TRE Accreditation Frequently Asked Questions

Version 1.0 January 2023

Pre-accreditation application

How do I decide whether my organisation needs to apply for accreditation?

The default route for the majority of research will be via the Our Future Health Trusted Research Environment. It is most likely your research needs will be met this way. Materials describing the Our Future Health TRE features and functionality are available on our website.

However, there could be occasions where the Our Future Health TRE may not be able to meet certain specific research requirements and an organisation may decide to apply to accredit its TRE. You can read more about this on our website.

Why are you making the data available in multiple TREs?

The Our Future Health trusted research environment will be the default route for the majority of researchers accessing our data. We recognise that there could be occasions where it may not be able to meet certain specific research requirements. For example, this may be because organisations already have their own large datasets that can't be moved for legal reasons. Or because they have developed complex software or analytical tools that would be hard, or even impossible, to recreate in our research environment. So, when there is a good reason for doing so and they are able to meet the same strict standards as our own TRE, we will allow other trusted research environments to host de-identified Our Future Health data to run approved research projects.

You can find out more about this in our TRE accreditation policy, which can be found here.

How much does accreditation cost?

Costs are all outlined in our accreditation fee document, which can be found here.

When does the accreditation process open and close?

The accreditation process is currently accepting applications. It is intended that the accreditation process will remain open for the foreseeable future. Six months' notice will be given before we stop accepting accreditation applications.

How do I get support?

In the first instance, refer to the comprehensive accreditation documentation. The core documents can be found here. Supplementary documents will be shared with you once you begin your application.

Once you have read the documentation, if you need further support and have not yet begun an application, email treaccreditation@ourfuturehealth.org.uk.

If you have begun an application, email the assessors at ourfuturehealth@Dionach.com.

Which organisations are eligible to apply for accreditation?

Accreditation is open to all research organisations, except large commercial organisations that aren't Our Future Health founding members. You can read more about our agreements with founding members here.

Examples of organisations that are eligible to apply include: our founding members; small and medium size enterprises (companies with fewer than 250 employees and a turnover of less than

€50m); academic institutions; charities; and NHS organisations. Eligible organisation must conduct research studies.

Who will review the accreditation application?

A third-party assessor, Dionach Ltd, was appointed via a Request for Proposal process. Dionach is an independent global provider of information security solutions, is [ISO 27001 certified](#), a [PCI-Certified security assessor](#), and is approved by the [Council for Registered Ethical Security Testers](#).

Dionach assess the applications by following a risk-based scoring system. The scoring system can be seen in the self-assessment questionnaire, found [here](#). The assessment includes submission of a self-assessment questionnaire, related evidence, and attendance at interviews with the assessor. Refer to the accreditation of a trusted research environment standard operating procedure for more information, which can be found [here](#).

Can my organisation apply to accredit a TRE if the data will be stored outside the UK?

All data must be held and processed in accordance with the UK GDPR. If your organisation plans to apply for an accredited TRE which hosts the data outside the UK, a Transfer Impact Assessment will be conducted as part of the accreditation assessment. Whether this is necessary, along with your eligibility to apply for accreditation, will be confirmed following receipt of your declaration of interest form.

Following the Transfer Impact Assessment, technical, operational and contractual controls will be put in place to ensure adherence to the UK GDPR.

How did you develop the accreditation process?

The Our Future Health accreditation process was developed during 2022 working with legal, data governance and security experts and in close consultation with others in the wider life sciences ecosystem, including our charity and industry partners; other health research organisations; government leads in all UK nations; the NHS; the Information Commissioner's Office; our own Public Advisory Board and wider members of the public. Our Future Health's Technology, Scientific and Ethics Advisory Boards, and a specific Technology Task Force, made up of experts from across the life sciences sector, have provided input throughout.

The final process is based on well-established and regarded standards and frameworks, such as the Office for National Statistics Five Safes framework, the UK GDPR, and international cyber security standard ISO 27001.

How does my organisation apply for accreditation?

In the first instance, you should refer to the accreditation of a trusted research environment standard operating procedure, which can be found [here](#).

The first step is to submit the declaration of interest form, found [here](#).

Is the Our Future Health TRE accreditation the same as the NHS England secure data environments accreditation?

The Our Future Health TRE accreditation process is separate from the NHS England process. However, we have worked closely with them as we have developed our process to share best practice and to align where possible. We continue to engage with them as they develop their

process. Our Future Health have reused existing frameworks and standards (such as UK GPDR and ISO 27001) where possible.

How can we benchmark our application?

A scoring guide is provided within the self-assessment questionnaire, found here.

How long will it take to receive accreditation?

Timings are set out in the accreditation of a trusted research environment standard operating procedure, found here. The maximum timeframe from receipt of application is 90 days.

How is this related to the Access Process?

All researchers (no matter which accredited TRE they plan to work within) must submit their studies to the Our Future Health Access Board via our Access Process. The Access Board will review every study following the Access Process and approval will be needed before a study can proceed. You can find out more about this here.

Th Access Process is separate to the TRE accreditation process. If you plan to work within an external accredited TRE, then you will need **both** TRE accreditation **and** study approval from the Access Board. You can apply to both of these processes concurrently.

Post-accreditation

What is the process for data transfer into an accredited TRE?

Providing your organisation has received accreditation, researchers have been registered, and a study has been approved by the access board, you are eligible to initiate the data transfer process. This is done by contacting support@ourfuturehealth.org.uk. Our Future Health will work with you to create, test and complete the data transfer.

After failure to receive accreditation, can my organisation re-apply?

You may re-apply after 12 months.