Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 18 August 2022

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Prof. Nicola Fear	Specialist Academic Member (Items 4.3 to 8.1)
Dr. Robert French	Specialist Academic / Statistician Member
Kirsty Irvine	IGARD Chair
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Chair
IGARD MEMBERS NOT IN ATTENDANCE:	
Maria Clark	Lay Member
Dr. Maurice Smith	Specialist GP Member
Jenny Westaway	Lay Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Dave Cronin	Data Access Request Services (DARS) (**SAT Observer**: items 4.3, 4.4)
Louise Dunn	Data Access Request Services (DARS) (**SAT Observer**: items 3.1, 4.1)
Mujiba Ejaz	Data Access Request Services (DARS) (Items 4.3, 4.4)
Liz Gaffney	Head of Data Access, Data Access Request Service (DARS) (Item 8.1)
David Morris	Data Access Request Services (DARS) (Item 4.2)
Karen Myers	IGARD Secretariat
Karen Nicholson	Data Access Request Services (DARS) (Observer: items 3.1, 4.1, 4.2)
Tania Palmariellodiviney	Data Access Request Services (DARS) (**SAT Observer**: item 4.2)
Aisha Powell	Data Access Request Services (DARS) (Observer: items 4.3, 4.4)
Vicki Williams	IGARD Secretariat

Tom Wright	Head of Data Services for Commissioners (DSfC) (Items 3.1, 4.1)
***SAT** – Senior Approval Team (DARS)	
NHS ENGLAND STAFF IN ATTENDANCE:	
Ayub Bhayat	Director of Insight and Data Platform (item 2 and 3.1 only)
Gemma Dodds	Consultancy Programme Lead - North of England Commissioning Support (item 2 and 3.1 only)
Wendy Harrison	Deputy Head of IG (item 2 and 3.1 only)

1	**Declaration of interests:** There were no declarations of interest. **Review of previous minutes and actions:** The minutes of the 11th August 2022 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record the meeting **Out of committee recommendations:** An out of committee report was received (see Appendix A).
2	IGARD / NHS England – Meet and Greet Session / fact finding session As part of their consideration of the Faster Data Flow Acute Patient Activity briefing paper (item 3.1), IGARD invited colleagues from the NHS England to attend in order to find out from the subject matter experts' further information and background about the datasets and purpose. It was also an opportunity for IGARD to raise general overarching queries and points of clarification that would support them with the briefing paper / application discussion later that morning. IGARD thanked the Head of Data Service for Commissioners (DSfC) for arranging the session, and thanked NHS England for attending and providing helpful background information.
3	**Briefing Notes**
3.1	Faster Data Flow Acute Patient Activity Briefing Paper (Presenter: Tom Wright) This briefing paper was to inform IGARD that NHS England have directed NHS Digital to create a daily collection of identifiable patient level data about admission, inpatient, discharge and outpatient activity from acute providers in England. NHS England will use the data for operational purposes to support and accelerate elective recovery, providing operational planning data to Integrated Care Boards / Integrated Care Systems / Providers for the co-ordination, management and improvement of care pathways. Where possible, the data will be used to fulfil reporting requirements and replace the need for manual, aggregate collections.

	NHS England are instructing NHS Digital to use Foundry, a Palantir product to collect and land the data in the GEM Data Services for Commissioners Regional Office (DSCRO). **Outcome:** IGARD welcomed the briefing paper and associated supporting documents and made the following high-level comments: 1. IGARD thanked NHS England for their helpful verbal update with regards to the differences between this dataset and the Uncurated Low Latency dataset and the unmet needs that this data set aimed to address. 2. NHS Digital agreed to update the briefing paper to reflect that NHS England are a joint Data Controller. 3. NHS Digital agreed that the Data Provision Notice "Benefits" needed to be updated to ensure that they accurately reflected the collection and processing. 4. IGARD were advised that both NHS England and NHS Digital's privacy notices were clear that Palantir Technologies UK Ltd was a data processer for aspects of the processing of the data and IGARD noted that this was essential for transparency. 5. Noting the NHS England update in respect of engagement with Stakeholders, IGARD suggested that thought be given to publishing relevant assurance reports, and other stakeholder reports, to address any potential public criticism with regards to whether or not this was necessary processing and / or why it was necessary to use Palantir Technologies UK Ltd as a Data Processor and the Foundry platform, rather than existing public sector processors, tools and data flows. IGARD welcomed the draft briefing paper and looked forward to receiving a finalised briefing paper, along with any relevant supporting documents, tabled at a future meeting.
4	**Data Applications**
4.1	<u>NHS England (Quarry House): NHS England Faster Data Programme (Presenter: Tom Wright) NIC-616043-S9R4P-v0.2</u> **Application:** This was a new application for a daily flow of pseudonymised Acute Activity Data Set. The purpose of the application is for The Faster Data Flows (FDF) programme, which has been established to provide more timely data to the system to support elective recovery, individual care coordination across Integrated Care Boards (ICBs) and to reduce the data reporting burden on providers. FDF will deliver this by implementing an automated daily flow of patient level data into the NHS National Data Platform (Foundry). The initial scope of work will focus on the collection of core patient identifiable data items for current admissions, inpatient, discharge and outpatient. This purpose of collecting the data is to support clinicians to access information about individuals in their care that covers patient pathways and to show where care has been accessed in other organisations to give the ability to make the right decisions. Also, to support local and national commissioners / decision makers, with timely data about current services for planning, benchmarking, service improvement, response to crisis, and to comply with their statutory duties. Existing flows are either not frequent or granular enough to support local planning and individual care co-ordination. **Discussion:** IGARD noted that the Faster Data Flow Acute Patient Activity Briefing Paper (item 2.1) was in relation to this application. IGARD noted that the sub-licensing arrangements were set out in section 10 (Sub-licensing), however advised that within the public facing section of the application, sub-licensing had not

	been referred to. IGARD asked that for transparency, and in line with NHS Digital DARS standard for sub-licencing and onward sharing, section 5(a) (Objective for Processing) was updated, with a description of the sub-licensing arrangements. In addition, IGARD asked that the sub-licensing special conditions in section 10 and the sub-licence specifications, mapped to what was happening in practice, for example, re-identification. IGARD noted the "*Third party sub-licensees"* listed within section 10, however, asked that this was linked to the permitted parties as outlined within the Data Services for Commissioners Direction 2015, and followed the Direction at all times (including when the amendments are finalised and as the Direction may be amended from time to time). IGARD also queried if there was any deviation from NHS Digital DARS standard for sub-licencing and onward sharing, for example, if it was a direct throughput of data, and if so, to explain the policy justification for deviating from the usual restriction as outlined in the published DARS Standard. IGARD asked that, for future reference, section 1 (Abstract) should always be updated with a clear explanation of any deviation from due NHS Digital process. IGARD had queried in advance of the meeting the role of the clinicians and that section 5(a) implied that clinicians may have access to identifiable data and queried what was happening in respect of any re-identification of patients. NHS Digital had noted that clinicians did not have access to identifiable data. IGARD asked that section 5 (Purpose / Methods / Outputs) was updated with further clarification; and that it reflected the special condition relating to the sub-licensees; and / or to update the sub-licensing special condition in section 10 so that it reflected the factual scenario outlined in section 5. Noting that the ICO guidance on consulting with data subjects, IGARD suggested that both NHS Digital and NHS England's Data Protection Impact Assessments (DPIAs) were updated to expressly address why no consultation with data subjects has been undertaken. IGARD also suggested that given the innovative use of technology and the volume of data, including personal data flowing, that NHS Digital and NHS England considered publishing their respective DPIAs for transparency to the public. As discussed as part of the Faster Data Flow Acute Patient Activity Briefing Paper, IGARD suggested that NHS England may wish to consider publishing or summarising the extensive stakeholder engagement, which justified the collection of the data and use of Palantir Technologies UK Ltd Foundry tool, noting that this may be of interest to the public. IGARD noted the references to *"foundry"* throughout the application, and asked that these were corrected to ensure this stated the defined term *"Foundry"*. IGARD noted that NHS Digital, NHS England and the Foundry platform were all holding both identifiable and pseudonymised data; and asked that section 5 was updated with a clear description of where the identifiable and pseudonymised data are held and a statement that the two types of data are kept separate. IGARD queried the reference in section 3(b) (Additional Data Access Requested) to the frequency of the data flowing was "*Ad-hoc irregular dissemination*"; and asked that this was updated to more accurately state that the flow of data was daily. IGARD queried the statement in section 5(b) (Processing Activities) that the Foundry platform was *"located, stored and accessed in the **UK**"*; and noting that the territory of use in section 2(c) was stated as being *"England and Wales"*, asked that the statement in section 5(b) was amended to reflect England and Wales; or, if the territory of use was in fact the *"UK"* and not England and Wales, IGARD asked that section 2(c) (Territory of Use) was amended accordingly.

	IGARD had queried in advance of the meeting the statement in section 5(b) *"The NHS National Data Platform (Foundry) sits on a Microsoft Azure platform under contract with NHS England"*, however noted the conflicting special condition in section 6 (Special Conditions) that stated *"Amazon Web Services supply Cloud Services for The Foundry Platform"*. NHS Digital advised IGARD that the reference to Microsoft Azure was an error and that this would be removed from the application. IGARD noted the verbal update from NHS Digital, and supported the update to the application to ensure all references to Microsoft Azure being a Data Processor were removed. IGARD noted modest aspirations outlined within the Data Provision Notice (DPN), and asked that and in line with NHS Digital DARS Standard for Objective for Processing that section 5(a) was updated to reflect this information. In addition, IGARD asked that the 28 expected benefits in section 5(d) (Benefits) (ii) (Expected Measurable Benefits to Health and / or Social Care) were either updated or removed, to also reflect the more modest aspirations as outlined in the DPN in line with NHS Digital DARS Standard for Expected Measurable Benefits. IGARD queried the statement in section 5(b) to opt-outs being applied, and noting that this was incorrect, asked that the statement was removed as it was not relevant. IGARD noted the reference in section 5(b) *"All access to data is managed under Role-Based Access Controls…"*, and noting that this was incorrect, asked that this was removed. As section 5 forms NHS Digital's data uses register, IGARD asked that section 5(a) was amended, to ensure that all acronyms upon first use be defined and further explained if the meaning was not self-evident, for example *"ERS data"*. **Outcome:** recommendation to approve subject to the following condition: 1. In respect of the sub-licensing and in line with NHS Digital DARS standard for sub-licencing and onward sharing: a) To update section 5(a) with a description of the sub-licensing arrangements. b) To ensure the sub-licensing special conditions in section 10 and sub-licence specifications, map to what is happening in practice, for example, re-identification. c) To ensure the definition of *"Third party sub-licensees"* in section 10 links to the permitted parties as outlined within the Direction, and follows the Direction at all times. d) To update section 1 with an explanation of any deviation from NHS Digital DARS standard for sub-licencing and onward sharing, for example, if it is a direct throughput of data, to explain the policy justification for deviating from the usual restriction. The following amendments were requested: 1. To update section 5 to clarify what is happening with the re-identification and ensure it reflects the special condition relating to the sub-licensees (and/or to update the sub-licensing special condition so that it reflects the factual scenario outlined in section 5). 2. To update the application throughout to ensure Microsoft Azure are removed as a Data Processor. 3. As section 5 forms NHS Digital's data uses register, to amend section 5(a) throughout, to ensure acronyms be defined upon first use, for example *"ERS data"*. 4. To accurately reflect the DPN:

	a) To update the objectives for processing in section 5(a) to reflect the more modest aspirations as outlined in the DPN and in line with NHS Digital DARS Standard for Objective for Processing: and. b) To update / remove the 28 expected benefits in section 5(d) (ii) to reflect the more modest aspirations as outlined in the DPN in line with NHS Digital DARS Standard for Expected Measurable Benefits. 5. In respect of the territory of use: a) To update the reference in section 5(b) to the Foundry platform *"located, stored and accessed in the **UK**"* to reflect that this is England and Wales; or, b) To amend the territory of use in section 2(c) from *"England and Wales"* to *"UK"*. 6. In respect of the Foundry platform: a) To update the application throughout to ensure that all references to *"**f**oundry"* are corrected to ensure this states the defined term *"**F**oundry"*. b) To update section 5 with a clear description of where the identifiable and pseudonymised data are held and a statement that the two types of data are kept separate. 7. To remove the incorrect reference in section 5(b) to opt-outs being applied as this is not relevant. 8. To update section 5 to remove reference to *"role based access"*. 9. To update section 3(b) to reflect that the flow of data is daily The following advice was given: 1. In respect of the DPIA(s): a) IGARD suggested that both NHS Digital and NHS England's DPIAs expressly addresses why no consultation with data subjects has been undertaken. b) IGARD suggested that both NHS Digital and NHS England consider publishing their respective DPIAs. 2. In respect of transparency: a) IGARD suggested that NHS England may wish to consider publishing or summarising the extensive Stakeholder engagement which justifies the collection of the data and use of Palantir Technologies UK Ltd Foundry tool. It was agreed the condition would be approved out of committee (OOC) by IGARD members.
4.2	Isle of Man Department of Health & Social Care: Isle of Man Manx Care - Commissioning purposes (Presenter: David Morris) NIC-173508-F4X6P-v7.5 **Application:** This was a renewal application to permit the holding and processing of pseudonymised Secondary Use Service (SUS) for Commissioners data for the purpose of providing intelligence to support the commissioning of health services. It was also an amendment application to **1)** change the Data Controller from Manx Care to the Isle of Man Department of Health & Social Care (IM DHSC); **2)** to add Manx Care as a Data Processor; **3)** to change the legal basis for dissemination from "Section 261 - Other" to "Section 261(5)(d)". Currently patients on the Isle of Man that require treatment from services not available on the Isle of Man have to undertake travel to England / Wales to receive treatment. The IM DHSC wish to understand the rate of patients being sent to the mainland to assist in understanding what services require commissioning locally. NHS Digital noted that in advance of the meeting an IGARD member had submitted a query in respect of section 261(5)(d), and whether a Manx Act satisfied the definition of a "*relevant*

	Act". NHS Digital advised that the query had been submitted to Privacy, Transparency, Ethics and Legal (PTEL) for a response. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD meetings on the 3rd May 2018, 13th August 2020 and the 28th January 2021. It was also discussed as part of the 'applications progressed via NHS Digital's SIRO Precedent route' on the 14th January 2021. IGARD noted and commended the applicant on the excellent yielded benefits outlined in section 5(d) (Benefits) (iii) (Yielded Benefits). IGARD noted to NHS Digital that these exemplars could be used as a resource to support ongoing learning and development of NHS Digital staff and what to look for in applications; or as an exemplar when speaking to ICBs but limiting the yielded benefits to 2 or 3 examples. IGARD noted the verbal update in respect of the query submitted by an IGARD member, in relation to section 261(5)(d), and whether an Isle of Man (Manx) Act met the definition of a "*relevant Act*", and that this query was currently with PTEL. IGARD asked that, upon receipt, the written confirmation from PTEL was provided to IGARD for information; and that the written response from PTEL was uploaded to NHS Digital's customer relationships management (CRM) system for future reference. IGARD noted that on some of the recent applications submitted for review, a special condition had been added to section 6 (Special Conditions), stating that if the term of the data sharing agreement (DSA) was more than 1-year in length, the DSA must include a special condition requiring the data recipient to submit an Annual Confirmation Report, using the latest DARS template, on or prior to the anniversary of the DSA Start Date. **Separate to this application:** IGARD requested that DARS SAT provide an update to IGARD, on the current status requirement to have an annual confirmation report, in line with the NHS Digital DARS Term of Data Sharing Agreement, noting that the requirement is in some applications, but not others. IGARD noted the large number of storage and processing locations in section 2 (Locations), and, noting this may cause difficulty for NHS Digital in respect of auditing, suggested that NHS Digital worked with the applicant to review and consider if the locations could be consolidated, in line with NHS Digital's DARS Standard for processing and storage locations. IGARD noted section 2(c) (Territory of Use) stated that the territory of use was "*worldwide*" due to the Isle of Man being a British Crown dependency; however, noting that NHS Digital were unable to add further information into section 2(c), IGARD asked that the statement in section 5(b) (Processing Activities) *"Data can only be stored at the addresses listed under storage addresses these are restricted to England / Wales and the Isle of Man"*, was also replicated as a special condition in section 6. IGARD noted the references in section 5 (Purpose / Methods / Outputs) to *"patients that…"*, and as section 5 forms NHS Digital's data uses register asked that these were updated to *"patients who…"*. IGARD queried the statement in section 1 (Abstract) and section 5(a) (Objective for Processing) *"The UK government has made a statement that the EU GDPR continues to apply* ***until after 01/01/2021****…"*; and asked that this was updated, to reflect the position beyond this date.

	IGARD noted the statement in section 5(b) "*Patient level data will not be shared outside of Manx Care unless it is for the purpose of Direct Care…*", and noting that there was no further information within the application on this matter, asked that the application was updated throughout, in line with all other current commissioning applications, in respect of the re-identification for the purpose of direct care. **Outcome:** recommendation to approve The following amendments were requested: 1. IGARD noted the large number of storage and processing locations, and, noting this may cause difficulty for NHS Digital in respect of auditing, suggested that NHS Digital worked with the applicant to review and consider if the locations could be consolidated, in line with NHS Digital's DARS Standard for processing and storage locations. 2. In respect of the legal basis: a) To provide written confirmation from PTEL, whether in respect of section 261(5)(d), that a Manx Act satisfies the definition of a "relevant Act". b) To upload the written confirmation from PTEL to NHS Digital's CRM system for future reference. 3. To insert a special condition in section 6 replicating the narrative in section 5(b) that the data will be held and processed in England, Wales or the Isle of Man. 4. As section 5 forms NHS Digital's data uses register, to amend the references in section 5(a) and section 5(b) from *"patients that…"* to *"patients who…"*. 5. To update the statement in section 1 and section 5(a) *"…EU GDPR continues to apply until after 01/01/2021…"* to reflect the position beyond this date. 6. To update the application throughout, in line with all other current commissioning applications, in respect of the re-identification for the purpose of direct care. **Separate to this application:** IGARD requested that DARS SAT provide an update to IGARD, on the current status requirement to have an annual confirmation report, in line with the NHS Digital DARS Term of Data Sharing Agreement, noting that the requirement is in some applications, but not others.
4.3	Imperial College London: neoWONDER: Neonatal Whole Population Data linkage approach to improving long-term health and wellbeing of preterm and sick babies (Presenter: Mujiba Ejaz) NIC-609893-N5P5L-v0.11 **Application:** This was a new application for identifiable Demographics data, that will flow to the Department for Education (DfE) to allow linkage to the National Pupil Database (NPD). Over the last 14 years in the UK, over 100,000 babies were born very premature (before 32 weeks) or with a condition requiring surgery in the first few weeks of life. With advances in neonatal care, more babies are surviving, but there is still a limited understanding of the long-term impact that many neonatal care and surgical interventions have. Understanding long-term impact requires following up children as they grow up. The purpose of the application is to link existing data for a cohort of approximately 120,000 very preterm and surgical babies in neonatal units born between 2007 and 2020 in England, with data available in the National Neonatal Research Database (NNRD), held at the Neonatal Data Analysis Unit (NDAU) at Imperial College London. The NNRD gives near-complete population coverage of all very preterm and sick new born babies admitted to NHS neonatal units. The cohort supplied for linkage represents a near complete population. A letter which has been supplied to NHS Digital, was sent out to all neonatal units asking whether the data they each contributed to the NNRD could be included in the study. Only data provided by the

	neonatal units that have not opted out will be included in the study and supplied to NHS Digital for linkage. The study hopes to provide population level data on the long-term outcomes of this cohort and looks to examine how interventions and exposures in the neonatal period affect these outcomes; with the view of identifying those that may be modified and improved through changes in clinical practice and policy. The processing outlined within the application is relying on s251 of the NHS Act 2006, for the flow of data in and out of NHS Digital. A sister application NIC-283774-B9Z6K (item 3.4) is also linked to this data sharing agreement (DSA). NHS Digital advised IGARD that the s251 obtained from Health Research Authority Confidentiality Advisory Group (HRA CAG), did currently not cover the flow of NHS Digital data to DfE; and that discussions were ongoing with the applicant and HRA CAG to ensure the s251 supported this flow of data. NHS Digital advised that the application was therefore coming for advice and would be brought back to a future IGARD meeting for a recommendation, once the outstanding s251 support was resolved. **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 the importance of the research given the significant benefits that may be achieved. IGARD had raised in advance of the meeting a query with regard to clarification as to how the common law duty of confidence was being met for the sending of data to DfE. IGARD noted the verbal update from NHS Digital in respect of the outstanding issue in respect of the s251 support for the flow of data to DfE; and asked that the applicant liaised with HRA CAG to obtain s251 support for the flow of identifiable data to the DfE. In addition, IGARD requested that a copy of the HRA CAG documentation was uploaded to NHS Digital's CRM system for future reference. In addition, and noting that IGARD saw considerable potential benefit to the research, IGARD suggested that NHS Digital pro-actively contacted HRA CAG in advance, to specifically advise them that the applicant would be contacting them to seek support for the flow of data to the DfE. IGARD asked that once the relevant HRA CAG support had been obtained, that the application was updated throughout to ensure the legal basis was reflected, and that the application be submitted to a future IGARD meeting as expediently as possible for a recommendation. IGARD queried what would happen to the unmatched data, for example, those cohort members whose data flows to DfE, but were not on the NDP, for example, those children and young people who did not attend state schools. IGARD asked that section 5 (Purpose / Methods / Outputs) was updated with a further explanation. IGARD noted the extensive parent and patient engagement, which must have been evaluated by HRA CAG and Research Ethics Committee (REC). However, statements in section 5(a) suggested a significant percentage of survey participants were unsure or unhappy with the linkage and IGARD emphasised the need to improve transparency about the study, linkage and how to opt-out from being part of the cohort.

	IGARD noted that they had previously reviewed a similar research application relating to the ECHILD programme (NIC-381972-Q5F0V); and queried how this study was unique and differed from ECHILD and other similar studies. IGARD asked that a narrative was provided in section 5(a) (Objective for Processing) in line with NHS Digital DARS Standard for Objective for Processing and the benefits in section 5(d) (Benefits) in line with NHS Digital DARS Standard for Expected Measurable Benefits. IGARD noted the references throughout the application to the Clinical Record Interactive Search (CRIS) system; however asked that these were updated to reflect that this was specifically referring to South London and Maudsley NHS Foundation Trust (SLaM) CRIS. Noting the small geographical cohort contained within SLaM CRIS, that was restricted to cohort members within South London and Maudsley; IGARD asked that an explanation was provided in section 5 as to why the small geographical cohort within SLaM CRIS was being used: and that section 5 was also updated with an indicative number of children within SLaM CRIS for transparency IGARD suggested that the applicant may wish to consider that a potential benefit to this focussed research would be encouraging or supporting additional funding or research into the **prevention** of pre-term births. IGARD suggested that the applicant update the study protocol to remove the incorrect reference to identifiers being sent to the Office for National Statistics (ONS), since this was incorrect. IGARD noted the statement in section 5(b) (Processing Activities) *"…all Demographics supplied by NHS Digital will be destroyed by the Department for Education as soon as successful linkage has been performed"*; and the statement in the HRA CAG letter of support dated the 22nd June 2021 "NHS Digital and Department for Education (DfE) to retain linkage keys for possible future applications". IGARD asked that the conflicting statements were reviewed and updated / aligned as appropriate to reflect the factual scenario. IGARD noted the projected dates for publication within the application, for example dates that were imminent, and asked that these were reviewed and updated as necessary to reflect the current position. 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 concerns about transparency around opting out of the study. **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 s251 support: a) The applicant to liaise with HRA CAG to obtain s251 support for the flow of identifiable data to the Department for Education; and b) To upload all the HRA CAG documentation to NHS Digital's CRM system for future reference. 2. To update the application throughout to ensure the legal basis is reflected. 3. To update section 5 with an explanation as to what will happen to the unmatched data, i.e. those cohort members whose data flow to DfE but are not on the NPD. 4. To update section 5(a) **and** section 5(d) with confirmation as to how this study is unique and differs from similar studies, including (but not limited to) the ECHILD programme.

	5. In respect of SLaM CRIS: a) To update the application throughout to ensure that any reference to *"CRIS"* is updated to reflect that this is *"SLaM CRIS"*. b) To provide an explanation in section 5 as to why the small geographical cohort within SLaM CRIS is being used: and c) To update section 5 with an indicative number of children within SLaM CRIS. 6. To review the conflicting statements in the application and supporting document in respect of data destruction and update / align as appropriate to reflect the factual scenario. 7. To review the projected dates for publication within the application and update as necessary to reflect the current position. 8. To update section 5 with information regarding whether it is possible for individuals to apply the neoWONDER opt out once data has flowed to NHS Digital. The following advice was given: 1. IGARD suggested that the applicant may wish to consider that a potential benefit to this focussed research will encourage or support additional funding or research into the **prevention** of pre-term births. 2. IGARD suggested that the applicant update the study protocol to remove the incorrect reference to identifiers being sent to ONS. 3. IGARD suggested that given the significant percentage of survey participants who were unsure or unhappy with the linkage; and coupled with the HRA CAG transparency special condition; thought needs to be given on how to improve transparency about the study, linkage and how to opt-out from being part of the cohort. 4. Noting that IGARD were supportive of this application, IGARD suggested that NHS Digital, pro-actively contacted HRA CAG to specifically advise them that the applicant would be contacting them directly to seek support for the flow of DfE data. 5. IGARD advised that they would wish to review this application when it comes up for renewal or extension, due to the concerns about transparency around opting out of the study. 6. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the concerns about transparency around opting out of the study.
4.4	<u>Imperial College London: neoWONDER: Neonatal Whole Population Data linkage approach to improving long-term health and wellbeing of preterm and sick babies (Presenter: Mujiba Ejaz) NIC-283774-B9Z6K-v0.19</u> **Application:** This was a new application for pseudonymised Civil Registration (Deaths) - Secondary Care Cut, Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC), HES Critical Care, HES Outpatients, Emergency Care Data Set (ECDS), Mental Health Services Data Set (MHSDS) and HES:Civil Registration (Deaths) bridge. Over the last 14 years in the UK, over 100,000 babies were born very premature (before 32 weeks) or with a condition requiring surgery in the first few weeks of life. With advances in neonatal care, more babies are surviving, but there is still a limited understanding of the long-term impact that many neonatal care and surgical interventions have. Understanding long-term impact requires following up children as they grow up. The purpose of the application is to link the NHS Digital data with data from the Neonatal Data Analysis Unit (NDAU) at Imperial College London and a pseudonymised dataset will flow back

	to NDAU. The cohort will include approximately 120,000 very preterm and surgical babies in neonatal units born between 2007 and 2020 in England, with data available in the National Neonatal Research Database (NNRD) at the NDAU. The NNRD gives near-complete population coverage of all very preterm and sick new born babies admitted to NHS neonatal units. The cohort supplied for linkage is therefore near-population. A letter which has been supplied to NHS Digital, was sent out to all neonatal units asking whether the data they each contributed to the NNRD could be included in the study. Only data provided by the neonatal units that have not opted out will be included in the study and supplied to NHS Digital for linkage. The study hopes to provide population level data on the long-term outcomes of this cohort and looks to examine how interventions and exposures in the neonatal period affect these outcomes; with the view of identifying those that may be modified and improved through changes in clinical practice and policy. The processing outlined within the application is relying on s251 of the NHS Act 2006, for the flow of data in and out of NHS Digital. A sister application NIC-609893-N5P5L (item 3.3) is also linked to this data sharing agreement (DSA). **Discussion:** IGARD noted the importance of the research - given the current limited investigation into the impact of pre-term birth - and the significant benefits that may be achieved. **ACTION:** IGARD reiterated their action from the 28th July 2022 IGARD meeting: Noting that although the flow of data **from** NHS Digital was classified as pseudonymised, in the hands of the recipient it was potentially identifiable patient data as they have the technical means to reidentify. IGARD suggested that NHS Digital queried this point with the Health Research Authority Confidentiality Advisory Group (HRA CAG). IGARD requested an update by the end of August 2022. In addition, in respect of the published HRA CAG Register and the HRA CAG support, IGARD asked that the applicant confirmed with HRA CAG, that they are content that even though the applicant has the ability to re-identify the cohort, sufficient controls were in place to satisfy the requirements of the data flowing back being *"pseudonymised"*, as per the entry on the HRA CAG register; and to upload any relevant / supporting documentation to NHS Digital's Customer Relationship Management (CRM) system for future reference. IGARD noted the extensive parent and patient engagement, which must have been evaluated by HRA CAG and Research Ethics Committee (REC). However, statements in section 5(a) suggested a significant percentage of survey participants were unsure or unhappy with the linkage and IGARD emphasised the need to improve transparency about the study, linkage and how to opt-out from being part of the cohort. IGARD noted that they had previously reviewed a similar research application relating to the ECHILD programme (NIC-381972-Q5F0V); and queried how this study was unique and differed from the ECHILD and other similar studies. IGARD asked that a narrative was provided in section 5(a) (Objective for Processing) in line with NHS Digital DARS Standard for Objective for Processing and the benefits in section 5(d) (Benefits) in line with NHS Digital DARS Standard for Expected Measurable Benefits. IGARD noted the references throughout the application to the Clinical Record Interactive Search (CRIS) system; however asked that these were updated to reflect that this was specifically referring to South London and Maudsley NHS Foundation Trust (SLaM) CRIS.

	Noting the small geographical cohort contained within SLaM CRIS, that was restricted to cohort members within South London and Maudsley; IGARD asked that an explanation was provided in section 5 (Purpose / Methods / Outputs) as to why the small geographical cohort within SLaM CRIS was being used: and that section 5 was also updated with an indicative number of children within SLaM CRIS for transparency. IGARD suggested that the applicant may wish to consider that a potential benefit to this focussed research would be encouraging or supporting additional funding or research into the prevention of pre-term births. IGARD noted the statement in section 5(b) (Processing Activities)…*"all Demographics supplied by NHS Digital will be destroyed by the Department for Education as soon as successful linkage has been performed"*; and the statement in the HRA CAG letter of support dated the 22nd June 2021 *"NHS Digital and Department for Education (DfE) to retain linkage keys for possible future applications"*. IGARD asked that the conflicting statements were reviewed and updated / aligned as appropriate to reflect the factual scenario. IGARD noted the special condition in section 6 (Special Conditions) in respect of data destruction, however advised that this was updated, or a separate special condition was inserted, that data will be destroyed once linkage has been completed. NHS Digital noted the length of the DSA (3 years) and wondered whether this could be shortened given the temporary nature of the data processing, IGARD were in agreement with the approach. IGARD noted the projected dates for publication within the application, and asked that these were reviewed and updated as necessary to reflect the current position. 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 concerns about transparency around opting out of the study. **Outcome:** recommendation to approve subject to the following condition: 1. In respect of the published HRA CAG Register and HRA CAG support: a) The applicant to confirm with HRA CAG that they are content that even though the applicant has the ability to re-identify the cohort, sufficient controls are in place to satisfy the requirements of the data flowing back being "pseudonymised", as per the entry on the HRA CAG register; and b) To upload any relevant / supporting documentation to NHS Digital's CRM system for future reference. The following amendments were requested: 1. To update section 5(a) **and** section 5(d) with confirmation as to how this study is unique and differs from similar studies, including (but not limited to) the ECHILD programme. 2. In respect of SLaM CRIS: a) To update the application throughout to ensure that any reference to *"CRIS"* is updated to reflect that this is *"SLaM CRIS"*. b) To provide an explanation in section 5 as to why the small geographical cohort within SLaM CRIS is being used: and c) To update section 5 with an indicative number of children within SLaM CRIS.

	3. To review the conflicting statements in the application and supporting document in respect of data destruction and update / align as appropriate to reflect the factual scenario. 4. To review the projected dates for publication within the application and update as necessary to reflect the current position. 5. To insert a special condition in section 6 that data will be destroyed once linkage has been completed. 6. To update section 5 with information regarding whether it is possible for individuals to apply the neoWONDER opt out once data has flowed to NHS Digital. The following advice was given: 1. IGARD suggested that the applicant may wish to consider that a potential benefit to this focussed research is encouraging or supporting additional funding or research into the **prevention** of pre-term births. 2. IGARD suggested that, given the significant percentage of survey participants who were unsure or unhappy with the linkage, thought needs to be given on how to improve transparency about the study, linkage and how to opt-out from being part of the cohort. 3. IGARD advised that they would wish to review this application when it comes up for renewal or extension, due to the concerns about transparency around opting out of the study. 4. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the concerns about transparency around opting out of the study. It was agreed the conditions would be approved out of committee (OOC) by IGARD members. **Subsequent to the meeting**: Following attendance at IGARD on the 25th August by a member of the Senior Approvals Team, it was agreed that the recommendation would remove reference to "1 year", more detail can be found under AOB in the 25th August 2022 IGARD minutes. **ACTION:** IGARD reiterated their action from the 28th July 2022 IGARD meeting: Noting that although the flow of data **from** NHS Digital is classified as pseudonymised, in the hands of the recipient it is potentially identifiable patient data as they have the technical means to reidentify; and the s251 support is only for the original flow of data to NHS Digital. IGARD suggested that NHS Digital confirmed with HRA CAG that there are **no** confidentiality issues for the receipt of data by the party who have the means to re-identify. IGARD requested an update by the end of August 2022.
5	<u>Applications progressed via NHS Digital's Precedent route, including the SIRO Precedent</u> Applications that have been progressed via NHS Digital's Precedent route, including the SIRO Precedent, and NHS Digital have notified IGARD in writing (via the Secretariat). <u>GRAIL Bio UK Ltd - NIC-604847-S4B5L-v1.2 (No Presenter)</u> The purpose of this application is to carry out follow-up analysis based on a cohort of patients who are being recruited to a clinical trial called 'NHS-Galleri'. IGARD noted that this application was last reviewed at the IGARD business as usual meeting on the 13th January 2022 where IGARD had recommended for approval for one year; and were unable to recommend for approval for a three-year DSA, until such time the NHS Digital DARS Standard(s) has been updated.

	IGARD noted that on the 10th May 2022, NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had agreed to authorise an extension to the Data Sharing Agreement (DSA) of eight years, which reflected the length of DSA's for other similar applications SYMPLIFY and NHS Galleri (NIC-604847-S4B5L) (as published in the IGARD minutes on the 19th May 2022). IGARD noted that on the 12th August, NHS Digital had advised in writing (via the IGARD Secretariat) that this application had proceeded via NHS Digital's Simple Amendment Precedent, to amend the data specification for the datasets provided by the National Disease Registration Service (NDRS) National Cancer Registration and Analysis Service (NCRAS). NHS Digital have confirmed that this is purely to undertake minor amendments in field selection and frequency of data provisioning, and that there is no change to the purpose of the study nor the primary / secondary endpoint objectives IGARD noted and thanked NHS Digital for the written update.
6	<u>Oversight & Assurance</u> IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. Due to the volume and complexity of applications at today's meeting, IGARD were unable to review any Data Access Request Service (DARS) applications as part of their oversight and assurance role. The NHS Digital SIRO was currently reviewing the feedback provided on the IG release registers by IGARD for the period March 2020 to May 2022, alongside the process of review, and as discussed on the 11th August 2022, would come back to IGARD in due course with any feedback or response. IGARD noted that the NHS Digital webpage Excel spreadsheet had now been updated for the period March 2020 to April 2022: NHS Digital Data Uses Register - NHS Digital. IGARD noted that May 2022 appeared to be outstanding, following them returning their comments on the May 2022 release register on 1st July 2022.
7	<u>COVID-19 update</u> *No items discussed*
8 **8.1**	<u>AOB:</u> <u>Head of Data Access Update</u> The Head of Data Access attended (part of) the meeting as part of her regular catch-up with IGARD. A brief update was provided by the Head of Data Access with regard to the NHS Digital transition work, a discovery phase around the Customer Relationship Management (CRM) system in order to improve its utilization for internal and external stakeholders, and the NHS Digital DARS Standards with regard to providing more guidance notes (noting that IGARD had suggested providing additional narrative and guidance notes in 2018/19 and prior to the publication of the NHS Digital DARS Standards, but that this had not been accepted at the time by NHS Digital).

	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 12/08/22

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