



PRO CoMiDa Form

Patient Reported Outcome (PRO) Completion and Missing Data (CoMiDa) Form

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.

<Paste onto clinical trial/study letterhead>

<Insert name of trial/study> 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-completing (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>

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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).

- 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