CRIS Service Manual

CRIS provides direct access to clinical data for research and audit purposes in a way that protects the legal and ethical rights of patients.

CRIS was launched in 2009. The growth in projects applying to use CRIS is a testament to the potential value of clinical data for research.

Year	2009	2010	2011	2012	2013	2014
CRIS project applications	39	41	49	55	98	127

The CRIS Service aims to help users through the various stages of a CRIS project, e.g. addressing questions such as: -
- Is it feasible to answer my question from CRIS data?
- Has anyone else used CRIS to research the same question or area?
- What data should I extract and how?
- How am I going to process the data?
- Am I meeting the required governance standards for accessing and using clinical data for research/audit?

Guiding Principle to Services

The CRIS Support Service aims to guide users rather than instruct them – helping users help themselves by making effective and appropriate decisions.
Using clinical data for secondary purposes such as research presents an interesting challenge, for example, data may be incomplete or inconsistent; the same information may be recorded in different places, in different formats and may change over time; etc. In the light of these challenges different approaches or methods may be appropriate for different research questions.
The CRIS Support Service does not instruct users on the best approach or method. Rather, we aim to provide the best information and options available to enable users to develop the approach they deem most academically suitable for themselves.

The CRIS service is based in the BRC Nucleus, Mapother House on the Maudsley Hospital site. CRIS users can access advice from 9am-5pm Monday to Friday. For further information, please contact the CRIS administrator cris.administrator@slam.nhs.uk or 020 3228 8553.

CRIS project life cycle

The CRIS Support Service provides a range of services designed to support users throughout the life-span of their project, from initial interest through to data extraction and processing. This service catalogue presents the services available at different stages throughout this process.

Stage 1 –Interest in CRIS as a research tool

Stage 2 – Expression of interest, project feasibility and system demonstration

Stage 3 – Project application and approval

Stage 4 – Development of a project specification and suitable extraction method

Stage 5 – Project data extraction

Stage 6 – Project data analysis

Stage 7 – Ongoing user support and project monitoring

CRIS Service Catalogue

Stage 1: increasing awareness and inviting interest

A 'live', written communications plan details a range of methods employed to inform relevant stakeholders about CRIS and to invite further interest and queries. Methods employed include:

- information about CRIS, including a list of all approved research projects, is available on public-facing BRC and SLAM websites;
- routine presentations and generic demonstrations to CAG and other SLAM NHS Trust groups;
- posters and leaflets are distributed throughout SLAM NHS Trust sites informing staff and service users about CRIS;
- monthly CRIS drop-in clinics are held to provide general information and advice on using CRIS;
- CRIS.Admin email address invites interested parties and potential users to seek further information.

Stage 2: responding to expressions of interest

New users may approach the Service to find out more about CRIS and its potential to support specific projects or grant applications. Services to support initial enquiries include:

- Simple feasibility checks and queries are undertaken to assess the potential to use CRIS for a particular study, e.g. potential cohort sizes;
- Users are directed to the on-line list of approved CRIS projects to consider possible overlaps or collaborations with others;
- Focused demonstrations are given to individuals or groups with specific research questions in mind, including discussions around feasibility, available tools and any potential special requirements or constraints.
- Information about the CRIS project application process and other relevant security and governance arrangements is made available
- Information about CRIS use governance requirements including those covering access to linked datasets is provided

Stage 3 – supporting project application and approval

Following initial expressions of interest users are required to submit a project-specific application for approval before they can proceed. Services to support project application and approval include:

- A link to the on-line application form, including relevant guidance notes on completing the application, is made available;
- Once the application form has been submitted, all communication between the applicant and the approval body – the CRIS Oversight Committee – is supported by the Service, including distribution of the completed application form, questions and responses, confirmation of the final decision;
- Confirmation of project approval is sent to the applicant along with an information sheet including relevant information on next steps / requirements;

Stage 4 – developing a data-extraction specification and extraction method

Following project approval, there are services available to help users develop data extraction specifications, data extraction and processing methods; Services include:

- Initial one-day CRIS training, covering the benefits and challenges of using clinical data for research, an introduction to CRIS data via the CRIS front end query builder, options for simple and complex querying;

Note – introduction of a second one-day training course to introduce users to complex querying using SQL may be launched in 2015;

- Access to secure network drive with written, approved user guidance and training documents and storage areas for project specification development templates and feasibility data extracts
- One-to-one project consultation with the Training and Development lead for project specific support including; an introduction to CRIS data extraction and management tools, project relevant data challenges with strategic approaches and methods to meet these.
- Supported development of iterative project specification document and extraction method.

The service also aims to offer information and support tailored to the requirements of each project and each user. These requirements are user led; the service recognises the need for the user themselves to determine project specifications that meet their own academic requirement.

Stage 5 – Supporting project data extraction
Once data requirement specification is complete, users may extract CRIS data themselves using the most appropriate method. Should assistance with extraction be required, the CRIS service includes the following:
- CRIS Informatician led extraction of the data from SQL CRIS database against agreed specification requirements
- SQL user working area and secure network drive storage for SQL data extraction
- Supported use of CRIS front end to construct queries

Stage 6 – Providing an environment for CRIS data analysis
The CRIS service maintains licences to a catalogue of data analysis software. Services include:
- Access for CRIS users to licensed analysis software via onsite SLaM desktops

Stage 7 – Study Monitoring/Audit
The CRIS team maintain a purpose built project database for monitoring project progress and accurate record keeping. Up to date records facilitate the provision of services such as:
- Service updates (infrastructure developments, service downtimes etc) via an administrator managed current user email list.
- Provision of CRIS project metrics as required for BRC, CRIS users, or NHS Trust reporting
- Storage and review of CRIS project audit logs according to Trust Information Governance security requirements
- Regular communication with CRIS users for project support, progress and output monitoring.
- Storage of completed datasets for a period of 10 years in line with research governance guidelines
- Secure disposal of data in accordance with the SLaM Confidential Waste Procedure and ICT Security Policy.

Appendix 1 CRIS - Support Tools

User needs (stage)	Tools currently supported/available
Increased awareness (stage 1)	Communications plan, Service user leaflets, posters, website written info and video, project archive, CRIS publications list, Video introduction to CRIS for researchers, CRIS academics videos, CRIS admin email address, CRIS demo powerpoint
Initial interest, Feasibility, Demonstration (stage 2)	SQL_CRIS, CRIS front end, project archive, CRIS publications list, 'Introduction to CRIS' written guide, Introduction to CRIS for researchers video
Project application and approval (stage 3)	Online application form, CRIS admin email address, Project database, 'Introduction to CRIS' written guide
Developing a data-extraction specification and extraction method (stage 4)	CRIS training, Access to CRIS training slides, project specification templates, CRIS front end, Texthunter
Project data extraction (stage 5)	CRIS front end, SQL_CRIS, SQL_CRIS User, Notepad text coding, Texthunter, T'drive storage space
An environment for CRIS data analysis (stage 6)	Hotdesks, Licenced software library
Ongoing project support and monitoring (stage 7)	Project database, CRIS admin email, CRIS front end, SQL_CRIS