Advisory Group for Data (AGD) – Meeting Minutes

Thursday, 28th November 2024

09:00 – 15:05

(Remote meeting via videoconference)

AGD INDEPENDENT / NHS ENGLAND MEMBERS IN ATTENDANCE:	
Name:	**Role:**
Paul Affleck (PA)	AGD independent member (Specialist Ethics Adviser)
Claire Delaney-Pope (CDP)	AGD independent member (Specialist Information Governance Adviser)
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
Dan Goodwin (DG)	Data Access and Partnerships, Data and Analytics, Transformation Directorate (**Observer:** item 5.4)
Madeline Laughton (ML)	Data Access and Partnerships, Data and Analytics, Transformation Directorate (**Observer:** item 5.5)
Joe Lawson (JL)	Data Access and Partnerships, Data and Analytics, Transformation Directorate (**Observer:** item 5.1)
Jorge Marin (JM)	Data Access and Partnerships, Data and Analytics, Transformation Directorate (**Observer:** item 5.4)

Karen Myers (KM)	AGD Secretariat Officer, Privacy, Transparency and Trust (PTT), Delivery Directorate
Jodie Taylor-Brown (JTB)	Data Access and Partnerships, Data and Analytics, Transformation Directorate (**Observer:** items 5.1 to 5.3)
James Watts (JW)	Data Access and Partnerships, Data and Analytics, Transformation Directorate (**Observer:** items 5.5 and 5.6)
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)
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 21st November 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 applications NIC-739358-R1C7S and NIC-740323-Y4T3F) or staff involved, and it was agreed that this was not a conflict of interest. Claire Delaney-Pope noted a professional link to King's College London (NIC-651858-F5H2J) 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 BRIEFING PAPER(S) / DIRECTIONS:	

There were no items discussed		
5 EXTERNAL DATA DISSEMINATION REQUESTS:		
5.1	**Reference Number:** NIC-433176-J8Q2S-v4.3 **Applicant and Data Controller:** AstraZeneca AB **Application Title:** DAPA MI - A Registry-based, Randomised, Double-blind, Placebo-Controlled Cardiovascular Outcomes Trial **Observers:** Jodie Taylor-Brown and Joe Lawson **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 31st March 2022, 10th March 2022 and the 25th March 2021. The application and relevant supporting documents were previously presented / discussed at the IGARD COVID-19 response meetings on the 16th March 2021, 9th March 2021 and the 2nd March 2021. **Application:** This was an amendment application. The purpose of the application is for a study, that will evaluate the effect of the drug dapagliflozin (10 mg) versus a placebo, given once daily, in addition to Standard of Care therapies for patients with myocardial infarction (MI), for the prevention of hospitalisation for heart failure or cardiovascular (CV) death. The study seeks to determine dapagliflozin's potential in the early prevention of serious complications, hospitalisations for heart failure or CV death, immediately following an MI. 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: 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. **5.1.1** The NHS England SIRO Representative noted that the territory of use in section 2(c) (Territory of Use) of the application was the *"UK and the European Economic Area (EEA)"*; and advised that the application would be updated to be clear that access to the data would only be permitted in the UK and Sweden. The Group noted and supported the update outlined. **5.1.2** AGD suggested that NHS England's Data Access Service (DAS) make clear to the applicant that whilst they may have participant consent to access and transfer	

	the data to other jurisdictions, the application will have strict contractual restrictions on where the data can be accessed, i.e. the UK and Sweden. **5.1.3** 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 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. **5.1.4** AGD noted the benefit outlined in section 5(d) (Benefits) iii (Yielded Benefits) of the application *"…the researchers found that the win ratio was 1.34. This meant that the participants who took dapagliflozin with standard care had improved health outcomes compared to the participants who took the placebo with standard care"*; and suggested that section 5(e) (Is the Purpose of this Application in Anyway Commercial) and section 5(a) (Objective for Processing) were updated to reflect this indication of the likelihood of success of the drug and consequent impact on how the balance between public and commercial benefit is assessed and described, in line with NHS England's DAS Standard for Objective for Processing and NHS England's DAS Standard for Commercial Purpose.	
5.2	**Reference Number:** NIC-739358-R1C7S-v0.7 **Applicant and Data Controller:** University of Leeds **Application Title:** FReSH START RCT **Observer:** Jodie Taylor-Brown **Application:** This was a new application. The purpose of the application is for a programme of research to develop and evaluate a new approach for helping individuals who repeatedly self-harms. 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: **5.2.1** AGD noted that the 'Leeds Analytics Secure Environment for Research' (LASER) was covered by a separate Data Security and Protection Toolkit (DSPT) to the Leeds University Clinical Trials Research Unit; and suggested that NHS England satisfy themselves that the application included all relevant DSPTs, and that the application was updated as may be appropriate. **5.2.2** AGD noted the data fields in the data flowing from the University of Leeds to NHS England included *"gender"*; and advised that this may lead to a 'nil return' if	

there was a mismatch between the gender data field and an NHS England dataset that may only contain *"sex"* data. The Group suggested that the NHS England Data Access Service (DAS) discuss this further with the applicant (for example remove gender as a matching field or not discounting records with mismatches), noting that date of birth, postcode and / or NHS number should be sufficient in this instance for linkage.

5.2.3 AGD noted the statement in section 5(b) (Processing Activities) of the application *"There will be no requirement and no attempt to reidentify individuals…"*; and suggested that, given it is a consented cohort, and the subject matter, there may be instances where it would be beneficial to re-identify individuals, for example to notify their GP. It was suggested that this was reviewed and updated as may be necessary to reflect the correct information; or that the statement was removed.

5.2.4 AGD noted the special condition in section 6 (Special Conditions) of the application, in respect of the NHS Business Services Authority (NHSBSA) Medicines Data; and following the discussion at the AGD meeting on the 8th August 2024, on the broader scope of the NHSBSA Medicines Data Directions 2019, it was suggested that the restrictive wording at the start of the special condition was removed.

5.2.5 In addition, AGD suggested that NHS England's DAS advise the applicant that the scope of the NHSBSA Medicines Data Directions 2019 will become broader, and that whilst the scope of the application is within scope of the previous Direction, the Group would be supportive of the application being amended if required to reflect the scope of the updated Direction, if this aligned with the consent, and subject to the relevant approvals.

5.2.6 Separate to the application and for NHS England and AGD to note: The AGD NHS England Data Protection Office (DPO) Representative noted that work was ongoing to progress the updated NHSBSA Medicines Data Directions 2019 and confirmed to AGD that the Directions had now finished the NHS England consultation stage and were going out for signature today.

5.2.7 AGD noted that reference in the protocol and on the website to a number of *"co-investigators"*. The Group suggested that NHS England explore this further with the applicant, to seek assurance that these individuals were **not** responsible for determining the purpose and means of processing, and were therefore **not** carrying out any data controllership activities, in line with the NHS England's DARS Standard for Data Controllers.

5.2.8 In addition, AGD suggested that the applicant clarify any commercial benefits to the co-investigators, and that section 5(e) (Is the Purpose of this Application in Anyway Commercial) and section 5(a) (Objective for Processing) of the application were updated to provide further clarity, in line with NHS England's DAS Standard for Objective for Processing and NHS England's DAS Standard for Commercial Purpose.

	5.2.9 AGD queried the references in section 5(b) of the application to remote processing / access taking place from "*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. **5.2.10** AGD noted in section 5(a) that substantive employees of University of Leeds would access the data; and suggested the applicant may wish to consider whether access would also be required by students of the institution, with appropriate controls in place and relevant updates to the application. **5.2.11** AGD noted and commended the applicant on the patient and public involvement and engagement (PPIE) group that has been established, and the number of initiatives of this group, including, but not limited to, helping to inform the dissemination strategy. **5.2.12** AGD noted the reference in section 5(a) to an *"…analysis of social media postings"*; and suggested that NHS England's DAS clarify with the applicant whether this was a general social media 'scrape' (review), or, whether this was a targeted social media search on the individuals in the study. The Group suggested that there may be ethical issue with both, noting that social media posts may be found from individuals in the study via a general social media scrape, and suggested that the applicant discuss this further with the PPIE group. **5.2.13** 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-740323-Y4T3F-v0.9 **Applicant:** University of Leeds **Data Controllers:** Bradford Teaching Hospitals NHS Foundation Trust and University of Leeds **Application Title:** PROSPER Definitive Trial **Observer:** Jodie Taylor-Brown **Application:** This was a new application. The purpose of the application is to evaluate the clinical and cost-effectiveness of Personalised Care Planning for older people with frailty, when compared with usual care alone. 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 noted that the 'Leeds Analytics Secure Environment for Research' (LASER) was covered by a separate Data Security and Protection Toolkit (DSPT) to the Leeds University Clinical Trials Research Unit; and suggested that NHS England satisfy themselves that the application included **all** relevant DSPTs, and that the application was updated as may be appropriate.

5.3.2 AGD noted in section 5(a) (Objective for Processing) of the application the role of the University of Exeter and that they would not have access to the data; however, suggested that NHS England's Data Access Service (DAS) explore this further with the applicant, to clarify that they were not determining the purpose and means of processing and were therefore not carrying out any data controllership activities in line with the NHS England DAS Standard for Data Controllers; and that the application was updated as may be required to reflect the correct / factual information.

5.3.3 AGD noted the references in the supporting documents provided, including, but not limited to, the protocol, to a number of *"co-investigators"*. The Group suggested that NHS England explore this further with the applicant, to seek assurance that these individuals were **not** responsible for determining the purpose and means of processing, and were therefore **not** carrying out any data controllership activities, in line with the NHS England's DARS Standard for Data Controllers.

5.3.4 AGD noted the statement in section 5(b) (Processing Activities) of the application *"There will be no requirement and no attempt to reidentify individuals…"*; and suggested that given it is a consented cohort, and the subject matter, there may be instances where it would be beneficial to re-identify individuals, for example to notify their GP. It was suggested that this was reviewed and updated as may be necessary to reflect the correct information; or that the statement was removed.

5.3.5 AGD noted the special condition in section 6 (Special Conditions) of the application, in respect of the NHS Business Services Authority (NHSBSA) Medicines Data; and following the discussion at the AGD meeting on the 8th August 2024, on the broader scope of the NHSBSA Medicines Data Directions 2019, it was suggested that the restrictive wording at the start of the special condition was removed.

5.3.6 In addition, AGD suggested that NHS England's DAS advise the applicant that the scope of the NHSBSA Medicines Data Directions 2019 will become broader, and that whilst the scope of the application is within scope of the previous Direction, the Group would be supportive of the application being amended if required to reflect the scope of the updated Direction, if this aligned with the consent, and subject to the relevant approvals.

5.3.7 AGD noted that, if a cohort member initially provided consent, and then lost capacity but continued in the study by way of consultee advice, AGD were of the view that the individual **should** be able to remain in the cohort and that the National

	Data Opt-out (NDO) would **not** be applied, as they did have capacity at the time they provided the initial consent. The Group advised that they did **not** support the removal of those in the study under consultee advice unless they were only in the study via consultee advice and the person had an applicable NDO. **5.3.8 Separate to the application and for NHS England to consider:** AGD reiterated the point made at the AGD meeting on the 12th November 2024, regarding the practice by some researchers of excluding certain parts of their cohort, to avoid the cost of two flows of data due to the technical application of the NDO, and suggested this was explored further by NHS England Data and Analytics, AGD were concerned that the costing model was potentially weakening research and wasting the contribution to research of individuals included in studies under consultee advice (the consultee advice individuals being excluded so as to avoid a second flow of data with the NDO applied). **ACTION:** NHS England Data and Analytics to explore whether there was a different cost charging model, or technical solution, to stop the practice by some researchers of excluding certain parts of their cohort, due to the technical application of the NDO. **5.3.9** 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. **5.3.10** AGD noted in section 5(a) that substantive employees of University of Leeds would access the data; and suggested the applicant may wish to consider whether access would also be required by students of the institution, with appropriate controls in place and relevant updates to the application. **5.3.11** AGD noted and commended the applicant on the study specific privacy notice. **5.3.12** 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.	D&A Rep
5.4	**Reference Number:** NIC-754175-W2Z4T-v0.3 **Applicant and Data Controller:** Imperial College London **Application Title:** Assessing the Impact of Service Models Separating Adult Elective and Emergency Surgical Care on Health Inequalities in England **Observers:** Dan Goodwin and Jorge Marin **Application:** This was a new application. The purpose of the application is for a research project, to understand the impact of service models separating adult elective and emergency surgical care on health inequalities in England.	

	The project will be divided into two studies: **1)** Mapping GP referrals for elective adult surgical care in England; and **2)** Analysing the impact of surgical hubs on equity of access to elective surgery in England. NHS England were seeking general advice on the application. Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** AGD were supportive of the application and wished to draw to the attention of the SIRO the following substantive comments: **5.4.1** Noting the large volume of data requested under this application, and that this would be flowing as a data extract; AGD queried why the extract could not be placed in NHS England's Secure Data Environment (SDE), in line with the Department of Health and Social Care (DHSC) Data Access Policy that states *"Secure Data Environments (SDEs) will become the primary route for accessing NHS data for research"*. It was strongly suggested that this was given further consideration by NHS England. **5.4.2 Separate to this application and for NHS England to consider:** AGD reiterated the point from the 17th October 2025, and asked that NHS England provide an update to the Group as to how they are complying with the DHSC Data Access Policy in respect of the SDEs becoming the primary route for accessing NHS data for research. **ACTION:** The AGD NHS England Data and Analytics Representative to provide an update to AGD, to provide further information as to how NHS England are complying with the DHSC Data Access Policy in respect of the SDEs becoming the primary route for accessing NHS data for research. 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 potential shortcoming of the ethnicity fields in the Emergency Care Data Set (ECDS) dataset; and suggested that NHS England ensure that the applicant is aware of this; and ensures that this is reflected in any outputs and / or recommendations from the research. **5.4.4 Separate to this application and for NHS England to consider:** The AGD NHS England Caldicott Guardian Team Representative reiterated a point from the 17th October 2024, that research using datasets with incomplete ethnicity data may introduce bias into the results; and advised that further discussions would be held internally on this point to discuss possible solutions, such as a dedicated dataset. AGD noted that they were supportive of this, noting that this was an issue they had discussed previously.	D&A Rep

	ACTION: The AGD NHS England Caldicott Guardian Team Representative to discuss with NHS England colleagues, options for improving access to reliable ethnicity data.	CG Rep
	5.4.5 AGD noted in section 5(a) (Objective for Processing) of the application that there had been no patient and public involvement and engagement (PPIE) with refining the purpose of the research, however there would be PPIE with the dissemination of the findings. AGD suggested that there was ongoing PPIE throughout the lifecycle of the work. The HRA guidance on Public Involvement is a useful guide.	
	5.4.6 In addition, AGD suggested that the applicant include Clinicians who do the referring, and those that design / write the pathways / referral forms as part of the PPIE.	
	5.4.7 Separate to the application and for NHS England to consider: AGD reiterated a point last raised on the 8th August 2024, that NHS England should take a position on PPIE and consider whether or not a brief NHS England DAS Standard, referring to current best practice, should be drafted as a pragmatic approach to address this point in the interim. In addition to the point previously raised, the Group suggested that as part of a NHS England DAS Standard, consideration could be given to challenges faced by PhD students in respect of undertaking PPIE; and the importance of this when requesting large volumes of data.	
	ACTION: the NHS England SIRO Representative to discuss the practicalities and implementation of a new NHS England DAS Standard for PPIE with the AGD NHS England Data and Analytics Representative.	SIRO Rep
	5.4.8 AGD noted in section 5(a) of the application that substantive employees of Imperial College London would access the data; however, noting that this was a PhD project, the Group suggested that the application was updated to either reflect that the PhD student was a substantive employee of Imperial College London; or to reflect the access by the PhD student.	
	5.4.9 AGD noted the helpful and clear information within the protocol provided as a supporting document (SD2), and suggested that for the purpose of transparency, section 5(a) of the application was updated / edited to add some of the information from the protocol, in line with NHS England DAS Standard for Objective for Processing.	
	5.4.10 AGD noted the information at the end of section 5(a) of the application, in respect of the Elective Recovery Taskforce, the Royal College of Surgeons and Get It Right First Time; and suggested that this was reviewed and updated to either: ensure that there were no hyperbolic statements in respect of their involvement, and to be clearer on what the *"project"* is that is referred to; or to remove the information if not relevant.	

	5.4.11 AGD queried the references in section 5(b) (Processing Activities) 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. **5.4.12** AGD noted and commended the applicant on the use of the "theyworkforyou" website to identify individual MPs potentially interested in this research.	
5.5	**Reference Number:** NIC-688768-Y9Q9S-v0.4 **Applicant and Data Controller(s):** Institute of Cancer Research **Application Title:** A service evaluation to review the baseline demographics of patients undergoing radical treatment for oropharyngeal cancer – and a comparison with the TORPEdO study cohort **Observers:** James Watts and Madeline Laughton **Application:** This was a new application. The purpose of the application is for a project that will undertake a service evaluation of all patients treated with radiotherapy for oropharyngeal cancer in England, and compare the demographics found in this general population with that of patients participating in 'TOxicity Reduction using Proton bEam therapy for Oropharyngeal cancer' (TORPEdO). 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 comment: **5.5.1** The NHS England SIRO Representative noted that the National Disease Registration Service (NDRS) Systemic Anti-Cancer Therapy Dataset (SACT) was identifiable due to this containing **full** postcode; and as currently drafted, the application does not reflect the processing of this confidential data, for example, the references throughout to the data being *"pseudonymised"*. The Group suggested that NHS England's Data Access Service (DAS) work with the applicant to establish a legal basis for the flow of confidential data, for example s251 support; or determine whether there is an alternative data field or alternative solution for the applicant to receive the geographical data for the cohort, in order to carry out the service evaluation aims, noting geographical location is a key component of assessing access. In addition, AGD made the following observations on the application and / or supporting documentation provided as part of the review: **5.5.2** AGD welcomed the application and noted the potential utility of the Service Evaluation.	

	5.5.3 AGD also noted the importance and potential benefit from the Study, and supported the use of wider factors affecting inclusion in the cohort that might be explored from within the health data, even if additional non-identifiable data was required. **5.5.4** AGD noted that the applicant had followed the appropriate steps in order to determine that the project was service evaluation and not research, and that NHS England's DAS had asked the appropriate follow-up questions. The Group advised that there may be further questions to ask in respect of this being research, however, advised that they would not provide advice on this, noting that this had already been explored. **5.5.5** AGD noted the efforts undertaken by the applicant to establish that they do not require NHS Research Ethics Committee (REC) support, noting that the purpose is for Service Evaluation. The Group also noted the letter from the Royal Marsden NHS Foundation Trust provided as a supporting document (SD3.0) that confirmed an ethical review was not required. AGD suggested that the applicant could approach their own institutional ethics committee (Institute of Cancer Research or the University of London) on whether an ethical review is required in accordance with NHS England's DAS Standard for Ethical Approval. **5.5.6** AGD queried the references in section 5(b) (Processing Activities) 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. **5.5.7** AGD noted and commended the applicant on the patient and public involvement and engagement (PPIE).	
5.6	**Reference Number:** NIC-651858-F5H2J-v0.21 **Applicant and Data Controller(s):** King's College London **Application Title:** Mapping the local and regional characteristics of maternity population in England **Observer:** James Watts **Application:** This was a new application. The purpose of the application is for a research project that aims to **1)** quantify the risks of maternal morbidity, such as eclampsia, caesarean section use, and babies adverse outcomes including death, and Fetal Growth Restriction (FGR) for individual ethnic groups in the UK; **2)** to provide summary estimates of a range of maternity outcomes adjusting for patient characteristics, such as pre-existing medical conditions, past and current pregnancy problems, and healthcare utilization and trust influence; and **3)** To provide policymakers with essential information on ways to provide more equitable and equal interventions for negative maternal outcomes.	

	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 on the presumption that the SIRO would **not** approve this application until such time as issues relating to the queries raised on the NMPA, linkage and date of death legal basis had been resolved to the SIRO's satisfaction, and wished to draw to the attention of the SIRO the following substantive comments: **5.6.1** AGD noted that prior to the meeting, an AGD member had raised a query with NHS England's Data Access Service (DAS) in respect of the proposed aim of the research, noting that this seems to fall within the remit of the National Maternity and Perinatal Audit (NMPA). The queries raised were whether this research project replicates the work of the NMPA; and whether the NMPA been consulted. The Group noted that the applicant had responded (via NHS England's DAS) on this point, and had advised that a member of the Research Team worked on both the NMPA and the research outlined in this application, and that they were aware of the NMPA activities and objectives, and that the analysis proposed would complement the NMPA work, by focussing on regional differences. The Group thanked the applicant for the response to their query. **5.6.2** The Group, however, suggested that NHS England follow up further to ascertain what the differences are between this research and that carried out by the NMPA, noting that they appeared to have very similar goals; and this this was made clear in section 5(a) (Objective for Processing) of the application for transparency. It was suggested that a letter of support from the NMPA would give reassurance that there would not be a duplication of processing and that a copy of such a letter be uploaded to NHS England's customer relationship management (CRM) system. **5.6.3** The NHS England SIRO Representative advised the Group that date of death data would be flowing under this application. The Group noted and advised that NHS England's DAS should establish the legal basis for this data to flow, noting that this item may make the data identifiable and would therefore be classed as confidential data. **5.6.4** AGD advised that it may cause potential distress to a small number of the cohort to be linked for a period of time, as part of a mother and baby pair, for example, if baby was separated from the mother at birth, and suggested that this small risk was acknowledged in the Data Protection Impact Assessment (DPIA), the protocol (if available) and / or discussed with the patient and public involvement and engagement (PPIE) group. **5.6.5** In addition, the NHS England SIRO Representative queried how the applicant is doing the linkage between the mother and baby with the Maternity Services Data	

	Set (MSDS) and the death data, and how this will be kept pseudonymised; and asked that further clarity was provided on this. In addition, AGD made the following observations on the application and / or supporting documentation provided as part of the review: **5.6.6 Separate to the application and for NHS England to consider:** Noting that a protocol had **not** been provided to NHS England's DAS, but where Research Ethics Committee (REC) approval has been sourced, it was suggested by the Group that there are mechanisms in place to request the 'statement of research' or similar summary document that was provided to the REC. **ACTION:** In the absence of a protocol, but where REC approval has been sourced, NHS England's DAS to ensure there are mechanisms in place to request the 'statement of research' or similar summary document that was provided to NHS REC. **5.6.7** AGD noted that section 3 (Datasets Held / Requested) of the application referred to the Common Law Duty of Confidentiality being addressed by s251; and suggested that this was removed as it was incorrect. **5.6.8** AGD noted that King's College London had a number of Data Security and Protection Toolkits (DSPTs); and suggested that NHS England satisfy themselves that **all** the individuals accessing, processing and / or analysing the data are covered by the relevant DSPTs, and that the application was updated as may be appropriate. **5.6.9** AGD noted the statement in section 5(a) of the application *"The total population of Black Minority Ethnic groups has the potential to increase from 13% in 2006 to 28% in 2031, and* ***as high as 44%*** *by 2056…"*; and suggested that this was changed to state *"...up to 44%...."*. **5.6.10** AGD queried the statement in section 5(a) of the application in respect of the patient and public involvement and engagement (PPIE) group having *"…no objections in consideration of diverse public views…"*; and suggested that further information was provided as to what the PPIE group were asked and how they responded, as this is unclear. **5.6.11** AGD queried the references in section 5(b) (Processing Activities) 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. **5.6.12** AGD noted the expected benefits in section 5(d) (ii) ((Expected Measurable Benefits to Health and / or Social Care) of the application, however suggested that in line with NHS England DAS Standard for Expected Measurable Benefits, that this information was reviewed and updated / amended to retain the details provided of two or three specific yielded benefits accrued to date, and asked that it was clear as to the benefits to both the patients and the health and social care system more	DAS

	generally (particularly those benefits that the study may be able to achieve beyond what the NMPA are doing). **5.6.13 Separate to the application and for NHS England to consider:** AGD queried the data quality of the ethnic category within the Maternity Services Data Set (MSDS); and asked that an update be provided to the Group. **ACTION:** The NHS England Data and Analytics Representative to clarify the data quality of the ethnic category within the Maternity Services Data Set (MSDS).	D&A Rep
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		
There were no items discussed		
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 considering the request. **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 on the 5th December 2024. **Subsequent to the meeting:** It was noted that the AGD minutes from the 14th November 2024 and the 21st November 2024 incorrectly referred to AGD still operating using the precedent and framework standard as an interim arrangement since *"March 2024"*, and that this should have stated *"February 2023"*.	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.	
9.3	**AGD Stakeholder Engagement** The AGD Chair noted to the Group that she had met with Dr. Tony Calland, the Chair of the Health Research Authority Confidentiality Advisory Group (HRA CAG) and Dr. Nicola Byrne, the National Data Guardian for health and adult social care in England, on Tuesday 26th November 2024, as part of their regular engagement.	
9.4	**AGD Project Work** *There were no items discussed*	
10 Any Other Business		
10.1	**Location Restrictions (Presenter: Garry Coleman)** AGD noted that, prior to the meeting, an AGD member had raised a query with the NHS England SIRO Representative, in respect of why there are restrictions on the locations (such as country) from which a user can access NHS England data, when that data is held in a Data Security and Protection Toolkit (DSPT) compliant Trusted Research Environment (TRE) and a remote desktop is used. The NHS England SIRO Representative advised that, accessing data via a TRE or Secure Data Environment (SDE) is still processing the data. In relation to the access itself, the processing occurs in the country from where the access takes place, for example, if accessing the data from the United States of America (USA), then processing is occurring in the USA. The Group were advised that the Information Commissioner's Office (ICO) has recently published guidance with such an example, so as to clarify the position; and the position taken by NHS England and previously NHS Digital is consistent with that clarification. The NHS England SIRO Representative advised that, separately, the question often arises about remote access, and whether (for example) a researcher could access a TRE with their own device, or perhaps that of another organisation. It was noted that the issue here is one of security, what controls are in place to ensure that the remote device is secure. An extreme example perhaps, is whether one would be content for a laptop with a well out of date operating system and software, all with well-known security flaws to access a secure network. This would clearly would not be acceptable, which is why NHS England ask the Data Controller to ensure that they have adequate security across all remote devices, i.e. the various security software, updates, scanning etc must also apply to the remote device. That may mean that the	

	remote device has to be one supported by the Data Controller and is within their network control; or sometimes it clarifies that it is someone accessing the data as a Data Processor for the organisation (and not an honorary contract), and that the Data Processor has its own security model which has been documented and accepted by NHS England. The Group noted and thanked the NHS England SIRO Representative for the update.	
10.2	**Briefing about the NHS England Post-AGD Process (Presenter: Tom Wright)** The Group were provided with a brief overview of the NHS England post-AGD process, including, but not limited to, the meetings that take place following an AGD meeting with the AGD NHS England Data and Analytics Representative, the NHS England SIRO Representative and Data and Analytics colleagues; and how applications are progressed following receipt of AGD advice. The Group noted the process outlined for applications that progress down the NHS England precedent route, without further input / oversight from the NHS England SIRO Representative and observed these are subject to the AGD oversight and assurance process. Where AGD advice had been provided at an AGD meeting, but the SIRO Representative did not specifically ask to see that application again (the majority of applications going through this route) it was suggested by AGD and the NHS England SIRO Representative that there should be some oversight and assurance on these applications, to ensure that previous AGD points had been sufficiently considered, and there was a clear audit trail of actions taken, or not taken, for these “non-SIRO” internal sign offs. It was agreed that the NHS England Data and Analytics Representative would discuss this with colleagues and provide an update at a future AGD meeting. **ACTION:** The NHS England Data and Analytics Representative to provide an update at a future January 2025 AGD meeting. AGD thanked Tom for providing an overview on the process and looked forward to an update at a future AGD meeting.	D&A Rep
10.3	**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.	
Meeting Closure As there was no further business raised, the Chair thanked attendees for their time and closed the meeting.		