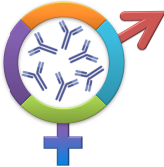





TITLE	  <p>Promoting gender equality in H2020 and the ERA</p>   <p><small>This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 741874.</small></p> <p align="center">CRF - 02 Registration and baseline</p>
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1. Patient registration

Date of registration / /
Month Day Year

Patient key

Only record in the paper form. Not necessary in the web database: the information is automatically generated.

2. Patient data

Sex (biological make up)

- Female
- Male
- Intersex
- Transexual. Specify:
 - Male to Female
 - Female to Male

Cancer type (check one)

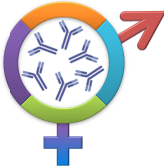


- Melanoma
- Lung
- Head and neck
- Breast
- Renal
- Other urogenital
Spec. _____

Age at time of consent _____

3. Medical conditions

Parameter	Unit	Result
Height	Cm	
Weight	Kg	
BMI (<i>authomatic calculation</i>)	Kg/m ²	
Body surface	m ²	
Waist Circumference	Cm	
Body Temperature	°C	
Respiratory rate	breaths/minute	
Heart rate	beats/minute	
Systolic Blood Pressure	mmHg	
Diastolic Blood Pressure	mmHg	
Blood oxygen saturation	%	

Patient code

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ECOG performance status

- 0
- 1
- 2

Female reproductive status

- Fertility
- Pre-menopause or Menopause <2 years
- Menopause ≥2 years
- Unknown or Not Reported

Comorbidities

ICD-10 number Letter (A to Z) Number

—

Instructions: comorbidities according to clinical judgement.
ICD-10 Version: 2016
https://en.wikipedia.org/wiki/ICD-10_Chapter_V:_Mental_and_behavioural_disorders
<https://icd.who.int/browse10/2016/en>

General physical examination

Not done

If abnormal, describe briefly

If done:

- Normal
- Abnormal

Allergies

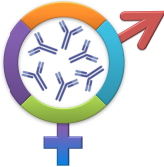



- No
- Yes

If Yes, specify: _____

Appendectomy

- No
- Yes

Patient code

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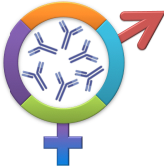


4. Clinical history

Autoimmune disorders No Yes

If yes, specify type:

	Status	Grade
<input type="checkbox"/> Type 1 diabetes	<input type="checkbox"/> Active <input type="checkbox"/> Inactive <input type="checkbox"/> Pathology not present	
<input type="checkbox"/> Inflammatory bowel disease (IBD)	<input type="checkbox"/> Active <input type="checkbox"/> Inactive <input type="checkbox"/> Pathology not present	
<input type="checkbox"/> Rheumatoid arthritis	<input type="checkbox"/> Active <input type="checkbox"/> Inactive <input type="checkbox"/> Pathology not present	
<input type="checkbox"/> Psoriasis/psoriatic arthritis <input type="checkbox"/> Other reumathological disorders	<input type="checkbox"/> Active <input type="checkbox"/> Inactive <input type="checkbox"/> Pathology not present	
<input type="checkbox"/> Systemic lupus erythematosus (SLE) <input type="checkbox"/> Other immunological disorders	<input type="checkbox"/> Active <input type="checkbox"/> Inactive <input type="checkbox"/> Pathology not present	
<input type="checkbox"/> Multiple sclerosis	<input type="checkbox"/> Active <input type="checkbox"/> Inactive <input type="checkbox"/> Pathology not present	
<input type="checkbox"/> Coeliac disease	<input type="checkbox"/> Active <input type="checkbox"/> Inactive <input type="checkbox"/> Pathology not present	
<input type="checkbox"/> Graves' disease/Hashimoto's thyroiditis	<input type="checkbox"/> Active <input type="checkbox"/> Inactive <input type="checkbox"/> Pathology not present	
<input type="checkbox"/> Other _____	<input type="checkbox"/> Active <input type="checkbox"/> Inactive <input type="checkbox"/> Pathology not present	

Patient code

TITLE	  GENDER-NET Plus Promoting gender equality in H2020 and the ERA G-DEFINER  <small>This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 741814.</small>
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Previous treatment for primary cancer diagnosis

No Yes

If yes, specify:

Surgery No Yes

RT No Yes

CT No Yes

ICI No Yes

Other treatment

If previous ICI, specify:

CTLA-4

PD-1

PD-L1

Other (spec)

Setting:

Neoadjuvant

Adjuvant

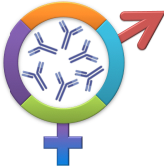



Advanced disease

Lines: 1st 2nd >2nd

Maintenance

Notes: _____

Patient code

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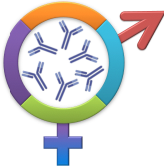


5. Cancer type

Cancer type	Clinical stage at ICI start (1)			Histology
	T	N	M (2)	
<input type="checkbox"/> Melanoma				<input type="checkbox"/> Cutaneous melanoma <ul style="list-style-type: none"> <input type="checkbox"/> Superficial spreading <input type="checkbox"/> Lentigo maligna <input type="checkbox"/> Nodular <input type="checkbox"/> Acral <input type="checkbox"/> Melanoma with unknown primary <input type="checkbox"/> Mucosal melanoma <input type="checkbox"/> Uveal melanoma <input type="checkbox"/> Unknown or Not Reported
<input type="checkbox"/> Lung				<input type="checkbox"/> Small cell l.c. <input type="checkbox"/> Squamous NSCLC <input type="checkbox"/> Non squamous NSCLC <input type="checkbox"/> Other <input type="checkbox"/> Unknown or Not Reported
<input type="checkbox"/> Head and neck				<input type="checkbox"/> Squamous cell <input type="checkbox"/> Non squamous cell <input type="checkbox"/> Unknown or Not Reported
<input type="checkbox"/> Renal				<input type="checkbox"/> Clear cell <input type="checkbox"/> Papillar <input type="checkbox"/> Other <input type="checkbox"/> Unknown or Not Reported
<input type="checkbox"/> Other urogenital _____				<input type="checkbox"/> Urothelial <input type="checkbox"/> Other <input type="checkbox"/> Unknown or Not Reported
<input type="checkbox"/> Breast				<input type="checkbox"/> Adenocarcinoma <input type="checkbox"/> Other <input type="checkbox"/> Unknown or Not Reported

(1) For adjuvant ICI, indicate clinical stage before radical curative intent.

(2) M0, M+ (specify a, b, c)

Patient code

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6. "ICI and other oncologic treatments"

Instructions: Register here information related to ICI, CT, RT and targeted therapy as prescribed. Additional information on ICI (e.g. dates, doses, scheduling) must be registered in section "ICI and oncologic treatments log" (paper CRF09).

ICI treatment

Setting

- Neoadjuvant
- Adjuvant
- Advanced disease
- Maintenance

If advanced disease, specify line:

- 1st
- 2nd
- >2nd

ICI type (multiple choice is possible)

- CTLA-4
- PD-1
- PD-L1

Drug name _____

Dose (mg/Kg) _____

Dose (mg) (Total mg only for drugs approved at flat dose) _____
 number of cycles _____ every _____ days

- CTLA-4
- PD-1
- PD-L1

Drug name _____

Dose (mg/Kg) _____

Dose (mg) (Total mg only for drugs approved at flat dose) _____
 number of cycles _____ every _____ days


Other (spec)

Drug name _____


Dose (mg/Kg) _____

Dose (mg) (Total mg only for drugs approved at flat dose) _____
 number of cycles _____ every _____ days

Patient code

TITLE	 <p style="text-align: center;">CRF - 02 Registration and baseline</p>
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Patient code

TITLE	 <p style="text-align: center;">CRF - 02 Registration and baseline</p>
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Concomitant oncologic treatments

Chemotherapy Yes No

If yes specify

Type _____

number of cycles _____

Targeted therapy Yes No

If yes specify

type _____

number of cycles _____


Radiotherapy Yes No

If yes specify

type _____

Location _____

Patient code

TITLE	 <p style="text-align: center;">CRF - 02 Registration and baseline</p>
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7. Gender-related characteristics

Personal sense of being

- Woman
- Man
- Neutral
- Other Specify _____
- Unknown or Not Reported

Ethnicity/Race

Are you of Hispanic, Latino, or of Spanish origin?"

- Yes
- No
- Unknown or Not Reported

How would you describe yourself?

- American Indian or Alaska Native
- Asian
- Black or African American
- Native Hawaiian or other Pacific Island
- White
- Asian
- Multiracial (check at least 2)
- Unknown or Not Reported

Marital status

- Married / unmarried couple
- Divorced /Separated
- Widowed
- Never married
- Unknown or Not Reported

Living arrangement

- Alone
- With partner
- With partner and children
- With children
- With parent/s
- With parent/s & siblings
- Other
- Unknown or Not Reported

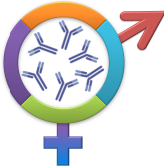


Occupational status

- Worker
- Unemployed
- Student
- Care family
- Retired
- Other _____
- Unknown or Not Reported

If worker, occupation type

- Sales/clerical/service
- Mechanic/operator/agriculture
- Managerial
- Teaching
- Other _____
- Unknown or Not Reported

Patient code

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Highest educational level completed:

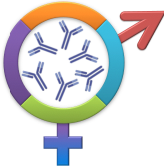



- Low (less than high school or ≤ 9 years)
- Intermediate (high school or 10-12 years)
- High (≥ 13 years)
- Graduation
- More than graduation (PhD/Master/Other)
- Unknown or Not Reported

Monthly household income (Euro)

>5000?	<input type="checkbox"/> Yes	>7000?	<input type="checkbox"/> Yes	>10000?	<input type="checkbox"/> Yes	
			<input type="checkbox"/> No		<input type="checkbox"/> No	
			<input type="checkbox"/> Unk/NR		<input type="checkbox"/> Unk/NR	
	<input type="checkbox"/> No	>3000?	<input type="checkbox"/> Yes			
			<input type="checkbox"/> No	>2000?	<input type="checkbox"/> Yes	
			<input type="checkbox"/> Unk/NR		<input type="checkbox"/> No	
					<input type="checkbox"/> Unk/NR	
	<input type="checkbox"/> Unk/NR					

Unk/NR: Unknown or Not Reported

Patient code

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8. Behavioral health factors

Smoker

- Never smoked
- Former
- Current
- Unknown or Not Reported

If former or current:

Average N. cigarettes per day

Total years as smoker

Pack-years _____

Alcohol drinker (beer, wine, spirits)

- No
- Former
- Current
- Unknown or Not Reported

If Former or Current:

Total years as drinker

- 1 drink/day
- 2-3 drinks/day
- 4 or more drinks/day

Physical activity

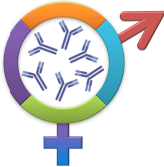


- Inactive
- Active
- Unknown or Not Reported

If Active:*

- Very low intensity
- Low intensity
- Moderate intensity
- High intensity

* Very low intensity (occasionally); Low intensity (e.g. gym 1 time/week); moderate intensity (e.g. gym 2/3 times/week, running); High intensity (e.g. daily activities);

Patient code

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Document history

Version N.	Date	Reviewer	Details of changes
0.1	February 26th 2019	RM	Creation unique document for all paper CRFs
0.2	March 22nd 2019	RM +G Lo Russo	Expanded sections gender. Unique document for all paper CRFs
0.3	May 21st 2019	RM	Added drugs associated to microbioma. Unique document for all paper CRFs.
1.0	May 29 th 2019	RM	Split documents, separated CRFs for the different sections. Added fup
2.0	June 20th 2019	RM	Added gender section
2.1	August 16th 2019	Naoise Kelly	1. Autoimmune disorders (added status, grade); 2.
2.2	September 6th 2019	RM	Comorbidities: no list of pre-defined comorbidities but dynamic sequence of ICD numbers
3.0	September 12nd 2019	RM	Eliminated info on ICI treatment and concomitant oncologic treatments from CRF02 and included in the new CRF09 as a separate treatment log. Eliminated concomitant medications and included in the new CRF10 as a separate log.
3.1	October 11th 2019	Meeting with partners	Curative RT may be included.

Patient code