

# The ROMIO Study

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Sponsor: University Hospitals Bristol and Weston NHS Foundation Trust

Chief Investigator: Prof Chris Metcalfe, Professor of Medical Statistics, University of Bristol

## Privacy Notice

This notice explains how we collect, process, transfer and store health data for ROMIO study. It forms part of our duty of accountability and transparency under the General Data Protection Regulation (GDPR) and Data Protection Act (2018) (DPA). These laws require us to tell our participants how we will use health data and to give study participants the opportunity to tell us not to use their data in that way.

### What data have we collected?

Between October 2016 and August 2019 the ROMIO study recruited 363 patient participants from 9 UK hospitals to join the study. All the patients taking part had cancer of the gullet (oesophagus) and had surgery to treat their cancer. 328 ROMIO participants had either 'open' surgery or 'combined surgery'. A small group of ROMIO participants (35 patients) had 'keyhole surgery'.

ROMIO study collected direct identifiers and study data (health data and questionnaire data). Direct identifiers included name, address, NHS or CHI number, postcode, GP details, telephone number, ethnicity and demography.

All ROMIO participants were 'followed-up' during their hospital stay and for at least 2 years after surgery. The last study patient will completed their follow-up in August 2021. During follow-up we collected more study data. This included information about patient health and recovery and more questionnaire data.

### Who controls the use of ROMIO data

The University of Bristol and University Hospitals Bristol and Weston NHS Foundation Trust are joint Data Controllers for the ROMIO study. A Data Controller is an organisation who determines why and how personal data are processed. This is defined in the Data Protection Act (2018).

The University of Bristol can be contacted at:

Data Protection Officer  
University of Bristol  
Beacon House  
Queens Road  
Bristol BS8 1QU, UK

Email: [data-protection@bristol.ac.uk](mailto:data-protection@bristol.ac.uk)

University Hospitals Bristol and Weston NHS Foundation Trust can be contacted at:

Information Governance  
Trust Headquarters  
Marlborough Street  
Bristol  
BS1 3NU

Email: [InformationGovernance@uhbw.nhs.uk](mailto:InformationGovernance@uhbw.nhs.uk)

Phone: 0117 34 23701/0117 34 23794

## Consent

All the patients taking part in ROMIO were given written information about the study before deciding to take part. This included information about what data we would collect, how it would be stored and used. Patients had the chance to ask questions and made their decision about taking part freely without pressure. All gave their agreement (consent) to take part voluntarily and in writing. This included consent for ROMIO study to send their identifiable data to NHS Digital.

If you are a ROMIO participant and you wish to withdraw your consent for this study you can do so at any time, without giving a reason, by contacting the Study Manager via email at [romio-study@bristol.ac.uk](mailto:romio-study@bristol.ac.uk).

## What will the ROMIO study use data for?

ROMIO will find out if there is a difference in patient recovery between 'open' and 'combined' oesophagectomy operations. This is the 'primary outcome'. ROMIO will also analyse some 'secondary outcomes'. We will see if there are any differences in patient survival or cost-effectiveness between 'open' and 'combined' operations.

We will use information from participants that had 'keyhole' surgery in a sub-study. This will describe in detail 'keyhole' surgery. 'Keyhole' surgery is relatively new so it is an 'exploratory' comparison.

## How will ROMIO study use data?

To do the data linking a member of the ROMIO research team at University of Bristol will save study patients' identifiable data, including their study identifiers (IDs) to a computer file. The identifiable data that the ROMIO research team will send to NHS Digital are NHS number and date of birth. Start and end dates will also be sent for each patient. These are the dates patients have consented for the ROMIO study team to access their data.

NHS Digital will create a Secure Electronic File Transfer (SEFT) account for the ROMIO research team. The research team will upload the patients' identifiable data to the SEFT account. NHS Digital will use the identifiable data to extract the routine data about hospital healthcare use. NHS Digital will take out any direct identifiers from the routine data. This includes removing any names, addresses, dates of birth, NHS numbers or anything else that could identify an individual apart from study ID. NHS Digital will then upload the dataset to the SEFT. The ROMIO team at University of Bristol will download the dataset, save and store it to an encapsulated virtual machine (eVM). This is a very

secure method to store electronic data. eVMs have been designed in conjunction with NHS Digital (with Michael Robinson: michael.robinson10@nhs.net). Only a few members of the ROMIO study team will be able to access linked data on the eVM. Using the eVM, the ROMIO research team at the University of Bristol will join the NHS Digital dataset and the study data together. This 'linked' dataset will not contain any direct identifiable data, only study IDs.

We will only 'link' study data and routine data for patients from England.

### Where is ROMIO data stored?

We store both direct identifiers and study data on a study specific ROMIO study database against a study ID. Each ROMIO patient has a unique study ID. University Hospitals Bristol and Weston NHS Foundation Trust hosts the ROMIO study database.

The University of Bristol will store the 'linked' data on an encapsulated virtual machine (EVM). The eVM is located at the Slough Data Centre and is run by Virtus This is a very secure method to store electronic data. Only a few members of the ROMIO study team will be able to access linked data on the EVM.

### How long will ROMIO store the data?

The 'linked' data set will be stored on the EVM at the University of Bristol until the end of the data sharing agreement with NHS Digital (anticipated to be August 2025).

### Our Legal Basis

ROMIO study is conducting scientific research that aims to improve the public good and public health.

Our legal basis for using your information, under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is:

1. Performance of a task carried out in the public interest (Article 6(1)(e) in the GDPR); and, where sensitive personal information is involved:
2. Processing for scientific research (Article 9(2)(j) in the GDPR)

The GDPR defines data concerning health as 'sensitive personal information'.

This legal basis within GDPR and the Data Protection Act 2018 is separate to, and in addition to, our seeking patient consent to take part in the ROMIO study, which we have used to help ensure our research is ethical and complies with other applicable laws (see 'consent').

### Rights of the Individual

The GDPR provides rights for individuals; the right to be informed, the right of access, the right to rectification, the right to erasure, the right to restrict processing, the right to data portability, the right to object to processing and rights in relation to automated decision making and profiling. There is no automated decision making (making a decision solely by automated means without any human

involvement) or profiling (automated processing of personal data to evaluate certain things about an individual) involved in this study. The rights available to you depend on the reasons why we are processing your data. In certain circumstances, you have the right to request the restriction of the processing of your personal data. This means that you can limit the way that an organisation involved in this study uses your data. You may contest the accuracy of your personal data, you may feel that your data has been unlawfully processed, you may wish for an organisation to keep your data for a longer period in relation to a legal claim, or you may object to the articles under which an organisation has processed your data.

These requests can be made in writing or verbally. You can contact the ROMIO study manager via email at [romio-study@bristol.ac.uk](mailto:romio-study@bristol.ac.uk).

### **Complaints or queries**

If you would like to complain about our handling of your data, please contact the Data Protection Officer at the University of Bristol: [data-protection@bristol.ac.uk](mailto:data-protection@bristol.ac.uk).

You may also contact the Information Governance team at University Hospitals Bristol and Weston NHS Foundation Trust: [InformationGovernance@uhbw.nhs.uk](mailto:InformationGovernance@uhbw.nhs.uk).

You may also a complain to the Information Commissioner's Office. Their helpline number is 0303 123 1113 or website: <https://ico.org.uk/make-a-complaint/>.