

May 2017

Welcome to this edition of the R&I monthly e-bulletin. If you have an item to add to the next bulletin, please [email us](#) by Monday 12th June 2017.

Celebrating International Clinical Trials Day

Last week, University Hospitals Bristol NHS Foundation Trust were celebrating International Clinical Trials Day (20 May) with a series of activities and information events, to highlight the importance of taking part in research.

Research teams from throughout the Trust have been showcasing the studies they're involved in as well as providing interactive opportunities for people to find out more about how trials are improving patient care.

Events have included presentations from the Women's & Children's research team, highlighting the reproductive health research they've undertaken; the Bristol Eye Hospital team giving people the opportunity to try on a pair of glasses to see the effects of different eye diseases; an interactive display for children about why blood tests are taken, how they're done and how researchers spin blood; and the chance to take part in an example of a randomised trial at the Bristol Haematology Oncology Centre;

Have a look at our [website](#) to see photos and more information about the events.

Thank you to everyone who has been involved in helping to raise awareness of research.



This month's message from

Diana Benton
Head of Research & Innovation

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1. News

ICH Good Clinical Practice

The ICH Good Clinical Practice E6 Guideline has been amended to reflect the changes in complexity, cost and technology in research over the last 20 years and will be effective from June 2017. The changes clarify standards on electronic records and essential documents and provide updated sponsor responsibilities. Examples include:

- A new section on Quality Management (specifically related to risk management)
- An increased requirement of sponsor oversight of delegated tasks
- A requirement for SOPs to cover electronic data handling
- An increase in risk based monitoring
- Sponsor responsibilities for resolving non-compliance.

The full addendum E6-R2 can be found [here](#).

The key message of ICH GCP remains the same. The standards are there to protect the rights, safety and wellbeing of research participants and to produce high quality research data. You do not need to book into updated GCP training as a result of these changes but it is strongly recommended that you familiarise yourselves with the updated addendum. Any future GCP courses you are booked into after June 2017 will incorporate these changes.

Research Design Service South West e-bulletin

Latest e-bulletin – [click here](#)

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Research Design Service
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National Institute for
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NIHR – CRN West of England

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National Institute for
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CLAHRC West



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People & Research West of England (PHWE)

Latest newsflash – [click here](#)



Better involvement · Better research · Better health

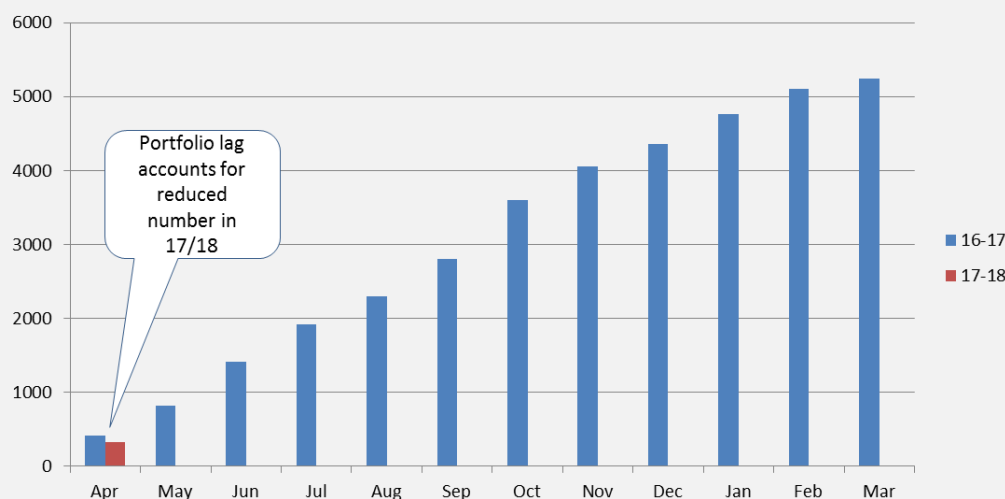
CTEU Bristol newsletter

Clinical Trials and Evaluation Unit news – [click here](#)



2. UHBristol Performance

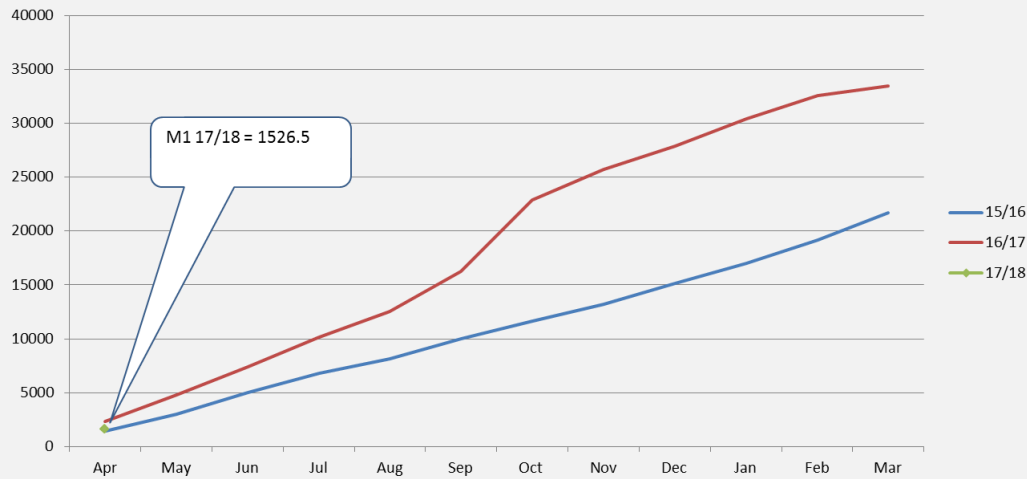
Cumulative Recruitment in Commercial and Non Commercial NIHR studies



The above is taken from the CPMS which is issued with a 4 week lag of data.

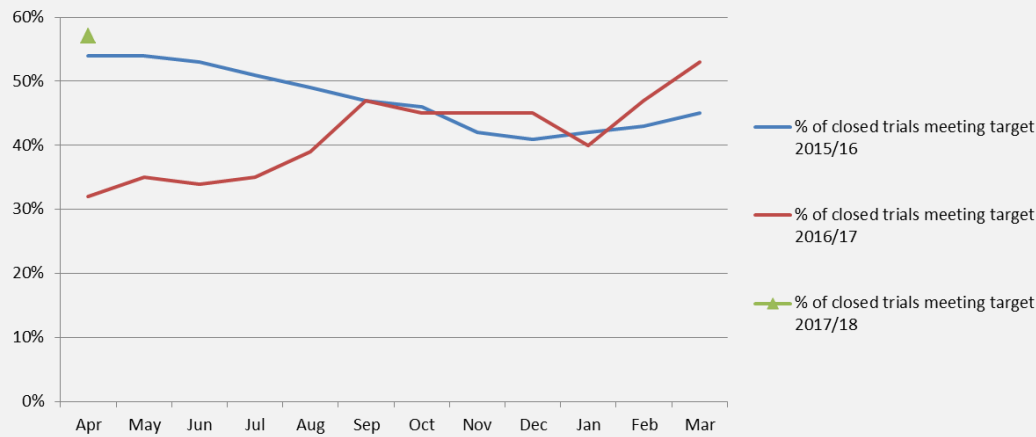
NHS
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Cumulative Weighted Recruitment to date 2017/18 compared to 2016/17 and 2015/16



This data is extracted from the NIHR portfolio report which issued with a 4 week lag of data.

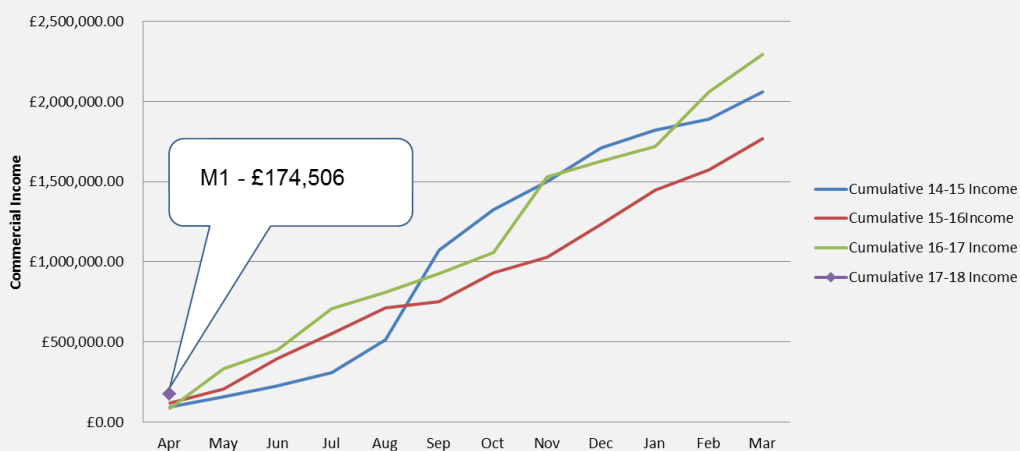
Percentage of commercial clinical trials closed to recruitment during the reporting period meeting time to target



This data is taken from EDGE on a rolling 12 months basis. Latest figures therefore show number of clinical trials closed to recruitment in reporting period between 01/05/2016 and 30/04/2017 meeting time to target (i.e. the preceding 12 months).

Monthly Commercial Research Income

Cumulative Commercial Income



Actual income data derived from monthly reports provided by finance on value of invoices raised.

3. Celebrating Successes

A world First for BHOC CTU

Huge congratulations to the BHOC Clinical Trials Team who opened a new trial on 9th May for patients following a bone marrow transplant. The trial, CYP-GVHD-PI-01 run by Cynata, is of a new cellular therapy product (iMSC) for graft versus host disease following a bone marrow transplant.

Thanks to their dedication and great work with other teams, the team administered the first dose of a new cellular therapy product to a patient on 12th May – a first for us in the Trust but also the first time this therapy product was given to a patient anywhere in the world. We know just how important research is in bringing in treatments for the future, but it also gives our patients another treatment option.

BHOC has recruited the 1st UK patient to the Trilogy trial

Well done to all involved in the Trilogy trial – BHOC has now recruited the 1st UK patient with very good timelines (considering multidepartment involvement). The study went to Research forum January 13th, open to recruitment 21st April, 1st patient consented 2nd May and randomised on 15th May.

The Principal Investigator for the study is Chris Herbert, with Research Nurses Stephen Lang & Nick Robins, and Matt Baxter who co-ordinated.

The Empire study has surpassed the recruitment target

Congratulations to the Medical Research team who have recruited over target for the Empire study which has led to reaching the 200 milestone. The target at UHBristol was 2 and the team have now recruited 3 patients.

The Celtaxsys Study Team said;

Today we achieved the major milestone of completing enrolment into the EMPIRE study with our 200th patient randomizing today.

This could not have happened without the hard work and dedication of your study teams, and most importantly, the willingness of your patients to contribute to efforts that could potentially help CF patients in the future.

Predict-Cat study

CRN West of England is ranked 2nd for recruitment per million for ophthalmology. Predict-Cat continues to recruit well having opened a second site within the LCRN, doubling recruitment compared to 2015-16. Performance in this study accounts for over three quarters of recruitment within the LCRN.

This is a huge achievement and real testament to all of those involved. Thank you to everyone for your tremendous efforts.

VIOLET study

Congratulations to The Surgical Research Team and the Thoracic Teams for reaching a milestone for the VIOLET study.

Research Nurse Karen Bobruk recruited the 100th patient to the study - Video assisted thoroscopic lobectomy versus conventional Open LobEctomy for lung cancer, a multi-centre randomised controlled trial with an internal pilot.



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The Surgical Research Team recruited its 3000th patient

The team was created by Andy Ness in October 2010 and headed by Katrina Hurley and has gone from strength to strength.

Louise Flintoff and PI Stephen Broomfield recruited the patient into the OTO Phase 3 study, a study looking at a gel to hold the steroid used to treat Menieres disease, in the inner ear for longer.

Here's to the next 3000!

Stroke research success – Signum study

This is a study that anyone who's had a stroke is eligible to take part in and is looking at identifying different types of stroke with a view to improving long term outcomes.

The stroke team, Mairead, Amy and Lucy Belle, with initially only 2 weeks to reach the 70 day target, have managed to reach their annual target of 50 in just 2 months! They've worked really hard to achieve this and should be very proud!

4. Grants & Upcoming Awards

Are you planning to submit a grant application to NIHR?

Wednesday 28 June 2017 - Bournemouth University

The Research Design Service is holding a one day event aimed at helping you to improve your chances of success.

The **morning seminar session** is open to anyone to come and hear Simon Goodwin, RfPB Programme Manager for the South West, and RDS advisers give presentations on what makes a good grant proposal.

The **afternoon support session** of one-to-one appointments is for those who would like to discuss their own proposal with Simon and/or an RDS adviser.

Registration is **FREE** and lunch will be provided. **Places are limited** and will be allocated on a 'first come, first served' basis. Registration deadline: 1pm, **19 June 2017** [Find out more and register](#)

Research Design Service
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National Institute for
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Funding Finder

The West of England Academic Health Science Network Innovation Funding Bulletin

For funding opportunities [click here](#)



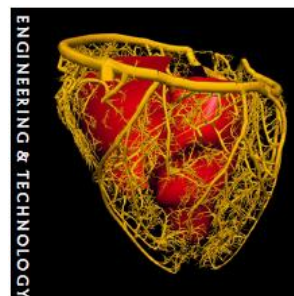
5. Events

New perspectives for the treatment of Cardiorespiratory Disease

Wednesday 31 May 2017, 7:30pm

Bath Royal Literary & Scientific Institution – 16 Queen Square, Bath, BA1 2HN
Dr Alain Nogaret – Department of Physics, University of Bath

[More information click here](#) or contact 01225 312084



Registration now open for the biennial International Meeting on Conversation Analysis and Clinical Encounters

12 July 2017 – 14 July 2017

CACE is a biennial international meeting for academics and clinicians interested in the application of conversation analytic (CA) methods to communication in medical care.

Plenary speakers

- Tanya Stivers (University of California Los Angeles, USA)
- Anna Lindström (Uppsala University, Sweden)
- Ruth Parry (University of Nottingham, UK)
- Elizabeth Stokoe (Loughborough University, UK)

[Find out more and register here](#) – last booking date **30 June 2017**

Public Health Research (PHR) Information Events

Gain a greater understanding of the [NIHR Public Health Research \(PHR\) programme](#). The PHR Programme funds research to generate evidence to inform the delivery of non-NHS interventions intended to improve the health of the public and reduce inequalities in health. Its scope is multi-disciplinary and broad, covering a wide range of interventions that improve public health.

Registration is FREE and refreshments provided. Senior PHR programme staff will be joined by [Research Design Service \(RDS\)](#) colleagues and a local PHR funding panel or board member to give a presentation followed by a Q&A session.

Following this plenary session, there will be individual one-to-one sessions for anyone wishing to take advantage of the opportunity to discuss their project ideas (subject to availability) with PHR programme and/or RDS staff.

In order to secure your place at one of these events please complete the [online booking form](#). Events are being arranged in the following areas:

- Bristol **14 July 2017**
- Newcastle 23 November 2017
- Liverpool TBC

For further information, please [visit the website](#).

CLAHRC West


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Health Research



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Health Research

6. Training and Employment

Do you have a great idea that could transform care?

The first Quality Improvement Academy session received very positive feedback from all participants. The QI team are looking for another group of 20-25 people to attend the next Bronze-level Programme of the Quality Improvement (QI) Academy session on **13 June (8:30am-12:30pm)**.

The Bronze Programme will give attendees the skills to conduct QI projects in their local workspace, through knowledge of QI theory and a practical toolkit. The QI Academy is one of the ways we are promoting and encouraging innovation and improvement, so that staff with good ideas can bring them to life, benefitting patients, staff, the Trust and the wider NHS.

You don't necessarily need an improvement idea to attend. The session is open to anyone who would like to learn new skills or enhance their knowledge of implementing improvement ideas.

To register your place or to get involved, please contact Stephen Brown on ext. 26703 or Stephen.brown2@uhbristol.nhs.uk or visit [Connect](#) for more information.

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