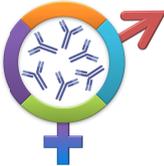


| | |
|-----------------------|--|
| TITLE |   <p>Promoting gender equality in H2020 and the ERA</p>  <p><small>This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 741874.</small></p> <p align="center">CRF 05 - Questionnaires distress and health</p> |
| Document type | Form |
| Version number | 0.4 |
| Date | October 8th 2019 |

Time

- Baseline (before starting treatment)
 At second infusion
 Occurrence of fist irAE G \geq 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 \geq 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

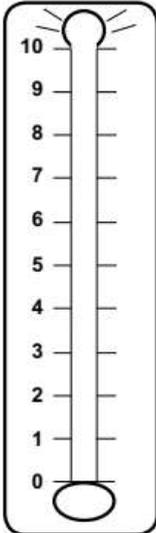
Distress questionnaire

Patient key

| | |
|----------------|--|
| TITLE |  <p style="text-align: center;">CRF 05 - Questionnaires distress and health</p> |
| Document type | Form |
| Version number | 0.4 |
| Date | October 8 th 2019 |



NCCN Distress Thermometer and Problem List for Patients

| <p>NCCN DISTRESS THERMOMETER</p> <p>Instructions: Please circle the number (0–10) that best describes how much distress you have been experiencing in the past week including today.</p> <div style="display: flex; align-items: center; justify-content: center; margin-top: 20px;"> <div style="text-align: right; margin-right: 10px;">Extreme distress</div>  <div style="text-align: left; margin-left: 10px;">No distress</div> </div> | <p>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.</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left; width: 50%;">YES NO <u>Practical Problems</u></th> <th style="text-align: left; width: 50%;">YES NO <u>Physical Problems</u></th> </tr> </thead> <tbody> <tr> <td><input type="checkbox"/> <input type="checkbox"/> Child care</td> <td><input type="checkbox"/> <input type="checkbox"/> Appearance</td> </tr> <tr> <td><input type="checkbox"/> <input type="checkbox"/> Housing</td> <td><input type="checkbox"/> <input type="checkbox"/> Bathing/dressing</td> </tr> <tr> <td><input type="checkbox"/> <input type="checkbox"/> Insurance/financial</td> <td><input type="checkbox"/> <input type="checkbox"/> Breathing</td> </tr> <tr> <td><input type="checkbox"/> <input type="checkbox"/> Transportation</td> <td><input type="checkbox"/> <input type="checkbox"/> Changes in urination</td> </tr> <tr> <td><input type="checkbox"/> <input type="checkbox"/> Work/school</td> <td><input type="checkbox"/> <input type="checkbox"/> Constipation</td> </tr> <tr> <td><input type="checkbox"/> <input type="checkbox"/> Treatment decisions</td> <td><input type="checkbox"/> <input type="checkbox"/> Diarrhea</td> </tr> <tr> <td></td> <td><input type="checkbox"/> <input type="checkbox"/> Eating</td> </tr> <tr> <td></td> <td><input type="checkbox"/> <input type="checkbox"/> Fatigue</td> </tr> <tr> <td></td> <td><input type="checkbox"/> <input type="checkbox"/> Feeling swollen</td> </tr> <tr> <td></td> <td><input type="checkbox"/> <input type="checkbox"/> Fevers</td> </tr> <tr> <td></td> <td><input type="checkbox"/> <input type="checkbox"/> Getting around</td> </tr> <tr> <td></td> <td><input type="checkbox"/> <input type="checkbox"/> Indigestion</td> </tr> <tr> <td></td> <td><input type="checkbox"/> <input type="checkbox"/> Memory/concentration</td> </tr> <tr> <td></td> <td><input type="checkbox"/> <input type="checkbox"/> Mouth sores</td> </tr> <tr> <td></td> <td><input type="checkbox"/> <input type="checkbox"/> Nausea</td> </tr> <tr> <td></td> <td><input type="checkbox"/> <input type="checkbox"/> Nose dry/congested</td> </tr> <tr> <td></td> <td><input type="checkbox"/> <input type="checkbox"/> Pain</td> </tr> <tr> <td></td> <td><input type="checkbox"/> <input type="checkbox"/> Sexual</td> </tr> <tr> <td></td> <td><input type="checkbox"/> <input type="checkbox"/> Skin dry/itchy</td> </tr> <tr> <td></td> <td><input type="checkbox"/> <input type="checkbox"/> Sleep</td> </tr> <tr> <td></td> <td><input type="checkbox"/> <input type="checkbox"/> Substance use</td> </tr> <tr> <td></td> <td><input type="checkbox"/> <input type="checkbox"/> Tingling in hands/feet</td> </tr> <tr> <td colspan="2" style="padding-top: 10px;"> <p style="text-align: center;"><u>Family Problems</u></p> <p><input type="checkbox"/> <input type="checkbox"/> Dealing with children</p> <p><input type="checkbox"/> <input type="checkbox"/> Dealing with partner</p> <p><input type="checkbox"/> <input type="checkbox"/> Ability to have children</p> <p><input type="checkbox"/> <input type="checkbox"/> Family health issues</p> </td> </tr> <tr> <td colspan="2" style="padding-top: 10px;"> <p style="text-align: center;"><u>Emotional Problems</u></p> <p><input type="checkbox"/> <input type="checkbox"/> Depression</p> <p><input type="checkbox"/> <input type="checkbox"/> Fears</p> <p><input type="checkbox"/> <input type="checkbox"/> Nervousness</p> <p><input type="checkbox"/> <input type="checkbox"/> Sadness</p> <p><input type="checkbox"/> <input type="checkbox"/> Worry</p> <p><input type="checkbox"/> <input type="checkbox"/> Loss of interest in usual activities</p> </td> </tr> <tr> <td colspan="2" style="padding-top: 10px;"> <p><input type="checkbox"/> <input type="checkbox"/> <u>Spiritual/religious concerns</u></p> </td> </tr> <tr> <td colspan="2" style="padding-top: 10px;"> <p>Other Problems: _____</p> </td> </tr> </tbody> </table> | YES NO <u>Practical Problems</u> | YES NO <u>Physical Problems</u> | <input type="checkbox"/> <input type="checkbox"/> Child care | <input type="checkbox"/> <input type="checkbox"/> Appearance | <input type="checkbox"/> <input type="checkbox"/> Housing | <input type="checkbox"/> <input type="checkbox"/> Bathing/dressing | <input type="checkbox"/> <input type="checkbox"/> Insurance/financial | <input type="checkbox"/> <input type="checkbox"/> Breathing | <input type="checkbox"/> <input type="checkbox"/> Transportation | <input type="checkbox"/> <input type="checkbox"/> Changes in urination | <input type="checkbox"/> <input type="checkbox"/> Work/school | <input type="checkbox"/> <input type="checkbox"/> Constipation | <input type="checkbox"/> <input type="checkbox"/> Treatment decisions | <input type="checkbox"/> <input type="checkbox"/> Diarrhea | | <input type="checkbox"/> <input type="checkbox"/> Eating | | <input type="checkbox"/> <input type="checkbox"/> Fatigue | | <input type="checkbox"/> <input type="checkbox"/> Feeling swollen | | <input type="checkbox"/> <input type="checkbox"/> Fevers | | <input type="checkbox"/> <input type="checkbox"/> Getting around | | <input type="checkbox"/> <input type="checkbox"/> Indigestion | | <input type="checkbox"/> <input type="checkbox"/> Memory/concentration | | <input type="checkbox"/> <input type="checkbox"/> Mouth sores | | <input type="checkbox"/> <input type="checkbox"/> Nausea | | <input type="checkbox"/> <input type="checkbox"/> Nose dry/congested | | <input type="checkbox"/> <input type="checkbox"/> Pain | | <input type="checkbox"/> <input type="checkbox"/> Sexual | | <input type="checkbox"/> <input type="checkbox"/> Skin dry/itchy | | <input type="checkbox"/> <input type="checkbox"/> Sleep | | <input type="checkbox"/> <input type="checkbox"/> Substance use | | <input type="checkbox"/> <input type="checkbox"/> Tingling in hands/feet | <p style="text-align: center;"><u>Family Problems</u></p> <p><input type="checkbox"/> <input type="checkbox"/> Dealing with children</p> <p><input type="checkbox"/> <input type="checkbox"/> Dealing with partner</p> <p><input type="checkbox"/> <input type="checkbox"/> Ability to have children</p> <p><input type="checkbox"/> <input type="checkbox"/> Family health issues</p> | | <p style="text-align: center;"><u>Emotional Problems</u></p> <p><input type="checkbox"/> <input type="checkbox"/> Depression</p> <p><input type="checkbox"/> <input type="checkbox"/> Fears</p> <p><input type="checkbox"/> <input type="checkbox"/> Nervousness</p> <p><input type="checkbox"/> <input type="checkbox"/> Sadness</p> <p><input type="checkbox"/> <input type="checkbox"/> Worry</p> <p><input type="checkbox"/> <input type="checkbox"/> Loss of interest in usual activities</p> | | <p><input type="checkbox"/> <input type="checkbox"/> <u>Spiritual/religious concerns</u></p> | | <p>Other Problems: _____</p> | |
|--|--|----------------------------------|---------------------------------|--|--|---|--|---|---|--|--|---|--|---|--|--|--|--|---|--|---|--|--|--|--|--|---|--|--|--|---|--|--|--|--|--|--|--|--|--|--|--|---|--|---|--|--|---|--|---|--|---|--|-------------------------------------|--|
| YES NO <u>Practical Problems</u> | YES NO <u>Physical Problems</u> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> <input type="checkbox"/> Child care | <input type="checkbox"/> <input type="checkbox"/> Appearance | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> <input type="checkbox"/> Housing | <input type="checkbox"/> <input type="checkbox"/> Bathing/dressing | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> <input type="checkbox"/> Insurance/financial | <input type="checkbox"/> <input type="checkbox"/> Breathing | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> <input type="checkbox"/> Transportation | <input type="checkbox"/> <input type="checkbox"/> Changes in urination | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> <input type="checkbox"/> Work/school | <input type="checkbox"/> <input type="checkbox"/> Constipation | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> <input type="checkbox"/> Treatment decisions | <input type="checkbox"/> <input type="checkbox"/> Diarrhea | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | <input type="checkbox"/> <input type="checkbox"/> Eating | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | <input type="checkbox"/> <input type="checkbox"/> Fatigue | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | <input type="checkbox"/> <input type="checkbox"/> Feeling swollen | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | <input type="checkbox"/> <input type="checkbox"/> Fevers | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | <input type="checkbox"/> <input type="checkbox"/> Getting around | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | <input type="checkbox"/> <input type="checkbox"/> Indigestion | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | <input type="checkbox"/> <input type="checkbox"/> Memory/concentration | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | <input type="checkbox"/> <input type="checkbox"/> Mouth sores | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | <input type="checkbox"/> <input type="checkbox"/> Nausea | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | <input type="checkbox"/> <input type="checkbox"/> Nose dry/congested | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | <input type="checkbox"/> <input type="checkbox"/> Pain | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | <input type="checkbox"/> <input type="checkbox"/> Sexual | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | <input type="checkbox"/> <input type="checkbox"/> Skin dry/itchy | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | <input type="checkbox"/> <input type="checkbox"/> Sleep | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | <input type="checkbox"/> <input type="checkbox"/> Substance use | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | <input type="checkbox"/> <input type="checkbox"/> Tingling in hands/feet | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p style="text-align: center;"><u>Family Problems</u></p> <p><input type="checkbox"/> <input type="checkbox"/> Dealing with children</p> <p><input type="checkbox"/> <input type="checkbox"/> Dealing with partner</p> <p><input type="checkbox"/> <input type="checkbox"/> Ability to have children</p> <p><input type="checkbox"/> <input type="checkbox"/> Family health issues</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p style="text-align: center;"><u>Emotional Problems</u></p> <p><input type="checkbox"/> <input type="checkbox"/> Depression</p> <p><input type="checkbox"/> <input type="checkbox"/> Fears</p> <p><input type="checkbox"/> <input type="checkbox"/> Nervousness</p> <p><input type="checkbox"/> <input type="checkbox"/> Sadness</p> <p><input type="checkbox"/> <input type="checkbox"/> Worry</p> <p><input type="checkbox"/> <input type="checkbox"/> Loss of interest in usual activities</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p><input type="checkbox"/> <input type="checkbox"/> <u>Spiritual/religious concerns</u></p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>Other Problems: _____</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

Version 2.2018, 02/23/18. The NCCN Clinical Practice Guidelines (NCCN Guidelines®) are a statement of evidence and consensus of the authors regarding their views of currently accepted approaches to treatment. Any clinician seeking to apply or consult the NCCN Guidelines is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient's care or treatment. The National Comprehensive Cancer Network® (NCCN®) makes no representations or warranties of any kind regarding their content, use or application and disclaims any responsibility for their application or use in any way. The NCCN Guidelines are copyrighted by National Comprehensive Cancer Network®. All rights reserved. The NCCN Guidelines and the illustrations herein may not be reproduced in any form without the express written permission of NCCN. ©2018.

| | |
|----------------|--|
| TITLE |  <p style="text-align: center;">CRF 05 - Questionnaires distress and health</p> |
| Document type | Form |
| Version number | 0.4 |
| Date | October 8 th 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

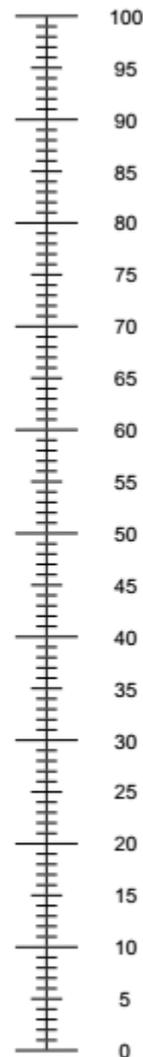
- I am not anxious or depressed
- I am slightly anxious or depressed
- I am moderately anxious or depressed
- I am severely anxious or depressed
- I am extremely anxious or depressed

| | |
|----------------|--|
| TITLE |  <p style="text-align: center;">CRF 05 - Questionnaires distress and health</p> |
| Document type | Form |
| Version number | 0.4 |
| Date | October 8 th 2019 |

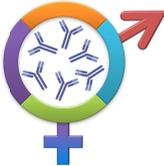
- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the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

YOUR HEALTH TODAY =

The best health
you can imagine



The worst health
you can imagine

| | |
|-----------------------|---|
| 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 741814.</small></p> <p>CRF 05 - Questionnaires distress and health</p> |
| 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 times: baseline, 2nd infusion and occurrence of first irAE G \geq 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 respect to those listed. Eliminated times (first y and 2 nd y) |

Patient key