

Advisory Group for Data (AGD) – Meeting Minutes

Thursday, 10th October 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) (Not in attendance for item 6.6)
Michael Chapman (MC)	NHS England member (Data and Analytics Representative (not in attendance for part of items 6.3 and 6.4))
Dr. Robert French (RF)	AGD independent member (Specialist Academic / Statistician Adviser)
Kirsty Irvine (KI)	AGD independent member (Chair)
Dr. Phil Koczan (PK)	NHS England member (Caldicott Guardian Team Representative (Delegate for Dr. Jonathan Osborn)) (Items 5.1 and 6.5 to 11)
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) (Items 1 to 4 and 6.1 to 6.4)
Jenny Westaway (JW)	AGD independent member (Lay Adviser)
Miranda Winram (MW)	AGD independent member (Lay Adviser) (not in attendance for part of item 6.6, 10.1 to 10.4, and 11.1 to 11.2)
NHS ENGLAND STAFF IN ATTENDANCE:	
Name:	Role / Area:
Laura Bellingham (LB)	Deputy Director, Data Access and Partnerships, Data and Analytics (Presenter: item 5.1)
Jack Bennett (JB)	NHS DigiTrials, Data and Analytics, Transformation Directorate (Observer: item 6.6)

Victoria Byrne-Watts (VBW)	Senior Assurance Manager, Data Governance and Assurance, Data Access and Partnerships, Transformation Directorate (Observer: item 6.5)
Laura Evans (LE)	NHS DigiTrials, Data and Analytics, Transformation Directorate (Observer: item 6.6)
Dickie Langley (DL)	NHS England SIRO Representative (Delegate for Garry Coleman)
Karen Myers (KM)	AGD Secretariat Officer, Privacy, Transparency and Trust (PTT), Delivery Directorate
Jodie Taylor-Brown (JTB)	Data Access and Partnerships, Data and Analytics, Transformation Directorate (Observer: items 6.3 and 6.4)
James Watts (JW)	Data Access and Partnerships, Data and Analytics, Transformation Directorate (Observer: items 6.1 and 6.2)
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:
Claire Delaney-Pope (CDP)	AGD independent member (Specialist Information Governance Adviser)
Prof. Nicola Fear (NF)	AGD independent member (Specialist Academic Adviser)
Jon Moore (JM)	NHS England member (Data Protection Office Representative)
NHS ENGLAND STAFF NOT IN ATTENDANCE	
Garry Coleman (GC)	NHS England SIRO Representative
EXTERNAL STAFF IN ATTENDANCE (ITEM 5.1)	
Rachel Brophy (RB)	Interim Lead for Information and Research Governance, Health Data Research UK (HDRUK) (Presenter: item 5.1)
Ross Forsyth (RF)	Research Project Manager, Health Data Research UK (HDRUK) (Presenter: item 5.1)
Prof. Reecha Sofat (RS)	Associate Director, Cohorts Lead at the British Heart Foundation (BHF) Data Science Centre, (Presenter: item 5.1)

1	<p>Welcome and Introductions:</p> <p>The AGD Chair welcomed attendees to the meeting.</p> <p>AGD noted that, due to a prior commitment, only two AGD NHS England members were in attendance for the full discussions of items 6.3 and 6.4.</p> <p>Noting that the AGD Terms of Reference state that “<i>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...</i>”, the Group agreed that, as there were two AGD NHS England members present, the meeting was still quorate for items 6.3 and 6.4 and agreed to proceed on that basis.</p>
2	<p>Review of previous AGD minutes:</p> <p>The minutes of the AGD meeting on the 3rd October 2024 were reviewed and, after several minor amendments, were agreed as an accurate record of the meeting.</p>
3	<p>Declaration of interests:</p> <p>Dr Robert French noted a professional link to the British Heart Foundation (BHF) Data Science Centre UK Clinical Cohorts TRE (UK CliC) (item 5.1) as part of his role at Cardiff University, it was agreed this was not a conflict of interest.</p> <p>An AGD member noted a personal perspective to the study outlined in NIC-737073-H1C6D (The Institute of Cancer Research). It was agreed this did not preclude the AGD member taking part in the discussion about this item and welcomed their insight.</p> <p>An AGD member noted a personal perspective to the study outlined in NIC-744993 (Methods Analytics Ltd). It was agreed this did not preclude the AGD member taking part in the discussion about this item and welcomed their insight.</p> <p>Jenny Westaway noted that she had undertaken some paid contract work for Templar Executives to contribute to data protection training courses for Our Future Health. It was agreed this did not preclude the Jenny from taking part in the discussions about the Our Future Health application (NIC-411795-X5N2V).</p> <p>Paul Affleck noted a professional link to NIC-743571-K7X4R (University of Oxford) and requested not to be part of the discussion. It was agreed that Paul would leave the virtual room for the discussion of this application.</p>
4	<p>AGD Action Log:</p> <p><i>The action log was not discussed.</i></p>
<p>5 BRIEFING PAPER(S) / DIRECTIONS:</p>	

5.1	<p>Title: British Heart Foundation Data Science Centre (BHF DSC) UK Clinical Cohorts TRE (UK CliC) Briefing Paper / Data Protection Impact Assessment (DPIA)</p> <p>Presenters: Laura Bellingham, Ross Forsyth, Prof. Reecha Sofat and Rachel Brophy</p> <p>The BHF DSC, as part of Health Data Research UK (HDR UK) have established a Trusted Research Environment (TRE) to house UK Clinical Cohorts (UK CliC), with the TRE platform provided by SAIL Databank. UK CliC will provide cohort data custodians from across the UK a safe, transparent and secure mechanism to store their data, have this data linked to health records and allow this linked data to be securely accessed by approved members of the wider research community.</p> <p>The BHF DSC seek to establish a framework which they would like to test, with NHS England to allow batch application and batch data transfer to UK CliC who will act on behalf of UK wide disease specific cohorts.</p> <p>NHS England were seeking advice on the following points:</p> <ol style="list-style-type: none"> 1. The assurances NHS England would need to have in place to support this programme. <p>Outcome of discussion: The AGD Chair welcomed colleagues from Health Data Research UK and the British Heart Foundation Data Science Centre, who were in attendance with NHS England colleagues to provide a brief overview to the Group and to answer any questions on the information provided.</p> <p>The Group thanked Prof. Sofat, Ross and Rachel for attending the meeting, and for the information provided.</p> <p>Following the departure from the meeting by Prof. Sofat, Ross and Rachel, the Group made the following observations / comments:</p> <p>In response to point 1:</p> <p>5.1.1 AGD noted that a number of options were being explored by NHS England, in respect of this area of work, and that this was being reviewed in line with the possible benefits to the health and social care system.</p> <p>5.1.2 AGD noted the importance of the consent reviews being undertaken by the correct personnel to ensure there was a legal basis for processing the data as described to the Group.</p> <p>5.1.3 AGD advised that they would welcome / be supportive of further discussions / updates on this work, as required by NHS England.</p>	
6 EXTERNAL DATA DISSEMINATION REQUESTS:		
6.1	<p>Reference Number: NIC-15293-R6V2H-v15.9</p> <p>Applicant: Health iQ LTD</p>	

<p>Application Title: Health iQ - Benchmarking and reporting</p> <p>Observer: James Watts</p> <p>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 2nd July 2020, 11th June 2020, 30th January 2020, 8th November 2018 and the 20th September 2018.</p> <p>The application and relevant supporting documents were previously presented / discussed at the Data Access Advisory Group (DAAG) meetings on the 16th August 2016 and the 19th July 2016.</p> <p>Linked applications: This application is linked to NIC-422044-Z5K5Q.</p> <p>Application: This was an amendment application.</p> <p>The amendments are to 1) add Mental Health Services Data Set and Diagnostic Imaging Data Set to the application; and 2) a request to retain data for six-years.</p> <p>NHS England were seeking general advice on the application.</p> <p>Should an application be approved by NHS England, further details would be made available within the Data Uses Register.</p> <p>Outcome of discussion: AGD were supportive of the application and wished to draw to the attention of the SIRO the following substantive comments:</p> <p>6.1.1 AGD noted, in the internal Data Access Service (DAS) Escalation Form, that two other data sharing agreements (DSAs) held by Health iQ LTD had expired: NIC-656864-X5H4L expired on the 19th July 2023 and NIC-656866-V3H6X had expired on the 7th September 2024. The Group noted that the applicant had not provided an update to NHS England as to whether this data had been destroyed. As previously advised by the SIRO Representative, the Group suggested data should not flow until the issues with the two expired DSAs had been resolved.</p> <p>6.1.2 Separate to this application: AGD noted that there was a process for dealing with expired DSAs (as discussed at the AGD meeting on the 26th September 2024); however, advised that they would be supportive of NHS England undertaking checks to identify issues with other DSAs as part of the review for any new DSAs, and suggested that any new applications were paused at a certain point until contractual issues with other DSAs had been resolved.</p> <p>ACTION: The AGD NHS Data and Analytics Representative to explore with colleagues, whether checks could be undertaken to identify issues with other DSAs, as part of the review for any new DSAs; and whether any new applications were paused at a certain point until contractual issues had been resolved.</p> <p>6.1.3 It was also suggested by the Group that applicants are made aware, at an early stage in the process, that contractual issues with other DSAs could impact on other applications in the system.</p>	<p>D&A Rep</p>
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<p>6.1.4 The AGD NHS England Caldicott Guardian Team Representative expressed concerns on the volume of sensitive mental health data flowing as an extract and not processed in NHS England's Secure Data Environment (SDE).</p> <p>6.1.5 In addition, the AGD NHS England Caldicott Guardian Team Representative queried whether the objective for processing could be achieved with the mental health data requested, for example, compliance with the medication taken.</p> <p>6.1.6 AGD noted, in the DAS Escalation Form, that the data could not be processed in the SDE, due to the applicant's Vantage Tool not being compatible. It was suggested that NHS England explore this further with the applicant to determine whether there was a solution to this issue that would enable the processing to be undertaken in the NHS England SDE.</p> <p>6.1.7 In addition, noting that the 'gender' field had been selected in section 3(b) (Additional Data Access Requested) of the application, the AGD NHS England Caldicott Guardian Team Representative advised that NHS England would need to have regard to the Gender Recognition Act 2004 (legislation.gov.uk) and the risk of data flowing and any linkage that may lead to re-identification of an individual.</p> <p>6.1.8 The Group suggested that NHS England assure itself that the Mental Health Services Data Set was the correct data to be flowing, and suggested that that engage with Health IQ LTD's clinical expertise on this point, as referenced in the DAS Escalation Form.</p> <p>6.1.9 The NHS England SIRO Representative noted that date of death data was flowing, and suggested that this was reviewed / assessed to determine whether this would in fact make the data identifiable and would therefore be confidential patient data. The AGD Chair noted that NHS Digital had reached a position with the National Data Guardian in that NHS Digital / England should be carrying out an assessment about the risk of identification, and asked that the AGD NHS England Data and Analytics Representative check that assessments were part of the Q&A process.</p> <p>ACTION: The AGD NHS England Data and Analytics Representative to check that discussions around date of death are part of the Q&A / internal process checks.</p> <p>In addition, AGD made the following observations on the application and / or supporting documentation provided as part of the review:</p> <p>6.1.10 AGD queried whether the outputs in section 5(c) (Specific Outputs Expected) and the benefits in section 5(d) (Benefits) of the application, were specifically related to the data flowing under this application; and suggested that these were reviewed and updated to also reflect the outputs and benefits from the new data flowing, in line with NHS England DAS Standard for Expected Outcomes and NHS England DAS Standard for Expected Measurable Benefits.</p> <p>6.1.11 The AGD Specialist Academic / Statistician member noted that some of the outputs in section 5(c), such as the diabetic study had limited novel information and</p>	<p>D&A Rep</p>
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	<p>may function more as a demonstrator of the tool and suggested that this was explored further to ensure 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.</p> <p>6.1.12 AGD suggested that the commercial aspect of the application in section 5(e) (Is the Purpose of this Application in Anyway Commercial); 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.</p> <p>6.1.13 Separate to this application: AGD suggested that DAS ensure that their internal processes reflect that the commercial aspect of the application in the unpublished section 5(e); was also replicated for transparency in (the published) section 5(a).</p> <p>ACTION: DAS to ensure that their internal processes reflect that the commercial aspect of the application in the unpublished section 5(e); was also replicated for transparency in (the published on the NHS England data uses register) section 5(a).</p> <p>6.1.14 AGD noted that Health iQ LTD were part of a group of companies; and suggested that NHS England make the applicant aware that only those organisations specified in the application were able to access the data, and that this would not extend to any parent company, sister companies and / or subsidiaries.</p> <p>6.1.15 The Group suggested that NHS England explore the role of CorEvitas further with the applicant, to clarify that they were not determining the purpose and means of processing and were therefore not carrying out any data controllership activities in line with the NHS England DAS Standard for Data Controllers; and that the application was updated as may be required to reflect the correct / factual information.</p> <p>6.1.16 Noting that the CorEvitas website refers to linking NHS England data to national cancer registry and ONS data; it was suggested that the processing under this application was specifically mentioned, especially relevant noting the other two applications referenced in 6.1.1 above had expired.</p> <p>6.1.17 AGD noted that whilst the applicant does have a general privacy notice on their website, they do not have a study specific privacy notice, and suggested either the existing privacy notice was amended to reflect the processing under this application; or that a separate study specific privacy notice was published, in line with the contractual requirement in section 4 (Privacy Notice) of the data sharing agreement (DSA) and the UK General Data Protection Regulation (UK GDPR).</p> <p>6.1.18 AGD noted the terms and conditions table in the supporting document provided (SD1) and suggested that the information relating to 'Hosted Services/Modules Included Under this Agreement' (row 4) was reviewed and updated to be clear that no identifying data would be flowing.</p>	DAS
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	<p>6.1.19 AGD suggested that the special conditions in section 6 (Special Conditions) of the application were reviewed and updated as may be necessary, to ensure that they reflected the new data flowing under this iteration of the application, and six years of data being retained.</p>	
6.2	<p>Reference Number: NIC-737073-H1C6D-v0.6</p> <p>Applicant: The Institute of Cancer Research</p> <p>Application Title: Late effects of treatments in breast cancer survivors in England</p> <p>Observer: James Watts</p> <p>Application: This was a new application.</p> <p>The purpose of the application is for a retrospective study, which aims to investigate the late effects of treatment in breast cancer survivors in a national cohort to provide real-world evidence for modern breast cancer treatment regimens. Specifically, the study team will assess the risks of subsequent malignancies, cardiovascular and other chronic diseases in relation to specific types of radiotherapy and chemotherapy received by breast cancer patients.</p> <p>NHS England were seeking general advice on the application.</p> <p>Should an application be approved by NHS England, further details would be made available within the Data Uses Register.</p> <p>Outcome of discussion: AGD were supportive of the application and wished to draw to the attention of the SIRO the following high-level comments:</p> <p>6.2.1 AGD noted the information in the Data Access Service (DAS) internal application assessment form in respect of the role of The Royal Marsden Hospital, i.e. that they will be working in an advisory capacity; and suggested that NHS England explore this further with the applicant, to clarify that they were not determining the purpose and means of processing and were therefore not carrying out any data controllership activities in line with the NHS England DAS Standard for Data Controllers; and that the application was updated as may be required to reflect the correct / factual information.</p> <p>6.2.2 AGD noted in the DAS internal application assessment form that this application did not require approval from Health Research Authority Research Ethics Committee due to the data being pseudonymised, but that the applicant had consulted the Royal Marsden Hospital Ethics Committee; however, suggested that NHS England clarify with the applicant what the outcome had been of the internal ethics committee; or, whether the application did not meet the threshold for an ethical review; and that any paperwork / supporting evidence related to this point was shared with NHS England and uploaded to NHS England's customer relationships management (CRM) system, and in line with NHS England's Standard for Ethical Approvals .</p>	

	<p>6.2.3 AGD noted that prior to the meeting, a query had been raised with DAS, in respect of data specification and data minimisation noting the conflicting / unclear information in the DAS internal application assessment form in respect of the age range of the cohort and years of follow-up. NHS England noted that, due to timing and resource pressures in NHS England, the application had been presented to AGD prior to the data fields in section 3(b) (Additional Data Access Requested) being analysed by the National Disease Registration Service (NDRS) Analyst. AGD noted the verbal update that the NDRS Analysts are yet to review this application and suggested that a careful review of the data requested be undertaken and before data flows, including but not limited to clarifying the date range of the data required.</p> <p>6.2.4 AGD noted the statement in section 5(a) (Objective for Processing) <i>“The funder will have no ability to suppress or otherwise limit the publication of findings”</i>; and suggested that this was removed, noting that the funder was also the Data Controller.</p> <p>6.2.5 AGD advised that, noting the quantum of data flowing and the nature of the research; this was an example of where it would be suitable for this type of processing to be carried out within NHS England’s Secure Data Environment (SDE).</p> <p>6.2.6 AGD noted that there had been no patient and public involvement and engagement (PPIE) undertaken to date but commended the applicant on the planned PPIE, as outlined in the application.</p> <p>6.2.7 Separate to this application: AGD noted that, whilst not noted in the documentation provided, The Institute of Cancer Research had been subject to an NHS England audit. It was suggested that, for ease of reference, the DAS internal application assessment form template and the DAS Escalation Form templates were updated, to include a section specifically related to audits, which would support reviews by both AGD and NHS England colleagues.</p> <p>ACTION: The AGD NHS England Data and Analytics Representative to discuss with colleagues whether the DAS internal application assessment form template and the DAS Escalation Form templates could be updated, to include a section specifically related to audits.</p>	D&A Rep
6.3	<p>Reference Number: NIC-744993-Z8K2K-v0.7</p> <p>Applicant: Methods Analytics Ltd</p> <p>Application Title: Triple Negative Breast Cancer Study</p> <p>Observer: Jodie Taylor-Brown</p> <p>Application: This was a new application.</p> <p>The purpose of the application is for a research project, which aims to describe and characterise the <i>“Real World”</i> treatment of Triple Negative Breast Cancer (both early and metastatic) in multiple centres in England.</p>	

NHS England were seeking advice on the following points, including general advice on any other aspect of the application:

1. The data controllership arrangements.
2. The proposed purpose and use of data.

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

Outcome of discussion: AGD were supportive of the application if the following substantive comments were addressed, and wished to draw to the attention of the SIRO the following substantive comments:

In response to points 1 and 2:

6.3.1 AGD noted that, prior to the meeting, a query had been raised with NHS England's Data Access Service (DAS), in respect of the commercial interest of Gilead Science Ltd, noting that this was unclear in the application. The Group noted that a copy of the Work Order Agreement between Methods Analytics Ltd and Gilead Science Ltd had been provided, and that DAS had raised queries on some of the information within this document, that suggests Gilead Science Ltd may be determining the purpose and means of processing and would therefore be carrying out data controllership activities in line with the [NHS England DAS Standard for Data Controllers](#).

6.3.2 The Group suggested that NHS England explore the role of Gilead Science Ltd in line with [NHS England DAS Standard for Data Controllers](#), and that the application was updated as may be required to reflect the correct / factual information.

6.3.3 In addition, AGD suggested that NHS England explore the direct or indirect commercial benefits to Gilead Science Ltd, in line with [NHS England DAS Standard for Commercial Purpose](#), and that the application was updated as may be required to reflect the correct / factual information.

6.3.4 AGD suggested that the commercial aspect of the application in (the unpublished) section 5(e) (Is the Purpose of this Application in Anyway Commercial); was replicated for transparency in (the published in the NHS England data uses register) section 5(a) (Objective for Processing), in line with [NHS England's DAS Standard for Objective for Processing](#).

6.3.5 Noting the statement in section 5(d) (Benefits) of the application "...*Methods have been in contact with consultants in oncology and are actively exploring opportunities to collaborate with them as co-authors on the study*", AGD suggested that NHS England explore this further with the applicant, to clarify that the co-authors would not be determining the purpose and means of processing and would not therefore **be** carrying out any data controllership activities in line with the [NHS England DAS Standard for Data Controllers](#); and that the application was updated as may be required to reflect the correct / factual information.

	<p>6.3.6 In addition, the Group suggested that NHS England satisfy themselves that any collaboration taking place was within the confinements of the data sharing agreement (DSA).</p> <p>6.3.7 AGD noted in the DAS internal application assessment form that the application would not include data from any of the years since Trodelvy was brought to market; and advised that this should not be barrier to the additional data flowing if this was required / beneficial to the research. It was suggested that NHS England explore this further with the applicant, and that the application was updated to reflect any additional data that was required / may flow, with the appropriate robust justification included in section 5 of the application.</p> <p>6.3.8 AGD noted the statement in section 5(a) “<i>Methods Analytics Ltd has determined the processing is necessary for its legitimate interests in being able to provide research to improve healthcare for patients</i>”; and suggested that this was reviewed and updated to also be clear that part of the legitimate interests was that Methods Analytics Ltd was a commercial organisation charging a fee for its services.</p> <p>6.3.9 AGD noted in the DAS internal application assessment form, that the applicant had engaged with their internal ethics board; however, noting that it was unclear what the outcome of this was, it was suggested that NHS England explore this further with the applicant, and any paperwork / supporting evidence related to this point was shared with NHS England and uploaded to NHS England’s customer relationships management (CRM) system, and in line with NHS England’s Standard for Ethical Approvals.</p> <p>In addition, AGD made the following observations on the application and / or supporting documentation provided as part of the review:</p> <p>6.3.10 AGD noted that whilst the applicant does have a general privacy notice for website visitors on their website, they do not have a study specific privacy notice, and suggested either the existing privacy notice was amended to reflect the processing under this application; or that a separate study specific privacy notice was published, in line with the contractual requirement in section 4 (Privacy Notice) of the data sharing agreement (DSA) and the UK General Data Protection Regulation (UK GDPR).</p> <p>6.3.11 NHS England advised the Group that there were ongoing discussions to determine whether the data would be processed via a dissemination of data or within NHS England’s Secure Data Environment (SDE). The Group noted and advised that they were supportive of the data being processed within NHS England’s SDE; or via a data dissemination if access in the SDE was not possible at this time.</p>	
6.4	<p>Reference Number: NIC-726539-S6T2F-v0.6</p> <p>Applicant: Manchester University NHS Foundation Trust</p> <p>Application Title: The UHSM Cardiovascular Magnetic Resonance Study</p>	

Observer: Jodie Taylor-Brown

Application: This was a new application.

The purpose of the application is for a study, which aims to investigate how Cardiac Magnetic Resonance (CMR) can be used to diagnose heart conditions and how certain findings can be used to predict people's life expectancy and quality of 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:

6.4.1 AGD noted the queries raised with the applicant by NHS England's Data Access Service (DAS) in respect of transparency; and advised that they were supportive of the suggestion, by DAS, that the applicant has a study specific website. The Group noted that if a study specific website was not possible due to resources, that another option could be having a study specific webpage on the Manchester University NHS Foundation Trust website.

6.4.2 In addition, it was suggested that any contact with the cohort, for example via telephone, newsletter etc, could make reference to the study specific website or webpage; and that all historical documents, for example consent materials, patient information sheets etc could be made available on the website / webpage for ease of reference.

6.4.3 AGD queried the information in the DAS internal application assessment form in respect of the funding; and suggested that NHS England clarified with the applicant that there is funding in place for the duration of the data sharing agreement (DSA).

6.4.4 AGD noted that point 7.2 in the study protocol, provided as a supporting document, referred to additional funders with a startup / commercial angle; and suggested that NHS England explore this further, in line with [NHS England DAS Standard for Commercial Purpose](#), and that the application was updated as appropriate to reflect the additional funders and any commercial benefits etc.

6.4.5 AGD noted that one of the Chief Investigators has a National Institute for Health and Care Research (NIHR) fellowship that overlaps with the research in this application; and suggested that NHS England explored this further with the applicant to determine if there are any commercial aspects, for example, in respect of industry access to data and machine learning.

6.4.6 AGD noted that data would be accessed by individuals with an honorary contract with Manchester University NHS Foundation Trust; and advised that whilst they were content with the process described for the honorary contracts, it was

	<p>unclear why they were needed, and suggested that the application was updated to clarify this point.</p> <p>6.4.7 AGD noted the application made reference to data retention; and suggested that further clarification was provided on the timescales for the data retention, noting that this was currently unclear within section 5 of the application.</p> <p>6.4.8 AGD noted that one of the parties involved had been named on a published paper in January 2024 on a similar subject to the study outlined in this application, that referred to NHS Digital data; and suggested that NHS England clarify whether there was an application in the system that was linked to the work outlined in this application, and, if so, to make a note of any “sister” applications in internal documentation, for ease of reference.</p> <p>6.4.9 The NHS England SIRO Representative noted in section 1(b) (Data Controller(s)) of the application, that the Data Sharing Framework Contract (DSFC) for Manchester University NHS Foundation Trust had expired on the 1st October 2024; and asked that this was updated with the latest information.</p>	
6.5	<p>Reference Number: NIC-411795-X5N2V-v0.9</p> <p>Applicant: Our Future Health</p> <p>Application Title: Our Future Health Outcomes TRE Data Linkage Application with Sublicensing</p> <p>Observer: Victoria Byrne-Watts</p> <p>Previous Reviews: The application and relevant supporting documents were previously presented / discussed at the AGD meetings on the 13th June 2024, 7th September 2023 and the 13th July 2023.</p> <p>The application and relevant supporting documents were previously presented / discussed at the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) meeting on the 22nd September 2022.</p> <p>Linked applications: This application is linked to NIC-414067-K8R6J.</p> <p>Application: This was a seeking early advice application.</p> <p>It is proposed that the application is amended to reflect that the data will be shared with both the Founding Members and their Affiliates, in the Our Future Health (OFH) Trusted Research Environment (TRE) via sublicensing.</p> <p>NHS England were seeking advice on the following points only:</p> <ol style="list-style-type: none"> 1. Proposed sub-licensing model; and 2. Potential use cases. <p>Should an application be approved by NHS England, further details would be made available within the Data Uses Register.</p>	

	<p>Outcome of discussion: AGD noted that they were specifically asked to provide advice in relation to the proposed sub-licensing model and potential use cases, 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 (noting that the points may not be relevant once the additional detail on the application is clear):</p> <p>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.</p> <p>In response to points 1 and 2:</p> <p>6.5.1 AGD noted and commended NHS England’s Data Access Service (DAS) on the papers provided in advance of the meeting, that supported the discussion including the mock application (based on v0.9 live application) and the slide pack. AGD also applauded the governance information provided in the slide pack (slide 7) and suggested that this was used as an exemplar for other applications.</p> <p>6.5.2 AGD queried the definition of the ‘Founding Members’ and ‘Affiliates’ and suggested that, to ensure consistency, these words were further defined using language in existing documents / consent materials already seen / signed by the cohort.</p> <p>6.5.3 Separate to this application: AGD reiterated a previous action last discussed on the 12th September 2024, that, noting that the word “<i>affiliated</i>” had been incorrectly used in other applications, it was suggested by the independent advisers that the NHS England Data and Analytics Representative remind DAS that this should only be used in an application if it is correct in context, i.e. for those with an association with an organisation but who are not substantially employed or enrolled, and then explained further. The aim should be to describe the relationship in the most specific sense possible. In this specific case it was potentially very problematic to retain this standard wording as there was also a defined term for “<i>Affiliates</i>”.</p> <p>ACTION: NHS England Data and Analytics representative to remind DAS that the word “<i>affiliated</i>” should only be used in an application if correct in context and always explained further; the aim should be to describe the relationship in the most specific sense possible.</p> <p>6.5.4 AGD noted that there was a gateway in consent for sub-licensing the data with the Founding Members and their Affiliates, noting that the consent materials do state that companies can receive the data; however, referred to previous engagement with the cohort where it was indicated that this was not comprehensively appreciated.</p> <p>6.5.5 In respect of the sub-licenses, AGD noted the statement in section 10 (Sub-licensing) of the application “<i>NHS England retains the right to publish this information</i>”; and suggested that NHS England consider amending this, for example to state that OFH publish this information three-months in arrears on their website.</p>	<p>D&A Rep</p>
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	<p>6.5.6 AGD suggested that, as part of the regular updates to participants, it would be a useful opportunity to highlight use cases of the data, to increase awareness of the commercial use of the data, and link to the website; this would highlight good use of the data.</p> <p>6.5.7 AGD noted that there was a Data Processor with an address in the United States of America, and noted that this was due to the processing taking place in the UK, which was the permitted territory of use. The Group noted the Data Processor does not have a UK base. It was suggested that NHS England ensure that the current territory of use and jurisdiction of the user is in line / consistent with NHS England policy.</p> <p>6.5.8 Separate to the application; AGD suggested that NHS England may wish to consider whether the NHS England DAS Standard for Territory of Use needs amending.</p> <p>ACTION: NHS England Data and Analytics to consider whether the NHS England Territory of Use Standard requires an uplift.</p>	D&A Rep
<p>AGD noted that an independent member left the meeting mid-way through item 6.6 and so there was an even number of AGD independent members (three) and AGD NHS England members (three) in attendance for item 6.6, 10.1 to 10.4, and 11.1 to 11.2.</p> <p>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.</p> <p>The NHS England SIRO representative stated that should AGD members be required to vote on any issues for those items, 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 independent members. The Group noted and agreed with this proposal.</p> <p>Noting that the AGD Terms of Reference state that “<i>The majority of the members of the Group or Sub-Group involved in any meeting should be independent members...</i>”, the Group agreed that the meeting for those particular items, was still quorate and agreed to proceed on that basis.</p>		
6.6	<p>Reference Number: NIC-743571-K7X4R-v0.2 University of Oxford</p> <p>Applicant: NIC-743571-K7X4R-v0.2 University of Oxford</p> <p>Application Title: MyMelanoma Study – NHS DigiTrials Recruitment Service</p> <p>Observers: Laura Evans and Jack Bennett</p> <p>Application: This was a new application.</p> <p>The purpose of the application is to recruit and maintain contact with a large group of melanoma patients to build the biggest melanoma data resource ever collected in</p>	

<p>the UK. It is hoped this resource will enable researchers to answer key unanswered questions about melanoma.</p> <p>NHS England were seeking general advice on the application.</p> <p>Should an application be approved by NHS England, further details would be made available within the Data Uses Register.</p> <p>Outcome of discussion: AGD were supportive of the application and wished to draw to the attention of the SIRO the following comments:</p> <p>6.6.1 AGD noted that they were supportive of the proposed use of the data.</p> <p>6.6.2 AGD noted that Hospital Episode Statistics (HES) data had been requested to support the recruitment of individuals, but queried whether this was the correct data to be processing. The Group suggested that NHS England review and consider whether Cancer Registration data, in addition to the HES data, may provide more accurate information, noting that some melanoma cancer diagnoses would be treated outside of a hospital setting and therefore not captured in HES data.</p> <p>6.6.3 AGD noted the conflicting information in the documents provided, in respect of the expected uptake rate, noting that this was stated as being 3.4% in the application and 12% in other documents provided. Noting that the aim was to recruit 20,000 individuals, the Group suggested that the application was updated in line with the Health Research Authority Confidentiality Advisory Group (HRA CAG) support, which does not have a cap set on the number of individuals that can be contacted.</p> <p>6.6.4 AGD queried how many times an individual would be contacted; and were advised by NHS England's Data Access Service (DAS), that individuals would only be contacted once, via the invitation letter. AGD noted and thanked DAS for the verbal update.</p> <p>In respect of the invitation letter template (SD5):</p> <p>6.6.5 AGD noted that the letter template was not clear that individuals were being contacted on the virtue of a diagnosis of melanoma, and that it did appear to suggest that they had been randomly selected; and suggested that the template was updated to be clearer / more transparent on this point.</p> <p>6.6.6 AGD noted that the letter template did not refer to the study specific opt-out; and suggested that the template was updated to make reference to this.</p> <p>6.6.7 In addition, AGD noted in the Participation Panel summary from the 26th March 2024, that a commitment had been made by the applicant, that the National Data Opt-out (NDO) would be referenced in the invitation letter; however, advised that this had not been referred to in the letter template provided. It was suggested that from an ethical perspective, the template was updated to specifically reference the NDO as per the commitment made to the Participation Panel.</p> <p>6.6.8 AGD discussed the risk of the incorrect person opening the letter, that contains confidential information, i.e. that the individual had received a diagnosis of</p>	
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<p>melanoma; and the impact on an individual receiving a letter of this kind; and suggested that these issues / concerns could be addressed as part of any patient and public involvement and engagement (PPIE), which could include specific melanoma charities.</p> <p>6.6.9 In addition, AGD also discussed the impact on a family member receiving a letter for an individual that was now deceased; and were advised by NHS England, that steps were being taken to address this, i.e. that there would be a refresh of the data 24 hours prior to the letter being sent out that would remove all individuals who had recently deceased up to that point. AGD noted the assurances provided by NHS England.</p> <p>In respect of the patient information sheet (PIS) (SD6):</p> <p>6.6.10 AGD noted that the application stated that the data would be minimised to individuals aged 18 or over; however, the PIS and letter template states that the eligibility criteria was anyone aged 16 and over. The Group suggested that this was discussed with the applicant, and that the PIS and any other supporting information was updated to reflect the correct / factual information.</p> <p>6.6.11 AGD noted the historical / out of data references in the PIS, for example, “<i>NHS Digital</i>” and “<i>PHE</i>”; and suggested that the document was reviewed and updated throughout to ensure that the correct / most recent language and organisations were referenced.</p> <p>*Public Health England</p> <p>6.6.12 AGD noted that the PIS states that the data would not include identifiable information, such as the hospital you were treated; and queried whether this would be included in the HES data. If this data was captured in the HES data, the Group suggested that this was discussed with the applicant, and that the PIS and any other supporting information was updated to reflect the correct / factual information.</p> <p>6.6.13 AGD noted in the Participation Panel summary from the 26th March 2024 that it is stated that the NHS logo would be used on the envelope of all mailed study invitations; and suggested that NHS England ensure the relevant approvals had been obtained to support this, in line with relevant NHS England policy on the use of the NHS logo.</p> <p>6.6.14 Separate to this application: AGD reiterated the point made on the 12th September 2024, that the NHS England SIRO Representative clarify NHS England’s policy with the Group, outlining the process for seeking permission to use the NHS logo or name on a project and what criteria are used to decide whether such requests should be granted; and to keep the Group updated with any decisions / outcomes on this point.</p> <p>6.6.15 In addition, AGD reiterated the advice that they would be supportive of feeding into any discussions on the criteria for projects to use of the NHS logo or state that they are working with the NHS, should NHS England require this input.</p>	
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	<p>ACTION: The NHS England SIRO representative to clarify NHS England's policy with the Group, and outline the process and criteria for projects to gain permission to use the NHS logo or state that they are working with NHS (and to keep the Group updated with any decisions / outcomes on this point).</p> <p>6.6.16 AGD queried what consideration had been given to targeting underrepresented groups, for example, socio-economic status; and suggested that this was clarified in the application.</p> <p>6.6.17 The NHS England SIRO Representative noted the reference in section 5(a) (Objective for Processing) to a Data Processing Agreement between NHS England and University of Oxford; and suggested that this was reviewed and updated to reflect the correct / factual information.</p>	SIRO Rep
7 INTERNAL DATA DISSEMINATION REQUESTS:		
<i>There were no items discussed</i>		
8 EXTERNAL DATA DISSEMINATION - SIRO APPROVED / SEEKING SIRO APPROVAL		
8.1	<p>Reference Number: NIC-615981-K2W5D-v3.2</p> <p>Applicant: NHS South East London ICB</p> <p>Application Title: DSfC - NHS South East London Integrated Care Board - IV, RS & Comm</p> <p>Previous Reviews: The application and relevant supporting documents had previously been presented / discussed at the AGD meeting on the 2nd May 2024. The SIRO approval was for a nine-month renewal.</p> <p>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.</p>	
9 OVERSIGHT AND ASSURANCE		
<i>There were no items discussed</i>		
10 AGD OPERATIONS		
10.1	<p>Risk Management Framework</p> <p>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</p>	

	<p>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.</p> <p>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</p>	SIRO Rep
10.2	<p>Standard Operating Procedures (SOPs)</p> <p>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.</p>	
10.3	<p>AGD Stakeholder Engagement</p> <p>A brief update was given by the Group’s Representative on the Federated Data Platform Data Governance Group.</p>	
10.4	<p>AGD Project Work</p> <p><i>There were no items discussed</i></p>	
11 Any Other Business		
11.1	<p>AGD NHS England Caldicott Guardian Team Representative / Delegate: Dr. Phil Koczan</p> <p>The Group noted that due to other work commitments, this would be the last AGD meeting that Dr. Phil Koczan would be attending as delegate for Dr. Jonathan Osborn (AGD NHS England Caldicott Guardian Team Representative).</p> <p>The Group thanked Dr. Koczan for his valuable contributions to AGD as delegate for Dr. Osborn.</p>	
11.2	<p>AGD NHS England Data and Analytics Representative / Delegates: Narissa Leyland and Dave Cronin</p> <p>The Group noted at the AGD meeting on the 3rd October 2024, that Tom Wright would be the AGD NHS England Data and Analytics Representative on behalf of Michael Chapman (AGD NHS England Data and Analytics Representative) from the 17th October 2024.</p> <p>The Group thanked Narissa Leyland and Dave Cronin for their valuable contributions to AGD as delegates for Michael.</p>	
<p>Meeting Closure</p> <p>As there was no further business raised, the Chair thanked attendees for their time and closed the meeting.</p>		