

Advisory Group for Data (AGD) – Meeting Minutes

Thursday, 18th September 2025

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)
Eleanor Berg (EB)	NHS England member (Data Protection Office Representative (Delegate for Jon Moore)) (Items 1 to 4.1 and 5.2 to 11.1) (Observer: item 5.1)
Dave Cronin (DC)	NHS England member (Data and Analytics Representative (Delegate for Michael Chapman))
Claire Delaney-Pope (CDP)	AGD independent member (Specialist Information Governance Adviser)
Kirsty Irvine (KI)	AGD independent member (Chair)
Dr. Jonathan Osborn (JO)	NHS England member (Caldicott Guardian Team Representative)
Ellie Ward (EW)	NHS England member (Data Protection Office Representative (Delegate for Jon Moore)) (Item 5.1 only)
Jenny Westaway (JW)	AGD independent member (Lay Adviser)
NHS ENGLAND STAFF IN ATTENDANCE:	
Name:	Role / Area:
Garry Coleman (GC)	NHS England SIRO Representative
Louise Dunn (LD)	Principal Operational Delivery Manager, Data Access and Partnerships, Data Portfolio Management, Transformation Directorate (Observer: item 5.1)
Rachel Fernandez (RF)	IG Lead, Data Protection Office & Trust, Privacy, Transparency, and Trust (PTT), Deputy Chief Executive Directorate (Observer: item 4.1)
Dan Goodwin (DG)	Data Access and Partnerships, Data and Analytics, Transformation Directorate (Observer: item 5.1)
Dickie Langley (DL)	Assistant Director of IG (Digital Operations), Privacy, Transparency, and Trust (PTT), Deputy Chief Executive Directorate (Observer: item 4.1)

Madeline Laughton (ML)	Data Access and Partnerships, Data and Analytics, Transformation Directorate (Observer: item 5.4)
Joe Lawson (JL)	Data Access and Partnerships, Data and Analytics, Transformation Directorate (Observer: item 5.6)
Tiaro Micah (TM)	Data Access and Partnerships, Data and Analytics, Transformation Directorate (Observer: item 5.5)
Narissa Leyland (NL)	Head of Data Governance and Assurance, Data Access and Partnerships, Data and Analytics, Transformation Directorate (Presenter: item 9)
Karen Myers (KM)	AGD Secretariat Officer, Privacy, Transparency and Trust (PTT), Deputy Chief Executive Directorate
Terry Service (TS)	Transformation Directorate (Presenter: item 4.1)
Jodie Taylor-Brown (JTB)	Data Access and Partnerships, Data and Analytics, Transformation Directorate (Observer: items 5.3 and 5.6)
Vicki Williams (VW)	AGD Secretariat Manager, Privacy, Transparency and Trust (PTT), Deputy Chief Executive Directorate
INDEPENDENT ADVISER OBSERVERS IN ATTENDANCE	
Mr Christopher Barben (CB)	AGD independent adviser
Dr. Jon Fistein (JF)	AGD independent adviser
Professor Jo Knight (JK)	AGD independent adviser
Dr. Mark McCartney (MM)	AGD independent adviser
AGD INDEPENDENT MEMBERS / NHS ENGLAND MEMBERS <u>NOT</u> IN ATTENDANCE:	
Name:	Role / Area:
Michael Chapman (MC)	NHS England member (Data and Analytics Representative)
Dr. Robert French (RF)	AGD independent member (Specialist Academic / Statistician Adviser)
Jon Moore (JM)	NHS England member (Data Protection Office Representative)
Miranda Winram (MW)	AGD independent member (Lay Adviser)
EXTERNAL STAFF IN ATTENDANCE (PART OF ITEM 5.1)	
Mark Kewley (MK)	Programme Director, London SDE, NHS England (London Region)

1	Welcome and Introductions: The AGD Chair welcomed attendees to the meeting.
2	Review of previous AGD minutes: The minutes of the AGD meeting on the 11 th September 2025 were reviewed and, after several minor amendments, were agreed as an accurate record of the meeting.
3	Declaration of interests: Claire Delaney-Pope noted a professional link to NIC-772509-D0L2P as part of her role within the South-East London Integrated Care System (SEL ICS). It was agreed that Claire would remain in the room but would not be part of the discussion of this application.
4 BRIEFING PAPER(S) / DIRECTIONS:	
4.1	<p>Title: OpenSAFELY Draft Application Process</p> <p>Presenter: Terry Service</p> <p>Observer: Dickie Langley and Rachel Fernandez</p> <p>Previous Reviews:</p> <p>The NHS OpenSAFELY Data Analytics Service Pilot Directions 2025, published in June 2025, instruct NHS England to establish a secure data analytics service using the OpenSAFELY technology to enable the running of queries on pseudonymised GP and NHS England patient data held by GP IT system suppliers within the GP System Suppliers secure environments and obtain outputs for specific purposes.</p> <p>The process of managing applications to access GP data using these Directions is under development in collaboration with NHS England and the Bennett Institute for Applied Data Science and is broadly in line with existing NHS England Data Access Request Service (DARS) process and is being refined.</p> <p>The purpose of the briefing paper and supporting documents, is to provide the Group with the relevant information in advance of the AGD plenary meeting on the 25th September 2025, where two ‘test’ applications under the pilot Directions are scheduled for review.</p> <p>Outcome of discussion: AGD welcomed the briefing paper and supporting documents and made the following observations / comments:</p> <p>4.1.1 AGD noted the contents of the briefing paper and the supporting documents provided, and advised that they were supportive of the OpenSAFELY governance aligning with other access routes to NHS England data.</p> <p>4.1.2 AGD noted and queried the information provided in respect of opt-outs, and advised that AGD felt that the information provided across the various supporting documents did not align, and was difficult to understand. Additionally, the Directions exemptions to Type One objections, and it was advised that public engagement and involvement was necessary to inform any changes in policy on opt-outs.</p>

	<p>4.1.3 The Group discussed the draft 'Profession Advisory Group' (PAG) Terms of Reference (ToR), provided as a supporting document; and reiterated the point previously made by both the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) and AGD, that they would be supportive of PAG reviewing applications in common with AGD.</p> <p>4.1.4 AGD made a number of comments on the PAG ToR including noting the statement in the PAG ToR "...precedents will be subject to approval by PAG, SIRO and AGD and may be audited via AGD..."; and suggested that this was updated, to accurately reflect that AGD provide advice to NHS England's SIRO; and that they undertake oversight and assurance, as opposed to audit. In addition, the NHS England SIRO Representative suggested that this statement was also amended to reflect that, subject to finalised PAG ToR, PAG provide advice to NHS England and do not provide approval, nor advice to AGD.</p> <p>4.1.5 AGD noted that Data Provision Notice (DPN) that had been provided as a supporting document, and suggested 1) this was updated to reference the role of PAG; and 2) a link to the DPN Specification Framework.</p> <p>4.1.6 The Group were advised by NHS England that there would be a period of consultation with the profession on the PAG ToR, and that comments provided by the Group, would be considered prior to this. The NHS England SIRO Representative requested that the Group were updated on the outcome of the consultation as may be appropriate.</p> <p>4.1.7 AGD were also advised advice that the 'test' applications that the Group would review at the AGD plenary meeting on the 25th September 2025, have not been reviewed by PAG as yet.</p> <p>4.1.8 The Group thanked NHS England for the information provided prior to and in the meeting, which would support the discussion at the AGD plenary on the 25th September 2025.</p>	
5 EXTERNAL DATA DISSEMINATION REQUESTS:		
5.1	<p>Reference Number: NIC-772509-D0L2P</p> <p>Applicant: Information Governance Services</p> <p>Data Controllers: NHS North Central London ICB, NHS North East London ICB, NHS North West London ICB, NHS South East London ICB, NHS South West London ICB</p> <p>Application Title: "OneLondon Secure Data Environment (The OneLondon SDE)"</p> <p>Attendee: Mark Kewley (not present for the review / discussion of the application by AGD)</p> <p>Observers: Dan Goodwin and Louise Dunn</p> <p>Previous Reviews: The application and relevant supporting documents were previously presented / discussed at the meeting on the 20th March 2025.</p> <p>Application: This was a new application.</p> <p>NHS England were seeking advice on the following points, including general advice on any other aspect of the application:</p> <ol style="list-style-type: none"> 1. Noting the differences between this application and the proposals from other regional SDEs, whether NHS England should support the requested dataflows for all of the three purposes specified. 	

2. The proposed processes for data access being requested and approved as documented in section 4 of the application.
3. Are the controls outlined in section 4 sufficient to ensure that the identifiable data is used appropriately.
4. Does AGD support this application; if not, what are the specific concerns and what could the applicant do to address them.

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

Prior to the review / discussion of the application by AGD, and prior to AGD providing advice to the NHS England SIRO Representative, Mark Kewley attended the meeting to provide a brief overview to the Group on the work being undertaken by The OneLondon SDE. The Group thanked Mark for attending the meeting, and for the brief overview and update provided around The OneLondon SDE.

Outcome of discussion: The Group were broadly supportive of the purpose outlined in the documentation provided, but were **not** supportive of the application **at this time** and wished to draw to the attention of the SIRO the following substantive comments, and suggested the application be brought back to a future meeting:

5.1.1 AGD noted that as part of an NHS England Data Access Request Service (DARS) pilot (discussed at the AGD meeting on the 7th August 2025), the Group had been provided with a new NHS England DARS application form that contained summary information that, once finalised, would be included in the data sharing agreement (DSA).

In response to points 1 to 4:

5.1.2 AGD noted that one of the aims of the application was to make the data available to third parties for the purpose of direct care. The Group expressed concern that there was **not** a clear definition set out of what was meant by 'direct care', which was particularly needed given that some of the examples given did **not** appear to be direct care. It was noted that this was an evolving area, and AGD suggested that OneLondon and NHS England ensure that the direct care uses clearly and completely aligns with current policy.

5.1.3 AGD suggested that the audit and oversight processes for the direct care purposes needed to be clear, and that NHS England should consider whether this could be best achieved by having a separate data sharing agreement (DSA) for the direct care purposes of the application; and suggested that NHS England discuss this further with the applicant.

5.1.4 AGD noted that part of the data proposed to be accessed for direct care would capture details on ex-residents and deceased individuals' care; and suggested that NHS England explore this further with the applicant given that direct care would appear **not** to support such a flow, and that the application was updated as needed.

5.1.5 AGD queried what the process was for rectifying data that was incorrect in the dashboards that would be created to support direct care; and suggested that NHS England explore this further with the applicant, and that the application was updated with further information.

5.1.6 AGD advised that assurances were sought and documented as to how it would be ensured that data required for the purpose of direct care is only accessed by the appropriate individuals.

	<p>5.1.7 AGD noted that the Health Research Authority Confidentiality Advisory Group (HRA CAG) support was in place, however, was conditional on a number of issues, including, but not limited to, providing outputs of further public involvement on the acceptability of using confidential patient information without consent. The Group suggested that NHS England satisfy itself that the HRA CAG support was unconditional, and that a copy of the unconditional support documentation was uploaded to NHS England's customer relationship management (CRM) system.</p> <p>5.1.8 AGD suggested that further information was provided on 1) the controls in place for the separation of data; and 2) how the appropriate data is being used for the appropriate purpose.</p> <p>5.1.9 AGD noted that as currently described, the application suggests that there is only one process, however advised that, given the complexity of the data flows, and the distinct different purposes, legal basis, and the application of the National Data Opt-out that the application was updated with further granular details.</p> <p>5.1.10 AGD noted that the Data Controllers outlined in the application, did not align with other supporting documents provided, for example, the Data Protection Impact Assessment (DPIA); and suggested that this was reviewed and updated as appropriate to ensure the correct information was reflected, in line with NHS England DARS Standard for Data Controllers.</p> <p>5.1.11 The AGD Caldicott Guardian Team Representative stressed the importance of ensuring the Caldicott Guardians in the Integrated Care Boards (ICBs) and NHS Trusts are given sufficient resources, training, peer support etc, noting that they may not have had to support access to this type of data previously.</p> <p>5.1.12 AGD queried how the work outlined in the application would align with the development of the Single Patient Record (SPR); and noting the risks of non-alignment suggested that this was aligned with current discussion and policy within NHS England on the SPR.</p> <p>5.1.13 AGD noted and commended NHS England Data Access Request Service (DARS) and the applicant for the work undertaken on this application to date, including, but not limited to, the responses / actions to the previous points raised by the Group on the 20th March 2025.</p> <p>In addition, AGD made the following observations on the application and / or supporting documentation provided as part of the review:</p> <p>5.1.14 The NHS England SIRO Representative thanked AGD members / delegates for their time spent reviewing this application and for the advice provided, noting the complexities outlined / discussed.</p> <p>5.1.15 AGD noted that there was a commercial aspect to the application.</p>	
5.2	<p>Reference Number: NIC-780520-H6M3S</p> <p>Applicant and Data Controller: Health Data Research UK (HDRUK)</p> <p>Application Title: "Big Data for Complex Disease Programme"</p> <p>Application: This was a seeking early advice application.</p>	

	<p>NHS England were seeking general advice on the proposals in advance of a future 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 providing advice as requested by NHS England, and made the following observations on the documentation provided as part of the review.</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>5.2.1 AGD noted that as part of an NHS England Data Access Request Service (DARS) pilot (discussed at the AGD meeting on the 7th August 2025), the Group had been provided with a new NHS England DARS application form that contained summary information that, once finalised, would be included in the data sharing agreement (DSA).</p> <p>5.2.2 AGD noted the concept outlined in the draft application and suggested that this was worthy of further investigation, including, but not limited to, the checks and balances.</p> <p>5.2.3 The Group suggested that, with the appropriate governance structures, the proposed work outlined could be run as a ‘pilot’ with a form of oversight and assurance, for example, by AGD; and suggested that NHS England explore this further with the applicant / internal NHS England colleagues.</p> <p>5.2.4 AGD noted that there was an ‘Approvals and Oversight Board of the Big Data for Complex Disease Programme – Population Data Resource’; and queried if there were appropriately defined parameters for the Board to operate within, including, but not limited to, 1) the quoracy of Board members required to provide approval; 2) whether the scope of “<i>complex disease</i>” is clearly defined; and 3) if the inclusion criteria are clearly defined, for example, around certain commercial applications, noting that organisations may have access to data that they may not have access to if they had applied via the usual NHS England Data Access Request Service (DARS) route.</p> <p>5.2.5 AGD noted that the information within the draft application and the ‘Approvals and Oversight Board Annex A – Project Review / Triage / Approval Process and Guidance’ document, contained information in respect of AI and machine learning; and suggested that this information was reviewed and updated to ensure it was aligned and noted the correct information.</p> <p>5.2.6 Separate to the application and for NHS England to consider: AGD suggested that NHS England consider producing a policy on AI and machine learning.</p> <p>5.2.7 AGD noted references in the draft application to the data, within the NHS England Secure Data Environment (SDE) for this programme which imply it is not ‘personal data’. The Group suggested that NHS England and HDRUK discussed this further, to ensure that both organisations have a shared understanding on the status of the data, and one that was consistent with other applications.</p> <p>In addition, AGD made the following observations on the application and / or supporting documentation provided as part of the review:</p> <p>5.2.8 Noting AGD was only asked to advise on specific points reviewed, no AGD member noted any substantive commercial aspects.</p>	<p>SIRO Rep</p>
--	---	---------------------

5.3

Reference Number: NIC-589868-W0K1B-v1.4

Applicant and Data Controller: University of Sheffield

Application Title: "CUREd+ Centre for Urgent and Emergency Care Research Database"

Observer: Jodie Taylor-Brown

Previous Reviews: The application and relevant supporting documents were previously presented / discussed at the AGD meeting on the 3rd August 2023.

Application: This was an amendment application.

NHS England were seeking advice on the following points only:

1. The two amendments outlined to **1)** expand access to the CUREd+ research database to 'Approved Researchers' including commercial collaborators; and **2)** the update to section 5(e) (Is the Purpose of this Application in Anyway Commercial), changed from no to yes, to account for the allowance of 'Approved Researchers' from commercial collaborator organisations to access and analyse CUREd+ data as part of collaborative research projects led by the University of Sheffield.

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

Outcome of discussion: AGD were **not** supportive of the application **at this time** and wished to draw to the attention of the SIRO the following significant comments, and suggested that the application be brought back to a future meeting:

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.

In response to point 1:

5.3.1 AGD noted that at the AGD meeting on the 3rd August 2023, they had queried whether access could be extended to other researchers, noting the useful processing and outputs expected from this application; and therefore, commended the applicant on the proposed amendment in respect of this. The Group did however, suggest that the governance to support this is amended to reflect one of NHS England's usual mechanisms for supporting sharing of data **with** other researchers, which could include one of the following options: **1)** joint data controllership in line with [NHS England DARS Standard for Data Controllers](#); **2)** an honorary contract in line with [NHS England's DARS Standard for Honorary Contracts](#); **3)** a sub-licencing agreement in line with [NHS England DARS standard for sub-licencing and onward sharing](#) or **4)** Researchers **only** accessing data that was aggregated with small numbers suppressed and sufficiently derived, so the data could no longer be classed as NHS England data. The Group suggested that, in this instance, a sub-licence might be the appropriate option, and would give NHS England the requisite contractual control in respect of the end users of the data, and was consistent with other similar arrangements for other applicants.

5.3.2 AGD noted the governance arrangements outlined in the application, for example, the CUREd+ Data Access Committee (DAC) and the CUREd+ Data Access Request Form (DARF) that the DAC were responsible for. The Group did however suggest that further clarification was added to the DAC Terms of Reference, in respect of **1)** the roles of the DAC members including the quoracy rules and voting system; **2)** how the balance between public

<p>and commercial benefits was assessed and was proportionate, in line the NDG guidance on benefits; and 3) consideration was given to having an independent DAC Chair, noting that, as currently drafted, the current DAC Chair would be precluded from the discussion of the majority of applications due to their involvement with a number of applications.</p> <p>5.3.3 AGD noted from the internal NHS England Data Access Request Service (DARS) Escalation From, that, in order to be designated 'Approved Researchers' by DAC, researchers must be collaborating with a Principal Investigator from the Sheffield Centre for Health and Related Research; and suggested that this should be reviewed, noting that this was quite restrictive.</p> <p>5.3.4 AGD suggested that all of the key points from the commercial aspect of the application outlined in section 5(e) (Is the Purpose of this Application in Anyway Commercial), were replicated / expanded for transparency in (the published) section 5(a) (Objective for Processing), in line with NHS England's DARS Standard for Commercial Purpose.</p> <p>In addition, AGD made the following observations on the application and / or supporting documentation provided as part of the review:</p> <p>5.3.5 AGD reiterated the point raised by the Group on the 3rd August 2023 (point 5.5.11), in that, noting the applicant was in receipt of sensitive General Practice (GP) codes, and noting that conclusions could be drawn about GP practices or Primary Care Network (PCN) performance, suggested that a special condition be included in section 6 (Special Conditions) that no GP practice or PCN could be identified in any published outputs. AGD noted that the study had not been designed to address GP / PCN performance and the applicant was not receiving all the necessary data to accurately access GP / PCN performance, for example, the applicant would need other contextual data to make these such outputs robust.</p> <p>5.3.6 AGD suggested that the Medicines dispensed in Primary Care (NHSBSA data) special condition in section 6 (Special Conditions) was reviewed and updated by NHS England, to remove any restrictive wording that is no longer relevant; but suggested that the 'suppression methodology' remained.</p> <p>5.3.7 AGD noted the refence to AI machine learning in the supporting documents provided, and suggested that further information on this was added to section 5 (Purpose / Methods / Outputs) of the application.</p> <p>5.3.8 AGD suggested that the yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits) were reviewed and edited to 1) ensure that only information on the yielded benefits was reflected, in line with NHS England DARS Standard for Expected Measurable Benefits; and 2) the expected timing of the yielded benefits was noted.</p> <p>5.3.9 The NHS England SIRO Representative queried the yielded benefit in section 5(d) (iii) "<i>The Risk of Adverse Outcomes after a Suspected Seizure Study (RADOSS)</i>"; and suggested that 1) clarification was sought as to whether medical devices or decision-making tools would be developed as result of this; and 2) if medical devices or decision making tools would be developed, that the applicant satisfies itself that the appropriate permissions had been obtained for this.</p> <p>5.3.10 AGD noted that there was a commercial aspect to the application.</p>	
---	--

<p>5.4</p>	<p>Reference Number: NIC-759203-S1P1T-v0.6</p> <p>Applicant and Data Controller: St George's University Hospitals NHS Foundation Trust</p> <p>Application Title: "Impact of renal impairment on immediate and long-term outcomes in acute heart failure patients in England over the last 15 years"</p> <p>Observer: Madeline Laughton</p> <p>Application: This was a new application.</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>5.4.1 AGD noted in the NHS England internal application assessment form, that NHS England's Data Access Request Service (DARS), had queried with the applicant whether the work described in the application was "<i>service evaluation</i>" as outlined, or was in fact "<i>research</i>"; and that the applicant had confirmed that it was service evaluation. AGD advised that there were a number of factors that suggested the work outlined was "research", including, but not limited to, aim number six in section 5(a) (Objective for Processing) to "<i>develop a risk prediction tool for adverse outcomes in patients with acute heart failure</i>". Notwithstanding the questions already asked by NHS England, AGD suggested that 1) NHS England explore this point further with the applicant, and that this could be mapped against the Health Research Authority Decision Making Tool; and 2) the application was updated as appropriate to reflect the correct / factual information, in line with NHS England's DARS Standards.</p> <p>In addition, AGD made the following observations on the application and / or supporting documentation provided as part of the review:</p> <p>5.4.2 AGD noted the planned patient and public involvement and engagement (PPIE) in section 5(a); however, suggested that 1) PPIE was undertaken prior to the applicant having access to the data; and 2) there was ongoing PPIE throughout the lifecycle of the work. The HRA guidance on Public Involvement is a useful guide.</p> <p>5.4.3 AGD noted the statement in section 5(b) (Processing Activities) that "<i>St Georges Hospital NHS Foundation Trust stores data backup on the Cloud...</i>"; and suggested that NHS England explore this further to determine whether 1) if this was the Cloud storage of one of the Data Processors; or 2), if the Cloud storage was being provided from another entity, then the application should be updated as appropriate, in line with the NHS England DARS Standard for Data Processors.</p> <p>5.4.4 AGD noted the information in section 5(b) that referred to internal NHS England data flows, and suggested that this was removed, noting that this was not necessary to include.</p> <p>5.4.5 AGD noted in section 5(d) (Benefits) (ii) (Expected Measurable Benefits to Health and / or Social Care) that a risk assessment tool was being developed; and suggested that NHS England this further with the application, for example, to determine whether 1) any other software that was required to support the development of the tool; 2) any other parties that</p>	
-------------------	---	--

	<p>are involved; and 3) will the data requested support the development of the tool, or are further data flows required.</p> <p>5.4.6 Noting the volume of data requested, AGD (including the clinicians on the Group) discussed data minimisation and agreed that, on balance, there was a justification for this volume of data given the desired outcomes. AGD did however note that it would have been helpful to have received information on the NICOR data fields, to support the discussion / understanding.</p> <p>5.4.7 Separate to the application and for NHS England to consider: AGD suggested that NHS England Data and Analytics consider providing AGD with information on the NICOR data fields requested by applicants.</p> <p>5.4.8 In addition, AGD suggested that NHS England clarify with the applicant whether all of the service evaluation aims can be achieved with the data that will be accessed, for example, it was unclear if the 'doses' are recorded in the NICOR dataset, which would be relevant to the application.</p> <p>5.4.9 No AGD member noted a commercial aspect to the application.</p>	D&A Rep / SIRO Rep
5.5	<p>Reference Number: NIC-776828-L9R1G-v0.10</p> <p>Applicant: University Hospitals Birmingham NHS Foundation Trust</p> <p>Data Controller: The University of Manchester</p> <p>Application Title: "Routinely collected treatment data to evaluate the uptake and utility of UK paediatric early phase trial infrastructure"</p> <p>Observer: Tiaro Micah</p> <p>Previous Reviews: The application and relevant supporting documents were previously presented / discussed at the AGD meeting on the 7th August 2025.</p> <p>Application: This was a new application.</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: The majority of the Group were not supportive of the application at this time; a minority of the Group were supportive of the application. The Group wished to draw to the attention of the SIRO the following substantive comments:</p> <p>5.5.1 AGD noted the responses made to the previous points raised by the Group on the 7th August 2025, and in respect of the point made on linkage (5.3.1), noted that some of the linkage was being done under consent, and advised that based on the consent materials provided (version 4.0), that there was a legal gateway for this linkage. The Group did however suggest that NHS England satisfy itself that any earlier or later versions of the consent contain similar text that also provides a legal gateway in consent.</p> <p>5.5.2 AGD noted that NHS England were dealing with a cohort under consent and s251, with the national data opt-out being applied to both; the Group suggested that NHS England should consider how this can be addressed, for example, via two separate data sharing agreements.</p>	

	<p>5.5.3 AGD also noted that some members of the cohort may now be over the age of 16, and that NHS England should explore with the applicant how consent for these individuals will be managed, for example advice could be sought from their Health Research Authority Research Ethics Committee (HRA REC).</p> <p>5.5.4 AGD noted in the consent materials provided (version 4.0), that the Institute for Cancer Research (ICR) was the Data Controller and would be responsible for looking after participants' information and using it properly; and noting that this was not reflected in the application, advised that there was an ethical obligation to ensure it is honoured. The Group suggested that NHS England explore this further with the applicant; and that the application was updated as may be appropriate, in line with NHS England DARS Standard for Data Controllers.</p> <p>5.5.5 AGD suggested that in respect to the points raised by the Group on the 7th August 2025, in respect of transparency obligations (5.3.6), ICR involvement may be pertinent, given that participants would be unlikely to find out about the processing via the West Midlands Secure Data Environment (SDE) website. AGD suggested that was explored further by the applicant, once the role of ICR has been established.</p> <p>5.5.6 AGD suggested that in respect to the points raised by the Group on the 7th August 2025, in respect of data controllership and the University of Manchester (5.3.3); and noting the response that "<i>Licensing agreements put in place for each researcher organisation...</i>", suggested that NHS England satisfy itself, that if any researchers are accessing NHS England data covered via this application, then there would need to be an appropriate pathway for this, which would either be 1) joint data controllership in line with NHS England DARS Standard for Data Controllers; 2) an honorary contract in line with NHS England's DARS Standard for Honorary Contracts; 3) a sub-licensing agreement in line with NHS England DARS Standard for Sub-licensing and Onward Sharing of Data.</p> <p>In addition, AGD made the following observations on the application and / or supporting documentation provided as part of the review:</p> <p>5.5.7 The Group welcomed the application and noted that they were supportive of the aims of the application.</p> <p>5.5.8 No AGD member noted a commercial aspect to the application.</p>	
<p>5.6</p>	<p>Reference Number: NIC-393510-D6H1D-v11</p> <p>Applicant and Data Controller: University College London (UCL)</p> <p>Application Title: "Children and Families Policy Research Unit and Great Ormond Street Hospital Biomedical Research Centre"</p> <p>Observer: Jodie Taylor-Brown and Joe Lawson</p> <p>Previous Reviews: The application and relevant supporting documents were previously presented / discussed at the AGD meeting on the 4th May 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) meetings on the 26th May 2022, 17th February 2022, 4th March 2021, 27th June 2019 and the 20th July 2017.</p>	

Linked applications: This application is linked to NIC-419453-G3G1G, NIC-381972-Q5F0V and NIC-196263-J9Q7Z.

Application: This was an amendment application.

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

1. The permitted use of the data and controls in place;
2. Has the process by which projects are agreed been sufficiently defined;
3. Are the roles of the parties involved (i.e. UCL and the Department of Health and Social Care (DHSC)) clearly defined.

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

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

AGD noted that they had been provided with a curated set of documentation and noted that they would be providing observations based on these documents.

5.6.1 AGD noted that as part of an NHS England Data Access Request Service (DARS) pilot (discussed at the AGD meeting on the 7th August 2025), the Group had been provided with a new NHS England DARS application form that contained summary information that, once finalised, would be included in the data sharing agreement (DSA).

In response to points 1 to 3:

5.6.2 AGD welcomed the student access with the appropriate supervision, and suggested that this could also be extended to undergraduate students, with the appropriate processes and supervision in place.

5.6.3 AGD noted the information in section 4.3.1 (Who is eligible to request and be given access to the data), and suggested that this was updated, to **1**) provide further clarity on the reference to “*UCL personnel*” and that this aligned with the Data Sharing Framework Contract (DSFC); and **2**) provide further clarity on the reference to the nature of the “*contract*”.

5.6.4 AGD noted the statement in section 4.3.6 (What is the end-to-end process for requesting use of the data through to approval and access?) “*All projects complete the online HRA Ethics Tool to guide whether NHS REC approval is indicated...*”; and noting the data is pseudonymised, advised that tool would have limited utility. The Group suggested that a requirement could be added to consider institutional ethical support, similar to the [NHS England DARS Standard for Ethical Approval](#).

5.6.5 AGD noted the “*deterministic and probabilistic linkage*” of mothers and babies and suggested that they would be supportive of the relevant maternity dataset flowing, which already has the linked mother and baby information, if there was the appropriate legal basis to do so.

5.6.6 In addition, AGD noted that if the data was able to be linked and the mother and baby identified, then this would call into question the identifiability of the data.

	<p>5.6.7 AGD queried the data minimisation, in particular, the reference to data for males under the age of 56 and suggested that each of the purposes outlined are linked back to the overarching premise, which is research concerning children and young people.</p> <p>5.6.8 AGD suggested that a restriction was included in the application, that no research can be undertaken that does not align with the overarching premise of children and young people, for which they have the NIHR funding.</p> <p>5.6.9 AGD suggested that section 4.10 (Special Conditions) was updated to revise the citation special condition wording, in line with NHS England DARS Standard for Special Conditions.</p> <p>5.6.10 AGD queried if they had a mechanism for identifying COVID-19 related research, given the breadth of data and the number of individuals involved in carrying out research; in order to comply with the special condition in respect of COVID-19 related research.</p> <p>5.6.11 AGD noted the stated purposes in respect of miscalculation of identifying linkage areas, and strongly suggested that this research limb was carried in collaboration with NHS England and the appropriate subject matter experts, who may be able to assist with this.</p> <p>5.6.12 No AGD member noted a commercial aspect to the application.</p>	
6 INTERNAL DATA DISSEMINATION REQUESTS:		
<i>There were no items discussed</i>		
7 EXTERNAL DATA DISSEMINATION - SIRO APPROVED / SEEKING SIRO APPROVAL		
7.1	<p>Reference Number: NIC-615960-G7W1L-v4.3</p> <p>Applicant and Data Controller: NHS Kent and Medway Integrated Care Board</p> <p>Application Title: “DSfC - Kent and Medway ICB - Comm, RS & IV”</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 26th January 2023, 6th October 2022, 25th August 2022, 4th August 2022 and the 30th June 2022.</p> <p>The SIRO approval was to permit access to commissioning datasets by a Masters Student enrolled with the University of Southampton.</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.</p> <p>AGD thanked NHS England for the written update and made the following observations on the documentation provided:</p> <p>7.1.1 AGD noted that, prior to the meeting, an AGD independent member raised the following query with the NHS England SIRO Representative in respect of 1) whether the University of Southampton has a data controllership role; and 2) whether there will be a breach of the data sharing agreement, noting that “research” is not outlined as a purpose; and section 7 (Ethics Approval) states ethics approval is not required because “<i>The data will be used exclusively for non-research purposes</i>”. The NHS England SIRO Representative advised that the Masters student was in effect working for the ICB in delivering the work,</p>	

	<p>and therefore it was not felt that the University was a joint controller. NHS England would ensure that the application was consistent in relation to its reference to research.</p> <p>The NHS England SIRO representative thanked AGD for their time.</p>	
8 OVERSIGHT AND ASSURANCE		
<i>There were no items discussed</i>		
9	<p>Data Sharing Framework Contracts (DSFC) / Data Sharing Agreement (DSA) and moving special conditions from DSA to DSFC (Presenter: Narissa Leyland)</p> <p>The Group were provided with an update / summary of the feedback / outcomes from the DSFC and Special Conditions Workshops, which were attended by some of the AGD independent members on the 23rd July 2025.</p> <p>The Group were advised that the workshops highlighted that there was duplication across the DSAs and the DSFC in respect of some special conditions; that a streamlined governance process is recommended to avoid further duplication; and that a review and update of the current version of the DSFC was required.</p> <p>The Group were advised by Narissa, that this was an ongoing programme of work, and nothing had been formally agreed in respect of implementing the proposed changes.</p> <p>AGD advised that NHS England should give further consideration to the timing of any new DSA / DSFC updates and any contractual implications this may have.</p> <p>The Group were advised by Narissa that further information presented in-meeting, would be shared (via the AGD Secretariat) following the meeting.</p> <p>ACTION: Narissa to share the in-meeting presentation with the AGD Secretariat.</p> <p>ACTION: AGD Secretariat to circulate the presentation with AGD members, once received.</p> <p>AGD thanked Narissa for the work undertaken on this area of work to date, and looked forward to a further update in due course.</p>	<p>NL AGD Sec</p>
10 AGD OPERATIONS		
10.1	<p>Risk Management Framework</p> <p>The AGD Chair asked for an update on the risk management framework referred to in the Group's Terms of Reference. The NHS England SIRO Representative updated the Group that there was ongoing work with this outstanding action, and that a further update would be provided in the coming weeks.</p> <p>ACTION: The NHS England SIRO Representative to provide a written response to AGD on the progress by the end of in September 2025, of the risk management framework.</p>	<p>SIRO Rep</p>
10.2	<p>AGD Stakeholder Engagement</p> <p><i>There were no items discussed</i></p>	
10.3	<p>AGD Project Work</p> <p><i>There were no items discussed</i></p>	

11 Any Other Business

11.1 AGD independent member contractual arrangements

Following on from the discussions at the AGD meeting on the 11th September 2025 and the 4th September 2025, in respect of AGD independent member contractual arrangements with NHS England; the Group were advised, by the NHS England SIRO Representative that further discussions had taken place internally on this issue, and that an update would be shared with AGD independent members as soon as possible, noting that the new arrangements are intended to start from the 1st October 2025 for the majority of independent members.

Meeting Closure

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