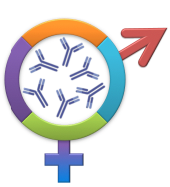
TITLE	  **CRF 05 - Questionnaires distress and health**
Document type	**Form**
Version number	**0.4**
Date	**October 8th 2019**

Time

☐ Baseline (before starting treatment)
☐ At second infusion
☐ Occurrence of fist irAE G≥3
☐ Not scheduled*

Date

☐☐ / ☐☐ / ☐☐☐☐
Month *Day* *Year*

** Tick if wishing to register the questionnaires pertaining to a time period other than baseline, 2nd infusion, 1st irAE G≥3.*

If the patient did not INTENTIONALLY fill out the questionnaire at any of the scheduled 3 time periods, please specify the reason:

_____

ECOG performance status

☐ 0 ☐ 1 ☐ 2 ☐ Not done

Distress questionnaire

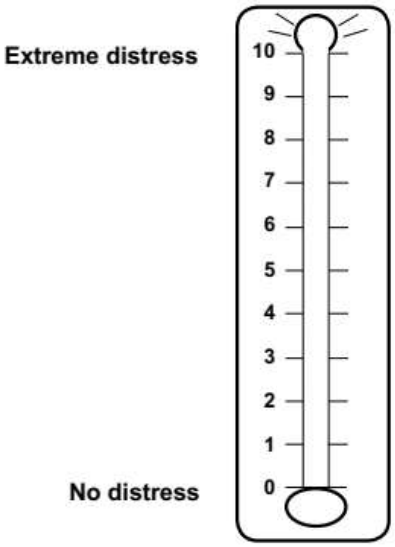
TITLE	CRF 05 - Questionnaires distress and health
Document type	Form
Version number	0.4
Date	October 8th 2019

National Comprehensive Cancer Network®

NCCN Distress Thermometer and Problem List for Patients

NCCN DISTRESS THERMOMETER

Instructions: Please circle the number (0–10) that best describes how much distress you have been experiencing in the past week including today.



PROBLEM LIST

Please indicate if any of the following has been a problem for you in the past week including today.

Be sure to check YES or NO for each.

YES	NO	Practical Problems
❑	❑	Child care
❑	❑	Housing
❑	❑	Insurance/financial
❑	❑	Transportation
❑	❑	Work/school
❑	❑	Treatment decisions

YES	NO	Family Problems
❑	❑	Dealing with children
❑	❑	Dealing with partner
❑	❑	Ability to have children
❑	❑	Family health issues

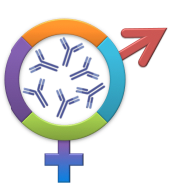
YES	NO	Emotional Problems
❑	❑	Depression
❑	❑	Fears
❑	❑	Nervousness
❑	❑	Sadness
❑	❑	Worry
❑	❑	Loss of interest in usual activities

YES	NO	Spiritual/religious concerns
❑	❑	

YES	NO	Physical Problems
❑	❑	Appearance
❑	❑	Bathing/dressing
❑	❑	Breathing
❑	❑	Changes in urination
❑	❑	Constipation
❑	❑	Diarrhea
❑	❑	Eating
❑	❑	Fatigue
❑	❑	Feeling swollen
❑	❑	Fevers
❑	❑	Getting around
❑	❑	Indigestion
❑	❑	Memory/concentration
❑	❑	Mouth sores
❑	❑	Nausea
❑	❑	Nose dry/congested
❑	❑	Pain
❑	❑	Sexual
❑	❑	Skin dry/itchy
❑	❑	Sleep
❑	❑	Substance use
❑	❑	Tingling in hands/feet

Other Problems: _____

_____

TITLE	  This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 741874 **CRF 05 - Questionnaires distress and health**
Document type	**Form**
Version number	**0.4**
Date	**October 8th 2019**

Health questionnaire EQ-5D-5L

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

- I have no problems in walking about ❑
- I have slight problems in walking about ❑
- I have moderate problems in walking about ❑
- I have severe problems in walking about ❑
- I am unable to walk about ❑

SELF-CARE

- I have no problems washing or dressing myself ❑
- I have slight problems washing or dressing myself ❑
- I have moderate problems washing or dressing myself ❑
- I have severe problems washing or dressing myself ❑
- I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

- I have no problems doing my usual activities ❑
- I have slight problems doing my usual activities ❑
- I have moderate problems doing my usual activities ❑
- I have severe problems doing my usual activities ❑
- I am unable to do my usual activities ❑

PAIN / DISCOMFORT

- I have no pain or discomfort ❑
- I have slight pain or discomfort ❑
- I have moderate pain or discomfort ❑
- I have severe pain or discomfort ❑
- I have extreme pain or discomfort ❑

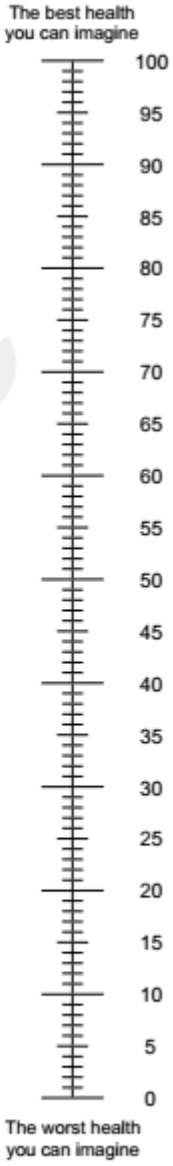
ANXIETY / DEPRESSION

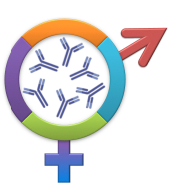
- I am not anxious or depressed ❑
- I am slightly anxious or depressed ❑
- I am moderately anxious or depressed ❑
- I am severely anxious or depressed ❑
- I am extremely anxious or depressed ❑

Patient key ☐☐☐☐☐☐☐☐☐☐

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



TITLE	  **CRF 05 - Questionnaires distress and health**
Document type	**Form**
Version number	**0.4**
Date	**October 8th 2019**

Document history

Version N.	Date	Reviewer	Details of changes
0.1	20th June 2019	RM	First creation
0.2	18th July 2019	RM	New item to allow specification of whether the patients did not answered to the questionnaires
0.3	September 26th 2019	RM	Modified the new item to allow specification of whether the patients did not answered to the questionnaires at pre-specified timesbaseline, 2nd infusion and occurrence of first irAE G≥3.
0.4	October 8th 2019	RM	Eliminated the above new item and included option ”not scheduled” in ”time” to be checked if the questionnaires are registered at a different time period respecto to those listed. Eliminated times (first y and 2nd y)