# Performance in Initiating Research (PIN);

# Studies given NHS Permission between 01/04/2015 – 01/04/2016 (Q4)

| Local ID | Id | Research Ethics Committee Reference Number | Integrated Research Application System Number | Submission Type | Name of Trial | Date of Receipt of Valid Research Application | Date of NHS Permission | First Patient Recruited? | Date of First Patient Recruited | Duration between VRA and NHS Permission | Duration between NHS Permission and First Patient | Duration between VRA and First Patient | Benchmark Met | Date Study Initiated | Date Site Invited | Date Site Selected | HRA Approval Date | Date Site Confirmed By Sponsor | Date Site Confirmed | Non-Confirmation Status | Date Site Ready To Start | A - Permissions delayed/denied | B - Suspended by sponsor | C - Closed by sponsor | D - Sponsor Delays | E - Staff availability issues | F - No patients seen | G - No patients consented | H - Contracting delays | I - Rare diseases | J - Other | Comments | Reasons for delay correspond to: |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 15-03-04 | 75195 | 12/LO/1322 | 99922 | NHS Permission | Diabetes Prevention using SMS | 19/05/2015 | 20/05/2015 | Yes | 14/07/2015 | 1 | 55 | 56 | Yes | | | | | | | | | | | | | | | | | | | | |
| 15-02-09 | 75196 | 13/EM/0251 | 13150 | NHS Permission | Serelaxin when added to standard therapy in acute heart failure | 27/04/2015 | 30/04/2015 | No | | 3 | | | No | | | | | | | | | | | | | Y | | | | | Patients failing to meet the inclusion criteria (as they must be recruited in a very strict timef-frame at presentation). Patients are being managed in community leading to reduced opportunity to screen. | Neither |
| 14-08-05 | 75197 | 13/LO/1096 | 89630 | NHS Permission | MID-FRAIL PROJECT | 11/05/2015 | 11/05/2015 | Yes | 24/06/2015 | 0 | 44 | 44 | Yes | | | | | | | | | | | | | | | | | | | | |
| 15-04-04 | 75198 | 14/SC/1219 | 159391 | NHS Permission | AIRWAYS-2 | 14/04/2015 | 18/05/2015 | Yes | 10/11/2015 | 34 | 176 | 210 | No | | | | | | | | | | | | Y | | | | | | Y | Delay in first patients seen; Consent follows patient resuscitation. Patient survival is only 20% and therefore likelihood of being able to identify an eligible patient is severely reduced. Benchmark not met; RA submitted as single SSI; Sponsor failed to name local collaborator, ITU consultant, ED consultant, or ED research nurse. | Neither |
| 14-12-02 | 75199 | 13/EE/0038 | 111368 | NHS Permission | HALT-IT | 13/05/2015 | 10/06/2015 | No | | 28 | | | No | | | | | | | | | | | | | Y | | | | | New PI has recently been selected. | NHS Provider |
| 13-04-13 | 75200 | 12/NW/0766 | 56508 | NHS Permission | PREDNOS 2 | 18/08/2015 | 24/08/2015 | Yes | 25/08/2015 | 6 | 1 | 7 | Yes | | | | | | | | | | | | | | | | | | | | |
| 15-02-02 | 75201 | 14/SS/1096 | 164274 | NHS Permission | RAPID CTCA | 22/10/2015 | 26/10/2015 | Yes | 17/12/2015 | 4 | 52 | 56 | Yes | | | | | | | | | | | | | | | | | | | | |
| 15-05-10 | 75202 | 14/EM/1267 | 166568 | NHS Permission | PARADIGM: LCZ696 in patients from Paradigm HF study | 12/11/2015 | 12/11/2015 | Yes | 30/11/2015 | 0 | 18 | 18 | Yes | | | | | | | | | | | | | | | | | | | | |
| 15-05-04 | 75203 | 14/WA/1056 | 154468 | NHS Permission | AML 19 | 03/12/2015 | 03/12/2015 | No | | 0 | | | No | | | | | | | | | | | | | | | | | | Y | Delays in uploading the local chemotherapy regime to the Chemocare Prescribing system by the Y&H CRN. | Neither |
| 15-10-02 | 75204 | 15/YH/0428 | 188418 | NHS Permission | DUAL VIII | 18/12/2015 | 18/12/2015 | No | | 0 | | | No | | | | | | | | | | | | | | | Y | | | | Recruitment is proving difficult as patients are not consenting to the trial while in care at the hospital. There is hope that the recruitment figure may increase with efforts in community care. | Neither |
| 15-04-12 | 75213 | 15/NW/0156 | 168118 | NHS Permission | SENIOR (Assessing the Safety and Efficacy of HDE901U300 Versus Lantus in Older Patients with Type 2 Diabetes Inadequately Controlled on Antidiabetic Regimens Either Including no Insulin, or with Basal Insulin as Their Only Insulin) | 13/06/2015 | 25/06/2015 | Yes | 06/10/2015 | 12 | 103 | 115 | No | | | | | | | | | | | | | | | | | Y | | | | Recruitment is proving difficult as patients are not consenting to the trial while in consultation at the hospital. | Neither |
| 15-05-09 | 75214 | 14/YH/0085 | 126738 | NHS Permission | FLAIR (Front-line therapy in CLL: Assessment of Ibrutinib + Rituximab) | 24/03/2016 | 24/03/2016 | No | | 0 | | | Within 70 Days | | | | | | | | | | | | | | Y | | | | | Newly approved study. No patients have yet been seen that meet the inclusion criteria. | Neither |
| 15-06-04 | 75215 | 15/SC/0115 | 167694 | NHS Permission | Harmony Outcomes (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 mellitus) | 06/10/2015 | 08/10/2015 | Yes | 06/11/2015 | 2 | 29 | 31 | Yes | | | | | | | | | Y | | | | | | | | | | | | |
| 15-10-04 | 75216 | 15/YH/0458 | 188061 | NHS Permission | SMART COPD | 21/03/2016 | 24/03/2016 | No | | 3 | | | Within 70 Days | | | | | | | | | | | | | | Y | | | | | Newly approved study. No patients have yet been seen that meet the inclusion criteria. | Neither |

## Performance in Delivering Research (PID);

## Commercial Studies closed to Recruitment between 01/04/2015 – 01/04/2016 (Q4)

| Local ID | Id | Research Ethics Committee Reference Number | Integrated Research Application System Number | Name of Trial | Target Number Of Patients Agreed? | Minimum Number Of Patients Agreed (Enter Same In Both If Only One Number) | Maximum Number Of Patients Agreed (Enter Same In Both If Only One Number) | Target Date To Recruit Patients Agreed? | Date Agreed to recruit target number of patients | Total Number Of Patients Recruited At The Agreed Target Date | Date That The Trial Closed To Recruitment | Reason For Closure Of Trial | Comments |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 14-01-10 | 2969 | 13/EE/0449 | 143616 | REPLACE | Number Agreed | 8 | 8 | Date Agreed | 15/05/2015 | 13 | 15/05/2015 | Recruitment Finished | |
| 09-11-05 | 2971 | 09/H0406/110 | 131150 | PARADIGM | Number Agreed | 6 | 6 | Date Agreed | 15/01/2016 | 6 | 15/01/2016 | Recruitment Finished | |