

**South Central - Hampshire B Research Ethics  
Committee**

**Annual Report**

**01 April 2017 - 31 March 2018**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	South Central - Hampshire B Research Ethics Committee
<b>Type of REC:</b>	RECs recognised to review CTIMPS in patients - type iii
<b>Type of Flag:</b>	Research Tissue Bank, IRB Registered
<b>Chair:</b>	Dr Vincenzo Libri
<b>Vice-Chair:</b>	Dr Andrew Scott (01/04/17 – 31/07/17) Dr Julie Merriman-Jones (Acting 01/08/2017 – 06/11/2017) Dr Julie Merriman-Jones (06/11/2017– 06/11/2017)
<b>Alternate Vice-Chair:</b>	Mr Brian Birch
<b>REC Manager:</b>	Dr Sarah Graves
<b>REC Assistant:</b>	Miss Noorisha Rahman (from 07/03/2018 - 31/03/2018) Miss Charmaine Orchard (from 17/01/2018 – until 14/02/2108) Miss Alison Doherty (from 23/08/2017- until 16/01/2018) Mr Alex Martin (from 01/04/2017- until 31/07/2017)
<b>Committee Address:</b>	Level 3 Block B Whitefriars Lewins Mead Bristol BS1 2NT
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## Chair's overview of the past year:

2017/18 represented a busy year for the Hampshire B Committee. This year the main Committee has dealt with 47 applications, all within the 60-day time limit. Proportionate Review Sub-Committees dealt with 26 validated applications with two applications exceeding the target of 21 days. Ordinary Sub-Committees dealt with no less than 119 Substantial Amendments with four over 35 days. In addition, the Sub-Committee dealt with seven modified amendments with four exceeding the 14-day target. Whilst the work of the Committee can be assessed only in part in such numerical terms, these figures indicate a continuing commitment to undertaking its review work for the HRA both diligently and efficiently. All contributing members, as well as those backing them up in the South Central office, are to be congratulated on this.

The REC has experienced a number of changes in Membership in the 2017/18 REC year. Dr Andrew Scott decided to retire from the Vice Chair post in July 2017 as did with our pharmacist, Mrs Janet Brember, both after completing 4 years of service. Ms Maisie Gibson also left the Committee in July to relocate for a new job after a year of service. Dr Merriman- Jones agreed to act as Vice Chair and was then successfully appointed at interview in November 2017. In August 2017, we were delighted to welcome a new member in Professor Chris Colbourn, a retired chartered psychologist. At the end of the REC year, Dr Alex Gregory decided not to return to service after a break in service for the birth of his first child.

Dr Sarah Graves has remained our constant, acting as REC Manager to the Committee for this whole REC year. However, she has been supported by four REC assistants during the year, two of whom stayed for very short periods. This has undoubtedly contributed to some communication issues and more studies exceeding the target time lines than the previous year.

I look forward to continuing working with all Committee members and, jointly, contributing to our common undertaking of promoting respect for research volunteers and protecting their well-being and rights.

## South Central - Hampshire B Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Diane Ackerley	Retired Doctor	Expert	01/01/2016	
Mrs Ravina Barrett	Pharmacist	Expert	25/11/2015	
Mr Brian Birch	Consultant Urological Surgeon	Expert	01/04/2018	
Mrs Janet Brember	Pharmacist	Expert	01/04/2013	31/07/2017
Ms Julie Brinton	Retired Speech and Language Therapist	Expert	23/02/2015	
Professor Christopher Colbourn	Emeritus Professor & Chartered Psychologist	Expert	16/08/2017	
Dr Sue Edwards	Contract Manager	Lay	27/01/2015	
Ms Maisie Gibson	Graduate	Lay Plus	01/08/2016	31/07/2017
Dr Alex Gregory	Lecturer in Philosophy	Lay Plus	01/08/2016	31/03/2018
Mrs Angela Iveson	Acute Oncology Clinical Nurse Specialist	Expert	01/04/2013	
Dr Vincenzo Libri	Medical Consultant in Clinical Pharmacology	Expert	31/08/2016	
Mr Geoff Lowndes	Chartered Engineer (Retired)	Lay Plus	01/04/2013	
Dr Julie Merriman-Jones	Research Scientist	Expert	24/06/2016	
Miss Becci Petch	Study Start up Associate	Lay	08/02/2016	
Dr Andrew Scott	Course Leader, M.Sc. Clinical Exercise Science	Expert	01/04/2013	31/07/2017
Mrs Samantha Trace	Research Assistant	Lay Plus	01/09/2016	

## South Central - Hampshire B Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended

## South Central - Hampshire B Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Miss Stephanie Ellis, BEM	Former Civil Servant	Lay Plus	29/11/2017
Dr James Gavin	Academic (Exercise Physiology)	Lay Plus	20/08/2017
Mr Trevor Olding	Clinical Coordinator	Lay	20/08/2017
Dr Deborah Scholey	Regulatory Affairs Consultant	Lay	26/07 2017

## South Central - Hampshire B Research Ethics Committee: Members' Declarations of

Name	Declaration of Interest	Date
Dr Diane Ackerley	None	07/03/2018
Mrs Ravina Barrett	Retirement Pension and savings may hold shares in index listed firms involved in the conduct of healthcare research. As an academic involved in pharmacy practice research (self-directed, university funded)	23/02/2017
Mr Brian Birch	Honoraria to speak at, chair and attend meetings or liaised/received educational material from representatives of the following companies over the last 15 years: Astellas; Pfizer; Ipsen; Glaxo Smith Kline; Sanofi; Lilly; Bayer; Amgen; Ferring; Takeda; AstraZeneca; Janssen-Cilag; Janssen The latest was from Janssen to attend the prostate cancer summit in the UK (2018) Has acted as a paid advisor (ad hoc) for Astellas and Janssen.	07/03/2018
Ms Julie Brinton	None	30/03/2018
Dr Sue Edwards	Employed by SCW Commissioning Support Unit, principally supporting West Hampshire CCG. Theoretical possibility that CCG could commission research – but very unlikely.	19/03/2018
Mrs Angela Iveson	None	02/08/2017
Dr Vincenzo Libri	GSK shares received while employed by GSK between 2004-2009. No shares received since termination of employment (March 2009).	06/03/2018
Mr Geoff Lowndes	Shire Pharmaceuticals ~ £5K	30/03/2018
Dr Julie Merriman-Jones	University of Southampton, Faculty of Medicine Ethics Committee (FoMEC) – Ethical Reviewer; University of Southampton, University Animal Welfare and Ethical Review Board (AWERB) – Ethical reviewer (via Sub-committee of Scientific Ethical Review Group (SERG)); University of Southampton, University Ethics Committee (UEC) – Faculty of Natural Environmental Sciences (FNES) representative.	29/03/2018
Miss Becci Petch	Study start up associate at ICON PLC.	09/03/2018
Mrs Samantha Trace	MRES Student at University of Portsmouth attached to the school of Health and Social Work.	05/03/2018
Professor Chris Colbourn	Worked at Teeside University (now retired); Peer reviewer for various psychology research journals	31/03/2018

### Meetings for Full Ethical Review 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	26/04/2017	10
May	31/05/2017	8
July	26/07/2017	10
August	30/08/2017	11
September	27/09/2017	9
October	25/10/2017	10
November	29/11/2017	12
January	31/01/2018	10
February	28/02/2018	9

9 full committee meetings were held during the reporting period.

### Proportionate Review Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	19/04/2017	3
June	15/06/2017	3
July	13/07/2017	3
August	10/08/2017	3
September	14/09/2017	3
October	12/10/2017	3
November	09/11/2017	3
January	11/01/2018	3
February	08/02/2018	3
March	08/03/2018	3

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

### Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	06/04/2017	2
April	10/04/2017	2
April	18/04/2017	2
April	27/04/2017	2
May	11/05/2017	2
May	25/05/2017	2
June	02/06/2017	2
June	08/06/2017	2
June	22/06/2017	2
June	27/06/2017	2
July	13/07/2017	2
July	27/07/2017	2

August	10/08/2017	2
August	18/08/2017	2
August	24/08/2017	2
September	14/09/2017	2
September	28/09/2017	2
October	12/10/2017	2
October	26/10/2017	2
November	09/11/2017	2
November	23/11/2017	2
December	07/12/2017	2
December	21/12/2017	2
January	11/01/2018	2
January	25/01/2018	2
February	08/02/2018	2
February	22/02/2018	2
March	08/03/2018	3
March	12/03/2018	2
March	20/03/2018	2
March	22/03/2018	2

31 sub-committee meetings were held during the reporting period.

#### Details of inquorate meeting held:01 April 2017 - 31 March 2018

None

**Attendance of Members at full committee meetings:01 April 2017 - 31 March 2018**

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Diane Ackerley	6
Mrs Ravina Barrett	4
Mr Brian Birch	6
Mrs Janet Brember	3
Ms Julie Brinton	7
Professor Christopher Colbourn	6
Dr Sue Edwards	4
Ms Maisie Gibson	2
Dr Alex Gregory	5
Mrs Angela Iveson	4
Dr Vincenzo Libri	7
Mr Geoff Lowndes	9
Dr Julie Merriman-Jones	8
Miss Becci Petch	6
Dr Andrew Scott	1
Mrs Samantha Trace	7

**Attendance of Members at proportionate review sub-committee meetings: 01 April 2017 - 31 March 2018**

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Diane Ackerley	2
Mrs Ravina Barrett	1
Mr Brian Birch	4
Ms Julie Brinton	2
Professor Christopher Colbourn	2
Dr Sue Edwards	2
Ms Maisie Gibson	1
Dr Alex Gregory	2
Mrs Angela Iveson	2
Dr Vincenzo Libri	3
Mr Geoff Lowndes	1
Dr Julie Merriman-Jones	3
Miss Becci Petch	2
Dr Andrew Scott	1
Mrs Samantha Trace	2



**Attendance of Members at sub-committee meetings: 01 April 2017 - 31 March 2018**

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Diane Ackerley	3
Mrs Ravina Barrett	2
Mr Brian Birch	10
Mrs Janet Brember	1
Ms Julie Brinton	5
Professor Christopher Colbourn	2
Dr Sue Edwards	3
Ms Maisie Gibson	1
Dr Alex Gregory	2
Mrs Angela Iveson	3
Dr Vincenzo Libri	10
Dr Julie Merriman-Jones	10
Miss Becci Petch	3
Dr Andrew Scott	6
Mrs Samantha Trace	2

**Training 01 April 2017 - 31 March 2018**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Diane Ackerley	07/02/2018	Reviewing the Research Design of Clinical Trials
Dr Diane Ackerley	28/03/2018	Research Involving Human Tissue
Mrs Ravina Barrett	01/02/2018	Reading Medical Ethics by Michael Boylan
Mrs Ravina Barrett	01/03/2018	MRC Research Data and Confidentiality eLearning
Mr Brian Birch	14/10/2017	Informed Consent with Adults Lacking Capacity
Mr Brian Birch	14/10/2017	Informed Consent in Paediatric Research
Mr Brian Birch	14/10/2017	Introduction to Good Clinical Practice eLearning (Secondary
Mr Brian Birch	20/03/2018	Complex Cases
Ms Julie Brinton	12/10/2017	Human Tissue Act (Use of Human Samples in Research) - An Introductory Level
Professor Christopher Colbourn	20/02/2018	Human Tissue Act (Use of Human Samples in Research) - An Introductory Level
Professor Christopher Colbourn	06/03/2018	'Assessing the Risk and Consequences of Research
Dr Sue Edwards	30/03/2018	Quality review and qualitative research
Mrs Angela Iveson	12/09/2017	ESMO Conference
Mrs Angela Iveson	27/09/2017	Leading in Breast Cancer
Mrs Angela Iveson	11/10/2017	Non Medical Prescribing Conference
Mrs Angela Iveson	11/11/2017	UKONS Annula Conference- Lets get personal
Mrs Angela Iveson	05/02/2018	Clinical research Nurses working in cancer
Dr Vincenzo Libri	03/05/2017	London area Chairs' Meeting
Dr Vincenzo Libri	03/05/2017	Chairs meeting
Dr Vincenzo Libri	05/10/2017	Training - Introduction to Phase 1 Research - Trials & Regulation
Dr Vincenzo Libri	06/11/2017	HRA Chairs meeting
Dr Vincenzo Libri	24/11/2017	HRA National Chairs' Day and Policy Event
Dr Vincenzo Libri	28/02/2018	Ethical Issues in Phase One Research: An Advanced Training Course
Mr Geoff Lowndes	30/03/2018	'Quality review and qualitative research'
Dr Julie Merriman-Jones	17/10/2017	Training for new REC Chairs
Dr Julie Merriman-Jones	07/02/2018	Training - Introduction to Phase 1 Research - Trials & Regulation
Dr Julie Merriman-Jones	13/02/2018	The Ethical Issues of Research Involving Children
Dr Julie Merriman-Jones	28/02/2018	Ethical Issues in Phase One Research: An Advanced Training

		Course
Miss Becci Petch	26/05/2017	Introduction to EU legislation on CT legislation
Mrs Samantha Trace	23/05/2017	Medical Devices Training day
Mrs Samantha Trace	05/10/2017	Training - Medical Devices Training Day
Mrs Samantha Trace	12/10/2017	- Human Tissue Act (Use of Human Samples in Research) - An Introductory Level
Mrs Samantha Trace	14/11/2017	Training - Handling Health-Related Findings in Research (Joint MRC/HRA)
Mrs Samantha Trace	12/02/2018	The Ethical Issues of Research Involving Children
Ms Sue Edwards	30/03/2018	Local Training Day – with David Carpenter 5 hours

## 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	13	27.66
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	3	6.38
Research Database (including renewals)	0	0.00
Others	31	65.96
<b>Total Applications Reviewed</b>	<b>47</b>	<b>100</b>

**Table 2: Breakdown of full applications and other activity during reporting period**

Number of applications made invalid by the REC Manager	0
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	14
Number of paediatric applications reviewed	6
Number of device applications reviewed	3
Number of prisoner applications reviewed	1
Number of applications involving adults unable consent reviewed	1
Number of applications reviewed that are funded by the US DHHS	1
Number of qualitative applications reviewed	3

**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	2	4.26
Favourable Opinion with Additional Conditions	7	14.89
Unfavourable Opinion	3	6.38
Provisional Opinion	34	72.34
Provisional Opinion Pending Consultation with Referee	1	2.13
<b>Total</b>	<b>47</b>	<b>100</b>
Number of studies sent back to full committee meeting for final opinion	0	

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

<b>Status of applications at date of generation of report</b>	<b>Number</b>	<b>%</b>
Further Information Favourable Opinion with Standard Conditions	27	57.45
Further Information Favourable Opinion with Additional Conditions	4	8.51
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	4.26
Favourable Opinion with Additional Conditions	7	14.89
Unfavourable Opinion	3	6.38
Provisional Opinion	3	6.38
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	1	2.13
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
<b>Total</b>	<b>47</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>26</b>
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**Table 6: Breakdown of PRS applications and other activity during reporting period:**

Number of applications made invalid by the REC Manager	1
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	8
Number of paediatric applications reviewed	5
Number of device applications reviewed	0
Number of qualitative applications reviewed	7

**Table 7: Decisions given at proportionate review sub-committee meetings held within the reporting period**

<b>Decisions taken at proportionate review sub-committee meetings</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	2	7.69
Favourable Opinion with Additional Conditions	8	30.77
No Opinion transfer to full committee for review	3	11.54
Provisional Opinion	13	50.00
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>26</b>	<b>100</b>

**Table 8: Other Management Information based on the number of completed applications for the reporting period:**

<b>Average number of applications reviewed per full meeting</b>	5.22
<b>Number of completed applications for full ethical review</b>	47
<b>Number of completed applications for full ethical review over 60 days</b>	0
<b>Number of completed applications over 60 days as a % of total</b>	0.00%
<b>Number of completed applications for full ethical review over 40 days</b>	11
<b>Number of completed applications over 40 days as a % of total</b>	23.40%
<b>Number of days taken to final decision – average (mean)</b>	35
<b>Number of completed proportionate review applications for ethical review</b>	23
<b>Number of completed proportionate review applications for ethical review over 21 days</b>	2
<b>Number of completed proportionate review applications over 21 days as a % of total</b>	8.70%
<b>Number of SSAs (non-Phase 1) reviewed</b>	4
<b>Number of completed applications for SSA review over 25 days</b>	1
<b>Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs</b>	25.00%
<b>Number of SSAs (Phase 1) reviewed</b>	0
<b>Number of completed applications for SSA review over 14 days</b>	0
<b>Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs</b>	0.00%
<b>Number of substantial amendments reviewed</b>	119
<b>Number of completed substantial amendments over 35 days</b>	4
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	3.36%
<b>Number of completed substantial amendments over 28 days</b>	49
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	41.18%
<b>Number of modified amendments reviewed</b>	7
<b>Number of completed modified amendments over 14 days</b>	4
<b>Number of completed modified amendments over 14 days as a % of total modified amendments</b>	57.14%
<b>Number of non substantial amendments received</b>	85
<b>Number of substantial amendments received for information</b>	3
<b>Number of substantial amendments received for new sites/PIs</b>	38
<b>Number of annual progress reports received</b>	86
<b>Number of safety reports received</b>	34
<b>Number of Serious Adverse Events received</b>	0

<b>Number of final reports received</b>	5
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**Table 9.1: Breakdown of current status of all full applications reviewed within the reporting period**

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/SC/0224	Pancreatic replacement therapy and glycaemic control in diabetes	36
17/SC/0256	Exercise as an immunomodulatory mechanism in asthma-a pilot study	44
17/SC/0268	UFE for Fibroids: Comparison of Gel-Bead to Common Embolic Agents	39
17/SC/0279	The development & piloting of a QoL questionnaire for VCD	54
17/SC/0280	Exploring the cause and prevalence of memory problems in mental health	51
17/SC/0281	LIK066 in Type 2 Diabetes Mellitus Patients with Heart Failure	37
17/SC/0340	MEDI0680 with Durvalumab vs Nivolumab Alone	31
17/SC/0452	Pazopanib in Renal Cell Carcinoma after checkpoint inhibitor treatment	42
17/SC/0454	CITADEL-204	25
17/SC/0456	Joint Pain and Inflammation in Osteoarthritis	35
17/SC/0463	Reducing Cognitive Impairment in Older Adults: Development Phase	36
17/SC/0526	CA209-9ER: Advanced or Metastatic Renal Cell Carcinoma	44
17/SC/0527	STEC transmission case-control study	49
17/SC/0534	The Ball Assisted Latent Labour (BALL) trial	38
17/SC/0566	Evaluation of CTCA in assessing plaque pathology and physiology	25
17/SC/0569	Denosumab Follow-up Study in Patients with Giant Cell Tumour of Bone	33
17/SC/0572	HaemBio Biobank Version 1.0	29
17/SC/0573	Epilepsy Society Brain and Tissue Bank	57
17/SC/0603	The genetic factors for stroke in children with sickle cell disease	44
17/SC/0604	BMN 270-902: Non-Interventional Study in Severe Hemophilia A Patients	37
17/SC/0637	Method validation for new Nitrogen/Sulfur species analysis techniques	58
17/SC/0638	BCX7353 long term safety study	38
18/SC/0038	PUSH UP	33
18/SC/0040	Returning to the community following an Acquired Brain Injury.	26
18/SC/0066	What thoughts permit people with COPD to continue smoking?	31
18/SC/0085	L.O.S.E Weight Version 1.0	40
18/SC/0101	Preoperative pancreatic enzyme supplementation in Whipple's procedure	38

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/SC/0370	Experience of partners of mothers who have been admitted to an MBU	41

17/SC/0372	Use of the Sit-To-Stand task to screen for sarcopenia Version 1	28
17/SC/0467	Relationship between patient satisfaction and time on shift in CT. V1	56
17/SC/0561	Recovery in ethnic minorities using forensic mental health hospitals	33

#### Further Information Unfavourable Opinion

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

REC Reference	Title	Number of Days on Clock
17/SC/0233	Glucagon in MODY	23
18/SC/0048	Understanding strange feelings and experiences	26

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/SC/0225	MagnUM Pilot Study	23
17/SC/0228	Avelumab with SOC Chemoradiotherapy in Head and Neck Cancer	24
17/SC/0253	MonarchE: Phase 3 Study of Abemaciclib in Breast Cancer (JPCF)	22
17/SC/0371	IDEA	26
17/SC/0455	Fluenz Tetra Enhanced Safety Surveillance 2017 - 2018	27
18/SC/0046	LOOMIS- myeLOma bOne Mrl Study	26
18/SC/0098	Subcut Daratumumab in combination with standard treatment regimens	27

#### Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
17/SC/0159	Southampton Eye Biobank (SEB)	26
17/SC/0426	Treatment of irreparable rotator cuff tears using sub-acromial spacer	38
17/SC/0427	Pilot study to develop a placebo far-infrared (FIR) device	27

#### Provisional Opinion

REC Reference	Title	Number of Days on Clock
17/SC/0230	Association between morphine-6-glucuronide levels and subjective pain	n/a

17/SC/0486	Prevention of saphenous vein harvest wound infection following CABG	n/a
18/SC/0069	Tertiary care with or without manual therapy for chronic migraine	n/a

### Provisional Opinion Pending Consultation with Referee

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

REC Reference	Title	Number of Days on Clock
18/SC/0105	Epigenetics of Severe Asthma	n/a

### Withdrawn after the meeting

REC Reference	Title	Number of Days on Clock
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**Table 9.2: Breakdown of current status of all PRS applications reviewed within the reporting period**

### Further Information Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
17/SC/0196	ARISE - Vitamin D	22
17/SC/0197	Acne interview study	27
17/SC/0350	The Impact of an Expert Trainer Role on Patient Rated Outcomes	19
17/SC/0352	The effect of different breakfast drinks on glucose levels Version 1	19
17/SC/0353	Access to treatment for long-term lung disease in people with a SMI	19
17/SC/0487	Analysis of anal cancer population in a screening tertiary centre	17
17/SC/0547	Exploring women's experience of antenatal physical activity	18
17/SC/0548	General, Local, and Regional Anaesthesia in Emergency Surgery (GALORE)	17
17/SC/0602	Motivational techniques to help patients improve their oral health	16
18/SC/0082	Understanding and addressing IU in children with ASD and ID	16

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/SC/0305	Content validity of the EORTC QLQ-C30	10
18/SC/0123	Cervical screening informed choice tool for women with mental illness	19

<b>Further Information Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/SC/0351	Post Drainage NEL Detection	16
18/SC/0027	Minimally invasive kidney transplantation	6

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/SC/0301	A realist evaluation of care planning (version 1)	15
17/SC/0302	Molecular multiplex biochip array verification using urine samples	15
17/SC/0307	Exploring adolescent's perceptions of Thrombosis (Ex-APT-AT) (v 3.0)	18
17/SC/0596	Patient Perspectives	7
18/SC/0023	Children's information needs prior to clinical procedures	20
18/SC/0025	Knowledge sharing in eczema: refining and verifying mindlines	21
18/SC/0031	ProSec 3	19
18/SC/0122	Patient-cEntred oesophagogastric Cancer care UK (PEACE Study)	13

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Provisional Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/SC/0484	Chronic pain post colorectal surgery	n/a

**Further information response not complete**

REC Reference	Title	Number of Days on Clock
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**Withdrawn after the meeting**

REC Reference	Title	Number of Days on Clock
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**Table 10.1: Breakdown of current status of all substantial amendments reviewed within the reporting period**

<b>Favourable opinion</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
07/H0504/187/AM07	The pathogenesis and immunoregulation of skin cancer.	Amendment number 7, 04/10/2017	04/10/2017	15
08/H0501/85/AM08	Peritoneal Fluid Biology in Health and Disease	Amendment number 7 (03/02/2017)	03/02/2018	34
08/H0504/15/AM63	Response adapted therapy in Hodgkin lymphoma Version number 2.3	RATHL – Change of Trust name –	02/01/2018	6
09/H0504/104+5/AM06	Cardiovascular Biomedical Research Unit Biobank	Amendment 06 dated 7th April 2	06/04/2017	24
09/H0504/104+5/AM07	Cardiovascular Biomedical Research Unit Biobank	Amendment 07 dated 7th Sept 20	07/09/2017	27
09/H0504/129/AM11	3rd Generation Isle of Wight Birth Cohort (Version 1)	8 - 05/02/2018	05/02/2018	31
10/H0504/18/AM02	Evaluating vector-mediated gene transfer to human corneas	Change of CI dated 17 November	17/11/2017	22
11/SC/0084/AM09	ProT4 (Prophylactic Transfer of CD4 Lymphocytes)	6	27/03/2017	35
11/SC/0084/AM10	ProT4 (Prophylactic Transfer of CD4 Lymphocytes)	Amendment 07, 09/08/2017	10/11/2017	27
11/SC/0529/AM02	Modelling Placental Nutrient Transport	2 27/09/17	04/10/2017	17
11/SC/0543/AM07	FOR-DMD	AM07_Substantial amendment 7 d	21/02/2017	31
11/SC/0543/AM08	FOR-DMD	Substantial Amendment 8	26/06/2017	27
12/SC/0267/AM04	Understanding liver fat metabolism:version 1	2 18/01/2018	18/01/2018	23
12/SC/0359/AM03	Immune cell dysfunction in severe alcoholic hepatitis	AM03_Amendment number 1 Date 0	03/05/2017	34
12/SC/0394/AM17	COMPLEMENT A + B:	AM17_Protocol Amendment 09	13/04/2017	28
12/SC/0411/AM12	Physiotherapy Rehabilitation for Osteoporotic Vertebral	Substantial 10	31/05/2017	15

	fracture(PROVE			
12/SC/0492/AM10	OXWATCH- Women and Wellbeing Study	AM10/ SA No: 8 30/11/2016	30/11/2016	36
12/SC/0574/AM03	Clinical v patient reported outcome in treatment of Dupuytren's disease	AM03/ Amendment 1 dated 02/03/	02/03/2017	33
12/SC/0731/AM05	TARGET-B Trial of radiotherapy in higher risk breast cancer patients	Amendment number 3	11/12/2017	35
13/SC/0092/AM21	CBAF312A2304 siponimod in secondary progressive multiple sclerosis v1	CBAF312A2304 - PICF V9	14/12/2017	34
13/SC/0102/AM25	MK3475-010-00	SA16 IB13 & PIS update	31/03/2017	33
13/SC/0102/AM28	MK3475-010-00	19	09/08/2017	33
13/SC/0102/AM29	MK3475-010-00	SA21- IB Update	24/10/2017	27
13/SC/0102/AM30	MK3475-010-00	SA22 - Protocol 15 & PIS ICF	28/02/2018	28
13/SC/0323/AM14	PCI-32765DBL3001	AM14/ Ibrutinib IB Edition 10	16/03/2017	41
13/SC/0323/AM17	PCI-32765DBL3001	Substantial Amendment- Protoco	21/11/2017	33
13/SC/0323/AM18	PCI-32765DBL3001	NOSA for Ibrutinib IB Edition	18/01/2018	34
13/SC/0391/AM02	Social-emotional Under 4's Screening and Intervention. Version 1.1	Substantial Amendment 2 - 8th	08/05/2017	28
13/SC/0409/AM05	SPRING Southampton Pregnancy Intervention for the Next Generation	RHM MED1131, dated 08 Jan 2018	08/01/2018	32
13/SC/0478/AM23	LGX818, MEK162 and LGX818 vs vemurafenib in melanoma patients.	AM23_IB ed 14	17/05/2017	29
13/SC/0478/AM26	LGX818, MEK162 and LGX818 vs vemurafenib in melanoma patients.	Protocol V5_IB ED 9_ICF PartIV	30/10/2017	7
13/SC/0592/AM04	Barts Pancreas Tissue Bank	Substantial Amendment 3 10/10/	10/10/2017	11
13/SC/0593/AM02	Pancreatic Cancer Research Fund Tissue Bank	AM02-Substantial amendment 2 -	04/04/2017	26
13/SC/0593/AM03	Pancreatic Cancer Research Fund Tissue Bank	Substantial	29/09/2017	2

		Amendment 3 29/09/		
13/SC/0644/AM10	UNBLOCS: UriNary oBstruction relieved by Laser Or Conventional Surgery	AM10_ Amendment 6, dated 04/0	04/05/2017	28
13/SC/0645/AM14	PHOENIX Study - Version 1	AM14- SA7 - dated 01/03/17	01/03/2017	35
14/SC/0221/AM14	CONCEPT	12	04/07/2017	26
14/SC/0221/AM16	CONCEPT	Amendment 14	21/09/2017	10
14/SC/0221/AM17	CONCEPT	Amendment 15	18/12/2017	18
14/SC/1056/AM03	COMPARE	Substantial Amendment	12/06/2017	28
14/SC/1126/AM04	GALA-BIDD	Amendment 4.0	18/07/2017	39
14/SC/1223/AM13	CALIBER	SA4 - 23.06.2017	23/06/2017	28
14/SC/1227/AM02	Patients' expectations and experience of caudal epidural injections	14/SC/1227/AM02	25/08/2017	11
14/SC/1236/AM04	GO28399 Open label extension study of Vemurafenib	Am 4 - IB v14 & ICF v7	16/06/2017	27
14/SC/1236/AM05	GO28399 Open label extension study of Vemurafenib	15	01/11/2017	33
14/SC/1323/AM02	EDC Biomarker Discovery in Colorectal and Lung Cancer	Amendment 2 dated 12/10/2017	12/10/2017	6
14/SC/1337/AM14	200977 Study of Albiglutide in patients with Type 2 Diabetes Mellitus	9	03/07/2017	28
14/SC/1340/AM22	LEGATO-HD (Laquinimod Efficacy and Safety in a Global Trial Of HD)	am22- Investigator's Brochure	06/04/2017	35
15/SC/0112/AM05	A community based Liver Service in vulnerable adults	Substantial Amendment 4 - 24 M	24/05/2017	30
15/SC/0289/AM08	AMG 319 in HPV negative HNSCC	SA8 - 31 May 2017	31/05/2017	34
15/SC/0289/AM09	AMG 319 in HPV negative HNSCC	CRUKD/15/004 version 4.1 03-	30/08/2017	34
15/SC/0291/AM08	MO29518 - A phase II Study of MPDL3280A in Advanced Solid Tumours	SA09 - Protocol Version 5 and	23/11/2017	33
15/SC/0429/AM02	Prospective study of understudied drugs in children	Substantial Amendment 2 -	09/05/2017	28



		09.0		
15/SC/0430/AM03	JVDB: Second Line Gastric/Gastroesophageal Cancer	AM03 - Substantial - IB brochu	13/04/2017	27
15/SC/0442/AM14	The ANODE Trial	Substantial Amendment 12	05/12/2017	7
15/SC/0442/AM15	The ANODE Trial	Substantial Amendment 13	05/12/2017	27
15/SC/0478/AM04	The DON'T ITCH Trial. Version 1.0	SA01 - Protocol v4, dated 29 J	29/06/2017	25
15/SC/0569/AM02	Royal Brompton & Harefield NHS Foundation Trust Tissue Bank V2.0	SA1 dated 12 Dec 2016	12/12/2016	4
15/SC/0630/AM02	Endoringsâ,,ç assisted colonoscopy for polyp detection (version 1.0)	SA01 26/01/2018	26/01/2018	25
15/SC/0640/AM06	CALYPSO	AM06- Substantial amendment 6	24/04/2017	22
15/SC/0702/AM02	Growth in gastroschisis	2	08/08/2017	34
16/SC/0030/AM01	South Coast Observational Study	Amendment 1 , dated 06/07/2017	06/07/2017	33
16/SC/0038/AM04	Anxiety and sexual function	AM04- SA Northamptonshire Trus	27/03/2017	35
16/SC/0038/AM05	Anxiety and sexual function	Substantial Amendment 5.1 - 05	05/05/2017	30
16/SC/0038/AM06	Anxiety and sexual function	5.2 17727	06/10/2017	22
16/SC/0041/AM02	Integrating palliative care into management of advanced liver disease	Amendment 2 13.11.2017	13/11/2017	11
16/SC/0041/AM03	Integrating palliative care into management of advanced liver disease	Amendment 3 16.11.2017	22/12/2017	7
16/SC/0106/AM03	POINT, v1.1 06Aug15	SA3 dated 18 July 2017	18/07/2017	29
16/SC/0229/AM05	SIMPLANT	AM05 - Substantial 3, amendment	13/04/2017	28
16/SC/0275/AM03	Effect of Multi injections of Elamipretide on Patients with Chronic HF	Substantial Amendment 1 dated	23/03/2017	27
16/SC/0275/AM04	Effect of Multi injections of Elamipretide on Patients with	AM04_ Substantial	21/03/2017	27

	Chronic HF	Amendment 1		
16/SC/0275/AM06	Effect of Multi injections of Elamipretide on Patients with Chronic HF	SA3 - 21 June 2017	21/06/2017	28
16/SC/0275/AM07	Effect of Multi injections of Elamipretide on Patients with Chronic HF	Substantial amendment 4	20/07/2017	32
16/SC/0390/AM01	Efficacy & safety of ofatumumab vs teriflunomide in RMS (OMB2301)	SA 1: COMB157G2301: Protocol v	28/06/2017	18
16/SC/0391/AM03	Efficacy & safety of ofatumumab vs teriflunomide in RMS (OMB2302)	SA 2: COMB157G2302: Protocol v	28/06/2017	18
16/SC/0407/AM02	Healthy Paths	AM02- Protocol v4 dated 24/02/	24/02/2017	29
16/SC/0451/AM04	Extension study of Patisiran in patients with FAP	Patient Newsletters issues 1-1	12/01/2018	30
16/SC/0454/AM02	SHP626-201 Volixibat in Adults with Nonalcoholic Steatohepatitis	AM02_Substantial Protocol Amen	22/03/2017	28
16/SC/0454/AM03	SHP626-201 Volixibat in Adults with Nonalcoholic Steatohepatitis	4.0	20/09/2017	27
16/SC/0476/AM02	Pilot study of Navigated Subthreshold Microsecond Laser for DMO V1	pilot study protocol v1.2 24/1	24/01/2018	16
16/SC/0629/AM03	The ASSIST Study: case finding and 'at risk' case management	Substantial amendment 3	12/06/2017	33
16/SC/0630/AM06	Efficacy and Safety of Filgotinib in Active Crohn's Disease	Protocol Amendment 4 dated 15-	10/07/2017	32
16/SC/0631/AM04	Long Term Safety of Filgotinib in Active Crohn's Disease	SA3 -Protocol Amendment 3 date	10/07/2017	32
16/SC/0673/AM01	CESOTUG Study v1.0	Amendment 1 1¼ 6 November 2017	21/11/2017	31
17/SC/0008/AM01	Development of a new clamp	AM01_Substantial amendment 1 d	18/05/2017	33
17/SC/0008/AM02	Development of a new clamp	Substantial 2	13/07/2017	35
17/SC/0044/AM01	Implementing and Evaluating the GENIE tool in Southampton ICOPD Team.	AM01_Sub_Amend ment 1 dated 11/	11/05/2017	31

17/SC/0044/AM02	Implementing and Evaluating the GENIE tool in Southampton ICOPD Team.	Amendment 2	29/09/2017	28
17/SC/0081/AM04	Acadia ACP-103-033	Amendment02-GB	30/01/2017	31
17/SC/0081/AM05	Acadia ACP-103-033	Protocol Amendment 3_ and Inve	30/11/2017	28
17/SC/0088/AM02	Mobile Mindfulness for Asthma	1	18/07/2017	36
17/SC/0096/AM01	Trial of a group programme intervention for men who abuse women	Substantial amendment 1.2	19/07/2017	33
17/SC/0096/AM02	Trial of a group programme intervention for men who abuse women	Amendment 2, 09/02/2018	09/02/2018	9
17/SC/0098/AM01	Salt-Swap	1.0 24 Nov 2017	04/12/2017	16
17/SC/0148/AM01	Beet the Cold	19-06-17 version 1.2	19/06/2017	26
17/SC/0148/AM02	Beet the Cold	1.3	15/08/2017	8
17/SC/0158/AM02	Epacadostat and nivolumab in Selected Advanced Cancers	Nivolumab IB v16 Epacadostat I	23/02/2018	24
17/SC/0228/AM03	Avelumab with SOC Chemoradiotherapy in Head and Neck Cancer	7	31/03/2017	15
17/SC/0253/AM02	MonarchE: Phase 3 Study of Abemaciclib in Breast Cancer (JPCF)	SA2: Abema IB_ Protocol (a)_ M	31/10/2017	19
17/SC/0253/AM04	MonarchE: Phase 3 Study of Abemaciclib in Breast Cancer (JPCF)	SA4: Poster, Site closure, IQV	02/03/2018	21
17/SC/0281/AM05	LIK066 in Type 2 Diabetes Mellitus Patients with Heart Failure	SA4 - Partner Pregnancy Form v	21/09/2017	33
17/SC/0281/AM07	LIK066 in Type 2 Diabetes Mellitus Patients with Heart Failure	SA6 - Protocol Amendment 1 and	06/11/2017	23
17/SC/0281/AM08	LIK066 in Type 2 Diabetes Mellitus Patients with Heart Failure	SA7 - Recruitment and Retentio	10/11/2017	31
17/SC/0281/AM10	LIK066 in Type 2 Diabetes Mellitus Patients with Heart Failure	SA5 - Change of UK Chief Inves	19/12/2017	20
17/SC/0281/AM11	LIK066 in Type 2 Diabetes Mellitus Patients with Heart Failure	SA8: Protocol Amendment 2, Gyc	05/03/2018	23
17/SC/0307/AM01	Exploring adolescent's perceptions of Thrombosis (Ex-APT-AT) (v 3.0)	Project Proposal V 4.0	23/06/2017	16
17/SC/0307/AM02	Exploring adolescent's perceptions of Thrombosis (Ex-APT-AT) (v 3.0)	V 5.0 20/10/2017	20/10/2017	15

17/SC/0340/AM02	MEDI0680 with Durvalumab vs Nivolumab Alone	SA3 - Updated IB Ed 12 and Adu	08/01/2018	28
17/SC/0352/AM01	The effect of different breakfast drinks on glucose levels Version 1	Amendment 1 <sup>3/4</sup> Date 08/09/2017	12/09/2017	26
17/SC/0454/AM04	CITADEL-204	Substantial Amendment 3, dated	02/01/2018	5
17/SC/0454/AM05	CITADEL-204	Substantial Amendment 4	27/02/2018	14
17/SC/0527/AM01	STEC transmission case-control study	Amendment #1	01/02/2018	16
17/SC/0569/AM01	Denosumab Follow-up Study in Patients with Giant Cell Tumour of Bone	Amendment 1	06/02/2018	13
17/SC/0637/AM01	Method validation for new Nitrogen/Sulfur species analysis techniques	SA1, dated 15.01.2018	15/01/2018	25

<b>Unfavourable opinion</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
07/H0504/187/AM06	The pathogenesis and immunoregulation of skin cancer.	Substantial Amendment 6	15/03/2017	29
12/SC/0166/AM04	Preoperative pancreatic enzyme supplementation in Whipple's procedure	RHMGSU0176 8	13/11/2017	29
16/SC/0629/AM02	The ASSIST Study: case finding and 'at risk' case management	AM02 - Substantial amendment 2	15/03/2017	35
17/SC/0225/AM01	MagnUM Pilot Study	Version 1.4, 19th July 2017	19/10/2017	34
17/SC/0526/AM02	CA209-9ER: Advanced or Metastatic Renal Cell Carcinoma	SA01	18/01/2018	35

**Table 10.2: Breakdown of current status of all modified amendments reviewed within the reporting period**

<b>Favourable opinion timeline</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>

07/H0504/187/AM06/1	The pathogenesis and immunoregulation of skin cancer.	AM06/1 - Amendment number 6 mo	21/04/2017	21
13/SC/0643/AM01/1	Prevalence of cardiac ATTR amyloidosis in the elderly	MODIFIED Amendment 1 dated 12	12/06/2017	14
14/SC/1340/AM20/2	LEGATO-HD (Laquinimod Efficacy and Safety in a GlobAI Trial Of HD)	am20/2 Investigators brochure	29/03/2017	30
16/SC/0141/AM01/1	Oxford Vaccine Centre Biobank	Modified to SA1	22/03/2017	19
16/SC/0451/AM01/3	Extension study of Patisiran in patients with FAP	AM01/03 - dated 11 May 2017	11/05/2017	7
17/SC/0526/AM02/1	CA209-9ER: Advanced or Metastatic Renal Cell Carcinoma	SA01 - appeal process	07/03/2018	9

<b>Unfavourable opinion timeline</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
16/SC/0451/AM01/2	Extension study of Patisiran in patients with FAP	Modified Amendment AM01, received 04/04/17	04/04/2017	36

**Table 11: Items exceeding timelines****Full applications for ethical review over 60 day timeline**

REC Reference	Title	Number of Days on Clock
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**Proportionate review applications for ethical review over 21 day timeline**

REC Reference	Title	Number of Days on Clock
17/SC/0196	ARISE - Vitamin D	22
17/SC/0197	Acne interview study	27

**SSAs (non Phase 1) over 25 day timeline**

REC Reference	Title	Number of Days on Clock
17/SC/0332	MonarchE: Protocol I3Y-MC-JPCF	27

**SSAs (Phase 1) over 14 day timeline**

REC Reference	Title	Number of Days on Clock
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**Substantial Amendments over 35 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
12/SC/0492/AM10	OXWATCH- Women and Wellbeing Study	AM10/ SA No: 8 30/11/2016	30/11/2016	36
13/SC/0323/AM14	PCI-32765DBL3001	AM14/ Ibrutinib IB Edition 10	16/03/2017	41
14/SC/1126/AM04	GALA-BIDD	Amendment 4.0	18/07/2017	39
17/SC/0088/AM02	Mobile Mindfulness for Asthma	1	18/07/2017	36

<b>Modified Amendments over 14 day timeline</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
07/H0504/187/AM06/1	The pathogenesis and immunoregulation of skin cancer.	AM06/1 - Amendment number 6 mo	21/04/2017	21
14/SC/1340/AM20/2	LEGATO-HD (Laquinimod Efficacy and Safety in a GlobAI Trial Of HD)	am20/2 Investigators brochure	29/03/2017	30
16/SC/0141/AM01/1	Oxford Vaccine Centre Biobank	Modified to SA1	22/03/2017	19
16/SC/0451/AM01/2	Extension study of Patisiran in patients with FAP	Modified Amendment AM01, received 04/04/17	04/04/2017	36