Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 1 December 2022

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member / Co-Deputy IGARD Chair
Maria Clark	Lay Member
Dr. Robert French	Specialist Academic / Statistician Member
Kirsty Irvine	IGARD Chair
Dr. Imran Khan	Specialist GP Member / Co-Deputy IGARD Chair
Jenny Westaway	Lay Member (Item 8)
IGARD MEMBERS NOT IN ATTENDANCE:	
Prof. Nicola Fear	Specialist Academic Member
Dr. Geoffrey Schrecker	Specialist GP Member
Dr. Maurice Smith	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Garry Coleman	Associate Director, Deputy SIRO & Audit Services (Presenter: items 7.2 and 8)
Dave Cronin	Data Access Request Services (DARS) (**SAT Observer**: items 3.2) (**Presenter**: items 3.3 and 7.1)
Catherine Day	Data Access Request Services (DARS SAT) (**SAT Observer**: item 3.2, 3.5, 3.6)
Louise Dunn	Data Access Request Services (DARS SAT) (**SAT Observer**: item 3.1 and 3.4)
Duncan Easton	Data Access Request Services (DARS SAT) (**SAT Observer**: item 3.7 and 4.1)
Kathryn Griffiths	Privacy, Transparency, Ethics & Legal (PTEL) (**Observer**: item 3.3)
Suzanne Hartley	Data Access Request Services (DARS) (**Presenter**: item 7.2)
Dickie Langley	Privacy, Transparency, Ethics & Legal (PTEL) (**Observer**: item 8)
Mary Kisanga	Data Access Request Services (DARS SAT) (**SAT Observer**: item 3.4)

David Morris	Data Access Request Services (DARS) (**Presenter**: item 3.7)
Karen Myers	IGARD Secretariat Team
Amy Ogborne	Privacy, Transparency, Ethics & Legal (PTEL) (**Observer**: item 3.3)
Dr. Jonathan Osborn	Deputy Caldicott Guardian (**Observer**: items 3.3 and 8)
Frances Perry	Digi-Trials (**Presenter:** item 3.1)
Denise Pine	Data Access Request Services (DARS) (**Presenter**: item 7.2)
Aisha Powell	Data Access Request Services (DARS) (**Presenter**: item 3.2) (**Observer**: item 3.3)
Charlotte Skinner	Data Access Request Services (DARS) (**Presenter:** item 3.5)
Jodie Taylor-Brown	Data Access Request Services (DARS) (**Observer**: item 3.3)
James Watts	Data Access Request Services (DARS SAT) (**Presenter**: item 3.4)
Vicki Williams	IGARD Secretariat Team
Clare Wright	Data Access Request Services (DARS) (**Presenter:** item 3.6)
***SAT** – Senior Approval Team (DARS)	

1	**Declaration of interests:** Maria Clark noted professional links as part of her role as external member of the University of Sheffield Research Ethics Committee. However, she noted no specific connections with the application, or the staff involved, and it was agreed that this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 24th November 2022 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record of the meeting **Out of committee recommendations:** An out of committee report was received (see Appendix A).
2	**Briefing Notes**
	There were no briefing papers submitted for review.
3	**Data Applications**
3.1	Our Future Health: Our Future Health Recruitment Programme (Presenter: Frances Perry) NIC-414067-K8R6J-v1.3 **Application:** This was an amendment application to increase the number of invitations to 12 million to meet recruitment targets.

	The purpose of the application is for a research programme to support people living healthier lives for longer through better prevention, earlier detection and improved treatment of diseases. The programme will aim to speed up the discovery of new methods of early disease detection, and the evaluation of new diagnostic tools, to help identify and treat diseases early when outcomes are usually better. The aims of the research are to **1)** build a resource linking multiple sources of health and health-relevant information, including genetic data, on millions of people in the UK, to facilitate basic discovery research by academic and commercial researchers on early indicators of disease; **2)** to analyse the data in the resource to estimate personal disease risk information for participants, based on genetic and non-genetic information, and offer this estimated personal health information to participants who wish to receive it; **3)** to re-contact sub-groups of participants generally for additional samples, non-routine data and secondary studies over time; and **4)** to re-contact participants on a risk-stratified basis, specifically to enable secondary studies by academic and commercial researchers that is greatly enhanced by being able to identify highly enriched sub-populations / sub-cohorts of participants. This application is linked to NIC-411795-X5N2V. The study is relying on s251 of the NHS Act 2006, for the flow of data out of NHS Digital. NHS Digital advised IGARD that the special condition in section 6 (Special Conditions), relating to the NHS Digital data citation, would need updating to reflect the correct wording. NHS Digital also advised IGARD that following an update from the Privacy, Transparency, Ethics and Legal (PTEL) Team; the application would be amended to cite s261(5)(d) of the Health and Social Care Act 2012, as the legal basis for NHS Digital to disseminate the data, noting the Data Controller was a charity, and it was therefore necessary for them to have the data for the purpose of exercising functions conferred under or by virtue of the Charities Act. NHS Digital confirmed that the common law duty of confidentiality would be met by s251 of the NHS Act 2006. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD meeting on the 5th May 2022. The application was also discussed under 'AOB' on the 26th May 2022; and on the 17th November 2022, where NHS Digital attended the meeting, to advise IGARD that the applicant had submitted an urgent amendment to their DSA, to request permission to increase the number of potential participants contacted for the study from 3 million to 12 million. The Deputy SIRO noted during this discussion, that he was **not** minded to approve via the NHS Digital SIRO Precedent the request to increase to 12 million, however had been comfortable to increase the request to 5 million as long as the application returned to IGARD for an independent review before the end of the year (please see item 4.3). IGARD noted that the application and relevant supporting documents for NIC-411795-X5N2V had previously been presented at the IGARD meeting on the 22nd September 2022. IGARD noted the verbal update from NHS Digital in respect of the amendments to the NHS Digital data citation special condition in section 6; and supported the update to the application. IGARD also noted that verbal update in respect of the update from PTEL on the s261 legal basis; and asked that the relevant updates were made to the application to ensure the correct legal basis was cited. IGARD confirmed that they were of the view that the relevant s251 support was broadly compatible with the processing outlined in the application.

	IGARD queried the information in section 5(a) (Objective for Processing) that the cohort inclusion criteria was for individuals over the age of 18; and asked that a further justification was provided as to why under 18s were **not** included, noting that the research could impact this specific age group, and expressed concern that a proportion of society were being excluded. IGARD noted the information in section 5(a) relating to the funding of the research, however, asked that for transparency, this was updated further to include an explicit statement confirming the quantum of commercial funding, for example, any funding from life science companies. In addition, IGARD noted a risk to NHS Digital that they may be facilitating research where the data subjects were **not** fully cognisant of the extent of the commercial funding underpinning the charity or the commercial aspects of the research. IGARD suggested that in order to mitigate this risk, the applicant could undertake further public involvement and engagement (PPIE) engagement, for example, the applicant could share the videos with the DigiTrials patient and PPIE group for their feedback. IGARD suggested that DigiTrials considered the advantage for 'first movers' given the limited pool of research subjects, limiting recruitment possibilities for other pharmaceutical companies or researchers. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO precedent, for **any** increase to the number of invitations issued or any change to the target group. **Outcome:** recommendation to approve The following amendments were requested: 1. To update the application throughout with the correct legal basis (as per the verbal update from NHS Digital). 2. To amend the special condition in section 6, 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"* (as per the verbal update from NHS Digital). 3. To update section 5(a) with a justification why the cohort is over 18s only. 4. To update section 5(a) with an explicit statement of the quantum of commercial funding. The following advice was given: 1. IGARD suggested that DigiTrials considered the advantage for 'first movers' given the limited pool of research subjects, limiting recruitment possibilities for other pharmaceutical companies or researchers. 2. IGARD suggested the applicant could share the videos to the Digi-Trials PPIE group for feedback (in terms of understanding the extent of the commercial aspect (see Risk Area below)). 3. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO precedent for any increase to the number of invitations issued or any change to the target group. **Risk Area**: NHS Digital may be facilitating research where the data subjects are not fully cognisant of the extent of the commercial funding underpinning the charity or the commercial aspects of the research.

3.2	IQVIA IES UK Limited: Pulmonary Arterial Hypertension (PAH) population epidemiological analysis platform formation (Presenter: Aisha Powell) NIC-58999-K6P8B-v5.4 **Application:** This was an extension application to permit the holding and processing of pseudonymised Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC) and HES Outpatients. It was also an amendment application to update the application in line with NHS Digital DARS Standards. The purpose of the application is to permit IQVIA Ltd, IQVIA Technology Services Ltd and Sheffield Teaching Hospitals NHS Foundation Trust to continue to hold the data for one year and process it for the verification of published findings if required. Pulmonary Arterial Hypertension (PAH) is a disease primarily of small arteries in the lung which results in a progressive rise in lung blood pressure and heart failure. There are several types of PAH including idiopathic PAH (iPAH) and Associated PAH related to a range of disease processes, including cirrhosis, connective tissue disease, congenital heart disease, HIV infection and sickle-cell disease. The overall aim of the application was for a study focused on diagnosis pathways but also considered post-diagnosis treatment patterns of patients. The study team believe there are opportunities to identify iPAH patients earlier based on the pattern of patients' interaction with secondary care facilities, symptoms shown and demographics, therefore identifying predictive signals/ markers which could lead to an earlier diagnosis of iPAH patients. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD meeting on the 13th April 2017. IGARD noted that prior to the meeting, a query had been raised by an IGARD member, in relation to the conflicting statements in section 5(c) (Specific Outputs Expected) "*Under this agreement, no new Outputs are planned as the Data Controller **only** wishes to retain the data only (with processing only to occur when questions have been raised as a result of publications)"*; **and** "*Continued retention of HES data is required to both support any supplementary questions arising from publications and to support further publications in this area*". NHS Digital advised IGARD that the statement referring to the continued retention of the HES data had been removed from the application because it was incorrect. IGARD noted and thanked NHS Digital for the verbal update and supported the update to the application as outlined. In addition, IGARD queried the justification for retaining the data, and were advised by NHS Digital that this should be made clearer within the application, for example, in line with the applicant's organisational data retention and destruction policy. IGARD noted the verbal update from NHS Digital and asked that section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) were updated with a written justification for retaining the data; **and** the plan for deleting the data in terms of an organisational data retention and destruction policy. IGARD noted the statement in section 5(a) (Objective for Processing) *"This data set now comprises of pseudonymised data only and any identifiable data has been destroyed…"*; and asked that for transparency / audit, section 5(a) was updated with confirmation that the appropriate data destruction procedure had been adhered to and a certificate of destruction had been issued for the identifying data.

	IGARD noted the information in section 5(a) relating to the two cohorts; and asked that this was updated further with a sample size for cohort 2, noting that the size of this cohort was currently unclear. IGARD noted references to specific dates and publications in section 5(c), and asked that this was reviewed and updated as necessary, to ensure that the most recent and relevant information was included, in line with NHS Digital DARS Standard for Expected Outcomes. IGARD noted that the citation special condition had been added in section 6 (Special Conditions), however asked that this was updated, 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".* **Outcome:** recommendation to approve subject to the following condition: 1. In respect of the retention / deletions of the data: a) To provide written justification, in section 1 and section 5, for retaining the data; and, b) To provide written confirmation in section 1 and section 5 outlining the plan for deleting the data in terms of an organisational data retention and destruction policy. The following amendments were requested: 1. To provide confirmation in section 5(a) that the appropriate data destruction procedure has been adhered to and a certificate of destruction has been issued for the identifying data. 2. To update section 5(a) with a sample size for cohort 2. 3. To review and amend the dates and publications cited in section 5(c) in line with NHS Digital DARS Standard for Expected Outcomes. 4. To amend the special condition in section 6, 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".* It was agreed the conditions would be approved out of committee (OOC) by the IGARD Chair. **Subsequent to the meeting**: NHS Digital advised IGARD on the 8th December 2022 that *"IQVIA IES UK Limited"* had been incorrectly noted as the applicant on this DSA; and advised that this had been updated to correctly reflect that ***"IQVIA Ltd"*** were the applicant. IGARD thanked NHS Digital for the update however noted that they had reviewed the application and provided their recommendations based on the application being *"IQVIA IES UK Limited"*.
3.3	University College London (UCL): UK Early Life Cohort Feasibility Study (ELC-FS) NIC-482185-K8G0F-v0.17 (Presenter: Dave Cronin) NIC-482185-K8G0F-v0.17 **Application:** This was a new application for identifiable Demographics data. The purpose of the application is for a study that will test proof of concept for a new national birth cohort study for the UK. It will collect rich data on babies born across the UK during two consecutive months of 2022 or 2023 and their parents, capturing the economic and social environments into which these babies are born, and their health, well-being and development in their first 6-10 months. The study will provide vital evidence on new lives across the UK at a critical time, particularly with regards to the shock to health and the economy induced by the COVID-19 pandemic, as well as the as yet unknown impacts of Brexit on our economy and society. It will highlight major sources of early developmental inequalities and family stressors, and identify potential foci for early intervention and support.

	This application seeks approval for the recruitment and sampling elements of the study, including sampling participants for the study from birth registrations linked to birth notifications. The study is relying on s251 of the NHS Act 2006, for the flow of data out of NHS Digital. **Discussion:** IGARD noted that NHS Digital were specifically seeking advice on any potential risks to individuals from taking part in the study. IGARD noted that observers in attendance for the discussion on this application included NHS Digital's Privacy, Transparency, Ethics and Legal (PTEL) colleagues and the Deputy Caldicott Guardian. IGARD noted and commended NHS Digital on the information provided within the application and supporting documents provided, which supported the review of the application by members. IGARD noted the value from longitudinal studies and welcomed the application which came for advice and without prejudice to any additional issues that may arise when the application is fully reviewed. IGARD reiterated their previous observations made on other similar applications, that any bespoke data curation or onboarding, with the intention of flowing data to a single recipient, did set a precedent and that there was a reputational risk to NHS Digital that there was not equality of access to data. Such a risk could be mitigated by NHS Digital publicising this data asset to make other researchers aware, and to provide researchers with a mechanism to apply for access. IGARD had a lengthy discussion on the data subjects, in particular, the potential vulnerability of the cohort, i.e. women that had recently given birth; the potential risks of a home visit **unless** individuals opted out; and the risks involved in respect of data being shared for both parents. IGARD noted the potential risk, distress or harm to individuals of the proposed approach including, but not limited to, the active steps required by an individual, to be taken to stop a home visit; and noted that the requirement to *"opt out"* from an unsolicited home visit, was **not** in line with other health research where NHS Digital data was being used to identify cases. IGARD were concerned that individuals may feel under pressure to provide consent to take part and may not distinguish the purpose of the home visit from other routine visits made following the birth of a child, for example, health visitors, social workers or family support workers. NHS Digital's PTEL had also raised similar concerns to DARS. IGARD suggested that careful consideration was given to specific sensitivities of the data subjects, including, but not limited to, families / individuals subjected to domestic violence; and noted concern on the data protection and confidentiality issues in respect of with one parent being asked to give details of the other parent, without the other person's consent. NHS Digital's PTEL had also noted this concern to DARS. IGARD queried whether consent would be freely given from the potentially vulnerable cohort in order to meet the requirements of the common law duty of confidentiality and expressed concerns that the NHS Digital DARS Standard for Duty of Confidentiality would not be satisfied, i.e. factors to be considered in respect of whether consent was valid. NHS Digital advised IGARD that they were **not** currently in receipt of the full suite of historical Health Research Authority Confidentiality Advisory Group (HRA CAG) and HRA Research Ethics Committee (REC) approval documents; and would be seeking to obtain these from the

	applicant. IGARD noted the verbal update from NHS Digital and supported the assessment that the full suite of HRA CAG and HRA REC documents were required. IGARD noted concern that some of the information relating to the review history presented to HRA CAG and HRA REC was incorrect and / or misleading, including, but not limited to, the reference to Digi-Trials using the mechanism outlined for 'opting out', as outlined in the HRA CAG form ***"There are a number of precedents to support an opt-out approach... DigiTrials – patients are identified and invited to take part in a trial";*** and IGARD having reviewed and supported this mechanism as outlined in the draft 'Opt-out' letters that state *"We also have special approval to contact you from the NHS Health Research Authority's Confidentiality Advisory Group* ***and NHS Digital's Independent Group Advising on the Release of Data****"*. IGARD noted, quite firmly, that they did not support this mechanism as described and had not reviewed it prior to today's meeting. NHS Digital's PTEL advised IGARD that they were undertaking a number of reviews on the legal aspect of this application, including the scope of the s251 approval received from HRA CAG. IGARD noted the verbal update from PTEL, and requested sight of the forthcoming PTEL advice on the scope of HRA CAG approval. IGARD noted the volume of sensitive data requested by the applicant; and asked that confirmation was provided, that **all** data minimisation efforts had been fully explored, in line with NHS Digital DARS standard for data minimisation. IGARD noted in section 1 (Abstract) that the applicant had requested permission to use NHS Digital's logo in the 'Opt-out' letter; and that there were concerns that, although this may potentially aid transparency in respect of the source of data, it could be viewed as an endorsement of the study or give a misleading impression of NHS Digital's involvement in the study. IGARD advised that they were in agreement with NHS Digital, that the use of the NHS Digital logo on the letter would **not** be appropriate, for the reasons outlined by NHS Digital; and reiterated the concerns already discussed in respect of conflating this research with other health-related home visits. IGARD suggested that the applicant undertake extensive patient and public involvement and engagement (PPIE), including, but not limited to, the home visits and individuals having to contact the researchers to prevent them. IGARD also noted that any consultation should be with a similar group of potential cohort members with a similar lived experience, for example woman who had just given birth. IGARD suggested that NHS Digital should formally seek the view of the Caldicott Guardian on the validity of consent taken in the circumstances outlined with the application and supporting documentation. **Outcome:** IGARD welcomed the application which came for advice and without prejudice to any additional issues that may arise when the application is fully reviewed. 1. IGARD reiterated their previous observations that any bespoke data curation or onboarding, with the intention of flowing data to a single recipient, does set a precedent and there is a reputational risk to NHS Digital that there is not equality of access to data. Such a risk could be mitigated by NHS Digital publicising this data asset to make other researchers aware, and to provide researchers with a mechanism to apply for access. 2. In respect of the data subjects: a) IGARD suggested that careful consideration was given to specific sensitivities of the data subjects, including, but not limited to, families / individuals subjected to

	domestic violence; and noted concern on the data protection and confidentiality issues in respect of one parent being asked to give details of the other parent. b) IGARD noted the potential risk, distress or harm to individuals of the proposed approach including (but not limited to) the active steps required to be taken to stop a home visit and the requirement to *"opt out"* from an unsolicited home visit, was **not** in line with other health research where NHS Digital data was being used to identify cases. c) IGARD queried whether consent was freely given from the potentially vulnerable cohort and expressed concerns that the NHS Digital Duty of Confidentiality Standard (factors to be considered whether consent was valid) would not be satisfied. d) IGARD were concerned that individuals may feel under pressure to provide consent and may not distinguish the purpose of the home visit from other visits made, for example, by health visitors, social workers or family support workers. 3. In respect of the HRA CAG and HRA REC support: a) IGARD supported NHS Digital's assessment that the full suite of HRA CAG and HRA REC documents were required. b) IGARD were concerned that some of the information relating to the review history presented to HRA CAG and HRA REC was incorrect / misleading, including: i. Reference to Digi-Trials using this mechanism. ii. IGARD having reviewed and supported this mechanism. 4. IGARD requested sight of the forthcoming PTEL advice on the scope of HRA CAG approval. 5. To provide confirmation that data minimisation efforts had been fully explored. 6. IGARD were in agreement with NHS Digital that use of the NHS Digital logo on study materials would **not** be appropriate for the reasons outlined above regarding conflating this research with health-related home visits. 7. IGARD suggested that the applicant undertake extensive PPIE, including (but not limited to) the home visits and the individual having to contact the researchers to prevent them. 8. IGARD suggest NHS Digital formally seek the views of the Caldicott Guardian on the validity of consent taken in the circumstances outlined.
3.4	<u>University of Sheffield: Investigating the Application of Causal Inference Methods for Modelling the Impact of Treatment Sequences in Health Economic Evaluations: Utilising Real-world Evidence from the English Cancer Registry (Presenter: James Watts) NIC-661854-W9V1H-v0.6</u> **Application:** This was a new application for pseudonymised National Disease Registration Service (NDRS) Cancer Registry, NDRS Linked Cancer Waiting Times (Treatments only), NDRS Linked Hospital Episode Statistics Accident and Emergency (HES A&E), NDRS Linked HES Outpatient, NDRS National Radiotherapy Dataset (RTDS) and NDRS Systemic Anti-Cancer Therapy Dataset (SACT). The purpose of the application is to investigate whether English Cancer registry data is sufficient for reliably comparing the effectiveness of different sequential treatments in treating cancer patients in the NHS. Patients can sometimes receive a series of treatments in a sequence instead of a single line of therapy. Alternating the order of treatments may result in different overall effectiveness and costs of medical treatments. Thus, it is essential to consider the sequence of treatments when

	making health resource allocation decisions, particularly for cancer treatments as they usually impact a patient's survival. Treatment effects are usually compared in clinical trials. However, a major limitation of some clinical trials is that they often do not provide details about patients' treatment histories or treatment sequences. In this case, analysing routine healthcare data may help provide a better understanding of the effect of sequential treatments. **Discussion:** IGARD queried the statement within the data minimisation column in section 3(b) (Additional Data Access Requested) and in section 5(a) (Objective for Processing) *"…the data requested is limited to individuals aged over 18 with a diagnosis of prostate cancer (C61) or renal cell carcinoma (C64)"*; and asked that a justification was provided in section 5(a) as to why the cohort was limited to individuals over the age of 18, for example, were the specific types of cancer being studied rare in under 18s; and noting that if this was the case, then this would **not** be considered data minimisation and in line with the NHS Digital DARS Standard for Data Minimisation. IGARD noted the technical language towards the end of section 5(a) (Objective for Processing) in the paragraph that starts *"The study proposes using a Target Trial emulation approach…"*; and asked that this public facing section that forms NHS Digital's data uses register was updated in line with NHS Digital DARS Standard for Objective for Processing, to ensure it was written in a manner suitable for a lay reader. IGARD queried the statement in section 6 (Special Conditions), *"The data are collated, maintained and quality assured by the National Disease Registration Service, which is part of NHS Digital"*; and noting the imminent organisational change for NHS Digital, who are merging into NHS England; asked that this statement / special condition was reviewed and amended / futureproofed as appropriate. **Separate to this application:** Noting concerns previously raised in respect of transparency of the Registry Datasets, for example, at the IGARD meetings on the 15th September 2022 and 20th October 2022; IGARD supported the ongoing discussions with the NDRS Engagement and Awareness Team and an IGARD member to discuss progress. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 5(a) with a justification why the cohort is over 18s only. 2. To update the first paragraph of section 5(a) to ensure this is written in a manner suitable for a lay reader, including (but not limited to) the paragraph *"The study proposes using a Target Trial emulation approach…"*. 3. To review the statement in section 6 *"…which is part of NHS Digital…"*; and amend as appropriate to futureproof, noting the imminent NHS Digital organisational changes. **Separate to this application:** Noting concerns previously raised in respect of transparency of the Registry Datasets, IGARD supported the ongoing discussions with the NDRS Engagement and Awareness Team and an IGARD member to discuss progress.
3.5	Archus Limited: Archus Limited direct HES data feed (Presenter: Charlotte Skinner) NIC-648561-Z8L8M-v0.16 **Application:** This was a new application for pseudonymised Emergency Care Data Set (ECDS), Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC), HES Critical Care and HES Outpatients.

	The purpose of the application is to enable Archus Limited to provide consultancy to NHS organisations with validation against the performance of other peer NHS organisations. The data would also be used to populate the software tools Archus Limited use to generate consultancy reports for its clients. Since HES data is the prime, nationally recognised and cleansed data source for hospital care in England, this represents the most reliable basis for analysis. NHS Digital advised IGARD that following an update from the Privacy, Transparency, Ethics and Legal (PTEL) Team; the application would be amended to remove reference to *"s261 other"* and instead cite s261(2)(a) of the Health and Social Care Act 2012, as the legal basis for NHS Digital to disseminate the data. **Discussion:** IGARD noted the verbal update in respect of the update from PTEL on the s261 legal basis; and asked that the relevant updates were made to the application to ensure the correct legal basis was cited. IGARD noted that the applicant would be a new recipient of NHS Digital data; and queried whether the applicant had the requisite health data experience and analysts, noting that the applicant previously had a track record in infrastructure. IGARD queried what due diligence had been undertaken by NHS Digital, in addition to the usual security checks, and were informed by NHS Digital that no additional due diligence checks had been undertaken. IGARD asked that for transparency and reassurance to the public, section 1 (Abstract) and section 5(a) (Objective for Processing) were updated to clarify that the applicant has the requisite health data experience and analysts. IGARD also raised this as a risk to NHS Digital, in respect of contracting for the first time with a commercial entity with no track record of managing NHS Digital data. IGARD reiterated previous advice to NHS Digital, that a due diligence Standard would be an appropriate and valuable risk mitigation tool . IGARD noted that the applicant was requesting six years national data, however, there was no explanation within the application for such a large volume of data, and therefore asked that section 1 and section 5 was updated with a clear justification for the request for **national** data for six years; and, to clarify in section 1 and section 5 why they the applicant had not been able to populate the tool with geographical strata or subsets of the data. IGARD noted that section 5(a) contained a substantial amount of marketing information, that was not relevant to the application; and noting that section 5 forms NHS Digital's data uses register, asked that section 5(a) was edited, to remove marketing text, and that this was updated as appropriate in line with NHS Digital DARS Standard for Objective for Processing. IGARD also noted that section 5(a) contained a long list of clients that the applicant had worked with previously; and again, noting that this was not relevant, asked that this information was amended to remove the list of clients; and to update section 5(a) with an indicative number of clients; and further information of the type(s) of clients that were relevant to this application, in line with NHS Digital DARS Standard for Objective for Processing. IGARD asked that once the relevant updates had been made to section 5(a), including, but not limited to, the updated information in respect of the clients; that section 5(c) (Specific Outputs Expected) was updated to reflect the expected outcomes, in line with NHS Digital DARS Standard for Expected Outcomes; and the expected benefits in section 5(d) (Benefits) (ii) (Expected Measurable Benefits to Health and / or Social Care) were updated in line with NHS Digital DARS Standard for Expected Measurable Benefits. IGARD also asked that section 5(c) and section 5(d) were both updated to reflect the intended outputs from the use of the NHS Digital data.

	IGARD queried the statements in section 5(b) (Processing Activities) *"Amazon Web Services (AWS) provide a UK-based processing and storage environment…"*; and noting that AWS were **not** listed as a Data Processor, asked that clarity was provided in section 5(b) that AWS were a Data Processor; and, to also update section 1(c) ((Data Processor(s)) to reflect that AWS were a Data Processor. IGARD noted the conflicting information within the application, that stated the territory of use was *"England and Wales"*; and the data flow diagram provided as a supporting document that referred to the territory of use as being the *"UK"*. NHS Digital advised IGARD that the application would need updating to correctly state that the territory of use was the *"UK"*. IGARD noted the verbal update from NHS Digital and supported the update to the application. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the outstanding points raised as part of the review, and the fact that this was a new commercial company with no previous track record of using NHS Digital data. **Outcome:** recommendation to defer, pending: 1. To update the application throughout to reflect the correct legal basis (as per the verbal update from NHS Digital). 2. To update section 1 and section 5(a) to clarify that the applicant has requisite health data experience and analysts (noting the applicant's track record in infrastructure). 3. In respect of the data requested: a) To update section 1 and section 5 with a clear justification for the request for **national** data for six years; and, b) To clarify in section 1 and section 5 why they the applicant had not been able to populate the tool with geographical strata or subsets of the data. 4. In respect of section 5(a): a) To update section 5(a) to remove marketing text and update in line with NHS Digital DARS Standard for Objective for Processing. b) To amend section 5(a) to remove the list of clients; and, c) To update section 5(a) with an indicative number of clients; and, d) To clarify in section 5(a) the type(s) of clients. 5. In respect of section 5(c) and in line with NHS Digital DARS Standard for Expected Outcomes: a) To update section 5(c) to align with the updated section 5(a). b) To amend / edit section 5(c) to reflect the intended outputs from the use of the NHS Digital data. 6. In respect of section 5(d) and in line with NHS Digital DARS Standard for Expected Measurable Benefits: a) To update section 5(d) to align with updated section 5(a). b) To amend / edit section 5(d) to reflect the intended outputs from the use of the NHS Digital data 7. In respect of AWS: a) To clarify in section 5 if AWS are a Data Processor; and if so, b) To update section 1(c) to reflect that AWS are a Data Processor. 8. To amend section 2(c) to state the territory of use is *"UK"*. 9. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the outstanding points raised as part of the

	review, and the fact that this was a new commercial company with no previous track record of using NHS Digital data. 10. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the outstanding points raised as part of the review, and the fact that this was a new commercial company with no previous track record of using NHS Digital data. **Risk Factor**: NHS Digital contracting for the first time with a commercial entity with no track record of managing NHS Digital data. IGARD reiterated previous advice that a due diligence Standard would mitigate potential risk.
3.6	University Hospital Southampton NHS FT: Risk Of Aneurysm Rupture Study (Presenter: Clare Wright) NIC-334745-L4J6P-v0.7 **Application:** This was a new application for identifiable Civil Registration (Deaths) data and Hospital Episode Statistics Admitted Patient Care (HES APC). Unruptured intracranial aneurysms (UIA) (a bulge in a blood vessel caused by a weakness in the blood vessel wall) are a common condition (3% of the population) which have life threatening implications for the patient if they rupture. Patients who suffer a ruptured brain aneurysm frequently die or are left severely disabled. Decision making around the prophylactic treatment (a prophylactic is a medication, or a treatment designed and used to prevent a disease from occurring) of unruptured brain aneurysms is part of routine practice in neurosurgery and the results from this study will help predict a patient's risk of rupture and thus guide the clinical management of these patients. The purpose of the application, is for a study, to describe the natural history of UIA in Great Britain. The condition is of great clinical importance because of the high prevalence of UIA with diagnoses continually increasing due to the widespread availability of imaging and increasing age of the population. Despite this there are great uncertainties as to how to manage patients with UIA. The management is fundamentally based on the balance of risk between treatment and the natural history of the UIA. However, our understanding of UIA natural history is flawed and thus currently patients are potentially being subjected to the risk of over- or under-treatment. The possible negative outcomes from either unnecessary prophylactic aneurysm treatment or from subarachnoid haemorrhage (SAH), include stroke, long term disability and death, and thus it is crucial that patients are provided with most accurate information possible for their treatment decisions. The cohort is approximately 10,000 patients; and the study is relying on s251 of the NHS Act 2006, for the flow of data out of NHS Digital. NHS Digital also advised IGARD that following an update from the Privacy, Transparency, Ethics and Legal (PTEL) Team; the application would be amended from s261(7) to correctly cite s261(5)(d) of the Health and Social Care Act 2012, as the legal basis for NHS Digital to disseminate the data. NHS Digital confirmed that the common law duty of confidentiality would be met by 251 of the NHS Act 2006. **Discussion:** IGARD noted and commended the supporting information provided by NHS Digital for this application, in particular the application assessment process undertaken by NHS Digital, and detailed information outlining the discussions with the applicant; which supported the review of the application by members. IGARD confirmed that they were of the view that the relevant s251 support was broadly compatible with the processing outlined in the application.

	IGARD noted the verbal update in respect of the update from PTEL on the s261 legal basis; and asked that the relevant updates were made to the application to ensure the correct legal basis was cited. IGARD queried why the confidential data was being used to create the cohort; and why the cohort could not be created using pseudonymised NHS Digital data; and noting that this was currently unclear, asked that section 5(b) (Processing Activities) was updated with clarification. IGARD noted that section 1(b) (Data Controller(s)) stated, for the Data Security and Protection Toolkit (DSPT),*"Standards Not Fully Met (Plan Agreed)"*; and asked that section 1 (Abstract) was updated with confirmation of the DSPT *"plan"* and how this would be met. IGARD noted within section 5(a) (Objective for Processing) that the study cohort eligibility was for individuals aged 18 years or older; and asked that further information was provided justifying why the cohort was for over 18s only and why under 18s had been excluded; and suggested that if not including under 18s was for the purpose of data minimisation, the applicant may wish to consider including under 18s within the study cohort. IGARD queried the statement in section 5(b) *"The data will not leave the UK at any time"*; and noting that section 2(c) (Territory of Use) stated the territory of use was *"England and Wales"* and not the UK; asked that section 5(b) as updated as appropriate to clarity that the data will **not** leave England and Wales. **Outcome:** recommendation to approve The following amendments were requested: 1. To update the application throughout with the correct legal basis (as per the verbal update from NHS Digital). 2. In respect of the confidential data: a. To clarify in section 5(b) why the confidential data is being used to create the cohort; and, b. To clarify in section 5(b) why the cohort could not be created with pseudonymised NHS Digital data. 3. To update section 1 with further confirmation of the DSPT plan and how this will be met. 4. To update section 5(a) with a justification why the cohort is over 18s only. 5. To update section 5(b) with clarity that the data will **not** leave England and Wales.
3.7	<u>NHS North East and North Cumbria Integrated Care Board (ICB): DSfC - NHS North East and North Cumbria ICB - Linkage to Education Data (Presenter: David Morris) NIC-617767-K0F6W-v0.2</u> **Application:** This was a new application for pseudonymised Commissioning Datasets. The purpose of the application is for Commissioning, to provide intelligence to support the commissioning of health services. The data (containing both clinical and financial information) is analysed so that health care provision can be planned to support the needs of the population within the Integrated Care Board (ICB) area. As part of Special Educational Needs and Disabilities (SEND) work programmes in NHS North East and North Cumbria ICB, Sunderland and South Tyneside Local Authorities have identified a need to link health data (ICB controlled commissioning datasets and primary care data) with education data (SEND and School data) and social care data.

	The purpose of processing linked health, education and children's social care data covers linked data being used to create a local data dashboard to inform monitoring, planning and delivery of services for those with SEND needs in the local areas of Sunderland and South Tyneside by health and care partners. The education data needs to be processed and linked to health and children's social care data to allow a needs analysis in the local areas. The intelligence gained from the linked data will inform the strategic commissioning of services based on the needs of children and young people (CYP) with SEND. The linked data will allow a service evaluation to better understand the barriers to timely identification and assessment of SEND across agencies. The linked data and analysis created from it will enable the identification of patterns, trends and potential shortfalls in care across the agencies of health and education. Analysts will use the information to help understand the impact SEND is having on children within in terms of their ability to access services, educational achievement and wellbeing This will assist local commissioners within Sunderland and South Tyneside to better understand need and service provision and identify those at greatest risk. **Discussion:** IGARD queried whether NHS Digital had analysed the processing and outputs; and whether they were content that these were connected with health; **and** had the appropriate legal basis for dissemination; and asked that section 1 (Abstract) was updated with confirmation. IGARD noted that prior to the meeting, they had requested sight of the applicant's Data Protection Impact Assessment (DPIA); and that a draft copy of the DPIA had been shared with members. NHS Digital advised IGARD that the DPIA made reference to the University of Sunderland accessing the data via honorary contract(s), however advised that this had **not** been addressed / referenced within the application. IGARD noted the verbal update from NHS Digital, and asked that further information was sought on this issue, and that section 1 was updated with confirmation of the University of Sunderland honorary contract arrangements; and, to also confirm in section 1 that NHS Digital were satisfied with the honorary contract arrangements. IGARD queried whether Type 1 Opt-outs would be applied for the data leaving the GP practices; and were advised by NHS Digital that Type 1 Opt-outs would be applied. IGARD noted the verbal update from NHS Digital, however queried whether the data leaving the GP practice was therefore identifiable in light of the Type 1 Opt-outs being applied, and asked that clarification was provided in section 5 (Purpose / Methods / Outputs). In addition, IGARD asked that section 5 as updated with clarity of the legal basis in terms of satisfying the common law duty of confidentiality (CLDoC), for the processing of the data leaving the GP practice. IGARD suggested that NHS Digital discussed with the Caldicott Guardian the proposed processing; and noting that this was already in progress in respect of a recent application (from the 24th November 2022), IGARD asked that this request was linked to that enquiry and that a response was shared with IGARD members. IGARD asked that for transparency, and noting that section 5 forms NHS Digital's data uses register, that section 5(a) (Objective for Processing) was updated with clarification of how citizens could object to their data being processed; and what citizens could object to. IGARD noted that section 5(a) did contain information in respect of the novel linkage that formed part of this application; but asked that for ease of reference, a brief explanation of the linkage was added to the beginning of section 5(a). IGARD queried the statement in section 5(c) (Specific Outputs Expected) *"Identification of patterns, trends and **shortfalls in terminology** across the agencies of health and education"*,

	when referring to the Special Educational Needs and Disabilities (SEND) / Education Data; and asked that a further explanation was provided in section 5(c). IGARD queried whether there had been any patient and public involvement and engagement (PPIE), in relation to the linkage of primary care, secondary care, social care and educational data. NHS Digital advised that the Sunderland Parent and Carer Forum has been sighted on this project through the Sunderland Partnership Group; and that further PPIE was planned in South Tyneside. IGARD noted the verbal update from NHS Digital, but suggested that more extensive PPIE was undertaken with the parent and carer group that had already been consulted to discuss a number of issues, including, but not limited to, the potentially contentious linkage and use of primary care data. IGARD also suggested that as part of the PPIE, the applicant could engage with the local authority SENDIASS service or similar organisation(s) that represented the needs of children with special education requirements. IGARD suggested that **all** PPIE undertaken was done in line with Article 35 of the UK General Data Protection Regulation (UK GDPR) which states *"Where appropriate, the controller shall seek the views of data subjects or their representatives on the intended processing, without prejudice to the protection of commercial or public interests or the security of processing operations"*. IGARD noted that the citation special condition had been added in section 6 (Special Conditions), however asked that this was updated, 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".* **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of the University of Sunderland: a) To update section 1 with confirmation of the University of Sunderland honorary contract arrangements; and, b) To confirm in section 1 that NHS Digital are satisfied with the honorary contract arrangements. 2. In respect of the data leaving the GP practices: a) To clarify in section 5 whether the data leaving the GP practice is identifiable (noting that Type 1 objection is applied); and, b) To clarify in section 5 the legal basis in terms of satisfying the CLDoC, for the processing of the data leaving the GP practice. (see advice point 1) 3. In respect of the opt-outs: a) To clarify in section 5(a) how citizens can object to their data being processed; and, b) To clarify in section 5(a) what citizens can object to. 4. To amend section 5(a) to add a brief explanation at the start of the novel linkage. 5. To update section 5(c) to explain the *"shortfalls in terminology*". 6. To update section 1 with confirmation that NHS Digital have analysed the processing / outputs and are content that these are connected with health; and have the appropriate legal basis for dissemination. 7. To amend the special condition in section 6, 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".* The following advice was given:

	1. IGARD suggested NHS Digital discuss the proposed processing with NHS Digital's Caldicott Guardian. Noting that this was already in progress in respect of a recent application, IGARD asked that this request was linked to that enquiry and a response was shared. 2. In respect of the PPIE: a) IGARD suggested that more extensive PPIE was undertaken with the parent and carer group that had already been consulted; to discuss a number of issues, including (but not limited to), the potentially contentious linkage and use of primary care data. b) IGARD suggested that as part of the PPIE, the applicant could engage with the local authority SENDIASS service or similar organisation(s) representing the needs of children with special education requirements. c) IGARD suggested that all PPIE undertaken was done in line with Article 35 of UK GDPR.
4	Applications progressed / to be progressed via NHS Digital's SIRO Precedent route Applications that have been progressed or will / may be progressed via NHS Digital's Precedent route, including the SIRO Precedent, and NHS Digital have notified IGARD in writing (via the Secretariat).
4.1	NHS England (Quarry House): NHS England Faster Data Programme (Presenter: Duncan Easton) NIC-616043-S9R4P-v0.2 **Application:** This was a new application for a daily flow of pseudonymised Acute Activity Data Set. The purpose of the application is for The Faster Data Flows (FDF) programme, which has been established to provide more timely data to the system to support elective recovery, individual care coordination across Integrated Care Boards (ICBs) and to reduce the data reporting burden on providers. FDF will deliver this by implementing an automated daily flow of patient level data into the NHS National Data Platform (Foundry). The initial scope of work will focus on the collection of core patient identifiable data items for current admissions, inpatient, discharge and outpatient. IGARD noted that this application was last reviewed at the IGARD business as usual meeting on the 18th August 2022; where, IGARD had recommended for approval with conditions, amendments and advice. IGARD noted that on the 24th November 2022 NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had agreed to flow the data to NHS England. IGARD noted and thanked NHS Digital for the update; however expressed concern that due to an internal processing error within NHS Digital, it appeared that this application had **not** been returned to IGARD for an out of committee review on the outstanding condition from the 18th August 2022 and in line with the published out of committee standard operating procedure; and had instead been progressed down the SIRO Precedent route three months following the meeting.
4.2	NHS England (Quarry House): Rapid Diagnostic Centre - Cancer TRE (No Presenter) NIC-411785-Z6X7M

	Application: This application was to request access to the Cancer Trusted Research Environment (TRE) service for England, to undertake a programme of work evaluating the impact of the national roll out of Rapid Diagnostic Centres (RDCs). RDCs are being rolled out nationally as an important part of a broader strategy to deliver faster and earlier diagnosis and improved patient experience. In time, it is the vision for RDCs to offer: **1)** a single point of access to a diagnostic pathway for all patients with symptoms that could indicate cancer; **2)** a personalised, accurate and rapid diagnosis of patients' symptoms by integrating existing diagnostic provision and utilising networked clinical expertise and information locally. IGARD noted that this application was last reviewed at the IGARD business as usual meeting on the 21st January 2021; where, IGARD had recommended for approval with conditions, amendments and advice; and that the conditions had been approved by a quorum of IGARD members on the 29th April 2021. IGARD noted that on the 16th November 2022 NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had agreed a short-term extension to the end of January 2023. IGARD noted and thanked NHS Digital for the written update and asked that the next iteration of the DSA should be brought to a future IGARD meeting.
4.3	<u>Our Future Health: Our Future Health Recruitment Programme (No Presenter) NIC-414067-K8R6J-v1.3</u> **Application:** The purpose of the application is for a research programme to support people living healthier lives for longer through better prevention, earlier detection and improved treatment of diseases. The programme will aim to speed up the discovery of new methods of early disease detection, and the evaluation of new diagnostic tools, to help identify and treat diseases early when outcomes are usually better. IGARD noted that this application was last reviewed at the IGARD business as usual meeting on the 5th May 2022; where IGARD had recommended for approval with amendments and advice. IGARD noted that this application was discussed under 'AOB' on the 17th November, where the NHS Digital Deputy SIRO and a member of NHS Digital's Digi-Trials Team attended the meeting to advise IGARD that the applicant had submitted an urgent amendment to their DSA; to request permission to increase the number of potential participants contacted for the study from 3 million to 12 million. The Deputy SIRO noted that he was **not** minded to approve via the NHS Digital SIRO Precedent the request to increase to 12 million, however had been comfortable to increase the request to 5 million as long as the application returned to IGARD for an independent review before the end of the year. IGARD noted that on the 23rd November 2022 NHS Digital had advised in writing (via the IGARD Secretariat) that the Deputy SIRO had agreed to amend the DSA, To permit 5 million potential participants to be recruited into Our Future Health, subject to an imminent review by IGARD (please see item 3.1).
5	<u>Oversight & Assurance</u>

	IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. Due to the volume and complexity of applications at today's meeting, IGARD were unable to review any Data Access Request Service (DARS) applications as part of their oversight and assurance role. The NHS Digital SIRO was currently reviewing the feedback provided on the IG release registers by IGARD for the period March 2020 to May 2022, alongside the process of review, and as discussed on the 11th August 2022, would come back to IGARD in due course with any feedback or response. IGARD noted that the NHS Digital webpage Excel spreadsheet had now been updated for the period March 2020 to April 2022: NHS Digital Data Uses Register - NHS Digital. IGARD noted that May 2022 appeared to be outstanding, following them returning their comments on the May 2022 release register on 1st July 2022.
6	COVID-19 update *No items discussed*
7 **7.1**	AOB: NHS Digital DARS Standards and Precedents (Presenter: Dave Cronin) NHS Digital attended the meeting to discuss comments provided by IGARD members on a number of Standards and Precedents that IGARD had provided feedback on via email on the 3rd November 2022. IGARD noted that despite queries being raised, NHS Digital had updated the 'standards of information expected in a data access application' webpage and sent an email to IGARD on the 29th November with the six finalised precedents and standards*. NHS Digital attended the meeting to inform IGARD that the previously finalised precedents and standards had been rolled back to the previous versions in order to speak to IGARD further on their outstanding queries and comments. IGARD and NHS Digital agreed that a further discussion would take place at the IGARD meeting on the 8th December 2022 with regard to the three precedents and three standards. *Precedent 1 Extensions and Renewals, Precedent 2 Removal of a Processor, Precedent 3 Addition of a Data Processor, Standard 1 Extensions & Renewals, Standard 5d Expected Measurable Benefits and Standard 11 Territory of Use.
7.2	NIC-381633-K9Y2T - University of Oxford (Presenters: Garry Coleman / Suzanne Hartley / Denise Pine) NHS Digital attended the meeting to discuss a breach that had been identified on NIC-381633-K9Y2T University of Oxford, in respect of data being shared outside the permitted territory of use to support the marketing authorisation of the Oxford-Astra Zeneca COVID-19 vaccine in a clinical trial. IGARD noted that this application had been discussed at the COVID-19 response meeting on the 2nd June 2020 and that it had never been to an IGARD business as usual meeting for a recommendation, however it had seemingly progressed a number of times via the NHS Digital precedent route. NHS Digital advised that work was in progress to amend the application to outline in the agreement what had happened and set out that the applicant is permitted to share the data

	variables sourced from NHS Digital data with Astra Zeneca and regular, subject to specific controls; and to bring the application under an agreement, noting the last DSA had expired on the 30th June 2022. NHS Digital also noted that this application would be submitted to IGARD for a review in due course. IGARD noted and thanked NHS Digital for the verbal update; and noted that the application would be submitted for a review at a future IGARD meeting. There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.
8	<u>NHS Digital / NHS England merger (Presenter: Garry Coleman)</u> NHS Digital's Deputy SIRO and Audit Services attended the meeting to further discuss the latest developments on NHS Digital's merger with NHS England and the possible future of IGARD, or its successor, up to and beyond the merger. This briefing was part of the ongoing engagement with IGARD following the initial presentation to IGARD on the 24th November 2022. The Deputy SIRO will provide further updates as this area of work develops. IGARD noted that following the IGARD meeting on the 24th November 2022 they had provided NHS Digital with written feedback / queries in respect of the verbal information provided at that meeting. The Deputy SIRO noted that this information had been received, and a response would be provided as soon as possible. IGARD thanked the Deputy SIRO for attending the meeting, and it was agreed that this item would be a weekly item on the IGARD meeting agenda.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 25/11/22

These applications were previously recommended for approval with conditions by IGARD, and since the previous Out of Committee Report the conditions have been agreed as met out of committee.

NIC Reference	Applicant	IGARD meeting date	Recommendation conditions as set at IGARD meeting	IGARD minutes stated that conditions should be agreed by:	Conditions agreed as being met in the updated application by:	Notes of out of committee review (inc. any changes)
NIC-10620-V9D8R-v6.6	Nottingham University	29/09/2022	1. In respect of section 2(a) and section 2(b): a) To update section 2(a) and 2(b) as required in line with NHS Digital DARS Standard for Processing and Storage Locations; and, b) To update section 2(a) and section 2(b) to reflect any storage of data that may be happening outside the NHS Digital data access environment that is **not** aggregated with small numbers suppressed. 2. To update section 5 with a statement restricting AHSN access to data to citizens within geographical location, except where national bench marking is justified.	IGARD members	OOC by a quorum of IGARD members	*N/A*

In addition, a number of applications were processed by NHS Digital following the Precedents approval route. IGARD carries out oversight of such approvals and further details of this process can be found in the Oversight and Assurance Report.

In addition, a number of applications were approved under class action addition of:

Liaison Financial Service and Cloud storage:

- None

Optum Health Solutions UK Limited Class Actions:

- None

Graphnet Class Actions:

- None