



NHS Research Scotland works collaboratively across all Health Boards to provide a comprehensive and complete service. This national approach results in fast, efficient and reliable support to deliver high-quality clinical trials in Scotland.

GlaxoSmithKline (GSK) HARMONY Study

A long-term, randomised, double-blind, placebo controlled study to determine the effect of albiglutide when added to standard blood glucose lowering therapies on major cardiovascular events in patients with Type 2 diabetes.

TOTAL POPULATIONS: 9400 randomised patients from 590 sites over 29 countries.

SITES: 19 UK Sites initially, moving to 26

- 5 NRS (secondary care in Scotland)
- 3 primary care sites in Scotland
- 11 additional sites in the UK:
8 secondary care, 3 primary care

Streamlined processes in Scotland supported the rapid set-up and delivery of GSK HARMONY study

START UP

Overall, average study set-up time was fastest at NRS sites when compared to other sites in the UK

- Average contract negotiation time was 64 days shorter in NRS when compared with other sites in the UK and 17 days shorter than the UK average
- Average time to NHS permission from submission of full document set was 80 days shorter in NRS sites when compared with other secondary care sites in the UK and 30 days faster than the UK average
- Average time to site activation from full document set was 32 days shorter in NRS sites when compared with other secondary care sites in the UK and 14 days shorter compared to the UK average

RECRUITMENT

Significant recruitment achievements included first UK patient randomised and highest recruiting UK site

- NRS sites had the shortest average time between site activation and both first subject first visit (FSFV) and First Subject Randomised
- Recruitment to NRS sites has been rapid and steady
 - o NRS achieved 83% recruitment compared to 71% nationally and 63% in other UK secondary care sites
 - o 80% of sites in Scotland (4/5) have achieved 90% of their recruitment target
 - o NRS have randomised more patients to the study than any other group of sites
 - o NRS are 15th internationally in terms of percentage recruitment to target compared with 22nd for the UK overall.

NHS Research Scotland aims to streamline the start-up of studies with more than one site in Scotland.

Our Approach

The NRS Generic Review process allocates an experienced reviewer as the initial single point for Sponsors/CROs to perform a study-level governance review and negotiate a single contract draft and budget for all sites in Scotland.

The single budget and contract draft process is based on the following assumptions:

- Use of the ABPI model Clinical Trial Agreement (mCTA)
- Use of the current version of the NIHR costing templates completed to reflect the requirements of protocol

While the generic review is ongoing, local site staff can work in parallel to prepare site for study initiation.

Communications and proactivity of the Sponsor during the review and negotiation process accelerates the start-up process.



NRS Generic Review process and commitment to a single NRS price and contract template resulted in rapid average contract negotiation timelines and fast overall start-up when compared to other sites in the UK.

Notes:

- HARMONY study data was provided by GSK on 15/9/2016 (GLP116174 – HARMONY) and key points relating to start-up and recruitment performance were extracted by the NHS Industry Liaison Manager.
- NRS sites are defined as Secondary Care NHS sites.
- Thanks to Steven Lauder (GSK Harmony Project Manager) and Catharine Matonti (GSK Field Team Manager)

Further information

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