

Performance in Initiating - Q4: 2016/2017 (1st April 2016 - 31st March 2017) - 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	NA	05/01/2017	02/02/2017	Sponsor Delays. Delays with REC/HRA approvals