

# PERCEIVE

May 2013



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## Centres

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

## Medidata Helpdesk / Technical Support

All numbers are Toll Free

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

## Latest consent figures\*

**3723 one year**

**1402 two years**

**1139 indefinite**

**A big thank you to all for your hard work**

*\*(17 May 2013)*

## International Time Zones

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

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## New EDC Version

We have finally upgraded to the new version of the Electronic Data Capture System.

This current version should enhance system stability whilst overcoming some of the problems we have experienced in the past.

We are aware that there can be a compatibility issue with users of Internet Explorer 10, this can be overcome by using the compatibility mode. Please see instructions in the adjacent box.

It should not impact on your ability to enter data and deal with queries, nonetheless should you experience any errors, we would be grateful if you could 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](mailto:perceive@tri-london.a.uk) as well as informing the Medidata helpdesk at [helpdesk@mdsol.com](mailto:helpdesk@mdsol.com).

Sorry for any inconvenience caused and thank you all very much for bearing with us during the upgrade.

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

## Internet Explorer 10

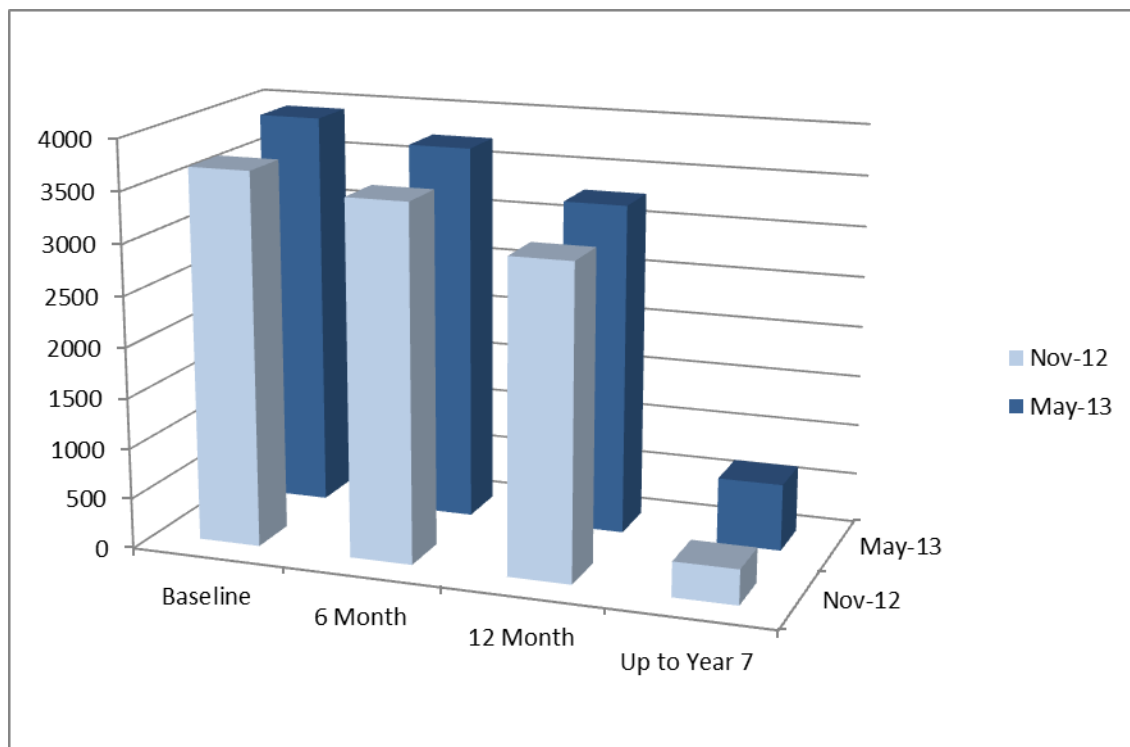
### Compatibility Mode

If you are using Internet Explorer 10, please follow these instructions to work in compatibility Mode:

1. Open Internet Explorer 10.
2. Click on the "Tools" option on the right top corner of the browser itself.
3. Click on "Compatibility View Settings" link.
4. After the new window pops-up enter "mdsol.com<http://mdsol.com/>" in the empty bar under the "Add this website" sign.
5. Click on "Add" in order to add the site as compatible.
6. Restart the browser

## Data Progression Comparison

(November 2012 to May 2013)



## 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.

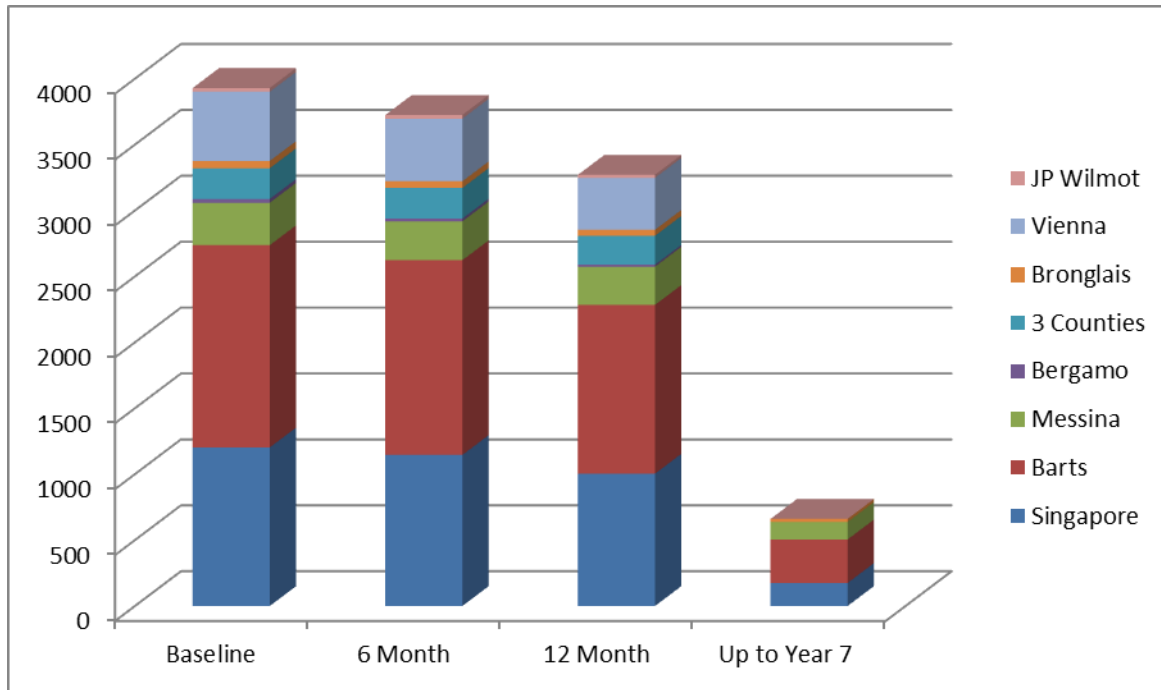
**Bloods: one per month:** Please note that in order for us to consider the folder complete the following blood data must be entered.

- 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.

## Overall Follow-up Data

(May 2013)



## Totals Figures per consent type

(May 2013)

