North Ease and North Cumbria
TRE strategy Information

Overview

The North East and North Cumbria (NENC) Integrated Care System (ICS) has identified the development of a regional Trusted Research Environment (TRE) as a key development in it's Digital Strategy 2020-2024 (see appendix D.)

The first stage is to develop a regional strategy in early 2021. Development of the strategy will involve consultation with a range of regional stakeholders on the benefits, challenges and services required for a North East and North Cumbria TRE.

Individual conversations will be followed by an online presentation and discussion forum involving stakeholder group representatives to develop a plan for a regional service and identify priorities for development.

How will the Information from my conversation with you be used?

Information will be:

- used in both the online presentation and in the strategy document.

- conversations will be recorded to aid transcription and the recording will be retained for 6 months following the strategy approval, currently planned for April 2021.

Information and anonymised quotes from the conversations will be used in the strategy. Everyone will be acknowledged in the document. More detailed information on the approach is in appendix A 'project initiation document'.

Conversation Format

Our conversation with you will take about a 1 hour and we will be as flexible as possible to work around your time commitments.

We will ensure you have the relevant background information to support some of the questions – this information is for reference and to aid conversations as required and can be changed or disregarded at your discretion.

Useful On-line Seminar

'UsemyData' held an on-line TRE event in November 2020 which you may find useful, the notes and recording are at:

http://www.usemydata.org/webinars.php?webinar=2020-11-25

How would a Trusted Research Environment Work?

The Trusted Research Environment (TRE) is a safe environment for researchers and data analysts to perform complex analytics on healthcare data to help improve local healthcare services and citizen outcomes. The development and ongoing use of a TRE would be overseen by our local health and care organisations.

A dedicated local governance body would decide projects for the Trusted Research Environment (TRE.) This would be based on the most important regional healthcare challenges. The governance body will ensure that projects meet all legal and regulatory standards in order to proceed, and then monitor them for compliance and transparency.

Each projects aims, outcomes and governance will be fully documented and agreed by all of the organisations involved in the study, for instance a NHS hospital Trust, a Local Authority and a University.

This agreement will also define the data to be released for the project from each organisation, ensuring the project meets all necessary data security, protection and confidentiality requirements.

Any data used will be put into an anonymised format so individual people cannot be identified from it. The data will be transferred from the organisations into the TRE using secure transfer methods, where it is held in a secure 'airlock' for security and quality checking before being transferred into the TRE.

Each project will operate in a secure area within the TRE dedicated to it. Only the healthcare analysts and university researchers with prior accreditation, and who have been approved to take part in the study, can access a secure area.

Each secure area is compartmentalised, so users cannot get access to other compartments or projects, unless they are approved.

The data specific to the project is contained in its dedicated area only for the length of time required by the study, and then it is safely archived or discarded. Data cannot be removed from the TRE on an 'ad-hoc' basis. The 'master' version of the data always stays with the healthcare organisation it came from, for their ongoing use in providing healthcare services.

The users of the TRE bring together their different skills and experience to study the data in their secure area, using software tools which are part of the TRE. Each TRE project will produce findings and new tools that will help improve our local healthcare services and outcomes for citizens in our region.

Appendices

TRE Background Information

Appendix 1: NENC TRE Design Principles

A1.1 Design Principles (1): TRE Design Principles: The '5 Safes'

The NENC TRE would adhere to the '5 Safes' as developed by the UK Health Data Research Alliance as design principles for development (see Appendix C, page 10 for full definitions):

1.1.1 Safe people

Individuals allowed access to TREs should be able to demonstrate appropriate credentials. They must be hosted by organisations that are prepared to take responsibility for their actions and vouch for each individual. Users would be required to sign legally binding terms of use, including:

- not trying to re-identify individuals from data
- immediately report any security weakness found when using the system and not attempting to exploit it
- not share their login credentials with any other individual
- informing the TRE service if they are changing institutions before they have done so
- Individuals will also be required to carry out and refresh agreed information governance training and any training specific to the TRE and/or project datasets.

1.1.2 Safe project

Projects must ensure that the use of data is appropriate and has the potential for public benefit. The TRE must also have the capability to enable use to be audited to ensure compliance.

1.1.3 Safe setting

At minimum a safe setting needs to implement:

- a system to hold data securely such that individual level data cannot be exported.
- for transparency the security design and implementations should be independently audited with reports reviewed by a patient/public oversight group and made public.
- systems to allow secure remote access by users to carry out analysis with the ability to keep track of user activity (to ensure compliance with "safe projects") and that ensures accounts cannot be shared (to ensure compliance with "safe people").
- an environment containing a set of tools to allow data to be analysed.

- Because the types of analysis that users wish to carry out will go beyond that which can be provided by standard statistical packages (e.g. SPSS) it must also be possible for users to bring their algorithms into the safe setting. This would require 'air lock' capability to ensure that imported tools are scanned to ensure that they will not compromise the security and integrity of the TRE and in particular, do not facilitate the export of record level data.
- Similarly, because researchers may wish to analyse data in the safe setting along with data held outside, the safe setting must provide mechanisms to support importing and linkage of data. As with tools, this will require 'air lock' capability to allow for the secure importing of user supplied data.

1.1.4 Safe data

- TREs should also ensure that the data accessible to users within the safe setting is as non-disclosive as possible and in line with GDPR requirements, (or any revision due to the UK leaving the EU.) This means ensuring processes to import data into the safe setting carry out de-identification to ensure individuals cannot be directly identified and, where possible, anonymisation of fields where this will not impact research analysis but will reduce the risk of accidental re-identification of individuals.

1.1.5 Safe outputs

- As outlined in Safe Setting (1.1.3) TREs must implement a barrier (or "air lock") between the safe setting environment and the outside world to prevent unauthorised data export.
- TREs must implement processes and systems to allow approved data to cross this barrier (air lock.) Systems require functionality to track requests and decisions, supporting cycles of rejection and revision.
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Appendix 2: Draft Trusted Research Environment Definition/Characteristics

TRE Definition - Short Version

The Trusted Research Environment is a safe environment for researchers and data analysts to access and perform complex analytics on healthcare data.

TRE Definition - Long Version

The Trusted Research Environment is a safe environment for researchers and data analysts to access and perform complex analytics on healthcare data.

The TRE supports improvements and innovation and brings benefits such as economies of scale as researchers and healthcare and analysts don't need to develop their own environments. It keeps the data safe as it can't be removed and is only used for its specified purpose.

Researchers and analysts can apply complex mathematical modelling tools to the TRE – which means they can gain valuable insights for applications such as research and service improvements.

By working together and having a regional TRE we can share the investment and, with robust governance and security, help researchers and analysts get access to data which will facilitate collaboration across sectors and improve outcomes and insight for our population.

Characteristics of a TRE

- A public cloud based service to industry and public sector standards (e.g. ISO27001.)
- Dynamic scaling with capability to store significant data-sets on a regional scale
- Use for a range of analytical purposes including research, support for service improvements and planning.
- High performance computational capability to support complex algorithms
- Provision of industry standard analytics software tools
- Secure workspaces for each approved project with access limited to defined people and machines and secure 'air-locks' to allow secure import of data and algorithms.
- Secure data transfer, encryption, storage and disposal.
- Ability to link agreed and approved datasets securely
- Effective TRE user support processes
- Provision of secure access services (e.g. HSCN) and internet facing services
- Some data storage, virtual workstations and application hosted solely on HSCN.
- Secure access using virtual machines and user authentication (e.g. 2-factor.)
- Information security:
  - Confidentiality: data is only accessible to authorised individuals in transfer, storage and analysis processes
  - Integrity: no data is lost or corrupted

- o Availability: best efforts to provide safe and secure access at all times.
- o Disaster \ business recovery processes
- Ability to federate securely and safely with other approved and agreed TREs where appropriate
- A clear and robust quality / governance management system to industry standards including
  - o Governance system to safely and securely manage usage and access including project approval, prioritisation and monitoring
  - o A fully resourced TRE planning and operational management system, with clear roles, responsibilities and accountabilities
  - o Documented protocols, contracts and agreements for all usage including projects and use of data (e.g. research purpose, service improvement, evaluation), breach protocols and liability protection.
  - o Documented information governance protocols, templates and processes ensuring compliance with relevant regulations and standards including GDPR and NHS Digital Data Security and Protection Toolkit (DSPT.)
  - o Monitoring and audit capabilities, including breach protocols
  - o Data quality management processes and protocols to agreed standards
  - o Data management including encryption protocols ensuring data access is to only accredited users
  - o User accreditation, training, access controls and monitoring including internal processes to manage personal data of any users of the system
- A clear public engagement and communication process to build and sustain public trust and involvement
- Capability to use both anonymised and identifiable datasets with public transparency and oversight, with protocols for recording population preferences.

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Reference Information / Optional Reading

Appendix A: TRE Strategy Development Project Initiation Document

NENC TRE Strategy
PID v1.0.doc

Appendix B: Overview of UK TRE Developments

Overview of United
Kingdom TRE Develop

Appendix C: UK Health Data Research Alliance TRE paper

UK Health Data
Research TRE Green F

Appendix D: NENC ICS Digital Strategy 2020-2024

NENC ICS Digital
Strategy 2020_v011_D

Appendix E: Great North Care Record Technical Vision (July 2017)

GNCR Technical
Vision.pdf