Data Access Request Form (DARF)

Applicants should ensure that they have reviewed the accompanying HQIP guidance and have discussed this request with the organisation(s) commissioned by HQIP to deliver the relevant clinical audit or clinical outcome review programme. The audit or clinical outcome review programme acts as data processor to HQIP and is referred to as the 'data provider' for the purpose of this data access request.

Once completed please return this signed form to datasharing@hqip.org.uk

All sections within this form are mandatory unless specifically stated otherwise. Unless this form is completed in full, it will be returned to the applicant which will extend the time to data receipt.

For HQIP office use only			
HQIP application number	HQIP425	**Date of submission to HQIP**	05/10/2022
If applicable, any linked application number(s)	Click or tap here to enter text.	**Charging category**	1. Basic
Tracking history	05/10/2022: Application received. 18/10/2022 (Pre-screening): **Section 4** Please enter the project's objective / rationale. MJA: This has been added. **Section 11** Why are there two data flow diagrams (the one in this DARF, and the more detailed one sent via e-mail attachment)? Please clarify which one is correct. MJA: The more detailed version has now been added to this document. 03/11/2022 – DS reviewed updated form and sought further clarification, as below:		

	• Section 8 – please include the start and end date of the period in addition to the years (i.e. 1 January 2016 to 31 December 2022); • Section 8 – Periodic updates – please tick the box which applies; • Section 11 • Table of processing locations - you refer to both anonymised (personal data) and anonymous data in the table – please clarify. If the University of Exeter processes both of these categories, the request will not be for fully anonymous data and you would need to complete additional sections of the form. • Please confirm where the data transformation will happen – at the University of Exeter or within the SSNAP team? • Data flow map - Please add the type of data and method of transfer at each step of the journey. 07/11/2022 – Updated form received with simplified the data flows to reflect they are asking SSNAP to process the data to a level that is anonymous. Application to be reviewed at November DARG. Post-DARG – 21/11/2022 **Section 4** – Please include how SSNAP data will be used, and by whom. Response: This has been added. Briefly, SSNAP data will be used by the modelling team to train machine learning models, and to derive parameters of a stroke pathway model. Both types of model operate at a hospital level. **Section 5** – Please clarify "General high level results", in geographical terms, e.g. is it national? Response: This has been added; results will be analysed at a hospital level at the highest level of detail, but hospitals will be pseudo-anonymised for academic publication (e.g. similar to reporting of results in our previous work: see https://www.ahajournals.org/doi/10.1161/STROKEAHA.121.038454). **Section 7** – Please explain Prof. James' DoI given his role on the project is not define in the application. Response: This has been added; Prof James is the clinical lead for the project helping to direct general project aims, but will not have access to the returned SSNAP data. **Section 21** – If Prof. James does have a declarable interest, please could someone else sign on behalf of the program.

	Response: An alternative SSNAP signature has been added: Dr Ajay Bhalla, who is the Associate Clinical Director of SSNAP. Suitable for Chair's action upon completion. 05/12 – Candidate responses added in green. YS reviewed and agreed suitable for Chair's action. 07/12 – Approved via Chair's action.
Expiry date	07/12/2023

Section 1	Primary applicant information			
Title of project	SAMueL-2: Use of simulation and machine learning to identify key levers for maximising the disability benefit of intravenous thrombolysis in acute stroke pathways			
Name of primary applicant organisation	University of Exeter			
Name of any partner organisation (s) if applicable *(ensure partner form also completed)*	Click or tap here to enter text.			
Address of primary applicant organisation	St Luke's Campus, Heavitree Road, Exeter, EX1 2LU			
Primary contact *(must be a permanent senior member of staff)*	Michael Allen	**Job title**	Senior Research Fellow	
Telephone	07809 297290	**Email**	m.allen@exeter.ac.uk	
Organisation type	**NHS Healthcare Provider**	**Academic Institution**	**Healthcare Regulator**	**Other Healthcare Body**
	☐	☒	☐	☐
	Local Authority	**Individual Citizen(s)**	**Commercial Body**	**Other (please state)**
	☐	☐	☐	☐
HQIP projects from which data is requested *(For reference a list of HQIP projects and their Project Managers are listed on the HQIP website)*	**Please list below the name(s) of each of the HQIP-commissioned projects from which you are requesting data.**			
	Sentinel Stroke National Audit Programme (SSNAP)			

Section 2	Application type
Please tick at least one box below confirming whether the application is for a new application, extension or amendment. For extensions or amendments, you must highlight the specific information within this form that has been updated and provide updated signatures in order for the request to be processed.	

Request	Provide original HQIP application number and approval date and any subsequent amendment approval dates.	Summary of changes and rationale for the change to your original application. In addition all changes must be made as highlighted edits within this form.
☒ **New Application** Including applications that have not previously been approved by HQIP.	**N/A**	**N/A**
☐ **Extension** Request to extend the term of a current data sharing agreement.	Click or tap here to enter text.	Click or tap here to enter text.
☐ **Amendment** Request to change the scope, data fields requested or any other change to an application previously approved by DARG.	Click or tap here to enter text.	Click or tap here to enter text.

Section 3	**Project type**			
Please select the most appropriate answer	**Research**	**Service Evaluation**	**Clinical Audit**	**Other (please state)**
	☐	☒	☐	☐ Click or tap here to enter text.
Is ethics approval required?	**If the request is for research purposes you must enclose evidence of NHS ethics approval or evidence that this is not required**			
	YES Confirmation of NHS ethics needs to be submitted with this application.			☐
	NOT REQUIRED Confirmation needs to be submitted with this application from the HRA decision tool http://www.hra-decisiontools.org.uk/ethics/ or confirmation from your local Research and Development Department that NHS ethics is not required.			☒

Section 4	**Project details**
Please provide full details of the project below. You should describe and justify the project's objectives, rationale and methodology.	

Objective/Rationale	In England and Wales, 11%-12% of emergency stroke patients receive thrombolysis (clot-busting medication), significantly below the NHS Long Term Plan target of 20% by 2025. Use varies significantly between hospitals – ranging from 5% to 25%. Our project seeks to understand the key sources in variation between hospitals in the use of clot-busting medication ('thrombolysis') treatment in emergency stroke admissions. Better understanding of the causes will allow better targeted efforts to improve thrombolysis use.
Methodology	**Please include:** ▪ **A summary of your project methodology, ensuring this description aligns with the dataset requested** ▪ **A justification of sample size, analyses proposed and plans for patient and/or user group involvement**
	BACKGROUND AND OVERALL AIM In England and Wales, 11%-12% of emergency stroke patients receive thrombolysis, significantly below the NHS Long Term Plan target of 20% by 2025. The overall aim of SAMUeL-2 is to work with the Sentinel Stroke National Audit Programme (SSNAP) to increase the impact of national audit by providing advanced tools for in-depth comparisons between hospitals, helping to address the gap between actual and achievable thrombolysis use. In previous work (SAMueL-1) we have used clinical pathway simulation and machine learning to model stroke pathways to thrombolysis at all (anonymised) hospitals, and to compare decision-making between hospitals. We found that about half of the current inter-hospital variation in thrombolysis use comes from differences in local patient populations and the other half from differences in hospital processes and decision-making. We found that stroke thrombolysis use could be reasonably expected to reach 18%-19% of hospitalised stroke patients. The largest single improvement would come from clinical decision-making at all hospitals being similar to 30 top- 'benchmark' hospitals with higher thrombolysis use. The next largest improvement would come from increasing the proportion of stroke patients whose stroke onset time is determined, to a level currently achieved by hospitals achieving upper quartile performance. Finally, speeding the stroke pathway at all hospitals would increase thrombolysis use, but by the smallest margin - although speeding the stroke pathway increases the clinical benefit of thrombolysis for all treated patients. SPECIFIC OBJECTIVES Specific objectives are based on feedback received during SAMueL-1, and feedback on the SAMueL-2 bid proposal. 1. Expansion of SAMueL-1 modelling to include: 1) outcome and adverse event prediction at patient-level, 2) inclusion of pre-hospital times in pathway model, 3) use of organisational factors (such as staffing) in predicting use of thrombolysis, and 4) piloting of a model that incorporates use of thrombectomy alongside thrombolysis.

2. Incorporation of health economic outcomes (Quality Adjusted Life Years): These will be adapted from other NIHR projects involving this team that have already developed health economic models for thrombolysis in acute ischaemic stroke.

3. Promote acceptance of the modelling by increased transparency and explainability: 1) make use of Shapley values to show the contribution of individual features to the prediction that the model is making, 2) improved methods for clustering of patients to clarify patterns of differences in clinical decision-making between hospitals and to allow identification of 'similar hospitals' (by patient population) for comparison,
3) investigation of bias in model (e.g. accuracy analysis by patient subgroups), 4) generation of dashboards and other interrogative methods.

4. Generation of synthetic data and artificial patient vignettes: 1) build on pilot work already performed for generating synthetic patient-level stroke data that may be shared freely and used for discussion of 'virtual' patients, 2) automatic generation of artificial clinical vignettes from real or synthetic SSNAP data.

5. Co-production of project outputs with clinicians to promote acceptance and use for local quality improvement: By using both information gathering (through interviews) and intervention refinement (in workshops) we will incrementally modify and improve the content and style of our intervention (SAMueL tool). Working with our Public and Patient Involvement (PPI) group we will also produce key public-facing output.

Note: We wish to make synthetic data available along with our code so people can test the model using realistic data. Though we are requesting anonymised data, synthetic data adds another level of security above data anonymisation. Synthetic data will be guaranteed to be a minimum distance from any real data point. We will also use these data to make patient vignettes. We will apply for an DARF extension when we have that synthetic data available, providing the methods and comparison with real data.

Use of SSNAP data

SSNAP data will be by the Exeter modelling team (Michael Allen, Kerry Pearn, Anna Laws) used for:

1) Training of machine learning models, at a hospital level, that learn what type of patient each hospital would, or would not, give thrombolysis to. Note: Using the SSNAP data, we are learning the general patterns of use of thrombolysis in each hospital (in order to aid discussion on variation in clinical practice between hospitals); we are **not** developing a point-of-care tool to recommend treatment.
2) Determining the parameters for the emergency stroke pathway simulation at a hospital level (e.g. the mean and standard deviation of process step timings, such as time from onset to arrival, time from arrival to scan, time from scan to thrombolysis). This allows us to see what effect changing those parameters (e.g. improving speed to scan) would have on the number of

	people receiving thrombolysis, and the expected change in clinical outcome (as faster treatment leads to greater effect of thrombolysis).
Please describe the expected measurable benefits to health and/or social care including target date	We hope that by applying the developed tools in the routine SSNAP audits, we may help hospitals identify an appropriate hospital-specific target for use of thrombolysis, and identify which changes would lead to most improvement from current use and/or speed.
Proposed completion date of the project	31/12/2024
Lay Title and Summary	**Please provide a lay summary of your project (max 300 words).** The lay summary should be written in plain English and must enable a non- medical audience to understand the research question and aims of the project. If your request is approved, this paragraph (title and summary) will be published on the HQIP website.
	SAMueL-2: Use of computer simulation and machine learning to maximise the benefit of clot-busting medicines in stroke BACKGROUND Stroke is a common cause of adult disability. Expert opinion is that about one in five patients should receive clot-busting drugs to break up the blood clot that is causing their stroke, but on average only about one in nine patients actually receive this treatment in the UK. There is a lot of variation between hospitals, which means that the same patient might receive different treatment in different hospitals. AIM We will develop a computer-based tool for doctors to help them improve the speed and use of life-changing treatment for stroke. It compares their stroke pathway with other hospitals, and helps to answer the question “What treatment would this patient receive in other hospitals?” METHODS We predict clinical decisions using a computer technique called machine learning. This learns to predict decisions by asking “what happened with similar patients before?” In addition to predicting clinical decisions, which allow us to compare decision making between hospitals, we plan to see how good machine learning is at predicting patient outcomes. We model hospital processes by replicating the stroke pathway in a computer model, so that we can, for example, see the effect of changing time from arrival at hospital to receiving a brain scan. We will explore outcomes for patients measured in “Quality Adjusted Life Years”, which will allow comparison with other treatments for other conditions. This allows us to explore the cost-effectiveness of making changes to the care pathway. We will do research to better understand how doctors would use this tool to improve the care that they give, and how we can make it more engaging for doctors and other staff. We plan to pick a set of doctors we can talk with through the lifetime of the project, sharing knowledge between us throughout the project. They will act as our expert resource.

	(For a plain English summary of previous work, see: https://bit.ly/sam1_plain_english)

Section 5	**Publications and other outputs**			
Please include all intended outputs of the project including publications. Outputs include all types of disseminations produced from the project data. For each output include the highest level of detail of data/information that will be displayed.				
Outputs including publications *(add more rows if required)*	**What is the highest level of detail that will be displayed in the output** *(e.g. case record, unit, hospital, trust, network, regional, national, whole study, study group)*	**Will this output be published?**	**Expected Date of Publication**	**Confirm that published output will be anonymised to the level required by ISB1523: Anonymisation Standard for Publishing Health and Social Care Data**
NIHR report	Synthetic patient vignette . We will also report hospital-level results (but hospitals will be pseudo-anonymised for academic publication, including the NIHR report)	Yes	01/01/2024	Yes
GitHub repository with code and synthetic data	Synthetic patient data	Yes	01/01/2023	Yes
Summary paper	Hospital-level results (hospitals will be pseudo-anonymised for academic publication)	Yes	01/01/2023	Yes

Reports to local/regional stroke teams	Summary results a t a hospital level, and synthetic patient vignettes	No	NA	Yes

Section 6	**Project funding**	
Please indicate whether your project has received dedicated funding. Please also indicate whether there is a commercial interest in the project, either by funding or direct input into project design or team.		
Funding *(please select one answer)*	**No** ☐	
	Yes ☒	**If yes**, please provide the name of the funding body below NIHR Health & Social Care Delivery Research (NIHR134326)
Commercial interest *(please select one answer)*	**No** ☒	
	Yes ☐	**If yes**, please provide the name of the organisation and the nature of any interest into the project design below. Please also note information required in Section 7 Click or tap here to enter text.

Section 7	**Declaration of Interest**	
Please indicate whether any individuals named in this application have an interest to declare about this application. All interests that might unduly influence an individual's judgement and objectivity in the use of the data being requested from DARG are of relevance. Particular consideration should be given to declaring interests involving payment or financial inducement for use of the data being requested. These will be considered by DARG to determine if there is any potential conflict of interest identified as part of the request.		
Declaration of interest ***(please select one answer)***	**No** ☐	
	Yes ☒	**If yes**, please provide the name and details of the declaration for each individual below Prof. Martin James is Clinical Director of the Stroke Programme. The Stroke Programme includes the national stroke audit (SSNAP), which Is both the data provider, and where we hope the methods being developed here will be utilised. There is no commercial aspect to this work; methods and code will be passed at no cost, and with an open use licence, from the research team to SSNAP. Independent peer-review has been conducted as part of the NIHR-funding process. Prof James will not have access to the retrieved SSNAP data, but is the principle clinical lead of this project, helping to direct the project to ensure that the modelling work addresses questions that are

		important to the clinical community involved in emergency stroke care.

Section 8	**Data Summary**		
Please tick the box(es) confirming the geographical coverage of the data you are requesting. Coverage is defined as the location of the healthcare services who originated / initially provided the extract of data you are requesting. *NB. HQIP's DARG can only approve applications for access to the datasets which HQIP commission and thereby act as Data Controller.*			
Geographical coverage	☒ **England**	☒ **Wales**	☐ **Scotland**
	☐ **Northern Ireland**	☐ **Republic of Ireland**	☐ **Other**, please state: Click or tap here to enter text.
Inclusion and exclusion criteria (including date parameters)	**Describe precisely the criteria which define the patients to be included and to be excluded from the data extract you are requesting.** Please include precise date parameters for the start and end of the range requested (dd/mm/yy) and explain which dated project field will be used to define the requested cohort (e.g. date of admission or date of operation).		
	All SSNAP admissions to routinely admitting stroke teams 1st Jan 2016 to 31st December 2021 (six complete years based on SSNAP data field "SSNAP data field 1.11 Date/time of onset/awareness of symptoms), but excluding in-hospital stroke onset.		
Periodic updates	**Periodic updates may sometimes be available.** These must be agreed with the HQIP data provider in advance and any falling outside of the term of the Data Sharing Agreement will be subject to an application extension being agreed. Please provide details below including reasons.		
	☒ **None** ☐ **Monthly** ☐ **Quarterly** ☐ **Bi-annual (6 monthly)** ☐ **Annual** ☐ **Other**, please state: Click or tap here to enter text.		

Project/linked data *(please tick all that apply)*	**HQIP commissioned projects routinely link the data that they collect to other external datasets. The requirements of each data controller vary and there may not be an agreed process for onward sharing of linked project data. Please contact HQIP for advice before completing this form if you wish to apply for project data that has been linked with other datasets.** Please confirm whether you are applying for unlinked project data, or project data that has been linked to an external dataset.	
	☒ **Unlinked project data**	☐ **Project data linked with HES**
	☐ **Project data linked with ONS**	☐ **Project data linked with PEDW**
	☐ **Project data linked with Civil Registration data**	☐ **Project data linked with another dataset** Please provide details below: Click or tap here to enter text.

Section 9	**Data Type**
First discuss your request with the data provider and then indicate in this section the type of data you are requesting (tick all that apply). Note that what is relevant here is the identifiability of the data you are requesting at the point it leaves the HQIP data provider and not the level disclosed in any future publication. For further information on these categories of identifiability please see the Understanding patient data guidance **https://understandingpatientdata.org.uk/what-does-anonymised-mean**	
☒ **Anonymous data** This is information from many people combined together (aggregated), so that it would not be possible to identify an individual from the data. Information about small groups or people with rare conditions could potentially allow someone to be identified and so would not be considered anonymous. Individual patient level data may also very occasionally be categorised as anonymous. In this case, the information in each record requested would also potentially be true for many other similar individuals, and so could not be used to deduce the person's identity.	Though we wish to access patient-level data, data will be fully anonymised (following the MRC Regulatory Support Centre Guidance note 5 *on Identifiability, anonymisation and pseudonymisation*) We have minimised any risk of any re-identification by applying the following steps: No patient ID (including pseudo-anonymised ID) will be supplied. Replacing all dates and times with derived variables and intervals. Date of admission has been replaced with year and weekday (e.g. Mon, Tues, etc) of admission. Time of admission is given in 3 hour epochs (e.g. 6am to 9am). All other timings are given relative to this non-precise arrival date/time.

	Defining age by 5 year bands (e.g. 80-84). No geographic information is provided beyond the stroke team the patient attended. No ethnicity to be provided. Using only data collected directly by SSNAP and not including data linked from any other source (such as NHS Digital or ONS). e.g. a female patient, aged 80-84, arrived at hospital X between 3pm and 6pm on a Thursday in 2020.
☐ **De-personalised data** This is information that does not identify an individual, because identifiers have been removed or encrypted. However the information is still about an individual person and so needs to be handled with care. It might, in theory, be possible to re-identify the individual if the data was not adequately protected, for example if it was combined with different sources of information.	**HQIP data provider to provide a description for how the data will be de-identified to reduce any risk of re-identification.**
☐ **Personally identifiable data** This is information that identifies a specific person. Identifiers might include: name, address, full postcode, date of birth or NHS number. Personally identifiable data fields that are requested solely for the purpose of linkage still need to be described here and in Section 10, even if they are removed before the data reaches the applicant.	Click or tap here to enter text.

Section 10	**Data Fields**		
Please detail in the table below the data fields required as part of this request. All fields required to leave the data provider must be included here including linkage fields. Justification for these should include whether they will be retained or destroyed once linkage is complete. This should also be clear on the data flow map in Section 11. Applicants should only request the minimum data set required to address the purpose stated within this application.			
Data field requested	**Data source** *(Audit/project, HES, ONS, PEDW etc.)*	**Transformation applied** **This must be completed for every data field requested:** ▪ **None**	**Justification** *Please justify your use of each*

		▪ **Explain the transformation applied** (e.g. pseudonymisation (including who holds the key to reverse), time elapsed, age banding etc.)	*data item requested*
data_fields_requested.xlsx			
Stroke Team	SSNAP	None	Allow linkage to published organisational audit
S1AgeOnArrival (Age in years)	SSNAP	Age to be restricted to five year bands (e.g. 70-75).	Input to machine learning model predicting use of thrombolysis and outcome.
S1Gender (Gender)	SSNAP	None	Input to machine learning model predicting use of thrombolysis and outcome.
S1OnsetDateTime	SSNAP	Derived data: Onset time will be in minutes relative to arrival time, but arrival time will not be known precisely (3 hour interval, day of week, year; no actual date/time or month of year).	Used to calculate stroke pathway timings These are used in the stroke pathway simulation. Input to machine learning model predicting use of thrombolysis and outcome. S2NewAFDiagnosis Was a new diagnosis of AF made on admission?
S1OnsetDateType and S1OnsetTimeType (How accurate is time of onset?: Precise, best estimate, stroke during sleep)	SSNAP	None	Input to machine learning model predicting use of thrombolysis and outcome.

S1ArriveByAmbulance (Did the patient arrive by ambulance?)	SSNAP	None	Input to machine learning model predicting use of thrombolysis and outcome.
S1FirstArrivalDateTime (Date time patient arrived at first hospital)	SSNAP	Arrival date/time will be restricted to 3 hour interval (e.g. midnight to 3am), day of week, and year. No actual data/time will be provided.	Used to calculate stroke pathway timings These are used in the stroke pathway simulation. Input to machine learning model predicting use of thrombolysis and outcome. simulation.
S2CoM Comorbidities: CongestiveHeartFailure Hypertension AtrialFibrilation Diabetes StrokeTIA AFAntiplatelet AFAnticoagulent AFAnticoagulentVitK AFAnticoagulentDOAC AFAnticoagulentHeparin	SSNAP	None	Input to machine learning model predicting use of thrombolysis and outcome.
International Normalised ratio (INR) on arrival at hospital: S2INR S2INRHigh S2INRNK	SSNAP	None	Input to machine learning model predicting use of thrombolysis and outcome.
S2NewAFDiagnosis Was a new diagnosis of AF made on admission?	SSNAP	None	Input to machine learning model predicting use of thrombolysis and outcome.
S2RankinBeforeStroke What was the patient's modified Rankin Scale score before this stroke?	SSNAP	None	Input to machine learning model predicting use of

			thrombolysis and outcome.
S2NihssArrival What was the patient's NIHSS score on arrival? Include breakdown of score: Loc LocQuestions LocCommands BestGaze Visual FacialPalsy MotorArmLeft MotorArmRight MotorLegLeft MotorLegRight LimbAtaxia Sensory BestLanguage Dysarthria ExtinctionInattention	SSNAP	None	Input to machine learning model predicting use of thrombolysis and outcome.
S2BrainImagingDateTime (Date/Time of brain imaging)	SSNAP	Derived data: time will be in minutes relative to arrival time, but arrival time will not be known precisely (3 hour interval, day of week, year; no actual date/time).	Used to calculate stroke pathway timings These are used in the stroke pathway simulation. Input to machine learning model predicting use of thrombolysis and outcome
S2StrokeType (Infarction, haemorrhage)	SSNAP	None	Input to machine learning model predicting use of thrombolysis and outcome.
S2Thrombolysis (Thrombolysis given)	SSNAP	None	Label for machine learning model
S2ThrombolysisNoReason Reason for not giving	SSNAP	None	Used in general data analysis and

thrombolysis. Includes breakdown: Haemorrhagic TimeWindow Comorbidity Medication Refusal Age Improving TooMildSevere TimeUnknownWakeUp OtherMedical			to aid understanding of machine learning model outputs
S2ThrombolysisDateTime (Date and time of thrombolysis)	SSNAP	Derived data: time will be in minutes relative to arrival time, but arrival time will not be known precisely (3 hour interval, day of week, year; no actual date/time).	Used to calculate stroke pathway timings These are used in the stroke pathway simulation.
S2TIAInLastMonth (TIA in last month)		None	Input to machine learning model predicting use of thrombolysis and outcome.
Thrombectomy use: S2IAIArterialPunctureDateTime		Derived data for timing of arterial puncture: will be in minutes relative to arrival time, but arrival time will not be known precisely (3 hour interval, day of week, year; no actual date/time).	Used to ascertain whether thrombectomy has been used. These will be used to build pilot simulation and machine learning models for thrombectomy, and will be used to modify outcome modelling.
6 month outcome: S8Rankin6Month S8Rankin6MonthNK		None	Label for machine learning model to predict outcome of thrombolysis

Discharge: S7DischargeType S7StrokeUnitDeath S7DeathDate S7RankinDischarge		Derived data for death date, relative to arrival date which is only known by year and day of week.	Label for machine learning model to predict outcome of thrombolysis
Ambulance times: Date and time of 999 call being connected to the ambulance service by the operator Date and time of arrival at patient location Date and time of departure from patient location Date and time of arrival outside the hospital: If wheels stop time is not known, as measured by the mobile data terminals Date and time of arrival outside the hospital: As measured by the time at which the wheels stop Pre-hospital clinical impression		Derived data: time will be in minutes relative to arrival time, but arrival time will not be known precisely (3 hour interval, day of week, year; no actual date/time).	Used to calculate stroke pathway timings These are used in the stroke pathway simulation.

Section 11	**Processing locations and data flows**			
Please list all locations where processing will be undertaken, for the avoidance of doubt storage is considered processing. For each separate organisation processing data which is not fully anonymous a separate partner organisation form must also be completed.				
Processing location	**Organisation name**	**Processing or storage**	**Data type processed** *(anonymous, de-personalised, personally identifiable)*	**How will data be transferred to this location?**
University of Exeter staff laptops and desktop PCs (encrypted Linux machines)	University of Exeter	Storage of anonymised data.	Anonymous	SSNAP will send data to a secure

		We intend to apply for an extension to this request to publish synthetic data.		University 'dropbox' with end-to-end encryption.

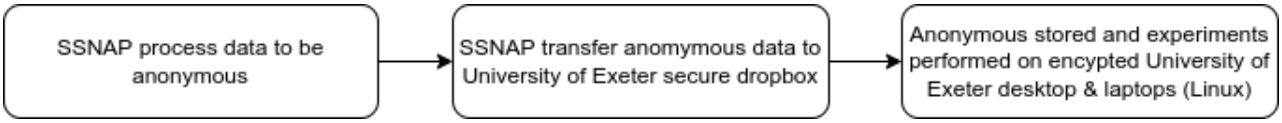
Will data be transferred outside of the European Economic Area? *If yes please state to where and give details of how that will be in compliance with the Data Protection Act 2018.*	☒ **No**	☐ **Yes**
	If yes, please provide details: Click or tap here to enter text.	

Data Flows

Please insert a data flow diagram which graphically describes:

1. **All locations where data is processed**
2. **All transfers that take place between locations and organisations**
3. **Data linkages to other data sets**

Please insert data flow diagram here



Section 12	**Project team employed by the applicant organisation**

Please list the name and job title of each member of the applicant organisation who will have access to the data for the purposes of this request. Please also confirm that they have a formal contract with the applicant organisation and will therefore be covered by the HQIP Data Sharing Agreement. Please add additional rows if necessary.

Where the data map in Section 11 details processing of data which is not anonymous by additional organisations, a partner organisation form is required to be completed for each.

Team member	**Name**	**Job title**	**Contract in place with applicant organisation**
Principal investigator	Michael Allen	Senior Research Follow	☐ **No** ☒ **Yes**
Project member 1	Kerry Pearn	Research Fellow	☐ **No** ☒ **Yes**
Project member 2	Anna Laws	Associate Research Fellow	☐ **No** ☒ **Yes**

Section 13	Data Protection
As a data controller your organisation should be registered with the Information Commissioners Office (ICO). Please provide the following information.	
Registered name *(if different to applicant name, please state reason)*	University of Exeter
Registration number	Z5785872
Expiry date	01/11/2023

Section 14	Legal basis (of the processing you intend to undertake)
If you are requesting data that is fully anonymous, please proceed to section 20	
GDPR Legal Basis	**Article 6 legal basis:** Click or tap here to enter text. **Justification:** Click or tap here to enter text.
	Article 9 legal basis: Click or tap here to enter text. **Justification:** Click or tap here to enter text.
Common law of duty of confidentiality is addressed by	**If the data you are requesting is personally identifiable please explain how you have addressed the common law duty of confidentiality below.**
	☐ **Explicit informed consent** *(please enclose consent form and patient information sheet with this application)*
	☐ **Approval under section 251 of the NHS Act 2006** *(please enclose both the application and the approval letter)*
	The section 251 approval enables the applicant to: ☐ **Hold/receive personal data** ☐ **Transfer/access personal data** ☐ **Operate on and link personal data**
	☐ **Other legal basis** If other legal basis selected, please provide further information here with reference to the statute, regulation or other provision relied upon: Click or tap here to enter text.

Section 15	Fair Processing
Please describe what transparency information has been provided to the data subjects that the data requested relates to. Please ensure you enclose copies of any privacy notices and other material you rely on when submitting this application.	
Information provided by the HQIP project	Though we are requesting anonymised data, we include data on SSNAP data source for completeness: SSNAP currently has approval under Section 251 to collect patient level data on the first six months of patient care (ECC 6- 02(FT3)/2012). More information on section 251 is available here: https://www.hqip.org.uk/wp-content/uploads/2022/01/DARG-Meetings-2022-WEBSITE.docx . The rationale for this legal basis is that many stroke patients are extremely unwell in the acute phase of their treatment and it is therefore not feasible to rely on patient consent during this time period. Patient consent is explicitly sought at six months post-stroke though it can also be recorded during the patient's inpatient stay. Where a patient refuses consent for inclusion in SSNAP, all their personal identifiable information will be wiped from the dataset and no further linkages to other data sources will therefore be possible, however their non-identifiable data will continue to be held on the database as it is important for the purpose of SSNAP to analyse all data without selection bias. The SSNAP team do not have access to patient identifiable information at any point in the patient pathway. https://www.strokeaudit.org/SupportFiles/Documents/Governance/Data-flow-diagram.aspx More detailed information on how SSNAP collects and shares data securely is available in SSNAP's Fair Processing Notice for users (https://www.strokeaudit.org/SupportFiles/Documents/Governance/KCL-July-2018-update/Fair-Processing-Statement-for-SSNAP-users-v1-0.aspx) and SSNAP's Fair Processing Statement for patients (https://www.strokeaudit.org/SupportFiles/Documents/Patient-Docs/Fair-processing-statement-for-patients-v6-0.aspx) Additional information relevant to patients and carers is available in the info for patients area of the webtool (https://www.strokeaudit.org/PatientInfo.aspx) lick or tap here to enter text.
Information provided by the applicant	Click or tap here to enter text.

Section 16	Security		
Each organisation processing data that is not fully anonymous as part of this project must demonstrate that they have appropriate security arrangements are in place. Please confirm whether the applicant organisation has a compliant Data Security and Protection Toolkit. *(Please note that additional organisations processing data which is not fully anonymous must complete a partner organisation form and evidence of security arrangements)*			
Applicant organisation *(please select one answer)*	☐ **Yes** *If yes, please provide evidence with this application.*	**ODS code**	Click or tap here to enter text.
		Status	Click or tap here to enter text.
		Published date	Click or tap to enter a date.
	☐ **No**	**If no, please provide below alternative evidence of adequate organisational and technical measures; to ensure the security of processing and preserve the confidentiality, integrity and availability of data.**	
		Click or tap here to enter text.	

Section 17	Retention and destruction
Please state the date until which you are seeking to retain the data and the reason. ***NB. That the requirement to extend the Data Sharing Agreement*** *(if retention is requested for longer than its original term) would still apply.*	Project due to complete April 2024. Allow 12 months data access for report writing and editing.
Please provide details of how you intend to destroy the data at the end of the retention period.	
Please confirm that you will submit a certificate of destruction to HQIP within 5 business days of destruction of the data.	☐ **Yes**

Section 18	Intention to link data

Do you intend for the requested data set to be linked with any additional data sets? If yes, please provide full details of the data controller(s) of the secondary dataset(s) and a description of which organisation will perform the linkage and how the linkage will take place. HQIP will work to the principle that other relevant requests are in process. *(Please select one answer)*	
☐ **No intended linkage**	☐ **Intention to link the data.** *Please provide full details of linkage below.*
If there is an intention to link the data, please provide full details here: Click or tap here to enter text.	

Section 19	**Further information**
Please use the section below to add any additional information to support your request.	
Click or tap here to enter text.	

Section 20	Attachments Checklist

Please use the table below to ensure that the documents / information listed are either contained within the application or submitted as attachments.

	Applicant organisation(s)						Data provider	
Type of data / Level of data	Data items spreadsheet	Evidence of Data Security and Protection (DSPT) Toolkit or equivalent	Data flow map	Ethics approval OR confirmation that it is not required	Fair processing information	Legal basis supporting evidence (such as, consent form and patient leaflet, s251 application and approval letter or any other evidence)	Description for how the data will be de-identified to reduce any risk of re-identification	Fair processing information
Anonymous	✓		✓					
De-personalised	✓	✓	✓	✓	✓	✓	✓	✓
Personally Identifiable	✓	✓	✓	✓	✓	✓		✓

Terms and Conditions for Use of HQIP Data

BACKGROUND

(A) HQIP agrees to share the HQIP Data (defined below) with the Applicant on the terms set out in the Contract (as defined below).

(B) The Applicant agrees to use the HQIP Data on the terms set out in the Contract.

(C) The Applicant has submitted a request to HQIP using the Data Access Request Form (defined below) for access to the HQIP Data. These Conditions together with the Data Access Request Form comprise the Contract.

AGREED TERMS

1. Interpretation

The following definitions and rules of interpretation apply:

1.1 Definitions:

Agreed Purpose: the purpose(s) for which the Applicant wishes to use the HQIP Data, as set out in section 3, section 4 and section 5 of the Data Access Request Form as such purposes may be amended by written agreement from HQIP from time to time, subject to the payment of any related Charges.

Anonymous Data: has the meaning set out in the Data Access Request Form.

Applicant: the party named as such in the Data Access Request Form.

Business Day: a day other than a Saturday, Sunday or public holiday in England when banks in London are open for business.

Change Fees: the fees notified by HQIP to the Applicant, to be paid by the Applicant to HQIP, in relation to a change in the HQIP Data that the Applicant wishes to access.

Conditions: the terms and conditions set out in this document as amended from time to time in accordance with condition 27.

Contract: the contract between HQIP and the Applicant for the sharing of the HQIP Data by HQIP with the Applicant in accordance with these Conditions, the Data Access Request Form and any attachments to the Data Access Request Form.

Data Access Request Form: the Applicant's request to HQIP for access to the HQIP Data set out on the form attached to these Conditions and approved by HQIP and any subsequent form(s) as completed by the Applicant and approved by HQIP which refer to these Conditions.

Data Destruction Certificate: HQIP's required form of certificate in relation to data destruction as set out in the Schedule to these Conditions.

Data Sharing Code: the Information Commissioner's Data Sharing Code of Practice of May 2011, as updated or amended from time to time.

Data Protection Legislation: all applicable data protection and privacy legislation in force from time to time in the UK including the General Data Protection Regulation (*(EU) 2016/679*) (**GDPR**); the Data Protection Act 2018 (**DPA 2018**); the Privacy and Electronic Communications Directive 2002/58/EC (as updated by Directive 2009/136/EC) and the Privacy and Electronic Communications Regulations 2003 (SI 2003 No. 2426) as amended; any other European Union legislation relating to personal data and all other legislation and regulatory requirements in force from time to time which apply to a party relating to the use of Personal Data (including, without limitation, the privacy of electronic communications); and the guidance and codes of practice issued by the relevant data protection or supervisory authority and applicable to a party, including the Data Sharing Code.

De-personalised Data: has the meaning set out in the Data Access Request Form.

EEA: European Economic Area.

Fees: the Initial Fees, the Renewal Fees and the Change Fees, as the case may be.

FOIA: the Freedom of Information Act 2000.

HQIP: Healthcare Quality Improvement Partnership (company number 6498947) whose registered office is at 70 Wimpole Street, London W1G 8AX.

HQIP Data: the Anonymous Data, De-personalised Data and Shared Personal Data to be shared with the Applicant by HQIP.

Initial Fees: the fees notified by HQIP to the Applicant, to be paid by the Applicant to HQIP prior to the relevant data sharing taking place, in relation to the Basic, Standard and Complex HQIP Data (identified in the Data Access Request Form) that the Applicant wishes to access.

Personal Data Breach: a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to the Shared Personal Data.

Personally Identifiable Data: has the meaning set out in the Data Access Request Form**.**

Renewal Fees: the annual renewal fees notified by HQIP to the Applicant, to be paid by the Applicant to HQIP prior to each anniversary of the date of the initial sharing of the HQIP Data by HQIP with the Applicant.

Shared Personal Data: the Personally Identifiable Data (including Personal Data and Special Category Personal Data) and De-personalised data which can be reverse engineered to be Personally Identifiable Data to be shared between the parties under condition 5 of these Conditions.

Subject Access Request: the exercise by a data subject of his or her rights under Article 15 of the GDPR and the DPA 2018.

Supervisory Authority: the relevant supervisory authority in the territories where the parties to the Contract are established.

Transfer Dates: the date or dates when the HQIP Data is transferred to the Applicant.

Term: the length of time for the data sharing with the expiry date specified by HQIP in the Data Access Request Form.

1.2 **Controller**, **Processor**, **Data Subject** and **Personal Data**, **Special Categories of Personal Data**, **Processing** and "appropriate technical and organisational measures" shall have the meanings given to them in the Data Protection Legislation.

1.3 A reference to a company shall include any company, corporation or other body corporate, wherever and however incorporated or established.

1.4 A reference to a statue or statutory provision shall include all subordinate legislation made from time to time under that statute or statutory provision.

1.5 References to conditions and schedules are to the conditions and schedules of these Conditions.

1.6 Any words following the terms **including**, **include**, **in particular** or **for example** or any similar phrase shall be construed as illustrative and shall not limit the generality of the related general words.

1.7 A reference to **writing** or **written** includes email.

1.8 In the event of any inconsistency, discrepancy or conflict between a Data Access Request Form, these Conditions and the Schedule, the conflict in relation to the HQIP Data covered by that Data Access Request Form should be resolved in the following descending order of priority:

(a) the Data Access Request Form (including any attachments to the Data Access Request Form)**;**

(b) these Conditions;

(c) the Schedule.

2. Commencement and Term

2.1 The data sharing shall commence on the date set out in the Data Access Request Form and shall continue for the Term, unless terminated earlier in accordance with condition 12, condition 14 and condition 17, when it shall terminate automatically without notice.

2.2 Without prejudice to condition 2.1 it is the Applicant's responsibility to instigate any request for an extension to the Term in good time to allow for HQIP to consider whether to approve the Applicant's request and HQIP cannot be held responsible if the Applicant's request is not made to allow sufficient time for the HQIP approval process.

3. Purpose

3.1 The Applicant shall only process that HQIP Data for the Agreed Purpose.

4. Compliance with data protection laws

4.1 The Contract sets out the framework for the sharing of HQIP Data between HQIP, and the Applicant. Where HQIP is sharing Shared Personal Data with the Applicant HQIP acts as a Controller when it discloses such Shared Personal Data and the Applicant acts as a Controller when it receives such Shared Personal Data. It defines the principles and procedures that the parties shall adhere to and the responsibilities the parties owe to each other.

4.2 Each Party must ensure compliance with applicable national data protection laws at all times.

4.3 In the event the data protection law or approach to compliance of two or more countries conflict, the requirements of the country that necessitates stricter or additional requirements to protect data subjects' privacy and personal data shall be applied.

4.4 Each party has such valid registrations and or paid such fees as are required by its national Supervisory Authority which, by the time that the data sharing is expected to commence, covers the intended data sharing pursuant to the Contract, unless an exemption applies.

5. Shared Personal Data

5.1 The categories of HQIP Data that will be shared by HQIP with the Applicant are set out in the Data Access Request Form at section 9 and section 10 together with any access and processing restrictions required by HQIP.

6. Lawful, fair and transparent processing

6.1 The Applicant shall ensure that it processes the Shared Personal Data fairly and lawfully in accordance with condition 6.2 while the sharing of the Shared Personal Data is taking place.

6.2 The Applicant shall ensure that it has legitimate grounds under the Data Protection Legislation for the processing of Shared Personal Data.

6.3 The Applicant undertakes to inform the Data Subjects, in accordance with the Data Protection Legislation, of the purposes for which it will process their Personal Data, the legal basis for such purposes and such other information as is required by Article 14 of the GDPR including:

(a) if Shared Personal Data will be transferred to a third party, that fact and sufficient information about such transfer and the purpose of such transfer to enable the data subject to understand the purpose and risks of such transfer; and

(b) if Shared Personal Data will be transferred outside the EEA pursuant to condition 10, that fact and sufficient information about such transfer, the purpose of such transfer and the safeguards put in place by the Applicant to enable the data subject to understand the purpose and risks of such transfer.

6.4 HQIP Data is provided on the understanding that it will not be matched to any other datasets, even to depersonalised or aggregated datasets, unless HQIP has agreed to the proposed processing matching.

6.5 The Applicant is the Controller of Shared Personal Data that HQIP has supplied. The Applicant is responsible for complying with the Data Protection Legislation, all other applicable laws and its own internal policies and procedures in relation to the Applicant's processing of the Shared Personal Data.

7. Data quality

7.1 Shared Personal Data shall be limited to the Personal Data and Special Category Data listed at section 9 and section 10 of the Data Access Request Form.

7.2 The Shared Personal Data shall not be irrelevant or excessive with regard to the Agreed Purpose.

8. Data subjects' rights

8.1 The parties each agree to provide such assistance as is reasonably required to enable the other party to comply with requests from Data Subjects to exercise their rights under the Data Protection Legislation within the time limits imposed by the Data Protection Legislation.

8.2 Each party is responsible for maintaining a record of individual requests for information, the decisions made and any information that was exchanged. Records must include copies of the request for information, details of the data accessed and shared and where relevant, notes of any meeting, correspondence or phone calls relating to the request.

9. Data retention and deletion

9.1 The Applicant shall not retain or process HQIP Data for longer than is necessary to carry out the Agreed Purposes.

9.2 The Applicant shall not retain HQIP Data after the end of the Term.

9.3 The Applicant shall ensure that any HQIP Data are, unless otherwise required by HQIP, destroyed securely and in accordance with the Applicant's organisational policy and standards of best practice at the end of the Term or, if earlier, once processing of the HQIP Data is no longer necessary for the Agreed Purposes.

9.4 Following the deletion of HQIP Data in accordance with condition 9.3, the Applicant shall notify HQIP that the HQIP Data in question has been deleted and provide HQIP with a data destruction certificate in the form of the Data Destruction Certificate within five (5) Business Days.

10. Transfers

10.1 For the purposes of this condition, transfers of Shared Personal Data shall mean any sharing of Shared Personal Data by the Applicant with a third party, and shall include, but is not limited to, the following:

(a) subcontracting the processing of Shared Personal Data;

(b) granting a third party controller access to the Shared Personal Data.

10.2 Shared Personal Data must not be shared by the Applicant with any other organisations or individuals unless such sharing is included on the Data Access Request Form and agreed to in writing by HQIP.

10.3 If, with HQIP's prior consent, the Applicant appoints a third party processor to process the Shared Personal Data it shall comply with Article 28 and Article 30 of the GDPR and shall remain liable to HQIP for the acts and/or omissions of the processor.

10.4 The Applicant may not transfer Shared Personal Data to a third party located outside the EEA unless this has been requested by the Applicant in the Data Access Request Form and it has been approved by HQIP in writing subject to such conditions as HQIP may impose in relation to such a transfer which (as a minimum) shall include that it;

(a) complies with the provisions of Articles 26 of the GDPR (in the event the third party is a joint controller); and.

(b) ensures that (i) the transfer is to a country approved by the European Commission as providing adequate protection pursuant to Article 45 of the GDPR; (ii) there are appropriate safeguards in place pursuant to Article 46 of the GDPR; or (iii) one of the derogations for specific situations in Article 49 of the GDPR applies to the transfer.

11. Security and training

11.1 HQIP shall only provide the Shared Personal Data to the Applicant by using secure methods.

11.2 The Applicant undertakes to have in place appropriate technical and organisational security measures to:

(a) prevent:

(i) unauthorised or unlawful processing of the Shared Personal Data; and

(ii) the accidental loss or destruction of, or damage to, the Shared Personal Data

(b) ensure a level of security appropriate to:

(i) the harm that might result from such unauthorised or unlawful processing or accidental loss, destruction or damage; and

(ii) the nature of the Shared Personal Data to be protected.

11.3 It is the responsibility of the Applicant to ensure that its staff members are appropriately trained to handle and process the Shared Personal Data in accordance with any applicable national data protection laws and the Data Protection Legislation and guidance and have entered into confidentiality agreements with such staff relating to the processing of personal data.

11.4 The level, content and regularity of training referred to in condition 11.3 shall be proportionate to the staff members' role, responsibility and frequency with respect to their handling and processing of the Shared Personal Data.

11.5 Consistent with the Applicant's responsibilities as a Controller in accordance with applicable national data protection laws and the Data Protection Legislation the Applicant shall implement and comply with its own security policy as evidence of the Applicant's management's commitment to information security and the security measures to be taken to cover the temporary removal of any Shared Personal Data or confidential information from the Applicant's premises.

11.6 The Applicant shall ensure that access to any buildings or rooms within the Applicant's premises where Shared Personal Data is stored and/or can be accessed is controlled and that casual passers-by cannot read information off screens ordocuments.

11.7 The Applicant shall not disclose or allow access to any HQIP Data other than to a person placed by the Applicant under the same obligations as those set out in the Contract who is variously employed or engaged by the Applicant or any sub-contractor, contractor, servant, agent or other person within the control of the Applicant.

11.8 Confidential information (including Shared Personal Data) transferred between HQIP and the Applicant in electronic form must be encrypted and if sent by email must be password protected with the password sent in a separate email or text message.

11.9 The Applicant will have in place appropriate security on external routes into its organisation, for example internet firewalls and secure dial-in facilities.

11.10 The Applicant shall ensure that any system whereby any Shared Personal Data may be disclosed over the telephone is protected by a procedure for authenticating identity prior to the disclosure of that Personal Data.

11.11 The Applicant's computer systems must be password protected. Passwords must give access only to Shared Personal Data which an employee has a proper need to access and not to all levels of the system. Passwords must be known only to authorised people and changed regularly.

11.12 The Applicant shall have a satisfactory procedure for cleaning media (such as hard drives and disks) before they are reused or new data written over old. The Applicant shall ensure that printed material is disposed of securely, for example byshredding.

11.13 The Applicant confirms that the Shared Personal Data will not be removed from the Applicant's secure premises nor worked on by employees on their own electronic devices unless this is permitted by the Applicants Bring Your Own Device Policy and subject to the Applicant's requirements in relation to secure Virtual Private Networks. The Applicant shall take adequate precautions against burglary, fire or natural disaster. The Applicant shall ensure that all HQIP Data is protected against corruption by viruses or other forms of intrusion.

11.14 All duplicate copies or back-up copies of the Shared Personal Data are held by the Applicant subject to the terms of the Contract and shall be securely destroyed when they are no longer required to be processed for the Agreed Purpose.

11.15 The Applicant shall ensure that proper weight is given to the discretion and integrity of staff when they are being considered by the Applicant for employment or promotion or for a move to an area of work where they will have access to Shared Personal Data. The Applicant shall ensure staff are aware of their responsibilities and given training to ensure their knowledge is up to date.

11.16 The Applicant shall ensure that disciplinary rules and procedures take account of the requirements of the Data Protection Legislation. In the case of an employee of the Applicant being found to be unreliable or unsuitable for access to Shared Personal Data, the Applicant shall ensure that his or her access to Shared Personal Data is withdrawn immediately

11.17 The Applicant shall ensure that its staff are aware that Shared Personal Data should only be accessed for the Agreed Purpose and not for their own private purposes.

11.18 The Applicant shall ensure that audit trails are kept so that access to Shared Personal Data is logged and can be attributed to a particular person.

12. Personal data breaches and reporting procedures

12.1 The Applicant shall ensure that any Personal Data Breaches are properly investigated and remedied as soon as possible, particularly when damage or distress could be caused to an individual. The Applicant shall notify HQIP immediately should such a breach occur. Upon receipt of such a notification HQIP shall have the right:

(a) to immediately suspend provision of the HQIP Data under the Contract or any other contract for the sharing of HQIP Data with the Applicant; and/or

(b) to terminate immediately the Contract or any other contract for the sharing of HQIP Data with the Applicant; and/or

(c) to terminate immediately all other contracts for the sharing of HQIP Data with the Applicant that are entered into under this Contract; and/or

(d) to immediately suspend and/or terminate any existing applications by the Applicant to access the HQIP Data**.**

12.2 Each party shall comply with its obligation as controller to report a Personal Data Breach to the appropriate Supervisory Authority and (where applicable) data subjects under Article 33 of the GDPR.

13. Resolution of disputes with data subjects or the Supervisory Authority

13.1 In the event of a dispute or claim brought by a data subject or the Supervisory Authority concerning the processing of Shared Personal Data against either or both parties, the parties will inform each other about any such disputes or claims, and will cooperate with a view to settling them amicably in a timely fashion.

13.2 The parties agree to respond to any generally available non-binding mediation procedure initiated by a data subject or by the Supervisory Authority. If they do participate in the proceedings, the parties may elect to do so remotely (such as by telephone or other electronic means). The parties also agree to consider participating in any other arbitration, mediation or other dispute resolution proceedings developed for data protection disputes.

13.3 Each party shall abide by a decision of a competent court of HQIP's country of establishment or of the Supervisory Authority.

13.4 Subject to conditions 13.1 to 13.3 the Parties shall attempt to resolve any disagreement arising from the Contract informally and promptly by officers who have day-to-day responsibility for the operation of the Contract.

13.5 If the disagreement cannot be resolved further to condition 13.4 within fourteen (14) days of it arising, the matter shall be referred to the Chief Executives (or the corresponding individuals) of the Parties.

14. Fees

14.1 The Applicant shall pay to HQIP the Fees to cover the cost to HQIP of considering the Applicant's request to access the HQIP Data and, if approved by HQIP, the cost of providing access to the Applicant of the HQIP Data during the Term.

14.2 All Fees shall be paid by the Applicant to HQIP to its nominated bank account detailed below within thirty (30) days of the due date, in cleared funds, without withholding, set-off or deduction are non-refundable and time for payment is of the essence. The Fees shall be due and payable in full to HQIP annually in advance.

14.3 The Initial Fees for the first year of the HQIP Data sharing shall be paid within thirty (30) days of the Applicant's submission of the signed Pro Forma Invoice which will be sent to them once the completed Data Access Request Form has been received and approved by HQIP;

14.4 The Renewal Fees for the second and subsequent years of the HQIP Data sharing shall be paid within thirty (30) days of HQIP's submission of the invoice for those fees;

14.5 The Change Fees shall be paid within thirty (30) days of HQIP's submission of the invoice for those fees;

14.6 HQIP'S bank details are:

Lloyds Bank plc

(Threadneedle Street Branch)

Account No. 00322010

Sort Code 30-00-09.

14.7 Where the Applicant fails to make payment of any Fees by the due date, HQIP shall be entitled (but shall not be obliged) to withhold the HQIP Data requested until payment is made. Where the Applicant fails to make payment within a further fourteen (14) days from the first date that any sums are due, HQIP shall be entitled (but shall not be obliged) to do any, or a combination of, the following on written notice to the Applicant:

(a) to immediately suspend provision of the HQIP Data under the Contract or any other contract for the sharing of HQIP Data with the Applicant; and/or

(b) to terminate immediately the Contract or any other contract for the sharing of HQIP Data with the Applicant; and/or

(c) to terminate immediately all other contracts for the sharing of HQIP Data with the Applicant that are entered into under this Contract; and/or

(d) to immediately suspend and/or terminate any existing applications by the Applicant to access the HQIP Data.

14.8 HQIP may charge interest at an annual rate of 4% above the base rate of Lloyds Bank, calculated on a daily basis in respect of any sum which is due and unpaid, that interest to run from the date on which that sum is due and payable until receipt by HQIP of the full amount, whether before or after judgment.

14.9 All Fees are to be paid in pounds sterling (£) and are exclusive of VAT or any other applicable sales tax, which shall be paid by the Applicant at the rate and in the manner for the time being prescribed by law, unless a current proof of VAT exemption is provided to HQIP.

14.10 HQIP may, at any time after the date of the initial sharing of the HQIP Data by HQIP with the Applicant, by giving 90 days' prior written notice, vary the Renewal Fees and the Change Fees and the basis on which they are calculated. The Applicant may terminate the Contract for the HQIP Data Sharing from the date on which that variation is intended to take effect, provided that the Applicant gives HQIP written notice of termination of the Contract within 60 days of the date of HQIP's notice.

14.11 Where an amendment to the provisions of the Contract (other than the Fees or the basis on which they are calculated) is required as a result of an addition to the HQIP Data sharing service or the relevant HQIP Data sharing service (including, for example, an amendment to acknowledge third party rights), HQIP may give the Applicant reasonable notice in writing of the Change Fees that will take effect on the date specified in that notice.

15. Confidentiality

15.1 Each party undertakes that it shall not at any time disclose to any person any Shared Personal Data or confidential information concerning the business, affairs, customers, clients or suppliers of the other party or of any member of the group of companies to which the other party belongs, except as permitted by Condition 15.2;

15.2 Each party may disclose the other party's confidential information:

(a) to its employees, officers, representatives or advisers who need to know such information for the purposes of exercising the party's rights or carrying out its obligations under or in connection with the Contract. Each party shall ensure that its employees, officers, representatives or advisers to whom it discloses the other party's confidential information comply with this condition 15; and

(b) as may be required by law, a court of competent jurisdiction or any governmental or regulatory authority.

15.3 HQIP may disclose details of the Applicant's Data Access Request Form to bodies who licence the HQIP Data to HQIP.

15.4 HQIP may publish details of the Applicant's Data Access Request Form on a public register of HQIP's data sharing activities.

15.5 The Applicant may discuss adverse device outcomes findings with competent authorities (e.g. MHRA).

15.6 No party shall use any other party's confidential information for any purpose other than to exercise its rights and perform its obligations under or in connection with the Contract.

16. Publication

16.1 This condition only applies to HQIP Data supplied by the National Joint Registry. The Applicant shall provide a copy of any paper proposed for publication to HQIP approval at least one (1) month before submitting for publication or making public any information that has been derived utilising the HQIP Data.

16.2 The Applicant shall acknowledge HQIP and all such bodies who licence the HQIP Data to HQIP and set out in the attachment to the Data Access Request Form, in all work published arising from any research undertaken on the HQIP data and will provide copies of such published work to HQIP. The applicant shall use the following wording for the HQIP acknowledgement:

'Data has been provided by the Healthcare Quality Improvement Partnership from the xxx Programme'

Separate wording will be required for applications relating to HQIP Data supplied by the National Joint Registry. Applicants must use the NJR acknowledgement guidance located at http://www.njrcentre.org.uk/njrcentre/Research/Research-requests.

16.3 Where HQIP shares Shared Personal Data with the Applicant, data shall not be published, except in compliance with all subsisting legal requirements as to confidentiality and provided that there is a lawful basis for such publishing.

17. Rights to inspection and withdrawal of data sharing

17.1 HQIP reserves its rights to inspect the Applicant's arrangements for the processing of the shared Personal Data at any time without prior notice, at the Applicant's cost, and shall be entitled (but shall not be obliged) to do any, or a combination of, the following on written notice to the Applicant:

(a) to immediately suspend provision of the HQIP Data under the Contract or any other contract for the sharing of HQIP Data with the Applicant; and/or

(b) to terminate immediately the Contract or any other contract for the sharing of HQIP Data with the Applicant; and/or

(c) to terminate immediately all other contracts for the sharing of HQIP Data with the Applicant that are entered into under this Contract; and/or

(d) to immediately suspend and/or terminate any existing applications by the Applicant to access the HQIP Data.

where it considers the Applicant is not processing the Personal Data in accordance with the Contract.

18. Freedom of Information

18.1 The Applicant acknowledges that HQIP, although not itself a public authority subject to the FOIA, HQIP may be required to facilitate FOI requests for information made by third parties on such bodies who licence the HQIP Data to HQIP where such bodies are subject to FOIA.

18.2 If the Applicant is a public authority and it receives an FOIA request regarding the HQIP Data, the Applicant must consult with the body that licences the HQIP Data to HQIP (as notified by HQIP to the Applicant in any attachment to the Data Access Request Form) prior to any release of the HQIP Data and shall take into account such licensee's views before responding to any FOIA request. Notwithstanding this condition 18.2, bodies who licence the HQIP Data to HQIP acknowledge and the Applicant accepts that the Applicant is responsible in its absolute discretion for determining whether information regarding the HQIP Data is exempt from disclosure under FOIA.

18.3 The Applicant shall ensure that its sub-contractors, servants, suppliers, agents or any other person in the control of the Applicant shall adhere to the terms of this condition 18.

19. Research

19.1 Article 89 of the GDPR and Part 6 of Schedule 2 of the DPA 2018 contain various exemptions and relaxations in relation to the processing of Personal Data only for research purposes in compliance with the relevant conditions (as such terms are defined in the GDPR and the DPA 2018), including in relation to the second Data Protection Principle, the keeping of Personal Data indefinitely and the right of access to Personal Data.

19.2 If the Applicant intends to claim its use of any Personal Data is covered by Article 89 of the GDPR and Part 6 of Schedule 2 of the DPA 2018, the Applicant warrants to HQIP that its use

of Personal Data conforms with the required conditions of Article 89 of the GDPR and Part 6 of Schedule 2 of the DPA 2018 and the Data Access Request Form shall set out the relevant information.

20. Reporting Requirements

20.1 The Applicant will comply with any reporting requirements made known to it by HQIP when the Applicant submits its Data Access Request Form and which are reflected in an attachment to the signed Data Access Request form signed by both of the parties.

20.2 HQIP reserves the right to request a written update from the Applicant at any stage during the Term.

20.3 This condition only applies to HQIP Data supplied by the National Joint Registry. The Applicant shall provide a written project summary update to the National Joint Registry in the form and detail required by the National Joint Registry. The written summary shall be submitted to National Joint Registry six (6) months after the Transfer Dates and then at six (6) monthly intervals ('**Six Monthly Updates**') until the HQIP Data has been deleted. After the Applicant has finished processing the HQIP Data in accordance with the Agreed Purposes, a final written report shall be sent to National Joint Registry within three (3) months after the end of the Term.

21. Language

21.1 The Contract is drafted in the English language. If the Contract is translated into any other language, the English language version shall prevail.

21.2 Any notice given under or in connection with this Contract shall be in English. All other documents provided under or in connection with this Contract shall be in English, or accompanied by an English translation certified as accurate by a notary experienced in the relevant foreign language and with the appropriate technical and legal experience in relation to the relevant document to be translated.

21.3 The English language version of this Contract and any notice or other document relating to this Contract shall prevail if there is a conflict.

22. Warranties

22.1 The Applicant warrants and undertakes that it will:

(a) Process the Shared Personal Data in compliance with all applicable laws, enactments, regulations, orders, standards and other similar instruments that apply to its personal data processing operations.

(b) Make available on request to the data subjects who are third party beneficiaries a copy of the Contract, unless the Contract contains confidential information.

(c) Respond within a reasonable time and as far as reasonably possible to enquiries from the relevant Supervisory Authority in relation to the Shared Personal Data.

(d) Respond to Subject Access Requests in accordance with the Data Protection Legislation.

(e) Where applicable, maintain registration or pay the appropriate fees with all relevant Supervisory Authorities to process all Shared Personal Data for the Agreed Purpose.

(f) Take all appropriate steps to ensure compliance with the security measures set out in condition 11 above.

22.2 HQIP warrants and undertakes that it is entitled to provide the Shared Personal Data to the Applicant. The Applicant warrants and undertakes that it will not disclose or transfer the Shared Personal Data to a third party controller located outside the EEA unless it complies with the obligations set out in condition 10.4 above.

22.3 Except as expressly stated in the Contract, all warranties, conditions and terms, whether express or implied by statute, common law or otherwise are hereby excluded to the extent permitted by law.

23. Indemnity

23.1 The Applicant indemnifies, and shall keep indemnified, HQIP against any liability, costs, damages, expenses (including legal fees), losses, claims, administrative sanction, fine, penalty, action or other liability or proceedings whatsoever arising under any statute or at common law or for breach of contract in respect of:

(a) damage to property, real or personal, including any infringement of third party intellectual property rights; and

(b) injury to persons, including injury resulting in death; and

(c) any direct economic or financial loss; and

(d) any enquiry or complaint by a Data Subject; and

(e) any enquiry or investigation by the Supervisory Authority; and

(f) any claim or action brought by any third party against HQIP

arising out of, in connection with any act, omission or default of the Applicant, its staff, agents or sub-contractors in relation to the HQIP Data. The indemnity in this condition shall be separate, distinct from and not subject to any exclusions and limitations on liability in the Contract.

24. Allocation of cost

24.1 Except as otherwise stated each party shall perform its obligations under the Contract at its own cost.

25. Limitation of liability

25.1 Neither party excludes or limits liability to the other party for:

(a) fraud or fraudulent misrepresentation;

(b) death or personal injury caused by negligence;

(c) a breach of any obligations implied by section 12 of the Sale of Goods Act 1979 or section 2 of the Supply of Goods and Services Act 1982;

(d) any matter for which it would be unlawful for the parties to exclude liability; or

(e) in relation to the indemnity in condition 23.

25.2 Subject to condition 25.1, neither party shall in any circumstances be liable whether in contract, tort (including for negligence and breach of statutory duty howsoever arising), misrepresentation (whether innocent or negligent), restitution or otherwise, for:

(a) any loss (whether direct or indirect) of profits, business, business opportunities, revenue, turnover, reputation or goodwill;

(b) loss (whether direct or indirect) of anticipated savings or wasted expenditure (including management time); or

(c) any loss or liability (whether direct or indirect) under or in relation to any other contract.

25.3 HQIP takes no responsibility for the accuracy, currency, reliability and correctness of the HQIP Data, nor for the accuracy, currency, reliability and correctness of links or references to other information sources and disclaims all warranties in relation to such data, links and references to the maximum extent permitted by legislation. The Applicant uses or relies on the HQIP Data at its own risk.

26. Third party rights

26.1 Except as expressly provided in condition 8 (data subjects rights) and such bodies who licence the HQIP Data to HQIP, set out in the attachment to the Data Access Request Form and to the extent required by such bodies in that attachment, contract holders with, and funders to, HQIP, a person who is not a party to the Contract shall not have any rights under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of the Contract. This does not affect any right or remedy of a third party which exists, or is available, apart from that Act.

27. Variation

27.1 Except as set out in the Contract, no variation of the Contract, including the introduction of any additional terms and conditions shall be effective unless it is agreed in writing and signed by the Applicant.

28. Waiver

28.1 No failure or delay by a party to exercise any right or remedy provided under the Contract or by law shall constitute a waiver of that or any other right or remedy, nor shall it prevent or restrict the further exercise of that or any other right or remedy. No single or partial exercise of such right or remedy shall prevent or restrict the further exercise of that or any other right or remedy.

29. Severance

29.1 If any provision or part-provision of the Contract is or becomes invalid, illegal or unenforceable, it shall be deemed deleted, but that shall not affect the validity and enforceability of the rest of the Contract. If any provision or part-provision of this Contract is deemed deleted under condition 29, the parties shall negotiate in good faith to agree a replacement provision that, to the greatest extent possible, achieves the intended commercial result of the original provision.

30. Changes to the applicable law

30.1 If the Data Protection Legislation change in a way that the Contract is no longer adequate for the purpose of governing lawful data sharing exercises, the Parties agree that they will negotiate in good faith to review the Contract in the light of the new legislation.

31. No partnership or agency

31.1 Nothing in the Contract is intended to, or shall be deemed to, establish any partnership or joint venture between any of the parties, constitute any party the agent of another party, or authorise any party to make or enter into any commitments for or on behalf of any other party. Each party confirms it is acting on its own behalf and not for the benefit of any other

person except that HQIP enters into the Contract for the benefit of such bodies who licence the HQIP Data to HQIP, set out in the attachment to the Data Access Request Form and to the extent required by such bodies in that attachment.

32. Entire agreement

32.1 The Contract constitutes the entire agreement between the parties and supersedes and extinguishes all previous agreements, promises, assurances, warranties, representations and understandings between them, whether written or oral, relating to its subject matter. Each party acknowledges that in entering into the Contract it does not rely on, and shall have no remedies in respect of any statement, representation, assurance or warranty (whether made innocently or negligently) that is not set out in the Contract. Each party agrees that it shall have no claim for innocent or negligent misrepresentation or negligent misrepresentation based on any statement in the Contract**.**

33. Further assurance

33.1 Each party shall, and shall use all reasonable endeavours to procure that any necessary third party shall, promptly execute and deliver such documents and perform such acts as may reasonably be required for the purpose of giving full effect to the Contract.

34. Rights and remedies

34.1 The rights and remedies provided under the Contract are in addition to, and not exclusive of, any rights or remedies provided by law.

35. Notice

35.1 Any notice or other communication given to a party under or in connection with the Contract shall be in writing, addressed to the Data Protection Officer and shall be:

(a) delivered by hand or by pre-paid first-class post or other next working day delivery service at its registered office (if a company) or its principal place of business (in any other case); or

(b) sent by email to HQIP at datasharing@hqip.org.uk and to the email address provided by the Applicant in the Data Access Request Form.

35.2 Any notice or communication shall be deemed to have been received:

(a) if delivered by hand, on signature of a delivery receipt or at the time the notice is left at the proper address;

(b) if sent by pre-paid first-class post or other next working day delivery service, at 9.00 am on the second Business Day after posting or at the time recorded by the delivery service; and

(c) 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. In this condition 35.2(c) business hours means 9:00 am to 5:00 pm Monday to Friday on a day that is not a public holiday in the place of receipt.

35.3 This condition does not apply to the service of any proceedings or other documents in any legal action or, where applicable, any arbitration or other method of dispute resolution.

36. Governing law

36.1 The Contract and any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with it or its subject matter or formation shall be governed by and construed in accordance with the law of England and Wales.

37. Jurisdiction

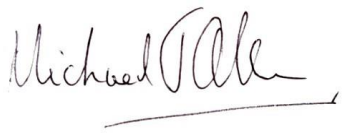
37.1 Each party irrevocably agrees that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim (including non-contractual disputes or claims), arising out of or in connection with the Contract or its subject matter or formation.

The Schedule: Data Deletion Certificate

Certificate of Destruction

Certificate of Destruction	
In accordance with the Data Access Request Form and Data Sharing Agreement, this form must be completed by applicants at the end of their data retention period and a copy sent to HQIP at datasharing@hqip.org.uk.	
Data Access Request Form reference number	Click or tap here to enter text.
Organisation	Click or tap here to enter text.
Method of destruction	Click or tap here to enter text.
Please detail the method used for destruction of the data	Click or tap here to enter text.
Date of destruction	Click or tap to enter a date.

Name:	Click or tap here to enter text.
Position:	Click or tap here to enter text.
Signature:	
Date of signature:	Click or tap to enter a date.

Section 21	Authorised signatories	
Please note that this agreement is not valid until all parties have signed and agreed this document.		
Applicant *The applicant confirms that the details provided in the application above are accurate, valid and true. HQIP reserves the right at all times to confirm that it is so. The applicant will give HQIP all reasonable assistance and access in order to confirm any matters arising from this applicant whether now or in the future. The applicant acknowledges and agrees that the application is made on and subject to the terms and conditions for use of HQIP Data and any grant of access to the data will at all times be subject also to that agreement.*	**Name**	Michael Allen
	Position	Senior Research Fellow
	Signature	
	Date of signature	01/09/2022
Clinical lead or appropriate project scientific committee chairman *The clinical lead / Chair of an appropriate audit or Outcome Review Programme Scientific Committee confirms that the information included within this application would represent a clinically appropriate usage of the data requested.*	**Name**	Dr Ajay Bhalla
	Position	Associate Clinical Director, SSNAP
	Signature	
	Date of signature	24/11/2022
Data provider (statistician, methodologist or project manager): *The provider confirms that the information included within this application represents a methodologically appropriate usage of the data requested. Where de-personalised data has been requested, the data provider confirms that the data will be appropriately de-identified before release to minimise any risk of re-identification.*	**Name**	Kaili Stanley
	Position	Stroke Programme Manager
	Signature	
	Date of signature	16/09/2022
HQIP / data controller: *Authorises release of the data described in this application as data controller.*	**Name**	Jane Ingham
	Position	CEO, HQIP
	Signature	
	Date of signature	07/12/2022
For HQIP use only *Comments to note (if applicable)*	Click or tap here to enter text.	

Once completed please return this signed form to datasharing@hqip.org.uk

Partner Organisation Form

Partner applicant	
Title of project	Click or tap here to enter text.
Primary contact within partner organisation (must be a permanent senior member of staff)	Click or tap here to enter text.
Name of partner applicant organisation	Click or tap here to enter text.
Address of partner applicant organisation	Click or tap here to enter text.

Data protection	
As a data controller your organisation should be registered with the Information Commissioners Office (ICO). Please provide the following information.	
Registered name *(if different to applicant name, please state reason)*	Click or tap here to enter text.
Registration number	Click or tap here to enter text.
Expiry date	Click or tap to enter a date.

Legal basis (of the processing you intend to undertake)	
GDPR Legal Basis	**Article 6 legal basis:** Click or tap here to enter text. **Justification:** Click or tap here to enter text.
	Article 9 legal basis: Click or tap here to enter text. **Justification:** Click or tap here to enter text.
Common law of duty of confidentiality is addressed by	**If the data you are requesting is personally identifiable please explain how you have addressed the common law duty of confidentiality below.**
	☐ **Explicit informed consent** *(please enclose consent form and patient information sheet with this application)*
	☐ **Approval under section 251 of the NHS Act 2006** *(please enclose both the application and the approval letter)*

	The section 251 approval enables the applicant to: **☐ Hold/receive personal data**	**☐ Transfer/access personal data**	**☐ Operate on and link personal data**
	☐ Other legal basis **If other legal basis selected**, please provide further information here with reference to the statute, regulation or other provision relied upon: Click or tap here to enter text.		

Security			
Each organisation processing data that is not fully anonymous as part of this project must demonstrate that they have appropriate security arrangements are in place. Please confirm whether the partner organisation has a compliant Data Security and Protection Toolkit.			
Applicant organisation **(please select one answer)**	**☐ Yes** ***If yes**, please provide evidence with this application.*	**ODS code**	**☐ Yes** ***If yes**, please provide evidence with this application.*
		Status	Click or tap here to enter text.
		Published date	Click or tap to enter a date.
	☐ No	**If no, please provide below alternative evidence of adequate organisational and technical measures; to ensure the security of processing and preserve the confidentiality, integrity and availability of data.**	
		Click or tap here to enter text.	

Retention and destruction	
Please state the date until which you are seeking to retain the data (MM/YY) and the reason. Note also that the requirement to extend the Data Sharing Agreement (if retention is requested for longer than its original term) would still apply	Click or tap here to enter text.

Please provide details of how you intend to destroy the data at the end of the retention period?	Click or tap here to enter text.
Please confirm that you will submit a certificate of destruction to HQIP within 5 business days of destruction of the data	☐ **Yes**

Authorised signatories		
Please note that this agreement is not valid until all parties have signed and agreed the HQIP application.		
Partner Applicant *The partner applicant confirms that the details provided in the application above are accurate, valid and true. HQIP reserves the right at all times to confirm that it is so. The partner applicant will give HQIP all reasonable assistance and access in order to confirm any matters arising from this applicant whether now or in the future. The partner applicant acknowledges and agrees that the application is made on and subject to the terms and conditions for use of HQIP Data and any grant of access to the data will at all times be subject also to that agreement.*	**Name**	Click or tap here to enter text.
	Position	Click or tap here to enter text.
	Signature	
	Date of signature	Click or tap to enter a date.