Patient-Reported Outcomes CHECKLIST for New CONCEPTS

Are you planning to include patient-reported outcomes (PROs) and/or health-related quality of life (HRQL) in your trial?

- ☐ Yes, *please follow* ***pathway A***
- ☐ No, *please follow* ***pathway B***

*For more information, please refer to '**WHY INCLUDE HRQL AS AN ENDPOINT IN MY CANCER CLINICAL TRIAL?**'*

Definitions of patient-reported outcomes (PROs) and health-related quality of life (HRQL) and the relationship between the two can be found at the end of this document.

Pathway A: An analysis of PRO/HRQL is either being considered or some rationale has been proposed that supports its consideration.

1. What is your study design?

Trial

- ☐ Phase I
- ☐ Phase II non-randomised
- ☐ Phase II randomised
- ☐ Phase III
- ☐ Phase IV

Other

- ☐ Cross-sectional
- ☐ Prospective cohort
- ☐ Registry development
- ☐ PRO instrument validation
- ☐ Other

Please specify:

_____

2. Which PROs or aspects of HRQL are likely to be impacted by the study treatment/intervention (*choose all that apply*)?
   - ☐ Symptoms of disease
   - ☐ Side effects of treatment
   - ☐ Psychological symptoms (e.g. anxiety, depression, etc.)
   - ☐ Core aspects of function (e.g. physical, social, emotional, cognitive, behavioural, or role function)
   - ☐ Sexual function
   - ☐ Body image
   - ☐ Satisfaction with healthcare
   - ☐ Financial wellbeing
   - ☐ Other

   Please specify:

   _____

3. Do you plan to use a validated instrument to measure relevant PRO/HRQL?
   (*You may need to obtain permission, register use, pay fees, and check availability of language translations and e-versions*)
   - ☐ Yes

     Which one/s: _____
   - ☐ No

     Why?: _____
   - ☐ Unsure

4. Do you expect differences in PRO/HRQL between groups?
   - ☐ Yes *(please describe)*
   - ☐ No

   Description: _____

5. Do you expect changes in PRO/HRQL over time (within or between groups)?
   - ☐ Yes *(please describe)*
   - ☐ No

   Description: _____

6. What are the assessment time-points during, or following, treatment/intervention when PRO/HRQL is likely to be different between groups or over time (when are you likely to see the benefits, side-effects, or differences)?

   Description: _____

7. Will PRO/HRQL be assessed by proxy (a parent, carer or health professional) because the target patient population is too young, or is/may become too sick or cognitively impaired?
   - ☐ Yes
   - ☐ No

Recommendation:

If your responses indicate you are assessing PRO/HRQL, please refer to the following QOL-TS resources as you develop your study:

Guidance for Grant Applications with PROs

SPIRIT-PRO Checklist *for what to include in your study protocol*

Pathway B: PRO/HRQL is not currently being considered, but it would be helpful to assess whether it might be relevant.

1. What is your study design?

Trial

- ☐ Phase I
- ☐ Phase II non-randomised
- ☐ Phase II randomised
- ☐ Phase III
- ☐ Phase IV

Other

- ☐ Cross-sectional
- ☐ Prospective cohort
- ☐ Registry development
- ☐ PRO instrument validation
- ☐ Other

Please specify:

_____

2. Is the intervention/treatment likely to have any impact on any of the following? (*choose all that apply*)

- ☐ Symptoms of disease
- ☐ Side effects of treatment
- ☐ Psychological symptoms (e.g. anxiety, depression, etc.)
- ☐ Core aspects of function (e.g. physical, social, emotional, cognitive, behavioural, or role function
- ☐ Sexual function
- ☐ Body image
- ☐ Satisfaction with healthcare
- ☐ Financial wellbeing
- ☐ None *(go to question 5)*
- ☐ Other

Please specify:

_____

3. If you ticked any of the boxes in Question 2, you should consider collecting this information **from patients**, as patient self-report is the most valid and reliable way to assess the impacts in Question 2**. A proxy** *(e.g. parent, carer, or health professional)* may be suitable when patients are too sick, too young, or cognitively impaired; in this case, a questionnaire that has been validated for proxy-report should be used.

   Are you now considering patient or proxy assessment?

   - ☐ Yes
   - ☐ No
   - ☐ Not applicable – the intervention/treatment is unlikely to have any of the impacts listed above

Please describe expected impacts – what will be affected? How (improved/deteriorated)? At what time-points (e.g. end of treatment, acute versus persistent impacts)?

_____

_____

4. Have you planned to collect data **from patients** regarding symptomatic manifestations of treatment toxicity or adverse events related to the intervention?

   - ☐ Yes
   - ☐ No

Recommendation:

*If you answered **yes** to questions 2 or 4, please review pathway A on the previous page, and refer to the following QOL-TS resources as you develop your study:*

Guidance for Grant Applications with PROs

SPIRIT-PRO Checklist *for what to include in your protocol*

Explanation of terms: PRO, PROM, HRQL

- Patient-reported outcomes (PROs) are the outcomes per se, e.g. fatigue, pain, sexual function.
- Patient-reported outcome measures (PROMs) are the questionnaires used to assess the target PRO, e.g. FACT-Fatigue.
- Health-related quality of life (HRQL) is a multidimensional PRO, and HRQL questionnaires (e.g. QLQ-C30) are PROMs.
- The International Society for Quality Of Life research now recommends using the term health-related quality of life (rather than simply quality of life, which is a much broader construct encompassing issues beyond disease and treatment), and the abbreviation HRQL rather than HRQoL or QoL. You might like to change this throughout.