Advisory Group for Data (AGD) – Meeting Minutes

Thursday, 14th March 2024

09:30 – 16:45

(Remote meeting via videoconference)

INDEPENDENT ADVISERS IN ATTENDANCE:	
Name:	**Role:**
Paul Affleck (PA)	Specialist Ethics Adviser (items 6 and 14 only)
Claire Delaney-Pope (CDP)	Specialist Information Governance Adviser (items 6 and 14 only)
Dr. Robert French (RF)	Specialist Academic / Statistician Adviser
Kirsty Irvine (KI)	Chair
Dr. Imran Khan (IK)	Specialist GP Adviser (not in attendance for part of item 6, 13 and 14)
Dr. Geoffrey Schrecker (GS)	Specialist GP Adviser
Jenny Westaway (JW)	Lay Adviser
Miranda Winram (MW)	Lay Adviser (item 6 only)
NHS ENGLAND STAFF IN ATTENDANCE:	
Name:	**Role / Area:**
Raj Bhatt (RB)	Assistant Director of Analytics – Urgent and Emergency Care**,** Data and Analytics (**Observer:** item 4.1)
Garry Coleman (GC)	NHS England SIRO Representative
Dave Cronin (DC)	Assurance Lead, Data Governance and Assurance, Data and Analytics (**Observer**: item 5.1)
Dan Goodwin (DG)	Data Access and Partnerships, Data and Analytics (**Observer**: item 5.3)
Suzanne Hartley (SH)	Data Access and Partnerships, Data and Analytics (**Presenter**: item 6)
Tom Latham (TL)	Data and Analytics (**Observer:** item 4.1)

Narissa Leyland (NL)	NHS England Data and Analytics Representative (Delegate for Michael Chapman) (**Presenter**: item 4.2)
Abi Lucas (AL)	Data Access and Partnerships, Data and Analytics (**Observer**: item 5.1)
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
Ed Onslow (EO)	Data Set Development Lead (MSDS, CHC), Data Set Development Service, Data and Analytics (**Presenter:** item 4.1)
Jonathan Osborn (JO)	NHS England Caldicott Guardian Team Representative
Joanne Treddenick (JT)	Information Governance Lead, Privacy, Transparency and Trust (PTT), Delivery Directorate (**Observer:** item 4.1)
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. Maurice Smith (MS)	Specialist GP Adviser
NHS ENGLAND STAFF NOT IN ATTENDANCE:	
Michael Chapman (MC)	NHS England 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 7th March 2024 AGD meeting were reviewed in-meeting and subject to a number of amendments were agreed as an accurate record of the meeting; with the exception of item 15 which was reviewed out of committee by the AGD Chair and the NHS England Caldicott Guardian Team representative.
3	**AGD Action Log** The group reviewed the 'open actions' on the AGD action log, and agreed where actions could be moved to the 'non-live actions' list, or where further information was required.
4	**Declaration of interests:** Dr. Robert French noted professional links to the University of Bristol 'Avon Longitudinal Study of Parents and Children' (ALSPAC) study (NIC-152414-W3P6Q), but noted no specific connection with the application, projects, or staff involved and it was agreed this was not a conflict of interest. Dr. Robert French noted a social link with one of the Directors of the company producing the GetUBetter app (NIC-616088-L5G0W), but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest.
BRIEFING PAPER(S) / DIRECTIONS:	
4.1	**Title:** All Age Continuing Care (AACC) Directions 2024 **Presenter:** Ed Onslow **Observer:** Joanne Treddenick, Raj Bhatt, Tom Latham The AACC is a patient-level data set that will cover all aspects of AACC, where AACC refers to the following commissioned services, as described in the National Framework for NHS Continuing Healthcare and NHS-funded Nursing Care and the National Framework for

	Children and Young People's Continuing Care: **1)** NHS Continuing Healthcare (NHS CHC); **2)** NHS-funded Nursing Care (FNC); **3)** Joint packages of health and social care; and **4)** Children and Young People's Continuing Care (CYPCC). The AACC data set will capture the end-to-end commissioning of AACC services, from initial checklist through to assessment, to the commissioning and monitoring of individual care packages, regular and ad-hoc care package and eligibility reviews, and eligibility disputes. NHS England has previously been directed under section 254 of the Health and Social Care Act 2012 by NHS England under the NHS Continuing Healthcare Directions 2022 (Original Directions) to establish and operate a system for the collection of information about NHS Continuing Healthcare data, which has been collected since April 2022 for the NHS CHC Patient Level Data Set. The Original Directions purposes are to be updated and the Original Direction will be revoked and replaced by the NHS All Age Continuing Care (AACC) Directions 2024 (AACC Directions). NHS England were seeking advice on the following points: 1. To ensure that the materials provided and the approval process undertaken have ensured transparency on this extended scope of collection. 2. To advise that NHS England are relying on the new AACC Directions in relation to legal basis and purpose, and to seek AGD feedback on this approach. **Outcome of discussion:** The group welcomed the briefing paper and made the following observations / comments: **4.1.1** The group noted that they were supportive of the data collection. In response to points 1 and 2: **4.1.2** In the pack provided to the group, there was some internal inconsistency between documents with regard to the circumstances where AGD review would take place. The Chair also raised a concern that the list of potential applicants for data was not a full list of who can apply for data via the NHS England Data Access Service (DAS) and may be misleading by omission (for example not including commercial applicants in the long list of potential applicants). Accordingly, the group suggested that for future reference, the national directors' briefing paper provided as a supporting document (and any transparency materials based on these supporting documents) was uplifted with a clear statement of the assurance process for the applications requesting the AACC dataset, including, but not limited to, the route the applications will proceed down, for example, via the usual NHS England DAS process with all the appropriate transparency, checks and balances; and which of the applications would be submitted to AGD for advice (if any); and what the criteria is for applications to be submitted to AGD. **4.1.3** In addition, it was suggested by the group, that further clarification was provided within the briefing paper as to the expected benefits of processing the AACC dataset.

	4.1.4 The group also suggested that the purpose outlined in the briefing paper, be clear with regard to what the data collection will help to achieve, and the extent of the data collection, for transparency. **4.1.5** The group suggested that NHS England provide additional transparency and clarity about the dissemination of the dataset, including, but not limited to, who can apply for the dataset, how you can apply for the dataset (via NHS England DAS) and how the Common Law Duty of Confidentiality would be satisfied, and to update the briefing paper appropriately. **4.1.6** The independent advisers noted that some of the supporting documents provided, referred to NHS England seeking *"approval"* from AGD; and suggested that this reference was updated to be clear that AGD provide *"advice"* and **not** "*approval*". **4.1.7** The group looked forward to receiving the finalised briefing paper, either out of committee (OOC) or tabled at a future meeting. The group provided the following observations / comments, separate to the briefing paper: **4.1.8** The group noted that existing groups are already operating within NHS England that can provide support with patient and public involvement and engagement (PPIE) when Directions are being drafted.
4.2	**Title:** 'New' Products Briefing **Presenter:** Narissa Leyland As part of the discission of NIC-414067-K8R6J (Our Future Health) at the AGD meeting on the 18th January 2024; the group asked that NHS England's Data and Analytics provided briefing on any new data products onboarded to NHS England, including, but not limited to, the new data products included in NIC-414067-K8R6J. The briefing (**for information only**) was to advise the group that new products were present in the application for NIC-414067-K8R6J-v5.2 replacing an existing product (Demographics) which had previously been used in the absence of a more suitable product or products. NHS England's Data Access and Partnerships confirmed that there were no other new data products that require a briefing to AGD at the present time including any related to NIC-414067-K8R6J. NHS England Data Access and Partnerships are currently exploring future options around briefings on new products to AGD. **Outcome of discussion:** the group welcomed the briefing paper and made the following observations / comments: **4.2.1** The group noted that NHS England were not seeking advice on the briefing paper provided, and that this had been submitted to the group for information only. **4.2.2** The group advised that they looked forward to receiving further briefing papers when further new data products were onboarded to NHS England.
EXTERNAL DATA DISSEMINATION REQUESTS:	

5.1	**Reference Number:** NIC-604851-W0M3S **Applicant:** GRAIL Bio UK Ltd **Application Title:** SYMPLIFY Study Clinical Trial Outcomes Data Request **Observers:** Dave Cronin, Abi Lucas **Previous Reviews:** The application and relevant supporting documents were previously presented / discussed at the AGD meeting on the 23rd February 2023. The application and relevant supporting documents were previously presented / discussed at the AGD / IGARD / DAAG meetings on the 12th January 2023, 5th May 2022, 10th March 2022, 3rd February 2022, 13th January 2022 and the 15th December 2022. **Linked applications:** This application is linked to NIC-604847-S4B5L, NIC-661736-Y2Q9R, NIC-456778-J0G3H and NIC-651660-J5T6C. **Application:** This was an application seeking advice. The purpose of the application is for a multi-centre, observational study with prospective collection and retrospective analysis of blood samples to evaluate the performance of a multi-cancer early detection test within the NHS in England and Wales. An additional 12 months of follow-up data to identify where the Galleri test has been giving rise to true false positives or false negatives, compared with where both the Galleri test result and the clinical surfacing of the cancer do align, but only between 12-24 months following the initial blood draw. NHS England were seeking advice on the following points: 1. whether the mechanism proposed by the University of Oxford / GRAIL Bio UK Ltd is sufficient to address the Common Law Duty of Confidentiality for obtaining further outcomes data. 2. whether the original consent is sufficient to enable re-contact (using the NHS DigiTrials Communications Service), or whether an alternative legal basis, such as s251, is required this time around to enable further participant contact via these means (please refer to point 5.1.1). 3. on the draft letter to participants about the change in follow-up period, and whether this provides sufficient information regarding the additional processing. 4. for those participants that might have died between 12 and 24 months follow-up (as identified by the list clean), whether it should be recommended that s251 support is sought. Should an application be approved by NHS England, further details would be made available within the Data Uses Register.	

	Outcome of discussion: The group noted that they were specifically asked to provide advice in relation to the four advice points (above) with limited documentation provided, and that the remainder of the application was subject to additional work. However, to assist in the development of the application, the group provided the following advice to the SIRO representative (noting that the points may or may not be relevant once the additional detail on the application is clear): **5.1.1** NHS England advised in-meeting, that the second advice point had been updated and should state *"whether the original consent is sufficient to enable re-contact (using the NHS DigiTrials Communications Service), or whether an alternative legal basis, such as s251,* ***is required to enable re-contact using the NHS DigiTrials Communications Service****".* The group noted the updated request. In response to points 1 to 4: **5.1.2** The NHS England Data Protection Office (DPO) representative noted the time limiting statement within the patient information sheet provided as a supporting document *"We would like to collect information on the tests and appointments you have, their results, plus any diagnosis of your symptoms and how that is treated for up to* ***12 months*** *after enrolment in the study"*. **5.1.3** In addition, the NHS England DPO representative also noted that legal advice had been sought from the legacy NHS Digital's Privacy, Transparency, Ethics and Legal (PTEL) in 2022 which stated that consent would need to be expressly provided to extended follow up beyond the 12 months stated on the consent form and suggested that this was reviewed by NHS England's Privacy, Transparency and Trust (PTT), noting that some time had passed since the legal advice was originally provided by NHS Digital's PTEL and received by the Data Access Service (DAS). The group acknowledged that the DAS team had written to PTT to check if anything had changed, but they were still awaiting a response. **5.1.4** It was noted by the independent advisers that the original protocol document stated that the follow-up period would be for 12 months and that this part of the study had now concluded. It was therefore suggested by the group, that the applicant considered producing a further iteration of the protocol to include the additional follow-up proposed in the amendment. **5.1.5** The independent advisers also suggested that any new iteration of the protocol would also need updated ethical support (which would also be required for any s251 support from the Health Research Authority Confidentiality Advisory Committee (HRA CAG) if the applicant chose that route). **5.1.6** The group noted that whilst seeking s251 support was an option, a substantial justification might need to be provided as to why re-consenting would cause unbearable loss to the follow-up which would risk undermining the study.	

	5.1.7 The group suggested that the applicant considered re-consenting a living sub-population group, which could reduce the burden on the applicant and be a more efficient use of resources, to enable the applicant to focus on consent. **5.1.8** The group advised that they were supportive of the living cohort being re-contacted, and that it was their view that the option to use an opt-out approach would **not** be viable, noting how recently the consent was provided and how specific it was on the length of follow-up. **5.1.9** The group agreed with the assessment made by NHS England that extending the follow up period beyond the 12 months specified in the consent required action to address the Common Law Duty of Confidentiality, and that it was **not** a UK General Data Protection Regulation (UK GDPR) issue. The group suggested, that re-consenting the cohort would be the most desirable way to satisfy the Common Law Duty of Confidentiality, compared with a s251 approach. **5.1.10** The group noted that the applicant was in the process of looking at patient and public involvement and engagement (PPIE) options; and advised that they were supportive of this approach. **5.1.11** It was therefore suggested by the group, that as part of any PPIE engagement, robust questions were asked to the living participants about *"expectations",* that is, their expectations such as did they expect their data to still be collected even though they had only consented for 12 months, and not just what they would / would not be content with. **5.1.12** It was also noted by the group that PPIE would likely be needed to be evidenced as part of any s251 application to HRA CAG. **5.1.13** The group noted that as reconsenting or opting in / out was not an option for those participants that had died between 12 and 24 months follow-up, the group agreed with NHS England's assessment that an alternative legal basis would be required for the follow-up of these particular cohort members to meet the Common Law Duty of Confidentiality. **5.1.14** It was suggested by the group, that if it was the intention of the applicant to re-purpose the participant letters; that the first statement within this, should be clear that the purpose of the letter was to seek consent for the extended use of the data beyond what was originally consented, rather than this being first introduced further down. The group also questioned whether it was necessary to include so much detail about what data would be flowing to the United States of America, given that this had been the focus of a recent letter to participants and suggested and that that this content was separated out from the main body of the letter so as not to dilute the key message.	
5.2	**Reference Number:** NIC-152414-W3P6Q-v3.21 **Applicant:** University of Bristol	

	Application Title: Continuation of AVON LONGITUDINAL STUDY OF PARENTS AND CHILDREN (ALSPAC) **Previous Reviews:** The application and relevant supporting documents were previously presented / discussed at the IGARD meetings on the 19th April 2018, 15th February 2018 and the 25th January 2018. **Application:** This was an amendment application. The purpose of the application is for a transgenerational prospective birth cohort study, that investigates influences on health, wellbeing, and development across the life course. The amendment was the addition of 25 new projects. 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 **not** supportive of the application until the following significant comments were addressed, and wished to draw to the attention of the SIRO the following substantive points: **5.2.1** The group welcomed the application and noted the potentially valuable work each of the projects was hoping to achieve. **5.2.2** The group noted that they were providing advice on the basis that the applicant was relying on consent for the linkage to education and crime data, but noted that the relevant details of the legal bases for supply of this data to the applicant had not been put forward by the applicant. The SIRO representative agreed with the approach. **5.2.3** The group noted that the projects outlined in section 5(a) (Objective for Processing) of the application were connected to health and social care; and appeared to be in the scope of the consent, noting that they had only been provided with a consent review for cohort 1 as part of the agenda pack. **5.2.4** The group noted that an NHS England consent review had **not** been provided for cohorts 0 and cohort 2; and suggested that if a further AGD review and advice was required, that these consent reviews should be provided as supporting documents by NHS England. **5.2.5** It was noted that linkage to crime and education data is via consent, and queried whether the s251 support cohort would be included in any linkage to such data or not, since it was unclear, and was an essential point to explore as HRA CAG cannot offer support for non-health related data. The group suggested that further clarification was provided. **5.2.6** The independent advisers suggested that if the applicant wishes to advance linkage for non-consented cohort members, i.e. s251 support cohort members; then the linkage for crime and education data would need to be explained in more detail than currently provided.	

5.2.7 The independent advisers noted that the University of Bristol website, made reference to researchers at University College London (UCL) undertaking the research in 'research projects using your records' and elsewhere seemed to say that outside researchers could apply for access for data; and noting that this did not align with the information in the application, suggested that this was reviewed and updated as appropriate to reflect the correct information.

5.2.8 It was also suggested by the group that the applicant was more transparent to the cohort on their website with regard to the whole range projects being undertaken; and the other parties handling the data.

5.2.9 Noting the volume of information provided and the complexity of the application; the group agreed that they would review each of the projects 1 to 25, as outlined in section 5(a) of the application.

5.2.10 As an overarching point, the group suggested that if any of the projects in section 5(a) were being linked to crime or education data, that this was made clear within the application.

5.2.11 In respect of **project 7** (Parental and child alcohol use and later child criminality and injury outcomes), the independent advisers queried whether a link to crime data would be required for this project, noting that the validity of self-reporting crime may be an issue; and suggested that this was clarified and updated to reflect the correct information.

5.2.12 In addition, the group queried whether **project 7** was being carried out through a health and social care lens as opposed to a criminality lens; and suggested that this was clarified further within the application.

5.2.13 In respect of **project 12** (Comparison of proposed HES extract with ALSPACs historical HES extract), noting that this project was now completed, the independent advisers suggested that application was updated with the usual archiving clauses, including, but not limited to, any special conditions in section 6 (Special Conditions).

5.2.14 In respect of **project 15** (Assessments of G0 Mid-Life Change on Cognitive Function and Physical Capability) and **project 16** (Perinatal Depression and Anxiety in G0 Mothers and Fathers and Mental Health Outcomes), it was queried whether cohort 0 would be expecting the research to be solely about them, as opposed to how their health has impacted on the next generation. As the group had not seen a consent review for cohort 0, this was unclear.

5.2.15 In respect of **Project 21** (Mapping Neurodevelopmental Trajectories for Adult Psychiatric Disorder: ALSPAC-MRI-II), the group queried why the publicly available transparency material regarding that project listed *"Researchers at University College London (UCL)"* who will carry out the research, as this was not consistent with the data access described in the application.

	5.2.16 In respect of **project 24** (Using A Machine Learning Approach to Develop and Validate a Prediction Model for The Onset of Bipolar Disorder), the independent advisers noted the potential bias in artificial intelligence (AI) and queried the mix / variety of the cohort and whether the applicant had considered whether any algorithm generated may be biased. **5.2.17** The group noted the significant amount of work that had gone into the 'project overview' document provided as a supporting document (SD16); and suggested that this was updated to include a column to specify which parties can access the data (other than the University of Bristol and Swansea University), the basis for accessing the data, for example via an honorary contract, which cohorts (0, 1 and/or 2) would be included in each of the projects, the legal basis for any inflow of data (for example crime or education) and the legal basis for any data linkage. **5.2.18** It was also noted by the SIRO representative that honorary contracts could not be used to circumvent data controllership arrangements; and suggested that in line with NHS England's DAS Standard for Data Controllers; this was reviewed and the application / supporting documents were updated as may be relevant to reflect the correct / factual information. **5.2.19** The independent advisers queried whether there should be an element of flexibility for the applicant to bring in visiting researchers and suggested that a number of safeguards were put in place, including, but not limited to, a clear upper limit for the number of visiting researchers on honorary contracts; that those on honorary contracts were under the responsibility / supervision of a substantive employee of the applicant; and that the visiting researchers were **not** undertaking any data controllership activities. **5.2.20** The independent advisers queried the information in section 7.8 (restrictions) of the Data Access Service (DAS) escalation form, that Hospital Episode Statistics (HES) Critical Care data was not requested due to the dataset being of minimal use as it did not contain many records. It was suggested that NHS England feed this information back to the Information Asset Owner for information / further investigation.	
5.3	**Reference Number:** NIC-381948-L9M8Y-v0.28 **Applicant:** Northumbria Healthcare NHS Foundation Trust **Application Title:** Data-linkage project between the UK Bone and Joint Infection Registry (BAJIR) for Hospital Episode Statistics Admitted Patient Care (HES APC) and mortality data for the purposes of data quality assurance **Observer:** Dan Goodwin **Application:** This was a new application.	

	The purpose of the application is to examine and update the quality of the data contained within The Bone and Joint Infection Registry (BAJIR), that is inputted by local NHS teams to ensure the data is complete and accurate. 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 substantive comments: **5.3.1** The independent advisers noted that the s251 support was for service evaluation and local audit, but noted that aspects of the processing outlined in the application appeared to be for a research registry. It was suggested that NHS England work with the applicant, to ensure that the use of NHS England data is aligned with the s251 support; and that the application is amended to reflect the s251 support. **5.3.2** If the applicant does wish to proceed with a research registry element of the work outlined in the application, the applicant would need to submit a separate application for the additional work; and seek ethical support from Health Research Authority Research Ethics Committee (HRA REC) and further s251 support for this element of the processing. **5.3.3** The independent advisers noted the second paragraph in section 5(d) (Benefits) (ii) (Expected Measurable Benefits to Health and / or Social Care) "…*the findings from processing the BAJIR registry are expected to contribute to the development of understanding regarding variation in treatment of patients with a musculoskeletal infection and how care can be best improved*"; and noting that this was research as opposed to service evaluation and local audit, suggested this was removed. In addition, the group made the following observations on the application and / or supporting documentation provided as part of the review: **5.3.4** The independent advisers suggested that the various flows of data that will be shared back with the NHS Trust(s) are carefully constrained since HES data may contain data from across the country and therefore the data the Trust is receiving may not just be from their trust, or the HES data about its patients may differ from the Trust's own data. Both these may have a bearing on the legal basis for this data being shared with the Trust. **5.3.5** The independent advisers queried whether the data processed to update the Registry locally could be undertaken with aggregated data; and suggested that this was given further consideration. **5.3.6** The independent advisers queried whether NHS England would be notified of any inconsistencies in the NHS England data noted by the NHS Trust(s); and suggested that this was clarified in the internal application assessment form and the application, if appropriate.	

	5.3.7 Noting the reference to commercial organisations being able to apply to access data in the Registry in the internal application assessment form; it was suggested that section 5(a) (Objective for Processing) was updated to be clear that commercial applicants must be reviewed by the BAJIR Steering Committee, and that in each case there is an assessment of whether there is proportionate balance between public and the commercial benefit, in line with NHS England's DAS Standard for Expected Measurable Benefits and the National Data Guardian (NDG) guidance on benefits. **5.3.8** Noting the statement in section 5(b) (Processing Activities) "*During this process reidentification of individuals from the study ID provided by NHS England will be required to map to linked data to specific patients contained within the registry*"; and suggested that it was clarified what data the Trust is receiving back from NHS England and who has access to this data. **5.3.9** In addition, it was suggested that once it was determined who had access to the Registry, that the applicant ensure their website is updated with this information for transparency to the cohort and as per the consent materials.	
5.4	**Reference Number:** NIC-616088-L5G0W-v1.4 **Applicant:** NHS Birmingham and Solihull Integrated Care Board (ICB) **Application Title:** DSfC - NHS Birmingham and Solihull Integrated Care Board - IV, RS & Comm **Application:** This was an amendment application. The amendment is to add linkage to Musculoskeletal (GetUBetter) data. NHS England are seeking support for an NHS England Precedent for this amendment so other ICBs can also add linkage to Musculoskeletal (GetUBetter) data to their own data sharing agreements (DSA). 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 substantive comments: **Separate to the application**, the group had been asked to consider whether they were supportive or a new NHS England Precedent. The group were **not** supportive of an NHS England Precedent for the linkage of NHS England data to Musculoskeletal (GetUBetter) data at this time. **5.4.1** The group noted that *"GetUBetter"* had been discussed on the 4th May 2023 (NIC-616029-Y7G7K); and reiterated the point made at this review, in respect of the transparency arrangements and ensuring that users were aware of where their data was flowing; and noting that the GetUBetter privacy notice did not address this, suggested that the applicant should explore with the app provider making sure that	

	clear information is provided to the users of the app when they register / log-on, to make them aware that where their data will be flowing, for instance to the ICB. **5.4.2** In addition, it was noted that a greater depth of transparency was required on the GetUBetter app, including, but not limited to, the GetUBetter journey, which would need to be clear who the data was being shared with and for what purpose. **5.4.3** In addition, noting that the privacy notice was difficult to locate, it was noted that GetUBetter should maintain a UK General Data Protection Regulation (UK GDPR) compliant, **publicly accessible** transparency notice(s). In addition, the group made the following observations on the application and / or supporting documentation provided as part of the review: **5.4.4** The independent advisers suggested that the section 5(e) should be amended to indicate that there is a commercial aspect and that information on the commercial aspect of the application in (the published) section 5(a) (Objective for Processing); was replicated in (the unpublished) section 5(e) (Is the Purpose of this Application in Anyway Commercial), in line with NHS England's DAS Standard for Commercial Purpose. **5.4.5** The group noted the yielded benefits outlined in section 5(d) (Benefits) (iii) (Yielded Benefits) of the application; however, suggested that this section was reviewed and any 'expected benefits' were moved to section 5(d) (ii) (Expected Measurable Benefits to Health and / or Social Care) in line with NHS England's DAS Standard for Expected Measurable Benefits.	
5.5	**Reference Number:** NIC-706945-F6W2C-v0.4 **Applicant:** York and Scarborough Teaching Hospitals NHS Foundation Trust (FT) **Application Title:** Prevalence of cirrhosis and its related complications amongst patients with hereditary haemochromatosis in England **Application:** This was a new application. The purpose of the application is for a research project, to characterise the prevalence of cirrhosis in patients with the genetic disorder of hereditary haemochromatosis and also its related complications which are ascites (fluid in the abdomen), haematemesis (vomiting blood), jaundice (yellowing of the skin or eyes), hepatic encephalopathy (confusion) and hepatocellular carcinoma (liver cancer). 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 substantive comment: **5.5.1** Noting that the University of Hull were listed as a joint Data Processor, the independent advisers queried whether they had data controllership responsibilities, noting that the internal application assessment form stated the Chief Investigator	

	was employed by the University of Hull. It was suggested that this was explored further by NHS England, in line with NHS England's DAS Standard for Data Controllers and that the internal application assessment form and the application were updated as may be appropriate to reflect the factual scenario. In addition, the group made the following observations on the application and / or supporting documentation provided as part of the review: **5.5.2** The independent advisers noted reference in the internal application assessment form to a Memorandum of Understanding (MoU) between the University of Hull and York and Scarborough Teaching hospital NHS FT; and noting this was not a legal contract between parties, suggested that NHS England explored this further with the applicant, to ensure there was an appropriate contractual arrangement between the relevant parties. **5.5.3** The independent advisers noted that the data requested was for a period of sixteen years; and suggested that a fuller justification for this length of time was added to section 5 (Purpose / Methods / Outputs) of the application, in line with NHS England's DAS standard for data minimisation. **5.5.4** The independent advisers noted in the internal application assessment form and the application, that Health Research Authority Research Ethics Committee (HRA REC) ethics approval was not required due to the category of data requested. However, suggested that the applicant approach their institutional ethics committee and ask whether an ethical review is required; and that any supporting documentation is uploaded to NHS England's customer relationships management (CRM) system for future reference. **5.5.5 Separate to the application**: the independent advisers suggested that the NHS England Data and Analytics representative remind staff in the Data Access Service (DAS) to advise applicants, that due consideration should be given to the revised (July 2023) NHS England Ethical Approval Standard (particularly for University research applications which do not require HRA REC but University-level ethical support may still be indicated); and that section 5.3 (local ethical requirements) of the internal application assessment form should be completed, confirming that ethical support from their institution had been sought / obtained; or that ethical support was not required. **ACTION:** the NHS England Data and Analytics representative to remind staff in DAS, to advise applicants, that due consideration should be given to the revised (July 2023) NHS England Ethical Approval Standard (particularly for University research applications which do not require HRA REC but University-level ethical support may still be indicated); and that section 5.3 of the internal application assessment form should be completed. **5.5.6** The independent advisers noted that the application outlined that **no** patient and public involvement and engagement (PPIE) had been undertaken, other than the engagement of a lay person in reviewing the grant application; and suggested	D&A Rep

	that the applicant undertakes **ongoing** PPIE, for example, via the Haemochromatosis UK who were the charity funding the research project. The HRA guidance on Public Involvement is a useful guide.	
6	**Derived Data (Presenter: Suzanne Hartley)** Suzanne Hartley gave an update to the group, following her attendance at AGD on the 23rd February 2023. Suzanne had provided a discussion paper in advance of the meeting in respect of work undertaken by NHS England to support Data Controllers in declaring data as 'Derived Data', and to inform a transparent and reproducible process for NHS England to use to make decisions relating to the verification of derived data. The group discussed the content of the paper with Suzanne, and suggested that a number of points were addressed in addition to the information already provided, including, but not limited to, the legal and / or ethical issues; the reputational risk(s) to NHS England; and the overall purpose of deriving the data. The group thanked Suzanne for the work undertaken to date on this valuable piece of work; and looked forward to future updates.	
AGD Operations		
7	**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. The AGD Chair referred to the requirement within the published Statutory Guidance for an annual review; and that further thought / consideration was needed, on how the annual report would be presented, for example, on an NHS England standard template or other means. **ACTION:** The group to give further thought / consideration as needed, on how the annual report would be presented, for example, on an NHS England standard template or other means. The AGD Chair advised the group that a meeting would be held in April 2024 (date TBC) with Jackie Gray, Director of Privacy and Information Governance, Privacy, Transparency and Trust (PTT) (and any relevant colleagues within PTT) to discuss the annual report further. It was noted that the AGD Chair had requested that the AGD Secretariat attend this meeting, to ensure they have the correct / relevant information to support this work. The group noted that the AGD Chair would provide further information in due course. **ACTION:** AGD Chair to update the group on the April 2024 meeting to discuss the annual report. The SIRO representative noted an outstanding action in respect of providing a written response to AGD on the risk management framework; and noted that this was progressing under the NHS England Precedents and Standards work.	AGD AGD Chair SIRO Rep
8	**AGD Terms of Reference (ToR)** The independent advisers noted that over nine months had passed since the Statutory Guidance had been published, requiring a ToR to be agreed and published. The AGD Chair noted that on the 23rd February 2024, Jackie Gray had shared with the group, a **final** draft version 0.16 of the ToR and had advised that this document was being sent to Steve Russell, NHS England's Chief Delivery Officer, National Director for Vaccinations and Screening and Senior Information Risk Owner (SIRO) for final approval, ahead of seeking approval from the Data, Digital and Technology Committee (DDAT) of the NHS England Board. It was noted that Jackie has also advised that as per the previous commitment made to the group, if there are any changes to this version of the ToR following review by Steve Russell and / or DDAT, an updated version would be shared with the group prior to publication. The group noted that clarification had been provided with the final draft ToR, showing updates made to the document reviewed at the workshop on the 27th November 2023 and further updates / clarifications made by the AGD Chair in early	

	February 2024. The group looked forward to being notified of the formal approval of the ToR by NHS England. **ACTION:** The SIRO representative to advise AGD when the ToR have been formally approved by NHS England.	SIRO Rep
9	**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, work was ongoing to progress and finalise the AGD SOPs, in line with the progression of the AGD ToR. It was noted that following the workshop that was held with the group on the 7th March 2024, further work was being undertaken on the progression of the SOPs out of committee; and that further updates would be provided to the group in due course.	To note
10	**Oversight and Assurance (Presenters: Garry Coleman / Kirsty Irvine / Jenny Westaway)** Following the workshop at the AGD meeting on the 7th March 2024, the group noted that the draft oversight and assurance template, that will be used to support reviews undertaken by AGD independent advisers, had now been updated. The group noted that the current NHS England Precedents used by NHS England when progressing applications would need to be provided to the group; and an action was taken by the NHS England Data and Analytics representative. **ACTION:** NHS England Data and Analytics representative to ensure that AGD have sight of the latest versions of the NHS England Precedents used by NHS England DAS when progressing applications via the precedent route, in order to support oversight and assurance reviews by independent advisers. The group noted that the first oversight and assurance review would take place at the AGD meeting on the 14th March 2024. As previously discussed, and agreed, it was noted that the summary of the oversight and assurance review and advice would be included in the AGD published minutes for transparency.	D&A Rep
11	**AGD Stakeholder Engagement** The AGD Chair and SIRO representative noted that they had attended the UK Health Data Research Alliance Pan-UK Data Governance Steering Group, on the 13th March 2024 and that minutes from this meeting would be published in due course.	To note
12	**AGD Project Work**	

	The group noted that Imran Khan and Miranda Winram had been attending the NHS England OpenSAFELY Direction - Working Group; and that the last meeting had taken place on the 11th March 2024. The group were advised by Imran that further work was being undertaken within NHS England on the OpenSAFELY Direction, and that this would be presented at a future AGD meeting in due course.	To note
Any Other Business		
13	**Independent advisers pay uplift (Presenter: Vicki Williams)** Following the update at the AGD meeting on the 11th January 2024**,** Vicki advised the group that the 5% uplift to current independent adviser day / hour rates, in line with the NHS Agenda for Change 2023/24 pay award, should be paid in March 2024 salaries, alongside any back pay to when they onboarded to NHS England zero hours contracts. The independent advisers noted and thanked Vicki for the update. The independent advisers noted concerns with the different levels of pay between lay and specialist roles (for independent advisers); and were advised by the SIRO representative that work was ongoing within NHS England to review pay rates for AGD independent advisers, and that further information would be provided in due course, and before recruitment started for AGD independent advisers. **ACTION:** The SIRO representative to provide an update on AGD independent adviser pay review. The independent advisers noted the verbal update from the SIRO representative and looked forward to an update on the pay review in due course.	SIRO Rep
14	**Dr. Geoffrey Schrecker** Both independent advisers and NHS England noted that this was Dr. Geoffrey Schrecker's final meeting and wished to extend their sincere thanks for his significant contribution over the last five years during his tenure on IGARD and the interim AGD.	
Meeting Closure As there was no further business raised, the Chair thanked attendees for their time and closed the meeting.		