This study was caught up in the changeover to HRA approvals. We received notification of HRA approval on 8.6.16 and continued with our study set-up processes.

The set-up of this study has been impacted by the Sponsor issuing an amendment during the introduction of HRA Approval, which meant HRA Approval had to await. Subsequent to this, the Sponsor is awaiting some outstanding documentation from the study team before the green light can be given.

The Sponsor has made changes to the study protocol which means approval has been delayed. Subsequent to this, the Sponsor is awaiting some outstanding documentation from the study team before the green light can be given.