Advisory Group for Data (AGD) – Meeting Minutes

Thursday, 15th June 2023

09:30 – 16:30

(Remote meeting via videoconference)

INDEPENDENT ADVISERS IN ATTENDANCE:	
Name:	**Role:**
Paul Affleck (PA)	Specialist Ethics Adviser
Prof. Nicola Fear (NF)	Specialist Academic Adviser
Dr. Robert French (RF)	Specialist Academic / Statistician Adviser
Kirsty Irvine (KI)	Chair
Jenny Westaway (JW)	Lay Adviser
NHS ENGLAND STAFF IN ATTENDANCE:	
Name:	**Role / Area:**
Mary Bythell (MB)	Rare Disease Lead, National Disease Registration Service (**Presenter**: item 4.1)
Garry Coleman (GC)	NHS England SIRO Representative (**Presenter**: item 10.1)
Ben Cromack (BC)	Data Access Request Service (DARS) (**Observer**: item 5.1) (**Presenter**: item 5.4)
Dave Cronin (DC)	Data Access Request Service Senior Approval Team (DARS SAT) (**Presenter**: item 5.1) (**SAT Observer**: items 5.2 to 5.3)
Cath Day (CD)	Data Access Request Service Senior Approval Team (DARS SAT) (**SAT Observer**: item 5.6)
Louise Dunn (LD)	Data Access Request Service Senior Approval Team (DARS SAT) (**SAT Observer**: items 5.4 to 5.5)
Kate Fleming (KF)	NHS England Data & Analytics Representative (Delegate for Michael Chapman)
Dan Goodwin (DG)	Data Access Request Service (DARS) (**Observer**: items 5.2 to 5.3)
Dickie Langley (DL)	NHS England DPO Representative (Delegate for Jon Moore)
Sara Lubbock (SL)	Data Access Request Service (DARS) (**Observer**: item 5.6)

Karen Myers (KM)	AGD Secretariat Team
Rahima Oliver (RO)	Privacy, Transparency, Ethics & Legal (PTEL) (**Observer**: item 4.1)
Dr. Jonathan Osborn (JO)	Caldicott Guardian Team representative (**Presenter**: item 11)
Jodie Taylor-Brown (JTB)	Data Access Request Service (DARS) (**Observer**: items 5.2 to 5.3)
James Watts (JW)	Data Access Request Service (DARS) (**Presenter**: item 5.5)
Vicki Williams (VW)	AGD Secretariat Team (**Presenter**: item 9)
Clare Wright (CW)	Data Access Request Service (DARS) (**Presenter**: item 5.6)
INDEPENDENT ADVISERS NOT IN ATTENDANCE:	
Dr. Imran Khan (IK)	Specialist GP Adviser
Dr. Geoffrey Schrecker (GS)	Specialist GP Adviser
Dr. Maurice Smith (MS)	Specialist GP Adviser
NHS ENGLAND STAFF NOT IN ATTENDANCE:	
Michael Chapman (MCh)	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 advised attendees that, noting the statutory guidance and the AGD Terms of Reference (ToR) had not yet been agreed, the meeting could not be held under the draft ToR, until they have been approved, and recognised that the draft ToR may change as the statutory guidance evolves. As NHS England would like to seek advice on a number of areas, the NHS England SIRO Representative therefore 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; 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 8th June 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:** Dr. Robert French noted a professional link to a study using a beta version of the Longitudinal Study (LS) (NIC-705741-K8K9G), but noted no specific connection with the application or other staff involved, and it was agreed that this was not a conflict of interest. Prof. Nicola Fear noted a professional link to a study using a beta version of the Longitudinal Study (LS) (NIC-705741-K8K9G), but noted no specific connection with the application or other staff involved, and it was agreed that this was not a conflict of interest. Jenny Westaway noted a professional link to the Royal College of Anaesthetists, the funders of NIC-438551-P4C0G - University of Nottingham. It was agreed this did not preclude Jenny from taking part in the discussion about this application. Prof. Nicola Fear noted professional links to NIC-438551-P4C0G - University of Nottingham but noted no specific connections with the application or staff involved and it was agreed that this was not a conflict of interest. Prof. Nicola Fear noted a personal and professional link to the former Head of the Centre for Longitudinal Studies (CLS) unit at University College London (NIC-49297-Q7G1Q), but noted no specific connection with the application or other staff involved, and it was agreed that this was not a conflict of interest. Paul Affleck noted that he was a public contributor to the UK Longitudinal Linkage Collaboration referenced in NIC-49297-Q7G1Q-v4.15 University College London, but noted no specific connections with the application or staff involved and it was agreed that this was not a conflict of interest.	
INTERNAL DATA DISSEMINATION REQUEST(S):		
4.1	**Title:** National Disease Registration Service (NDRS) – COVID-19 Therapeutics data access **Presenter:** Mary Bythell **Observer:** Rahima Oliver **Previous Reviews:** The COVID-19 Therapeutics Programme Dataset – Briefing Presentation was previously presented at the IGARD meetings on the 4th August 2022 and the 11th August 2022. The purpose of processing the COVID-19 therapeutics data in NDRS is to support the understanding of how COVID-19 impacted people with cancer and rare diseases in England and therefore drive improvements to policy, healthcare delivery and ultimately, patient	

	outcomes. Many people with rare diseases are in the groups considered at highest risk of getting seriously ill from COVID-19 and were eligible for COVID therapeutics as treatment to prevent severe COVID illness if they had tested positive for COVID infection. The purpose of this analysis is to improve the understanding of the impact of COVID-19 on immunocompromised people with rare disease and cancer. The output of the analysis will inform government policy and healthcare decision-making by both clinicians and patients. NDRS provides inter-disciplinary expertise across the whole clinical care pathway for rare disease and cancer to enable disparate data feeds to become high-quality intelligence that leads to actionable output. NDRS data is used for direct care, service evaluation and audit, production of official statistics, policy development and delivery, supporting commissioning decisions, as well as research and other purposes as described in the NDRS Specifications. The aim of this linkage is to provide data relevant to policy makers, clinicians, and patients to support the effort to minimise the ongoing impact of COVID-19 on people with conditions or on treatments likely to affect their ability to produce antibodies. Data will be disseminated in non-disclosive aggregate form through reports, publications, stakeholder events and other outlets, where appropriate. Lay summaries will be made available for all output and shared with relevant patient charities. MELODY Study findings will be shared with participants via the Digi-Trials texting service. **Outcome of discussion:** The group were supportive of the internal data dissemination request, and welcomed the two supporting papers, and wished to draw to the attention of the SIRO the following high-level comments / observations: **4.1.1** The group noted that the Data Protection Impact Assessment (DPIA) had been submitted for review and that advice would be provided on the content of this document. **4.1.2** However, separate to this agenda item, the independent advisers advised NHS England, that for future agenda items where documentation was being presented without a covering briefing paper, it would be helpful if it was highlighted in advance of the meeting if the subject matter was an internal data flow, what the purpose of the AGD review was and what AGD advice was being sought, by way of a cover note or similar. **ACTION:** NHS England to ensure that all future AGD agenda items are provided with the relevant background information / clarity on the specific request from AGD, by way of a cover note to the existing internal documentation, if a briefing paper is not being submitted. **4.1.3** The group noted the letter from the Secretary of State for Health and Social Care had providing support for the data flow, noting this would help to inform decision making for the protection of vulnerable groups that may have an impaired response to COVID-19 vaccination and remain at higher risk of severe COVID-19. **4.1.4** The NHS England SIRO representative noted the multiple legal basis cited, and it was suggested by the independent advisers that the legal basis was narrowed to one legal basis, in relation to the processing (or if different aspects of the processing relied on different legal bases, to note this). **4.1.5** The independent advisers suggested that section 3 (purpose of the processing) of the DPIA was updated with an express statement highlighting that, due to the nature of some of the datasets, they were restricted to COVID-19 related research **only**.	NHSE

	4.1.6 The independent advisers suggested that the DPIA was updated with information in relation to the deletion policy, noting that this process was currently unclear. **4.1.7** It was suggested that, for transparency, the DPIA was updated to include indicative sample sizes, to support the understanding of the magnitude of the processing being undertaken. **4.1.8** The independent advisers noted that the identifiers listed in section 8 (*Is it necessary to collect and process all data items*) of the DPIA did not align with the information in section 4 (description of the processing); and suggested that this was aligned and updated as appropriate. **4.1.9** The independent advisers noted the transparency information in section 7 (*What steps have you taken to ensure individuals are informed about the ways in which their personal data is being used*) of the DPIA; and suggested that this was updated further with information of the patient and public involvement and engagement (PPIE) undertaken and / or planned. **4.1.10** In respect of section 9 (*Describe if personal datasets are to be matched, combined or linked with other datasets*) of the DPIA, the independent advisers suggested that this was updated to ensure that **all** datasets were listed, including the linked datasets. **4.1.11** It was suggested that NHS England consider publishing this DPIA. **4.1.12** It was suggested that NHS England ensure that the public facing website was updated to ensure transparency to the public.	
EXTERNAL DATA DISSEMINATION REQUESTS:		
5.1	**Reference Number:** NIC-705741-K8K9G-v0.2 **Applicant:** Office for National Statistics (ONS) **Application Title:** ONS Longitudinal Study **Presenter:** Dave Cronin **Observer:** Ben Cromack **Linked applications:** This application is linked to NIC-194340-D6F3B **Application:** This was a new application. This application is intended to replace the existing data sharing agreement (DSA) NIC-194340-D6F3B. The purpose of the application is for a Longitudinal Study (LS), which has linked records at each Census since 1971 for people born on one of four selected dates in a calendar year; the four dates were used to update the sample at the 1981, 1991, 2001, 2011 and 2021 Censuses. ONS produces the LS Research Database which contains pseudonymised patient level data with unique LS Member IDs being used in place of identifying data; and contains some NHS England variables and some information derived from NHS England data. ONS actively promotes wide use of the LS Research Database; Researchers need to make an application to access the LS for research purposes.	

	Should this 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** NHS England advised the group that following the review of NIC-194340-D6F3B by the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) on the 24th March 2022, where the application was submitted for 'advice'; that this application had been updated with specific attention focussed on the following points raised at that meeting: **1)** consulting the Health Research Authority (HRA) to seek advice on whether an ethics review was required; **2)** Transparency; and **3)** consulting with the Information Commissioner's Office (ICO) about what information should be provided to the public to enable data subjects included in this study to exercise their UK General Data Protection Regulation (UK GDPR) rights. **5.1.2** The independent advisers noted within the application that it was stated that HRA ethics approval was **not** required, as ethics approval was sought from the National Statistician's Data Ethics Advisory Committee (NSDEC) rather than from the HRA Research Ethics Committee (REC); and suggested that, as per the previous IGARD advice, that as the role of the HRA is to protect and promote the interests of patients and the public in health research, NHS England / ONS should consult the HRA to see if the study requires review by a HRA REC. In addition, the group made the following observations on the application and / or supporting documentation provided as part of the review: **5.1.3** In respect of transparency, the independent advisers noted that improvements had been made to the public facing website; however, suggested that further work could be undertaken, including, but not limited to, ensuring compliance with UK GDPR, for example in relation to clarity about any data subject rights that were applicable to this specific study (rather than linking to a generic page). **5.1.4** The independent advisers noted that ONS had consulted with the ICO, as per the previous IGARD advice; and noted from the internal application assessment form that there were no issues / concerns raised by the ICO; however, queried whether the ICO had been expressly advised about the non-disclosure of the four selected birth dates, noting that this was not clear from the information relayed via DARS. **5.1.5** The independent advisers noted in the internal application assessment form, and the public facing website, it was stated that disclosure of the four birth dates would significantly increase the risk of identification; and suggested that for transparency, the website was updated to clearly outline at what stage of the processing disclosure of the birth dates would result in increased risk of identification. **5.1.6** The independent advisers queried the reliance of section 43 of The Statistics and Registration Service Act 2007 (SRSA) as referenced in the application; and suggested that this was removed or updated, noting this legal basis was not for research but for the purpose of population statistics.	

	5.1.7 Noting the importance of this long running study, the independent advisers noted the impactful and significant outputs and yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits). **5.1.8** Noting that there were no special conditions in section 6 (Special Conditions), the independent advisers suggested that NHS England considered including appropriate special conditions, including, but not limited to, the standard storage location special condition; and the citation special condition, to state that, where practicable, outputs cite the source of the data as *"This work uses data provided by patients and collected by the NHS as part of their care and support".* **5.1.9** Separate to this application, NHS England advised the group, that work was ongoing to review all special conditions that may go in section 6; and that further information on this would be presented at a future AGD meeting. **ACTION:** NHS England to provide further information to AGD, in respect of special conditions for section 6.	NHSE
5.2	**Reference Number:** NIC-49297-Q7G1Q-v4.15 **Applicant:** University College London (UCL) **Application Title:** Centre for Longitudinal Studies Birth Cohort Studies Data Linkage: National Child Development Study **Presenter:** Dave Cronin **SAT Observers**: Dan Goodwin / Jodie Taylor-Brown **Previous Reviews:** The application and relevant supporting documents were previously presented / discussed at the IGARD meetings on the 20th July 2017, 10th August 2017, 6th August 2020, 3rd September 2020 and the 13th January 2022. The application and relevant supporting documents were previously presented / discussed at the IGARD COVID-19 response meetings on the 29th September 2020. **Linked applications:** This application is linked to NIC-51342-V1M5W, NIC-49826-T0J7C and NIC-49826-T0J7C. **Application:** This was an amendment application. NHS England were seeking advice on the following point: 1. to confirm AGD advice to NHS England in respect of the Next Steps study (NIC-51342-V1M5W) and whether registration with UK Data Service (UKDS) must be a mandatory requirement required by the DSA (as per the AGD minutes from the 30th March 2023). Should the 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: In respect of point 1 above: **5.2.1** NHS England advised the group, that as part of this review, they were seeking advice for all four of the linked applications to be amended, to allow researchers at The Centre for	

	Longitudinal Studies (CLS) at UCL to access the data outside of the UKDS; and noted that the four applications would be updated as may be appropriate (including NIC-51342-V1M5W which had been to AGD on the 30th March 2023). The independent advisers were supportive of this approach. **5.2.2** Noting that comments had already been provided by AGD at the AGD meeting on the 30th March 2023 with regard to NIC-51342-V1M5W, in respect of whether registration with UK Data Service (UKDS) must be a mandatory requirement required by the DSA; the independent advisers suggested the applicant **1)** contact UKDS to seek their advice on a meaningful way of showing adherence to UKDS requirements and / or **2)** seek guidance on this issue from their Health Research Authority Research Ethics Committee (HRA REC). **5.2.3** The independent advisers commended NHS England and the applicant on the work undertaken on the application. **5.2.4** The independent advisers noted the information within the internal application assessment form, in respect of ongoing / future transparency; and suggested that there was further transparency in the future about projects undertaken using the data flowing under this data sharing agreement (DSA).	
5.3	**Reference Number:** NIC-346693-F2X1G-v5.10 **Applicant:** University College London (UCL) **Application Title:** Whitehall II **Presenter:** Dave Cronin **SAT Observer**: Dan Goodwin / Jodie Taylor-Brown **Previous Reviews:** The application and relevant supporting documents were previously presented / discussed at the IGARD meetings on the 6th July 2017 and the 3rd August 2017. The application and relevant supporting documents were previously presented / discussed at the DAAG meetings on the 6th October 2015 and the 15th September 2015. **Application:** This was an amendment application. The amendment is to request access to the following datasets **1)** Emergency Care Data Set (ECDS); **2)** COVID-19 Second Generation Surveillance System (SGSS); and **3)** COVID-19 Vaccination Status. Should the 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 this was an application for academic programmatic access, however advised that, as currently presented, it did not align with other similar applications. This includes, but is not limited to, the governance in respect of how projects were selected, for example, there were no Terms of Reference for a governance group, covering assessment of benefits to health and social care; an assessment of the commercial benefits and proportionate balancing with public benefits; oversight of the nature of the funding; data minimisation; purpose limitation; compliance with	

	UK General Data Protection Regulation (UK GDPR) principles; and compliance with the NHS England data sharing agreement (DSA). **5.3.2** The independent advisers noted that another significant feature of programmatic access should be lay involvement. While this was not a legal requirement, best practice would be for lay involvement at either part the oversight structure or as part of the individual work project design. **5.3.3** It was also noted by the independent advisers that, for programmatic access, there would usually be transparency on the projects that had been approved, in line with UK GDPR; and further information of how the benefits had been assessed in line with the National Data Guardian (NDG) guidance on benefits. There did not appear to be any plans addressing this point. **5.3.4** In respect of the amendment to add the additional datasets to the data sharing application, the independent advisers suggested that NHS England satisfy itself that the current ethical support extends to the proposed additional datasets and updates to the purpose for processing; and that this should be undertaken **before** the additional datasets flow. **5.3.5** In addition, the independent advisers suggested that NHS England satisfy itself that Health Research Authority Confidentiality Advisory Group (HRA CAG) support is still in place, noting the specific condition of support that *"Consent needs to be explicitly sought for the data linkages from patients who are still actively responding. Provide feedback to the CAG **within one month** from the date of this letter"* does not appear to have been met within the timeframe specified. In addition, the group made the following observations on the application and / or supporting documentation provided as part of the review: **5.3.6** The independent advisers suggested that NHS England may wish to consider updating the questions and answers (Q&A) for programmatic access in the internal assessment form to ensure all the various requirements were addressed (as highlighted above). **ACTION:** NHS England to discuss the Q&A process for programmatic access for the internal assessment form at a future AGD meeting. **5.3.7** Noting the addition of the COVID-19 datasets to the data sharing agreement (DSA), NHS England advised the group, that section 6 (Special Conditions) would need updating to include the special condition that they were restricted to COVID-19 related research only, in line with NHS England's DARS Standard for Special Conditions. The group noted the verbal update. **5.3.8** The independent advisers queried the potential conflict that might be inherent in the functions of the Principal Investigator and the Chief Investigator in light of the statements in section 5(a) (Objective for Processing), that *"The Chief Investigator and Principal Investigators discuss and approve draft funding applications prior to submission…"* and *"Only Whitehall II study Principal Investigators are permitted to submit proposals..."*; and suggested that further clarification was provided on the roles.	NHSE
5.4	**Reference Number:** NIC-606839-V5X2P-v0.13	

	Applicant: The Boston Consulting Group UK LLP **Application Title:** Boston Consulting Group UK - NHS England Data Extract **Presenter:** Ben Cromack **SAT Observer:** Louise Dunn **Application:** This was a new application. NHS England were seeking advice on the following point: 1. NHS England's assessment that the purpose of the application is not to use the data for marketing purposes and that the outputs, as with many outputs generated by all applications, may be used to promote services and they have been transparent about the use of the data for this purpose. Should the 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: In respect of point 1 above: **5.4.1** Noting the statement in the NHS England DARS Standard for Commercial Purpose *"…will not approve requests for data where the purpose is for marketing purposes, including promoting or selling products or services, market research or advertising";* the independent advisers noted that the data would not be used directly for marketing, however they suggested that a special condition was added to section 6 (Special Conditions) to state *"The applicant will not use the data to undertake analysis of the market for its products, to identify potential customers within the NHS, or otherwise to generate marketing leads"*, or similar. **ACTION:** NHS England to undertake a review of the NHS England DARS Standard for Commercial Purpose, taking advice from AGD, with the aim of clarifying the points on marketing, potentially with reference to case studies. **5.4.2** The NHS England SIRO representative queried whether the data sharing agreement (DSA) accurately reflects the territory of use; and it was suggested by the group that given the global nature of consultancy work, and the likelihood of travel by the employee(s) of the applicant, that a special condition was added to section 6 specifically highlighting the restrictions of the permitted territory of use. **5.4.3** Noting the current length of the data sharing agreement was 12-months, the group discussed whether this should be longer, to allow sufficient time for the data to flow and work to accrue, and it was suggested that this could be a 15-month DSA. The independent advisers suggested that a special condition was added to section 6, that the applicant submit the application and relevant supporting documents no later than three months prior to the expiry date, for extension / renewal etc; and that information should be provided at this point as to anticipated and actual workflow, types of clients etc, in line with other similar commercial applications. **5.4.4** In addition, the independent advisers advised that the special condition in section 6, should reflect that when an extension / renewal application was submitted to NHS England, the applicant should provide a list of projects that had been approved, in line with the UK	NHSE

	General Data Protection Regulation (UK GDPR); and further information of how the benefits had been assessed in line with the National Data Guardian (NDG) guidance on benefits. **5.4.5** Noting the contractual requirement in section 4 (Privacy Notice) in respect of transparency; the independent advisers suggested that either a special condition was added to section 6, that a UK GDPR compliant, publicly accessible transparency notice was maintained, throughout the life of the DSA; or, that NHS England carried out additional checks on the transparency notice for this application before any data flows, noting that The Boston Consulting Group UK LLP was a new commerical user of NHS England data. **5.4.6** The group discussed the importance of UK-based transparency for this application and noted the challenges for a first-time user of NHS England data. In addition, the group made the following observations on the application and / or supporting documentation provided as part of the review: **5.4.7** Noting that The Boston Consulting Group UK LLP was a new recipient of NHS England data, the independent advisers reiterated the query raised at the AGD meeting on the 8th June 2023, what, if any, due diligence had been undertaken by NHS England on this organisation, beyond the usual NHS England checks. **5.4.8** Separate to this application, if NHS England do not currently undertake any due diligence on new applicants, the independent advisers suggested that this was given further consideration. **ACTION:** NHS England to consider undertaking additional due diligence for new recipients of NHS England data; or providing an update to the group (for information) on what due diligence was undertaken. **5.4.9** The independent advisers queried the reliance of s261(2)(a) of the Health and Social Care Act 2012 to disseminate the data; and suggested that this was reviewed and updated as necessary, noting that this subsection alone does **not** provide the power to disseminate. **5.4.10** In addition, the NHS England DPO representative advised the group that further information would be shared with the group at a future AGD meeting in respect of the guidance followed on this and other legal bases. **ACTION:** NHS England DPO representative to provide further information on the legal basis guidance. **5.4.11** The independent advisers noted in the internal application assessment form information in relation to the applicant's American parent company; and highlighted the potential risks of NHS England data flowing to the USA, and referred back to the previous discussions on this subject, including the update from NHS England at the AGD meeting on the 23rd March 2023 (reiterated at the AGD meeting on the 20th April 2023); where the independent advisers noted that the impact of the USA Patriot Act and other federal legislation with a global impact and the risks associated with this, should be determined at NHS England Board level; and that it was not necessarily the responsibility of colleagues within DARS to undertake additional checks. **5.4.12** Following the discussion on the USA Patriot Act at the AGD meeting on the 23rd March 2023, the NHS England SIRO representative advised that an interim policy position	NHSE DPO

	would need to be agreed within NHS England, for example, to determine what checks will be undertaken; and that further information would be provided to the group in due course. **ACTION:** the NHS England SIRO representative to provide further information to the group on the impact of the USA Patriot Act and other US legislation with a similar reach and the risks associated with this. **5.4.13** NHS England advised the group that efforts had been undertaken to ensure that an appropriate quantum of data would flow to the applicant, in line with NHS England's DARS standard for data minimisation, and in line with similar commercial applications. The group noted the verbal update and suggested that any additional information in respect of this was added to the internal application assessment form and / or the application as necessary for background / transparency. **5.4.14** In addition, the NHS England SIRO representative asked that section 5 (Purpose / Methods / Outputs) of the application was updated to ensure that it was clear on the rolling nature of the data request, for transparency. **5.4.15** Noting the statement in section 4.5 of the internal application assessment form *"Applicant has considered several areas that may impact the rights of the data subject. The applicant states none of these are included in the processing of this data"*, the independent advisers suggested that this was updated noting the current form of wording suggests that the data subjects do not have any rights.	SIRO
5.5	**Reference Number:** NIC-664530-K6Q5H-v0.5 **Applicant:** Imperial College London **Application Title:** The Role of Early Detection and Treatment of Anal Intraepithelial Neoplasia in the Prevention of Anal Squamous Cell Carcinoma in Women: Establishing the Disease Burden in Women with Genital Cancer **Presenter:** James Watts **SAT Observer:** Louise Dunn **Application:** This was a new application. The purpose of the application is for a study aiming to clarify how many women in England with anal cancer have also been diagnosed with genital High-Grade Squamous Intraepithelial Lesions (HSIL) and/or cancer and will explore the effects of specific sociodemographic risk factors on the incidence of synchronous anal and genital pathology; this will help determine which patients are likely to benefit from closer anogenital surveillance. Furthermore, this study aims to add to a body of research that can be used to develop guidelines and services that are targeted at the early detection and treatment of anal cancer in women. Should the 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:	

	5.5.1 NHS England advised the group that the application would need updating to reflect the standard National Disease Registration Service (NDRS) citation special condition in section 6 (Special Conditions). The group noted the verbal update. **5.5.2** In addition, the independent advisers noted that the special condition, stating that the funder would not have influence on the outcomes nor suppress any of the findings of the research, was missing from section 6, and suggested that this was included as per process. NHS England noted the suggestion and advised that the questions and answers (Q&A) for the internal application assessment form would need updating to reflect this special condition. **ACTION:** NHS England to update the Q&A process to include a special condition for funders. **5.5.3** The independent advisers noted that the internal application assessment form was clear on the justification for a three-year data sharing agreement, however advised that this was not clear in the application form; and suggested that for transparency, section 5 (Purpose / Methods / Outputs) was updated with a justification for this. **5.5.4** The independent advisers noted the conflicting information in the internal application assessment form and the application that stated *"…the earliest vulval and/or vaginal and/or cervical cancer and/or HSIL diagnosis will be in **1981**…"*; and the Health Research Authority Research Ethics Committee (HRA REC) forms provided as supporting documents, that refer to *"**1995** onwards"*; and suggested that the information was reviewed and aligned with the correct information. **5.5.5** The independent advisers noted in section 1(b) (Data Controller(s)) that the security assurance will expire on the 30th June 2023, and suggested that NHS England ensure that this has been renewed, and that the application was updated as necessary. **5.5.6** Noting that the work outlined in the application was an educational project, the independent advisers suggested that this was noted in section 5 of the application for transparency. In addition, it was noted by NHS England that this was currently not in the questions and answers (Q&A) for the internal application assessment form and would need updating to reflect that where work is student led, that this needs to be transparent in the application. **ACTION:** NHS England to update the Q&A process to ensure that where work is student led, that this is transparent in the application. **5.5.7** The independent advisers noted that processing of the data under this data sharing agreement (DSA) could be done remotely; and suggested that NHS England needs a clear policy on remote access. **ACTION:** NHS England to provide its position to AGD on remote access *(as previously requested and agreed at the AGD meeting on the 2nd February 2023)*.	NHSE NHSE NHSE
5.6	**Reference Number:** NIC-438551-P4C0G-v0.16 **Applicant:** University of Nottingham **Application Title:** The 3rd Sprint National Anaesthesia Project (SNAP 3) **Presenter:** Clare Wright	

	SAT Observer: Cath Day **Observer:** Sara Lubbock **Application:** This was a new application. The purpose of the application is an observational cohort study, that aims to describe the impact of frailty and delirium whilst finding associations between frailty, comorbidity, multimorbidity, and delirium and their management, with outcomes following surgery in older people. It will consist of a short period of data collection from potentially every eligible patient having surgery in a defined period. Should the 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: **5.6.1** The independent advisers noted the list of organisations in section 5(a) (Objective for Processing) that were involved with the study, but who were not permitted to access the data; and suggested that University College London (UCL) were also added to the list, noting the reference to the study statistician in the protocol and that UCL were not referenced in the application. **5.6.2** In addition, the independent advisers queried the role of the UCL statistician referred to in the protocol; and suggested that if they do have a role then this should be made clear within the application; and that, if appropriate, an honorary contract should be in place for this individual. In addition, the group made the following observations on the application and / or supporting documentation provided as part of the review: **5.6.3** The independent advisers commended NHS England on the work undertaken to review the consent materials, and the consent review document shared with the group in advance of the meeting. **5.6.4** NHS England advised group that prior to the meeting, they had undertaken a review of the applicant's study specific privacy notice, and noticed that the UK General Data Protection Regulation (UK GDPR) legal basis cited was incorrect and did not align with the application; and also, that that processing under this application was not correctly aligned with the study specific privacy notice. NHS England noted that they would be discussing both of these points with the applicant. The group noted the verbal update. **5.6.5** The independent advisers noted the helpful information provided in the consultee advice proforma provided as a supporting document and suggested that it would be helpful if the pro forma also included a clear conclusion at the end (e.g. *"compatible with the proposed processing"* etc). **5.6.6** Noting the statement in section 5(a) *"The funders will have no ability to suppress or otherwise limit the publication of findings"*; the independent advisers suggested that the questions and answers (Q&A) for the internal application assessment form would need updating to reflect the standard wording previously used. **ACTION:** NHS England to update the Q&A for the internal application assessment form to reflect the standard wording previously used.	NHSE

EXTERNAL DATA DISSEMINATION - SIRO APPROVED / SEEKING SIRO APPROVAL		
6.1	**Reference Number:** NIC-656860-Q5Q9Q-v2.2 **Applicant:** Guy's and St Thomas' NHS FT **Application Title:** A follow-up of GLACIER (a study to investigate the Genetics of LobulAr Carcinoma In situ in EuRope) and ICICLE (A study to Investigate the genetiCs of In situ Carcinoma of the ductaLsubtypE). (ODR1920_145) **Presenter:** No Presenter **Previous Reviews:** The application and relevant supporting documents had previously been presented / discussed at the IGARD meeting on the 19th January 2023. **Application:** The purpose of the application is for a study, with the aim of obtaining survival data on participants with lobular carcinoma in situ, invasive lobular carcinoma and ductal carcinoma in situ who were recruited to the GLACIER and ICICLE studies between 2007 and 2013. **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 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. **6.1.2** The independent advisers noted the reference to *"King's College London"* (KCL) in section 1 (Abstract) of the application, however they were not listed as a data controller or data processor., It was suggested that this was explored further, and the application was updated to reflect the correct / factual information. **6.1.3** The independent advisers suggested that the application was updated to reflect the standard NDRS citation special condition in section 6 (Special Conditions). The NHS England SIRO representative thanked the group for their time.	
6.2	**Reference Number:** NIC-175120-W5G2X-v11.2 **Applicant:** Office for National Statistics (ONS) **Application Title:** D5 - Office for National Statistics requirements for NHS-Digital data, for the purposes of Statistics and Statistical Research, under section 45 of the Statistics and Registration Services Act 2007 as amended by the Digital Economy Act 2017 **Presenter:** No Presenter **Previous Reviews:** The application and relevant supporting documents had previously been presented / discussed at the AGD meetings on the 16th March 2023 and the 8th June 2023. **Application:** The purpose of the application is to use data previously disseminated under this data sharing agreement (DSA) for the PSS CQUIN project, for this new project the Social Network Research Study.	

	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: **6.2.1** The independent advisers noted in the supporting documentation the discussions as to what was permitted under various sections of the Statistics and Registration Service Act 2007 and that this is being monitored and followed up by the NHS England's Audit and Assurance team. The independent advisers asked that further information on this matter be provided to the group in due course. **ACTION:** NHS England to provide a further update on what is permitted under various sections of the Statistics and Registration Service Act 2007. The group thanked NHS England for the written update and advised that they had no further comments to make on the documentation provided. The NHS England SIRO representative thanked the group for their time.	
6.3	**Reference Number:** NIC-419335-H5P8T-v1.7 **Applicant:** University of Oxford **Application Title:** Outcomes of Patients who survived Treatment on an Intensive Care unit for COVID-19 in England and Wales (OPTIC-19): a comparative retrospective cohort study. **Presenter:** No Presenter **Previous Reviews:** The application and relevant supporting documents had previously been presented / discussed at the IGARD BAU meetings on the 15th July 2021 and the 16th September 2021. **Application:** The purpose of the application is for a retrospective cohort study, which aims to estimate the risk of adverse outcomes (death, emergency hospital readmission, heart attacks, strokes) in patients treated on an intensive care unit with COVID-19 in England and Wales, one year after discharge from hospital. The study team will compare these risks to patients treated in ICU for other conditions. **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 advised that they had no further comments to make on the documentation provided. The NHS England SIRO representative thanked the group for their time.	
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. **ACTION:** NHS England to provide further clarity on the risk management framework.	NHSE
8	**AGD Terms of Reference**	

	The independent advisers noted that the latest draft AGD Terms of Reference had been circulated on the 30th May 2023. As per the request from NHS England's Executive Director, Privacy, Transparency, Ethics & Legal (PTEL), the independent advisers noted that formal comments / feedback on the draft ToR would be returned by the 16th June 2023.	To note
9	**Standard operating procedures** The ongoing forward plan of work for creating Standard Operating Procedures was discussed.	To note
10 **10.1**	**New Operational Actions & those carried forward from previous meetings of AGD:** **Zero Hours contracts for independent advisers** Garry Coleman noted that NHS England were actively working on putting zero hours contracts in place for all independent advisers.	To note
Any Other Business		
11	**PAG Process** The group note at the AGD meeting on the 18th May 2023, the NHS England Caldicott Guardian Team representative took an action to ensure there was a clear, consistent, and transparent approach to the review of applications / applicants requesting the GDPPR dataset; and that this was clearly communicated to the public, profession etc; for example, in respect of the process for applications that have previously received PAG support. Following the meeting on the 18th May 2023, it was noted that further information had been circulated by the NHS England Caldicott Guardian Team representative in respect of this issue out of committee. The group had a further discussion on this issue, in particular focussing on engagement with the British Medical Association (BMA) and the Royal College of General Practitioners (RCGP), transparency to the public and how to engage the BMA and RCGP with any *"new"* reviews for GDPPR data. The group noted that there would be further discussions on this issue in due course.	
12	**Department for Health and Social Care (DHSC) Data access policy update** The group noted that DHSC had published a draft data access policy update, and that comments on this were due by the 23rd June 2023. It was agreed that a note would be circulated by NHS England and comments would be collated out of committee prior to the next AGD meeting on the 23rd June 2023; and that a further discussion would be held at this meeting, with comments being returned to NHS England's Privacy, Transparency, Ethics & Legal (PTEL) by the deadline.	
Meeting Closure As there was no further business raised, the Chair thanked attendees for their time and closed the meeting.		