

# PERCEIVE

EASTER GREETINGS

APRIL 2012



**Clinical Trials Unit**  
**Thrombosis Research Institute**  
**Emmanuel Kaye Building**  
**Manresa Road**  
**Chelsea**  
**London SW3 6LR**  
**United Kingdom**

**e-mail: [perceive@tri-london.ac.uk](mailto:perceive@tri-london.ac.uk)**

**Tel: +44 (0)20 7351 8395**

**Fax: +44 (0)20 7351 8324**

## 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)

## International Time Zones

	UTC
<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)



## NEWS SUMMARY

- 2** Follow-up Time Frame
- 2** Reminders
- 2** Overall follow-up data
- 3** Message from Monitoring Team
- 3** Query Resolution Charts
- 5** Congratulations

## 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:** Collected here 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:** Collected here events occurring between month 7 and 12 post date of histological diagnosis: date of F-U should 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:** Collected here events occurring in year 2, 3, 4... x post date of histological diagnosis. Date of F-U should at least 24, 36, 48... x12 months after the date of

## Reminders

### 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

### TNM - Staging

For the purposes of this registry, please refer to the text in the help-box on-line and the instruction on the investigator's folder for the definitions.

### 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

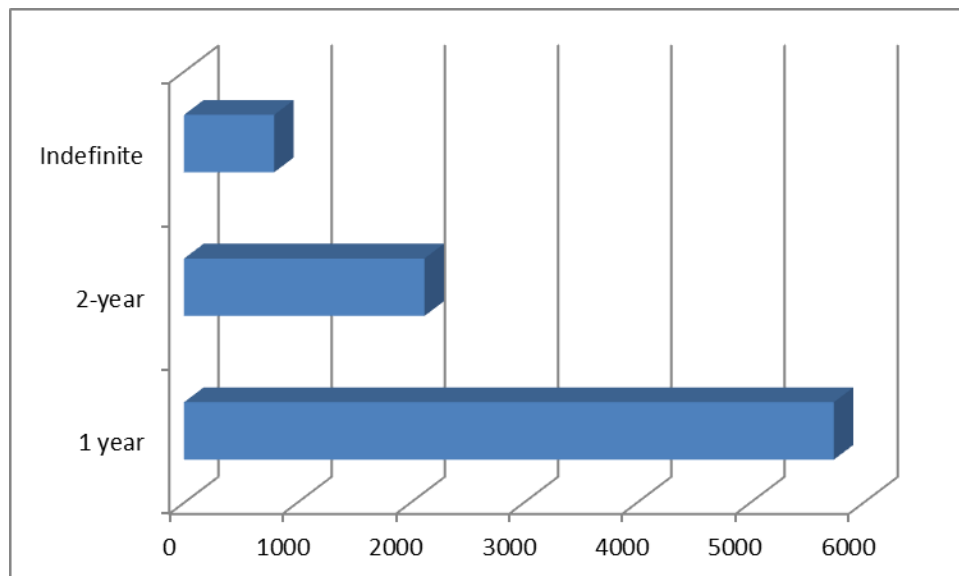
In case of death during a follow-up period, the date of death for that period should be the date of death. That is the date the subject exits the trial and the date up to which we record their data.

In case of lost to follow 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.

### Imaging

Only imaging done for suspicion or diagnostic for VTE should be recorded

## Overall follow-up data



# Message to CRAs

## From Monitoring Team

We at the Thrombosis Research Institute wish to thank you for all the hard work you have undertaken this past year and wish to convey to you all a Happy Easter.

We have had excellent re-consent rates and there has been very good progress in collecting long-term data.

Query resolution is also progressing at a good rate. To help you in this important task, please note that actions required by you, including a query report, are available on your main page in the top right corner of the webpage:

Task Summary: Site	Subjects
▶ Requiring Signature	647
▶ NonConformant Data	28
▶ Open Queries	40
▶ Sticky Notes	289
▶ Overdue Data	163

If you click on any of the sections it will take to the data that requires your attention.

Figure 1

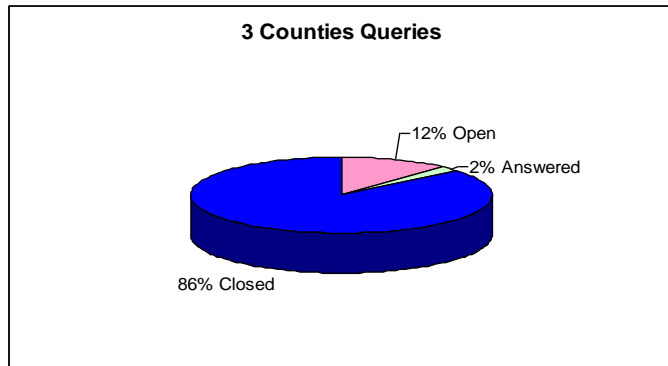
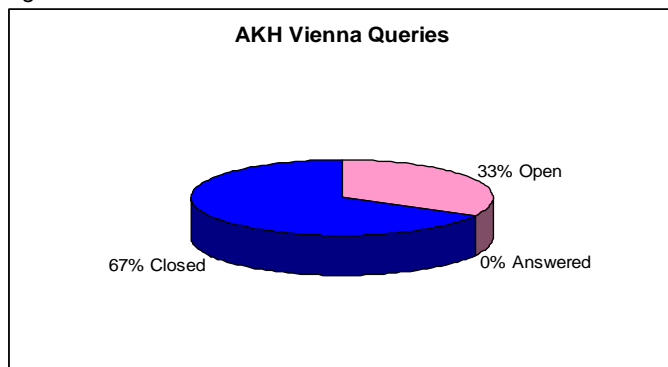


Figure 2



# Query Resolution

As previously mention we have had an outstanding effort by various sites in resolving the total number outstanding queries.

Figures 1 through to 10 demonstrate how effective we have all been in cleaning up the data in preparation for analysis as of 28 March 2012. These figures highlight the number of resolved (closed) queries, those which still remain to be answered (open) and queries which have been answered but not yet closed.

Figure 3

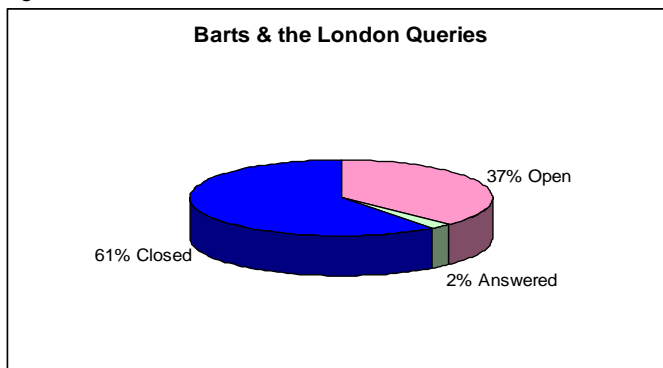


Figure 4

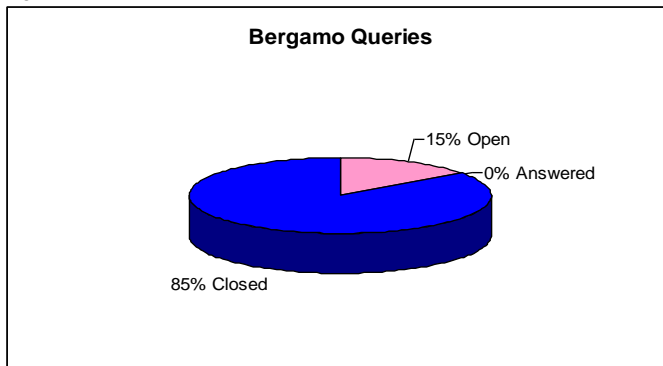


Figure 5

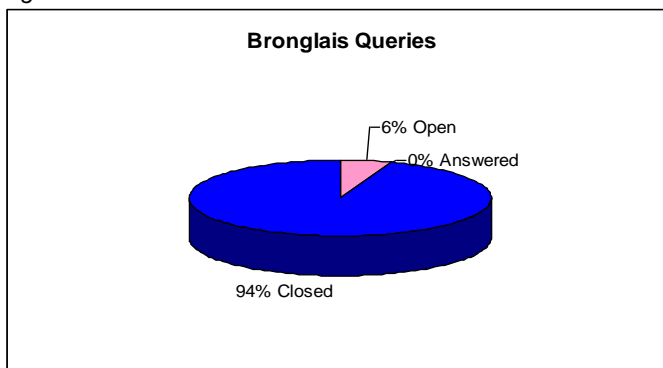


Figure 6

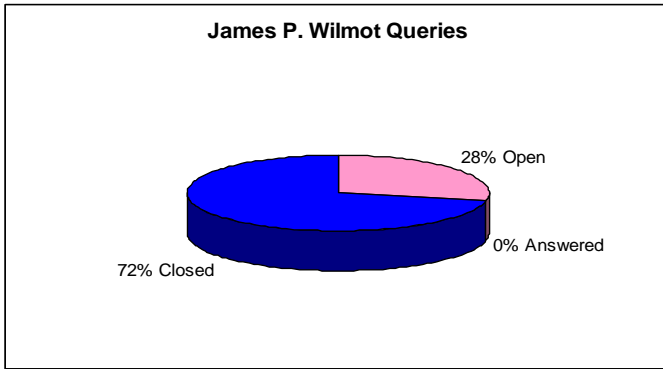


Figure 8

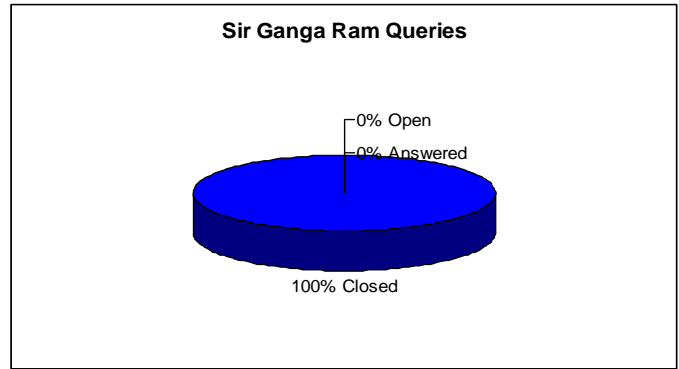


Figure 7

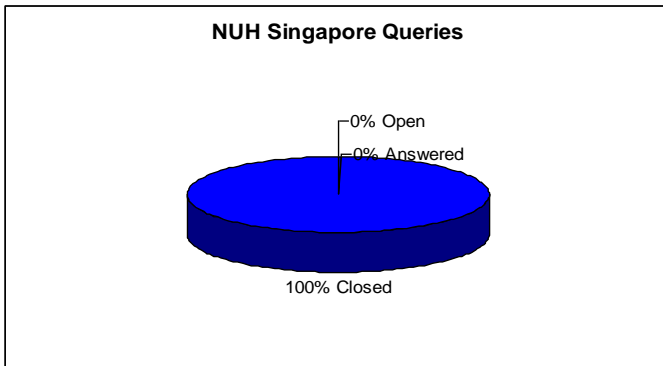


Figure 9

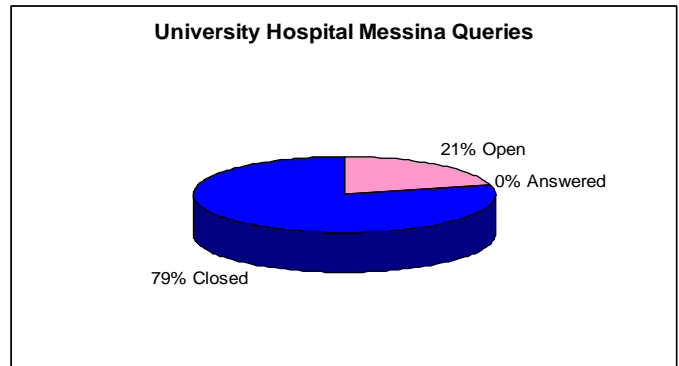
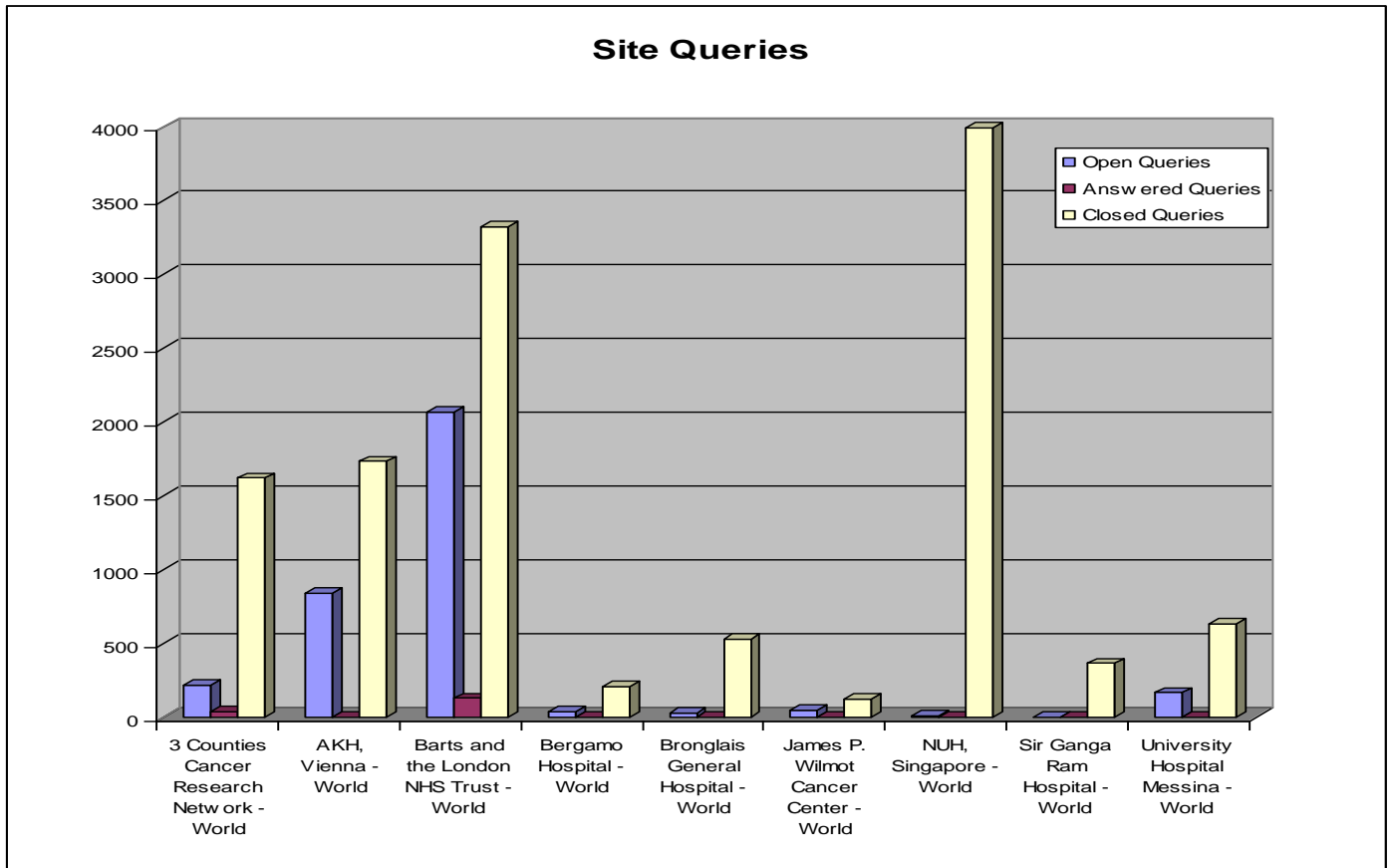


Figure 10



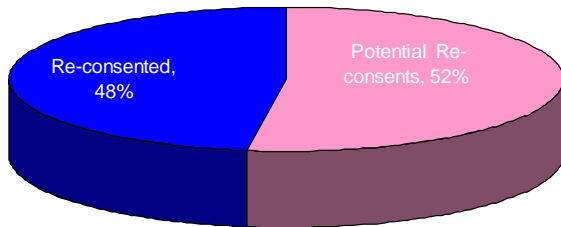
## Congratulations to:

### Singapore

- For the best re-consent rate – averaging 51 per month.
- Query resolution – Only 2 subjects have outstanding queries.
- For excellent rate of data entry.

### Bronglais

- For re-consenting almost half of their subject population



### Barts

- For outstanding indefinite re-consent – achieving a total of 570.

### 3 Counties

- For outstanding query resolution rate – clearing over 150 subject queries in the past two months alone.

### AKH Vienna

- For a strong effort in both data entry and query resolution.

### Messina, Bergamo and JP Wilmott

- Thank you for all your continued effort in devising a strategy for re-consenting.

