

Background

Dr Kath Watson's research group ([Biologic Studies Group](#)) is based at the University and the group work with multiple hospitals and NHS Trusts across the UK. They capture routinely collected rheumatology healthcare data to help the pharmaceutical companies and the regulators (MHRA, EMA, FDA) to monitor the long-term safety in the real world of biologics and other new drugs prescribed to treat inflammatory conditions.

The Biologic Studies Group was one of the early adopters of MS365 in 2020 and have been using MS Teams as a collaboration platform for the internal Biologic Studies Group staff in their research activity for nearly two years. The internal BSG Team has 21 users who work on the projects, all of which are University staff. More recently, the BSG have been using MS Teams Guest Access as a collaborative tool with NHS sites where possible.

The BSRBR-RA online database

The flagship study, the [BSRBR-RA](#), which has been collecting data for over 20 years, moved from a paper-based system to an [online clinical database](#) in 2019. The data captured in the BSRBR-RA is sensitive patient healthcare data, classified under the University Data Classification System as [Highly Restricted](#). All University of Manchester requirements for the appropriate governance and security of this database, including the Data Management Plan, the SLSP, IGMF Quarterly Reports and other necessary agreements, can be found [here](#). Data is handled in accordance with the University [Information Classification, Ownership and Secure Handling](#) processes and guidance.

The University of Manchester is the data controller and the funder, The British Society for Rheumatology, owns the data. The end users or collaborators of the online database are either NHS staff or the University of Manchester staff/students who work on the project. All database users have an NHS email ([name@trust.nhs.uk](#) or [name@nhs.net](#)) or a University of Manchester email account ([name@manchester.ac.uk](#) or [name@postgrad.manchester.ac.uk](#)). The database has end-to-end encryption meaning the data is encrypted on the sender's computer and decrypted on the receiver's computer, therefore is fully protected in transit and only the sender/receiver can view or edit the data. The crucial aspect is that the sender and receiver have appropriate permissions and approvals in place to use the system for both internal (University) and external (NHS) users. This information is stored within the online database with detailed audit trails. University of Manchester users require approval from the research Information Governance Lead/Chief Investigator. NHS users are required to have HRA and R&D approval from their Trust to use the system ([Substantial Amendment 27](#)), the local [Principal Investigator needs to approve NHS accounts](#) at the Trust before they can become active, and all NHS users need to supply an up to date [CV and GCP certificate](#) (all stored within the database). NHS users can only view the data for patients at their Trust which is individual patient-level data and as this is NHS clinical data, treat it with the same conditions as they would all data as part of their role and conditions of employment in the NHS.

In addition, the Group has put [Transport Layer Security](#) in place with the pharmaceutical stakeholders to allow the protected transfer of confidential aggregated data reports for the drug regulators.