

TVS SDE SERVICES AND DATA ACCESS REVIEW COMMITTEE

Terms of Reference

1. STATUS AND AUTHORITY OF COMMITTEE

- 1.1 NHS organisations in the Thames Valley and Surrey ("**TVS**") region are working together to establish a sub national secure data environment ("**TVS SDE**") that will allow routinely-collected health and care data to be used without the need for that data to leave the NHS.
- 1.2 The TVS SDE supports analysis of health and care data including research and development within and across the region such as the development, deployment, and validation of new data-driven innovations alongside non-research uses such as clinical audit and improvement.
- 1.3 The TVS SDE is sponsored by NHS England's Data for R&D Programme. Oxford University Hospitals NHS Foundation Trust ("**OUH**") is the Host Organisation for the TVS SDE.
- 1.4 The TVS SDE Programme Board (the "**Programme Board**") has agreed to establish the Service and data Access Review Committee ("**SARC Committee**").
- 1.5 These terms of reference (the "**Terms of Reference**") set out the roles and responsibilities, function, membership, decision making and reporting arrangements of the Committee.

2. ROLE OF THE COMMITTEE

The Committee's role is to:

- 2.1 set policy relating to data held by the TVS SDE;
- 2.2 assess and determine the outcome of applications for access to data held in the TVS SDE, having regard to the scope of the TVS SDE Purposes set out in the TVS SDE Provider Terms; and
- 2.3 agree the appropriate controls that are required for any approved applications.
- 2.4 The Committee, in line with the rest of the SDE, shall use the Five Safes, as a framework for its work.

3. RESPONSIBILITIES OF THE COMMITTEE

The Committee has the following responsibilities:

- 3.1 **Safe Settings and Data** – supporting SDE policy and practice by:
 - 3.1.1 making recommendations regarding the policies and procedures for data management within the TVS SDE.
 - 3.1.2 setting the parameters for delegation to the TVS SDE Senior Management Team.
 - 3.1.3 determining the content and form of the TVS SDE Data, taking into account recommendations from the TVS SDE Senior Management Team.
 - 3.1.4 assessing and make recommendations on the nature of datasets held by the TVS SDE.

- 3.1.5 ensuring that the decisions are made utilising the range of perspectives amongst Committee Members, and by commissioning and considering expert, independent advice as needed.
 - 3.1.6 establishing working groups or sub-committees within its membership and delegate decision-making to these groups where appropriate.
 - 3.1.7 work with counterparts in other organisations to help ensure consistency of decision-making across SDEs, and convergence or equivalence over time.
 - 3.1.8 retrospectively review decisions made by the SDE Senior Management Team around compliance with delegated authority.
- 3.2 **Safe Projects and Outputs** – ensuring that the Projects that are given access to the SDE represent an appropriate use of the TVS SDE in line with the TVS SDE Purpose and in line with the NHS Values as set out in the NHS Constitution¹. Users and Projects will be evaluated on their individual merit rather than preference given to particular organisations. The Committee will do this by:
- taking into consideration the assessment and recommendations received from the SDE Senior Management Team.
 - assessing potential benefits – for example to patients, healthcare professionals, the health and care system and to society more broadly.
 - assessing potential risks – for example to the privacy of patients and healthcare professionals, to the reputation of health and care organisations, to the SDE, to public trust in the health and care system, and in NHS data programmes in particular.
- 3.2.1 If the Committee decides to approve a proposal, then it may impose additional, project-specific controls by constraining the means of access employed and the data or code imported or the export and usage of results. For example:
 - requiring the Access and data Committee review and approval of any in-project request.
 - specific restrictions upon the use and dissemination of results.
 - turning on screen monitoring, having a data concierge as a Project member, running this as an eyes-off, code-to-data Project.
 - 3.2.2 Any controls required will form part of the contract with the User. If the User does not wish to agree to them, the Project proposal will need to be revised, re-submitted, and re-reviewed.
 - 3.2.3 Where a Project is not approved, the Committee shall provide feedback to the SDE Senior Management Team on the reasons that the Project was unsuccessful. The applicant may subsequently elect to re-submit or withdraw their application.
- 3.3 ensure the perspectives of patients and the public are included in all decision-making;
 - 3.4 promote communication and transparency through the timely publication of decisions and recommendations.

¹ <https://www.gov.uk/government/publications/the-nhs-constitution-for-england/the-nhs-constitution-for-england>

4. FUNCTIONS OF THE COMMITTEE

- 4.1 The Committee shall have decision making or advisory capabilities in accordance with these Terms of Reference only.
- 4.2 Functions not delegated to the Committee in accordance with these Terms of Reference are retained by the Programme Board.

5. MEMBERSHIP

- 5.1 The Committee shall be comprised of Public Members and Health & Care Members.
- 5.2 Public Members shall comprise at least 30% of the Committee.
- 5.3 Public Members will be appointed following an open and transparent application process led by the Committee Chair.
- 5.4 Health & Care Members shall be drawn from a range of professional backgrounds and shall include representation from across different sectors as set out below:
 - 5.4.1 An NHS Acute Trust, providing perspective from across the acute sector;
 - 5.4.2 An NHS Mental Health Trust providing perspective from across the mental health sector;
 - 5.4.3 An NHS Ambulance Trust providing perspective from across the ambulance sector;
 - 5.4.4 An NHS Community Care provider providing perspective from across the community provider sector;
 - 5.4.5 An NHS Primary Care provider providing perspective from across primary care sector;
 - 5.4.6 The Integrated Care Systems that the TVS SDE manages data on behalf of, providing perspective from that geography;
- 5.5 Health & Care Members shall also include:
 - 5.5.1 A director from a Health Innovation Network that operates in the Thames Valley & Surrey representing the relationship with innovators and health innovation;
 - 5.5.2 A representative of the TVS SDE Senior Management Team representing the strategic and operational perspectives of the TVS SDE;
 - 5.5.3 An independent ethics expert, appointed in collaboration with the University of Oxford ETHOX centre (non-voting), to provide a research ethics perspective and act as a bridge to support from ETHOX as needed ;
 - 5.5.4 An independent research & development professional (non-voting) to ;
 - 5.5.5 An independent information governance expert (non-voting) to provide advice and guidance related to information governance legislation and policy;
 - 5.5.6 The TVS SDE Coproduction Lead (non-voting) to provide support and guidance
- 5.6 Each Health & Care Member will be appointed by the Committee Chair, in a process agreed with the Providers which operate in the sector which the Health & Care Member

will represent. Health & Care Members may represent the views of more than one sector.

- 5.7 Observers and staff, as approved by the Chair, may attend a meeting as a non-member from time to time.
- 5.8 The Members of the Committee are required to comply with the TVS SDE policy on declaring and managing interests.

6. COMMITTEE CHAIR

- 6.1 The Committee Chair is responsible for the operation of the Committee.
- 6.2 The Committee Chair will chair all TVS SDE SARC meetings, when present.
- 6.3 The Committee Chair will ensure that the Committee discusses key and appropriate issues in a timely manner with all the necessary information and advice being made available to the committee to inform the debate and ultimate resolutions.
- 6.4 The Committee Chair will ensure that there is equitable input and consideration from all members.
- 6.5 The Committee Chair will be independent of the SDE Senior Management Team.
- 6.6 In the Committee Chair's absence, the Committee shall nominate an interim chair for that meeting.
- 6.7 The Committee Chair shall hold their position for a period of two (2) years (the "Term").
- 6.8 The Committee will nominate a new Committee Chair at the last meeting prior to the expiry of the Term, as subsequently ratified by the Programme Board before the first meeting following expiry of the Term.
- 6.9 Removal of the Chair or another Member shall require the approval of the Programme Board.

7. MEETINGS

- 7.1 The Committee will meet at least 12 times a year.
- 7.2 The Committee may be stood down with agreement of the Committee Chair where there is insufficient business to conduct.
- 7.3 The Committee may meet at other times during the year as agreed between the Committee Chair and Members of the Committee or as otherwise requested or required.
- 7.4 Only Members have the right to attend Committee meetings but other persons and external advisers may be invited to attend all or part of any meeting as and when appropriate.
- 7.5 Any Member or attendee may participate in the Committee's meetings by secure telephone or video conference, provided that all those participating are able to hear each other such that they can contribute to discussions and decisions. Participation in a meeting via electronic means shall constitute presence in person at the meeting.
- 7.6 The Committee is entitled to delegate discrete work packages to sub-groups who will conduct research and report their findings back to the Committee at a meeting. The constitution of the subgroup will be decided by the Committee, at the sole discretion of the Chair.

8. QUORUM AND DECISION MAKING

- 8.1 Each Member shall have one vote.
- 8.2 Where decisions are required the Committee shall reach decisions by a simple majority of Members present. Where there is an equality of votes the Committee Chair has a second and deciding vote provided that they are not conflicted.
- 8.3 A meeting shall be quorate with the following Members in attendance:
 - 8.3.1 Committee Chair or agreed deputy;
 - 8.3.2 At least three Public Members;
 - 8.3.3 At least two Health & Care Members;
 - 8.3.4 A representative of the TVS SDE Senior Management Team.
- 8.4 If any Member cannot attend the meeting, they shall, if possible inform the TVS SDE Programme Support Manager at least five (5) working days in advance
- 8.5 If any Health & Care Member cannot attend the meeting, they shall provide the name of the suitably empowered deputy nominated to attend the meeting in their stead.
- 8.6 If any Member is disqualified from voting due to a conflict of interest they shall not count towards the quorum.
- 8.7 Decisions may be made by the Committee outside of a meeting, at the discretion of the Committee Chair. Agreement or dissent being received by those members listed at section 8.3. Confirmation that all Members received notice in advance of any such decisions being considered is required, with reasonable time given for each Member to input their own consideration.
- 8.8 Decisions and recommendations made by the Committee shall be notified to the Board at the next Board meeting.
- 8.9 The Members have a collective responsibility for the operation of the Committee. They will participate in discussion, review evidence, and provide objective input to the best of their knowledge and ability, and endeavour to reach a collective view. They will take advice where relevant.

9. REPORTING

- 9.1 The Committee Chair shall report to the next Board meeting on its proceedings.
- 9.2 The Committee shall make whatever recommendations to the Board it deems appropriate on any area within its remit where action or improvement is needed.

10. ADMINISTRATIVE

- 10.1 A schedule of meetings of the Committees shall be drawn up for each financial year and circulated to the Members. A copy of the schedule of meetings shall be made available to the Board and regular attendees.
- 10.2 The agenda for the Committee shall be determined collectively by the Committee Chair based on a standard agenda template, plus any further matters arising.
- 10.3 Meeting papers shall be distributed electronically no less than five (5) business days prior the Committee meeting. Exceptions to this are at the discretion of the Committee Chair.
- 10.4 Minutes shall be taken of the meetings of the Committee. Minutes of the meeting of the Committee shall be prepared within ten (10) business days of the meeting and

submitted to the Committee Chair for approval. Once the Committee Chair has approved the minutes and signed them as a true record of the meeting they will be circulated to the Members. Any corrections required to the minutes will be tabled at the next meeting.

10.5 Conflicts of interest will be recorded in the minutes.

10.6 Minutes and any Committee papers shall be made available to the Programme Board.

11. GENERAL MATTERS

11.1 The Committee shall arrange for periodic reviews of its own performance and, at least once a year, review these Terms of Reference to ensure it is operating at maximum effectiveness and recommend any changes it considers necessary to the Board for approval.

11.2 The Committee shall have access to sufficient resources in order to carry out its duties.

11.3 The Committee shall give due consideration to all laws and regulations as appropriate.

12. DEFINITIONS

12.1 In these Terms of Reference the following terms shall have the following meanings:

Health & Care Member	means a Member who is an employee or sub-contractor to a health and care organisation that is appointed to the Committee on the basis of their expertise or role.
Host Organisation	means Oxford University Hospitals NHS Foundation Trust whose administrative offices are at the John Radcliffe Hospital, Headley Way, Headington, Oxford, OX3 9DU, England.
Member(s)	means the members comprising the Committee as set out at Paragraph 5.4 .
Project Proposal	means the proposal put forward by a prospective user for access to de-identified data held on the TVS SDE for a specific purpose.
Providers	means the providers of clinical patient data to the TVS SDE that has signed an Accession Agreement.
Public Member	means to someone who serves on a committee, governance group or panel of an organisation to provide views from a public and/or patient perspective. A public member is someone who is not employed by statutory health and care services, or within research.
TVS SDE Data	means the patient data provided by the Providers or other organisations to the Host Organisation under the Provider Terms or other agreements.
TVS SDE Senior Management Team	means the management team as detailed in the organisational tree set out at Schedule 1.
TVS SDE Purpose	means an academic and/or research purpose which falls within the scope of a relevant Section 251 Approval and/ or one or more Use Cases(s).
Section 251 Approval	means the approval granted in favour of the TVS SDE in accordance with s251 of the NHS Act 2006 dated 7 July 2023 and as updated or amended from time

	to time, and any such other approval granted in accordance with s251 of the NHS Act concerning a proposed Use Case relating to the TVS SDE Purpose.
Use Cases	<p>means the approved uses for patient data agreed by the Providers, as defined in the TVS SDE Provider Terms and which include:</p> <ul style="list-style-type: none"> (a) Research Use Cases such as: <ul style="list-style-type: none"> ○ Real world studies; ○ Translational research; ○ Epidemiological studies; ○ Artificial Intelligence (AI) development; ○ Health research systems; and (b) Non research uses cases such as <ul style="list-style-type: none"> ○ clinical/non-financial audit; ○ service evaluation, improvement and development; ○ health services planning; and ○ health surveillance. <p>Applications in respect of other activities, such as clinical trials or clinical audit, may also be approved by the Committee on a case by case basis, following approval by the relevant Providers.</p>

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