Advisory Group for Data (AGD) – Meeting Minutes

Thursday, 12th October 2023

09:30 – 13:00

(Remote meeting via videoconference)

INDEPENDENT ADVISERS IN ATTENDANCE:	
Name:	**Role:**
Dr. Robert French (RF)	Specialist Academic / Statistician Adviser
Kirsty Irvine (KI)	Chair
Dr. Imran Khan (IK)	Specialist GP Adviser
Dr. Geoffrey Schrecker (GS)	Specialist GP Adviser
Miranda Winram (MW)	Lay Adviser
NHS ENGLAND STAFF IN ATTENDANCE:	
Name:	**Role / Area:**
Noela Almeida (NE)	NHS England Data Protection Office Representative (Delegate for Jon Moore) (Items 4.2 and 4.3)
Vicky Byrne-Watts (VBW)	Data Access Request Service Senior Approval Team (DARS SAT) (**SAT Observer**: items 4.1 to 4.3)
Michael Chapman (MC)	Data and Analytics representative
Garry Coleman (GC)	NHS England SIRO Representative (**Presenter**: items 5, 6, and 8.2)
Dickie Langley (DL)	NHS England Data Protection Office Representative (Delegate for Jon Moore) (Items 1 to 4.1 and 5 to 8.2)
Abigail Lucas (AL)	Data Access Request Service (DARS) (**Observer**: items 4.1 and 4.2)
Karen Myers (KM)	AGD Secretariat Team
Jonathan Osborn (JO)	NHS England Caldicott Guardian Team Representative
Vicki Williams (VW)	AGD Secretariat Team (**Presenter**: item 7)
INDEPENDENT ADVISERS NOT IN ATTENDANCE:	

Paul Affleck (PA)	Specialist Ethics Adviser
Claire Delaney-Pope (CDP)	Independent Specialist Information Governance Adviser
Prof. Nicola Fear (NF)	Specialist Academic Adviser
Dr. Maurice Smith (MS)	Specialist GP Adviser
Jenny Westaway (JW)	Lay Adviser
NHS ENGLAND STAFF NOT IN ATTENDANCE:	
Jon Moore (JM)	NHS England Data Protection Office Representative

1	**Welcome and Introductions** The NHS England Senior Information Risk Owner (SIRO) Representative, noting the Advisory Group for Data (AGD) Terms of Reference (ToR) had not yet been agreed, proposed that: • Kirsty Irvine (as an independent adviser) will be asked to Chair the AGD meetings; • The meeting will be minuted, with advice and minutes published; • Attendees will include both independent advisers from outside NHS England and representatives from within NHS England. Attendees from NHS England include representatives covering the offices of the Data Protection Officer (DPO); the Caldicott Guardian; Data and Analytics; and the SIRO. • Attendees would not be listed as "members" in minutes during the transitional period; • NHS England representatives would not, during the transitional period, be formally part of any consensus that is reached, but would be active participants in the meeting; • It was agreed to use the Data Access Request Service (DARS) Standards / Precedents in relation to applications for external data sharing. The attendees present at the meeting considered the proposal put forward by the NHS England SIRO Representative and, as no objections were raised, it was agreed that the meeting would proceed on this basis. Kirsty Irvine noted and accepted the request from the NHS England SIRO Representative to chair; and welcomed attendees to the meeting.
2	**Review of previous AGD minutes:** The minutes of the 5th October 2023 AGD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record of the meeting.
3	**Declaration of interests:**

	There were no declarations of interest.
EXTERNAL DATA DISSEMINATION REQUESTS:	
4.1	**Reference Number:** NIC-398405-S0M4K-v0.11 **Applicant:** London School of Hygiene and Tropical Medicine **Application Title:** CRASH-4 Trial - Intramuscular tranexamic acid for the treatment of symptomatic mild traumatic brain injury in older adults: a randomised, double-blind, placebo-controlled trial **SAT Observer:** Vicky Byrne-Watts **Observer:** Abigail Lucas **Application:** This was a new application. The purpose of the application is for a randomised, double-blind, placebo-controlled clinical trial, which aims to assess the effects of early intramuscular tranexamic acid (TXA) on intracranial haemorrhage, disability, death, and dementia in older adults with symptomatic mild traumatic brain injury (TBI). To assess safety and effectiveness, CRASH-4 need to monitor deaths due to intracranial bleeding and other causes, and the risk of dementia at one year. Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** The group were supportive of the application and wished to draw to the attention of the SIRO the following comments: **4.1.1** The group welcomed the application and noted the importance of the programme, which potentially may bring substantial benefits to patients. **4.1.2** The independent advisers noted and commended the work undertaken by NHS England's Data Access Request Service (DARS) on the internal application assessment form. **4.1.3** In respect of the transparency, it was suggested by the independent advisers, that the applicant review the online transparency materials, for example, the privacy notice and any online consent materials; to ensure that they were clear and accurate, including, but not limited to, ensuring there is sufficient contact information for participants who would like to withdraw consent. **4.1.4 Separate to the application:** the independent advisers suggested that NHS England should consider the current transparency on the effectiveness of the National Data Opt-out (NDO) and requested further discussions on this. The NHS England SIRO Representative and NHS England Data and Analytics representative noted the points raised and the request, and advised that a meeting would be arranged to discuss this further, with NHS England data policy colleagues.

	ACTION: A meeting to be arranged to discuss the current transparency on the effectiveness of the NDO with NHS England data policy colleagues. **4.1.5** It was suggested by the clinicians in the group that the applicant should consider the known complications following traumatic brain injury (TBI), for example, chronic subdural haematoma; and expressed concerns that the current flows of data would be insufficient to capture the chronic subdural haematoma outcome data in the future, and noted that the consent would support any additional flows of data. The group advised that they would be supportive of any additional data flows for this additional outcome, and suggested that a further review by the group would **not** be required for this. **4.1.6** The independent advisers suggested that for transparency, section 5(a) (Objective for Processing) was updated to include further information on an indicative number of individuals that had been entered into the study via the legal representative. **4.1.7** Noting that the application refers to the data as being *"pseudonymised"* in the hands of the researchers, it was suggested by the group, that it would be more accurate to describe the data as *"identifying"* up until the point that it is anonymised for use by other researchers; and that the application should be updated as appropriate to reflect this. **4.1.8** The group commended the applicant on the excellent patient and public involvement and engagement (PPIE)	GC / MC
4.2	**Reference Number:** NIC-148336-V4SL1-v5.2 **Applicant:** University of Bristol **Application Title:** Caerphilly Prospective Study (CaPS) **SAT Observer:** Vicky Byrne-Watts **Observer:** Abigail Lucas **Previous Reviews:** The application and relevant supporting documents were previously presented / discussed at the IGARD meeting on the 4th April 2019. **Linked applications:** This application is linked to NIC-147814-86GS4 and NIC-147837-RJMRN. **Application:** This was a renewal and amendment application. The purpose of the application is for a study, which aims to enhance the understanding of life course influences on the causes of chronic disease and physiological traits by examining lifestyle, genetic and other exposures at various times in the life course and determine whether these predict a wide range of different outcomes.	

	The amendment is to update the application into a programmatic data sharing agreement (DSA), which also enables derived data to be shared externally subject to controls. NHS England were seeking advice on the following point: 1. Any suggestions / amendments that should be made to the terms and conditions/ data access request form to align with NHS England's expectations for programmatic governance. Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** The group were supportive of the application and wished to draw to the attention of the SIRO the following substantive comments: In respect of point 1: **4.2.1** The group suggested that NHS England's Data Access Request Service (DARS) worked with the SIRO representative to agree a set of contractual measures / special conditions, that would give appropriate contractual controls and oversight of access to the data by third party researchers. It was noted that the group would **not** request further review of the contractual measures once they had been agreed between DARS and the SIRO representative. **ACTION:** NHS England's DARS to work with the SIRO representative to agree a set of contractual measures / special conditions, that would give appropriate contractual controls, over access to the data. **4.2.2** The group noted and supported the comments / suggestions made by NHS England's DARS on the 'Terms and Conditions between Population Health Sciences, University of Bristol and potential collaborators utilising research materials from the former MRC Epidemiology Unit (South Wales)' paper, provided as a supporting document; and suggested that these were noted by the applicant and the documention was updated in line with the comments / suggestions made. In addition, the group made the following observations on the application and / or supporting documentation provided as part of the review: **4.2.3** The independent advisers noted that the Masters / PhD students enrolled with the University of Bristol would have access to the data; and advised that whilst they were supportive of the process outlined for the students, suggested that NHS England's DARS seek clarity from the applicant, on the potential number of students accessing via this route. **4.2.4** The independent advisers queried if the surviving cohort members had been kept up to date on what was happening with their data; and suggested that if this was not currently being done, then the applicant should give further consideration to this.	SIRO / DARS

	4.2.5 Noting the reference in the application to the new data access committee including one or more lay members; it was noted by the independent advisers that the number of lay members should be proportionate to the size of the data access committee. NHS England advised the group that the data access committee was interim and would be reviewed, and would be moving to a more robust oversight committee in the future. **4.2.6** The independent advisers noted and commended the reference / consideration in section 5 (Purpose / Methods / Outputs) of the application and supporting documents to the National Data Guardian (NDG) guidance on benefits.	
4.3	**Reference Number:** NIC-05429-H7X6R-v9.3 **Applicant:** Device Access UK Ltd **Application Title:** Device Access - HES Application 2023 **SAT Observer:** Vicky Byrne-Watts **Previous Reviews:** The application and relevant supporting documents were previously presented / discussed at the IGARD meetings on the 4th August 2022, 26th May 2022, 21st December 2017, 6th July 2017, 8th June 2017, 25th May 2017 and the 16th March 2017. **Application:** This was a renewal application. The purpose of the application is for a programme of work which identifies where medical and diagnostic technologies can best be used by NHS providers in NHS patient care pathways to improve patient outcomes, reduce lengths of stay, elective and diagnostic waiting times. Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** The group were supportive of NHS England providing a three-month extension to this data sharing agreement (DSA) to permit the applicant to hold and process the data, whilst the applicant work on the points raised, if the following substantive comments were addressed; and would be supportive of NHS England **not** renewing the DSA beyond the three-months if the points raised have **not** been adequately addressed. **4.3.1** The independent advisers noted that when this application was previously reviewed by the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) on the 26th May 2022, a number of comments had been made in respect of transparency to the public, for example, in respect of public information available about the Device Access UK Limited (DAUK) Data Access Review Group (DADARG), for instance whether minutes from DADARG meetings were available to the public. It was noted in the internal application assessment form, that in response to this, the applicant had advised that they would be able to implement this by the end of the calendar year and retroactively publish previous years reviews and	

	approval numbers. The independent advisers noted that they would support this approach suggested by the applicant, however, would also suggest that NHS England request quarterly updates in arrears, noting that this was consistent with other organisations who were also subject to non-disclosure agreements with commercial companies. **4.3.2** The independent advisers noted the importance of transparency for NHS England, to enable them to ascertain whether the commercial benefit accruing to the commercial organisation is proportionate to the benefit to health and social care. This transparency would help NHS England assess whether or not they were complying with the National Data Guardian (NDG) guidance on benefits as their role of Data Controller of the data being disseminated to the applicant. **4.3.3** In respect of the commercial aspect of the applicant, the independent advisers queried the devices that have the support and data from DAUK, what proportion of these devices are then subsequently available on the NHS only; what is the uptake of the devices on the NHS; and what proportion of the devices are sold to consumers directly; and suggested that further clarification of this was provided. **4.3.4** To ascertain the extent of commercial verse public benefit, it was suggested by the independent advisers, that NHS England seek further clarity from the applicant on the income streams from the different areas of work as percentages of different types of work may not give an accurate picture. If these figures would be misleading because pro-bono or below-market value work for the NHS was undertaken, then this should be explained, **4.3.5** In addition, it was queried by the independent advisers, whether, if it was not for the input of DAUK, would the devices have been approved by the National Institute for Health and Care Excellence (NICE) anyway. If the applicant had any information to identify how many of the NICE approvals were dependent on the NHS data then this should be provided. This is because it is currently unclear what weight NICE is giving to the DAUK data and analysis. In addition, the group made the following observations on the application and / or supporting documentation provided as part of the review: **4.3.6** The independent advisers noted that the published privacy notice was **not** fully transparent on the use of data and the breadth of data users; and advised that the applicant was required to maintain a UK General Data Protection Regulation (UK GDPR) compliant, publicly accessible transparency notice(s) for the lifetime of the agreement, in line with the contractual requirement in section 4 (Privacy Notice) of the data sharing agreement (DSA). **4.3.7** In addition, it was noted by an NHS England representative that the privacy notice and the data reuse agreement, provided as a supporting document made reference to *"NHS Digital"*, and suggested that this was updated to correctly refer to *"NHS England"*.	

	4.3.8 It was noted by the independent advisers that the first two paragraphs in section 5(a) (Objective for Processing) in respect of the description / emphasis of the purpose of the work being for the NHS and other public sector organisations was misleading, and suggested that this was updated to reflect the correct / factual information. In addition this information should be moved further down section 5(a), and after any non-public sector organisations. **4.3.9** In addition, noting that 90% of DAUK's clients are MedTech companies, it was suggested by the independent advisers that this was reflected throughout section 5(a); and that the statement "*DAUK have carried out data analysis for approximately 100 MedTech companies and NHS organisations"* should be updated to reflect how many were commercial users and how many were non-commercial companies / organisations, for example by way of percentages, or actual numbers. **4.3.10** Noting the DADARG application of the *PICO formula, it was suggested by the independent advisers that the formula is further developed to include consideration of the National Data Guardian (NDG) guidance on benefits. It was noted that this was important to support the applicant in assessing applications; and highlighted the importance of having a public record of this, i.e. published minutes, to support NHS England in assessing and identifying that users of NHS England data are applying the NDG guidance on benefits. **P**opulation - Who would the technology treat II. **I**ndication - how the technology works III. **C**omparator - How care is currently delivered to the population IV. **O**utcome - Are the benefits in line with the Health and Social Care Act 2012 **4.3.11** The independent advisers noted that point seven in section 5(d) (Benefits) (iii) (Yielded Benefits) was clearly set out in terms of the yielded benefits; however, suggested that points one to six were reviewed and updated, in line with NHS England's DARS Standard for Expected Measurable Benefits, to ensure the yielded benefit was clearly outlined; or moved to section 5(c) (Specific Outputs Expected) if they were deemed to be outputs and **not** yielded benefits. **4.3.12** The group noted that the processing under this application would be a good example of the type of work that should be done in NHS England's Secure Data Environment (SDE); and suggest that this application was prioritised at such time NHS England have the appropriate resources / facilities to support this. **4.3.13** The group advised that they would be supportive of this application being reviewed at a future AGD meeting, due to the points raised as part of this review, the commercial use of data and the significant number of commercial clients.	
AGD Operations		
5	**Statutory Guidance**	

	The independent advisers again noted the reference to reviewing materials in accordance with *"a clearly understood risk management framework"* within the published Statutory Guidance and advised that they were **not** aware of an agreed risk management framework, and requested that NHS England provide further information/ clarity on this, noting this topic had been raised by Lord Hunt in the House of Lords on the 26th June 2023, and was answered by Lord Markham on the 5th July 2023: Written questions, answers and statements – UK Parliament. The NHS England SIRO Representative had provided further clarity on the risk management framework via email to the group, which confirmed that NHS England were asking the interim data advisory group to use the NHS England DARS Standards and Precedent model to assess the risk factors in relation to items presented to the interim data advisory group for advice; however the independent advisers noted that the wording in the in the statutory guidance "…*using a clearly understood risk management framework, precedent approaches and standards that requests must meet*…", suggested that the risk management framework is **separate** to the DARS Standards and Precedents, and asked that this be clarified by NHS England. It was noted during the meeting that an Oversight and Assurance Programme of applications that had not be subject to AGD review could form part of this Risk Management Framework. **ACTION:** NHS England SIRO representative to provide a written response addressed to AGD with further clarity on the risk management framework.	GC
6	**AGD Terms of Reference (ToR)** The independent advisers noted that over four months had passed since the Statutory Guidance had been published, requiring a ToR to be agreed and published, and queried whether there was any further update on the progress of the AGD ToR. The SIRO representative noted that NHS England were still considering comments from stakeholders on the AGD ToR. **ACTION:** The NHS England SIRO representative noted a previous action to clarify when a revised draft of the AGD ToR would be presented to AGD and when the AGD ToR was scheduled to be considered by the NHS England Board / subcommittee of the Board.	GC
7	**Standard operating procedures** The ongoing forward plan of work for creating Standard Operating Procedures was discussed and noted that this could not progress further without sight of the final draft of the ToR.	To note
Any Other Business		

8.1	**Federated Data Platform (FDP)** The group noted that, following a request from NHS England, an independent specialist adviser was attending / contributing to the FDP Information Governance Group meetings; and that further information in relation to this would be discussed at a future meeting.
8.2	**NHS England Transformation** The SIRO representative gave a brief update to the group on the internal transformation programme of work following the merger of NHS Digital into NHS England on the 1st February 2023; and the merger of Health Education England into NHS England on the 1st April 2023; and advised that the group would continue to be updated on a regular basis.

Meeting Closure

As there was no further business raised, the Chair thanked attendees for their time and closed the meeting.