Advisory Group for Data (AGD) – Meeting Minutes

Thursday, 11th January 2024

09:30 – 17:20

(Remote meeting via videoconference)

INDEPENDENT ADVISERS IN ATTENDANCE:	
Name:	**Role:**
Paul Affleck (PA)	Specialist Ethics Adviser
Claire Delaney-Pope (CDP)	Specialist Information Governance Adviser
Kirsty Irvine (KI)	Chair
Dr. Robert French (RF)	Specialist Academic / Statistician Adviser (Items 7, 10, 11.1, 11.2)
Dr. Geoffrey Schrecker (GS)	Specialist GP Adviser (Items 7, 10, 11.1, 11.2)
Jenny Westaway (JW)	Lay Adviser
Miranda Winram (MW)	Lay Adviser
NHS ENGLAND STAFF IN ATTENDANCE:	
Name:	**Role / Area:**
Garry Coleman (GC)	NHS England SIRO Representative (**Observer**: Items 7, 11.1 and 11.2)
Wendy Harrison (WH)	Interim Deputy Director of IG Delivery for Data & Analytics, Privacy, Transparency & Trust (PTT) (**Presenter:** Item 10)
Suzanne Hartley (SH)	Assurance Team, Data Access Service (DAS) (**Observer**: items 4.1 and 4.2)
Narissa Leyland (NL)	Data and Analytics Representative (Delegate for Michael Chapman)
Andrew Martin (AM)	NHS England Data Protection Office Representative (Delegate for Jon Moore)
Karen Myers (KM)	AGD Secretariat Officer, Privacy, Transparency and Trust (PTT), Delivery Directorate
Jonathan Osborn (JO)	NHS England Caldicott Guardian Team Representative

Jodie Taylor-Brown (JTB)	Applications Team, Data Access Service (DAS) (**Observer**: items 4.1 and 4.2)
Joanne Treddenick (JT)	Information Governance Lead (Data and Analytics), Privacy, Transparency and Trust (PTT), Delivery Directorate (**Presenter:** Item 10)
Vicki Williams (VW)	AGD Secretariat Manager, Privacy, Transparency and Trust (PTT), Delivery Directorate
INDEPENDENT ADVISERS NOT IN ATTENDANCE:	
Prof. Nicola Fear (NF)	Specialist Academic Adviser
Dr. Imran Khan (IK)	Specialist GP Adviser
Dr. Maurice Smith (MS)	Specialist GP Adviser
NHS ENGLAND STAFF NOT IN ATTENDANCE:	
Michael Chapman (MC)	Data and Analytics Representative
Jon Moore (JM)	NHS England Data Protection Office Representative

1	**Welcome and Introductions** The NHS England Senior Information Risk Owner (SIRO) Representative, noting the Advisory Group for Data (AGD) Terms of Reference (ToR) had not yet been agreed, proposed that: • Kirsty Irvine (as an independent adviser) will be asked to Chair the AGD meetings; • The meeting will be minuted, with advice and minutes published; • Attendees will include both independent advisers from outside NHS England and representatives from within NHS England. Attendees from NHS England include representatives covering the offices of the Data Protection Officer (DPO); the Caldicott Guardian; Data and Analytics; and the SIRO. • Attendees would not be listed as “members” in minutes during the transitional period; • NHS England representatives would not, during the transitional period, be formally part of any consensus that is reached, but would be active participants in the meeting; • It was agreed to use the Data Access Service (DAS) Standards / Precedents in relation to applications for external data sharing. The attendees present at the meeting considered the proposal put forward by the NHS England SIRO Representative and, as no objections were raised, it was agreed that the meeting would proceed on this basis.

	Kirsty Irvine noted and accepted the request from the NHS England SIRO Representative to chair; and welcomed attendees to the meeting.	
2	**Review of previous AGD minutes:** The minutes of the 14th December 2023 AGD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record of the meeting.	
3	**Declaration of interests:** Kirsty Irvine noted a personal link to Genomics England (items 4.1 and 4.2). It was agreed this did not preclude Kirsty taking part in the discussion about this item.	
EXTERNAL DATA DISSEMINATION REQUESTS:		
4.1	**Reference Number:** NIC-12784-R8W7V-v15.2 **Applicant:** Genomics England **Application Title:** Genomics England: Use of data within the National Genomics Research Library (NGRL) **Observers:** Suzanne Hartley, JodieTaylor-Brown **Previous Reviews:** The application and relevant supporting documents were previously presented / discussed at the AGD meetings on the 30th November 2023 and the 17th August 2023. The application and relevant supporting documents were previously presented / discussed at the IGARD BAU meetings on the 28th April 2022, 13th August 2020, 7th February 2019, and the 13th April 2017 The application and relevant supporting documents were previously presented / discussed at the DAAG BAU meetings on the 20th December 2016, 6th December 2016, 1st November 2016, 5th April 2016, and the 15th March 2016 **Linked applications:** This application is linked to NIC-733503-V0X9Q (item 4.2). **Application:** This was a renewal, extension amendment application The purpose of the application is for the National Genomics Research Library (NGRL), which operates as a Trusted Research Environment (TRE). The NGRL contains NHS England Data linked at record-level with data on the 100,000 Genomes Project cohort. Genomics England will also store NHS England Data linked at record-level with data on other Genomics England programmes. The amendments are to **1)** request additional data for inclusion of the data for the Genomics Medicines Service (GMS) and use of data within the NGRL; **2)** the removal of Demographics data and Patient Record Outcome Measures (PROMS) data following data destruction; **3)** updating section 5 (Purpose / Methods / Outputs)	

	to put the focus on the data being used broadly within the NGRL / Library / Genomics TRE under sublicense; **4)** Addition of the following statement in section 5(a) (Objective for Processing): *"This DSA also permits the reuse of Data from the GMS Rare Diseases or Cancer cohorts and/or from the 100K Genomes cohort alongside the Generations cohort data obtained under DARS-NIC-733503-V0X9Q".* Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** The group were supportive of the application and wished to draw to the attention of the SIRO the following comments: **4.1.1** The group noted in the internal application assessment form, that there was an outstanding query with NHS England's Privacy, Transparency and Trust (PTT) (formerly Privacy, Transparency, Ethics and Legal (PTEL)) in respect of the worldwide data usage. Noting that this query had originally been raised on the 22nd July 2022, the SIRO representative advised that outside of the meeting he would liaise with colleagues in the Data Access Service (DAS) (formerly Data Access Request Service (DARS)) and colleagues in PTT to obtain a response and to ensure that the outstanding PTT 'ticket' for this query is resolved. **4.1.2** The independent advisers noted, in the internal application assessment form, the suggestion by DAS that a possible legal basis for the worldwide data usage under UK General Data Protection Regulation (UK GDPR) could be explicit consent; however, the independent advisers cautioned against relying on explicit consent to address UK GDPR. **4.1.3** The independent advisers noted, in the internal application assessment form, that there were 73 participants that were recruited via consultee advice; and were advised by NHS England verbally, that the 73 participants had now been removed from the cohort, noting that there may be no legal gateway to disseminate data for participants recruited via consultee advice where the Data Controller is relying on Article 6(1)(f) of UK GDPR. The independent advisers noted the verbal update, however, suggested that if a legal basis for the 73 participants could be determined, they were re-included in the cohort. **4.1.4** The independent advisers noted the information on the commercial aspect of the application in (the unpublished) section 5(e) (Is the Purpose of this Application in Anyway Commercial); and suggested that this 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. **4.1.5 Separate to this application:** the independent advisers reiterated a previous request raised in IGARD and more recently in AGD, with the Data and Analytics representative, whether it would be possible for section 5(e) of the application to be published in the Data Uses Register alongside section 5(a) to section 5(d) (Benefits); and to provide feedback at a future meeting as to a resolution date.	

	ACTION: the Data and Analytics representative to come back to a future AGD meeting with a timeline for when section 5(e) of the application can be published in the Data Uses Register. **4.1.6** The independent advisers noted the published Genomics England research register but queried whether it was possible for the research registry to indicate the commercial users / uses of the data; and suggested that the applicant give this consideration as to whether the functionality was possible for transparency. **4.1.7** It was suggested by the independent advisers that, for transparency, NHS England explore with the applicant the ability to create a sub-licence register, to sit alongside the Genomics England research registry to enable the public to be aware of who has access to sub-licensed data. This would reflect similar requests to other applicants that have sub-licensed their data. **4.1.8** Noting the special condition in section 10 (Sub-licensing) of the application that stated *"…which must be maintained under change control…"*, it was suggested by the group that this was removed and updated to be explicit that any changes to the sub-licensing arrangements must be agreed in writing in advance with NHS England, and that NHS England should be provided with a tracked version copy of any updated documents. **4.1.9** It was noted by the independent advisers that the consent and transparency materials were an exemplar. They also noted the information in the internal application assessment form that NHS England were discussing further improvements with the applicant, and cautioned against too much additional information being added at the 'initial' layer for participants, noting the current information was already well structured and presented. It was suggested that any further improvements / additional information should focus on the nature of the commercial involvement and the worldwide data usage, for example, ensuring cohort members do not think an international researcher is travelling to the data in the UK, when there will be via remote access from locations outside of England and Wales. **4.1.10** The SIRO representative noted that the application was for a renewal and extension (and amendment) and noting that it could not be both a *"renewal"* and *"extension"* asked that the application was updated.	NL
4.2	**Reference Number:** NIC-733503-V0X9Q-v0.2 **Applicant:** Genomics England **Application Title:** Genomics England: Generations Study cohort data for use in the National Genomics Research Library (NGRL) **Observers:** Suzanne Hartley, Jodie Taylor-Brown **Linked applications:** This application is linked to NIC-12784-R8W7V (item 4.1).	

	Application: This was a new application. The purpose of the application is for Genomics England to receive NHS England Data linked to the Generations Study cohort and that Data will be accessed via the National Genomics Research Library (NGRL). The 3 research questions that Genomics England hope to answer are: **1)** Can we better diagnose, and therefore care for, children with rare diseases; **2)** Can we give researchers opportunities to improve their understanding of rare disease, to develop new treatments, and diagnoses, and better understand how our genes affect our health; **3)** Should we, and if so how should we, use a baby's genome throughout their lifetime as a resource they and their doctors can use if, for example, they become ill as they get older. Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** The group were supportive of the application and wished to draw to the attention of the SIRO the following comments: **4.2.1** The independent advisers noted and endorsed the points raised in the NHS England consent review (SD8) provided as a supporting document; and suggested that this should be an area of focus for the applicant, supporting the way forward outlined by DAS. **4.2.2** The independent advisers noted the information on the commercial aspect of the application in section 5(e) (Is the Purpose of this Application in Anyway Commercial); and suggested that this was replicated for transparency in section 5(a) (Objective for Processing), in line with NHS England's DAS Standard for Objective for Processing. **4.2.3 Separate to this application:** the independent advisers reiterated a previous request raised in IGARD and more recently in AGD, with the Data and Analytics representative, whether it would be possible for section 5(e) of the application to be published in the Data Uses Register alongside sections 5(a) to 5(d) (Benefits); and to provide feedback at a future meeting as to a resolution date. **ACTION:** the Data and Analytics representative to come back to a future AGD meeting with a timeline for when section 5(e) of the application can be published in the Data Uses Register. **4.2.4** The independent advisers noted the published Genomics England research register but queried whether it was possible for the research registry to indicate the commercial users / uses of the data; and suggested that the applicant give this consideration as to whether the functionality was possible for transparency. **4.2.5** It was suggested by the independent advisers that for transparency, NHS England explore with the applicant the ability to create a sub-license register, to sit alongside the Genomics England research registry to enable the public to be aware	NL

	of who has access to sub-licensed data. This would reflect similar requests to other applicants that have sub-licensed their data. **4.2.6** Noting the special condition in section 10 (Sub-licensing) of the application that stated *"…which must be maintained under change control…"*, it was suggested by the group that this was removed and updated to be explicit that any changes to the sub-licensing arrangements must be agreed in writing in advance with NHS England, and that NHS England should be provided with a tracked version copy of any updated documents. **4.2.7** The independent advisers queried the statement in section 5(a) of the application *"NHS England has commissioned Genomics England to undertake the work. NHS England does not specify what Data are required to deliver the work nor how the Data shall be processed to achieve that purpose. Such decisions are taken by Genomics England"*; and suggested that this was reviewed and updated as may be necessary to ensure it was factually correct.	
4.3	**Reference Number:** NIC-309246-L8C4C-v0.18 **Applicant:** University of Nottingham **Application Title:** The clinical and cost-effectiveness of testing for Group B Streptococcus: a cluster randomised trial with economic and acceptability evaluations (GBS3) **Application:** This was a new application. The purpose of the application is for a for the purpose of medical research which aims to evaluate routine testing of Group B Streptococcus (GBS) colonisation in pregnant women via the GBS3 trial. GBS is a bacterium present in the vagina in 25% of pregnant women. Routinely collected data will be used from NHS England and other health national data systems to answer the principal research question: *"Does routine testing of women for Group B Streptococcus (GBS) colonisation either in late pregnancy or during labour reduce the occurrence of early-onset neonatal (new-born baby) sepsis (an extreme response to an infection), compared to the current risk factor-based strategy?".* Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** The group were broadly supportive of the application if the following significant comments were addressed, and wished to draw to the attention of the SIRO the following significant comments: **4.3.1** The independent advisers noted the statement in the Health Research Authority Confidentiality Advisory Group (HRA CAG) letter dated the 7th October 2019, that was provided as a supporting document (SD3.1) *"The applicant provided evidence from NHS Digital to support that it was not able to operate a project-*	

specific dissenting mechanism. As such, the national data opt-out (NDO) was being relied upon as the means for objection for the study". It was suggested that a locally managed opt-out was explored and reconsidered by NHS England, to avoid the use of the NDO, which has a wider impact on research generally.

4.3.2 In addition, the independent advisers noted the practical obstacles for parents registering an NDO for babies in this cohort, which could include having to wait several weeks until the baby is born to be able to start the NDO process and then having to complete a paper process in the days after the birth. It was suggested that this was also explored further by NHS England when considering whether a local opt-out mechanism should be operated on this or other projects.

4.3.3 Separate to the flow of data from NHS England, the independent specialist ethics adviser raised significant concerns about the design of the study, specifically in relation to whether the autonomy of the data subjects had been respected. The adviser noted that in the protocol provided as a supporting document (SD2), it was stated that the allocated test strategies would be adopted as standard clinical practice by allocated sites, when they were in fact being compared with standard clinical practice as part of a trial. Whilst verbal consent was to be taken for vaginal and rectal swabs there was **no** consent for participating in the trial (and the women might have made different decisions about whether to be swabbed if they had known they were in a trial rather than necessarily receiving national standard care). Also, there was reliance on s251 as a legal basis for setting aside the common law duty of confidentiality, when consent could have been obtained.

4.3.4 Notwithstanding the concerns raised, the independent specialist ethics adviser noted that s251 did provide a legal gateway for the data to flow, and the research could deliver public benefits. The group noted the independent adviser's concerns but were satisfied there was a legal basis to flow the data.

4.3.5 The independent advisers noted that they had reviewed the poster and leaflets for informing the study subjects and noted that they had the support of HRA CAG and the HRA Research Ethics Committee (REC). However, independent advisers were concerned that supporting documents suggested that study leaflets were only handed out when requested and were not pro-actively offered to women when they attended clinic. It seemed that posters in waiting areas may have been relied on to inform women that a study was taking place and data about them would be used, even though these might not have been seen or understood. The independent advisers noted that it was their view, based on the information provided, that not enough had been done to inform women that they were part of this study and that this was **not** part of routine care.

4.3.6 It was noted by the independent advisers that the poster was not lay / reader friendly, for example, the title contained an acronym which was not explained, and the font size was very small and could only be read if a person went to the poster to

	read it; and suggested that a leaflet would further support the transparency of the study. In addition, the group made the following observations on the application and / or supporting documentation provided as part of the review: **4.3.7** The group welcomed the application and noted the importance of the study. **4.3.8** Noting that funding for the study was only in place until the 31st May 2024, and data was due to flow after this date in June 2024; it was suggested by the independent advisers that there may be a risk that funding may end before the second drop of data, and suggested that NHS England keep this in view. **4.3.9** Noting the statement in section 5(a) (Objective for Processing) of the application that access to the data was restricted to *"…substantive employees of the University of Nottingham, University of Dundee and the University of Oxford"*; it was suggested by the independent advisers that this was reviewed and that they would be supportive of an amendment to reflect that students could access the data either now or in the future in line with due process, and advised that any students accessing the data should be compliant with all institutional rules and processes as may be appropriate. **4.3.10** The independent advisers commended the Data Access Service (DAS) (formerly Data Access Request Service (DARS) on the work undertaken to ensure the application complies with NHS England's DAS standard for data minimisation, as outlined in the internal application assessment form. **4.3.11** Noting the issues raised on this application, the group agreed that a copy of these minutes would be shared with HRA CAG and HRA REC following ratification at the AGD meeting on the 18th January 2024. **ACTION:** AGD Secretariat to ensure that a copy of the 11th January 2024 AGD minutes are shared with HRA CAG and HRA REC following ratification. **Subsequent to the meeting:** Several of the independent advisers looked again at the supporting documents provided, the study website and resources on the Internet. Their understanding was that sites would give women the RCOG/ Group B Strep Support *"Group B Streptococcus (GBS) in pregnancy and newborn babies"* leaflet, with the sites allocated to the novel testing regimes receiving an amended leaflet. The amendment being the inclusion of a brief mention of the study and a link to the trial website. It was unclear to the independent advisers why the participant information sheet could not have been provided with the original leaflet instead. This would have enabled consent to be taken for the trial including its gathering of data, or, at the very least, informed mothers of their ability to opt out of data collection. The independent advisers also questioned whether the Public and Patient Involvement (PPI) was sufficiently broad, and whether it had included enough mothers who have not experienced a Group B Streptococcus infection.	VW/KM

4.4	**Reference Number:** NIC-663093-K1B0K-v1.5 **Applicant:** Ipsos* MORI UK Limited **Application Title:** OHID**/Ipsos* Infant Feeding Survey 2023/2024 *(Office for Health Improvements and Disparities) **(Institut Public de Sondage d'Opinion Secteur Market and Opinion Research International) **Previous Reviews:** The application and relevant supporting documents were previously presented / discussed at the AGD meeting on the 28th September 2023 and 3rd August 2023. **Application:** This was an amendment application. The amendments are to **1)** update section 5(a) (Objective for Processing) to cover both the pilot and mainstage study; **2)** to update section 3(a) (Data Access Already Given) and section 3(b) (Additional Data Access Requested) to accurately reflect the data already held and data added; **3)** to update section 5(a) to cover the additional opt-outs. Prior to NHS England disseminating Extract 2, Ipsos will supply a list of individuals (name, postcode and DOB) who have opted out of the survey via an online form managed by the Infant Feeding Survey. NHS England will ensure these individuals are excluded from Extract 2.- this process was already carried out for the Pilot (2 individuals opted out). Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** The **majority** of the group were supportive of the application and wished to draw to the attention of the SIRO the following significant comments. A **minority** of the group (one independent adviser) was **not** supportive of the application **at this time**, due to the lack of detail provided with regard to the outstanding queries on the ten mothers who had received SMS reminders in error as part of the pilot. They were concerned that, depending on why these mothers should not have received a message and whether the root cause was now sufficiently addressed, that the issue might recur with this larger cohort, impacting on individual mothers and on public trust and confidence that NHS England is assuring itself that data recipients are able to handle data with sufficient care. **4.4.1** The group noted that there had been an incident, whereby Ipsos MORI had recently sent ten mothers SMS reminders who shouldn't have received any further communication, due to an incorrect file being downloaded by the applicant. The group noted steps had been taken to prevent a recurrence but also noted that there was limited information provided on the women affected or the file downloaded, and it was suggested by the independent advisers that NHS England seek further information / clarification on this, for example, the characteristics of the women	

	affected, what type of file and how the file had been downloaded; and that this has been appropriately handled, noting that Ipsos MORI judged it did not warrant being reported as a breach to the Information Commissioner's Office (ICO). **4.4.2** In addition, it was suggested by the SIRO representative that NHS England seek assurance from the Data Controller that the root cause of the data issue had been addressed, i.e. in respect of the incorrect file being downloaded, to reduce the risk of a similar incident occurring again in the future. In addition, the group made the following observations on the application and / or supporting documentation provided as part of the review: **4.4.3** The independent advisers noted the statement in section 5(e) (Is the Purpose of this Application in Anyway Commercial) of the application *"While this project is not commercial…"*; and suggested that this phrase was removed as it was not relevant. **4.4.4** The independent advisers noted the information on the commercial aspect of the application in section 5(e); and suggested that this was replicated for transparency in section 5(a) (Objective for Processing), in line with NHS England's DAS Standard for Objective for Processing. **4.4.5** Noting the criteria outlined in the internal application assessment form of the participants that will be included in the sampling database, it was suggested that the reference to *"The mother known to have died"* was updated to correctly state *"The mother **not** known to have died"*. **4.4.6** The independent advisers noted the statement in section 7 (Ethics Approval) of the application *"Ethics approval is not required because the data will be used exclusively for non-research purposes"*; however, suggested the uses of the word 'research' and 'researchers' in the application were reviewed in the light of this statement and the work being supported by a non-research Health Research Authority Confidentiality Advisory Group (HRA CAG) application, provided as a supporting document.	
4.5	**Reference Number:** NIC-674822-S2K9T-v0.4 **Applicant:** University of Oxford **Application Title:** The Children's Surgery Outcome Reporting research database (CSOR) - DigiTrials Comms Service - Patient List Update Service **Previous Reviews:** The application and relevant supporting documents were previously presented / discussed at the AGD meeting on the 21st September 2023 and the 27th July 2023. **Linked applications:** This application is linked to NIC-608743-H5X9Z (item 4.6). **Application:** This was a new application. The purpose of the application is for a study to investigate whether it is possible to collect paediatric surgical outcomes data, using a system that links routinely	

	collected health data and parent reported outcomes data and provides a platform for centre specific feedback of outcomes in order to reduce unwarranted outcome variation. The request is for NHS England to undertake Vital Status checks of the cohorts of very young children to ensure they have not passed away before sending out communications to their parents or guardians related to the project, The Children's Surgery Outcome Reporting research database (CSOR). Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** The group were supportive of the application and wished to draw to the attention of the SIRO the following comments: **4.5.1** The group noted and were supportive of how the points raised at the AGD meeting on the 21st September 2023 had been addressed**;** however suggested that points raised in respect of the National Data Opt-out (NDO) (point 5.2.7) and the concern raised on the number of reminders and contact methods (point 5.2.8) would be raised directly with HRA CAG at the AGD meeting on the 25th January 2024, which HRA CAG are scheduled to attend. **4.5.2** Noting the statement in section 3(b) (Additional Data Access Requested) of the application *"Limited to a cohort of participants in the CSOR Trial"*; it was suggested by the independent advisers that this was updated to reflect that it also includes *"invitees"* and not just participants. **4.5.3** The independent advisers noted the statement in section 5(a) (Objective for Processing) of the application *"National Data Opt-Outs (NDO) will be upheld"*; and suggested that NHS England consider whether applying the NDO to the entire cohort is compatible with the NDO policy, i.e. in relation to data subjects who have provided the consent. It was noted that the usual advice would be to split the application into two separate applications for those who have provided consent, and those who have not provided consent, so that the NDO is only applied to the relevant section of the cohort. A concern was noted that NHS England would not be respecting the choices of the data subjects that had provided consent for the study and had an NDO.	
4.6	**Reference Number:** NIC-608743-H5X9Z-v0.2 **Applicant:** University of Oxford **Application Title:** Children's Surgery Outcome Reporting (CSOR) Research Database - Clinical Data **Linked applications:** This application is linked to NIC-674822-S2K9T (item 4.5) **Application:** This was a new application.	

	The purpose of the application is for a programme, which is working to improve the health and wellbeing of children with surgical conditions. There are six main workstreams to this programme of work, with the overall aim of the programme to investigate whether it is possible to collect paediatric surgical outcomes data using a system that links routinely collected data and parent reported outcome data and provides a platform for centre specific feedback of outcomes in order to reduce unwarranted outcome variation. The data covered by this data sharing agreement (DSA) is for workstream 4 - Developing the CSOR research database to collect the minimum dataset from multiple sources. Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** The group were supportive of the application. The group made the following observation / points of advice on the application and / or supporting documentation provided as part of the review: **4.6.1** The group noted that the application had s251 support from the Health Research Authority Confidentiality Advisory Group (HRA CAG); however in respect of the content of the application provided, it was agreed that this needed to be updated to ensure it was streamlined, and much more focussed on the use of the specific data requested, since it currently contained a lot of future or proposed processing which was not relevant for this particular project. **4.6.2** In addition, it was suggested that where the application refers to using the data to consent parents, for example the statement in section 5(a) (Objective for Processing) of the application *"These contact details will be used to contact and obtain consent from parents…"*; it needs to be clearer that the data is being used to *"…**engage** with the parents to participate in the CSOR programme to provide parent-proxy reported quality of life data about their child"*. **4.6.3** The independent specialist Information Governance adviser noted that they were happy to provide support to colleagues in Data Access Service (DAS) (formerly Data Access Request Service (DARS)) both at a future meeting and out of committee, to progress this application and better understand the specific project. **4.6.4** Noting the statement in section 5(b) (Processing Activities) of the application "*Where consent is not received from parents, all identifiable data will be removed within 13 months of being received*"; the independent advisers suggested that a robust justification was provided for the data being held for 13 months, noting this seemed excessive.	
4.7	**Reference Number:** **Applicant:** Integrated Care Boards / NHS England	

	Application Title: An amendment for Commissioners to receive: NDRS Cancer Registry / NDRS Cancer Pathway / NDRS Rapid Cancer Registrations **Application:** This was an amendment application. The application is for a Class Action amendment for Commissioners to receive National Disease Registration Service (NDRS) Cancer Registry, NDRS Cancer Pathway and NDRS Rapid Cancer Registrations data. Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** The group were supportive of the class action application for the provision of NDRS data to ICBs, and wished to draw to the attention of the SIRO the following comments: **4.7.1** The independent advisers noted that the application provided was **not** the main data sharing agreement (DSA), nor had they been provided with the main DSA as a supporting document; and, noting that it was currently unclear, queried whether the information in this application would be copied across to the main DSA, or whether this was a side agreement to the main DSA (and if the latter, how it would be executed so as to ensure it was a legally binding and enforceable contract for each of the individual applicants). **4.7.2** The independent advisers queried how the details of this application would be made transparent to the public; noting that if this is a side agreement to the main DSA, then this would **not** be published on the Data Uses Register; and suggested that NHS England gave this further consideration. **4.7.3** The independent advisers suggested that NHS England ensure that the stated functions and proposed activities with the data, are within the permitted remit of ICBs and commissioners. **4.7.4** It was suggested by the independent advisers that Cancer Alliances, which the ICBs are a part of, may get the same data; and if so, to clarify if there will be different uses for the data; noting there is a risk to NHS England from the perspective if data is flowing for the same purpose twice, i.e. in terms of over processing data. **4.7.5** The independent advisers noted that any similar class action applications submitted to AGD for review, should have considered all of the points raised above prior to submission and that all relevant information be provided as supporting documentation.	
EXTERNAL DATA DISSEMINATION - SIRO APPROVED / SEEKING SIRO APPROVAL		
5.1	**Reference Number:** NIC-682048-S9P4H-v1.2 **Applicant:** LA-SER Europe Limited	

	Application Title: Clinical and economic burden of graft versus host disease in allogeneic stem cell transplant recipients in England – A retrospective cohort study **Previous Reviews:** The application and relevant supporting documents had previously been presented / discussed at the AGD meeting on 21st September 2023 The SIRO approval was for an amendment to the data sharing agreement (DSA). **Outcome of discussion:** The group noted that the NHS England SIRO had already provided SIRO approval. The group thanked NHS England for the written update and made the following observations on the documentation provided: **5.1.1** The group noted that prior to the meeting, the independent advisers had raised some queries directly with the SIRO representative, in respect of **1)** providing a justification why CSL Behring Incorporated is not considered a Data Controller (if they are a Sponsor); **2)** the clear distinction and role of each legal entity. **5.1.2** It was noted that the SIRO representative and independent advisers had discussed the queries raised prior to the meeting and the SIRO had provided an update out of committee: **1)** this would need to be explored further; and **2)** the distinction and role of each legal entity has been discussed with the applicant, i.e. LA-SER Europe Limited and Cetara France S.A.R.L. and has been accurately described in the application. The NHS England SIRO representative thanked the group for their time. **Subsequent to the meeting:** The SIRO Representative noted that CSL Behring were the sponsor, noting that the Director of Privacy, Transparency and Trust (PTT), had confirmed to the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) in early 2021, that the NHS Health Research Authority (HRA) guidance on 'Controllers and personal data in health and care research' states that study sponsors are automatically deemed data controllers and if they are not, then NHS England should include a rebuttal statement in section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) of the application detailing the analysis undertaken by NHS England that the study sponsor is not undertaking any data controllership activities, if supported by the facts. The SIRO Representative confirmed that CSL Behring was a funder, and that they had no influence in the management or outcome of the study and were not a sponsor and / or joint Data Controller. The group noted the update received following the meeting and suggested that the application was revised at the next opportunity as outlined above.	
5.2	**Reference Number:** NIC-656880-K7V7P-v2.8 **Applicant:** Novartis Pharmaceuticals UK Limited / Health IQ Limited	

	Application Title: Treatment Pathway of HR+/HER2- Metastatic Breast Cancer in England (ODR2021_059) **Previous Reviews:** The application and relevant supporting documents had previously been presented / discussed at the AGD meeting on the 21st September 2023. The SIRO approval was for a twelve month extension. **Outcome of discussion:** The group noted that the NHS England SIRO had already provided SIRO approval and confirmed that they were supportive of this. The group thanked NHS England for the written update and made the following observations on the documentation provided: **5.2.1** The group noted that, prior to the meeting, the independent advisers had raised some queries directly with the SIRO representative, in respect of the internal application assessment form that had not been provided as part of the meeting pack. The AGD Secretariat noted that this was an error on their part, and had on this occasion forgot to provide this in advance of the meeting; and apologised for any inconvenience caused. The NHS England SIRO representative thanked the group for their time.	
5.3	**Reference Number:** NIC-311182-N0L1Y-v8.3 **Applicant:** National Centre for Social Research (NATCEN) **Application Title:** English Longitudinal Study of Ageing (ELSA) **Previous Reviews:** The application and relevant supporting documents had previously been presented / discussed at the IGARD meetings on the 29th April 2021, 1st March 2021 and 8th February 2021. The application and relevant supporting documents had previously been presented / discussed at the DAAG meetings on the 4th October 2016, 19th July 2016, 14th June 2016 and 19th April 2016. The SIRO approval was for a three month extension. **Outcome of discussion:** The group noted that the NHS England SIRO had already provided SIRO approval and confirmed that they were supportive of this. The group thanked NHS England for the written update and made the following observations on the documentation provided: **5.3.1** The group noted that, prior to the meeting, the independent advisers had raised some queries directly with the SIRO representative, in respect of whether the applicant is aware that they can only continue to hold and process the data if a short term extension of the data sharing agreement (DSA) is in place; and whether this needs to be communicated directly from the SIRO to the applicant, to ensure they	

	are aware of their contractual responsibilities, with the applicant confirming they understand them. **5.3.2** It was noted that the SIRO representative and independent advisers had discussed the queries raised prior to the meeting and the SIRO had provided an update out of committee: that where there is a caveat from the SIRO, or a specific expectation being set, then NHS England will ensure that the customer is aware of the requirement; that may also be reinforced via a special condition in the application. The NHS England SIRO representative thanked the group for their time.	
5.4	**Reference Number:** NIC-291941-Z2Q1C-v5.15 **Applicant:** Cardiff University / Velindre University NHS Trust **Application Title:** MR1314: FRAGMATIC: A randomised phase III clinical trial investigating the effect of FRAGMin® Added to standard Therapy In patients with lung Cancer. **Previous Reviews:** The application and relevant supporting documents had previously been presented / discussed at the IGARD meeting on the 28th March 2019. The SIRO approval was for an extension and amendment for the purpose of archiving. **Outcome of discussion:** The group noted that the NHS England SIRO had already provided SIRO approval and confirmed that they were supportive of this. The group thanked NHS England for the written update and made the following observations on the documentation provided: **5.4.1** The group noted that prior to the meeting, the independent advisers had raised some queries directly with the SIRO representative, in respect of **1)** the reference in the SIRO approval form to the data sharing being *"retrospectively approved in a previous version of this DSA"*; **2)** the restrictive wording in section 5(a) (Objective for Processing) of the application in respect of restricting analysis to *"…repeating previous analyses described in this DSA"* and *"Cardiff University may not undertake different analyses to those undertaken during the original analysis"*; and **3)** why there is a December 2024 end date if the applicants wants to retain data for 15 years post-trial. **5.4.2** It was noted that the SIRO representative and independent advisers had discussed the queries raised prior to the meeting and the SIRO had provided an update out of committee: where it was confirmed that further discussions would be held with colleagues in Data Access Service (DAS) (formerly Data Access Request Service (DARS) on some of the points raised; and provided clarity that the SIRO	

	approval was to only cover a short period, such that it could then fall back into the usual system / process for approvals. The NHS England SIRO representative thanked the group for their time.	
5.5	**Reference Number:** NIC-234297-P4M5G-v4.3 **Applicant:** University College London (UCL) **Application Title:** Congenital Heart Audit: Measuring Progress In Outcomes Nationally (CHAMPION) and LAUNCHES QI: Linking AUdit and National datasets in Congenital HEart Services for Quality Improvement. **Previous Reviews:** The application and relevant supporting documents had previously been presented / discussed at the IGARD meetings on the 12th January 2023, 15th December 2022, 7th July 2021, 1st July 2021, and 3rd October 2019. The SIRO approval was for an amendment to the data sharing agreement (DSA) until the 17th December 2026. **Outcome of discussion:** The group noted that the NHS England SIRO had already provided SIRO approval and confirmed that they were supportive of this. The group thanked NHS England for the written update and made the following observations on the documentation provided: **5.5.1** The group noted that prior to the meeting, the independent advisers had raised some queries directly with the SIRO representative, in respect of the statement in section 3(c) (Patient Objections) of the application *"In line with the national data opt-out policy, opt-outs are not applied because the data is not Confidential Patient Information"*, noting that the original inflow of data from NICOR was under s251, and therefore, NHS Digital did process confidential data and should have applied the NDO. **5.5.2** It was noted that the SIRO representative and independent advisers had discussed the queries raised prior to the meeting and the SIRO had provided an update out of committee: where it was confirmed that only the amendment to purpose had been reviewed as part of this SIRO approval; and that it may be that the initial policy approach was that opt-outs did not apply if confidential data was not being released, however advised that this would be explored further. The NHS England SIRO representative thanked the group for their time.	
AGD Operations		
6	**Statutory Guidance** The independent advisers again noted the reference to reviewing materials in accordance with *"a clearly understood risk management framework"* within the published Statutory Guidance and advised that they were not aware of an agreed risk management framework, and requested that NHS England provide further	

	information/ clarity on this, noting this topic had been raised by Lord Hunt in the House of Lords on the 26th June 2023, and was answered by Lord Markham on the 5th July 2023: Written questions, answers and statements – UK Parliament. The NHS England SIRO Representative had provided further clarity on the risk management framework via email to the group, which confirmed that NHS England were asking the interim data advisory group to use the NHS England DAS Standards and Precedents model to assess the risk factors in relation to items presented to the interim data advisory group for advice; however the independent advisers noted that the wording in the statutory guidance "…*using a clearly understood risk management framework, precedent approaches and standards that requests must meet*…", suggested that the risk management framework is separate to the DAS Standards and Precedents, and asked that this be clarified by NHS England. The group noted that the Deputy Director, Data Access and Partnerships, Data and Analytics attended the meeting on the 23rd November 2023, and noted that plans for this work were in train. It had been noted previously that an Oversight and Assurance Programme of applications that had not be subject to AGD review could form part of this Risk Management Framework. **ACTION:** NHS England SIRO representative to provide a written response addressed to AGD with further clarity on the risk management framework.	GC
7	**AGD Terms of Reference (ToR)** The independent advisers noted that eight months had passed since the Statutory Guidance had been published, requiring a ToR to be agreed and published. The SIRO representative advised that following the workshop on the 27th November 2023, the draft ToR had been reviewed / updated by the Director of Privacy, Transparency and Trust (PTT); and shared with AGD for information-only prior to this meeting. The independent advisers noted that following a Freedom of Information Request the minutes from a Data, Digital and Technology Committee (DDaTC) meeting on the 12th July 2023 had been released (*Data, Digital and Technology Committee of the Board (mid 2023) – a Freedom of Information request to NHS England – WhatDoTheyKnow*) and noted that the meeting had considered the AGD draft ToR. The DDaTC minutes raised a number of concerns for AGD: AGD had not been informed that the draft ToR had been submitted to DDaTC; the AGD was not informed about any DDaTC feedback on the AGD ToR (when AGD had been previously informed that there had been no consultation or feedback on the ToR between May and November 2023); and the content of DDaTC minutes suggested a possible misunderstanding about AGD's advisory role. The SIRO Representative noted the draft AGD ToR had been socialised with DDaTC and other stakeholder including the Cyber Risk and Security Committee	

	(CRSC) and that feedback received had been updated to the draft ToR provided to AGD for the 27th November 2023 workshop. The group requested that the version control on the ToR be updated to reflect the full circulation of the document and the timing of such circulation. The Group reiterated their request to see the next draft of the ToR before it moved on to the next stage of ratification. **ACTION:** The SIRO representative to provide a copy of the final draft of the ToR prior to this document being submitted to the NHS England Board / subcommittee of the Board. In addition, the group reiterated that they looked forward to further information on the timeline for progressing the ToR, including when this would be considered by the NHS England Board / subcommittee of the Board. **ACTION:** The SIRO representative to provide further information to the group on the timeline for progressing the draft ToR, including when this would be considered by the NHS England Board / subcommittee of the Board.	GC GC
8	**Standard Operating Procedures (SOPs)** The ongoing forward plan of work for creating Standard Operating Procedures was discussed and noted that although this could not progress further without sight of the final ToR, there would be further discussion in January / February 2024 of a work plan to progress and finalise the AGD SOPs, in line with the progression of the AGD ToR.	To note
9	**AGD Action Log** The group reviewed the outstanding actions on the AGD action log, that consists of all actions captured at AGD meetings from the 2nd February 2023. The AGD Secretariat asked that if anyone had any further updates to the AGD action log, to ensure they were forwarded to the team before Wednesday so that that next iteration of the action log could be circulated prior to discussion at the next AGD meeting	ALL
10	**Education Session: Directions Briefing** Joanne Treddenick and Wendy Harrison attended the meeting, to provide an education session to the group on the following areas: • An introduction of the legal framework of NHS England in relation to transferred functions from NHS Digital • An overview, of the different types of Directions under s254 of the Health and Social Care Act 2012, including the key documentation involved • An overview of System Delivery Directions issued under Regulation 32 of the NICE Regulations	

	• To prove an overview of the IG and Governance Process Joanne agreed that it may be helpful for AGD to receive a copy of the quarterly Board report for information in relation to Directions. **ACTION:** AGD Secretariat and Joanne to plan in quarterly report submissions to AGD for information with regard to Directions. The group thanked Joanne and Wendy for the education session with regard to a Directions overview; and noting that there was not enough time to discuss specific questions relating to real world queries raised in-meeting, noted it would be helpful for the team to attend a future AGD meeting to discuss any outstanding questions and also to provide an overview of "requests". **ACTION:** AGD Secretariat to liaise with Joanne and Wendy to agree a date for a further education session with regard to any outstanding questions around Directions, and to provide an overview on "requests".	VW / KM / JT VW / KM
Any Other Business		
11.1	**Forward look for January 2024 (Presenter: Garry Coleman)** The SIRO representative provided a verbal update / overview to the group, of ongoing / future work within NHS England, and the role of AGD in supporting this, including but not limited to, the federated data platform (FDP); secure data environments (SDE); upcoming changes to the Data Security and Protection Toolkit (DSPT); how the SIRO function interacts with Data Protection Impact Assessment (DPIAs), Directions and internal uses of data; a future education session with regard to audit; the Data Protection and Digital Information Bill; and high level reflections on workload over the next 12 months. It was noted that further information would be presented to the group in due course. The group noted and thanked the SIRO representative for the verbal update and looked forward to receiving further information at future AGD meetings.	
11.2	**Independent adviser recruitment / day rate (Presenter: Garry Coleman)** The SIRO representative noted the 5% uplift to current independent adviser day / hour rates (set in 2016), in line with the NHS Agenda for Change 2023/24 pay award, had been submitted to NHS England HR in December 2023, with a hope that this new rate would be paid in January / February 2024 (alongside any back pay), as outlined by the AGD Secretariat Manager on the 14th December 2023. Following this update, the SIRO representative advised that a request for a further 10% uplift (15% in total) had been submitted to NHS England; and that this was due to be considered on the 19th January 2024, and that an update would be provided following this date.	

	The independent advisers noted and thanked the SIRO representative for the update; and looked forward to an update on or after the 19th January 2024.	
11.3	**NIC-382794-T3L3M-v8.2 at AGD 30th November 2023 – query from applicant regarding the minutes** The group agreed that the minutes from the 30th November 2023 was an accurate reflection of the discussion on the day and based on the documentation provided by NHS England for AGD to review in order to provide advice to the SIRO Representative. AGD raised in advance of the meeting with NHS England Data Access Service (DAS) the following queries, but were not provided with a response and so were unable to provide further advice on the points: a) The independent advisers noted that with regard to the minute points 4.3.2 and 4.3.3: the QResearch website states the NDO is applied (https://www.qresearch.org/information/information-for-practices and https://www.qresearch.org/information/patient-information-and-privacy-notice/). However, the NDO only applies to confidential information and the application is predicated on the data that flows to QResearch from NHS England and GP practices being non-confidential. According to the application NHS England is not applying the NDO. The QResearch protocol (https://www.qresearch.org/media/id4bahkp/qresearch-protocol-version-100.pdf) states "*Patients are excluded from the uploads if they have a read code indicating they have opted out of QResearch (EMISNQOP15) or the Summary Care Record*". It does not seem to mention the NDO so the independent advisers assume GP practices are not applying the NDO either. If QResearch are applying the NDO themselves the independent advisers would expect this, and the relevant methodology, to be explained in the protocol. If the applicant is erroneously telling data subjects, they can opt out via an NDO it raises concerns as to transparency and trust. Given transparency is a key requirement of UK General Data Protection Regulation (UK GDPR) (data must not be processed in a way that is unduly detrimental, unexpected or misleading to the individuals concerned) the customer may need to consult the Information Commissioner's Office (ICO) on these implications. b) The independent advisers noted that in relation to minute points 4.3.12 and 4.3.13 they would need to understand what these concerns were so as to determine what was "*causing confusion*". Should NHS England wish for AGD to provide further advice, they would welcome the application being brought back to a future meeting under "AOB" alongside the DAS case officer, following further discussion with the applicant.	

Meeting Closure

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