

BTS DATA ACCESS POLICY

Version 2.6

June 2026

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British Thoracic Society

Data Access Policy June 2026

1. Introduction

The British Thoracic Society collects data for audit and quality improvement purposes through three main programmes:

- The BTS Clinical Audit Programme
- The BTS Lung Disease Registry Programme
- The BTS MDR-TB Clinical Advice Service.

2. Scope and Purpose

This policy is designed to ensure fair, transparent and ethical access to BTS Audit, Registry and MDR-TB data for high quality research, service evaluation and audit use for the purpose of improving care, quality of life and clinical outcomes of people with lung disease. BTS Definitions of data processing for the purpose of research, service evaluation and audit are detailed in Appendix 1 – *BTS Data Processing Categories*

Data requests will only be granted if in line with:

- relevant ethical or other approvals in place for the above programmes, including consent provided by people whose data is held on the Registry and MDR-TB databases; and
- relevant Data Protection Legislation, including the Data Protection Act 2018 and UK General Data Protection Regulation (UK GDPR) 2021.

This policy applies to applications for access to data for the above programmes by:

- BTS members (including BTS clinical leads and BTS Committee members) who wish to obtain data for analysis for projects other than those that have been directly commissioned by the Society (see below);
- Individuals or organisations external to BTS.

3. Eligible applications

The policy applies to requests from organisations that participate in data entry to the above programmes, as well as from organisations that have not been involved in data entry.

The policy is applicable to data requests pertaining to audit, service evaluation and research.

Requests for data for multi-centre studies will be considered as will requests from organisations outside the UK.

Requests for data which support studies to further the development, availability, or evaluation of new therapies for people with lung disease will be considered.

Requests for data for the purposes of marketing or promotion of products (including data to be used in connection as evidence in national consultations for single therapies) will **not** be granted.

This policy does not apply where an individual needs access only to the Audit/Registry/MDR-TB data submitted for their own organisation as registered users have access to their own institution data.

This policy does not apply to analysis conducted by BTS head office for the provision of internal reports to the appropriate Committee or Steering Group, or to the production of annual reports on programme activity including national audit reports prepared by BTS Head Office in collaboration with the clinical audit lead as well as to annual reports prepared by members of the Registry/MDR-TB Steering Groups on behalf of BTS.

4. Available datasets

The following datasets are available for access requests:

BTS Audit programme

National Clinical Audit datasets for each national audit offered from April 2018 onwards

BTS Lung Disease registry Programme

UK IPF Registry: dataset to the end of the last quarter, from 2018 onwards

UK Sarcoidosis Registry: dataset to the end of the last quarter, from 2018 onwards

UK ILD Registry: dataset to the end of the last quarter, from 2023 onwards

MDR-TB Clinical Advice Service

Dataset to the end of the last quarter, from 2018 onwards

Full details of the datasets available for access are provided on the BTS website at: <https://www.brit-thoracic.org.uk/quality-improvement/bts-clinical-data-policy-and-data-access/>

BTS Head Office is not able to provide analysis of the above datasets or analytical assistance with specific applications.

5. Submitting a request

All requests must be submitted using the Data Request application form (Appendix 2) available for download from <https://www.brit-thoracic.org.uk/quality-improvement/bts-clinical-data-policy-and-data-access/> and emailed to bts@brit-thoracic.org.uk.

A member of the BTS Head Office Team will acknowledge receipt of the request.

6. Initial Review

A member of the BTS Head Office Team will check the request for missing or unclear information prior to circulation to the Quality Improvement Committee (QIC) for evaluation.

The application must include:

- Which dataset is the subject of the request
- A list of the specific data items required, with a justification for each item
- The cohort/date range required and why
- Whether the project has been granted funding support, and if so, where from
- A list of the entire research team including their role and institution, and this must include a clinician with appropriate experience for the study in question and appropriate statistical support.
- Details of the expected output (i.e. the medium through which results would be published – journal, abstract, poster, etc.). It is expected that outputs would be peer-reviewed unless there is appropriate justification for this not being the case.

7. Evaluation

The Quality Improvement Committee will evaluate the application to reach a decision on whether the request for data will be granted.

The QIC will not provide applicants with detailed feedback on its review of the application. In relation to formal peer review of the project concerned, it is anticipated that this will be performed by the editorial/scientific committee involved in reviewing conference and journal submissions, prior to the publication of any results resulting from the research study.

When considering the application, QIC members will evaluate the scientific validity and the ethical appropriateness of the research question for which the data is requested. Consideration will also be given to the appropriateness of the proposed research team, collaborators, analysis methodology.

It is expected that researchers will register the individual research projects with their local Research and Development departments and obtain the relevant ethical approvals on the advice of their R&D departments.

The QIC may invite advice on an individual application from clinical members of either the QIC, the Registry Steering Group or the MDR-TB Steering Group in order to evaluation the suitability of Data Requests using the following criteria:

Is the research question appropriate?	Y/N
Is the suggested methodological approach appropriate and scientifically valid?	Y/N
Are there any concerns in relation to the ethical approach?	Y/N
Are the data items requested appropriate?	Y/N
Are the data items required available?	Y/N
Does the application demonstrate a clear understanding of the data or clinical background?	Y/N More information needed
Are there queries about the anticipated outputs?	Y/N
Is the Research team appropriately configured to comply with information governance standards?	Y/N/ More info needed
Does the research team include appropriate clinical and statistical expertise?	Y/N
Is the request in line with the BTS policy for data release?	Y/N
<i>Please indicate decision: (The default position is to grant data where data is exploring clinical questions with a competent team even if the rationale is not compelling to the panel since this is an issue of more detailed peer review)</i>	Approved – data to be provided Rejected More information required.
Comments – please provide justification for decision indicated, or indicate what information is required to allow a decision to be reached.	

8. Decision

A member of the BTS Head Office Team will provide a summary of all evaluation feedback from members of the QIC to the Chair for a final decision to be made.

The Chair will agree a written response based on summary of feedback which will be sent by BTS Head Office, along with a copy of each evaluation form, back to the QIC for review/confirmation. QIC

members have ten working days to raise queries or concerns about the final decision before the Chair's decision is passed on to the applicant.

A report will be made to the QIC at each meeting as part of the Data Access standing agenda item. BTS Head Office will also inform applicants if similar work is already being undertaken as part of another data request (in general terms only).

A list of approved requests will be made available on the BTS website including a plain English summary of the project.

9. Timescale

BTS Head Office will aim to provide the applicant with a decision from the QIC within 3 months of receipt of the request. Data will be provided within 4 weeks after a positive decision has been confirmed (provided Data Sharing Agreement has been signed - see 10 below).

10. Data sharing agreement

When approval has been given, the applicant and the senior investigator for the project will be asked to sign a data sharing agreement (see Appendix 3). Data will not be extracted until a signed copy of this agreement has been returned to BTS Head Office.

11. Data release conditions

Only the minimum data will be provided.

The minimum data, justified by the applicant, will be provided as:

- Patient level, anonymised (no patient identifiers* will be included)

(*Patient identifiers include: First name; Surname; NHS number; CHI number; Full date of birth; Full date of death; Full post code (Regarding date of birth and death, where possible, age will be provided in years.)

Individual full postcodes will not be given out. For research requiring location for analysis such as deprivation scores, where possible already derived postcode related deprivations scores will be provided if these are available.

12. Small numbers

BTS complies with Office of National Statistics guidance on small denominators. Where a denominator is less than five the actual number is to be suppressed and this must be noted in any publication deriving from BTS data.

13. Requests from members of BTS Committees/Steering Groups

Where a member of a BTS Committee or Steering Group is a member of the research team named in the application, they must be declared as a collaborator on the Data Request form. Any individual so named will not be included in the evaluation process, and the final decision will be communicated as per the usual process for external requesters.

14. Chair's action

The Chair of the Quality Improvement Committee (QIC) may take Chair's action where a request is a resubmission as a result of feedback from the QIC that now clearly meets the requirements, or is an amendment to a request previously approved by the QIC. The decision will be documented by BTS Head Office and reported back to the QIC as part of the Data Request standing agenda item at meetings of the Committee.

15. Project completion and data destruction

Upon project completion applicants will provide details of their project outputs to BTS Head Office.

Applicants will be required to confirm that any dataset provided has been destroyed at 12 months from the date it was provided by returning a data destruction form. An application for extension (which would usually be limited to a maximum of one extension for one year) may be made before the initial 12 month period has expired.

16. Data extraction fees

BTS sets a fee for covering the administrative cost of data handling (including extract and cleaning), application processing and related administration. The charging structure outlined below is designed to be fair, proportionate, and transparent whilst furthering the Society's aim of stimulating use of the data for the benefit of people with lung disease. This is in line with the Society's aim of supporting high quality research conducted by appropriately configured groups. As such, there is an expectation that non-commercial research use of BTS data will be grant funded, and that such a grant will incorporate the costs laid out below.

17. Fee categories

Standard charge for academic research

This will apply to research groups making an application for access to one dataset for a single time period.

Reduced charge for academic research (participating organisations)

Applications for a data extract made by a research group where the principal investigator is an employee (honorary or substantive) of an NHS Trust that has entered data into the BTS programme concerned are eligible for a reduction of 50% of the standard charge.

Charge for commercial applications

This will apply to research groups where the financial sponsor is a commercial organisation (biomedical industry, independent healthcare providers etc).

Item	Cost
Standard Charge: Extract from single database for one time period	£2,500 +VAT
Reduced Charge (participating organisation): Extract from single database for one time period	£1,000 +VAT
Standard Commercial Charge: Extract from a single database for one time period	£6,000 +VAT
Non-Standard Commercial Charge (e.g. for additional assurance checks for applications from countries not compliant with UK/EU GDPR standards): Extract from a single database for one time period	£8,000 +VAT

The Society will review data charges on an annual basis.

18. Exemptions

The Society reserves the right to grant other exemptions on a case-by-case basis.

19. Enquiries

Any enquiries in relation to data access requests should be sent to: sally.welham@brit-thoracic.org.uk

BTS Quality Improvement Programmes

BTS Data Processing Categories

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1 Introduction

- 1.1 This document was created to clarify how definitions for different categories of data processing relate to data held within BTS Quality Improvement programme projects, including BTS Audits, Disease Registries and Clinical Advice Services. The aim of the document is to define each category of processing sufficiently that 'grey areas', where data processing falls between categories, are eliminated and that it is clear how data collected via each of the systems can be reported.
- 1.2 This document relates to processing of health data as part of BTS Quality Improvement activities only. It excludes scenarios which involve changing interventions for research and it also excludes processing of other personal data (such as the details of clinical audit/Registry user account holders) which is required for administration of BTS QI programmes.

2 Data Processing Categories

- 2.1 The HRA document *Defining Research* identifies five categories of medical data processing:
 1. Usual practice (in public health)
 2. Surveillance
 3. Clinical audit
 4. Service evaluation
 5. Research
- 2.2 The first two categories – of 'usual practice in public health' and 'public health surveillance' – are outside the scope of BTS activities and will not be considered in this document. Further details of these categories are included in *Defining Research* (included as Appendix 2).

3 Data Processing for the Purpose of Clinical Audit

- 3.1 Drawing from HRA guidance (see Appendix 1) some key features of processing patient data for the purpose of clinical audit are:
 - Processing is designed and conducted to produce information to inform delivery of best care (answering "Does this service reach a predetermined standard?").

- Audit always measures against a set standard.
- Usually involves analysis of existing data but may include administration of simple interview or questionnaire.
- Patient care/interventions are never affected by the audit taking place.
- Processing does not require REC review.

3.2 Clinical Audit: BTS Clinical Audit Programme

Within the context of the BTS Clinical Audit Programme data processing for the purpose of clinical audit will be limited to processing designed to determine whether the relevant audit standards for a given audit (e.g. BTS or NICE Guidelines and Quality Standards) are being met by participating institutions. This includes (but is not limited to) analysing:

- i. Data regarding patient demographics – *patient demographics may be collected to:*
 - a. *provide information on case mix*
 - b. *analyse whether different groups receive different standards of care*
- ii. Patient treatment data – *data on investigations and treatments, including the timings of those interventions and which staff were involved, will be analysed against national standards to establish whether these are being met and to provide wider context for adherence to standards.*
- iii. Patient outcomes – *patient outcome data may be analysed to obtain new knowledge regarding the outcome of cases according to whether national standards are met or not.*

Patient demographics, patient treatment data and patient outcomes may also be analysed to identify any unwarranted variation and potential outliers for the purpose of reporting back to participating institutions so that improvements can be made where necessary.

3.3 Clinical Audit: BTS Interstitial Lung Disease Registries

Within the context of the BTS Interstitial Lung Disease Registries data processing for the purpose of clinical audit may be undertaken where a standard is available against which health services may be measured. This includes (but is not limited to) analysing:

- i. Data relating to available Quality Standards – *collected data which relate directly to how centres are performing against available quality standards may be used to determine how each site is performing against these standard criteria. For example, the BTS IPF Registry holds data against the NICE IPF Quality Standards and therefore hospitals may use the IPF Registry to determine how their unit is performing against those standards.*
- ii. Data relating to other available standards where appropriate – *collected data which relate directly to how centres are performing against other available standards may be used to determine how each site is performing against these criteria. For example, clinical statements and similar formal documents may include suggested standards for patient treatment.*

3.4 Clinical Audit: BTS MDR-TB Clinical Advice Service

Within the context of the BTS MDR-TB Clinical Advice Service data processing for the purpose of clinical audit may be undertaken where a standard is available against which health services may be measured. This includes (but is not limited to) analysing:

- i. Data relating to available Quality Standards – *collected data which relate directly to how centres are performing against available quality standards may be used to determine how each site is performing against these standard criteria. For example, Clinical Advice Service data may be processed to determine how health services are performing against appropriate measures laid out in the NICE Tuberculosis Quality Standards (such as the provision of directly observed therapy).*
- ii. Data relating to other available standards where appropriate – *collected data which relate directly to how centres are performing against other available standards may be used to determine how each site is performing against these criteria. For example, clinical statements (such as the BTS Clinical Statement on the Management of Multidrug-resistant Tuberculosis) and similar formal documents may include suggested standards for patient treatment.*

4 Service Evaluation

4.1 Drawing from HRA guidance (see Appendix 1) some key features of processing patient data for the purpose of service evaluation are:

- Processing is designed and conducted solely to define or judge the current service (answering the question “What standard does this service achieve?”).
- Service evaluation does not measure against a set standard (but may reference targets).
- Usually involves analysis of existing data but may include administration of interviews or questionnaires.
- Patient care/interventions are never affected by the service evaluation taking place.
- Processing does not require REC review.

4.2 In the context of this document *Service Evaluation* refers to the evaluation of services offered by BTS.

4.3 Service Evaluation: BTS Clinical Audit Programme

Within the context of the BTS Clinical Audit Programme data processing for the purpose of service evaluation will be limited to processing designed to determine what standard each Audit achieves in relation to service standards This includes (but is not limited to) analysing:

- i. Data regarding the completion rates of individual questions – *this may be used to determine the relevance/uptake of each question in a BTS audit.*
- ii. Number of cases entered – *broken down by time period, hospital, age, sex, etc. where the breakdown may be justified in terms of service evaluation. For example, number of cases over time could be used to track BTS audit uptake over time and to focus communications/promotion from BTS.*

- iii. Quality checking of Registry data – *reviewing submitted data to determine if any figures should be checked/amended by participating clinicians. For example, an FVC of several hundred percent or a patient height of several metres are likely to be inputting errors and should be rectified to ensure data held are accurate and therefore usable.*

4.4 Service Evaluation: BTS Interstitial Lung Disease Registries

Within the context of the BTS Interstitial Lung Disease Registries data processing for the purpose of service evaluation will be limited to processing designed to determine what standard each Registry achieves and the reach/uptake of each Registry. This includes (but is not limited to) analysing:

- i. Data regarding the completion rates of individual questions – *this may be used to determine the relevance/uptake of each question.*
- ii. Number of cases on the service – *broken down by time period, hospital, age, sex, etc. where the breakdown may be justified in terms of service evaluation. For example, number of cases over time could be used to track Registry uptake over time and to focus communications/promotion from BTS.*
- iii. Quality checking of Registry data – *reviewing submitted data to determine if any figures should be checked/amended by participating clinicians. For example, an FVC of several hundred percent or a patient height of several metres are likely to be inputting errors and should be rectified to ensure data held are accurate and therefore usable.*

4.5 Service Evaluation: BTS MDR-TB Clinical Advice Service

Within the context of the BTS MDR-TB Clinical Advice Service data processing for the purpose of service evaluation will be limited to processing designed to determine what standard the Service achieves. This includes (but is not limited to) analysing:

- i. Data regarding the completion rates of individual questions – *this may be used to determine the relevance/uptake of each question.*
- ii. Number of cases on the service – *broken down by time period, disease category, age, sex, etc. where the breakdown may be justified in terms of service evaluation. For example, number of paediatric cases by time by disease category may be used to identify what proportion of paediatric MDR-TB cases are discussed on the Service over time.*
- iii. High level data regarding treatment given – *summarised data giving number of cases where individual drugs were used, broken down where the breakdown may be justified in terms of service evaluation. For example, individual drugs given at start of TB treatment, by disease category, compared with individual drugs given after time may be used in an attempt to identify if the provision of advice has led to a change in treatment given.*
- iv. Data relating to virtual multidisciplinary team (MDT) meetings – *data on cases eligible for discussion at MDT and those which were actually discussed, broken down by any factors which may be justified in terms of service evaluation. For*

example, data may be used to identify the proportion of cases of suspected MDR-TB discussed at MDT within one month of being brought to the service.

- v. Details of requests for ratification of drug access applications – *details relating to requests (including approvals and refusals) for ratification of applications to use bedaquiline, delamanid or any other TB drug where access is controlled in a similar manner. Data may be broken down by any factors which may be justified in terms of service evaluation.*
- vi. Quality checking of Service data – *reviewing submitted data to determine if any figures should be checked/amended by participating clinicians. For example, dates referring to the year 1019 or records of treatment with a particular drug ceasing before the date it was started are likely to be the result of inputting errors and should be rectified to ensure data held are accurate and therefore usable.*

4.6 Data processing will not be considered to be carried out for the purpose of service evaluation where it could fall under the description given for data processing for the purpose of research (see Section 5).

5. Research

5.1 Drawing from HRA guidance (see Appendix 1) some key features of processing patient data for the purpose of research are:

- Processing is designed to derive generalisable or transferable new knowledge to answer questions with scientifically sound methods including studies that aim to generate hypotheses as well as studies that aim to test them, in addition to simply descriptive studies.
- **Quantitative research** - addresses clearly defined questions, aims and objectives, and may involve evaluating or comparing interventions. May include descriptive research through a postal survey, etc.
- **Qualitative research** – usually has clear aims and objectives but may not establish the exact questions to be asked until research is underway. Can be used to generate a hypothesis, usually identifies/explores themes.
- This usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve investigations additional to routine care and may involve data collected from interviews, focus groups and/or observation.
- Processing normally requires REC review but not always. Refer to <http://hra-decisiontools.org.uk/ethics/> for more information.

5.2 Research: BTS Clinical Audit Programme

Within the context of the BTS Clinical Audit Programme data processing for the purpose of research will be limited to processing which is in line with relevant data protection legislation and where relevant ethical and other approvals are in place. Such research may be conducted by BTS member or individuals or organisations external to BTS. Processing will not be permitted for the purposes of marketing or promotion of products (including data to be used as evidence in national consultations for single therapies). Processing of BTS Clinical Audit Programme data for research includes (but is not limited to) analysing:

- i. Data regarding patient demographics– *patient demographics data may be analysed to obtain new knowledge regarding the patient population in the UK and how these change over time and to provide information on casemix.*
- ii. Patient treatment data – *data on investigations and treatments may be analysed to obtain new knowledge and identify treatment patterns. For example, identifying national trends on the use of certain drugs over time, broken down by patient lung function values, etc.; or to support studies to further the development, availability, or evaluation of new therapies for people with lung disease.*
- iii. Patient outcomes – *patient outcome data may be analysed to obtain new knowledge regarding the outcome of cases by type of disease/age/staging, etc.*

5.3 Research: BTS Interstitial Lung Disease Registries

Within the context of the BTS Lung Disease Registries data processing for the purpose of research (provided all appropriate approvals are in place) is all processing which is not designed to determine what standard each Registry achieves or the reach/uptake of each Registry. This means all processing which is not defined under Section 4.4. This includes (but is not limited to) analysing:

- i. Data regarding patient demographics– *patient demographics data may be analysed to obtain new knowledge regarding the patient population in the UK and how these change over time.*
- ii. Patient treatment data – *drug treatment data may be analysed to obtain new knowledge and identify treatment patterns. For example, identifying national trends on the use of certain drugs over time, broken down by patient lung function values, etc.*
- iii. Patient outcomes – *patient outcome data may be analysed to obtain new knowledge regarding the outcome of cases by type of disease/age/GAP staging, etc.*

5.4 Research: BTS MDR-TB Clinical Advice Service

Within the context of the BTS MDR-TB Clinical Advice Service data processing for the purpose of research (provided all appropriate approvals are in place) is all processing which is not designed to determine the standard which the Service achieves. This means all processing which is not defined under Section 4.5. This includes (but is not limited to) analysing:

- i. Data regarding patient demographics– *patient demographics data may be analysed to obtain new knowledge regarding the patient population in the UK and how these change over time.*
- ii. Drug regimen data – *drug regimen data may be analysed to obtain new knowledge and identify treatment patterns. For example, identifying national trends on the use of certain drugs over time, broken down by type of disease.*

- iii. Drug toxicity data – *drug toxicity data may be analysed to obtain new knowledge regarding toxicity patterns across the UK over time, broken down by type of disease/age/country of birth, etc.*
- iv. Patient outcomes – *patient outcome data may be analysed to obtain new knowledge regarding the outcome of cases by type of disease/age/country of birth, etc.*

6. How Data are Presented by BTS

All data processed for the purpose of research must be processed in line with BTS policies/procedures (including the BTS Data Access Policy where third party researchers are involved) and must be in line with any approvals from the Research Ethics Committee (REC) or similar bodies where appropriate. A report produced at 6.1 or 6.2 would be presented to the appropriate Committee (eg QIC) for approval before publication. Similarly any publication that is produced on behalf of BTS for publication in an external journal (eg a report on registry data for the BMJORR) would similarly be overseen/approved by the appropriate committee or group before it is submitted.

6.1 Data in written reports provided to centres

Summarised data are made available to participating centres in the form of reports downloadable through each Quality Improvement project website. These reports include summarised data for the individual participating institution and/or summarised national data, facilitating benchmarking and clinical audit.

6.2 Data published in publicly available written reports

Information which identifies hospital/Trust (or equivalent) performance may also be made available by BTS through these reports, provided this was previously communicated to the hospital/Trust (or equivalent) in question. For example, BTS national audit registration forms state that 'reports, including those that identify individual hospital performance, may also be published by BTS and made publicly available'.

- i. Data processed for the purpose of clinical audit
Summary data may be published in written form and distributed publicly (e.g. published BTS Clinical Audit Reports are made available publicly through the BTS website).
- ii. Data processed for the purpose of service evaluation
Summary data may be published in written form and distributed without restriction.
- iii. Data processed for the purpose of research
Summary data may be published in written form and distributed publicly in the form of annual reports, published articles in journals, etc.

6.3 Data published through presentations

Information which identifies hospital/Trust (or equivalent) performance may also be made available by BTS through presentations, provided this was previously communicated to the hospital/Trust (or equivalent) in question, as described in Section 6.2.

- i. Data processed for the purpose of clinical audit
Summary data may be used in BTS presentations at both BTS events (including Winter and Summer Meeting presentations) and external events. Summarised national data may be made publicly available through BTS presentations without restriction.

- ii. Data processed for the purpose of service evaluation
Summary data may be used in BTS presentations at both BTS events (including Winter and Summer Meeting presentations) and external events without restriction.

Information which identifies hospital/Trust (or equivalent) performance will not be made available where data presented are those published for the purpose of service evaluation (see Section 4.2).

- iii. Data processed for the purpose of research
Summary data may be used in BTS presentations at both BTS events (including Winter and Summer Meeting presentations) and external events.

BTS Data Processing Categories - Appendix 1 – Health Research Authority Shortened Guidance on Data Processing Definitions (Published October 2022)

This table describes the key characteristics of research, service evaluation, audit and health surveillance projects in order to assist with deciding how a project should be managed. Each of these project types has their own separate governance requirements which you will need to arrange before starting the work. A programme of work may involve more than one project type, but each individual project within the programme should sit clearly under one column. If you find that your planned project spans more than one column, it is likely that its scope and purpose is not defined clearly enough. Consider making revisions to the project design to ensure that it clearly sets out what you want to achieve, and the methodology you will use.

	RESEARCH*	SERVICE EVALUATION / IMPROVEMENT / DEVELOPMENT	CLINICAL/ NON-FINANCIAL AUDIT	HEALTH SURVEILLANCE
PURPOSE	A key feature of research is that it is intentionally planned and designed using documented methodology which will allow results to be extrapolated or applied from the study sample to a larger population. This extrapolation / application is what the terms ‘generalisable’ and ‘transferable’ refer to. In the case of quantitative research, statistical methods are used to achieve results that are ‘generalisable’ from a sample to the sampled population. In the case of qualitative research, the context and findings are described and defined so that the conclusions can be applied or transferred to other settings.	Designed and conducted solely to define or judge current care or service, or to deliver and measure improvements in quality of the current service.	Designed and conducted to produce information to inform delivery of best care.	Designed and conducted to assess priorities, evaluate interventions, and detect and manage threats to health and adverse health status (including incidents, risk factors, hazards, outbreaks and epidemics, may also address health inequalities).
QUESTION/ HYPOTHESIS	Aims to generate a new hypothesis or test a hypothesis. The approach to this may be quantitative, qualitative or both.	Service evaluation is designed to answer the question: “What standard does this service achieve?” This is normally addressed by asking those in receipt of the service. Service development or improvement seeks to find out what improvement can be achieved within that service only.	Designed to answer the question: “Does this service reach a predetermined, recognised or pre-established standard?”	Designed to answer the questions: “Is there a need to start, continue or stop defined public health interventions”, or “Is there need for further investigations”, or “What is the cause of this outbreak (often of a disease) or incident and how do we manage it?”
AIM	Has clearly defined aims and objectives. The project seeks to answer a specific research question or questions.	Measures current service without reference to a standard. (In the case of service improvement / development the current service may be compared to the previous service).	Measures against a standard.	Measures against historical (or geographical) comparators and/or defined levels (triggers) for action. Systematic, quantitative or qualitative methods may be used.

INTERVENTIONS	May involve evaluating or comparing interventions, particularly new ones. Not all research involves interventions.	Service evaluation involves an intervention or service already in use only. Service improvement or development involves a new intervention or service, or one that is new to that context. The choice of treatment, care or services is that of the care professional and patient/service user according to guidance, professional standards and/or patient/ service user preference.	Involves an intervention or service already in use only. The choice of treatment, care or services is that of the care professional and patient/service user according to guidance, professional standards and/or patient/service user preference.	Intervention (if relevant) in use only. Any choice of intervention, treatment, care or services is based on best public health evidence or professional consensus, but may also be used to assess the need for an intervention when none is being taken currently.
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DATA	Usually involves collecting data that are additional to those for routine care or service (but not always). May involve comparing data on treatments, samples or investigations additional to routine care. May involve data collected from interviews, focus groups and/or observation.	Usually involves analysis of existing data but may also include administration of interview(s) or questionnaire(s).	Usually involves analysis of existing data but may include administration of simple interviews or questionnaires.	May involve analysis of existing routine data supplied under licence, agreement or administration of interview or questionnaire to those in the population of interest. This includes collection of data on hazards, exposures and other data to enable interpretation of issues relevant to the population rather than the individual. May also require evidence review.
PARTICIPANT ALLOCATION	Quantitative research study design may involve allocating patients/service users/healthy volunteers to an intervention. Purely qualitative research does not usually involve allocating participants to an intervention.	No allocation to intervention: the care professional and patient/service user have chosen intervention independently of the service evaluation / improvement / development.	No allocation to intervention: the care professional and patient/service user have chosen intervention before audit.	Not applicable. Collects data on issue of concern <i>in situ</i> . May involve allocation to control group to assess risk and identify source of incident, but no allocation to intervention.
RANDOMISATION	May involve randomisation.	May involve randomisation for sampling, but not for treatment/ care/ intervention.	May involve randomisation for sampling, but not for treatment/ care/ intervention.	May involve randomisation for sampling, but not for treatment/ care/ intervention.
NHS REC review required?	Normally requires NHS REC review but not always. Refer to http://hra-decisiontools.org.uk/ethics/ for more information.	Does not require REC review.	Does not require REC review.	Does not require REC review.

*The UK Policy Framework for Health and Social Care Research defines research as:

“3.1 For the purpose of this policy framework, research is defined as the attempt to derive generalisable or transferable¹ new² knowledge to answer or refine relevant questions with scientifically sound methods³. This excludes audits of practice and service evaluations. It includes activities that are carried out in preparation for or as a consequence of the interventional part⁴ of the research, such as screening potential participants for eligibility, obtaining participants’ consent and publishing results. It also includes non-interventional health and social care research (i.e. projects that do not involve any change in standard treatment, care or other services), projects that aim to generate hypotheses, methodological research and descriptive research. Projects whose primary purpose is educational to the researcher, either in obtaining an educational qualification or in otherwise acquiring research skills, but which also fall into the definition of research, are in scope of this policy framework. Activities that are not research according to this definition should not be presented as research and need not be conducted or managed in accordance with this framework. A decision tool that provides a definitive answer about whether a project counts as research under this policy framework is available at www.hra-decisiontools.org.uk/research.

¹ NB This definition involves an attempt at generalisability or transferability, i.e. the project deliberately uses methods intended to achieve quantitative or qualitative findings that can be applied to settings or contexts other than those in which they were tested. The actual generalisability or transferability of some research findings may only become apparent once the project has been completed.

² Including new knowledge about existing treatments or care.

³ Projects that are not designed well enough to meet this definition are not exempt from this policy framework – see paragraph 9.10.a.

⁴ This means the part of the research where a change in treatment, care or other services is made for the purpose of the research. It does not refer to other methodological ‘interventions’, e.g. issuing a postal survey.

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Appendix 2

DATA REQUEST FORM

This form is for requests for data from the BTS Clinical Audit programme/BTS Lung Disease Registry/MDR-TB CAS. Data requests will be considered by the BTS Quality Improvement Committee, whose decision whether to provide data, and whether to make a charge for it, will be final.

Please read the BTS Data Access Request Policy available here <https://www.brit-thoracic.org.uk/quality-improvement/bts-clinical-data-policy-and-data-access/> and the guidance notes for completion of this form.

Please email the completed form to bts@brit-thoracic.org.uk

Applicant details			
Name:			
Position:			
Job title			
Institution / Company / Organisation:			
Details of your organisation (including purpose, website links, etc.) if not a hospital:			
Address:			
Email:			
Contact telephone:			
Please provide details of all members of the research team (add more rows as required):			
Name	Role in team	Job title Institution	Email
	Principal Investigator		
	Statistical analysis		
	<i>Please complete</i>		
	<i>Please complete</i>		
	<i>Please note that only those individuals named above will be granted access to the data should the request be approved.</i>		

Which BTS dataset is required for this application (name and date period)?	
Who is the financial sponsor for this project?	
Does this project have any links with industry? If so please give details:	
Does the proposed project require ethics or other approvals? Please include an export/screenshot from the HRA decision tool (http://www.hra-decisiontools.org.uk/ethics) <i>Please note BTS is not able to advise on whether ethical approval is required.</i>	
Did your organisation contribute to the dataset you require? If yes please give brief details	☐ Yes ☐ No Details:
Date of request:	
Date by which dataset is required:	
Anticipated project timescale:	

Study details
Project Title:
Plain English summary (100 words)(if approved this information will appear on the BTS website):
Aims and objectives of the project (max 300 words):
Brief description and rationale of the project methods, etc. – including the purpose for which the data are required:

List intended uses of the data and what outputs are anticipated: *(incl. anticipated outputs such as publications, reports, presentations, analyses etc.)*

List of data items required with justification for each item: *(list of variables, e.g. years, age group, sex, geographic area, data fields, etc. – with reference to dataset question numbers)*

Dataset/year:

Variables: Justification:

Dataset, year:	
Variables:	Justification:

Where will the data set be stored?
Please give details of data security measures in place at this location.

Where will the data set be processed?

Pease give details of data security measures in place at this location.

Where will the data set be processed?

Where will the data set be processed?

Signature of applicant:

Date

On submission this form will be processed according to the terms set out in the BTS Data Access Policy and that if the request is approved, a Data Sharing Agreement will be provided for completion and submission to BTS before the dataset can be released.

Any dataset will be provided for the period of 12 months following which confirmation of destruction must be returned to BTS.

Date

On submission this form will be processed according to the terms set out in the BTS Data Access Policy and that if the request is approved, a Data Sharing Agreement will be provided for completion and submission to BTS before the dataset can be released.

Any dataset will be provided for the period of 12 months following which confirmation of destruction must be returned to BTS.

On submission this form will be processed according to the terms set out in the BTS Data Access Policy and that if the request is approved, a Data Sharing Agreement will be provided for completion and submission to BTS before the dataset can be released.

Any dataset will be provided for the period of 12 months following which confirmation of destruction must be returned to BTS.

Any dataset will be provided for the period of 12 months following which confirmation of destruction must be returned to BTS.

BTS use only

TEMPLATE DATA SHARING AGREEMENT

BACKGROUND

- (A) BTS has received a completed data request form (the “**BTS Data Request Form**”) from the Applicant which requests access to the BTS Data for the Purpose.
- (B) This agreement (“**Agreement**”) relates to the sharing of the BTS Data between the parties, to ensure such sharing complies with the requirements of the UK Data Protection Act 2018, the Human Rights Act 1998 and the common law duty of confidentiality.
- (C) BTS has agreed to share the BTS Data with the Applicant for the Purpose, on the terms of this Agreement.

1 DATA SHARING SUMMARY

Parties	(1) The British Thoracic Society [•] (“ BTS ”)
	(2) [•]
Description of data being shared by BTS (the “ BTS Data ”)	Data from the BTS Lung Disease Registry / BTS Audit System/ MDR-TB CAS <i>[delete as appropriate]</i>
Data sharing purpose, (the “ Purpose ”)	[•], as described in more detail in the Data Request Form.
Explanation as to why the data being shared cannot be further minimised	[•]
Is the data being shared Personal Data?	Yes / No <i>[delete as appropriate]</i> - Personal Data relating to: <i>[describe individuals]</i> - Containing: <i>[describe personal data – e.g. medical records]</i> - Processing operations: <i>[describe what the Applicant will do with the Personal Data – e.g. Upload, encrypt, sort, filter for [X]]</i>
Reports	[•] An update on the progress of the study must be submitted to BTS at the end of the first year, with a final report on the completed study submitted within two years. If further time is required for the study then this should be requested in writing to BTS and an extension may be agreed.
Approved sub-contractors	
Date of Agreement	

2 DEFINITIONS AND INTERPRETATION

2.1 In this Agreement the following definitions and rules of interpretation shall apply:

“Data Protection Legislation” means the Data Protection Act 2018, the General Data Protection Regulation (originally (EU) 2016/679, and now the ‘UK GDPR’) and all other legislation and regulatory requirements in force from time to time which apply to a party relating to the use of Personal Data (including, without limitation, the privacy of electronic communications);

capitalised terms used but not otherwise defined in this Agreement shall bear the meanings given to them in the Data Protection Legislation; and

any words following the terms including, include, in particular, for example or any similar expression shall be construed as illustrative and shall not limit the sense of the words, description, definition, phrase or term preceding those terms.

3 CONNECTION

3.1 The parties shall use reasonable efforts to establish connectivity between their respective systems promptly, in order to share the BTS Data as contemplated under this Agreement. Unless agreed otherwise with BTS, the BTS Data will be transferred to the Applicant in electronic form via secure file transfer protocol.

4 SECURITY AND PASSWORDS

4.1 The Applicant shall ensure that the BTS Data transferred to it are kept secure and in an encrypted form, and shall use all reasonable security practices and systems applicable to prevent, and take prompt and proper remedial action against, unauthorised access, copying, modification, storage, reproduction, display or distribution of the BTS Data. In particular, the Applicant shall ensure that the BTS Data is only accessed by the named members of the Applicant’s research team identified in the BTS Data Request Form, at the locations identified on the BTS Data Request Form.

4.2 The Applicant shall promptly notify BTS if it becomes aware of any unauthorised or unlawful processing of the BTS Data, or that the BTS Data are lost, destroyed or have become damaged, corrupted or unusable. When the Applicant becomes aware of any such incident, it shall without undue delay provide BTS with:

4.2.1 a description of the nature of the incident, including the BTS Data records concerned and the likely consequences of the incident;

4.2.2 if relevant, the categories and approximate number of Data Subjects concerned; and

4.2.3 a description of the measures taken, or proposed to be taken to address the incident, including measures to mitigate its possible adverse effects.

4.3 The Applicant shall only make copies of the BTS Data to the extent reasonably necessary for the Purpose (which includes, for clarity, backup, mirroring (and similar availability enhancement techniques), security, disaster recovery and testing of the BTS Data).

4.4 The Applicant shall not extract, re-utilise, use, exploit, redistribute, re-disseminate, copy or store the BTS Data other than for the Purpose

- 4.5 The Applicant will maintain the confidentiality of the BTS Data and will not disclose the BTS Data to third parties unless BTS or this Agreement specifically authorises the disclosure, or as required by law. If a law, court, regulator or supervisory authority requires the Applicant to process or disclose BTS Data, the Applicant must first inform BTS of the legal or regulatory requirement and give BTS an opportunity to object or challenge the requirement, unless the relevant obligation to disclose also prohibits such notice.

5 APPLICANT'S PERSONNEL

- 5.1 The Applicant shall designate a single point of contact for liaising with BTS in connection with security matters relevant to the BTS Data, and notify BTS of such individual as well as their contact details within one week of the date of this Agreement.
- 5.2 The Applicant will ensure that all employees:
- 5.2.1 are informed of the confidential nature of the BTS Data and are bound by confidentiality obligations and use restrictions in respect of the BTS Data;
 - 5.2.2 have undertaken training on the Data Protection Legislation relating to handling Personal Data and how it applies to their particular duties; and
 - 5.2.3 are aware both of the Applicant's duties and their personal duties and obligations under the Data Protection Legislation and this Agreement.

6 SUBCONTRACTING

- 6.1 The Applicant may not authorise any third party or subcontractor to process the BTS Data unless BTS provides prior written consent to the appointment of each subcontractor. As at the date of this Agreement, the subcontractors approved for the purposes of this clause are set out in the Data Sharing Summary at clause 1.
- 6.2 Any consent provided by BTS pursuant to clause 6.1 shall require the Applicant to ensure that it enters into a written contract with the subcontractor that contains terms substantially the same as those set out in this Agreement, and which:
- 6.2.1 ensures the Applicant maintains control over all BTS Data it entrusts to the subcontractor;
 - 6.2.2 ensures that the subcontractor's access to the BTS Data terminates automatically on termination of this Agreement for any reason; and
 - 6.2.3 complies with applicable Data Protection Legislation.
- 6.3 Where the subcontractor fails to fulfil its obligations under such written agreement, the Applicant remains fully liable to BTS for the subcontractor's performance.

7 INTELLECTUAL PROPERTY RIGHTS

- 7.1 The parties acknowledge that:
- 7.1.1 all Intellectual Property Rights in the BTS Data are and will remain the property of BTS or its licensors, as the case may be;
 - 7.1.2 all Intellectual Property Rights in the data supplied by the Applicant (or its licensors (other than the BTS Data)) are and will remain the property of the Applicant or its licensors, as the case may be;

- 7.1.3 the Applicant shall have no rights in or to the BTS Data other than the licence to receive and use it for the Purpose in accordance with this Agreement; and
- 7.1.4 references in any element of the BTS Data and the Applicant Data respectively to trade names or proprietary products where no specific acknowledgement of such names or products is made does not imply that such names or products may be regarded by the Applicant or BTS (as the case may be) as free for general use, outside the scope of the Purpose.
- 7.2 The Applicant grants to BTS a non-exclusive, royalty-free, transferable, irrevocable, perpetual, sub-licensable licence to use the reports provided by the Applicant to BTS pursuant to this Agreement (including in combination with other materials) for its general operational and charitable purposes.
- 7.3 The Applicant assigns to BTS, its Intellectual Property Rights in any data it may create under this Agreement that derives from the Applicant having processed the BTS Data under this Agreement (whether or not in combination with any other data) by way of present assignment of future rights. The Applicant shall execute such confirmatory assignments as BTS may require.
- 8 PERSONAL DATA PROCESSING**
- 8.1 This clause shall apply only if the BTS Data being shared between the parties are Personal Data, as identified in the data sharing summary at clause 1.
- 8.2 The Applicant will reasonably assist BTS with meeting BTS's compliance obligations under the Data Protection Legislation, taking into account the nature of the Applicant's processing and the information available to the Applicant, including in relation to Data Subject rights, data protection impact assessments and reporting to and consulting with supervisory authorities under the Data Protection Legislation.
- 8.3 The Applicant must notify BTS immediately if it receives any complaint, notice or communication that relates directly or indirectly to the processing of the Personal Data or to either party's compliance with the Data Protection Legislation.
- 8.4 The Applicant must take such technical and organisational measures as may be appropriate, and promptly provide such information to BTS as BTS may reasonably require, to enable BTS to comply with the rights of Data Subjects under the Data Protection Legislation, including subject access rights, the rights to rectify and erase personal data, object to the processing and automated processing of personal data, and restrict the processing of personal data; and information or assessment notices served on the Customer by any supervisory authority under the Data Protection Legislation.
- 8.5 In the event of a notification to BTS by the Applicant under clause 4.2 which is also a Personal Data Breach, the Applicant:
 - 8.5.1 shall co-operate with BTS in BTS's handling of the matter (including assisting with any investigation, providing BTS with physical access to any facilities and operations affected, and making available all relevant records, logs, files, data reporting and other materials required to comply with Data Protection Legislation or as otherwise reasonably required by BTS); and
 - 8.5.2 acknowledges that BTS has the sole right to determine whether to provide notice of the Personal Data Breach to any Data Subjects, Supervisory Authorities, regulators, law enforcement agencies or others, as required by law or regulation

or in BTS's discretion, including the contents and delivery method of the notice, as well as whether to offer any type of remedy to affected Data Subjects.

- 8.6 The Applicant must promptly notify BTS of any changes to Data Protection Legislation that may adversely affect the Applicant's performance of this Agreement.
- 8.7 The Applicant must not transfer or otherwise process Personal Data outside the UK or the European Economic Area (EEA) without obtaining BTS's prior written consent.
- 8.8 If BTS consents to appointment by the Applicant of a subcontractor located outside the UK or the EEA in accordance with clause 8.6, then the Customer authorises the Provider to enter into SCC with the subcontractor in BTS's name and on its behalf. The Applicant will make the executed SCC available to BTS on request.
- 8.9 The Applicant will permit BTS and its third-party representatives to audit the Applicant's compliance with its Agreement obligations, on at least 10 days' notice. The Applicant will give BTS and its third-party representatives all necessary assistance to conduct such audits.

9 DESTRUCTION OF BTS DATA

- 9.1 At BTS's request, the Applicant will give BTS a copy of or access to all or part of the BTS Data in its possession or control in the format and on the media reasonably specified by BTS.
- 9.2 On termination of this Agreement for any reason or expiry of its term, the Applicant will securely delete or destroy or, if directed in writing by BTS, return and not retain, all or any BTS Data in its possession or control by a date to be specified at the time of termination/expiry. The Applicant will certify in writing to BTS that it has destroyed the Personal Data within [•] days after it completes the destruction.
- 9.3 If any law, regulation, or government or regulatory body requires the Applicant to retain any documents or materials that the Applicant would otherwise be required to return or destroy, it will notify BTS in writing of that retention requirement, giving details of the documents or materials that it must retain, the legal basis for retention, and establishing a specific timeline for destruction once the retention requirement ends.

10 PUBLICATIONS

- 10.1 The Applicant shall not publish any materials which include or derive from the BTS Data without obtaining BTS's consent. Before such consent is granted, the Applicant acknowledges that:
 - 10.1.1 BTS will require a copy of the proposed publication for review at least one month before its intended publication date; and
 - 10.1.2 consent will not be granted by BTS until the publication contains at least the appropriate acknowledgements of the institutions which contributed to the BTS Data, as well as the following disclaimer:

This publication makes use of data provided by the British Thoracic Society [Lung Disease Registry Programme/Clinical Audit Programme/MDR-TB CAS], which has no responsibility or liability for the accuracy, currency or correctness of this publication

11 FREEDOM OF INFORMATION

- 11.1 While BTS and the project for which the Applicant has obtained data are not subject to the Freedom of Information Act (FOIA) – in general BTS will respond to FOI requests where reasonable and appropriate.
- 11.2 In the event of an FOI request made to BTS, the Applicant must provide all reasonable cooperation to enable BTS to comply with its obligations under the FOIA. The Applicant must provide BTS, on written request, with all information required to respond to the FOI request within two working days.
- 11.3 Any FOI requests made directly to the Applicant and relating to the BTS Data should be referred to BTS.

12 BTS'S WARRANTIES

- 12.1 The Applicant accepts responsibility for the selection of the BTS Data to achieve its intended results and acknowledges that the BTS Data has not been developed to meet the individual requirements of the Applicant. The Applicant accepts that the BTS Data is provided "as is" and expressly subject to the disclaimer at clause 12.2.
- 12.2 All other conditions, warranties or other terms which might have effect between the parties or be implied or incorporated into this Agreement or any collateral contract, whether by statute, common law or otherwise, are hereby excluded, including the implied conditions, warranties or other terms as to satisfactory quality, fitness for purpose or the use of reasonable skill and care.

13 LIABILITY & INDEMNITY

- 13.1 Neither party excludes or limits its liability to the other for fraud or fraudulent misrepresentation, death or personal injury caused by negligence, or any other liability which cannot be limited by law.
- 13.2 Subject to clause 13.1, neither party shall in any circumstances be liable, whether in contract, tort (including negligence and breach of statutory duty however arising), misrepresentation (whether innocent or negligent) restitution or otherwise, arising in connection with the performance or contemplated performance of this Agreement for any indirect or consequential loss.
- 13.3 Subject to clause 13.2, the total liability of BTS whether in contract, tort (including negligence) or otherwise and whether in connection with this Agreement or any collateral contract, shall in no circumstances exceed £5,000.
- 13.4 The Applicant agrees to indemnify, keep indemnified and defend at its own expense BTS against all costs, claims, damages or expenses incurred by BTS or for which BTS may become liable due to any failure by the Applicant or its employees, subcontractors or agents to comply with any of its obligations under this Agreement or the Data Protection Legislation

14 TERM AND TERMINATION

- 14.1 This Agreement shall commence on the date stated on the first page, and shall continue until either party terminates this Agreement with immediate effect by giving written notice to the other.
- 14.2 On termination of this Agreement, the Applicant shall as soon as reasonably possible return or destroy (as directed by BTS) all BTS Data, information, software and other materials provided to it by BTS in connection with this Agreement within the timeframe specified in 9.2 above. If the Applicant is required or requested by any law, regulation or government or

regulatory body to retain any documents or materials that it would otherwise be required to return or destroy under this clause, it shall notify BTS in writing of that retention, giving details of the relevant documents or materials.

Please complete and sign:

For completion by the Applicant

Signed: _____ **Date:** _____

Print Name: _____

Position: _____

Institution: _____

For completion by the unit Clinical Director or similar

Signed: _____ **Date:** _____

Print Name: _____

Position: _____

Institution: _____

Please return to:

Email: bts@brit-thoracic.org.uk

For British Thoracic Society use only

Data approval

Signed: _____

Print Name: _____

Position: _____ **Date:** _____

A signed copy must be provided to the BTS Chief Executive