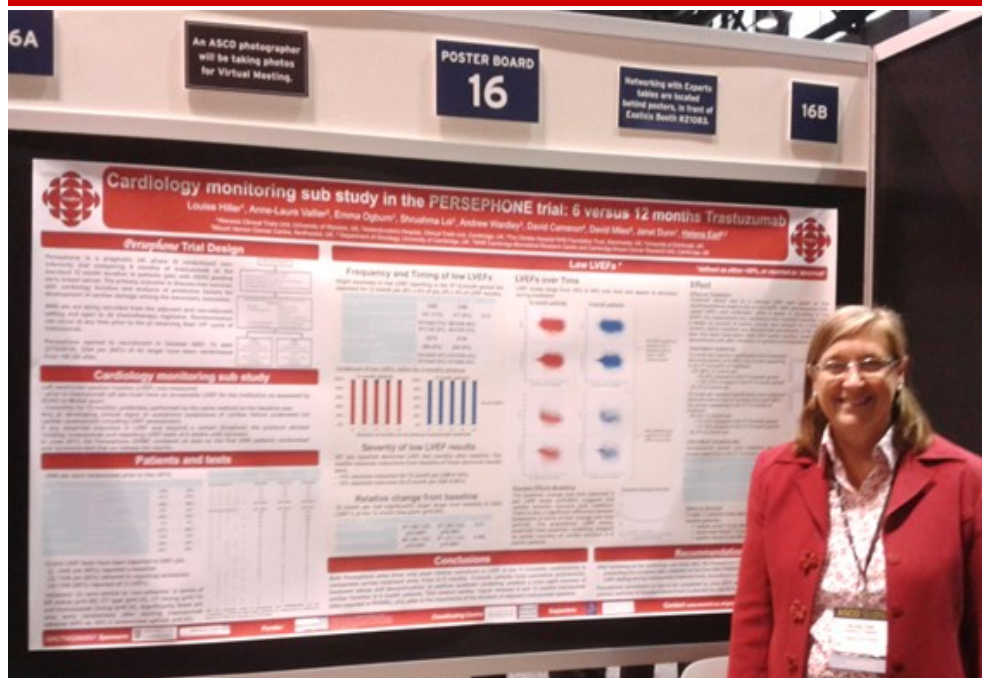


ASCO cardiology monitoring sub-study data poster



Dr Helena Earl, CI Persephone Trial at ASCO June 2014, Chicago

Our Chief Investigator, Dr Helena Earl recently presented the PERSEPHONE Cardiology monitoring sub-study data at ASCO 2014, Chicago. Data on the first 2500 patients recruited to the PERSEPHONE trial was included in the analysis. The poster presentation received a huge response. You can view the poster at the link:

<http://meetinglibrary.asco.org/content/96934>

Or please contact the Warwick PERSEPHONE Trial Office for a copy.

"Thank you"

We would like to say a BIG thank you to all our Sites for returning LVEF data and related queries to us. This huge effort helped us ensure the cardiology data was as complete and clean as possible for the poster. We really appreciate your continued support.

Latest recruitment news

Congratulations and very well done to all staff at **Chesterfield Royal Hospital** and **Yeovil District Hospital**

for entering the most patients in May 14.

Both hospitals entered **3** patients.....

a hamper full of sweet goodies is on its way to you!

Main staff at Chesterfield Royal Hospital: Dr Din Omar (PI), Emma Hudson (RN)

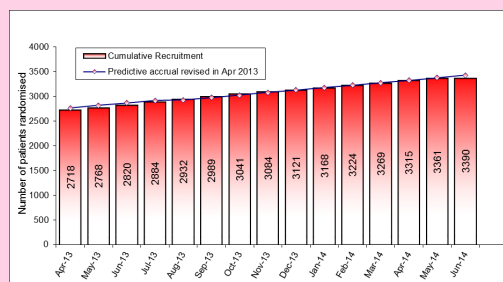
Main staff at Yeovil District Hospital: Dr Geoffrey Sparrow (PI), Dr Urmila Barthakur, Kerry Rennie (RN)

We have almost reached 85% of the recruitment target

That's just over **500** patients more to go!

Recruitment: 3390 patients (18.06.14)

- ▶ A total of **154 sites** are now open.
- ▶ We have 2 more Sites in set-up.
- ▶ **3390 patients** randomised by 18th June. 46 patients in April and 46 in May means that recruitment is steady.
- ▶ Keep up the good work and please help us reach 3500 patients this summer.
- ▶ We need to push recruitment to 50+ patients a month in order to finish recruitment of 4000 patients by end of June 2016.



Top 20 recruiters (as of 18.06.14)

Addenbrooke's Hospital	83
Peterborough City Hospital	67
Norfolk & Norwich University Hospital	63
Royal Sussex County Hospital	61
Southampton General Hospital	57
St Bartholomew's Hospital	57
Royal Derby Hospital	55
Southend Hospital	54
New Cross Hospital	53
Queen's Hospital (Romford)	51
Maidstone Hospital	51
Royal Liverpool University Hospital	51
Wexham Park Hospital	50
Luton and Dunstable Hospital	49
Charing Cross Hospital	46
Cumberland Infirmary	46
Christie Hospital	45
Eastbourne District General Hospital	44
Royal Hampshire County Hospital	43
Royal Shrewsbury Hospital	42

A big thank you to all site staff involved in screening, consenting and randomising patients into the trial.

Healthcare At Home (H@H) - Good news!

We have recently been informed that the contract between Bath ASU and H@H has finally been signed. H@H are currently in the process of training their chemotherapy delivery nurses on the new protocol procedures. Please ensure your SLA and Technical Agreement are updated directly with H@H.

CRFs outstanding request

The Data Input Clerks will be sending out the next request for all outstanding CRFs. Please ensure you return all outstanding CRFs to us by the deadline stated.

Currently CRF return rate is an average 95%.

Please help to us to bring this even closer to the 100% mark. If you are having problems returning CRFs to us please let us know and we will do our utmost to help.

QoL questionnaires

Please remember to give your patients the correct questionnaire at the correct time point. The questionnaires are due at the following protocol stated time-points:

- ◆ Baseline, before Trastuzumab start date
- ◆ 3 monthly, every 3 months for a year
- ◆ 6 monthly, every 6 months during year 2

A patient-specific questionnaire scheduling report is sent to Sites after each randomisation.

Screening Log request

Requests for Screening Logs will be sent out shortly. Please fax your completed Log to:

Fax: 02476 151 1586

The Log should include details of all new patients that were screened, approached and randomised (and declined) to the trial since that last request for Screening Logs was sent.

REMINDER regarding new version of the Site Signature and Delegation Log version 2.0 Oct '13

Any change in staff at Site automatically triggers the use of the new version of the Log. Please continue to use this Log from the point where a new member of staff is delegated any responsibility on the Persephone trial at Site. All responsibilities and contact details for new Staff must be provided on the Log.

Where a new Co-Investigator wishes to join the trial, please remember to provide a recent signed and dated CV.

Note, the Registration forms are no longer required except for Pathology and Pharmacy staff.

PI changes

If there is a PI change at your Site please ensure you notify the PERSEPHONE Trial Office as soon as possible. We will require the following documents in order to process the change:

1. Recent signed and dated CV for new PI
2. Countersigned CTA
3. R&D Approval for new PI
4. New version of Site Delegation log including new PI and Co-Inv
5. Old version of the Site Delegation Log, countersigned (pg1) and counter initialled (all pg2 with active staff

We will notify the REC and send you copy of the approval once we receive this.

News about the staff

We welcome on board Peter Bell, Data input Clerk who started with us just over a month ago.

We wish farewell to John Carey who worked with us as a temporary Data Input Clerk on PERSEPHONE.

PERSEPHONE team

Trial Coordination (Warwick)	Mrs Shrushma Loi	Persephone@warwick.ac.uk Phone: 0247 615 0492
Clinical Trial Administration (Warwick)	Miss Donna Howe	Persephone@warwick.ac.uk Phone: 0247 615 0600
Data Management (Warwick)	Miss Lisa Poulton Mr Peter Bell	Persephone@warwick.ac.uk Phone: 0247 615 1665 Persephone@warwick.ac.uk Phone: 0247 615 1127
Pharmacovigilance & Pharmacy (Cambridge)	Mrs Anne-Laure Vallier	anne-laure.vallier@addenbrookes.nhs.uk Phone: 01223 348086
Translational Studies (Cambridge)	Mr Kevin Baker	Kevin.Baker@addenbrookes.nhs.uk Phone: 01223 348083