

Secure Data Environments for Research and Development

Frequently Asked Questions and Answers

Definitions

1) What is the difference between a sub-national Secure Data Environment for Research & Development (SDE for R&D) and a sub-national Trusted Research Environment (SNTRE)?

There is no difference between what were previously called SNTREs and what are currently called SDEs for R&D. The term 'Secure Data Environment' is now the recommended alternative term to 'Trusted Research Environments'.

2) What is a multi-disciplinary leadership team?

The following roles will be considered core to the multi-disciplinary leadership team: Finance Lead, Operational Service Lead, Senior Technical Lead, and Patient and Public Involvement and Engagement Lead. The list above should not be taken as exhaustive and the leadership team could also include other key lead roles such as Commercial, R&D, Clinical, amongst others.

SDE for R&D partnerships

1) Which organisations can submit an Expression of Interest (EOI)?

Expressions of Interest to establish an SDE for R&D must be submitted by a lead NHS organisation on behalf of all local partners in their SDE for R&D locality.

2) Which organisation can act as the Lead Delivery Organisation?

There must be a Lead NHS Delivery Organisation within the partnership of organisations named in the funding bid. This could be an NHS trust or an Integrated Care Board (ICB).

3) Does the Lead Respondent need to be from the Lead Delivery Organisation?

No. The Lead Respondent does not necessarily need to be from the Lead NHS organisation. The Lead Respondent will be the key point of contact for correspondence and follow-up questions for this Expression of Interest process.

4) Who can be nominated as Senior Responsible Officer?

The Senior Responsible Officer should be an NHS senior leader within the locality (e.g. Chief Executive, Chief Information or Chief Digital Officer), who will be accountable for successful delivery of the programme.

5) Can a university be the Lead Delivery Organisation for an SDE for R&D?

No. Every SDE for R&D must be established under NHS operational control and governance. Universities may be named as partners in an SDE for R&D locality but cannot lead delivery of an SDE for R&D.

6) Do NHS organisations that wish to collaborate in an SDE for R&D need to be in the same geographic region/area?

NHS organisations in the same region are strongly encouraged to collaborate and submit a single Expression of Interest to develop an SDE for R&D in their region. The exception is where they are already in an established partnership (e.g clinical research network) with a neighbouring region. We encourage you to discuss with the NHSE Data for R&D team if you are unclear to agree.

7) Which organisations can be named as partners in an EOI submission?

The EOI submission must be led by an NHS organisation, which could be an NHS trust or an ICB. However, it is expected that localities will also include a variety of other partners such as Local Authorities, Higher Education Institutions, Voluntary Community and Social Enterprises.

8) Should we include industry partners in our bid?

We would expect you to name any significant industry partners for your SDE for R&D in the EOI section on your key research partnerships. We would not expect any industry partner to lead the delivery, operational management, or governance of SDE for R&D. NHS data needs to remain under the control of the NHS.

9) What is the expected population coverage for an SDE for R&D?

It is anticipated that SDEs for R&D will operate at sufficient scale to undertake meaningful research. Each SDE for R&D should cover a minimum population of 3 million local people with the ability to scale to 5+ million as additional partners join the collaborative. As this is will be driven by NHS data on a regional footprint the population size will be assessed in terms of GP registrations.

Data Assets & Data Governance

1) What types of data are SDEs for R&D expected to offer?

Each SDE for R&D is expected to offer linked, near real time, multi-modal data for the local population. Over time this is likely to include structured and unstructured data from electronic health records and case management systems, diagnostic test results and images, genomics, wider social determinants of health and data from wearables and devices. Localities are expected to include a high-level roadmap and timescales for achievement of these objectives as part of their submission using the table supplied or equivalent local documentation.

2) How will you ensure a consistent approach to Ethics and Information Governance across the network of SDEs?

Agreeing a common approach to Information Governance across the SDEs is a critical component of the programme. The NHSE Data for R&D team will work closely with SDE teams (in Wave 1 and Wave 2) and other national IG, ethics and policy bodies to establish an approach and documentation set that can be utilised across the network of SDEs.

Patient and Public Engagement

1) What national patient engagement is planned?

There will be national communication to patients and the public around the Data Saves Lives strategy, which includes the development of SDEs for R&D. Specifics and timescales for this national communication exercise are to be confirmed. National activities are expected to compliment, but not replace, ongoing local patient and public engagement by the SDE R&D partnership, and local data controllers, in line with their existing legal duties.

Relationship with other initiatives

1) What is the difference between the sub-national SDEs and the NHS Digital national SDE?

The NHS Digital national SDE for R&D will provide access to national population level data, making use of existing national level data sets and registries. While some of this data may also flow into sub-national SDEs (to be determined by the sub-national SDE for R&D partnership and agreement with NHS Digital), the sub-national SDEs will include a wider range of near real-time, real-world, multi-modal data flowing from local NHS and other systems.

2) What is the relationship with the Federated Data Platform programme?

These are separate but aligned national investments. The Federated Data Platform (FDP) has five initial specific use cases, which relate to population health management and planning. The national FDP programme does not include a research use case and is not funded to do so. Localities may choose to utilise local FDP instances and capabilities to provide data warehousing, or other capabilities, that support their SDE for R&D infrastructure, as long as data is available in the right formats and timeliness to support diverse local, regional, national and international research needs.

3) How do SDEs for R&D align with HDRUK Hubs and DARE UK activities?

Across all bids, we expect to see how existing, local NHS-academic infrastructure, skills and services will be leveraged. In some geographies, this may include HDR Hubs and UKRI-funded AI Centres of Excellence. The NHSE Data for R&D team are working closely with the HDR UK and UKRI to ensure alignment in this approach.

Across the country, DARE UK projects are exploring topics relevant to the design and operation of TREs/secure data environments (for healthcare data and other domains). Where appropriate, we expect teams to build on this research in their design and approach. Further details of the projects can be found here: <https://dareuk.org.uk/our-work/sprint-exemplar-projects/>.

4) Will there be a national user accreditation service?

There are plans in place to implement a national research user accreditation service. However, there are no confirmed timescales at present for this service to be available.

Finance

1) How are localities expected to manage capital charges and depreciation costs?

SDE for R&D Directors of Finance are responsible for determining whether these costs are covered locally by a single organisation or through a contribution from partners. It is anticipated that ongoing costs beyond March 2025 will be covered by local revenue generated through the SDE for R&D commercial operating model.

2) Can funding be carried over between financial years?

Funding allocated to an SDE for R&D team must be spent in year and cannot be carried over to the next financial year. SDE for R&D finance leads should account for the funding in year but may choose to accrue locally.

3) Can the Finance Lead be from any NHS organisation?

As part of the SDE for R&D investment is Public Dividend Capital (PDC) it must be managed by a nominated NHS Trust Director of Finance. The NHS Trust is expected to account for any assets created using Public Dividend Capital in line with Standard Financial Instructions. The NHS Trust which receives investment on behalf of the locality should have a mechanism in place to distribute funding to other NHS, or non-NHS, delivery partners and to receive contributions from other partners towards capital charges and depreciation costs, such as through a Memorandum of Understanding.

4) Is matched funding required?

There is no requirement for financial matched funding. However, it is expected that localities will be able to demonstrate significant 'in-kind' investment. This may be through existing or planned local investment in technical or data infrastructure or provision of resources and subject matter experts who will contribute to implementation and operational delivery of the SDE for R&D. Localities submitting an EOI for Wave funding should include an estimate of the total value of local 'in-kind' investment with their EOI submissions. Other localities will be expected to submit details about their 'in-kind' matched funding contribution when they submit their strategic plans and business case.

5) Will there be any further national funding after 2025?

It is not expected there will be funding to establish *new* SDEs for R&D after 2025. The Data for R&D programme team will develop a case for ongoing investment in existing SDEs for R&D to enable them to scale further and become financially self-sufficient. However, we are unable to guarantee that there will be national funding beyond 2025 at this time so localities are encouraged to plan for their SDEs for R&D to become financially self-sufficient.

6) Do localities need to have an existing SDE for R&D?

Localities do not need to have an existing SDE for R&D to submit an Expression of Interest, but it is expected that those applying for wave 1 funding can meet the following criteria:

- Commitment from an NHS Trust finance director that the regional partnership can spend £1.3 revenue and £2.5m PDC this financial year.
- Commitment from NHS leadership teams that this is a system priority and sufficient resources will be allocated to facilitate delivery at pace.
- Established governance structure with representation from all NHS stakeholders to ensure effective decision making.
- Evidence of patient and public involvement in governance and decision making.
- A single Data Access Committee in place or plans to implement one.
- Plans to ensure data for research can be processed legally.
- A technical strategy for development of the SDE for R&D, including plans to build, buy or develop different components.
- A roadmap to ensure the SDE for R&D meets the mandatory SDE accreditation criteria described in Appendix B.

7) What happens if there are several bids from the same NHS England region?

Regional digital directors have been asked to support the coordination of submissions from their region and to encourage collaboration across their region. Investment will be offered to a locality within each NHS England region to ensure all regions are able to commence work on implementation of a sub-national SDE for R&D. Investment will be not allocated to more than two localities in the same NHS England region unless there has been prior discussion and agreement with the NHSE Data for R&D programme team. It is strongly advised that localities within the same region who are planning to submit separate Expressions of Interest Questions and Response template should consider opportunities for collaboration before they submit their bids.

8) How will funding decisions be made?

There will be equitable investment across the country with at least one SDE for R&D in each NHS England region receiving funding. Further details are provided in the Expression of Interest guidance document and Evaluation criteria (Appendix D).

9) Will you provide a business case template for SDEs for R&D teams to complete?

Yes. The Data for R&D team will provide a business case template to all successful localities to submit as part of their Work Package 1 deliverables.

Central hub and Community of Practice

1) What is the role of the central hub?

The 'central hub' is the Data for R&D team who will help SDEs for R&D teams to address any common delivery challenges that are identified. They will also support liaison with other NHS England teams, such as Information Governance, Chief Technology Officer, and Data Policy.

2) What is a Community of Practice and what will it do?

All SDEs for R&D are expected to join and contribute to the Community of Practice, which will initially be led by Wave 1 SDEs for R&D. These teams will share learning, create service blueprints, and contribute materials to a resource hub, which can be utilised by other teams. The Community of Practice should enable Wave 2 SDEs for R&D to make more rapid progress by learning from Wave 1 SDE for R&D activities.