Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 10 November 2022

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Dr. Robert French	Specialist Academic / Statistician Member
Kirsty Irvine	IGARD Chair
Dr. Imran Khan	Specialist GP Member / Co-Deputy IGARD Chair
Dr. Geoffrey Schrecker	Specialist GP Member
Jenny Westaway	Lay Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Paul Affleck	Specialist Ethics Member / Co-Deputy IGARD Chair
Maria Clark	Lay Member
Prof. Nicola Fear	Specialist Academic Member
Dr. Maurice Smith	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Michael Ball (MB)	Data Access Request Services (DARS) (**Presenter**: item 3.1)
Dave Cronin (DC)	Data Access Request Services (DARS SAT) (**SAT Observer**: item 3.4)
Catherine Day (CD)	Data Access Request Services (DARS SAT) (**Presenter:** item 3.2) (**SAT Observer**: item 3.3 to 3.4)
Louise Dunn (LD)	Data Access Request Services (DARS SAT) (**Presenter**: item 3.2) (**SAT Observer**: item 3.3)
Duncan Easton (DE)	Data Access Request Services (DARS SAT) (**SAT Observer**: item 3.1)
Liz Gaffney (LG)	Head of Data Access, Data Access Request Service (DARS) (**Presenter**: item 7.3)
Dan Goodwin (DG)	Data Access Request Services (DARS) (**Observer:** item 3.2) (**Presenter:** items 3.5 to 3.6)
Mary Kisanga (MK)	Data Access Request Services (DARS SAT) (**SAT Observer**: item 3.6)

Joseph Lawson (JL)	Data Access Request Services (DARS) (**Observer:** items 3.1 to 3.4)
Karen Myers	IGARD Secretariat
Frances Perry (FP)	DigiTrials (**Presenter:** item 3.3)
Charlotte Skinner (CS)	Data Access Request Services (DARS) (**Presenter**: item 3.4)
Kimberley Watson	Data Access Request Services (DARS SAT) (**SAT Observer**: items 3.5 to 3.6) (**Presenter**: items 7.1 to 7.2)
Vicki Williams	IGARD Secretariat
***SAT** – Senior Approval Team (DARS)	
NHS ENGLAND STAFF IN ATTENDANCE:	
Nathan Abbotts	Senior Data Services Lead (**Observer**: item 3.1)

1	**Declaration of interests:** There were no declarations of interest. **Review of previous minutes and actions:** The minutes of the 3rd 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	NHS England (Quarry House): Access to HES via NHS Digital online portal (Previous NIC Number – NIC-09042-L9M1K) (Michael Ball) NIC-18798-V2J6C-v10.2 In line with the new process, as per the discussion at the IGARD meeting on the 8th September 2022 and agreed by NHS Digital via email, this application is being brought to IGARD for **advice only** and would then proceed under NHS Digital's SIRO precedent if appropriate. The new process, implemented from the 1st September 2022, was made in line with IGARD's published Terms of Reference and to support NHS Digital / NHS England ahead of the transition of NHS Digital into NHS England in January 2023, where both organisations will become one entity. **Application:** This was a renewal application to permit the processing of the following data via NHS Digital's Data Access Environment (DAE) / NHS Digital Portal; pseudonymised Emergency Care Data Set (ECDS), Hospital Episode Statistics Accident and Emergency (HES

	A&E), Hospital Episode Statistics Admitted Patient Care (HES APC), HES Critical Care and HES Outpatients. It was also an amendment application to **1)** change the legal basis for dissemination from 'Section 261 – Other' to 'Section 261 (5) (d)'; **2)** to amend the references from *"CCG"* to *"ICB"*; and **3)** to remove references to *"NHS Improvement"* as they are no longer a separate legal entity. The purpose of the application is to support NHS England's responsibilities to support health and social care within England, including, commissioning; policy; finance; economic development and research and analysis. The purposes outlined all assist NHS England in its aim to create the culture and conditions for health and care services and staff to deliver the highest standard of care and ensure that valuable public resources are used effectively to get the best outcomes for individuals, communities and society for now and for future generations. **Discussion:** IGARD noted that in line with the new process outlined to NHS Digital via email on the 22nd August 2022, and as discussed at the IGARD meeting on the 8th September 2022, this application was being brought to IGARD for advice only and would then proceed under NHS Digital's SIRO precedent if appropriate. IGARD noted that the application and relevant supporting documents had previously been presented at the Data Access Advisory Group (IGARD's predecessor) meeting on the 29th November 2016. It was also discussed as part of the 'applications progressed via NHS Digital's SIRO Precedent route' on the 6th October 2022, where IGARD and the NHS Digital Deputy SIRO had requested that the application returned for a review before mid-November 2022. IGARD also noted that this application had previously been discussed as part of the 'returning applications' section of the IGARD business as usual (BAU) meeting on the 7th May 2020. IGARD noted that some of the information in section 5(a) (Objective for Processing) under the heading *"ongoing requirements"* was now out of date, for example, the information relating to the 'Public Account Committee's 2019 report on NHS Waiting Times for Elective and Cancer Treatment', which had now concluded. As this section will form part of NHS Digital's data uses register,, IGARD asked that this information was reviewed and updated to ensure that it contained current / relevant information. IGARD queried the statement in section 5(b) (Processing Activities) *"These are encrypted by Bitlocker to the AES-256 standard"*; and suggested that this was amended and replaced with less technical / restrictive wording, for example, *"appropriate encryption"* or similar; or that the text should be removed completely. IGARD noted the yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits) and, in line with NHS Digital's DARS Standard for Expected Measurable Benefits, asked that this public facing section, which forms NHS Digital's data uses register, was updated / amended to retain the details provided of two or three specific yielded benefits accrued to date, and asked that it was clear as to the benefits to both the patients and the health and social care system more generally. IGARD suggested that following the relevant updates to the yielded benefits in section 5(d) (iii); NHS England considered updating the "How we use your information" page on their website or other suitable page, to reflect the updated yielded benefits. This was to provide transparency to the public on the valuable use of the data, which would build public trust and

	would likely be an important limb of complying with the forthcoming National Data Guardian (NDG) public benefit guidance. In addition to the suggested updates to the NHS England website in respect of the addition of the yielded benefits; IGARD suggested that NHS England should ensure that **all** public facing information was in a language suitable for a lay reader. IGARD queried the statement in section 6 (Special Conditions) *"…that are covered by the GIA arrangement…"*; and asked that for clarity / transparency, the acronym *"GIA"* was further defined within the special condition. IGARD asked that in line with NHS Digital DARS Standard for Special Conditions, a special condition was inserted in section 6, that, following the signing of the DSA, a detailed annual review was scheduled in twelve months. The relevant supporting documents should be provided during the calendar month preceding the Annual Review Date and these documents should be uploaded to NHS Digital's customer relationship management (CRM) system for future reference. IGARD asked that a special condition was inserted in section 6, 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"* (use MY data - our data citation project), in line with NHS Digital DARS Standard for Special Conditions. **Advice Outcome:** IGARD confirmed that they were supportive of the renewal and extension to the application and amendment points, but wished to draw to the attention of the SIRO the following points: 1. To amend the "ongoing requirements" in section 5(a) with current / relevant information. 2. To amend or remove the reference in section 5(b) *"…Bitlocker to the AES-256 standard …"*; and replace with *"appropriate encryption"* or similar. 3. 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, in line with NHS Digital DARS Standard for Expected Measurable Benefits. 4. In respect of the special conditions in section 6: a) To expand the acronym "GIA" in section 6. b) To insert a special condition in section 6, that, following the signing of the DSA, a detailed annual review was scheduled in twelve months. The relevant supporting documents should be provided by the applicant to NHS Digital during the calendar month preceding the Annual Review Date. These documents should be uploaded to NHS Digital's CRM system for future reference. c) To insert a special condition in section 6, 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"*, in line with the NHS Digital DARS Standard for Special Conditions. The following advice was given: 1. IGARD suggested that following the relevant updates to the yielded benefits in section 5(d) (iii); NHS England considered updating the "How we use your information" page on their website, to reflect the updated yielded benefits. This is to provide transparency to the public on the valuable use of their data, which will build public trust and would

	likely be an important limb of complying with the forthcoming NDG public benefit guidance. 2. IGARD suggested that NHS England ensured that all public-facing information on their website was in language suitable for a lay reader.
3.2	<u>Medicines and Healthcare Products Regulatory Agency (MHRA) / Clinical Practice Research Datalink (CPRD): R23 - CPRD Routine Linkages Application (Presenter: Louise Dunn / Catherine Day) NIC-15625-T8K6L-v12.2</u> **Application:** This was a renewal and extension application to permit the holding and processing of a number of NHS Digital datasets, which have yet to be determined / agreed. It was also an amendment application to **1)** review and tidy the application throughout; **2)** to remove any datasets no longer required (to be determined); **3)** the addition of Maternity Services Data Set (MSDS) v2.0; **4)** the addition of Medicines dispensed in Primary Care (NHSBSA) dataset; **5)** the addition of Civil Registration data which replaces the secondary care cut only **and** the removal of Civil Registration (Deaths) secondary Care cut data; **6)** the removal of storage and processing locations; **7)** the removal of COVID-19 Second Generation Surveillance System (SGSS) **and** COVID-19 Hospitalization in England Surveillance System (CHESS) (now called *"SARI Watch")* COPI conditions as these now have s251 support; **8)** the removal of the Patient Reported Outcome Measures (PROMs) terms and conditions; **9)** the addition of Microsoft Azure Cloud as a Data Processor; **10**) to reflect that the datasets will be provided as latest available to CPRD at 6 monthly intervals. CPRD is a government not for profit research service delivered by the MHRA, with support from the National Institute of Health and Care Research (NIHR), that provides access to pseudonymised health data for studies to safeguard and improve patient and public health. CPRD provides data to researchers under sublicense agreements, access to primary care data linked to secondary health care datasets for both observational research and to supplement clinical trial data. Linked data greatly increases the scale, depth, completeness and value of data available for public health and clinical research. Linked data are also used to assess study feasibility and create lists of eligible patients who could potentially be included in clinical trials. In addition, linked data are used by CPRD to generate derived fields that improve the quality of the primary care data for e.g. ethnicity records. The outputs of such research based on linked data inform clinical guidance and best practice for patients in the UK. **Discussion:** IGARD welcomed the application which came for advice and without prejudice to any additional issues that may arise when the application is fully reviewed. IGARD noted that a CPRD briefing paper had been submitted for review at the IGARD meeting on the 27th January 2022, that provided IGARD with an update on previous points raised on this application. IGARD noted that the application and relevant supporting documents had previously been presented at the Data Access Advisory Group (DAAG) (IGARD's predecessor) meeting on the 24th January 2017; and at the IGARD meetings on the 22nd June 2017, 20th September 2018, 17th October 2019, 6th February 2020, 27th February 2020 (application withdrawn by presenter), 19th March 2020, 16th July 2020 and 28th April 2022. IGARD noted that this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 12th May 2020, 19th May 2020, 26th May 2020, 6th October 2020 and 13th October 2020.

	It was also discussed as part of the 'applications progressed via NHS Digital's SIRO Precedent route' on the 8th November 2018; and as part of 'AOB' on the 27th August 2020. IGARD noted that earlier this year the Office for National Statistics (ONS) had contributed to NHS Digital's Data Sharing Remote Audit of CPRD, in order to confirm that the documented technical and contractual measures in relation to the release of data were in place and were being followed in relation to the steps taken to reduce the risk of re-identification. IGARD noted the references within the application to the data being *"effectively anonymised"* but the data was treated as personal data in the CPRD environment and asked that written confirmation was provided, as to whether ONS supported the statements, noting that this was currently unclear and had not been addressed by ONS in the NHS Digital Data Sharing Remote Audit (provided as a supporting document, to which ONS had contributed some of the content). In addition, and once confirmation had been provided by ONS, IGARD asked that the application was updated accordingly, for example, by removing the statement that CPRD holds *"effectively anonymised data"*. If, however, ONS supported the statement that data was *"effectively anonymised"* in the CPRD environment, IGARD asked that a justification was provided in section 5(a) (Objective for Processing) as to why this view had been taken. IGARD noted that there was no reference within the audit documentation provided as a supporting document of an audit or examination of the data environment of CPRD clients by ONS or NHS Digital. In addition, while the ONS analysis of datasets disseminated by CPRD indicated a low risk of re-identification it was not clear whether ONS's view was that the data would be effectively anonymised in the hands of recipients. IGARD asked that written confirmation was provided by ONS, that the data held by the CPRD clients was *"effectively anonymised"*, since that remained unclear. IGARD queried the reference within section 1.4 of the NHS Digital Data Sharing Remote Audit, that referred to *"low risk"*; and noting that this was not a recognised UK General Data Protection Regulation (UK GDPR) concept, asked that further clarity was provided outlining what *"low risk"* meant. Noting that each CPRD client may hold different sets of data, IGARD suggested that it may be helpful if NHS Digital exercised their contractual ability to audit the sub-licensees. IGARD offered NHS Digital support to scope future audit(s) of CPRD and its sub-licensees noting that they were familiar with the challenges this complex application presents; and would welcome the opportunity to support NHS Digital, for example, by helping to form any future audit questions. IGARD made a number of observations in respect of the patient information poster provided as a supporting document; including, that this was an outdated version of the poster which did not include the changes recognised by CAG in their letter of support, also the statement within the poster *"If you do not want anonymised information from your patient record to be used in research you can opt out by speaking to your doctor"*; and suggested that this was updated to remove advice to speak to your doctor, and instead update the poster with a link / guidance advising where patients could find further information on the National Data Opt-out (NDO). IGARD noted that the poster did not make reference to the s251 support obtained from Health Research Authority Confidentiality Advisory Group (HRA CAG) or the wording that HRA CAG had suggested should be included on patient posters and suggested that, for transparency, the poster was updated to include this information. IGARD asked that following any updates to the poster, the applicant shared a copy of the poster with NHS Digital, and that the latest version was uploaded to NHS Digital's customer

	relationships management (CRM) system. In addition, IGARD suggested that the updated / latest copy of the poster was provided as a supporting document at any future IGARD review(s). IGARD noted there was no transparency to the public in respect of the GP Practices that participate in the CPRD research and suggested that CPRD listed the participating GP Practices on the CPRD website, in line with UK GDPR. IGARD queried if there was a risk of re-identification of the women with children, for example, if a recipient of data had requested maternity datasets **and** other datasets that would identify and link the date of the birth of child / children of the women; which would increase the risk of re-identification. IGARD suggested that this example was addressed when considering whether data was "effectively anonymised". IGARD observed that the risk of reidentification in this instance was disproportionately borne by women. IGARD noted the statement in section 5(d) (Benefits) (iii) (Yielded Benefits) *"CPRD publish…a register of all approved studies of which the detail on each study includes a **lay** and technical summary…"*; and advised that although CPRD do publish a technical summary for the approved studies, not all the approved studies included a lay summary. IGARD suggested that the published list of approved studies were updated to include a lay summary, in addition to the technical summary, for **all** approved studies. IGARD queried whether there was lay involvement on the committees that are part of the revised Research Data Governance process at CPRD; and asked that further clarity was provided in section 5(a). IGARD queried the special condition in section 10 (Sub-licensing) that stated *"CHESS and SGSS data cannot be included in the CPRD organisation-wide multi-study annual licence, nor in studies with any data processing outside the EEA"*; and asked that this was reviewed and updated accordingly noting the geographical restrictions on these datasets (previously IGARD had been informed that the datasets may only be used in England and Wales). **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. In respect of the Patient Information Poster: a) IGARD suggested that the patient information poster was updated to remove reference to discussing opting out with the GP; and b) To provide a link / guidance on where to find further information on the NDO; and, c) To reflect the HRA CAG s251 support obtained and the wording suggested by HRA CAG for the poster. d) To upload a copy of the updated patient information poster to NHS Digital's CRM system; and, e) To provide a copy of the updated / latest copy of the patient information poster at the next IGARD review. 2. IGARD suggested that the participating GP Practices were listed on CPRD website for transparency and compliance with UK GDPR. 3. In respect of the ONS analysis: a) To provide written confirmation as to whether ONS support the statement that CPRD holds *"effectively anonymised data"* in the CPRD environment; and, b) To update the application accordingly following the written confirmation from ONS, for example, removing the statement that CPRD holds *"effectively anonymised data"*; or,

	c) If ONS support the statement that that CPRD holds *"effectively anonymised data"*, to provide a justification in section 5(a). d) To provide written confirmation as to whether ONS support the statement that the data held by the CPRD clients was *"effectively anonymised"*. e) To amend / provide further clarity on the references to "*low risk*". 4. In respect of future audits: a) IGARD suggested that it may be helpful if NHS Digital exercised their contractual ability to audit the sub-licensees. b) IGARD offered NHS Digital support to scope future audit(s) of CPRD and sub-licensees noting they are familiar with the challenges this complex application presents. 5. In respect of re-identification: a) To confirm if there is an increased risk of re-identification for women with children; and, b) To address any gender inequality issues if there is an increased risk of re-identification for women with children. 6. IGARD suggest the published list of approved studies had a lay summary (in addition to the technical summary) for **all** approved studies. 7. To provide clarity in section 5(a) of the lay involvement in CPRD's Research Data Governance process. 8. To update section 10 with clarification of the geographical restrictions for the CHESS / SGSS datasets
3.3	University College London (UCL): SUMMIT Study: Cancer screening study with or without low-dose lung CT to validate a multi-cancer early detection test (Previously ODR1718_316) (Presenter: Frances Perry) NIC-656813-F4H5W-v1.3 **Application:** This was a renewal and extension application to permit the holding and processing of pseudonymised National Disease Registration Service (NDRS) Cancer Registry. It was also an amendment application to add the following datasets to the data sharing agreement: NDRS Rapid Cancer Registrations, NDRS Systemic Anti-Cancer Therapy Dataset (SACT), NDRS National Radiotherapy Dataset (RTDS), NDRS Linked HES Admitted Patient Care (HES APC), NDRS Linked HES Outpatients, NDRS Somatic Molecular Dataset, Emergency Care Dataset (ECDS), NDRS Linked Diagnostic Imaging Dataset (DIDS) and NDRS National Lung Cancer Audit (NLCA). The purpose of the application is for a prospective cohort study of approximately 13,000 participants from London, designed to investigate how cancer screening can be improved and delivered. The study will recruit individuals at high risk for cancer, especially lung cancer, due to significant smoking history. The study has two main aims: **1)** to develop and evaluate the performance of the GRAIL blood test for the detection of multiple cancer types and the identification of tissue of cancer origin; and **2)** to examine the performance and feasibility of delivering a low dose CT (LDCT) screening service for lung cancer to a high-risk population in London and the surrounding area. NHS Digital noted that the Amazon Web Services Inc. (AWS) ISO27001:2013 International Organisation for Standardisation (ISO) certificate was due to expire on the 30th November 2022 and had raised this with the applicant. NHS Digital had inserted a special condition in section 6 (Special Conditions), that data could not flow until the provision of the ISO certificate had been received by NHS Digital.

	NHS Digital noted that they had updated the terminology in section 5(a) (Objective for Processing) "*SUMMIT: cancer screening with or without low-dose lung CT to validate a multi-cancer early detection text*" to provide a lay summary and expand the acronym. **Discussion:** IGARD noted the NDRS datasets had previously flowed from Public Health England (PHE) (under agreement ODR1718_316) prior to its closure at the end of September 2021; and therefore, had not had a previous IGARD review. 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 supported the verbal updates from NHS Digital in respect of the inclusion of a special condition in section 6, with regard to the provision of the ISO certificate for AWS, and the update in section 5(a) to include more lay friendly terminology. IGARD noted this was important research. IGARD also noted that the description of the data fields in section 3(b) (Additional Data Access Requested) was particular well written in terms of how each data field was being used, and thanked NHS Digital for the narrative. IGARD noted that the consent materials only permitted follow up of cohort members to 2031. The IGARD specialist member clinicians noted that screening research could take some years to fully understand the impact for a cohort member, and suggested that the applicant may wish to follow up the cohort beyond 2031. IGARD therefore suggested that the applicant may wish to consider a reconsent now, rather than waiting until 2031, for a longer follow-up period. IGARD also suggested that NHS Digital undertake a review of the consent materials to check if there was provision for the applicant to hold NHS Digital data beyond 2031. Noting the explicit end date of 2031 in the consent materials provided as supporting documents, IGARD asked that a special condition be inserted in section 6 (Special Conditions) that no new data could flow under this data sharing agreement (DSA) **beyond** 2031. IGARD acknowledged that they, and many other commentators, were of the view that genetic data may be considered 'personal data' under UK General Data Protection Regulation (UK GDPR) (not anonymous), see for example the ICO commissioned analysis by the PHG Foundation, and suggested that a declarative statement was inserted in section 5(a) to reflect that UCL are **not** processing genetic information. IGARD also suggested that the applicant update their privacy notice to be clear that the UCL is **not** processing genetic information. IGARD asked that a special condition was updated in section 6 (Special Conditions), 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"* (use MY data - our data citation project), in line with NHS Digital DARS Standard for Special Conditions. IGARD noted reference in section 6 to the annual confirmation report being submitted 12 months after the start date, and **separate to this application**, asked NHS Digital to provide an update of the status of the annual confirmation report for the other Grail application, which is nearing its anniversary date early next year, noting that the annual confirmation report is still in draft and still with NHS Digital to finalise. IGARD noted that some of the benefits outlined in section 5(d) (Benefits) (iii) (Yielded Benefits) were expected benefits, not yielded benefits, and asked that section 5(d) was updated to move all the benefits from section 5(d) (iii) to section 5(d)(ii).

	In addition, IGARD suggested that the expected benefits outlined should distinguish between the expected benefits of the use of NHS Digital data and those of the early screening programme, and are in line with the NHS Digital DARS Standard for Expected Measurable Benefits. IGARD suggested that this application would be suitable for NHS Digital's Precedent route, including the SIRO Precedent, for any amendments **up to 2031** only. 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; for any requests **beyond 2031,** due to the declarative statement in the consent materials **Outcome:** recommendation to approve The following amendments were suggested: 1. In respect of special conditions: a. To insert a special condition in section 6 that no new data can flow under this DSA beyond 2031. b. To update the special condition in section 6, 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"*, in line with the NHS Digital DARS Standard for Special Conditions. 2. In respect of benefits and in line with the NHS Digital DARS Standard for expected measurable benefits: a. To move all benefits from section 5(d)(iii) to section 5(d)(ii). b. To update section 5(d)(ii) to distinguish expected benefits between use of NHS Digital data and the early screening programme. 3. To provide a declarative statement in section 5(a) to reflect that UCL are **not** processing genetic information. The following advice was given: 1. IGARD suggested that the applicant update their privacy notice to reflect the fact that UCL is **not** processing genetic information. 2. IGARD suggested that the applicant may wish to follow cohort members well beyond 2031, and suggested that the applicant may wish to consider re-consenting for longer period of follow-up now. 3. IGARD advised that this application would be suitable for NHS Digital's Precedent route if all qualifying DARS Standards are met for any amendments **up to** 2031 only. 4. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, for any requests beyond 2031 due to the declarative statement in the consent materials. 5. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, for any requests beyond 2031 due to the declarative statement in the consent materials. **ACTION / separate to this application:** NHS Digital to provide a status update with regard to annual confirmation report for the other Grail application which is nearing its anniversary data early next year.

3.4	University Hospitals Bristol and Weston NHS FT: 'UK Cohort study to Investigate the prevention of Parastomal Hernia' (The CIPHER study) - (Presenter: Charlotte Skinner) NIC-134719-D5W2Y-v0.17 **Application:** This was a new application for identifiable Bridge file: Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC), HES Critical Care, HES Outpatients, Diagnostic Imaging Dataset (DIDs), Hospital Episode Statistics to DIDs, Civil Registration (Deaths) - Secondary Care Cut, Emergency Care Data Set (ECDS) and HES:Civil Registration (Deaths) bridge. The formation of a stoma can be associated with future complications, including the risk of developing a Parastomal Hernia (PSH); which are relatively common and affect approximately 40% of patients within 2 years of their bowel surgery. Complications of PSH can be severe and are known to negatively influence patients' quality of life. Both patient and surgical factors are believed to influence the development of PSH; however, the way in which surgeons create stomata is very varied and research is needed to investigate whether these factors influence the risk of developing a PSH. Modification of the technical aspects of surgery may reduce the incidence of PSH and could lead to improvements in the health of patients, better quality of life, a reduction in direct stoma appliance and accessory costs and fewer PSH repairs. The modifications offer the potential for significant savings for the NHS as well as benefit for individual patients. Unfortunately, existing studies on surgical technique relating to stoma formation are limited by poor design and generalisability and, consequently, further high-quality research is urgently needed. The purpose of the application, is for the Royal Devon University Healthcare NHS Foundation Trust and the University of Bristol to access the data, for **Phase B** of a study that aims to establish the incidence of symptomatic and radiologically confirmed PSH during a minimum of 2 years follow up. Additionally, the study aims to evaluate the effects of key technical surgical steps during index stoma formation on the risk of subsequent PSH formation. **Phase A** of the study has been completed; the aim of this, was to undertake feasibility work to inform the design of Phase B. This included identifying the surgical steps and other factors relevant to PSH development and developing a Patient Reported Outcome Measure to use in Phase B to identify symptomatic PSH. The study cohort consists of 2,175 consented participants who have undergone stoma formation surgery. **Discussion:** IGARD noted and commended NHS Digital and the applicant, on the quality of the information within the application, which supported the review of the application by members. 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 queried the statement in section 3(c) (Patient Objections) that patient objections would be applied; and were advised by NHS Digital that this was an error, and would need to be updated to reflect that patient objections would **not** be applied. IGARD noted the verbal update from NHS Digital and asked that section 3(c) be updated to correctly reflect that patient objections would **not** be applied. IGARD noted that section 5(d) (Benefits) (ii) (Expected Measurable Benefits to Health and / or Social Care) contained narrative on patient and public involvement and engagement (PPIE); and asked that it was removed from section 5(d) (ii) (Expected Measurable Benefits to Health

	and / or Social Care) and correctly moved to section 5(a) (Objective for Processing) in line with NHS Digital DARS Standard for Objective for Processing and section 5(c) (Specific Outputs Expected) in line with NHS Digital DARS Standard for Expected Outcomes as appropriate. **Outcome:** recommendation to approve The following amendments were requested: 1. To amend section 3(c) to reflect that patient objections would **not** be applied. 2. In respect of the PPIE: a) To remove the PPIE narrative from section 5(d) (ii); and, b) To update section 5(a) and section 5(c) with the PPIE information as appropriate.
3.5	University College London (UCL): Stratifying Genomic Causes of Intellectual Disability by Mental Health Outcomes in Childhood and Adolescence (IMAGINE-2) (Presenter: Dan Goodwin) NIC-168879-K2N8Q-v0.15 **Application:** This was a new application for identifiable Emergency Care Data Set (ECDS), Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC), HES Critical Care, HES Outpatients; and pseudonymised Mental Health of Children and Young People data. The purpose of the application is for a study, that aims to investigate the impact of genetic disorders that are associated with learning difficulties on children and young people's mental health. The study is a follow-up project of a previous study called Intellectual Disability and Mental Health: Assessing Genomic Impact on Neurodevelopment (IMAGINE-ID). This application is for the purpose of **Workstream 1**, which aims to map trajectories of developmental risk for individuals with different types of Intellectual Disability (ID); and is led by UCL. **Workstream 2** is led by Cardiff University and involves a face-to-face follow-up study of young people as part of IMAGINE-ID, who have been identified as carrying a genetic variation which is high-risk for mental health problems. Cardiff University will independently collect data from participants in IMAGINE-2 by direct contact with the identified high-risk subset of families whom they will visit at home. Cardiff University will **not** have access to the NHS Digital data. This study (workstream 1) relies on three different ways of meeting the common law duty of confidentiality to allow the flow of confidential information: **1)** Informed Parental Consent *(for those under the age of 16 on recruitment)*; **2)** Informed Patient Consent *(for those who are over the age of 16 on recruitment and also for those who come of age during the study and have the mental capacity to do so)*; **3)** Mental Capacity Act 2005 (*for those over the age of 16 on recruitment who do not have the mental capacity to consent, and also for those who come of age during the study and do not have the mental capacity to consent. Therefore, a nominated consultee of the individual will be approached asking for an opinion on whether the individual would want to take part.).* NHS Digital noted that section 2(c) (Territory of Use) incorrectly stated that the territory of use was the *"UK"* and advised that this would be amended to correctly reflect that the territory of use was *"England and Wales"*. NHS Digital advised that the application referred to a cohort for approximately 4,000 participants, however advised that this would need updating to only reflect those participants that consented in England, which was approximately 1,130.

	Discussion: IGARD noted and commended the applicants public facing website outlining clear information on the study. IGARD noted the verbal update from NHS Digital in respect of the territory of use; and supported the update to section 2(c) to correctly reflect that the territory of use was *"England and Wales"*. IGARD noted the verbal update from NHS Digital in respect of the cohort numbers, and supported the relevant updates to the application, to ensure it referenced the correct cohort numbers for this application. In addition, IGARD suggested that the control cohort decreased in line with the decrease in cohort numbers; and that if the control cohort did not decrease, suggested that for transparency / future reference, a justification was provided for retaining the original control cohort size of approximately 4,000. IGARD suggested that the applicant clarified why there were no child assent materials alongside the parental consent for those cohort members under the age of 16, in light of the research having NHS Health Research Authority Research Ethics Committee (HRA REC) support; and in light of the unique makeup of the cohort, i.e. young people with intellectual disabilities; and in line with the NHS HRA guidance on this point (particularly the section headed *"Children and young people's wishes and assent"*). IGARD noted that the applicant had requested that the National Data Opt-out (NDO) was upheld for participants who were recruited via consultee advice, and queried why they had requested this. NHS Digital advised that they were unable to clarify / provide further information on this point. IGARD suggested that in the absence of policy on this point, they would potentially support the NDO being set aside for those cohort members included under consultee advice in this particular instance. IGARD also suggested that NHS Digital's Caldicott Guardian considered the particular application of upholding the NDO in the context of the Mental Capacity Act 2005, in the instance where a child becomes an adult, and does not have the capacity to consent. **ACTION:** IGARD suggest NHS Digital review its consent review materials to prompt questions around child assent alongside the parental consent for under 16s and in line with HRA Guidance on this point (See: NHS HRA guidance (particularly the section headed "Children and young people's wishes and assent")) . **ACTION:** Caldicott Guardian review of application of NDO when relying on consultee advice, particularly in cases such as this where a national data opt-out may have been registered on behalf of a child by the consultee. IGARD queried the role of the University of Cardiff Investigator, noting the narrative within the application and the supporting documents provided, that suggested a close linkage between the design of workstream 1 and workstream 2. IGARD asked that section 1 (Abstract) **and** section 5(a) (Objective for Processing) were updated to confirm that the University of Cardiff Investigator has had **no** input on determining the purpose and means of the use of data in workstream 1. IGARD queried the frequency of the flow of data under this data sharing agreement (DSA), noting the conflicting information with the application that states that the request was for a *"one -off"* flow of data; and the protocol provided as a supporting document stated that the data would flow on an *"annual"* basis. IGARD asked that the application was reviewed and updated throughout as may be necessary to clarify the frequency of the data flow. IGARD confirmed

	that they would be supportive of the data flowing on an annual basis, if this was the correct frequency required. IGARD queried the statement in section 5(b) (Processing Activities) *"All research data held in the Data Safe Haven for analysis is not directly identifiable"*; and asked that this updated with further clarification of what data fields were in the Data Safe Haven. In addition, IGARD asked that the statement was updated to remove the incorrect reference to the data fields **not** being identifiable. IGARD queried if there had been any patient and public involvement and engagement (PPIE) in the design of the study; and asked if there had been any PPIE, that this was reflected in section 5(a) (Objective for Processing) in line with NHS Digital DARS Standard for Objective for Processing. IGARD queried the statement in section 5(d) (Benefits) (ii) (Expected Measurable Benefits to Health and / or Social Care) *"Clinicians in the NHS increasingly request specialist genetic investigations for children with ID. Usually, the results do not translate into specific recommendations for management or prognosis relating to behavioural adjustment, although **families would welcome such knowledge**"*; and asked that in line with NHS Digital DARS Standard for Expected Measurable Benefits, further information was provided on the reference to *"families would welcome such knowledge"*, for example, was this based on express feedback from any relevant family groups. IGARD noted that the NHS Digital citation special condition had been added in section 6 (Special Conditions), however asked that this was updated to also include the relevant quotation marks and other relevant tweaks, for example *"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. To amend section 2(c) to reflect the territory of use is *"England and Wales"* (as per the verbal update from NHS Digital) 2. To update the application throughout to reflect the correct cohort number applicable to this application. 3. In respect of the University of Cardiff Investigator: a) To update section 1 to confirm that the University of Cardiff Investigator has had no input on determining the purpose and means of workstream 1. b) To update section 5(a) to confirm that the University of Cardiff Investigator has had no input on determining the purpose and means of workstream 1. 4. To update the application throughout to review / clarify the frequency of the data flow, for example, one off vs annual. 5. In respect of the data fields: a) To amend section 5(b) to clarify what data fields are in the Data Safe Haven. b) To update section 5(b) to remove reference to the data fields **not** being identifiable. 6. To update section 5(a) with clarity of any PPIE in the design of the study. 7. To update section 5(d) with further information on the statement *"families would welcome such knowledge"*. 8. To insert a special condition in section 6, 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"*, in line with the NHS Digital DARS Standard for Special Conditions.

	The following advice was given: 1. IGARD suggested that the applicant clarified why there was no child assent materials alongside the parental consent for those cohort members under the age of 16, in light of the research having NHS HRA REC support and the unique make up of the cohort, i.e. young people with intellectual disabilities; and in line with the NHS HRA guidance on this point. 2. IGARD suggested that the control cohort decreases in line with the decrease in cohort numbers. If the control cohort does not decrease, IGARD suggested that a justification was provided for retaining the original control cohort size. 3. In respect of the NDO: a) Noting the applicant had requested that the NDO is upheld; IGARD suggested that in the absence of policy on this point, in this instance they would potentially support the NDO being set aside for those cohort members included on consultee advice; and, b) IGARD suggested that NHS Digital's Caldicott Guardian considered the particular application of upholding the NDO in the context of the Mental Capacity Act 2005, in the instance where a child becomes and adult, and does not have the capacity to consent in particular considering when their NDO may have been registered on their behalf by a parent. **ACTION:** IGARD suggest NHS Digital review its consent review materials to prompt questions around child assent alongside the parental consent for under 16s and in line with HRA Guidance on this point. **ACTION:** Caldicott Guardian review of application of NDO when children reaching adulthood are included in study on the basis of consultee advice.
3.6	Institute of Cancer Research: MR1211 - UK Genetic Prostate Cancer Study (Presenter: Dan Goodwin) NIC-148118-VCXW9-v4.2 **Application:** This was an application that was coming to IGARD for advice, to establish whether the consent materials used (either fully or in part) provide a legal basis to meet the common law duty of confidentiality. The existing data sharing agreement (DSA) is to permit the applicant to retain data supplied between 2011 and 2019 for an interim period. The purpose of the application, is for a study aiming to find genetic changes which are associated with prostate cancer risk. If the study can find alterations in genes that increase the chances of getting prostate cancer, it may be possible in the future to use this knowledge: **1)** to screen other family members to see if they are also at a higher risk of developing prostate cancer; and **2)** to develop new prostate cancer treatments for the future. **Discussion:** IGARD welcomed the application which came for advice on the consent materials and without prejudice to any additional issues that may arise when the application is fully reviewed. IGARD noted that the application and relevant supporting documents had previously been presented at the Data Access Advisory Group (IGARD's predecessor) meeting on the 16th November 2011. It was discussed as part of the 'applications progressed via NHS Digital's SIRO Precedent route' on the 6th October 2022, where IGARD had requested that the application returned for a review before mid-November 2022.

	IGARD noted that the applicant was currently not ready to proceed with a formal application for a full IGARD review, due to ongoing discussions with Health Research Authority Confidentiality Advisory Group (HRA CAG) on the validity of the consent materials; and in respect of obtaining s251 support for those cohort members recruited prior to 2009, noting that the consent materials for this group of cohort members were insufficient and did **not** meet the common law duty of confidentiality. IGARD advised that they were supportive of the applicant seeking s251 support for those cohort members consented prior to 2009. IGARD discussed the consent materials provided as supporting documents for those cohort members who consented in 2009 onwards (patient information sheet v14 and consent form v6 onwards); and advised that the consent materials were broadly compatible with the processing, and were supportive of the applicant relying on consent for this group of cohort members. IGARD suggested that it would be helpful if any NHS Digital consent reviews, provided as supporting documentation, included the author, date of review, date(s) of materials reviewed and a clear conclusion; to support any future review of the application / supporting documents by members. IGARD noted the UK General Data Protection Regulation (UK GDPR) Article 6 legal basis for the Institute of Cancer Research, cited was Article 6(1)(e) and Article 9(2)(j) *"public task"*; and asked that for transparency, the application was updated with a clear justification for using this specific UK GDPR legal basis, as opposed to, for example, legitimate interests. IGARD noted the researcher named within the consent and patient information materials provided as supporting documents; and cautioned against naming specific researchers in the consent / patient information materials. IGARD suggested that NHS Digital put in place a short-term extension until the advice points above had been addressed. IGARD advised that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the complex consent history, the s251 support and the amount of time that had passed since the last independent review. **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 were supportive of the applicant seeking s251 support for those cohort members consented prior to 2009 (prior to v14 of the patient information sheet and v6 of the consent form). 2. IGARD were supportive of the applicant relying on consent for those cohort members consented from 2009 onwards. 3. To provide a clear justification for citing Public Task as the UK GDPR legal basis for ICR (cf legitimate interests). 4. IGARD cautioned against naming specific individual researchers in the consent or PI materials 5. IGARD suggested that it would be helpful if any NHS Digital consent reviews provided, included the author, date of review, date(s) of materials reviewed, clear conclusion etc. 6. IGARD suggested that NHS Digital put in place a short-term extension until the advice points above had been addressed. 7. IGARD advised that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the complex consent history, the s251 support and the amount of time that had passed since the last independent review.

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). *No items discussed*
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:
7.1	OpenSafely (Presenter: Kimberley Watson) NHS Digital attended the meeting to advise IGARD, that in light of the extension to The Health Service Control of Patient Information (COPI) Regulations 2002, until the 30th April 2023; that NIC-397618-T8L8Z, the NHS England (OpenSafely) DSA has been extended and renewed until the 30th April 2022 under the SIRO approvals route. NHS Digital noted that the DSA end date goes beyond the NHS Digital / NHS England merger date (in January 2023), however, advised that the six-month extension will enable the future of this DSA to be addressed and to understand and agree the operating model under NHS England. IGARD noted and thanked NHS Digital for the verbal update.
7.2	National Data Opt-outs and the National Clinical Audits (Presenter: Kimberley Watson) NHS Digital attended the meeting, to advise IGARD, that DARS were receiving applications from certain national clinical audits, submitted to amend the National Data Opt-Out (NDO)section so that it would no longer be upheld. NHS Digital noted that a list of those applications that HRA CAG had given section 251 support for **not** applying the National Data Opt-Out had been published on the NHS Digital website. NHS Digital advised that for those clinical audits that have data sharing agreements (DSA) with NHS Digital, they would need to submit an amendment to their DSA to change the National Data Opt-Out from being "applied" to "not being applied". NHS Digital noted that DARS colleagues were proactively contacting clinical audit customers to ensure that they are aware of the need to submit an amendment to their DSA(s) and that this change in NDO application would not happen automatically. NHS Digital advised that they were proposing that when an amendment DSA is submitted to change the opt-out, these progress without a review of the application by IGARD and that IGARD would be notified of the applications that are amended under 'AOB' at future meetings. IGARD noted and thanked NHS Digital for the verbal update and advised that, given the consideration that HRA CAG had given to each audit they were supportive of the approach suggested. However, IGARD asked that this review by DARS was done on a careful case-by-case basis, for example, to check if HRA CAG had imposed any conditions, and that any application amendment mapped exactly to the HRA CAG support. In the case of any possible discrepancy or ambiguity, IGARD suggested that then the amendment application was submitted to IGARD for a full review.
7.3	Head of Data Access Update (Liz Gaffney) The Head of Data Access attended (part of) the meeting as part of her regular catch-up with IGARD. 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.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 04/11/22

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)
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