

PERCEIVE

December 2012



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Centres

| | |
|--|------------------|
| 3 Counties Cancer Research Network | UK |
| Allgemeines Krankenhaus der Stadt Wien, Vienna | Austria |
| Barts and the London NHS Trust | UK |
| Bronglais General Hospital | UK |
| James P. Wilmot Cancer Center | USA |
| National University Hospital, Singapore | Singapore |
| Ospedali Riuniti di Bergamo | Italy |
| University Hospital Messina | Italy |

Medidata Helpdesk / Technical Support

All numbers are Toll Free

| | |
|------------------|---------------------------|
| E-mail | helpdesk@mdsol.com |
| Austria | 0800677658 |
| India | 0008001006771 |
| Italy | 800-987-161 |
| Singapore | 8001204375 |
| UK | 0800-001-5212 |
| USA | 1-866-MEDIDATA (633-4328) |



International Time Zones

| | UTC |
|------------------|-----------------|
| Austria | + 1 hour (ECT) |
| India | + 5:30 hours |
| Italy | + 1 hour (ECT) |
| Singapore | + 8 hours |
| UK | + 0 hour (GMT) |
| USA | - 5 hours (EST) |

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Problems with EDC

Sorry for the inconvenience caused to some of the centres regarding EDC data entry errors and messages coming up while answering the queries. Data editing should now be possible again, but we are aware that query icons are at times being displayed incorrectly.

We will be sending updated lists of outstanding queries to help overcome this problem. We are doing our best in getting this issue resolved as soon as possible.

In the meantime, if you experience any errors, we would be grateful if you could:

1. Please take a screen shot of it, clicking on the error details ("click here to show Error Details") and send it to us at perceive@tri-london.a.uk
2. Report it to the Medidata helpdesk and please let us know the number you have been allocated

Message to CRAs

From Monitoring Team

We would like to formally welcome our new CRA from Bergamo Hospital (Italy)

There has been very good progress in collecting long-term data and query re-resolution despite the hold ups in the EDC, so please keep up the good work.

Could you kindly e-mail us with total numbers of subjects you have obtained consent for indefinite Follow-up either by signing the new consent form or by signing a re-consent form.

Essential Data Requirements:

Staging: Site and grading are essential requirements.

Please enter as much information as possible (either TNM or stage are mandatory). You can use clinical documents to complete the information that may not be available from the histology report alone. Please note this information is usually available in the records of multidisciplinary meetings (MDT) for the subject.

Data entry competed for this subject: With indefinite follow-up now, the form: "Data entry completed for this subject" should not be signed until the subject leaves the study (either dead or lost to Follow-up)

Essential Data Requirements *(cont.)*

Diagnosis to be eligible for the study we need histological diagnosis at some stage. Diagnoses obtained via imaging only are not valid

Date of Histological diagnosis: This is the date the specimen was collected. If it was a surgical specimen then enter the date of surgery or date of biopsy. Please **do not enter the date you received the histology report or the date it was signed** as these dates are always different. The diagnosis date can be the same date of surgery if the specimen was taken during surgery, but has to be **before surgery** in all other cases. This is because the date of histological diagnosis is the date when the first cancer proven specimen was taken.

Thromboprophylaxis: if the subject was given LMWH in Baseline (within 30 days of diagnosis) and the **start date and end date fall within the 30 day period** then enter both dates in the baseline folder. If the end date is after day- 30 from diagnosis, please only enter start date in the baseline period and tick the "ongoing" field. Please then enter the end date in the 6 month or 12 month follow up period as required. Please remember to tick ongoing if usage overlaps two periods.

TEDS: If TEDS have been used, especially in the peri-operative period, please make sure that it is recorded in thromboprophylaxis forms and within the correct time frame. Please attach a sticky note to confirm if no peri-operative thromboprophylaxis was given.

Follow-up data collection: If you are unable to collect the information from your hospital because of subjects having treatment or follow up visits elsewhere, please attempt to retrieve the information from their family physician or general practitioner before withdrawing them as lost to follow-up. Sample letter are available on demand.

Surgery: If the subject undergoes more than one surgical procedure in the same follow up period please let us know so that we can add a new surgery form for you to record the 2nd surgical procedure.

Site and grading: If the subject has two different primaries (for example a left and a right breast cancer) please let us know so that we can add a second site and grading form for you to enter the data.

Re-consent Process for Amendment 3

There are two aspects to the re-consent process:

1. Informed written consent to be signed by the patient and the member of the research team consenting the patient
2. Forms in the electronic database

Consenting the patient

From the date you obtained Approval of Amendment 3 at your site, all the subjects should have been consented for indefinite follow-up. Please make sure you have used the correct consent forms. There are currently two populations of subjects.

1. Subject consented in accordance with Amendment 3 compliant consent forms (the new consent form). They have been **consented indefinitely** and do not need to sign a re-consent form.
2. Subjects who were consented before Amendment 3 approval. These subjects have only been **consented up to the 12-month follow-up** and therefore would need to sign a re-consent form.

Entering data in the online database (EDC)

Please note this applies **only** to subjects who have given consent to be followed up indefinitely either by signing the new consent form or by signing a re-consent form.

There are two different CRF version in the database, and accordingly two populations of subjects (see above). Before adding a re-consent form please check if the patient was entered in the old version **CRF 297** or **new version 304**

1. Subject entered in the original CRF version **297**. This version was originally designed for 12 month follow-up only. To complete data entry for year 2 and above for those subjects, you need to create a linked S number and complete the re-consent form.
2. Subjects entered in the new CRF version 304 **do not need an on-line re-consent form** or a new S number. You can collect year 2 and above follow-up data by adding the yearly follow-up forms to the existing E number

Under no circumstances should a re-consent form be entered in an E number

F-U Time-frame

Date of histological diagnosis: That is the date that the first diagnostic specimen or biopsy was taken as specified on the histology report. Please do not use the date the histology report was approved, as it may be different. It is also day 0 of the study. It is the date used to calculate all F-U periods.

Baseline: Information on previous medical history is collected here. In addition all events occurring in the first 30 days following the date of histological diagnosis: day 0 to 30

Month 6: Record events occurring between month 2 and 6 post date of histological diagnosis: date of F-U should at least 5 months after the date of histological diagnosis and no later than 7 months after the date of histological diagnosis.

Month 12: Record events occurring between month 7 and 12 post date of histological diagnosis: date of F-U should be at least 12 months after the date of histological diagnosis and no later than 14 months after the date of histological diagnosis.

Yearly F-U: Record events occurring in year 2, 3, 4 etc. post date of histological diagnosis. Date of F-U should at least 24, 36, 48... x12 months after the date of histological diagnosis and no later than 26, 38, 50, ..., x12+2 months after the date of histological diagnosis.

Bloods: one per month: Please note that in order for us to consider the folder complete the following blood data must be entered.

- Baseline compulsory
- Month 6 ideally one per month (=5).
- Month 12 ideally one per month (=6)
- Yearly F-Us ideally one per month (=12)

If only fewer results are available, then please make sure to explain this in a note.

Reminders

TNM – Staging: There are two versions depending on which CRF is being utilized. Please refer to the help text within that page. We are aware that each centre may be using other classifications but for the purposes of this study please use the help text..

Baseline Surgery Please only record surgery that occurred within the first 30 days after diagnosis. All subsequent surgeries fall in the follow-up periods and should be recorded there.

Date of Follow-up In case of death during a follow-up period, the date of the follow-up period should be the date of death. That is the date the subject exits the trial and the date up to which we record their data.

In case of lost to follow up during a follow-up period, the date of follow up for that period should be the date the patient was last seen. That is the date the subject exits the trial and the date up to which we record their data.

Radiotherapy Section if patients were given two separate doses but within the same follow-up period then you can add the total doses and number of cycles.

Reminders *(cont.ed):*

Imaging - Only imaging done for suspicion or diagnostic of VTE should be recorded here.

Investigator’s Signature: only sign this page when all queries have been resolved

Yearly Follow-up Form: When entering data for year 2 follow-up and above, you need to add a yearly follow up form for each year. Please note that in the menu on the left, the folders are allocated a number in the bracket, for example the first folder entered will say (1). That does not relate to the follow-up period and should be ignored.

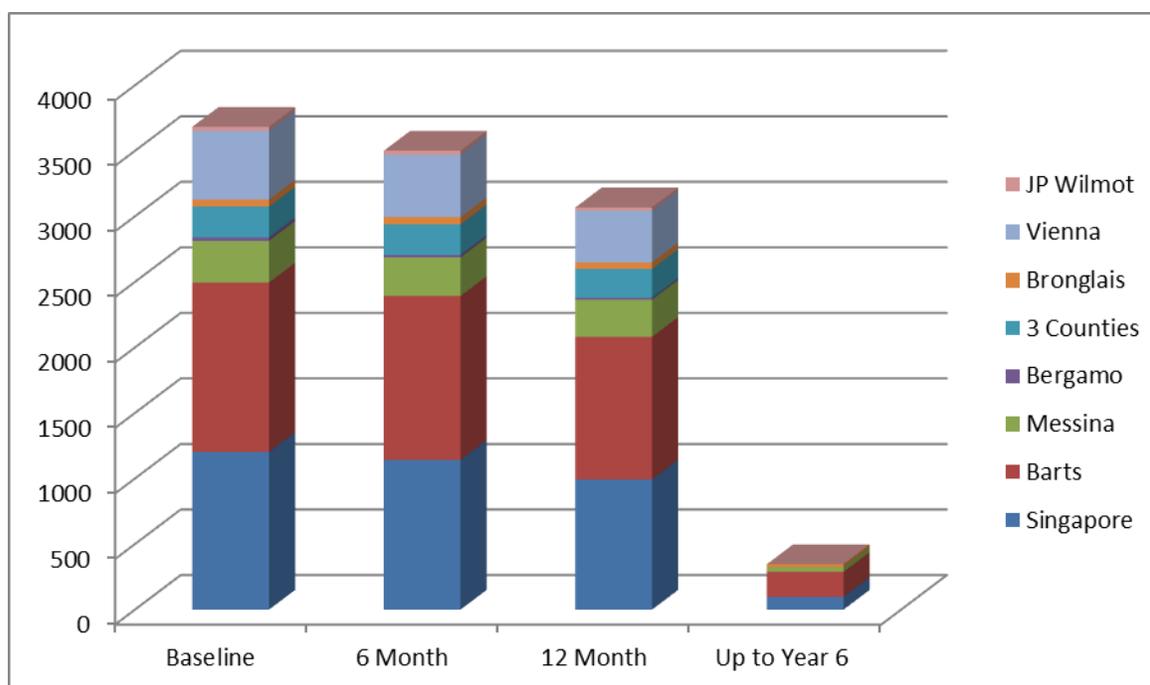
What defines the year of follow-up is the information entered, in the first form within the folder, called “yearly Follow-up”.

To specify the follow-up period: year 2, 3, etc you need to enter that information in the first form within the folder, called “yearly Follow-up” and choose the relevant year in the “Follow-up Year” Field. Please note that the first available option is 2 because year 1 follow-up data is recorded in the month 12 follow-up folder.

S Numbers: If by mistake you have created an S number then please screen that patient. You would need to click on the eligibility form and go to the inclusion criteria and click on the pencil for New diagnosis and change it to NO which will give you a Z number and the patient is screened.

Overall Follow-up Data

(November 2012)



Data Entry per Site

