Advisory Group for Data (AGD) – Meeting Minutes

Thursday, 5th October 2023

09:30 – 14:30

(Remote meeting via videoconference)

INDEPENDENT ADVISERS IN ATTENDANCE:	
Name:	**Role:**
Paul Affleck (PA)	Specialist Ethics Adviser
Claire Delaney-Pope (CDP)	Specialist Information Governance Adviser
Kirsty Irvine (KI)	Chair
Jenny Westaway (JW)	Lay Adviser
NHS ENGLAND STAFF IN ATTENDANCE:	
Name:	**Role / Area:**
Dave Cronin (DC)	Data Access Request Service Senior Approval Team (DARS SAT) (**SAT Observer**: items 4.1 to 4.5)
Kate Fleming (KF)	NHS England Data and Analytics representative (Delegate for Michael Chapman)
Dan Goodwin (DG)	Data Access Request Service (DARS) (**Observer**: item 4.2 to 4.3)
Dickie Langley (DL)	NHS England SIRO representative (Delegate for Garry Coleman)
Karen Myers (KM)	AGD Secretariat Team
Jonathan Osborn (JO)	NHS England Caldicott Guardian Team representative
Denise Pine (DP)	Data Access Request Service (DARS) (**Observer**: item 4.5)
Emma Whale (EW)	Data Access Request Service (DARS) (**Observer**: item 4.5)
Vicki Williams (VW)	AGD Secretariat Team
Clare Wright (CW)	Data Access Request Service (DARS) (**Observer**: item 4.1)
INDEPENDENT ADVISERS NOT IN ATTENDANCE:	
Prof. Nicola Fear (NF)	Specialist Academic Adviser

Dr. Robert French (RF)	Specialist Academic / Statistician Adviser
Dr. Imran Khan (IK)	Specialist GP Adviser
Dr. Geoffrey Schrecker (GS)	Specialist GP Adviser
Dr. Maurice Smith (MS)	Specialist GP Adviser
Miranda Winram (MW)	Lay Adviser
NHS ENGLAND STAFF NOT IN ATTENDANCE:	
Michael Chapman (MC)	Data and Analytics representative
Garry Coleman (GC)	NHS England SIRO representative
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.

	NHS England indicated that due to illness, the NHS England DPO representative was unable to attend, but NHS England were content for the meeting to continue with the NHS England DPO representative being updated upon his return. The group noted that the NHS England Data Protection Office (DPO) representative and their delegates were **not** available to attend AGD and noted their apologies. In the absence of a final Terms of Reference it was agreed that the meeting was still quorate for all agenda items, without a Data Protection Office representative (but that this would have posed an issue for quoracy had the AGD Terms of Reference been finalised in their current form). The group considered quoracy and agreed to proceed.
2	**Review of previous AGD minutes:** The minutes of the 28th September 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-366210-V2H5M-v5.2 **Applicant:** Imperial College London **Application Title:** Imperial College London research into UK Health Policy Reform **SAT Observer:** Dave Cronin **Observer:** Clare Wright **Previous Reviews:** The application and relevant supporting documents were previously presented / discussed at the IGARD meetings on the 25th June 2020, 28th May 2020, 6th December 2018 and the 19th October 2017. The application and relevant supporting documents were previously presented / discussed at the DAAG meeting on the 21st July 2015. **Application:** This was a renewal application. The purpose of the application is for a research project, to understand the implications for the NHS, and for the quality and volume of patient care, of major policy changes which affect either the funding and/or the delivery side of the NHS. 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 to the following substantive comments: **4.1.1** The Data Access Request Service Senior Approval Team (DARS SAT) observer drew to the attention of the group the information within the internal

	application assessment form and the application, in respect of the honorary contract arrangements, in particular, the reference to the *"small number of visiting researchers"* who may have an honorary contract, and the governance arrangements. **4.1.2** The group noted the information highlighted by the DARS SAT observer; and advised that they were supportive of an element of flexibility for the applicant to bring in visiting researchers; however, suggested that a number of safeguards were put in place, including, but not limited to, a clear upper limit for the number of visiting researchers on honorary contracts, for example, no more than ten; that those on honorary contracts were under the responsibility / supervision of a substantive employee of the applicant; and that the visiting researchers were **not** undertaking any data controllership activities. **4.1.3** It was also suggested by the group that NHS England DARS review and approve the form for the honorary contract in advance, and the applicant should ensure they keep NHS England appraised of **all** honorary contract holders, and that all the sufficient paperwork was in place for these individuals. **4.1.4 Separate to the application**: The independent advisers suggested there was a review of the NHS England DARS Honorary Contract Standard to further develop the concept of ensuring that data controllership is not diluted / devolved to an honorary contract holder. **ACTION:** NHS England to review the NHS England DARS Honorary Contract Standard to further develop the concept of ensuring that data controllership is not diluted / devolved to an honorary contract holder. This review could consider how both the number or nature of honorary contract holders may impact on a data controllership assessment and also whether the DARS standard should stipulate that honorary contract holders **must** be under the supervision of a substantive employee. **4.1.5** The independent advisers noted a risk that the visiting researcher, or the applicant who would be supervising the visiting researcher, may not be aware of the contractual restrictions on data access, for example that the data can only be accessed within the permitted territory of use, and may inadvertently breach the DSA. **4.1.6 Separate to the application**: The independent advisers suggested there was a review of the NHS England DARS Honorary Contract Standard that there may be a risk with any visiting researchers; that either the visiting researcher or the applicant who would be supervising the visiting researcher, may not be aware of the contractual restrictions on access. **ACTION:** NHS England to review the NHS England DARS Honorary Contract Standard to reflect that there may be a risk with any visiting researchers; that either the visiting researcher or the applicant who would be supervising the visiting	DARS DARS

researcher, may not be aware of the contractual restrictions on access, particularly as they relate to territory of use and/or remote access.

4.1.7 The independent advisers noted the second condition of support raised previously by the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) on the 28th May 2020 had been approved by Chair's action (see point 4.1.8 below): *"IGARD…noted that the applicant's Privacy Notice was aimed at research collaborators and not the research subjects; and asked that NHS Digital provide written confirmation that the applicant had provided a General Data Protection Regulation (GDPR) compliant Privacy Notice, including, but not limited to, ensuring it was study specific and reflected the volume of data held / requested".*

4.1.8 When the conditions had been reviewed out of committee (OOC) by IGARD, the IGARD Chair had noted a specific comment to NHS Digital's SIRO delegate and presenter via email and also published in the OOC report appended to the published IGARD minutes on the 25th June 2020 that: *"Members did not provide unanimous contentment that condition 2 was met and so the Chair by way of 'chair's action' has taken the view with regard to condition 2 that although technically the condition could be seen to be met because NHS Digital provided written confirmation, the substance of the condition was not met since the information was spread over three separate privacy notices. IGARD would expect on renewal that a study specific easily accessible privacy notice be available".*

4.1.9 The independent advisers reiterated previous comments made by IGARD that there should be a study specific easily accessible privacy notice; and 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) and UK GDPR.

In addition, the group made the following observations on the application and / or supporting documentation provided as part of the review:

4.1.10 The independent advisers noted in the internal application assessment form, and the application, that ethics approval was not required and had **not** been sought by the applicant, due to the category of data requested, and there being no ethical issues from the research. However, the applicant's website was clear with regard to seeking ethical review and suggested that the applicant approach their institutional ethics committee and ask whether an ethical review is required; and that any supporting documentation is uploaded to NHS England's customer relationships management (CRM) system for future reference.

4.1.11 Separate to the application: it was suggested by the independent advisers that NHS England's Ethical Approval Standard was reviewed, to ensure that there is an obligation on the applicant to seek ethical support from their institution and in line with their organisation's policy; or for the institution to confirm that ethical support was not required.

	ACTION: NHS England to review the NHS England's Ethical Approval Standard, to ensure that there is an obligation on the applicant to seek ethical support from their institution and in line with their organisation's policy; or for the institution to confirm that ethical support was not required. **4.1.12** The independent advisers noted the statement in section 5(a) (Objective for Processing) that there has been *"…no direct patient and public involvement and engagement (PPIE) for this study"*; and suggested that the applicant undertakes PPIE, noting the volume of data flowing and the national importance of the research; and that section 5 (Purpose / Methods / Outputs) be updated as appropriate, for example with an indicative plan of planned or future PPIE. The HRA guidance on Public Involvement is a useful guide. **4.1.13** The SIRO representative noted within the application that the funding expires before the DSA end date, and that the applicant will seek funding on an ongoing basis; and suggested that assurance was provided that Imperial College London can continue to support the research and researchers, should further funding **not** be available. **4.1.14 Separate to the application**: it was suggested that NHS England DARS update the internal Q&A document to ensure that assurance is provided that where the funding expires before the end of the DSA, the relevant institution / organisation is able to support the research and researchers, should further funding not be available. **ACTION:** NHS England DARS to update the Q&A document, to ensure that questions are asked about what will happen if funding expires before the end of the DSA and renewed funding is not granted; for example, will the relevant institution / organisation be able to support the research and researchers, or will data be deleted, should further funding not be available. **4.1.15** In respect of the projects outlined in the application, it was noted by the independent advisers that it was unclear whether the researchers were undertaking research in response to specific queries; or, if they are generating the research / ideas themselves. It was suggested that further clarification was provided in section 5(c) (Specific Outputs Expected) in line with NHS England's DARS Standard for Expected Outcomes; and that the benefits should be articulated in section 5(d) (Benefits) in line with NHS England's DARS Standard for Expected Measurable Benefits. **4.1.16** Noting the benefit in section 5(d) (ii) (Expected Measurable Benefits to Health and / or Social Care) in respect of the project looking at the impact of nursing staff absences on patient outcomes at a NHS trust, the independent advisers suggested that further clarity was provided, as to whether this was research paid for by an NHS Trust. If this was paid research, then it was suggested that the application was updated in section 5(a) in line with NHS England's DARS Standard for Objective for Processing, section 5(d) in line with NHS England's DARS Standard for Expected	DARS DARS

	Measurable Benefits and section 5(e) (Is the Purpose of this Application in Anyway Commercial) in line with NHS England's DARS Standard for Commercial Purpose. **4.1.17** The group noted and acknowledged the difficulty with identifying benefits where research is being undertaken to feed into policy development; and suggested that the statement in section 5(d) (iii) (Yielded Benefits) that outlines the difficulties, may be a good example for other similar applications.	
4.2	**Reference Number:** NIC-201243-R7L2M-v3.2 **Applicant:** Department of Health and Social Care (DHSC) **Application Title:** NHS Health Checks: linking primary care dataset to hospital and mortality data **SAT Observer:** Dave Cronin **Observer:** Dan Goodwin **Previous Reviews:** The application and relevant supporting documents were previously presented / discussed at the AGD meeting on the 3rd August 2023. The application and relevant supporting documents were previously presented / discussed at the IGARD meetings on the 25th June 2020 and the 28th June 2018. **Linked applications:** This application is linked to NIC-390154-Z4M0F. **Application:** This was an extension application. The purpose of the application is for the NHS Health Check programme. The NHS Health Check is a risk assessment, awareness, and management programme for adults in England aged 40-74. It is designed to reduce a person's chance of developing preventable non-communicable diseases such as kidney disease, heart disease, Type 2 diabetes, lung disease and some forms of dementia. It does this by assessing the top seven risk factors driving the burden of non-communicable disease in England and supporting people to reduce their risk through behaviour changes and/or clinical management. 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: **4.2.1** The independent advisers noted the references in section 5(a) (Objective for Processing) to the *"Data Extract Advisory Committee (DEAC)"*; and noted that there had been previous discussions on this as part of the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) reviews, in order to put in place the Direction to obtain the GP data to feed into this dataset. Concern was expressed on the transparency of DEAC, including, but not limited to, the lack of an update on the activities undertaken by DEAC and the information available to the public, for example published DEAC meeting minutes. It was suggested that NHS England	

	check with the applicant that DEAC is still in operation / meeting regularly, and, if they are, that they are encouraged to publish their minutes online. **4.2.2** In addition, noting that DEAC provides oversight on the uses of the data and the stated outputs and benefits; it was suggested that further information / clarification on this is ascertained **before** any further data flowed. **4.2.3** The independent advisers noted that IGARD had previously raised comments in respect of the applicant's privacy notice; and expressed concern that Data Access Request Service (DARS) had been advised in May 2023 and then August 2023 that the applicant was still working on this. It was noted 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). It was strongly advised that this outstanding issue was resolved as soon as possible. In addition, the group made the following observations on the application and / or supporting documentation provided as part of the review: **4.2.4** The DARS SAT Observer advised the group that the legal basis for processing the data was missing from section 3(a) (Data Access Already Given) of the application and noted that this would be updated to reflect the correct legal basis for processing. The group noted and supported the update to section 3(a). **4.2.5** Noting the dual purpose of the application, which is the monitoring and evaluation of the programme; the independent advisers queried whether any *"research"* would be undertaken, noting that section 5(d) (Benefits) of the application referred to a *"suite of research publications created with academic partnerships"*; and suggested that this was reviewed, and the application updated as may be appropriate. **4.2.6** In addition, noting the reference to academic partnerships, the independent advisers queried how this aligned with the statement in section 5(a) that *"data will only be accessed by individuals within DHSC who have authorisation to access the data for the purpose(s) described, all of whom are substantive employees of DHSC"*; and suggested that this was reviewed, and the application updated as may be appropriate. **4.2.7** Noting that Public Health England (PHE) closed at the end of September 2021, the independent advisers suggested that the application was reviewed, and all statements referring to PHE in the present tense were updated / removed, for example *"…PHE will then link this bridge file…"*. **4.2.8** The SIRO representative noted the challenges with the transfer of data due to the changing landscape of the various health bodies. It was suggested by the group that special conditions were added to section 6 (Special Conditions) as may be appropriate, to address any potential security risks that may occur from any transfer	

	of data or change to the way the reorganised bodies / organisations are managing data. **4.2.9** Noting the information in section 5(c) (Specific Outputs Expected) in respect of the *"dashboard"*, the independent advisers suggested that weblinks were added for the dashboards, for ease of reference, since section 5 (Purpose / Methods / Outputs) forms NHS England's Data Uses Register. **4.2.10** The group suggested that further information be added to section 5(c) in line NHS England's DARS Standard for Expected Outcomes and section 5(d) (Benefits) in line with NHS England's DARS Standard for Expected Measurable Benefits, to explain what steps the applicant has been able to take as a result of having access to this data to address the disparities in uptake of health checks between geography, ethnicity and areas of deprivation.	
4.3	**Reference Number:** NIC-662465-L3R5W-v0.3 **Applicant:** Cambridge University Hospitals NHS Foundation Trust **Application Title:** PHOSPHATE - Pragmatic randomised trial of High Or Standard PHosphAte Targets in End-stage kidney disease **SAT Observer:** Dave Cronin **Observer:** Dan Goodwin **Application:** This was a new application. The purpose of the application is for a study, which aims to assess whether phosphate levels within dialysis patients, and the current treatment guidelines suggesting a target reduction in phosphate levels result in improved health outcomes for patients. The primary objective of the study is to test the hypothesis that phosphate-lowering treatment to reduce serum phosphate level towards the normal level (≤1.5 mmol/L [millimoles per litre]) reduces fatal and non-fatal major cardiovascular events in patients receiving dialysis compared to a strategy of liberalised phosphate control with phosphate-lowering treatment for serum phosphate levels ≤2.5 mmol/L. NHS England were seeking advice on the following points: 1. Data Controllership 2. The linkage of data for participants who withdrew the relevant consent, after they have withdrawn consent, up to the date the consent was withdrawn. 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 **not** supportive for the flow of data for those participants that had withdrawn consent.	

	The group were supportive of the application and made the following observation / points of advice on the application and / or supporting documentation provided as part of the review: **4.3.1** The group commended NHS England on the work undertaken on the application. In response to points 1 and 2: **4.3.2** The group discussed the data controllership issues outlined in the internal application assessment form; and advised that it was a reasonable conclusion that Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge were the only joint Data Controllers; and that the other organisation outlined in the protocol are acting in an advisory capacity. **4.3.3** The majority of the group supported the concerns of the Data Access Request Service (DARS), in respect of the flow of data for those who had withdrawn their consent for data sharing; and highlighted that it was unclear how the Common Law Duty of Confidentiality would be met for such a disclosure of data even if the participants had been told that data may be received after the date they chose to stop participating. The group noted they were unaware of any case law in this area, and that this assessment could be open to other interpretations. **4.3.4** The group noted that section 5(b) (Processing Activities) of the application would need updating to reflect the data linkage being undertaken. **4.3.5** The SIRO representative noted that the application contained inconsistent information in respect of remote access to the data; and suggested that the application was reviewed and updated as appropriate, to ensure it contained the correct / consistent information on remote access.	
4.4	**Reference Number:** NIC-463165-H3R4K-v1.5 **Applicant:** Department of Health and Social Care (DHSC) **Application Title:** Department of Health and Social Care - Adult Social Care Data **SAT Observer:** Dave Cronin **Previous Reviews:** The application and relevant supporting documents were previously presented / discussed at the IGARD meeting on the 13th January 2022. **Application:** This was an amendment application. The amendments are to **1)** request Secondary Use Services (SUS) data. The request is to link SUS data to Adult Social Care data to help understanding of how secondary care has an impact of social care and vice versa. Metrics on the linked data will be used to identify what services are/aren't being delivered; and **2)** to allow DHSC to sublicense the linked data (ASC linked to SUS) to Local Authorities via a Dashboard designed by DHSC and hosted by NHS Arden and Greater East Midlands Commissioning Support Unit (AGEM CSU).	

	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 comment: **4.5.1** The independent advisers noted in the internal application assessment form, that the applicant had produced a transparency statement which describes the use of the data, and which was currently published on the NHS Arden and Greater East Midlands Commissioning Support Unit website, and that this would also be published on the gov.uk website. The independent advisers noted that the privacy notice, provided as a supporting document, appeared to be a policy briefing and **not** a privacy notice; 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). In addition, the group made the following observations on the application and / or supporting documentation provided as part of the review: **4.5.2** The group noted that the 'Adult Social Care Client Level Data Set (ASCCLDS) Briefing Paper' had been presented to the group at the meeting on the 14th September 2023; and that an updated / final briefing paper had **not** yet been received. The group noted that the 'finalised' briefing paper would usually be submitted with a first of type application, or before a first of type; and reiterated the advice from the 14th September 2023 meeting, that they looked forward to receiving the finalised briefing paper as per process. **4.5.3** The SIRO representative noted the statement in section 5(a) (Objective for Processing) *"Through the dashboard, local authorities and **other approved organisations** will also be able to access Client Level Data and linked health data…"*; and asked that further clarification be provided on who the other approved organisations were. **4.5.4** Noting the statement in section 5(d) (Benefits) (ii) (Expected Measurable Benefits to Health and / or Social Care) *"…is crucial to DHSC in circumstances where speedy analysis is required to react to either local public health, commissioning, or **research requirements**"*; the independent advisers queried this, in light of the information within the 'Draft Sub-licensing (Onward Sharing) commissioning data with Local Authorities' paper, provided as a supporting document, that states *"the data is intended **solely** for service planning and commissioning…"*. **4.5.5** In addition, it was also queried whether *"research"* could be undertaken under the scope of the 'Collection of Client Level Adult Social Care Data (No 3) Direction 2023' as per the discussion at the meeting on the 14th September 2023. It was noted	

	that any activity carried out which is not explicitly mentioned by the Direction may have an impact on public trust. **4.5.6** The independent advisers noted that the territory of use noted within the application and the 'Draft Sub-licensing (Onward Sharing) commissioning data with Local Authorities' paper were **not** aligned; and suggested that this was reviewed and updated / aligned to reflect the correct territory of use in both documents, i.e. *"UK"* or *"England and Wales"*. **4.5.7** The independent advisers noted in section 7 (Ethics Approval) of the application that *"Ethics approval is not required because only pseudonymised data is being released"*; and the internal application assessment that noted the applicant had consulted with the DHSC Data Ethics Team; and suggested that further clarification was provided as to what the outcome was of the discussion with the DHSC Ethics Team, and that the application was updated as appropriate, with any additional documentation received from the applicant uploaded to NHS England's customer relationship management (CRM) system as a future supporting document. **4.5.8** The independent advisers noted the expected benefits in section 5(d) (ii) had **not** been updated to reflect any expected benefits from the Local Authorities having access to the data via sub-licence; and suggested that this was reviewed and updated with further information on the expected benefits in line with NHS England's DARS Standard for Expected Measurable Benefits.	
4.5	**Reference Number:** NIC-668928-L9N5F-v0.6 **Applicant:** University of Oxford **Application Title:** DART: The Integration and Analysis of Data using Artificial Intelligence to Improve Patient Outcomes with Thoracic Diseases **SAT Observer:** Dave Cronin **Observers:** Denise Pine and Emma Whale **Application:** This was a new application. The purpose of the application is for a study, which aims to develop an integrated diagnostics, to enable the earlier diagnosis of lung cancer. This study, which began in 2020, aims to improve patient survival, yielding time and cost efficiencies to the NHS. The overall objective of the study is to link data from the Targeted Lung Health Checks (TLHC) programme, collected by the Lung Health Centres and sent to Oxford University Hospitals NHS Foundation Trust (OUH), with NHS England Data to better predict those who will benefit from lung cancer screening and to develop artificial intelligence systems that could improve understanding (through machine learning) of co-morbidities and confirm or improve standard clinical practices. 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: **4.5.1** Noting the roles of Optellum Ltd and GE Healthcare as set out in the internal application assessment form and the application, and noting that both do have access to the data; the group queried whether they should be considered Data Controllers or Data Processors, for example, in respect of them developing the AI algorithm and / or the intellectual property rights; and suggested that this was reviewed in line with NHS England's DARS Standard for Data Controllers and NHS England's DARS Standard for Data Processors. **4.5.2** The independent advisers noted that efforts had been made to address the commercial aspect of the application; however, suggested that further work be undertaken in line with NHS England's DARS Standard for Commercial Purpose, to fully address and be more specific on the potential commercial benefits, for example, clarifying the quantum of the *"in kind funding"*, and the development of the algorithm and any potential commercial benefit flowing from this. In addition, the group made the following observations on the application and / or supporting documentation provided as part of the review: **4.5.3** The independent advisers noted the information in the internal application assessment form, in respect of the language used in the patient information poster, i.e. "*Your data will be **anonymised**…"*; and agreed with the suggestion by the Data Access Request Service (DARS) to the applicant, that this should be updated to reflect the data will be *"pseudonymised"*. Notwithstanding the support from the Health Research Authority Confidentiality Advisory Group (HRA CAG), it was suggested that, in order to comply with UK General Data Protection Regulation (UK GDPR) and in line with Caldicott Principle 8, *"…A range of steps should be taken to ensure no surprises for patients and service users…",* they should confirm the understanding of the language used within the patient information poster with study participants (at least 3). **4.5.4** Noting the statement in section 5(a) (Objective for Processing) *"…which will be managed by the approved **Governance regulations** of the Confidentiality Advisory Group (CAG), Health Research Authority (HRA), and the Research and Development Department of the OUH"*; the group suggested that further clarification was provided as to what these regulations are, as this was currently unclear. **4.5.5** The SIRO representative queried the statement in section 5(a) *"The overall objective of the study is to link data…"*; and asked that further clarification was provided on the source of the linked data. **4.5.6** The group suggested that going forward, the applicant gave further consideration to the risk of bias when developing the algorithm, and how the bias could be mitigated. In addition, it was also suggested that further thought be given as to whether or not there would be automated decision making or profiling when	

	using the algorithm, and to consider the UK General Data Protection Regulation (UK GDPR) implications of the use of algorithms in a healthcare setting. **4.5.7 Separate to the application**: Noting that the legal basis was s251, the AGD Chair noted that they would discuss with the HRA CAG Chair an apparent increase in instances where there is the opportunity to take consent from participants but s251 support has been provided. **ACTION:** The AGD Chair to discuss with the HRA CAG Chair instances where there is the opportunity to take consent from participants, but s251 support has been provided.	AGD Chair
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
8	**Oversight & Assurance** The independent advisers noted that the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) had undertaken oversight and assurance of those applications which were proceeding down NHS England's precedent route and suggested that NHS England may wish to consider adding oversight activity to AGD's programme of work. **ACTION:** NHS England SIRO Representative to consider the oversight and assurance suggestion, and feed back to AGD at a future meeting. In addition and as noted by IGARD, the independent advisers noted that the legacy NHS Digital webpage Excel spreadsheet: COVID-19 (non DARS) Data Release Register was still showing March 2020 to April 2022 and suggested that for transparency, the documentation was updated in line with all releases and / or comments provided. An update on the register was also requested at a future meeting.	GC

Meeting Closure

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