

# PERCEIVE

WE HAVE REACHED 5,000 SUBJECTS

July 2011



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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>	<a href="mailto:helpdesk@mdsol.com">helpdesk@mdsol.com</a>
<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 recruitment\*

**5,095 Enrolled**  
**571 Screened**  
**194 Re-consented**

A big thank you to all for your hard work

*\*(27 July 2011)*

## 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)

## NEWS SUMMARY

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# 5,000<sup>th</sup> Subject Enrolled in May 2011

## News

From Core Team

Big thanks to all for exceeding the 5,000 mark in enrolment. This is truly a great achievement.

We have recently reviewed the progress of the Registry and have come to the conclusion that focus should now be on collect as much good quality long term data capitalizing on the subjects already in the registry.

It is therefore paramount that we all focus on re-consenting patients at the moment. For full instructions please refer to the newest investigator's Folder, pgs 134-136. Please do not hesitate to contact us should you require any further information.

**Could you therefore please ensure that no new subjects are enrolled from the 1<sup>st</sup> August 2011**

## Strategic Plan

For the next 6 Months

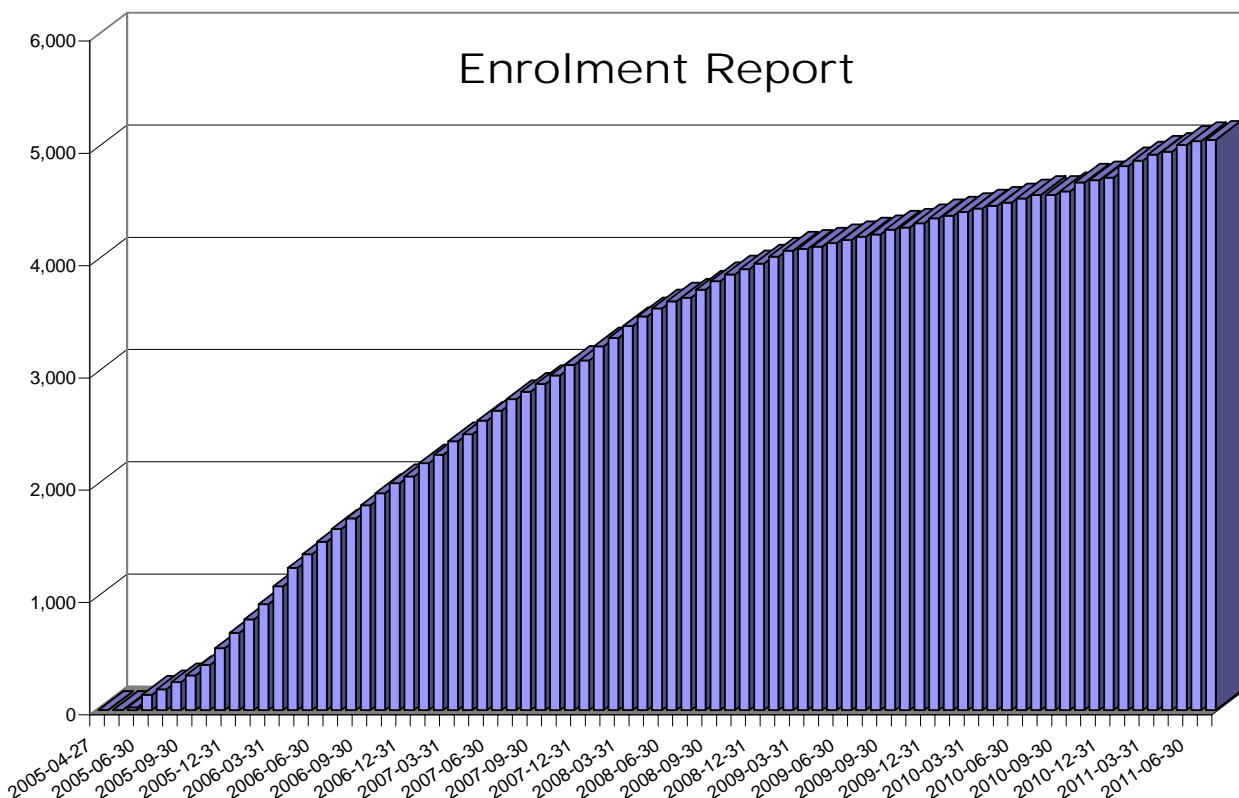
We would like to maximize the rate of re-consent aiming for 30% of the enrolled subjects to date.

Currently roughly 20-30% of the subjects have either passed away or have been withdrawn. Of the remaining 70-80% we estimate half may no longer be seen at the enrolling site hence lost to follow-up.

We would encourage all to stop new recruitment from the 1<sup>st</sup> of August and focus on re-consenting subjects already in the database and completing data entry and query resolution.

Analysis of the data is planned for January 2011

Future development of the Registry will be revisited in 3 months when actual re-consent data will be available



# Message to CRAs

From Monitoring Team

It is paramount that we all work together in clearing the outstanding queries. As of August 2011 we will no longer be sending query summary list to you all as a separate document. Please look at your site on-line to see what outstanding queries you have for your dataset.

Actions required by you, including query report is available on your main page in the top left 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.

Reminders in this page. Just a few points to improve data entry and reduce query generation.

Please let us know if you have any comments or suggestions.

## Reminders

### Bloods: one per month.

Please note that we would like blood results to be entered to consider the folder complete. Bloods must be entered as follows;

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

### Date of histological diagnosis

That is the date 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. All Follow-up dates are counted from the date of histological diagnosis

### 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

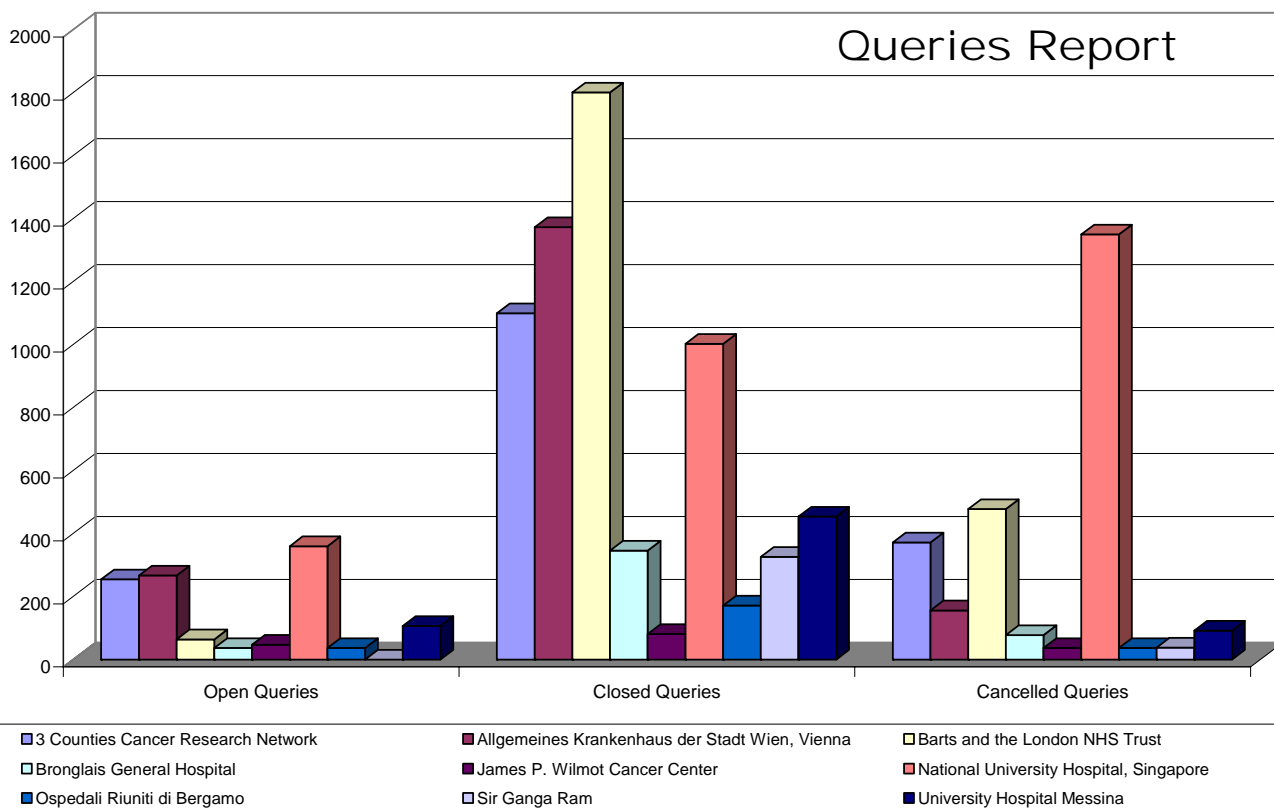
Please only record surgery that occurred within the first 30 days after diagnosis. All subsequent surgeries fall in the follow-up periods and should be recorded there.

### 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.

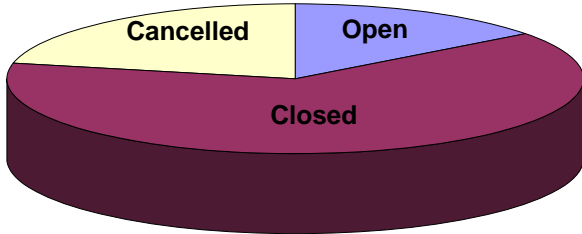
### Imaging

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

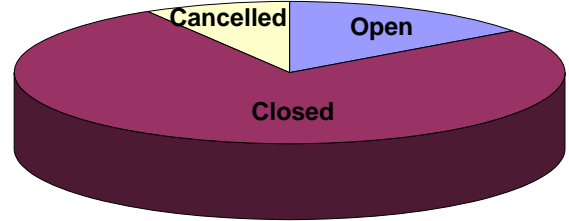


Query Report per site (in number of queries)

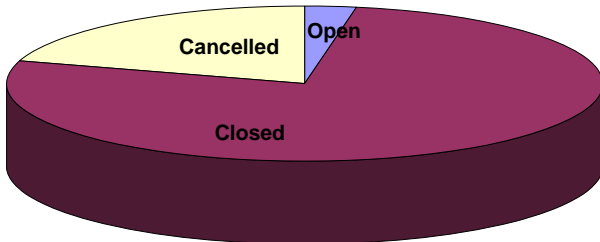
**3 Counties Cancer Research Network**



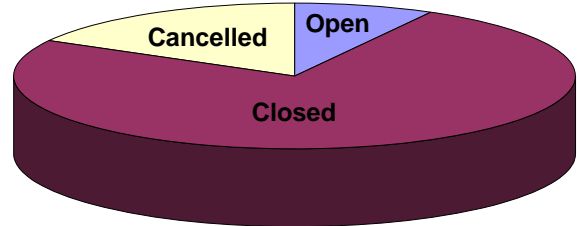
**Allgemeines Krankenhaus der Stadt Wien,**



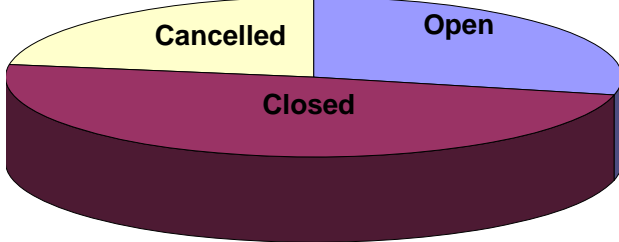
**Barts and the London NHS Trust**



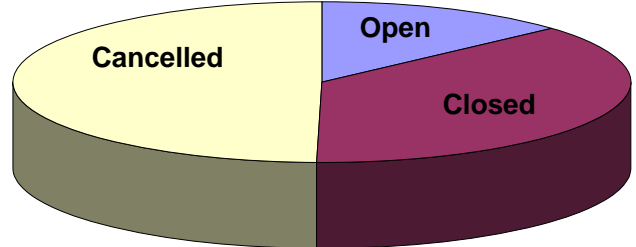
**Bronglais General Hospital**



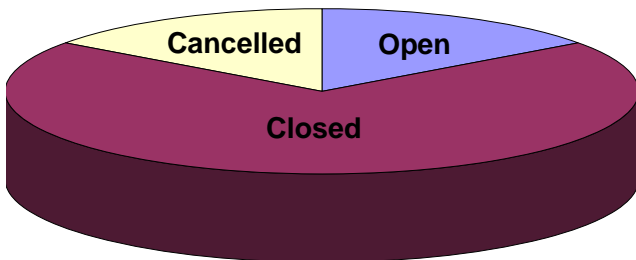
**James P. Wilmot Cancer Center**



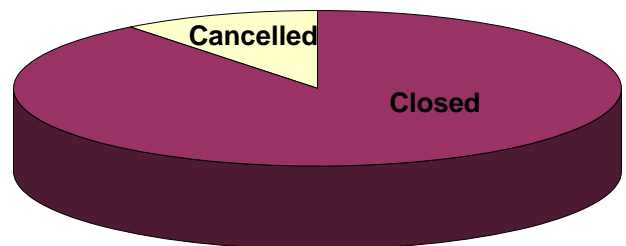
**National University Hospital, Singapore**



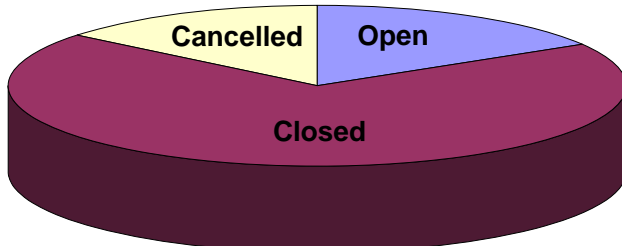
**Ospedali Riuniti di Bergamo**



**Sir Ganga Ram**



**University Hospital Messina**



**TOTAL**

