

Performance of Initiating Q4-2016-2017 South London and Maudsley NHS Foundation Trust:

Research Ethics Committee Reference Number	Integrated Research Application System Number	Submission Type	Name of Trial	Date of Receipt of Valid Research Application	Date of NHS Permission	First Patient Recruited?	Date of First Patient Recruited	Duration between VRA and NHS Permission	Duration between NHS Permission and First Patient	Duration between VRA and First Patient	Benchmark Met	Date Site Invited	Date Site Selected	HRA Approval Date	Date Site Confirmed By Sponsor	Date Site Confirmed	Date Site Ready To Start	Comments	Reasons for delay correspond to:
15/SC/0434	181955	NHS Permission	An Open-label, Long-term, Safety and Efficacy Study of Intranasal Esketamine in Treatment-resistant Depression	28/03/2016	15/04/2016	Yes	14/06/2016	18	60	78	No							Delayed SIV which took place a month after R&D approval. Study supplies only arrived 3rd June	Sponsor
13/LO/1758	136392	NHS Permission	A Phase III, Randomized, Placebo-Controlled, Parallel-Group, Double-Blind Clinical Trial to Study the Efficacy and Safety of MK-8931 (SCH 900931) in Subjects with Amnesiac Mild Cognitive Impairment Due to Alzheimer's Disease (Prodromal AD)	28/04/2016	29/04/2016	No		1			No							Team actively screened but no eligible patients were identified (as reported in last quarter, Q2 16-17). During this quarter (Q3 16-17) a suitable participant was found but the participant decided not to proceed and was not randomised. The trial is now closed to recruitment	Neither
15/SS/0032	165287	NHS Permission	An open-label extension study to evaluate the long-term safety and tolerability of Lu AE58054 as adjunctive treatment to donepezil in patients with mild-moderate Alzheimer's disease	29/03/2016	29/04/2016	Yes	11/05/2016	31	12	43	Yes							Benchmark met	Please Select...
16/LO/0071	187338	NHS Permission	Cognitive Bias Modification for Paranoia	21/03/2016	07/04/2016	Yes	23/05/2016	17	46	63	Yes							Benchmark met	Please Select...
14/LO/1696	158559	NHS Permission	Mentalisation based therapy (MBT) for Antisocial Personality Disorder	06/04/2016	06/04/2016	Yes	22/07/2016	0	107	107	No							There has been a lack of patients meeting the inclusion criteria, and some who did initially meet the inclusion criteria were recalled to prison prior to randomisation therefore making them ineligible for the trial.	Neither

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16/LO/0018	184627	NHS Permission	Approach Bias Modification Training in Bulimia Nervosa and Binge Eating Disorder: a randomised controlled trial (ABBA)	22/03/2016	13/04/2016	Yes	14/07/2016	22	92	114	No							There has been difficulty finding patients meeting the eligibility criteria and those that do meet the eligibility criteria had declined to take part.	Neither
16/LO/0199	197474	NHS Permission	Helping Families: Pilot randomised controlled trial of a psychoeducational parenting intervention for families with complex needs	29/03/2016	19/04/2016	Yes	26/04/2016	21	7	28	Yes							Benchmark met	Please Select...
16/LO/0231	192806	NHS Permission	Feasibility randomised controlled trial of a one day CBT workshop intervention (DISCOVER) for 15-18 year olds with anxiety and / or depression in clinical settings	22/03/2016	06/04/2016	Yes	15/04/2016	15	9	24	Yes							Benchmark met	Please Select...
16/LO/0095	188561	NHS Permission	Time Intensive CBT for a Specific Phobia of Vomiting using Single Case Experimental Design	21/03/2016	05/04/2016	Yes	09/06/2016	15	65	80	No							Recruitment has now started and reason for not meeting the benchmark was no eligible patients seen due to vomiting phobia being an uncommon condition.	Neither
16/LO/0223	190767	NHS Permission	Examining The Effects of a brief mindfulness Based Intervention (BMBI) on Mood and Cognitive Functioning in an Older Adult Population	15/04/2016	19/04/2016	Yes	20/05/2016	4	31	35	Yes							Benchmark met	Please Select...
16/WA/0064	171443	NHS Permission	Internet Delivered Cognitive Behaviour Therapy for adolescents	18/05/2016	18/05/2016	Yes	19/08/2016	0	93	93	No							Team have been actively screening but no eligible patients were seen within the 70 day period. Recruitment has now started	Neither

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			with Obsessive-Compulsive Disorder. An open trial																
15/LO/1907	189324	NHS Permission	Understanding the molecular basis for the use of adjunctive anti-inflammatory treatment in treatment resistant depression: a stratified, randomised, placebo-controlled experimental medicine study using minocycline (MINDEP)	29/03/2016	19/05/2016	Yes	15/09/2016	51	119	170	No							The Sponsor delayed the SIV due to a contract it required with the clinical trials unit. The study team then focussed initially on recruitment from self referrals, recruitment from the Trust has now started.	Sponsor
15/EE/0308	167511	NHS Permission	A three-arm, randomised controlled trial of the effectiveness and cost-effectiveness of adjunctive medication management and contingency management to enhance adherence to medications for relapse prevention in alcohol dependence	09/12/2015	13/07/2016	Yes	27/07/2016	217	14	231	No							Sponsor delayed start of trial at all sites due to delays in completing a contract between the Sponsor and third party	Sponsor

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16/LO/1102	177307	HRA Approval	The Role of Nitric Oxide in Cognition in Schizophrenia: the NOC study			Yes	06/03/2017				No	22/04/2016	15/08/2016	15/08/2016	08/09/2016	08/09/2016	08/09/2016	Recruitment was originally delayed by the Sponsor due to delays with them receiving the drug and placebo from their supplier. This has now been resolved, since then screening for potential participants started within the Trust, initially no patient met the inclusion criteria but the first patient has now been recruited into the study	Neither
16/LO/1299	200774	HRA Approval	The development of a psychoeducational tool to manage anxiety in people with Autism Spectrum Disorders: the Managing Anxiety in Autism Guide (MANAGE)			Yes	29/09/2016				Yes	22/06/2016	08/09/2016	08/09/2016	09/09/2016	09/09/2016	09/09/2016	Benchmark met. First patient recruited within 70 days of date site selected	Please Select...
16/LO/0990	171709	HRA Approval	Addition of contingency management to stop smoking services for in-treatment opiate addicts: a randomised controlled pilot study			Yes	26/10/2016				Yes	19/05/2016	09/09/2016	09/09/2016	09/09/2016	09/09/2016	09/09/2016	The Chief Investigator delayed start of recruitment in the Trust due to a temporary absence of a key collaborator in their team. This has now been resolved and the first patient recruited, but not within the benchmark	Sponsor
16/LO/1439	212222	HRA Approval	A pilot study of two sessions responsibility intervention for auditory hallucinations			Yes	23/02/2017				No	03/10/2016	18/10/2016	30/09/2016	25/10/2016	25/10/2016	25/10/2016	Screening has started, however no patients initially met the inclusion criteria. First patient has now been recruited	Neither
16/EE/0318	201898	HRA Approval	A randomised pragmatic trial comparing the clinical and cost effectiveness of lithium and quetiapine augmentation in treatment resistant depression			Yes	05/12/2016				Yes	08/07/2016	26/10/2016	20/10/2016	01/11/2016	01/11/2016	03/11/2016	Benchmark met. First patient recruited within 70 days of date site selected	Please Select...

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16/LO/0873	193362	HRA Approval	Psychosis and Diabetes Study (PODS) Integrating Diabetes Care into Community Mental Health Teams			Yes	12/12/2016				Yes	04/11/2016	21/11/2016	26/10/2016	09/12/2016	09/12/2016	09/12/2016	Benchmark met. First patient recruited within 70 days of date site selected	Please Select...
16/EE/0233	188916	HRA Approval	Cognitive Therapy for the treatment of post traumatic stress disorder (PTSD) in youth exposed to multiple traumatic stresses. A phase II randomised controlled trial			Yes	15/02/2017				No	24/05/2016	30/11/2016	15/08/2016	15/12/2016	15/12/2016	15/12/2016	Recruitment planned to start once study support staff and trial therapists were trained up. This was planned, and has now been completed. First patient has now been recruited.	Neither
16/LO/1862	206680	HRA Approval	The SloMo Trial: a randomised controlled trial of a digital therapy for people who fear harm from others			No					No	22/09/2016	07/12/2016	07/12/2016	20/12/2016	20/12/2016	20/12/2016	The Chief Investigator / Sponsor plans to open all sites to recruitment in May 2017	Sponsor
16/LO/1137	197113	HRA Approval	Carer Skills Training for inpatients with Anorexia Nervosa IcasK			Yes	31/01/2017				No	24/05/2016	02/11/2016	02/11/2016	09/01/2017	09/01/2017	09/01/2017	No patients met the inclusion criteria, first patient has now been recruited	Neither
16/LO/1377	197114	HRA Approval	TRIANGLE: A novel patient and carer intervention for Anorexia Nervosa			No					No	07/07/2016	28/09/2016	26/10/2016				Chief Investigator has delayed opening all sites for recruitment until May 2017 and has done this with the agreement of the funder (NIHR). Sites are currently waiting for all final documents from the CI to complete their assessment of capacity and capability, and are therefore not able to do this at the current time	Sponsor

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16/LO/1520	211032	HRA Approval	Imaging activation of microglia in humans by the experimental challenge, Interferon-alpha, using the novel TSPO tracer 11C PBR 28			No					No	27/07/2016	16/09/2016					HRA approval has not yet been issued. The Sponsor submitted a substantial amendment after REC approval but before HRA approval, with the agreement of the HRA assessor. The Trust is unable to issue confirmation of capacity and capability until the amendment is approved and HRA approval issued.	Sponsor
16/LO/1765	172751	HRA Approval	Acute Opioid Overdose: Improving understanding through a Phase IV Physiological Study			No					No	30/08/2016	19/01/2017	19/01/2017	13/03/2017	13/03/2017	13/03/2017	Sponsor has delayed opening the site as a substantial amendment is required before recruitment can commence	Sponsor
17/LO/0009	214063	HRA Approval	Is there a Relationship between Memory for Past Events and Motivation for Future Activities?			No					No	16/11/2016	19/01/2017	03/03/2017	07/03/2017	07/03/2017	07/03/2017	Start of recruitment in the Trust was delayed due to the need for the CI to develop materials to present to Trust teams when promoting the study, the CI also took annual leave during this time.	Sponsor
16/LO/1769	209909	HRA Approval	Autism Spectrum Treatment and Resilience (ASTAR) Study			Yes	14/02/2017				Yes	16/09/2016	04/01/2017	04/01/2017	11/01/2017	11/01/2017	11/01/2017		Please Select...
17/SC/0095	205780	HRA Approval	Glutamatergic Medication in the Treatment of Obsessive-Compulsive Disorder (OCD) and Autism Spectrum Disorder (ASD)			No					Within 70 Days	07/02/2017	23/03/2017						Please Select...
17/LO/0398	215653	HRA Approval	Does autobiographical memory increase access to the self in people with psychosis?			No					Within 70 Days	06/02/2017	24/02/2017						Please Select...
17/LO/0445	213707	HRA Approval	Balancing ACT: Evaluating the effectiveness of psychoeducation and Acceptance and Commitment			No					Within 70 Days	20/02/2017	23/03/2017	23/03/2017					Please Select...

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			Therapy (ACT) groups for people with bipolar disorder																
17/LO/0335	215147	HRA Approval	A novel intervention for self-criticism in IAPT services: pilot study			No					Within 70 Days	02/02/2017	10/02/2017						Please Select...
16/NW/0888	213646	HRA Approval	everyBody Plus - Using internet-based self-help to bridge waiting time for face-to-face outpatient treatment for bulimia nervosa, binge eating disorder and Other Specified Feeding and Eating Disorders (OSFED).			No					Within 70 Days	25/11/2016	02/02/2017						Please Select...
16/NW/0885	187946	HRA Approval	We Can – A randomised controlled trial of a web-based intervention for carers of individuals with anorexia nervosa			No					Within 70 Days	24/11/2016	28/02/2017						Please Select...
16/LO/1820	212826	HRA Approval	Randomised, double-blind, placebo controlled trial evaluating the effects of naloxone hydrochloride nasal spray on eating behaviours in bulimia nervosa			No					No	26/07/2016	29/09/2016	25/01/2017	01/11/2016	01/11/2016	22/02/2017	118 days from HRA initial assessment letter to HRA approval	Neither

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16/LO/1919	215456	HRA Approval	A Randomized, Double-Blind, Placebo-Controlled, Six-Month Study to Evaluate the Efficacy, Safety and Tolerability of Sarizotan in Patients with Rett Syndrome with Respiratory Symptoms			No					No	25/10/2016	01/11/2016	18/02/2017	14/02/2017	20/02/2017	22/02/2017	It took 108 days from HRA initial assessment letter to HRA approval. mCTA was fully executed two days after HRA approval and C&C issued two days after this.	Neither
17/LO/0066	215896	HRA Approval	A randomised, double-blind, placebo-controlled study of the safety, pharmacokinetics and exploratory pharmacodynamics of AUT00206 for 28 days as adjunctive therapy in patients with recently diagnosed schizophrenia (HMR Code: 15-504)			No					Within 70 Days	14/11/2016	24/03/2017	24/03/2017	31/03/2017			Within 70 days	Please Select...