Western Sussex Hospitals NHS Foundation Trust

Research Ethics Committee Reference Number	Integrated Research Application System (IRAS) number	Submission Type	Name of Trial	Date of Receipt of Valid Research Application (old metric)	Date Site Invited (new metric)	Date Site Selected (new metric)	HRA Approval Date (new metric)	Date Site Confirmed By Sponsor (new metric)	Date Site Confirmed (new metric)	Date Site Ready to Start (new metric)	Date of First Patient Recruited	Non-Confirmation Status (new metric)	Duration between VRA / Date site selected and First Patient (days)	Benchmark Met	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:
13/WA/0205	127379	HRA Light	A Trial for Older Patients with Acute Myeloid Leukaemia and High Risk Myelodysplastic Syndrome		05/09/2016	21/11/2016	15/06/2016	11/11/2016	21/11/2016	13/12/2016	06/01/2017		46	Yes												
14/WA/1056	154468	HRA Light	Adults with acute myeloid leukaemia or high-risk myelodysplastic syndrome (AML19)		02/09/2016	21/11/2016	15/06/2016	23/11/2016	29/11/2016	01/12/2016	05/12/2016		14	Yes												
15/LO/1302	169660	HRA Light	OCTOPUS: Ovarian Cancer Trials of Weekly Paclitaxel - Umbrella StudyA Randomised, Phase II Umbrella Trial of a Weekly Paclitxel +/- Novel Agents in Platinum-Resistant Ovarian Cancer		11/11/2016	09/01/2017	07/06/2016	03/05/2017	17/05/2017	07/06/2017	12/07/2017		184	No					Y							Internal capacity issues.	NHS Provider
15/EE/0421	191851	HRA Light	Pomalidomide in relapsed and refractory multiple myeloma		13/03/2017	30/03/2017	18/08/2016	24/04/2017	04/05/2017	08/06/2017	30/08/2017		153	No			Y	Y	Y						Delays receiving study drug and lab kits at site.	Both
BIO/MIL/01/03	135437	HRA Light	MILES - UK: Post Marketing, Multicenter, Single Arm, Observational Clinical Registry to Evaluate Safety and Efficacy of BioMime Sirolimus Eluting Stent System In All Comers Real World Population With Coronary Artery Stenosis in United Kingdom.		22/02/2017	10/05/2017	28/07/2016					Site declined to participate													Study abandoned: upon further review 'recruitment window' too narrow to ensure recruitment target is met.	
15/NW/0416	167060	HRA Light	A randomised phase II trial of Cyclophosphamide and Dexamethasone in combination with Ixazomib, in relapsed or refractory multiple myeloma (RRMM) patients who have relapsed after treatment with thalidomide, lenolidomide and bortezomib.		07/03/2017	06/04/2017	15/07/2016	19/05/2017	07/06/2017	28/06/2017	10/07/2017		96	No								Y				Delay due to additional contract with Myeloma UK caused by both NHS Provider and Myeloma UK.	NHS Provider

Western Sussex Hospitals NHS Foundation Trust

Research Ethics Committee Reference Number	Integrated Research Application System (IRAS) number	Submission Type	Name of Trial	Date of Receipt of Valid Research Application (old metric)	Date Site Invited (new metric)	Date Site Selected (new metric)	HRA Approval Date (new metric)	Date Site Confirmed By Sponsor (new metric)	Date Site Confirmed (new metric)	Date Site Ready to Start (new metric)	Date of First Patient Recruited	Non-Confirmation Status (new metric)	Duration between VRA / Date site selected and First Patient (days)	Benchmark Met	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:
14/YH/1199	153953	HRA Light	GALACTIC: GA101 (obinutuzumab) monocLonal Antibody as Consolidation Therapy In CLL		18/05/2016	06/07/2016	15/06/2016					Sponsor declined site confirmation		N/A			Y								Letter received from trial office 11/07/2016 advising that recruitment into GALACTIC is being stopped. This is due to recruitment nationally being significantly slower than anticipated and trial office no longer think it is achievable to meet the recruitment target.	Neither
16/WM/0036	180476	HRA Light	Accuracy of a rapid intrapartum test for maternal group B streptococcal colonisation and its potential to reduce antibiotic usage in mothers with risk factors.		28/12/2016	12/05/2017	23/08/2016	23/06/2017	05/07/2017									Y							Sub-category - delay intrinsic in study design Nature of delay - modifications to clinical testing guidelines	Sponsor
15/NS/0113	188563	HRA Light	The clinical and cost effectiveness of surgical interventions for stones in the lower kidney: The PUrE RCT- Percutaneous Nephrolithotomy (PNL), Flexible Ureterorenoscopy (FURS) and Extracorporeal Lithotripsy (ESWL) for lower pole Kidney stones.		04/05/2017	04/05/2017	09/06/2017	05/06/2017	14/06/2017	17/07/2017	21/07/2017		78	No	Y										Delays due to non-England lead review of study amendment to add WSHT as a site; amendment for WSHT as a site submitted 12/06/17 by sponsor, passed on by NRS to HRA on 04/07/17 and HRA confirmation (no HRA assessment required - non-substantial amendment) received 12/07/17. Advice received from NRS permissions stated "cannot open the study at the site until HRA Approval for the amendment is in place".	Neither
13/SC/0645	143871	HRA Light	Prognostic indicators of severe disEAse in women with late preterm pre-eClampsia tO guide deCision maKing on timing of delivery		21/03/2016	26/04/2017	15/06/2016	26/04/2017	17/05/2017	29/06/2017	12/07/2017		77	No						Y						Strict patient eligibility criteria apply to this study and hence low numbers of women are seen in our maternity services who are eligible for the study.	Neither
15/WM/0268	180518	HRA Light	Randomised, open label study of rituximab/ibrutinib vs rituximab/chemotherapy in older patients with untreated mantle cell lymphoma		11/08/2016	10/10/2017	26/08/2016	17/11/2017	29/11/2017					No					Y						DSS to DSC delay due to internal negotiations with pharmacy department. Site not ready to start due to NHS Provider staff capacity to undertake electronic prescription set-up.	NHS Provider

Please note this data has not been submitted to the Department of Health: as per the performance in Initiating and Delivering Clinical Research Guidelines Q1 2017/18.

Western Sussex Hospitals NHS Foundation Trust

Research Ethics Committee Reference Number	Integrated Research Application System (IRAS) number	Submission Type	Name of Trial	Date of Receipt of Valid Research Application (old metric)	Date Site Invited (new metric)	Date Site Selected (new metric)	HRA Approval Date (new metric)	Date Site Confirmed By Sponsor (new metric)	Date Site Confirmed (new metric)	Date Site Ready to Start (new metric)	Date of First Patient Recruited	Non-Confirmation Status (new metric)	Duration between VRA / Date site selected and First Patient (days)	Benchmark Met	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/LO/1402	183327	HRA Light	AV optimisation delivered with direct His bundle pacing, in patients with heart failure, long PR without left bundle branch block: randomised multi-centre clinical outcome study The His Optimised Pacing Evaluated for Heart Failure Trial (HOPE-HF)		17/02/2016	08/06/2017	N/A	08/09/2017	20/09/2017	27/09/2017	27/09/2017		111	No					Y						DSS to DSC delay due to internal capacity issues. DSC to FPR within 30 days.	NHS Provider
14/SC/1161	155743	HRA Light	Prospective,single-arm, multi-centre, observational registry to further validate safety and efficacy of the ultimaster DES in real-world patients.		25/07/2017	04/08/2017	N/A	17/11/2017	27/11/2017	30/11/2017	08/12/2017		126	No								Y			DSS to DSC delay due to contract negotiations between NHS Provider and sponsor. DSC to FPR within 30 days.	Both

Please note this data has not been submitted to the Department of Health: as per the performance in Initiating and Delivering Clinical Research Guidelines Q1 2017/18.