

The ROMIO Study

NEWSLETTER
ISSUE: 6 Autumn/Winter 2020

A message from the CI:



Thank you for your continued efforts with ROMIO in these (extremely!) challenging times. We are continuing with follow-up whilst the statistics team prepare the primary analysis. Well done to everyone for making ROMIO such a success.

Chris Metcalfe, Chief Investigator

Results meeting: 2021



With the many difficulties that the Coronavirus pandemic has thrown up, we are unable to give a full presentation of the primary results as planned for this month. We are now aiming to hold a meeting (most likely remote) in **Feb/Mar 2021** to share the results and hold a discussion. The datalock is booked for 30th Nov so please clear those last queries and watch this space.

ROMIO team staff changes

The ROMIO team has seen some changes this year. We were sad to say good-bye to Mr Paul Barham who retired this summer. Paul has been the chief investigator since ROMIO started in 2016, greatly benefitting the study with his expertise. Chris Metcalfe, Professor of Medical Statistics, will take the tiller as we bring ROMIO to completion, working with Jane Blazeby who will provide clinical oversight.

Liz Ward became our study manager when Rachel Brierley moved on to a new role at the start of this year, and having guided ROMIO through the current challenging period, Liz is now handing over to Robin Wickens, who is back for another stint with ROMIO. Chloe Beard is also moving on to a new role and will hand over to Stephen Palmer who is our new assistant co-ordinator. Many thanks to all for their contributions to ROMIO.

We are all working from home but would be delighted to hear from you via Zoom/Teams or phone.

Vital Status Check

Thank you for all your help and efforts in completing the vital status checks for us at sites. We are particularly grateful for attempts to find out information for patients who have died out of hospital as we appreciate this can be challenging.

Survival is an important outcome for the study so please do ensure that we are informed of all participant deaths (as SAEs), even for those patients who are no longer able to complete questionnaires. These need to be reported **within 24 hours** of awareness .

We hugely appreciate your help in working to get the final queries addressed and completed ahead of the database lock. Thank you.

Progression & Withdrawal

ROMIO Patient Name: _____	DISEASE RECURRENCE / PROGRESSION ROMIO Patient ID: _____
DETAILS OF THE DISEASE RECURRENCE / PROGRESSION <small>Please complete this form where there is evidence of recurrent disease during the follow-up period. Please specify the type of recurrence:</small>	
Local recurrence <input type="checkbox"/> <input type="checkbox"/>	No <input type="checkbox"/> <input type="checkbox"/>
Regional recurrence <input type="checkbox"/> <input type="checkbox"/>	Distant recurrence <input type="checkbox"/> <input type="checkbox"/>
New primary cancer <input type="checkbox"/> <input type="checkbox"/>	
Please provide the date that recurrence was reported: <small>dd/mm/yy</small>	

Please remember to complete a H5 form during follow-up for patients that have disease progression. We hope these patients will continue in the study but understand a small number will want to stop completing questionnaires. Please indicate this is the case on the withdrawal form, making it clear this is a withdrawal from questionnaire completion rather than from the study. Thank you.

ROMIO Patient Name: _____	WITHDRAWAL FORM ROMIO Patient ID: _____
WITHDRAWAL DETAILS	
Date of withdrawal from study <small>dd/mm/yy</small>	Was withdrawal from the study: <small>Before randomisation <input type="checkbox"/> After randomisation but before intervention <input type="checkbox"/> After intervention <input type="checkbox"/></small>



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@ROMIOStudy



The Clinical Trials and Evaluation Unit (CTEU), Bristol, responsible for managing the ROMIO Study, has come together with their sister unit the Bristol Randomised Trial Collaboration to form the **Bristol Trials Centre (BTC)**.

Surgical Publication

A paper detailing the development of an oesophagectomy rating tool for surgical quality assurance has been accepted for publication in the Annals of Surgery Journal.

The paper is available here:

<https://pubmed.ncbi.nlm.nih.gov/32224728/>



Covid-19 & follow-ups

We understand the immense pressures that our sites have been under during the Covid-19 pandemic and appreciate all of your efforts in continuing to conduct ROMIO related activities and answering any queries during this time. A massive THANK YOU from us.

The secondary ROMIO results are largely reliant on participant follow-ups being as complete as possible and as such, for those sites who have been unable to complete the follow-ups, we have brought back retired research nurse, Jo Nicklin, as part of the central ROMIO team. Jo, who was previously the lead research nurse for ROMIO at our Bristol site, is completing these follow-ups from home. A huge thank you to Jo for her help during this time.



Pathology QA assessment

Pathology slides from 10% of participants at each site have been requested over the past year. Thank you for sending these through to us. We are pleased to inform you that all slides have now been received in Bristol.

All but 2 slide sets have been reviewed by the ROMIO lead pathologist. This is excellent progress and we look forward to sharing the results of this part of the study with you.

We thank you for all your hard work in helping us to obtain the pathology slides.



Twitter

We are on twitter: @ROMIOWorkshop

If you or anyone at your site have any Tweet suggestions please email the ROMIO study mailbox.

ROMIO anagrams – can you guess the word?

Dusty - _____

Locational - _____

Palletts - _____

Seaside - _____

Odiums - _____

Done - _____

Eighth - _____

Earth - _____

Incinerate - _____

Elbow - _____



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