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.

The Form should be completed by the Data Manager, Research Nurse, or equivalent – whoever is responsible for QOL data collection. This person may be located at the site where QOL data is collected (e.g. at clinic), or centralised (e.g. when QOL assessments are completed at home), and will depend on each individual study.

Using the PRO CoMiDa Form Template

The template provided on the next page may be adapted to specific clinical trials/studies. The QOL Office is able to assist members of the National Cancer Clinical Trials Groups with this if needed.

The PRO CoMiDa Form may be adapted in the following ways:

1. pasting the content of the form onto a trial/study letterhead
2. inserting the specific clinical trial/study details
3. adapting the reasons for missing data to suit the likely applicable reasons for the given clinical trial/study
4. inserting the names of specific PRO measures used in the clinical trial/study
5. inserting the relevant contact details of the clinical trial manager or project coordinator
6. inserting the relevant return advice for the clinical trial/study

If you have any queries about the PRO CoMiDa Form, please contact qol.office@sydney.edu.au

When you finalise a PRO CoMiDa Form for a study, we would be grateful if you would forward a copy to the QOL Office for our private records so we can learn more about the formatting that you prefer and the circumstances in which PRO data are collected in your trials.
PRO CoMiDa Form

Today's date: ___/___/_______  Site name: __________________________  Site number: __________
Patient ID: ___________________  Patient's Initials: ________________  Patient's date of birth: ___/___/_______

Select the current PRO Assessment Timepoint: (NOTE: You may omit this item and create a CoMiDa Form for each timepoint)

☐ Baseline  ☐ Cycle 2  ☐ Cycle 3  ☐ Cycle 4  ☐ Cycle 5
☐ End Treatment (EOT)  ☐ 1 mth post-EOT  ☐ 3 mth post-EOT  ☐ 1 yr post-EOT  ☐ 3 yr post-EOT

1. Were the following PRO forms completed at this scheduled assessment?
   Please complete each box below with one of the following codes: 1 = Yes, 2= NA (not required at this timepoint), 3 = No
   <Insert name of PRO form/questionnaire here>, required at timepoint(s) <insert timepoint(s) as per assessment schedule for this questionnaire here>
   <Insert name of PRO form/questionnaire here>, required at timepoint(s) <insert timepoint(s) as per assessment schedule for this questionnaire here>
   <Add additional rows if required>

2. Did the patient require any assistance in completing the questionnaire?
   ☐ No
   ☐ Yes. Please describe: ___________________________________________________________________________

3. How were the questionnaires administered?
   ☐ At clinic  ☐ By telephone  ☐ Online  ☐ Other: ________________

4. What language were the questionnaires completed in?
   ☐ English  ☐ Other, please specify: ____________________________________________________________

   If the patient completed ALL questionnaires required for this scheduled assessment, you have completed this form. If any questionnaires were MISSED (i.e. if you answered '3' to any of the questionnaires in question 1 above), please continue.

5. Please select the most appropriate reason for non-completion of the questionnaire(s).
   ☐ Patient received the questionnaire/s, but did not return them
   ☐ Patient refused to complete questionnaire
   ☐ Unable to contact patient
   ☐ Patient missed appointment of scheduled assessment
   ☐ Patient withdrew from study
   ☐ Institution forgot to administer questionnaire
   ☐ Institution administered incorrect questionnaire
   ☐ Online questionnaire malfunction
   ☐ Patient has passed away (tick 'Yes' for Q6)
   ☐ Other. Please specify: ___________________________________________________________________________

6. Is the reason for non-completion (as stated above) related to the patient's illness?
   ☐ Yes
   ☐ No
   Notes: ___________________________________________________________________________________________

I have reviewed the PRO CoMiDa Form and PRO Forms. All forms are complete or an explanation is given for any missing data.

Person completing this form:
Name: __________________________  Signature: __________________________  Date: ___/___/_______

Return instructions:
<Insert name & address of Clinical Trial Manager/ study contact person>
123 GO Trial CoMiDa Form

Today’s date: _23/10/2011_  Site name: RPA  Site number: 1  Clinician: Dr Bob

Patient ID: 12  Patient’s Initials: PK  Patient’s date of birth: _4/5/1948_

Select the current PRO Assessment Timepoint:

- ✔ Baseline
- ✗ Cycle 2
- ✗ Cycle 3
- ✔ End Treatment (EOT)
- ✗ 6 mths post-EOT
- ✗ 1 yr post-EOT
- ✗ 3 yr post-EOT
- ✗ 5yr post-EOT

1. Were the following PRO forms completed at this scheduled assessment?
   Please complete each box below with one of the following codes: 1 = Yes, 2 = NA (not required at this timepoint), 3 = No
   - ✔ FACT-O required at ALL timepoint(s)
   - ✔ SF-36 required at BASELINE ONLY
   - ✗ Symptom Representation Questionnaire required at ALL timepoint(s)

2. Did the patient require any assistance in completing the questionnaire?
   - No
   - ✔ Yes. Please describe: Patient’s husband read questions to patient and filled in the form with patient’s responses

3. How were the questionnaires administered?
   - ❑ At clinic
   - ✗ By telephone
   - ✗ Online
   - ✗ Other: _______________________

4. What language were the questionnaires completed in?
   - ❑ English
   - ✗ Other, please specify: __________________________________________________________

   If the patient completed ALL questionnaires required for this scheduled assessment, you have completed this form. If any questionnaires were MISSED (i.e. if you answered ‘3’ to any of the questionnaires in question 1 above), please continue.

5. Please select the most appropriate reason for non-completion of the questionnaire(s).
   - No
   - ✔ Patient received the questionnaire/s, but did not return them
   - ✔ Patient refused to complete questionnaire
   - ✔ Unable to contact patient
   - ✔ Patient missed appointment of scheduled assessment
   - ✔ Patient withdrew from study
   - Institution forgot to administer questionnaire
   - Institution administered incorrect questionnaire
   - ✔ Patient has passed away (tick ‘Yes’ for Q6)
   - ✗ Other. Please specify: __________________________________________________________________________

6. Is the reason for non-completing (as stated above) related to the patient’s illness?
   - ✔ Yes
   - ✗ No

Notes: Patient felt too tired to complete the final questionnaire in the battery (FACT-O)

I have reviewed the PRO CoMiDa Form and PRO Forms. All forms are complete or an explanation is given for any missing data.

Person completing this form:
Name: Jane Jones  Signature: Jones  Date: 23/10/2011

Return instructions:
Return this form as soon as possible by attaching it to an email with scans of the patient’s QOL Forms.

Attention: Professor Zachary Smith
Email: zsmith@uni.com