



Newsletter

Welcome to the OMACS newsletter, which includes news and updates on the studies undertaken by the unit.

The UKCRC-registered Bristol Randomised Trials Collaboration (BRTC) and Clinical Trials and Evaluation Unit (CTEU) will be formally merging over the coming months to form one clinical trials unit. This will maximise the future opportunities for successful collaborations.

Studies in Recruitment

Study	Recruitment to date	Study	Recruitment to date
BY-BAND-SLEEVE	1254/1341	MARS2	213/328
CIPHER	551/4000	PEACOCK	46/78
EVALUATE	27/30	ROMIO	291/406
GAP	238/1686	STEM CELL	57/60
INVITE	19/60	TARGET	59/78
OMACS*	2135	THERMIC3	35/94
OXFORD ARTERY	214/210	VIOLET	503/498

Recruitment figures as of February 2019 *No target in place for this study.

Spotlight On...

Maria Pufulete is a senior research fellow in the CTEU, working with collaborators and other senior members of the CTEU. Her role includes; designing research studies, applying for funding, overseeing studies, and writing reports and publications. She is also responsible for initiating research collaborations across the University of Bristol and University Hospitals Bristol NHS Trust, and other external institutions. Maria's role is diverse, dynamic, and deadline driven.

Pre-funding stage

- 🔍 Identify the funding call
- 🔍 Identify the research question/s (for non-commissioned studies)
- 🔍 Design the study
- 🔍 Assemble the research team
- 🔍 Write the grant application
- 🔍 Calculate costs of the research
- 🔍 Submit the application
- 🔍 Respond to reviewer comments

Once a study is funded

- 👤 Oversee study set-up
- 👤 Provide advice on study conduct
- 👤 Work with the research team to deliver the study
- 👤 Provide progress reports to funder

When a study is finished

- ✍ Write end of study report
- ✍ Write publications arising from the study
- ✍ Think about the next study...!

Study Summaries



OMACS: A Research Nurse Perspective

OMACS is our largest cardiac surgery study and is aiming to examine short, medium and long term outcomes in cardiac surgery patients in order to evaluate interventions in the longer term. The research nurses are giving study information to as many cardiac surgery patients as possible at their preoperative clinic, and then approaching them for consent when they are admitted the day before surgery. This allows a full discussion with the patient and, as predicted, personal engagement with the patients has resulted in an increase in consent rates to the study (from 40% to 60-70%) when compared to the previous postal approach for consent. The study has a second phase, which involves collecting waste tissue, blood and urine to be used in other studies. This will present a challenge, as some patients feel too overwhelmed to think about the study and choose to be approached after their operation, and consent for sample collection must take place prior to surgery. We are hoping to overcome this by posting patient information sheets to elective patients in advance of surgery, giving more time to consider the study at home before coming into hospital.

OMACS is funded by the NIHR Bristol Biomedical Research Centre and British Heart Foundation Chair in Cardiac Surgery (CH/1992027/7163, sponsored by University Hospitals Bristol NHS Foundation Trust and led by Dr Lucy Culliford.

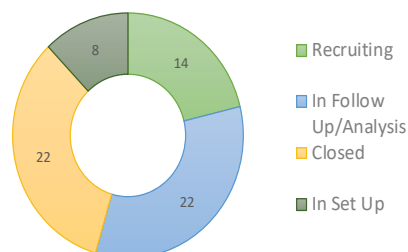


MARS 2 is a multi-centre

RCT comparing surgery and chemotherapy with chemotherapy alone in patients with pleural mesothelioma. This cancer affects the chest and lung, mainly due to previous exposure to asbestos. It has a poor prognosis and it is not clear from current evidence whether surgery improves length or quality of life compared to the current standard of care - chemotherapy alone. Patients will be followed-up for two years. The primary outcome is survival. Secondary outcomes include; quality of life, adverse events, resource use and disease progression. CTEU Bristol took over the running of the study, with 21 centres already recruiting and 10+ further centres in setup. The pilot trial recruited over 50 participants and we aim to recruit 328 participants within the next 3 years.

MARS2 is funded by the National Institute for Health Research Health Technology Assessment programme (project number 15/188/31), sponsored by The Royal Brompton and Harefield NHS Foundation Trust and led by Mr Eric Lim.

CTEU Studies 2002-2018



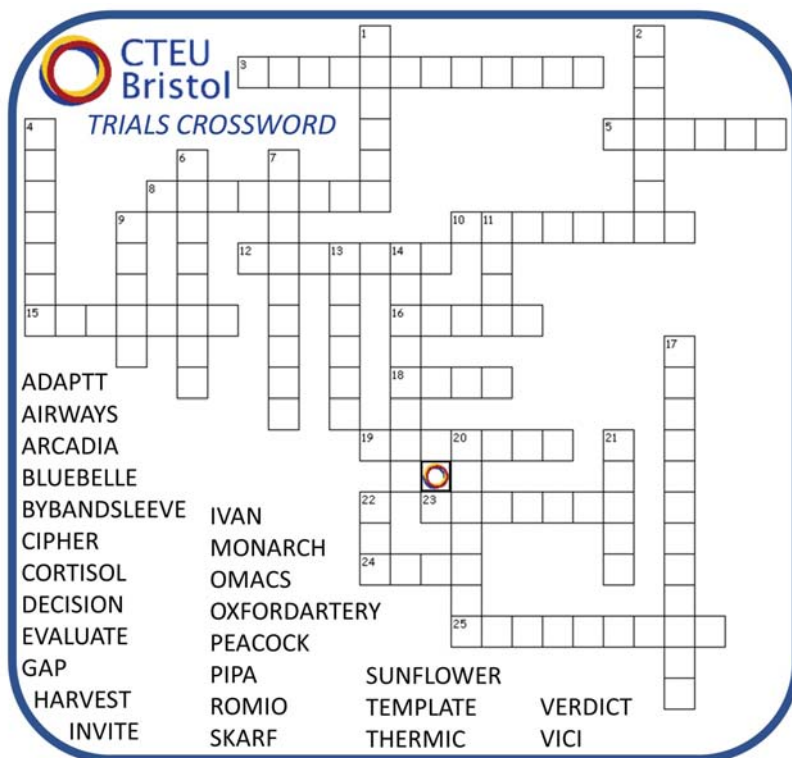
Total patients randomised since 2002: 26,796

PEOPLE IN HEALTH WEST OF ENGLAND (PHWE)

People in Health West of England (PHWE) promotes effective public involvement in health research and evidence-based service improvement. We are currently looking for a few more people with experience of cardiac conditions to join our patient advisory group for cardiovascular research. This is a group which meets a few times a year with cardiovascular researchers to help shape new and ongoing research. You don't need any experience of health research, just an interest in helping to improve healthcare, a willingness to work collaboratively with others and ability to use email. Payment for time and travel expenses is offered.



For more information about PHWE please visit www.phwe.org.uk or if you would like to find out more about joining the cardiovascular patient advisory group please email: enquiries@phwe.org.uk before 31st May 2019.



Studies in Set Up



Pro²PT²



CODEC INSPIRE
PLATELETS VENOUS

Study Output

ROMIO

Impact of question order on prioritisation of outcomes in the development of a core outcome set: a randomised controlled trial

In the development of a core outcome set for a clinical trial, the importance of potential outcomes can be anonymously ranked through multiple 'rounds' of

surveys, known as a Delphi survey. The ROMIO study group recently published the results of a study in which patients and professionals were presented patient-reported outcomes (PROs) and clinical outcomes in varying orders.

In patients, PROs were rated significantly more important, but only if they followed clinical outcomes. In health professionals, clinical outcomes were rated significantly more important, but only if they followed

PROs. This shows that the order of outcomes presented in a Delphi survey can impact the final core outcome set.

Brookes S.T., Chalmers K.A., Avery K.N.L., Coulman K., Blazeby J.M., ROMIO study group. (2018)

ROMIO is funded by the National Institute for Health Research Health Technology Assessment programme (project number 14/140/78), sponsored by University Hospitals Bristol Foundation Trust and led by Mr Paul Barham.