

The SISAQOL-IMI checklist for reviewing patient-reported outcomes in cancer clinical trial protocols: a resource for patient advocates and healthcare professionals



Description

This checklist has been developed based on the [SISAQOL-IMI recommendations](#) [Ref Guidebook] to support [patient advocates](#) and healthcare professionals who are involved in reviewing [cancer clinical trial protocols](#).

This checklist consists of a list of key questions that can be used to verify whether the research team or the principal investigator has applied the SISAQOL-IMI recommendations when planning a study with [patient-reported outcome measures \(PROMs\)](#).

This checklist should be used alongside the SPIRIT PRO checklist, which outlines the key points to consider when using PROMs in clinical studies.

This checklist focuses on a specific aspect of clinical trial protocols: the design, use, and analysis of PROMs in [cancer clinical trials](#). Not all items will be applicable to every trial or protocol.

Guidance on how to use this checklist (applicable to all items)

1. To access all features, please download the document. If viewing it in the browser, we recommend using Chrome to reduce potential issues.
2. Check whether that particular item has been addressed in the protocol. Examples are provided for clarification of the context. Consult the second column for suggested terms to search for in the protocol.
3. If required, review the SISAQOL-IMI recommendations using the references provided. [Link Guidebook, chapter 4]
4. Indicate whether an item has been addressed or not by checking the Yes/No or Not applicable checkboxes.
5. Add any notes, comments or questions for clarification you may have in the column provided.
6. Share your assessment with the research team.

	General points
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	Description of a relevant PRO score interpretation threshold
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	Strategy for handling intercurrent events , including drop out for various reasons
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	Items for consideration	Terms to search for in the protocol	YES	NO	N/A	Notes/Comments	Relevant references
1	<p>Does the protocol clearly explain the aim or objective of the <u>patient-reported outcome (PRO)</u> in the study?</p> <p>Example</p>	<ul style="list-style-type: none"> <input type="radio"/> Aim of study <input type="radio"/> <u>Objective</u> of the study <input type="radio"/> Purpose of the study <input type="radio"/> Rationale of study <input type="radio"/> <u>Goal of the trial</u> 					SISAQOL-IMI recommendations (EstFrame1_GEN_RCT, EstFrame1_GEN_SAT, EstFrame2_SAT, Spirit PRO)
2	<p>Does the protocol define the PRO variable of interest?</p> <p>Explanation</p>	<ul style="list-style-type: none"> <input type="radio"/> <u>Estimand</u> <input type="radio"/> <u>Endpoint</u> <input type="radio"/> Variable of interest <input type="radio"/> Population-level summary 					SISAQOL-IMI recommendations (EstFrame1_GEN, EstFrame3_SAT, EstFrame4_SAT, EstFrame5_SAT, EstFrame6_SAT, Pop1_RCT, Pop2_RCT, Pop3_SAT, PROvar1_GEN, PROvar2_RCT)

	Items for consideration	Terms to search for in the protocol	YES	NO	N/A	Notes/Comments	Relevant references
3	<p>Does the protocol explain how the PRO will be measured?</p> <p>Explanation</p> <p>Example</p>	<ul style="list-style-type: none"> <input type="radio"/> Questionnaire <input type="radio"/> Measure <input type="radio"/> PROM <input type="radio"/> Assessment <input type="radio"/> Variable of interest <input type="radio"/> Time point 					SISAQOL-IMI recommendations (EstFrame1_GEN, Pop1_RCT, Pop2_RCT, EstFrame3_SAT, EstFrame4_SAT, EstFrame5_SAT, EstFrame6_SAT, Pop3_SAT, AnalMain9_SAT, PROvar2_RCT)
4	<p>Is the chosen PRO in line with the PRO objective?</p> <p>Explanation</p>	<ul style="list-style-type: none"> <input type="radio"/> Estimand <input type="radio"/> Endpoint <input type="radio"/> Variable of interest <input type="radio"/> Population-level summary 					SISAQOL-IMI recommendations (EstFrame1_GEN, Pop1_RCT, Pop2_RCT, EstFrame3_SAT, EstFrame4_SAT, EstFrame5_SAT, EstFrame6_SAT, Pop3_SAT, AnalMain9_SAT, PROvar2_RCT)

	Items for consideration	Terms to search for in the protocol	YES	NO	N/A	Notes/Comments	Relevant references
Evaluation of validity							
5	<p>Are the chosen <u>PROMs</u> (questionnaires) relevant to and valid for the current patient group?</p> <p>Explanation</p>	<ul style="list-style-type: none"> <input type="radio"/> PROM <input type="radio"/> Questionnaire <input type="radio"/> <u>Instruments</u> <input type="radio"/> Validity <input type="radio"/> Validated <input type="radio"/> Reliability <input type="radio"/> Psychometric testing 					SPIRIT-PRO
8	<p>Have the chosen <u>PROMs</u> been, or will they be, reviewed and tested to ensure that they are relevant, easy to fill in and suitable to answer the PRO-specific <u>objective</u> or research question?</p> <p>Explanation</p>	<ul style="list-style-type: none"> <input type="radio"/> PROM <input type="radio"/> Questionnaire <input type="radio"/> <u>Instruments</u> 					SPIRIT-PRO

	Items for consideration	Terms to search for in the protocol	YES	NO	N/A	Notes/Comments	Relevant references
Evaluation of PRO time points							
10	<p>Does the project description or protocol define each assessment time point, including the corresponding <u>time window</u> for data collection?</p> <p>Explanation</p> <p>Example</p>	<ul style="list-style-type: none"> <input type="radio"/> PRO assessment <input type="radio"/> <u>Time windows</u> <input type="radio"/> Time points <input type="radio"/> Assessment point <input type="radio"/> Measuring points 					SISAQOL-IMI recommendations (Design3_GEN, Design2_GEN, SPIRIT PRO)
11	<p>Do the researchers plan to use the same time points for the different groups when comparing them?</p>	<ul style="list-style-type: none"> <input type="radio"/> PRO assessment <input type="radio"/> <u>Time windows</u> <input type="radio"/> Time points <input type="radio"/> Assessment point <input type="radio"/> Measuring points 					SISAQOL-IMI recommendations (Design3_GEN, Design2_GEN, ExComp1_SAT, ExComp2_SAT, SPIRIT PRO)

	Items for consideration	Terms to search for in the protocol	YES	NO	N/A	Notes/Comments	Relevant references
PRO score interpretation thresholds							
12	<p>Are PRO score interpretation thresholds for the selected PROM and patient group described?</p> <p>Explanation</p> <p>Example</p>	<ul style="list-style-type: none"> ○ Thresholds, Clinical meaningful difference (CMD) ○ Clinically meaningful change (CMC) ○ Meaningful within-patient change (MWPC) ○ Meaningful score difference (MSD), 'responder definition' or 'responder threshold' ○ Minimal important difference (MID); Minimal clinically important difference (MCID) ○ Minimal important change (MIC) 					<p>SISAQOL-IMI recommendations (CMCselc6_GEN, CMCselc2_GEN, CMCimp6_GEN, CMCimp1_GEN, CMCimp5_GEN, CMCimp3_GEN, CMCimp2_GEN, CMCimp7_GEN, CMCimp9_RCT, CMCselc7_GEN, CMCselc1_GEN, CMCselc5_GEN, CMCselc3_GEN, CMCselc4_GEN, CMCimp14_GEN, CMCimp13_GEN, CMCrep1_GEN, CMCimp10_GEN, CMCimp11_GEN, CMCimp12_GEN)</p>

	Items for consideration	Terms to search for in the protocol	YES	NO	N/A	Notes/Comments	Relevant references
15	<p>Does the protocol describe how the patients <u>lost to follow-up</u> (dropouts) will be handled, beyond those cases explained by predefined <u>intercurrent events</u>?</p> <p>Explanation</p>	<ul style="list-style-type: none"> <input type="radio"/> <u>Patients lost to follow-up</u> <input type="radio"/> Dropouts <input type="radio"/> Attrition 					SISAQOL-IMI recommendations (ICEdisprog1_RCT, ICEdisprog3_RCT, ICEdisprog2_RCT, ICEdisprog5_RCT, ICEdisprog4_RCT, ICE3_RCT)
16	<p>Will the study continue to measure PROs after disease progression? If not, does the protocol justify why not?</p> <p>Explanation</p>	<ul style="list-style-type: none"> <input type="radio"/> Disease progression <input type="radio"/> Relapse of disease 					SISAQOL-IMI recommendations (ICEdisprog1_RCT, ICEdisprog3_RCT, ICEdisprog2_RCT, ICEdisprog5_RCT, ICEdisprog4_RCT, ICE3_RCT)

	Items for consideration	Terms to search for in the protocol	YES	NO	N/A	Notes/Comments	Relevant references
17	<p>Will the study continue to measure patient reported outcomes after <u>treatment discontinuation</u>? If not, does the protocol justify why not?</p> <p>Explanation</p>	<ul style="list-style-type: none"> <input type="radio"/> <u>Discontinuation of treatment</u> <input type="radio"/> Stop treatment <input type="radio"/> Withdraw/Withdrawal from study 					<p>SISAQOL-IMI recommendations:</p> <p>ICEdisc1_GEN</p> <p>ICE3_RCT</p> <p>EstFrame5_SAT</p> <p>EstFrame6_SAT</p>
18	<p>Does the protocol describe how <u>intercurrent events, deviations from the protocol-defined treatment</u>, and death will be handled, along with the rationale for each approach?</p> <p>Explanation</p> <p>Example</p>	<ul style="list-style-type: none"> <input type="radio"/> <u>Deviation from protocol-defined treatment</u> <input type="radio"/> <u>Concomitant therapies</u> <input type="radio"/> <u>Intercurrent events</u> 					<p>SISAQOL-IMI recommendations:</p> <p>ICEprodev1_RCT</p> <p>ICEprodev3_RCT</p> <p>ICEprodev2_RCT</p> <p>ICEprodev5_RCT</p> <p>ICEprodev4_RCT</p>

	Items for consideration	Terms to search for in the protocol	YES	NO	N/A	Notes/Comments	Relevant references
19	Does the protocol describe statistical methods for handling <u>missing data</u> and data from participants who are <u>lost to follow up</u> ?	<ul style="list-style-type: none"> <input type="radio"/> <u>Missing data</u> <input type="radio"/> <u>Lost to follow up</u> 					SISAQOL-IMI recommendations (AnalMain7_GEN, AnalSens3_GEN, Design4_GEN, Psum1_GEN, Psum2_GEN, AnalSens4_SAT)
20	Does the protocol describe how the study will handle the PRO data for patients who have died? <div style="border: 1px solid black; border-radius: 15px; padding: 5px; display: inline-block; background-color: #f0f0f0;">Explanation</div>	<ul style="list-style-type: none"> <input type="radio"/> <u>Intercurrent event</u> <input type="radio"/> Death 					SISAQOL-IMI recommendations (ICEdeath1_RCT, AnalMain8_RCT, EstFrame5_SAT, EstFrame6_SAT, ICEdeath3_SAT, ICEdeath4_SAT, ICE5_SAT, ICEdeath2_SAT)

Other useful resources:

The current checklist is not a stand-alone reviewing checklist and should be used alongside other resources for better robust feedback.

Spirit-PRO guidance

Spirit-PRO patient checklist

SISAQOL-IMI glossary

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