

Pan-UK Data Governance Steering Group

21 June 2023

Chair: Cassie Smith

Summary of Key Discussion Points

Introduction

- Prof Andrew Morris emphasised the need for good governance and acknowledged the progress made by the Steering Group and the important outputs from the three Action Forces. He put emphasis on the significance of navigating the challenge that is adoption and uptake, encouraging thoughtful, ambitious discussions from the meeting.
- The Chair welcomed the new Head of Public Involvement and Engagement, Doreen Tembo, and thanked everyone, especially the public representatives, for their hard work and commitment.

Update on Action Forces

The Chair presented an update on the outputs and next steps for all three Action Forces. She highlighted that all Action Forces welcome feedback on the outputs to date and what the next priority areas should be:

TRE Legal Toolkit

- The [TRE Data Access Agreement \(DAA\) template](#) mapped against the Fives Safes Framework and underpinned by a common set of defined data access principles agreed by the Action Force was presented. The template contains customisable annexes such as intellectual property, training credentials and includes guidance for each. It also includes click through 'terms of use' for approved researchers to accept before using a TRE.
- The DAA template has been reviewed by contracts leads, industry representatives and ABPI.
- A manuscript has been submitted to the International Journal of Population Data Science Special Issue on Advances and Innovation in Data Governance. If accepted, publication of the principles should help with consensus and understanding amongst the wider TRE/research community.
- **Next steps** are adoption and implementation of the DAA and principles by data custodians. The UK Longitudinal Linkage Collaboration (UK LLC) are reviewing the DAA for potential adoption, but we are putting a call out for further volunteers. If you would like to work with the Action Force in adopting and implementing the standardised DAA, please contact Rachel.Brophy@hdruk.ac.uk
- **Potential future work** includes creating guidance for use of the DAA template to be developed with patient and public input. Further work with commercial partners to examine how DAA can work for specific needs – multi-study approval, audit, feasibility counts, costing and Intellectual property. The group is keen for this to be useful for all users across the ecosystem.

Actions:

- 1. Submit suggestions for what the TRE Legal Toolkit Action Force should prioritise next and or any complex legal questions/cases you think the group should focus on.**
- 2. Call for volunteers to adopt the template Data Access Agreement**

Rachel.Brophy@hdruk.ac.uk

Data Access Mapping Tool

- The Data Access Tube Map has been created together with a companion tool, encouraged by the Goldacre Review findings that recommended data access processes be made available on one page. The Data access Map was inspired by the London Tube map and is set out in four “zones”. The companion tool is an interactive process map which gives a simpler view of the data access process for a specific Trusted Research Environment (TRE)/ Secure Data Environment (SDE). This was created with the involvement of the public representatives and the tool has been launched for consultation. The tool is now live, and an email was circulated on Tuesday 27th June containing details on how to access it.
- **Next steps:** The companion tool will go live later this year. The Action Force will have a further workshop with public members to aid transparency. It is a priority that the map is accessible to all including those not engaged in data science and the research process, public members will advise on this. Other processes mapped out will be published and disseminated. Feedback is welcome as to how this can be achieved, perhaps with an instructional video.

Actions:

Please do email Edel.McNamara@hdruk.ac.uk If you have any feedback on the map, companion tool and/or the addition of new TREs/ processes.

Five Safes Action Force

- The group has developed transparency standards with input from the Public Advisory Board and the Action Force, shared as part of the papers for the meeting. This will be sent to the Alliance for further review and discussion at Alliance Council on 13 July 2023.
- The Chair also highlighted the blog written by Alan Holcroft which introduces a set of standards aimed at promoting clear communication of data access processes with members of the public. Blog can be found here [How well is information on data access processes shared with the public? Introducing standards to inform good practice – HDR UK](#)
- **Next steps** are to present the transparency standards to the Alliance Council in the upcoming July meeting and test the standards with volunteers from the Steering Group and or Alliance members; we are encouraging full adoption of the transparency standards by Alliance members. We aim to set up a workshop with the individuals within data custodians responsible for their websites e.g. communication teams to support taking the recommendations forward.

Actions:

Please provide any further feedback on the transparency standards to Yemi.macaulay@hdruk.ac.uk

Public Patient Involvement and Engagement lead (PPIE) Updates

- We have had two Public Advisory Board (PAB) members join the Steering group in May.
- We are celebrating the first-year anniversary of [Public Engagement in Data Research Initiative](#) (PEDRI). The PEDRI [draft Best Practice Standards](#) are currently in public consultation. We have had very strong numbers of responses, almost 100 so far. We have had a particularly strong responses from members of the public. However, we would really like to boost the number of responses PPIE professionals and researchers, as they are the ones that would implement these standards in practice. We are therefore extending the consultation until Friday 14/07/23.

Action: We ask PIE professionals to please respond to the PEDRI [draft Best Practice Standards](#) by 14 July. Please contact ben.thomas@hdruk.ac.uk for further information.

International Data Transfers

- Edel summarised the legal regime for international data transfers, including highlighting the 3 criteria for data transfers identified [by the European Data Protection Board](#).
- The presentation summarised the requirements for international transfers when there is no adequacy decision including (i) the need for a transfer risk assessment, which are burdensome and require legal expertise and (ii) need for lawful transfer mechanisms such as Standard Contractual Clauses, which can often be difficult, particularly in cases where the transfer is to the US. Clarity is lacking as to whether the exception for ‘important reasons of public interest’ is applicable for health data and research.
- The ICO’s [draft guidance on anonymisation](#) potentially provides more flexibility for international data transfers by introducing a new category of “effectively anonymised” data which is not considered personal data and therefore may be freely transferred. However, HDR UK’s Public Advisory Board have raised concerns about the impact of this new guidance on public trust.
- **A case study** on the approach taken by Clinical Practice Research Datalink (CPRD) was presented by John Latham-Mollart. CPRD renders its data ‘effectively anonymised’ when processed by the recipient. The criteria used by CPRD in deciding of international transfer includes but is not limited to processes applied to the data before the CPRD database is formed, the new client application risk assessment process, the context and content of the data being requested and the contractual controls. There are also a consideration of the organisations Information Governance and InfoSec maturity (i.e., adherence to international standards such as ISO27001) if they have had a breach and a review of their policies, processes etc. Overall CPRD’s data has low risk of re-identification, a finding of NHSE and the ONS during a recent audit: [NHS Digital Data Sharing Remote Audit: Clinical Practice Research Datalink - NHS Digital](#)
- **A case study** – Jason Swedlow (Program Director, Wellcome Leap) presented on the difficulties encountered working on the Delta Tissue Program (<https://wellcomeleap.org/delta-tissue/> which aims to build a tissue repository, which would involve various data transfers including diagnostic information, patient outcomes, tissue transitions). This highlighted some of the issues on what is required for international transfers from and to UK, including unclear guidance, significant confusion on how the laws apply, and gaps in understanding on the legal and regulatory concepts. These challenges are affecting users of the data and halting research progress; a national effort is needed to clarify this.
- Both case studies highlighted the need for a national consensus to help organisations understand what the right process should be, given that current practices and interpretations of the law vary.
- The group discussed the complexity and the potential opportunity in using the resources from the Steering Group to start tackling the critical concepts. The ICO is seen as a key stakeholder in this.
- **Next steps**- for this group to set up an Action Force focussing on international data transfers and to consider drafting and publishing an opinion piece which may help drive clarity. There was also a suggestion for the new Action Force to draft a letter to the ICO highlighting this issue, referencing case studies.

Action: Please contact edel.mcnamara@hdruk.ac.uk if you would like to join the International Data Access Action Force.

Data Access application form Questions

- [The DHSC data access policy update](#) out for consultation may be an opportunity to start discussions around streamlining of data access application form questions. There was general agreement within the meeting that putting streamlining of data access questions and processes back on the agenda was a sensible and worthwhile.
- It was highlighted that the Alliance has made some progress, but it is still a challenging space in terms of next steps and organisations coming together on a work plan that leads to adoption.

Open Forum

- An open forum enabled attendees to raise hot topics and emerging issues.
- **Sponsorship**- Discussion around sponsorship and the difficulties it creates, including the importance of prioritising this for the benefit of researcher who sometimes find it difficult to gain sponsorships.
- **Sudlow Review** – The group were briefed on the Sudlow review. This consultation has now been extended by a week and will be open till the 7th of July 2023- [The Sudlow Review - HDR UK](#) with a workshop planned in July 31st at 4.15pm. This will be a final chance for any organisation who has not had the opportunity to provide comments to do so via the workshop.
- **Next topic area:** The next Pan-UK Steering Group meeting will discuss deriving value from data.

Action: Contribute to the Sudlow Review by 7 July: see [The Sudlow Review - HDR UK](#)

Attendees:

In person

Name	Organisation
John Lathan-Mollart	
Nadia Azimikorf	Clinical Practice Research Datalink (CPRD)
Hans-Erik Aronson	
Fergus McDonald	Data and Analytics Research Environments UK (DARE)
Andrew Morris	
Cassie Smith	
Edel McNamara	
Rachel Brophy	
Yemi Macaulay	
Ester Bellavia	HDR UK
Paola Quattroni	
Stephen Burrows	Health Data Research Alliance, HDR UK
Alex Bailey	MRC Regulatory Support Centre
Maeve Groot Bluemink	Our Future Health
Sara-Jane McAteer	Public Member/ HDRUK Public Advisory board

Andy Boyd	UK Longitudinal Linkage Collaboration (UK LLC)
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Online

Name	Organisation
Janet Valentine	ABPI
Emma Gordon	Administrative Data Research UK (ADR UK)
Neena Modi	British Medical Association (BMA)
Doreen Tembo Cathie Sudlow Lara Edwards Eilidh Ferguson	HDR UK
Allison Knight	Health Research Authority
Vicky Chico	National Data Guardian
Gary Coleman	NHS
Rebecca Cosgriff	NHS R&D
Frances Burns	Northern Ireland Health Social Care/ QUB
Konstantinos Kaoura	Our Future Health
Carole Morris	Public Health Scotland
Munisa Hashimi	Public Member/ HDRUK Public Advisory board
Angela Coulter	Public Representative
Roger Halliday	Research Data Scotland
Cynthia McNearney	Secure Anonymised Information Linkage Databank (SAIL)
Simon Whitworth	UK Stats Authority
Jason Swedlow	Wellcome Leap