Advisory Group for Data (AGD) – Meeting Minutes

Thursday, 14th September 2023

09:30 – 15:30

(Remote meeting via videoconference)

INDEPENDENT ADVISERS IN ATTENDANCE:	
Name:	**Role:**
Paul Affleck (PA)	Specialist Ethics Adviser
Claire Delaney-Pope (CDP)	Independent Specialist Adviser **(Observer – new AGD member)**
Prof. Nicola Fear (NF)	Specialist Academic Adviser
Kirsty Irvine (KI)	Chair
Dr. Imran Khan (IK)	Specialist GP Adviser
Jenny Westaway (JW)	Lay Adviser
NHS ENGLAND STAFF IN ATTENDANCE:	
Name:	**Role / Area:**
Angela Blakeney (AB)	Senior information Governance Manager, Data Governance, Delivery Directorate (**Observer**: item 4.2)
Nicola Bootland (NB)	Onboarding Team, Data and Analytics, Transformation Directorate (**Observer**: item 4.1)
Mark Bougourd (MB)	Flu Operations and Policy Engagement Lead, Vaccination Digital Services, Transformation Directorate (**Presenter:** item 4.2)
Garry Coleman (GC)	NHS England SIRO Representative (**Presenter**: item 10.1)
Jon Coolican (JC)	NHS Arden and Greater East Midlands Commissioning Support Unit (**Presenter**: item 4.1)
Rick Cooper (RC)	Vaccine Digital Services, Transformation Directorate (**Observer**: item 4.2)
Ben Cromack (BC)	Data Access Request Service (**Observer:** item 5.1)

Dave Cronin (DC)	Data Access Request Service Senior Approval Team (DARS SAT) (**Observer:** item 5.1)
Louise Dunn (LD)	Data Access Request Service Senior Approval Team (DARS SAT) (**Observer:** items 5.3 to 5.5)
Duncan Easton (DE)	Data Access Request Service Senior Approval Team (DARS SAT) (**SAT Observer**: items 2.1 to 5.2)
Kate Fleming (KF)	NHS England Data and Analytics Representative (Delegate for Michael Chapman)
Suzanne Hartley (SH)	Data Access Request Service (**Observer:** item 5.1)
Chris Hutchins (CH)	Senior Analytical Lead, Transformation Directorate (**Observer**: item 4.2)
Andrew Martin (AM)	NHS England Data Protection Office Representative (Delegate for Jon Moore)
Karen Myers (KM)	AGD Secretariat Team
Jonathan Osborn (JO)	NHS England Caldicott Guardian Team Representative
Scott Pryde	Director of Clinical Analytics and Delivery Director for the Outcomes and Registries Programme (**Presenter**: item 4.3)
Pritpal Rayat (PR)	Head of Medicines & Adult Social Care Data Products & Developments, Data and Analytics (**Presenter**: item 4.1)
Simon Snowden (SS)	Senior Systems and Solutions Development Manager, Strategy and Development, Data and Analytics (**Presenter:** item 4.3)
INDEPENDENT ADVISERS NOT IN ATTENDANCE:	
Dr. Robert French (RF)	Specialist Academic / Statistician Adviser
Dr. Geoffrey Schrecker (GS)	Specialist GP Adviser
Dr. Maurice Smith (MS)	Specialist GP Adviser
Miranda Winram (MW)	Independent Lay Adviser **(Observer – new AGD member)**
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 Request Service (DARS) 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 September 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:** Prof. Nicola Fear noted a professional link to the Trauma Audit and Research Network (TARN) (item 4.3) as part of her role at King's College London. It was agreed this was not a conflict of interest. Prof. Nicola Fear noted a noted a professional link to Clinical Practice Research Datalink (CPRD) (NIC-15625-T8K6L) as part of her role at King's College London. It was agreed this did not preclude Prof. Fear from taking part in the discussion on this application. Kate Fleming noted a professional link to CPRD (NIC-15625-T8K6L), in that she was a scientific member of the CPRD Central Advisory Committee; and chair of a CPRD Expert Review Committee, providing expert scientific advice (to CPRD) on individual applications

	requesting access to CPRD for public health research purposes, as well as quality assurance of CPRD's research data governance process. It was agreed this was not a conflict of interest. Kate Fleming noted a professional link to the National Disease Registration Service (NDRS) (NIC-15625-T8K6L, NIC-656866-V3H6X). It was agreed this was not a conflict of interest.
BRIEFING PAPER(S):	
4.1	**Title:** Adult Social Care Client Level Data Set (ASCCLDS) Briefing Paper **Presenter:** Pritpal Rayat, Jon Coolican **Observer:** Nicola Bootland **SAT Observer:** Duncan Easton **Previous Reviews:** The briefing paper was previously presented at the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) meeting on the 6th May 2021. The ASCCLDS collects Adult Social Care activity on requests, reviews, assessments and services at a client level from local authorities in England. In due course it will replace the existing aggregate Short and Long Term (SALT) data collection. IGARD were previously supportive of applications for Adult Social Care data as part of the 'North West Pilot', which was subsequently extended to cover the whole of England on a voluntary basis. The 'North West Pilot', and the voluntary collection extended across England, informed both the approach being taken and an updated data specification so that the collection could be rolled out nationally on a mandatory basis from 1st April 2023. Whilst the ASCCLDS does not contain a large time series of data, due to significant interest in the data set NHS England intend to make it available to request via the Data Access Request Service (DARS) from the end of September 2023. The first mandatory submissions were received in July 2023 and whilst as a minimum these submissions cover the first quarter of 2023/24; some councils may choose to submit historic data as well as some historic data being available for those councils who participated in the voluntary collection. NHS England were seeking advice on the following point: 1. To note the dataset being onboarded and for any comments / concerns relating to this. **Outcome of discussion:** The group welcomed the briefing paper and made the following observations / comments: In response to point 1 above: **4.1.1** The group advised that they were supportive of the data collection and noted that this would be a valuable resource. **4.1.2** The independent advisers noted that an earlier iteration of the briefing paper had been reviewed by IGARD on the 6th May 2021; and reiterated a point made by IGARD at this review, that further consideration was given to widening the potential access to this data since

	it could be valuable to a wide range of other researchers; noting that there could be a challenge to NHS Digital (now NHS England) in respect of the data being restricted to a small number of bodies able to request this data. **4.1.3** The group noted the verbal update from NHS England, that there was a legal gateway to disseminate the data wider than NHS England, Integrated Care Boards (ICBs) and Local Authorities; however, noted that if the dissemination powers of s261 of the Health and Social Care Act 2012 were relied on, that any use of the data by researchers would need to be strictly within the stated purpose of the use of the data as outlined in the Collection of Client Level Adult Social Care Data (No 3) Directions 2023. **4.1.4** In addition, it was suggested by the group that NHS England's Data Access Request Service (DARS) Onboarding Team ensure that the restricted purposes for processing the data were flagged, to ensure that this is picked up with applicants for the data at an early stage in the process, i.e. when the data is being applied for. **4.1.5** The SIRO representative advised the group that a meeting would be convened with the relevant NHS England colleagues, to ensure there was a clear legal gateway audit trail to disseminate the data under s261 of the Health and Social Care Act 2012. **ACTION:** NHS England DARS Onboarding Team to ensure that the the dissemination powers of s261 for this data flow by researchers would need to be strictly within the stated purpose of the use of the data as outlined in the Collection of Client Level Adult Social Care Data (No 3) Directions 2023. **4.1.6** The independent advisers noted that although the Collection of Client Level Adult Social Care Data (No 3) Directions 2023 does **not** make reference to general researchers, the privacy notice does; and suggested that NHS England review the privacy notice to ensure it is clear and accurate as to who can apply for the data and when. **4.1.7** Noting the data flow diagrams in section 7 of the briefing paper, it was suggested by the independent advisers that the Local Authorities be clearer in respect of where the data is flowing to and from; and to ensure that the Common Law Duty of Confidentiality is being addressed for the identifiable data. **4.1.8** The group suggested to NHS England, that any first use / request of the data was submitted / reviewed by the group, for example, first use by an ICB, Local Authority etc. **4.1.9** The group looked forward to receiving the finalised briefing paper alongside any first of type application.
4.2	**Title:** Flu Seasonal Vaccination Campaign **Presenter:** Mark Bougourd **Observers:** Angela Blakeney, Rick Cooper, Chris Hutchins **SAT Observer:** Duncan Easton

	Previous Reviews: The Flu Vaccination Data Briefing Paper was previously presented at the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) BAU meeting on the 25th November 2021. The Seasonal Flu programme provides direct protection to those at higher risk of flu associated morbidity and mortality, including older people, pregnant women, and those in clinical risk groups and is guided by advice from the Joint Committee on Vaccination and Immunisation (JCVI), an independent departmental expert committee. In addition, based on the JCVI 2012 recommendation, a vaccination programme for children using live attenuated influenza vaccine (LAIV) provides individual protection to the children and reduces transmission to the wider population. NHS England has delegated authority to exercise the Secretary of State's public health functions under s7A of the National Health Service Act 2006. NHS England will commission the services listed as outlined in the Data Protection Impact Assessment (DPIA) provided as a supporting document. These services will be provided in accordance with the relevant individual service and pathway requirements specifications. This includes **1)** Seasonal influenza immunisation programme; and **2)** Seasonal influenza immunisation programme for children. NHS England were seeking advice on the following point: 1. To note the information provided and for any comments / concerns relating to this. **Outcome of discussion:** The group welcomed the briefing paper and made the following observations / comments: In response to point 1 above: **4.2.1** The group were supportive of this programme reverting back to the pre-COVID-19 pandemic status of relying on Regulation 3 of the Health Service (Control of Patient Information) Regulations 2002 (COPI) for non-research activity; which was endorsed by the NHS England Data Protection Office Representative in-meeting. **4.2.2** The group queried how the data could be used for purposes that were not direct care when type one objections had not been applied. The group stressed that if there were situations where type one objections were overridden (so identifiable patient data is shared outside of a GP practice for direct care but is then used for another purpose regardless of an objection) then this needs to be justified and clearly communicated to patients. **4.2.3** Noting that the National Immunisation Management System (NIMS) Data Protection Impact Assessment (DPIA) had been submitted as a supporting document, the group suggested that this was updated to clarify how the Common Law Duty of Confidentiality (CLDoC) was addressed. In particular the group queried whether the NHS Counter Fraud Authority Directions and the associated supplemental directions to the NHS Business Services Authority (NHS BSA), provided a CLDoC basis for the full range of NHS BSA activities as set out in the supplied Memorandum of Understanding (MOU) with NHS England, and if not, to clarify how the CLDoC has been addressed.

	4.2.4 The group looked forward to receiving the finalised briefing paper.
4.3	**Title:** IG10154 Outcomes Registers and Trauma Registry / DPIA approval **Presenter:** Simon Stone / Scott Pryde **SAT Observer:** Duncan Easton The Outcomes and Registries Directions 2023 is to require NHS England to collect and analyse information from across both the NHS and the private sector for the purposes of improving clinical safety and patient outcomes, reducing variation in clinical practice, and also to support the government response to the recommendations of the Independent Medicines and Medical Devices Safety Review and the Paterson Inquiry. This will be achieved by establishing and operating information systems to collect, link and analyse data in connection with outcome registries, and developing and operating information and communication systems to deliver services in connection with outcome registries. The NHS England Outcomes and Registries platform will support improved patient safety by enabling analysis to facilitate surveillance of surgical devices and implants through linkage of component data modules, including associated patient outcomes, to support patient focussed activities such as review or recall of specific devices. NHS England were seeking advice on the following points: 1. AGD are asked to provide advice in relation to this approach under these new Directions to consolidate approved outcomes and registries collections under one Direction. 2. Does the processing raise any risks for NHS England which have not been adequately addressed within the documents provided? 3. Are there reputational risks resulting to NHS England? 4. Are there any elements of the proposed data collection or processing which the group feel may result in harm to patients? **Outcome of discussion:** The group welcomed the briefing paper and made the following observations / comments: In response to points 1 to 4 above: **4.3.1** The independent advisers noted the importance of the work outlined in the briefing paper and the potential benefits this would bring to patients. **4.3.2** The independent advisers queried the information within the privacy notice in respect of opt outs, and suggested that the privacy notice was reviewed and updated as may be required, to ensure that it accurately reflects the non-application or otherwise, of the National Data Opt-out; and to accurately reflect what will / will not happen in practice. **4.3.3** The independent advisers queried if any work was being undertaken to engage with the research community in respect of the Outcomes Registers and Trauma Registry; and were advised by NHS England that discussions were ongoing with the relevant patient groups on

	this point. The group noted the verbal updated and advised that they were supportive of this work being progressed. **4.3.4** Noting the statement in the briefing paper that referred to NHS England *"contacting patients directly"*, it was suggested by the group that this was unlikely to be happening in practice; and suggested that this statement should be reviewed and amended as may be necessary to ensure it reflect the correct information. **4.3.5** The group looked forward to receiving the finalised briefing paper, either out of committee (OOC) or tabled at a future meeting.	
EXTERNAL DATA DISSEMINATION REQUESTS:		
5.1	**Reference Number:** NIC-400304-S1P1B-v6.2 **Applicant:** Office for National Statistics (ONS) **Application Title:** Investigating COVID-19 **Presenter:** None **SAT Observer:** Duncan Easton **Previous Reviews: Previous Reviews:** The application and relevant supporting documents were previously discussed at the meeting on the 11th May 2023. The application and relevant supporting documents had previously been presented / discussed at the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) BAU meetings on the 27th October 2022, 17th March 2022, 3rd March 2022, 10th February 2022, 27th January 2022, 15th April 2021, 18th February 2021, 3rd December 2020, 26th November 2020, 19th November 2020 and the 17th September 2020. The application and relevant supporting documents were previously presented / discussed at the IGARD COVID-19 response meetings on the 15th September 2020 and the 8th September 2020. The application was previously presented at the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 18th November 2020 and the 9th September 2020. **Linked applications:** This application is linked to NIC-388794-Z9P3J. **Application:** This was a renewal and extension application. The purpose of the application is to support the national response to the COVID-19 pandemic; by supporting the production of official national statistics. NHS England were seeking advice on the following points: 1. Whether NHS England require further ethical assessment or approval by an additional authority, i.e. the Health Research Authority.	

	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: **5.1.1** The independent advisers noted that as agreed at the AGD meeting on the 27th July, the draft '*How AGD consults with the Profession re General Practice Extraction Service (GPES) Data for Pandemic Planning & Research (COVID-19) (GDPPR) Data Standard Operating Procedure'* was circulated to colleagues within NHS England's Data Access Request Service Senior Approvals Team (DARS SAT) following this meeting; with the advice that this was an interim document to support any General Practice Extraction Service (GPES) Data for Pandemic Planning and Research (GDPPR) applications, and that the interim document outlined the current interim arrangements put in place by the Profession Advisory Group (PAG) Chair. **5.1.2** As part of this review, it was queried by the independent advisers if the process outlined in the interim document had been followed by NHS England for the GDPPR data requested under this iteration of the data sharing agreement (DSA), in particular, in respect of the winter pressures work. The group were advised by NHS England that the process had **not** been followed for this application, and that this would be picked up outside of the meeting with the PAG Chair. The group noted the verbal update and advised that without the view being sought from the PAG Chair in advance of the meeting, they would be **unable** to provide a view on this aspect of the application. In addition, the group made the following observations on the application and / or supporting documentation provided as part of the review: In respect of point 1: **5.1.3** As previously noted by IGARD in relation to ONS applications, the independent advisers observed that since ONS were receiving identifiable data for health research, that research may fall within the remit of the Health Research Authority (HRA) and require review by a HRA Research Ethics Committee. NHS England stated there are on-going discussions. **5.1.4** The independent advisers noted and commended the efforts undertaken by NHS England, in respect of the support provided to ONS to update their transparency materials. **5.1.5 Separate to this application**, the independent advisers reiterated the advice from the AGD meetings on the 17th August and 10th August 2023, that NHS England considered having an NHS England DARS Standard for programmatic access, that addressed what, if any, difference in approach would be taken for commercial programmatic access; and how any programmatic access is aligned with the Department of Health and Social Care draft data access policy update that states *"Secure data environments (SDEs) will become the default route for accessing NHS*	

	data for research and external uses. Instances of disseminating NHS data outside of an SDE for research and external uses will be extremely limited". **ACTION:** NHS England to consider having an NHS England DARS Standard for programmatic access. **5.1.6** Noting the three objectives for processing outlined in section 5(a) (Objective for Processing), it was suggested by the group that the objectives were updated / refined to be more specific / descriptive. **5.1.7** In addition, it was suggested that section 5 (Purpose / Methods / Outputs) and the special conditions in section 6 (Special Conditions) were aligned as may be appropriate to ensure that each 'use' case referred to in the application, falls under one of the three objectives for processing, and was therefore permitted under this DSA. **5.1.8** The independent advisers noted in the application that there would be a pre-approval process by NHS England for any *"new"* purposes to the application, and suggested that, for transparency, this pre-approval process was clearly articulated in section 5(a). **5.1.9** The independent advisers noted that section 2(c) (Territory of Use) stated that the territory of use was *"England and Wales"*, however section 5(b) (Processing Activities) referred to *"England"* only'. It was therefore suggested that section 5(b) was updated to correctly reflect that the territory of use was England **and Wales**.	NHSE
5.2	**Reference Number:** NIC-384326-R9V7S-v1.16 **Applicant:** Nuffield Department of Primary Health Sciences **Application Title:** Evaluating the effectiveness of screening for chronic kidney disease (CKD) in primary care by linking the OxRen/NewKi study with the Oxford RCGP Research and Surveillance Centre ORCHID database and NHS England data. **Presenter:** None **SAT Observer:** Duncan Easton **Previous Reviews:** The application and relevant supporting documents were previously presented / discussed at the AGD meeting on the 27th July 2023. The application and relevant supporting documents had previously been discussed at the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) BAU meeting on the 4th March 2021. **Application:** This was a renewal, extension and amendment application. The purpose of the application is for a study with a number of aims and objectives, including, but not limited to, estimating the mortality rate and cardiovascular disease (CVD) incidence of CKD patients; estimate and compare the mortality rates and CVD incidence for CKD patients identified routinely by clinical practice, and for CKD	

	patients identified by means of screening and identify predictors for mortality and CKD incidence to help clinicians identify those at greatest risk for closer monitoring, medication review or other medical interventions. The amendments are to **1)** request Civil Registry Deaths (previously received Civil Registry Deaths Secondary Care Cut) and Cancer Registration data (additional dataset); **2)** extend the cohort to include additional participants without Chronic Kidney Disease; **3)** to update section 5(a) (Objective for Processing) with additional Objectives. 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: **5.2.1** Notwithstanding the title of the application, it was noted in the meeting that there would be **no** linkage of the NHS England data and the ORCHID data, under this data sharing agreement (DSA). It was therefore suggested that the title of the application was updated to remove any misleading information that linkage would be taking place. **5.2.2** The group discussed the practicalities of keeping the NHS England data separate from the ORCHID data; and suggested that NHS England ensure that there were robust contractual controls, for example, by way of special conditions in section 6 (Special Conditions), that expressly preventing linkage with the ORCHID data. **5.2.3** In addition, the independent advisers suggested that NHS England should consider undertaking an audit of this DSA, to ensure that no linkage of the NHS England data and the ORCHID data had taken place. **5.2.4** The independent advisers noted that although the cohort were consented and therefore would have received written information on the study; they were unable to locate a published privacy notice for this study, and suggested that to support ongoing communication with the cohort / transparency, it would be advisable to publish a privacy notice.	
5.3	**Reference Number:** NIC-15625-T8K6L-v13.2 **Applicant:** Medicines and Healthcare Products Regulatory Agency (MHRA) / Clinical Practice Research Datalink (CPRD) **Application Title:** R23 - Clinical Practice Research Datalink (CPRD) Routine Linkages Application **Presenter:** None **SAT Observer:** Louise Dunn	

	Previous Reviews: The application and relevant supporting documents were previously presented / discussed at the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) BAU meetings on the 15th December 2022, 10th November 2022, 28th April 2022, 27th January 2022, 27th August 2020, 16th July 2020, 9th April 2020, 19th March 2020, 27th February 2020, 6th February 2020, 7th November 2019, 31st October 2019, 17th October 2019, 8th November 2018, 20th September 2018 and the 22nd June 2017. The application and relevant supporting documents were previously presented / discussed at the IGARD COVID-19 response meetings on the 13th October 2020, 6th October 2020, 26th May 2020, 19th May 2020 and the 12th May 2020. The application and relevant supporting documents were previously presented / discussed at the DAAG meeting on the 21st January 2017. **Linked applications:** This application was linked to NIC-656848-T9J1Q. **Application:** This was an amendment application. The amendment is to merge NIC-656848-T9J1Q into this data sharing agreement (DSA). The National Disease Registration Service (NDRS) datasets requested under NIC-656848-T9J1Q had previously flowed from Public Health England (PHE) prior to its closure at the end of September 2021. 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 high-level comments: **5.3.1** The independent advisers reiterated the point previously raised by the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) on the 15th December 2022, that the applicant seek advice from Health Research Authority Confidentiality Advisory Group (HRA CAG) and the HRA Research Ethics Committee (REC), in respect of listing the participating GP Practices on the CPRD website. **5.3.2** If it was determined that HRA CAG / HRA REC had **not** been approached by the applicant to seek advice on this point; it was advised that there should be a clearer narrative on the CPRD website clarifying why the list of participating GP Practices was not published. **5.3.3** The group noted that, prior to the meeting, a query had been raised with NHS England by an independent adviser, in respect of how some of the previous points (1 - 4) raised by IGARD on the 15th December 2022 had been addressed; noting that the internal application assessment form was not clear on this. It was noted that a response had **not** been provided in advance of the meeting, and the group were therefore unable to assess whether these points had been satisfactorily addressed.	

	5.3.4 Noting that CPRD had not received any NHS England data for approximately twelve to eighteen months; it was suggested by the group that this was made clear in section 5(a) (Objective for Processing) of the application. **5.3.5** The SIRO representative asked that NHS England update the application to ensure that this aligns with the latest version of the NHS England's DARS standard for sub-licencing and onward sharing. **5.3.6** The SIRO representative suggested that it would be beneficial for NHS England to observe a meeting of CPRDs Central Advisory Committee, to seek further confirmation of how the NHS England data has been processed over the past 12 months. **5.3.7** The SIRO representative noted the information in section 5(b) (Processing Activities) relating to an audit which had determined that the risk to the data becoming identifiable was low; and asked that this was updated to confirm that this was a targeted audit that did not offer any specific view of the re-identifiability of the data. **5.3.8** The independent advisers noted the transparency information on the CPRD website and advised that the information relating to opt-outs was potentially inaccurate. It was suggested that this information was reviewed and updated as may be appropriate, for example, by ensuring that Type 1 opt outs are referred to, and to accurately describe the operation of the National Data Opt-out (NDO) in relation to the data CPRD receives and disseminates. **5.3.9** The independent advisers noted that CPRD's release register did not appear to have been updated since July 2022, and suggested that this was updated as may be necessary. **5.3.10** Noting the statement in section 5(b) that there is a CPRD client audit programme *"…which aims to audit 6 clients per year to ensure compliance with licence terms"*; it was queried whether these had been carried out as there was no recent evidence on CPRD's website; and suggested that CPRD update their website with the most recent information.	
5.4	**Reference Number:** NIC-662451-S5L8J-v0.18 **Applicant:** Milton Keynes University Hospital NHS Foundation Trust **Application Title:** FINESSE database outcome study - NHS England Linkage project **Presenter:** None **SAT Observer:** Louise Dunn **Application:** This was a new application. The purpose of the application is for a project, to develop a predictive model for chest pain sufferers based on their clinical characteristics, risk factor profiles, and	

	the outcome of their SE, which was part of the patients' standard care investigations. The required and collected information is known as major cardiovascular events (MACE) and includes all cause death and non-fatal heart attack over the intermediate and long term. 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: **5.4.1** The independent advisers queried the honorary contract arrangements for the University of Leicester PhD student; and suggested that NHS England review this in line with NHS England's DARS Honorary Contract Standard (currently in the process of being published on the NHS England website). **5.4.2** Noting the information within the application and supporting documents in respect of the Open University being a collaborator; it was suggested that NHS England explore this further to determine whether or not the Open University was considered a joint Data Controller, in line with NHS Digital DARS Standard for Data Controllers. In addition, the group made the following observations on the application and / or supporting documentation provided as part of the review: **5.4.3** Noting the nature of the data flowing and the information held by the researchers, the independent advisers asked that the application was updated to be clear that the data flowing is identifiable and not pseudonymised. **5.4.4** Noting the aim of the project in section 5(a) (Objective for Processing) which is to *"…develop a predictive model for chest pain sufferers based on their clinical characteristics, risk factor profiles, and the outcome of their Stress echocardiography, which was part of the patients' standard care investigations"*; the group queried whether the applicant was receiving a sufficient amount of data to build a robust algorithm, and to provide further confirmation of any potential limitations and how any potential bias could be addressed. **5.4.5** The independent advisers noted the content of the poster provided as a supporting document, and advised that it was not accurate to describe the data as being *"anonymised"*; and suggested that in order to comply with UK General Data Protection Regulation (UK GDPR) and in line with Caldicott Principle 8, *"…A range of steps should be taken to ensure no surprises for patients and service users…";* the poster was updated to clearly outline that *"identifiable"* data is being processed with the support of the Health Research Authority Confidentiality Advisory Group (HRA CAG). **5.4.6** The independent advisers noted the conflicting information is section 5(b) (Processing Activities) in respect of the destruction of the data; and suggested that this was reviewed and updated as may be appropriate to clarify at what stage the	

	data will be destroyed from the research database; and to clarify that data will **not** be deleted from the audit database. **5.4.7** The SIRO representative queried the conflicting information in section 5(b) in respect of where the data would be stored; and asked that this was reviewed and updated to correctly reflect what is happening in practice. **5.4.8** The independent advisers noted the dates cited in section 5(c) (Specific Outputs Expected), and suggested that these were revised and updated as appropriate to ensure they were realistic, noting that some of the dates were imminent. **5.4.9** Noting that the Data Security and Protection Toolkit (DSPT) had **not** yet been reviewed by NHS England; the independent advisers suggested that this was kept under surveillance and the application was updated as per usual process once reviewed to reflect the outcome of the DSPT review.	
5.5	**Reference Number:** NIC-636813-T2D1L-v0.6 **Applicant:** Sheffield Teaching Hospitals NHS Foundation Trust **Application Title:** Do Patients With Autoimmune Hepatitis Have An Excessive Incidence Of Cardio- And Cerebro- Vascular Disease And Is This Related To Corticosteroid Treatment? **Presenter:** None **SAT Observer:** Cath Day **Application:** This was a new application. The purpose of the application is for a research project, aiming to determine if patients with Autoimmune hepatitis (AIH) have a greater rate of first hospital admission (or death) with cardio- or cerebrovascular disease (primary outcome) than the general population. Several secondary outcomes, including total number of vascular-related hospital admissions, prevalence of metabolic risk factors and relationship to treatment with corticosteroids, will also be evaluated. 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: **5.5.1** The group noted that they were content with the application submitted, in terms of it meeting NHS England's DARS Standards, however, queried how the objective for processing could be met with the data requested. It was suggested that the applicant provide further information / clarification to a data and analytics expert within NHS England as to how the objective for processing could be met with the data requested; and to provide reassurance that they have the sufficient expertise and appropriate protocol to process the data.	

	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 group welcomed the application and noted the importance of the research. **5.5.3** An NHS England representative queried how the data from Sheffield Teaching Hospitals NHS Foundation Trust would be linked; and whether this was retrospective or prospective; and suggested that further clarification was provided in section 5(b) (Processing Activities).	
EXTERNAL DATA DISSEMINATION - SIRO APPROVED / SEEKING SIRO APPROVAL		
6.1	**Reference Number:** NIC-656866-V3H6X-v1.4 **Applicant:** Health IQ Ltd **Application Title:** THE CREPE STUDY: Outcomes and treatment pathways for Castration Resistant Prostate Cancer in England: A Real-World Data Study (ODR1920_232) **Presenter:** No Presenter **Previous Reviews:** The application and relevant supporting documents had previously been discussed at the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) meeting on the 3rd November 2022. The NDRS datasets requested under this DSA had previously flowed from Public Health England (PHE) prior to its closure at the end of September 2021; and therefore, had not had a previous independent review. **Application:** The purpose of the application is for a study, aiming to **1)** describe the demographic and clinical characteristics of men with metastatic castration-resistant prostate cancer; **2)** to quantify the treatments used and to describe the treatment among men with metastatic castration-resistant prostate cancer; **3)** to describe clinical outcomes, in terms of progression-free survival and overall survival, among men with metastatic castration-resistant prostate cancer; and **4)** to describe healthcare resource use in men with metastatic castration-resistant prostate cancer. The SIRO approval was for a 12-month extension. **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: **6.1.1** The independent advisers noted that there would be a commercial purpose to this application, and queried whether NHS England should review the process for commercial applications proceeding down the NHS England Precedent route, that have not had a previous independent review.	

	6.1.2 It was also suggested by the independent advisers, that the application should be explicitly clear on the extent of commercial purpose, in line with NHS England's DARS Standard for Commercial Purpose The NHS England SIRO representative thanked the group for their time.	
AGD Operations		
8	**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 DARS Standards and Precedent 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 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 DARS Standards and Precedents, and asked that this be clarified by NHS England. **ACTION:** NHS England SIRO Representative to provide a written response addressed to AGD with further clarity on the risk management framework.	GC
9	**AGD Terms of Reference (ToR)** Garry Coleman noted that NHS England were still considering comments from stakeholders on the AGD ToR. **ACTION:** The NHS England SIRO Representative noted a previous action to clarify when a revised draft of the AGD ToR would be presented to AGD and when the AGD ToR was scheduled to be considered by the NHS England Board / subcommittee of the Board.	GC
10	**Standard operating procedures** The ongoing forward plan of work for creating Standard Operating Procedures was discussed.	To note
Any Other Business		

11	**NIC-656816-Z3N6R-v1.4 - University of Oxford** The group noted that as part of the ratification of the minutes from the 7th September 2023, it had been drawn to the attention of the AGD Secretariat by NHS England, that the legal basis for processing the data under NIC-656816-Z3N6R-v1.4 - University of Oxford, was not consent (as advised in the meeting). The SIRO representative took and action to look in to this further, and that clarification would be provided to the group as soon as possible. **ACTION:** To provide confirmation of the legal basis to process the data under NIC-656816-Z3N6R-v1.4 University of Oxford.	GC

Meeting Closure

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