

Performance in Initiating - Q3: 2016/2017 (1st January 2016 - 31st December 2016) - HRA studies

Research Ethics Committee Reference Number	IRAS number	Name of Trial	Site Invited	Site Selected	HRA Approval	Site Confirmed by Sponsor	Site Confirmed	Non Confirmation Status	Site Ready to Start	First Patient Recruited	Reasons for delay
16/NE/0147	204478	RESOLVE-IT: A Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase III Study to Evaluate the Efficacy and Safety of Elafibranor in Patients with Nonalcoholic Steatohepatitis (NASH) and fibrosis	04/04/2016	17/06/2016	15/06/2016	17/08/2016	12/09/2016	NA	03/11/2016	04/11/2016	NHS Provider. Delayed SIV due to PI availability. IRMER took 2 months to sign off.
16/LO/1001	199167	Safety and effect on central retinal thickness of BI1026706 in patients with DME	17/06/2016	17/06/2016	08/09/2016	30/09/2016	11/10/2016				
14/LO/0727	153790	ITIND: Study to assess the efficacy of Meditate TIND in BPH	16/03/2016	03/08/2016	15/06/2016	26/10/2016	27/10/2016	NA	31/10/2016	31/10/2016	Sponsor. Delay in protocol clarifications and budget confirmation from Sponsor
12/WA/0374	98726	HART: Hughes Abdominal Repair Trial	13/07/2015	06/07/2016	11/05/2016	12/08/2016	05/12/2016	NA	12/12/2016		Sponsor. Delay in response from Sponsor regarding radiology queries