Advisory Group for Data (AGD) – Meeting Minutes

Thursday, 18th July 2024

09:00 – 15:15

(Remote meeting via videoconference)

AGD INDEPENDENT / NHS ENGLAND MEMBERS IN ATTENDANCE:	
Name:	**Role:**
Paul Affleck (PA)	AGD independent member (Specialist Ethics Adviser and Chair)
Dave Cronin (DC)	NHS England member (Data and Analytics Representative (Delegate for Michael Chapman)) (Items 6.2 to 11)
Claire Delaney-Pope (CDP)	AGD independent member (Specialist Information Governance Adviser)
Rachel Fernandez (RF)	NHS England member (Data Protection Office Representative (Delegate for Jon Moore))
Dr. Robert French (RF)	AGD independent member (Specialist Academic / Statistician Adviser)
Dr. Phil Koczan (PK)	NHS England member (Caldicott Guardian Team Representative (Delegate for Dr. Jonathan Osborn)) (Items 1 to 6.2, part of 6.4 and 6.5 to 11)
Narissa Leyland (NL)	NHS England member (Data and Analytics Representative (Delegate for Michael Chapman)) (Items 1 to 6.1)
Jenny Westaway (JW)	AGD independent member (Lay Adviser)
Miranda Winram (MW)	AGD independent member (Lay Adviser) (items 1 to 6.2)
NHS ENGLAND STAFF IN ATTENDANCE:	
Name:	**Role / Area:**
Oluwatosin (Mariam) Arowolo (OA)	Information Governance Apprentice, Data Protection and Trust, Privacy, Transparency and Trust, Delivery (**Observer:** items 5.1 to 6.2)
Jack Bennett (JB)	Digi-Trials (**Observer:** items 5.2 and 6.1)
Garry Coleman (GC)	NHS England SIRO Representative

Karen Myers (KM)	AGD Secretariat Officer, Privacy, Transparency and Trust (PTT), Delivery Directorate
Abigail Lucas (AL)	Data Access and Partnerships, Data and Analytics (**Observer:** items 5.2 and 6.1)
James Watts (JW)	Data Access and Partnerships, Data and Analytics (**Observer:** item 6.6)
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, Delivery (**Presenter:** item 2.1)
AGD INDEPENDENT MEMBERS / NHS ENGLAND MEMBERS NOT 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)
Kirsty Irvine (KI)	AGD independent member (Chair)
Jon Moore (JM)	NHS England member (Data Protection Office Representative)
Dr. Jonathan Osborn (JO)	NHS England member (Caldicott Guardian Team Representative)

1	**Welcome and Introductions:** The AGD meeting Chair welcomed attendees to the meeting.
2	**Review of previous AGD minutes:** The minutes of the AGD meeting on the 11th July 2024 were reviewed and, after several minor amendments, were agreed as an accurate record of the meeting.
3	**Declaration of interests:** Jenny Westaway noted that she had some involvement in discussions about the common law duty of confidentiality in relation to one of the activities outlined in NIC-742629-H5M4F, through her National Data Guardian (NDG) role. It was agreed this did not preclude Jenny from taking part in the discussions about the London Ambulance Service NHS Trust application.

	Dr. Robert French noted a declaration of interest with NIC-316558-W0T8G and NIC-184980-J5B6C (Cardiff University), as part of his role at Cardiff University; but noted no specific connection with the applications or applicants and it was agreed that there was no conflict of interest. Claire Delaney-Pope noted a professional link to NIC-707682-B4H2R-v0.5 University of York, as part of her role at South London and Maudsley NHS Foundation Trust. It was agreed this did not preclude Claire from taking part in the discussion on this application.
4	**AGD Action Log:** *The action log was not discussed.*
5 BRIEFING PAPER(S) / DIRECTIONS:	
5.1	**Title:** NHS England Operational Insights External Data Processors – Briefing **Presenter:** Chris Wilson The purpose of the briefing paper is to make AGD aware of a proposal to make pseudonymised personal data available to Data Processors for external organisations, by providing access within the confines of the Unified Data Access Layer (UDAL) environment. To date, the UDAL Pseudonymised Data Environment (PDE) has been limited to access by NHS England Analysts only. The data would include data collected under Directions comprised of Cancer Waiting Times (CWT) dataset, Secondary Uses Service (SUS), Hospital Episodes Statistics (HES) and Waiting List Minimum Dataset (WLMDS). The request follows a strategic decision to open access to UDAL to those not employed by NHS England in some circumstances, where either data processing agreements or data sharing agreements are in place. NHS England were seeking advice on the following point: 1. Whether data processing in this manner is within an acceptable level of risk and sufficiently transparent. **Outcome of discussion:** AGD welcomed the briefing paper and made the following observations / comments: **In response to point 1:** **5.1.1** AGD noted that analysts from the Office for National Statistics (ONS) would be processing the data on behalf of NHS England; and that this analysis would take place via Royal Wolverhampton NHS Trust. Whilst AGD recognised the potential need for, and benefits from, the contractual arrangements proposed, they suggested NHS England consider whether more direct arrangements would increase transparency and be of lower risk. **5.1.2** AGD noted the information in the privacy notice which NHS England had not updated recently; however suggested that this was reviewed and edited as may be appropriate, in line with the Information Commissioner's Office guidance on transparency, including but not

	limited to the type of data; if any external access is permitted in UDAL; the processing being undertaken. In particular lay advisers observed that they thought the level of technical detail would mean the privacy notice was not readily intelligible to a lay reader and suggested using a layered communications approach. **5.1.3** AGD noted the statement in the briefing paper *"Any formal analysis outputs are assessed for disclosure and appropriate suppression and disclosure controls used…"*; and suggested that further clarity was provided on this point, for example, who is responsible for this and how robust is the process. **5.1.4** AGD noted that they had not been provided with a copy of the Data Protection Impact Assessment (DPIA) and some of their queries may have been answered in that document. **5.1.5** AGD looked forward to receiving the finalised briefing paper tabled at a future meeting.
5.2	**Title:** BEST4 HH Consent Review (linked to NIC-753801-J5B3X Queen Mary University of London (item 6.1)) **Observer:** Abigail Lucas and Jack Bennett This briefing paper was to provide further information on the consent materials / review for the BEST4 Heartburn Health Programme. NIC-753801-J5B3X (item 6.1) is an NHS DigiTrials Recruitment Service application covering the BEST4 Heartburn Health Programme; and is covered by s251 support, and will enable NHS England to share the details of potential BEST4 Heartburn Health Programme participants with a messaging provider (iPLATO), who will in turn send SMS messages to those potential participants; and will refer them to a website to find out more about the Programme. The website will hold the Programme Invitation and Survey (used as the consent form equivalent) and Participant Information Sheet. It is essential that the consent materials meet the future needs of the BEST4 Heartburn Health Programme, which are likely to include one or more 'Outcomes' Data Sharing Agreements (DSAs) with NHS England, and may also include 'Communications' DSAs. The consent materials therefore need to be reviewed separately from, but at a similar time to, NIC-753801-J5B3X, to reduce the chances of having to re-consent participants, should they complete consent materials during their recruitment which NHS England subsequently find to be insufficient for future purposes. NHS England were seeking advice on the following point: 1. On the suitability of the consent materials for facilitating any future health data or participant communication requests via NHS England; for the purposes of the overarching Heartburn Health Programme (HHP) and any associated trials. **Outcome of discussion:** AGD welcomed the briefing paper and supporting papers and made the following observations / comments: **5.2.1** AGD welcomed the early engagement on this matter; and commended NHS England's Data Access Service (DAS) on the work undertaken to date.

	In response to point 1: AGD discussed each of the five suggested consent review recommendations provided by DAS, and noted that they were broadly supportive of the recommendations, endorsing recommendations three, four and five with no comments. They made the following comments on recommendations one and two: **5.2.2 Recommendation 1** – In addition to the DAS recommendations which AGD endorsed, AGD also suggested being clearer that enrolment in specific studies is automatic when signing up to the programme; and that any updates are for the purpose of clarity, suggesting a layered transparency approach. **5.2.3 Recommendation 2** – In addition to the DAS recommendations which AGD endorse, AGD queried whether "*relevant heartburn related health information*" was in fact the right term to be using since it would be unknown if the information was *"heartburn"* related until after the research had been undertaken, and because members of the public might be surprised if HHP asked for anything other than very obviously heartburn-related information; and suggested the term 'health information' was used with the stated research aims being relied upon to define how the information will be used. **5.2.4** In addition to the five DAS recommendations made in respect of the consent materials, AGD suggested that further updates could be made, including, but not limited to, updating the patient information sheet (PIS) to be clear at the start, the options for withdrawing consent; and providing a clear explanation as to who will have access to the data. **5.2.5** AGD suggested that further work was undertaken to ensure the consent questions in the survey aligned with the content of the PIS, for example in relation to the commercial involvement, which is currently explained in the PIS, but not surfaced in the consent questions. It was suggested that there may need to be further consent questions added to the survey form to ensure clarity of understanding by the participant. **5.2.6** It was also suggested that the commercial aspects were more clearly outlined, including, but not limited to, who would / would not profit and those who would benefit commercially from the work. It was noted by one AGD member that 'commercial' may be a clearer way of communicating the planned use than the phrase 'for profit'. **5.2.7** In addition, it was suggested that the applicant could undertake some patient and public involvement and engagement (PPIE) on this point, to ensure the information was as transparent as possible. The HRA guidance on Public Involvement is a useful guide. **5.2.8** AGD noted a reference in the PIS and the consent form to *"personal details*" not being shared outside the University of Cambridge, Queen Mary University of London or King's College London, and suggested that participants might understand this to mean no personal data would be shared. AGD suggested this was reviewed and updated to "*contact details*" if applicable to align with the processing anticipated. **5.2.9** AGD noted that the patient information referred to those who had signed up, learning ways to look after their own health; and suggested that further information was provided as to what support would be provided.

	5.2.10 AGD noted the commitment to obtaining *"UK ethics"* approval for future research; however, the Group noted that the Health Research Authority may consider research with pseudonymised information to be outside its remit. It was however suggested that the applicant could approach their own institutional ethics committee on whether an ethical review is required in accordance with NHS England's DAS Standard for Ethical Approval. **5.2.11** AGD advised that, considering other cohort studies, once data and samples have been gathered it is often realised that there is potential to support wider research that is not covered by the consent. The Group suggested that the applicant consider engaging with the UK Longitudinal Linkage Collaboration (UK LLC) to discuss this further, and to ensure they do **not** inadvertently restrict potentially valuable future research. **5.2.12** AGD noted that some of the AGD independent members had some additional minor comments and suggestions; and it was noted that these would be sent to the AGD Secretariat out of committee; who would collate and send to DAS colleagues. It was noted however that these comments and suggestions were individual comments only and were **not** on behalf of AGD. **5.2.13** AGD looked forward to receiving an updated briefing paper, if appropriate, tabled at a future meeting.	
6 EXTERNAL DATA DISSEMINATION REQUESTS:		
6.1	**Reference Number:** NIC-753801-J5B3X-v0.2 **Applicant:** Queen Mary University of London **Application Title:** BEST-4 Heartburn Health Programme - Recruitment **Observer:** Abigail Lucas and Jack Bennett **Application:** This was a new application. The purpose of the application is to create a resource of participants with heartburn, indigestion or acid reflux. The Programme aims to build a community of volunteers with heartburn and allow experts to research issues such as: **1)** how to manage symptoms more effectively and reduce the need for long-term medication; and **2)** how to find more serious health problems such as severe inflammation and cancer early, when they are easier to treat. 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 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 significant comments, and suggested that the application be brought back to a future meeting: **6.1.1** AGD noted that a briefing paper was provided in relation to this application (please see item 5.2).	

	6.1.2 AGD noted that whilst they were supportive of the overall purpose of the work outlined in the application, and the intention behind the recruitment; felt that the cyber risks needed to be fully mitigated, noting that general security guidance is to never click on a link in an email or text unless you are certain as to the sender. **6.1.3** AGD noted in section 3.4 (data subjects) of the DAS internal application assessment form, that the invite would be sent to approximately 4.5 million individuals via short message service (SMS); and queried whether there should be an option within the text to opt-out. **6.1.4** AGD queried the quality of the data being provided to support the SMS messages being sent, and whether all of the intended recipients would actually receive the SMS correctly, or whether there was a risk that this would be sent to other individuals. It was noted however, that the information in the SMS would likely be very limited in terms of the personal information provided. **6.1.5 Separate to this application**: AGD queried whether there should be a process for participants to opt out of DigiTrials invitations without submitting a National Data Opt-out (NDO), noting that this would have wider opt-out implications; and suggested that NHS England explore this further. **ACTION:** NHS England Data and Analytics to consider whether there should be a process for participants to opt out of DigiTrials invitations without submitting a National Data Opt-out (NDO). **6.1.6** AGD noted that a draft copy of the SMS had been provided, and supported the challenge by NHS England in terms of the reference to NHS funding; and queried whether there was an error in respect of the reference to the name of the GP practice being included, noting that the data is not flowing the GP practice name. **6.1.7** The Group discussed the results of the patient and public involvement and engagement (PPIE) survey, which indicated that 9% of those eligible for an invite to the study, would **not** want their personal details to be used in this way, which would equate to approximately 400,000 recipients. It was noted however, that some of these individuals may have submitted an NDO and would not therefore receive an invite. On this basis some of the AGD members felt it was reasonable to proceed with this approach, while others did not. In addition, AGD made the following observations on the application and / or supporting documentation provided as part of the review: **6.1.8** AGD noted the statement in section 5(a) (Objective for Processing) *"Where the number of invitees is less than the population available, invoking a system to choose invitees at random"*; and suggested that this was updated to be clearer. **6.1.9** AGD noted the statement in section 5(a) *"...participants will have consented to health-related data collection..."* and noted that the draft consent materials do **not** ask for consent to *"health-related data"*, rather to *"heartburn related health information"*.	D&A Rep

	6.1.10 AGD queried the statement in section 5(c) (Specific Outputs Expected) *"Identifiable health data requested from NHS England will only be used to identify and invite potential participants"*; and suggested that NHS England ensure that this aligns with the consent / patient information sheet. **6.1.11** AGD noted the ambitious recruitment rate in section 5(a) of the application; and queried the implications of the expected recruitment rate not being achieved. It was suggested that NHS England explore this further with the applicant. **6.1.12** AGD noted that whilst they were supportive of projects like this where the public benefit justifies the associated commercial benefits, there was a need for transparency about the commercial benefit. **6.1.13** AGD noted the statement in section 1 (details of parties and other organisations involved) of the DAS internal application assessment form, in relation to other commercial entities being involved, and that the applicant would make NHS England aware. The Group noted that whilst this was correct, and NHS England should be made aware, there must also be an obligation on the applicant to make sure that participants were notified and in line with the NHS England DAS Standard for Commercial Purpose. **6.1.14** AGD noted the information in section 1 of the DAS internal application assessment form, in relation to data controllership; and commended DAS for their efforts and rigour in seeking clarification / information on this point. The Group noted that they endorsed the advice DAS provided to the applicant on determining data controllership and in line with the NHS England DAS Standard for Data Controllers. **6.1.15** AGD noted that the application cited an Article 9 UK General Data Protection Regulation (UK GDPR) condition, but the application was unclear what special category data was involved. AGD did note that the information was owed a Duty of Confidentiality. **6.1.16** AGD noted that the Data Security and Protection Toolkit (DSPT) information needed updating in section 1(b) (Data Controller(s)) and section 1(c) (Data Processor(s)) of the application, and the Data Access Service (DAS) internal application assessment form, to include the output of the 2023/24 submission for Cambridge University Hospitals NHS Trust. It was recognised that data would **not** flow unless DSPT was in place.	
6.2	**Reference Number:** NIC-742629-H5M4F-v0.2 **Applicant:** London Ambulance Service NHS Trust **Application Title:** London Ambulance Service NHS Trust – Service and Evaluation/Auditing purpose **Previous Reviews:** The application and relevant supporting documents were previously presented / discussed at the AGD meeting on the 13th June 2024.	

	Application: This was a new application. The purpose of the application is to use linked outcome data to analyse patterns, which will aim to inform development needs and best practice identification. The provision of linked data will allow ambulance service clinicians to continue to build on their confidence, competence, and knowledge to improve the delivery of care to patients through the understanding of the impact of their own clinical practice on the patient outcomes through the clinical supervision process. Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** AGD were supportive of the application and wished to draw to the attention of the SIRO the following comments: **6.2.1** AGD reiterated the points from the 13th June 2024 AGD meeting, that the Group noted the references in section 5(a) (Objective for Processing) and section 5(d) (Benefits) of the application to *"benchmarking clinician activity"*; and noted a number of concerns with this, including, but not limited to **1)** if the Common Law Duty of Confidentiality applied to the Clinician data; **2)** the HRA CAG support would not cover this data as it only applies to patient confidential data; **3)** is the benchmarking covered by employment policies, for example, have the relevant Trade Unions been consulted and are the Clinicians supportive; and, **4)** is the data requested adequate for the processing outlined and are they able to meet their objective for processing. **6.2.2** The SIRO representative noted that a query had been raised in advance of the meeting by an AGD independent member, about a potential overlap between this and other work being undertaken by the London Ambulance Service; and AGD suggested that NHS England ensured that the approach relating to legal basis and purpose was consistent in all cases, and also aligned with other relevant stakeholders such as the National Data Guardian (NDG). **6.2.3** AGD noted that some of the information within the Data Access Service (DAS) internal application assessment form was confusing and did not align with the correct information within the application; and suggested that this was reviewed and updated as may be necessary to reflect the correct / most recent information.	
6.3	**Reference Number:** NIC-316558-W0T8G-v1.9 **Applicant:** Cardiff University **Application Title:** AML16 - A programme of development for older patients with acute myeloid leukaemia and high risk myelodysplastic syndrome **Application:** This was an amendment application. The purpose of the application is to permit processing of the Data for the purpose of secure storage and back up.	

	The amendments are to **1)** change in purpose: from patient follow up, analysis and results publication, to storage for archiving purposes only; **2)** the addition of a Data Processor: Microsoft Limited; **3)** the addition of detail in section 5(a) (Objective for Processing) and section 5(b) (Processing Activities) regarding the use of DeepStore Limited: and **3)** to uplift the purpose statement to align with Purpose Q&A for archiving. NHS England were seeking advice on the following points: 1. A new precedent / reusable decision to allow a data sharing agreement (DSA) to be amended to change the purpose section to reflect the data being archived without requiring further SIRO Authorisation or AGD review where the specified qualifying criteria are met and where the exclusion criteria do not apply. Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** AGD were supportive of the application and wished to draw to the attention of the SIRO the following high-level comments: AGD noted that they had been provided with a curated set of documentation and noted that they would be providing observations based on these documents. **6.3.1** AGD noted that they had **not** been provided with a copy of the consent materials or the NHS England consent review document; and advised that in order for the Group to form a complete view of the application / archiving proposal, they would need to have sight of these materials, for example, to ensure that the consent covered further retention of the data. **6.3.2** AGD noted that whilst NHS England's Data Access Service (DAS) were satisfied with the consent materials, the Group were unclear if there were any limitations or restrictions for example in respect of the end dates, that may impact on the archiving of the data. **6.3.3** AGD noted in the internal DAS Escalation Form, that the applicant had **not** completed the required cloud controls and risk model documentation, and noted that DAS had been chasing the applicant for an update on this. The Group noted the proposed special condition on this point, and noting that this was a pragmatic approach to manage the outstanding issue in the data sharing agreement (DSA), endorsed this approach. It was suggested however, that the special condition was updated with a date for this issue being resolved and NHS England being updated by the applicant. In addition, AGD made the following observations on the application and / or supporting documentation provided as part of the review: **6.3.4** AGD noted the information in the internal DAS Escalation Form, in respect of the identifiers **not** being destroyed, due to the data already been archived; and suggested that a special condition was added to section 6 (Special Conditions) of	

	the application requesting a clear justification for the identifiers being retained; or that appropriate action had been taken to delete the identifiers. **6.3.5** AGD noted that the current transparency materials may **not** be clear enough for participants to realise that they would be part of the cohort; and suggested that the materials were reviewed and updated as may be necessary to be clear on this point. **6.3.6** AGD queried whether a pre-archiving data minimisation process had been followed as should be a standard approach. **6.3.7 Separate to the application:** AGD reiterated previous advice given by the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) at the meeting on the 6th October 2022, which noted there was ongoing work within NHS Digital (now NHS England) in respect of designing a template for *"archiving"* applications and a new DARS (now DAS) Archiving Standard. AGD reiterated the previous suggestion made by IGARD, that NHS England DAS consider a number of key elements as it develops a new precedent / reusable decision, including, but not limited to: retaining the original purpose section but topping and tailing' to be clear the application was now for archiving; retaining the expected benefits which would enable the applicant to map these to the yielded benefits; and including a brief additional expected benefits with regard to the benefits of archiving, possibly using templated / standard wording. **ACTION:** NHS England DAS to consider a number of key elements for the precedent/reusable decision as outlined in point 6.3.7 and seek future input / advice from AGD as required. **6.3.8** AGD noted the benefits of the previous research in section 5(d) (Benefits) of the application and suggested that this was updated to also include the benefits of archiving the data. In addition, it was suggested that DAS have some standard benefit wording for archiving agreements going forward, which could also be incorporated into the template application. **ACTION:** NHS England DAS to consider having some standard benefit wording for archiving agreements, which could be incorporated into the application template. **6.3.9** AGD noted that the third paragraph in section 5(a) of the application relating to treatment choice and age, was difficult to understand; and suggested that this was updated to make this information clearer / understandable to a lay reader; or that the paragraph should be removed. **6.3.10** AGD noted the paragraph in section 5(a) that referred to the trial 'now' being complete, and suggested that this was updated to include a date of when the trial was completed. **6.3.11** AGD noted and commended the benefits to health and social care as outlined in section 5(d) (iii) (Yielded Benefits) of the application.	NHSE DAS NHSE DAS

	In response to point 1: AGD reviewed the six criteria points for a reusable decision outlined in section 4.3 (Qualifying Criteria for Reusable Decision) of the internal DAS Escalation Form and made the following comments, suggesting that the updated reusable decision be circulated to AGD members out of committee for any final comments: **6.3.12 Criteria Point 1**: *"Retention of the Data is necessary to comply with the recipient's data retention policy aligned to Clinical Trial Regulations or industry best practice"*. AGD suggested that this was updated to state, "*Retention of the Data is necessary to comply with the recipient's data retention policy aligned to Clinical Trial Regulations or best research practice".* **6.3.13 Criteria Point 2***: Retention complies with the common law duty of confidentiality."* AGD suggested this was updated to state, *"Retention would not breach the common law duty of confidentiality, in that individuals would reasonably expect their confidential patient information to be used in this way"*. **6.3.14 Criteria Point 4:** *"The application has been updated to reflect **only** the details of data being retained…".* AGD suggested that this was updated to remove the word *"only"*. **6.3.15 Criteria Point 5:** ***"****Either the applicant has provided evidence of data destruction in respect of any fields/datasets that are not required for the **purpose of archiving** or a special condition requiring confirmation of data destruction is added"*. AGD suggested that this was updated to state *"…purpose of archiving and checking results…"*. **6.3.16 Criteria Point 6:** ***"****The updated Purpose section aligns with best practice such as the use of the Q+A model (specifically the 'Q+A Variation for DSA for Archiving Purposes' template) and use of standard wording including clarification on whether the DSA permits further processing of the data for the purposes of…".* AGD suggested that "*The Purpose section is updated to include relevant details of the archiving and all updates align with the 'Q+A Variation for DSA for Archiving Purposes' template".* **6.3.17 Criteria Point 6b:** ***"****verifying findings in line with the original objectives of the study by repeating previous analyses described in this DSA".* AGD suggested that this was updated to make it less restrictive, for example *"validating statistical findings of previous research"*.	
6.4	**Reference Number:** NIC-184980-J5B6C-v9.5 **Applicant:** Cardiff University **Application Title:** AML15 - MRC working parties on leukaemia in adults & children acute myeloid leukaemia trial 15 **Previous Reviews:** The application and relevant supporting documents were previously presented / discussed at the Independent Group Advising (NHS Digital)	

on the Release of Data (IGARD) meetings on the 3rd March 2022 and the 1st November 2018.

Application: This was an amendment application.

The amendments are to **1)** change in purpose: from patient follow up, analysis and results publication, to storage for archiving purposes only; **2)** the addition of a Data Processor: Microsoft Limited; **3)** the addition of detail in section 5(a) (Objective for Processing) and section 5(b) (Processing Activities) regarding the use of DeepStore Limited: and **3)** to uplift the purpose statement to align with Purpose Q&A for archiving.

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

Outcome of discussion: AGD was evenly split between being supportive of the archiving outlined but not supportive of the application (two AGD independent members and one NHSE member), and supportive of the archiving application (two AGD independent members and one NHSE member).

One AGD member abstained from offering a view of the application, noting that they were not in attendance for the full discussion.

The Group wished to draw to the attention of the SIRO the following substantive comments:

AGD noted that they had been provided with a curated set of documentation and noted that they would be providing observations based on these documents.

6.4.1 AGD queried whether the data would be archived at Cardiff University only, or if a copy of the data would also be archived at the University of Birmingham; and suggested that this was clarified in section 5(b) of the application since the documentation provided seemed to indicate archiving was being undertaken at both Universities.

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

6.4.2 AGD noted that they had not been provided with a copy of the consent materials or the NHS England consent review document; and advised that in order for the Group to form a complete view of the application / archiving proposal, they would need to have sight of these materials, for example, to ensure that the consent covered the further retention of the data.

6.4.3 AGD noted that whilst NHS England's Data Access Service (DAS) were satisfied with the consent materials, the Group were unclear if there were any limitations or restrictions for example in respect of the end dates, that may impact on the archiving of the data.

6.4.4 AGD noted that comments had been made by the Group and previously IGARD, in respect of children and young people included in the study via parental

consent; and noted that they had no concerns in respect of the archiving of data for these participants.

6.4.5 AGD noted in the internal DAS Escalation Form, that the applicant would like to retain the data beyond the 15 years for which consent was given, until December 2028, which is the date that any living minor participant would reach the age of adulthood; and suggested that the justification for this was explained further within section 5 (Purpose / Methods / Outputs) of the application.

6.4.6 AGD noted in the internal DAS Escalation Form, that the applicant had **not** completed the required cloud controls and risk model documentation, and noted that DAS had been chasing the applicant for an update on this. The Group noted the proposed special condition on this point, and noting that this was a pragmatic approach to manage the outstanding issue in the data sharing agreement (DSA), endorsed this approach. It was suggested however, that the special condition was updated with a date for this issue being resolved and NHS England being updated by the applicant.

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

6.4.7 AGD noted the information in the internal DAS Escalation Form, in respect of the identifiers **not** being destroyed, due to the data already been archived; and suggested that a special condition was added to section 6 (Special Conditions) of the application requesting a clear justification for the identifiers being retained; or that appropriate action had been taken to delete the identifiers.

6.4.8 AGD noted that the current transparency materials may not be clear enough for participants to realise that they would be part of the cohort; and suggested that the materials were reviewed and updated as may be necessary to be clear on this point. This was especially important as some participants would have been included on the basis of parental consent.

6.4.9 AGD queried whether a pre-archiving data minimisation process had been followed as should be a standard approach.

6.4.10 Separate to the application: AGD reiterated previous advice given by the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) at the meeting on the 6th October 2022, which noted there was ongoing work within NHS Digital (now NHS England) in respect of designing a template for *"archiving"* applications and a new DARS (now DAS) Archiving Standard. AGD reiterated the previous suggestion made by IGARD, that NHS England DAS consider a number of key elements as it develops a new precedent / reusable decision, including, but not limited to: retaining the original purpose section but topping and tailing' to be clear the application was now for archiving; retaining the expected benefits which would enable the applicant to map these to the yielded benefits; and including a brief

	additional expected benefits with regard to the benefits of archiving, possibly using templated / standard wording. **ACTION:** NHS England DAS to consider a number of key elements for the precedent/reusable decision as outlined in point 6.3.7 and seek future input / advice from AGD as required. **6.4.11** AGD noted the benefits of the previous research in section 5(d) (Benefits) of the application and suggested that this was updated to also include the benefits of archiving the data. In addition, it was suggested that DAS have some standard benefit wording for archiving agreements going forward, which could also be incorporated into the template application. **ACTION:** NHS England DAS to consider having some standard benefit wording for archiving agreements, which could be incorporated into the application template. **6.4.12** AGD noted the paragraph in section 5(a) that refers to the trial 'now' being complete, and suggested that this was updated to include a date of when the trial was completed. **6.4.13** AGD noted and commended the benefits to health and social care as outlined in section 5(d) (iii) (Yielded Benefits) of the application.	NHSE DAS NHSE DAS
6.5	**Reference Number:** NIC-707682-B4H2R-v0.5 **Applicant:** University of York **Application Title:** Parent and professional experience of 24/7 paediatric end-of-life care: a mixed methods study **Application:** This was a new application. The purpose of the application is for a research project, which aims to determine whether there are disparities in end-of-life care for children associated with demographics and the provision of 24/7 paediatric palliative care services. Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** AGD were supportive of the purpose but were not supportive of the current application, because of the uncertain status of the data that would flow, and wished to draw to the attention of the SIRO the following substantive comments: **6.5.1** AGD noted the role of the University of York outlined in section 5(b) (Processing Activities) of the application, in particular the statement that *"The **exact address** of death will be removed from the analysis dataset…"*; and queried whether, given exact addresses would flow, the data was therefore identifiable and not pseudonymised as described elsewhere in the application. It was suggested that NHS England explore this further, and that the application was updated throughout to reflect the correct information.	

	6.5.2 AGD queried whether the ethnicity fields in the Emergency Care Data Set (ECDS) were sufficient in terms of quality of data to achieve the aims of the analysis; and suggested that this was explored by NHS England. If the data was not of a sufficient standard, the Group advised that they would be supportive of the addition of an alternate dataset to the data sharing agreement (DSA) that provides the most relevant ethnicity information, with the relevant justifications added to the application. In addition, AGD made the following observations on the application and / or supporting documentation provided as part of the review: **6.5.3** The AGD independent specialist academic / statistician adviser noted the complexity of the datasets requested, and queried whether the first year (age 0 to 1) of data would be required and, if so, what was the data required for; and suggested that NHS England explore this further with the applicant. **6.5.4** AGD noted that the funding was in place until March 2025; however, noting that the end date of the data sharing agreement (DSA) is March 2027, suggested that NHS England explore this further with the applicant to ensure that there is funding in place for the duration of the DSA, or that there are internal resources available to support the DSA beyond March 2025. **6.5.5** AGD queried the statement in section 5(b) *"Access is restricted to employees or **agents** of…"* and suggested that either further information was provided as to who would be covered by "*agents*", and whether this aligned with the Data Sharing Framework Contract (DSFC); or that this was removed as may be necessary to reflect the facts. **6.5.6** In addition, the Group noted the statement in section 5(a) (Objective for Processing) that data would be accessed by *"substantive employees of the University of York"*; and noting that this conflicted with point 6.5.5, suggested that the application was reviewed throughout and updated to ensure it reflected the correct facts. **6.5.7** AGD noted the reference in section 5(d) (Benefits) of the application to *"clients"*; and suggested that this was either updated with further clarification, or removed. **6.5.8** AGD noted and commended the applicant on the well-written privacy notice; however, suggested that the reference to the National Data Opt-out being applied was removed, noting that this was incorrect. **6.5.9** AGD noted and commended the applicant on the excellent patient and public involvement and engagement (PPIE) undertaken to date, but suggested that, **if applicable**, the PPIE group were updated on the status of the data requested, and whether this was identifiable, not pseudonymised. **6.5.10** AGD noted in the DAS internal application assessment form, that the applicant had considered accessing the data in NHS England's Secure Data Environment (SDE), however had opted for an extract instead, partly due to the SDE	

	being too costly. The Group reiterated advice from the 13th June 2024 AGD meeting, that NHS England continue to explore all avenues / barriers to applicants accessing the SDE and how they can support applicants. **ACTION:** NHS England Data and Analytics Representative explore all avenues / barriers to applicants accessing the SDE and how they can support applicants.	D&A Rep
6.6	**Reference Number:** NIC-682551-T8V0S-v0.7 **Applicant:** University of Southampton **Application Title:** CANDID - Cancer diagnosis decision rules **Observer:** James Watts **Application:** This was a new application. The purpose of the application is for a research project which aims to **1)** develop and validate Clinical Prediction Rules predicting cancer in patients presenting with symptoms in the lung and colon separately; and **2)** to explore the incremental utility of incorporating additional measures (e.g. genetic, inflammatory, and lifestyle information including smoking and alcohol status) in the prediction models. Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** AGD were supportive of the application and wished to draw to the attention of the SIRO the following comments: **6.6.1** AGD queried whether the information in the Data Access Service (DAS) internal application assessment form, that the applicant is intending on linking data **for each individual up to five years from their date of consent** was achievable; and were reassured by the AGD NHS England Data and Analytics representative that this processing could be undertaken. **6.6.2** AGD noted they had been provided with a copy of the consent materials and whilst the information contained in the consent materials was ambiguous, in terms of the follow-up being for five years versus the data being processed for five years; the Group agreed that the documentation did not preclude the proposed processing outlined in the application. **6.6.3** AGD noted that the applicant's website had been updated to clarify how and when the five-year follow-up would be undertaken, however it was unclear how participants would know to check for a website; and suggested that the applicant consider providing others means of communication, including, but not limited to, posters in GP practices. **6.6.4** AGD noted that the privacy notice had been updated, however, suggested that the applicant review this, to ensure the correct tenses were used throughout, not just in the updated section, so that it would be clear to participants what has already happened, and what was happening now and in the future.	

7 INTERNAL DATA DISSEMINATION REQUESTS:		
There were no items discussed		
8 EXTERNAL DATA DISSEMINATION - SIRO APPROVED / SEEKING SIRO APPROVAL		
8.1	**Reference Number:** NIC-331142-P5K6M-v3.4 **Applicant:** University of Bristol **Application Title:** National Child Mortality Database (NCMD) **Previous Reviews:** The application and relevant supporting documents had previously been presented / discussed at the AGD meeting on the 29th June 2023. 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 18th November 2021 and the 19th August 2021. The application and relevant supporting documents had previously been presented / discussed at the IGARD COVID-19 Response meetings on the 24th November 2020 and the 7th July 2020. The SIRO approval was for a six month extension that permits the applicant to hold, but not otherwise 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.	
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	**AGD Standard Operating Procedures (SOPs) (Presenter: Vicki Williams)** 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** *There were no items discussed*	
11 Any Other Business		
There were no items discussed		
Meeting Closure As there was no further business raised, the Chair thanked attendees for their time and closed the meeting.		