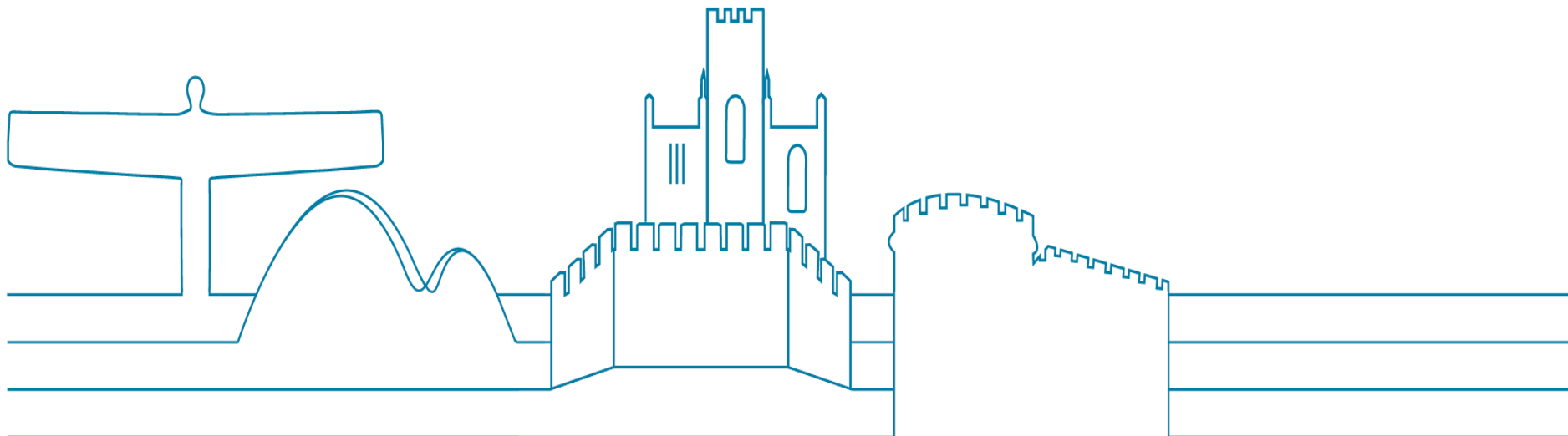




Trusted Research and Evaluation Environment (TREE) Strategy

Mark Walsh
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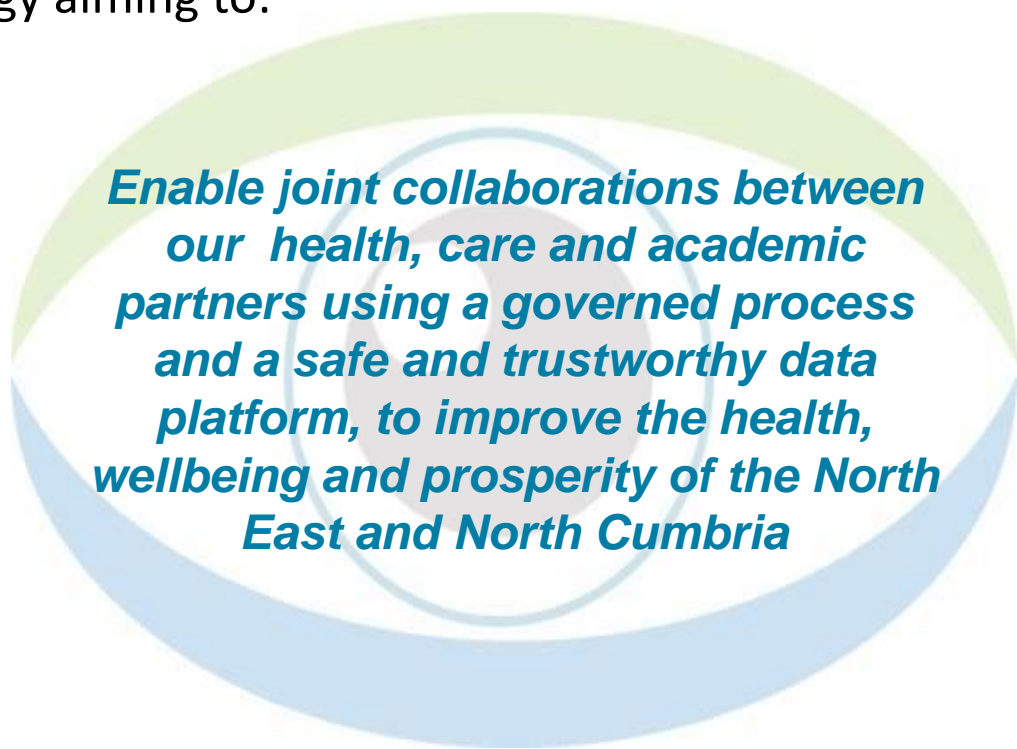
Status: Final
May 2021



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TREE Vision

The Trusted Research and Evaluation Environment (TREE) is a fundamental component of the North East and North Cumbria Digital Strategy aiming to:



Enable joint collaborations between our health, care and academic partners using a governed process and a safe and trustworthy data platform, to improve the health, wellbeing and prosperity of the North East and North Cumbria

Achieving the vision will require partnership working and leadership from across our health, care and academic sectors

TREE aims and objectives

The TREE strategy is fundamentally about providing a capability based on common governance, processes and a data platform to support evidence based transformation, requiring close alignment of our health and care system and our academic partners with joint leadership to:

Unlock the value of our data by bringing together the expertise and knowledge of our regional academic, health and care communities, in partnership with our citizens, to improve and sustain better health and well-being outcomes in our region.



Enable an evidence based regional care system to better understand our health trends and challenges, inform decision making and provide intelligence towards better delivery of healthcare outcomes and improvements (a *learning health system.*)

Enable joint collaborations to focus on local health and care priorities and opportunities for service improvements, innovative treatments and evaluation.



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TREE aims and objectives



Support for learning resources for teaching and skills development for our current and future workforce

Provide a capability recognised by all our stakeholders as inclusive, accessible, safe, secure, ethical and well governed




Have a nationally recognised TREE of choice for future industry collaborations, generating funding for regional health and care improvements

Strategic outcomes

The TREE will provide a number of strategic outcomes to support the regional health and care ambitions.

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Developing public and partner trust and assurance on use of data through a transparent, safe and effective capability

Cultivating our health, care and academic expertise through collaboration and a 'learning health system', to improve real-world, regional challenges

Delivering projects that are focussed on improving our populations health and wellbeing, using a safe and secure data analytics capability




Providing a nationally assured, safe, scalable and sustainable capability to support the regions digital development and economic growth

National and regional context

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The NHS England NHS Long Term Plan (January 2019) sets out the need for health and care reconfiguration with closer integration based on population need and more personalised care, moving to Integrated Care Systems (ICS).

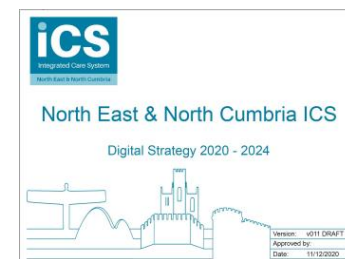
The North East and North Cumbria (NENC) ICS moves from shadow form to a formal entity in April 2022, bringing together local organisations to redesign care and improve population health, creating shared leadership and action based on four regional Integrated Care Partnerships (ICPs.)

The NENC Digital Strategy 2020-2024 aims to support this transformation by providing agile solutions allowing information to be available when and where required, and by making better use of data to understand local health trends, service requirements and to develop innovative new treatments and technologies using services including the TREE.

The NENC TREE will also support the regional research agenda and national initiatives including Health Data Research UK (HDRUK) and the UK Health Data Research Alliance.

The COVID-19- pandemic has demonstrated the need for rapid use of timely data to monitor regional and sub-regional health and care trends, inform service requirements, develop new treatments and evaluate interventions. The TREE will support this through project based collaborations using regional and national data, working within the NENC population health management agenda.

Being trustworthy is key to the TREE: with our public in allowing their data to be used for the right purposes in a safe and secure environment and based on their individual preferences; and with our organisations requiring timely, meaningful insights while knowing that the data they control is being used safely and appropriately.



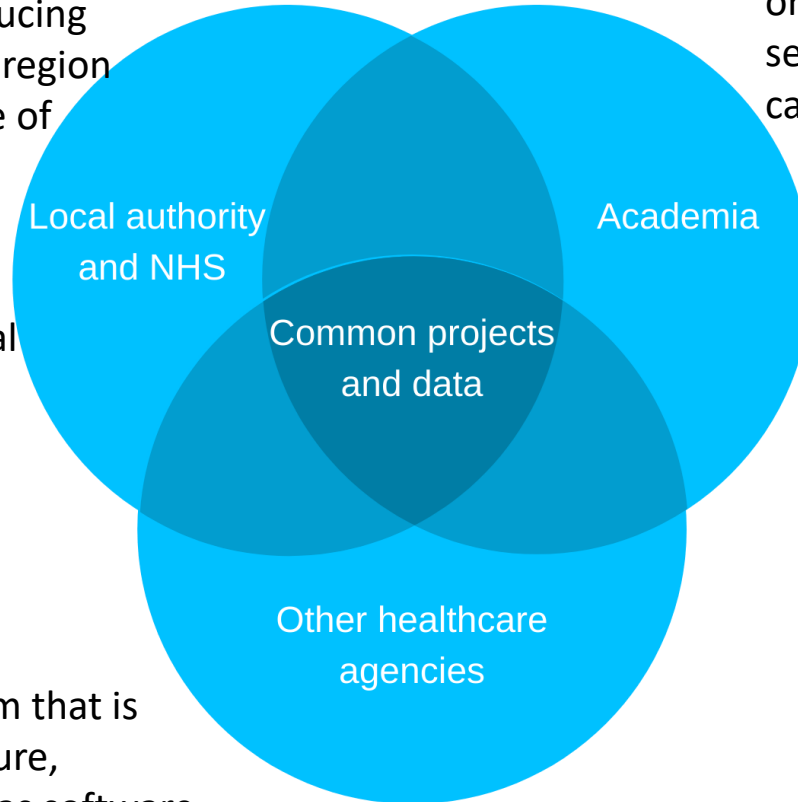
What a TREE Provides

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A focus on improving health and care outcomes and reducing inequalities in our region through better use of data

Support for national and international research studies involving regional organisations

A data platform that is governed, secure, scalable and has software and tools embedded



Value in project collaborations between organisations and sectors using a common capability

Support for agreed, priority projects including organisational or place based service improvements, evaluation and research

Brings together knowledge and skills from different sectors around a common question or problem

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TREE Overview

1 Dedicated governance reviews the aims **outcomes** and **priorities** of each TREE **project** before approval

There is **transparency** on **outcomes** for organisations, governance and public groups.

The project agreement defines and assures what happens to the **data** when the **project ends**.

8 Authorised users can **only access assigned projects**

7 **Access** is only by an approved **remote connection** via a secure laptop or pc

2 For project approval the **data management arrangements**, including **legal basis** for use, is agreed with the health and care providers as data controllers

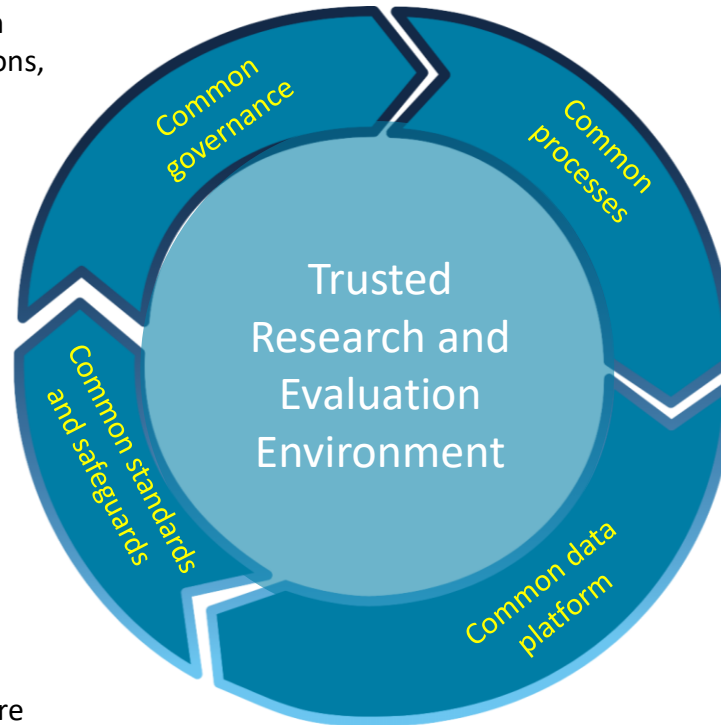
3 a. Each approved project has **secure dedicated space** within the TREE platform

3 b. **Data cannot be removed** without authorisation

3 c. Approved analytics **software is provided** in the TREE and projects can securely add bespoke algorithms

4 a Data is **security checked and cleansed** in a secure area before being made available to the TREE project.

4 b Data can be **bespoke** (one-off) or from a **regional regular flow** and can include **external sources** such as ONS or meteorological



5 Data is typically **anonymised or pseudonymised**. The use of patient identifiable data will be reviewed for applicable future projects ensuring the right governance.

5 Data from different organisations and sectors can be **linked**

Supporting the NENC Digital Strategy

The TREE supports the five core inter-linked themes of the Digital Strategy



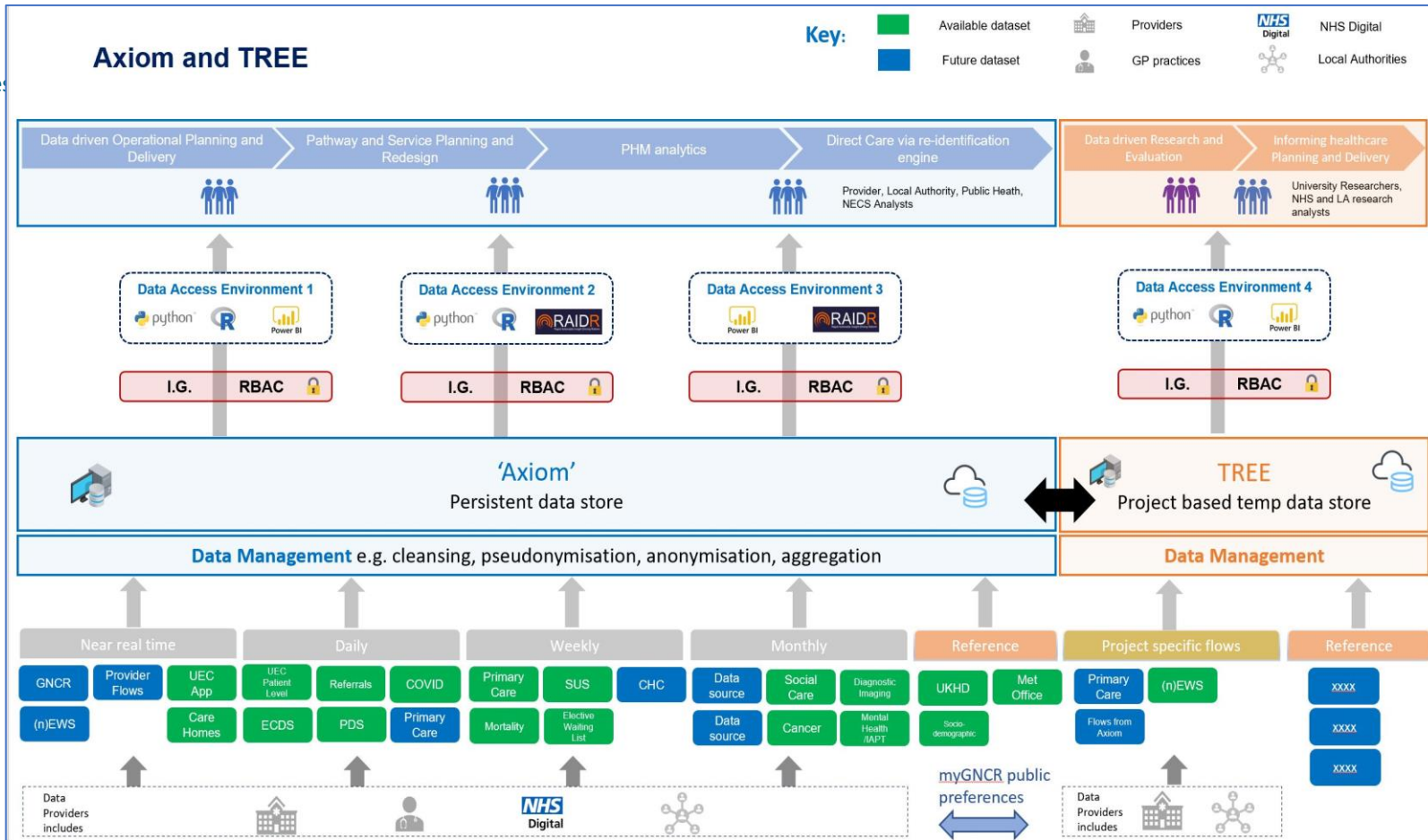
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Support for NENC Digital Strategy

Consistent and quality data will be available to the TREE from the emerging regional data service 'Axiom.'

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The TREE is part of the regional Digital and Population Health Management programme and will aim to integrate with products and share services.

Our Partners and Projects

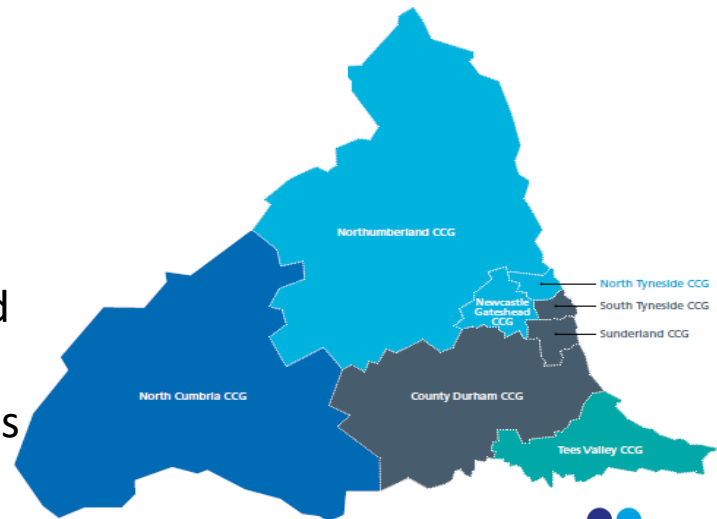
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We will develop our initial core partnership as the TREE progresses to include other organisations involved in our regions health and wellbeing

- Regional partners include:
- Public groups
 - Local authorities
 - NHS
 - Universities

The TREE will focus on health and care projects for the citizens and organisations of the North East and North Cumbria, with support for agreed UK and international studies



TREE case for change

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For our public

The TREE will provide increased understanding of how data can be safely used to deliver new and innovative health and care services and treatments. The capability will provide transparency on data sources, how the data is used and what outcomes it leads to. It will empower our public through their representation in its governance and by using individual preferences for data-sharing through interacting with tools such as MyGNCR



For the NENC region



The TREE will provide a common capability for collaborations between our health, care and academic sectors to focus on local challenges, improvements and innovations. The TREE will help develop a more skilled workforce, research leaders and attract new talent and funding, while also positioning the region for national collaborations and future industry partnerships.

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For our universities

The TREE provides our six Universities with a common capability to improve collaboration with the regional health and care system, on projects and studies that will have a direct and measurable impact on local healthcare. It will be the default environment for access to linked, timely healthcare data in a safe, secure and governed environment with appropriate policies and standards. The TREE will attract undergraduate and post-graduate researchers providing educational, research embedded teaching and learning and post graduate training opportunities.



For our health and care orgs

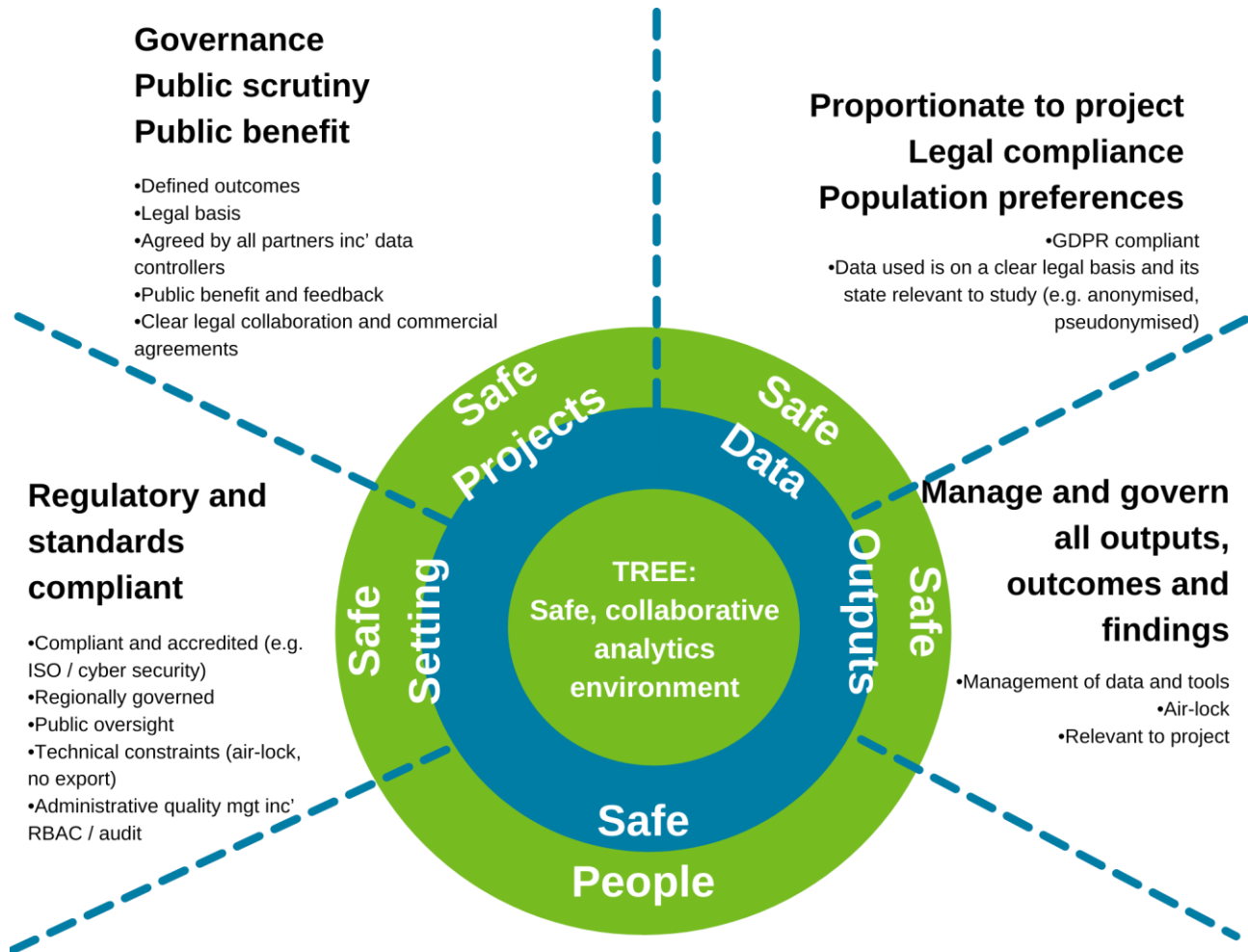


NHS and local authorities need an environment to support collaboration with healthcare partners, while harnessing the expertise of our universities in order to rapidly evaluate and improve services and to provide a common innovation and research capability. The TREE provides a safe environment meeting relevant security and technical standards, where data can be linked and accessed overcoming infrastructure constraints.

TREE principles: the '5 safes'

Common principles to develop the collaboration and provide assurance

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Governance
Public scrutiny
Public benefit

- Defined outcomes
- Legal basis
- Agreed by all partners inc' data controllers
- Public benefit and feedback
- Clear legal collaboration and commercial agreements

Proportionate to project
Legal compliance
Population preferences

- GDPR compliant
- Data used is on a clear legal basis and its state relevant to study (e.g. anonymised, pseudonymised)

Regulatory and standards compliant

- Compliant and accredited (e.g. ISO / cyber security)
- Regionally governed
- Public oversight
- Technical constraints (air-lock, no export)
- Administrative quality mgt inc' RBAC / audit

Manage and govern all outputs, outcomes and findings

- Management of data and tools
- Air-lock
- Relevant to project

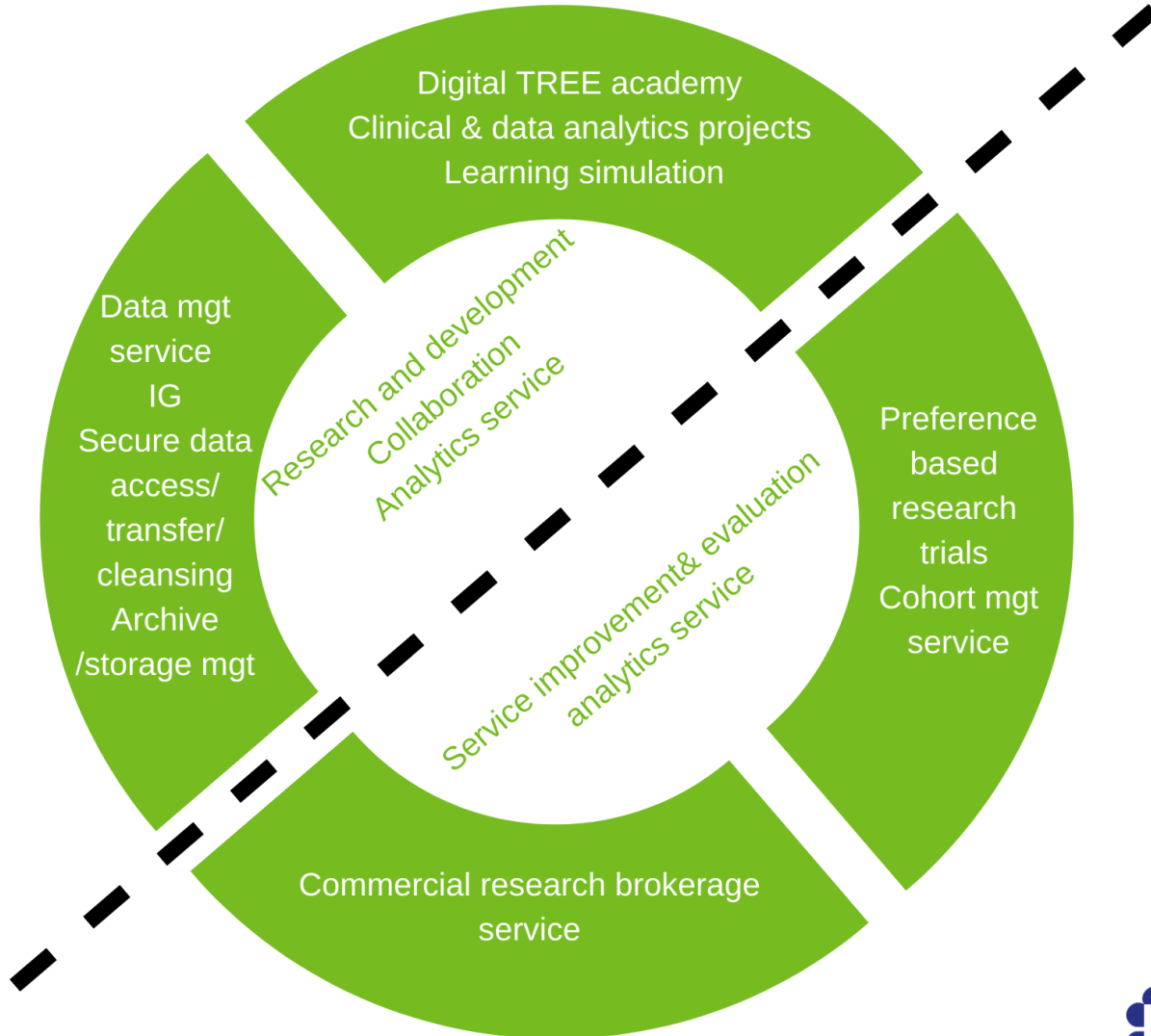
Accredited and trained
Compliance with TREE ethics

- Trained and accredited users
- Contract for use
- No re-identification or extraction

TREE Applications

The TREE has a range of potential applications:

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TREE Applications - Priorities

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The first priority is to create the platform to **allow projects to be setup and governed** and have a **secure and compliant data management service** with access, information governance, extraction, cleansing and disposal or archive. We will work with the regional Population Health Management programme to provide this service for ‘bespoke’ data-flows (project specific.) We may use an interim hosting platform to allow the NENC TREE to progress and initial projects to start.

We will monitor developments in the regional Population Health Management programme regarding provision of **regular data flows** from our provider organisations. These could be used for a range of regional purposes including for applicable TREE projects.



TREE Applications – Future Potential Applications

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The TREE could provide data in a safe, secure way for **clinical and data analytical learning simulations**. The region has current clinical pathway simulations and informatics training, which require use of ‘real-world’ data that is anonymised or synthesised. This would support workforce development programmes, under graduate and post graduate training and learning in ‘actual’ systems, data analysis and interpretation.



Regional research trials and cohort management support : using public preferences from tools such as MyGNCR, to identify and recruit cohorts of potential consenting participants for regional and national research and trials. This could also include services such as project design and data advisory.

TREE Applications – Future Potential Applications

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When the TREE is established with robust governance and policies we will review the potential for a **commercial research brokerage service**. This will support partnerships with industry (e.g. pharmaceuticals) for the development of new treatments and techniques on behalf of the region, with the potential of new funding sources for the North East and North Cumbria health, care and research communities.



This will require rigorous review prior to proceeding, with transparent governance and public representation.

Governance and accountability

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The TREE will have governance representation from the public and the organisations and sectors involved, ensuring rigour on the environment and it's use while assuring that services are efficient and accessible.

ICS governance will be through the regional Digital and Population Health Management Boards.

A TREE Board will provide strategic direction, investment decisions, oversee the funding and business model and provide performance accountability

A Steering Group will oversee the TREE implementation; partnership and policy development; procurement; project approval and governance; and review service performance.

Projects and services will be accountable to the TREE Steering Group



TREE assurance and expert groups

Vision

Strategic outcomes

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The TREE will require groups that can provide guidance, advice and support to the TREE governance.



A Citizens Forum to advise on development and monitor TREE use and outcomes, with governance representation

Technical Group to advise and monitor infrastructure, information governance and data developments and ensure compliance with appropriate standards and regulations.



Ethics Group to advise on the use of data for the specified purpose

Expert User Group to advise on potential projects/applications and look at future project resourcing opportunities



Joint Universities to review funding opportunities and joint working, project resourcing and evaluation opportunities.

We will use current groups where available and recognise that local protocols currently exist

Services required to support the TREE

The TREE will provide services to support everyday use:

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Data management to liaise with our providers to securely extract, quality assure, cleanse and transfer data into the TREE; ensure data is appropriately anonymised/pseudonymised and monitor for appropriate use.



Information Governance to define and monitor security and information protocols and ensure regulatory and legal compliance.

Business Support for formal agreements between partners and projects with support including finance, procurement, IPR, funding opportunities and research.



Analytics Support for training, access control and provision of tools.

TREE Development Roadmap

We will design for the future so applications can be accommodated as they are prioritised

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The TREE strategy goes for approval to the regional Digital Delivery Group on 6th May 2021.

When approved we start the implementation as outlined in this strategy



Achieving the vision will require partnership working and leadership from across our health, care and academic sectors

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The following pages provide an overview of the implementation approach and more detailed activities to supplement the roadmap plan.

Appendix

Overall TREE Organisational and Change Strategy

Current Stage

TREE Planning & Preparation

- Establish program & governance
- Agree integrated TREE strategy devt plan
- Design / safe principles
- Voices exercise
- Define point B & target outcomes
- Define point A – where are we now?
- Gap analysis & key devts
- TRE strategy planning
- Case for Change
- Create the right infrastructure - steering group, change support team, design teams
- Workstream infrastructure built
- Prepare senior players to lead the change
- Decision making process finalised (roles, responsibilities, ARIAS)
- Funding
- processes developed

Engage & Mobilise

- Communications strategy & tools
- Creating a shared vision & early / breakthrough with public / key stakeholders
- development of TREE governance and public forum group for TRE input and involvement
- Stakeholder input to the TREE
- External benchmarking

Start up - Breakthrough wins - 3-5 'bespoke data flow' projects on interim platform

- Breakthrough projects developed and implemented
- Interim platform , support service & digital infrastructure agreed to launch & sustain priority projects
- Funding agreed and Initial Procurement delivered

Integrated design & devt

Technical infrastructure design

Incl integrated TREE platform and agreement on real time data mgt tech & support system & Hosting

Accountability \ authority \ Governance

QMS design , incl public role in governance
Collaboration & Commercial model

Innovation \ research & TRE wrap

around support system design including employment models & TREE digital academy

Phase 1 start

Up of integrated TREE

- Consultation completed
- TRE platform fully developed – detailed design complete
- Digital \ technical platform ready
- Initial support service agreed and recruited
- Governance and collaboration system agreed
- Business case & implementation plan developed
- Communications in place
- Cases signed off
- Funding and data sharing permissions all in place
- Implementation resource in place
- Go Live

TRE sustainability and development

- Implementation of phase1 devt
- Develop stage 2&3 plans
- Full regional, TRE and infrastructure in place
- Federation process and proactive bid development
- Commercial sustainability and industry collaborations developed

Jan – May /2021:

2021 /2022

2022 /2023

Stages in the 'TREE' Development

	Start- Up service Bespoke data flow and data mgt	Phase 1 Service Development Regular data flow from NHS providers and enhanced data mgt*	Phase 2 Service Dev' Enhanced data flow and federation	Phase 3 service devt – review & learning and development / patient recruitment	Phase 3
Technical / organisational	<ul style="list-style-type: none"> • TREE technical specification , standards & organisational design agreed • Hosting & Governance inc' ownership arrangements established • TREE procured/identified to deliver 3-5 projects • Core TREE operations team agreed and set up • Information governance and data management support system established • Design teams and expert group in place 	<ul style="list-style-type: none"> • Regular data flow system from acute designed • Data quality standards agreed • Regular flow system, tested and agreed • TREE capacity and data management support increased to manage regular flow • IG and ethics processes developed to include approving access to regular data flow 	<ul style="list-style-type: none"> • Additional data sources for regular flow development agreed (e.g. LA, 3rd sector etc) • Additional data sources development plan agreed • Phased addition of additional data sources • TREE federation plan and requirements developed 		
Partner, commercial, legal, arrangements	<ul style="list-style-type: none"> • Legal and policy / collaboration frameworks agreed for partnership • TREE start up plan , funding and legal contracts in place • Core TREE costing / funding model agreed • Commercialisation/ external projects / IP processes agreed 	<ul style="list-style-type: none"> • Legal and policy frameworks and collaboration agreements reviewed • Data transfer costs and additional resource needs agreed 	<ul style="list-style-type: none"> • Legal and policy frameworks and collaboration agreements reviewed for additional data flow and federation • Data transfer / federation costs and additional resource needs agreed 		
Key governance activities	<ul style="list-style-type: none"> • ICS partners including public engagement links and structure established • Terms of reference for steering groups and support / operations teams - clarity on ARIAS / RACI • Prioritisation/approval of 3-5 initial projects • QMS established including user skill requirements / TREE use protocols • Due diligence on TREE set up 	<ul style="list-style-type: none"> • Public engagement consultation and involvement ongoing in design • QMS reviewed and updated for regular flow • Due diligence review on new arrangements 	<ul style="list-style-type: none"> • Public engagement consultation and involvement in design • QMS reviewed and updated for regular flow • Due diligence review on new arrangements 		<ul style="list-style-type: none"> • Full legal entity established

*dependent on NENC pop health management programme development