


<b>TITLE</b>	 <p><b>GENDER-NET Plus</b> Promoting gender equality in H2020 and the ERA</p> <p><b>G-DEFINER</b></p> <p><small>This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 741814.</small></p> <p align="center"><b>CRF – 04 - Lab Tests and concomitant medications</b></p>
<b>Document type</b>	<b>Form</b>
<b>Version number</b>	<b>2.1</b>
<b>Date</b>	<b>January 13<sup>th</sup> 2020</b>

**Lab tests and concomitant medications**

*Instructions: register data of tests performed before any ICI administration. If the patient is experiencing any irAEs, please fill out AE log.*

**Time**

- Baseline (before starting treatment)
- At second infusion
- Occurrence of first irAE G≥3
- Not scheduled\*

**Date**

/  /   
 Month      Day      Year

*\* Tick if wishing to register the lab tests and concomitant medications pertaining to a time period other than baseline, 2<sup>nd</sup> infusion, 1<sup>st</sup> irAE G≥3.*

**Fasting**

- Yes
- No

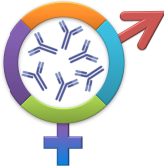


**Pregnancy test results:**

- Positive
- Negative
- Not available
- Not applicable

**ECOG performance status**

- 0  1  2  Not done

**Patient code**

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**Hematology Lab tests**

Tests carried out at Lab: \_\_\_\_\_

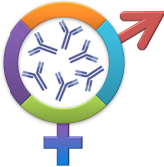


Test	Value	Unit	Classification*	Not done
White Blood Cell Count (WBC)			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Red Blood Cell Count (RBC)			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Platelets			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Hematocrit			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Hemoglobin			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Mean Corpuscular Volume (MCV)			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Mean Corpuscular Hemoglobin (MCH)			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Mean Corpuscular Hemoglobin Concentration (MCHC)(automatic calculation)			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Prothrombin time (PT)			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
PTT/aPTT			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Fibrinogen			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
International Normalized Ratio (INR)			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Thrombin			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>

	% Value	Absolute value	Unit	Classification*	Not done
Neutrophils				<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Lymphocytes				<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Monocytes				<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Eosinophils				<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Basophils				<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>

\* Low: below the lower limit; normal: within the normal range; High: above the upper limit.

NOTES: \_\_\_\_\_

Patient code

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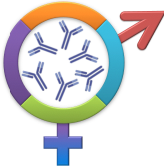


**Chemistry Lab tests**

Tests carried out at Lab: \_\_\_\_\_

Test	Value	Unit	Classification*	Not done
Sodium			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Potassium			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Chloride			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
CO2			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Creatinine			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Calcium			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
BUN or Urea			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
SGOT/AST			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
SGPT/ALT			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Alkaline Phosphatase			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Total bilirubin			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Albumin			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Amylase			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Glucose			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
LDH			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
LDL Cholesterol			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
HDL Cholesterol			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Cholesterol tot			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Triglycerides			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Glucose			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Creatinine Clearance Rate (automatic calculation)			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
eGFR)(automatic calculation)			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
C-reactive protein (CRP)			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>

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<b>Hormones Lab tests</b>
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Tests carried out at Lab: \_\_\_\_\_

<b>Test</b>	<b>Value</b>	<b>Unit</b>	<b>Classification*</b>	<b>Not done</b>
Thyroid Stimulating Hormone (TSH)			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
FT3			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
FT4			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Adrenocorticotrophic hormone (ACTH)			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Growth Hormone (GH)			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Prolactin			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Testosterone			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Cortisol			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Luteinizing hormone (LH)			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Follicle-stimulating hormone (FSH)			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Progesterone			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>
Oestradiol**			<input type="checkbox"/> Low <input type="checkbox"/> Normal <input type="checkbox"/> High	<input type="checkbox"/>

\* Low: below the lower limit; normal: within the normal range; High: above the upper limit.

\*\* Synonyms: E2, 17-β-oestradiol.

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## Concomitant medications

**Instructions: In general, medications administered within 7 days of the present visit . For Systemic antibiotics, type and time in days since last assumption.**


Associated with microbiome	Check if Yes	Reason for use	Check if continuing*
Systemic antibiotics If yes, specify: Type _____ Time (days) since last assumption _____			
Proton pump inhibitors			
Metformin			
NSAIDs and aspirin			
Statins			
Benzodiazepines			
Antidepressants			
Antihistamines			
Opioids			
Antipsychotics			
Osmotic laxatives			
Inflammatory bowel treatment			
Female hormones			
Systemic Steroid Treatment			
Other hormones			
Specify _____			

\* At baseline, means that the medication was taken pretreatment.

**Other concomitant medications**  Yes  No

If yes, please specify \_\_\_\_\_

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#### Document history

Version N.	Date	Reviewer	Details of changes
0.1	June 19th 2019	RM	First version
1.0	July 18th 2019	RM	Added concomitant medications associated with microbioma
1.1	August 16th 2019	Naoise Kelly	Some requests about lab ranges, fasting, concomitant medications changes from baseline
2.0	October 8th 2019	RM	Newly included 1) option for specifying fasting, 2) classification low, normal, high, eliminated times (first y and 2 <sup>nd</sup> y).
2.1	January 13th 2020	RM	1) Title changed, from "CRF – 04 - Lab Tests" to "CRF – 04 - Lab Tests and concomitant medications" because actually the form includes also concomitant medication info (cyclic). Notice: eliminated previous form "CRF 10 - Concomitant medications log - 0.1 08.10.2019" . 2) Systemic antibiotics: if yes, it is possible to specify type and the days from last assumption (if less than 1 month influences microbiota)

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