QOL Office Checklist of instructions for the administration of Patient Reported Outcome Measures

The QOL Office recommends that this this checklist is used in conjunction with the PROtocol Checklist and PRO CoMiDa Form

Preamble

Patient-Reported Outcome measures (PROMs) should be administered in a standardised manner to maximise PRO completion rates and reduce the potential for response bias - which may be caused when patients are given different information or instructions about the PRO study.

The Quality of Life Office has developed this checklist for PROM administration for site coordinators working on the Cancer Clinical Trials Group (CCTG)-led trials. CCTGs may use this checklist to develop PRO aspects of site manuals or standardised operating procedures for trial staff.

There are two parts to this checklist: 1) paper-based PRO administration; 2) electronic PRO administration. The checklist includes examples of how to address each checklist item in a study coordinator's manual. These examples are illustrative only and CCTGs may adapt the text to suit specific trials.

This document was prepared by Rebecca Mercieca-Bebber on behalf of the QOL Office, drawing on published literature, existing guidance from international trials groups (South West Oncology Group (SWOG) Training Module, presented by Dr Lisa Hansen; and the EORTC Clinical Trial Guidelines); interviews with Australian site coordinators, and the QOL Office's experience with PRO administration. We acknowledge early feedback on required content at the 2013 Inter-group QOL Management and Planning Meeting by representatives from the Cancer Clinical Trials Groups (CCTGs), specifically Dianne Lindsay, Corinna Beckmore (ANZBCTG), Janey Stone (ALLG), Elizabeth Paton (ANZMTG), Dagmara Poprawski (ANZUP), Haryana Dhillon (ANZUP, ALLG, PoCoG), Rasha Cosman (COGNO) and Melissa Crain (TROG), as well as feedback provided on the final draft at the2015 Inter-group QOL Management and Planning Meeting by CCTG representatives: Howard Chan (AGITG/ANZUP), Megan Sanders (ALLG), Natasha Roberts (ALTG),: Peey-Sei Kok (ANZGOG/ALTG), Ashleigh Qama (PC4), Joan Torony (TROG), Margaret-Ann Tait (QOL Office), Corrina Beckmore (ANZBCTG), Janelle Jones (ANZCHOG), Linda Cowan (ASSG), Renee Swanson, Merryn Hall (COGNO).

Acronyms

CCTGs	Cancer Clinical Trials Groups
CoMiDa Form	The PRO Completion and Missing Data Form Available at: http://www.pocog.org.au/docview.aspx?id=211
PROtocol Checklist	Patient-Reported Outcomes Protocol Checklist Available at: http://www.pocog.org.au/docview.aspx?id=212
PRO	Patient-Reported Outcomes (including QOL)

PROM	Patient-Reported Outcomes Measure (questionnaire)
QOL	Quality of life

Paper-based PRO administration

Section	Checklist item	Elaboration	Example
Delegation log/responsible person/s	1. Name the staff member/s responsible for PRO administration	Ensure staff are aware of their responsibility to administer PROs. PRO administration may also be recorded as a task in the Trial Delegation Log.	**Responsible person** Jane Smith, Site coordinator, is responsible for administration of PROs and associated follow-up in the ABC123 trial at Site X
Informed consent process	2. Procedures for providing information about the PRO study 3. Aspects of PRO study to discuss with patient	Ensure patients are adequately informed about the PRO study (purpose, assessment schedule, who will see the data, when and how PRO data will be used)	**Informed consent process** Patients usually are overwhelmed with clinical information at the consent stage, however the site coordinator should discuss the following aspects of PRO assessment & ensure the patient understands (in addition to Patient Information Sheet) : • why PROs are being assessed (e.g. to determine whether and how long X surgery has an impact on the patient's daily functioning & specific symptoms); • schedule of PRO assessments (e.g. baseline, hospital discharge, 3 months post-surgery, 1 year); • responses should be honest and the patient's own; • only the central research team will view their PRO responses. • De-identified data will be analysed in one year and at the end of the study (in approx. 3 years); • PRO data will not be used to inform their care. Health concerns should be raised with their clinician; • PRO questionnaires and data will be securely stored; • More information on the PRO study is included in the Information Statement or they can contact the site coordinator.
Patient eligibility/ Registration/ randomisation	4. PRO-specific eligibility criteria 5. PRO-specific registration requirements 6. Procedures for registering participants to the PRO study (if separate from main study)	Specify any PRO study-specific eligibility criteria (language/s of questionnaire availability, physical ability to complete forms). Specify any PRO study registration requirements (baseline PRO completion,	**Eligibility:** • Patient must be able to read/write Afrikaans, Arabic, Cantonese, Dutch, English, French, German or Russian to take part in the PRO study; **Registration/randomisation requirements**: • Baseline PRO assessment must be complete prior to trial randomisation; • Patients are automatically registered onto the PRO study as part of the trial registration. If patient is ineligible for the PRO study, please complete XX form

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		additional consent – if required). Baseline PRO assessment is crucial for analysis and interpretation of PRO data, and it is commonly a trial inclusion criterion.	
Preparation	7. Instructions for preparing for PRO assessment	Specify how PRO measures should be prepared (e.g. insertion of participant ID numbers, etc)	**Preparation** • Insert the patient's trial registration number and date onto the cover and each subsequent page of the questionnaire booklet with black or blue ink. • Participants should complete the questionnaire in black or blue ink.
PRO administration	8. Verbal instructions for the patient (at first PRO assessment and subsequent assessments, if necessary) 9. Specify time of PRO completion 10. Specify place of PRO completion	If patients are unaware of the purpose and importance of PRO data, they may miss questions or fail to complete questionnaires, thus this should be explained to patients at their first assessment, and at subsequent assessments, if required.	**Instructions for the patient (at first PRO assessment and subsequent assessments, if necessary)** • Explain the purpose of PRO assessment and read questionnaire instructions to the patient and ensure they understand. The following script may assist: *"We are interested in learning about how this treatment impacts your daily life throughout treatment and into your recovery. This questionnaire lists some issues that you may or may not be experiencing. Each question has four response options: "not at all, a little, quite a bit, very much".* *Please answer all of the questions <u>yourself</u> by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential and wont impact the treatment that you receive. It's really important that you answer all of the questions as best you can, and that you are honest – as this information will be very useful for future patients.* *If you make a mistake, cross the incorrect answer out and circle the correct answer. Write your initials next to the change.* *If you have any questions or if the questionnaire raises any concerns for you, please let me know."* **Timing and place of completion** • Patients should complete questionnaires prior to seeing their clinician; • Patient should complete questionnaires independently, in a quiet/private location; • Discourage patients from taking questionnaires home;
Patients in need of assistance	11. Nature of assistance allowed from coordinators	Some patients may need assistance completing questionnaires. Not providing	**Allowable levels of patient assistance** • A trained site coordinator can provide assistance to patients if required; for example if the patient:

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		assistance when required may lead to missing data. It is important that assistance is provided in an objective manner and that the nature of assistance is documented.	○ is too ill (e.g. severe nausea, fatigue) or if they are confused about how to complete questionnaires; ○ forgot reading glasses; ○ has severe arthritis, preventing them from being able to write; • The patient's family/friend should not provide assistance. • This assisting staff member should: ○ read questions and record patient's responses; ○ always allow the participant to choose responses; ○ remain objective, with a neutral expression and don't make any comments on the patient's responses; ○ avoid rephrasing the questions if patient asks for clarification; ○ document the level of assistance required on the CoMiDa form.
	12. Instructions for non-English-speaking patients (if permitted by the protocol)	If validated questionnaire translations are available, participants may choose to complete questionnaires in their preferred language. Assistance may be required for informed consent. English questionnaires should not be translated by staff or family members as this may introduce bias,	**Non-English-speaking participants** • Patients may choose to complete the questionnaire in any of the following languages, for which validated language translations are available : Afrikaans, Arabic, Cantonese, Dutch, English, French, German, Russian….etc • Verbal translators should NOT be used as they can introduce bias. • If a validated questionnaire translation is not available for a certain language, the participant may need to be excluded from the PRO study. Contact the central trial office for advice.
Proxy assessment (if allowable)	13. Conditions proxy assessment is allowed 14. Suitable proxies 15. Special/additional instructions for proxy assessment	Some patients are not able to self-report, e.g. Severe cognitive impairment, young children. Proxy assessment may be permitted for these patients, if permitted by the protocol. This involves a third party completing a questionnaire about the health status of the patient.	**Proxy assessments** • Proxy assessment may be permitted for patients who are unable to self-report due to cognitive impairment. This involves a third party completing a questionnaire about the health status of the patient. • If proxies must be used, ensure each patient uses the same proxy to complete all assessments (i.e. always the mother of Patient 345, always the husband of Patient 320). This will improve reliability of responses for each patient. • A close family member or friend may act as the proxy. If no one suitable is available, a nurse who is familiar with the patient may act as proxy. • Document the relationship of the proxy to the patient on the CoMiDa Form.
Common problems	16. Procedures (as per protocol) for assessing PROs in patients who come off the trial early. 17. Procedures(as per protocol) for	When participants are taken off trial for toxicity or progression, the decision of whether to continue administering PROs	**Patients who withdraw/deviate from treatment protocol** • All patients, regardless of treatment status, should be assessed at all scheduled PRO assessment timepoints (final assessment two-years post treatment commencement).

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	patients who withdraw from the PRO study 18. Assessment schedules for when patient's treatment schedule differs from the treatment protocol	depends on the trial. Please consult the trial protocol. Some trials will continue to administer PROs indefinitely, until patient is too sick to complete. If the participant's treatment schedule differs from the treatment protocol, a decision needs to be made whether to adjust the patient's PRO assessment schedule.	• If a patient wishes to withdraw from the PRO study, do not administer further PRO assessments. Complete the PRO withdrawal form in RedCap. • If a patient's treatment schedule is altered during the trial, only PRO assessments scheduled during treatment (Cycle 2 and Cycle 4) should be adjusted to take place on the first day of each treatment cycle. Subsequent assessments (6, 12, 18, 24 months post-treatment commencement) should not be altered (i.e. they should be calculated using Day 1 of treatment as the reference point).
Completed PRO assessments	19. Procedures for obtaining completed forms 20. Procedures for checking completed forms 21. Procedures for addressing common problems	Staff should show appreciation when completed questionnaires are submitted as this will reinforce the importance of PRO data to patients. Staff should also check for any missing data or other problems and resolve any completion problems with patients immediately, before they leave the clinic.	**Completed PRO assessments** While the patient is still in the clinic, staff should: • show appreciation when questionnaires are completed; • ask the patient if they have any concerns; • review questionnaires for completeness while the patient is present, focussing on completeness of responses only; o Site staff should remain neutral when checking questionnaires. Don't express opinion about responses; o How to address common problems: ▪ **Two responses for one question?** Ask patient to check & choose the response that best describes their health status. ▪ **Missed question?** Politely inform the patient they have missed the question and ask if they would like to answer it. If not, note that the patient declined to complete the question on the CoMiDa form. ▪ **Incomplete forms (pages stuck together, double-sided forms only completed on one side)?** Politely inform the patient they have missed some of the questionnaire and ask if they would like to complete the remainder. If necessary, ask if they would like some assistance. If the patient does not wish to complete the questionnaire, include a note accordingly on the PRO CoMiDa Form.
Missed/late PRO assessments	22. Specify procedures for following up missed PRO assessments (e.g. alternative mode of administration)	Every effort should be made to obtain the required PRO data within the assessment time-window – to avoid missing data. This may be due to a missed clinic appointment or running out of time when the patient is in the	**Missed PRO assessments** Every effort should be made to obtain the required PRO data within the assessment time-window. This may involve: • rescheduling appointments so that data may be collected in the clinic; • administering the questionnaire by phone • posting the questionnaire to the patient

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		clinic. In such cases, the questionnaire can be administered by an alternative mode. A recent systematic review confirmed that changing the mode of questionnaire administration does not lead to bias.	Document the mode of completion on the CoMiDa Form. If the questionnaire is not completed within the time window, document the reason for non-completion on the CoMiDa Form. Please contact the central office with any queries.
Concerning PRO data	23. Procedures if patient reports concerning symptoms/health status	Procedures for handling concerning PRO data, or concerns raised as a result of PRO questionnaire completion, should be discussed with the clinician and referred on if necessary. Procedures should be implemented consistently so not to introduce bias.	**Concerning PRO data** • If a patient is concerned about their health or symptoms after completing a questionnaire, or if the site coordinator feels a patient is distressed by their health, the site coordinator should alert the treating clinician immediately. The clinician will decide whether to refer the patient to other health services. • Keep a record of any referrals the patient receives.
PRO CoMiDa Form	24. Complete the PRO CoMiDa Form	The PRO CoMiDa Form is a data management tool, designed to provide standardised documentation of the completion or reasons for non-completion of PRO assessments by patients in a clinical trial/study. Such documentation is crucial for quality assurance since missing data are the greatest threat to the integrity and interpretability of PRO data.	**Complete the PRO CoMiDa Form** • complete the PRO CoMiDa Form – for each patient, for each assessment (upon completion, or by the end of assessment time window if PROs not completed)
Adverse events	25. Procedures for adverse events relevant to PRO study		**Adverse Events** • Adverse events related to PRO assessment should be treated in same manner as for main trial, as per protocol.
Forwarding PRO data to central office	26. Procedures for returning completed forms to central office / data entry		**Forwarding PRO data to central office** • The site coordinator should enter PRO data into RedCap within two weeks of completion. • Store completed questionnaires at the site
Data storage	27. Data storage requirements		**Data storage** • Completed questionnaires should be stored securely at the site or approved archive centre for 15 years.

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			• After this period, contact the central office for instructions.

Electronic-PRO administration

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Delegation log/responsible person/s	1. Name the staff member/s responsible for PRO administration	Ensure staff are aware of their responsibility to administer PROs. PRO administration may also be recorded as a task in the Trial Delegation Log.	**Responsible person** Jane Smith, Site coordinator, is responsible for contacting patients and all related administration for the e-PRO study of the ABC123 trial, for patients recruited from Site X
Informed consent process	2. Procedures for providing information about the PRO study 3. Aspects of PRO study to discuss with patient	Ensure patients are adequately informed about the PRO study (purpose, assessment schedule, who will see the data, when and how PRO data will be used). Consider how and where consent will be obtained. E.g. face-to-face in the clinic or online. If obtaining consent electronically, ensure patients have access to clear information about the PRO study & contact details of an authorised member of the team with whom to discuss queries.	**Informed consent process** Patients usually are overwhelmed with clinical information at the consent stage, however the site coordinator should discuss the following aspects of PRO assessment & ensure the patient understands (in addition to Patient Information Sheet) : • why PROs are being assessed (e.g. to determine whether and how long X surgery has an impact on the patient's daily functioning & specific symptoms); • schedule of PRO assessments (e.g. baseline, hospital discharge, 3 months post-surgery, 1 year); • Patients must have access to a computer and personal email address to take part; • All assessments will be completed online –from anywhere that has an internet connection. Patients will receive an email to complete PRO assessments and a reminder. • Patients will be issued a log-in and password which they need to use for the duration of the study. • Patients can contact the site coordinator for technical assistance. • responses should be honest and the patient's own; • only the central research team will view their PRO responses. • De-identified data will be analysed in one year and at the end of the study (in approx. 3 years);

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			• PRO data will not be used to inform their care. Health concerns should be raised with their clinician; • PRO data will be securely stored; • More information on the PRO study is included in the Information Statement or they can contact the site coordinator.
Patient details	4. Specify what contact information is required 5. Procedures for maintaining up-to-date patient records	The patient's email address is required; Additional contact details may be needed if following-up patients by alternative modes (postal, phone); Keep details and treatment records (particularly death dates) up-to-date;	**Patient contact details** • The patient's email address and phone number is required; • Keep details and treatment records (particularly death dates) up-to-date; • Update patient records regularly by checking patient details at clinic visits, or contacting patient GPs.
Information about the questionnaire database	6. Provide link to questionnaire 7. Provide basic information about how the questionnaire database works 8. Details of contact person for technical support	Provide details of the steps involved in administering questionnaire online. Site staff require training in how to use the device and how to trouble shoot basic technical issues.	**The Questionnaire database** • The PRO assessment database is available at <<insert web link>> • The LANDING page includes the participant information sheet, an administration link and log-in/password fields. • The site coordinator should click the ADMINISTRATION link to issue the participants with a database log-in (trial registration ID).Ask the patient to choose their own password (6-10 characters). • Records the patient's log-in details and one the participant information booklet (for the participant to keep). • Participants log-in to the assessment on the landing page. • Once logged in, participants will see a list of all PRO assessments scheduled for the trial. The assessment due will be in RED text. Completed assessments will be in GREEN. Future assessments are in grey font. The database will automatically calculate when assessments are due and make the questionnaire available. • Participants will only be able to access surveys during the active PRO assessment time windows. • The site coordinator will need to keep track of when assessments are due in order to send reminders to patients. • Participants should click on the assessment hyperlink to access the survey. • Instructions for the patient are included in the email text. Staff will send reminder emails to participants prior to each upcoming assessment. • Questions will display one at a time. Once the participant chooses a response they will automatically progress to the next question. Once all questions are completed, the participant will need to click SUBMIT. They will automatically be logged out of the system.

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			• Contact _____ for technical support on <email> and <phone> • A hardcopy of the questions is included as an appendix. This can be photocopied for use in case of technical fault.
Patient eligibility/ Registration/ randomisation	9. PRO-specific eligibility criteria 10. PRO-specific registration requirements 11. Procedures for registering participants to the PRO study (if separate from main study)	Specify any PRO study-specific eligibility criteria (language/s of questionnaire availability, physical ability to complete forms). Specify any PRO study registration requirements (baseline PRO completion, additional consent – if required). Baseline PRO assessment is crucial for analysis and interpretation of PRO data, and it is commonly a trial inclusion criterion.	**Eligibility:** • Patient must be able to read/write English to take part in the PRO study; • have access to a personal computer; • have a personal email address (for sending the survey link and reminders). It is not acceptable for patients to use a family member's or friend's email address; • understand how to use email/computer **Registration/randomisation requirements**: • Baseline PRO assessment must be completed immediately after the participant's trial registration number is issued, using the iPads provided.; • On the ADMINISTRATION page: The site coordinator should register the patient to the PRO study database using the participant's trial registration ID as log-in and participant's own chosen password. • Return to the landing page so the participant can enter their log-in information. • Once logged in, participants should click the assessment due (in RED text). • If patient is ineligible for the PRO study, please complete XX form in RedCap.
PRO administration (first assessment – iPad in clinic)	12. Verbal instructions for the patient (at first PRO assessment in the clinic)	If patients are unaware of the purpose and importance of PRO data, they may miss questions or fail to complete questionnaires, thus this should be explained to patients at their first assessment, and at subsequent assessments, if required.	**Instructions for the patient (at first PRO assessment – iPad in the clinic)** • Explain that the patient will need to use their log-in to access this and all future surveys. • Explain the purpose of PRO assessment and read questionnaire instructions to the patient and ensure they understand. The following script may assist: *"We are interested in learning about how this treatment impacts your daily life throughout treatment and into your recovery. This questionnaire lists some issues that you may or may not be experiencing. Each question has four response options: "not at all, a little, quite a bit, very much".* *Please answer all of the questions <u>yourself</u> by ticking the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential and wont impact the treatment that you receive. It's really important that you answer all of the questions as best you can, and that you are honest – as this information will be very useful for future patients.* *If you have any questions or if the questionnaire raises any concerns for you, please let me know."*
PRO administration (subsequent assessments	13. Procedures for Contacting patients for PRO assessments		**PRO administration (subsequent assessments at home via internet):** • Email the survey link & patient's username to the patient on the day the

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at home via internet)	14. Who patients can contact if they require technical assistance		assessment window opens. Instructions for how the participant can access and complete the questionnaire should be included in the email text. • The email should include who the patient can contact for technical assistance, including lost passwords, access problems or other technical faults.
Assessment reminders (if permitted)	15. Specify PRO assessment reminder schedule 16. Specify PRO assessment reminder procedures	In addition to email reminders, specify whether/when reminders by phone or post are permitted. Include email templates.	**Assessment reminders:** • Use the email templates provided for all email correspondence. • Contact the patient to complete their assessment Day 1 of the assessment time window. • If the patient has not completed the questionnaire by the middle of the time-window, send an email reminder according to the following reminder schedule: o Contact 1: sent Day 1 of time window o Reminder 1: mid-time window o Reminder 2: day before time window ends • If no response is received by the time of the second reminder, you may call the patient to alert them of the assessment.
Patients in need of assistance	17. Nature of assistance allowed	Some patients may need assistance completing questionnaires. Not providing assistance when required may lead to missing data. It is important that assistance is provided in an objective manner and that the nature of assistance is documented.	**Allowable levels of patient assistance** • A trained site coordinator can read questions to participant over the phone and complete the questionnaire with the participant's responses if required or if the participant cannot get access to the internet during the study window; • This assisting staff member should: o read questions and record patient's responses; o always allow the participant to choose responses; o maintain an objective voice tone, without making any comments on the patient's responses; o avoid rephrasing the questions if patient asks for clarification; o document the level of assistance required on the CoMiDa form.
Email bounces & missed assessments	18. Specify procedures for email bounces 19. Specify procedures for missed assessments (e.g. whether PRO questionnaire may be completed by another mode (phone, posted hard-copy));	Every effort should be made to obtain the required PRO data within the assessment time-window – to avoid missing data. For example, the questionnaire can be administered by an alternative mode. A recent systematic review confirmed that changing the mode of questionnaire administration	**Email bounces & missed assessments:** • If emails bounce, attempt to contact the patient by phone to update email address; • If the patient cannot complete the questionnaire online within the assessment window for whatever reason, you may: o interview-administer the questionnaire over the phone. Record the patient's answers directly into the database. o Post a hard-copy version of the questionnaire to the patient with a stamped, self-addressed envelope. You will need to enter the patients responses directly into the database once the questionnaire is

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		does not lead to bias.	returned. • If the patient cannot be contacted, record failure to contact patient or reasons for missed assessments on the PRO CoMiDa Form
Common problems	20. Procedures for assessing PROs in patients who come off the trial early. 21. Procedures for patients who withdraw from the PRO study 22. Assessment schedules for when patient's treatment schedule differs from the treatment protocol 23. Who to contact in the event of technical problems	When participants are taken off trial for toxicity or progression, the decision of whether to continue administering PROs depends on the trial. Please consult the trial protocol. Some trials will continue to administer PROs indefinitely, until patient is too sick to complete. If the participant's treatment schedule differs from the treatment protocol, a decision needs to be made whether to adjust the patient's PRO assessment schedule. Provide guidance for handling common technical problems, for example incorrect log-in used or no internet connection.	**Patients who withdraw/deviate from treatment protocol** • All patients, regardless of treatment status, should be assessed at all scheduled PRO assessment timepoints (final assessment two-years post treatment commencement). • If a patient wishes to withdraw from the PRO study, do not administer further PRO assessments. Complete the PRO withdrawal form in RedCap. • If a patient's treatment schedule is altered during the trial, the PRO assessment schedule should <u>not</u> be altered. **Technical issues** • Contact <*support person*> for technical support on <*email*> and <*phone*> • If the patient is having trouble completing the assessment online at home, try to offer guidance over the phone. If not possible, you may use a hardcopy of the questionnaire (see appendix) and read the questions to the patient. Record the answers and enter these into the study database later. • Record the assistance provided on the CoMiDa Form
Concerning PRO data	24. Procedures if patient reports concerning symptoms/health status	Procedures for handling concerning PRO data, or concerns raised as a result of PRO questionnaire completion, should be discussed with the clinician and referred on if necessary. Procedures should be implemented consistently so not to introduce bias.	**Concerning PRO data** • If a patient is concerned about their health or symptoms after completing a questionnaire, or if the site coordinator feels a patient is distressed by their health, the site coordinator should alert the treating clinician immediately. The clinician will decide whether to refer the patient to other health services. • Keep a record of any referrals the patient receives.
PRO CoMiDa Form	25. Complete the PRO CoMiDa Form	The PRO CoMiDa Form is a data management tool, designed to provide standardised documentation of the completion or reasons for non-completion of	**Complete the PRO CoMiDa Form** • complete the PRO CoMiDa Form – for each patient, for each assessment (upon completion, or by the end of assessment time window if PROs not completed)

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		PRO assessments by patients in a clinical trial/study. Such documentation is crucial for quality assurance since missing data are the greatest threat to the integrity and interpretability of PRO data.	