Advisory Group for Data (AGD) – Meeting Minutes

Thursday, 8th August 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) (Items 1 to 6.2)
Noela Almeida (NA)	NHS England member (Data Protection Office Representative (Delegate for Jon Moore))
Claire Delaney-Pope (CDP)	AGD independent member (Specialist Information Governance Adviser)
Kirsty Irvine (KI)	AGD independent member (Chair)
Narissa Leyland (NL)	NHS England member (Data and Analytics Representative (Delegate for Michael Chapman))
Dr. Jonathan Osborn (JO)	NHS England member (Caldicott Guardian Team Representative)
NHS ENGLAND STAFF IN ATTENDANCE:	
Name:	**Role / Area:**
Dr. Shabnum Ali (SA)	Associate Caldicott Guardian and Senior Clinical Lead, Medical Directorate (**Observer:** items 5.1 to 6.2)
Laura Bellingham (LB)	Deputy Director, Data Access and Partnerships, Data and Analytics (**Presenter:** item 5.2)
Ian Bullard (IB)	Senior Data Product Manager, Data and Analytics (**Presenter**: item 5.1)
Garry Coleman (GC)	NHS England SIRO Representative (not in attendance for part of item 6.3)
Claire Edgeworth (CE)	IG and Ethics Lead, Data for R&D Programme (**Presenter:** item 5.2)

Dan Goodwin (DG)	Data Access and Partnerships, Data and Analytics (**Observer:** item 6.2)
Nicki Maher (NM)	NHS England SIRO Representative (Delegate for Garry Coleman)) (item 6.3)
Karen Myers (KM)	AGD Secretariat Officer, Privacy, Transparency and Trust (PTT), Delivery Directorate
Pritpal Rayat (PR)	Information Analysis Lead Manager, Head of Medicines and Adult Social Care Data Products and Developments, Analytics and Insights, Data and Analytics Directorate (**Presenter**: item 5.1)
Dr. Chris Russell (CR)	Head of NHS Research SDE Network, NHS Transformation Directorate (**Presenter:** item 5.2)
Joanne Treddenick (JT)	Information Governance Lead, Data and Analytics, Privacy, Transparency and Trust (PTT), Delivery Directorate (**Presenter**: item 5.1)
Emma Whale (EW)	Data Access and Partnerships, Data and Analytics (**Observer:** item 6.1)
Vicki Williams (VW)	AGD Secretariat Manager, Privacy, Transparency and Trust (PTT), Delivery Directorate
Kevin Willis (KW)	Head of Information Law, NHS England Legal Team, Chief Delivery Officer Directorate (**Presenter**: item 5.1)
AGD INDEPENDENT MEMBERS / NHS ENGLAND MEMBERS <u>NOT</u> IN ATTENDANCE:	
Name:	**Role / Area:**
Michael Chapman (MC)	NHS England member (Data and Analytics Representative)
Prof. Nicola Fear (NF)	AGD independent member (Specialist Academic Adviser)
Dr. Robert French (RF)	AGD independent member (Specialist Academic / Statistician Adviser)
Jon Moore (JM)	NHS England member (Data Protection Office Representative)
Jenny Westaway (JW)	AGD independent member (Lay Adviser)
Miranda Winram (MW)	AGD independent member (Lay Adviser)

EXTERNAL STAFF IN ATTENDANCE (ITEM 5.2):	
Michael Ball (MB)	Senior Delivery Manager – Data Assurance, NECS, NENC SDE
Prof. Jim Davies (JD)	Professor of Software Engineering, University of Oxford
Dr. Sanjay Gautama (SG)	Consultant anaesthetist, CCIO and Caldicott Guardian - Imperial College Healthcare NHS Trust and NW London ICB
Jamie Neale (JN)	Data Access Policy, Department of Health and Social Care

1	**Welcome and Introductions:** The AGD Chair welcomed attendees to the meeting. AGD noted that, due to the lack of availability of independent members, there was an even number of AGD independent members (three) and AGD NHS England members (three) in attendance for items 1 to 6.2; but for items 6.3 to 11 only, two AGD independent members and three AGD NHS England members were in attendance at the meeting. The importance of the AGD independent member majority was acknowledged by those present, and it was suggested that an annual review / possible inclusion in the AGD annual report of the number of meetings where an independent majority had not been present would be useful, as this would allow consideration of whether any action needed to be taken to improve the proportion of meetings with an AGD independent member majority. The NHS England SIRO representative stated that should AGD members be required to vote (items 1 to 6.2), then one AGD NHS England member would be asked to not participate, to ensure the appropriate balance of votes, i.e. that the majority was by AGD independent members. The Group noted and agreed with this proposal. The NHS England SIRO representative stated that for items 6.3 to 11, it would not be possible to ask one AGD NHS England member to not participate, without affecting the NHS England member quoracy. Accordingly, a balance of votes was **not** available for those items. The Group noted and agreed with this proposal. Noting that the AGD Terms of Reference state at clause 7.13: *"The quorum for meetings of the Group or a Sub-Group is **five members, including at least three independent members**, one of whom may be the Chair, Deputy Chair or Acting Chair and two of the three NHSE Members. In addition, a representative of the SIRO must also be in attendance for any meetings of the Group or a Sub-Group. **In exceptional circumstances the Chair and the representative of the SIRO may agree for the Group to still meet and conduct its business, but the minutes should note the meeting was not quorate and provide details of the number of NHSE members and independent members who were in attendance***

	and provided advice on any matters"; the Group agreed that the meeting was quorate for items 1 to 6.2, but was **not** quorate for agenda items 6.3 to 11. The Chair and the SIRO representative agreed to proceed in "exceptional circumstances" in accordance with clause 7.13. The members in attendance for each item are noted in the table above.
2	**Review of previous AGD minutes:** The minutes of the AGD meeting on the 1st August 2024 were reviewed and, after several minor amendments, were agreed as an accurate record of the meeting.
3	**Declaration of interests:** Claire Delaney-Pope noted a professional link to the NHS Research Secure Data Environment (SDE) Network – access to NHS England datasets - Briefing Paper, as part of her role at the South-East London Integrated Care System. It was agreed this did not preclude Claire from taking part in the discussion on this briefing paper. Claire Delaney-Pope noted a professional link to NIC-392669-T1F8B-v5.5 University of Oxford, 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. Claire Delaney-Pope noted a professional link to NIC-703431-L0W3R-v0.3 Adelphi Group Limited, 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 Business Services Authority (NHSBSA) Medicines Data Directions 2019 **Presenters:** Joanne Treddenick, Kevin Willis, Pritpal Rayat and Ian Bullard **Observer:** Dr. Shabnum Ali **Previous Reviews:** The NHSBSA Medicines Data Directions 2019 were previously discussed at the AGD meeting on the 20th July 2023. A patient level medicines dataset is already flowing into NHS England from NHSBSA under the NHS Business Services Authority Medicines Data Directions 2019 (Original Directions), approved for acceptance by, the then NHS Digital and issued to NHS Digital by the Department of Health and Social Care on the 9th August 2019. AGD raised a query on the 20th July 2023, on the original scope of the Direction, noting that it was open to interpretation and potentially could be misinterpreted. As a result, the Directions have been amended to clarify the scope of the data that may be received from the NHSBSA and the purpose for which it can be used.

	The purposes of the amendment are to **1)** clarify the scope of the Data which the NHSBSA Medicines Data Information may collect and analyse; and, **2)** provide a more detailed description and greater clarity in relation to the purposes for which the data obtained by virtue of the Original Directions may be used. NHS England were seeking advice on the following points: 1. Do you consider the update to the Direction adequately addresses previous AGD advice and describes the purpose of NHSE's collection and analysis to deliver the Information System and NHSE's uses of the data? 2. Do you consider that the update to the Specification adequately addresses previous AGD advice, regarding the wider uses of the data, including purposes for dissemination? **Outcome of discussion:** AGD noted the briefing paper had been updated in line with points previously raised, and confirmed they had no further observations / comments. The briefing paper was therefore finalised as an artefact to be included as a supporting document, as and when required. In response to the additional advice being sought on the Direction and Specification, AGD made the following observations / comments: **In response to points 1 and 2:** **5.1.1** AGD noted the work that had been ongoing since the last discussion at the AGD meeting on the 20th July 2023, and thanked NHS England for the documents provided in advance of the meeting to support the discussion. **5.1.2** AGD noted and understood NHS England's legal powers to collect and disseminate the data; and noted that going forward, where NHSBSA data was requested by an applicant, a special condition will **not** automatically be added to section 6 (Special Conditions) of the application, in respect of the constraints on the use of data. It was however noted that NHS England may add a special condition at its discretion, if it was felt that this was appropriate / relevant to a particular applicant or proposed processing. **5.1.3** Noting the importance of transparency to the public, AGD noted that the 'Requirements Specification for NHSBSA Medicine Data Directions 2019' document, contained a list of recipients of the NHSBSA data; and suggested that this was expanded to also include recipients of this data via NHS England's Data Access Service (DAS); or, that a reference / weblink to NHS England's DAS was provided within the document. It was noted that, as this document was currently written, it may be a surprise that legitimate applicants for data, who do not fall within the list as currently written, such as management consultants, would be able to receive the data. **5.1.4** AGD noted the amendments to the NHSBSA Medicines Data Directions 2019, meant it had a much wider application and would cover various different use cases, including use cases previously brought to AGD meetings. It was suggested that the three bullets in the Direction amendment letter, provided as a supporting document, relating to the purpose of the

	Direction, were updated to reflect that the second and third bullets were specific potential use cases encompassed by the wide-ranging bullet point one. **5.1.5** AGD noted the statement in the 'Requirements Specification for NHSBSA Medicine Data Directions 2019' document *"We will only share personal data about **you**…"*; and suggested that the reference to *"you"* was reviewed and amended as may be necessary, noting that it may not be deemed appropriate in this document. **5.1.6** AGD looked forward to receiving any further updates as may be appropriate in due course.
5.2	**Title:** NHS Research Secure Data Environment (SDE) Network – access to NHS England datasets - Briefing Paper **Presenters:** Laura Bellingham, Claire Edgeworth and Dr. Chris Russell **Observers:** Michael Ball, Professor Jim Davies, Dr. Sanjay Gautama, Jamie Neale and Dr. Shabnum Ali The purpose of this briefing paper is to advise AGD that SDEs are collectively seeking approval from NHS England to flow the relevant local subset of NHS England datasets to them. The NHS Research SDE Network consists of eleven regional / sub national SDE teams and the NHS England SDE. The NHS Research SDE Network will become the default route for researchers to access NHS health and social care data (with limited exceptions in line with the Department of Health and Social Care (DHSC) Data Access Policy which supports this work). There is a need to develop a repeatable, reproducible approach for a regular data flow from NHS England to any NHS Research SDE Network SDE. This approach must be legal, safe and transparent but also proportionate, given the time, cost and quality expectations of SDE users. NHS England were seeking advice on the following point: 1. Advice on the assurances and key areas of alignment that are required from SDEs so that NHS England data, collected under Direction, can be provided to SDEs, linked to other data (provisioned under local data sharing agreements), including multimodal data, and be made available for access in anonymised form within an SDE. **Outcome of discussion:** The AGD Chair welcomed colleagues from a number of organisations to the meeting, who were in attendance with NHS England colleagues to observe the general overview / discussion on the NHS Research Secure Data Environment (SDE) Network, and to answer any questions raised on the information provided. The Group thanked Michael Ball, Prof. Jim Davies, Dr. Sanjay Gautama and Jamie Neale for attending the meeting. Following the departure from the meeting of the observers, AGD made the following observations / comments:

	In response to point 1: **5.2.1** Noting the references in the briefing paper to *"standardised data access process"*, AGD queried how, having three potential models to ingest NHS England data, aligned with having a standardised process across all 13 SDEs; and why there was not just one model. The Group were advised by the presenters that each of the three models were tried and tested, and that having a 'one size fits all' approach would not work at this time; however noted that work would be ongoing to review this as the work progresses **5.2.2** In particular, the Group noted that different models had different legal bases for handling identifying patient data, originally collected for direct care. The Group observed that NHS England would need to satisfy itself as to the robustness of the legal basis regarding the common law duty of confidence for each SDE, for all aspects of that SDE's processing. **5.2.3** AGD queried how NHS England could demonstrate that the regional / sub national SDEs were doing something different to the national NHS England SDE, since NHS England cannot pass through its data obligations and the sub national / regional SDEs have to be doing something distinct to the national SDE. **5.2.4** AGD queried how NHS England would comply with its data safe haven obligations since the challenge may be delegating 'down' for someone else to manage the data by having mirrored data access groups. **5.2.5** AGD noted that the Department of Health and Social Care (DHSC) were producing the policy on the regional / sub national SDE data access groups, and would be happy to support DSHC, if appropriate. **5.2.6** AGD queried whether the National Data Opt-out (NDO) would be applied, and whether all SDEs would take the same approach, and were advised by the presenters that work was ongoing to produce a policy on opt-outs, the options available, and how these would be applied. **5.2.7** AGD noted concern around the transparency, noting that work was ongoing on this aspect; it was suggested that as part of the opt-out policy that was being developed, consideration was also given to how the various opt-out options would be managed and made transparent to the public. **5.2.8** The Group noted that they would welcome further discussion on this subject, as and when appropriate.	
6 EXTERNAL DATA DISSEMINATION REQUESTS:		
6.1	**Reference Number:** NIC-759654-D8H5M-v0.4 **Applicant:** Royal National Orthopaedic Hospital NHS Trust (RNOH) **Application Title:** Private Health Data - GIRFT extension program at the Royal National Orthopaedic Hospital (RNOH) NHS Trust **Observers:** Emma Whale and Dr. Shabnum Ali	

Previous Reviews: A briefing paper linked to this application was previously presented / discussed at the AGD meeting on the 27th June 2023.

Application: This was a new application.

The purpose of the application is a request for NHS England to share The Getting It Right First Time (GIRFT) dataset and provide access to the GIRFT coding recipes in the NHS England Unified Data Access Layer (UDAL) secure data environment, and to enable receipt and processing of RNOH client data within UDAL, so that outputs can be compared accurately against GIRFT metrics for NHS providers. This will include processing private patient data for independent sector providers.

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:

6.1.1 AGD reiterated the point (5.1.1) raised at the AGD meeting on the 27th June 2023; "*that the key issue was how the parties allocated the Data Controller / Data Processor roles in line with the UK General Data Protection Regulation (UK GDPR) and the NHS England DARS Standard for Data Controllers and NHS England DARS Standard for Data Processors, and borne of the facts, for example it may be a joint Data Controllership arrangement, or a Data Controller / Data Processor arrangement*". The Group noted that colleagues had engaged with legacy NHS England's information governance team and legal team previously on a number of topics, however the AGD NHS DPO Representative (on the 23rd June 2023) had suggested that the Data Controller / Data Processor relationship aspect be discussed again with NHS England's IG and Legal teams. The AGD Chair had supported this suggestion".

6.1.2 The Group reviewed the revised application but were still not clear on the full extent of each party's role and noted that there was some inconsistency both internally and between the DSA and other supporting documents. AGD requested that the DSA was revised so that it was clear which party was carrying out a controller or processing role (or both) and what activities each party was carrying out.

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

6.1.3 AGD noted that at the meeting on the 23rd June 2023, a query had been raised in respect of concerns around the potential commercial exclusivity of the approach. The Group also cautioned the Unified Data Access Layer (UDAL) being used exclusively for private work by one organisation. Noting the response to this point in the DAS internal application assessment form had not fully addressed the original point raised, the Group emphasised that the point was in respect of commercial use

	of UDAL, and the exclusion of other parties, and suggested that this was considered further by NHS England. **6.1.4** AGD noted that, at the meeting on the 23rd June 2023, a query had been raised in respect of what transparency materials would be available for data subjects (point 5.1.3); and noted that as part of the response to this in the DAS internal application assessment form a weblink had been provided to the GIRFT page on the NHS England website. The Group suggested that in addition to this, the Data Controller should also have information on their own website. **6.1.5** The AGD NHS England Data Protection Office (DPO) representative queried whether NHS England had sought and received legal / IG advice in respect of the legal basis for processing; and suggested that this was clarified, and that legal basis cited in the application aligned with any advice received. **6.1.6** AGD advised that they were assuming that Edge Health Ltd was **not** accessing the data on client systems in the format that NHS England holds it; noting the information in section 1.7 (onward sharing) of the Data Access Service (DAS) internal application assessment form contradicted this, i.e. accessing the client data on the client systems; and suggested that the information in this section was reviewed and updated to ensure the correct / factual information is reflected. **6.1.7** AGD also queried why there was a Data Processing Agreement with Edge Health Ltd as outlined in section 1.7 of the DAS internal application assessment form, and suggested that further clarification was provided. **6.1.8** AGD noted the reference in section 5(c) (Specific Outputs Expected) of the application that NHS England *"…acting as a processor for RNOH, calculates GIRFT metrics from client data…"* and suggested that NHS England ensure that all of the parties involved are clear on their roles and responsibilities; that all of the appropriate documentation is in place; and that the application and supporting documents were aligned and reflect the correct / factual scenario. **6.1.9** AGD noted the statements in section 5(e) (Is the Purpose of this Application in Anyway Commercial) of the application*, for example "the trust does not regard it as a commercial venture…"*. It was suggested that section 5(e) was reviewed and updated to be clear on the potential commercial benefit from the research, in line with NHS England DAS Standard for Commercial Purpose. It was also noted that the public would expect the NHS to benefit appropriately from such commercial activity. **6.1.10** AGD suggested that the updated information on the commercial aspect of the application in (the unpublished) section 5(e); was replicated for transparency in (the published) section 5(a) (Objective for Processing), in line with NHS England's DAS Standard for Objective for Processing. **6.1.11 Separate to the application:** AGD asked that the NHS England AGD Data and Analytics Representative ensure that colleagues in NHS England's Data Access	

	Service (DAS), ensure that the commercial aspect of the application in (the unpublished) section 5(e); was replicated for transparency in (the published) section 5(a), in line with NHS England's DAS Standard for Objective for Processing. **ACTION:** The NHS England AGD Data and Analytics Representative ensure that colleagues in NHS England's DAS, ensure that the commercial aspect of the application in (the unpublished) section 5(e); was replicated for transparency in (the published) section 5(a), in line with NHS England's DAS Standard for Objective for Processing. **6.1.12** AGD noted the outdated information in respect of the Data Security and Protection Toolkit (DSPT) in section 1(b) (Data Controller(s)) of the application; and suggested that this was updated with the most recent information.	D&A Rep
6.2	**Reference Number:** NIC-414309-R7H4W-v0.16 **Applicant:** University College London (UCL) **Application Title:** EVenti: The Prognostic Performance of the Enhanced Liver Fibrosis Test in UK Patients with Chronic Liver Disease Assessed 20 Years After Recruitment to the EUROGOLF study (EVenti) **Observers:** Dan Goodwin and Dr. Shabnum Ali **Application:** This was a new application. The purpose of the application is a follow-up to the EUROGOLF study, to assess the prognostic performance of the enhanced liver fibrosis (ELF) test, liver biopsy and liver blood tests, and understand the value of ELF and/or blood tests as part of an evaluation of liver disease risk in middle life. 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: **6.2.1** AGD welcomed the application and noted the importance of the research. **6.2.2** The Group noted that it was highly problematic to give advice not knowing the basis on which participants were originally consented, however it was noted that s251 was in place and aligned with the processing outlined in the application. **6.2.3** Noting the original commercial funding, and the ongoing associated commercial product that is available to purchase; it was suggested by the Group, that this was reflected in section 5(e) (Is the Purpose of this Application in Anyway Commercial), in line with NHS England DAS Standard for Commercial Purpose. **6.2.4** AGD suggested that the updated information on the commercial aspect of the application in (the unpublished) section 5(e); was replicated for transparency in (the	

	published) section 5(a) (Objective for Processing), in line with NHS England's DAS Standard for Objective for Processing. **6.2.5 Separate to the application:** AGD asked that the NHS England AGD Data and Analytics Representative ensure that colleagues in NHS England's Data Access Service (DAS), ensure that the commercial aspect of the application in (the unpublished) section 5(e); was replicated for transparency in (the published) section 5(a), in line with NHS England's DAS Standard for Objective for Processing. **ACTION:** The NHS England AGD Data and Analytics Representative ensure that colleagues in NHS England's DAS, ensure that the commercial aspect of the application in (the unpublished) section 5(e); was replicated for transparency in (the published) section 5(a), in line with NHS England's DAS Standard for Objective for Processing. **6.2.6** In respect of transparency, noting the seven original recruitment sites, AGD queried where the applicant's privacy notice would be located, to ensure that this information was easy to locate by cohort members; and suggested that NHS England explore this further with the applicant. **6.2.7** AGD noted the information in the Health Research Authority Integrated Research Application System (IRAS) form (SD3.0), that the applicant had produced a poster describing the study and that the original participating clinics would be asked to display it in their clinic areas. AGD noted that they were supportive of this approach. **6.2.8** AGD suggested that the transparency materials were reviewed and updated as may be necessary to ensure that the information within these, was explained in a manner suitable for a lay audience. **6.2.9** AGD noted that the applicant had undertaken some patient and public involvement and engagement (PPIE), however the Group suggested that there was ongoing PPIE throughout the lifecycle of the work. The HRA guidance on Public Involvement is a useful guide. **6.2.10** In addition, AGD also suggested that the applicant engaged / worked with relevant charities to highlight the ongoing research. **6.2.11** AGD noted that there was an individual's e-mail address noted as the contact point for withdrawing from the study in the transparency materials and, since this could be viewed as a single point of failure, suggested that the applicant considered having a more generic / team e-mail as the contact point. **6.2.12** AGD queried the statement in section 5(b) (Processing Activities) *"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.	D&A Rep

	6.2.13 In addition, AGD suggested that section 5(b) was updated to reflect that a PhD student would also be accessing the data, unless they are also an employee of UCL, in which case they would be covered by the current text.	
6.3	**Reference Number:** NIC-392669-T1F8B-v5.5 **Applicant:** University of Oxford **Application Title:** The Oxford Heart Vessels and Fat (ox-HVF) Cohort **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 30th January 2020, 27th June 2019, 7th December 2017, 16th November 2017 and the 25th May 2017. **Application:** This was a renewal application. The purpose of the application is for a study, is to discover new blood, genetic, and imaging biomarkers that differ between patients with advanced coronary atherosclerosis and healthy individuals. NHS England were seeking advice on the following point: 1. The newest consent materials which had not previously been subject to independent review. Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** AGD acknowledged that they would **not** be quorate for the discussion of this application noting only two independent members and three AGD NHS England members were available; noting that the AGD Terms of Reference states that ***"In exceptional circumstances the Chair and the representative of the SIRO may agree for the Group to still meet and conduct its business…"*** the Group agreed to discuss the application (see Section 1 above). AGD were supportive of the applicant to hold, but not otherwise process, the data, and wished to draw to the attention of the SIRO the following substantive comments and suggested that the application be brought back to a future meeting: **6.3.1** AGD noted that they had not provided any comments or observations on the application. **6.3.2** AGD noted that based on the original consent forms from 2011 (*AdipoRedOx study); that the consent taken for the AdipoReDox study was valid for ten years, therefore this would allow data for those participants that provided consent in 2011, to be processed until 2021. It was noted that there was no information within the application / supporting documents provided (including the internal consent review), outlining whether this cohort had been reconsented. If reconsent did not occur there is also no evidence of a mechanism to stop data flowing, for those participants whose consent had ended in 2021. The AGD NHS England Data and Analytics	

	representative advised the Group, that no data had flowed for any participants beyond 2021. The Group noted the verbal update, however suggested that NHS England satisfy itself that no data had flowed for individuals where their consent had ended in 2021; and that the application was updated to reflect that data can only flow for participants where there is valid / active consent in place. *'*Interactions between adipose tissue, vascular wall and myocardium in human atherosclerosis' (AdipoRedOx Study)* **6.3.3** If NHS England discover that data had flowed for individuals beyond the expiry of the consent provided, then AGD suggested that further information should be provided as to the legal basis for this data flow. **6.3.4** AGD also suggested that section 5 (Purpose / Method / Outputs) of the application should clearly articulate that data can only flow for those participants where valid consent was in place. **6.3.5 Separate to the application** AGD noted that question 8 in the internal consent review, provided as a supporting document (SD5), had not been answered adequately and should have been able to identify the queries raised by AGD in-meeting around consent. **6.3.6** AGD queried whether, if a participant provided consent later than 2011 on the same consent materials, whether they were providing consent for ten years; or whether they were providing consent for the remaining period from the date of consent to 2021. If it was the former (they had, for example, provided consent in 2015), then it was noted that their consent will end in 2025 unless they are reconsented. **6.3.7** AGD and the AGD NHS England Caldicott Guardian Team representative noted that updating the website to inform participants that the study was ongoing, would not be sufficient in terms of addressing the Common Law Duty of Confidentiality. **In response to point 1:** **6.3.8** AGD noted that they were broadly content with the latest iterations of the consent materials and were content that these were compatible with the processing outlined in the application. **6.3.9** AGD noted the statements in the patient information sheets (PIS) (SD4 and SD4.1) in respect of what would happen to the data if a participant withdrew their consent; and suggested that this information was reviewed and it was made clearer what would / would not happen to the data after consent is withdrawn; being clear that data cannot be removed once it had been anonymised; to update the reference from *"NHS Digital"* to *"NHS England"*; and update to be clearer on the linkage taking place.	

	6.3.10 Noting the outdated references in the consent materials to *"NHS Digital"*, AGD also suggested that these were reviewed and updated to correctly refer to *"NHS England"*.	
6.4	**Reference Number:** NIC-434725-J7B7D-v0.19 **Applicant:** University Hospitals Coventry and Warwickshire NHS Trust **Application Title:** University Hospitals Coventry and Warwickshire NHS Trust (UHCW) ICS and Benchmarking Project **Application:** This was a new application. The purpose of the application is for national and local Benchmarking, service planning, evaluation, and service improvement. The core purpose of the project is to address the limitations of historical approaches to analysis by expanding the scope of reports from individual trust-level performance comparison to look at how acute healthcare providers within our local healthcare region, working together, are performing in contrast to the best performing examples of collaborative care found nationally. NHS England were seeking general advice on the application. Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** AGD acknowledged that they would **not** be quorate for the discussion of this application noting only two independent members and three AGD NHS England members were available; noting that the AGD Terms of Reference states that ***"In exceptional circumstances the Chair and the representative of the SIRO may agree for the Group to still meet and conduct its business…"*** the Group agreed to discuss the application (see section 1 above). AGD were **only** supportive of the flow of data that could not be obtained via the Integrated Care Board (ICB). AGD were **not** supportive of any other aspect of this application, the sub-licensing and benchmarking, because the applicant should be able to receive that data via the ICB. The Group wished to draw to the attention of the SIRO the following high level comments: **6.4.1** AGD noted the title of the application was misleading, and suggested that this was reviewed and updated so that it was clear that the purpose of the application was for purposes beyond benchmarking. **6.4.2** Notwithstanding the fact that the application was for other purposes and not just benchmarking, AGD noted that they were mindful that the application should be reviewed in line with other benchmarking applications, for example, NIC-616027-	

	W7K5H (NHS Norfolk and Waveney ICB) that was discussed at the AGD meetings on the 18th April 2024 and 29th February 2024. **6.4.3** The AGD NHS England Data and Analytics representative, advised the group that as per the advice on the 29th February 2024, NHS England Data Access Service (DAS) were in the process of producing a Data Access Environment (DAE) template application for benchmarking. The Group noted and welcomed the update, and look forward to seeing the template utilised in due course. **6.4.4** AGD suggested that to avoid excessive / duplication of data flowing unnecessarily in line with the UK General Data Protection Regulation (UK GDPR), that the applicant, who is also part of an Integrated Care System (ICS) seek data for the purpose of benchmarking via the ICB and ask the ICB to apply for and complete the DAE template application for benchmarking via the DAS service (if they have not already done so); or if the ICB already receives that data via the DAE template application for benchmarking, to ask the ICB to supply that data to them **6.4.5** AGD noted that there is a mechanism in place for the ICB to sub-license the data to the ICS organisations in their area. **6.4.6** AGD suggested that NHS England may wish to speak with the ICB direct, on behalf of the applicant, to support the applicant obtaining the data via their ICB. **6.4.7** AGD noted that it was not clear in the application or the DAS internal application assessment form, why NHS England's Secure Data Environment (SDE) was not being used for the processing of this data; and suggested that further clarification be provided in the DAS internal application assessment form. **6.4.8 Separate to this application:** AGD requested that the AGD NHS England Data and Analytics representative, ensure that for transparency, colleagues in DAS clarify in the DAS internal application assessment form, why data cannot be accessed / processed in NHS England's SDE. **ACTION:** The AGD NHS England Data and Analytics representative to ensure that colleagues in DAS clarify in the DAS internal application assessment form, why data cannot not be accessed / processed in NHS England's SDE. **6.4.9** Noting that mortality data had been requested, AGD suggested that the legal basis for this request was reviewed, assuming that this data was for the purpose of direct care and not for performance management. It was also suggested that the applicant engage / consult with staff on this, noting the potential risks. **6.4.10** Noting the statement in section 5(b) (Processing Activities) of the application *"There will be no requirement and no attempt to reidentify individuals…"*; AGD noted that this was inconsistent with the re-identification of the mortality data; and suggested that the application was updated to reflect this. **6.4.11** AGD queried whether there were any other Data Controllers that should be noted in the application, for example, as part of the ICS. It was suggested that NHS England DAS explore this further with the applicant and amend the application / DAS	D&A Rep

	internal application assessment form as may be required, to reflect the factual scenario, in line with NHS England's DAS Standard for Data Controllers. **6.4.12** AGD noted the references in the application and the DAS internal application assessment form to the *"Commercial Analytics department"*; and asked that further information was provided as to who they are and what their role / responsibilities were. **6.4.13** AGD noted the outdated information in respect of the Data Security and Protection Toolkit (DSPT); and suggested that this was updated with the most recent information. **6.4.14** AGD noted that they were comfortable with a span of ten years' worth of data, particularly noting the disruption caused by the COVID-19 pandemic.	
6.5	**Reference Number:** NIC-703431-L0W3R-v0.3 **Applicant:** Adelphi Group Limited **Application Title:** "Incidence and characteristics of Invasive Fungal Infections in patients treated with Systemic Anti-cancer Therapies (SACT) in England" **Application:** This was a new application. The purpose of the application, is for a study which aims to provide evidence to support healthcare providers and policymakers to better understand the healthcare burden of invasive fungal infections (IFIs), with respect to the incidence, mortality, and treatment and associated costs, to inform the design of appropriate prevention and treatment strategies as well as inform international guidelines related to the prevention and treatment of IFIs. NHS England were seeking advice on the following points: 1. Does AGD support the provision of access to the requested data to the named organisations for the stated purpose. 2. Would AGD recommend any actions or points of clarification which must be resolved before the provision of access to the data. 3. Noting that section 5 of the application would be updated using the standard model, would AGD wish to highlight any particular text in the current application to retain in the updated version for clarity and transparency about the purpose, methods, outputs or benefits. Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** AGD acknowledged that they would **not** be quorate for the discussion of this application noting only two independent members and three AGD NHS England members were available; noting that the AGD Terms of Reference states that ***"In exceptional circumstances the Chair and the***	

	representative of the SIRO may agree for the Group to still meet and conduct its business…" the Group agreed to discuss the application (see section 1 above). AGD were supportive of the application. AGD made the following observation / points of advice on the application and / or supporting documentation provided as part of the review: **6.5.1** AGD welcomed the application and noted the importance of the research. **6.5.2** AGD noted, that whilst this application had only come for advice on specific points, they would be supportive of the application proceeding without a further review, assuming there were no substantive changes, and the points raised below had been adequately addressed. **In response to points 1 to 3:** **6.5.3** AGD noted in the DAS internal application assessment form, that the applicant had opted for an extract of data prior to any discussions taking place about accessing the data in NHS England's Secure Data Environment (SDE). Noting that it was unclear why this decision had been reached, it was suggested that further clarification be provided in the DAS internal application assessment form as to why the SDE was not considered / appropriate. **6.5.4 Separate to this application:** AGD requested that the AGD NHS England Data and Analytics representative, ensure that for transparency, colleagues in DAS clarify in the DAS internal application assessment form, why data cannot be accessed / processed in NHS England's SDE. **ACTION:** The AGD NHS England Data and Analytics representative to ensure that colleagues in DAS clarify in the DAS internal application assessment form, why data cannot not be accessed / processed in NHS England's SDE. **6.5.5** AGD noted the statements in section 5(e) (Is the Purpose of the Application in Anyway Commercial?) of the *application "Although this study is **neither solely nor directly for commercial purposes**…"* and *"…while acknowledging potential **indirect gain**…"*; and suggested that these statements were incorrect. It was therefore suggested that section 5(e) was reviewed and updated to be clear on the potential commercial benefit from the research, in line with NHS England DAS Standard for Commercial Purpose. **6.5.6** AGD suggested that the updated information on the commercial aspect of the application in (the unpublished) section 5(e); was replicated for transparency in (the published) section 5(a) (Objective for Processing), in line with NHS England's DAS Standard for Objective for Processing. **6.5.7 Separate to the application:** AGD asked that the NHS England AGD Data and Analytics Representative ensure that colleagues in NHS England's Data Access Service (DAS), ensure that the commercial aspect of the application in (the unpublished) section 5(e) ; was replicated for transparency in (the published) section	D&A Rep

	5(a) (Objective for Processing), in line with NHS England's DAS Standard for Objective for Processing. **ACTION:** The NHS England AGD Data and Analytics Representative ensure that colleagues in NHS England's DAS, ensure that the commercial aspect of the application in (the unpublished) section 5(e); was replicated for transparency in (the published) section 5(a), in line with NHS England's DAS Standard for Objective for Processing. **6.5.8** It was also suggested that section 5(a) of the application was updated to be clear that Pfizer in the future may or may not develop a drug, or repurpose an existing drug, in order to meet an unmet need identified by this research. **6.5.9** Noting the commercial nature of the applicant **and** the funder, it was suggested that more information was provided in section 5(a) and section 5(d) (Benefits) of the application, as to the commercial benefits to both organisations, and whether there is a proportionate balance between public and commercial benefit, in line with NHS Digital DAS Standard for Expected Measurable Benefits and NHS England's DAS Standard for Commercial Purpose and the National Data Guardian (NDG) guidance on benefits. **6.5.10** AGD noted that section 2.4 (commercial benefit evaluation) of the DAS internal application assessment form had **not** been completed, and advised that it would have been helpful for this to be populated with some key information, which could have then aligned with the application. **6.5.11** AGD noted that section 2.3 (benefits evaluation) of the DAS internal application assessment form had **not** been completed, and advised that it would have been helpful for this to be populated with some key information, which could have then aligned with the application. **6.5.12** AGD noted in section 5(a) of the application and section 1 of the DAS internal application assessment form, that *"Pfizer Limited…has determined the **purpose** of processing. Adelphi Group Limited…will make decisions about the **means** of processing"*; and were therefore joint Data Controllers. The Group assumed that both parties were meeting their requirements / obligations via a joint data controllership agreement, and by complying with UK General Data Protection Regulation (UK GDPR). It was suggested that information on this was made available to data subjects for the purpose of transparency. **6.5.13** AGD noted the statement in section 5(b) (Processing Activities) *"Adelphi Group Ltd will act as the joint Data Processor…"*; and suggested that this was updated to reflect that Adelphi Group Ltd is a Data Controller who also processes the data. **6.5.14** The NHS England SIRO representative noted the inconsistent information in section 5 (Purpose / Methods / Outputs), in respect of who would be accessing the	D&A Rep

	data; and suggested that this was reviewed and updated / aligned to ensure the correct information was reflected. **6.5.15** The NHS England SIRO representative suggested that the application was reviewed and updated to ensure that it accurately reflects the legal standing of the parties involved, and this aligns with the holders of the Data Security and Protection Toolkit (DSPT). **6.5.16** AGD noted that section 3(b) (Additional Data Access Requested) and section 5(b) were currently blank and would need updating to clarify the data fields that would be flowing. **6.5.17** AGD noted that section 5(a) would need reviewing and amending as appropriate to ensure the correct headers / information were correct, for example, in respect of ethical considerations and opt-out's. **6.5.18** AGD noted that NHS England's Data Access Service (DAS) had engaged with the applicant on patient and public involvement and engagement (PPIE), and had been advised that no PPIE has yet been undertaken, however it was the applicant's intention to undertake some PPIE when the results dissemination. The group noted this was **not** PPIE but rather a mechanism to disseminate the results. The Group suggested that there was ongoing PPIE throughout the lifecycle of the work. The HRA guidance on Public Involvement is a useful guide. **6.5.19 Separate to the application:** AGD reiterated a point last raised on the 27th June 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. **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. **6.5.20** AGD suggested that section 6 (Special Conditions) of the application was updated to include a special condition relation to the Annual Confirmation Report (ACR), in line with NHS England DAS Standard for Special Conditions.	SIRO Rep / D&A Rep
7 INTERNAL DATA DISSEMINATION REQUESTS:		
There were no items discussed		
8 EXTERNAL DATA DISSEMINATION - SIRO APPROVED / SEEKING SIRO APPROVAL		
8.1	**Reference Number:** NIC-172334-W0G2L-v4.14 **Applicant:** Imperial College London **Application Title:** Effectiveness and Value for Money of Prescribed Specialised Services Commissioning for Quality and Innovation (CQUIN)	

	Previous Reviews: The application and relevant supporting documents had previously been presented / discussed at the AGD meetings on the 9th March 2023 and the 9th February 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) meetings on the 29th September 2022, 6th February 2020, 20th August 2020, 12th July 2018 and the 17th May 2018. The SIRO approval was for an honorary contractor to access the data held within the UK (at Imperial College London) from Denmark, France, Spain and Portugal. The researcher is substantively employed in Denmark but spends substantive time in the other countries. **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	
9.1	**Oversight & Assurance workshop** The Group noted that the Chair and Deputy Chair had been invited to an oversight and assurance workshop on the 22nd August 2024 where NHS England had proposed the following agenda: 1. An update of actions arising from the oversight and assurance precedents 2. Forward planning for oversight and assurance of the extensions, renewals and amendments (ERA) governance pathway, and 3. Forward planning for the oversight and assurance of annual confirmation reports (ACR)s AGD noted the agenda above, but suggested that item three (above) be expanded to include up to 16 ACRs for review by the Chair and Deputy Chair. The AGD Secretariat Manager noted that the documentation would need to be disseminated by no later than Wednesday, 14th August 2024 and that the outputs from the workshop would be captured within the oversight and assurance section of the 5th September 2024 minutes, alongside an appendix detailing any high level comments. The NHS England SIRO Representative agreed with the approach, noting AGD would be providing assurance on the judgement, and the audit team would be providing assurance around the process.
10 AGD OPERATIONS	
10.1	**Risk Management Framework**

	As last noted in the AGD minutes from the 21st March 2024, the independent members noted the reference to reviewing materials in accordance with *"a clearly understood risk management framework"* within the published Statutory Guidance and advised that they were not aware of an agreed risk management framework, and reiterated a previous request that NHS England provide further information/ clarity on this to the Group, noting this topic had been raised by Lord Hunt in the House of Lords on the 26th June 2023, and was answered by Lord Markham on the 5th July 2023: Written questions, answers and statements – UK Parliament. The NHS England SIRO Representative had provided further clarity on the risk management framework via email to the Group, which confirmed that NHS England were asking AGD (and previously the interim data advisory group) to use the NHS England DAS Standards and Precedents model to assess the risk factors in relation to items presented to AGD for advice; however the independent members noted that the wording in the statutory guidance "…*using a clearly understood risk management framework, precedent approaches and standards that requests must meet*…", suggested that the risk management framework is separate to the DAS Standards and Precedents, and asked that this be clarified by NHS England. The Group noted that plans for this work were in train. It had been noted previously by the interim data advisory group that the Oversight and Assurance Programme of applications that had not be subject to AGD review could form part of this Risk Management Framework. The NHS England SIRO representative noted an outstanding action in respect of providing a written response to AGD on the risk management framework; and noted that this was progressing under the NHS England Precedents and Standards work. **ACTION:** The NHS England SIRO Representative to provide a written response to AGD on the risk management framework	SIRO Rep
10.2	**Standard Operating Procedures (SOPs)** The ongoing forward plan of work for creating the AGD Standard Operating Procedures was discussed; and noting that the AGD Terms of Reference (ToR) had now been approved, it was noted that work was progressing in order to finalise relevant AGD SOPs in line with the approved AGD ToR.	
10.3	**AGD Stakeholder Engagement** *There were no items discussed*	
10.4	**AGD Project Work** *There were no items discussed*	
11 Any Other Business		

11.1	*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.