Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 19 January 2023

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
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
Dr. Maurice Smith	Specialist GP Member (not in attendance for item 3.4)
IGARD MEMBERS NOT IN ATTENDANCE:	
Paul Affleck	Specialist Ethics Member / Co-Deputy IGARD Chair
Prof. Nicola Fear	Specialist Academic Member
Dr. Geoffrey Schrecker	Specialist GP Member
Jenny Westaway	Lay Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Michael Ball	Data Access Request Services (DARS) (**Presenter**: item 2.1)
Garry Coleman	Associate Director / Senior Information Risk Owner (SIRO) (**Observer**: item 8)
Dave Cronin	Data Access Request Services (DARS SAT) (**SAT Observer**: item 3.4)
Louise Dunn	Data Access Request Services (DARS SAT) (**SAT Observer**: items 3.5 to 3.6) (**Observer**: item 8)
Duncan Easton	Data Access Request Services (DARS SAT) (**SAT Observer**: item 3.3)
Dan Goodwin	Data Access Request Services (DARS) (**Presenter**: item 3.4)
Shaista Majid	Data Access Request Services (DARS) (**Presenter**: item 3.6)
Karen Myers	IGARD Secretariat Team
Jonathan Osborn	Deputy Caldicott Guardian (**Observer**: item 8)
Tania Palmariellodiviney	Data Access Request Services (DARS SAT) (**SAT Observer**: item 3.2)

Aisha Powell	Data Access Request Services (DARS) (**Presenter:** item 3.5)
Jodie Taylor-Brown	Data Access Request Services (DARS) (**Observer**: item 3.5)
Anna Weaver	Data Access Request Services (DARS) (**Presenter**: items 3.2 to 3.3)
Vicki Williams	IGARD Secretariat Team
Tom Wright	Head of Service, Data Services for Commissioners (DSfC) (**Observer**: item 2.1)
***SAT** – Senior Approval Team (DARS)	

1	**Declaration of interests:** There were no declarations of interest. **Review of previous minutes and actions:** The minutes of the 12th January 2023 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**
2.1	<u>The National Asthma and Chronic Obstructive Pulmonary Disease (COPD) Audit programme (NACAP) – Pulmonary Rehabilitation Clinical Audit dataset (Presenter: Michael Ball)</u> This briefing paper was to inform IGARD about The National Asthma and Chronic Obstructive Pulmonary Disease (COPD) Audit programme (NACAP) Pulmonary Rehabilitation audit dataset. It includes the Data Extract Schema that is, or will be, collected by NHS Digital. The dataset has been commissioned by the Healthcare Quality Improvement Partnership (HQIP) as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP) and currently covers England and Wales. The audit programme aims to improve the quality of care, services, and clinical outcomes for people with asthma (adults, children, and young people) and COPD. Spanning the entire patient care pathway, NACAP works closely with asthma and COPD patients, as well as healthcare professionals, and aspires to set out a vision for services which put patient needs first. The programme is led by the Royal College of Physicians (RCP) and works closely with a broad range of organisations including Asthma UK-British Lung Foundation, the British Thoracic Society, Primary Care Respiratory Society UK, Royal College of General Practitioners and the Royal College of Paediatrics and Child Health. NACAP's pulmonary rehabilitation (PR) continuous clinical audit is built upon the learning from the National COPD Audit Programme snapshot clinical audit. The clinical audit operates on a patient consent model.

	Outcome: IGARD welcomed the briefing paper and made the following high-level comments: 1. To provide further clarity on the statement *"All PR services in England, Scotland and Wales that treated patients with COPD **(n=227)** were eligible to participate in the clinical audit"*. 2. To provide further clarification on Point 3 'Details of the data controllers and data processors', by providing further information describing the process, i.e. the references to *"NHS Digital"*. 3. To update the data flow diagram to correctly reflect the data flows. 4. NHS Digital to ensure all embedded documents within briefing papers are provided as separate supporting documents at future reviews and that supporting documents are clearly identified. IGARD welcomed the draft and looked forward to receiving the finalised briefing paper, either out of committee (OOC) or tabled at a future meeting (before, or contemporaneously with, any first of type applications received by IGARD or its successor group).
3	**Data Applications**
3.1	Oxford University Hospitals NHS FT: Antibiotic Reduction and Conservation in Hospitals (ARK-Hospital): An observational analysis of Hospital Episode Statistics and outcomes in acute/general medical inpatients in England. (No Presenter) NIC-534137-X3X6N-v0.6 The application was withdrawn by the applicant / presenter.
3.2	Imperial College London: Estimating the Impact of Patient Safety Incidents on Quality of Life using Patient Reported Outcome Measures (Presenter: Anna Weaver) NIC-209174-W2H3G-v4.9 **Application:** This was a renewal and extension application to permit the holding and processing of pseudonymised Hospital Episode Statistics Admitted Patient Care (HES APC) and Patient Reported Outcome Measures (PROMs) (Linkable to HES). It was also an amendment application to **1)** change the territory of use to UK and EEA to permit users working remotely in other countries to access and process the data; **2)** add details of honorary contract holders; and **3)** add clarity regarding the data re-used under this data sharing agreement from (DSA) NIC-172334-W0G2L. The purpose of the application is for a study, analysing the impact of patient safety incidents on quality of life. It will do so by comparing the quality-of-life improvements between groups of patients that do and do not experience relevant events according to established patient safety indicators. The initial analysis will focus on patients with PROMs conditions that do and do not experience a patient safety event. Imperial College London (ICL) will not divide the data set, but specify a dummy variable that indicates whether the patient experienced a patient safety event or not which will be used in multi-variable regression analysis to estimate the difference in quality-of-life gain from operation between the two groups. This difference is equal to the quality-of-life cost of experiencing an event. In the second part of the analysis ICL will identify patients with other (non-PROMs) conditions who experienced the same type of patient safety events to estimate the total impact of patient safety events on quality of life. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD meetings on the 11th October 2018.

	IGARD noted that **NIC-172334-W0G2L** had previously been presented at the IGARD meetings on the 17th May 2018, 6th February 2020 and the 29th September 2022. It was also discussed under 'AOB' at the IGARD meeting on the 20th August 2020. IGARD noted and commended NHS Digital on the information provided within section 1 (Abstract) of the application, which supported the review of the application by members. IGARD noted the amendment to the data to the DSA in respect of changing the territory of use to the UK **and** EEA, to permit users working remotely in other countries to access and process the data; and queried if this was restricted to specific countries. NHS Digital advised that when seeking advice from NHS Digital's Privacy, Transparency, Ethics and Legal (PTEL), they had been asked to provide a list of specific countries. IGARD noted the verbal update from NHS Digital and asked that section 5 (Purpose / Methods / Outputs) was updated to make reference to the specific EEA countries; and that a special condition was inserted in section 6 (Special Conditions), outlining the specific EEA countries the DSA applies to, in line with NHS Digital DARS Standard for Special Conditions. IGARD queried the statement in section 7 (Ethics Approval) *"Ethics approval is not required because this is a retrospective descriptive study using de-identified routinely collected data"*; and the statement in section 1 *"Applicant has confirmed that the NHS HRA tool was used prior to the start of the study to ensure that Ethics was not required. A copy of this has not been provided."*. IGARD asked that section 7 was updated to reflect that **HRA** Ethics was **not** required as there was no confidential flow of data; and, that section 1 **and** section 7 were updated to reflect that the University ethical framework has been considered and University ethical approval was **not** required; and that written evidence was uploaded to NHS Digital's customer relationships management (CRM) system for future reference, that the University ethical framework has been considered and University ethical approval was **not** required. If, following the consideration of the University ethical framework, it was confirmed that University ethical approval was required; IGARD asked that section 1 and section 7 were updated accordingly, and that the University ethics support was uploaded to NHS Digital's CRM system for future reference. IGARD queried what the indicative size of the cohort was, noting that the application was not clear on this point; and asked that for transparency, section 3 (Datasets Held / Requested) and section 5 were updated with an indicative size of the cohort. IGARD noted the statement in section 5(a) (Objective for Processing) *"Aylin and Bottle (2009) have validated that these events can be identified in HES data"*; and asked that this was updated to add the full reference and weblink to the statement, for ease of reference and transparency, and in line with NHS Digital DARS Standard for Objective for Processing. IGARD queried the statement in section 5(a) *"In the second part of the analysis Imperial College London will identify patients with other (non-PROMs) conditions who experienced the same type of patient safety events to estimate the total impact of patient safety events on quality of life."*; and asked that further clarity was provided as to where the 'Quality of Life' data was being obtained from for the **non**-PROMS cohort. As section 5 forms NHS Digital's data uses register, IGARD asked that section 5(b) (Processing Activities) was amended to ensure that technical terms were used only where necessary and explained in a manner suitable for a lay audience. IGARD queried the information in section 5(b) (Processing Activities) relating to the technical specifications / programmes; and asked that this was amended to reduce the narrative, and to use less restrictive wording, in line with NHS Digital DARS Standard for processing activities. **Outcome:** recommendation to approve

	The following amendments were requested: 1. In respect of the EEA countries: a) To update section 5 to make reference to the specific EEA countries. b) To insert a special condition in section 6 outlining the specific EEA countries the DSA applies to, in line with NHS Digital DARS Standard for Special Conditions 2. In respect of ethical support: a) To update section 7 to reflect that **HRA** Ethics is **not** required as there is no confidential flow of data; and, b) To update section 1 to reflect that the University ethical framework has been considered and University ethical approval is **not** required; and, c) To update section 7 to reflect that the University ethical framework has been considered and University ethical approval is **not** required; and, d) To upload written evidence that the University ethical framework has been considered and University ethical approval is **not** required; or, e) To update section 1 to reflect that University ethical framework is required; and, f) To update section 7 to reflect that University ethical framework is required; and, g) To upload the University ethics support to NHS Digital's CRM system for future reference. 3. In respect of the cohort: a) To update section 3 with an indicative size of cohort; and, b) To update section 5 with an indicative size of the cohort. 4. In respect of section 5(b) and in line with NHS Digital DARS Standard for processing activities: a) As section 5 forms NHS Digital's data uses register, to amend section 5(b) to ensure that technical terms are used only where necessary and explained in a manner suitable for a lay audience. b) To amend section 5(b) to reduce the narrative relating to the technical specifications / programmes. 5. In respect of section 5(a) and in line with NHS Digital DARS Standard for Objective for Processing: a) To update section 5(a) to add the full reference / weblink to the *"Aylin and Bottle"* reference. b) To provide clarity in section 5(a) as to where the 'Quality of Life' data is being obtained from for the non-PROMS cohort.
3.3	Carnall Farrar Limited: Application for Carnall Farrar to access NHS Digital data, to permit more detailed insights into the needs of the population and the challenges facing the system when shaping clinically and financially sustainable health and social care services across England (Presenter: Anna Weaver) NIC-243790-Y8K8C-v5.4 **Application:** This was a renewal and extension application to permit the holding and processing of pseudonymised Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (HES APC), HES Critical Care, HES Outpatients, HES-ID to MPS-ID HES APC, HES-ID to MPS-ID HES Outpatients, Emergency Care Data Set (ECDS), Secondary Uses Service Payment By Results (SUS PbR) A&E, SUS PbR Episodes, SUS PbR Outpatients and SUS PbR Spells. It was also an amendment application to **1)** add Community Services Dataset (CSDS); and **2)** add Diagnostic Imaging Dataset (DIDs) to the data sharing agreement (DSA).

	The purpose is to control the conditions of data aggregation, perform bench-marking analysis as well as specific demands of the NHS stakeholders, to allow them to make effective decisions based on the most up-to-date information. The applicant uses NHS data to provide meaningful analytics, to positively impact NHS organisations; however, the data available directly from NHS organisations is aggregate data and does not include diagnostic (clinical) codes therefore limiting the results. The purpose of this application, is to use the NHS Digital data, to expand the products currently on offer for NHS Clients. The record level data disseminated under this DSA, although pseudonymised, is richer and more accurate than the data held by individual NHS organisations. The NHS Digital data will provide more in-depth tools and products for NHS clients, therefore producing more accurate insight into the areas of the NHS requiring improvement and how these improvements can be made. The applicant requires the NHS Digital data, to hopefully provide additional benefits to NHS clients by expanding the capabilities of existing products and reducing costs to the NHS. NHS Digital advised IGARD that as of the 21st December 2022, the oldest year of data had been destroyed by the applicant; and that section 1 (Abstract) would be updated accordingly to reflect this updated information. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD meetings on the 26th September 2019 and the 27th February 2020. IGARD noted that this application had previously been discussed as part of the 'returning applications' section of the IGARD meeting on the 10th December 2020; and under 'AOB' on the 10th October 2019 and the 3rd March 2020. IGARD noted the verbal update from NHS Digital, in respect of the data destruction of the oldest year of data; and supported the update to section 1 to reflect this. IGARD noted the information in section 5(b) (Processing Activities) in respect of the Carnall Farrar Limited internal Data Security Committee; and asked that - although some brief information was included - detailed written confirmation was provided on the set-up of the Committee, including, but not limited to, the membership, the frequency of the Committee meetings both now and in the future and what the Committee have achieved to date. In addition, IGARD asked that the applicant provided a copy of the Committees Terms of reference (ToR) and any Standard operating Procedures, noting that this information had not been provided as supporting documents, and IGARD were unable to locate this via a website etc. IGARD asked, that to ensure consistency with other commercial applications / applicants, including, but not limited to, IQVIA Ltd (NIC-373563-N8Z9J), that a copy of any log(s) from the Committee, for example, outlining who has access to the data warehouse and secondary users requests were provided to NHS Digital. IGARD asked that **all** written confirmation provided, and additional supporting documents, relating to the Committee were uploaded to NHS Digital's customer relationships management (CRM) system for future reference. IGARD suggested that a copy of the Internal Data Security Committees log of activities was provided to NHS Digital on an annual basis; and, that a copy of the Internal Data Security Committees log of activities was provided at **all** future reviews. IGARD noted that a report to NHS Digital outlining the uses of the data for the purposes described in the agreement, including but not limited to how many NHS organisations the applicant had bene working with; the categories of services provided to them in line with the purposes of the DSA; and example of work done demonstrating the requirement for the extent

	of the data provided, had not been provided as a supporting document, and asked that this was uploaded to NHS Digital's CRM system for future reference. IGARD reiterated advice previously provided at the IGARD reviews on the 26th September 2019 and the 27th February 2020, that the applicant may wish to consider independent patient and public involvement and engagement (PPIE) as part of the Committee. IGARD highlighted a risk Area to NHS Digital, in that there was concern that there was no common level of approach for commercial users of NHS Digital data, for example, in respect of providing written evidence on an annual basis from the Committee. **ACTION:** NHS Digital to review governance approach for all commercial applicants of data, and keep a written record as to why there is a difference in the governance approach / expectation. IGARD noted the amendments to add the CSDS and DIDs datasets to the DSA; and noting the large quantum of data within these datasets, asked that for transparency, the public facing section, that forms NHS Digital's data uses register was updated to provide an indication of the size of the datasets requested. IGARD also asked that section 3 (Datasets Held / Requested) and section 5 (Purpose / Methods / Outputs) were updated, with clarification of the data minimisation efforts undertaken in respect of data minimisation, and in line with NHS Digital DARS standard for data minimisation. IGARD noted the significant volume of data flowing and recommended that, if not already done so, the applicant carry out a Data Protection Impact Assessment (DPIA) **before** processing commences in line with Article 35 of UK General Data Protection Regulation (UK GDPR). A copy of the DPIA should be uploaded to NHS Digital's customer relationships management (CRM) system for future reference. IGARD noted the incorrect statement in section 5(e) (Is the Purpose of this Application in Anyway Commercial) *"The commercial element while present and relevant is secondary to the primary purpose of processing data to provide services to NHS clients with the aim of supporting improvements in patient care"*; and asked that this was removed as it was incorrect for a commercial company. IGARD noted that section 5(a) (Objective for Processing) was silent on the commercial aspect of the application, and asked that the useful narrative in section 5(e) (following the above update), was replicated in section 5(a), in with NHS Digital DARS Standard for Commercial Purpose and NHS Digital DARS Standard for Objective for Processing. IGARD noted that it was unclear in the application, what the size of the cohort / population was; and asked that for transparency, section 5(a) was updated with clarification of the indication of the cohort / population size; in line with NHS Digital DARS Standard for Objective for Processing. IGARD noted a number of references throughout the application to *"savings"*, for example *"…leading to an opportunity saving of £154m…"*; and asked that the application was reviewed throughout, and all references to cost savings were either amended to provide factually correct information, including specifying whether savings were true cash releasing efficiencies and/or which were modelled transactional savings; or that the references were removed if not correct / relevant. IGARD queried if the applicant still required the mental health datasets previously flowed under an earlier iteration of the DSA; and were advised by NHS Digital that the applicant wants to retain the existing data, however did not require a further flow of the relevant mental health datasets. IGARD noted the verbal update from NHS Digital, and asked that section 3(a) (Data Access Already Given) and section 5 was updated to specify the mental health datasets

	that have previously flowed and were still held by the applicant, noting that this was not currently clear. In addition, IGARD also asked that section 5 was updated with clarification as to why new flows of mental health data were not required. IGARD noted the benefits expected benefits in section 5(d) (Benefits) (ii) (Expected Measurable Benefits to Health and / or Social Care) and the yielded benefits in section 5(d) (iii) (Yielded Benefits); however, asked that section 5(d) was updated throughout, in line with NHS Digital DARS Standard for Expected Measurable Benefits and NHS Digital DARS Standard for Commercial Purpose. IGARD asked that section 5(d) was reviewed and updated throughout, as may be necessary, in line with the National Data Guardian public benefit guidance that was published on the 14th December 2022. IGARD noted the volume of information in section 5(d) (iii) and asked, that given the significant volume of data requested, section 5(d) (iii) was updated, to provide two or three specific yielded benefits accrued to date and ensure these were clear as to the benefits to either patients or the health and care system more generally. As section 5 forms NHS Digital's data uses register, to amend section 5(d) to ensure that technical terms are used only where necessary and explained in a manner suitable for a lay audience, for example *"Multivariate regression analysis*". IGARD queried the statement in section 5(a) *"There is unlikely to be any moral or ethical issue arising from the processing of this data…"*; and asked that this statement was removed, as it was incorrect. IGARD queried the statement in section 5(a) *"…CF could no longer track users as this work was **subsumed** into the NHSE foundry tooling…";* and asked that this was reviewed and amended as appropriate, or removed, as it was not clear what the reference to *"subsumed"* meant. IGARD noted the information in section 5(a) relating to the predictive nature of the tool, for example *"This tool predicts up to 20 years into the future…"*; and asked that this was reviewed and amended as appropriate to ensure its factually correct, or removed. IGARD queried the statements in section 5(a) *"Holistic medium-term plan that set out a clear ambition and necessary enablers that would allow the delivery of elective care across the ICB*"; and asked that this was amended in a manner suitable for a lay reader, or removed if not necessary. IGARD suggested that section 5 be updated to remove references to "*it will*…", and instead use a form of words such as "*it is hoped*…". As section 5 (Purpose / Methods / Outputs) forms NHS Digital's data uses register, IGARD asked that section 5(a) was amended throughout, to ensure acronyms be defined upon first use, for example *"HRG"*. IGARD queried the references in section 5 to *"22 unique power users"*; and noting that it was unclear what this was referring to, asked that a further explanation was provided. IGARD queried the references in section 5(c) (Specific Outputs Expected) to *"Python"*, and asked that further clarification was provided on what this was; or the references were amended as appropriate in a manner suitable for a lay reader. 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 commercial aspect of the study.

Outcome: recommendation to approve subject to the following condition:

1. In respect of the Internal Data Security Committee:
   a) To provide written confirmation of the set-up of the Committee, i.e. membership etc; and,
   b) To provide written confirmation of the frequency of the Committee meetings both now and in the future; and,
   c) To provide written confirmation of what the Committee have achieved to date; and,
   d) To provide a copy of the Committees ToR / SoP; and,
   e) To provide a copy of any log(s) from the Committee; and,
   f) To ensure that all written confirmation and additional supporting documents, relating to the Committee are uploaded to NHS Digital's CRM system for future reference.

The following amendments were requested:

1. In respect of the large quantum of data requested (CSDS and DIDs)
   a) To update section 5 to provide an indication of the size of the additional datasets requested; and,
   b) To provide further clarification in section 3 of the data minimisation undertaken, in line with NHS Digital DARS standard for data minimisation; and,
   c) To provide further clarification in section 5 of the data minimisation undertaken, in line with NHS Digital DARS standard for data minimisation.
2. In respect of the mental health datasets:
   a) To update section 3(a) to add the mental health datasets that have previously flowed / still held; and.
   b) To update section 5 to clarify the mental health datasets that have previously flowed / still held; and,
   c) To clarify in section 5 why new flows of mental health data are not required.
3. In respect of the commercial aspect of the application and in line with NHS Digital DARS Standard for Commercial Purpose:
   a) To amend section 5(e) to remove reference to *"The commercial element while present and relevant is secondary to the primary purpose…"* ; and,
   b) To replicate in section 5(a) the useful narrative in section 5(e) with regards to the commercial aspect of the application.
4. To update section 5(a) with an indication of the size of the cohort / population.
5. To review all references to *"savings"* throughout the application, and amend / remove if not correct / relevant.
6. To upload a copy of the 2022 use of data report to NHS Digital's CRM system for future reference.
7. In respect of section 5(d):
   a) To update section 5(d) in line with NHS Digital DARS Standard for Expected Measurable Benefits and NHS Digital DARS Standard for Commercial Purpose.
   b) Given the significant volume of data, to update section 5(d) (iii) to provide 2 or 3 specific yielded benefits accrued to date and ensure these are clear as to the benefits to either patients or the health and care system more generally.
   c) To update section 5(d) to align with the NDG public benefit guidance.
   d) to amend section 5(d) to ensure that technical terms are used only where necessary and explained in a manner suitable for a lay audience, for example,
8. In respect of the language in section 5:
   a) To remove the statement in section 5(a) *"…unlikely to be any moral or ethical issue"*.

	b) To review the references in section 5(a) *"subsumed"*; and amend / remove as appropriate. c) To amend / remove the information in section 5(a) relating to the predictive nature of the tool. d) To review the statement in section 5(a) *"Holistic medium-term plan that set out a clear ambition…"*; and amend as necessary or remove. e) To update section 5 to use a form of wording such as "*it is hoped* …", rather than "*it will…*". f) As section 5 forms NHS Digital's data uses register, to amend section 5(a) throughout, to ensure acronyms are defined upon first use. g) To provide further clarity in section 5 of the *"22 unique power users"* referred to. h) To provide further clarity on the references in section 5(c) to *"Python"*; or amend as appropriate in a manner suitable for a lay reader. 9. To update section 1 to reflect the recent data destruction (as per the verbal update from NHS Digital). The following advice was given: 1. In respect of the DPIA: a) IGARD suggested that due to the significant volume of data flowing, that the applicant carries out a DPIA (if not already done so) **before** processing commences in line with Article 35 of UK GDPR; and, b) To upload a copy of the DPIA to NHS Digital's CRM system for future reference. 2. In respect of the Internal Data Security Committee: a) IGARD suggested that a copy of the Internal Data Security Committees log of activities was provided to NHS Digital on an annual basis; and, b) IGARD suggested that a copy of the Internal Data Security Committees log of activities was provided at **all** future reviews; and, c) IGARD reiterated their previous suggestion, that Carnall Farrar's internal Data Security Committee may wish to consider independent PPIE. 3. IGARD advised that they wished their successor group to review this application when it comes up for renewal, extension or amendment, due to the commercial aspect of the application. 4. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the commercial aspect of the application. **Risk Area**: Concern that there is no common level of approach for commercial users of NHS Digital data. **ACTION:** NHS Digital to review governance approach for all commercial applicants of data, and keep a written record as to why there is a difference in the governance approach / expectation. It was agreed the condition would be approved out of committee (OOC) by IGARD's successor committee
3.4	London School of Economics and Political Science (LSE): Investigating the impact of the Health in Pregnancy Grant on birth outcomes in England, 2009-2011 (Presenter: Dan Goodwin) NIC-309029-P7H1D-v2.2 **Application:** This was an extension application to permit the holding and processing of pseudonymised Hospital Episode Statistics Admitted Patient Care (HES APC) and HES-ID to MPS-ID HES APC.

	The purpose is for a stand-alone research project, building on previous work conducted by LSE evaluating the Health in Pregnancy Grant (2009-2011). This grant was a lump sum of £190.00 given to all pregnant women in the UK from the third trimester of pregnancy, regardless of income or work status. The aims of the grant were to reduce low birthweight; and to reduce prematurity. Both low birthweight and prematurity are associated with low-income and lack of funds during pregnancy for healthy nutrition and lifestyle. The rationale of the grant, therefore, was that boosting women's incomes during pregnancy, would facilitate the purchase and consumption of healthier food, invest in healthy lifestyle choices and reduce any financial stress caused by having a baby. The cohort to be generated by NHS Digital could be approximately 5.7 million records. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD meetings on the 28th May 2020 and the 16th December 2021. IGARD noted and commended the applicant, on the responses / actions taken by the applicant, to address the previous points raised at the last IGARD review on the 16th December 2021. IGARD noted that as per the advice provided at the IGARD meeting on the 16th December 2021, the applicant had confirmed that they have now secured ethical approval from the University Ethics Committee, and that the letter of approval from the Chair of the University Ethics Committee had been provided as a supporting document. IGARD asked that section 7 was updated to reflect that University ethical approval was in place IGARD noted the language in section 5(d) (Benefits) (iii) (Yielded Benefits), for example *"Due to delays and errors in both the original dissemination and the re-dissemination…"*; and asked that this was reviewed throughout, to reflect more neutral language, for example *"The applicant did not receive the data in the timeframes expected…"*, or similar. IGARD suggested that the research project may benefit from 'day of birth' in addition to the data fields already requested. IGARD advised that they would be supportive of the applicant receiving the additional data field, to ensure they were working with as full set of relevant data as possible, subject to the relevant legal gateway being in place; and that an appropriate justification for this additional data should be added in section 5 (Purpose / Methods / Outputs) in line with NHS Digital DARS Standards; and the relevant reviews were undertaken as necessary and as per process. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of ethical support, to update section 7 to reflect that University ethical approval had been obtained. 2. To update the projected timeframe yielded benefit in section 5(d) (iii) to reflect more neutral language. The following advice was given: 1. IGARD suggested that the research project may benefit from 'day of birth' in addition to the data fields already requested. IGARD advised that they would be supportive of the applicant receiving the additional data field, to ensure they were working with as full set of relevant data as possible, subject to the relevant legal gateway being in place; and that an appropriate justification for this additional data should be added in section 5 in line with NHS Digital DARS Standards; and the relevant reviews were undertaken as necessary and as per process.

3.5	University College London (UCL): Camden & Islington Clinical Record Interactive Search (CRIS) Linkage with HES/Mortality Data (Presenter: Aisha Powell) NIC-408171-X7F8W-v1.6 **Application:** This was a renewal application to permit the holding and processing of pseudonymised Civil Registrations (Deaths), Demographics, Hospital Episode Statistics Accident and Emergency (HES A&E) and HES Admitted Patient Care (APC). It was also an amendment application to **1)** to expand the cohort from the original 2012-2018 requested, to instead be patients of the Camden and Islington NHS Foundation Trust with active records during the period from 1st January 2012 – 30th April 2022; and **2)** to update the application to reflect the minimisation of SLaM's role as a third-party Data Processor for the purpose of data linkage, limited to only hosting data. The purpose of the application is to link NHS Digital data with the Camden and Islington NHS Foundation Trust Clinical Record Interactive Search (CRIS) Research Database; for the purpose of a research resource, to be used for research projects aiming to investigate physical health outcomes (including mortality) and receipt of health care in people with mental and behavioural health disorders attending secondary mental health care services provided by Camden and Islington NHS Foundation Trust. It is hoped that proposed linkage would significantly increase high-quality research outputs that examine the interface between mental and physical health. The cohort consist of approximately 146,000 individuals from the Camden and Islington geographic catchment area between 2012/13 and 2021/22 and who attended hospital for any reason whilst resident in that catchment area. The study is relying on s251 of the NHS Act 2006, for the flow of data out of NHS Digital. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD meeting on the 22nd April 2021. 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 amendment extend the cohort (amendment point 1); and queried why the cohort was being extended; and noting that this was unclear in the application, asked that for transparency, a further justification and explanation was provided in section 5(a) (Objective for Processing), in line with the Health Research Authority Confidentiality Advisory Group (HRA CAG) support. IGARD queried the funding arrangements in place, noting that section 1 (Abstract) stated the funding ended on the 21st June 2021; however section 5(b) (Processing Activities) stated that recruitment would continue up to the 30th April 2022. IGARD asked that section 1 was updated with confirmation that funding was in place until the **end** of the research; and that any additional funding documentation was uploaded to NHS Digital's customer relationships management (CRM) system for future reference. IGARD noted the references to *"Public Health England"* (PHE) in section 5(a); and noting that PHE closed at the end of September 2021, asked that these references were removed, as they were no longer relevant. As section 5 forms NHS Digital's data uses register, to amend section 5(b) to ensure that technical terms are used only where necessary and explained in a manner suitable for a lay audience, for example *"General Architecture for Text Engineering (GATE) software"*, in line with NHS Digital DARS Standard for processing activities.

	IGARD queried the statement in section 5(c) (Specific Outputs Expected) *"The McPin Foundation are not considered Data Controllers as they have **any say** over the data processing methodology"*; and asked that this was amended, to say *"…no say…"*. IGARD noted the last statement in section 5(d) (Benefits) (iii) (Yielded Benefits) *"There have been no yielded benefits from this data linkage yet as **UCL** has not had a chance to work on the linked data to date"*; and asked that this was amended to remove the reference to *"UCL"*, noting that Camden and Islington NHS Foundation were the Data Controller and not UCL; and this statement was therefore incorrect. **Outcome:** recommendation to approve The following amendments were requested: 1. To provide a justification / explanation in section 5(a) of the extended cohort, in line with the HRA CAG support. 2. In respect of the funding: a) To provide confirmation in section 1 that funding is in place until the **end** of the research. b) To upload any additional funding documentation to NHS Digital's CRM system for future reference. 3. To remove the reference to *"Public Health England"* in section 5(a). 4. As section 5 forms NHS Digital's data uses register, to amend section 5(b) to ensure that technical terms are used only where necessary and explained in a manner suitable for a lay audience, for example 5. To amend the reference in section 5(c) from *"any say"* to *"no say"*. 6. To amend section 5(d) (iii) to remove reference to *"UCL"*. The following advice was given: 1. IGARD noted the reference in the HRA CAG amendment form provided as a supporting document *"…obtained IGARD authorisation…";* and advised that they provide recommendations to NHS Digital and not authorisation.
3.6	University of Bristol: UPSTREAM Phase II – Further Follow Up Study (Urodynamics for Prostate Surgery Trial; Randomised Evaluation of Assessment Methods (UPSTREAM)) (Presenter: Shaista Majid) NIC-305864-D0Y3W-v0.10 **Application:** This was a new application for pseudonymised Civil Registrations (Deaths), Hospital Episode Statistics Admitted Patient Care (HES APC) and HES Outpatients. The purpose of the application research project to support the diagnosis and management of bladder outlet obstruction in men. The research project consists of two phases; however this data request is **only** linked with phase II of the project. **UPSTREAM-Phase I** The UPSTREAM participants were originally recruited between 2014 and 2016 to join the main randomised controlled trial; with the purpose of evaluating the assessment of lower urinary tract symptoms (LUTS) in men, who were seeking further treatment for their LUTS, which may have included surgical intervention. **UPSTREAM - Phase II** Additional funding was obtained to conduct a second phase of the UPSTREAM project, to undertake the follow up of existing UPSTREAM participants at five years post-randomisation, aiming to identify: **1)** definitive surgery rates in the two arms; **2)** symptom outcomes of treatment, allowing enough time for full recovery from surgery; and **3)** the long-term impacts of

	LUTS and its therapy, including evaluation of the resource use and health economic implications. It is hoped that the long-term further follow up, will help understanding of the sustained response, placebo impact and the behaviour of storage LUTS over time. It will help the project to state for sure whether or not UDS delivered non-inferior symptom outcomes with lower surgery rates. Furthermore, there is very little information documented about men's attitudes to the long-term experience on LUTS and its treatments, and the European Association of Urology (EAU) has identified this as a priority research need. The study cohort of approximately 820 consented individuals. **Discussion:** IGARD confirmed that they were of the view that the **most recent** consent materials provided the appropriate legal gateway and were broadly compatible with the processing outlined in the application. IGARD noted and commended NHS Digital on the consent assessment provided, which supported the review of the application by members. IGARD noted that the National Institute of Health and Care Research (NIHR) funding support expired on the 31st December 2022, and queried the statement in section 1 (Abstract) that the applicant had advised that *"…a variation to contract will be completed when they have an agreement from NHS Digital on when the data will be disseminated"*. IGARD asked that section 1 was updated with confirmation that funding was in place until the **end** of the research project.; and that in line with NHS Digital DARS Standard for Special Conditions, a special condition was inserted in section 6 (Special Conditions), that funding will need to be in place until the **end** of the research project and before the data flows. IGARD asked that any additional funding documentation, was uploaded to NHS Digital's customer relationships management (CRM) system for future reference. IGARD noted the references in section 1 of data destruction taking place in 2024 and 2025; and asked that a special condition was inserted in section 6, clarifying what data would be destroyed in line with the consent; and when the data would be destroyed, in line with NHS Digital DARS Standard for Special Conditions. IGARD queried the statement in section 5(b) (Processing Activities) *"Named researchers accessing, processing and handling data have completed the UoB GDPR Information Security Training* ***scoring 80% or higher****"*; and asked that "***scoring 80% or higher*** "was removed, as it was not necessary to include. IGARD suggested that section 5(a) (Objective for Processing) and section 5(d) (Benefits) be updated to remove reference to "*it will*…", and instead use a form of words such as "*it is hoped*…". IGARD queried the statement in section 5(d) (ii) (Expected Measurable Benefits to Health and / or Social Care) *"…and they respond* ***deferentially*** *to treatment…"*; and asked that this was updated to correctly state *"differentially"*. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of the funding: a) To update section 1 with confirmation that funding is in place until the **end** of the research project. b) To insert a special condition in section 6, that funding will need to be in place until the **end** of the research project and before the data flows, in line with NHS Digital DARS Standard for Special Conditions.

	c) To upload any additional funding documentation to NHS Digital's CRM system for future reference. 2. To insert a special condition in section 6, clarifying what data will be destroyed in line with the consent; and when the data will be destroyed, in line with NHS Digital DARS Standard for Special Conditions. 3. To amend section 5(b) to remove the security training percentage score reference. 4. To update section 5(a) to use a form of wording such as "*it is hoped* …", rather than "*it will…*". 5. 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 use a form of wording such as "*it is hoped* …", rather than "*it will…*". b) To remove the reference in section 5(d) (ii) *"deferentially"* and replace with *"differentially"*.
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	University of Bristol: CAP study: Cluster randomised triAl of prostate specific antigen (PSA) testing for Prostate cancer (ODR1617_022) (No Presenter) NIC-656775-N0V8C-v1.6 The purpose of the application is for a study, evaluating the effectiveness and cost-effectiveness of population screening for prostate cancer by establishing a cluster randomised trial allocating general practices to either intensive case-finding (the ProtecT trial) or unscreened standard practice. IGARD noted 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 IGARD review. IGARD noted that on the 10th January 2023, NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had approved authorisation for this application to progress via NHS Digital's SIRO Precedent route. IGARD noted and thanked NHS Digital for the written update.
4.2	Southampton City Council: Audit of health inequalities in Southampton (ODR1819_291) (No Presenter) NIC-656845-G9J9W-v1.2 The purpose of the application is for an audit of health inequalities in Southampton. Understanding inequalities in the city helps better evidence-based decision making. Being able to identify the extent and magnitude of the health inequalities across the city will influence policy making, strategic plans, service design and commissioning plans. IGARD noted 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 IGARD review. IGARD noted that on the 10th January 2023, NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had approved authorisation for this application to progress via NHS Digital's SIRO Precedent route.

	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, due to the novel use of the GP code.
4.3	Guy's and St Thomas' NHS FT: 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) (No Presenter) NIC-656860-Q5Q9Q-v1.2 The purpose of the application is for a follow-up to the GLACIER and ICICLE studies, 5 to 10 years after the initial recruitment of participants, in order to investigate the survival of breast carcinoma, rates of recurrence and new diagnoses in women with different subtypes of disease. IGARD noted 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 IGARD review. IGARD noted that on the 10th January 2023, NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had approved authorisation for this application to progress via NHS Digital's SIRO Precedent route. IGARD noted and thanked NHS Digital for the written update.
5	Oversight & Assurance 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	AOB: *No items discussed* 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	NHS Digital / NHS England merger (Presenter: Garry Coleman)

	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 future of IGARD's successor, up to and beyond the merger from the 1st February 2023. As advised at the IGARD meeting on the 24th November 2022, this was part of the ongoing engagement with IGARD; and to provide further updates as this area of work develops. IGARD noted that following first consultation with IGARD at the BAU meeting on the 24th November 2022; IGARD had provided NHS Digital with written feedback / queries in respect of the verbal information provided at that meeting. The Deputy SIRO reiterated that a response would be provided as soon as possible. The Deputy SIRO also reiterated that work was ongoing to the draft guidance and was not considered ready to be shared with IGARD. The Deputy SIRO and IGARD discussed a number of options in terms of reviewing the large number applications currently in the DARS system, ranging from initial enquiry to customer sign off; to ensure these were progressed in a timely manner through to a live DSA, and with the appropriate oversight, and in particular for those novel, contentious or repercussive applications which would usually proceed to IGARD for review. A number of options were discussed, and it was agreed that the NHS Digital Deputy SIRO would come to next week's final meeting of IGARD to provide a clear outline of the application numbers which may need to be considered by IGARD, or its successor, to enable IGARD and NHS Digital to formulate a forward plan to support DARS and the applicants. IGARD thanked the Deputy SIRO for attending the meeting and looked forward to his update at next week's IGARD meeting. **"Guidance on NHS England's protection of patient data"** IGARD noted that they had received the above draft guidance for the first time on Wednesday 18 January 2023 and had been asked to provide comments to NHS Digital by Friday 20 January 2023. IGARD members agreed to provide comments on this important document by Friday 20 January 2023. IGARD members expressed grave concern that they were receiving a copy of this critical document for the first time at such a late stage in the drafting process.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 13/01/23

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)
None						

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