

PERFORMANCE IN INITIATING Q3 2017-2018

| Id     | Research Ethics Committee Reference Number | Integrated Research Application System Number | Name of Trial  | First Patient Recruited? | Date of First Patient Recruited | Duration between Date Site Selected and Date Site Confirmed | Duration between Date Site Confirmed and First Patient Recruited | Duration between Date Site Selected and First Patient Recruited | Benchmark Met | Date Site Invited | Date Site Selected | HRA Approval Date | Date Site Confirmed By Sponsor | Date Site Confirmed | Date Site Ready To Start | Reasons for Delay    | Comments   | Reasons for delay correspond to: |
|--------|--|---|--|--------------------------|---------------------------------|---|--|---|---------------|-------------------|--------------------|-------------------|--------------------------------|---------------------|--------------------------|----------------------|--|----------------------------------|
| 114424 | 16/NW/0465                                 | 189554  | Improving quality of life through the routine use of the Patient Concerns Inventory for head and neck cancer patients  | Yes                      | 08/02/2017                      | 0   | 23   | 23  | Yes           | 11/04/2016        | 16/01/2017         | 13/09/2016        | 16/01/2017                     | 16/01/2017          | 16/01/2017               |                      |  | Please Select...                 |
| 114425 | 16/WM/0006                                 | 192580  | WHIST - Wound Healing In Surgery for Trauma. A Randomised Controlled Trial of standard wound management versus negative pressure wound therapy in the treatment of adult patients having surgical incisions for major trauma to the lower limb | Yes                      | 03/02/2017                      | 6   | 18   | 24  | Yes           | 22/09/2016        | 10/01/2017         |                   | 30/01/2017                     | 16/01/2017          |                          |                      | This study was given HRA Approval for AUH to be added as a site. However, the original application was pre HRA Approval Process. | Please Select...                 |
| 114426 | 16/NW/0786                                 | 186990  | A feasibility study on integrating home-based metacognitive therapy for anxiety and depression in the cardiac rehabilitation pathway (PATHWAY STUDY 3)   | Yes                      | 10/04/2017                      | 14  | 42   | 56  | Yes           | 30/11/2016        | 13/02/2017         | 13/02/2017        | 13/02/2017                     | 27/02/2017          |                          |                      |  | Please Select...                 |
| 114427 | 13/SC/0530                                 | 123453  | An international multicenter randomised controlled trial of open versus laparoscopic liver surgery (hemihepatectomy and postero-superior segment resections).  | Yes                      | 14/09/2017                      | 12  | 87   | 99  | No            | 15/02/2017        | 07/06/2017         |                   | 14/06/2017                     | 19/06/2017          | 19/06/2017               | F - No patients seen | still within benchmark   | Neither                          |
| 114428 | 16/NS/0053                                 | 201313  | A randomised controlled trial comparing laparoscopic cholecystectomy with observational/conservative management for preventing recurrent symptoms and complications in adults with uncomplicated symptomatic gall stones                       | No                       |                                 | 33  |  |   | No            | 28/02/2017        | 05/05/2017         | 01/09/2016        | 02/06/2017                     | 07/06/2017          |                          | F - No patients seen | Difficult to recruit patients due to randomisation arm as patients did not want to be managed conservatively                     | Neither                          |
| 114429 | 16/NS/0094                                 | 206213  | BioImpedance Spectroscopy to Maintain Renal Output: The BISTRO trial   | Yes                      | 26/06/2017                      | 64  | 34   | 98  | No            | 03/03/2017        | 20/03/2017         | 04/10/2016        | 15/05/2017                     | 23/05/2017          | 19/06/2017               | D - Sponsor Delays   | Sponsor delay in providing site with agreement to commence recruitment   | Sponsor                          |
| 114430 | 16/EE/0065                                 | 192416  | Survival improvement with Cholecalciferol in patients on dialysis -The SIMPLIFIED Registry trial   | No                       |                                 | 62  |  |   | No            | 10/03/2017        | 10/03/2017         |                   | 10/03/2017                     | 11/05/2017          | 26/06/2017               | J - Other            | Delays due to discussions with Sponsor regarding Excess Treatment Costs  | Both                             |
| 114431 | 13/LO/0968                                 | 98339   | A randomized, double blind controlled trial comparing rituximab against intravenous  | Yes                      | 09/06/2017                      | 9   | 35   | 44  | Yes           | 18/12/2014        | 26/04/2017         |                   | 26/04/2017                     | 05/05/2017          | 05/05/2017               |                      |  | Please Select...                 |

PERFORMANCE IN INITIATING Q3 2017-2018

|        |            |        |  |     |            |     |    |    |     |            |            |            |            |            |            |                    |  |                  |
|--------|------------|--------|--|-----|------------|-----|----|----|-----|------------|------------|------------|------------|------------|------------|--------------------|--|------------------|
|        |            |        | cyclophosphamide in connective tissue disease associated interstitial lung disease   |     |            |     |    |    |     |            |            |            |            |            |            |                    |  |                  |
| 114432 | 16/SC/0089 | 196789 | A pragmatic randomised controlled trial to determine whether VV-ECCo2R in mechanically ventilated patients with hypoxemic respiratory failure improves 90 day mortality  | Yes | 26/06/2017 | 41  | 0  | 41 | Yes | 18/04/2016 | 16/05/2017 |            | 20/06/2017 | 26/06/2017 | 26/06/2017 |                    | Still within benchmark   | Please Select... |
| 114433 | 16/NW/0860 | 216349 | Assessing and optimising the performance of low cost devices for measuring intravenous fluid delivery and response   | Yes | 17/05/2017 | 1   | 21 | 22 | Yes | 13/10/2016 | 25/04/2017 | 02/02/2017 | 25/04/2017 | 26/04/2017 | 26/04/2017 |                    |  | Please Select... |
| 114434 | 15/WM/0268 | 180158 | Randomised, open label study of rituximab/ibrutinib vs rituximab/chemotherapy in older patients with untreated mantle cell lymphoma  | No  |            | 15  |    |    | No  | 17/03/2017 | 14/08/2017 |            | 24/08/2017 | 29/08/2017 | 31/08/2017 | I - Rare diseases  | There were pharmacy issues regarding excess treatment costs. This was relevant to the normal care pathway of the patients  | NHS Provider     |
| 114435 | 16/NW/0496 | 169304 | RESILIENT: Randomised, controlled, double blind Study to assess mechanistic effects of combination therapy of dapagliflozin with Exenatide LAR versus dapagliflozin alone in obese (BMI>30 kg/m2) patients with Type 2 diabetes mellitus.        | No  |            | 29  |    |    | No  | 27/10/2015 | 30/08/2017 | 12/06/2017 | 26/09/2017 | 28/09/2017 |            | D - Sponsor Delays | Confirm CC from the Trust but green light still awaited from Sponsor   | Sponsor          |
| 114436 | 16/NW/0517 | 188554 | A phase III study to determine the role of ixazomib as an Augmented Conditioning therapy in salvage autologous stem cell transplant (ASCT) and as a post-ASCT Consolidation and maintenance strategy in patients with Relapsed multiple myeloma. | No  |            | 139 |    |    | No  | 29/07/2016 | 15/02/2017 | 27/10/2016 | 17/07/2017 | 04/07/2017 | 04/07/2017 | J - Other          | This trial requires referral of patients to the Tranplant Centre. The Royal Liverpool is the Referral Centre. Our site could not open until the referral centre was open. This was the delay as the Royal did not open in line with our Trust. We could confirm site approval due to this reason at the request of the Sponsor | Sponsor          |
| 114437 | 17/LO/0447 | 211176 | A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study Assessing the Effect of   | Yes | 30/08/2017 | 19  | 43 | 62 | Yes | 26/02/2017 | 29/06/2017 | 28/06/2017 | 06/07/2017 | 18/07/2017 | 01/08/2017 |                    |  | Please Select... |

PERFORMANCE IN INITIATING Q3 2017-2018

|        |            |        |   |     |            |     |    |     |     |            |            |            |            |            |            |                        |  |                  |
|--------|------------|--------|---|-----|------------|-----|----|-----|-----|------------|------------|------------|------------|------------|------------|------------------------|--|------------------|
|        |            |        | Gelesis200 on Body Weight in Overweight and Obese Subjects with Prediabetes and Metformin-Treated Type 2 Diabetes (Protocol Num: GS-200-002)  |     |            |     |    |     |     |            |            |            |            |            |            |                        |  |                  |
| 114438 | 17/NE/0096 | 222956 | A randomised, double blind, placebo controlled multicentre Phase 2 dose ranging study to assess the safety and efficacy of multiple VAY736 doses administered subcutaneously in patients with moderate to severe primary Sjögren's syndrome | Yes | 22/08/2017 | 39  | 22 | 61  | Yes | 29/03/2017 | 22/06/2017 | 26/05/2016 | 25/07/2017 | 31/07/2017 | 16/08/2017 |                        |  | Please Select... |
| 115147 | 17/EM/0183 | 220783 | A randomised, double-blind, parallel group PhIII study to assess the clinical efficacy and safety of 100 mg SC Mepolizumab as an add on to maintenance treatment in adults with severe bilateral nasal polyps Protocol Number: 205687       | Yes | 01/12/2017 | 7   | 45 | 52  | Yes | 26/07/2016 | 10/10/2017 | 28/06/2017 | 11/10/2017 | 17/10/2017 | 17/10/2017 |                        |  | Please Select... |
| 115148 | 16/LO/0058 | 193773 | LAVA- Liver resection surgery versus thermal ablation for colorectal liver metastases   | No  |            | 193 |    |     | No  | 11/08/2016 | 23/03/2017 |            | 13/09/2017 | 02/10/2017 | 10/10/2017 | H - Contracting delays | Our site could not open until the full pathway was completed by a neighbouring Trust. The collaborating Trust provided radiology services and they were unable to provide approval within the specified time. Hence the delay. | NHS Provider     |
| 115149 | 15/YH/0478 | 186697 | A Phase 3, DoubleBlind, Randomized, LongTerm, PlaceboControlled, Multicenter Study Evaluating the Safety and Efficacy of Obeticholic Acid in Subjects with Nonalcoholic   | Yes | 01/12/2017 | 84  | 24 | 108 | No  | 20/04/2017 | 15/08/2017 | 26/04/2016 | 24/10/2017 | 07/11/2017 | 07/11/2017 | J - Other              | Pathology Service department external to the Trust   | Neither          |

PERFORMANCE IN INITIATING Q3 2017-2018

|        |             |        |   |     |            |     |    |    |                |            |            |            |            |            |            |                               |                       |                  |
|--------|-------------|--------|---|-----|------------|-----|----|----|----------------|------------|------------|------------|------------|------------|------------|-------------------------------|-----------------------|------------------|
|        |             |        | Steatohepatitis   |     |            |     |    |    |                |            |            |            |            |            |            |                               |                       |                  |
| 115150 | 17/EM/0192  | 223856 | A Phase 2, 24-week, Randomized, Double - Blind. Placebo - Controlled, Multicenter Study, Followed by a 24 - Week Extension, to Evaluate the Efficacy and Safety of CC - 90001 in Subjects with Idiopathic Pulmonary Fibrosis  | No  |            | 0   |    |    | Within 70 Days | 25/05/2017 | 07/11/2017 | 14/09/2017 | 25/10/2017 | 07/11/2017 | 07/11/2017 | I - Rare diseases             | Very rare condition   | Neither          |
| 115151 | 10/HO604/51 | 43801  | Natural history and pathogenesis of systemic IgG4 disease   | No  |            | 100 |    |    | No             | 04/05/2017 | 01/08/2017 | 30/08/2016 | 01/09/2017 | 09/11/2017 | 09/11/2017 | E - Staff availability issues | Staff workload issues | NHS Provider     |
| 115168 | 17/LO/116   | 225233 | SKIPPAIN (Speed of onset of SecuKinumab-Induced relief from Pain in Patients with Axial SpoNdyloarthritis) A 24-week, randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy and safety of secukinumab in controlling spinal pain in patients with axial spondyloarthritis                  | No  |            | 3   |    |    | Within 70 Days | 16/08/2017 | 15/12/2017 | 09/10/2017 | 08/12/2017 | 18/12/2017 | 18/12/2017 |                               |                       | Please Select... |
| 115169 | 17/SC/0237  | 220963 | A multi-centre, double-blind, parallel-group, randomised, placebo controlled phase 2a study to investigate safety, tolerability, pharmacodynamics, and pharmacokinetics of different doses of orally administered BI 1467335 during a 12 week treatment period compared to placebo in patients with clinical evidence of NASH | Yes | 16/01/2018 | 1   | 41 | 42 | Yes            | 04/10/2017 | 05/12/2017 | 17/10/2017 | 24/11/2017 | 06/12/2017 | 13/12/2017 |                               |                       | Please Select... |
| 115170 | 17/SW/0127  | 225959 | A multicentre randomised trial of First Line treatment pathways for newly diagnosed Immune Thrombocytopenia: Standard steroid treatment versus combined steroid and mycophenolate.  | No  |            | 9   |    |    | Within 70 Days | 27/10/2017 | 27/11/2017 | 03/07/2017 | 27/11/2017 | 06/12/2017 | 09/01/2018 |                               |                       | Please Select..  |