Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 11 August 2022

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member
Kirsty Irvine	IGARD Chair
Dr. Imran Khan	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Prof. Nicola Fear	Specialist Academic Member
Dr. Robert French	Specialist Academic / Statistician Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Chair
Dr. Maurice Smith	Specialist GP Member
Jenny Westaway	Lay Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Garry Coleman	Associate Director / Senior Information Risk Owner (SIRO) (Item 5)
Dave Cronin	Data Access Request Services (DARS) (**SAT Observer**: items 3.1, 3.4)
Louise Dunn	Data Access Request Services (DARS) (**SAT Observer**: item 3.3)
Liz Gaffney	Head of Data Access, Data Access Request Service (DARS) (Item 7.1)
Sara Lubbock	Data Access Request Services (DARS) (Observer: item 3.1)
Shaista Majid	Data Access Request Services (DARS) (items 3.2, 3.3)
Karen Myers	IGARD Secretariat
Tania Palmariellodiviney	Data Access Request Services (DARS) (**SAT Observer**: item 3.2)
Denise Pine	Data Access Request Services (DARS) (item 3.5)
Aisha Powell	Data Access Request Services (DARS) (items 3.4)
Kimberley Watson	Data Access Request Services (DARS) (**SAT Observer**: item 3.5)

Vicki Williams	IGARD Secretariat
Clare Wright	Data Access Request Services (DARS) (Item 3.1)
***SAT** – Senior Approval Team (DARS)	

1	**Declaration of interests:** Dr. Imran Khan noted a potential conflict with any applications reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG), as part of his roles as Deputy Chair of the Health Informatics Group at the RCGP and Co-deputy Chair of the Joint GP IT Committee. It was noted that although PAG had reviewed the COVID-19 Therapeutics Programme Dataset – Briefing Presentation (in relation to NIC-382794-T3L3M), PAG had not specifically reviewed the linked application as the dataset had already flowed, it was therefore agreed this was not a conflict of interest. Maria Clark noted a professional link with the British Medical Association (BMA), which applies to any applications reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG), as part of her role as officer of the BMA as Vice Chair of its Patient Liaison Group. However, she noted no specific connections with NIC-382794-T3L3M (noting PAG had reviewed the COVID-19 Therapeutics Programme Dataset – Briefing Presentation related to this application) or the staff involved and it was agreed that this was not a conflict of interest. Maria Clark noted professional links to NHS England (NIC-433629-H3M0G) but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest. Maria Clark noted professional links to the Chair of the University of Sheffield Research Ethics Committee (NIC-16274-J8H5T) but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest. Paul Affleck noted professional links to the University of Leeds (NIC-112910-R4X9X) but noted no specific connections with the application or staff involved and it was agreed that this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 4th August 2022 IGARD meeting were reviewed and, subject to a number of minor amendments, were agreed as an accurate record of the meeting. **Out of committee recommendations:** An out of committee report was received (see Appendix A).
2	**Briefing Notes**
	There were no briefing papers submitted for review.
3	**Data Applications**
3.1	University of Oxford: QResearch-Oxford Data Linkage Project (Presenter: Clare Wright) NIC-382794-T3L3M-v6.7

	Application: This was a renewal and extension application to permit the holding and processing of pseudonymised Civil Registration (Deaths) data, COVID-19 Hospitalization in England Surveillance System (CHESS), COVID-19 Second Generation Surveillance System (SGSS), COVID-19 UK Non-hospital Antigen Testing Results (pillar 2), COVID-19 Vaccination Adverse Reactions and Secondary Uses Service (SUS+) data Admitted Patient Care (beta version). It was also an amendment application to **1)** include a sublicence data sharing model; **2)** merge NIC-240279-Y2V2N HES / ECDS data and its purposes into this data sharing agreement (DSA); **3)** to amend the DSA title from ''QResearch - COVID-19 Risk Stratification project' to 'QResearch-Oxford Data Linkage Project' to reflect the combined DSAs; **4)** to add Nottingham University as a Data Processor (for the purpose of transferring from NIC-240279-Y2V2N); **5)** to remove Intensive Care National Audit & Research Centre (ICNARC), London School of Hygiene and Tropical Medicine, University of Liverpool, University of Leicester as Data Processors (these organisations will transfer to sublicences); **6)** to add COVID-19 Therapeutics Programme Data Set (already disseminated under PTE Letter of release); **7)** to add Maternity Services Data Set (MSDS); **8)** to change the frequency for COVID-19 Hospitalization in England Surveillance System (CHESS) and COVID-19 Vaccination Adverse Reactions data sets from monthly dissemination to annual dissemination; **9)** to change the frequency for HES/ECDS from quarterly dissemination to monthly dissemination; **10)** to change the territory of use from 'worldwide' to the 'UK'. QResearch is a database of linked medical records that has been used, and continues to be used, by a variety of research projects undertaken by UK Universities; and consists of the coded pseudonymised electronic health records from primary care patients registered with approximately 1,500 general practices spread throughout the UK. The purpose of this application is **1)** for use by the University of Oxford for specific research purposes; **2)** for use by the University of Nottingham for ongoing research studies; **3)** onward sharing to UK Universities via a sublicensing agreement. In addition, it will support QResearch's urgent COVID-19 research projects in response to the COVID-19 pandemic, for example, the development and maintenance of a COVID-19 risk stratification tool commissioned by the Chief Medical Officer (CMO). The application was previously considered on the 7th April 2022 where IGARD had deferred making a recommendation. **Discussion:** IGARD noted that the 'COVID-19 Therapeutics Programme Dataset – Briefing Presentation' was discussed at the IGARD business as usual (BAU) meeting on the on 4th August 2022. IGARD also noted that the Briefing Presentation only had also been reviewed by the GPES Data for Pandemic Planning and Research (GDPPR) – Profession Advisory Group (PAG) on the 27th April 2022 (see Appendix B); and that the notes clearly stated that a review of this application was not required by PAG. It was noted that PAG has not reviewed this application, their comments were related to the presentation and the IG release (IG6117 Record Level Therapeutics). IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD BAU meeting on the 7th April 2022. It was also discussed as part of the 'applications progressed via NHS Digital's SIRO Precedent route' on the 3rd March 2022 and the 16th June 2022.

	IGARD noted that this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 7th April 2020, 12th January 2021, 19th January 2021 and the 2nd March 2021. IGARD noted that **NIC-240279-Y2V2N** (see amendment point 2) had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 21st April 2020 and the 18th May 2021. IGARD noted that the application had been updated to address all the previous deferral points. IGARD noted that they had previously asked NHS Digital to advise on the s261 legal basis for NHS Digital's dissemination, for example which subsection of s261 of the Health and Social Care Act 2012 was relevant since NHS Digital appeared to be only citing the overarching s261 e.g. "*s261 other dissemination of information*". IGARD asked that section 3 (Datasets Held / Requested) be updated with the most appropriate s261 subsection, in line with the latest advice from NHS Digital's Privacy, Transparency & Ethics (PTE). IGARD also requested sight of the email exchange on this topic between PTE and DARS. IGARD noted the Data Protection Impact Assessment (DPIA) stated there was a risk that patients may "object" to type one opt-outs not being upheld. IGARD noted that patients had already objected when they had submitted their type 1 opt-outs, and that there was, more accurately, a risk to NHS Digital in respect of public trust and confidence as a data safe haven, that data was flowing without type one opt-outs being applied. IGARD noted that NHS Digital tells patients that if they are exercising a type 1 opt-out it prevents their information being shared outside of their GP practice for purposes other than direct care: Care information choices - NHS Digital. IGARD suggested that a possible partial mitigation to this risk, would be appropriate transparency on these special cases. IGARD noted that the approval for the dissemination of the dataset without type 1 opt-outs being applied to the *"at risk patients collection"* had been provided by NHS Digital's Executive Director Data Service, SIRO, Caldicott Guardian and Executive Director PTE, plus support had also been provided by NHS Digital's Chief Medical Officer. IGARD had a lengthy discussion on the COVID-19 Therapeutics Programme Dataset, that had already been disseminated under NHS Digital's Privacy, Transparency and Ethics (PTE) letter of release. IGARD noted that the privacy notice did **not** reflect any circumstances where Type 1 opt-outs would **not** be respected for the flow of COVID-19 Therapeutics Programme Dataset; and suggested that NHS Digital update their website as soon as possible, to reflect the factual scenario. IGARD noted that there was a reputational risk to NHS Digital, that the NHS Digital website **and** privacy notice did not note any circumstances where Type 1 opt-outs would **not** be respected, for example, this specific application, and other instances as referred to in the letter provided to IGARD as a supporting document from NHS Digital's Caldicott Guardian. In addition, IGARD noted that the privacy notice for the COVID-19 Therapeutics Programme Dataset, did **not** reflect that the data will be processed for the purpose of 'research' and suggested that NHS Digital update as soon as possible, to reflect the factual scenario. IGARD noted that there was a risk to NHS Digital, that their privacy notice did not reflect that the COVID-19 Therapeutics Programme Dataset may be processed for the purpose of research. IGARD reiterated their previous observation when the Briefing Presentation was discussed on the 4th August 2022, that the bespoke COVID-19 Therapeutics Programme Dataset, with the intention of flowing data to a single recipient, did set a precedent and there was a reputational

	risk to NHS Digital that there was not equality of access to data. Such a risk could be mitigated by NHS Digital publicising this data asset to make other researchers aware, and to provide researchers with a mechanism to apply for access. IGARD acknowledged that NHS Digital had noted that the dataset was not envisaged to be made more widely available through DARS, but that it may be onboarded at a later date, but discussions were still ongoing within NHS Digital. **Separate to this application:** IGARD noted within the IG Letter of Release**,** that the COVID-19 Therapeutics Programme Dataset was not subject to UK GDPR. IGARD raised concerns that this was setting a policy precedent, and may make it difficult to ensure transparency to the public on the use of their data. IGARD noted the references in section 5(a) (Objective for Processing) to *"Dancing House Consulting"* and noting that they were currently not referred to as a storage location in section 2, asked that in line with NHS Digital's DARS Standard for processing and storage locations the storage locations in section 2(b) (Storage Location(s)) were updated to reflect the factual scenario. IGARD queried what happened to the unmatched data, for example, the data that does not link to Egton Medical Information Systems (EMIS) data; and noting that it was currently unclear in the application, asked that section 5 (Purpose / Methods / Outputs) was updated with a further explanation. IGARD also asked that in line with NHS Digital DARS standard for sub licencing and onward sharing, section 5 was updated to clarify that unmatched data cannot flow under sub-license. IGARD noted and commended NHS Digital on providing a supporting document as part of the pack to IGARD members, outlining the details of NHS Digital's sub-licensing assessment. IGARD noted that the sub-licensing arrangements were not clear within the QResearch transparency materials, for example the privacy notice; and asked that in line with NHS Digital DARS standard for sub-licencing and onward sharing, QResearch updated their transparency materials to clearly reflect the sub-licensing arrangements. In addition, IGARD asked that a special condition was inserted in section 6 (Special Conditions) that **only** NHS Digital data that has been linked to the Q-Research database will be onwardly shared. IGARD suggested that to ensure consistency with similar applications utilising EMIS, such as ORCHID, the applicant may wish to provide a list or map of the participating GP practices, for transparency. IGARD queried the statement in section 5(a) *"Data will not be used for any solely commercial purposes."*, and asked that it was removed and instead, in line with the NHS Digital DARS Standard for Commercial Purpose, a full summary was provided in section 5(a) of the commercial aspects of this application, and that section 5(e) (Is the Purpose of this Application in Anyway (sic) Commercial) as appropriate, in parallel. IGARD queried the statement in section 5(b) (Processing Activities) *"NHS Digital will provide the **relevant records** from the Covid-19, SUS, HES, ECDS, MSDS and Mortality datasets to the University of Oxford"*; and asked that the reference to "relevant records" was reviewed and either updated with further clarification or removed. IGARD noted that there were two lay representatives noted within the supporting documentation provided, however suggested that further consideration was given to the nature of the lay representation on the QResearch Science Committee, to ensure there was a

	genuine lay voice, which may be helpful in assessing the benefit to health and social care and provide public assurance. NHS Digital noted the special condition in section 6 that stated an audit of this DSA must be undertaken on or around January 2023 and queried whether this could be removed as a special condition, noting that the audit had been agreed with NHS Digital's Senior Information Risk Owner (SIRO), and added to section 1 (Abstract) for future reference. IGARD noted the verbal update from NHS Digital and asked that the special condition was removed from section 6. In addition, IGARD confirmed that were supportive of an audit by NHS Digital, to be undertaken on or around January 2023. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the significant concerns raised on transparency. **Outcome:** unable to recommend for approval any retrospective amendments progressed under the SIRO route and / or data disseminated under the NHS Digital IG Letter of Release. **Outcome:** recommendation to approve in respect of the sub-licensing amendment only: The following amendments were requested: 1. To update section 3 with the legal basis for NHS Digital to disseminate data with the relevant subsection of s261 in line with the latest advice from NHS Digital's Privacy, Transparency & Ethics (PTE). 2. In line with NHS Digital's DARS Standard for processing and storage locations the storage locations in section 2(b) should be updated to reflect the factual scenario. 3. In respect of the unmatched data: a) To update section 5 with an explanation as to what will happen to the unmatched data, i.e. data that does not link to EMIS data. b) To update section 5 in line with NHS Digital DARS standard for sub licencing and onward sharing, to clarify that unmatched data cannot flow under sub-license. 4. In respect of sub-licencing and in line with NHS Digital DARS standard for sub-licencing and onward sharing: a) QResearch to update their transparency materials to reflect the sub-licensing arrangements. b) To insert a special condition in section 6 that only NHS Digital data that has been linked to the Q-Research database will be onwardly shared. 5. In respect of the commercial purpose: a) To amend section 5(a) to remove the statement *"Data will not be used for any solely commercial purposes."*; and b) In line with the NHS Digital DARS Standard for commercial purpose, to provide a full summary in section 5(a) of the commercial aspects of this application, and update section 5(e) in parallel. 6. To review the statement in section 5(b) that NHS Digital will provide the *"relevant records"* and either remove or provide further clarification. 7. In respect of the special conditions: a) To remove the special condition in section 6 relating to the timing of the NHS Digital Audit Requirement.

	b) To insert a special condition in section 6 that the COVID-19 Therapeutics Programme Data Set will not, in any form, be onwardly shared and is excluded from the sub-licensing model. The following advice was given: 1. In respect of the COVID-19 Therapeutics Programme Dataset: a) IGARD noted that the privacy notice does **not** reflect any circumstances where Type 1 Opt-outs will **not** be respected for the flow of COVID-19 Therapeutics Programme Dataset; and suggested that NHS Digital update their website as soon as possible, to reflect the factual scenario. b) IGARD noted that the privacy notice for the COVID-19 Therapeutics Programme Dataset, does **not** reflect that the data will be processed for the purpose of research and suggested that NHS Digital update as soon as possible, to reflect the factual scenario. c) IGARD reiterated their previous observation that the bespoke COVID-19 Therapeutics Programme Dataset, with the intention of flowing data to a single recipient, does set a precedent and there is a reputational risk to NHS Digital that there was not equality of access to data. Such a risk could be mitigated by NHS Digital publicising this data asset to make other researchers aware, and to provide researchers with a mechanism to apply for access. 2. IGARD noted the references within the risk assessment on the DPIA, that there is a risk that patients may "object". IGARD noted that patients have already objected, and that there was a risk to NHS Digital in respect of public trust and confidence as a data safe haven, that data was flowing without type one opt-outs being applied. IGARD suggested that a possible partial mitigation would be appropriate transparency on these special cases. 3. IGARD suggested that to ensure consistency with similar applications utilising EMIS, such as ORCHID, the applicant may wish to provide a list or map, of the participating GP practices for transparency. 4. IGARD suggested that further consideration was given to the nature of the lay representation on the QResearch Science Committee, to ensure there is a genuine lay voice, which may be helpful in assessing the benefit to health and social care and provide public assurance. 5. IGARD noted and supported an audit by NHS Digital, to be undertaken on or around January 2023. 6. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the significant concerns raised on transparency. 7. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the significant concerns raised on transparency. **RISK AREA:** Reputational risk to NHS Digital, that the NHS Digital website does not note any circumstances where Type 1 Opt-outs will not be respected, for example, this specific application, and other instances as referred to by the Caldicott Guardian in the supporting documents. **RISK AREA:** NHS Digital's privacy notice does not reflect any circumstances where Type 1 Opt-outs will **not** be respected for the flow of COVID-19 Therapeutics Programme Dataset.

	RISK AREA: NHS Digital's privacy notice does not reflect that the COVID-19 Therapeutics Programme Dataset may be processed for the purpose of research. **Separate to this application:** IGARD noted within the IG Letter of Release**,** that the COVID-19 Therapeutics Programme Dataset was not subject to UK GDPR. IGARD raised concerns that this was setting a policy precedent, and may make it difficult to ensure transparency to the public on the use of their data. **Subsequent to the meeting:** IGARD raised a query whether any of the following datasets: COVID-19 Hospitalization in England Surveillance System (CHESS), COVID-19 Second Generation Surveillance System (SGSS), COVID-19 UK Non-hospital Antigen Testing Results (pillar 2), COVID-19 Vaccination Adverse Reactions, were restricted to COVID-19 related research and if this carried through in the sub licence, and if so, suggested that a special condition outlining any restrictions was inserted in section 6.
3.2	University of Leeds: UK GRACE Risk Score Intervention Study (UKGRIS) (Presenter: Shaista Majid) NIC-112910-R4X9X-v3.4 **Application:** This was a renewal application to permit the holding and processing of identifiable Hospital Episode Statistics Admitted Patient Care (HES APC), Civil Registration (death) data and HES:Civil Registration (Deaths) bridge. It was also an amendment application to include additional HES APC data variables. The GRACE Score is a prospectively studied scoring system to risk stratify patients with diagnosed Acute Coronary Syndrome (ACS) to estimate their in-hospital and 6-month to 3-year mortality. The purpose of the application is for a study, aiming to investigate the effectiveness of the GRACE risk score on the management and outcome of patients hospitalised with non-ST elevation acute coronary syndrome for public health purposes. In addition, the Study Team, wish to investigate whether implementing the GRACE risk score increases the use of Class 1 guideline-indicated therapies for the management of Non ST-elevation ACS (NSTEACS), within the guideline recommended time, compared with current standard care in this population. The study will also investigate whether implementing the GRACE risk score reduces the composite endpoints of cardiovascular death, non-fatal myocardial infarction, new onset heart failure with hospitalisation and cardiovascular readmission at twelve months, compared with current standard care in this population. There were 2,160 participants recruited under version 3 of the consent material and 894 participants under version 4, making a total of 3054 recruited for the study. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD BAU meeting on the 24th January 2019. IGARD confirmed that they were of the view that the consent materials provided the appropriate gateway and were broadly compatible with the processing outlined in the application. IGARD queried what, if any, patient and public involvement and engagement (PPIE) there had been, or planned, since the application was silent on this point and asked that section 5 (Purpose / Methods / Outputs) was updated to provide further details of any PPIE carried out to date; or to provide an indicative plan of future PPIE activity, in line with HRA guidance on Public Involvement.

	IGARD suggested that, if not already happening, the applicant involved the relevant patient or groups, applicable to the stage of the project, in line with HRA guidance on Public Involvement. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 5 to provide details of any PPIE carried out to date. The following advice was given: 1. IGARD suggested that, if not already happening, the applicant involve relevant patient or public groups, applicable to the stage of the project, in line with HRA guidance on Public Involvement.
3.3	NIC-433629-H3M0G-v1.2: SMI Comprehensive Physical Health Checks (PHSMI) GPES Extract (Presenter: Shaista Majid) NHS England **Application:** This was an extension application to permit the holding and processing of pseudonymised Physical Health Checks for people with Severe Mental Illness (PHSMI) data. The purpose of the application is to enable NHS England to continue to use the data, collected via the General Practice Extraction Service (GPES), in order to monitor the delivery of the NHS Long Term Plan ambition to ensure that people with Severe Mental Illness (SMI) have their physical health needs met by receiving a comprehensive PHSMI and follow-up intervention. The aim of the application is to track delivery of PHSMI and reduce the levels of premature mortality for people living with severe mental illness by increasing early detection and expanding access to evidence-based physical care assessment and intervention each year. This data is expected to help clinicians understand how well they are performing in the diagnosis and management of six elements of the PHSMI. The extract will consist of routinely recorded GP data covering alcohol consumption, blood lipids, blood glucose, smoking, BMI and blood pressure. There will be one patient cohort, which will include patients of any age with a diagnosis of schizophrenia, bipolar affective disorder, and other psychoses up to and including the reporting period excluding patients recorded as 'in remission'. **Discussion:** IGARD noted that the application had **not** previously been presented at an IGARD business as usual (BAU) meeting. The application was discussed as part of the "returning applications" section of the meeting on the 22nd July 2021 and the 4th November 2021. It was also discussed as part of the 'applications progressed via NHS Digital's SIRO Precedent route' on the 20th January 2022. IGARD noted that they had provided comments OOC on the PHSMI Briefing Paper in February 2021, as referenced in the IGARD minutes on the 25th February 2021. IGARD reiterated the comments made in respect of *"...excluding patients recorded as 'in remission'"*, noting that there may be value in extending the offer of such checks to those in remission. IGARD queried the statement in section 5(a) (Objective for Processing) *"…in order to monitor the delivery of the NHS Long Term Plan ambition to ensure that **390 million people** with Severe Mental Illness (SMI) have their physical health needs met by receiving a*

	comprehensive physical health check (PHSMI) and follow-up intervention."; and asked that the figure stated was reviewed and amended as appropriate to reflect the correct number. IGARD queried the statement in section 5(c) (Specific Outputs Expected) *"…future considerations regarding releasing data at lower-level geographies (*PCNs and practice level) will be made following assessment of the robustness of the data at these levels. The format for this has yet to be finalised but will ultimately form a dashboard"*; and asked that the outputs in section 5(c) were updated, to further explain whether or not the findings will be by GP practice or how localised the outputs will be, noting that this was currently unclear. **PCN – primary care networks* IGARD noted the information in section 5(d) (Benefits) (iii) (Yielded Benefits) relating to SMI, and noting that there was currently insufficient information explaining how this was a yielded benefit, asked that in line with NHS Digital DARS Standard for Expected Measurable Benefits, this was updated with further details on the specific yielded benefit accruing to patients with SMI; or, if no benefit has been achieved due to the *"data reconciliation issues"* as currently stated, that the yielded benefit was removed. IGARD noted that this was 1-year agreement, and advised that on renewal or extension, they would expect to see further information within the yielded benefits in section 5(d) (iii), in line with NHS Digital DARS Standard for Expected Measurable Benefits. 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, except for minor amendments; to review the yielded benefits accrued to date or a detailed explanation as to the steps taken towards achieving the benefits outlined in section 5(d). **Outcome:** recommendation to approve The following amendments were requested: 1. To amend the reference in section 5(a) to *"**390 million** people with Severe Mental Illness"*, as may be appropriate to reflect the correct number. 2. To update the outputs in section 5(c) to further explain whether or not the findings will be by GP practice or how localised the outputs will be. 3. In respect of the yielded benefits and in line with NHS Digital DARS Standard for Expected Measurable Benefits: a) To update section 5(d) (iii) to provide further detail on the specific yielded benefit accruing to patients with SMI; or, b) To remove the specific yielded benefit relating to SMI if no benefit has been achieved due to the *"data reconciliation issues"*. The following advice was given: 1. IGARD noted that they had provided comments OOC on the PHSMI Briefing Paper in February 2021, as referenced in the IGARD minutes on the 25th February 2021. IGARD reiterated the comments made in respect of *"...excluding patients recorded as 'in remission'"*, noting that there may be value in extending the offer of such checks to those in remission. 2. IGARD noted that this was 1-year agreement, and asked that on renewal or extension, they would expect to see further information within the yielded benefits, in line with NHS Digital DARS Standard for Expected Measurable Benefits. 3. IGARD advised that they would wish to review this application when it comes up for renewal or extension, to review the yielded benefits accrued to date or a detailed

	explanation as to the steps taken towards achieving the benefits outlined in section 5(d). 4. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent except for minor amendments, to review the yielded benefits accrued to date or a detailed explanation as to the steps taken towards achieving the benefits outlined in section 5(d).
3.4	University of Southampton: MR1175 – **P**rospective study of **O**utcomes in **S**poradic versus **H**ereditary breast cancer (POSH) (Presenter: Aisha Powell) NIC-148334-51PXR-v3.10 **Application:** This was a renewal application to permit the holding and processing of identifiable Medical Research Information Service (MRIS) - Cause of Death Report, MRIS - Cohort Event Notification Report, MRIS - Flagging Current Status Report and MRIS - Members and Postings Report, Cancer Registration Data, Civil Registration – Deaths and Demographics data. It was also an amendment to remove University Hospital Southampton NHS Foundation Trust as a Data Controller and Data Processor. The purpose of the application is for a study looking at the prognosis for breast cancer patients with BRCA1 or BRCA2 gene mutations, at differences in patterns of recurrence and whether cancers in these patients have a distinct tumour phenotype or host tissue response. The study team are examining inherited high-risk genes for breast cancer, such as BRCA1 and BRCA2, with a view to developing treatments for genetic breast cancer; and are looking at the DNA from younger breast cancer patients to find out whether clues in the BRCA genes could help predict their response to treatment and the risk of the cancer returning. There is some evidence that BRCA1 gene carriers may be more sensitive to certain types of chemotherapy. The primary aims of the study are to determine whether **1)** the prognosis of patients with breast cancer who harbour BRCA1 or BRCA2 gene mutations differs from non-carrier patients matched for age and other major prognostic indicators; **2)** breast cancers occurring in patients with different predisposing inherited gene mutations have a consistent and distinct tumour phenotype; **3)** there are differences in the pattern of distant breast cancer recurrence between patients with BRCA1 or BRCA2 gene mutations and matched non carrier patients. The study cohort contains 2,888 patients in England and 2,756 patients in Wales. The study is relying on s251 of the NHS Act 2006, for the flow of data out of NHS Digital. The application was previously considered on the 13th September 2018 where IGARD had deferred making a recommendation. NHS Digital noted that section 1 (Abstract) stated that the next Health Research Authority Confidentiality Advisory Group (HRA CAG) annual review date was the 12th July 2022, however advised that this was incorrect, and confirmed that this would be updated to correctly state December 2022. **Discussion:** IGARD welcomed the application and noted the importance of the valuable study, in particular the two gene mutations and the younger age group of breast cancer patient being studied. In addition, IGARD noted and commended the applicant on the excellent yielded benefits achieved to date, as outlined in section 5(d) (Benefits) (iii) (Yielded Benefits) of the application.

	IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 13th September 2018. IGARD noted that the application had been updated to reflect all the previous deferral points. IGARD noted the verbal update from NHS Digital in respect of the HRA CAG annual review date, and supported the update to section 1 to reflect the correct date for the review. IGARD noted that some of the historical HRA CAG documentation was missing from the meeting pack provided prior to the meeting, and suggested that if the applicant was unable to locate the HRA CAG documentation, that they request a duplicate copy from HRA CAG. IGARD asked that any subsequent documentation received by NHS Digital be uploaded to NHS Digital's customer relationships management (CRM) system for future reference. IGARD queried if HRA CAG had been informed of the data controllership amendment, i.e. removing University Hospital Southampton NHS Foundation Trust as a Data Controller; and noting that this was unclear within the application and supporting documentation, asked that section 1 and section 5 (Purpose / Methods / Outputs) were updated with confirmation that HRA CAG had been informed. IGARD queried when the 20-year follow-up commenced, noting that the s251 Annual Review dated the 29th October 2021 stated "*Patients who were recruited to the POSH study were informed that the study would monitor outcomes for 20 years which means the final endpoint will be reached in January 2028 (last patient was recruited in January 2008)*."; version 6 of the patient information sheet stated "*The study plans to follow 3,000 women over 20 years*"; and the applicants response to HRA CAG (date of the letter not specified) stated that recruitment started in January 2000 suggesting follow up will exceed 20 years for some of the participants. IGARD asked that confirmation was provided in section 1 and section 5 of HRA CAG's interpretation of when the 20-year follow-up commenced. IGARD queried the reference in section 5(a) (Objective for Processing) to the University Hospital Southampton NHS Foundation Trust having *"…**tasked**…"* the University of Southampton; and asked that section 5(a) was updated, to state that whilst the University Hospital Southampton NHS Foundation Trust was the trial sponsor, they will **not** be carrying out any data controllership activities. **Separate to this application:** IGARD suggested that NHS Digital update their internal processes, to ensure that applications reflect that where sponsors are not carrying out data controllership activities, this was addressed in section 1 and section 5 of the application as a matter of course. IGARD suggested that the applicant may wish to update their protocol and transparency materials, as may be relevant, to reflect recent updates / amendments to the study. 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 (Privacy Notice), that a UK General Data Protection Regulation (UK GDPR) compliant, publicly accessible transparency notice was maintained throughout the life of the agreement. IGARD suggested that relevant updates were made to the privacy notice, to reflect the recent data controllership changes. IGARD noted the significant amount of funding for the study from AstraZeneca, and although the application was currently not for any commercial purpose, suggested that NHS Digital keep this aspect of the application under review and in line with NHS Digital DARS Standard for Commercial Purpose.

	Outcome: recommendation to approve The following amendments were requested. 1. In respect of HRA CAG: a) To provide confirmation in section 1 and section 5 that HRA CAG have been informed of the data controllership amendment. b) To provide confirmation in section 1 and section 5 what HRA CAG's interpretation is, of when the 20-year follow-up commences. c) To update section 1 with the correct HRA CAG annual review date (as per the verbal update from NHS Digital). 2. To update section 5(a) to state that whilst the University Hospital Southampton NHS Foundation Trust is the trial sponsor, they will **not** be carrying out any data controllership activities. The following advice was given: 1. IGARD suggested that the applicant may wish to update their protocol and transparency materials, as may be relevant, to reflect recent updates / amendments to the study. 2. IGARD noted that some of the historical HRA CAG documentation was missing, and suggested that if the applicant was unable to locate this that they could request a duplicate copy from HRA CAG, and upload to NHS CRM system for future reference. 3. 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 relevant updates were made to the privacy notice, to reflect the recent data controllership changes. **Separate to this application:** IGARD suggested that NHS Digital update their internal processes, to ensure that applications reflect that where sponsors are not carrying out data controllership activities, this is addressed in section 1 and section 5 of the application as a matter of course.
3.5	University of Sheffield: NIHR programme grant: The Design, Development, Commissioning and Evaluation of Patient Focused Vascular Services (Presenter: Denise Pine) NIC-16274-J8H5T-v4.4 **Application:** This was an extension application to permit the holding and processing of pseudonymised Civil Registration (Deaths) - Secondary Care Cut, Hospital Episode Statistics Admitted Patient Care (HES APC), HES Critical Care, HES Outpatients and HES:Civil Registration (Deaths) bridge. The purpose of the application is for a study looking at the design, development, commissioning and evaluation of vascular services in England. The programme had four workstreams: **1)** The identification of current service arrangements and analysis of Hospital Episode Statistics (HES); **2)** The identification and development of outcome measures; **3)** The evaluation of non-health service attributes; and 4) The development of vascular service models. The main results of the programme grant were published in 2021, however, the scope of the programme was widened, to include a 'Stream B - Post-Programme Grant'. The scope for this stream was defined as *"For researchers to develop and enhance the quality and value of an*

	existing or ongoing Programme Grant for Applied Research (PGfAR) award. Applications for such PDGs are only permitted from applicants whose PGfAR contracts are finishing within 12 months or have finished in the past 18 months.". NHS Digital noted that the s261 of the Health and Social Care Act 2012 was cited in the application as the legal basis for NHS Digital's dissemination of the data, however advised that this would need updating as per process to also state the s261 subsection. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 18th October 2018. IGARD noted the verbal update from NHS Digital, in respect of the s261 legal basis for NHS Digital's dissemination, and that that this would need updating, to also state the subsection of s261 of the Health and Social Care Act 2012. IGARD supported the update to section 3 (Datasets Held / Requested) with the most appropriate s261 subsection, in line with the latest advice from NHS Digital's Privacy, Transparency & Ethics (PTE). IGARD noted that section 7 (Ethics Approval) stated *"Ethics approval is not required because no flow of confidential data is included"*; however queried this, noting that a supporting document had been provided confirming that local institutional ethics had been obtained for the study. IGARD asked that the public facing section 5(a) (Objective for Processing) and section 7 were updated to reflect that there was local institutional ethics approval for the study. **Separate to this application:** IGARD noted that section 7 was not always clear that local institutional ethics has been received, and suggested that NHS Digital review their internal processes to determine if this can be accurately reflected within section 7 of the application. As section 5 forms NHS Digital's data uses register, IGARD asked that section 5 (Purpose / Methods / Outputs) was amended, to ensure that all acronyms upon first use be defined and further explained if the meaning was not self-evident, for example *"VSGBI"*. **Outcome:** recommendation to approve The following amendments were requested 1. To update section 3 with the legal basis for NHS Digital to disseminate data with the relevant subsection of s261 in line with the latest advice from NHS Digital's Privacy, Transparency & Ethics (PTE). 2. As section 5 forms NHS Digital's data uses register, to amend section 5(a) throughout, to ensure acronyms be defined upon first use, for example *"VSGBI"*. 3. To update section 5(a) and section 7 to reflect that there is local institutional ethics approval for the study. **Separate to this application:** IGARD noted that section 7 is not always clear that local institutional ethics has been received, and suggested that NHS Digital review their internal processes to determine if this can be accurately reflected within section 7 of the application.
4	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). *No items discussed*
5	Oversight & Assurance

	IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. Due to the volume and complexity of applications at today's meeting, IGARD were unable to review any Data Access Request Service (DARS) applications as part of their oversight and assurance role. The NHS Digital SIRO attended IGARD to discuss the IG release register. It was agreed that the NHS Digital SIRO would review the IG release register process that had been previously agreed in Spring 2020 and come back to IGARD in due course with an update, noting that it was also agreed that IGARD would not review any further IG Release Registers (from June 2022) until that feedback had been provided to IGARD. The NHS Digital SIRO would review the feedback provided on the IG release registers by IGARD for the period March 2020 to May 2022 and come back to IGARD in due course with any feedback or response. IGARD noted that the NHS Digital webpage excel spreadsheet had now been updated for the period March 2020 to April 2022: NHS Digital Data Uses Register - NHS Digital. IGARD noted that May 2022 appeared to be outstanding, following them returning their comments on the May 2022 release register on 1st July 2022.
6	COVID-19 update *No items discussed*
7 **7.1**	AOB: NHS Digital Transition (Presenter: Liz Gaffney) Following discussions at the IGARD meetings on the 28th July 2022 and the 4th August 2022, NHS Digital's Head of Data Access, Data Access Request Service (DARS), attended the meeting, to provide an update on the ongoing work within NHS Digital in respect of preparation for the transition of NHS Digital into NHS England. The Head of DARS attended IGARD to update members following the previous week's discussion on the current applications in the system, the predicted applications coming into the DARS service, and the proposed assurance process. The updated documentation provided was discussed in detail and IGARD made a number of verbal high-level comments on the proposals put forward. IGARD noted that other members not in attendance at today's BAU meeting may have further comments to make as the process moved forward. There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 05/08/22

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

NIC Reference	Applicant	IGARD meeting date	Recommendation conditions as set at IGARD meeting	IGARD minutes stated that conditions should be agreed by:	Conditions agreed as being met in the updated application by:	Notes of out of committee review (inc. any changes)
None						

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

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

Liaison Financial Service and Cloud storage:

- None

Optum Health Solutions UK Limited Class Actions:

- None

Graphnet Class Actions:

- None

Appendix B

GPES Data for Pandemic Planning and Research – Profession Advisory Group

Record of feedback: Wednesday, 27th April 2022

Application & application version number: IG6117 Record Level Therapeutics **Organisation name: Oxford University** **Profession Advisory Group Agenda item: 2**
PAG support the purpose of the data use subject to normal DARS assurance and governance processes being followed. For clarity the profession assume this will follow the normal DARS process. PAG note that type 1's are included in the at risk list but not in the list enriched by the GDPPR dataset. PAG assume this study cannot occur in the NHS Digital TRE. If a DARS application is submitted and the fundamental principles above are met, PAG do not need to see the application at a future PAG meeting.

Attendees	**Role**	**Organisation**
Jonathan Osborn	Deputy Chair, Caldicott Guardian	NHS Digital
Amir Mehrkar	GP, Clinical Researcher	RCGP
Mark Coley	Deputy IT Policy Lead	BMA
Liz Gaffney	Director, Data Access	NHS Digital
Pam Soorma	Secretariat	NHS Digital
Florence Geut	Secretariat (observer)	NHS Digital
Simone Chung	Analytical Section Head	NHS Digital
Rahima Oliver	Principal Information Assurance Specialist	NHS Digital