

## Performance of Initiating Q2-2016-2017

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	Comments	Reasons for delay correspond to:
14/LO/1615	113406	NHS Permission	Naltrexone Enhanced Addiction Treatment (NEAT): A randomised controlled trial of the clinical and cost-effectiveness of extended-release naltrexone and oral naltrexone.	28/09/2015	02/10/2015	Yes	02/02/2016	4	123	127	No	Sponsor delayed start of overall sites recruitment in order to submit and amendment to the REC and MHRA	Sponsor
15/LO/1338	177677	NHS Permission	MINDFULNESS BASED CRISIS INTERVENTIONS (MBCI) FOR PSYCHOSIS WITHIN ACUTE INPATIENT PSYCHIATRIC SETTINGS; A FEASIBILITY RANDOMISED CONTROLLED TRIAL (Brief Talking therapies ON wards (amBITION study) v.1)	19/10/2015	20/10/2015	Yes	24/11/2015	1	35	36	Yes		Please Select...
15/EM/0413	183496	NHS Permission	Improving injecting skills and preventing blood borne virus infection in people who inject drugs in the UK: A feasibility randomised control trial of a psychosocial intervention (Feasibility trial of psychosocial interventions for preventing BBV)	10/11/2015	12/11/2015	Yes	13/01/2016	2	62	64	Yes		Please Select...

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14/NW/1423	155550	NHS Permission	European Long-acting Antipsychotics in Schizophrenia Trial: EULAST	19/11/2015	20/11/2015	Yes	13/04/2016	1	145	146	No	A highly challenging study in terms of recruitment of acute and very sick patients where many refuse to take part or are not regarded as suitable by the clinical team due to their severe presentation.	Neither
14/LO/1588	147978	NHS Permission	A randomised, double blind, placebo controlled parallel group trial of vitamin D supplementation compared to placebo in people presenting with their First Episode of psychosis Neuroprotection Design (DFEND)	03/12/2015	04/12/2015	Yes	19/01/2016	1	46	47	Yes		Please Select...
15/LO/1557	168120	NHS Permission	The Cognitive Remediation in Bipolar (CRiB) Study: A Feasibility Trial of Cognitive Remediation Therapy in People with Bipolar Disorder versus Treatment as Usual	10/12/2015	14/12/2015	Yes	19/02/2016	4	67	71	No	Sponsor delayed start of recruitment in order to submit a substantial amendment to the REC which was required before the study could start. Amendment is now implemented and recruitment has started	Sponsor
15/SW/0306	188008	NHS Permission	Optimising engagement in an online brain training intervention for adults over 50	18/12/2015	21/12/2015	No		3			No	Study team focussing on another site initially and haven't started recruiting in SLaM yet	Neither

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15/NW/0052	160653	NHS Permission	The MILESTONE Study: Improving Transition from CAMHS to AMHS	20/11/2015	22/12/2015	Yes	07/01/2016	32	16	48	Yes		Please Select...
15/LO/1653	188004	NHS Permission	An Open-Label Multicentre Study Assessing the Long-Term Safety of a Once-Weekly and Once-Monthly, Long Acting Subcutaneous Injection Depot of Buprenorphine (CAM2038) in Adult Outpatients with Opioid Use Disorder	22/02/2016	24/02/2016	Yes	16/03/2016	2	21	23	Yes	Within 70 days	Please Select...
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 have been actively screening but no eligible patients have been seen to date	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		Please Select...

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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		Please Select...
14/LO/1696	158559	NHS Permission	Mentalisaion 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
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		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		Please Select...

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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		Please Select...
16/WA/0064	171443	NHS Permission	Internet Delivered Cognitive Behaviour Therapy for adolescents with Obsessive-Compulsive Disorder. An open trial	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	Neither

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
16/LO/0990	177307	HRA Approval	The Role of Nitric Oxide in Cognition in Schizophrenia: the NOC study			No						Within 70 days of date site selected	Please Select...
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					Recruited within 70 days of date site selected	Please Select...
16/LO/1102	171709	HRA Approval	Addition of contingency management to stop smoking services for in-treatment opiate addicts: a randomised controlled pilot study			No						Within 70 days of date site selected	Please Select...