Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 7 July 2022

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Kirsty Irvine (Chair)	IGARD Chair
Dr. Imran Khan	Specialist GP Member
Dr. Robert French	Specialist Academic / Statistician Member
Jenny Westaway	Lay Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Maria Clark	Lay Member
Prof. Nicola Fear	Specialist Academic Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Chair
Dr. Maurice Smith	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Helen Buckels	Data Access Request Services (DARS) (AOB Item 7.2)
Garry Coleman	SIRO (**Observer:** Item 5.2)
Dave Cronin	Data Access Request Services (DARS) (**SAT Observer**: items 3.1-3.2)
Louise Dunn	Data Access Request Services (DARS) (**SAT Observer**: items 3.4-3.5 & AOB Item 7.2)
Duncan Easton	Data Access Request Services (DARS) (**SAT Observer**: item 3.3)
Dan Goodwin	Data Access Request Services (DARS) (Items 3.3-3.4)
Nicola Jennings	Data Access Request Services (DARS) (**Observer**: Item 3.5)
Dickie Langley	Privacy, Transparency & Ethics (PTE) (Item 3.4)
Susan Main	Data Access Request Services (DARS) (AOB Item: 7.1)
Dr. Jonathan Osborn	Deputy Caldicott Guardian (Items 1 & 3.4)
Denise Pine	Data Access Request Services (DARS) (Items 3.1 & 3.2)

Anna Weaver (AW)	Data Access Request Services (DARS) (Item 3.5)
Emma Whale (EW)	Data Access Request Services (DARS) (**Observer**: Item 3.1-3.2)
Vicki Williams (VW)	IGARD Secretariat
***SAT** – Senior Approval Team (DARS)	

1	**Declaration of interests:** Dr Robert French noted a professional link to the staff involved with NIC-420168-K4N1F (University of Bristol), but noted no specific connection with this application and it was agreed this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 30th June 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	**Briefing Notes**
2.1	Mental Health Services Data Set (MHSDS) Version 5 - Letter of Note (no presenter) This was a letter of note to inform IGARD of the changes made in relation to MHSDS version 5 dataset which covers the period from October 2021 onwards. The version 5 product will be available for customers to request via a physical extract using a secure file transfer system such as Secure Electronic File Transfer (SEFT). Unlike versions 4.1 and 4.2 (which will be available in the Trusted Research Environment (TRE) in the future), version 5 will also be available for customer to access via the TRE immediately. Customers will continue to be able to request data by a choice of packages, with all packages considered to include sensitive and pseudonymised data items. Additional identifiable fields will be available for customers to request, however, for TRE users, the extracts and views created for MHSDS version 5 will not contain these identifiable fields. IGARD thanked NHS Digital for providing a comprehensive update by way of a "letter of note". **Outcome:** IGARD welcomed the letter of note and made the following high-level comment: Noting it was not clear in the letter of note provided, could NHS Digital confirm if all that is happening is the creation of two datasets based on date range changes. **Subsequent to the meeting:** NHS Digital clarified that the changes necessitating the creation of new products went beyond the purposes of the date range change, and highlighted the specification changes.
2.2	Maternity Services Data Set (MSDS) Version 2.0 - Letter of Note (no presenter) This was a letter of note to inform IGARD of the changes made in relation to MSDS version 2 dataset which covers the period from April 2019 onwards, and is an additional product (rather than a replacement of existing version 1.5 which contains data covering the periods 1st April 2015 to 31st March 2019). The version 2 product will be available for customers to request via a physical extract using a secure file transfer system such as Secure Electronic File Transfer

	(SEFT). Unlike version 1.5 (which will be available in the Trusted Research Environment (TRE) in the future), version 2 will also be available for customer to access via the TRE immediately. Customers will continue to be able to request data by a choice of packages, with all packages considered to include sensitive and pseudonymised data items. Additional identifiable fields will be available for customer to request (subject to the customer demonstrating they have the appropriate legal basis in place), however for TRE users, the extracts and views created for MSDS version 2 will not contain these identifiable fields. IGARD thanked NHS Digital for providing a comprehensive update by way of a "letter of note". **Outcome:** IGARD welcomed the letter of note and made the following high-level comment: Noting it was not clear in the letter of note provided, could NHS Digital confirm if all that is happening is the creation of two datasets based on date range changes. **Subsequent to the meeting:** NHS Digital clarified that the changes necessitating the creation of new products went beyond the purposes of the date range change, and highlighted the specification changes.
3	**Data Applications**
3.1	University of Oxford: MR1086 The Oxford Vascular Study (s251 support cohort) (Presenter: Denise Pine) NIC-148369-8PPWK **Application:** This was a renewal and extension application, to an existing data sharing agreement (DSA) which expired on the 30th June 2022 for identifiable Civil Registration (Death) data and Demographics data, in addition to data already held. It was also an amendment application to **1)** change the Common Law Duty of Confidentiality (CLDoC) basis from consent to section 251. Some of the cohort are still consented, however, patient Opt-outs cannot be applied to a single data sharing agreement (DSA) using mixed legal bases so those consented individuals are covered by a new DSA: NIC-653950-W8D4Z University of Oxford (item 3.2); and **2)** to make minor amendments to section 5 (Purpose / Methods / Outputs) to meet NHS Digital DARS Standards. The Oxford Vascular Study (OxVasc) began in April 2002 to determine mortality, disability, psychological morbidity, cognitive decline and cost of care following stroke, transient ischemic attack (TIA), acute coronary syndrome (ACS) and acute vascular events in patients registered in one of eight GP practices in Oxfordshire. OxVasc is one of a number of cohort studies funded by the National Institute for Health and Care Research (NIHR) and the Wellcome Trust to identify simple low-cost interventions and to inform the development of clinical trials to improve the treatment outcomes of vascular disease in the short and long term. NHS Digital noted that when they reviewed the consent materials in 2020, they determined the consent materials were incompatible with the data flows. NHS Digital advised the applicant to reconsent the participants using updated consent materials and / or obtain s251 from the Health Research Authority Confidentiality Advisory Group (HRA CAG). S251 support is only being used for participants recruited between April 2002 and June 2020, where the consent materials did not specifically allow linkage with NHS Digital datasets and who have not subsequently reconsented using updated consent forms. The cohort comprises of approximately 9,400 under s251 support. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meetings on the 14th February 2019, 2nd May 2019, 12th December 2019 and 20th January 2022.

	IGARD noted that this application was connected to item 3.2 NIC-653950-W8D4Z University of Oxford. NHS Digital noted that the HRA CAG supporting document provided states: "*s251' support would not extend to any patient in the pre-June 2020 cohort who has been fully re-consented, and would also not extend to patients consented post June 2020 with updated consent forms*", and that s251 support had been obtained to provide a legal basis for linkage under common law, for the entire cohort, with the exception of those who were fully consented. Since June 2020, all OxVasc participants now receive the study Privacy Notice, and the linkage is undertaken with consent as the legal basis for processing. NHS Digital confirmed that none of the participants had been re-consented and all those participants who had been consented using updated consent forms post June 2020 were not included in this application (NIC-148369-8PPWK) but were included in NIC-653950-W8D4Z. IGARD noted that the application would exclude 'consultee' participants up to such time as consultee advice had been assessed by NHS Digital against the procedure agreed by NHS Digital. IGARD noted that if the consultee documentation was assessed as appropriate, then IGARD would be supportive of those participants being included by way of a simple amendment without reverting back to IGARD. IGARD noted that due to the nature of study it was critical that those consultee participants were included, as long as the legal requirements were satisfied. **ACTION for NHS Digital:** IGARD reminded NHS Digital of the agreed process set out in the internal appendices of the published NHS Digital DARS Standard Duty of Confidentiality that where there is an issue around the scope of consent, that NHS Digital senior staff should liaise with HRA CAG before the applicant prepares and submits an application to HRA CAG. IGARD noted that the HRA CAG supporting document noted that one of the conditions of support was "*confirmation provided from the IG* Delivery Team at NHS Digital to the CAG that the relevant Data Security & Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold*", however IGARD noted that the University were not using DSPT, but were using a System Level Security Policy (SLSP), which had been reviewed and approved by NHS Digital's Security Team in January 2022. IGARD asked that written confirmation from HRA CAG was provided with regard to SLSP; and that any pertinent HRA CAG documentation was uploaded to NHS Digital's Customer Relationship Management (CRM) system for future reference. *Information Governance Separate to this application, IGARD noted that NHS Digital should ensure that all relevant HRA CAG documentation was provided to IGARD as supporting documents. IGARD noted reference in section 6 (Special Conditions) to a number of "*DSPT*" related special conditions and suggested in line with NHS Digital's DARS standard for Special Conditions that these special conditions be removed since they were not relevant to this application. IGARD suggested that new special conditions, as may be advised by NHS Digital's Security Advisor, be added to section 6 with regard to "*SLSP*". IGARD noted that they had asked NHS Digital to advise on the s261 legal basis for NHS Digital's dissemination, for example which section of s261 of the Health and Social Care Act 2012 was relevant since NHS Digital appeared to be only citing the overarching s261. NHS Digital's Privacy, Transparency & Ethics (PTE) attended and suggested the legal basis for NHS Digital to disseminate pseudonymised data to universities under s261 would likely be: s261(5)(d). IGARD asked that section 3 (Datasets Held / Requested) be updated with the most appropriate s261 subsection. NHS Digital noted that data was stored in an access-controlled server room which did not fully align with the text in section 5(b) (Processing Activities) and section 2(b) (Storage Locations).

	IGARD asked that in line with NHS Digital's DARS Standard for processing and storage locations the storage locations be updated to reflect the factual scenario. IGARD noted the statement in section 5(a) (Objective for Processing) that "*data subjects are patients*" and noting the helpful narrative at the start of section 5(a), asked that a definition be included or cross referenced to the cohort descriptions at the start of 5(a). IGARD noted reference in section 5(a) to "*the funders will expect the* ***department***…" and asked that it be clarified as to which department this was referring to. IGARD noted that it was unclear how the data would be analysed and suggested that a clear narrative be included in section 5(b) that although the study was split across two DSAs, that only one set of analysis would be undertaken. IGARD noted the engagement with participants was limited to informing only as outlined in the application, and suggested that, if not already happening, the applicant involved relevant public and patient groups for the lifecycle of the project in line with HRA guidance on Public Involvement. **Outcome**: recommendation to approve The following amendments were requested. 1. To update section 3 with the s261 legal basis for NHS Digital to disseminate data. 2. In respect of HRA CAG support: a. To provide evidence of confirmation from HRA CAG with regard to SLSP (noting the current support referenced DSPT), and b. To upload any pertinent documentation to support the above to NHS Digital's CRM system for future reference. 3. In line with NHS Digital's DARS Standard for processing and storage locations the storage locations should be updated to reflect the factual scenario. 4. To update section 5(a) when referencing "*data subjects are patients*" to include a definition or cross reference to the helpful cohort description at the start of section 5(a). 5. To update section 5(b) to be clear that although the study is split across two DSAs, that only one set of analysis will be undertaken. 6. To update section 5(a) when referencing "*the funders will expect the* ***department***…" to clarify which department this is referring to. 7. In respect of the special conditions and in line with NHS Digital's DARS standard for Special Conditions: a. To remove any special conditions referencing "*DSPT*" since they are not relevant to this application, and b. To insert relevant special conditions, as may be advised by NHS Digital's security advisor, with regard to SLSP. The following advice was given: 1. IGARD noted the engagement with participants was limited to informing only and suggested that, if not already happening, the applicant involve relevant public and patient groups for the lifecycle of the project in line with HRA guidance on Public Involvement. 2. IGARD noted that the application would exclude consultee participants up to such time as consultee advice had been assessed by NHS Digital against the procedure agreed by NHS Digital. IGARD noted that once the consultee participant documentation had been assessed, then IGARD would be supportive of those participants being included by way of a simple amendment without reverting back to IGARD. IGARD noted that

	due to the nature of study it was critical that those consultee participants were included, as long as the legal requirements were satisfied. **ACTION for NHS Digital:** IGARD reminded NHS Digital of the agreed process set out in the internal appendices of the published NHS Digital DARS Standard Duty of Confidentiality that where there is an issue around the scope of consent, that NHS Digital senior staff should liaise with HRA CAG before the applicant prepares and submits an application to HRA CAG.
3.2	University of Oxford: The Oxford Vascular Study (consented cohort) (Presenter: Denise Pine) NIC-653950-W8D4Z **Application:** This was a new application linked to NIC-148369-8PPWK (s251 cohort) for identifiable Civil Registration (Death) data and Demographics data. The Oxford Vascular Study (OxVasc) began in April 2002 to determine mortality, disability, psychological morbidity, cognitive decline and cost of care following stroke, transient ischemic attack (TIA), acute coronary syndrome (ACS) and acute vascular events in patients registered in one of eight GP practices in Oxfordshire. OxVasc is one of a number of cohort studies funded by the National Institute for Health and Care Research (NIHR) and the Wellcome Trust to identify simple low-cost interventions and to inform the development of clinical trials to improve the treatment outcomes of vascular disease in the short and long term. Consent is being used for participants recruited from June 2020 onward and was conducted by the applicant and reviewed by NHS Digital who were satisfied that the consent materials dated 27th February 2020 onwards were compatible with the proposed data flows. The cohort currently comprises of 958 individuals, with recruitment ongoing until 2027. **Discussion:** IGARD noted that this application was connected to item 3.1 NIC-148369-8PPWK University of Oxford which had previously been presented at the IGARD business as usual (BAU) meetings on the 14th February 2019, 2nd May 2019, 12th December 2019 and 20th January 2022. IGARD confirmed that they were of the view that the most recent consent materials provided the appropriate gateway and were broadly compatible with the processing outlined in the application. In advance of the meeting, IGARD had queried the fields flowing in the demographic data. NHS Digital had confirmed that the applicant was only requesting details of embarkations or lost to follow up and were not requesting any other demographic data to update their contact details. IGARD noted reference in section 6 (Special Conditions) to a number of "*DSPT*" related special conditions and suggested in line with NHS Digital's DARS standard for Special Conditions that these special conditions be removed since they were not relevant to this application. IGARD suggested that new special conditions, as may be advised by NHS Digital's Security Advisor, be added to section 6 with regard to "*SLSP*". IGARD noted that it was unclear how the data would be analysed and suggested that a clear narrative be included in section 5(b) (Processing Activities) that although the study was split across two DSAs, that only one set of analysis would be undertaken. IGARD noted the engagement with participants was limited to informing only as outlined in the application, and suggested that, if not already happening, the applicant involve relevant public and patient groups for the lifecycle of the project in line with HRA guidance on Public Involvement.

	IGARD noted that, given the years that had passed since consent had been taken, and noting it was long established study, good practice was to ensure continued communication with participants, and to ensure that transparency was updated accordingly with regard to, for example, but not limited to, the nature of the data flowing and how the process worked. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 5(b) to be clear that although the study is split across two DSAs, that only one set of analysis will be undertaken. 2. In respect of the special conditions and in line with NHS Digital's DARS standard for Special Conditions: a. To remove any special conditions referencing "*DSPT*" since they are not relevant to this application, and b. To insert relevant special conditions, as may be advised by NHS Digital's security advisor, with regard to SLSP. The following advice was given: 1. IGARD noted the engagement with participants was limited to informing only and suggested that, if not already happening, the applicant involve relevant public and patient groups for the lifecycle of the project in line with HRA guidance on Public Involvement. 2. IGARD noted that, given the years that had passed since consent had been taken, good practice was to ensure continued communication with participants, and to ensure that transparency was updated accordingly with regard to for example, but not limited to, the nature of the data flowing and how the process worked.
3.3	NHS England (Quarry House): Cancer TRE – targeted lung health check (TLHC) evaluation (Presenter: Dan Goodwin) NIC-287049-F7M1P **Application:** This was a new application for pseudonymised Cancer Waiting Times (CWT) dataset, Civil Registrations (Death) data and National Cancer Registration dataset. NHS England hold an active data sharing agreement (DSA) NIC-411785-Z6X7M covering access to NHS Digital's Trusted Research Environment (TRE) for the purpose of processing various NHS Digital datasets in support of cancer service, specifically rapid diagnostic centres (RDCs). The purpose of this DSA is to utilise the datasets available through the Cancer TRE for a separate purpose, focusing on a national evaluation of targeted lung health checks (TLHCs) which is a flagship programme of work in England which contribute to the ambitions of the NHS Long Term Plan to improve early diagnosis and survival for those diagnosed with cancer. The TLHC programme targets those most at risk of lung cancer and works with the Integrated Care Systems (ICSs) who have some of the highest rates of mortality from lunch cancer. The TLHC pilot programme works with 17 projects covering 14 Cancer Alliances to deliver the programme to approximately 600,000 eligible participants. People most at risk of lung cancer are identified based on age (i.e. 55 to 76), smoking status and other lifestyle factors and they are invited for a lunch health check, where a low dose computerized tomography (CT) scan checks their lungs for cancer. **Discussion:** IGARD noted that this NIC number (NIC-287049-F7M1P) had been presented to an IGARD BAU meeting on the 11th April 2019 as a class action application for 195 CCGs. IGARD noted that NIC-411785-Z6X7M NHS England (covering access to NHS Digital's TRE for the purpose of processing various NHS Digital datasets in support of cancer service,

	specifically rapid diagnostic centres) had been previously presented to the IGARD BAU meeting on the 21st January 2021. IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 8th December 2020 and 19th January 2021. IGARD had raised in advance of the meeting a query with regard to the merger of NHS England and NHS Improvement (NHS Trust Development Authority (TDA) / Monitor) which had taken effect on the 1st July 2022. IGARD suggested that the application should be updated throughout in respect of the Data Controller, and in line with NHS Digital's DARS Standards for Data Controllers, to remove any reference to NHS Improvement, NHS TDA or Monitor, since they no longer existed. In addition, any reference to *"NHSEI"* or *"NHSE/I"* should be removed and replaced with *"NHSE"* (NHS England), and the application should be updated throughout to be clear that NHS England was the sole Data Controller. IGARD queried the interplay between the various TREs since it was not clear in the application and in line with the NHS Digital DARS Standard for Objective for Processing asked that section 5(a) (Objective for Processing) was updated to clarify how this application was distinguished from other Cancer TRE applications, for example, but not limited to, the DATA-CAN application. In order to distinguish this application from for example, but not limited to, the DATA-CAN application, IGARD suggested that the title of this application was updated and before publication on the NHS Digital Data Uses Register to the "*Targeted Lung Health Check (TLHC) evaluation*". IGARD also suggested that when referring to NIC-411785-Z6X7M in this application, to also insert the title of the application "*Rapid Diagnostic Centre – Cancer TRE*" which would distinguish it from for example, but not limited to, the DATA-CAN application. IGARD noted in section 5(a) that "*Ipsos MORI colleagues will access the pseudonymised data within the TRE. Analysts will be able to access only the data they are permitted to see and can utilised a variant of analytical tools within the TRE platform*" and asked that line with the NHS Digital DARS Standard for Data Minimisation that an explanation be included in section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) detailing the controls in place to limit the data that can be accessed, for example, but not limited to, the physical or practical controls. If there were only contractual controls in place to limit the data that can be accessed, that a robust explanation be provided as to why in section 1 and section 5. In addition, IGARD asked that further clarification be provided as to what data that analysts were permitted to see and to align the statements about analysts' access in section 5(a), based on the outcome of whether there were or were not controls in place. IGARD also suggested that the publicly available transparency information be reviewed and to be clear that data access would take place in the NHS Digital TRE, and that the applicant and/or Data Processors would **not** be receiving data directly as was currently stated in the application. Furthermore, and noting the analysis outlined in the application and the aggregated outputs analysis, were supportive of more individual analysis taking place, noting that IGARD had noted that this may lead to more robust outputs. **ACTION for NHS Digital:** IGARD noted that it had been some time since they had last been given an update on the DAE / TRE workstream and asked that NHS Digital attended a future IGARD meeting to update IGARD members on work undertaken over the last two years, including but not limited to, queries IGARD had raised in 2020 around data minimisation and data handling. IGARD noted that they had asked NHS Digital to advise on the s261 legal basis for NHS Digital's dissemination, for example which section of s261 of the Health and Social Care Act 2012 was relevant since NHS Digital appeared to be only citing the overarching s261. NHS

	Digital's Privacy, Transparency & Ethics (PTE) attended and suggested that the legal basis for NHS Digital to disseminate pseudonymised data under s261 to an organisation to exercise its statutory functions was likely to be: s261(5)(d). IGARD asked that section 3 (Datasets Held / Requested) be updated with the most appropriate s261 subsection. IGARD queried the statement in section 5(b) (Processing Activities) that only summary, aggregate results data were exported from the TRE by Ipsos MORI subject to the "*approval of NHS Digital's trained output checkers"*; and asked whether or not this needed to be amended to clarify that NHS Digital do **not** check every output. IGARD noted a statement in section 5(c) (Specific Outputs Expected) that "*NHSE/I will determine the appropriateness of any information to be made publicly available*…" and suggested that the emphasis be shifted to a default of information sharing with the public, except where it was deemed sensitive or in any other way inappropriate. IGARD noted reference in section 5(d) (Benefits) to "…*increase early stage detection to as high as 75%"*, and asked that a publicly available web link or Harvard reference for a journal / book to the reference be inserted in section 5(d) in order for the public to read the relevant background information, which may promote stronger public support for the initiative. IGARD noted reference in section 5(c) to the "***strategy document** outlining the analytical questions to be answered*" and asked that a web link be provided to the document if publicly available and inserted in section 5(c), noting section 5 forms NHS Digital's data uses register. If the web link was not publicly available, IGARD suggested that the "*strategy document*" should be obtained from NHS England, and a copy of the strategy document uploaded to NHS Digital's Customer Relationship Management (CRM) system for future reference. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of the Data Controller and following the merger of NHS England with NHS Improvement on the 1st July 2022: a. To remove reference to NHS Improvement, Monitor and NHS TDA from throughout the application since they no longer exist, and b. To update the application throughout to be clear that NHS England is the sole Data Controller, and c. To remove any reference to *"NHSEI"* or *"NHSE/I"* and replace with *"NHSE"*. 2. In respect of section 5(a) and in line with the NHS Digital DARS Standard for Objective for Processing: a. To clarify how this application is distinguished from other Cancer TRE applications, for example, but not limited to, DATA-CAN, and b. To update the title of the application and before publication on the NHS Digital Data Uses Register to the "*Targeted Lung Health Check (TLHC) evaluation*", distinguishing it from for example, but not limited to, DATA-CAN, and c. When referring to NIC-411785-Z6X7M to also insert the title of the application "*Rapid Diagnostic Centre – Cancer TRE*" distinguishing it from for example, but not limited to, DATA-CAN. 3. To update section 3 with the s261 legal basis for NHS Digital to disseminate data. 4. In respect of Data Minimisation and in line with the NHS Digital DARS Standard for Data Minimisation: a. To explain in section1 and section 5 the controls in place to limit the data that can be accessed, for example, but not limited to, the physical or practical controls, or b. If only contractual controls are in place, to provide a robust explanation why in section 1 and section 5, and

	c. To clarify the data that analysts are permitted to see and to align the statements about analysts' access in section 5(a), based on the outcome of points (a) and (b) above. 5. In respect of sharing information with the public: a. To update the statement in section 5(c) "*NHSE/I will determine the appropriateness of any information to be made publicly available*…" to shift the emphasis to information sharing with the public, except where it is deemed sensitive or in any other way inappropriate, and b. To provide a publicly available web link or Harvard reference for a journal / book to the reference to "…*increase early stage detection to as high as 75%"* in order for the public to read the relevant background information which may promote stronger public support for the initiative. 6. In respect of the "***strategy document** outlining the analytical questions to be answered*" referenced in section 5(c): a. A web link should be provided if publicly available, noting section 5 forms NHS Digital's data uses register or, b. If not publicly available, the strategy document should be obtained from NHS England, and c. To upload a copy of the strategy document to NHS Digital's CRM system for future reference. 7. To amend, if necessary, the reference in section 5(b) *"…approval of NHS Digital's trained output checkers"* to clarify that NHS Digital do **not** check every output (unless this statement accurately reflects the facts). The following advice was given: 1. IGARD praised the clear explanation of the planned analysis but noted the analysis used aggregated data and were supportive of more individual level analysis taking place, noting that the IGARD Specialist Member had stated that this may lead to more robust outputs. 2. To review the publicly available transparency information to be clear that data access will take place in the NHS Digital TRE, and that the applicant and/or processors will **not** be receiving data directly as is currently stated. **ACTION for NHS Digital:** IGARD noted that it had been some time since they had last been given an update on the DAE / TRE work stream and asked that NHS Digital attend a future meeting to update IGARD members on work undertaken over the last two years, including but not limited to, queries IGARD had raised in 2020 around data minimisation and data handling.
3.4	University College London (UCL): **L**inking **AU**dit and **N**ational datasets in **C**ongenital **HE**art **S**ervices for **Q**uality **I**mprovement (LAUNCHES QI) (Presenter: Dan Goodwin) NIC-234297-P4M5G **Application:** This was an extension application to an existing data sharing agreement (DSA) which expired on the 30th June 2022, to permit the holding and processing of pseudonymised Civil Registration (Deaths) - Secondary Care Cut, Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC), HES Outpatients, HES:Civil Registration (Deaths) bridge, HES-ID to MPS-ID HES Accident and Emergency, HES-ID to MPS-ID HES Admitted Patient Care, LAUNCHES QI aims to indirectly improve services for congenital heart disease (CHD), by providing the first description of low CHD patients interact with the NHS acute sector and where variation in outcomes or service use exists. This information is the first crucial step in

	supporting service improvement by building the evidence base on which aspects of the current service offer the most potential for improvement programmes. The team will link for the first time NCHDA (National Congenital Heart Disease Audit), PICANet (paediatric intensive care audit), ICNARC CMP (adult intensive care audit), Life status and place of death, and HES (Hospital Episode Statistics) data. This will provide information on: **a)** the challenges in linking national data sets and whether it is feasible to do this routinely, and **b)** create a research datasets to examine the interactions CHD patients have with different NHS services over time. The team will aim to improve services by: describing patient care trajectories through secondary and tertiary care; identifying useful metrics for driving quality improvement (QI), informing commissioning and policy; and exploring variation across services to identify priorities for quality improvement. The study will produce: the first comprehensive understanding of care received by a complex population from birth to adulthood; a basis for creating a step change in how quality in CHD services is measured and improved. The study is relying on s251 of the NHS Act 2006, for the flow of data into NHS Digital. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meetings on the 3rd October 2019 and 1st July 2021. IGARD confirmed that they were of the view that the relevant s251 support provided the appropriate legal gateway and was broadly compatible with the processing outlined in the application. IGARD noted reference in section 5(a) (Objective for Processing) and section 5(b) (Processing Activities) to the "*unique record level study ID*" and asked for clarification as to whether the "*unique record level study **ID***" referred to in sections 5(a) and 5(b) needed to be held and if so to provide a justification as to why the "*ID*" it was needed. IGARD noted that if the "*unique record level study ID*" was not required, that reference to it be removed from section 5(a) and 5(b). IGARD noted that they had asked NHS Digital to advise on the s261 legal basis for NHS Digital's dissemination, for example which section of s261 of the Health and Social Care Act 2012 was relevant since NHS Digital appeared to be only citing the overarching s261. NHS Digital's Privacy, Transparency & Ethics (PTE) attended and suggested that the legal basis for NHS Digitals to disseminate pseudonymised data to universities under s261 was likely to be: s261(5)(d). IGARD asked that section 3 (Datasets Held / Requested) be updated with the most appropriate s261 subsection. IGARD acknowledged the excellent work done with regard to the advisory committee with patients and parents, however, noted that "*the patients and parents on the advisory committee attend annual advisory group meetings to receive updates and to provide feedback on any aspect of the study*", and suggested that more work could be undertaken to move from engagement to involvement for the lifecycle of the project in line with HRA guidance on Public Involvement. IGARD noted, in section 5(c) (Specific Outputs Expected), the challenges encountered by the applicant with regard to the process of accessing and linking datasets was reported in the British Medical Journal (BMJ) in July 2021 *"The road to hell is paved with good intentions: the experience of applying for national data for linkage and suggestions for improvement"* and presented at the HSRUK* conference 2021. Noting the BMJ article referenced in section 5(c), IGARD suggested that section 5(d) (Benefits) (iii) (Yielded Benefits) be reviewed in light of the article reference in section 5(c) and to make any necessary amendments to the application in

	consultation with the applicant to reflect the full facts OR to take any other such action as may be prudent. IGARD also suggested that NHS Digital may wish to send a service improvement feedback email to the applicant, noting the BMJ article. * Health Services Research UK **RISK AREA:** IGARD were concerned that there appeared to be no robust procedures in place to ensure NHS Digital was aware of, and could respond in a timely fashion to, complaints put in public domain. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 3 with the s261 legal basis for NHS Digital to disseminate data. 2. In respect of the "*unique record level study ID*": a. To clarify whether the "*unique record level study **ID***" referred to in sections 5(a) and 5(b) needs to be held, and b. If required, to update the application to provide a justification as to why the "*ID*" is needed, or c. If not required, to remove its reference from the application. The following advice was given: 1. IGARD acknowledged the excellent work done with regard to the advisory committee with patients and parents, however, IGARD noted that "*the patients and parents on the advisory committee attend annual advisory group meetings to receive updates and to provide feedback on any aspect of the study*" and suggested that more work could be undertaken to move from engagement to involvement for the lifecycle of the project in line with HRA guidance on Public Involvement. 2. Noting the BMJ article referenced in section 5(c), IGARD suggested that section 5(d)(iii) be reviewed in light of the article reference in section 5(c) and make any necessary amendments to the application in consultation with the applicant to reflect the full facts OR to take any other such action as may be prudent. 3. Noting the BMJ article, IGARD suggested that NHS Digital may wish to send a service improvement feedback email to the applicant. **RISK AREA:** IGARD were concerned that there appeared to be no robust procedures in place to ensure NHS Digital was aware of, and could respond in a timely fashion to, complaints in the public domain.
3.5	National Institute for Health Research (NIHR): MR1393 – join dementia research (Presenter: Anna Weaver) NIC-366913-C2V5F **Application:** This was an extension and renewal to an existing data sharing agreement (DSA) for the Department of Health and Social Care (DHSC) which expired on the 31st January 2022 for Demographics data. The Join Dementia Research (JDR) register is a national service funded and owned by the DHSC and enables members of the public from anywhere in the United Kingdom (UK) to register and be contacted about potential research studies. In registering they give their consent for their information to be made available to the dementia research community. The data subjects are those that have registered to be part of the JDR and this may include those who have dementia, or carers, or friends, or relatives of those with dementia. The data collected under this DSA only relates to participants in England and Wales. The delivery of the JDR service is managed by the Clinical Research Network Coordinating Centre (CRNNC) at the National Institute for Health and Care Research (NIHR) through an

	optional services work order between the DHSC and the consortium of the University of Leeds and Guy's & St Thomas' NHS Foundation Trust. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the Data Access Advisory Group (DAAG) (IGARD's predecessor) on the 19th January 2016; and the IGARD business as usual (BAU) meetings on the 11th July 2019 and 10th October 2019. IGARD noted that when previously presented to IGARD for advice on the consent materials, the applicant had cited Article 6(1)(a) and Article 9(2)(a) of the UK General Data Protection Regulation (UK GDPR). NHS Digital met with the applicant in 2019, following the IGARD meeting, and agreed that Article 6(1)(e) was the more appropriate UK GDPR lawful basis, and that consent should be used to meet the Common Law Duty of Confidentiality (CLDoC) rather than as a UK GDPR lawful basis, as advised by IGARD at the time. IGARD had not been informed at the time that the applicant and NHS Digital had taken IGARD's advice but were content now that the correct legal basis was cited. IGARD therefore suggested that the summarised narrative in section 1 (Abstract) be updated with regard to IGARD's previous review, to correctly reflect that it was the applicant, **not** IGARD, that were unclear on the most appropriate UK GDPR legal basis. Under the Mental Capacity Act 2005, the researcher seeks advice from a consultee on what the wishes and feelings of the person might be and whether or not they should take part. The consultee gives advice, not consent in law and so IGARD asked that section 1 and section 5(a) (Objective for Processing) referenced "*consultee **consent***" and noting that a consultee cannot give consent, they give advice, suggested that references were updated to "*consultee **advice***". IGARD noted that in respect of patient objections, section 3(c) (Patient Objections) should be amended from "*No*" to "*Mixed*" to accurately reflect that National Data Opt-outs (NDO) would be applied to those present in the cohort under consultee advice. IGARD suggested for future reference, section 1 and section 5(a) were updated, to provide a brief summary of the history of the application, and the transition from University College London (UCL) to the DHSC, including any timeline. IGARD noted the information provided on the commercial aspect of the application in section 5(e) (Is the Purpose of this Application in Anyway Commercial) and suggested that a brief summary of the commercial aspect be included, since commercial companies were applying to use the register. However noting that this was not public facing, asked that for transparency, and in line with NHS Digital DARS Standard for commercial purpose, a brief summary was also provided in section 5(a). Separate to the application, IGARD noted that NHS Digital may wish re-check the NHS Digital DARS Standard for commercial purpose to consider if such instances, for example, but not limited to, commercial organisations applying to use the register, was covered by the DARS Standard, and if any small tweaks were necessary to update the DARS Standard without recourse to IGARD. IGARD noted that Health Research Authority (HRA) endorsement had been cited in the application and noting that they had not seen such reference previously, asked via an **ACTION**: that NHS Digital should investigate the use of an *"HRA endorsement"* and find out what qualifying criteria are required, who can use this route and if it can be utilised in the future by other applicants. IGARD noted that their predecessor DAAG had also raised a query with regard to whether people on the register would be contacted multiple times, noting there were over 500 studies,

	and suggested that NHS Digital may wish to consider in the broader scheme what can be done to coordinate contact to participants by services such as Digi-trials and NIHR. **Outcome:** recommendation to approve The following amendments were requested: 1. To updated section 1 and section 5(a) with a brief summary of the history of the transition from UCL to the DHSC, including any timeline. 2. To update section 3(c) to "*mixed*", since NDOs will be applied to those present in the cohort under consultee advice. 3. To update the application throughout to remove reference to "***consent***" in "*consultee **consent***" and replace with "***advice***" as in "*consultee **advice***" 4. In line with the NHS Digital DARS Standard for commercial purpose, to provide a brief summary in section 5(a) and 5(e) of the commercial aspect of the output of this application, for example, but not limited to, how research commercial organisations access the register. 5. To amend the summary in section 1 with regard to IGARD's previous review, to be clear that it was the applicant, not IGARD, that were unclear on the UK GDPR legal basis. The following advice was given: 1. IGARD noted that NHS Digital may wish to consider in the broader scheme what can be done to coordinate contact to participants by services such as NHS DigiTrials and NIHR. **ACTION for NHS Digital:** IGARD noted that NHS Digital should investigate the use of an *"HRA endorsement"* and find out what qualifying criteria is required, who can use and if it can be utilised in the future by other applicants.
4 **4.1**	Applications progressed via NHS Digital's Precedent route, including the SIRO Precedent 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). NIC-16016-Y9H1D-v11.6 Wilmington Healthcare (no presenter) The purpose of the application was for the data to be used to support the NHS either directly through the delivery of tools and bespoke analysis, or indirectly through non-NHS organisations where solutions are provided with the NHS as the end beneficiary. IGARD noted that the application and supporting documents was last reviewed by IGARD as part of the returning applications (oversight & assurance) on the 5th November 2020, where IGARD had noted that the application was **not** suitable for the Precedent route, including SIRO, and that IGARD would wish to review on amendment, extension and / or renewal. IGARD noted that on the 28th June 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) until mid-August 2022 to give sufficient time for IGARD consideration and any resultant queries addressed. IGARD noted and thanked NHS Digital for the written update and asked that the next iteration of the DSA should be brought to a future IGARD BAU meeting and before mid-August 2022.
4.2	NIC-431881-N8B0Nv2.2 University of Oxford (Presenter: Denise Pine / Garry Coleman)

	The purpose of the application was to extend the data sharing agreement (DSA) which expired on the 31st March 2022, for the Remote COVID-19 Assessment in Primary Care (RECAP) project to assist primary care providers to improvement patient care and health outcomes. IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 23rd March 2021 and 16th March 2021. IGARD noted there was no evidence of a previous IGARD business as usual (BAU) review. IGARD noted that on the 28th June 2022 NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had agreed to authorise an extension to the DSA for 6-months to give sufficient time for the applicant to address the NHS Digital queries. IGARD noted that they had **not** undertaken a review of the application and had not been provided with any additional supporting documents. IGARD noted, as outlined in section 1 (Abstract), that special conditions, outlined in Section 6 (Special Conditions) had not been complied with. IGARD noted, as outlined in section 1, that a number of NHS Digital DARS Standards had not been met including, Data Minimisation, Objective for Processing, Processing Activities, Expected Outcomes, and Expected Measurable Benefits. IGARD noted, as outlined in section 1, that the extension permitted the continuing retention of the data for an interim period while the action plan was completed. IGARD understood that the application had been approved as part of a rapid response to the pandemic. However as the emergency response is replaced by business as usual, such applications needed to be updated to meet all DARS standards. IGARD therefore supported the requirement to complete the action plan IGARD therefore supported the requirement to complete the action plan to ensure that an agreement was in place, and data destruction was not required IGARD noted and thanked NHS Digital for the written update and for the SIRO attending the meeting, and asked that the next iteration of the DSA should be brought to a future IGARD BAU meeting and before the end of November 2022.
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. IGARD Members noted that they had not yet been updated on the issues raised at the 27th May 2021 IGARD business as usual (BAU) meeting with regard to previous comments made on the IG COVID-19 release registers March 2020 to May 2021. IGARD noted that in addition, they had not been updated on the issues raised on the IG COVID-19 release registers June 2021 to May 2022. 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.
6	COVID-19 update *No items discussed.*

7	AOB:
7.1	Improving Data Access Programme (Presenter: Susan Main) This was a verbal update by NHS Digital with regard to the improving data access programme workstream working with key internal and external stakeholders. NHS Digital noted that they were currently undertaken a review of the programme and would be able to share more information with IGARD later in the month.
7.2	NIC-420168-K4N1F-v2 University of Bristol (Presenters: Helen Buckels) This was a verbal update by NHS Digital following the application being presented to the IGARD business as usual meeting (IGARD) on the 23rd June 2022 for advice on the consent materials. IGARD noted that the complex discussion around legal basis and consent warranted more time than an AOB agenda slot and suggested NHS Digital add a main application agenda item if they required further advice and before the applicant took any further action.
7.3	S261 legal basis for NHS Digital (no presenter) IGARD noted that they had raised some time back for NHS Digital to advise on the s261 legal basis for NHS Digital's disseminations of pseudonymised data, for example which section of s261 was relevant since NHS Digital appeared, in applications, to be citing the overarching s261 and using "*261 – other dissemination of information*". NHS Digital's Privacy, Transparency & Ethics (PTE) had provided in advance of the meeting a "*review of National Disease Registration Service (NDRS) legal basis for dissemination table*". PTE had noted when attending for item 3.4 that the dissemination listed in DARS applications for universities to disseminate pseudonymised data was most likely to be "*s261(5)(d)"* not "*s261 other dissemination of information*". PTE, when attending for item 3.4, took away an action to confirm the s261 sub section legal basis for NHS Digital to disseminate pseudonymised data to commercial, charity and other such organisations who were not acting under statute.
	There was no further business raised, the Chair of the meeting thanked members and NHS Digital colleagues for their time and closed the meeting.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 01/07/22

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