Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 28 October 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark (Chair)	Lay Member
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Chair
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Prof. Nicola Fear	Specialist Academic Member
Kirsty Irvine	IGARD Chair
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Cath Day	Data Access Request Service (DARS)
Faris Dean	Data Access Request Service (DARS) (Observer: Items 1 – 3.4)
Frances Hancox	Data Access Request Service (DARS)
David Morris	Data Access Request Service (DARS)
Jonathan Osborn	Deputy Caldicott Guardian (Observer: items 1 – 3.2)
Denise Pine	Data Access Request Service (DARS)
Vicki Williams	IGARD Secretariat
Tom Wright	Data Services for Commissioners (DSfC)

1	**Declaration of interests:** Maria Clark noted professional links to the Royal College of Surgeons [NIC-59669-F6Y3W0] via her work with The College of General Dentistry, but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest. **Review of previous minutes and actions:**

	The minutes of the 21st October 2021 IGARD meeting were reviewed, and subject to a number of minor amendments were agreed as an accurate record of the meeting. **Out of committee recommendations:** An out of committee report was received (see Appendix A).
2	**Briefing Notes**
2.1	<u>ONE London Collaborative – Briefing Paper (Presenter: Tom Wright)</u> Following the Integrated Care System (ICS) sublicensing paper that was discussed at the IGARD business as usual (BAU) meeting on the 30th September 2021 and the CCGs sharing commissioning data with members of their ICS paper that was discussed at the IGARD BAU meeting on the 26th August 2021; this briefing paper, which was discussed at the IGARD BAU Meeting on the 7th October 2021, was to inform IGARD about an application from NHS North West London CCG (NWL), NHS North East London CCG (NEL) and NHS South West London CCG (SWL), to sub license identifiable Secondary Uses Service (SUS) for commissioners to the member organisations of their respective Integrated Care System (ICS) to enable both commissioning and direct care uses of the data. In May 2018, ONE London was one of the first three Local Health and Care Record Exemplars (LHCREs) to be announced by NHS England. Each LHCRE was expected to develop a Data Service that had 23 capabilities which included Data Integration & Data landing, Data processing, Data Rules Management, Data Transfer and Dissemination, and Deidentification/Re-Identification. At that time NEL, NWL and SWL decided to jointly develop the Discovery Data Service (DDS) as their integrated data store. From that time, they have been working to develop the data service to bring data together to support, Individual (direct) care, Population Health Management (including individual care), Public Health and Commissioning. To date the principal data feed into the DDS is from primary care with personal coded data being accessed in close to real time from all the 840 GP practices in the collaborative's ICS. The ICS Digital Teams are all expected to acquire information from all major contributors to the ICS – Primary Care, Secondary Care, Mental Health, Social Care and Community Care. Work is currently underway on secondary care data sources. A standard is being developed for admission, discharge and transfer (ADT) and Test result (ORU) HL7 feeds for the collaborative. In order to obtain a totally standardised extract and to acquire secondary care data from wherever their patients experienced it the collaborative will be making an application to NHS Digital via the Data Access Request Service (DARS). **Outcome:** IGARD welcomed the briefing paper and made the following high-level comments which would need to be updated within the briefing paper: 1. IGARD confirmed that they were supportive of the overall concept outlined in the briefing paper and thanked NHS Digital and the applicant for additional information provided including a number of supporting documents and detail on PPIE. 2. To update the briefing paper in line with all previous comments within published minutes and in line with any outcomes from the 18th November workshop, for example direct care in commissioning applications. 3. IGARD noted that ICSs were evolving and that in recent weeks it had been established that CCG functions would be transferring to ICS NHS Bodies which will

	be working with ICS health and care partnerships made up of Local Authorities and other organisations, these two bodies will operate together as an ICS. Care should be given to language used, for example, if each are different legal entities, which may have different legal bases, who may or may not be joint or sole data controllers within applications, with different statutory functions. 4. IGARD noted that for any ICS application it would need to be clear within any application, for example, which entity was doing what, who was using which data and for what purpose, and who was data controller as borne out of the facts, to ensure transparency for the public. 5. All applications should be in line with the NHS Digital DARS Standards. IGARD welcomed the draft briefing paper and looked forward to receiving the updated briefing paper at a future meeting, and before any first of type applications were received by IGARD.
2.2	Intensive Care National Audit and Research Centre (ICNARC) Case Mix Programme for Adult Critical Care data set Briefing Paper (v0.5) (No presenter) The briefing paper was to inform IGARD about the ICNARC Case Mix Programme (CMP) for Adult Critical Care data set, which will be made available via NHS Digital's Trusted Research Environment (TRE) and extract. NHS Digital will make data available for COVID-19 purposes only. Requests for use of data outside of COVID-19 would need to be requested via ICNARC directly and will not be handled or supplied by NHS Digital, under current arrangements. The primary purpose of this data collection is to assess quality of the care to guide local performance management and quality improvement. The data collected are also used for research purposes, ensuring maximum value from the data collection and validation processes. ICNARC collects and uses the data to enable customers to request regular comparative analyses from the CMP Database (of over 1.5 million admissions to critical care), detailing a range of established potential quality indicators. Approved requests will help to guide national decision making and recommend potential interventions to reduce the severity of COVID-19 outcomes. In making this data available, it will substantially enhance research, for example, researchers would be able to assess the impact of a wide range of prior health conditions, risk factors and medications. **Outcome:** IGARD welcomed the briefing paper and made the following high-level comments which would need to be updated within the briefing paper: 1. IGARD confirmed that they were supportive of the overall concept outlined in the briefing paper. 2. Although section 14 of the briefing paper was helpful, IGARD asked that as per usual agreed practice that the briefing paper be updated throughout to provide clarification of the points raised by IGARD on the 12th August 2021, alongside any additional points raised below, to ensure that the briefing paper was fully up to date for the reader (so the reader was not suddenly getting to the end of the briefing paper and realising amendments or comments had been made on previous sections), since the briefing paper would form part of the supporting documentation. 3. In respect of the Health Research Authority Confidentiality Advisory Group (HRA CAG):

	a. IGARD noted the update with regard to HRA CAG, but asked that written confirmation of HRA CAG's approval be provided as a supporting document for this briefing paper and any application to IGARD, for example by way of an email from HRA CAG, and b. Noting HRA CAG's comments and notification at the end of COPI, IGARD suggested that itemised actions which needed to be undertaken before and after expiry of the Health Service Control of Patient Information (COPI) Regulations 2002 should be listed. 4. To update the briefing paper to ensure acronyms be defined upon first use, and technical terms are explained in a manner suitable for a lay audience, for example "*CHESS*" and "*hospital mortalit*y". 5. IGARD noted reference within the briefing paper "*link the DPN when available*" and suggested that before a first of type application is brought to IGARD BAU meeting, that this link is updated within the briefing paper. 6. IGARD queried the following sentence in section5 "*ICNARC will send NHS Digital a historic extract as well as regular refreshes of data which will be (? Category of data)*" and suggested that the section was updated with the category of data. 7. IGARD suggested that the acronym in section 14 "*Peakanet*" was more likely to be "*PICAnet*" and suggested that the acronym be defined upon first use, but in all cases spelt correctly. IGARD welcomed the draft briefing paper and looked forward to receiving the updated briefing paper at a future meeting alongside a first of type applications as a supporting document, as per usual practice.
3	**Data Applications**
3.1	<u>Public Health Scotland: Quarterly HES data request (Presenter: Frances Hancox) NIC-402414-Q5R7Y-v0.4</u> **Application:** This was a new application to replace a previous Data Sharing Agreement (DSA) NIC-391119-T4J3R which expired on the 18th August 2020. Public Health Scotland (PHS) replaced the NHS National Services Scotland (NHS NSS) from the 1st April 2020. The application is different to NIC-391119-T4J3R in that **1)** a change in Data Controller from NHS NSS to PHS, **2)** Emergency Care Data Set (ECDS) added to replace Hospital Episode Statistics Accident & Emergency (HES A&E) data, **3)** frequency of data dissemination changed from monthly to quarterly, and **4)** PHS have confirmed that only 4 years of English data is required to be held for their Discovery Tool. Discovery is a web-based information system that provides approved users with access to a range of comparative health information to support performance and quality improvement in Health Boards across Scotland and it is an ongoing collaboration between NHS Boards, the Scottish Government and Public Health Scotland. PHS have requested access to pseudonymised data to provide benchmarking across a range of indicators including A&E waits, A&E % admitted, length of stay analysis, BADs day care rates, outpatient DNA rates, return to new outpatient ratios, and gestation at booking. Receiving data on all English NHS hospitals allows PHS to select the most appropriate peers for the hospitals based on the latest data and to be flexible when service changes take place. **Discussion:** IGARD noted that the predecessor application (NIC-391119-T4J3R) and relevant supporting documents had previously been presented at an IGARD business as

	usual (BAU) meeting on the 18th May 2017 and recommended for approval for three months only. NHS Digital verbally noted that the previous DSA had expired in August 2020. IGARD noted that the applicant appeared to have provided some rationale for the use of national data and minimal data minimisation for benchmarking purposes, however in line with NHS Digital's DARS Standard for Data Minimisation, asked that a rationale be provided in section 3 (Datasets Held / Requested) for the large amount of data required. In addition, IGARD asked that further narrative and a clear justification be provided in section 5(a) (Objective for Processing) as to why all English data had been requested, for example, why the applicant could not look at similar geographies to those in Scotland, types of Hospital Trust equivalent to those in Scotland, and as previously raised by IGARD on the 18th May 2017 under NIC-391119-T4J3R. IGARD also requested that the applicant provide evidence as to how the data had been used historically for that data which has not been included in the 'English peer analytical dashboard' and that a clear justification, if that data has not been used, as why this data (which is still held by the applicant) cannot be destroyed. IGARD members noted that Section 5(d) (benefits) (iii) (Yielded Benefits) did not appear to be in line with the NHS Digital DARS Standard for Expected Measurable Benefits and asked that this section was updated. In addition and noting the significant volume of data requested, asked that applicant provide 2 or 3 specific yielded benefits accrued to date in section 5(d) (iii) and to ensure these are clear about the benefits to both patients and the health care system more generally. IGARD noted a number of acronyms and technical terms in section 5 (Purpose / Methods / Outputs), and asked that this public facing section, that forms NHS Digital's data uses register, was amended throughout, to ensure acronyms be defined upon first use, and technical terms are explained in a manner suitable for a lay audience, for example "*BAD*s", "*NWIS*", "*N4*", "*flat file format*", "t*ableau dashboards*" etc. IGARD asked that section 3(c) (Patient Objections) be updated in answer to the question "*patient objections applied*" from "*yes*" to "*no*". IGARD noted the special condition in section 6 (Special Conditions) "*All data controllers and processors which rely on the annual completion and publication of the Data Security and Protection Toolkit (DSPT) to demonstrate security assurance for the purpose of this agreement must ensure…*" and suggested that this condition along with the three bullet points be removed since it was not relevant to this DSA. 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, given the significant volume of data. **Outcome:** recommendation to approve subject to the following conditions: 1. In respect of Data Minimisation and in line with the NHS Digital DARS Standard for Data Minimisation: a. To provide a rationale in section 3 of the large volume of data requested, and b. To provide a clearer justification in section 5 as to why all English data has been requested, for example why the applicant cannot look at similar geographies, type of Hospital Trust etc (as raised by IGARD on 18th May 2017), and

	c. To provide evidence as to how the applicant has used the data historically, which has not been included in the dashboard, and if not used, provide a justification as to why this data cannot be destroyed. 2. In respect of the Yielded Benefits in section 5(d)(iii) a. To update the yielded benefits in line with the NHS Digital DARS Standard for Expected Measurable Benefits, and b. Given the significant volume of data, to provide 2 or 3 specific yielded benefits accrued to date and ensure these are clear as to the benefits to both patients and the health care system more generally. The following amendments were requested: 1. To amend the answer to "*patient objections applied*" in section 3(c) from "*yes*" to "*no*". 2. As section 5 forms NHS Digital's data uses register, to amend section 5 throughout, a. to ensure acronyms be defined upon first use such as "*BADs*", "*NWIS*" etc, and b. technical terms are used only where necessary and explained in a manner suitable for a lay audience, for example "*N4*", "*flat file format*", "*tableau dashboards*" etc. 3. To remove the special condition in section 6 which refers to DSPT, since it is not relevant for this application The following advice was given: 1. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment given the significant volume of data. 2. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent given the significant volume of data. It was agreed the conditions would be approved out of committee (OOC) by IGARD members.
3.2	Office for National Statistics (ONS): use of PDS data to support the linkage of data required to inform statistical analysis of factors associated with the COVID-19 pandemic by providing NHS Number where the quality or completeness of personal identifiers are otherwise insufficient (Presenter: David Morris) NIC-413717-C8Y6K-v2.2 **Application:** This was an extension and renewal application to the Data Sharing Agreement (DSA) which expired on the 30th September 2021, and an amendment to **1)** Both Coronavirus Infection Survey (CIS) and School Infection Survey (SIS) have been extended to run until April 2022 and ONS have requested to continue to use Personal Demographics Service (PDS) data for the purposes described until the studies close, **2)** section 5 has been updated throughout to add clarity and context, and **3)** to change the collaborators involved in CIS from Public Health England (PHE) (now disbanded) to Northumbria University and SIS from PHE to the UK Health Security Authority (UKHSA). This DSA permits ONS to re-use a subset of the identifiable PDS data disseminated under NIC-20951-D2K6S for the purposes of supporting the CIS and SIS. ONS receives PDS under section 43 of the Statistics and Registration Services Act 2007. The data is used in the production and publication of statistics on the number and condition of the UK population.

	The purpose is to reuse the PDS data to facilitate linkage between other datasets for the purpose of COVID-19 related work. The proposed methodology is that datasets without complete sets of participant identifying details would be matched against the PDS data to obtain complete and latest identifying details before being linked to other datasets. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at an IGARD business as usual (BAU) meeting on the 19th November 2020. IGARD noted that this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 1st December 2020. IGARD members queried the use of section 45(a) of the Statistics and Registration Service Act (SRSA) 2007 which provided the legal basis for NHS Digital to permit this reuse of data, but noted that the participation in the study was voluntary. NHS Digital noted that the level of consent for SIS was assessed as being insufficient to rely on consent to meet the common law duty of confidentiality and as such to keep the DSA under a consistent legal basis throughout, NHS Digital deemed it appropriate for the applicant to rely on section 45(a) of the SRSA 2007, which provided a legal basis for NHS Digital to permit the reuse. NHS Digital also noted that the consent materials had not been revised but that a query remained outstanding with NHS Digital's Privacy, Transparency and Ethics Directorate. IGARD noted that the applicant had not updated the SIS cohort as to what was happening with their data and suggested that the patient information sheets and privacy notices should be revised, so that participants are informed and could use this information in any decisions they wish to make, for example whether to participate or continue to participate. IGARD also suggested, and in line with NHS Digital's DARS Standard for Transparency (fair processing), that the applicant should have a UK General Data Protection Regulation (UK GDPR) compliant, publicly accessible transparency notice which is maintained throughout the life of the agreement. IGARD also suggested that ONS may wish to refresh the advice previously received from the Information Commissioner's Office (ICO) in respect of transparency to the public. IGARD noted the importance of transparency and that the proposed processing was not currently reflected in the privacy notice, and that the only place where subjects would be made aware of this processing was currently in the NHS Digital Data Uses Register. IGARD suggested, and in line with NHS Digital's DARS Standard for Ethical Approval and the fact that this does fall under the remit of the Research Ethics Committee (REC), that the applicant consult with the REC, in respect of the processing in this DSA, and should undertake any actions that the REC consider necessary. In addition the applicant should provide a copy of the REC feedback for uploading to NHS Digital's customer relationship management (CRM) system for future reference. IGARD also reminded NHS Digital that the legal basis was section 45(a) and it was NHS Digital who was taking responsibility for the flow of data, therefore the onus was on NHS Digital. IGARD were unclear in section 5(b) (Processing Activities) of the data linkage being undertaken and asked that clarification was provided as to what was meant by "…*linkage with health datasets containing the NHS number*…". In addition, IGARD asked that further narrative be provided of the linkage taken place and to clarify where the data had come from.

	IGARD queried the benefits outlined in section 5(d) (Benefits), and noted that some of the information provided were outputs, and asked that section 5(d) was updated to remove any outputs and edited to only leave examples that reflect the benefits to patients and the Health and Social Care System; and in line with the NHS Digital DARS Standard for Expected Measurable Benefits. IGARD members noted that Section 5(d) (iii) (Yielded Benefits) did not appear to be in line with the NHS Digital DARS Standard for Expected Measurable Benefits and asked that this section was updated. In addition, IGARD asked that applicant provide 2 or 3 specific yielded benefits accrued to date in section 5(d) (iii) and to ensure these are clear to the benefits to both patients and the health care system more generally. IGARD noted a number of acronyms in section 5 (Purpose / Methods / Outputs) and asked that this public facing section, that forms NHS Digital's data uses register, be updated to ensure that all acronyms upon first use were expanded and clearly defined with a supportive explanation in a language suitable for a lay reader, for example "*CIS*" and "*SIS*". 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, given the need to inform study participants and the Data Access Request Service (DARS) ongoing enquiries. **Outcome:** recommendation to approve subject to the following condition: 1. In respect of the ethical approval and in line with NHS Digital's DARS Standard for Ethical Approval: a. To consult the REC in respect of the processing, and undertake any actions the REC consider necessary, and b. To provide a copy of the REC favourable approval (such as an email from REC), and c. To upload a copy of the written ethical confirmation from REC to NHS Digital's CRM system. The following amendments were requested: 1. In respect of section 5(b) and data linkage: a. To clarify what is meant by "…*linkage with health datasets containing the NHS number*…", and b. To clarify what linkage is taking place, and c. To clarify where this data has come from. 2. In respect of section 5(d) and in line with the NHS Digital's DARS Standards: a. To remove any specific outputs from section 5(d) and move to section 5(c), and b. To provide further details in section 5(d) of the yielded benefits accrued to date including 2 or 3 specific examples, and ensure these are clear as to the benefits to both patients and the health care system more generally. 3. As section 5 forms NHS Digital's Data Uses Register, to amend section 5 to ensure that all acronyms upon first use be defined and further explained if the meaning is not self-evident, for example "*CIS*", "*SIS*". The following advice was given: 1. In respect of the privacy notice and in line with NHS Digital's DARS Standard for Transparency (fair processing), IGARD wished to draw to the applicant's attention to the statement in section 4, that a UK GDPR compliant, publicly accessible

	transparency notice is maintained throughout the life of the agreement. IGARD suggested that ONS may wish to refresh the advice previously received from the ICO in respect of transparency to the public. 2. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment given the need to inform study participants and the DARS ongoing enquiries. 3. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent given the need to inform study participants and the DARS ongoing enquiries. **Significant Risk Area:** 1. IGARD noted the importance of transparency and that the proposed processing is not currently reflected in the privacy notice, the only place where subject would be made aware of this processing currently being the NHS Digital Data Uses Register. It was agreed the conditions would be approved out of committee (OOC) by IGARD members.
3.3	Royal College of Surgeons (RCS): National Vascular Registration – patient level HEs and Civil Registration Mortality data request (Presenter: Denise Pine) NIC-59669-F6Y3W-v1.9 **Application:** This was a renewal application which expires on the 20th May 2023 and an amendment to **1)** request mortality data for patients who are not registered in the National Vascular Registry (NVR) cohort but have been previously identified by relevant Office of Population Censuses and surveys (OPCS) codes to enable the applicant to determine the long-term mortality for all vascular patients in England and not just those that have been able to be linked to the NVR, and **2**) to permit utilisation of the data to address the impact of COVID-19 on the vascular patients and delivery of the vascular services in the UK. The Registry was established in 2013 and collects data from NHS Trusts providing vascular surgery in order to provide information on patient characteristics, pre-operative care, then range of surgery undertaken, and post-operative outcomes. The inclusion of COVID-19 questions are aligned to the general purpose of the clinical audit. The Audit had been previously advised by the Healthcare Quality Improvement Partnership (HQIP) to contact the Health Research Authority Confidentiality Advisory Group (HRA CAG) to ensure that any changes to the dataset being requested were covered. HRA CAG advised that if there was no change to the datasets requested then HRA CAG would not expect any amendment to be required to an audit application as it is expected that these audits would be looking at adverse events, and that is in line with the audit programme of work. The Audit are treating the inclusion of looking at the impact of COVID-19 as part of the general review of the audit data and the impact of any adverse events to the cohort. The audit programme is relaying on s251 of the NHS Act 2006, for the flow of data out of NHS Digital. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at an IGARD business as usual (BAU) meeting on the 21st May 2020.

	IGARD confirmed that they were of the view that the relevant s251 support provided the appropriate legal gateway and was compatible with the flows of identifiable data in to NHS Digital outlined in the application. IGARD had a lengthy conversation with regard to the use of data, especially the data for those patients not registered on the NVR, and asked that clarification was given to the type and extent of the data for patients not registered in the NVR being used for case ascertainment work, including the fields within each data set, for example, but not limited to, the OPCS codes flowing and any unit or consultant identifiers. IGARD asked that clarification was provided in section 5 (Purpose / Methods / Outputs) as to what data flows were being requested and what fields would be flowing for each data flow requested. IGARD were unclear if the data for those patients not registered in the NVR cohort was considered pseudonymised or confidential patient information, and asked that further clarification was provided in section 5 of the application. IGARD noted that the possible transfer and use of data for patients who have declined to participate in the NVR and noted that an individual who has declined participation in the NVR might be surprised to find that their pseudonymised data was flowing under this agreement. IGARD asked that a further justification was provided as to why Civil Registration (Deaths) data was being required for case ascertainment work for patients not registered in the NVR cohort. IGARD asked for clarification at what point the data for patients not registered in the NVR cohort used for case ascertainment and analysis was destroyed, since this was not clear in the application. Noting that some data subjects had been previously asked to give consent, IGARD asked that further narrative was provided in sections 3 (Datasets Held / Requested) and section 5 with regard to the application of the National Data Opt-Out (NDO). IGARD asked that the wording in section 5(c) (Specific Outputs Expected) be updated to clearly articulate that it will enable the RCS to provide information on the longer-term outcomes for patients undergoing vascular surgery. IGARD queried the implementation of the communications plan and noted the verbal update from NHS Digital that the applicant had confirmed that all actions outlined in the "*tentative communications plan*" had been implemented. IGARD noted the verbal update from NHS Digital and asked for further detail of the actions undertaken in the implementation of the communication plan, given that all actions within the plan have now been undertaken. IGARD noted the yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits) and, in line with NHS Digital's DARS Standard for Expected Measurable Benefits, asked that further details were provided of the specific yielded benefits accrued to date, and asked that it was clear as to the benefits to both the patients and the health and social care system more generally, noting that peer reviewed journal articles were an output, not a yielded benefit. IGARD suggested that section 5(d) be updated to remove reference to "*it will*…" or "*it can*…" and instead use a form of words such as "*it is expected"* or *"it is hoped …".* IGARD queried the statement in section 3(b) (Additional Data Access Requested) that *"GDPR does not apply to data solely relating to deceased individuals"*, however, noting that the status of those patients that are still alive would be revealed, asked that this was updated to include a UK General Data Protection Regulation (UK GDPR) legal basis for

	dissemination and receipt of data. IGARD noted that a query had been raised on this particular point with the Privacy, Transparency and Ethics (PTE) Directorate and welcomed an update from Data Access Request Service (DARS) in due course. **Outcome:** recommendation deferred, pending: 1. In respect of the data: a. To clarify the type and extent of data for patients not registered in the NVR being used for case ascertainment work, including fields, for example the OPCS codes flowing and any unit or consultant identifiers, and b. To clarify whether the data for patients not registered in the NVR cohort is considered pseudonymised or confidential patient data, and c. To clarify what the data for patients not registered in the NVR cohort is being used for, in relation to case ascertainment work and any other additional purposes, and d. To justify why Civil Registration (Deaths) data is being requested for case ascertainment work for patients not registered in the NVR cohort, and e. To clarify at what point the data for patients not registered in the NVR cohort used for case ascertainment and analysis is destroyed, and f. To clarify what data flows are being requested and what fields are flowing for each data flow. 2. To provide further narrative in section 3 and section 5 with regard to the application of the NDO, noting that some data subjects were previously asked to give consent. 3. To update section 3 to include a UK GDPR legal basis for those datasets that give information about cohort members who are still living, if this approach is supported by advice on this point from PTE. 4. To update section 5(a) and section 5(d) to use a form of wording such as "*it is hoped* …", rather than "*it will…*" or *"it can"*. 5. To provide further details in section 5(d) of the yielded benefits accrued to date and ensure these are clear as to the benefits to both patients and the health care system more generally, noting that peer reviewed journal articles are an output and not a benefit. 6. To update the wording in section 5(c) to clearly articulate that it will enable the RCS to provide information on the longer-term outcomes for patients undergoing vascular surgery. 7. To provide further detail of the actions undertaken in the implementation of the communication plan given that all actions within the plan have now been undertaken. **Risk area:** The possible transfer and use of data for patients who have declined to participate in the NVR. An individual who has declined participation in the NVR might be surprised to find that their pseudonymised data was flowing under this agreement.
3.4	<u>PrescQIPP CIC: Medicines dispensed in primary care pseudo anonymised data DARS application (Presenter: Catherine Day) NIC-408951-K3C1Y-v0.12</u> **Application:** This is a new application for pseudonymised Medicines dispensed in Primary Care (NHSBSA) data from April 2018 until latest available, then monthly thereafter. PrescQIPP CIC is a Community Interest Company (CIC) and having access to NHSBSA data will allow the team to review and report on prescribing and medicine safety changes and issues that have arisen because of the COVID-19 pandemic, and to report on change

	in prescribing and identify areas which may need further review. The applicant has requested data from April 2018 to allow them to monitor the impact of COVID-19 and monitor prescribing pre, during and post COVID-19 to deliver meaningful and clinically relevant data for commissioners and health care professions. **Discussion:** IGARD had a lengthy discussion with regard to the legal basis cited in the application, noting this was a community interest company. IGARD suggested that NHS Digital work with the applicant, if the applicant was relying on Article 9(2)(g) (substantial public interest), to correctly list and justify the applicable Data Protection Act (DPA) 2018 schedule 1 Part 2 conditions. In addition, if using Article 9(2)(g) legal basis, to provide a full justification for use of this Article in section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) in line with the Information Commissioner's Office (ICO) "what are reasons of substantial public interest", and the high bar set. If on reflection, the applicant decides to use a different Article 9 legal basis, such as for example the provision of health or social care, then the application should be updated throughout to ensure an appropriate legal gateway for NHS Digital to disseminate the data. IGARD advised that if the applicant decided to use Article 9(2)(g) (substantial public interest), then IGARD would wish to see confirmation of how the provision of a dashboard provided a benefit to **all**, in relation to the safety and effectiveness of medicines, and not just those who subscribed to the organisation's medicines optimisation service. IGARD asked that a special condition was inserted in section 6 (Special Conditions), that any use of the NHS Business Services Authority (BSA) Medicines dispensed in Primary Care data must be within the parameters of the relevant Direction authorising that collection. IGARD noted a number of technical terms in section 5, and asked that this public facing section, that forms NHS Digital's data uses register, was amended throughout, to ensure technical terms are explained in a manner suitable for a lay audience, for example "*medicines optimisation*" and "*tableau desktop and / or tableau prep software*" etc. IGARD queried if the medicines optimisation was just for clients who subscribed to the CIC or for unrestricted England-wide use and asked that clarification was provided in section 5. IGARD also queried how health care professionals would benefit from the work undertaken by the CIC, and asked that further clarification was provided in section 5. IGARD noted, that in line with the NHS Digital DARS Standard for Commercial Purpose, that the applicant should clearly outline in section 5 that they are a not for profit CIC, charging for its services. Separate to this application, IGARD suggested that NHS Digital may wish to take a view on CIC organisations and update their NHS Digital DARS Standard for Commercial Purpose, for example the 12 month limit on a Data Sharing Agreement (DSA) may not be appropriate for a CIC, which is an organisation which trades for social purposes and uses its profits and assets for public good. IGARD noted in section 5 reference to Clinical Commissioning Groups (CCGs) and suggested that narrative be updated to reflect the move from CCGs to Integrated Care System (ICS) NHS Bodies from the 1st April 2022. In addition, IGARD suggested that confirmation of the arrangements in place be provided in section 5, noting that the DSA will be active post 1st April 2022.

	IGARD noted a number of benefits had been cited in section 5(d) (Benefits) and suggested that reference to "*it is in the public interest*…" be removed. In addition, IGARD asked for further clarity on how "*specific safety measures are actioned at a patient level*" will be undertaken, noting that the data was pseudonymised. IGARD noted that section 5(d) (iii) (Yielded Benefits) was currently blank and look forward to seeing how the applicant used the data and the yielded benefits generated, and in line with NHS Digital's DARS Standard for Expected Measurable Benefits. IGARD noted that the storage and processing locations listed in section 2 (Locations) were that of the CIC and suggested that these were reviewed and amended as appropriate. to reflect the correct address, such as *"home working location England"*, as recorded in section 2(a). IGARD suggested that sections 5(a) (Objective for Processing) and 5(d) be updated to remove reference to "*it will*…" or "*it can…*" and instead use a form of words such as "*it is expected"* or *"it is hoped …".* IGARD noted that the spelling error in section 5(b) (Processing Activities) "*depravation data*" and asked for it to be corrected. **Outcome:** recommendation to approve subject to the following conditions: 1. In respect of the legal basis: a. If the applicant is relying on Article 9(2)(g) (substantial public interest) then sections 1 and 5 should be updated to clearly describe how the scheduled conditions are met under DPA 2018, and b. To provide a full justification for use of Article 9(2)(g) legal basis in line with the ICO's "what are reasons of substantial public interest" and the high bar set, or c. To amend the Article 9 legal basis to ensure an appropriate legal gateway for the dissemination of data by NHS Digital. 2. With regards the Article 9 legal basis, provide confirmation of how the provision of a dashboard provides a benefit to **all**, in relation to the safety and effectiveness of medicines, and not just those who subscribe to the organisation's medicines optimisation service. The following amendments: 1. As section 5 forms NHS Digital's data uses register, a. to amend throughout to ensure that technical terms are explained in a manner suitable for a lay audience, for example "*medicines optimisation*" and "*tableau desktop and / or tableau prep software*", and b. to clarify if medicines optimisation is just for clients or for England-wide, and c. to clarify how each health care professional will benefit from the work undertaken, and d. in line with the NHS Digital DARS Standard for Commercial Purpose, to outline they are a not for profit CIC charging for its services. 2. In respect of the NHSBSA dataset to insert a special condition in section 6, that any use of the NHSBSA data must be within the parameters of the relevant Direction authorising that collection. 3. To update the processing and storage locations to the *"home working location England"*. 4. To update the narrative in section 5 with regard to CCGs and their move to ICBs from 1st April 2022, and confirm the arrangements in place given that the proposed DSA will still be active post 1 April 2022.

	5. To update section 5(a) and section 5(d) to use a form of wording such as "*it is hoped* …", rather than "*it will…*" or *"it can"*. 6. In respect of section 5(d): a. To clarify how "*specific safety measures are actioned at a patient level*" will be undertaken with pseudonymised data, and b. To remove reference to "*it is in the public interest*…" from section 5(d). 7. To update in section 5(b) "*depravation data*" to a more suitable form of words. The following advice was given: 1. IGARD look forward to seeing how the applicant uses the data and the yielded benefits generated. 2. Separate to this application, IGARD suggested that NHS Digital may wish to take a view on CIC organisations and update their NHS Digital DARS Standard for Commercial Purpose, for example the 12 month limit on a DSA may not be appropriate for a CIC which is an organisation which trades for social purposes and uses its profits and assets for public good. It was agreed the conditions would be approved out of committee (OOC) by IGARD members.
3.5	University of Cambridge: INTERVAL and COMPARE trial cohorts: long term follow up of health outcomes and associations with genetic, biological and lifestyle traits (No Presenter) NIC-156334-711SX-v7 **Application:** This was a renewal and amendment application, to add identifiable COVID-19 UK Non-hospital Antibody Testing Results (Pillar 3) data, COVID-19 Vaccination Status data, COVID-19 Vaccination Adverse Reactions data, and the Sentinel Stroke National Audit Programme (SSNAP) data. The purpose is to create a multi-purpose resource, by linking detailed lifestyle and biological information collected on INTERVAL and COMPARE study participants with health-related records. This will enable detailed study of the health of blood donors and, more generally, allow studies of cardiovascular disease and other health-related outcomes. INTERVAL and COMPARE studies are multi-purpose, multi-stage research projects involving blood donors. The initial stage of these translational research studies has been related to blood donation research aiming to improve, NHS Blood and Transplants (NHSBT) core services, for example, safety and efficiency of blood donation. The INTERVAL study assessed the impact of varying the frequency of blood donation on donor health and the blood supply. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD BAU meeting on the 13th May 2021; where the application had been recommended for approval with conditions, amendments and advice. IGARD noted that as outlined in the Out of Committee (OOC) Standard Operating Procedure, any applications returned to the IGARD Secretariat for review OOC by the IGARD Chair or quorum of IGARD Members which were over three months old, would be automatically placed on the next available BAU meeting agenda for review by IGARD Members as per the current standard processes. Members would only review if the conditions have been met or not, and would not re-review the application, unless significant legislative or policy changes had occurred since last reviewed by a full meeting

	of IGARD or the application had been significantly updated, in which case the conditions may be updated to reflect such changes which will be noted for transparency in the published minutes and a full review of the application undertaken. The conditions from the 29th April 2021 BAU meeting were as follows: 1. In respect of the NHS England / Improvement approval: a. To provide written confirmation of the NHS England / Improvement approval for the use of the vaccine datasets, as per process. b. To upload the written confirmation to NHS Digital's CRM system. 2. In line with NHS Digital's policy on honorary contracts and in accordance with the special condition in this application: a. To provide an honorary contract that complies with this policy, in particular, counter signatory by the home research institution and / or employer. b. To upload a copy to NHS Digital's CRM system. 3. In respect of the PAG support: a. To send a copy of the updated application to PAG for information. b. To provide written confirmation from PAG that they have noted the updates to the application. c. To upload the written confirmation to NHS Digital's CRM system. A quorum of IGARD members were content that the conditions had been met subject to the following amendment: 1. To amend the small but significant typo in section 1 (Abstract) in relation to honorary contracts from "*employee*" to "***employer".***
4	<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). *No items discussed.*
5	<u>Oversight & Assurance</u> IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. Due to the volume and complexity of applications at today's meeting, IGARD were unable to review any Data Access Request Service (DARS) applications as part of their oversight and assurance role. IGARD noted that they had requested, an IG COVID-19 release register suite of documents on a particular data release for review by IGARD as part of their oversight and assurance, and as agreed in June 2020 with the Executive Director Privacy, Transparency and Ethics (PTE) when it had been agreed that IGARD review an agreed number per month, by way of a review of all documentation revised by PTE, and as part of continuous improvement and quality. Documentation had been received but had not yet been circulated to IGARD Members due to other conflicting priorities. 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.

	IGARD Members noted that the last IG COVID-19 release register that they had reviewed and provided comments on was July 2021.
6	<u>COVID-19 update</u> To support NHS Digital's response to COVID-19, from Tuesday 21st April 2020, IGARD will hold a separate weekly meeting, to discuss COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 urgent applications that have been submitted to NHS Digital. Although this is separate to the Thursday IGARD meetings, to ensure transparency of process, a meeting summary of the Tuesday meeting will be captured as part of IGARD's minutes each Thursday and published via the NHS Digital website as per usual process. The ratified action notes from **Tuesday, 26th October 2021** can be found attached to these minutes as Appendix B
7	<u>AOB:</u> There was no further business raised, the Chair of the IGARD meeting 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 15/10/21

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

NIC Reference	Applicant	IGARD meeting date	Recommendation conditions as set at IGARD meeting	IGARD minutes stated that conditions should be agreed by:	Conditions agreed as being met in the updated application by:	Notes of out of committee review (inc. any changes)
NIC-253220-Q1X8H	University of Manchester	11/03/21	1. To update section 1 and throughout section 5 to clarify that this study relates to the economic evaluation of point of prescription decision support and not just one commercial product.	IGARD Members	Quorum of IGARD Members	IGARD Member comment: • Amendment 1 "*To update section 5(e) to reflect any commercial aspects, for example, the IP rights*" The example cited in the outcome by IGARD was an example. IGARD suggest that the NHS Digital DARS Standard for Commercial Purpose is re-visited since for example OptimiseRX software may gain a commercial advantage and this is drawn out in point 2 of the published DARS Standard "*any party involved in the application receives any form of commercial benefit*[1] *(**including intangible or indirect commercial benefits***

						such as positive publicity for a commercial venture*) from the use of data, for example commercial funders or sponsors*."
NIC-484452-H8S1L-v0.3	Department of Health & Social Security	16/09/21	1. To provide written confirmation (such as an e-mail) that NHS Digital's Security Advisor has expressed satisfaction that the appropriate security is in place. 2. To provide a satisfactory update to the yielded benefits in section 5(d) (iii) to ensure they are clear as to the benefits to both the patients and the health and social care system more generally and comply with NHS Digital's DARS Standard for Expected Measurable Benefits.	IGARD Members	Quorum of IGARD Members	N/A
NIC 362237-Y5K7L-v3.2	NHS Bath & North East Somerset, Swindon & Wiltshire CCG	12/08/21	1. In respect of the yielded benefits: a) To provide a satisfactory update to the yielded benefits in section 5(d) (iii) to ensure they comply with NHS Digital's DARS Standard for Expected Measurable Benefits, and are clear as to the benefits to the local population and the health care system. b) To update the yielded benefits in section 5(d) (iii), to reflect the purpose(s) for processing. c) To update the yielded benefits in section 5(d) (iii) to clearly distinguish between 'initiatives' and 'strategic objectives'.	IGARD Members	Quorum of IGARD Members	N/A

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

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

Liaison Financial Service and Cloud storage:

- NIC-527503-Z3W0N-v0.3 NHS Wakefield CCG - Comm, IV, RS

Optum Health Solutions UK Limited Class Actions:

- NIC-281073-Y5G3F-v4.4 NHS Derby and Derbyshire CCG, Comm. IV and RS
- NIC-95040-Y0P3W-v4 NHS Cambridgeshire & Peterborough CCG

Graphnet Class Actions:

- None