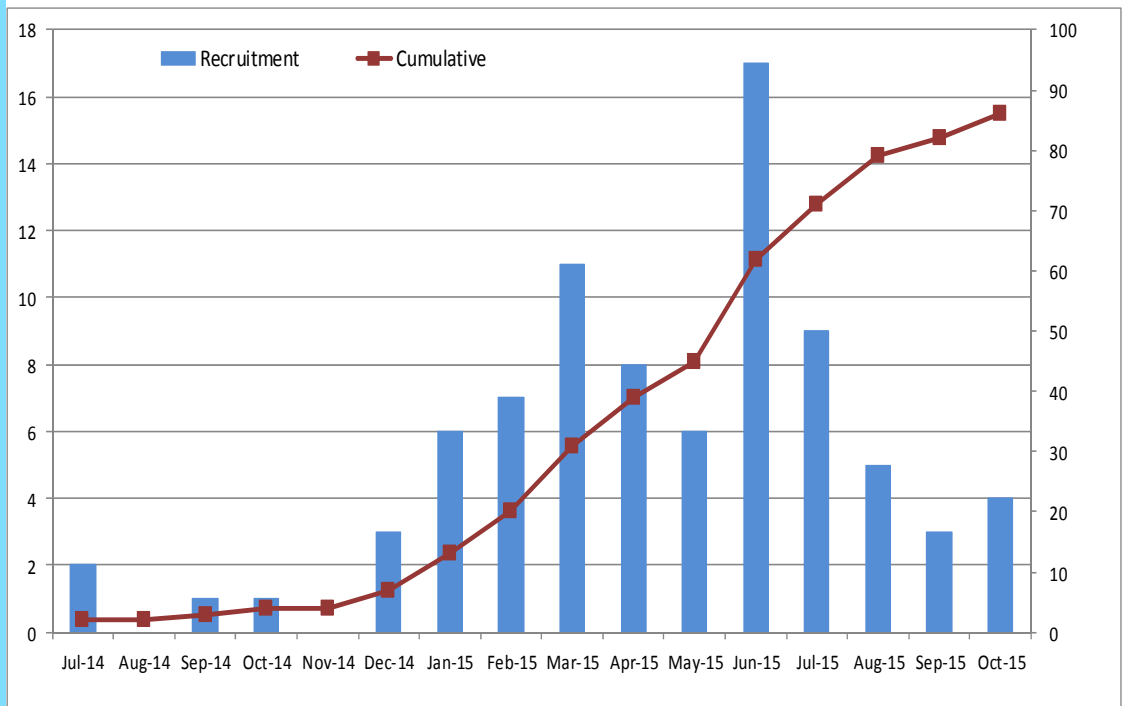




# BASIL Trials Newsletter

## BASIL-2 HTA Monitoring Meeting: New Targets

At the end of September the BASIL-2 Trial had a HTA Monitoring Meeting to assess how the trial is progressing in relation to its internal pilot targets and the overall recruitment target. We are pleased to relay that the trial will continue to be supported by the HTA and that we have been given some new recruitment targets which should be achievable. We need to get 12 patients this month (October) and increase by 2 patients per month thereafter until March 2016, then 25 in April 2016. Given that we intend to open 3 centres per month until the end of January, we should have 50 centres able to recruit so this is a very achievable goal. However, be aware that September was a dreadful month for recruitment with only 3 patients entering the trial in the whole of September.



Centre	Total	Centre	Total
St Thomas' Hospital	14	Frimley Park Hospital	2
Birmingham Heartlands Hospital	10	Sheffield	2
Hull Royal Infirmary	8	Addenbrookes	2
Royal Free Hospital	7	Royal Cornwall Hospital	2
Leeds General Infirmary	6	Royal Gwent Hospital	2
Russells Hall Hospital	6	Leicester Royal Infirmary	1
St George's Hospital	5	Northwick Park Hospital	1
St Mary's Hospital	4	Southampton General Hospital	1
Freeman Hospital	4	Worcestershire Royal Hospital	1
Manchester Royal Infirmary	3	Kent & Canterbury	1
Cumberland Infirmary	3	Ninewells Hospital	1
		<b>Grand Total</b>	<b>86</b>

### BASIL-2 Monthly Recruitment

As of the 16th October the trial was open at 41 sites and had recruited 86 patients.

As well as the sites shown above, there are another 19 sites which are currently able to recruit but have yet to do so.

**Targets: 12 patients during October, 14 patients during November, 16 patients during December**

Latest News on the BASIL-2 and BASIL-3 trials

# BASIL Trials Update

BASIL-2 is funded by the Health Technology Programme Grant 12/35/45

BASIL-3 is funded by the Health Technology Programme Grant 13/81/02

IRAS: 144764

IRAS: 183761

ISRCTN: 27728689

ISRCTN: tbc

## BASIL-3: Ethical Approval

We are delighted to report that the BASIL-3 Trial was approved by ethics on the 27th August and Practical Arrangement Forms should have reached all interested centres by now. If you haven't received information about this important trial and are interested in participating, please contact the BASIL Trials Office (BASIL-2@trials.bham.ac.uk) BASIL-3 will be a 3-armed trial looking at purely endovascular interventions; plain balloon with or without a bare metal stent (+/- BMS) v drug coated balloon +/- BMS v drug eluting stent.

## BASIL-2: Version Control Issues

Firstly, thank you to all the centres who have been sending in their data in response to our requests. Data returns are much more in line with what we would expect now, but we do urge you to keep sending these in within a couple of weeks of the scheduled visit.

However, we have noted some issues with version control. In particular, the SAE form (you should all be using version 2.0, 4th Sept 2014) and some of the consent /screening forms. For these patient-facing forms it is really a case of transcribing the correct version of the PIS onto the Consent Form. The correct version and dates of the patient-facing forms are as follows:

Screening Information Sheet: v1.0, 24th Jan. 2014      Screening Consent Form: v1.1, 1st April 2014  
Participant Information Sheet: v1.2, 1st April 2014      Participant Consent Form: v2.0, 31st July 2014

Correct versions are available for download at [BASIL-2@trials.bham.ac.uk](mailto:BASIL-2@trials.bham.ac.uk)

## COMPETITION: Win Restaurant Vouchers!

Until the end of October, then throughout each of November and December each time a recruiting centre recruits a patient to BASIL-2 they will get an entry into the monthly draw for £100 of restaurant vouchers of your choice to be shared by the winning team. The more patients you randomise in a calendar month, the more entries you get into the draw.

That's 3 prizes; 1 a month, from now until Jan 1st 2016.



## BASIL Trials: Forthcoming Meetings

4-6th November: British Society of Interventional Radiology, Glasgow —publicity stand + presence during drinks reception on Wednesday 4th, 18:15-18:45

11-13th November: Vascular Society of Great Britain & Ireland Annual Scientific Meeting—publicity stand + investigators meeting in the Bourne Suite, BICC from 12:30-13:30 on Thursday 12th November. Sandwich lunch provided.

**PLEASE INFORM THE BASIL OFFICE IF YOU WISH TO ATTEND EITHER SESSION**