London SDE: Data Access Request Form

New Requests

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Version History Below

Version	Date	Modified by	Updates
0.1	19/07/2023	Robin Johnson (IGS)	Initial Draft of Proposed Data Access Request form for data access requests to the London SNSDE environment through the Independent Information Access Group.
0.2	08/11/2023	Alex Rajagopalan (IGS)	Second draft with amendments based on feedback received from ICS IG Leads.
1.0	09/11/2023	IGS	Version control changed to reflect approval by the LIGSG
1.1	20/01/2025	IGS	Updates to reflect recent changes in policy. Minor corrections to ensure consistency, namely terms used and references.
1.2	30/06/2025	IGS	Updates to align with the SDE Network National DARF.
1.3	08/07/2025	IGS	Updates reflecting the feedback received from IG leads.
1.4	04/08/2025	IGS	Addition of clause 11 'Proprietary Rights in Data' to the Data Access Contract.
1.5	14/04/2026	London SDE	Amended 1.2 to highlight the question of external review. Added PPIE strategy, keywords, and lay summary (Section 4). Amended 8.2 to include collaborators and 9.2 to specify funding organisation. Amended Appendix A to update definitions. Amended Appendix B to replace Data Access Contract with the National SDE Data Access Agreement terms and conditions.
1.6	28/04/2026	London SDE	Amended selection for type of project to align with HRA selections. Added question on project organisation. Edited the data table options to be adaptive and supportive of a widening landscape of data types for London SDE.
1.7	07/05/2026	London SDE	Added section headings (Section A and B) to clarify requirements for applicants to only complete section A for submission and complete section B (data access contract) once approval is granted.

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SECTION A: THIS SECTION MUST BE FULLY COMPLETED FOR YOUR APPLICATION TO BE SUBMITTED

1. Key Project Information			
INTERNAL ADMIN USE ONLY - Project reference number:			
1.1	**Project Title:**		
1.2	**If applicable, please state if the project has been through an external review. Please provide any reference or unique identification number of previous applications or submissions.*** **this may relate to any previous IRAS, CAG or REC applications*		
1.3	**Does your project amount to Research, Service Evaluation or Cohort Recruitment for future research? *** **see Appendix A for key definitions, and for whether this project is considered as Research, please see the following link: Is my study research?*	**Service Evaluation**	☐
		Audit	☐
		Health Surveillance	☐
		Research	☐
1.4	**Does your project require research ethics or other ethics approval?** *Please contact the London Research Service Team (research.onelondon@nhs.net) for assistance in determining whether this is required.* *For those projects requiring REC review – instructions for submission of IRAS to CAG, as this is required prior to submission of this application to the London SDE's IIAG*	**Yes**	☐
		No	☐
		If 'No', please explain why it does not require research ethics or other ethics approval?	
1.5	**If 1.4 was answered 'Yes' have you already obtained research ethics approval?**	**Yes**	☐
		Research Ethics Approval Number:	
		No	☐
		If 'No', please explain why not, or what stage in the research ethics procedure you are currently in:	
	Please indicate which of the following priority use cases will be addressed by	**Real World Studies**	☐
		Epidemiological Studies	☐

1.6	the proposed project (select all that apply):	Health Systems Research	☐
		Clinical Trial Activities	☐
		Translational Research	☐
		AI/algorithm development	☐
1.7	Is this application a new request, does it relate to a previous request, or is it an extension request? In case this application relates to a previous request (approved or not) please provide the previous application ID	New Request	☐
		Relates to a previous request	☐
		Previous Application ID:	
		Extension Request	☐

2. Project Sponsorship Details

2.1	Is your project sponsored by an organisation (Data Controller) who is a party to the OneLondon SDE Data Sharing Specification?	Yes ☐	No ☐
2.2	If you answered 'Yes' to 2.1, which organisation (Data Controller) is sponsoring your project?		
2.3	You are required to have a Clinical Sponsor for your project. Please provide details about the Clinical Sponsor* for the project **See Appendix A for definitions*	Clinical Sponsor's name:	
		Clinical Sponsor's email address:	
		Clinical Sponsor's phone number:	
		Clinical Sponsor's organisation:	
		Clinical Sponsor's role within the project:	
		Clinical Sponsor's role within their organisation:	

3. Project Lead/ Principal Investigator (AKA "Requestor") Details:

3.1	Name:		
3.2	Job Title:		
3.3	Email Address:		
3.4	Phone Number:		
3.5	Employer:		
3.6	If different from the above, who should be the day-to-day contact point for this project? *This should be the person who will answer questions about the project and provide any additional details as/when required*	Same as above:	☐
		Different to the above:	☐

		Name	
		Job Title:	
		Email Address:	
		Phone number:	
		Employer:	

4. Project Purpose, Organisation and Patient Benefits

4.1	**In 300-700 words, please describe the main purpose of your project, the scientific rationale and why you are requesting access to the data. How will access to this data help achieve your project purpose?** **If this application is related to cohort recruitment, please also specify the type/s of study and/or the disease area(s) the recruitment is for:**
4.2	**Provide a brief lay summary of your project. Upon acceptance, this will be published online at onelondon.io**
4.3	**How will the use of the data collected deliver potential benefit to public and the NHS and health purpose? Please select at least one of the options provided below:** ☐ Further understanding of the health and care needs of the populations. ☐ Lead to the identification and progress of treatments and therapies to treat illness. ☐ Further understanding of regional and national trends in health and social care needs. ☐ Address healthcare inequities. ☐ Support the quality and safety of services. ☐ Inform planning health services and programmes. ☐ Inform design of prevention interventions and evaluation interventions. ☐ Inform decisions on how to effectively allocate and evaluate funding according to health needs? ☐ Other **If required, in clear and plain English, please explain how the outcomes of your project will directly benefit patients. What are the further potential benefits to this research project in addition to the public benefits** **i.e. professional, academic, commercial or organisational?** **For any extension requests, please state any additional benefit, or, if the benefits are the same as the original request, then please state the benefits are the same:**

4.4	**Provide a publishable lay summary of the benefits to patients. Upon acceptance, Upon acceptance, this will be published online at onelondon.io** **If this summary is the same as question (above), click here ☐**
4.5	**Provide an outline of the public and patient involvement and engagement (PPIE*) strategy for the project. If there is none, then please provide a justification (should be between 300 - 500 words).**
4.6	**Provide an outline of the Project Organisation, including steering groups and other oversight mechanisms, clinical engagement with both primary and secondary care as appropriate, any other stakeholders, and risk management approach. *The proposed project team should be diverse and diverse and equal, with membership likely to lead to transparent and well-informed decision-making.***
4.7	**Provide up to 10 keywords which best summarise your research project.**
4.8	**Health Research Classification System (HRCS) Category (select all that apply)**

☐ Blood
☐ Cancer and neoplasms
☐ Cardiovascular
☐ Congenital disorders
☐ Ear
☐ Eye
☐ Generic Health Relevance
☐ Infection
☐ Inflammatory and Immune System
☐ Injuries and accidents
☐ Mental Health

☐ Metabolic and Endocrine ☐ Musculoskeletal ☐ Neurological ☐ Oral and Gastrointestinal ☐ Renal and urogenital ☐ Reproductive Health and Childbirth ☐ Respiratory ☐ Skin ☐ Stroke ☐ Non health	
4.9	**In clear and plain English, what risks do you foresee for individuals, and what measures have you incorporated into your project to mitigate them, if any?**
4.10	**Outline the methodology you propose to employ, mentioning relevant statistical/analytical techniques and key variables.**

		5. Dataset requirements (insert as many rows as required); for reference please see Data Custodian - Health Data Research Gateway		
5.1	**Description of Information Required:** *Please include dates/timeframes for any analysis, and other specific indicators/categories required in the data such as specific codes/metrics.*	**Categories of data processing:**	**Sub-Categories (where applicable):**	**Tick as appropriate:**
		Example: Primary Care data	• *Index events (description)* • *Primary Care Usage*	☐
		Example: Demographic Information	• Type(s) of Demographics	☐
				☐
				☐

5.4	Is there a specific geographical area within London whose data you want to access?	No		☐
		Yes		☐
		If yes, please indicate which geographical area/s you are interested in:	North Central London	☐
			North East London	☐
			North West London	☐
			South East London	☐
			South West London	☐
5.5	Will you require access to any of the following services?	No		☐
		Yes		☐
		If yes, please select which one	Data (and SDE platform)	☐
			Consultancy Services	☐
			SDE platform only (bring your own data)	☐
			Other (specify)	
5.6	Please confirm if you would like to have periodic refreshes of the data. If yes, for what purpose?	No		☐
		Yes		☐
5.7	If applicable, please list the inclusion (including a time period for baseline and follow-up) and exclusion criteria for patient cohorts to be recruited	Inclusion Criteria:	Exclusion Criteria:	

6. Data Access Support			
6.1	Please note that the pseudonymised data will be made available in a SQL data warehouse. Some, or all of your Users will need to have SQL skills to be able to access and use the data. Please confirm whether you have Users with the necessary skills to access the data:	Yes	☐
		No	☐
6.2	Do any of the Users who will need access to the database, already have access to the pseudonymised database?	Yes	☐
		If 'Yes', please provide details of which individuals currently have access:	
		No	☐

7. Data Linkage, use of AI and whether to carry out a Data Protection Impact Assessment			
7.1	Are there any intentions to link the data you will receive access to with any other	No	☐
		Yes	☐
If 'Yes', what datasets will you be linking to the data? Please describe the data items which will be linked, where this data will be linked from, where any data will be accessed, and whether these data			
	The London Analytics Platform is a highly secure environment created to protect the confidentiality and security of patient data. However, linking the dataset with other datasets	We have carried out a Data Protection Impact Assessment for this project and will attach a copy of it to this application:	☐
		We have not carried out a Data Protection Impact Assessment:	☐

7.2	and/or using AI, Machine Learning or innovative technologies increases the risk to the rights and freedoms of patients and could require a Data Protection Impact Assessment being completed. If required, a DPIA must be submitted and reviewed/approved by research.onelondon@nhs.net prior to the submission of this application to the IIAG	If you have not carried out a Data Protection Impact Assessment, please explain why. You may also confirm that queries involving linkage data will not be requested, trialed, or completed prior to a completion and submission of a DPIA:	
7.3	Will the project use AI, Machine Learning or other innovative technologies on the dataset?	No	
		Yes	
If 'Yes' please describe how AI, Machine Learning or other innovative technologies will be used in the project:			

7.4	**If requiring access to support, modify, or use data engineering tools within the backend platform of the London SDE, please describe here the purpose, necessity, and justification for this access. Specify roles (whether access is requested for your team member(s)), actions, and any potential risks.**	

8. Access duration and Users requiring access			
8.1	Please specify how long you require access to the requested data? N.B - Maximum permitted duration is 12 months	Length requested:	
		Proposed start date:	
		Proposed end date:	

PLEASE NOTE: anyone accessing data will need to sign the Acceptable Use Policy, have completed their Information Governance training and signed the relevant Terms and Conditions (found within the Data Access Request Form)before they can have access to the data within the OneLondon SDE

8.2a	Please list all Users who will require access to the Secure Data Environment(s):		
User's name and Job Title	**User's Email Address**	**User's Organisation**	**Please tick the box below to confirm that each User:** • Has completed their Information Governance Training from the NHS on data access; • Has read, understood and signed the relevant Terms and Conditions ; and • Acknowledges that they will need to have read, understood and signed the relevant Acceptable Use Policy in order to be granted access to the data.
			☐
			☐
			☐
			☐
			☐
			☐
			☐
			☐

8.2b	Provide the name and contact details of any other team members and organisations who are collaborating on the project and will not require access to the Secure Data Environment(s).	
Name	**Email**	**Job title and role**

9. Funding arrangements			
9.1	**At any point or under any circumstance, has your project been Commercially/Third Party Funded?*** **see Appendix A for definition of Commercially/Third Party Funded*	**Yes**	☐
		No	☐
9.2	**At any point or under any circumstance, will this project result in Commercial Exploitation of any kind?*** **see Appendix A for definition of Commercial Exploitation*	**Yes**	☐
		No	☐
9.3	**If you answered 'Yes' to 9.1, who are the funder(s) for your project:**	**Name of the organisation:**	
		Name of the relevant individual at the organisation:	
		Designation:	
		Email address:	
		Contact number:	
9.4	**If required, have you paid or agreed to pay the required data access fee? Please contact research.onelondon@nhs.net for further information.**	**Yes**	☐
		No	☐
		If 'No', please explain why a data access fee has not/will not be paid (e.g. access free of charge with agreement of data controller etc.)	
9.5	**If you are funded by a research/ non-profit organisation, are there any relevant terms attached to the funding which restrict or are contrary to the terms of conditions below?**	**Yes**	☐
		If 'Yes', please specify the relevant restrictions:	
		No	☐

10. Project and Organisation Assurances			
10.1	Has your organisation reached at least 'Standards Met' in your most recent Data Protection (DSPT) Security Toolkit return?	Yes	☐
		ODS Code:	
		DSPT Status (*e.g. Standards Met, Standards Exceeded*):	
		DSPT Published Date:	
		No	☐
10.2	Please explain how the Users who will be accessing the data have been appropriately vetted:		
10.3	Please confirm that all Users who will be accessing the data have standard confidentiality clause in their contracts that prevents disclosure of confidential information outside the organisation:	I confirm that staff have appropriate confidentiality clauses:	☐
		The staff do not have appropriate confidentiality clauses:	☐
10.4	It is imperative that we understand if there are any issues with data quality in the database. If you experience any data quality issues, they must be reported via Support : OneLondon ServiceDesk	I understand the requirement for data quality issues to be reported and agree that I will report them via the OneLondon Service Desk.	☐
10.5	To gain access to the OneLondon SDE, the User's organisation must sign a Sub-Licensing agreement between themselves and all applicable Integrated Care Boards within London whose data they want to access. Until this agreement is signed, you will not be provided access	I understand that I will need to sign up to the Sub-Licensing Agreement for my organisation to gain access to the data	☐

11. Patient consent, safety and project feasibility N.B - FOR COHORT RECRUITMENT STUDIES ONLY			
11.1	**Please confirm that you have attached the following documentation with your application:**	**Patient Consent Forms** *N.B – The consent form patients will sign in order to participate in the study, not a consent to contact register*	☐
		Patient Privacy Notices/ Study Transparency Materials	☐
11.2	**If you are recruiting outside the Sponsor's Trust/Centre, outline your plans to ensure patient safety**	**N/A – Not recruiting outside the Trust/centre**	☐
		How will you maintain and ensure patient safety?	
11.3	**What feasibility findings have you undertaken for the proposed study?**		
11.4	**What plans do you have to involve and engage with members of the public as part of this research project proposal? If there is none, then please provide a justification (should be between 300 - 500 words).** Please write this section in lay language as public members of the committee review this section.'		

12. Study Publication Acknowledgements		
12.1	**Please indicate where you plan to publish or disseminate the results of the project after it is completed:**	

12.2	**Please note you are required to acknowledge the Relevant Partner and the OneLondon SDE in any publications of your project as per the terms and conditions below**	**I hereby acknowledge that I have read and understood the terms and conditions set out below and agree to acknowledge the Relevant Partner and the OneLondon SDE in any papers or publications as a result of the project, whilst also including the following text for any ethical section or relevant methodology:** *"The OneLondon SDE has secured Health Research Authority (HRA) approval, with researchers not required to seek further ethical approval for use of the One London SDE for research purposes for studies submitted to and approved by the IIAG and London Data Access Committees. (REC reference – 24/LO/0900; IRAS project ID – 352194)."*	☐
		I also acknowledge that I will share the paper or publication with the Independent Information Access Group once I am in a position to do so. Please send any/all publication DOI's to research.onelondon@nhs.net	☐

13. Conflicts of Interest			
13.1	**Does the clinical sponsor have any conflicts of interest* in this Project?** ***Please see the definition of Conflict of Interest in Appendix A before completing this section***	**No**	☐
		Yes	☐
If 'Yes', then please provide details of the relevant conflicts below:			
If 13.1 was answered 'Yes' or 'No', please sign against the following statement:			
I (the clinical sponsor) hereby confirm that the statement above (relating to Conflict of Interest) is true and complete to the best of my knowledge and accept any penalties imposed by the Agreement below should it transpire this was not the case.			
Clinical Sponsor Name:			
Clinical Sponsor Signature:			
Date Signed:			

14. Project Lead sign-off	
14.1	**By signing this form, I (the project lead) confirm that all information included in this form is accurate (to the best of my knowledge), that all Users who will be accessing data are listed in 8.2 of the form have completed their Information Governance training and have agreed to the Terms and Conditions listed below and have either signed, or intend to sign, an Acceptable Use Policy. I also confirm that my clinical sponsor also holds a substantive contract with one of the data controllers who is a party to the sharing specification for the London Analytics Platform under the OneLondon SDE Data Sharing Framework**

Project lead Name:	
Project Lead Signature:	
Date Signed:	

Appendix A: Key Definitions

Clinical Sponsor	The Clinical Sponsor should be the Head of Service, Clinical Director or Divisional Director responsible for overseeing the project and ensuring that data use is appropriate and in line with the approval application.
(Patient) Cohort Recruitment	The enrolment of a cohort of patients to a study or clinical trial. Access to the data platform will determine what patients are eligible/suitable for the study. An IRAS application and CAG approval, along with tasks as directed in the Re-identification Process, must be completed and made available along with this application.
Commercially/Third Party Funded	A project is considered as being Commercially/Third Party Funded if it is being funded by a private organisation in any form and/or the project has been allocated funds to carry out research by a governmental/non-profit body (e.g. NIHR/MRC/British Heart Foundation etc.). This arrangement can take a number of different forms and may well include a number of different bodies (including public sector bodies) who involved in the transaction. For example, a data analytics/pharmaceutical organisation sponsors a research study which is going to be delivered by a public sector body who has the necessary expertise to deliver it. Even if that public sector body is making the application, the project can reliably be considered as Commercially Funded because the outputs will be used by the aforementioned data analytics/pharmaceutical organisation.
Conflict of Interest	A potential or actual conflict of interest exists when your role in sponsoring this application is likely to be compromised by other material interests, or relationships (especially economic), particularly if those interests or commitments are not disclosed. This Conflict of Interest statement (in the form above) should be completed if the Clinical Sponsor has an economic interest in, or acts as an officer or a director of, any outside entity whose financial interests would reasonably appear to be affected by the approval of this application. The Clinical Sponsor should also disclose any personal, business, or volunteer affiliations that may give rise to a real or apparent conflict of interest. In deciding whether a conflict is likely, the Clinical Sponsor should consider any relevant policy guidance available by their employer, any regulations and guidelines in financial conflicts and they must be abided by. Clinical Sponsor's with a conflict of interest should refrain from sponsoring a project for consideration.
Audit	

Health Surveillance	
Research	The attempt to derive generalisable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods. 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 part 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. If you are unsure whether your project is research or a service evaluation, you can use the Health Research Authority's tool which should assist you with the definition: http://www.hra-decisiontools.org.uk/research/
Service Evaluation	Unlike research, service evaluations do not have a hypothesis and are undertaken to benefit the people using a particular health/social care service. They seek to assess how well a service is achieving its intended aims by analysing, defining, judging, or evaluating that service. Often, a current service is measured without referencing a particular standard and they are almost exclusively relevant to the population or setting in which the evaluation takes place, and the results are not generalisable. The results of service evaluations are mostly used to generate information that can inform local decision making. If you are unsure whether your project is research or a service evaluation, you can use the Health Research Authority's tool which should assist you with the definition: http://www.hra-decisiontools.org.uk/research/

SECTION B: THIS SECTION IS ONLY REQUIRED ONCE YOUR APPLICATION HAS BEEN APPROVED

Appendix B: Data Access Contract

Scope

This Agreement is intended for use where data (excluding personally identifiable patient data) is accessed within a Secure Data Environment (**SDE**) for the public good.

Between:

(1) [FULL NAME AND ADDRESS OF HOST ORGANISATION] (the **Host Organisation**) and
(2) [FULL NAME OF USER ORGANISATION] [incorporated and registered in England and Wales with company number [INSERT]] [of [INSERT FULL ADDRESS]] *OR* [whose registered office is at [INSERT REGISTERED OFFICE ADDRESS] (the **User Organisation**)

(each '**Party**' and together '**Parties**')

Where data access will occur within the following SDE:

[INSERT NAME OF SDE] (THE SDE)

The Data made available to the User Organisation in the SDE does not include Personal Data when in the hands of the User Organisation, however this Agreement is part of the SDE's overall "Five Safes" implementation and the contractual controls contained herein help to render the Data as de-identified.

The Host Organisation authorises access to Data in the SDE for Approved User(s) from the User Organisation who have accepted the Terms of Use Annex **1**. Access is authorised for the purposes of the Approved Project(s) **Annex 2** or Approved Purposes defined in **Annex 3** only:

PROJECT DETAILS	
Approved Project(s)	The [describe] Project as further defined in **Annex 2** and Approved Purposes defined in **Annex 3**.
Main Applicant	[INSERT]
User Organisation	[INSERT]
Territory	Worldwide excluding Sanctioned Countries
Term	[INSERT] from the date of this Agreement
Data	Deidentified data as further defined in the Data and Platform Specification in **Annex 4**.

Responsibility:

The User Organisation shall comply, and shall ensure that all Approved Users comply, with the terms of this Agreement, including all obligations of the User Organisation and the Terms of Use (Annex 1) as further specified below.

Approved Users are not required to sign this Agreement but must accept the Terms of Use before accessing the SDE.

The terms below (including those set out in the Annexes) govern the access to the Data:

1. Safe People	1. **1.1.** The User Organisation shall: 1.1.1. ensure Approved User(s) are aware of, and ensure Approved User(s) comply with, the terms of this Agreement and the Terms of Use, and the User Organisation acknowledges and agrees that any breach by an Approved User of the Terms of Use or this Agreement shall be a breach of the User Organisation of this Agreement; 1.1.2. notify the Host Organisation within 2 Working Days of changes to Approved User(s), including where an Approved User has left the User Organisation or is no longer authorised to work on the Approved Project(s) and/or Approved Purpose(s); 1.1.3. ensure that Approved Users do not share login details or access credentials to the SDE with any other person and do not attempt to access the Data or the SDE after they have been notified that they are no longer authorised to do so; 1.1.4. ensure Approved Users have passed all mandatory assessments communicated to it by the Host Organisation in respect of the SDE, and further ensure that any such assessments are re-taken at intervals confirmed by the Host Organisation. **1.2.** The User Organisation warrants that the Approved User(s) are appropriately trained and skilled in respect of their use of the SDE and in relation to data protection, confidentiality, governance and security, and to the standard specified in Annex 5 or as issued by the Host Organisation in connection with the SDE (as updated from time to time). **1.3.** In the event of a breach or suspected breach of this Agreement, including the Terms of Use, the User Organisation acknowledges and agrees that the Host Organisation may immediately suspend access to the Data for one or more Approved User(s) (as notified by the Host Organisation) and fully investigate the breach or suspected breach and may also apply the remedies and/or require remediations as set out in Annex 6 and Annex 16: **1.4.** The User Organisation acknowledges and agrees that the Host Organisation shall: 1.4.1. terminate access to the SDE and the Data on termination or expiry of the Agreement; 1.4.2. following notification in accordance with clause 1.1.2 above, terminate access to the SDE and the Data for the relevant Approved Users. **1.5.** If there is any conflict between the Terms of Use and this Agreement, this Agreement shall prevail. **1.6.** The User Organisation shall appoint and retain the Main Applicant who shall be the primary point of contact for the Host Organisation in relation to matters arising from this Agreement. Should the Main Applicant be replaced, the User Organisation shall promptly inform the Host Organisation in writing of the name and contact details for the new

	Main Applicant. Any Main Applicant appointed shall be of sufficient seniority and experience, and shall be approved by the User Organisation, to make project level decisions with the Host Organisation, including [approving the Data and Platform Specification, requesting changes to the Approved Project(s) and instructing new Approved Users to be added].

2. Safe Projects	2. **2.1.** The User Organisation shall access and use the Data in the SDE: 2.1.1. in accordance with Applicable Laws; 2.1.2. for the Approved Project(s) only, in line with the approved project scope for the public good as defined in Annex 2, or where access is permitted under this Agreement for other Approved Purposes as set out in Annex 3, and not for any other purposes; and 2.1.3. in accordance with all applicable ethical standards and approvals. **2.2.** The User Organisation agrees that the Host Organisation shall be permitted to publish accurate and up to date details of the Approved Project(s) and associated Approved Purpose(s) in a publicly available data use register. **2.3.** The Approved Project(s) may only be varied by following the procedure set out in Annex 7.
3. Safe Settings	3. **3.1.** The Host Organisation shall ensure that the SDE and processing arrangements implement appropriate technical and organisational measures in compliance with Data Protection Laws. **3.2.** The Host Organisation shall ensure that the Data within the SDE is de-identified such that it does not contain personal data under Data Protection Laws. **3.3.** The User Organisation shall: 3.3.1. keep the Data and any access credentials to the Data confidential in accordance with Applicable Laws and with at least the same degree of care used to protect its own confidential information, and shall ensure that the Approved Users do the same; 3.3.2. not access, use, or disclose the Data other than as permitted by this Agreement or as required by Applicable Laws, and shall ensure that the Approved Users do not do the same; and 3.3.3. use up to date software on machines with access to the Data and SDE, receive regular training on security and data protection, and use maintained anti-malware and anti-virus software so as to avoid and prevent the introducing or permitting the introduction of any Virus into the SDE or the Host Organisation's network and information systems, and shall ensure that the Approved Users do not do the same; and 3.3.4. shall ensure that the confidentiality requirements set out in Annex 8 are followed by the Approved User(s). **3.4.** The User Organisation acknowledges and agrees that the Host Organisation may monitor and audit the access to or use of the SDE and the Data by the User Organisation and its Approved User(s) to ensure compliance with the terms of this Agreement in accordance with the protocol set out in Annex 9.
4. Safe Data	4. **4.1.** The User Organisation shall not, and shall not attempt to: 4.1.1. identify individuals from the Data: 4.1.2. contact any individual whose data forms part of the Data ; or

	4.1.3. link or combine the Data with other information or data (including any information relating to an identified or identifiable natural person) available to the User Organisation without permission from the Host Organisation. and shall ensure that the Approved Users do not, and do not attempt to, do the same. **4.2.** The User Organisation acknowledges and agrees that it has sole responsibility, and the Host Organisation takes no responsibility, for interpretation or further analysis of the Data. **4.3.** The User Organisation acknowledges and agrees that the Host Organisation can delete any Data at any time without terminating the Agreement including (without limitation) if: 4.3.1. the Data is no longer available to the Host Organisation for inclusion in the SDE; or 4.3.2. the Host Organisation has reasonable concerns that the use of the Data for the Approved Project and/or Approved Purposes may not comply with Applicable Laws or poses an organisational or reputational risk, or a risk to the public trust in the SDE or use of health data ((to be determined by the Host Organisation at its sole discretion); or 4.3.3. the Host Organisation considers that the Host Organisation no longer has sufficient funding to support the provision of the relevant Data. The Host Organisation will notify the User Organisation within seven (7) days of deletion of any Data and Annex 6 shall apply **4.4.** The User Organisation will inform the Host Organisation without delay, and in any event within 48 hours of becoming aware of: 4.4.1. any unauthorised access, disclosure, loss damage or alteration of the Data; 4.4.2. any element within the Data that might permit the identification of an individual whose data forms part of the Data; 4.4.3. any event which may impact the confidentiality, integrity or availability of the Data including cyber security incidents; 4.4.4. any complaints in relation to the Data including complaints from an individual or supervisory authority; and 4.4.5. any request from an individual to exercise their rights in respect of the Data. **4.5.** To the extent required by Data Protection Laws, the Host Organisation shall notify data protection supervisory authorities and – where applicable – notify affected data subjects in the event of a personal data breach (provided that the User Organisation shall not be restricted from making such notifications in cases where such notifications are required by Data Protection Legislation. The parties will collaborate in this regard as appropriate. **4.6.** The Host Organisation shall be responsible for responding to data subject rights requests submitted to either Party in an appropriate and lawful manner. The User Organisation shall provide reasonable assistance to the Host Organisation where this is necessary in order to respond. **4.7.** For the avoidance of doubt, the Data to which the User Organisation has access shall be deidentified by the Host Organisation prior to access. **4.8.** Where the Approved Project(s) and/or Approved Purposes involve access to:

	4.8.1. Data which has come from NHS sources and been linked within the SDE to other datasets contained within the SDE ;or 4.8.2. third party Data, the User Organisation acknowledges and agrees that further third party terms may apply in addition to this Agreement.
5. Safe Outputs	5. **5.1.** The User Organisation may only publish, distribute, or otherwise share Analysis Outputs in accordance with Annex 10 and both the Analysis Output acknowledgment policy set and the SDE Publication Policy out in Annex 11. **5.2.** The User Organisation shall ensure that Analysis Outputs do not include Personal Data from the SDE. **5.3.** The User Organisation shall not: 5.3.1. use any Analysis Output for any purpose contrary to Applicable Laws or outside of Approved Project(s) or Approved Purposes; or 5.3.2. download, extract, transmit, transfer, remove, share, copy, or publish any of the Data from the SDE (but this shall not prevent the publication of Analysis Outputs in accordance with **Annex 10**). **5.4.** The User Organisation shall ensure compliance with both the Host Organisation Analysis Output acknowledgment policy and the SDE Publication Policy as set out in Annex 11. **5.5.** The User Organisation shall promptly notify the Host Organisation in writing of any Clinically Relevant Findings which form part of the Analysis Outputs and hereby grants to the Host Organisation a non-exclusive perpetual, irrevocable, royalty-free, worldwide licence to use such Clinically Relevant Findings for the purposes of patient care.
6. Intellectual Property	6. **6.1.** This Agreement is not intended to constitute any transfer of Intellectual Property Rights in the Data or the SDE. **6.2.** Ownership of Intellectual Property Rights is set out in **Annex 12**. **6.3.** The Host Organisation hereby grants to the User Organisation a non-exclusive licence under the Host Organisation's Intellectual Property Rights in the Data to use the Data for the Approved Purposes on the Approved Projects for the Term in the Territory. **6.4.** Unless otherwise specified in **Annex 12**, Intellectual Property Rights in the Analysis Outputs including any New Product shall belong to the User Organisation.
7. Outcomes uncertainty / no warranty	7. **7.1.** It is generally not possible to know with certainty at the outset of a project whether access to and use of particular datasets will produce valuable outputs, therefore to the fullest extent permitted under Applicable Laws, the Host Organisation: 7.1.1. makes no warranty, express or implied as to the quality of the Data or its suitability for the Approved Project(s); and 7.1.2. excludes all liability for actions, claims, proceedings, demands, losses, costs, awards, damages, and payments suffered or made by the User Organisation that may arise from their use of the Data or unavailability of the Data for whatever reason. **7.2.** The User Organisation acknowledges and agrees that the liability provisions in Annex 16 apply.
8. Compliance with Laws etc	8. **8.1.** Each Party shall comply with their respective obligations under all Applicable Laws, including Data Protection Laws. **8.2.** If a Party who is obliged to respond to requests under the Freedom of

	Information Act 2000 ("**FOIA**"[1]), receives a request regarding the Data, it shall endeavour to inform the other Party within 5 Working Days and the other Party shall provide reasonable assistance to the Party in receipt of the request to comply with its obligations under FOIA. The Party subject to any request under FOIA retains sole discretion for responding to requests made under FOIA. **8.3.** The User Organisation shall: 8.3.1. comply with any policy, conditions or guidance issued by the Host Organisation in connection with the SDE (as updated from time to time); and 8.3.2. provide the Host Organisation in a timely manner with such information and materials as the Host Organisation may reasonably require in order to perform its obligations under this Agreement, and ensure that all such information and materials it provides to the Host Organisation are complete and accurate.

9. Payments and Service Levels	9. **9.1.** In consideration of the Host Organisation providing the User Organisation with access to the SDE, use of the Data and any Technical Support and/or Consultation Services, the User Organisation shall make the payments set out in **Annex 13**. **9.2.** Applicable service levels and helpdesk support facilities provided by the Host Organisation are set out in Annex 15. **9.3.** The User Organisation acknowledges and agrees that the Host Organisation may from time to time update and/or make changes to the SDE, Technical Support and/or Consultation Services to: 9.3.1. improve performance or security; 9.3.2. modify functionality, which may involve discontinuing or replacing aspects of the SDE; 9.3.3. reflect changes and improvements to its software or operating systems; 9.3.4. comply with Applicable Laws, policy, best practice or guidance which the Host Organisation is required to have regard to, or it is otherwise reasonable for it to have regard to. **9.4.** The Host Organisation will use its reasonable endeavours to confirm any material changes under clause 9.3 to the User Organisation before they take effect.
10. Anti-Corruption and Sanctions	10. 10.1 The User Organisation warrants that, to the best of its knowledge and belief, neither it nor any member of its group or any Approved User: 10.1.1. has, at any stage, violated the Anti-Corruption Laws; 1.1.3 is being, or will be, investigated, in respect of any breach of the Anti-Corruption Laws; and/or 1.2.3 is, or will be, subject to sanctions (an "**Infringement/Investigation**"). 2.4 Save where such disclosure would constitute a breach of any Applicable Law, the User Organisation further warrants that it shall immediately, and in any event within 24 hours of becoming aware, notify the Host Organisation upon becoming aware of any Infringement/Investigation. 3.4 The User Organisation will not allow sanctioned persons or entities to access, directly or indirectly, the SDE and/or the Data. For the

		avoidance of doubt, the User Organisation is solely responsible for ensuring that its Approved Users are not sanctioned. The User Organisation must notify the Host Organisation immediately, and in any event within 24 hours of becoming aware, upon becoming aware of any use of the SDE and/or the Data by a sanctioned person or entity. 4.4 Any breach of clauses 10.1 to 10.3 above by the User Organisation shall be considered a material breach of this Agreement which cannot be remedied.
11	Further provisions	1. 1.1. This Agreement is drafted in the English language. If this Agreement is translated into any other language, the English language version shall prevail. All other documents provided under or in connection with this Agreement shall be in English or accompanied by a certified English translation. 1.2. This Agreement constitutes the entire agreement between the Parties and supersedes all previous understandings and negotiations in respect of the Parties' obligations as provided in this Agreement. Each of the Parties acknowledges and agrees that, in entering into this Agreement, it has not relied on, and shall have no remedy in respect of, any statement, representation, warranty or understanding (whether negligently or innocently made) of any person (whether a party to this Agreement or not) other than as expressly set out in this Agreement. 1.3. The delay or failure by a Party to insist upon the strict performance of any provision, term or condition of this Agreement or to exercise any right or remedy consequent upon the breach thereof shall not constitute a waiver of any such breach or any subsequent breach of such provision, term or condition. 1.4. If any provision of this Agreement is agreed or held to be invalid or unenforceable, such provision shall not have the effect of invalidating or rendering unenforceable the remainder of this Agreement and the Parties agree that they shall immediately commence in good faith negotiations to vary the terms of this Agreement in order to remedy such invalidity or unenforceability. 1.5. No variation of this Agreement shall be effective unless it is agreed in writing and signed by the Parties or their authorised representatives. 1.6. Any notices under this Agreement shall be in writing, sent to the Parties at their address above or their registered address or sent by email: for Host Organisation: [insert email address]; and for the User Organisation [insert email address]. A notice shall be deemed to have been received: 1.6.1. if delivered by hand, at the time of delivery; 1.6.2. if posted, at the expiration of 48 hours after the envelope containing the same was delivered into the custody of the postal authorities; or 1.6.3. if sent by email, at the time of transmission, or if this time falls outside business hours in the place of receipt, when business hours resume. 1.7. No person other than a Party to this Agreement shall have any rights to enforce any term of this Agreement. 1.8. This Agreement shall not take effect until fulfilment by each of the Parties of the conditions precedent in Annex 14. 1.9. The Term of this Agreement may be extended by following the procedure set out in Annex 7. 1.10. The Host Organisation may: 1.10.1. subcontract its obligations under this Agreement; 1.10.2. assign, novate or transfer this Agreement, or any or all

	of its rights or obligations under this Agreement, to any public or private sector body which performs the functions of the Host Organisation. 1.11. The User Organisation shall not assign, novate or deal in any other manner with any or all of its rights and obligations under this Agreement without the prior written consent of the Host Organisation. 1.12. This Agreement, its subject matter, or its formation (including non-contractual disputes or claims) shall be governed and construed in accordance with the laws of England and Wales. Each Party irrevocably agrees that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with this Agreement or its subject matter or formation. 2. The Host Organisation may notify updates and changes to these Terms and Conditions at any time by giving notice to the User Organisation. The User Organisation's continued access to Data in the SDE constitutes acceptance of the updated/changed terms unless the User Organisation notifies the Host Organisation that it does not wish to accept such terms within 30 days of the notice of updates/changes being given, in which case, this Agreement shall terminate on the Host Organisation's receipt of such notice from the User Organisation. 3. This Agreement is effective for the duration of the Term. 4. This Agreement may be executed in counterparts and both of those counterparts taken together will be deemed to constitute one and the same instrument. 5. The Parties agree that this Agreement may be signed by electronic signature and that this method of signature is as conclusive of our intention to be bound by this Agreement as if signed by each Party's manuscript signature.

Signatories:

Signed by an authorised representative for and on behalf of the **User Organisation:**	NAME: DATE:
Signed by an authorised representative for and on behalf of the **Host Organisation**:	NAME: DATE:

The following definitions apply in the Agreement:

"Agreement" means this Secure Data Environment (SDE) Data Access Agreement including the Annexes hereto and the Terms of Use.

"Analysis Output" means any data (excluding, for the avoidance of doubt, the Data itself), learning, discovery, insight, paper, publication, or other results arising out of an Approved Project.

"Anti-Corruption Laws" means all Applicable Laws including official guidance issued pursuant to such legislation or regulations, related to financial crime, including without limitation the Bribery Act 2010, the Criminal Finances Act 2017, The Money

Laundering, Terrorist Financing and Transfer of Funds (Information on the Payer) Regulations 2017, the Proceeds of Crime Act 2002 and the Terrorist Asset Freezing etc. Act 2010 or other applicable money laundering, terrorist financing legislation or sanctions legislation.

"Applicable Laws" means all applicable laws, statutes, regulations, and codes from time to time in force including Data Protection Laws and Anti-Corruption Laws.

"Approved Project(s)" means the project(s) identified in Annex 2 below.

"**Approved Purposes**" means the purposes identified in Annex 3 below.

"Approved User(s)" means those employees, agents and independent contractors of the User Organisation whose access to and use of the Data in the SDE for the Approved Project(s) or Approved Purposes has been authorised by the User Organisation subject to the terms of this Agreement, and who have entered into the Terms of Use, prior to such access or use.

"Clinically Relevant Findings" means results or observations identified during analysis of the Data that are significant enough to inform individual patient care decisions, or that might have a significant impact on patient care of individuals whose data is included in the Data.

"Commercial Exploitation" means any distribution or licensing of a New Product in exchange for remuneration for the purpose of making a profit.

"Consultation Services" means the consultation services described in Part C of Annex 15.

"Control" means the ability of a person to direct the affairs of another whether through ownership of share or equity interests, the exercise of management control, powers of appointment of directors or officers, contract or any other means.

"Data" means the data fields and datasets to which the User Organisation has been approved access as described in the Project Details above.

"Data Protection Laws" means any Applicable Laws with respect to data protection and privacy, including the General Data Protection Regulation ((EU) 2016/679) ("GDPR"), the UK GDPR (as defined in the UK Data Protection Act 2018) and/or Data Protection Act 2018, as applicable to either Party and or the activities under this Agreement.

"Fees" means the fees payable by the User Organisation pursuant to Part A of Annex 13.

"Group" means a person and any other person Controlling, Controlled by or under common Control with them.

"Host Organisation" means the organisation which is accredited to host and control the SDE.

"Insolvency Event" means the occurrence of any of the following events in respect of a Party:

i) that Party suspending, or threatening to suspend payment of its debts, being unable to pay its debts as they fall due, admitting inability to pay its debts or being deemed unable to pay its debts within the meaning of section 123 of the Insolvency Act 1986 as if the words "it is proved to the satisfaction of the court" did not appear in sections 123(1)(e) or 123(2) of the Insolvency Act 1986;

i) that Party commencing negotiations with all, or any class of, its creditors with a view to rescheduling any of its debts, or making a proposal for, or entering into any compromise or arrangement with its creditors other than for the sole purpose of a scheme for a solvent amalgamation of that Party with one or more other companies, or the solvent reconstruction of that Party;

i) that Party applying to court for, or obtaining, a moratorium under Part A1 of the Insolvency Act 1986

i) a petition is filed, a notice is given or a resolution is passed or an order is made, for or in connection with the winding up of that Party other than for the sole purpose of a scheme for a solvent amalgamation of that Party with one or more other companies, or the solvent reconstruction of that Party;

i) an application is made to court, or an order is made, for the appointment of an administrator, or a notice of intention to appoint an administrator is given or if an administrator is appointed, over that Party (being a company, partnership or limited liability partnership);

i) the holder of a qualifying floating charge over the assets of that Party (being a company or limited liability partnership) has become entitled to appoint or has appointed an administrative receiver;

i) a person becomes entitled to appoint a receiver over all or any of the assets of that Party or a receiver is appointed over all or any of the assets of that Party;

i) a creditor or encumbrancer of that Party attaches or takes possession of, or a distress, execution, sequestration or other such process is levied or enforced on or sued against, the whole or any part of that Party's assets and such

attachment or process is not discharged within 14 days;

i) any event occurs, or proceeding is taken, with respect to that Party in any jurisdiction to which it is subject that has an effect equivalent or similar to any of the events mentioned in paragraphs a) to h) above (inclusive).

"Intellectual Property Rights" means the patents, rights to inventions, copyright and related rights, moral rights, trademarks and service marks, business names and domain names, rights in get-up, goodwill and the right to sue for passing off, rights in designs, rights in computer software, database rights, rights to use, and protect the confidentiality of, confidential information (including know-how and trade secrets) and all other intellectual property rights including the right to sublicense such rights owned by third parties, in each case whether registered or unregistered and including all applications and rights to apply for and be granted, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world.

"Main Applicant" means for the User Organisation the individual specified in the Project Details above; or such other person notified by the User Organisation to the Host Organisation from time to time.

"New Product" means any improved, enhanced, validated or newly developed product or service by the User Organisation using and/or derived from the Data.

"Personal Data" has the meaning given to it in Data Protection Laws.

"Revenue Share" means the revenue share payable by the User Organisation pursuant to Part B of Annex 13 (where applicable).

"Sanctioned Countries" means any country, administration, or terrorist group against which sanctions are imposed by the UK Government (including those sanctions imposed by the United Nations), a list of which can be found here as at the date of this Agreement:

(https://www.gov.uk/government/collections/financial-sanctions-regime-specific-consolidated-lists-and-releases); and here:

(https://www.un.org/securitycouncil/sanctions/information).

"SDE" means the [insert SDE name here] Secure Data Environment, a regional NHS SDE hosted by the Host Organisation.

"Technical Support" means the technical support described in Part B of Annex 15.

"Term" means the duration of the Agreement as provided in the Project Details above.

"**Terms of Use**" means the Terms of Use of the SDE which will be accepted individually by Approved Users as users of the SDE, as set out in Annex 1.

"User Organisation" means the organisation which is responsible for individuals using a SDE service.

"Virus" means any thing or device (including any software, code, file or programme) which may:

d) prevent, impair or otherwise adversely affect the operation of any computer software, hardware or network, any telecommunications service, equipment or network or any other service or device;

d) prevent, impair or otherwise adversely affect access to or the operation of any programme or data, including the reliability of any programme or data (whether by re-arranging, altering or erasing the programme or data in whole or part or otherwise);

d) adversely affect the user experience; or

d) compromise the security of the SDE or the Data,

including worms, trojan horses, viruses and other similar things or devices.

"Working Day" means any day other than a Saturday, Sunday, or public holiday in the UK country in which the Host Organisation is based.

1. In this Agreement, unless the context otherwise requires:
   - 1.3 capitalised words and expressions shall have the meanings set out in the above definitions;
   - 2.3 words in the singular shall include the plural and in the plural shall include the singular; and
   - 3.3 references to clauses and annexes are to the clauses and annexes of this Agreement.
2. Clause and annex headings shall not affect the interpretation of this Agreement.
3. A reference to a statute or statutory provision is a reference to it as amended, extended or re-enacted from time to time.
4. A reference to a person includes any legal or natural person whether incorporated or not.

5. Any references following words: including, include, in particular, for example or any similar expression shall be interpreted as illustrative and shall not limit the sense of those words or references.

ANNEX 1 – TERMS OF USE

Scope

These Terms of Use ("Terms") constitute an agreement made between approved users and [insert Host Organisation name] ("Host Organisation"), concerning access to and use of data held within the [insert SDE name here] Secure Data Environment ("SDE"). Please read these Terms carefully before accessing data held within the SDE.

The Approved User agrees that they:

1. Have taken appropriate training in data protection and data security to the standards of the SDE Data Access Agreement and have completed such training prior to accessing the Data.
2. Have read and agree to comply with the terms of the Approved Purposes and Approved Project(s) (together "**SDE Documentation**"), as signed by the User Organisation.
3. Shall adhere to all relevant data protection legislation, including the UK General Data Protection Regulation (GDPR) and the UK Data Protection Act (2018).
4. Shall always preserve the confidentiality of the Data.
5. Shall use the data for the benefit of the public, patients, and the NHS and only within the Approved Project scope and purposes (as defined in Annex 2 of the SDE Data Access Agreement).
6. Shall access the SDE in a secure physical location where inadvertent disclosure can be prevented (for example not in a public place where they can be overlooked).
7. Shall use only IT equipment provided by the User Organisation which has up to date antivirus and firewall software and complies with any security requirements notified by the Host Organisation from time to time including the National Cyber Security Centre 10 Steps to Cyber Security.
8. Keep login details confidential and adhere to secure password guidelines.
9. Shall view and analyse data only as permitted for the Approved Purpose.
10. Understand that data is provided with no guarantee of data quality.
11. Understand that activity in the environment may be logged and recorded; this includes but is not limited to access to data and any code submitted.
12. Shall notify the Host Organisation immediately of any breach of Data (being the accidental or unauthorised destruction, loss, alteration, disclosure of or access to Data by an unauthorised person), or potential breach of Data in the SDE or incident that may have compromised the security of the Data.
13. Agree to follow all SDE Documentation.
14. Shall comply with the requirements of the User Organisation's Cyber Essentials certification (or any equivalent which is reasonably satisfactory to the Host Organisation) and can provide evidence of the same if requested.

The Approved User agrees that they shall not:

1. Share access credentials or give access to Data in the SDE to any other person.
2. Leave their device unattended while accessing the SDE.
3. Link data to any other dataset other than those defined in the Approved Project.
4. Download, extract, replicate, alter or otherwise interfere with the Data or the proper operation of the SDE.
5. Attempt to copy or remove analyses of the Data or other Analysis Output from the SDE without following the SDE Analysis Output Checking Policy below.

6. Use the database for any purpose other than that agreed in the Approved Project scope.
7. Show/share contents of the SDE with any unauthorised users.
8. Take and share screenshots of content within the SDE.
9. Save or duplicate datasets within the SDE, other than as permitted for the Approved Purpose.
10. Attempt to identify or contact any individual using Data in the SDE.

SDE Analysis Output Checking policy

The Approved User shall ensure that any Analysis Output complies with the terms of the SDE Analysis Output Checking Policy (as detailed in Annex 10 of the SDE Data Access Agreement) and does not contain any unauthorised Data or any Confidential Information of the Host Organisation.

Contact

If users have any queries regarding the SDE or these Terms please contact [insert Host Organisation contact details]

THE USER UNDERSTANDS THAT ANY BREACH OF THESE TERMS OF USE WILL RESULT IN ACCESS TO DATA BEING REVOKED AND POSSIBLE DISCIPLINARY ACTION. THE USER RECOGNISES THEIR RESPONSIBILITY TO ENSURE COMPLIANCE WITH ALL REQUIREMENTS UNDER THE DATA PROTECTION LEGISLATION.

I agree that I have fully read and understood the Data Access Agreement and the Terms of Use above:

Approved User Name:	
Email:	
Contact Phone Number:	
User Organisation:	
Signature	
Date:	

ANNEX 2 – PROJECT DESCRIPTION

[To be inserted]

ANNEX 3 - APPROVED PURPOSES FOR SDE ACCESS

Accessing the SDE by Approved Users to use the Data for the Approved Project(s) to create Analysis Outputs including New

Products.

ANNEX 4 - DATA AND PLATFORM SPECIFICATION

The Data will consist of [ ]:

(iii) •,

(iii) •, and

(iii) [data fields normally contained within the Electronic Patient Record (EPR) excluding personal data as identified below.]

Section	Details
Project	The [describe] Project
Objective	
Data Requirements	
Report language	[Full-text English report - Free-form text is acceptable for various purposes]
Exclusion criteria	

[Platform specification to be added]

ANNEX 5 - APPROVED USER TRAINING REQUIREMENTS

Sufficient training or accreditation for accessing and processing data as would be expected from a leading company within the field including in respect of:

- Data Protection Laws
- information security and the safeguarding of Personal Data
- The concepts of Legal basis of processing, confidentiality, consent, anonymisation and de-identification as applied to data in the UK
- The Host Organisation's policies regarding the SDE and relevant NHS policies, including the Five Safes
- the terms of this Agreement.

The User Organisation will provide details of such training and accreditation to the Host Organisation:

(iii) within 10 Working Days of the date of this Agreement, in respect of each Approved User as at the date of this Agreement;

(iii) within 2 Working Days of any further Approved User being added, in respect of that Approved User; and/or

(iii) on request from the Host Organisation at any time.

ANNEX 6 – TERM, TERMINATION AND SUSPENSION

1. This Agreement shall come into force on the date it is signed by both Parties and expire at the end of the Term unless (i) terminated earlier or (ii) the Parties agree terms to extend this Agreement in writing. The Parties shall meet (in person or virtually) and discuss the terms of any extension at least six months before the end of the Term. Any extension shall be documented by following the procedure set out in Annex 7.
2. The Host Organisation may terminate this Agreement by giving the User Organisation thirty (30) Working Days' written notice:
    1. in the event that it is directed to do so by the UK Department of Health and Social Care or NHS England.
    2. the Data is no longer available to the Host Organisation for inclusion in the SDE; or
    3. the Host Organisation considers that the Host Organisation no longer has sufficient funding to support the SDE; or
    4. the Host Organisation has reasonable concerns that the use of the Data for the Approved Project and/or Approved Purposes may not comply with Applicable Laws or poses an organisational or reputational risk, or a risk to the public trust in the SDE (to be determined by the Host Organisation at its sole discretion); or
    5. the Host Organisation reasonably considers that the User Organisation is in breach of this Agreement or Applicable Laws relating to use of the Data and where either this is a breach which is not capable or remedy by the User Organisation or, if the breach is capable of remedy, where the User Organisation has not demonstrated that it has cured this breach within 7 days of notice from the Host Organisation.
3. Either party may terminate this Agreement for any reason by giving the other party at least three (3) months' written notice.
4. The Host Organisation may terminate this Agreement with immediate effect by giving written notice if the User Organisation fails to pay any amount due under this Agreement on the due date for payment and remains in default not less than [seven] days after being notified to make such payment.
5. Neither Party shall be in breach of this Agreement nor liable for delay in performing, or failure to perform, any of its obligations under this Agreement if such delay or failure result from events, circumstances or causes beyond its reasonable control including, without limitation, acts of God, flood, drought, earthquake or other natural disaster; epidemic or pandemic; terrorist attack, cyber attack, civil war, civil commotion or riots, war, threat of or preparation for war, armed conflict, imposition of sanctions, embargo, or breaking off of diplomatic relations; nuclear, chemical or biological contamination or sonic boom; any law or action taken by a government or public authority, including imposing an export or import restriction, quota or prohibition, or failing to grant a necessary licence or consent; collapse of buildings, fire, explosion or accident; and any labour or trade dispute, strikes, industrial action or lockouts; non-performance by suppliers or subcontractors; and interruption or failure of utility service ("**Force Majeure**"). In such circumstances the affected Party shall be entitled to a reasonable extension of the time for performing such obligations. If the period of delay or non-performance continues for 3 months, the Party not affected may terminate this Agreement by giving 30 days' written notice to the affected Party.
6. Without affecting any other right or remedy available to it, either Party may terminate this Agreement with immediate effect by giving written notice to the other Party if:
    1. the other Party commits a material breach of any term of this Agreement which cannot be remedied or which the other Party fails to remedy within 30 days' notice in writing to do so;
    2. an Insolvency Event occurs in respect of the other Party; or
    3. the other Party suspends or ceases, or threatens to suspend or cease, carrying on all or a substantial part of its business.
7. Termination or expiry of this Agreement shall not affect any rights, remedies, obligations, or liabilities of the Parties that have accrued up to the date of termination or expiry, including the right to claim damages in respect of any breach of the Agreement which existed at or before the date of termination or expiry. Any provision of this Agreement that expressly or by implication is intended to come into or continue in force on or after termination or expiry of this Agreement shall come into or continue in full force and effect.
8. On termination for any reason or expiry of this Agreement:
    1. The User Organisation's access to the SDE shall cease;
    2. The User Organisation shall immediately pay the Host Organisation all sums due under this Agreement; and
    3. The provisions of Annex 8 shall continue to apply indefinitely and, where specified in Annex 13, the provisions of Annex 13 shall survive termination for the additional period described in Annex 13.
9. The Host Organisation may, at its sole discretion, suspend access to the SDE and the Data for the User Organisation,

either in whole or in part, in the event that:

1. the SDE is undergoing maintenance;
2. there are system outages which are outside of the Host Organisation's control;
3. the Host Organisation is investigating a breach or suspected breach of Applicable Law or this Agreement;
4. in any circumstances where the Host Organisation is permitted to terminate this Agreement pursuant to paragraphs 4 or 6 of this Annex 6; or
5. the Host Organisation has otherwise deemed it reasonably necessary to suspend access to the SDE and the Data including, while a potential data security risk is being investigated.

10. The Host Organisation's right to suspend access to the SDE and the Data under paragraph 9 of this Annex 6 does not affect or in any way limit any other right or remedy available to it.

ANNEX 7 - TERM AND CONDITIONS OF EXTENSION/AMENDMENT SUBMISSION

Any variations to this Agreement must be in writing and signed by both Parties.

ANNEX 8 - CONFIDENTIALITY

1. **Confidential Information** means all confidential information (however recorded or preserved) disclosed by one Party (the "**Disclosing Party**") or its Representatives (as defined below) to the other Party (the "**Recipient**") and its Representatives whether before or after the date of this Agreement in connection with this Agreement, including:
   a. the terms of this Agreement;
   b. the Data;
   c. login and access details for the SDE;
   d. any information (whether or not technical) that would be regarded as confidential by a reasonable business person.
2. **Representatives** means, in relation to a Party, its employees, officers and professional advisers.
3. The provisions of this Annex 8 shall not apply to any Confidential Information that:
   a. is or becomes generally available to the public (other than as a result of its disclosure by the Recipient in breach of this clause);
   b. was available to the Recipient on a non-confidential basis before disclosure by the Disclosing Party;
   c. was, is or becomes available to the Recipient on a non-confidential basis from a person who, to the Recipient's knowledge, is not bound by a confidentiality agreement with the Disclosing Party or otherwise prohibited from disclosing the information to the Recipient;
   d. the parties agree in writing is not confidential or may be disclosed; or
   e. is developed by or for the Recipient independently of the information disclosed by the Disclosing Party.
4. The Recipient shall use best endeavours to keep the Disclosing Party's Confidential Information confidential and shall not:
   a. use such Confidential Information except for the purpose of exercising or performing its rights and obligations under or in connection with this Agreement (**Permitted Purpose**); or
   b. disclose such Confidential Information in whole or in part to any third party, except as expressly permitted by this Annex 8.
5. The Recipient may disclose such parts of the Confidential Information to those of its Representatives who need to know such Confidential Information for the Permitted Purpose, provided that:
   a. it informs such Representatives of the confidential nature of the Confidential Information before disclosure; and
   b. it procures that its Representatives shall, in relation to any Confidential Information disclosed to them, comply

with the obligations set out in this clause as if they were a party to this Agreement,

and at all times, it is liable for the failure of any Representatives to comply with the obligations set out in this Annex 8.

6. The Recipient may disclose Confidential Information to the extent such Confidential Information is required to be disclosed by law, by any governmental or other regulatory authority (including any necessary reporting to a supervisory or commissioning body or regulator) or by a court or other authority of competent jurisdiction provided that, to the extent it is legally permitted to do so, it gives the Disclosing Party as much notice of such disclosure as possible and, where notice of disclosure is not prohibited and is given in accordance with this Annex 8, it takes into account the reasonable requests of the Disclosing Party in relation to the content of such disclosure.
7. The Disclosing Party reserves all rights in its Confidential Information. No rights or obligations in respect of the Confidential Information other than those expressly stated in this Agreement are granted to the other Party, or to be implied from this Agreement.
8. On termination or expiry of this Agreement, the Recipient shall:
    a. destroy or return to the Disclosing Party all documents and materials (and any copies) containing, reflecting, incorporating, or based on the Confidential Information;
    b. erase all the Confidential Information from its computer and communications systems and devices used by it, including such systems and data storage services provided by third parties (to the extent technically and legally practicable); and
    c. certify in writing to the Disclosing Party that it has complied with the requirements of this clause,

    provided that the Recipient may retain documents and materials containing, reflecting, incorporating, or based on the Confidential Information to the extent required by law or any applicable governmental or regulatory authority.
9. The provisions of this Annex 8 shall continue to apply after the expiry or earlier termination of this Agreement.

ANNEX 9 - SDE PROTOCOL ON MONITORING USE/AUDIT/COMPLIANCE

The Host Organisation shall be entitled at any time during the Term to audit User Organisation's access to or use of the SDE and/or the Data under this Agreement (including carrying out spot checks of the User Organisation's systems and facilities in business hours and on reasonable notice) should the Host Organisation have any concerns that the User Organisation and/or Approved Users are in breach of the terms of this Agreement. The User Organisation will provide the Host Organisation with all reasonable assistance in order to enable it to undertake an audit pursuant to this Annex 9.

Without prejudice to the Host Organisation's rights under Annex 6, the User Organisation shall comply with any corrective actions required by the Host Organisation in order to ensure User Organisation's compliance with the terms of this Agreement.

ANNEX 10 - SDE ANALYSIS OUTPUT CHECKING POLICY

User Organisation shall ensure that any Analysis Output (including New Products) complies with the terms of this Agreement and does not contain any Data or Confidential Information of the Host Organisation.

ANNEX 11 - ANALYSIS OUTPUT ACKNOWLEDGEMENT/PUBLICATIONS POLICY

The User Organisation shall ensure that any published Analysis Output that has made use of Data includes the following acknowledgement:

"This [project] has been conducted using resources of the [insert SDE name here]Secure Data Environment"

The User Organisation shall comply with the SDE Publication Policy set out below:

[insert SDE Publication Policy]

ANNEX 12 - INTELLECTUAL PROPERTY RIGHTS

The Host Organisation or its licensees is the maker or owner of the SDE and the Intellectual property Rights in the Data within it. Intellectual Property Rights in the SDE and the Data shall remain the property of the Host Organisation or its licensors and the User Organisation shall not acquire any title or any other Intellectual Property Rights in them under this Agreement.

Where agreed in Annex 13, Intellectual Property Rights in the Analysis Output shall belong to the User Organisation to the extent that any Intellectual Property Rights in them do not constitute or infringe Intellectual Property Rights in the Data.

The User Organisation may not create a database, including synthetic datasets, based on Data (except that for the avoidance of doubt the User Organisation may create a database from the Analysis Output) and may not remove, suppress or modify in any way any proprietary marking, including any trade mark or copyright or database right notice on or in the Data or other means by which the Data is made available to the User Organisation or which is visible during the access or use of the Data.

The User Organisation shall notify the Host Organisation immediately if the User Organisation becomes aware of any infringement of or unauthorised access to, use or copying of any part of the SDE or the Data.

ANNEX 13 - PAYMENTS

Part A – Fees

1. The User Organisation shall pay the following Fees to the Host Organisation at the following times:

(c) Data Provision and Set Up Fees

Phase	Fee
Completion of Phase 1	£•

[The above fees shall be paid within thirty days of the User Organisation's receipt of an invoice from the Host Organisation, which may be presented on completion of a Phase.]

(c) Annual Technical Support and Platform Service Fees

[INSERT FEES]

[The above fees shall be paid within thirty days of the User Organisation's receipt of an invoice from the Host Organisation, which may be presented on commencement of and on each anniversary of this Agreement.]

[On each anniversary of this Agreement, the above fees shall be increased by [any percentage increase in the Index during the previous 12 (twelve) months, where the Index is the [Retail Prices Index (All Items) as published by the Office for National Statistics] (or, if the [Retail Prices Index (All Items)], ceases to be published or is not published in any month, such alternative index which produces, as closely as possible, the same result).][**NOTE: RPI (All Items) has been included simply as a placeholder. The Host Organisation is to confirm which index or other uplift is to be used for annual reviews].**

Fees to be agreed between the Parties prior to commencement of service and support and inserted above, then reviewed annually.

(c) Fees for Consultation Services

[INSERT FEES]

[The above fees shall be paid within thirty days of the User Organisation's receipt of an invoice from the Host Organisation, which may be presented on commencement of the services and monthly in advance during the provision of the services.]

Fees to be agreed between the Parties prior to provision of services and inserted above.

Part B - Revenue Share

1. The User Organisation shall pay the following Revenue Share to the Host Organisation at the following times:

(e) Revenue Share will be payable annually by the User Organisation on Commercial Exploitation on a sliding scale as follows:

(iii) From the date of this Agreement, at least the Annual Minimum Revenue Share (defined below).

(iii) From first Commercial Exploitation anywhere in the world for a period of [•] years (**First Revenue Share Period**)

Phase	**Revenue Share Rate payable on [Price of New Product]**
Phase	%
Phase	%
Phase	%
Phase	%

(iii) From the end of the First Revenue Share Period for a further [ ] years: *[to be agreed]*

(e) Annual Minimum Revenue Share

During each year of the Term, the total Revenue Share payable by the User Organisation shall be at least £•(**Annual Minimum Revenue Share**). Where in any year of the Term the Revenue Share payable in accordance with paragraph 1(a) (ii) or 1(a)(iii) of this Part B is less than the Annual Minimum Revenue Share (for the avoidance of doubt, including any years before first Commercial Exploitation), the User Organisation shall in addition to any Revenue Share payments due pay the difference such that the total Revenue Share

payment in that year equals the Annual Minimum Revenue Share.

(e) Within 30 days of each anniversary of this Agreement, the User Organisation shall submit or cause to be submitted to the Host Organisation a statement in writing certified by a Director (or Company Secretary if a Director is unavailable) recording the calculation of such Revenue Share payable and in particular:

i. the Year for which the Revenue Share was calculated;

ii. the number of New Products licensed, supplied, or used during that year (including nil returns);

iii. the Price of each New Product supplied or used during the year;

iv. the amount of Revenue Share due and payable (including the Annual Minimum Revenue Share);

v. the amount of any withholding or other income taxes deductible or due to be deducted from the amount of Revenue Share due and payable; and

vi. any other particulars the Host Organisation may reasonably require.

(e) The User Organisation shall keep proper records and books of account showing the description and price of New Products licensed, supplied, or put into use. Such records and books shall be kept separate from any records and books not relating solely to the New Products and be open during normal business hours to inspection and audit by the Host Organisation (or its authorised representative), who shall be entitled to take copies of or extracts from them. If such inspection or audit should reveal a discrepancy in the Revenue Share paid from those payable under this Agreement, the User Organisation shall immediately make up the shortfall and, if on any such audit a shortfall in payments of greater than five per cent (5%) is discovered by the auditor in respect of the audit period, the User Organisation shall pay the Host Organisation's audit costs. Such right of inspection of the Host Organisation shall remain in effect for a period of one year after the later of the termination of this Agreement or seventeenth anniversary of the first Commercial Exploitation.

(e) All sums payable under paragraphs 1(a) and 1(b) of this Part B shall be paid within thirty days of the User Organisation's receipt of an invoice from the Host Organisation, which may be presented immediately following delivery of the report described in paragraph1(c) of this Part B.

Part C – Additional [Consideration/Payments]

[The Parties agree that the User Organisation shall own the Intellectual Property Rights in the Analysis Output and to the extent the Host Organisation obtains ownership of any Intellectual Property Rights in the Analysis Output it hereby assigns to the User Organisation all its right title and interest in the Intellectual Property Rights in the Analysis Output.

OR

[The Parties agree that the Host Organisation shall own the Intellectual Property Rights in the Analysis Output and to the extent the User Organisation obtains ownership of any Intellectual Property Rights in the Analysis Output it hereby assigns to the Host Organisation all its right title and interest in the Intellectual Property Rights in the Analysis Output. The Host Organisation hereby grants to the User Organisation a [non-]exclusive licence under the Host Organisation's Intellectual Property Rights in the Analysis Output to use the Analysis Output for the [**INSERT purpose]** on the for **[Years]** in the Territory.

a. [INSERT]

Part D – Payment arrangements

(f) Invoices shall be addressed to: [INSERT postal and email address etc]

i. The User Organisation will make all payments in pounds sterling or any currency replacing pounds sterling in its entirety unless the parties agree otherwise. For the purposes of calculating any amount payable by the User Organisation to the Host Organisation in a currency other than pounds sterling (or replacement

currency), the User Organisation shall apply an exchange rate equivalent to the applicable closing mid-rate quoted by the Financial Times as published in London on the Working Day on which the relevant Phase was completed or the last Working Day of the period to which the Revenue Share relates.

ii. Where the User Organisation has to withhold tax by law, the User Organisation will deduct the tax, pay it to the relevant taxing authority, and supply Host Organisation with a Certificate of Tax Deduction at the time of payment to the Host Organisation.

iii. In the event that full payment of any amount due from the User Organisation to the Host Organisation under this Agreement is not made by any of the dates stipulated, the User Organisation shall be liable to pay interest on the amount unpaid at the rate of five per cent (5%) per annum over the base rate for the time being of Barclays Bank plc. Such interest shall accrue on a daily basis from the date when payment was due until the date of actual payment of the overdue amount, whether before or after judgment, and shall be compounded quarterly.

iv. All sums payable under this Agreement exclude amounts in respect of value added tax ("VAT") which the User Organisation shall additionally be liable to pay to the Host Organisation at the prevailing rate (if appliable).

v. The Host Organisation may set off any liability of the User Organisation to the Host Organisation against any liability of Host Organisation to the User Organisation. Any exercise by the Host Organisation of its rights under this paragraph 9 of Annex 13 shall not limit or affect any other rights or remedies available to it under this Agreement or otherwise.

ANNEX 14 – CONDITIONS PRECEDENT

[to be inserted if relevant]

ANNEX 15- SERVICE LEVELS

Part A: Availability

The Host Organisation shall use reasonable endeavours to provide access to the Data within the SDE to the Approved Users through the Analysis Environment throughout the Term. Any dates for delivery of Data are estimates only and shall not be binding on the Host Organisation.

Any unavailability of the Analysis Environment is outside the control of the Host Organisation.

The Host Organisation may effect maintenance, repairs or updates to the SDE and the Data and wherever reasonably practicable shall give the Approved Users twenty-four (24) hours' notice of any interruption of access to the Data by email. In case of urgent maintenance or repairs, the SDE may be unavailable without notice.

Part B: Technical Support

The Host Organisation will provide reasonable technical support to the Approved Users on Working Days throughout the Term.

The Approved User will use reasonable endeavours to provide the Host Organisation with sufficient information required to answer any query submitted. The Host Organisation will use reasonable endeavours to respond to the Approved User's queries within a reasonable and if the Host Organisation reasonably considers that the Approved User is making excessive use of technical support, the Host Organisation at its sole discretion may charge the User Organisation a service fee for any further queries submitted.

Part C: Consultation Services

Upon User Organisation's request, Host Organisation may provide User Organisation with certain consultation services to assist User Organisation in understanding the content, physical structure, and relationships of the Data, as more particularly detailed in Annex 2 (Project Description) of this Agreement.. Such services shall be as agreed in writing with the Host Organisation and may include without limitation a demonstration of the content and format of the Data and answering various queries relating to the Data. Where the Host Organisation agrees in writing to provide consultation services, it will reasonably cooperate with User Organisation in its determination as to whether the Data:

(a) will meet User Organisation's requirements in connection with its intended use;

(b) will operate in combination with User Organisation's systems or equipment and is compatible with User Organisation's software, hardware, system or network; and/or,

(c) is capable of being validated as accurate and complete.

Host Organisation agrees to respond to any such requests or queries within a reasonable time. Fees shall be payable for consultation services, as agreed in writing with the Host Organisation prior to the provision of such services.

ANNEX 16 - LIABILITY

1. Liability
    a. The Host Organisation shall not in any circumstances have any liability for any losses or damages which may be suffered by the User Organisation (or any person claiming under or through the User Organisation), whether the same are suffered directly or indirectly or are immediate or consequential, and whether the same arise in contract, tort (including negligence) or otherwise howsoever, which fall within any of the following categories: (i) special damage, (ii) loss of profits; (iii) loss of anticipated savings; (iv) loss of business opportunity; (v) loss of or damage to goodwill; (vi) loss of use or corruption of software, information or data; (vii) indirect or consequential loss.
    b. The Host Organisation excludes all warranties in relation to the Data to the fullest extent permitted by law.
    c. The total aggregate liability of the Host Organisation, for any and all claims relating to the User Organisation's access to Data under this Agreement whether in contract, tort (including negligence) or otherwise and whether in connection with this Agreement or any collateral contract, shall in no circumstances exceed the lesser amount of (i) the total aggregate Fees paid under this Agreement or (ii) £50,000 (fifty thousand pounds).
    d. The exclusions in this Agreement shall apply to the fullest extent permissible at law, but the Host Organisation does not exclude or restrict liability for:

        i. death or personal injury caused by the negligence of the Host Organisation, its officers, employees, contractors, or agents;

        ii. fraud or fraudulent misrepresentation;

        iii. breach of the obligations implied by section 12 of the Sale of Goods Act 1979 or section 2 of the Supply of Goods and Services Act 1982; or

        iv. any other liability which may not be excluded by law.
2. The Host Organisation shall not be in breach of this Agreement to the extent that any neglect, default, act or omission of the User Organisation, its Approved Users, staff, agents, sub-licensees or subcontractors results in a breach of the Host Organisation's obligations under this Agreement.
3. The User Organisation shall indemnify the Host Organisation against all liabilities, costs, expenses, damages, and losses (including any direct, indirect, or consequential losses, loss of profit, loss of reputation and all interest, penalties and legal costs (calculated on a full indemnity basis) and all other reasonable professional costs and expenses) suffered or incurred by the Host Organisation arising out of or in connection with:
    a. the User Organisation's exercise of the rights granted to it under this Agreement;
    b. the User Organisation's breach or negligent performance or non-performance of this Agreement, including any product liability claim relating to New Products manufactured, supplied, or put into use by the Licensee;
    c. the User Organisation introducing or permitting the introduction of any Virus into the SDE or the Host

Organisation's network and information systems, or failing to ensure that shall ensure that the Approved Users do not do the same;

d. the enforcement of this Agreement; or
e. any claim made against the Host Organisation by a third party for death, personal injury or damage to property arising out of or in connection with defective New Products, to the extent that the defect in the New Products is attributable to the acts or omissions of the User Organisation, its Approved Users, staff, agents, sub-licensees or subcontractors or claims for infringement of third-party Intellectual Property Rights.