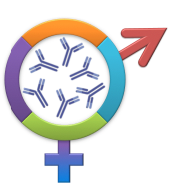
TITLE	  This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 741874 **CRF - 01 - screening and informed consent**
Document type	**Form**
Version number	**4.0**
Date	**January 20th 2020**

Site : ☐INT ☐DCU-SVUH ☐ OUH ☐ Onk-Pat KI

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

Informed consent

☐Obtained
☐Refused

Date of signature ☐☐ / ☐☐ / ☐☐☐☐
Month *Day* *Year*

Motivation for refusal:

Date and number of current protocol version _____

Date and number of current informed consent version _____

In case of informed consent refusal:

Consent to register personal data
☐Obtained
☐Refused

If consent to register personal data obtained**:**

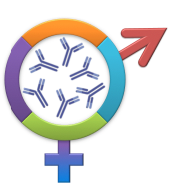
Sex (biological make up)
☐Female
☐Male
☐ Intersex
☐ Transexual. Specify:
☐ Male to Female
☐ Female to Male

Cancer type (check one)
☐Melanoma
☐Lung
☐Head and neck
☐Breast
☐Renal
☐Other urogenital Spec._____

Age at time of consent_____

Screening

Patient code ☐☐☐☐☐☐☐☐☐☐

TITLE	  **CRF - 01 - screening and informed consent**
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Date of assessment

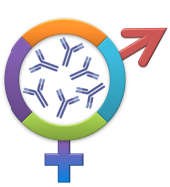
☐☐ / ☐☐ / ☐☐☐☐*

Month *Day* *Year*

Inclusion Criteria

Patients who meet ***all*** of the following criteria are eligible for enrollment as study participants:

	Yes	No
1. Signed informed consent.		
2. Histologically confirmed diagnosis of: melanoma, lung cancer, head and neck cancer, urogenital cancer, renal and breast cancer		
3. ICI therapy (either as single agent or in combination; combination of ICI and chemotherapy; combination of ICI and radiotherapy).		
4. Patient age ≥18 years		
5. Eastern Cooperative Oncology Group (ECOG) Performance Status of 0-2.		
6. Adequate bone marrow, liver and renal function.		
7. Life expectancy of at least 12 weeks.		

TITLE	  This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 741874 **CRF - 01 - screening and informed consent**
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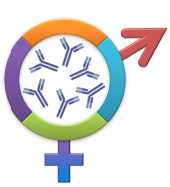
Exclusion Criteria

Patients not eligible for ICI-containing regimens.

Screening result

Is this patient a screening failure? ☐ Yes ☐ No
If yes, update the "Off Study" form

TITLE	  This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 741874 **CRF - 01 - screening and informed consent**
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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 29th 2019	RM	Split documents, separated CRFs for the different sections. Added fup
2.0	August 16th 2019	Naoise Kelly, RM	Order modification and added document history. Eliminated exclusion criteria and inclusion n.6 (not necessary, specification of diseases) (Naoise: "As Alex had previously mentioned once a patient has been deemed eligible to receive the ICI do we still need all these exclusion criteria. Keep criteria 8. " (only inclusion)". Patient data sectin included in CRF02.
3.0	September 26th 2019	RM	Added: 1) for patients not signing the informed consent data such sex, age and disease information, collected only if explicitly authorized by the patient. 2) inclusion criteria: possibility to recruit pts with combination ICI+RT. Exclusion criteria: no additional criteria; patients not eligible for ICI-containing regimens are not eligible for the study.
4.0	January 20th 2020	RM	Eliminated "reason for screening failure", which in included in CRF08 "off study"