

# BASIL Trials Newsletter



## New Addition to the BASIL Trials Family—BASIL-3!

The BASIL Trials Office is pleased to announce that the BASIL-3 trial has been successful in gaining funding from the HTA.

BASIL-3 is a 3-arm RCT that will look at patients with SLI due to femoro-popliteal disease and which compares plain balloon angioplasty, drug coated balloons and drug eluting stents.

The trial is due to formally start in August 2015 but the BASIL Trial Office will be inviting all BASIL-2 centres to participate in BASIL-3. We would like to have as many centres as possible in an advanced state of readiness prior to August and should be able to achieve this by using either the same or very similar documentation, as for BASIL-2. Be prepared.

## 3rd Substantial Amendment

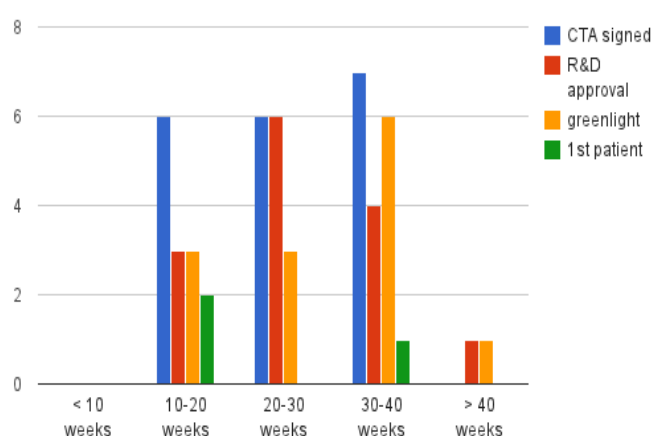
The third substantial amendment to BASIL-2 was approved on 12th November and relates to the patient-completed booklets. As with all substantial amendments, this should be formally acknowledged by your R&D and acted upon immediately subsequently.

Prior to this amendment, data about the patient's personal financial circumstances and use of primary and secondary care was achieved by having separate forms. These forms have now been compiled into the patient completed booklet because the nurse should check all booklets with the patient and it was felt that this was the most appropriate time to discuss these topics with them. Now, the patient is instructed to complete the majority of the booklet prior to their appointment, but the last two pages should be completed at their appointment

## Latest Progress

As of the 17th December the trial was open at 13 sites, in 8 regions and had recruited 6 patients. The BASIL-2 Trial pilot phase ends at the end of April and we are required to randomise 60 patients by this time. If each regional centre recruits the 2 patients per month as originally promised we can still hit this target. However, regional centres have not come close to achieving this rate so far. It is vital they do so here on in.

BASIL-2 Milestones



## Meeting News

BASIL-2 had a presence at 2 major meetings during the last quarter. The BSIR in Liverpool, where we had a stall, and the VSGBI in Glasgow where we held an Investigator's Meeting and a shared presence with EVRA. There was some discussion about the screening process and as a result the TMG is currently drafting an amended screening information sheet and has issued the following clarification.

1. All patients presenting with SLI should be screened and go on the screening log
2. The screening log is the only data that should be returned to BCTU, at present

Note: All newsletters produced by BASIL-2 are controlled documents.  
Print and file this in the Investigator Site Folder.