Advisory Group for Data (AGD) – Meeting Minutes

Thursday, 1st August 2024

09:00 – 15:40

(Remote meeting via videoconference)

AGD INDEPENDENT / NHS ENGLAND MEMBERS IN ATTENDANCE:	
Name:	**Role:**
Paul Affleck (PA)	AGD independent member (Specialist Ethics Adviser and Chair for items 6.1 to 8.2 and 9 to 11)
Claire Delaney-Pope (CDP)	AGD independent member (Specialist Information Governance Adviser)
Kirsty Irvine (KI)	AGD independent member (Chair) (items 1 to 5.2 and item 8.3)
Andrew Martin (AM)	NHS England member (Data Protection Office Representative (Delegate for Jon Moore))
Dr. Jonathan Osborn (JO)	NHS England member (Caldicott Guardian Team Representative)
Tom Wright (TW)	NHS England member (Data and Analytics Representative (Delegate for Michael Chapman))
NHS ENGLAND STAFF IN ATTENDANCE:	
Name:	**Role / Area:**
Garry Coleman (GC)	NHS England SIRO Representative
Louise Dunn (LD)	Internal & System Data Flows Lead, Data Portfolio Management, Data and Analytics (**Observer:** item 6.1)
Paul Harrison (PH)	National Proxy Service Delivery Manager, National Digital Channels Transformation Directorate (**Observer:** item 5.1)
Suzanne Hartley (SH)	Data Access and Partnerships, Data and Analytics (**Observer:** item 6.1)
Dr. Phil Koczan (PK)	Deputy Director – Caldicott Guardian (Interim), Medical Directorate (**Observer:** item 5.1)
Ameya Krishnamoorthy (AK)	Lead Service Designer for the National Proxy Service, National Digital Channels Transformation Directorate (**Presenter:** item 5.1)

Lucy Legge (LL)	Data Access and Partnerships, Data and Analytics (**Observer:** items 6.1 to 6.3)
Ruby Nicholls (RN)	Senior Analytical Manager, Operations and System Support Directorate (**Observer**: item 5.2)
James Watts (JW)	Data Access and Partnerships, Data and Analytics (**Observer:** items 6.4 and 6.5)
Louise Whitworth-Woodhead (LWW)	Deputy Director Information Governance Delivery (Digital & Operations), Privacy, Transparency and Trust (PTT), Delivery Directorate (**Observer:** item 5.1)
Vicki Williams (VW)	AGD Secretariat Manager, Privacy, Transparency and Trust (PTT), Delivery Directorate
Chris Wilson (CW)	Senior IG Manager - IG Delivery (Data and Analytics), Privacy, Transparency and Trust (PTT), Delivery Directorate (**Presenter:** item 5.2)
AGD INDEPENDENT MEMBERS / NHS ENGLAND MEMBERS <u>NOT</u> IN ATTENDANCE:	
Name:	**Role / Area:**
Michael Chapman (MC)	NHS England member (Data and Analytics Representative)
Prof. Nicola Fear (NF)	AGD independent member (Specialist Academic Adviser)
Dr. Robert French (RF)	AGD independent member (Specialist Academic / Statistician Adviser)
Jon Moore (JM)	NHS England member (Data Protection Office Representative)
Jenny Westaway (JW)	AGD independent member (Lay Adviser)
Miranda Winram (MW)	AGD independent member (Lay Adviser)

1	**Welcome and Introductions:** The AGD meeting Chair welcomed attendees to the meeting. AGD noted that, due to the lack of availability of independent members and one independent member giving apologies on the day to the AGD Chair, there was an even number of AGD independent members (three) and AGD NHS England members (three) in attendance for

	items 1 to 5.2 and item 8.3; but for items 6.1 to 8.2 and 9 to 11 only two AGD independent members and three AGD NHS England members were in attendance at the meeting. The importance of the AGD independent member majority was acknowledged by those present, and it was suggested that an annual review / possible inclusion in the AGD annual report of the number of meetings where an independent majority had not been present would be useful, as this would allow consideration of whether any action needed to be taken to improve the proportion of meetings with an AGD independent member majority. The NHS England SIRO representative stated that should AGD members be required to vote (items 1 to 5.2, and item 8.3), then one AGD NHS England member would be asked to not participate, to ensure the appropriate balance of votes, i.e. that the majority was by AGD independent members. The Group noted and agreed with this proposal. The NHS England SIRO representative stated that for items 6.1 to 8.2 and 9 to 11, it would not be possible to ask one AGD NHS England member to not participate, without affecting the NHS England member quoracy. Accordingly, a balance of votes was **not** available for those items. The Group noted and agreed with this proposal. Noting that the AGD Terms of Reference state that *"The quorum for meetings of the Group or a Sub-Group is **five members, including at least three independent members**, one of whom may be the Chair, Deputy Chair or Acting Chair and two of the three NHSE Members. In addition, a representative of the SIRO must also be in attendance for any meetings of the Group or a Sub-Group. **In exceptional circumstances the Chair and the representative of the SIRO may agree for the Group to still meet and conduct its business, but the minutes should note the meeting was not quorate and provide details of the number of NHSE members and independent members who were in attendance and provided advice on any matters***."; the Group agreed that the meeting was quorate for items 1 to 5.2, and item 8.3 but was **not** quorate for agenda items 6.1 to 8.2 and 9 to 11, and agreed to proceed in exceptional circumstances on that basis.
2	**Review of previous AGD minutes:** The minutes of the AGD meeting on the 25th July 2024 were reviewed and, after several minor amendments, were agreed as an accurate record of the meeting.
3	**Declaration of interests:** Paul Affleck noted professional links to Arrow Business Communications Ltd as part of his role at the University of Leeds but noted no specific connection with the relevant application (NIC-564296-L7V1M-v0.16) or staff involved. It was agreed this did not preclude Paul from taking part in the discussions about this application.
4	**AGD Action Log:** *The action log was not discussed.*
5 BRIEFING PAPER(S) / DIRECTIONS:	

5.1	**Title:** National Proxy Service – Briefing Paper **Presenter:** Ameya Krishnamoorthy **Observers:** Paul Harrison, Louise Whitworth-Woodhead and Dr. Phil Koczan The National Proxy Service has been through significant consultation with various bodies and colleges across health care, engagement with AGD forms part of this consultation. NHS England are seeking to deliver a National Proxy Service to enable people to more easily access services online for those they care for. To deliver this service, NHS England are in the process of obtaining a legal Direction to cover the processing necessary to deliver the service. Proxy access is where a trusted individual (Proxy) accesses health and care services, for example, ordering a repeat prescription or viewing a medical record, for patients they care for. The aim is to deliver a National Proxy Service that: **1)** enables proxies and patients to easily request proxy access from their GP through digital channels; **2)** support GPs in making informed decisions on granting proxy access through the provision of standards, guidance, and information from authoritative sources; **3)** enables proxies to use proxy relationships to access services provided through local and national clinical systems for patients they care for; and **4)** enables proxies, patients, and clinicians to manage access to ensure it remains safe and appropriate. NHS England were seeking advice on the following points: 1. General feedback on NHS England's processing of data as described in the briefing paper, which forms the basis of the Legal Direction. 2. Transparency. 3. Any other risks to be considered. **Outcome of discussion:** AGD welcomed the briefing paper and made the following observations / comments: **In response to points 1 to 3:** **5.1.1** AGD suggested that in order to be transparent as to why this legal basis (Direction) was being relied upon, that it be clearly articulated in the briefing paper and / or other supporting documentation for transparency, since the activity would seemingly be covered by existing legal powers. **5.1.2** The Group noted that the Data Protection Impact Assessment (DPIA) provided as a supporting document had been very helpful, and suggested this be updated to provide assurance that a proxy can be removed as quickly as it can be set up, this was particularly relevant for safeguarding; and point 17 be updated to be clear that not applying the National Data Opt-Out (NDO) was because it was for direct care, rather than implying it was because of the Direction	

	5.1.3 The Group noted that the transparency materials provided were not written with the public in mind and suggested that they be updated further to include further detail including, but not limited to, providing more lay friendly detail to support the reader, including those that are carers, or parents etc; any barriers to being a proxy such as any age restrictions for a parent accessing a child's health information; that work was being undertaken to expand the relationship information held so as not to disadvantage carer / child links beyond the birth mother / child link; and more lay friendly information about the legal basis to flow the data. **5.1.4** The Group suggested that NHS England may wish to consider patient and public involvement and engagement (PPIE) when updating their transparency materials, for example mental health groups. The HRA guidance on Public Involvement is a useful guide. **5.1.5** The Group discussed the GP involvement and whether any engagement had been undertaken with the GP profession, other than through the Royal College of General Practitioners (RCGP), and suggested NHS England involve the British Medical Association (BMA) and relevant GP Data Protection Officers (DPOs) or Integrated Care Board (ICB) DPOs. **5.1.6** The AGD NHS England Data Protection Officer (DPO) member noted there may be potential breaches with the proxy service due to mismatches in the data, noting that NHS England had investigated relevant mitigations via current operational processes and the team would be alerted to errors in matching. **5.1.7** AGD discussed whether NHS England should be considered a joint Data Controller or a Data Controller / Data Processor, in line with the NHS England DAS Standard for Data Controllers. NHS England noted that they had discussed this aspect with the NHS England Legal Team who had reached a position on this point. AGD noted that they had **not** been provided with a copy of the legal advice, and that some of their queries may have been answered / addressed in that document. **5.1.8 Separate to the briefing note:** the Group noted that NHS England had sought external legal advice in 2023 who had advised that independent members on the Group were part of the client group and therefore able to receive legally privileged information (see item 10.2, 17th August 2023), and asked that NHS England legal advice was provided for briefing papers. **ACTION:** AGD NHS England member sponsors to remind teams that legal advice, including legally privileged (with relevant caveats) should be included in the documentation pack. **5.1.9** Noting the NHS England 'inclusive digital health framework', which builds on the NHS Digital 'digital inclusion guide', the Group suggested that NHS England consider the use of language in their documentation; and note that particular groups face a higher risk of being digitally excluded and also face a higher risk of health inequalities, for example older people, disabled people and people with life	NHS Reps

	impacting conditions, and people living in rural or coastal areas with inadequate broadband and mobile data coverage. **5.1.10** AGD looked forward to receiving the finalised briefing paper tabled at a future meeting. AGD provided the following observations / comments, **separate to the briefing paper**: **5.1.11** Louise Whitworth-Woodhead asked the Group if system delivery Directions, where the data collection is only a small part of the Direction in that one item is collected to provide the technical system delivery, should be presented to the Group. The AGD Chair, noting the statutory guidance, suggested that NHS England consider all Directions coming to the Group for advice, especially where there had been no independent or lay involvement in the life cycle.	
5.2	**Title:** Process Mining Software Trial (Elective Improvement) – Briefing Paper **Presenter:** Chris Wilson **Observers:** Ruby Nicholls Process mining is a technique used to analyse and monitor processes. Through applying specialised algorithms to event log data, trends, patterns and details of how a process unfolds can be identified. 'Mining' event log data can help organisations understand the performance of their processes, revealing bottlenecks and other areas for improvement. Currently, the process mining technique isn't widely utilised across the NHS. The purpose of the briefing paper is to present a request to engage suppliers of process mining software (acting as Data Processors to NHS England) to conduct a trial of their products. The trial is to be undertaken with a view to supporting improvements in elective care services and increase efficiency, as well as helping to reduce waiting times as part of the recovery from COVID-19. This would represent a novel use of commissioning data collected under direction. NHS England were seeking advice on the following points: 1. Does utilising process mining software provided by external suppliers to analyse commissioning data derived from NHSE's pseudonymised data environment raise any risks which have not been adequately addressed as described in this document. 2. Does the processing of this data in this manner raise any specific risks to the transparency of the processing of data collected under Direction. **Outcome of discussion:** AGD welcomed the briefing paper and made the following observations / comments: **In response to points 1 and 2:**	

	5.2.1 AGD noted that they were supportive of the principle and proposal outlined in the documentation, but queried whether enough data was being used for the trial, and advised that they were supportive of further data being used with the relevant robust justification, for example additional data years or additional Trusts, without recourse to AGD. **5.2.2** The Group noted that three different suppliers were part of the pilot and that this was a strength, but that NHS England should be transparent around this aspect. **5.2.3** AGD noted the different Directions relied upon for the different flows of data, and suggested NHS England be explicitly clear that the data flowing under the COVID-19 Public Health Directions 2020 was for research and planning in relation to COVID-19 **only**. **5.2.4** The AGD NHS England Caldicott Guardian member, who is also a clinician, noted that consideration be given to the impact on the staff involved when comparing two different processes, or comparing the same process, since although they be technically doing the same surgery the technique may be different, for example full hip replacement surgery: some surgeons may be involved in more complicated full hip replacements compared to other surgeons, so there needs to be a degree of interpretation because not all things are equal. Consideration should also be given to how change impacts staff and ensuring staff are well supported through any periods of change. **5.2.5** AGD noted there may be a commercial aspect to the trial but noted this as a strength, since it was not something that NHS England may be able to offer in-house, and this should be applauded and highlighted in an appropriately transparent way. **5.2.6** AGD, whilst recognising the potential of process mining, also flagged the possibility of causing harm by amplifying biases in the data and reaching inaccurate conclusion due to quality issues with the input data. It was suggested that these issues of accuracy and fairness were considered further. **5.2.7 Separate to the briefing note** the Group noted that NHS England had sought external legal advice in 2023 who had advised that independent members on the group were part of the client group and therefore able to receive legally privileged information (see item 10.2, 17th August 2023), and asked that NHS England legal advice, Data Protection Impact Assessments (DPIAs) etc was provided for briefing papers. **ACTION:** AGD NHS England member sponsors to remind teams that legal advice, including legally privileged (with relevant caveats) should be included in the documentation pack. **5.2.8** AGD looked forward to receiving the finalised briefing paper tabled at a future meeting.	NHS Reps

6 EXTERNAL DATA DISSEMINATION REQUESTS:		
6.1	**Reference Number:** NIC-748645-R5G3D-v0.2 **Applicant:** Office for National Statistics (ONS) **Application Title:** NHS Diabetes Prevention Program (DPP) - for the purposes of Statistics and Statistical Research, under section 45 of the Statistics and Registration Services Act 2007 as amended by the Digital Economy Act 2017 **Observers:** Suzanne Hartley and Lucy Legge **Previous Reviews:** The application and relevant supporting documents were previously presented / discussed at the AGD meeting on the 9th May 2024. **Linked applications:** This application is linked to NIC-748653-S9J4H. **Application:** This was a new application. The purpose of the application is for ONS to use the data for its health and labour market statistical work programme, which is currently sponsored by His Majesty's (HM) Treasury and potentially other funding bodies in the future. The statistics this will enable are in line with ONS's function to produce statistics for the public good. NHS England were seeking general advice on the application. Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** AGD acknowledged that they would **not** be quorate for the discussion of this application noting only two independent members and three AGD NHS England members were available; noting that the AGD Terms of Reference states that ***"In exceptional circumstances the Chair and the representative of the SIRO may agree for the Group to still meet and conduct its business…"*** the Group agreed to discuss the application. AGD could see the potential value in the work outlined in the documentation provided, but were **not** supportive of the application at this time and wished to draw to the attention of the SIRO the following substantive comments, and suggested the application be brought back to a future meeting: **6.1.1** The Group noted that the lack of specific patient and public involvement and engagement (PPIE), and transparency, could lead to individuals being surprised by their data being processed in this way. **6.1.2** AGD acknowledged that NHS England would be mandated under Section 45C of the Statistics and Registration Service Act (SRSA) 2007 to flow the data to ONS. However, AGD also noted Section 45C (13)(b), **and** suggested that there is a need for specific PPIE and transparency, and that individuals may be surprised at this flow of data, since it would **not** currently meet the first data protection principle.	

	6.1.3 AGD reiterated their concerns that **no specific** PPIE had been undertaken; and suggested that there was ongoing PPIE throughout the lifecycle of the project. The HRA guidance on Public Involvement is a useful guide. **6.1.4** The Group acknowledged that the National Statistics Data Ethics Advisory Committee (NSDEC) had reviewed the application and relevant documentation had been provided; however noted that NSDEC had queried whether sufficient public specific engagement on the purpose and nature of the data had been undertaken and AGD were unclear if NSDEC had been satisfied on this point. **6.1.5** Noting the data would be used for its health and labour market statistical work programme, the Group felt it was novel and contentious to link health and financial information in this way, and again reiterated that this may be a surprise to individuals and emphasised the need to consult with the public as to whether this would be something they could / would support. **6.1.6** AGD noted that there appeared to be no mechanism for individuals to opt out if desired and emphasised the need to inform and consult with the public. **6.1.7** The Group also queried exactly how the economic data would be used, and why the applicant needed to link with such detailed measures of income, for example, and suggested this was further explored by NHS England. **6.1.8** AGD noted in section 5(b) (Processing Activities) of the application, reference to "*a list of approved users is available on request*" and suggested that this statement should be qualified that NHS England, rather than the public, can request the list of approved users. **6.1.9** AGD noted and commended the applicant and NHS England Data Access Service (DAS) on the amount of work undertaken on the application since it was last seen by AGD on the 9th May 2024. **6.1.10** AGD noted the limited response to point 6.2.3 (9th May 2024) with regard to the Health Research Authority Research Ethics Committee (HRA REC) and queried the reference to the discussion with the SIRO Representative. The Group asked that a copy of the discussion be tabled at a future AGD under 'Any Other Business' (AOB) and that a copy of the discussion be uploaded to NHS England's customer relationship management (CRM) system for future reference. **ACTION:** The AGD Secretariat to add to the AGD forward plan for discussion at a future AGD meeting **6.1.11** AGD queried why section 3(a) (Data Access Already Given) and section 3(b) (Additional Data Access Requested) of the application were currently blank. NHS England confirmed that section 3(a) and section 3(b) would be updated with the relevant datasets requested, as outlined in section 5 (Purpose / Methods / Outputs) of the application. Noting the large volume of data requested and outlined in section 5, the Group reiterated the need / importance for specific PPIE.	AGD Sec

	6.1.12 AGD noted that the applicant's Data Sharing Framework Contract (DSFC) was due to expire on the 17th August 2024, and presumed NHS England were working with the applicant on ensuring a DSFC was in place before that date. **6.1.13 Separate to the application:** The AGD NHS England Data Protection Officer (DPO) member queried the reference in the DAS internal application assessment form to "*this application is submitted to AGD to gain **approval** from the Caldicott Guardian and Data Protection Officer, and advice from the independent members, to inform SIRO authorisation*"; and suggested that the language be changed to "…*gain **support…***" since the AGD NHS England members do not "*approve*" as members of AGD.	
6.2	**Reference Number:** NIC-755472-Y7C7F-v0.6 **Applicant:** Care Quality Commission (CQC) **Application Title:** NHSE UDAL – CQC **Observers:** Louise Dunn and Lucy Legge **Linked applications:** This application is linked to NIC-359603-D2Q6M. **Application:** This was a new application. The purpose of the application is for a project, to evaluate and test the Unified Data Access Layer (UDAL) as an effective and efficient system for data sharing between CQC and NHS England. NHS England were seeking general advice on the application. Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** AGD acknowledged that they would **not** be quorate for the discussion of this application noting only two independent members and three AGD NHS England members were available; noting that the AGD Terms of Reference states that ***"In exceptional circumstances the Chair and the representative of the SIRO may agree for the Group to still meet and conduct its business…"*** the Group agreed to discuss the application. AGD were supportive of the purpose but were **not** supportive of the current application, requiring clarification with regard to the legal basis and the identifiability of the data, and wished to draw to the attention of the SIRO the following substantive comments: **6.2.1** AGD noted that the CQC receive identifiable Hospital Episode Statistics (HES), Emergency Care Data Set (ECDS), Mental Health Services Data Set (MHSDS), Community Services Data Set (CSDS), Maternity Services Data Set (MSDS) and Civil Registration of Death (CRD) in extract form via NIC-359603-D2Q6M. **6.2.2** AGD noted that section 3 (Datasets Held / Requested) of the application outlined that the request was for pseudonymised data, since UDAL holds	

	pseudonymised data, however the Group noted that the CQC also holds the same data locally in identifiable form under NIC-359603-D2Q6M, so once the data was downloaded from UDAL by the CQC, it would suggest that the pseudonymised data becomes identifiable in their hands. AGD suggested that a justification be provided in section 5 (Purpose / Methods / Outputs) of the application as to why / how the data could remain pseudonymised if extracted from UDAL. **6.2.3** AGD were unclear why the "*EEA*"* had been cited in section 2(c) (Territory of Use) of the application when there was no rationale provided as to why the data was being processed outside of the UK. The Group noted the Data Processor was based in Ireland, however AGD noted that the applicant could specifically request that the Data Processor process / store the data at one of their UK sites, and suggested this should be explored further. **European Economic Area* **6.2.4** The Group also noted reference in section 5(b) (Processing Activities) of the application to "*the data will not leave the EEA at any time*" and suggested this statement was amended to be explicitly clear that **no** data will be transferred to the EEA and that **no** remote access is permitted outside of the UK under this data sharing agreement (DSA). **6.2.5** The Group also queried the use of physical servers and suggested it be explicitly clear what data was stored / processed at each location, including the Cloud, within section 5 of the application **6.2.6** The Group noted this application was for the pilot phase only of accessing the data via UDAL and advised reminding the applicant that the DSA would need to be amended to progress beyond the pilot phase.	
6.3	**Reference Number:** NIC-564296-L7V1M-v0.16 **Applicant:** Renal Registry **Application Title:** Linking the National Registry of Rare Kidney Diseases with Hospital Episode Statistics for Research **Observer:** Lucy Legge **Application:** This was a new application. The purpose of the application is to link the National Registry of Rare Kidney Diseases (RaDaR) to address five research questions that it is hoped can benefit patient care for chronic kidney disease. NHS England were seeking advice on the following points, including general advice on any other aspect of the application: 1. The Renal Association is seeking permission to use data for a rolling programme of work.	

2. While the Renal Association does not propose to onwardly share the data under sub-licence, they do propose to offer analytical services to third parties using the data to produce aggregated outcomes.
3. The Renal Association is relying on informed patient consent for processing confidential patient information.

Should an application be approved by NHS England, further details would be made available within the Data Uses Register.

Outcome of discussion: AGD acknowledged that they would **not** be quorate for the discussion of this application noting only two independent members and three AGD NHS England members were available; noting that the AGD Terms of Reference states that ***"In exceptional circumstances the Chair and the representative of the SIRO may agree for the Group to still meet and conduct its business…"*** the Group agreed to discuss the application.

AGD were supportive of research into rare kidney diseases but were **not** supportive of the current application, and wished to draw to the attention of the SIRO the following substantive comments:

6.3.1 AGD noted that substantive work was required by the applicant in order to address the general points raised and notified to the applicant by NHS England, including the approach to the common law duty of confidentiality. AGD endorsed the points already made to the applicant by NHS England Data Access Service (DAS). As a result, AGD recognised that, having listened to their advice and the work already undertaken by NHS England, the SIRO is likely to reject the application until such time as the applicant had fully addressed the points raised.

6.3.2 At the request of the NHS England SIRO representative, the Group considered whether the current application was viable, concluding there were too many areas to resolve. This included, but was not limited to, the relationship between the existing s251 support for audit and research with the move to a consent model; and a careful analysis of the consent materials to see whether the consent was valid, or not; and whether consideration had been given to seeking further s251 support.

6.3.3 AGD noted the updated RaDaR DAG* Terms of Reference (ToR), provided as a supporting document (SD12), and suggested the applicant act on the advice already provided by NHS England, including but not limited to lay member involvement; quoracy rules; approval criteria; approval criteria specific to commercial interests / benefits; scenarios where linked HES and / or mortality data are to be analysed etc.

**National Registry of Rare Kidney Diseases (RaDaR) Data Analysis Group (DAG)*

6.3.4 Noting the applicant provided a response when asked about lay membership on the RaDaR DAG, in respect of them working closely with the Renal Association Patient Council, the Group suggested that the applicant make greater use of

	relevant patient and public involvement and engagement (PPIE) groups, and suggested that there was ongoing PPIE throughout the lifecycle of the project. The HRA guidance on Public Involvement is a useful guide. **6.3.5** The Group suggested that the applicant may wish to look at governance models for other organisations accessing data for similar purposes, for example UK Biobank, Genomics England or the Clinical Practice Research Datalink (CPRD). **6.3.6** AGD noted and commended NHS England DAS on the considerable amount of work undertaken on the application and with the applicant.	
6.4	**Reference Number:** NIC-147852-RV70L-v6.2 **Applicant:** University of Newcastle Upon Tyne **Application Title:** Long term sequelae of radiation exposure due to computed tomography and fluoroscopic cardiology in childhood **Previous Reviews:** The application and relevant supporting documents were previously presented / discussed at the AGD meeting on the 22nd February 2024. **Application:** This was an amendment application. The amendment is to permit sublicensing of the data to three named organisations based within the European Economic Area (EEA), including the International Agency for Research on Cancer (IARC) who have received data already. These organisations include: **1)** IARC, France; **2)** European Institute for Biomedical Imaging Research, Austria; and, **3)** Barcelona Institute of Global Health (ISGlobal), Spain. NHS England were seeking general advice on the application. Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** AGD acknowledged that they would **not** be quorate for the discussion of this application noting only two independent members and three AGD NHS England members were available; noting that the AGD Terms of Reference states that ***"In exceptional circumstances the Chair and the representative of the SIRO may agree for the Group to still meet and conduct its business…"*** the Group agreed to discuss the application. AGD were supportive of the application on the presumption that the SIRO would **not** approve this application until such time as the issues relating to the previous breach had been resolved to the SIRO's satisfaction, and wished to draw to the attention of the SIRO the following substantive comments: **6.4.1** The NHS England SIRO representative confirmed that the amendment to permit sublicensing of the data to the three organisations would **not** proceed until the issues around the previous breach with data flowing to the United States of America (USA) had been addressed. The NHS England SIRO representative noted that NIC-736175-V8B9C had been in the customer relationship management (CRM)	

	system for circa 9 months (has not been formally submitted by the applicant) and a DSA is not in place to cover the data being held in the USA. **6.4.2** AGD noted that they had been provided with a briefing on the approach to data sharing with IARC on the 27th June 2024 and that all applications would be carefully reviewed to ensure they fit with the bespoke terms/special conditions for IARC and that these were not inadvertently flowed down to other organisations where this would be inappropriate. Given the briefing from the NHS England legal team on the 27th June 2024, the Group suggested that the legal team approve the text of any contract put in place between IARC and Newcastle University, given the organisational status of the World Health Organisation (WHO). **6.4.3** The Group queried section 2(c) (Territory of Use) of the application which stated the territory of use as "*UK and EEA*"* and suggested this was amended as appropriate, since IARC (who are part of the World Health Organisation) are **not** subject to national law or jurisdiction as confirmed to AGD as part of NIC-670080-S6J0Y on the 2nd November 2023 (point 5.2.5) **European Economic Area* **6.4.4** AGD noted that NHS England's Privacy, Transparency and Trust (PTT) had provided advice to NHS England Data Access Service (DAS) with regard to the onward sharing to European organisations within Europe and that onward sharing to the USA should be covered under a separate data sharing agreement (DSA) (NIC-736175-V8B9C), however the documentary evidence had **not** been provided in the agenda pack. AGD were therefore unclear why PTT had specifically asked for the onward sharing to the USA, which had been subject to a data breach under previous iteration of this DSA, had been moved to a new application (NIC-736175-V8B9C). **6.4.5** AGD queried why the approach had been put forward to split the previous iteration of this application into two separate DSAs, and why NHS England had not requested that the data in the USA be deleted, but noted the significant research value and public value to flowing the data / organisations continuing to hold and process the data. **6.4.6** The Group noted there was a significant risk to NHS England, in that the data currently in the USA was **not** covered by this application, and nor by NIC-736175-V8B9C since it is **not** an active agreement. **6.4.7 Separate to the application:** the Group noted that NHS England had sought external legal advice in 2023 which had advised that independent members on the group were part of the client group and therefore able to receive legally privileged information (see item 10.2, 17th August 2023), and asked that NHS England PTT / legal advice was provided with applications. **ACTION:** AGD NHS England member sponsors to remind teams that PTT / legal advice, including legally privileged (with relevant caveats) should be included in the documentation pack.	NHS Reps

	6.4.8 AGD noted the large volume of data under this application and NIC-736175-V8B9C, and noted the valuable research being undertaken, and the importance of the international study. **6.4.9** The Group noted and commended the applicant on the public and patient involvement and engagement (PPIE), outlined in section 5 (Purpose / Methods / Outputs) of the application. **6.4.10** AGD noted that some of the storage and processing locations had appeared in section 2 (Location(s)) of the application and suggested these were removed, in line with current NHS England DAS policy to **not** include this level of detail in applications. **6.4.11** In addition, the Group suggested that section 5 (Purpose / Methods / Outputs) of the application be carefully reviewed with regard to the data storage and data accessed to ensure consistency of language across section 5(a) (Objective of Processing) and 5(b) (Processing Activities), for example where the servers are located and how the data is backed up. **6.4.12** In order to support the lay reader of section 5 of the application via the NHS England data uses register, the Group suggested that the application be updated to include a header where the narrative discussed *"sub licencing"* to bring clarity for the reader. **6.4.13** AGD praised the applicant for committing to recruiting to a lay / independent member but felt that one year was too long a period, especially with the DSA end date of 31st July 2025, and suggested that the special condition in section 6 (Special Conditions) of the application "*within 1 year, Newcastle University will introduce independent / lay representation to the NREDAG*"*, was amended to "*within 3 months of receiving the data*…" **Newcastle Radiation Epidemiology Data Advisory Group* **6.4.14** AGD noted that transparency could be further updated to include details of sublicensing, in order to inform the data subjects.	
6.5	**Reference Number:** NIC-682532-B4B5L-v0.4 **Applicant:** Hull University Teaching Hospitals NHS Trust **Application Title:** Evaluating the current standard of care for patients diagnosed with malignant melanoma of the head and neck – access to staging and surgical treatment. (ODR2122_2697) **Observer:** James Watts **Application:** This was a new application. The purpose of the application is for a research project, to examine how practice varies nationally, looking at who receives sentinel lymph node biopsy (SLNB) after melanoma of the head or neck, what treatments they go on to have, and whether	

	they recover from their melanoma or not; with the aim of identifying whether SLNB should be made available to everyone in this group. NHS England were seeking general advice on the application. Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** AGD acknowledged that they would **not** be quorate for the discussion of this application noting only two independent members and three AGD NHS England members were available; noting that the AGD Terms of Reference states that ***"In exceptional circumstances the Chair and the representative of the SIRO may agree for the Group to still meet and conduct its business…"*** the Group agreed to discuss the application. AGD were supportive of the application and wished to draw to the attention of the SIRO the following substantive comments: **6.5.1** AGD queried whether the University of Hull, who were the employing organisation for the researcher with the honorary contract at the NHS Trust, were a joint Data Controller; and suggested that NHS England seek assurance that the University were not determining the purpose and means of processing and were therefore not carrying out any data controllership activities in line with the NHS England DAS Standard for Data Controllers; and that the individual would not cite the University when publishing the results, since that would indicate they were acting on behalf of the University. **6.5.2** AGD noted that the Data Security and Protection Toolkit (DSPT) Hull University Teaching Hospital NHS Trust stated that "*standards not fully met (plan agreed)*", and noting the applicant had a history of **not** meeting the DSPT, it was recognised that data would **not** flow unless DSPT was in place or further investigation had been undertaken to understand what needed to be addressed. **6.5.3** Noting the work being undertaken by the honorary contract holder, the Group noted that it was important to ensure that the DSPT covered all their activities, for example the provision of a computer. In addition, AGD made the following observations on the application and / or supporting documentation provided as part of the review: **6.5.4** Noting that **no** public and patient involvement and engagement (PPIE) had been carried out for this study, because the applicant had stated that the study was aimed at generating data in preparation for a prospective clinical trial and the applicant felt there is enough mandate to conduct the current study, the Group suggested there was ongoing PPIE throughout the lifecycle of the project, since patient experience may give valuable insights to the project. The HRA guidance on Public Involvement is a useful guide. **6.5.5** NHS England noted that, due to timing and resource pressures within NHS England, the application had been presented to AGD prior to the data fields in	

	section 3(b) (Additional Data Access Requested) being analysed by a National Disease Registration Service (NDRS) Analyst. AGD noted the verbal update and suggested that a careful review of the data requested be undertaken and before the data flows. Also, if it was judged the project could use the NHS England Secure Data Environment (SDE), that the SDE be used instead of a dissemination. **6.5.6** Noting the type of research outlined in the application, the AGD NHS England Caldicott Guardian representative, who is also a clinician, did query if this research was towards an academic qualification, and noting this was not outlined in the application, the NHS England SIRO representative should remind the applicant that any research towards a PhD or other type of qualification would be in breach of the current application, and that the DSA would need to be resubmitted as an amendment.	
6.6	**Reference Number:** NIC-365469-G0P1Q-v0.17 **Applicant:** University College London (UCL) **Application Title:** Congenital Hypothyroidism with Gland in Situ: establishing risk factors and outcomes using population-based data linkage methods **Observer:** James Watts **Application:** This was a new application. The purpose of the application is to link the Great Ormond Street Hospital for Children NHS Foundation Trust (GOSH) Newborn Blood Spot Screening (NBS) database to a number of NHS England datasets, in order to examine risk factors for congenital hypothyroidism with gland in situ, and health outcomes for children affected with this condition. NHS England were seeking advice on the following points, including general advice on any other aspect of the application: 1. The purpose; 2. The proposed methods for accessing the data. Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** AGD acknowledged that they would **not** be quorate for the discussion of this application noting only two independent members and three AGD NHS England members were available; noting that the AGD Terms of Reference states that ***"In exceptional circumstances the Chair and the representative of the SIRO may agree for the Group to still meet and conduct its business…"*** the Group agreed to discuss the application. The Group were broadly supportive of the purpose outlined in the application, but were **not** supportive of the application **at this time** and wished to draw to the	

attention of the SIRO the following substantive comments, and suggested the application be brought back to a future meeting.

6.6.1 AGD recognised the complexity of the application and the potential benefits of the research that could be delivered to patients and the public.

6.6.2 AGD noted and commended the hard work undertaken by NHS England's Data Access Service (DAS) to get the application to this stage, for consideration by the Group.

6.6.3 The Group queried with the NHS England Data and Analytics representative if it was technically possible to do the linkage as described in the application, and suggested that the NHS England Data Production Team be consulted and asked to confirm if it was, **or** was not, possible.

6.6.4 Given the proposal to link health data and education records for millions of people, AGD felt that the project was contentious and that robust patient and public involvement and engagement (PPIE) was required, since the PPIE would need to evidence that this type of linkage was acceptable to the public. AGD suggested that NHS England may wish to review the PPIE questions asked and responses given by any PPIE group.

6.6.5 To support the applicant, the Group suggested that online questionnaires via social media or engaging platforms such as 'Mumsnet' may provide suitable PPIE. In addition, the applicant may wish to consider accessing parent forums via school networks, or targeting antenatal classes or clinics to start a conversation and gather opinions in the period prior to baby being born. The Group noted it may give the applicant more opportunities to engage people in consultation to support their research aims.

6.6.6 Noting the potential benefits of the research, the Group suggested that there was ongoing PPIE throughout the lifecycle of the project. The HRA guidance on Public Involvement is a useful guide.

6.6.7 The Group noted that it was not clear in the transparency materials how opt outs were observed and suggested that the materials be updated to be clear how someone can exercise a local opt out and how the local opt out is managed.

6.6.8 Given the data flows over a long period of time to create the datasets, the Group noted that it was important to remember that the opt outs would be exercised at different times and may not therefore match across the different datasets, and thought should be given by the applicant / NHS England as to how to handle this.

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

6.6.9 The Group noted there was a cohort study and a case-control study and suggested more detail be provided in section 5 (Purpose / Methods / Outputs) of the application about the two study groups, and the distinctions between the two.

	6.6.10 AGD noted the statement in section 5(a) (Objective for Processing) of the application that "…*NHS England will return linked identifying data to GOSH, who will in turn share with UCL*…" however UCL will only receive pseudonymised data and suggested that this sentence be amended, as appropriate to align with the facts. **6.6.11** AGD noted that they had been provided with a data flow diagram (SD7) as a supporting document, however the diagram and text in section 5 of the application were still not clear, and the Group suggested the data flow diagram be **amended** to cover, for example, the data flows in, the data flows out, the identifiability of each flow of data, and the legal basis for each flow.	
8 EXTERNAL DATA DISSEMINATION - SIRO APPROVED / SEEKING SIRO APPROVAL		
8.1	**Reference Number:** NIC-147811-YTH88-v4.3 **Applicant:** The University of Manchester **Application Title:** MR559 - The Norfolk Arthritis Register (NOAR) **Previous Reviews:** The application and relevant supporting documents had previously been presented / discussed at the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) meetings on the 3rd February 2022 and the 15th April 2021. **Linked applications:** This application is linked to NIC-333021-B6W2C (item 8.2) The SIRO approval was for a six-month extension to hold but not process the data. **Outcome of discussion:** AGD noted that the NHS England SIRO had already provided SIRO approval and confirmed that they were supportive of this. AGD thanked NHS England for the written update and advised that they had no further comments to make on the documentation provided. The NHS England SIRO representative thanked AGD for their time.	
8.2	**Reference Number:** NIC-333021-B6W2C-v3.3 **Applicant:** The University of Manchester **Application Title:** The Norfolk Arthritis Register (NOAR) a longitudinal observational study **Previous Reviews:** The application and relevant supporting documents had previously been presented / discussed at the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) meeting on the 2nd March 2017. The application and relevant supporting documents had previously been presented / discussed at the Data Access Advisory Group (DAAG) meeting on the 31st January 2017. **Linked applications:** This application is linked to NIC-147811-YTH88 (item 8.1).	

	The SIRO approval was for a six-month extension to hold but not process the data. **Outcome of discussion:** AGD noted that the NHS England SIRO had already provided SIRO approval and confirmed that they were supportive of this. AGD thanked NHS England for the written update and advised that they had no further comments to make on the documentation provided. The NHS England SIRO representative thanked AGD for their time.	
8.3	**Reference Number:** NIC-656837-J7G8S-v2.8 **Applicant:** Erasmus University Medical Centre **Application Title:** Metastatic cutaneous Squamous Cell Carcinoma (cSCC) in England 2013-2015– assessment of staging systems and histological risk factors for metastasis. (ODR1819_225) **Previous Reviews:** The application and relevant supporting documents had previously been presented / discussed at the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) meeting on the 15th December 2022. The SIRO approval was for a six-month extension. **Outcome of discussion:** AGD noted that the NHS England SIRO had already provided SIRO approval and confirmed that they were supportive of this. AGD thanked NHS England for the written update and advised that they had no further comments to make on the documentation provided. The NHS England SIRO representative thanked AGD for their time.	
9 OVERSIGHT AND ASSURANCE		
There were no items discussed.		
10 AGD OPERATIONS		
10.1	**Risk Management Framework** As last noted in the AGD minutes from the 21st March 2024, the independent members 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 reiterated a previous request that NHS England provide further information/ clarity on this to the Group, 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 AGD (and previously the interim data advisory group) to use the NHS	

	England DAS Standards and Precedents model to assess the risk factors in relation to items presented to AGD for advice; however the independent members noted that the wording 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 DAS Standards and Precedents, and asked that this be clarified by NHS England. The Group noted that plans for this work were in train. It had been noted previously by the interim data advisory group that the Oversight and Assurance Programme of applications that had not be subject to AGD review could form part of this Risk Management Framework. The NHS England SIRO representative noted an outstanding action in respect of providing a written response to AGD on the risk management framework; and noted that this was progressing under the NHS England Precedents and Standards work. **ACTION:** The NHS England SIRO Representative to provide a written response to AGD on the risk management framework	SIRO Rep
10.2	**Standard Operating Procedures (SOPs)** The ongoing forward plan of work for creating the AGD Standard Operating Procedures was discussed; and noting that the AGD Terms of Reference (ToR) had now been approved, it was noted that work was progressing in order to finalise relevant AGD SOPs in line with the approved AGD ToR.	
10.3	**AGD Stakeholder Engagement** *There were no items discussed.*	
10.4	**AGD Project Work** A brief update was given by the Group's representative on the Federated Data Platform Data Governance Group.	
11 Any Other Business		
11.1	**NHS England Secure Data Environment (SDE) – Special Condition** The NHS England SIRO representative advised the Group, that a special condition will be added to section 6 of new Data Sharing Agreements (DSAs), for the SDE, to be clear that if the user breaches their SDE user access agreement it will automatically be counted as a breach of the DSA. The Group noted and thanked the SIRO representative for the verbal update.	
11.2	**NHS England and Department of Health and Social Care (DHSC) Data Sharing Agreements (DSA's)**	

	The NHS England SIRO representative advised the Group, that work is underway to rationalise DSA's between NHS England and DHSC, to remove duplicate flows of the same datasets over multiple DSAs using different access routes. The Group noted and thanked the SIRO representative for the verbal update.

Meeting Closure

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