

**NRES Committee London -  
Bloomsbury**

**Annual Report**

**01 April 2013 – 31 March 2014**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee London - Bloomsbury
<b>Type of REC:</b>	Recognised, type I and type III
<b>Type of Flag:</b>	Phase 1 studies in healthy volunteers, Paediatric
<b>Chair:</b>	Dr Joe Brierley
<b>Vice-Chair:</b>	Reverend Jim Linthicum
<b>Alternate Vice-Chair:</b>	Professor Faith Gibson
<b>REC Manager:</b>	Dr Ashley Totenhofer
<b>REC Assistant:</b>	Miss Benita Cooke (April 2013 – October 2013)
<b>Committee Address:</b>	HRA NRES Centre Manchester Barlow House 3rd Floor 4 Minshull Street Manchester M1 3DZ
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### Chair's overview of the past year:

The Bloomsbury Research Ethics Committee had a challenging year with the loss of several long-standing members, to whom our thanks are due.

The committee has applied, after bespoke accredited training (thanks to Professor Gibson), to become flagged for qualitative research.

The continued lack of a pharmacist member has made CTIMP review a particular challenge, and the Committee are grateful to those external experts who have provided reviews for us.

Overall membership numbers are low and the Committee is grateful to all those members who have worked so hard to cover the increasing workload of Proportionate Reviews and subcommittees - especially during periods of Chair's absence - especially the Vice Chairs.

The Committee would like to commend its Administrator Dr Ashley Totenhofer for his diligence and communication skills which have enabled the Committee to continue to review applications.

## NRES Committee London - Bloomsbury Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Joe Brierley	Consultant Intensivist	Expert	12/05/2005	
Dr Fiona Castell	Clinical Oncologist	Expert	17/05/2011	16/04/2013
Ms Sally Doganis	Executive Producer and Media Consultant	Lay Plus	23/03/2011	
Dr Rashmi Gandhi	Neonatal registrar	Expert	24/09/2012	
Professor Faith Gibson	Clinical Professor of Children and Young People's Cancer Care	Expert	12/05/2005	
Mrs Toni Hall	Radiographer	Expert	25/07/2007	19/04/2013
Ms Claire Khalil	Pharmacist	Expert	31/07/2009	
Dr Rachel L Knowles	Clinical Research Fellow	Expert	17/10/2008	
Dr Leah Li	Statistician	Lay Plus	07/01/2013	
Dr Vincenzo Libri	Consultant in Clinical Pharmacology	Expert	24/09/2012	
Reverend Jim Linthicum	Lay member - Hospital Chaplain	Lay Plus	30/05/2007	
Michelle McPhail	Lecturer in Management Studies	Lay Plus	17/04/2013	
Dr Katie Elizabeth Myers Smith	Health Psychologist	Expert	11/06/2013	
Mrs Rosa Pizer	Lay member - Retired Teacher/Volunteer Jewish Chaplain	Lay Plus	09/07/2012	
Mr Roger Selby	Lay member - Retired Solicitor	Lay Plus	04/08/2004	
Ms Nabila Youssouf	Clinical Trials Manager	Expert	01/12/2011	

### Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

### Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Dr Simon Eaton	Senior Lecturer in Paediatric Surgery and Metabolic Biochemistry	Expert	03 June 2013 and 02 October 2013

## NRES Committee London - Bloomsbury: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr Rachel L Knowles	Medical Advisor to the British Paediatric Surveillance Unit	04/12/2013
Reverend Jim Linthicum	Staff councillor at Great Ormond Street Hospital NHS Foundation Trust members council	04/12/2013
Mr Roger Selby	None	04/12/2013
Ms Sally Doganis	None	04/12/2013
Mrs Rosa Pizer	Chair of a fundraising committee for Cancer Research UK	04/12/2013
Mrs Rosa Pizer	Member of Independent Prescribing Course Steering Committee at King's	04/12/2013
Ms Nabila Youssouf	Clinical Trials Manager & Sponsor's Representative for Joint Research Compliance Office at Imperial College London. Specialises in IMP (CTIMPs) and ensure they are not sent to Bloomsbury for ethical review.	04/12/2013
Dr Vincenzo Libri	Previously held GSK shares while employed by GSK. No shares received since termination of employment (March 2009)	14/12/2013
Professor Faith Gibson	Peer Reviewer on GOSH Clinical Adoption Committee	15/12/2013
Professor Faith Gibson	Occasionally requested to act as a Peer Reviewer projects from other universities.	15/12/2013
Dr Joe Brierley	Chair of the RCPCH Ethics and Law Advisory Committee	16/01/2014
Dr Joe Brierley	Member of the Nuffield Council on Bioethics Research in Children Working Group	16/01/2014
Dr Joe Brierley	President Elect of the European Society of Paediatric and Neonatal Intensive Care	16/01/2014
Dr Joe Brierley	Member of the National Organ Donation Committee	16/01/2014
Dr Joe Brierley	Peer Review/Review Studies for BUPA	16/01/2014
Dr Joe Brierley	Speakers Bureau: Astellas	16/01/2014
Dr Katie Elizabeth Myers Smith	I am the director of my own professional company – My Health Consultancy Limited	20/01/2014
Dr Katie Elizabeth Myers Smith	I am a research fellow and manager of an academic unit at Queen Mary University of London but I have no role in local R&D management.	20/01/2014
Dr Leah Li	Senior Lecturer in Medical Statistics and Epidemiology Centre for Paediatric Epidemiology & Biostatistics UCL Institute of Child Health	16/01/2014
Michelle McPhail	Unilever shares	16/01/2014
Michelle McPhail	Lecturer, Hertfordshire Business School, University of Hertfordshire	16/01/2014
Michelle McPhail	Member of Ethics Committees with Delegated Authority (ECDA) for Social Sciences Arts and Humanities; and Science and Technology University of Hertfordshire	16/01/2014
Michelle McPhail	Lay member, North and East Herts NHS trust R and D Steering Group (resigned October, 2013)	16/01/2014
Michelle McPhail	Lay reviewer and panel member, Programme Grants for Applied Research (NIHR)	16/01/2014
Michelle McPhail	Lay Reviewer, Research for Patient Benefit (NIHR)	16/01/2014
Michelle McPhail	Member, Clinical Practice Research Datalink – Primary Care Research Network (CPRD-PCRN) Implementation Board	16/01/2014

Michelle McPhail	Member, NIHR Health Technology Assessment Programme – Interventional Procedures Panel (HTA-IPP)	16/01/2014
Michelle McPhail	Member (Public Contributor), of the Programme Management Group and Trial Steering Committee for the Healthlines study.	16/01/2014
Michelle McPhail	Lay Member, Human Tissue and Biological Samples for use in Research (HTBS) Reference Group (MRC)	16/01/2014
Dr Rashmi Gandhi	None	04/03/2014

#### Meetings for Full Ethical Review 01 April 2013 - 31 March 2014:

Month	Date	Number of Members Present at Meeting
April	03/04/2013	9
May	01/05/2013	9
June	03/06/2013	8
July	03/07/2013	12
September	04/09/2013	7
October	02/10/2013	9
November	06/11/2013	8
December	04/12/2013	9
January	08/01/2014	8
March	05/03/2014	8

10 full committee meetings were held during the reporting period.

#### Proportionate Review Sub Committee Meetings held during 01 April 2013 - 31 March 2014:

Month	Date	Number of Members Present at Meeting
April	19/04/2013	3
May	24/05/2013	3
July	01/07/2013	3
August	06/08/2013	3
September	10/09/2013	4
January	17/01/2014	3
March	28/03/2014	4

7 proportionate review sub-committee meetings were held during the reporting period.

**Attendance of Members: 01 April 2013 – 31 March 2014:**

<b>Name</b>	<b>Number of Meetings Attended</b>
Ms Nabila Youssouf	9
Reverend Jim Linthicum	8
Michelle McPhail	8
Dr Rachel L Knowles	8
Dr Vincenzo Libri	8
Mrs Rosa Pizer	7
Ms Sally Doganis	6
Professor Faith Gibson	6
Dr Leah Li	6
Mr Roger Selby	5
Dr Rashmi Gandhi	5
Dr Joe Brierley	5
Dr Katie Elizabeth Myers Smith	2
Mrs Toni Hall	1
Ms Claire Khalil	1

**Number of inquorate meetings held: None**

**Attendance of Members at proportionate review sub-committee meetings:  
01 April 2013 – 31 March 2014:**

<b>Name</b>	<b>Number of Meetings Attended</b>
Ms Nabila Youssouf	5
Professor Faith Gibson	5
Reverend Jim Linthicum	4
Michelle McPhail	2
Dr Rashmi Gandhi	2
Dr Vincenzo Libri	1
Mr Roger Selby	1
Mrs Rosa Pizer	1
Dr Joe Brierley	1
Dr Rachel L Knowles	1

**Training 01 April 2013 – 31 March 2014:**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Ms Claire Khalil	02/05/2013 - 02/05/2013	Ethical Issues of Research Involving Children, HRA
Michelle McPhail	02/04/2013 - 02/04/2013	GOSH Clinical Ethics Symposium, GOSH
Dr Joe Brierley	03/07/2013 - 03/07/2013	Qualitative Research, NRES
Dr Katie Elizabeth Myers Smith	03/07/2013 - 03/07/2013	Qualitative Research, NRES
Dr Rachel L Knowles	03/07/2013 - 03/07/2013	Qualitative Research, NRES
Ms Nabila Youssouf	03/07/2013 - 03/07/2013	Qualitative Research, NRES
Mr Roger Selby	03/07/2013 - 03/07/2013	Qualitative Research, NRES
Mrs Rosa Pizer	03/07/2013 - 03/07/2013	Qualitative Research, NRES
Dr Vincenzo Libri	03/07/2013 - 03/07/2013	Qualitative Research, NRES
Dr Rashmi Gandhi	03/07/2013 - 03/07/2013	Qualitative Research, NRES
Dr Leah Li	03/07/2013 - 03/07/2013	Qualitative Research, NRES
Michelle McPhail	03/07/2013 - 03/07/2013	Qualitative Research, NRES
Dr Leah Li	04/07/2013 - 04/07/2013	Induction, NRES
Dr Joe Brierley	02/04/2013 - 02/04/2013	GOSH Paediatric Clinical Ethics Symposium, GOSH/ICH
Dr Joe Brierley	06/07/2013 - 07/07/2013	RCPCH Ethics Symposium, RCPCH
Mr Roger Selby	02/10/2013 - 02/10/2013	Self- Directed Learning - Read 'Bad Pharma'
Dr Katie Elizabeth Myers Smith	15/10/2013 - 15/10/2013	Equality & Diversity, Queen Mary University of London
Ms Nabila Youssouf	04/11/2013 - 04/11/2013	ICR Ethics and GCP Forum, ICR
Mrs Rosa Pizer	20/11/2013 - 20/11/2013	National Members Training Day, NRES
Michelle McPhail	20/11/2013 - 20/11/2013	National Members Training Day, NRES
Reverend Jim Linthicum	25/04/2013 - 25/04/2013	GOSH Clinical Ethics Symposium, GOSH
Reverend Jim Linthicum	19/06/2013 - 19/06/2013	United Kingdom Clinical Ethics Network Meeting
Reverend Jim Linthicum	18/10/2013 - 18/10/2013	United Kingdom Clinical Ethics Network Meeting
Professor Faith Gibson	03/07/2013 - 03/07/2013	Qualitative Research, NRES
Dr Rashmi Gandhi	02/04/2013 - 02/04/2013	GOSH Clinical Ethics Symposium, GOSH
Dr Rashmi Gandhi	04/01/2014 - 04/01/2014	Equality & Diversity, NRES
Dr Rashmi Gandhi	15/12/2013 - 15/12/2013	Adults Lacking Capacity Online Toolkit, NRES
Dr Rashmi Gandhi	01/09/2013 - 01/09/2013	Self- Directed Learning - Read 'Bad Pharma'
Dr Rachel L Knowles	02/05/2013 - 02/05/2013	Ethical Issues of Research Involving Children, HRA
Ms Sally Doganis	13/02/2014 - 13/02/2014	Assessing the Consequences (benefits and harms) of Research:, HRA

**Part 2: REC workload and activity during the reporting period.**

**Table 1: Applications assigned to a full committee meeting held within the reporting period:**

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
Clinical Trial of Investigational Medicinal Product	14	25.00
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	42	75.00
<b>Total Applications Reviewed</b>	<b>56</b>	<b>100</b>

**Table 2: Other REC activity during the reporting period:**

Number of applications made invalid by co-ordinator	4
Number of studies withdrawn prior to the meeting	10
Number of student applications reviewed	19
Number of paediatric applications reviewed	26
Number of device applications reviewed	0
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed funded by the US DHHS	0

**Table 3: Decisions given at meetings held within the reporting period:**

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	3	5.36
Favourable Opinion with Additional Conditions	16	28.57
Unfavourable Opinion	3	5.36
Provisional Opinion	34	60.71
Invalid	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>56</b>	<b>100</b>
Number of studies sent back to full committee meeting for final opinion	1	



**Table 4: Summary of current status of applications reviewed during the reporting period:**

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	16	28.57
Further Information Favourable Opinion with Additional Conditions	14	25.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	3	5.36
Favourable Opinion with Additional Conditions	16	28.57
Unfavourable Opinion	3	5.36
Provisional Opinion	2	3.57
Provisional Opinion Pending Consultation with Referee	0	0.00
Invalid	0	0.00
Further Information response not complete	0	0.00
No decision entered on RED	2	3.57
Number of studies withdrawn after the meeting	0	0.00
<b>Total</b>	<b>56</b>	<b>100</b>

**Table 5: Applications assigned to a proportionate review sub-committee within the reporting period:**

<b>Total Applications Reviewed</b>	<b>16</b>
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**Table 6: Decisions given at proportionate review sub-committee meetings held within the reporting period:**

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	5	31.25
No Opinion transfer to full committee for review	2	12.50
Provisional Opinion	9	56.25
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>16</b>	<b>100</b>

**Table 7: Other Management Information for the reporting period:**

<b>Average number of applications reviewed per full meeting</b>	5.60
<b>Number of applications for full ethical review over 60 days</b>	0
<b>Number of applications over 60 days as a % of total</b>	0.00%
<b>Number of days taken to final decision - average</b>	31
<b>Number of days taken to final decision - mode</b>	23
<b>Number of SSAs (non-Phase 1) reviewed</b>	2
<b>Number of applications for SSA review over 25 days</b>	0
<b>Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)</b>	0.0%
<b>Number of SSAs (Phase 1) reviewed</b>	1
<b>Number of applications for SSA review over 14 days</b>	0
<b>Number of applications for SSA review over 14 days as % of all Phase 1 (SSAs)</b>	0.0%
<b>Number of substantial amendments reviewed</b>	101
<b>Number of substantial amendments over 35 days</b>	0
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	0.0%
<b>Number of Section 30 applications reviewed</b>	0
<b>Number of Section 30 applications over 60 days</b>	0
<b>Number of Section 30 applications over 60 days as a % of total Section 30 applications</b>	0%
<b>Number of modified amendments reviewed</b>	9
<b>Number of modified amendments over 14 days</b>	0
<b>Number of modified amendments over 14 days as a % of total modified amendments</b>	0.0%
<b>Number of proportionate review applications for ethical review over 14 days</b>	3
<b>Number of proportionate review applications over 14 days as a % of total</b>	21.4%

**Table 8: Breakdown of current status of all applications reviewed within the reporting period:**

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
13/LO/0440	Airway Cells and Air Pollution (ACAP)	29
13/LO/0543	How are families affected by the experience of home V1	21
13/LO/0563	The TREATCASP study	33
13/LO/0578	BYM338 in COPD patients with cachexia	36
13/LO/0599	Study to test the safety, efficacy and PK properties of CSL627	57
13/LO/0630	What part does faith play in healthcare?	14
13/LO/0812	Autistic Spectrum Disorder in haemophilia	55
13/LO/0827	Patient and family centred care: learning with people at the frontline	12
13/LO/0962	Development of processing speed and attention in Preschool Children	35
13/LO/1056	The impact of an investment based intervention in bariatric patients	13
13/LO/1403	Defective Innate Immunity in Chronic Obstructive Pulmonary Disease	36
13/LO/1444	Safety, Effectiveness Study of RP103 in Patients with Cystinosis	29
13/LO/1461	Fish and shellfish allergy	15
13/LO/1466	A study on resistant bacteraemias in BTUH: 2010 -2013	15
13/LO/1611	Oxytocin and vasopressin pathophysiology in hypothalamic obesity v1.1	27
13/LO/1619	Amniotic Fluid Markers that Predict Gastroschisis Outcomes (version 1)	35
13/LO/1798	Sotatercept (ACE-011) in Subjects with End-Stage Kidney Disease	27
13/LO/1829	Dry Needling Versus Platelet Rich Plasma. Treatment of CET.	35
14/LO/0003	Manual versus powered tooth brushing in orthodontic patients: a RCT	36
14/LO/0008	Group Therapy for Schizophrenia	22
14/LO/0009	Study to investigate CSL689 in subjects with haemophilia (A or B)	44
14/LO/0550	Experiences of anxiety in patients with MS and their sig. others	11
14/LO/0555	Renal patients views on self-management of Renal Failure (v1)	17

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
13/LO/0418	Sildenafil in neonates with persistent pulmonary hypertension	49
13/LO/0770	Developing an EORTC Module to Assess Sexual Health in Cancer Patients	34
13/LO/0773	Personalising dosing strategy for amblyopia treatment	24
13/LO/0784	FDS-NBU-1034 - Elderly Volunteers Study	28

13/LO/1181	Effects of newborn screening	57
13/LO/1196	Collection of residual skin surface components from diabetic patients	49
13/LO/1237	EORTC QL Questionnaire Development Phases I/II - Thyroid Cancer	46
13/LO/1272	Phase 1/2 study of nab-paclitaxel in children with solid tumours	27
13/LO/1600	Extension study of LUM001 in Alagille Syndrome paediatric patients.	30
13/LO/1608	Study of efficacy and safety of nilotinib in paediatric CML patients	26
13/LO/1830	Diffusion Tensor Imaging of the myocardium	28
14/LO/0011	The experiences of people with a diagnosis of oral cancer	24
14/LO/0142	Predictors of Quality of Life in Children and Young People with ADHD	13
14/LO/0337	Phase 2/3 study comparing Masitinib/Placebo in ALS V1.1	24
14/LO/0357	Women's experience of gestational diabetes and co-morbid depression	33

#### Further Information Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
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#### Favourable Opinion with Standard Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/LO/0782	LUM001 and placebo in paediatric patients with Alagille Syndrome-IMAGO	19
13/LO/0783	Probiotic advice for preventing antibiotic use: a randomized trial	19
13/LO/1833	Improving diagnostics for seasonal Influenza	30

#### Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/LO/0322	Predicting lung function decline in adolescents with CF	20
13/LO/0389	Women's outcomes and experiences of an 'Outwith guidelines' clinic	20
13/LO/0395	Aneurysm CaRe Trial - Cardiac rehabilitation after aneurysm repair 1.0	20
13/LO/0558	Spinal Cord Injury: An Interpretative Phenomenological Analysis	23
13/LO/0562	Ambiguous Loss and Families of People in Low Awareness States	21
13/LO/0631	Dental pulp derived stem cells to enhance cornea and nerve repair	9
13/LO/0785	Osseointegrated amputee gait with two types of prosthetic feet	19
13/LO/0833	IBD Care Pathway	8
13/LO/1170	Guildford Hypertension 2000:RCT of exercise interventions version 1	59
13/LO/1229	Assessing the palliative care needs of people with cancer	13
13/LO/1230	Should community pharmacists receive patients' electronic DALs- v1	9

13/LO/1232	Digital Diabetes Project	13
13/LO/1329	Influence of HDF vs HD on growth and heart disease in children - V1	23
13/LO/1363	Decision making for children with high risk brain tumours	23
13/LO/1427	Pulse oximeter respiratory monitoring in wheezy young children	23
13/LO/1544	Care Augmentation by Location-linked Messaging (CALL-Me)	23
13/LO/1816	Intraocular Pressure And Tolerability Study - SPORT	21
13/LO/1824	Second Timed Appointment Study v0.8	22
14/LO/0012	The DECIDE Study. Version 1	21
14/LO/0035	Investigation of Periodontal Health of a Bariatric Care Population	21
14/LO/0323	Characteristics and outcomes of childhood moyamoya in the UK	28

#### Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/LO/0899	Autologous cell engineered bladder augmentation	20
13/LO/1226	Survey of Individuals with Recently Acquired HIV	20
13/LO/1394	PROMPT: Attentional processes and worry v1	23

#### Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
14/LO/0226	Growing bladders in the laboratory	N/A
14/LO/0378	Paediatric MS patients - Fingolomid versus interferon	N/A

#### Provisional Opinion Pending Consultation with Referee

REC Reference	Application Short Title	Number of Days on Clock
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#### Further information response not complete

REC Reference	Application Short Title	Number of Days on Clock
14/LO/0560	The EUROpean Dyspnoea survey in EMergency departments (EURODEM study)	N/A

#### Withdrawn after the meeting

REC Reference	Application Short Title	Number of Days on Clock
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#### Invalid Application

REC Reference	Application Short Title	Number of Days on Clock
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<b>No Opinion Pending Consultation with Referee</b>		
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REC Reference	Application Short Title	Number of Days on Clock
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**Table 9: Items exceeding timelines:**

<b>Full applications for ethical review over 60 day timeline</b>		
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REC Reference	Application Short Title	Number of Days on Clock
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<b>Proportionate review applications for ethical review over 14 days timeline</b>		
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REC Reference	Application Short Title	Number of Days on Clock
13/LO/1461	Fish and shellfish allergy	15
13/LO/1466	A study on resistant bacteraemias in BTUH: 2010 -2013	15
14/LO/0555	Renal patients views on self-management of Renal Failure (v1)	17

<b>SSAs (non Phase 1) over 25 days timeline</b>		
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REC Reference	Application Short Title	Number of Days on Clock
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<b>SSAs (Phase 1) over 14 days timeline</b>		
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REC Reference	Application Short Title	Number of Days on Clock
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<b>Substantial Amendments over 35 day timeline</b>			
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Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
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<b>Modified Amendments over 14 day timeline</b>			
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Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
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<b>Section 30 application over 60 day timeline</b>			
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Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
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