Policy

Policy Title	**Barts CTU Data Sharing Policy**		
Policy Reference	**Barts CTU_POL_01**	**Version Number**	1.0
Approval Date	05/Nov/2025	**Effective Date**	25/Nov/2025
Next Review Date	05/Nov/2028		

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Version	**Date Approved**	**Reason for Change**	**Author**
1.0	04/11/2025	N/A	M Saull

Table of Contents

1. Purpose and Objective 2
2. Scope 2
3. Facilitating data sharing 2
4. Mode of data sharing 3
5. Information for Patients 3
6. Anonymisation and Pseudonymisation of Data 3
7. Resource implications 4
8. Barts CTU Data Sharing Review Process 4
9. Transfers of data outside the EU 5
10. Documentation 5
    10.1 Agreement to data sharing by Data Sharing Agreement 5
    10.2 Agreement to data sharing by Data Access Request 6
    10.3 Review and Approval of agreement 6
    10.4 Review and Signing of agreement by legal entities 6
11. Data preparation 6

1. Purpose and Objective

This document is the Barts Clinical Trials Unit (Barts CTU) policy for sharing study data in line with legislation regarding how data is handled including the General Data Protection Regulation (2016); Data Protection Act (2018), ICO Data sharing code of practice (https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/data-sharing/data-sharing-a-code-of-practice/) and the Good Clinical Practice Guidelines (2016). The policy will be used as the basis for sharing Barts CTU data.

2. Scope

The policy applies to all Barts CTU clinical research data held on QMUL servers. It applies sharing of data with research collaborators in external organisations outside of the Barts CTU and also research data shared within QMUL with those not routinely authorised to access such data, whether or not the data remain wholly within the defined secure area, and control, of Barts CTU. This document does not apply to members of the trial team accessing the data for the purposes of trial conduct such as data managers, application programmers and statisticians, while it remains in the QMUL Data Safe Haven.

3. Facilitating data sharing

Barts CTU will facilitate appropriate data sharing to maximise the value of research data. In common with other academic institutions, the lawful basis on which Queen Mary University of London relies to process data is Article 6(1)(e) of the GDPR which describes processing of personal data that is "*necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller*".

Therefore, any data shared must fulfil this requirement. Requestors are expected to use the data to generate new knowledge and understanding with the intention to publish research findings for wider scientific community and eventual public benefit as per the MRC Data Sharing policy (https://www.ukri.org/publications/mrc-guidance-on-sharing-research-data-from-population-and-patient-studies/mrc-data-sharing-policy-guidance-for-sharing-data-about-people) and to demonstrate

this in their application to access the data (section 7). In any publications, the requestor should acknowledge the contribution of the original study team in accordance with academic standards. Requesters should be employees of a recognised academic institution, health service organisation or commercial research organisation with experience in medical research; and should be able to demonstrate their ability to carry out the proposed study e.g. through their own, or supervisor's, peer review publications.

Barts CTU will share data in a timely and responsible manner, recognising that original study investigators should have a period of exclusivity before key trial data are made available to other researchers. Researchers wishing to access data are encouraged to approach the Chief Investigator or Barts CTU Lead Investigator prior to submitting a data request.

4. Mode of data sharing

Data may be shared either by transferring the data out of the QMUL secure servers or by granting the recipient researcher access to the data while it remains on the QMUL secure servers. A Data Sharing Agreement is required for the former, and a Data Access Request for the latter. The Data Access Request is a simplified form of the Data Sharing Agreement, which removes the need for institutional sign off, and descriptions relevant to transfer and storage of the data.

The data requestor will be responsible for justifying the purpose of requesting a particular dataset(s) and the Chief Investigator and Trial oversight committee (if it exists) or the Barts CTU Lead Investigator/ delegate (as data custodian(s)) will be responsible for reviewing and approving the request. The Barts CTU Data Management Team will be delegated responsibility for implementing the sharing.

Data will only be shared with organisations that have adequate data security policies and procedures in place. These will be clarified in the specific Data Sharing Agreement.

The JRMO can provide a Data Sharing Agreement template, and a Data Access Request template is available in the Barts CTU Data Sharing SOP.

5. Information for Patients

Anonymised individual patient data can be shared without specific consent, as the Data Protection Act 2018 does not cover anonymised data. However, participants should be told if researchers intend to keep the data participants provide for use beyond a specific research study and if data may be shared anonymously with others in the future (see HRA for more information: http://hra-decisiontools.org.uk/consent/content-sheet-support.html#three). It is recommended to include the following statement in the consent form and the patient information sheet for research studies, if appropriate.

"I understand that the information collected about me will be used to support other ethically approved research in the future and may be shared anonymously with other researchers."

6. Anonymisation and Pseudonymisation of Data

Anonymising data is a process that balances producing safe data with reduced utility of the data, recognising that whether data are anonymised or not, is a function of both the data and the data environment (Information Commissioners Anonymisation Decision making Framework: https://ukanon.net/framework/).

'Pseudonymisation' of data (defined in Article 4(5) GDPR) means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person.

Fully anonymising the data, such that the risk of disclosing information referring to individuals is negligible, is required in order for the data to be exempt from the Data Protection Act. For the purposes of this policy, anonymous data will refer to data that has been processed in order that the risk of somebody being identified in the data is negligible. In other situations, some anonymisation work may still be carried out to reduce unnecessary risk but the data cannot be considered to be outside the Data Protection Act. Such data may still be shared subject to appropriate safeguards as laid out in this policy.

See Barts CTU Data Sharing SOP for more information about anonymisation and pseudonymisation.

7. Resource implications

Preparation of the data for sharing may require significant Barts CTU resources in order to appropriately anonymise the data and prepare the data for sharing, including providing appropriate documentation. The burden is likely to be higher for archived studies, or where no Barts CTU staff are currently assigned to the study, or where full anonymisation is required.

Barts CTU will assess resource implications and may charge data requestors for services if necessary. Such charges will be on a cost recovery basis. Barts CTU staff will ensure sufficient resources are available to undertake work required, prior to signing the Data Sharing Agreement or Data Access Request Form. When data are accessed on the QMUL Data Safe Haven, requestors will be required to undergo appropriate training, which includes Information Governance training in line with Barts CTU policies, and a charge may be levied to access accounts.

Where funders are willing to support data sharing activity, Barts CTU recommends Chief Investigators consider including the statistician and data management time for preparing a data sharing pack in the funding application. The data sharing pack should contain data dictionaries, blank case report forms, and associated documentation.

8. Barts CTU Data Sharing Review Process

The Data Sharing review process by the Chief Investigator and Barts CTU Lead Investigator/delegate, involves ensuring that:

1. a valid reason has been provided to access the data and that the data requested is relevant and necessary to fulfil the stated purpose

2. appropriate steps have been taken to minimise risk of identifying participants, taking into account whether consent for data sharing was sought from the research participants

3. where data are to be removed from QMUL Data Safe Haven, data security policies and procedures of the recipient organisation, including country of data recipient (if sharing abroad), and any other applicable regulatory requirements are adequate.

Both the data and the environment will be considered together when assessing the risk of re-identification, recognising that manipulating the data may adversely affect the utility of the data.

If an Oversight Committee is in place for the study, the Chief Investigator or a representative may be invited to the relevant study Oversight Committee to provide input regarding requests relating to the study. The committee will recommend a decision whether to approve the data sharing request or not and will communicate the decision with explanation to the requestor in a timely manner. Where the application has been rejected, the committee will describe what modifications are required to enable approval. Where an Oversight Committee is not in place the decision to approve or reject the data request will be the responsibility of the Chief Investigator and Barts CTU Lead Investigator/delegate.

Details of the application process and response times are described in the Barts Data Sharing SOP.

9. Transfers of data outside the EU

Barts CTU acts in accordance with the GDPR (2016) which restricts transfers of personal data outside the EEA unless the rights of the individual are protected in another way. Wherever possible Barts CTU will fully anonymise any data to be shared outside the EEA. If full anonymisation is not possible, while maintaining the utility of the data, the study Oversight Committee or Barts CTU Lead Investigator/ delegate will assess and document the steps taken to ensure there is an adequate level of protection as per the Information Commissioners Anonymisation Decision making Framework. In addition to the member states, the European Commission has assessed a number of countries as having an adequate level of protection (https://commission.europa.eu/law/law-topic/data-protection/international-dimension-data-protection/adequacy-decisions_en). For more information on international transfers, see the ICO website (https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/international-transfers-a-guide/)

10. Documentation

Third parties must sign an agreement before they can access data held by Barts CTU.

10.1 Agreement to data sharing by Data Sharing Agreement

Recipients of the data do not have the right to pass on data shared by Barts CTU to any other organisation or partner organisation unless that has been agreed as part of the original Data Sharing Agreement. Recipients must agree not to link the anonymised data provided with any other data set without the permission of the study Oversight Committee or Barts CTU Lead Investigator/ designee. Recipients must not attempt to identify any individual from the data provided.

The Barts CTU Lead Investigator or delegate will ensure that the Data Sharing Agreement contains appropriate clauses for the data request.

Any requests to further share the data are likely to be the subject to a separate Data Sharing Agreement where necessary.

Documentation

A written Data Sharing Agreement will detail:

1. Specific data requirements

2. Proposed research to be undertaken using the data including an analysis plan

3. Publication plan for the proposed research

4. Justification of the data access request

5. Summary description of data requested

6. All data custodian(s): usually the chief investigator(s) of study(ies) involved in the agreement

7. Data owner(s): i.e. study sponsor (Joint Research Management Office (JMRO) for Queen Mary University of London (QMUL))

8. Data recipient: this will be (a) named individual(s)/organisation(s) who will have access to the data

9. Details about the controlled access approach for sharing anonymised / pseudonymised individual patient data / study data aiming to protect patients' privacy and confidentiality

10. Details on data destruction or data archiving by the recipient

11. Secure data transfer method

12. Time period for which the approval has been granted

13. Where relevant, obligation on data recipients to commit to and apply security and confidentiality measures to the shared data according to NHS Digital (previously the Health & Social Care

Information Centre) Data Sharing Framework, which can be referred to for more guidance https://digital.nhs.uk/services/data-access-request-service-dars/data-access-request-service-dars-process).

14. Any constraints/requirements specified by data custodian/data controller

Where few data fields are to be shared these can be listed within the Data Sharing Agreement but in most cases a summary of the fields should be included in the Data Sharing Agreement with a full list of fields described in an accompanying technical document.

10.2 Agreement to data sharing by Data Access Request

Where third parties will access data on the QMUL Data Safe Haven a written Data Access Request will detail items 1-6, 8, 12–14 above.

10.3 Review and Approval of agreement on behalf of Barts CTU and individual researchers

The Data Sharing Agreement or Data Access Request will be reviewed and approved on behalf of Barts CTU by the Chair of the study Oversight Committee (if it exists), the Barts CTU Lead Investigator/delegate, the lead recipient researcher and the Chief Investigator (unless Chief Investigator no longer available e.g. retires).

10.4 Review and Signing of agreement by legal entities (Data Sharing Agreement only)

The Data Sharing Agreement will be reviewed and signed by the Data Custodian, Data Owner (usually the sponsor), Data recipient. For studies that are not sponsored by JRMO, the JRMO will also approve the document. After sign off, data will be made available by Barts CTU via a secure transfer method as agreed.

11. Data preparation

Barts CTU will prepare the dataset(s), either anonymised or pseudonymised, prior to sharing, in line with the signed Data Sharing Agreement or Data Access Request and using recommendations to minimise the risk of patient re-identification (see Section 5 above Anonymisation and Pseudonymisation of Data).

Barts CTU Data Sharing Policy_v1.0_5.11.25

Final Audit Report 2025-11-05

Created:	2025-11-05 (Greenwich Mean Time)
By:	Nadia Haidar (n.haidar@qmul.ac.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAAPhOsuKYPuHmvj4hA-k38gokDOM9t-2bV

"Barts CTU Data Sharing Policy_v1.0_5.11.25" History

Document created by Nadia Haidar (n.haidar@qmul.ac.uk)
2025-11-05 - 9:25:34 AM GMT

Document emailed to r.gabe@qmul.ac.uk for signature
2025-11-05 - 9:27:00 AM GMT

Email viewed by r.gabe@qmul.ac.uk
2025-11-05 - 9:30:15 AM GMT

Signer r.gabe@qmul.ac.uk entered name at signing as Rhian Gabe
2025-11-05 - 9:30:39 AM GMT

Document e-signed by Rhian Gabe (r.gabe@qmul.ac.uk)
Signing reason: I am the Approver of this document.
Signature Date: 2025-11-05 - 9:30:41 AM GMT - Time Source: server

Agreement completed.
2025-11-05 - 9:30:41 AM GMT