Advisory Group for Data (AGD) – Meeting Minutes

Thursday, 12th December 2024

09:00 – 16:00

(Remote meeting via videoconference)

AGD INDEPENDENT / NHS ENGLAND MEMBERS IN ATTENDANCE:	
Name:	**Role:**
Paul Affleck (PA)	AGD independent member (Specialist Ethics Adviser) (Chair of item 2.7)
Kirsty Irvine (KI)	AGD independent member (Chair)
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)
Jenny Westaway (JW)	AGD independent member (Lay Adviser)
Miranda Winram (MW)	AGD independent member (Lay Adviser)
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
Laura Evans (LE)	NHS DigiTrials, Data and Analytics, Transformation Directorate (**Observer:** item 5.1)
Louise Garnham (LG)	NHS DigiTrials, Data and Analytics, Transformation Directorate (**Observer:** item 5.1)
Dan Goodwin (DG)	Data Access and Partnerships, Data and Analytics, Transformation Directorate (**Observer:** item 5.5)
Suzanne Hartley (SH)	Data Access and Partnerships, Data and Analytics, Transformation Directorate (**Observer:** item 5.1)
Joseph Lawson (JL)	Data Access and Partnerships, Data and Analytics, Transformation Directorate (**Observer:** item 5.2)

Karen Myers (KM)	AGD Secretariat Officer, Privacy, Transparency and Trust (PTT), Delivery Directorate
Azeez Oladipupo (AO)	Data Access and Partnerships, Data and Analytics, Transformation Directorate (**Observer:** items 5.1 to 5.4)
Suzanne Shallcross (SS)	Data Access and Partnerships, Data and Analytics, Transformation Directorate (**Observer:** item 5.5)
Prof. Matthew Sydes (MS)	Head of Data-Driven Clinical Trials and Cohorts, Transformation Directorate (**Observer:** items 5.1 and 5.2)
James Watts (JWa)	Data Access and Partnerships, Data and Analytics, Transformation Directorate (**Observer:** item 5.6)
Emma Whale (EW)	Data Access and Partnerships, Data and Analytics, Transformation Directorate (**Observer:** item 5.4)
Vicki Williams (VW)	AGD Secretariat Manager, Privacy, Transparency and Trust (PTT), Delivery Directorate
AGD INDEPENDENT MEMBERS / NHS ENGLAND MEMBERS NOT IN ATTENDANCE:	
Name:	**Role / Area:**
Michael Chapman (MC)	NHS England member (Data and Analytics Representative)
Claire Delaney-Pope (CDP)	AGD independent member (Specialist Information Governance Adviser)
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)

1	**Welcome and Introductions:** The AGD Chair welcomed attendees to the meeting.
2	**Review of previous AGD minutes:** The minutes of the AGD meeting on the 5th December 2024 were reviewed and, after several minor amendments, were agreed as an accurate record of the meeting.

3	**Declaration of interests:** Paul Affleck noted a professional link to the University of Leeds but noted no specific connections with the application NIC-699963-K1C6T (Queen Mary University of London) or staff involved, and it was agreed that this was not a conflict of interest. Paul Affleck noted a professional link to the University of Leeds but noted no specific connections with the application NIC-739472-P2Y8X (University of Hull) or staff involved, and it was agreed that this was not a conflict of interest. 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-739472-P2Y8X) or staff involved. It was agreed this did not preclude Paul from taking part in the discussions about this application.
4 BRIEFING PAPER(S) / DIRECTIONS:	
There were no items discussed	
5 EXTERNAL DATA DISSEMINATION REQUESTS:	
5.1	**Reference Number:** NIC-699963-K1C6T-v0.2 **Applicant and Data Controller(s):** Queen Mary University of London **Application Title:** Protect-C: Population Based Germline Testing for Early Detection and Prevention of Cancer - Recruitment Agreement **Observers:** Laura Evans, Louise Garnham, Suzanne Hartley, Prof. Matthew Sydes and Azeez Oladipupo **Application:** This was a new application. The purpose of the application is for a study to evaluate the impact of implementing a population-based genetic testing strategy for high and moderate penetrance cancer susceptibility genes. The study will identify women at moderate/high risk of breast, ovarian, endometrial, and bowel cancer; and will evaluate impact on health behaviour, psycho-social health, participant experience, satisfaction, screening and prevention uptake, and cost effectiveness. 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 were supportive of the application and wished to draw to the attention of the SIRO the following comments: **5.1.1** AGD noted that there was a follow-up period of eight years, and queried why this potentially restrictive time period had been selected; and advised that they would be supportive of a longer follow-up period if this was transparent to those who provide

	consent, with the relevant justification outlined in section 5 (Purpose / Methods / Outputs) and NHS England approvals in place. **5.1.2** AGD noted ongoing concerns / issues raised by the Group and previously by the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) since 2020, in respect of participants not being able to specifically opt out of DigiTrials invitations. An individual could take out a National Data Opt-out (NDO), but this would stop their data from being used for many other things the individual might support. **5.1.3 Separate to this application and for NHS England to consider:** AGD asked that an update was provided by the NHS England Data and Analytics Representative and / or the NHS England SIRO Representative, as to whether there would be a process for participants to opt out of DigiTrials invitations without submitting an NDO. **ACTION:** The NHS England Data and Analytics Representative and / or the NHS England SIRO Representative to provide an update to AGD as to whether there would be a process for participants to opt out of DigiTrials invitations without submitting an NDO. **5.1.4** The AGD NHS England Data Protection Office Representative noted a concern in respect of whether there was consistency with other DigiTrials invitations regarding transparency about the NDO; and suggested that this was explored further. **5.1.5** AGD noted the statement in section 5(a) (Objective for Processing) of the application *"PROTECT-C is performing a Study Within a Trial (SWAT) to evaluate the uptake of participants to the study, based on the invitation letter received"*; and advised that they had differing opinions as to whether the consent would permit the transfer of confidential information for the purpose of the SWAT. The Group noted that some AGD members were of the view that participants would **not** be surprised; whilst the majority of AGD members raised issues in respect of further transparency to the cohort in the patient information sheet (PIS), including, but not limited to, further information on the SWAT and other aspects of the study, for example, the follow-up. **5.1.6 Separate to this application and for NHS England to consider:** AGD noted previous comments made by IGARD in respect of similar applications trialling different types of letters and forms of communication; and noted that concerns had been raised on whether participants were being recruited with less information depending on the type of letter used. **5.1.7** AGD noted that the protocol provided as a supporting document (SD1.0) referred to recruitment based on biological 'sex', however the field selected in the Personal Demographics Service dataset was 'gender'. The Group suggested NHS England's Data Access Service (DAS) engage with the applicant, to be clear that there may be a mismatch between the population that has been targeted, and the group of people that will receive the invites. It was also noted that for some individuals, receiving an invite for a study that they are unable to join or benefit from,	D&A Rep / SIRO Rep

	may cause some distress. In addition, there may be an unintended consequence of excluding some individuals that could join the study based on their biological sex. **5.1.8** AGD noted that the applicant had obtained NHS Research Ethics Committee (REC) support, however, noted the statement in the PIS *"We do not believe there are significant risks of taking part in this study or receiving information about genetic testing"*. The Group suggested that the PIS be updated to highlight potential risks, including, but not limited to, overtreatment, that the outcomes may be distressing for those undergoing the genetic testing process and may have long-term mental health implications. **5.1.9** The Group noted a **significant risk** in respect of delayed presentation, for example, an individual not seeking immediate medical advice on potentially worrying symptoms, if they had received false reassurance of a 'nil return' on a genetic test. The Group did, however, note that the PIS does refer to ongoing support for individuals, and suggested that any risks highlighted may be addressed by this ongoing care. **5.1.10** AGD noted that PSL Print Management Ltd were listed as a Data Processor in section 1(c) (Data Processor(s)) of the application, however they were not mentioned in section 5 of the application and noted that it was unclear what they were doing; and suggested that section 5(a) was updated with further clarification of their role; or if they were not considered a Data Processor, to remove them from the application. **5.1.11** AGD noted the reference in section 5(a) of the application that the invite letter will *"…appeal to certain characteristics…"*; and suggested that this was updated to alternative wording so that it would not be inaccurately inferred that this was a reference to protected characteristics. **5.1.12** AGD noted the territory of use in section 2(c) (Territory of Use) of the application had not been completed, and suggested that this was updated with the correct information.	
5.2	**Reference Number:** NIC-737333-K2F1T-v0.3 **Applicant and Data Controller(s):** Queen Mary University of London **Application Title:** Investigating the impact of London's Ultra Low Emission Zone on children's respiratory health: evidence from NHS health records CHILL-HR: Children's Health in London and Luton: Health Records Study **Observer(s):** Joseph Lawson, Prof. Matthew Sydes and Azeez Oladipupo **Application:** This was a new application. The purpose of the application is for a research project to assess the impact of air pollution and London's Ultra Low Emission Zone (ULEZ) on child health outcomes. In addition, these datasets are also required to capture a comprehensive record of healthcare use that, together with national reference costs, enables the assessment	

	of children's healthcare costs, a key component of the economic evaluation of London's ULEZ. 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 were supportive of the application and wished to draw to the attention of the SIRO the following substantive comments: **5.2.1** AGD noted there was currently **no** legal gateway for the applicant to undertake linkage with the National Pupil Database (NPD), and suggested that the NPD linkage was removed from the application. The NHS England SIRO Representative noted that NHS England would **not** be supportive of having contractual provisions that were reliant upon future consent / ongoing actions that have **not** yet been resolved within an application. The Group suggested that once the legal basis for the NPD linkage had been addressed / resolved, that the applicant could submit an amendment request via the usual NHS England Data Access Service (DAS) process. **5.2.2** Noting the point above in respect of removing the linkage to the NPD, AGD thought it may be helpful to advise, for future reference, that students **not** in state education were included in the study, however advised that the NPD would **not** include all students, for example, those that are home schooled and some of those independently schooled. **5.2.3** AGD noted concerns that the application did **not** sufficiently address the benefits to health and social care, and suggested that section 5(d) (Benefits) of the application was reviewed and updated in line with NHS England DAS Standard for Expected Measurable Benefits. In addition, AGD made the following observations on the application and / or supporting documentation provided as part of the review: **5.2.4** AGD welcomed the application and noted the importance of the research. **5.2.5** AGD noted the statement in section 5(a) (Objective for Processing) that data would be accessed by *"Undergraduate, Masters, or PhD students enrolled with QMUL"*; and suggested that this was updated to state that these were students would be *"working on this study"*. **5.2.6** In addition, AGD suggested that the application was updated to provide an estimate of the number of students who could be working on the study / accessing the data, noting that the current wording in the application was quite broad. **5.2.7** AGD queried the statement in section 5(b) (Processing Activities) of the application *"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 word was removed as may be necessary to reflect the facts.	

	5.2.8 AGD queried the references in section 5(b) of the application to remote processing / access taking place in "*secure locations*"; and suggested that this was reviewed and updated if not correct, for example, to refer to the security of the remote connection and not the physical location. **5.2.9** The NHS England Data Protection Office (DPO) Representative noted and commended the applicant on the study specific privacy notice, as suggested by NHS England's DAS. **5.2.10** An AGD independent lay member noted and commended the work undertaken by the applicant on the parental consent and engagement with the children. In addition, some of the AGD members emphasised the importance of continued communication with the cohort, due to the unusual consent model. **5.2.11** AGD noted and commended the work undertaken by NHS England's DAS on the internal application assessment form, which supported the review of the application.	
5.3	**Reference Number:** NIC-739472-P2Y8X-v0.4 **Applicant and Data Controller:** University of Hull **Application Title:** Evaluating the effectiveness and acceptability of free door to door transport to increase the uptake of breast screening appointments in Yorkshire: A cluster randomised GP feasibility trial (DOORSTEP) **Observer:** Azeez Oladipupo **Application:** This was a new application. The purpose of the application is for a study, which will assess whether offering free, bookable, door to door transport to and from breast cancer screening appointments could increase the number of women attending screening, by comparing two groups: **1)** Intervention arm - women registered at GPs in group one will receive information about booking free transport alongside their breast screening invitation; and **2)** Control arm - women registered at GPs in group two will receive the breast screening invitation as normal with no additional offer of transport. 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 were supportive of the application and wished to draw to the attention of the SIRO the following comments: **5.3.1** AGD welcomed the application and noted the importance of the study in respect of addressing health inequalities. **5.3.2** AGD noted the potential shortcoming of the ethnicity fields in the Hospital Episode Statistics (HES) dataset; and noted in the Data Access Service (DAS)	

	internal application assessment form, that NHS England had discussed this with the applicant. **5.3.3** The Group queried whether the socioeconomic status to be derived from HES would be dated, for example, if it was linked to a hospital admission many years earlier, and how accurate this would be; and suggested that NHS England's DAS discuss this with the applicant and determine whether more accurate data could be obtained. If it was determined that the HES data was the most viable option, then the Group queried whether the 25 years of data was proportionate, and suggested that section 3(b) (Additional Data Access Requested) and section 5(a) (Objective for Processing) were updated were updated to provide a clear justification for this, and to be clear on the data fields requested. **5.3.4** AGD queried whether breast cancer screening data could be used to obtain the ethnicity and / or socioeconomic data, noting that any shortcomings in the pilot study may be magnified if this was then rolled out on a national basis, either now or in the future. **5.3.5** AGD noted the reference to 'BOX Governance file storage system' in section 5(b) (Processing Activities) of the application; and queried whether they should be listed as a Data Processor, and suggested that NHS England's DAS explore this further with the applicant, in line with NHS England DAS Standard for Data Processors. **5.3.6** In addition, if it was determined that 'BOX Governance file storage system' were considered a Data Processor, it was suggested that NHS England's DAS clarify their territory of use in line with NHS England DAS Standard for Territory of Use and that this aligned with the application. **5.3.7** AGD queried whether the appropriate arrangements were in place if the health economists from the University of Leeds needed to access the data, noting that this was **not** currently permitted under this application; and advised that they would be supportive of this, if the appropriate contractual arrangements were in place.	
5.4	**Reference Number:** NIC-757823-Y6Q1H-v0.5 **Applicant:** University of Birmingham **Data Controller:** University Hospitals Birmingham NHS Foundation Trust **Application Title:** Frequency and outcomes of pulmonary valve replacement by valve type in England and Wales over 20 years **Observers:** Emma Whale and Azeez Oladipupo **Application:** This was a new application. The purpose of the application is to evaluate the frequency and outcomes of Bioprosthetic pulmonary valve replacement, by valve type using routinely collected data from all centres in England and Wales over a 20-year period, to determine	

	changes in practice over time, freedom from pulmonary valve prosthesis reintervention and survival by valve type. The data will also be used to inform the development of a multi-centre clinical trial, including the impact of other factors such as valve size and age at implantation to inform the anticipated effect size. 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 were supportive of the application and wished to draw to the attention of the SIRO the following substantive comments: **5.4.1** AGD noted that NHS England's Data Access Service (DAS) had discussed with the applicant whether the application was service evaluation or research, and that the applicant had advised that it was service evaluation. The Group noted however, that that application still reflected that the work being undertaken was research, including, but not limited to, the UK General Data Protection Regulation (UK GDPR) legal basis cited; references throughout section 5 (Purpose / Methods / Outputs) to *"research project"* and *"research sponsor"*; and the outputs to research papers. The Group suggested that NHS England's DAS discuss this further with the applicant, and that the application was updated as appropriate to reflect the correct / factual information. **5.4.2** The NHS England SIRO Representative noted that University of Birmingham Data Security and Protection Toolkit (DSPT) was *"approaching standards"* and that an agreed action plan was in place with NHS England's Data Security Team; and asked that clarification was provided as to why this had been ongoing for two years. In addition, AGD made the following observations on the application and / or supporting documentation provided as part of the review: **5.4.3** AGD noted the reliance on a research passport, and notwithstanding the special condition in section 6 (Special Conditions) of the application in respect of honorary contracts, suggested that NHS England's DAS satisfy themselves that either the appropriate honorary contracts were in place; or that the research passport has been reviewed and fulfils the essential requirements of an honorary contract in line with NHS England's DAS Standard for Honorary Contracts. **5.4.4 Separate to this application and for NHS England to consider:** AGD suggested that as part of the ongoing work within NHS England in reviewing / updating the NHS England DAS Standards, research passports should be addressed as part of the NHS England's DAS Standard for Honorary Contracts discussion. **ACTION:** The AGD independent members involved with the NHS England DAS Standards Workshops, to discuss research passports as part of the NHS England's DAS Standard for Honorary Contracts. **5.4.5** The Group noted and discussed the 'National Institute for Cardiovascular Outcomes Research' (NICOR) data that would be linked; and noting that NICOR is part of NHS England, suggested that NHS England explore and clarify whether there	KI / PA / CDP

	are any restrictions on the data, for example, legal or technical. The Group noted that following the outcome of this, that NICOR may need to update their published privacy notice, or that application may need to be updated to reflect the factual information. **5.4.6** AGD noted that death data was flowing and suggested that this was reviewed / assessed to determine whether this would in fact make the data identifiable and would therefore be confidential patient data. The AGD Chair reiterated a point from the 10th October 2024, that NHS Digital had reached a position with the National Data Guardian in that NHS Digital / England should be carrying out an assessment about the risk of identification, and asked that the AGD NHS England Data and Analytics Representative check that assessments were part of the Q&A process. The AGD NHS England Data and Analytics Representative advised that there was an internal process to check this information, and that a further update would be provided to the Group in January 2025. **ACTION:** The AGD NHS England Data and Analytics Representative to provide an update to the Group in January 2025 as to the process in place to ensure date of death assessments are part of the Q&A / internal process checks. **5.4.7** The NHS England Caldicott Guardian Team Representative noted that whilst no commercial element had been identified in the application; there may be potential significant ramifications of the findings of the service evaluation; and suggested that NHS England's DAS ask the applicant if there had been any involvement by device manufacturers or associated companies, for example, by funding in kind or other support, in line with NHS England DAS Standard for Commercial Purpose.	D&A Rep
5.5	**Reference Number:** NIC-749612-D9M1V-v0.4 **Applicant and Data Controller:** Queen Mary University of London **Application Title:** The distributional and financial impacts of the soft drinks industry levy on childhood dental caries in England **Observers:** Dan Goodwin and Suzanne Shallcross **Application:** This was a new application. The purpose of the application is for a project to evaluate the impact of the Soft Drinks Industry Levy (SDIL) on social inequalities in severe dental caries among children in England. The objectives of this project are: **1)** to evaluate the impact of the SDIL on absolute and relative inequalities in hospital admissions for caries-related extractions according to area deprivation, ethnicity and urbanicity; and **2)** to evaluate the distributional consequences of the SDIL in terms of both financial and health outcomes through an extended cost-effectiveness analysis. 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 were supportive of the application and wished to draw to the attention of the SIRO the following comments: **5.5.1** AGD noted the e-mails provided as a supporting document (SD3.1) that made reference to ethical approval; and noting that it was unclear whether institutional ethical support had been obtained; suggested that NHS England Data Access Service (DAS) follow this up with the applicant; and that any supporting document was uploaded to NHS England's customer relationships management (CRM) system for future reference. **5.5.2** In addition, AGD noted that section 7 (Approval Considerations) stated that NHS ethical approval was **not** required, however, suggested that this was updated to reflect whether institutional ethical support had been obtained. **5.5.3** AGD noted and commended the work undertaken by NHS England's DAS on the internal application assessment form, which supported the review of the application.	
5.6	**Reference Number:** NIC-648118-L0Q2Z-v0.4 **Applicant:** King's College London **Data Controllers:** Guy's and St Thomas' NHS Foundation Trust, King's College Hospital NHS Foundation Trust, King's College London and South London and Maudsley NHS Foundation Trust **Application Title:** eLIXIR, Born in South London- Early Lifecourse data Cross-Linkage in Research **Observer:** James Watts **Application:** This was a new application. The purpose of the application is to **1)** develop a research registry of a UK inner-city deprived population which provides a continuous link between maternal and paediatric clinical and mental health data; **2)** to provide a robust security model regarding access to patient information that protects the legal and ethical rights of these patients; and **3)** to define and set up an operational service to provide appropriate and ongoing access to the eLIXIR user community. 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 were supportive of the application if the following substantive comments were addressed and wished to draw to the attention of the SIRO the following substantive comments: **5.6.1** The NHS England SIRO Representative advised the Group that Guy's and St Thomas' NHS Foundation Trust were in breach on another data sharing agreement	

	(DSA), and that **no** data would flow under this application until the issue had been addressed / resolved. **5.6.2** The NHS England SIRO Representative noted in section 8.1 (security assurance) of the NHS England Data Access Service (DAS) internal application assessment form, that Guy's and St Thomas' NHS Foundation Trust's Data Security and Protection Toolkit (DSPT) was *"approaching standards"* and that an agreed action plan was in place with NHS England's Data Security Team. The Group were advised that NHS Trusts **must** have DSPT and that an ISO 27001 Certificate would **not** be a suitable alternative; and this **must** be addressed before any data flows. **5.6.3** AGD noted that a similar application (NIC-309066-X9B9L-v0.9) was presented to the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) on the 17th June 2021, where IGARD had been unable to recommend for approval, and a number of significant comments had been made. AGD suggested that NHS England's DAS review the previous minutes and ensure that **all** of the previous points were reviewed and addressed as part of this application as may be appropriate, before this application progresses. **5.6.4** AGD noted the programmatic access envisaged in the application, and advised that the eLIXIR Oversight Committee Terms of Reference provided as a supporting document (SD7.0) appeared to be robust; however, suggested that the application was updated with general parameters of where programmatic access will be given as part of the research registry, for example, by posting some of the terms and conditions into the application. **5.6.5** In addition, AGD suggested that this application should show evidence of alignment with other programmatic applications, including, but not limited to, published minutes and a publicly accessible data release register. AGD noted that a number of these aspects had been addressed but cautioned NHS England about the need to ensure a consistency of approach across all applicants. In addition, AGD made the following observations on the application and / or supporting documentation provided as part of the review: **5.6.6** AGD noted that data from the Lambeth Data Net (LDN) may be linked as part of this work outlined in this application, however reiterated advice previously given to other applicants by IGARD, that the LDN patient-facing transparency materials stated that they only disseminated *"anonymous"* or *"anonymised"* data, which, by definition, cannot be linked and the information on LDN's website was misleading and should be updated as a matter of urgency. **5.6.7** AGD noted the reference on the study website to *"…opt-out consent…"*; and noting that consent was not being relied on and this reference could be misleading, suggested that this was reviewed and updated to reflect that the applicant is collecting routine data and there is the ability to opt-out.	

	5.6.8 AGD noted the content of the privacy notice and other transparency materials provided as supporting document, however, suggested that they were updated and aligned where necessary with additional information, including, but not limited to, clearer information that the project will run for a significant number of years and that national records will be accessed. **5.6.9** In addition, the Group suggested that the applicant gave further consideration as to how and when the cohort will be kept up to date as the study progresses, noting that this was currently unclear.	
5.7	**Reference Number:** NIC-625086-L6T3P-v0.2 **Applicant:** University of Birmingham **Data Controller:** University Hospitals Birmingham NHS Foundation Trust **Application Title:** Prevalence of liver disease, pulmonary disease and cardiovascular disease in alpha-1 antitrypsin deficiency **Application:** This was a new application. Alpha-1 antitrypsin deficiency (AATD) is a rare, autosomal codominant condition which predisposes the individual to developing early onset pulmonary emphysema and less frequently liver cirrhosis. As AATD is a rare condition, there are limited studies looking at important outcomes such as liver disease, cardiovascular disease and acute pulmonary exacerbations. The purpose of the application is to identify the incidence of these important health outcomes from patients who are prospectively followed up as part of the UK alpha-1 antitrypsin deficiency registry. 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 were supportive of the application **if** the following substantive comments were addressed, and wished to draw to the attention of the SIRO the following substantive comments. **5.7.1** AGD discussed the consent materials provided as supporting document, and advised that there were a number of statements that were ambiguous and potentially problematic, including, but not limited to, the reference to accessing data five years prior to consent and not being explicit that they would also access data relating to the time period after consent , which would particularly be an issue when accessing death date. AGD noted that there were differing views within the Group as to whether, as a whole, the consent was sufficient. **5.7.2** In addition, AGD noted that unless everyone consented in the last year, there would **not** be five years of historical data; and suggested that NHS England discussed this further with the applicant, and that the application was reviewed and updated	

	accordingly, including, but not limited to, the information in section 5(c) (Specific Outputs Expected) *"Data collected will be incorporated into our existing AATD database with plans to update the NHS England data extract on a **5 yearly basis**"*. **5.7.3** AGD noted the inconsistent information in the consent materials that state **one** direct identifier would be flowing, and section 5(b) that states more than one direct identifier would be flowing; and suggested that this was reviewed and aligned as appropriate to reflect the correct / factual information. **5.7.4** AGD suggested that the applicant undertake patient and public involvement and engagement (PPIE) with a sample of the cohort, including, but not limited to, reviewing the consent materials to check understanding on what identifiers would be flowing to NHS England; what data would be accessed, i.e. data before / after consent; and whether the statement regarding funding being provided to researchers completely independent of any drug company and whether this was compatible with the application. **5.7.5** AGD noted the information in section 3(b) (Additional Data Access Requested) in respect of data minimisation, however suggested that this was reviewed and updated, to be clearer as to who would be minimising the data based on the date of consent, i.e. NHS England or the applicant. **5.7.6** The Group noted that if the applicant was undertaking the data minimisation, that, as per the usual process, a special condition was added to section 6 (Special Conditions) of the application, stating that the applicant was required to carry out additional minimisation work and destroy the excess data. **5.7.7** The Group also suggested that a specific timeframe was added to the special condition confirming when the excess data should be destroyed by. **5.7.8** In addition, it was suggested that the data destruction being undertaken by the applicant should be noted in section 5(b) (Processing Activities) of the application for transparency. **5.7.9 Separate to this application and for NHS England to consider:** AGD noted the risks involved with excess data flowing and the possible reliance on the applicant to destroy data; and suggested that this could be incorporated into the NHS England consideration of the risks, checks and balances for the various modes of data access. **ACTION:** The AGD NHS England Data and Analytics Representative to consider addressing the risks involved with excess data flowing and the reliance on the applicant to destroy data; and to consider the risks, checks and balances for the various modes of data access. In addition, AGD made the following observations on the application and / or supporting documentation provided as part of the review:	D&A Rep

5.7.10 AGD noted the statement in the protocol provided as a supporting document (SD1.0) that *"Consent will be reaffirmed at every visit"* as part of the trial assessments and that there would be an ongoing relationship with the cohort.

5.7.11 The NHS England SIRO Representative noted that the consent material stated that data would only be held for one year after the end of the study; and asked that a special condition was added to section 6 of the application stating that data could only be held for one year after the end of the study; **or** at the end of the data sharing agreement, whichever comes first.

5.7.12 AGD noted the information in section 2.3 (benefits evaluation) of the NHS England Data Access Service (DAS) internal application assessment form, that stated the benefits would **not** be contentious; however, suggested that this was reviewed and the application updated as may be appropriate to address any potential contentious issues.

5.7.13 AGD noted the reference to the funders in section 5(a) (Objective for Processing) of the application, however suggested that for transparency, this was updated with the information in section 5(e) (Is the Purpose of this Application in Anyway Commercial) of the application in line with NHS England DAS Standard for Commercial Purpose; and further clarity as to how their interests were being met in the work outlined in the application, and what they may be receiving in respect of headline outputs.

5.7.14 In addition, AGD noted the information in section 5(e) in respect of the commercial funders and the statement *"Access to Hospital Episode Statistics (HES) data would facilitate a better understanding of…"*; and suggested that this was reviewed and updated to be clear that the commercial funders would not have access to the data.

5.7.15 AGD noted that the protocol referred to those with null or rare variants of AATD will have pseudo-anonymised data sent to the Centre for Regenerative Medicine, Boston, Massachusetts, USA; and suggested that clarification was sought that data that flowed under this agreement would **not** flow outside England and Wales for this purpose.

5.7.16 AGD queried the statement in section 5(b) of the application *"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 word was removed as may be necessary to reflect the facts.

5.7.17 AGD queried the references in section 5(b) of the application to remote processing / access taking place in "*secure locations*"; and suggested that this was reviewed and updated if not correct, for example, to refer to the security of the remote connection and not the physical location.

	5.7.18 AGD noted and commended the work undertaken by NHS England's DAS on the queries raised with the applicant on the role of the organisations involved, as outlined in the NHS England DAS internal application assessment form.	
6 INTERNAL DATA DISSEMINATION REQUESTS:		
There were no items discussed		
7 EXTERNAL DATA DISSEMINATION - SIRO APPROVED / SEEKING SIRO APPROVAL		
There were no items discussed		
8 OVERSIGHT AND ASSURANCE		
8.1	**Oversight & Assurance of Application Compliance Reports (ACRs) (Presenter: Tom Wright)** AGD noted at the AGD meeting on the 7th November 2024 and the 5th September 2024, that the Group had suggested that there was a further review of the ACRs, following the review undertaken on the 22nd August 2024 (and noted in the AGD minutes on the 5th September 2024). The Group noted that the next ACR review would take place at the 23rd January 2025 AGD meeting. In advance of the next ACR review on the 23rd January 2025, Tom provided a verbal update to the Group on the number of 'live' applications that had the ACR special condition included in section 6 of the application in line with NHS England DAS Standard for Special Conditions, circa 243 out of 983 (as at 9th December 2024) The Group were also advised that there was an ongoing programme of work to ensure that the special condition was added to all of the relevant applications moving forward, and that processes within NHS England were being updated to support this work programme. An AGD independent lay member requested that any future updates on statistics were also provided in percentages. Tom advised that a further update on statistics and this ongoing programme of work would be provided at a future AGD meeting in January / February 2025. **ACTION:** AGD Secretariat to add a review of the latest statistics / update on the ACR programme of work to the AGD Forward Planner for a January / February 2025 AGD meeting.	AGD Sec
9 AGD OPERATIONS		
9.1	**Risk Management Framework** AGD has been previously informed that a risk management framework is being developed by Data Access and had commented on early thinking about such a Framework. Nonetheless, presently AGD were still operating using the precedent and	

	standard framework as an interim arrangement since February 2023 and AGD were concerned that the permanent Risk Management Framework was not in place. The Group discussed the NHS England corporate risk management framework (see minutes of 14th November 2024) and the AGD chair subsequently formally asked via email if the NHS England corporate risk management framework could be used. The NHS England SIRO Representative updated the Group that NHS England was still considering the request, including how the NHS England corporate risk management framework could be adapted for AGD; and noted that there would be a further update in January 2025. **ACTION:** The NHS England SIRO Representative to provide a written response to AGD on the progress, and expected time frame for implementation, of the risk management framework. The Group noted the NHS England SIRO Representative's response and asked for an update in January 2025.	SIRO Rep
9.2	**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. The Group noted that prior to the meeting, they had been provided with draft copies of **1)** the 'Declaration of Interest' table; **2)** the 'Applicant is a member of AGD' SOP; and **3)** the 'Registered and Regulated Clinicians on AGD' SOP. The Group discussed the three documents and suggested some minor tweaks prior to finalising / publication on the AGD webpage.	
9.3	**AGD Stakeholder Engagement** **National Data Opt-out (NDO) Review / Consultation** An AGD independent member requested that AGD are engaged with any planned review / consultation on the NDO. The NHS England SIRO Representative noted the request and advised that he would engage with the relevant team within NHS England and offer the support of AGD as part of any planned review / consultation. **ACTION:** The NHS England SIRO Representative to engage with the relevant team within NHS England and offer the support of AGD as part of any planned review / consultation on the NDO.	SIRO Rep
	NHS England consent assurance group	

	An AGD independent member noted the reference in the National Data Guardian (NDG) Annual Report to NHS England's consent assurance group; and asked the NHS England SIRO Representative for an update on this when available. The NHS England SIRO Representative noted the request and advised an update would be provided in due course. **ACTION:** The NHS England SIRO Representative to provide an update to the Group on the NHS England consent assurance group.	SIRO Rep
9.4	**AGD Project Work** *There were no items discussed*	
10 Any Other Business		
10.1	**AGD collaboration on in-meeting documentation proposal** AGD noted that at the AGD plenary meeting on the 26th September 2024, potential different ways of working prior to the AGD meetings had been discussed, for example, the Group reviewing / commenting on meeting documents in a shared space, that may reduce duplication of efforts by AGD members, in terms of issues being highlighted; and will then support the discussion in-meeting. The Group noted that the AGD Secretariat had provided a proposed process for AGD members to review / comment on meeting documents in a shared space, prior to the AGD meetings. The Group noted the content of the proposed process, and agreed that from January 2025, a pilot would commence to review a sample of documents for review / discussion at AGD meetings, with a review of how this was working at the end of January 2025. The Group thanked the AGD Secretariat for their work undertaken on establishing a process for the pilot and looked forward to a review at the end of January 2025. **ACTION:** AGD Secretariat to add a review of the AGD collaboration on in-meeting documentation to the AGD Forward Planner for the 30th January 2025 AGD meeting.	AGD Sec
10.2	**AGD SharePoint Site (Presenter: Karen Myers)** The Group were provided with a brief overview of the new AGD internal SharePoint site, that would be utilised from January 2025 for all AGD related documentation. The Group noted and thanked Karen for providing the update.	
10.3	**AGD Recruitment** AGD members asked if there was any update to the discussion at the AGD meeting on the 21st November 2024 in respect of AGD recruitment. The NHS England SIRO Representative	

	noted that discussions were ongoing with NHS England HR with regard to pay rates, contract arrangements and recruitment.

Meeting Closure

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