

Consultation by Health Data Research UK (HDR-UK)

[Response from use MY data](#)

Subject: Project: Aligning approach to Trusted Research Environments

Document: “Trusted Research Environments (TRE): A strategy to build public trust and meet changing health data science needs”

Closure: 21 May, 2020

Sent to: enquiries@hdruk.ac.uk

Background to the consultation:

In March 2020, the UK Health Data Research Alliance hosted a workshop “that brought together a community of experts interested in improving the use of data for research in a safe and ethical way through the development of TREs”

The outputs from this workshop informed the draft of a Green Paper which is now open for wider consultation, until 21 May 2020.

Introductory Note

We asked the members of the use MY data Advisory Group for views on the content of the consultation, which we have incorporated into a coordinated use MY data response.

We have also drawn from previous work we have done with our members, within our workshops and other projects which we have undertaken, to bring as wide a response as possible.

As with all the responses we collate on behalf of use MY data, these may contain contrasting views from members. It is inevitable that we will receive a range of views from members, and all these will be included in our response. We have always seen our ability to represent contrasting views as a strength.

Our members have been extensively involved in conversations about the uses of wider data, and have previously responded to consultations on Artificial Intelligence, the Centre for Ethics, the National Data Guardian and the National Data Strategy.

We hope that the comments from use MY data are helpful.

We are happy to be contacted by the consultation team, and we are happy for our response to be shared as required by the consultation team. Our response, once submitted, will also be added to the use MY data website (www.useMYdata.org.uk)

Any contact should be made through Alison Stone, use MY data Coordinator, at alison@usemydata.org.uk

On behalf of the use MY data Advisory Group



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Responses to the consultation

The significance of the role of Trusted Research Environments (TREs) was recognised by our members. Some specific points which were raised were:

“On the basis of seeing how researchers struggle to meet the IG requirements for use of data when it is passed to them for analysis on their own organisation’s infrastructure and the researchers’ time wasted and the funder’s funds wasted on trying to meet the IG requirements I am a firm supporter of the concept of TRE’s.”

“The five or possibly as proposed six ‘safes’ seem a good overarching structure for validating the infrastructure and its controls, the data to be held, the researchers and the research aims and methods. The consultation principally asks for how the ‘safes’ should be implemented. I don’t have the competence to draft something of value on that but I would like the opportunity to comment on drafts by older(?) and wiser people.”

“One further observation is that when I first started to read I suspected it was a power grab by HDR i.e. they would set up an overarching UK health TRE. I was pleased that it did not in the end go down that route but suggested a range of parallel TRE’s. Obviously, whilst supporting this approach, it will introduce its own bureaucratic problems/delays in getting TRE operators to cooperate for data linkages and will mean the data cannot be anonymous but at best pseudonymised. There are obviously lots of issues to be worked through on that.”

Commenting on the contents of the [Workshop Report](#), we were encouraged to read:

“...it is particularly important to consider PPIE when thinking about TRE accreditation and capture and public and patient views”

“the importance of involvement of patients and the public at each stage of the process:

- o Setting the rules and governance*
- o Defining the standards*
- o Data Access Committee membership”*

“Need a widely accepted approach to accreditation that would meet the requirements of data custodians, regulatory bodies and patients and public representatives.”

“Perception of Safe Users influences public trust. Academic research is generally more easily accepted than health data research by multi-national pharmaceutical companies. Thus, it is particularly important to consider PPIE when thinking about TRE accreditation and capture and public and patient views”

We would agree with all these points.

There were some quite specific comments from our members on the [Workshop Report](#), which are shown below:

Requirements

Bullet 2 - *‘Some data custodians already implement and use a subset of ‘Five Safes’, but a common agreed set of rules and specifications for TREs would be extremely helpful to build understanding across communities and to facilitate access to and use of health data in a safe analytical environment.’*

“Totally agree and is fundamental to the development of public trust! (which should be highlighted within the bullet text. Same comment applies to bullet 4.”

Bullet 3 - *‘TREs should permit software and algorithms to be imported...’.*

“A balance needs to be struck between the time to check the safety of imported software and delays that such checks would inevitably introduce. This is an additional aspect where there would be public concern & reassurance around the appropriateness of risk mitigation steps.”

Bullet 4 - *‘The adoption of common standards’*

“These need to apply to access guidelines/ethics and I would strongly favour a ‘one-stop’ approach covering all TREs - in order to speed data access”

Bullet 7 (PPIE)

“Totally agree but it needs to go beyond this. Not only does that involvement have to be meaningful (as opposed to tokenistic) but there needs to be public awareness of such involvement”

Bullet 8 *‘Cultural Change’*

“Providing that a ‘no worse’ environment, functionality & governance is provided, then use of TREs for this data could be mandated i.e. no other option cultural change - is this a practical suggestion?”

Final Bullet *‘Perception of Safe Users influences public trust.’ This is not just about Safe Users but all of the five safes. ‘... capture and public and patient views.’*

“No. This could be interpreted as the classic tokenistic approach - there is a need to not only capture views but to let those views shape development AND a need to feedback about what specific impact those views had.”

“Is there a need to have a requirement regarding avoidance of data duplication & competition and encouragement a spirit of of collaboration between TRE’s?”

TRE Federation

Bullet 7 - *'The concept of accredited researchers or safe people might also be different for different TREs, where individuals may have expertise with different data types and data users may be regarded as safe for one TRE and not for another.'*

"Really? Depends on how 'safe' is defined. Are we in danger unnecessarily introducing complexity by this?"

Bullet 8 - *'Potential risk of data leakage if a single TRE hosts data from different projects with different access rules.'*

"Not sure I follow the logic here about potential for leaks - surely simpler if the access rules are the same across all TREs"

On the contents of the [Green Paper](#), we think that the Green Paper nicely describes the case for TREs (page 7). We noted the comment that:

"It is now being circulated for wider consultation with patients, the public, researchers and innovators to determine best practice approaches for research on UK health data. The intention is to consolidate feedback into an updated paper and implementation plan for sharing at the HDR UK One Institute Event on 16th June."

We were pleased that this was an explicit aim, but the mechanism for wider patient and public consultation was not entirely clear. This is important when the Green Paper highlights that:

"achieving the confidence and trust of patients and the public in the use of this data is central to achieving our vision."

We would agree.

Specifically on next steps, one key point is summed up by a member:

"On the assumption that there will be a second phase of consultation when more specific proposals are available, I hope that patients will be fully involved to comment on those."

On this last point, we would be happy to work with you on this.

About use MY data

use MY data is a movement of patients, carers and relatives

use MY data supports and promotes the protection of individual choice, freedom and privacy in the sharing of healthcare data to improve patient treatments and outcomes.

use MY data endeavours to highlight the many benefits that appropriate usage of healthcare data can make, to save lives and improve care for all.

use MY data aims to educate and harness the patient voice to understand aspirations and concerns around the use of data in healthcare delivery, in service improvement and in research, aimed at improving patient decision making, treatment and experience.

Our vision

Our vision is of every patient willingly giving their data to help others, knowing that effective safeguards to maintain the confidentiality and anonymity of their data are applied consistently, transparently and rigorously.

What we do

- ❖ We promote the benefits of sharing and using data to improve patient outcomes with sensible safeguards against misuse.
- ❖ We act as a sounding board for patient concerns and aspirations over the sharing and using of data in healthcare and health research.
- ❖ We provide learning resources for patient advocates on patient data issues, including:
 - hosting workshops for patients and the public, focussing on topics related to patient data
 - a library of resources of data security, consent
 - narratives from individuals about how collecting, storing and using data can help patients.
- ❖ We advocate public policy that supports the effective use of patient data within appropriate frameworks of consent, security and privacy, and with the aim of providing benefit to patients and their health care services.

www.useMYdata.org.uk
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 [@useMYdata](https://twitter.com/useMYdata)