	<div>sae_conc_stat_f1</div>	<div>Section Header: <i>Concomitant treatments/Procedures(e.g. : prophylactic medications, procedures to obtain central venous access)</i></div>	<div>radio</div> <div><div>1</div><div>None</div></div> <div><div>2</div><div>Applicable</div></div> <div><div>99</div><div>UK</div></div> <div>Custom alignment: RH</div>
1043	<div>sae_conc_name1_f1</div> <div>Show the field ONLY if: [sae_conc_stat_f1] = '2'</div>	<div>1. Name</div> <div><i>Do not list in this section drugs used to treat the SAE</i></div>	text Custom alignment: RH
1044	<div>sae_conc_dose1_f1</div> <div>Show the field ONLY if: [sae_conc_name1_f1] <> "</div>	1. Total daily dose and unit	text Custom alignment: RH
1045	<div>sae_conc_route1_f1</div> <div>Show the field ONLY if: [sae_conc_name1_f1] <> "</div>	1. Route	<div>dropdown</div> <div><div>1</div><div>OS</div></div> <div><div>2</div><div>Parenteral</div></div> <div><div>3</div><div>Inhalation</div></div> <div><div>4</div><div>Sublingual</div></div> <div><div>5</div><div>Transdermic</div></div> <div><div>6</div><div>Rectal</div></div> <div><div>7</div><div>Other</div></div> <div>Custom alignment: RH</div>
1046	<div>sae_conc_sdate1_f1</div> <div>Show the field ONLY if: [sae_conc_name1_f1] <> "</div>	<div>1. Start date</div> <div><i>(dd/mm/yyyy)</i></div>	text (date_dmy) Custom alignment: RH
1047	<div>sae_conc_edate1_f1</div> <div>Show the field ONLY if: [sae_conc_name1_f1] <> "</div>	<div>1. Stop date</div> <div><i>(dd/mm/yyyy)</i></div>	text (date_dmy) Custom alignment: RH
1048	<div>sae_conc_ong1_f1</div> <div>Show the field ONLY if: [sae_conc_name1_f1] <> "</div>		<div>radio</div> <div><div>1</div><div>ongoing</div></div> <div>Custom alignment: RH</div>
1049	<div>sae_conc_prim1_f1</div> <div>Show the field ONLY if: [sae_conc_name1_f1] <> "</div>	1. Primary cause of the SAE/s?	<div>dropdown</div> <div><div>1</div><div>Certain</div></div> <div><div>2</div><div>Probable</div></div> <div><div>3</div><div>Possible</div></div> <div><div>4</div><div>Unlikely</div></div> <div><div>5</div><div>Unrelated</div></div> <div><div>6</div><div>Conditional/Unclassified</div></div> <div><div>7</div><div>Unassessable/Unclassifiable</div></div> <div>Custom alignment: RH</div>
1050	<div>sae_conc_prim_num1_f1</div> <div>Show the field ONLY if: [sae_conc_name1_f1] <> "</div>	2. If primary cause, specify which SAE number (i.e. 1,3)	text (integer) Custom alignment: RH
1051	<div>sae_conc_name2_f1</div> <div>Show the field ONLY if: [sae_conc_stat_f1] = '2'</div>	<div>2. Name</div> <div><i>Do not list in this section drugs used to treat the SAE</i></div>	text Custom alignment: RH

1052	<div>sae_conc_dose2_f1</div> <div>Show the field ONLY if: [sae_conc_name2_f1] <> "</div>	2. Total daily dose and unit	text Custom alignment: RH														
1053	<div>sae_conc_route2_f1</div> <div>Show the field ONLY if: [sae_conc_name2_f1] <> "</div>	2. Route	<div>dropdown</div> <table><tr><td>1</td><td>OS</td></tr><tr><td>2</td><td>Parenteral</td></tr><tr><td>3</td><td>Inhalation</td></tr><tr><td>4</td><td>Sublingual</td></tr><tr><td>5</td><td>Transdermic</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Other</td></tr></table> <div>Custom alignment: RH</div>	1	OS	2	Parenteral	3	Inhalation	4	Sublingual	5	Transdermic	6	Rectal	7	Other
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4	Sublingual																
5	Transdermic																
6	Rectal																
7	Other																
1054	<div>sae_conc_sdate2_f1</div> <div>Show the field ONLY if: [sae_conc_name2_f1] <> "</div>	2. Start date <i>(dd/mm/yyyy)</i>	text (date_dmy) Custom alignment: RH														
1055	<div>sae_conc_edate2_f1</div> <div>Show the field ONLY if: [sae_conc_name2_f1] <> "</div>	2. Stop date <i>(dd/mm/yyyy)</i>	text (date_dmy) Custom alignment: RH														
1056	<div>sae_conc_ong2_f1</div> <div>Show the field ONLY if: [sae_conc_name2_f1] <> "</div>		<div>radio</div> <table><tr><td>1</td><td>ongoing</td></tr></table> <div>Custom alignment: RH</div>	1	ongoing												
1	ongoing																
1057	<div>sae_conc_prim2_f1</div> <div>Show the field ONLY if: [sae_conc_name2_f1] <> "</div>	2. Primary cause of the SAE/s?	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Conditional/Unclassified</td></tr><tr><td>7</td><td>Unassessable/Unclassifiable</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Conditional/Unclassified	7	Unassessable/Unclassifiable
1	Certain																
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7	Unassessable/Unclassifiable																
1058	<div>sae_conc_prim_num2_f1</div> <div>Show the field ONLY if: [sae_conc_name2_f1] <> "</div>	2. If primary cause, specify which SAE number (i.e. 1,3)	text (integer) Custom alignment: RH														
1059	<div>sae_conc_name3_f1</div> <div>Show the field ONLY if: [sae_conc_stat_f1] = '2'</div>	3. Name <i>Do not list in this section drugs used to treat the SAE</i>	text Custom alignment: RH														
1060	<div>sae_conc_dose3_f1</div> <div>Show the field ONLY if: [sae_conc_name3_f1] <> "</div>	3. Total daily dose and unit	text Custom alignment: RH														
1061	<div>sae_conc_route3_f1</div> <div>Show the field ONLY if: [sae_conc_name3_f1] <> "</div>	3. Route	<div>dropdown</div> <table><tr><td>1</td><td>OS</td></tr><tr><td>2</td><td>Parenteral</td></tr><tr><td>3</td><td>Inhalation</td></tr><tr><td>4</td><td>Sublingual</td></tr><tr><td>5</td><td>Transdermic</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Other</td></tr></table> <div>Custom alignment: RH</div>	1	OS	2	Parenteral	3	Inhalation	4	Sublingual	5	Transdermic	6	Rectal	7	Other
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1062	<div>sae_conc_sdate3_f1</div> <div>Show the field ONLY if: [sae_conc_name3_f1] <> "</div>	3. Start date <i>(dd/mm/yyyy)</i>	text (date_dmy) Custom alignment: RH														
1063	<div>sae_conc_edate3_f1</div> <div>Show the field ONLY if: [sae_conc_name3_f1] <> "</div>	3. Stop date <i>(dd/mm/yyyy)</i>	text (date_dmy) Custom alignment: RH														
1064	<div>sae_conc_ong3_f1</div> <div>Show the field ONLY if: [sae_conc_name3_f1] <> "</div>		<div>radio</div> <table><tr><td>1</td><td>ongoing</td></tr></table> <div>Custom alignment: RH</div>	1	ongoing												
1	ongoing																

1065	<div>sae_conc_prim3_f1</div> <div>Show the field ONLY if: [sae_conc_name3_f1] <> "</div>	3. Primary cause of the SAE/s?	<div>dropdown</div> <div><div>1</div><div>Certain</div></div> <div><div>2</div><div>Probable</div></div> <div><div>3</div><div>Possible</div></div> <div><div>4</div><div>Unlikely</div></div> <div><div>5</div><div>Unrelated</div></div> <div><div>6</div><div>Conditional/Unclassified</div></div> <div><div>7</div><div>Unassessable/Unclassifiable</div></div> <div>Custom alignment: RH</div>
1066	<div>sae_conc_prim_num3_f1</div> <div>Show the field ONLY if: [sae_conc_name3_f1] <> "</div>	3. If primary cause, specify which SAE number (i.e. 1,3)	<div>text (integer)</div> <div>Custom alignment: RH</div>
1067	<div>sae_conc_name4_f1</div> <div>Show the field ONLY if: [sae_conc_stat_f1] = '2'</div>	<div>4. Name</div> <div>Do not list in this section drugs used to treat the SAE</div>	<div>text</div> <div>Custom alignment: RH</div>
1068	<div>sae_conc_dose4_f1</div> <div>Show the field ONLY if: [sae_conc_name4_f1] <> "</div>	4. Total daily dose and unit	<div>text</div> <div>Custom alignment: RH</div>
1069	<div>sae_conc_route4_f1</div> <div>Show the field ONLY if: [sae_conc_name4_f1] <> "</div>	4. Route	<div>dropdown</div> <div><div>1</div><div>OS</div></div> <div><div>2</div><div>Parenteral</div></div> <div><div>3</div><div>Inhalation</div></div> <div><div>4</div><div>Sublingual</div></div> <div><div>5</div><div>Transdermic</div></div> <div><div>6</div><div>Rectal</div></div> <div><div>7</div><div>Other</div></div> <div>Custom alignment: RH</div>
1070	<div>sae_conc_sdate4_f1</div> <div>Show the field ONLY if: [sae_conc_name4_f1] <> "</div>	<div>4. Start date</div> <div>(dd/mm/yyyy)</div>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>
1071	<div>sae_conc_edate4_f1</div> <div>Show the field ONLY if: [sae_conc_name4_f1] <> "</div>	<div>4. Stop date</div> <div>(dd/mm/yyyy)</div>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>
1072	<div>sae_conc_ong4_f1</div> <div>Show the field ONLY if: [sae_conc_name4_f1] <> "</div>		<div>radio</div> <div><div>1</div><div>ongoing</div></div> <div>Custom alignment: RH</div>
1073	<div>sae_conc_prim4_f1</div> <div>Show the field ONLY if: [sae_conc_name4_f1] <> "</div>	4. Primary cause of the SAE/s?	<div>dropdown</div> <div><div>1</div><div>Certain</div></div> <div><div>2</div><div>Probable</div></div> <div><div>3</div><div>Possible</div></div> <div><div>4</div><div>Unlikely</div></div> <div><div>5</div><div>Unrelated</div></div> <div><div>6</div><div>Conditional/Unclassified</div></div> <div><div>7</div><div>Unassessable/Unclassifiable</div></div> <div>Custom alignment: RH</div>
1074	<div>sae_conc_prim_num4_f1</div> <div>Show the field ONLY if: [sae_conc_name4_f1] <> "</div>	4. If primary cause, specify which SAE number (i.e. 1,3)	<div>text (integer)</div> <div>Custom alignment: RH</div>
1075	<div>sae_conc_name5_f1</div> <div>Show the field ONLY if: [sae_conc_stat_f1] = '2'</div>	<div>5. Name</div> <div>Do not list in this section drugs used to treat the SAE</div>	<div>text</div> <div>Custom alignment: RH</div>
1076	<div>sae_conc_dose5_f1</div> <div>Show the field ONLY if: [sae_conc_name5_f1] <> "</div>	5. Total daily dose and unit	<div>text</div> <div>Custom alignment: RH</div>

1077	<div>sae_conc_route5_f1</div> <div>Show the field ONLY if: [sae_conc_name5_f1] <> "</div>	5. Route	<div>dropdown</div> <table><tr><td>1</td><td>OS</td></tr><tr><td>2</td><td>Parenteral</td></tr><tr><td>3</td><td>Inhalation</td></tr><tr><td>4</td><td>Sublingual</td></tr><tr><td>5</td><td>Transdermic</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Other</td></tr></table> <div>Custom alignment: RH</div>	1	OS	2	Parenteral	3	Inhalation	4	Sublingual	5	Transdermic	6	Rectal	7	Other
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1078	<div>sae_conc_sdate5_f1</div> <div>Show the field ONLY if: [sae_conc_name5_f1] <> "</div>	5. Start date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
1079	<div>sae_conc_edate5_f1</div> <div>Show the field ONLY if: [sae_conc_name5_f1] <> "</div>	5. Stop date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
1080	<div>sae_conc_ong5_f1</div> <div>Show the field ONLY if: [sae_conc_name5_f1] <> "</div>		<div>radio</div> <table><tr><td>1</td><td>ongoing</td></tr></table> <div>Custom alignment: RH</div>	1	ongoing												
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1081	<div>sae_conc_prim5_f1</div> <div>Show the field ONLY if: [sae_conc_name5_f1] <> "</div>	5. Primary cause of the SAE/s?	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Conditional/Unclassified</td></tr><tr><td>7</td><td>Unassessable/Unclassifiable</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Conditional/Unclassified	7	Unassessable/Unclassifiable
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1082	<div>sae_conc_prim_num5_f1</div> <div>Show the field ONLY if: [sae_conc_name5_f1] <> "</div>	5. If primary cause, specify which SAE number (i.e. 1,3)	<div>text (integer)</div> <div>Custom alignment: RH</div>														
1083	<div>sae_conc_name6_f1</div> <div>Show the field ONLY if: [sae_conc_stat_f1] = '2'</div>	6. Name <i>Do not list in this section drugs used to treat the SAE</i>	<div>text</div> <div>Custom alignment: RH</div>														
1084	<div>sae_conc_dose6_f1</div> <div>Show the field ONLY if: [sae_conc_name6_f1] <> "</div>	6. Total daily dose and unit	<div>text</div> <div>Custom alignment: RH</div>														
1085	<div>sae_conc_route6_f1</div> <div>Show the field ONLY if: [sae_conc_name6_f1] <> "</div>	6. Route	<div>dropdown</div> <table><tr><td>1</td><td>OS</td></tr><tr><td>2</td><td>Parenteral</td></tr><tr><td>3</td><td>Inhalation</td></tr><tr><td>4</td><td>Sublingual</td></tr><tr><td>5</td><td>Transdermic</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Other</td></tr></table> <div>Custom alignment: RH</div>	1	OS	2	Parenteral	3	Inhalation	4	Sublingual	5	Transdermic	6	Rectal	7	Other
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1086	<div>sae_conc_sdate6_f1</div> <div>Show the field ONLY if: [sae_conc_name6_f1] <> "</div>	6. Start date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
1087	<div>sae_conc_edate6_f1</div> <div>Show the field ONLY if: [sae_conc_name6_f1] <> "</div>	6. Stop date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
1088	<div>sae_conc_ong6_f1</div> <div>Show the field ONLY if: [sae_conc_name6_f1] <> "</div>		<div>radio</div> <table><tr><td>1</td><td>ongoing</td></tr></table> <div>Custom alignment: RH</div>	1	ongoing												
1	ongoing																

1089	<div>sae_conc_prim6_f1</div> <div>Show the field ONLY if: [sae_conc_name6_f1] <> "</div>	6. Primary cause of the SAE/s?	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Conditional/Unclassified</td></tr><tr><td>7</td><td>Unassessable/Unclassifiable</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Conditional/Unclassified	7	Unassessable/Unclassifiable
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7	Unassessable/Unclassifiable																
1090	<div>sae_conc_prim_num6_f1</div> <div>Show the field ONLY if: [sae_conc_name6_f1] <> "</div>	6. If primary cause, specify which SAE number (i.e. 1,3)	<div>text (integer)</div> <div>Custom alignment: RH</div>														
1091	<div>sae_relev_stat_f1</div>	Section Header: 6. <i>Relevant Medical Conditions (pre-existing relevant medical conditions, family history)</i>	<div>radio</div> <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Applicable</td></tr><tr><td>99</td><td>UK</td></tr></table> <div>Custom alignment: RH</div>	1	None	2	Applicable	99	UK								
1	None																
2	Applicable																
99	UK																
1092	<div>sae_dise1_f1</div> <div>Show the field ONLY if: [sae_relev_stat_f1] = '2'</div>	1. Disease/Allergy/Risk Factor	<div>text</div> <div>Custom alignment: RH</div>														
1093	<div>sae_rele_sdate1_f1</div> <div>Show the field ONLY if: [sae_dise1_f1] <> "</div>	1. Start date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
1094	<div>sae_rele_edate1_f1</div> <div>Show the field ONLY if: [sae_dise1_f1] <> "</div>	1. Stop date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
1095	<div>sae_rele_ong1_f1</div> <div>Show the field ONLY if: [sae_dise1_f1] <> "</div>		<div>radio</div> <table><tr><td>1</td><td>ongoing</td></tr></table> <div>Custom alignment: RH</div>	1	ongoing												
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1096	<div>sae_rele_prim1_f1</div> <div>Show the field ONLY if: [sae_dise1_f1] <> "</div>	1. Primary cause of the SAE/s?	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Conditional/Unclassified</td></tr><tr><td>7</td><td>Unassessable/Unclassifiable</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Conditional/Unclassified	7	Unassessable/Unclassifiable
1	Certain																
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1097	<div>sae_rele_prim_num1_f1</div> <div>Show the field ONLY if: [sae_dise1_f1] <> "</div>	1. If primary cause, specify which SAE number (i.e. 1,3)	<div>text (integer)</div> <div>Custom alignment: RH</div>														
1098	<div>sae_dise2_f1</div> <div>Show the field ONLY if: [sae_relev_stat_f1] = '2'</div>	2. Disease/Allergy/Risk Factor	<div>text</div> <div>Custom alignment: RH</div>														
1099	<div>sae_rele_sdate2_f1</div> <div>Show the field ONLY if: [sae_dise2_f1] <> "</div>	2. Start date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
1100	<div>sae_rele_edate2_f1</div> <div>Show the field ONLY if: [sae_dise2_f1] <> "</div>	2. Stop date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
1101	<div>sae_rele_ong2_f1</div> <div>Show the field ONLY if: [sae_dise2_f1] <> "</div>		<div>radio</div> <table><tr><td>1</td><td>ongoing</td></tr></table> <div>Custom alignment: RH</div>	1	ongoing												
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1102	<div>sae_rele_prim2_f1</div> <div>Show the field ONLY if: [sae_dise2_f1] <> "</div>	2. Primary cause of the SAE/s?	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Conditional/Unclassified</td></tr><tr><td>7</td><td>Unassessable/Unclassifiable</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Conditional/Unclassified	7	Unassessable/Unclassifiable
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7	Unassessable/Unclassifiable																
1103	<div>sae_rele_prim_num2_f1</div> <div>Show the field ONLY if: [sae_dise2_f1] <> "</div>	2. If primary cause, specify which SAE number (i.e. 1,3)	<div>text (integer)</div> <div>Custom alignment: RH</div>														
1104	<div>sae_dise3_f1</div> <div>Show the field ONLY if: [sae_relev_stat_f1] = '2'</div>	3. Disease/Allergy/Risk Factor	<div>text</div> <div>Custom alignment: RH</div>														
1105	<div>sae_rele_sdate3_f1</div> <div>Show the field ONLY if: [sae_dise3_f1] <> "</div>	3. Start date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
1106	<div>sae_rele_edate3_f1</div> <div>Show the field ONLY if: [sae_dise3_f1] <> "</div>	3. Stop date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
1107	<div>sae_rele_ong3_f1</div> <div>Show the field ONLY if: [sae_dise3_f1] <> "</div>		<div>radio</div> <table><tr><td>1</td><td>ongoing</td></tr></table> <div>Custom alignment: RH</div>	1	ongoing												
1	ongoing																
1108	<div>sae_rele_prim3_f1</div> <div>Show the field ONLY if: [sae_dise3_f1] <> "</div>	3. Primary cause of the SAE/s?	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Conditional/Unclassified</td></tr><tr><td>7</td><td>Unassessable/Unclassifiable</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Conditional/Unclassified	7	Unassessable/Unclassifiable
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1109	<div>sae_rele_prim_num3_f1</div> <div>Show the field ONLY if: [sae_dise3_f1] <> "</div>	3. If primary cause, specify which SAE number (i.e. 1,3)	<div>text (integer)</div> <div>Custom alignment: RH</div>														
1110	<div>sae_dise4_f1</div> <div>Show the field ONLY if: [sae_relev_stat_f1] = '2'</div>	4. Disease/Allergy/Risk Factor	<div>text</div> <div>Custom alignment: RH</div>														
1111	<div>sae_rele_sdate4_f1</div> <div>Show the field ONLY if: [sae_dise4_f1] <> "</div>	4. Start date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
1112	<div>sae_rele_edate4_f1</div> <div>Show the field ONLY if: [sae_dise4_f1] <> "</div>	4. Stop date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
1113	<div>sae_rele_ong4_f1</div> <div>Show the field ONLY if: [sae_dise4_f1] <> "</div>		<div>radio</div> <table><tr><td>1</td><td>ongoing</td></tr></table> <div>Custom alignment: RH</div>	1	ongoing												
1	ongoing																
1114	<div>sae_rele_prim4_f1</div> <div>Show the field ONLY if: [sae_dise4_f1] <> "</div>	4. Primary cause of the SAE/s?	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Conditional/Unclassified</td></tr><tr><td>7</td><td>Unassessable/Unclassifiable</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Conditional/Unclassified	7	Unassessable/Unclassifiable
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7	Unassessable/Unclassifiable																

1115	sae_rele_prim_num4_f1 Show the field ONLY if: [sae_dise4_f1] <> "	4. If primary cause, specify which SAE number (i.e. 1,3)	text (integer) Custom alignment: RH
1116	sae_dise5_f1 Show the field ONLY if: [sae_relev_stat_f1] = '2'	5. Disease/Allergy/Risk Factor	text Custom alignment: RH
1117	sae_rele_sdate5_f1 Show the field ONLY if: [sae_dise5_f1] <> "	5. Start date (dd/mm/yyyy)	text (date_dmy) Custom alignment: RH
1118	sae_rele_edate5_f1 Show the field ONLY if: [sae_dise5_f1] <> "	5. Stop date (dd/mm/yyyy)	text (date_dmy) Custom alignment: RH
1119	sae_rele_ong5_f1 Show the field ONLY if: [sae_dise5_f1] <> "		radio <div>1 ongoing</div> Custom alignment: RH
1120	sae_rele_prim5_f1 Show the field ONLY if: [sae_dise5_f1] <> "	5. Primary cause of the SAE/s?	dropdown <div> <div>1 Certain</div> <div>2 Probable</div> <div>3 Possible</div> <div>4 Unlikely</div> <div>5 Unrelated</div> <div>6 Conditional/Unclassified</div> <div>7 Unassessable/Unclassifiable</div> </div> Custom alignment: RH
1121	sae_rele_prim_num5_f1 Show the field ONLY if: [sae_dise5_f1] <> "	5. If primary cause, specify which SAE number (i.e. 1,3)	text (integer) Custom alignment: RH
1122	sae_description_f1	7. SAE narrative(Please describe chronologically the clinical sequence of the events, results of any confirmatory procedures, treatment of the event and outcome.\nAttach separately laboratory results and other relevant documents like hospital or post-mortem reports when available)	notes
1123	sae_diag_stat_f1	Section Header: 8. Relevant Diagnostic Tests(including laboratory values preceding the event)	radio <div> <div>1 None</div> <div>2 Applicable</div> </div> Custom alignment: RH
1124	sae_test1_f1 Show the field ONLY if: [sae_diag_stat_f1] = '2'	1. Test	text
1125	sae_test_date1_f1 Show the field ONLY if: [sae_test1_f1] <> "	1. Date (dd/mm/yyyy)	text (date_dmy)
1126	sae_test_resu1_f1 Show the field ONLY if: [sae_test1_f1] <> "	1. Result	text
1127	sae_test_refe1_f1 Show the field ONLY if: [sae_test1_f1] <> "	1. Reference range (if applicabile ULN-LLN)	text
1128	sae_test2_f1 Show the field ONLY if: [sae_diag_stat_f1] = '2'	2. Test	text
1129	sae_test_date2_f1 Show the field ONLY if: [sae_test2_f1] <> "	2. Date (dd/mm/yyyy)	text (date_dmy)
1130	sae_test_resu2_f1 Show the field ONLY if: [sae_test2_f1] <> "	2. Result	text
1131	sae_test_refe2_f1 Show the field ONLY if: [sae_test2_f1] <> "	2. Reference range (if applicabile ULN-LLN)	text

1132	sae_test3_f1 Show the field ONLY if: [sae_diag_stat_f1] = '2'	3. Test	text														
1133	sae_test_date3_f1 Show the field ONLY if: [sae_test3_f1] <> "	3. Date (dd/mm/yyyy)	text (date_dmy)														
1134	sae_test_resu3_f1 Show the field ONLY if: [sae_test3_f1] <> "	3. Result	text														
1135	sae_test_refe3_f1 Show the field ONLY if: [sae_test3_f1] <> "	3. Reference range (if applicabile ULN-LLN)	text														
1136	sae_test4_f1 Show the field ONLY if: [sae_diag_stat_f1] = '2'	4. Test	text														
1137	sae_test_date4_f1 Show the field ONLY if: [sae_test4_f1] <> "	4. Date (dd/mm/yyyy)	text (date_dmy)														
1138	sae_test_resu4_f1 Show the field ONLY if: [sae_test4_f1] <> "	4. Result	text														
1139	sae_test_refe4_f1 Show the field ONLY if: [sae_test4_f1] <> "	4. Reference range (if applicabile ULN-LLN)	text														
1140	sae_test5_f1 Show the field ONLY if: [sae_diag_stat_f1] = '2'	5. Test	text														
1141	sae_test_date5_f1 Show the field ONLY if: [sae_test5_f1] <> "	5. Date (dd/mm/yyyy)	text (date_dmy)														
1142	sae_test_resu5_f1 Show the field ONLY if: [sae_test5_f1] <> "	5. Result	text														
1143	sae_test_refe5_f1 Show the field ONLY if: [sae_test5_f1] <> "	5. Reference range (if applicabile ULN-LLN)	text														
1144	sae_tre_stat_f1	Section Header: 9. Treatments/Procedures for SAE	radio <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Applicable</td></tr></table> Custom alignment: RH	1	None	2	Applicable										
1	None																
2	Applicable																
1145	sae_tre_name1_f1 Show the field ONLY if: [sae_tre_stat_f1] = '2'	1. Name	text Custom alignment: RH														
1146	sae_tre_dose1_f1 Show the field ONLY if: [sae_tre_name1_f1] <> "	1. Daily dose and unit	text Custom alignment: RH														
1147	sae_tre_route1_f1 Show the field ONLY if: [sae_tre_name1_f1] <> "	1. Route	dropdown <table><tr><td>1</td><td>OS</td></tr><tr><td>2</td><td>Parenteral</td></tr><tr><td>3</td><td>Inhalation</td></tr><tr><td>4</td><td>Sublingual</td></tr><tr><td>5</td><td>Transdermic</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Other</td></tr></table> Custom alignment: RH	1	OS	2	Parenteral	3	Inhalation	4	Sublingual	5	Transdermic	6	Rectal	7	Other
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1148	sae_tre_sdate1_f1 Show the field ONLY if: [sae_tre_name1_f1] <> "	1. Start date (dd/mm/yyyy)	text (date_dmy) Custom alignment: RH														
1149	sae_tre_edate1_f1 Show the field ONLY if: [sae_tre_name1_f1] <> "	1. Stop date (dd/mm/yyyy)	text (date_dmy) Custom alignment: RH														

1150	sae_tre_ong_f1 Show the field ONLY if: [sae_tre_name1_f1] <> "		radio 1 ongoing Custom alignment: RH
1151	sae_tre_name2_f1 Show the field ONLY if: [sae_tre_stat_f1] = '2'	2. Name	text Custom alignment: RH
1152	sae_tre_dose2_f1 Show the field ONLY if: [sae_tre_name2_f1] <> "	2. Daily dose and unit	text Custom alignment: RH
1153	sae_tre_route2_f1 Show the field ONLY if: [sae_tre_name2_f1] <> "	2. Route	dropdown 1 OS 2 Parenteral 3 Inhalation 4 Sublingual 5 Transdermic 6 Rectal 7 Other Custom alignment: RH
1154	sae_tre_sdate2_f1 Show the field ONLY if: [sae_tre_name2_f1] <> "	2. Start date (dd/mm/yyyy)	text (date_dmy) Custom alignment: RH
1155	sae_tre_edate2_f1 Show the field ONLY if: [sae_tre_name2_f1] <> "	2. Stop date (dd/mm/yyyy)	text (date_dmy) Custom alignment: RH
1156	sae_tre_ong_2_f1 Show the field ONLY if: [sae_tre_name2_f1] <> "		radio 1 ongoing Custom alignment: RH
1157	sae_tre_name3_f1 Show the field ONLY if: [sae_tre_stat_f1] = '2'	3. Name	text Custom alignment: RH
1158	sae_tre_dose3_f1 Show the field ONLY if: [sae_tre_name3_f1] <> "	3. Daily dose and unit	text Custom alignment: RH
1159	sae_tre_route3_f1 Show the field ONLY if: [sae_tre_name3_f1] <> "	3. Route	dropdown 1 OS 2 Parenteral 3 Inhalation 4 Sublingual 5 Transdermic 6 Rectal 7 Other Custom alignment: RH
1160	sae_tre_sdate3_f1 Show the field ONLY if: [sae_tre_name3_f1] <> "	3. Start date (dd/mm/yyyy)	text (date_dmy) Custom alignment: RH
1161	sae_tre_edate3_f1 Show the field ONLY if: [sae_tre_name3_f1] <> "	3. Stop date (dd/mm/yyyy)	text (date_dmy) Custom alignment: RH
1162	sae_tre_ong_3_f1 Show the field ONLY if: [sae_tre_name3_f1] <> "		radio 1 ongoing Custom alignment: RH
1163	sae_tre_name4_f1 Show the field ONLY if: [sae_tre_stat_f1] = '2'	4. Name	text Custom alignment: RH
1164	sae_tre_dose4_f1 Show the field ONLY if: [sae_tre_name4_f1] <> "	4. Daily dose and unit	text Custom alignment: RH

1165	<div>sae_tre_route4_f1</div> <div>Show the field ONLY if: [sae_tre_name4_f1] <> "</div>	4. Route	<div>dropdown</div> <div><div>1</div><div>OS</div></div> <div><div>2</div><div>Parenteral</div></div> <div><div>3</div><div>Inhalation</div></div> <div><div>4</div><div>Sublingual</div></div> <div><div>5</div><div>Transdermic</div></div> <div><div>6</div><div>Rectal</div></div> <div><div>7</div><div>Other</div></div> <div>Custom alignment: RH</div>
1166	<div>sae_tre_sdate4_f1</div> <div>Show the field ONLY if: [sae_tre_name4_f1] <> "</div>	4. Start date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>
1167	<div>sae_tre_ede4_f1</div> <div>Show the field ONLY if: [sae_tre_name4_f1] <> "</div>	4. Stop date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>
1168	<div>sae_tre_ong_4_f1</div> <div>Show the field ONLY if: [sae_tre_name4_f1] <> "</div>		<div>radio</div> <div><div>1</div><div>ongoing</div></div> <div>Custom alignment: RH</div>
1169	<div>sae_tre_name5_f1</div> <div>Show the field ONLY if: [sae_tre_stat_f1] = '2'</div>	5. Name	<div>text</div> <div>Custom alignment: RH</div>
1170	<div>sae_tre_dose5_f1</div> <div>Show the field ONLY if: [sae_tre_name5_f1] <> "</div>	5. Daily dose and unit	<div>text</div> <div>Custom alignment: RH</div>
1171	<div>sae_tre_route5_f1</div> <div>Show the field ONLY if: [sae_tre_name5_f1] <> "</div>	5. Route	<div>dropdown</div> <div><div>1</div><div>OS</div></div> <div><div>2</div><div>Parenteral</div></div> <div><div>3</div><div>Inhalation</div></div> <div><div>4</div><div>Sublingual</div></div> <div><div>5</div><div>Transdermic</div></div> <div><div>6</div><div>Rectal</div></div> <div><div>7</div><div>Other</div></div> <div>Custom alignment: RH</div>
1172	<div>sae_tre_sdate5_f1</div> <div>Show the field ONLY if: [sae_tre_name5_f1] <> "</div>	5. Start date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>
1173	<div>sae_tre_ede5_f1</div> <div>Show the field ONLY if: [sae_tre_name5_f1] <> "</div>	5. Stop date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>
1174	<div>sae_tre_ong_5_f1</div> <div>Show the field ONLY if: [sae_tre_name5_f1] <> "</div>		<div>radio</div> <div><div>1</div><div>ongoing</div></div> <div>Custom alignment: RH</div>
1175	<div>sae_tre_name6_f1</div> <div>Show the field ONLY if: [sae_tre_stat_f1] = '2'</div>	6. Name	<div>text</div> <div>Custom alignment: RH</div>
1176	<div>sae_tre_dose6_f1</div> <div>Show the field ONLY if: [sae_tre_name6_f1] <> "</div>	6. Daily dose and unit	<div>text</div> <div>Custom alignment: RH</div>
1177	<div>sae_tre_sdate6_f1</div> <div>Show the field ONLY if: [sae_tre_name6_f1] <> "</div>	6. Start date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>
1178	<div>sae_tre_ede6_f1</div> <div>Show the field ONLY if: [sae_tre_name5_f1] <> "</div>	6. Stop date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>
1179	<div>sae_tre_ong_6_f1</div> <div>Show the field ONLY if: [sae_tre_name6_f1] <> "</div>		<div>radio</div> <div><div>1</div><div>ongoing</div></div> <div>Custom alignment: RH</div>

1180	sae_tre_name7_f1 Show the field ONLY if: [sae_tre_stat_f1] = '2'	7. Name	text Custom alignment: RH
1181	sae_tre_dose7_f1 Show the field ONLY if: [sae_tre_name7_f1] <> "	7. Daily dose and unit	text Custom alignment: RH
1182	sae_tre_sdate7_f1 Show the field ONLY if: [sae_tre_name7_f1] <> "	7. Start date <i>(dd/mm/yyyy)</i>	text (date_dmy) Custom alignment: RH
1183	sae_tre_edate7_f1 Show the field ONLY if: [sae_tre_name7_f1] <> "	7. Stop date <i>(dd/mm/yyyy)</i>	text (date_dmy) Custom alignment: RH
1184	sae_tre_ong_7_f1 Show the field ONLY if: [sae_tre_name7_f1] <> "		radio <div><div>1</div>ongoing</div> Custom alignment: RH
1185	sae_tre_name8_f1 Show the field ONLY if: [sae_tre_stat_f1] = '2'	8. Name	text Custom alignment: RH
1186	sae_tre_dose8_f1 Show the field ONLY if: [sae_tre_name8_f1] <> "	8. Daily dose and unit	text Custom alignment: RH
1187	sae_tre_sdate8_f1 Show the field ONLY if: [sae_tre_name8_f1] <> "	8. Start date <i>(dd/mm/yyyy)</i>	text (date_dmy) Custom alignment: RH
1188	sae_tre_edate8_f1 Show the field ONLY if: [sae_tre_name8_f1] <> "	8. Stop date <i>(dd/mm/yyyy)</i>	text (date_dmy) Custom alignment: RH
1189	sae_tre_ong_8_f1 Show the field ONLY if: [sae_tre_name8_f1] <> "		radio <div><div>1</div>ongoing</div> Custom alignment: RH
1190	sae_report_date_f1	Section Header: ----- DATE OF REPORT <i>(dd/mm/yyyy)</i>	text (date_dmy) Custom alignment: RH
1191	sae_report_f1	REPORTED BY <i>(full name)</i>	text Custom alignment: RH
1192	sae_invest_f1	INVESTIGATOR <i>(If different from reporter) (full name)</i>	text
1193	sae_signat_f1	Signature <i>(please, draw signature with mouse or finger)</i>	file (signature) Custom alignment: RH
1194	sae_indic_titolo_2	To send the notification of the SAE form to the Sponsor safety desk, click Save. Please, complete the SAE form with all information available before saving.	descriptive
1195	serious_averse_event_follow_up_report_1_complete	Section Header: <i>Form Status</i> Complete?	dropdown <div><div>0</div>Incomplete</div> <div><div>1</div>Unverified</div> <div><div>2</div>Complete</div>

Instrument: **Serious Averse Event Follow Up Report 2** (serious_averse_event_follow_up_report_2)[^ Collapse](#)

1196	ud_sae2	<div>Section Header: Record ID/Patient [baseline_arm_1][record_id] - Treatment [baseline_arm_1][randomization] SERIOUS ADVERSE EVENT FORM - FOLLOW UP REPORT 21. Patient Information</div> <div>Upload document</div>	file
1197	sae_birth_f2	<div>Year of birth</div> <div>(yyyy)</div>	text (integer, Min: 1920, Max: 2020)
1198	sae_sex_f2	<div>Sex</div>	<div>dropdown</div> <div><div><div>1</div><div>M</div></div><div><div>2</div><div>F</div></div></div> <div>Field Annotation: @DEFAULT=[baseline_arm_1][d_gender]</div>
1199	sae_height_f2	<div>Height (cm)</div> <div>(cm)</div>	<div>text (integer)</div> <div>Field Annotation: @DEFAULT="[baseline_arm_1][height]"</div>
1200	sae_weight_f2	<div>Weight (Kg)</div> <div>(Kg)</div>	<div>text (number_1dp, Min: 30.0, Max: 100.0)</div> <div>Field Annotation: @DEFAULT= "[baseline_arm_1][weight]"</div>

1201	<div>sae_imp1_fadm_date_f2</div> <div>Show the field ONLY if: [sae_imp1_f2] <> "</div>	<div>Section Header: 2. Investigational Medicinal Product (IMP)/Study Drugs</div> <div>Date of first admin.</div>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>										
1202	<div>sae_imp1_ladm_date_f2</div> <div>Show the field ONLY if: [sae_imp1_f2] <> "</div>	<div>Date of last admin.</div>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>										
1203	<div>sae_imp1_idose_f2</div>	<div>Intended dose & unit</div>	<div>text</div> <div>Custom alignment: RH</div>										
1204	<div>sae_imp1_adose_f2</div>	<div>Administered dose & unit</div>	<div>text</div> <div>Custom alignment: RH</div>										
1205	<div>sae_aware_date_f2</div>	<div>Section Header: SAE Details</div> <div>Date of SAE awareness (dd/mm/yyyy)</div>	<div>text (date_dmy)</div>										
1206	<div>sae_term1_f2</div> <div>Show the field ONLY if: [sae_aware_date_f2] <> "</div>	<div>1. SAE Term/Diagnosis</div>	<div>text</div>										
1207	<div>sae_grade1_f2</div> <div>Show the field ONLY if: [sae_term1_f2] <> "</div>	<div>1. SAE NCI-CTC AE Grade</div>	<div>dropdown</div> <table><tr><td>1</td><td>Grade 1/Mild</td></tr><tr><td>2</td><td>Grade 2/Moderate</td></tr><tr><td>3</td><td>Grade 3/Severe</td></tr><tr><td>4</td><td>Grade 4/Life Threatening</td></tr><tr><td>5</td><td>Grade 5/Death</td></tr></table>	1	Grade 1/Mild	2	Grade 2/Moderate	3	Grade 3/Severe	4	Grade 4/Life Threatening	5	Grade 5/Death
1	Grade 1/Mild												
2	Grade 2/Moderate												
3	Grade 3/Severe												
4	Grade 4/Life Threatening												
5	Grade 5/Death												
1208	<div>ctc_ae_link1_f2</div> <div>Show the field ONLY if: [sae_term1_f2] <> "</div>	<div>Please click on file attachment to reference the CTCAE v 4.03:</div>	<div>descriptive</div>										
1209	<div>sae_death1_f2</div> <div>Show the field ONLY if: [sae_term1_f2] <> "</div>	<div>1. Death</div>	<div>radio</div> <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	0	No	1	Yes	99	Unknown				
0	No												
1	Yes												
99	Unknown												
1210	<div>sae_death_date1_f2</div> <div>Show the field ONLY if: [sae_death1_f2] = '1' and [sae_term1_f2] <> "</div>	<div>If Death, Date of Death:</div>	<div>text (date_dmy)</div>										
1211	<div>sae_death_due1_f2</div> <div>Show the field ONLY if: [sae_death1_f2] = '1' and [sae_term1_f2] <> "</div>	<div>Death due to the SAE</div>	<div>radio</div> <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	0	No	1	Yes	99	Unknown				
0	No												
1	Yes												
99	Unknown												
1212	<div>sae_auto_perf1_f2</div> <div>Show the field ONLY if: [sae_death1_f2] = '1' and [sae_term1_f2] <> "</div>	<div>Was an autopsy performed?</div>	<div>radio</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr></table> <div>Custom alignment: RH</div>	1	Yes	2	No						
1	Yes												
2	No												
1213	<div>sae_life_threa1_f2</div> <div>Show the field ONLY if: [sae_term1_f2] <> "</div>	<div>Life-threatening</div>	<div>radio (Matrix)</div> <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	0	No	1	Yes	99	Unknown				
0	No												
1	Yes												
99	Unknown												
1214	<div>sae_hosp1_f2</div> <div>Show the field ONLY if: [sae_term1_f2] <> "</div>	<div>Hospitalisation/Prolonged Hospitalisation</div>	<div>radio (Matrix)</div> <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	0	No	1	Yes	99	Unknown				
0	No												
1	Yes												
99	Unknown												
1215	<div>sae_disabi1_f2</div> <div>Show the field ONLY if: [sae_term1_f2] <> "</div>	<div>Persistent or significant Disability/Incapacity</div>	<div>radio (Matrix)</div> <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	0	No	1	Yes	99	Unknown				
0	No												
1	Yes												
99	Unknown												
1216	<div>sae_anoma1_f2</div> <div>Show the field ONLY if: [sae_term1_f2] <> "</div>	<div>Congenital Anomaly/Birth defect</div>	<div>radio (Matrix)</div> <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	0	No	1	Yes	99	Unknown				
0	No												
1	Yes												
99	Unknown												

1217	<div>sae_med_even1_f2</div> <div>Show the field ONLY if: [sae_term1_f2] <> "</div>	Important Medical Event	<div>radio (Matrix)</div> <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	0	No	1	Yes	99	Unknown						
0	No														
1	Yes														
99	Unknown														
1218	<div>sae_imp1_causa1_f2</div> <div>Show the field ONLY if: [sae_term1_f2] <> "</div>	1. Causal relation to IMP/Study drug (1)	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
1	Certain														
2	Probable														
3	Possible														
4	Unlikely														
5	Unrelated														
6	Unknown														
1219	<div>sae_imp2_causa1_f2</div> <div>Show the field ONLY if: [sae_term1_f2] <> "</div>	1. Causal relation to IMP/Study drug (2)	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
1	Certain														
2	Probable														
3	Possible														
4	Unlikely														
5	Unrelated														
6	Unknown														
1220	<div>sae_imp3_causa1_f2</div> <div>Show the field ONLY if: [sae_term1_f2] <> "</div>	1. Causal relation to IMP/Study drug (3)	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
1	Certain														
2	Probable														
3	Possible														
4	Unlikely														
5	Unrelated														
6	Unknown														
1221	<div>sae_sdate1_f2</div> <div>Show the field ONLY if: [sae_term1_f2] <> "</div>	1. Start date <i>(dd/mm/yyyy hh:mm)</i>	text (datetime_dmy)												
1222	<div>sae_edate1_f2</div> <div>Show the field ONLY if: [sae_term1_f2] <> "</div>	1. Stop date <i>(dd/mm/yyyy hh:mm)</i>	text (datetime_dmy)												
1223	<div>sae_outcome_stat1_f2</div> <div>Show the field ONLY if: [sae_term1_f2] <> "</div>	1. Outcome	<div>dropdown</div> <table><tr><td>1</td><td>Resolved</td></tr><tr><td>2</td><td>Resolving</td></tr><tr><td>3</td><td>Resolved with sequelae</td></tr><tr><td>4</td><td>Not resolved</td></tr><tr><td>5</td><td>Fatal</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Resolved	2	Resolving	3	Resolved with sequelae	4	Not resolved	5	Fatal	6	Unknown
1	Resolved														
2	Resolving														
3	Resolved with sequelae														
4	Not resolved														
5	Fatal														
6	Unknown														
1224	<div>sae_imp1_action1_f2</div> <div>Show the field ONLY if: [sae_term1_f2] <> "</div>	1. Action taken with the IMP/s drug (1)	<div>dropdown</div> <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr><tr><td>5</td><td>IMP withdrawn</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	None	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced	5	IMP withdrawn	6	Unknown
1	None														
2	Dose delayed														
3	Dose reduced														
4	Dose delayed and reduced														
5	IMP withdrawn														
6	Unknown														

1225	<div>sae_imp2_action1_f2</div> <div>Show the field ONLY if: [sae_term1_f2] <> "</div>	1. Action taken with the IMP/s drug (2)	<div>dropdown</div> <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr><tr><td>5</td><td>IMP withdrawn</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	None	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced	5	IMP withdrawn	6	Unknown
1	None														
2	Dose delayed														
3	Dose reduced														
4	Dose delayed and reduced														
5	IMP withdrawn														
6	Unknown														
1226	<div>sae_imp3_action1_f2</div> <div>Show the field ONLY if: [sae_term1_f2] <> "</div>	1. Action taken with the IMP/s drug (3)	<div>dropdown</div> <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr><tr><td>5</td><td>IMP withdrawn</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	None	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced	5	IMP withdrawn	6	Unknown
1	None														
2	Dose delayed														
3	Dose reduced														
4	Dose delayed and reduced														
5	IMP withdrawn														
6	Unknown														
1227	<div>sae_term2_f2</div> <div>Show the field ONLY if: [sae_aware_date_f2] <> "</div>	2. SAE Term/Diagnosis	text												
1228	<div>sae_grade2_f2</div> <div>Show the field ONLY if: [sae_term2_f2] <> "</div>	2. SAE NCI-CTC AE Grade	<div>dropdown</div> <table><tr><td>1</td><td>Grade 1/Mild</td></tr><tr><td>2</td><td>Grade 2/Moderate</td></tr><tr><td>3</td><td>Grade 3/Severe</td></tr><tr><td>4</td><td>Grade 4/Life Threatening</td></tr><tr><td>5</td><td>Grade 5/Death</td></tr></table>	1	Grade 1/Mild	2	Grade 2/Moderate	3	Grade 3/Severe	4	Grade 4/Life Threatening	5	Grade 5/Death		
1	Grade 1/Mild														
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3	Grade 3/Severe														
4	Grade 4/Life Threatening														
5	Grade 5/Death														
1229	<div>ctc_ae_link2_f2</div> <div>Show the field ONLY if: [sae_term2_f2] <> "</div>	Please click on file attachment to reference the CTCAE v 4.03:	descriptive												
1230	<div>sae_death2_f2</div> <div>Show the field ONLY if: [sae_term2_f2] <> "</div>	2. Death	<div>radio</div> <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	0	No	1	Yes	99	Unknown						
0	No														
1	Yes														
99	Unknown														
1231	<div>sae_death_date2_f2</div> <div>Show the field ONLY if: [sae_death2_f2] = '1' and [sae_term2_f2] <> "</div>	If Death, Date of Death:	text (date_dmy)												
1232	<div>sae_death_due2_f2</div> <div>Show the field ONLY if: [sae_death2_f2] = '1' and [sae_term2_f2] <> "</div>	Death due to the SAE	<div>radio</div> <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	0	No	1	Yes	99	Unknown						
0	No														
1	Yes														
99	Unknown														
1233	<div>sae_auto_perf2_f2</div> <div>Show the field ONLY if: [sae_death2_f2] = '1' and [sae_term2_f2] <> "</div>	Was an autopsy performed?	<div>radio</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr></table> <div>Custom alignment: RH</div>	1	Yes	2	No								
1	Yes														
2	No														
1234	<div>sae_life_threa2_f2</div> <div>Show the field ONLY if: [sae_term2_f2] <> "</div>	Life-threatening	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
1	No														
2	Yes														
99	Unknown														
1235	<div>sae_hospi2_f2</div> <div>Show the field ONLY if: [sae_term2_f2] <> "</div>	Hospitalisation/Prolonged Hospitalisation	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
1	No														
2	Yes														
99	Unknown														

1236	<div>sae_disabi2_f2</div> <div>Show the field ONLY if: [sae_term2_f2] <> "</div>	Persistent or significant Disability/Prolonged Hospitalisation	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
1	No														
2	Yes														
99	Unknown														
1237	<div>sae_anoma2_f2</div> <div>Show the field ONLY if: [sae_term2_f2] <> "</div>	Congenital Anomaly/Birth defect	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
1	No														
2	Yes														
99	Unknown														
1238	<div>sae_med_even2_f2</div> <div>Show the field ONLY if: [sae_term2_f2] <> "</div>	Important Medical Event	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
1	No														
2	Yes														
99	Unknown														
1239	<div>sae_imp1_causa2_f2</div> <div>Show the field ONLY if: [sae_term2_f2] <> "</div>	2. Causal relation to IMP/Study drug (1)	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
1	Certain														
2	Probable														
3	Possible														
4	Unlikely														
5	Unrelated														
6	Unknown														
1240	<div>sae_imp2_causa2_f2</div> <div>Show the field ONLY if: [sae_term2_f2] <> "</div>	2. Causal relation to IMP/Study drug (2)	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
1	Certain														
2	Probable														
3	Possible														
4	Unlikely														
5	Unrelated														
6	Unknown														
1241	<div>sae_imp3_causa2_f2</div> <div>Show the field ONLY if: [sae_term2_f2] <> "</div>	2. Causal relation to IMP/Study drug (3)	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
1	Certain														
2	Probable														
3	Possible														
4	Unlikely														
5	Unrelated														
6	Unknown														
1242	<div>sae_sdate2_f2</div> <div>Show the field ONLY if: [sae_term2_f2] <> "</div>	<div>2. Start date</div> <div>(dd/mm/yyyy hh:mm)</div>	<div>text (datetime_dmy)</div>												
1243	<div>sae_edate2_f2</div> <div>Show the field ONLY if: [sae_term2_f2] <> "</div>	<div>2. Stop date</div> <div>(dd/mm/yyyy hh:mm)</div>	<div>text (datetime_dmy)</div>												
1244	<div>sae_outcome_stat2_f2</div> <div>Show the field ONLY if: [sae_term2_f2] <> "</div>	2. Outcome	<div>dropdown</div> <table><tr><td>1</td><td>Resolved</td></tr><tr><td>2</td><td>Resolving</td></tr><tr><td>3</td><td>Resolved with sequelae</td></tr><tr><td>4</td><td>Not resolved</td></tr><tr><td>5</td><td>Fatal</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Resolved	2	Resolving	3	Resolved with sequelae	4	Not resolved	5	Fatal	6	Unknown
1	Resolved														
2	Resolving														
3	Resolved with sequelae														
4	Not resolved														
5	Fatal														
6	Unknown														
1245	<div>sae_imp1_action2_f2</div> <div>Show the field ONLY if: [sae_term2_f2] <> "</div>	2. Action taken with the IMP/s drug (1)	<div>dropdown</div> <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr><tr><td>5</td><td>IMP withdrawn</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	None	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced	5	IMP withdrawn	6	Unknown
1	None														
2	Dose delayed														
3	Dose reduced														
4	Dose delayed and reduced														
5	IMP withdrawn														
6	Unknown														

1246	<div>sae_imp2_action2_f2</div> <div>Show the field ONLY if: [sae_term2_f2] <> "</div>	2. Action taken with the IMP/s drug (2)	<div>dropdown</div> <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr><tr><td>5</td><td>IMP withdrawn</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	None	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced	5	IMP withdrawn	6	Unknown
1	None														
2	Dose delayed														
3	Dose reduced														
4	Dose delayed and reduced														
5	IMP withdrawn														
6	Unknown														
1247	<div>sae_imp3_action2_f2</div> <div>Show the field ONLY if: [sae_term2_f2] <> "</div>	2. Action taken with the IMP/s drug (3)	<div>dropdown</div> <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr><tr><td>5</td><td>IMP withdrawn</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	None	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced	5	IMP withdrawn	6	Unknown
1	None														
2	Dose delayed														
3	Dose reduced														
4	Dose delayed and reduced														
5	IMP withdrawn														
6	Unknown														
1248	<div>sae_term3_f2</div> <div>Show the field ONLY if: [sae_awaar_date_f2] <> "</div>	3. SAE Term/Diagnosis	text												
1249	<div>sae_grade3_f2</div> <div>Show the field ONLY if: [sae_term3_f2] <> "</div>	3. SAE NCI-CTC AE Grade	<div>dropdown</div> <table><tr><td>1</td><td>Grade 1/Mild</td></tr><tr><td>2</td><td>Grade 2/Moderate</td></tr><tr><td>3</td><td>Grade 3/Severe</td></tr><tr><td>4</td><td>Grade 4/Life Threatening</td></tr><tr><td>5</td><td>Grade 5/Death</td></tr></table>	1	Grade 1/Mild	2	Grade 2/Moderate	3	Grade 3/Severe	4	Grade 4/Life Threatening	5	Grade 5/Death		
1	Grade 1/Mild														
2	Grade 2/Moderate														
3	Grade 3/Severe														
4	Grade 4/Life Threatening														
5	Grade 5/Death														
1250	<div>ctc_ae_link3_f2</div> <div>Show the field ONLY if: [sae_term3_f2] <> "</div>	Please click on file attachment to reference the CTCAE v 4.03:	descriptive												
1251	<div>sae_death3_f2</div> <div>Show the field ONLY if: [sae_term3_f2] <> "</div>	3. Death	<div>radio</div> <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	0	No	1	Yes	99	Unknown						
0	No														
1	Yes														
99	Unknown														
1252	<div>sae_death_date3_f2</div> <div>Show the field ONLY if: [sae_death3_f2] = '1' and [sae_term3_f2] <> "</div>	If Death, Date of Death:	text (date_dmy)												
1253	<div>sae_death_due3_f2</div> <div>Show the field ONLY if: [sae_death3_f2] = '1' and [sae_term3_f2] <> "</div>	Death due to the SAE	<div>radio</div> <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	0	No	1	Yes	99	Unknown						
0	No														
1	Yes														
99	Unknown														
1254	<div>sae_auto_perf3_f2</div> <div>Show the field ONLY if: [sae_death3_f2] = '1' and [sae_term3_f2] <> "</div>	Was an autopsy performed?	<div>radio</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr></table> <div>Custom alignment: RH</div>	1	Yes	2	No								
1	Yes														
2	No														
1255	<div>sae_life_threa3_f2</div> <div>Show the field ONLY if: [sae_term3_f2] <> "</div>	Life-threatening	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
1	No														
2	Yes														
99	Unknown														
1256	<div>sae_hospi3_f2</div> <div>Show the field ONLY if: [sae_term3_f2] <> "</div>	Hospitalisation/Prolonged Hospitalisation	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
1	No														
2	Yes														
99	Unknown														

1257	<div>sae_disabi3_f2</div> <div>Show the field ONLY if: [sae_term3_f2] <> "</div>	Significant Disability	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
1	No														
2	Yes														
99	Unknown														
1258	<div>sae_anoma3_f2</div> <div>Show the field ONLY if: [sae_term3_f2] <> "</div>	Congenital Anomaly/ Birth defect	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
1	No														
2	Yes														
99	Unknown														
1259	<div>sae_med_even3_f2</div> <div>Show the field ONLY if: [sae_term3_f2] <> "</div>	Important Medical Event	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
1	No														
2	Yes														
99	Unknown														
1260	<div>sae_imp1_causa3_f2</div> <div>Show the field ONLY if: [sae_term3_f2] <> "</div>	3. Causal relation to IMP/Study drug (1)	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
1	Certain														
2	Probable														
3	Possible														
4	Unlikely														
5	Unrelated														
6	Unknown														
1261	<div>sae_imp2_causa3_f2</div> <div>Show the field ONLY if: [sae_term3_f2] <> "</div>	3. Causal relation to IMP/Study drug (2)	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
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1262	<div>sae_imp3_causa3_f2</div> <div>Show the field ONLY if: [sae_term3_f2] <> "</div>	3. Causal relation to IMP/Study drug (3)	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
1	Certain														
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1263	<div>sae_sdate3_f2</div> <div>Show the field ONLY if: [sae_term3_f2] <> "</div>	<div>3. Start date</div> <div>(dd/mm/yyyy hh:mm)</div>	<div>text (datetime_dmy)</div>												
1264	<div>sae_edate3_f2</div> <div>Show the field ONLY if: [sae_term3_f2] <> "</div>	<div>3. Stop date</div> <div>(dd/mm/yyyy hh:mm)</div>	<div>text (datetime_dmy)</div>												
1265	<div>sae_outcome_stat3_f2</div> <div>Show the field ONLY if: [sae_term3_f2] <> "</div>	3. Outcome	<div>dropdown</div> <table><tr><td>1</td><td>Resolved</td></tr><tr><td>2</td><td>Resolving</td></tr><tr><td>3</td><td>Resolved with sequelae</td></tr><tr><td>4</td><td>Not resolved</td></tr><tr><td>5</td><td>Fatal</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Resolved	2	Resolving	3	Resolved with sequelae	4	Not resolved	5	Fatal	6	Unknown
1	Resolved														
2	Resolving														
3	Resolved with sequelae														
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1266	<div>sae_imp1_action3_f2</div> <div>Show the field ONLY if: [sae_term3_f2] <> "</div>	3. Action taken with the IMP/s drug (1)	<div>dropdown</div> <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr><tr><td>5</td><td>IMP withdrawn</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	None	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced	5	IMP withdrawn	6	Unknown
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1267	<div>sae_imp2_action3_f2</div> <div>Show the field ONLY if: [sae_term3_f2] <> "</div>	3. Action taken with the IMP/s drug (2)	<div>dropdown</div> <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr><tr><td>5</td><td>IMP withdrawn</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	None	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced	5	IMP withdrawn	6	Unknown
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1268	<div>sae_imp3_action3_f2</div> <div>Show the field ONLY if: [sae_term3_f2] <> "</div>	3. Action taken with the IMP/s drug (3)	<div>dropdown</div> <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr><tr><td>5</td><td>IMP withdrawn</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	None	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced	5	IMP withdrawn	6	Unknown
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6	Unknown														
1269	<div>sae_term4_f2</div> <div>Show the field ONLY if: [sae_awaar_date_f2] <> "</div>	4. SAE Term/Diagnosis	text												
1270	<div>sae_grade4_f2</div> <div>Show the field ONLY if: [sae_term4_f2] <> "</div>	4. SAE NCI-CTC AE Grade	<div>dropdown</div> <table><tr><td>1</td><td>Grade 1/Mild</td></tr><tr><td>2</td><td>Grade 2/Moderate</td></tr><tr><td>3</td><td>Grade 3/Severe</td></tr><tr><td>4</td><td>Grade 4/Life Threatening</td></tr><tr><td>5</td><td>Grade 5/Death</td></tr></table>	1	Grade 1/Mild	2	Grade 2/Moderate	3	Grade 3/Severe	4	Grade 4/Life Threatening	5	Grade 5/Death		
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1271	<div>ctc_ae_link4_f2</div> <div>Show the field ONLY if: [sae_term4_f2] <> "</div>	Please click on file attachment to reference the CTCAE v 4.03:	descriptive												
1272	<div>sae_death4_f2</div> <div>Show the field ONLY if: [sae_term4_f2] <> "</div>	4. Death	<div>radio</div> <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	0	No	1	Yes	99	Unknown						
0	No														
1	Yes														
99	Unknown														
1273	<div>sae_death_date4_f2</div> <div>Show the field ONLY if: [sae_death4_f2] = '1' and [sae_term4_f2] <> "</div>	If Death, Date of Death:	text (date_dmy)												
1274	<div>sae_death_due4_f2</div> <div>Show the field ONLY if: [sae_death4_f2] = '1' and [sae_term4_f2] <> "</div>	Death due to the SAE	<div>radio</div> <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	0	No	1	Yes	99	Unknown						
0	No														
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1275	<div>sae_auto_perf4_f2</div> <div>Show the field ONLY if: [sae_death4_f2] = '1' and [sae_term4_f2] <> "</div>	Was an autopsy performed?	<div>radio</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr></table> <div>Custom alignment: RH</div>	1	Yes	2	No								
1	Yes														
2	No														
1276	<div>sae_life_threa4_f2</div> <div>Show the field ONLY if: [sae_term4_f2] <> "</div>	Life-threatening	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
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1277	<div>sae_hospi4_f2</div> <div>Show the field ONLY if: [sae_term4_f2] <> "</div>	Hospitalisation/Prolonged Hospitalisation	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
1	No														
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1278	sae_disabi4_f2 Show the field ONLY if: [sae_term4_f2] <> "	Significant Disability	radio (Matrix) 1 No 2 Yes 99 Unknown
1279	sae_anoma4_f2 Show the field ONLY if: [sae_term4_f2] <> "	Congenital Anomaly/Birth defect	radio (Matrix) 1 No 2 Yes 99 Unknown
1280	sae_med_even4_f2 Show the field ONLY if: [sae_term4_f2] <> "	Important Medical Event	radio (Matrix) 1 No 2 Yes 99 Unknown
1281	sae_imp1_causa4_f2 Show the field ONLY if: [sae_term4_f2] <> "	4. Causal relation to IMP/Study drug (1)	dropdown 1 Certain 2 Probable 3 Possible 4 Unlikely 5 Unrelated 6 Unknown Custom alignment: RH
1282	sae_imp2_causa4_f2 Show the field ONLY if: [sae_term4_f2] <> "	4. Causal relation to IMP/Study drug (2)	dropdown 1 Certain 2 Probable 3 Possible 4 Unlikely 5 Unrelated 6 Unknown Custom alignment: RH
1283	sae_imp3_causa4_f2 Show the field ONLY if: [sae_term4_f2] <> "	4. Causal relation to IMP/Study drug (3)	dropdown 1 Certain 2 Probable 3 Possible 4 Unlikely 5 Unrelated 6 Unknown Custom alignment: RH
1284	sae_sdate4_f2 Show the field ONLY if: [sae_term4_f2] <> "	4. Start date (dd/mm/yyyy hh:mm)	text (datetime_dmy)
1285	sae_edate4_f2 Show the field ONLY if: [sae_term4_f2] <> "	4. Stop date (dd/mm/yyyy hh:mm)	text (datetime_dmy)
1286	sae_outcome_stat4_f2 Show the field ONLY if: [sae_term4_f2] <> "	4. Outcome	dropdown 1 Resolved 2 Resolving 3 Resolved with sequelae 4 Not resolved 5 Fatal 6 Unknown
1287	sae_imp1_action4_f2 Show the field ONLY if: [sae_term4_f2] <> "	4. Action taken with the IMP/s drug (1)	dropdown 1 None 2 Dose delayed 3 Dose reduced 4 Dose delayed and reduced 5 IMP withdrawn 6 Unknown Custom alignment: RH

1288	<div>sae_imp2_action4_f2</div> <div>Show the field ONLY if: [sae_term4_f2] <> "</div>	4. Action taken with the IMP/s drug (2)	<div>dropdown</div> <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr><tr><td>5</td><td>IMP withdrawn</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	None	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced	5	IMP withdrawn	6	Unknown
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3	Dose reduced														
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1289	<div>sae_imp3_action4_f2</div> <div>Show the field ONLY if: [sae_term4_f2] <> "</div>	4. Action taken with the IMP/s drug (3)	<div>dropdown</div> <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr><tr><td>5</td><td>IMP withdrawn</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	None	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced	5	IMP withdrawn	6	Unknown
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1290	<div>sae_term5_f2</div> <div>Show the field ONLY if: [sae_awaar_date_f2] <> "</div>	5. SAE Term/Diagnosis	text												
1291	<div>sae_grade5_f2</div> <div>Show the field ONLY if: [sae_term5_f2] <> "</div>	5. SAE NCI-CTC AE Grade	<div>dropdown</div> <table><tr><td>1</td><td>Grade 1/Mild</td></tr><tr><td>2</td><td>Grade 2/Moderate</td></tr><tr><td>3</td><td>Grade 3/Severe</td></tr><tr><td>4</td><td>Grade 4/Life Threatening</td></tr><tr><td>5</td><td>Grade 5/Death</td></tr></table>	1	Grade 1/Mild	2	Grade 2/Moderate	3	Grade 3/Severe	4	Grade 4/Life Threatening	5	Grade 5/Death		
1	Grade 1/Mild														
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1292	<div>ctc_ae_link5_f2</div> <div>Show the field ONLY if: [sae_term5_f2] <> "</div>	Please click on file attachment to reference the CTCAE v 4.03:	descriptive												
1293	<div>sae_death5_f2</div> <div>Show the field ONLY if: [sae_term5_f2] <> "</div>	5. Death	<div>radio</div> <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	0	No	1	Yes	99	Unknown						
0	No														
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1294	<div>sae_death_date5_f2</div> <div>Show the field ONLY if: [sae_death5_f2] = '1' and [sae_term5_f2] <> "</div>	If Death, Date of Death:	text (date_dmy)												
1295	<div>sae_death_due5_f2</div> <div>Show the field ONLY if: [sae_death5_f2] = '1' and [sae_term5_f2] <> "</div>	Death due to the SAE	<div>radio</div> <table><tr><td>0</td><td>No</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	0	No	1	Yes	99	Unknown						
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1	Yes														
99	Unknown														
1296	<div>sae_auto_perf5_f2</div> <div>Show the field ONLY if: [sae_death5_f2] = '1' and [sae_term5_f2] <> "</div>	Was an autopsy performed?	<div>radio</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr></table> <div>Custom alignment: RH</div>	1	Yes	2	No								
1	Yes														
2	No														
1297	<div>sae_life_threa5_f2</div> <div>Show the field ONLY if: [sae_term5_f2] <> "</div>	Life-threatening	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
1	No														
2	Yes														
99	Unknown														
1298	<div>sae_hospis5_f2</div> <div>Show the field ONLY if: [sae_term5_f2] <> "</div>	Hospitalisation/Prolonged Hospitalisation	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
1	No														
2	Yes														
99	Unknown														

1299	<div>sae_disabi5_f2</div> <div>Show the field ONLY if: [sae_term5_f2] <> "</div>	Significant Disability	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
1	No														
2	Yes														
99	Unknown														
1300	<div>sae_anoma5_f2</div> <div>Show the field ONLY if: [sae_term5_f2] <> "</div>	Congenital Anomaly/Birth defect	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
1	No														
2	Yes														
99	Unknown														
1301	<div>sae_med_even5_f2</div> <div>Show the field ONLY if: [sae_term5_f2] <> "</div>	Important Medical Event	<div>radio (Matrix)</div> <table><tr><td>1</td><td>No</td></tr><tr><td>2</td><td>Yes</td></tr><tr><td>99</td><td>Unknown</td></tr></table>	1	No	2	Yes	99	Unknown						
1	No														
2	Yes														
99	Unknown														
1302	<div>sae_imp1_causa5_f2</div> <div>Show the field ONLY if: [sae_term5_f2] <> "</div>	5. Causal relation to IMP/Study drug (1)	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
1	Certain														
2	Probable														
3	Possible														
4	Unlikely														
5	Unrelated														
6	Unknown														
1303	<div>sae_imp2_causa5_f2</div> <div>Show the field ONLY if: [sae_term5_f2] <> "</div>	5. Causal relation to IMP/Study drug (2)	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
1	Certain														
2	Probable														
3	Possible														
4	Unlikely														
5	Unrelated														
6	Unknown														
1304	<div>sae_imp3_causa5_f2</div> <div>Show the field ONLY if: [sae_term5_f2] <> "</div>	5. Causal relation to IMP/Study drug (3)	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Unknown
1	Certain														
2	Probable														
3	Possible														
4	Unlikely														
5	Unrelated														
6	Unknown														
1305	<div>sae_sdate5_f2</div> <div>Show the field ONLY if: [sae_term5_f2] <> "</div>	5. Start date <i>(mm/dd/yyyy hh:mm)</i>	text (datetime_dmy)												
1306	<div>sae_edate5_f2</div> <div>Show the field ONLY if: [sae_term5_f2] <> "</div>	5. Stop date <i>(mm/dd/yyyy hh:mm)</i>	text (datetime_dmy)												
1307	<div>sae_outcome_stat5_f2</div> <div>Show the field ONLY if: [sae_term5_f2] <> "</div>	5. Outcome	<div>dropdown</div> <table><tr><td>1</td><td>Resolved</td></tr><tr><td>2</td><td>Resolving</td></tr><tr><td>3</td><td>Resolved with sequelae</td></tr><tr><td>4</td><td>Not resolved</td></tr><tr><td>5</td><td>Fatal</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Resolved	2	Resolving	3	Resolved with sequelae	4	Not resolved	5	Fatal	6	Unknown
1	Resolved														
2	Resolving														
3	Resolved with sequelae														
4	Not resolved														
5	Fatal														
6	Unknown														
1308	<div>sae_imp1_action5_f2</div> <div>Show the field ONLY if: [sae_term5_f2] <> "</div>	5. Action taken with the IMP/s drug (1)	<div>dropdown</div> <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr><tr><td>5</td><td>IMP withdrawn</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	None	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced	5	IMP withdrawn	6	Unknown
1	None														
2	Dose delayed														
3	Dose reduced														
4	Dose delayed and reduced														
5	IMP withdrawn														
6	Unknown														

1309	<div>sae_imp2_action5_f2</div> <div>Show the field ONLY if: [sae_term5_f2] <> "</div>	5. Action taken with the IMP/s drug (2)	<div>dropdown</div> <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr><tr><td>5</td><td>IMP withdrawn</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	None	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced	5	IMP withdrawn	6	Unknown
1	None														
2	Dose delayed														
3	Dose reduced														
4	Dose delayed and reduced														
5	IMP withdrawn														
6	Unknown														
1310	<div>sae_imp3_action5_f2</div> <div>Show the field ONLY if: [sae_term5_f2] <> "</div>	5. Action taken with the IMP/s drug (3)	<div>dropdown</div> <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Dose delayed</td></tr><tr><td>3</td><td>Dose reduced</td></tr><tr><td>4</td><td>Dose delayed and reduced</td></tr><tr><td>5</td><td>IMP withdrawn</td></tr><tr><td>6</td><td>Unknown</td></tr></table> <div>Custom alignment: RH</div>	1	None	2	Dose delayed	3	Dose reduced	4	Dose delayed and reduced	5	IMP withdrawn	6	Unknown
1	None														
2	Dose delayed														
3	Dose reduced														
4	Dose delayed and reduced														
5	IMP withdrawn														
6	Unknown														
1311	<div>sae_afte_stop_drug1_f2</div>	<div>Section Header: <i>DECHALLENGE</i></div> <div>Did event abate after stopping drug(s)?</div>	<div>dropdown</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr><tr><td>3</td><td>NA</td></tr></table> <div>Custom alignment: RH</div>	1	Yes	2	No	3	NA						
1	Yes														
2	No														
3	NA														
1312	<div>sae_dech_spec1_f2</div> <div>Show the field ONLY if: [sae_afte_stop_drug1_f2] = '1'</div>	IMP1	<div>radio (Matrix)</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr></table>	1	Yes	2	No								
1	Yes														
2	No														
1313	<div>sae_dech_spec2_f2</div> <div>Show the field ONLY if: [sae_afte_stop_drug1_f2] = '1'</div>	IMP2	<div>radio (Matrix)</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr></table>	1	Yes	2	No								
1	Yes														
2	No														
1314	<div>sae_dech_spec3_f2</div> <div>Show the field ONLY if: [sae_afte_stop_drug1_f2] = '1'</div>	IMP3	<div>radio (Matrix)</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr></table>	1	Yes	2	No								
1	Yes														
2	No														
1315	<div>sae_dech_num_f2</div> <div>Show the field ONLY if: [sae_afte_stop_drug1_f2] = '1'</div>	Specify SAE number	<div>text (integer)</div> <div>Custom alignment: RH</div>												
1316	<div>sae_susp_readm1_f2</div>	<div>Section Header: <i>RECHALLENGE</i></div> <div>Was suspected drug(s) re-administered?</div>	<div>dropdown</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr><tr><td>3</td><td>NA</td></tr></table> <div>Custom alignment: RH</div>	1	Yes	2	No	3	NA						
1	Yes														
2	No														
3	NA														
1317	<div>sae_rech_spec1_f2</div> <div>Show the field ONLY if: [sae_susp_readm1_f2] = '1'</div>	IMP1	<div>checkbox</div> <table><tr><td>1</td><td>sae_rech_spec1_f2__1</td><td>Yes</td></tr><tr><td>2</td><td>sae_rech_spec1_f2__2</td><td>No</td></tr></table>	1	sae_rech_spec1_f2__1	Yes	2	sae_rech_spec1_f2__2	No						
1	sae_rech_spec1_f2__1	Yes													
2	sae_rech_spec1_f2__2	No													
1318	<div>sae_rech_spec2_f2</div> <div>Show the field ONLY if: [sae_susp_readm1_f2] = '1'</div>	IMP2	<div>checkbox</div> <table><tr><td>1</td><td>sae_rech_spec2_f2__1</td><td>Yes</td></tr><tr><td>2</td><td>sae_rech_spec2_f2__2</td><td>No</td></tr></table>	1	sae_rech_spec2_f2__1	Yes	2	sae_rech_spec2_f2__2	No						
1	sae_rech_spec2_f2__1	Yes													
2	sae_rech_spec2_f2__2	No													
1319	<div>sae_rech_spec3_f2</div> <div>Show the field ONLY if: [sae_susp_readm1_f2] = '1'</div>	IMP3	<div>checkbox</div> <table><tr><td>1</td><td>sae_rech_spec3_f2__1</td><td>Yes</td></tr><tr><td>2</td><td>sae_rech_spec3_f2__2</td><td>No</td></tr></table>	1	sae_rech_spec3_f2__1	Yes	2	sae_rech_spec3_f2__2	No						
1	sae_rech_spec3_f2__1	Yes													
2	sae_rech_spec3_f2__2	No													
1320	<div>sae_rech_date_f2</div> <div>Show the field ONLY if: [sae_susp_readm1_f2] = '1' and [sae_susp_readm1_f2] = '1'</div>	Specify the date	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>												
1321	<div>sae_reap_reint1_f2</div> <div>Show the field ONLY if: [sae_susp_readm1_f2] = '1'</div>	Did event reappear after drug(s) reintroduction?	<div>dropdown</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr><tr><td>3</td><td>NA</td></tr></table> <div>Custom alignment: RH</div>	1	Yes	2	No	3	NA						
1	Yes														
2	No														
3	NA														

1322	<div>sae_dech_num_2_f2</div> <div>Show the field ONLY if: [sae_reap_reint1_f2]= '1' and [sae_susp_readm1_f2] = '1'</div>	<div>Specify SAE number</div>	<div>text (integer)</div> <div>Custom alignment: RH</div>
1323	<div>sae_dise_under1_f2</div>	<div>Section Header: <i>Disease under study</i></div> <div>Was the disease under study the primary cause of the SAE?</div>	<div>dropdown</div> <div><div>1</div><div>Certain</div></div> <div><div>2</div><div>Probable</div></div> <div><div>3</div><div>Possible</div></div> <div><div>4</div><div>Unlikely</div></div> <div><div>5</div><div>Unrelated</div></div> <div><div>6</div><div>Conditional/Unclassified</div></div> <div><div>7</div><div>Unassessable/Unclassifiable</div></div>
1324	<div>sae_dise_spec1_f2</div>	<div>If disease primary cause, please specify which SAE</div>	<div>text</div>
1325	<div>sae_conc_stat_f2</div>	<div>Section Header: <i>Concomitant treatments/Procedures(e.g. : prophylactic medications, procedures to obtain central venous access)</i></div>	<div>radio</div> <div><div>1</div><div>None</div></div> <div><div>2</div><div>Applicable</div></div> <div><div>99</div><div>UK</div></div> <div>Custom alignment: RH</div>
1326	<div>sae_conc_name1_f2</div> <div>Show the field ONLY if: [sae_conc_stat_f2] = '2'</div>	<div>1. Name</div> <div><i>Do not list in this section drugs used to treat the SAE</i></div>	<div>text</div> <div>Custom alignment: RH</div>
1327	<div>sae_conc_dose1_f2</div> <div>Show the field ONLY if: [sae_conc_name1_f2] <> "</div>	<div>1. Total daily dose and unit</div>	<div>text</div> <div>Custom alignment: RH</div>
1328	<div>sae_conc_route1_f2</div> <div>Show the field ONLY if: [sae_conc_name1_f2] <> "</div>	<div>1. Route</div>	<div>dropdown</div> <div><div>1</div><div>OS</div></div> <div><div>2</div><div>Parenteral</div></div> <div><div>3</div><div>Inhalation</div></div> <div><div>4</div><div>Sublingual</div></div> <div><div>5</div><div>Transdermic</div></div> <div><div>6</div><div>Rectal</div></div> <div><div>7</div><div>Other</div></div> <div>Custom alignment: RH</div>
1329	<div>sae_conc_sdate1_f2</div> <div>Show the field ONLY if: [sae_conc_name1_f2] <> "</div>	<div>1. Start date</div> <div><i>(dd/mm/yyyy)</i></div>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>
1330	<div>sae_conc_edate1_f2</div> <div>Show the field ONLY if: [sae_conc_name1_f2] <> "</div>	<div>1. Stop date</div> <div><i>(dd/mm/yyyy)</i></div>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>
1331	<div>sae_conc_ong1_f2</div> <div>Show the field ONLY if: [sae_conc_name1_f2] <> "</div>		<div>radio</div> <div><div>1</div><div>ongoing</div></div> <div>Custom alignment: RH</div>
1332	<div>sae_conc_prim1_f2</div> <div>Show the field ONLY if: [sae_conc_name1_f2] <> "</div>	<div>1. Primary cause of the SAE/s?</div>	<div>dropdown</div> <div><div>1</div><div>Certain</div></div> <div><div>2</div><div>Probable</div></div> <div><div>3</div><div>Possible</div></div> <div><div>4</div><div>Unlikely</div></div> <div><div>5</div><div>Unrelated</div></div> <div><div>6</div><div>Conditional/Unclassified</div></div> <div><div>7</div><div>Unassessable/Unclassifiable</div></div> <div>Custom alignment: RH</div>
1333	<div>sae_conc_prim_num1_f2</div> <div>Show the field ONLY if: [sae_conc_name1_f2] <> "</div>	<div>2. If primary cause, specify which SAE number (i.e. 1,3)</div>	<div>text (integer)</div> <div>Custom alignment: RH</div>
1334	<div>sae_conc_name2_f2</div> <div>Show the field ONLY if: [sae_conc_stat_f2] = '2'</div>	<div>2. Name</div> <div><i>Do not list in this section drugs used to treat the SAE</i></div>	<div>text</div> <div>Custom alignment: RH</div>

1335	sae_conc_dose2_f2 Show the field ONLY if: [sae_conc_name2_f2] <> "	2. Total daily dose and unit	text Custom alignment: RH														
1336	sae_conc_route2_f2 Show the field ONLY if: [sae_conc_name2_f2] <> "	2. Route	dropdown <table><tr><td>1</td><td>OS</td></tr><tr><td>2</td><td>Parenteral</td></tr><tr><td>3</td><td>Inhalation</td></tr><tr><td>4</td><td>Sublingual</td></tr><tr><td>5</td><td>Transdermic</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Other</td></tr></table> Custom alignment: RH	1	OS	2	Parenteral	3	Inhalation	4	Sublingual	5	Transdermic	6	Rectal	7	Other
1	OS																
2	Parenteral																
3	Inhalation																
4	Sublingual																
5	Transdermic																
6	Rectal																
7	Other																
1337	sae_conc_sdate2_f2 Show the field ONLY if: [sae_conc_name2_f2] <> "	2. Start date (dd/mm/yyyy)	text (date_dmy) Custom alignment: RH														
1338	sae_conc_edate2_f2 Show the field ONLY if: [sae_conc_name2_f2] <> "	2. Stop date (dd/mm/yyyy)	text (date_dmy) Custom alignment: RH														
1339	sae_conc_ong2_f2 Show the field ONLY if: [sae_conc_name2_f2] <> "		radio <table><tr><td>1</td><td>ongoing</td></tr></table> Custom alignment: RH	1	ongoing												
1	ongoing																
1340	sae_conc_prim2_f2 Show the field ONLY if: [sae_conc_name2_f2] <> "	2. Primary cause of the SAE/s?	dropdown <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Conditional/Unclassified</td></tr><tr><td>7</td><td>Unassessable/Unclassifiable</td></tr></table> Custom alignment: RH	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Conditional/Unclassified	7	Unassessable/Unclassifiable
1	Certain																
2	Probable																
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4	Unlikely																
5	Unrelated																
6	Conditional/Unclassified																
7	Unassessable/Unclassifiable																
1341	sae_conc_prim_num2_f2 Show the field ONLY if: [sae_conc_name2_f2] <> "	2. If primary cause, specify which SAE number (i.e. 1,3)	text (integer) Custom alignment: RH														
1342	sae_conc_name3_f2 Show the field ONLY if: [sae_conc_stat_f2] = '2'	3. Name Do not list in this section drugs used to treat the SAE	text Custom alignment: RH														
1343	sae_conc_dose3_f2 Show the field ONLY if: [sae_conc_name3_f2] <> "	3. Total daily dose and unit	text Custom alignment: RH														
1344	sae_conc_route3_f2 Show the field ONLY if: [sae_conc_name3_f2] <> "	3. Route	dropdown <table><tr><td>1</td><td>OS</td></tr><tr><td>2</td><td>Parenteral</td></tr><tr><td>3</td><td>Inhalation</td></tr><tr><td>4</td><td>Sublingual</td></tr><tr><td>5</td><td>Transdermic</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Other</td></tr></table> Custom alignment: RH	1	OS	2	Parenteral	3	Inhalation	4	Sublingual	5	Transdermic	6	Rectal	7	Other
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2	Parenteral																
3	Inhalation																
4	Sublingual																
5	Transdermic																
6	Rectal																
7	Other																
1345	sae_conc_sdate3_f2 Show the field ONLY if: [sae_conc_name3_f2] <> "	3. Start date (dd/mm/yyyy)	text (date_dmy) Custom alignment: RH														
1346	sae_conc_edate3_f2 Show the field ONLY if: [sae_conc_name3_f2] <> "	3. Stop date (dd/mm/yyyy)	text (date_dmy) Custom alignment: RH														
1347	sae_conc_ong3_f2 Show the field ONLY if: [sae_conc_name3_f2] <> "		radio <table><tr><td>1</td><td>ongoing</td></tr></table> Custom alignment: RH	1	ongoing												
1	ongoing																

1348	<div>sae_conc_prim3_f2</div> <div>Show the field ONLY if: [sae_conc_name3_f2] <> "</div>	3. Primary cause of the SAE/s?	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Conditional/Unclassified</td></tr><tr><td>7</td><td>Unassessable/Unclassifiable</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Conditional/Unclassified	7	Unassessable/Unclassifiable
1	Certain																
2	Probable																
3	Possible																
4	Unlikely																
5	Unrelated																
6	Conditional/Unclassified																
7	Unassessable/Unclassifiable																
1349	<div>sae_conc_prim_num3_f2</div> <div>Show the field ONLY if: [sae_conc_name3_f2] <> "</div>	3. If primary cause, specify which SAE number (i.e. 1,3)	<div>text (integer)</div> <div>Custom alignment: RH</div>														
1350	<div>sae_conc_name4_f2</div> <div>Show the field ONLY if: [sae_conc_stat_f2] = '2'</div>	<div>4. Name</div> <div>Do not list in this section drugs used to treat the SAE</div>	<div>text</div> <div>Custom alignment: RH</div>														
1351	<div>sae_conc_dose4_f2</div> <div>Show the field ONLY if: [sae_conc_name4_f2] <> "</div>	4. Total daily dose and unit	<div>text</div> <div>Custom alignment: RH</div>														
1352	<div>sae_conc_route4_f2</div> <div>Show the field ONLY if: [sae_conc_name4_f2] <> "</div>	4. Route	<div>dropdown</div> <table><tr><td>1</td><td>OS</td></tr><tr><td>2</td><td>Parenteral</td></tr><tr><td>3</td><td>Inhalation</td></tr><tr><td>4</td><td>Sublingual</td></tr><tr><td>5</td><td>Transdermic</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Other</td></tr></table> <div>Custom alignment: RH</div>	1	OS	2	Parenteral	3	Inhalation	4	Sublingual	5	Transdermic	6	Rectal	7	Other
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1353	<div>sae_conc_sdate4_f2</div> <div>Show the field ONLY if: [sae_conc_name4_f2] <> "</div>	<div>4. Start date</div> <div>(dd/mm/yyyy)</div>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
1354	<div>sae_conc_edate4_f2</div> <div>Show the field ONLY if: [sae_conc_name4_f2] <> "</div>	<div>4. Stop date</div> <div>(dd/mm/yyyy)</div>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
1355	<div>sae_conc_ong4_f2</div> <div>Show the field ONLY if: [sae_conc_name4_f2] <> "</div>		<div>radio</div> <table><tr><td>1</td><td>ongoing</td></tr></table> <div>Custom alignment: RH</div>	1	ongoing												
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1356	<div>sae_conc_prim4_f2</div> <div>Show the field ONLY if: [sae_conc_name4_f2] <> "</div>	4. Primary cause of the SAE/s?	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Conditional/Unclassified</td></tr><tr><td>7</td><td>Unassessable/Unclassifiable</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Conditional/Unclassified	7	Unassessable/Unclassifiable
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1357	<div>sae_conc_prim_num4_f2</div> <div>Show the field ONLY if: [sae_conc_name4_f2] <> "</div>	4. If primary cause, specify which SAE number (i.e. 1,3)	<div>text (integer)</div> <div>Custom alignment: RH</div>														
1358	<div>sae_conc_name5_f2</div> <div>Show the field ONLY if: [sae_conc_stat_f2] = '2'</div>	<div>5. Name</div> <div>Do not list in this section drugs used to treat the SAE</div>	<div>text</div> <div>Custom alignment: RH</div>														
1359	<div>sae_conc_dose5_f2</div> <div>Show the field ONLY if: [sae_conc_name5_f2] <> "</div>	5. Total daily dose and unit	<div>text</div> <div>Custom alignment: RH</div>														

1360	<div>sae_conc_route5_f2</div> <div>Show the field ONLY if: [sae_conc_name5_f2] <> "</div>	5. Route	<div>dropdown</div> <table><tr><td>1</td><td>OS</td></tr><tr><td>2</td><td>Parenteral</td></tr><tr><td>3</td><td>Inhalation</td></tr><tr><td>4</td><td>Sublingual</td></tr><tr><td>5</td><td>Transdermic</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Other</td></tr></table> <div>Custom alignment: RH</div>	1	OS	2	Parenteral	3	Inhalation	4	Sublingual	5	Transdermic	6	Rectal	7	Other
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1361	<div>sae_conc_sdate5_f2</div> <div>Show the field ONLY if: [sae_conc_name5_f2] <> "</div>	5. Start date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
1362	<div>sae_conc_edate5_f2</div> <div>Show the field ONLY if: [sae_conc_name5_f2] <> "</div>	5. Stop date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
1363	<div>sae_conc_ong5_f2</div> <div>Show the field ONLY if: [sae_conc_name5_f2] <> "</div>		<div>radio</div> <table><tr><td>1</td><td>ongoing</td></tr></table> <div>Custom alignment: RH</div>	1	ongoing												
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1364	<div>sae_conc_prim5_f2</div> <div>Show the field ONLY if: [sae_conc_name5_f2] <> "</div>	5. Primary cause of the SAE/s?	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Conditional/Unclassified</td></tr><tr><td>7</td><td>Unassessable/Unclassifiable</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Conditional/Unclassified	7	Unassessable/Unclassifiable
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1366	<div>sae_conc_name6_f2</div> <div>Show the field ONLY if: [sae_conc_stat_f2] = '2'</div>	6. Name <i>Do not list in this section drugs used to treat the SAE</i>	<div>text</div> <div>Custom alignment: RH</div>														
1367	<div>sae_conc_dose6_f2</div> <div>Show the field ONLY if: [sae_conc_name6_f2] <> "</div>	6. Total daily dose and unit	<div>text</div> <div>Custom alignment: RH</div>														
1368	<div>sae_conc_route6_f2</div> <div>Show the field ONLY if: [sae_conc_name6_f2] <> "</div>	6. Route	<div>dropdown</div> <table><tr><td>1</td><td>OS</td></tr><tr><td>2</td><td>Parenteral</td></tr><tr><td>3</td><td>Inhalation</td></tr><tr><td>4</td><td>Sublingual</td></tr><tr><td>5</td><td>Transdermic</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Other</td></tr></table> <div>Custom alignment: RH</div>	1	OS	2	Parenteral	3	Inhalation	4	Sublingual	5	Transdermic	6	Rectal	7	Other
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1370	<div>sae_conc_edate6_f2</div> <div>Show the field ONLY if: [sae_conc_name6_f2] <> "</div>	6. Stop date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
1371	<div>sae_conc_ong6_f2</div> <div>Show the field ONLY if: [sae_conc_name6_f2] <> "</div>		<div>radio</div> <table><tr><td>1</td><td>ongoing</td></tr></table> <div>Custom alignment: RH</div>	1	ongoing												
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1372	<div>sae_conc_prim6_f2</div> <div>Show the field ONLY if: [sae_conc_name6_f2] <> "</div>	6. Primary cause of the SAE/s?	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Conditional/Unclassified</td></tr><tr><td>7</td><td>Unassessable/Unclassifiable</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Conditional/Unclassified	7	Unassessable/Unclassifiable
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1373	<div>sae_conc_prim_num6_f2</div> <div>Show the field ONLY if: [sae_conc_name6_f2] <> "</div>	6. If primary cause, specify which SAE number (i.e. 1,3)	<div>text (integer)</div> <div>Custom alignment: RH</div>														
1374	<div>sae_relev_stat_f2</div>	Section Header: 6. <i>Relevant Medical Conditions (pre-existing relevant medical conditions, family history)</i>	<div>radio</div> <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Applicable</td></tr><tr><td>99</td><td>UK</td></tr></table> <div>Custom alignment: RH</div>	1	None	2	Applicable	99	UK								
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1375	<div>sae_dise1_f2</div> <div>Show the field ONLY if: [sae_relev_stat_f2] = '2'</div>	1. Disease/Allergy/Risk Factor	<div>text</div> <div>Custom alignment: RH</div>														
1376	<div>sae_rele_sdate1_f2</div> <div>Show the field ONLY if: [sae_dise1_f2] <> "</div>	1. Start date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
1377	<div>sae_rele_edate1_f2</div> <div>Show the field ONLY if: [sae_dise1_f2] <> "</div>	1. Stop date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
1378	<div>sae_rele_ong1_f2</div> <div>Show the field ONLY if: [sae_dise1_f2] <> "</div>		<div>radio</div> <table><tr><td>1</td><td>ongoing</td></tr></table> <div>Custom alignment: RH</div>	1	ongoing												
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1379	<div>sae_rele_prim1_f2</div> <div>Show the field ONLY if: [sae_dise1_f2] <> "</div>	1. Primary cause of the SAE/s?	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Conditional/Unclassified</td></tr><tr><td>7</td><td>Unassessable/Unclassifiable</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Conditional/Unclassified	7	Unassessable/Unclassifiable
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1380	<div>sae_rele_prim_num1_f2</div> <div>Show the field ONLY if: [sae_dise1_f2] <> "</div>	1. If primary cause, specify which SAE number (i.e. 1,3)	<div>text (integer)</div> <div>Custom alignment: RH</div>														
1381	<div>sae_dise2_f2</div> <div>Show the field ONLY if: [sae_relev_stat_f2] = '2'</div>	2. Disease/Allergy/Risk Factor	<div>text</div> <div>Custom alignment: RH</div>														
1382	<div>sae_rele_sdate2_f2</div> <div>Show the field ONLY if: [sae_dise2_f2] <> "</div>	2. Start date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
1383	<div>sae_rele_edate2_f2</div> <div>Show the field ONLY if: [sae_dise2_f2] <> "</div>	2. Stop date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
1384	<div>sae_rele_ong2_f2</div> <div>Show the field ONLY if: [sae_dise2_f2] <> "</div>		<div>radio</div> <table><tr><td>1</td><td>ongoing</td></tr></table> <div>Custom alignment: RH</div>	1	ongoing												
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1385	<div>sae_rele_prim2_f2</div> <div>Show the field ONLY if: [sae_dise2_f2] <> "</div>	2. Primary cause of the SAE/s?	<div>dropdown</div> <table><tr><td>1</td><td>Certain</td></tr><tr><td>2</td><td>Probable</td></tr><tr><td>3</td><td>Possible</td></tr><tr><td>4</td><td>Unlikely</td></tr><tr><td>5</td><td>Unrelated</td></tr><tr><td>6</td><td>Conditional/Unclassified</td></tr><tr><td>7</td><td>Unassessable/Unclassifiable</td></tr></table> <div>Custom alignment: RH</div>	1	Certain	2	Probable	3	Possible	4	Unlikely	5	Unrelated	6	Conditional/Unclassified	7	Unassessable/Unclassifiable
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1386	<div>sae_rele_prim_num2_f2</div> <div>Show the field ONLY if: [sae_dise2_f2] <> "</div>	2. If primary cause, specify which SAE number (i.e. 1,3)	<div>text (integer)</div> <div>Custom alignment: RH</div>														
1387	<div>sae_dise3_f2</div> <div>Show the field ONLY if: [sae_relev_stat_f2] = '2'</div>	3. Disease/Allergy/Risk Factor	<div>text</div> <div>Custom alignment: RH</div>														
1388	<div>sae_rele_sdate3_f2</div> <div>Show the field ONLY if: [sae_dise3_f2] <> "</div>	3. Start date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
1389	<div>sae_rele_edate3_f2</div> <div>Show the field ONLY if: [sae_dise3_f2] <> "</div>	3. Stop date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
1390	<div>sae_rele_ong3_f2</div> <div>Show the field ONLY if: [sae_dise3_f2] <> "</div>		<div>radio</div> <table><tr><td>1</td><td>ongoing</td></tr></table> <div>Custom alignment: RH</div>	1	ongoing												
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1393	<div>sae_dise4_f2</div> <div>Show the field ONLY if: [sae_relev_stat_f2] = '2'</div>	4. Disease/Allergy/Risk Factor	<div>text</div> <div>Custom alignment: RH</div>														
1394	<div>sae_rele_sdate4_f2</div> <div>Show the field ONLY if: [sae_dise4_f2] <> "</div>	4. Start date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
1395	<div>sae_rele_edate4_f2</div> <div>Show the field ONLY if: [sae_dise4_f2] <> "</div>	4. Stop date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>														
1396	<div>sae_rele_ong4_f2</div> <div>Show the field ONLY if: [sae_dise4_f2] <> "</div>		<div>radio</div> <table><tr><td>1</td><td>ongoing</td></tr></table> <div>Custom alignment: RH</div>	1	ongoing												
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1398	sae_rele_prim_num4_f2 Show the field ONLY if: [sae_dise4_f2] <> "	4. If primary cause, specify which SAE number (i.e. 1,3)	text (integer) Custom alignment: RH
1399	sae_dise5_f2 Show the field ONLY if: [sae_relev_stat_f2] = '2'	5. Disease/Allergy/Risk Factor	text Custom alignment: RH
1400	sae_rele_sdate5_f2 Show the field ONLY if: [sae_dise5_f2] <> "	5. Start date (dd/mm/yyyy)	text (date_dmy) Custom alignment: RH
1401	sae_rele_edate5_f2 Show the field ONLY if: [sae_dise5_f2] <> "	5. Stop date (dd/mm/yyyy)	text (date_dmy) Custom alignment: RH
1402	sae_rele_ong5_f2 Show the field ONLY if: [sae_dise5_f2] <> "		radio <div>1 ongoing</div> Custom alignment: RH
1403	sae_rele_prim5_f2 Show the field ONLY if: [sae_dise5_f2] <> "	5. Primary cause of the SAE/s?	dropdown <div> <div>1 Certain</div> <div>2 Probable</div> <div>3 Possible</div> <div>4 Unlikely</div> <div>5 Unrelated</div> <div>6 Conditional/Unclassified</div> <div>7 Unassessable/Unclassifiable</div> </div> Custom alignment: RH
1404	sae_rele_prim_num5_f2 Show the field ONLY if: [sae_dise5_f2] <> "	5. If primary cause, specify which SAE number (i.e. 1,3)	text (integer) Custom alignment: RH
1405	sae_description_f2	7. SAE narrative(Please describe chronologically the clinical sequence of the events, results of any confirmatory procedures, treatment of the event and outcome.\nAttach separately laboratory results and other relevant documents like hospital or post-mortem reports when available)	notes
1406	sae_diag_stat_f2	Section Header: 8. Relevant Diagnostic Tests(including laboratory values preceding the event)	radio <div> <div>1 None</div> <div>2 Applicable</div> </div> Custom alignment: RH
1407	sae_test1_f2 Show the field ONLY if: [sae_diag_stat_f2] = '2'	1. Test	text
1408	sae_test_date1_f2 Show the field ONLY if: [sae_test1_f2] <> "	1. Date (dd/mm/yyyy)	text (date_dmy)
1409	sae_test_resu1_f2 Show the field ONLY if: [sae_test1_f2] <> "	1. Result	text
1410	sae_test_refe1_f2 Show the field ONLY if: [sae_test1_f2] <> "	1. Reference range (if applicabile ULN-LLN)	text
1411	sae_test2_f2 Show the field ONLY if: [sae_diag_stat_f2] = '2'	2. Test	text
1412	sae_test_date2_f2 Show the field ONLY if: [sae_test2_f2] <> "	2. Date (dd/mm/yyyy)	text (date_dmy)
1413	sae_test_resu2_f2 Show the field ONLY if: [sae_test2_f2] <> "	2. Result	text
1414	sae_test_refe2_f2 Show the field ONLY if: [sae_test2_f2] <> "	2. Reference range (if applicabile ULN-LLN)	text

1415	sae_test3_f2 Show the field ONLY if: [sae_diag_stat_f2] = '2'	3. Test	text														
1416	sae_test_date3_f2 Show the field ONLY if: [sae_test3_f2] <> "	3. Date <i>(dd/mm/yyyy)</i>	text (date_dmy)														
1417	sae_test_resu3_f2 Show the field ONLY if: [sae_test3_f2] <> "	3. Result	text														
1418	sae_test_refe3_f2 Show the field ONLY if: [sae_test3_f2] <> "	3. Reference range <i>(if applicabile ULN-LLN)</i>	text														
1419	sae_test4_f2 Show the field ONLY if: [sae_diag_stat_f2] = '2'	4. Test	text														
1420	sae_test_date4_f2 Show the field ONLY if: [sae_test4_f2] <> "	4. Date <i>(dd/mm/yyyy)</i>	text (date_dmy)														
1421	sae_test_resu4_f2 Show the field ONLY if: [sae_test4_f2] <> "	4. Result	text														
1422	sae_test_refe4_f2 Show the field ONLY if: [sae_test4_f2] <> "	4. Reference range <i>(if applicabile ULN-LLN)</i>	text														
1423	sae_test5_f2 Show the field ONLY if: [sae_diag_stat_f2] = '2'	5. Test	text														
1424	sae_test_date5_f2 Show the field ONLY if: [sae_test5_f2] <> "	5. Date <i>(dd/mm/yyyy)</i>	text (date_dmy)														
1425	sae_test_resu5_f2 Show the field ONLY if: [sae_test5_f2] <> "	5. Result	text														
1426	sae_test_refe5_f2 Show the field ONLY if: [sae_test5_f2] <> "	5. Reference range <i>(if applicabile ULN-LLN)</i>	text														
1427	sae_tre_stat_f2	Section Header: 9. <i>Treatments/Procedures for SAE</i>	radio <table><tr><td>1</td><td>None</td></tr><tr><td>2</td><td>Applicable</td></tr></table> Custom alignment: RH	1	None	2	Applicable										
1	None																
2	Applicable																
1428	sae_tre_name1_f2 Show the field ONLY if: [sae_tre_stat_f2] = '2'	1. Name	text Custom alignment: RH														
1429	sae_tre_dose1_f2 Show the field ONLY if: [sae_tre_name1_f2] <> "	1. Daily dose and unit	text Custom alignment: RH														
1430	sae_tre_route1_f2 Show the field ONLY if: [sae_tre_name1_f2] <> "	1. Route	dropdown <table><tr><td>1</td><td>OS</td></tr><tr><td>2</td><td>Parenteral</td></tr><tr><td>3</td><td>Inhalation</td></tr><tr><td>4</td><td>Sublingual</td></tr><tr><td>5</td><td>Transdermic</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Other</td></tr></table> Custom alignment: RH	1	OS	2	Parenteral	3	Inhalation	4	Sublingual	5	Transdermic	6	Rectal	7	Other
1	OS																
2	Parenteral																
3	Inhalation																
4	Sublingual																
5	Transdermic																
6	Rectal																
7	Other																
1431	sae_tre_sdate1_f2 Show the field ONLY if: [sae_tre_name1_f2] <> "	1. Start date <i>(dd/mm/yyyy)</i>	text (date_dmy) Custom alignment: RH														
1432	sae_tre_edate1_f2 Show the field ONLY if: [sae_tre_name1_f2] <> "	1. Stop date <i>(dd/mm/yyyy)</i>	text (date_dmy) Custom alignment: RH														

1433	sae_tre_ong_f2 Show the field ONLY if: [sae_tre_name1_f2] <> "		radio 1 ongoing Custom alignment: RH
1434	sae_tre_name2_f2 Show the field ONLY if: [sae_tre_stat_f2] = '2'	2. Name	text Custom alignment: RH
1435	sae_tre_dose2_f2 Show the field ONLY if: [sae_tre_name2_f2] <> "	2. Daily dose and unit	text Custom alignment: RH
1436	sae_tre_route2_f2 Show the field ONLY if: [sae_tre_name2_f2] <> "	2. Route	dropdown 1 OS 2 Parenteral 3 Inhalation 4 Sublingual 5 Transdermic 6 Rectal 7 Other Custom alignment: RH
1437	sae_tre_sdate2_f2 Show the field ONLY if: [sae_tre_name2_f2] <> "	2. Start date (dd/mm/yyyy)	text (date_dmy) Custom alignment: RH
1438	sae_tre_edate2_f2 Show the field ONLY if: [sae_tre_name2_f2] <> "	2. Stop date (dd/mm/yyyy)	text (date_dmy) Custom alignment: RH
1439	sae_tre_ong_2_f2 Show the field ONLY if: [sae_tre_name2_f2] <> "		radio 1 ongoing Custom alignment: RH
1440	sae_tre_name3_f2 Show the field ONLY if: [sae_tre_stat_f2] = '2'	3. Name	text Custom alignment: RH
1441	sae_tre_dose3_f2 Show the field ONLY if: [sae_tre_name3_f2] <> "	3. Daily dose and unit	text Custom alignment: RH
1442	sae_tre_route3_f2 Show the field ONLY if: [sae_tre_name3_f2] <> "	3. Route	dropdown 1 OS 2 Parenteral 3 Inhalation 4 Sublingual 5 Transdermic 6 Rectal 7 Other Custom alignment: RH
1443	sae_tre_sdate3_f2 Show the field ONLY if: [sae_tre_name3_f2] <> "	3. Start date (dd/mm/yyyy)	text (date_dmy) Custom alignment: RH
1444	sae_tre_edate3_f2 Show the field ONLY if: [sae_tre_name3_f2] <> "	3. Stop date (dd/mm/yyyy)	text (date_dmy) Custom alignment: RH
1445	sae_tre_ong_3_f2 Show the field ONLY if: [sae_tre_name3_f2] <> "		radio 1 ongoing Custom alignment: RH
1446	sae_tre_name4_f2 Show the field ONLY if: [sae_tre_stat_f2] = '2'	4. Name	text Custom alignment: RH
1447	sae_tre_dose4_f2 Show the field ONLY if: [sae_tre_name4_f2] <> "	4. Daily dose and unit	text Custom alignment: RH

1448	<div>sae_tre_route4_f2</div> <div>Show the field ONLY if: [sae_tre_name4_f2] <> "</div>	4. Route	<div>dropdown</div> <div><div>1</div><div>OS</div></div> <div><div>2</div><div>Parenteral</div></div> <div><div>3</div><div>Inhalation</div></div> <div><div>4</div><div>Sublingual</div></div> <div><div>5</div><div>Transdermic</div></div> <div><div>6</div><div>Rectal</div></div> <div><div>7</div><div>Other</div></div> <div>Custom alignment: RH</div>
1449	<div>sae_tre_sdate4_f2</div> <div>Show the field ONLY if: [sae_tre_name4_f2] <> "</div>	4. Start date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>
1450	<div>sae_tre_edeate4_f2</div> <div>Show the field ONLY if: [sae_tre_name4_f2] <> "</div>	4. Stop date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>
1451	<div>sae_tre_ong_4_f2</div> <div>Show the field ONLY if: [sae_tre_name4_f2] <> "</div>		<div>radio</div> <div><div>1</div><div>ongoing</div></div> <div>Custom alignment: RH</div>
1452	<div>sae_tre_name5_f2</div> <div>Show the field ONLY if: [sae_tre_stat_f2] = '2'</div>	5. Name	<div>text</div> <div>Custom alignment: RH</div>
1453	<div>sae_tre_dose5_f2</div> <div>Show the field ONLY if: [sae_tre_name5_f2] <> "</div>	5. Daily dose and unit	<div>text</div> <div>Custom alignment: RH</div>
1454	<div>sae_tre_route5_f2</div> <div>Show the field ONLY if: [sae_tre_name5_f2] <> "</div>	5. Route	<div>dropdown</div> <div><div>1</div><div>OS</div></div> <div><div>2</div><div>Parenteral</div></div> <div><div>3</div><div>Inhalation</div></div> <div><div>4</div><div>Sublingual</div></div> <div><div>5</div><div>Transdermic</div></div> <div><div>6</div><div>Rectal</div></div> <div><div>7</div><div>Other</div></div> <div>Custom alignment: RH</div>
1455	<div>sae_tre_sdate5_f2</div> <div>Show the field ONLY if: [sae_tre_name5_f2] <> "</div>	5. Start date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>
1456	<div>sae_tre_edeate5_f2</div> <div>Show the field ONLY if: [sae_tre_name5_f2] <> "</div>	5. Stop date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>
1457	<div>sae_tre_ong_5_f2</div> <div>Show the field ONLY if: [sae_tre_name5_f2] <> "</div>		<div>radio</div> <div><div>1</div><div>ongoing</div></div> <div>Custom alignment: RH</div>
1458	<div>sae_tre_name6_f2</div> <div>Show the field ONLY if: [sae_tre_stat_f2] = '2'</div>	6. Name	<div>text</div> <div>Custom alignment: RH</div>
1459	<div>sae_tre_dose6_f2</div> <div>Show the field ONLY if: [sae_tre_name6_f2] <> "</div>	6. Daily dose and unit	<div>text</div> <div>Custom alignment: RH</div>
1460	<div>sae_tre_sdate6_f2</div> <div>Show the field ONLY if: [sae_tre_name6_f2] <> "</div>	6. Start date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>
1461	<div>sae_tre_edeate6_f2</div> <div>Show the field ONLY if: [sae_tre_name5_f2] <> "</div>	6. Stop date <i>(dd/mm/yyyy)</i>	<div>text (date_dmy)</div> <div>Custom alignment: RH</div>
1462	<div>sae_tre_ong_6_f2</div> <div>Show the field ONLY if: [sae_tre_name6_f2] <> "</div>		<div>radio</div> <div><div>1</div><div>ongoing</div></div> <div>Custom alignment: RH</div>

1463	sae_tre_name7_f2 Show the field ONLY if: [sae_tre_stat_f2] = '2'	7. Name	text Custom alignment: RH
1464	sae_tre_dose7_f2 Show the field ONLY if: [sae_tre_name7_f2] <> "	7. Daily dose and unit	text Custom alignment: RH
1465	sae_tre_sdate7_f2 Show the field ONLY if: [sae_tre_name7_f2] <> "	7. Start date <i>(dd/mm/yyyy)</i>	text (date_dmy) Custom alignment: RH
1466	sae_tre_edate7_f2 Show the field ONLY if: [sae_tre_name7_f2] <> "	7. Stop date <i>(dd/mm/yyyy)</i>	text (date_dmy) Custom alignment: RH
1467	sae_tre_ong_7_f2 Show the field ONLY if: [sae_tre_name7_f2] <> "		radio <div><div>1</div> ongoing</div> Custom alignment: RH
1468	sae_tre_name8_f2 Show the field ONLY if: [sae_tre_stat_f2] = '2'	8. Name	text Custom alignment: RH
1469	sae_tre_dose8_f2 Show the field ONLY if: [sae_tre_name8_f2] <> "	8. Daily dose and unit	text Custom alignment: RH
1470	sae_tre_sdate8_f2 Show the field ONLY if: [sae_tre_name8_f2] <> "	8. Start date <i>(dd/mm/yyyy)</i>	text (date_dmy) Custom alignment: RH
1471	sae_tre_edate8_f2 Show the field ONLY if: [sae_tre_name8_f2] <> "	8. Stop date <i>(dd/mm/yyyy)</i>	text (date_dmy) Custom alignment: RH
1472	sae_tre_ong_8_f2 Show the field ONLY if: [sae_tre_name8_f2] <> "		radio <div><div>1</div> ongoing</div> Custom alignment: RH
1473	sae_report_date_f2	Section Header: _____ DATE OF REPORT <i>(dd/mm/yyyy)</i>	text (date_dmy) Custom alignment: RH
1474	sae_report_f2	REPORTED BY <i>(full name)</i>	text Custom alignment: RH
1475	sae_invest_f2	INVESTIGATOR <i>(If different from reporter) (full name)</i>	text
1476	sae_signat_f2	Signature <i>(please, draw signature with mouse or finger)</i>	file (signature) Custom alignment: RH
1477	sae_indic_titolo_3	To send the notification of the SAE form to the Sponsor safety desk, click Save. Please, complete the SAE form with all information available before saving.	descriptive
1478	serious_averse_event_follow_up_report_2_complete	Section Header: <i>Form Status</i> Complete?	dropdown <div><div>0</div> Incomplete</div> <div><div>1</div> Unverified</div> <div><div>2</div> Complete</div>

Instrument: **UNBLINDING FORM** (unblinding_form)[^ Collapse](#)

1479	alert_ubf	Please, note that unblinding of patients' treatment allocation should occur only in exceptional circumstances. The Investigator is encouraged to maintain the blind as far as possible and to discuss the possibility to break the code.	descriptive				
1480	date_cb	Date of patient code break:	text (date_dmy)				
1481	discussed	The unblinding procedure was discussed?	radio <table><tr><td>1</td><td>yes</td></tr><tr><td>2</td><td>no</td></tr></table> Custom alignment: RH	1	yes	2	no
1	yes						
2	no						
1482	alert_disclosed	Please, remember that in no case the treatment arm must be disclosed to the patient, other study personnel, both verbally and in written form.	descriptive				

1483	reason_cb	Reason for unblinding procedure?	dropdown 1 safety 2 other Custom alignment: RH
1484	reason_cb_specify Show the field ONLY if: [reason_cb]=2	Please, specify	text Custom alignment: RH
1485	continue_study	Did the patient continue the study treatment after the code break?	radio 1 yes 2 no Custom alignment: RH
1486	unblinding_form_complete	Section Header: <i>Form Status</i> Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: WITHDRAWAL FORM (withdrawal_form)			^ Collapse
1487	withdrawal_date	Date of withdrawal/drug discontinuation	text (date_dmy)
1488	withdrawal_reason	Reason for withdrawal	dropdown 1 Toxicity* 2 Deterioration of clinical conditions or clinical decision 3 Patient decision** 4 Lost to follow-up 5 Death 6 Consent withdrawal 7 Non compliance 8 Pregnancy or intent to become pregnant 9 Logistic organization
1489	wf_toxicity Show the field ONLY if: [withdrawal_reason]=1	Is the toxicity event serious?	dropdown 1 Yes 2 no
1490	wf_p_dec Show the field ONLY if: [withdrawal_reason]=3	** If patient decision, please specify:	text
1491	withdrawal_form_complete	Section Header: <i>Form Status</i> Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete