Making Requests to NHS Digital Easier

NIHR E-Trials Call April 2017

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Abstract The NIHR funded a one year project from August 2017 to work with NHS Digital to try to improve clinical trials units access/request process to datasets provided by NHS Digital for clinical research. The project aimed to bring together parts of the trials community to act as one voice with a common purpose when discussing issues with NHS digital. During the project the communication between the trials unit community and NHS Digital improved, with both parties gaining a better understanding of the other's needs.

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Introduction

Hospital Episode Statistics (HES) is a data warehouse containing details for all admissions, outpatient appointments and A&E attendances at NHS hospitals in England (http://content.digital.nhs.uk/hes). The curation and governance of this data warehouse is the responsibility of NHS Digital (formally the Health and Social Care Information Centre).

Many academic trials units make use of HES data to aid in cost and clinical effectiveness analysis in clinical trials, to determine incidence levels of disease relating to trials or to confirm clinical pathways, which appears to be becoming an expectation from funders.

Access to HES data for trialists is often a difficult and time-consuming path (due to lack of guidance around how NHS digital processes work), ensuring that the rights of the patients are not infringed, and that appropriate consent and information governance is in place, often with conflicting advice provided by staff within NHS Digital, resulting in many changes to the application and therefore delays in the process. This is further complicated by what has been seen to be requirements changes within NHS Digital for trial consent forms and patient information sheets.

Once data has been sent to trials units, NHS Digital currently has a requirement that periodic (1-5 years – with an associated cost) requests have to be made in order to retain these data in line with clinical trials regulations (which could be as long as 25 years). Work undertaken by Leeds CTRU with NHS Digital, suggests that this may be possible by changing the status of the data to archive at a point when no further processing activities will take place.

Other areas that require agreement and work are (but not limited to): data sharing within multicentre trials with centres not within the EEA and making data from trials available for further analysis by other parties/researchers once the final report had been produced (also a requirement from funders).

There have been several meetings between members of the registered Clinical Trial Units (CTUs) and NHS Digital, as well as meetings between individual CTUs, which has led to some progress and improvements by both parties. It is also acknowledged that NHS Digital are meeting with other stakeholders, such as the HRA to improve the process, as such, it is important to build on this work in support of the current application. However, there still needs to be a significant amount of work done to improve this process, thereby reducing work load and delays from both parties (it is acknowledged that NHS Digital have employed additional staff in an attempt to reduce delays).

Within this project we would aim to provide specific guidance on what CTUs need to include in their consent forms, patient information sheets and mechanisms for keeping participants informed of how their data is being used and by whom when requesting data from NHS Digital, with example applications showing how to complete the NHS Digital DARS application process in the context of clinical trials linking the expectations of the curation of these data with the day-to-day practicalities. The suggested guidance coupled to an explanation of HES aimed at CTUs should ultimately result in a more streamlined application process for CTUs.

The output of this project will be a more streamlined and efficient application process for HES data, minimising delays in trials and the associated analysis coupled to how to implement the requirements of the data sharing agreement for these data (i.e. security, archiving, and destruction)

These outputs will be shared via the UKCRC network, the Hubs for Trials Methodology Research network and provided by NHS Digital to CTUs.

Methods

This project was delivered by the process of networking and meetings with the different stakeholders, building a network of interested parties so as to act as a unified voice with greater weight when discussing issues with NHS Digital.

The project milestones as of December 2017 is shown in Table 1: Project Milestone as agreed in 12/2017.

Suggested Milestones	**Estimated completion date**	**Completion date**
Initial Meeting with NHS Digital	September 2017	19/09/2017
Employ Staff to work on project (at Leeds)	November 2017	01/12/2017
Combined meeting with CTU's/CTU Network/NHS Digital to identify priorities	November 2017	26/01/2018
Scoping what is undertaken by other Stakeholders	02/03/2018	02/03/2018

Meeting with NHS Digital to agree priorities to address	02/03/2018	22/03/2018 (and subsequent)
Disseminate Meeting report and agreed priorities to CTU's	31/03/2018	
Engagement with NHSD Research Advisory Group	Ongoing	Via Louise Dunn and Kimberley Watson
Status update to CTU's	01/06/2018	16/05/2018 at UKCRC Directors meeting
Status update to CTU's	30/09/2018	15/11/2018

Table 1: Project Milestone as agreed in 12/2017

In delivering this project a series of meetings were held with stake holders (not just NHS Digital), the list of those meetings (required to push the agenda with NHS Digital and to engage with the wider community) is shown in Appendix 1: List of Formal Meetings held as part of this project with stakeholders.

Combined CTU Network meeting

In January 2018, the UKCRC registered Clinical Trials Unit (CTU) and NHS Digital hosted a joint workshop in Leeds to explore issues related to access to routine data through NHS Digital processes. The agenda included a discussion on priorities identified by the NIHR Efficient Trial Conduct project, and NHS Digital provided an update on the work that they had agreed to undertake following their meeting with the UKCRC RDA group in Birmingham 2016 – many of these deliverables had been achieved. The agenda is shown below:

- Update from NHS Digital
- Completed actions from NHS Digital
- Ongoing actions from NHS Digital
- New and ongoing challenges
- GDPR (General Data Protection Regulation)
- National opt-out
- Group Discussion: Issues arising in the CTUs not covered above

The remainder, along with those following the round table discussion in the afternoon session formed the outputs of the work that this project would also undertake going forwards.

This meeting was reported in newsletters via NHS Digital and the UKCRC-CTU.

Links made as part of project

Dr Fiona Lugg-Widger: routine data lead at the Cardiff University who has published on challenges related to use of routine data. The plan is to invite Fiona to join the UKCRC Routine Data Access Task &Finish group.

NIHR: we share common goals with the NIHR Speciality Cluster. Where possible, we aim to work with Prof Seymour, Dr Jonathon Gower and Dom Povey to provide the wider research community with access to information to improve the quality application of applications and align expectations for timelines and escalation of issues impacting on access to data via NHS Digital.

UKCRC CTU:

1) UKCRC Routine Data Access Task and Finish group plan to meet in February 2019. Kimberly Watson from NHS Digital will align to this group to allow for prompt resolution of issues. Work plan for this group will be confirmed at a T&F group, to be scheduled by UKCRC CTU in Q1 2019.

2) UKCRC programme manager has agreed for us to update CTUs via their website and forums.

Results

During the scope of the project the aims and expected outcomes have changed out of necessity to reflect the changing environment and regulations to be complied with.

The following outputs were expected from this project:

1. Provide specific guidance on what CTUs need to include in their consent forms, patient information sheets and mechanisms for keeping participants informed of how their data is being used and by whom when requesting data from NHS Digital
2. Example applications showing how to complete the NHS Digital DARS application process
3. A more streamlined and efficient application process for HES data, minimising delays in trials and the associated analysis coupled to how to implement the requirements of the data sharing agreement for these data (i.e. security, archiving, and destruction)

Output (1): the position on consent and fair processing has changed following implementation of GDPR. Consent is no longer the legal basis for the processing of the data under GDPR as the bar for that is extremely high. It is clear that consent is a dynamic process, not a one-off compliance and GDPR introduces requirements for data controllers to ensure they obtain and maintain, as well as demonstrate, valid consent.

There is an expectation for consent to meet the common law duty of confidentiality. Guidance is available on what to include about processing data, and although template wording is not available, it is becoming clearer what to include in patient information materials. NHS Digital are also able to comment on specific cases where required.

Output (2) as with output (1) this has been superseded by the work that NHS Digital have being undertaking on improving the quality of DARS applications (including Roadshows and Digital Guidance). Presentations delivered as part of this project have focused on 1)

organisation and 2) application readiness to complement the guidance now available on how to access data and complete the DARS.

Output (3) it become apparent that one of the key issues to streamlining the application process was a lack of understanding about the process and requirements from NHS Digital to allow them to disseminate data. NHS Digital have developed guidance, which is accessible via their website and webinar series. As mentioned above our focus identified 1) organisation and 2) application readiness as areas where information was needed, and this formed the basis of recent dissemination activity. NHS Digital are committed to improve their process and advancements have been made with regards to development templates where possible. This includes archiving templates and wording for NIHR funded studies. We will continue to work with NHS Digital to make recommendations for templates.

In addition to the stated outcomes at the start of the project, additional outcomes (44, of which only 11 remain open) were agreed and taken over from the UKCRC Task and Finish RDA group, these along with their current status are summarised in Appendix 3. These deliverables were included as they were important to the overall project of improving access to HES data. It is important to note that in the last year a significant degree of progress has been made in the domain covered by this project.

Conclusions/Recommendations

This was a difficult project to deliver the regulatory landscape changed during the course of the project (implementation of GDPR and the associated interpretation of those regulations around clinical data). In addition, the project has been reliant on the goodwill of NHS Digital in taking on board and listening to the views of their user community.

NHS Digital has agreed to work with our team to produce regular updates on items including: 1) What has changed and how this impacts on existing / new projects (e.g. change in ONS, DoD, GDPR); 2) What's coming-up / being considered / out for consultation; 3) Calls for projects (like the sharing data / international sharing). It is anticipated that these updates will be disseminated using the UKCRC CTU website.

The nature of the work started as part of this project will continue as part of both the UKCRC Routine Data Access Task and Finish group and ongoing plans at Leeds and the relationships created during the course of this work.

Having a central location to facilitate communication between the UK clinical trials community and NHS Digital is important. At an institutional level NHS Digital have dedicated account managers allocated to specific institutions, making an understanding of how the different institutions operate easier from their perspective, however higher-level operational communication should be maintained (as it will during the tenure of the UKCRC RDA for the next few years) in order to provide for specific interpretation and guidance of documentation provided by NHS Digital.

Dissemination

The status and progress of this project have been disseminated to the wider community in the form of presentations and newsletters. The current list of dissemination activities related to this project are listed in Appendix 2: List of Presentations relating to this project.

Over the next few years additional updates will be published on the UKCRC registered trials network and NHS Digital websites.

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Duncan Appelbe (Head of Information Systems, CTRC) was employed by The University of Liverpool during this project, providing direction in collaboration with Hartley.

Suzanne Hartley (Head of Trial Management, CTRU) is employed by The University of Leeds, providing direction in collaboration with Appelbe and line managed Parker.

Catriona Parker (Senior Trial Manager, CTRU) was part funded by this grant and The University of Leeds, acting as the day-to-day conduit for work on the project.

We also acknowledge the support of the UKCRC Registered Trials network.

Conflicts of Interest Declaration

The authors had no conflicts of interest with relevance to this project.

Appendix 1: List of Formal Meetings held as part of this project with stakeholders

Date	Stakeholder - attendees	Purpose
19/09/2017	**NHS Digital** - Garry Coleman / Dickie Langley	To outline the project and aims
08/12/2017	**NHS Digital** - Garry Colman, Estelle Spence, **MRC Regulatory Support Centre** - Dr Alex Bailey	To discuss alignment of the project with the Research Advisory Group (RAG), hosted by NHS Digital.
15/12/2017	**NHS Digital** - Louise Dunn	Update on issues affecting access to NHS Digital.
08/01/2018	**NHS Digital** - Gaynor Dalton, Louise Dunn	Planning for the UKCRC CTU meeting
02/2018	**n/a**	Meeting cancelled due to adverse weather
22/03/2018	**NHS Digital** - Louise Dunn	Update on issues affecting access to NHS Digital.
11/05/2018	**NHS Digital** - Louise Dunn	Update on issues affecting access to NHS Digital.
06/07/2018	**NHS Digital** - Louise Dunn	Update on issues affecting access to NHS Digital.
22/08/2018	**NIHR Speciality Cluster** – Prof Matt Seymour, Dr Jonathan Gower	Discussion on how to work with the NIHR MIDL programme (Medical Informatics & Data Linkage)
31/08/2018	**NIHR Speciality Cluster** - Dr Jonathan Gower, **NHS Digital** – various including Matt Neligan, Garry Coleman, Gaynor Dalton, Louise Dunn, IGARD	Overview of NHS Digital Data Access and discussion on how to work more efficiently.
18/09/2018	**NHS Digital** - Dickie Langley, Louise Dunn	To discuss perceived barriers to onwards sharing of data disseminated via NHS Digital

Appendix 2: List of Presentations relating to this project

Event: Joint Workshop on Access to Routine Data from NHS Digital
Date and location: 26/01/2018, Leeds.
Presentation title: See workshop agenda
Presenter: Duncan Appelbe, Suzanne Hartley (facilitator). **NHS Digital -** Terry Hill, Gaynor Dalton, Louise Dunn
Audience: 47 delegates from 35 CTUs.

Event: UKCRC CTU Directors meeting
Date and location: 16/05/2018, London
Presentation title: Making Requests to NHS Digital Easier
Presenter: Duncan Appelbe
Audience: ~45

Event: UKCRC CTU IS Group Meeting.
Date and location: 24/10/2018, Sheffield
Presentation title: NIHR E-Trials call update
Presenter: Ian Kennedy/Sharon Kean (on behalf of Duncan Appelbe)
Audience: ~45.

Event: UK Trial Manager Network Annual Meeting.
Date and location: 04/10/2018, ETC venues, Edgware Road, London, WC1H 9JP
Presentation title: Workshop on Use of Routine Data in trials.
Presenter: Suzanne Hartley, Fiona Lugg-Widger (Cardiff University), Louise Dunn (NHS Digital)
Audience: 20+ Trial Managers from across the UK.

Event: NHS Digital and NIHR Clinical Research Network joint workshop: Harnessing the Power of Information for Clinical research
Date and location: 14/11/2018, BMA House, Tavistock Square, London, WC1H 9JP
Presentation title: Top Tips for researchers from the CTU perspective
Presenter: Suzanne Hartley
Audience: 50+ representatives from NIHR speciality cluster, CTUs, NHS Digital and Public Health England.

Newsletters

- Joint workshop on Access to Routine Data from NHS Digital
  https://cdn.ymaws.com/www.ukcrc-ctu.org.uk/resource/resmgr/news/RDA_Workshop_Jan18.pdf

  Output disseminated via NHS Digital in the ***April health and social care data research news***, published in April 2018 and accessible on the UKCRC-CTU website.

Appendix 3: Project Priorities status

Project Theme	Outputs	Date	Notes
1. Organisational Level Procedures	Joint UKCRC Network & NHS Digital Workshop – Leeds	January 2018	47 delegates from 35 CTUs explored issues relating to access of routine data. Presentations available on UKCRC website. Write up in UKCRC CTU newsletter: https://cdn.ymaws.com/www.ukcrc-ctu.org.uk/resource/resmgr/news/RDA_Workshop_Jan18.pdf
	Report to UKCRC Directors Meeting	May 2018	Duncan Appelbe (DA) and Gill Booth (GB) reported to UKCRC CTU Network Directors meeting on project and implications of GDPR.
	Privacy notice issues	Ongoing	
2. Trial level Procedures – Pre application	Establishment of dedicated link for CTUs at NHS Digital and RAG	Ongoing	Louise Dunn - Senior Business and Operational Delivery Manager Data Access Request Service NHS Digital
3. Making an application	Developing guidance document for CTUs for making applications to NHSD	Ongoing	Link with Dr Fiona Lugg-Widger, Cardiff University Template development
	Hints/tips guidance developed for CRN	November 2018	"Route maps" process, "top tips" guidance document developed.
	Develop annotated DARS application	Planned	To be made available via UKCRC CTU website. Use HERO application as example.

Project Theme	Outputs	Date	Notes
	Suggest topics and develop webinars with NHSD you-tube channel	Ongoing	DARS application suggested to NHSD.

4. Trial level procedures – Post Application	Archiving template wording	December 2018 - Ongoing	Update Email from Dave Cronin at NHSD (Fri 07/12/2018) We (NHS Digital) have actually implemented a 5-year Data Sharing Agreement for archived data. The cost after the first year is halved so effectively a 5-year archive Agreement costs the same as a 3-year Agreement. We have produced a template which will be reviewed by IGARD next week along with a prototype application. If IGARD are content, we would be looking to implement the template in the New Year. The archive Agreement permits the processing required to archive the data (which may involve processing to pseudonymise the data prior to archiving) and additionally permits further processing of the data for the purposes of audit or for repeating previous analyses if required to verify results following challenges, etc. raised during peer review or post-publication. No other processing is permitted apart from ongoing secure storage of the data. More information would be published on our website when the service is fully launched but I envisage the process for applying for an archive Agreement would be to submit an 'Amendment' request to the existing active Data Sharing Agreement (via DARS Online) and make clear to us either in the application or via separate contact with the DARS team that the intention is to archive the data. We would then edit the application in line with the template and it would go through a simplified approvals process on the basis that it follows an approved precedent. Based on current charges, a 3-year Agreement extension would cost £1,820 plus VAT. A 5-year archive Agreement would cost the same. There was quite a bit of feedback at the workshop that even with the reduction in cost for the 5-year Agreement, it

Project Theme	Outputs	Date	Notes
			would be problematic to fund because studies typically aren't funded beyond the point where they are completed and the data is archived. At this point, there has been no change to our charging policy so funding would have to be obtained. If you would like to articulate a case for us reviewing our charging policy in respect of such Agreements, I would be happy to pass that onto the key decision-makers for consideration. Alternatively, this is the sort of issue that you can raise directly via our Research Advisory Group (RAG) (see: https://digital.nhs.uk/services/research-advisory-group). We have been discussing with some DARS customers the idea that they would deposit the data with us at the end of the study (essentially getting us to archive it for them) rather than retaining the data themselves which would result in them not needing an active Data Sharing Agreement. The data would be encrypted with only the customer having the encryption key so that we would not be able to decrypt it. The potential downside with this approach is that should the data be needed by the customer for any reason after it was deposited with us, the customer would need to apply via the DARS process for a Data Sharing Agreement to permit them to receive the data back from us to process it for whatever reason and there would be standard costs associated with that. At this stage, this remains an option we are considering but whether it is considered to be a viable option for DARS customers remains to be seen

Project Theme	Outputs	Date	Notes
5. Use of NHS Digital Datasets to Optimise Efficiency of Clinical Trials Research	Link with NHSD Scoping exercise with CTUs – Estelle Spence, NHSD	August 2018 – ongoing	NHSD scoping support service for clinical trialists.
	Link with MIDL (Medical Informatics & Data Linkage) programme	August 2018	MIDL led by Dr Jonathan Gower, Assistant Specialty Cluster Lead (Cancer, Surgery and Oral and Dental Health) & Prof Matt Seymour, Speciality Lead (Cancer, Surgery and Oral and Dental Health), NIHR. MIDL themes: • Working with NHSD & PHE to improve access to data (eg producing toolkits, tips for getting application right. • Promote use of studies using routine patient data on/or PROMs as outcome measures
6. Legal Basis	Guidance	August 2018	NHSD guidance available
Dissemination Routes	Workshop at UK Trial Manager Network (UKTMN) Annual Meeting 2018	October 2018	Hartley delivered workshop - Top tips for researchers from the CTU perspective
	UKCRC website/newsletter with regular updates	Winter 2018 & Ongoing	• Signposting existing resources • Updates every newsletter for new info/tips/issues

Project Theme	Outputs	Date	Notes
	UKTMN Website & Newsletters	Ongoing	• Signposting via UKTMN website • Regular updates in UKTMN newsletters – new info, tips