Advisory Group for Data (AGD) – Meeting Minutes

Thursday, 7th November 2024

09:00 – 16:00

(Remote meeting via videoconference)

AGD INDEPENDENT / NHS ENGLAND MEMBERS IN ATTENDANCE:	
Name:	**Role:**
Paul Affleck (PA)	AGD independent member (Specialist Ethics Adviser) (**Chair**: item 1 to 4.1)
Claire Delaney-Pope (CDP)	AGD independent member (Specialist Information Governance Adviser)
Dr. Robert French (RF)	AGD independent member (Specialist Academic / Statistician Adviser)
Kirsty Irvine (KI)	AGD independent member (Chair) (not in attendance for items 1 to part of 4.1)
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)) (**Presenter**: item 8.1)
NHS ENGLAND STAFF IN ATTENDANCE:	
Name:	**Role / Area:**
Garry Coleman (GC)	NHS England SIRO Representative
Louise Dunn (LD)	Internal & System Data Flows Lead, Data Portfolio Management, Data and Analytics, Transformation Directorate (**Observer**: item 5.4)
Joseph Gamble (JG)	Director, NHS Notify, Cohorting Pillar - Products and Platforms Directorate (**Observer**: item 4.1)

Dan Goodwin (DG)	Data Access and Partnerships, Data and Analytics, Transformation Directorate (**Observer:** items 5.1 and 5.2)
Andrew Ireland (AI)	Information Governance Specialist, IG Risk and Assurance (**Presenter**: item 8.1)
Thomas Knight (TK)	Product Manager, NHS Notify, Cohorting Pillar - Products and Platforms Directorate (**Presenter:** item 4.1)
Narissa Leyland (NL)	Head of Data Governance and Assurance, Data Access and Partnerships, Data and Analytics, Transformation Directorate (**Presenter**: item 10.1)
Nicki Maher (NM)	Information Governance Lead, IG Assurance and Risk, IG Audit Services Lead (Interim), Privacy, Transparency, and Trust (PTT), Delivery Directorate (**Presenter**: item 8.1)
Richard McStay (RM)	Head of Delivery, NHS Notify, Cohorting Pillar - Products and Platforms Directorate (**Observer**: item 4.1)
Karen Myers (KM)	AGD Secretariat Officer, Privacy, Transparency and Trust (PTT), Delivery Directorate
Louise Whitworth-Woodhead (LWW)	Deputy Director Information Governance Delivery (Digital & Operations), Privacy, Transparency and Trust (PTT), Delivery Directorate (**Observer:** item 4.1)
Vicki Williams (VW)	AGD Secretariat Manager, Privacy, Transparency and Trust (PTT), Delivery Directorate
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)
Jon Moore (JM)	NHS England member (Data Protection Office Representative)

1	**Welcome and Introductions:** The AGD meeting Chair welcomed attendees to the meeting.
2	**Review of previous AGD minutes:**

	The minutes of the AGD meeting on the 24th October 2024 were reviewed out of committee by the Group and, after several minor amendments, were agreed as an accurate record of the meeting by the AGD Chair, on behalf of the Group.	
3	**Declaration of interests:** There were no declarations of interest.	
4 BRIEFING PAPER(S) / DIRECTIONS:		
4.1	**Title:** NHS Notify **Presenter:** Thomas Knight **Observers:** Joseph Gamble, Richard McStay, Louise Whitworth-Woodhead **Previous Reviews:** The briefing paper was previously presented / discussed at the AGD meeting on the 2nd May 2024. The NHS Notify Programme is an NHS England service that supports NHS healthcare organisations to communicate with patients (including supporting accessibility purposes) simply and easily through a variety of digital (NHS App, Short Message Service (SMS) and email) and physical messaging (letters) individually or as part of a defined patient cohort in a standard way. The purpose of the briefing paper is to provide an update on the latest position of the service, with progressing a Legal Direction with the Department of Health and Social Care, which will allow the NHS Notify service to be used by health and adult social care and service providing organisations (provided they have a legal basis and permitted purpose) in addition to the current use which is for NHS England only. NHS England were seeking advice on the following points: 1. The draft Direction 2. Any key risks (and mitigations) that we should consider in relation to this wider work, and document within the DPIA **Outcome of discussion:** AGD welcomed the updated briefing paper and made the following observations / comments: **In response to point 1 above:** **4.1.1** AGD noted the statement in the draft Direction *"Communications from Consuming Organisations using the NHS Notify Service, **must be limited to purposes that include**…"*; and suggested that this was reviewed and refined further. **4.1.2** AGD noted the reference in the draft Direction to "*service messaging*", and suggested that the definition could be explained in a linked document, for example the terms and conditions.	

	4.1.3 AGD suggested that various items within point 4.1 of the draft Direction could be separated out into separate points. **4.1.4** AGD noted the references to *"consuming organisations"* in the draft Direction, and suggested that further clarity was provided as to what this was referring to. **4.1.5** AGD noted the reference in point 4.1.1 of the draft Direction, to patients being identified, and suggested that further clarification / examples were provided as to why / when this may happen. **4.1.6** Noting the reference in point 4.1 of the Draft Direction to *"Arms Length Bodies"*, AGD suggested that this was further defined. **In response to point 2 above:** **4.1.7** AGD reiterated the concern raised at the AGD meeting on the 2nd May 2024, that if the purpose was expanded beyond direct care, and multiple NHS organisations were using it, there may be an increase in National Data Opt-outs (NDOs) if patients felt that too many messages were being sent. It was suggested that NHS England address this point through patient and public involvement and engagement (PPIE), to carefully test tolerances and preferences so as not to overstep what individuals would want from this service. **4.1.8** AGD suggested that further consideration was given to how NHS England could monitor and evaluate the services provided by NHS Notify; and how this may provide further updates / changes to the service in the future. **4.1.9** AGD queried whether there was the opportunity to build in a feedback mechanism to analyse the service provided by NHS Notify; and use this feedback to further refine the service provided. AGD advised NHS England that they would welcome further discussions on this area of work as may be required. **4.1.10** AGD suggested that the Data Protection Impact Assessment (DPIA) should be updated to also include additional information on the benefits from NHS Notify. **4.1.11** Noting that NHS Notify would benefit adult social care, AGD queried whether there was scope to also include children's social care in the future; and suggested that this was given further consideration.	
5 EXTERNAL DATA DISSEMINATION REQUESTS:		
5.1	**Reference Number:** NIC-749150-S0M7G-v0.1 **Applicant:** Evidera Ltd **Data Controller:** Takeda Development Center Americas, Inc. **Application Title:** Characteristics, Treatment Patterns and Outcomes of patients with Refractory Metastatic Colorectal Cancer **Observer:** Dan Goodwin	

Application: This was a seeking early advice application.

The purpose of the application is for a study, which aims to examine the demographic and clinical characteristics, treatment patterns, and outcomes among patients with metastatic colorectal cancer (mCRC) who have been treated with at least 3 lines of therapy (overall cohort). Analyses will also be conducted in separate groups of patients receiving third-line (3L) and fourth-line (4L) treatment for mCRC who were previously treated with fluoropyrimidine, oxaliplatin, and irinotecan-based chemotherapy, and an anti-VEGF biological therapy.

NHS England were seeking advice on the following points:

1. The commercial benefits;
2. Data Controllership; and
3. Data access.

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

Outcome of discussion: AGD noted that they were specifically asked to provide advice in relation to the commercial benefits; data controllership; and data access, and that the remainder of the application was subject to additional work. However, to assist in the development of the application, AGD provided the following advice to the SIRO, at their request (noting that the points may not be relevant once the additional detail on the application is clear):

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 AGD welcomed and supported the application being brought for early advice.

In response to point 1:

5.1.2 AGD noted that NHS England's Data Access Service (DAS) had undertaken a review of the potential benefits to health and social care in England and Wales and the commercial benefits to the applicant; and NHS England DAS had concluded that there was **not a proportionate balance** between the two. The Group discussed this point at length and concluded that there could be a proportionate balance, however the NHS England Standards had **not** been met and the applicant could address this by updating the application in line with NHS England's DAS Standard for Expected Measurable Benefits, the NHS England's DAS Standard for Commercial Purpose and the National Data Guardian (NDG) guidance on benefits.

5.1.3 AGD noted the draft information within section 5(e) (Is the Purpose of this Application in Anyway Commercial) of the application in respect of the commercial benefits, and suggested that this was reviewed and updated in line with NHS England's DAS Standard for Commercial Purpose, including, but not limited to, removing the incorrect statement *"…there are no expected direct benefits expected to Takeda or Evidera"*; to include clearer information on the commercial benefits;

	and, to acknowledge that the size of the potential market may be ascertained by the study. **In response to point 2:** **5.1.4** The SIRO Representative advised the Group that, noting the location of the Data Controller was in the USA, should the application progress, that the appropriate contractual clauses would be added to the application by NHS England, in addition to the usual checks and balances. Additionally, a data sharing framework contract (DSFC) would need to be in place with any data controller. **5.1.5** AGD noted that NHS England's DAS had explored data controllership with the applicant, and accepted the conclusion reached that Evidera Ltd was a Data Processor and **not** a Data Controller. The Group noted that this was also in line with other applications where Evidera Ltd were involved. **5.1.6** AGD suggested that NHS England should consider auditing one of the applications where Evidera Ltd was a Data Processor, noting that any findings may impact on other applications. **In response to point 3:** **5.1.7** AGD noted and supported the access of data under this application in NHS England's Secure Data Environment (SDE); however, suggested that section 5(a) (Objective for Processing) was updated to reference that the data would be accessed in the SDE, noting this was currently unclear. **5.1.8** AGD queried the statements in section 5(b) (Processing Activities) that data access would only be assigned to substantive employees for Evidera *"resident in the UK"*; and suggested that this was reviewed and updated, in line with NHS England policy on where access to the data in the SDE is permitted (since a resident of the UK may choose to access the SDE from outside the UK). **5.1.9** AGD noted that in addition to the data sharing agreement (DSA), there was also a 'User Agreement' for those individuals accessing data in NHS England's SDE, that covers off key points, including, but not limited to, specific user access and restrictions on exporting data; and suggested that this was referred to in section 5(b) (Processing Activities) of the application. **5.1.10 Separate to the application:** AGD suggested that the AGD NHS England Data and Analytics Representative ensure that where an applicant is accessing data in NHS England's SDE, that DAS colleagues ensure that the 'User Agreement' is referred to in section 5 (Purpose / Methods / Outputs) of the application for transparency, as part of NHS England's data uses register. **ACTION:** NHS England Data and Analytics Representative to ensure that DAS colleagues refer to the 'User Agreement' in section 5 of the application for clarity about the controls in the user agreement transparency.	D&A Rep

	5.1.11 AGD noted the incorrect statement in section 5(a) of the application *"Data will not be made available to any third parties other than those specified…"*; and suggested that this was removed. In addition, AGD made the following observations on the **draft** application and / or supporting documentation provided as part of the review, at the request of the SIRO Representative: **5.1.12** AGD noted that Article 6(1)(f) *(legitimate interests)* of the UK General Data Protection Regulation (UK GDPR) had been cited as the legal basis for processing, but the application **did not** clearly explain the Data Controller's legitimate interests in respect of the proposed data processing, and suggested that the application was updated to include this information. **5.1.13** The Group also suggested that the Data Controller should provide a copy of their Legitimate Interest Assessment to NHS England in order to clarify the relevant legitimate interests being relied on, and that a copy be uploaded to NHS England customer relationship management (CRM) system. **5.1.14** AGD suggested that section 5(c) (Specific Outputs Expected) of the application was updated to be clear how the knowledge and benefits from this study, could be accessed by clinicians and other relevant stakeholders in England and Wales and how the outputs were specific to the health and social care in England and Wales. **5.1.15** AGD noted that section 3(b) (Additional Data Access Requested) of the application would need updating to include the identifiability of the data. **5.1.16** AGD noted that section 3(c) (Patient Objections) of the application would need updating to include a statement on the Cancer Registration opt-out. **5.1.17** AGD suggested that a statement was added to section 5(a) of the application in respect of the other data sources that would be utilised, for example, the data sources from Spain and France. **5.1.18** Noting this was a two year DSA, AGD suggested that section 6 (Special Conditions) of the application was updated to include a special condition relating to the Annual Confirmation Report (ACR), in line with NHS England DAS Standard for Special Conditions. **5.1.19** AGD noted that there was a good likelihood of success of the drug entering the UK market, based on success in other jurisdictions; and suggested that, to further support this, the applicant / Data Controller could engage with relevant parties in the UK to determine if there was an opportunity in the market, and whether the drug could be adopted for the uses outlined.	
5.2	**Reference Number:** NIC-748004-M6G9X-v0.1 **Applicant:** Evidera Ltd	

	Data Controller: Takeda Development Center Americas, Inc. **Application Title:** A retrospective observational study to evaluate demographic/clinical characteristics, treatments, patterns of therapy, and outcomes of patients with advanced non-small cell lung cancer (aNSCLC) in England **Observer:** Dan Goodwin **Application:** This was a seeking early advice application. The purpose of the application is for a study, to ascertain what the demographic / clinical characteristics, treatment patterns, and real-world outcomes of patients with aNSCLC are in England overall and by disease histology, treatment regimen received, and line of therapy. NHS England were seeking advice on the following points: 1. The commercial benefits; 2. Data Controllership; and 3. Data access. Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** AGD noted that they were specifically asked to provide advice in relation to the commercial benefits; data controllership; and data access, and that the remainder of the application was subject to additional work. However, to assist in the development of the application, AGD provided the following advice to the SIRO, at their request (noting that the points may not be relevant once the additional detail on the application is clear): 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. **5.2.1** AGD welcomed and supported the application being brought for early advice. **In response to point 1:** **5.2.2** AGD noted that NHS England's Data Access Service (DAS) had undertaken a review of the potential benefits to health and social care in England and Wales and the commercial benefits to the applicant; and NHS England DAS had concluded that there was not a **proportionate balance** between the two. The Group noted that the commercial benefits from this application may be difficult to ascertain, noting that it was relating to a class of drugs, rather than a specific drug, however suggested there may be a proportionate balance and that the application was updated, with the potential benefits to the health and social care in England and Wales, and the commercial benefits in line with NHS England's DAS Standard for Expected Measurable Benefits, the NHS England's DAS Standard for Commercial Purpose and the National Data Guardian (NDG) guidance on benefits. **5.2.3** AGD noted the draft information within section 5(e) (Is the Purpose of this Application in Anyway Commercial) of the application in respect of the commercial	

	benefits, and suggested that this was reviewed and updated in line with NHS England's DAS Standard for Commercial Purpose, including, but not limited to, removing the incorrect statement *"…there are no expected direct benefits expected to Takeda or Evidera"*; to include clearer information on the commercial benefits; and, to acknowledge that the size of the potential market may be ascertained by the study. **5.2.4** AGD noted the reference in section 5(e) of the application to *"clinical trials"*, and suggested that further information was added to the application on this point, including where the clinical trials would / were expected to take place. **5.2.5** AGD suggested that section 5(a) (Objective for Processing) of the application, was reviewed and updated to include details on the commercial nature of the applicant and the Data Controller. **In response to point 2:** **5.2.6** The SIRO Representative advised the Group that, noting the location of the Data Controller was in the USA, should the application progress, that the appropriate contractual clauses would be added to the application by NHS England, in addition to the usual checks and balances. Additionally, a data sharing framework contract (DSFC) would need to be in place with any data controller. **5.2.7** AGD noted that NHS England's DAS had explored data controllership with the applicant, and accepted the conclusion reached that Evidera Ltd was a Data Processor and **not** a Data Controller. The Group noted that this was also in line with other applications where Evidera Ltd were involved. **5.2.8** AGD suggested that NHS England should consider auditing one of the applications where Evidera Ltd was a Data Processor, noting that any findings may impact on other applications. **In response to point 3:** **5.2.9** AGD noted that the data flowing under this application would be via a data extract; and strongly suggested that NHS England reviewed this and consideration given to the data processing being undertaken in NHS England's Secure Data Environment (SDE). **5.2.10** AGD queried the statements in section 5(b) (Processing Activities) that data access would only be assigned to substantive employees for Evidera *"resident in the UK"*; and suggested that this was reviewed and updated, in line with NHS England policy on where access to the data in the SDE is permitted (since a resident of the UK may choose to access the SDE from outside the UK). **5.2.11** AGD noted the incorrect statement in section 5(a) of the application *"Data will not be made available to any third parties other than those specified…"*; and suggested that this was removed.	

	In addition, AGD made the following observations on the **draft** application and / or supporting documentation provided as part of the review, at the request of the SIRO Representative: **5.2.12** AGD noted that Article 6(1)(f) *(legitimate interests)* of the UK General Data Protection Regulation (UK GDPR) had been cited as the legal basis for processing, but the application did not clearly explain the Data Controller's legitimate interests in respect of the proposed data processing, and suggested that the application was updated to include this information. **5.2.13** The Group also suggested that the Data Controller should provide a copy of their Legitimate Interest Assessment to NHS England in order to clarify the relevant legitimate interests being relied on, and that a copy be uploaded to NHS England customer relationship management (CRM) system. **5.2.14** AGD suggested that section 5(c) (Specific Outputs Expected) of the application was updated to be clear how the knowledge and benefits from this study, could be accessed by clinicians and other relevant stakeholders in England and Wales; and how the outputs were specific to the health and social care in England and Wales. **5.2.15** AGD noted that section 3(b) (Additional Data Access Requested) of the application would need updating to include the identifiability of the data. **5.2.16** AGD noted that section 3(c) of the application would need updating to include a statement on the Cancer Registration opt-out. **5.2.17** AGD suggested that section 5(a) of the application was updated in line with NHS England's DAS Q&A method and NHS England DAS Standard for Objective for Processing. **5.2.18** Noting this was a draft application for a three year DSA, AGD suggested that section 6 (Special Conditions) of the application was updated to include a special condition relating to the Annual Confirmation Report (ACR), in line with NHS England DAS Standard for Special Conditions.	
5.3	**Reference Number:** NIC-692602-Q6P4F-v3 **Applicant and Data Controller:** Neo Health Hub Limited **Application Title:** Data modelling and analytics **Previous Reviews:** The application and relevant supporting documents were previously presented / discussed at the AGD meetings on the 5th July 2024, 7th December 2023, 17th August 2023 and the 25th May 2023. **Application:** This was a renewal application. The purpose of the application is for NeoHealthHub Limited to access NHS England data for the purpose of providing services to clients in the health sector. The data will be used to provide the following services only: benchmarking, care pathway	

	analysis, hospital feedback services, health economics and outcomes research studies and clinical trial analysis. NHS England were seeking general advice on the application. Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** AGD were supportive of the application and wished to draw to the attention of the SIRO the following substantive comments: **5.3.1** AGD advised that they were unable to locate a published privacy notice, and suggested the applicant was reminded that they were required to maintain a UK General Data Protection Regulation (UK GDPR) compliant, **publicly accessible** transparency notice(s) for the lifetime of the agreement, in line with the contractual requirement in section 4 (Privacy Notice) of the data sharing agreement (DSA). In addition, AGD made the following observations on the application and / or supporting documentation provided as part of the review: **5.3.2** AGD noted and commended NHS England's Data Access Service (DAS), and the applicant, on the diligent work undertaken to address the previous points raised by the Group. **5.3.3** AGD noted that at the AGD meeting on the 7th December 2023, the Group had queried the statement in section 5(d) (Benefits) (ii) (Expected Measurable Benefits to Health and / or Social Care) *"NeoHealthHub will also seek external review by a **current member of the NHS** who holds a relevant position…to ascertain the relevance of the project and the balance of benefit to the health and social care sector, patients and the commercial benefit to the private sector"*. The Group noted the response, in the NHS England Data Access Service (DAS) internal application assessment form, that the applicant has several NHS colleagues working with the organisation on a temporary contract basis. AGD suggested that this was explored further, including, but not limited to, determining what capacity the NHS colleagues were involved in the project, how many people were involved, whether there were any independence issues, or whether there were data controllership issues that need to be explored further. **5.3.4** AGD noted that the applicant had communicated with colleagues from ICBs via a presentation, however suggested that NHS England clarify whether/how many of the ICBs were engaged with the product on an ongoing basis and what the feedback was following the presentation. In addition, it was suggested that the application clarify whether there was any ongoing communication / engagement between the applicant and the ICBs. **5.3.5** AGD noted that the Legitimate Interest Assessment (LIA) had been provided as a supporting document, however, suggested that this was updated to provide further information on the potential benefits to the applicant following the processing.	

	5.3.6 AGD noted in section 5.1 (REC approval) of the DAS internal application assessment form, that the need for a full ethics review had been considered and the NeoHealthHub Limited Board deemed that the application did not merit this. The Group suggested that other ethical input was explored in line with NHS England DAS Standard for Ethical Approval **before** the conclusion was reached that this was not required. **5.3.7** Noting the statement in section 5(e) (Is the Purpose of this Application in Anyway Commercial) of the application, that private sector users *"…will not use the service to market or promote their products"*; AGD suggested that NHS England reviewed this and ensure that it aligns with NHS England policy and the proposed use of the data, as outlined within the application. **5.3.8** AGD queried the statement in section 5(b) (Processing Activities) of the application *"Access is restricted to employees or **agents** of…"* and suggested that either further information was provided as to who would be covered by "*agents*", and whether this aligned with the Data Sharing Framework Contract (DSFC); or that this word was removed as may be necessary to reflect the facts. **5.3.9** AGD noted the following text within section 5(a) (Objective for Processing) "*[delete or add others as appropriate]"*; and suggested that this was removed. **5.3.10** AGD noted the references in section 5(d) (Benefits) (iii) (Yielded Benefits) to *"offenders"*; and suggested that this was reviewed and updated with a more appropriate language.	
5.4	**Reference Number:** Integrated Care Board (ICB) Template (CACI Amendment) **Observer:** Louise Dunn **Application:** This was an amendment to an application template. The purpose of the application is to amend an existing template to provide access to a data product called Acorn produced by a company called CACI. Acorn provides socio-demographic information relating to a postcode area. The CACI contract with NHS England permits the data to be shared with ICBs. NHS England were seeking general advice on the draft application template. 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 proposal to add ACORN data to the template 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.	

	5.4.1 AGD suggested that NHS England ensure that that there is an appropriate mechanism in place to enable the ICBs to understand what is required of them following receipt of the data. **5.4.2** AGD noted the statement in section 10 (Sub-licensing) of the application, that Local Authorities *"may not"* receive CACI data; and suggested that this was reviewed and updated to *"shall not"*. **5.4.3** AGD advised that they were supportive of the addition of Acorn data to the ICB applications without recourse to AGD.	
5.5	**Reference Number:** NIC-756799-M4K3V-v0.6 **Applicant and Data Controller:** Liverpool University Hospitals NHS Foundation Trust **Application Title:** Safety and feasibility of triage and rapid discharge of patients with chest pain from emergency room: a pragmatic, randomised non-inferiority control trial of the European Society of Cardiology (ESC) 0–1 hour pathway vs. conventional 0-3 hour accelerated diagnostic protocol **Application:** This was a new application. The current practice in Liverpool University Hospital Foundation Trust is to take a blood sample when the patient presents to accident and emergency and then to repeat this after 3 hours; if the blood tests detect a rise in the troponin levels, then the patient is likely to have suffered a heart attack. It is also possible to repeat the test at 1 hour rather than 3 hours. The study purpose is to introduce the 0/1-hour pathway in Liverpool University Hospital Foundation Trust, which is approved for use; and the purpose of the application, is for a study, to understand if, in practice, it performs better than the current 0/3-hour pathway being used. 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:** The majority of the Group (6 members) were supportive of the application; a minority of the Group (3 members) were **not** supportive of the application **at this time**. **5.5.1** AGD discussed the flow of death data and suggested that NHS England clarify whether the use of this data is covered by the proposed legal basis, noting that the usual purpose for using the Demographics Batch Service (DBS) is for direct care, which is not the case with this application. **5.5.2** In addition, AGD noted that the consent materials, provided as supporting documents, referred to Hospital Episode Statistics (HES) data only, and no other data which the death data may be ascertained from.	

5.5.3 AGD noted and commended NHS England's Data Access Service (DAS) on the questions raised with the applicant, in respect of the various parties / organisations involved with the application. The Group discussed the various parties / organisations involved, and whether there was consent for the involvement of these parties / organisations; and whether there were any data protection legislation transparency requirements, and whether these has been addressed and were in agreement with the conclusion reached by NHS England's DAS that there was a legal basis to flow the data.

5.5.4 In respect of Abbott Diagnostics, the Group noted that they would be receiving a product containing anonymised data. It was noted that the consent materials state that the commercial parties / organisation would **not** receive a direct commercial benefit, and the patient information sheet state that the commercial parties / organisations would have **no** access to the data. AGD suggested that NHS England seek confirmation from the applicant, that the data product being accessed by Abbott Diagnostics is sufficiently derived, such as not to be classed as NHS England data and to not be classified as patient data.

5.5.5 AGD suggested that the outputs in section 5(c) (Specific Outputs Expected) of the application were updated, to make reference to the product that Abbott Diagnostics would have access to.

5.5.6 AGD suggested that the application was updated to provide further information on the role of Abbott Diagnostics and Menarini UK, and their commercial interests.

5.5.7 The Group noted the helpful information in the application in respect of the commercial interests of the other parties / organisations.

5.5.8 The Group reminded the applicant that they were required to maintain a UK General Data Protection Regulation (UK GDPR) compliant, publicly accessible transparency notice for the lifetime of the agreement, in line with the contractual requirement in section 4 (Privacy Notice) of the data sharing agreement (DSA).

5.5.9 AGD noted in the DAS internal application assessment form, that DAS had explored transparency issues with the applicant, noting that the applicant did **not** have a study specific website. It was strongly suggested by the Group that the applicant did have a study specific website or webpage, to ensure that there was ongoing transparency with the cohort, and to ensure an easy process was made available to support individuals to withdraw from the study.

5.5.10 AGD considered whether or not the statement in the consent materials that there was no direct commercial benefit impacted on the legal gateway, however, it agreed that on balance, there was a legal gateway in consent for the processing outlined in the application.

5.5.11 AGD noted the information in the study protocol that referred to some individuals having access to raw data that were **not** employed by the Data Controller or Data Processor; and noting that this would **not** be permitted under the application,

	suggested that the application and protocol were reviewed and aligned to reflect the correct / factual information. **5.5.12** It was suggested by AGD that the application was reviewed and updated as may be necessary, to ensure that there is consistent language in how the data being provided was referred to, noting that the recipient would hold relevant identifiers. **5.5.13** AGD noted the statement in section 5(b) (Processing Activities) of the application *"There will be no requirement and no attempt to reidentify individuals when using the Data"*; and suggested that this was removed as it may be necessary, and legitimate, in a consented trial. **5.5.14** AGD noted in the DAS internal application assessment form, that the applicant would be provided with more data than was requested, due to NHS England being unable to further minimise prior to dissemination. It was suggested that, as per the usual process, a special condition was added to section 6 (Special Conditions) of the application, stating that the applicant was required to carry out additional minimisation work and destroy the excess data. The Group also suggested that a specific timeframe was added to the special condition confirming when the excess data should be destroyed by. **5.5.15** In addition, it was suggested that the data destruction being undertaken by the applicant should be noted in section 5(b) of the application for transparency. **5.5.16 Separate to this application:** AGD noted the risks involved with excess data flowing and the reliance on the applicant to destroy data; and suggested that this could be incorporated into the NHS England consideration of the risks, checks and balances for the various modes of data access. **ACTION:** The AGD NHS England Data and Analytics Representative to consider addressing the risks involved with excess data flowing and the reliance on the applicant to destroy the data; and to consider the risks, checks and balances for the various modes of data access. **5.5.17** AGD noted that section 3(b) (Additional Data Access Requested) of the application would need updating to include the identifiability of the data. **5.5.18** AGD noted the statement in section 5(a) (Objective for Processing) of the application, that the manufacturers would be *"…looking to use the data that is published, independently as evidence **to get** NICE approval in the UK for their devices"*; and suggested that this was reviewed and updated to state they would be *"seeking"* NICE approval. **5.5.19** AGD queried the statement in section 5(b) of the application *"Access is restricted to employees or **agents** of…"* and suggested that either further information was provided as to who would be covered by "*agents*", and whether this aligned with the Data Sharing Framework Contract (DSFC); or that this word was removed as may be necessary to reflect the facts.	D&A Rep

	5.5.20 AGD noted that the NHS England citation special condition in section 6 (Special Conditions) of the application differed from previous standard wording, and suggested that the application should be updated with the correct standard wording. **5.5.21** AGD noted that section 2(a) (Processing Location(s)), section 2(b) (Storage Location(s)) and section 2(c) (Territory of Use) of the application had not been completed, and suggested that these were populated with the relevant information.	
5.6	**Reference Number:** NIC-742907-Z5F3Y-v0.6 **Applicant:** University of Southampton **Data Controller:** University Hospital Southampton NHS Foundation Trust **Application Title:** BRITISH Study - Using cardiovascular magnetic resonance identified scar as the Benchmark Risk Indication Tool for Implantable cardioverter defibrillators in patients with non-Ischemic Cardiomyopathy and Severe systolic Heart failure **Application:** This was a new application. The purpose of the application is for a research project, to 1) determine, if implantable cardioverter defibrillators (ICD) therapy reduces all-cause mortality compared to no ICD therapy in patients with non-ischaemic cardiomyopathy (NICM), Cardiac Magnetic Resonance Imaging (CMR)-detected ventricular scar, and Left Ventricular Ejection Fraction (LVEF) ≤35%; and 2) to determine whether an ICD alters the mode of death or rate of non-fatal events, and affects wellbeing. 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: **5.6.1** AGD noted and commended the work undertaken by the applicant and NHS England's Data Access Service (DAS) on this application and NHS England internal application assessment form. **5.6.2** AGD noted and commended the applicant on the excellent patient and public involvement and engagement (PPIE), as outlined in section 5(a) (Objective for Processing) of the application. **5.6.3** AGD noted and commended the applicant on the excellent expected benefits outlined in section 5(d) (Benefits) (ii) (Expected Measurable Benefits to Health and / or Social Care) of the application. **5.6.4** AGD queried the statement in section 5(b) (Processing Activities) of the application *"Only relevant members of The University of Southampton Clinical Trials*	

	*Unit can download data from the **database**"*; and suggested that this was reviewed and updated as may be necessary to reflect that there was more than one database.	
6 INTERNAL DATA DISSEMINATION REQUESTS:		
There were no items discussed		
7 EXTERNAL DATA DISSEMINATION - SIRO APPROVED / SEEKING SIRO APPROVAL		
There were no items discussed		
8 OVERSIGHT AND ASSURANCE		
8.1	**Oversight and Assurance (O&A) (Presenters: Nicki Maher and Andrew Ireland)** Following the discussion at the AGD meeting on the 26th September 2024, the Group were provided with further information on the O&A process ahead of the O&A reviews re-commencing in the 21st November 2024 meeting, including, but not limited to, an overview of the revised O&A forms that would be used to support the reviews; and a demonstration of the new online forms that would need completing by AGD. The Group noted that O&A review previously had been undertaken by AGD independent members only; and agreed that moving forward, AGD NHS England members / delegates would also be involved with the O&A reviews. The Group noted and acknowledged that NHS England would need to support AGD NHS England members / delegates having protected time to undertake O&A reviews. The Group noted that the papers for the next O&S review would be circulated on the 8th November 2024, in advance of the discussion at the AGD meeting on the 21st November 2024. AGD thanked Nicki, Andrew and other colleagues for the work they were doing on this programme of work, and looked forward to a further discussion at the AGD meeting on the 21st November 2024. **Oversight & Assurance of Application Compliance Reports (ACRs)** Separate to the general O&A programme of work, the Group reiterated the suggestion / action made at the AGD meeting on the 5th September 2024, that a further review of ACRs takes place at the 5th December 2024 plenary meeting, reviewing ACRs from the 1st September 2024 onwards.	
9 AGD OPERATIONS		
9.1	**Risk Management Framework** AGD has been previously informed that a risk management framework is being developed by Data Access. However, AGD noted that the Group's Terms of Reference have been in place since March 2024 and charge the Group with	

	operating in line with NHS England's risk management framework, and it is therefore of concern that there is still **not** a Risk Management Framework in place. The AGD Chair referred to an existing NHS England corporate risk management framework that were being used by DAS and queried if this could usefully be utilised as a reference point for the Risk Management Framework required by the Statutory Guidance and AGD Terms of Reference. **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. It was agreed to discuss the NHS England corporate risk management framework, and its possible adaption for AGD advice, at the next meeting of AGD.	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** *There were no items discussed*	
9.4	**AGD Project Work** *There were no items discussed*	
10 Any Other Business		
10.1	**General Practice Extraction Service (GPES) Data for Pandemic Planning and Research – Profession Advisory Group (PAG) (Presenter: Narissa Leyland and Dr. Jonathan Osborn)** The Group were advised that as previously discussed at the AGD meeting on the 22nd February 2024, there were ongoing discussions with NHS England, the British Medical Association (BMA) and the Royal College of General Practitioners (RCGP) on the future / scope of PAG and how it will operate. It was noted that a further update would be provided in due course. The Group reiterated the point made on the 22nd February 2024, that the current draft AGD Terms of Reference does not preclude PAG meeting in common with AGD. AGD were advised that the current PAG arrangements were still in place, as noted in the published minutes of the 27th July 2023 (item 8) and 14th September 2023 (item 5.1.1) and that NHS England would follow the process, as outlined in the previously circulated to NHS England draft 'How AGD consults with the Profession re General Practice Extraction Service	

	(GPES) Data for Pandemic Planning & Research (COVID-19) (GDPPR) Data Standard Operating Procedure' . The Group noted the verbal update from Narrissa and Jonathan and looked forward to further information at a future meeting.
10.2	**Freedom of Information (Presenter: Garry Coleman)** The SIRO Representative advised the Group, that there would be a learning session at a future AGD Plenary meeting. The Group were reminded of NHS England's Freedom of Information and Environmental Information Regulations policy.
Meeting Closure As there was no further business raised, the Chair thanked attendees for their time and closed the meeting.	