DATA SHARING AGREEMENT

Between

Medicines and Healthcare products Regulatory Agency (MHRA)

And

Serious Hazards of Transfusion (SHOT)

Version: 1.0

Date:

Introduction

This data sharing agreement sets out the terms and conditions on which data will be shared between the parties, as specified below, and serves to demonstrate that all parties are mindful of and work in accordance with the relevant Regulations, Directives, Acts, Codes of Practice and guidance relating to the conduct of the parties involved. By signing this agreement, the parties agree to be bound by these terms and conditions. Adherence to this agreement does not provide legal indemnity from the Data Protection Act or any other legislation.

1. Defined Terms

For this Agreement, the following terms shall be understood to mean:

"Agreement"	this Data Sharing Agreement.
"Authorised User"	individuals authorised by each Party to access Data stored on each of their respective systems for the sole purpose of carrying out the Project.
"**Confidential Information**"	information of a confidential nature in whatever form (whether written, oral, visual or electronic) that has been designated as confidential by the provider of that information (or ought to be considered as confidential), including all personal data and special category or criminal offence personal data data within the meaning of the General Data Protection Regulation.
"**Data**"	means all data and/or information shared under the terms of this Agreement (including personal identifiers and information relating to the physical or mental health and condition of patients included in the Project).
"DPB"	Data Protection Bill 2017 - 2019
"Data provider"	the organisation from which Data originates and which is providing data to the recipient organisation, including those working in and/or authorised by the providing organisation to use the Data for the purposes of conducting this Project.
"Data recipient"	the organisation receiving data from the Data provider, including those working in and/or authorised by the recipient organisation to use the Data for the purposes of conducting this Project.
"Derived data"	any data, algorithms or information, including results, derived from the use or analysis of the data in by each party in carrying out the Project.
"IG requirements"	The data provider's own information governance requirements to safeguard confidential information. Assurance that these have been met can take the form of 1) a declaration to confirm adoption of the provider's IG policies and procedures, or 2) an independent assurance certificate, for example, ISO 27001; IG Toolkit or its successor (the Data Security and Protection Toolkit) compliance, or 3) the data provider may view the recipient's security policies, procedures or controls to ensure they are acceptable, complete and up-to-date.

"Lead Investigator"	the lead person responsible for overall management and conduct of the parties in each organisation.
"SHOT"	Serious Hazards of Transfusion SHOT Office, Manchester Blood Centre, Plymouth Grove, Manchester, M13 9LL
"Party"	an organisation sharing data for the purposes of conducting this Project, including those working in and/or authorised by the organisation to use the Data for the purposes of carrying out the Project.
"Principal Investigator"	the Principal Investigator for each organisation are the Senior Haemovigilance Specialist (MHRA) and theMedical Director SHOT
"**Term**"	5 years, to be renewed automatically for succeeding terms of one year, unless either Party gives notice to the other at least one month prior to the expiration of any term or unless otherwise terminated in accordance with section 10.1.

2. Use of the Data

2.1 The Joint UK Reporting Arrangement workflow and details of how the Data will be stored, shared and other security measures in place for safeguarding confidentiality are detailed in this agreement and in general terms, in the MHRA's and SHOTS Information Management and Security policies.

2.2 Each Party acknowledges and agrees that only authorised users are permitted to have access to and to use the data through the MHRA online SABRE system. Each party, and in particular their respective Lead Investigator, will be responsible for independently maintaining their own register of authorised users and for ensuring that the data is used solely for undertaking the Joint UK Reporting Arrangement and for MHRA within the regulatory framework of the Blood Safety and Quality Regulations (BSQRs) and shared with SHOT, for a legitimate purpose, to improve patient safety within the clinical and laboratory areas of haemovigilance and not for any other purpose.

2.3 The information shared through this agreement may not be shared with any other organisation not party to this agreement without the prior written consent of the organisation deemed the original provider of that data and with a clear indication of what the information, if shared, will be used for.

2.4 Each party will undertake to make no attempt to link the data to other datasets held by different recipients not party to this agreement or for different projects without the prior written consent from the Principal Investigator and relevant data provider, or to use the data to identify data subjects or further information about them of a confidential nature other than for purposes of carrying out the requirements of UK Joint Hemovigilance reporting and within the regulatory framework of the BSQR's.

2.5 Each party will hold and use the data in accordance with:

2.5.1 the IG requirements of the relevant data provider;

2.5.2 the IG requirements of the relevant data provider;

2.5.3 If the data constitutes personal data within the legislation of section 1(1) Data Protection Bill 2017 2019 and the Data Protection Act 2018 Part 1 section 2. Each party shall hold the data, by the Data Controllers for each individual organisation, (as this term is defined in the said Regulation) and subject to the legal responsibilities of a Data Controller.

2.5.4 As an Agency the MHRA collect and store data in accordance with BSQR's, Directive 2002/98 Article 14.3, but with reference to the General Data Protection Regulation (GDPR) MHRA will not use reporter's data for anything other than for a regulatory purpose and within the BSQR regulatory framework. A consequence of the Joint haemovigilance reporting platform SHOT have access to the reporters mailing list. MHRA have a legitimate reason to share the collected data with SHOT to help maximise the analysis of data to ensure its correct interpretation and therefore help with safe transfusion practice methods. SHOT use this data to send out SHOT-related communications, for example advertising the symposium, surveys related to SHOTs work and SHOT newsletters. To comply with the GDPR regulations SHOT are responsible for obtaining reporters consent, in advance, to use their data for direct marketing sent electronically (email, SMS or social media direct message) and respect their wishes should they want to stop receiving the information from SHOT.

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2.6 Each party undertakes not to use data or derived data for any commercial purpose or any purpose that is subject to consulting or licensing obligations to third parties without prior written consent from the Principal Investigator and relevant Data Provider.; and will consult their respective Data Protection Officers before processing the data for any new purpose.

3. Incident Reporting

3.1 If there is a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of or access to the data, the responsible organisation will report this immediately, or as soon as practicable but not more than 48 Hours, to the Data Provider and to the other Principal Investigator and their respective Data Protection Officers who will determine whether the incident requires reporting to the Information Commissioner's Office.

3.2 The Data Provider will then work with the responsible organisation, if not the same, to manage the incident according to the relevant local procedures. Outcomes of their investigation and the lessons arising should be shared with all organisations party to this agreement.

4. Management of Agreement

4.1 The MHRA and SHOT are responsible for maintaining signed copies of this agreement and for ensuring that the agreement is subject to regular formal review following

changes to law, ethics and policy in relation to the security and confidentiality of information.

4.2 Any amendments to this agreement must be agreed by each party signatory and a revised agreement produced and signed.

5. Ownership of Data and Intellectual Property

5.1 The data pertinent to the regulatory purpose it collected for and all intellectual property rights therein will remain the property of the MHRA Data Provider at all times and no right, title or interest in or to the data is granted to the data recipient other than as expressly set out in this agreement.

5.2 Each party will own all derived data that they derive and intellectual property rights therein. They will hereby grant to all others a non-exclusive, royalty-free perpetual licence (with the right to grant sub-licences) to use the derived data for education and research purposes subject to approval from the Principal Investigator.

6. Confidentiality

6.1 The Data recipient shall keep confidential the data, derived data and any confidential Information for so long as such data, derived data and/or confidential information remain confidential in nature, notwithstanding termination or expiry of this agreement.

6.2 The obligation in Clause 6.1 shall not apply where the data recipient can prove that the data, derived data and/or confidential information

6.2.1 was already known to the data recipient prior to disclosure by the data provider or was independently obtained by the recipient party without use of or recourse to the data, derived data and/or confidential information;

6.2.2 was disclosed to the data recipient by a third party not under any obligation of confidence to the data provider; or

6.2.3 Is required to be disclosed by law or by requirement of a regulatory body or court order, including any requirements for disclosure under the Freedom of Information Act 2000 or the Freedom of Information (Scotland) Act 2002 ("FOIA") and the Codes of Practice issued under the FOIA as may be amended, updated or replaced from time to time and any subordinate legislation made under these Acts from time to time.

6.3 As MHRA have a legitimate reason to share collected data with SHOT there is no requirement for the MHRA to give the data provider an opt out option of sharing their data with SHOT but should a patient/ data provider exercise their right to dissent to have their information used for any purpose outside the requirements of using the data for best practice and patient safety practices SHOT will operate in line with their wishes unless their information is required to be disclosed by law or by requirement of a regulatory body or court order.

7. Publications

7.1 Each Party agrees that any publications of results arising from analysis of the data will be made jointly with the Principal Investigator and will be produced in accordance with normal academic practice including (without limitation) appropriate acknowledgement of co-authors, any published paper from which the Data derives, the version of the

data used, the role of each Party, the relevant primary collectors of the data and their funders.

8. Disclaimers

8.1 Each recipient party acknowledges and agrees that their access to and use of the provided data is on an “as is” basis. The data provider gives no warranty, express or implied, that:-

8.1.1 their data is accurate or complete;

8.1.2 their data is fit for any particular purpose;

8.1.3 use of their data will not infringe any third party intellectual property or other rights.

8.2 Each party acknowledges and agrees that their access to and use of data derived by the other party is on an “as is” basis. The provider of derived data gives no warranty, express or implied that: -

8.2.1 the derived data is accurate or complete;

8.2.2 the derived data is fit for any particular purpose;

8.2.3 use of the derived data will not infringe any third party intellectual property or other rights.

8.3 Each party agrees that neither party shall be liable for any indirect or consequential damages incurred by the other party under or in connection with this agreement howsoever caused.

8.4 Nothing in this agreement excludes, restricts or otherwise limits either party’s liability for any death or personal injury arising from its negligence or for any loss suffered by the other party as a result of its fraud.

9. Term and Termination of Access

9.1 Each party agrees to share the data during the term only. Each party accepts and agrees that their role under this data sharing agreement may be terminated:

9.1.1 by either party forthwith upon any breach of this agreement; or

9.1.2 by either party upon giving one month’s written notice to the other,

9.2 On termination or expiry of this agreement, the data recipient shall immediately and securely destroy all tangible copies of the data in their possession and (to the extent it is possible to do so) delete all copies of the data from their computer systems and confirm in writing to the Principal Investigator and relevant data provider that this has been done.

9.3 Each party acknowledges and agrees that the provisions of this agreement will continue in full force and effect following expiry of the term or termination of their role.

MHRA hereby accepts the foregoing terms and conditions:

For and on behalf of **MHRA**:

Signed: _____ Date: _____

Name: _____ Title: _____

As the **MHRA Lead Investigator and Principal Investigator** – I acknowledge receipt of a copy of this Agreement and confirm that I will abide by its terms insofar as those terms are applicable to me.

Signed: _____ Date: _____

Name: _____ Title: _____

As the **MHRA Caldicott Guardian** – I acknowledge receipt of a copy of this Agreement and confirm that I will abide by its terms insofar as those terms are applicable to me.

Signed: _____ Date: _____

Name: _____ Title: _____

SHOT hereby accepts the foregoing terms and conditions:

For and on behalf of **SHOT**:

Signed: _____ Date: _____

Name: _____ Title: _____

As the **SHOT Lead and Principle investigator** – I acknowledge receipt of a copy of this Agreement and confirm that I will abide by its terms insofar as those terms are applicable to me.

Signed: _____ Date: _____

Name: _____ Title: _____

As the **SHOT Caldicott Guardian** – I acknowledge receipt of a copy of this Agreement and confirm that I will abide by its terms insofar as those terms are applicable to me.

Signed: _____ Date: _____

Name: _____ Title: _____