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|--|--|--|---|---|--|-----------------------------------|---|---|--|---|--------------------------------|--|
| Research Ethics<br>Committee (REC)<br>Reference Number | Integrated<br>Research<br>Application<br>System (IRAS)<br>Number | Name of the Clinical Trial   | Target<br>Number<br>Of<br>Patients<br>Agreed? | Minimum<br>Number Of<br>Patients<br>Agreed (Enter<br>Same In Both If<br>Only One<br>Number) | Maximum<br>Number Of<br>Patients Agreed<br>(Enter Same In<br>Both If Only One<br>Number) | To Recruit<br>Patients<br>Agreed? | Date Agreed to<br>Recruit Target<br>Number of<br>Patients |   | Total Number of<br>Study Participants<br>Recruited | Date That The Trial<br>Closed To<br>Recruitment | Reason For<br>Closure Of Trial | Comments   |
| 16/WM/0365   | 210358   | A multi-centre,<br>randomised, double-blind<br>(sponsor unblinded),<br>placebo controlled study<br>with open label extension<br>to investigate the safety<br>and tolerability,<br>pharmacokinetics,<br>pharmacodynamics and<br>efficacy of GSK2982772 in<br>subjects with active<br>ulcerative colitis |   | 2   | 2  | Date agreed                       | 02/11/2018  | 1 | 1  | 28/01/2019                                      | Recruitment<br>finished        | Was due to close 02/11/18 but recruitment was<br>extended to 18/12/18 and then indefinitely until<br>global target achieved. Recruitment finally closed<br>on 28/01/19. Site target of 2 not achieved. 2<br>consents but one screen failed. Many patients<br>screened but were too ill and needed to be<br>commenced immediately on other meds for their<br>symptoms. By the time the dose was stabilised as<br>per protocol, they didn't fit the inclusion criteria as<br>their disease had improved.                                 |
| 17/NE/0092   | 220929   | CLOVER: A Phase 3,<br>Placebo-Controlled,<br>Randomized, Observer-<br>Blinded Study to Evaluate<br>the Efficacy, Safety and<br>Tolerability of a<br>Clostridium Difficile<br>Vaccine in Adults 50 Years<br>of Age and Older  |   | 17  | 17   | Date agreed                       | 11/01/2019  | 3 | 3  | 14/01/2019                                      | Recruitment<br>finished        | Originally no recruitment deadline but substantial<br>amendment 01 formally confirmed as 11/01/19. 3<br>patients recruited by then with actual close<br>14/01/19. Issues with recruitment included<br>patients lack of willingness to deal with stool<br>sample decants from diarrhoea episodes, all study<br>visits being above routine care, with only travel/<br>food reimbursed and no inconvenience payments,<br>double contraception methods needed for women<br>of child bearing potential and new drug so<br>reticence to try. |