Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 6 October 2022

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member / Co-Deputy IGARD Chair
Maria Clark	Lay Member
Prof. Nicola Fear	Specialist Academic Member (Items 1 to 3.1, 3.3 to 7.1)
Kirsty Irvine	IGARD Chair
Dr. Geoffrey Schrecker	Specialist GP Member (Items 3.1 to 3.2)
IGARD MEMBERS NOT IN ATTENDANCE:	
Dr. Robert French	Specialist Academic / Statistician Member
Dr. Imran Khan	Specialist GP Member / Co-Deputy IGARD Chair
Dr. Maurice Smith	Specialist GP Member
Jenny Westaway	Lay Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Vicky Byrne-Watts	Data Access Request Services (DARS) (**SAT Observer**: item 3.4)
Dave Cronin	Data Access Request Services (DARS) (**SAT Observer**: items 3.2 to 3.3)
Duncan Easton	Data Access Request Services (DARS) (**SAT Observer**: item 3.1)
Mujiba Ejaz	Data Access Request Services (DARS) (Item 3.5)
James Gray	Digi-Trials (Item 3.1)
Dickie Langley	Privacy, Transparency, Ethics and Legal (PTEL) (Item 7.1)
Madeline Laughton	Data Access Request Services (DARS) (**Observer**: items 3.1 - 3.3)
Karen Myers	IGARD Secretariat
Dr. Jonathan Osborn	Deputy Caldicott Guardian (Observer: item 3.1)
Tania Palmariellodiviney	Data Access Request Services (DARS) (**SAT Observer**: item 3.5)
Aisha Powell	Data Access Request Services (DARS) (Item 3.3)

Charlotte Skinner	Data Access Request Services (DARS) (Item 3.4)
Anna Weaver	Data Access Request Services (DARS) (Item 3.2)
Vicki Williams	IGARD Secretariat
***SAT** – Senior Approval Team (DARS)	

1	**Declaration of interests:** There were no declarations of interest. **Review of previous minutes and actions:** The minutes of the 29th September 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: R1 (D09) - Data support to COVID-19 RCT (RECOVERY) (Presenter: James Gray) NIC-365354-R3M0Q-v9.4 **Application:** This was a renewal application to permit the holding and processing of identifiable Cancer Registration Data, Civil Registration (Deaths), COVID-19 Hospitalization in England Surveillance System (CHESS) (now called *"SARI Watch"*), COVID-19 Second Generation Surveillance System (SGSS), Covid-19 UK Non-hospital Antigen Testing Results (pillar 2), Demographics, Electronic Prescribing and Medicines Administration (EPMA) data in Secondary Care for COVID-19, GPES Data for Pandemic Planning and Research (COVID-19) (GDPPR), Hospital Episode Statistics Admitted Patient Care (HES APC), HES Critical Care, Medicines dispensed in Primary Care (NHSBSA data), SUS plus - Admitted Patient Care (beta version); and pseudonymised Emergency Care Data Set (ECDS), COVID-19 Vaccination Status and HES-ID to MPS-ID HES Admitted Patient Care. It was also an amendment application to **1)** extend the data sharing agreement (DSA) expiry date to the 5th October 2025; **2)** the addition of Trial Arm Parts J, K and L for Sotrovimab (a monoclonal antibody treatment against the spike protein), Molnupiravir (an antiviral treatment) and Paxlovid (an antiviral treatment) respectively; **3)** the continuation of data drops, albeit with reduced frequency from September 2022 (or in some cases stopping the data drops completely); **4)** the addition of a regular drop of Demographics data; **5)** the sub-licence special condition amendment in section 10 - sub-licencees may now have an access agreement with University of Oxford which reflects the term of this DSA (i.e. previously 1 year and now 3 years max). The Randomised Evaluation of COVid-19 thERapY (RECOVERY) trial aims to compare different treatments that may be useful for patients with COVID-19, that have been

	recommended by an expert panel that advises the Chief Medical Officer in England. This trial allows reliable assessment of the effects of multiple different treatments (including re-purposed and novel drugs) on major outcomes in COVID-19. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD meetings on the 11th June 2020, 30th July 2020, 12th November 2020, 26th August 2021 and 14th October 2021. It was also discussed as part of the 'applications progressed via NHS Digital's SIRO Precedent route' on the 27th January 2022 and the 23rd June 2022. IGARD noted that aspects of this application had been previously seen at the IGARD – NHS Digital COVID-19 Response meetings on the 21st April 2020, 28th April 2020, 5th May 2020, 12th May 2020, 19th May 2020, 7th July 2020, 21st July 2020, 22nd September 2020, 1st December 2020, 26th January 2021, 28th September 2021 and 5th October 2021. IGARD noted that they had reviewed an early version of the consent materials in March 2020 and had provided a paper with suggestions and comments to NHS Digital. IGARD noted that this application had been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 4th June 2020 *(notes from that meeting had been attached to the IGARD minutes from the 11th June 2020)*; and the 25th August 2021 *(notes from that meeting had been attached to the IGARD minutes from the 26th August 2021)*; and the 20th July 2022 (please see appendix B). IGARD welcomed the application and noted the national and global importance of the trial. IGARD noted and commended the applicant on the excellent yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits), that were an exemplar of good practice, detailing the extremely valuable trial benefits to the UK and worldwide and that they could be provided to other applicants as an example. IGARD expressed concern that the previous comments made, in respect of the consent for the trial, did not appear to have been taken in the manner intended; for example, previous versions of the application had proceeded via NHS Digital's SIRO Precedent approval route without NHS Digital's Senior Information Risk Owner (SIRO) being notified of the issues raised by IGARD. At the meeting on the 14th October 2021, IGARD had noted that Research Ethics Committee (REC) approval was in place, however, advised that it was unclear if the applicant had advised REC regarding the proposed onward sharing of data, and that this may be beyond the scope of the original participant consent and REC approval. IGARD reiterated their previous point that the applicant update the REC about the onward sharing of data and that if the REC wished to update the support, that the positive support was appropriately documented for future reference. IGARD noted that in response to the advice previously given, section 1 (Abstract) of the application stated that the applicant had contacted the Director of Approvals Service at the Health Research Authority; which IGARD noted was not what they had previously advised in respect of contacting the original REC. IGARD again reiterated the original advice provided. IGARD noted that at the meeting on the 14th October 2021, they had queried the statement in section 5(a) (Objective for Processing) that *"NHS Digital waive the right to audit the regulator or manufacturer of treatment(s) evaluated in the RECOVERY trial."*; and queried if this was a contractual arrangement between NHS Digital and the University of Oxford. IGARD were advised by NHS Digital that a Data Sharing Agreement (DSA) had already been signed by the manufacturer(s) with the University of Oxford, and due to the pace and urgency of the trial it

	had been assessed by NHS Digital that as the data flowing to the manufacturer was 'anonymous in context', the need for an audit was considered low risk. IGARD had suggested that NHS Digital considered their policy position on this going forward, noting the audit requirement in NHS Digital's DARS Standard for Sublicensing and Onward Sharing of Data, and asked that section 5(a) was updated to reflect that NHS Digital's policy decision to waive the right to audit was under review. IGARD also noted that in this version of the application, the SIRO has agreed to reinstate the statement in 5(a) *"NHS Digital waive the right to audit the regulator or manufacturer of treatment(s) evaluated in the RECOVERY trial"*. IGARD therefore noted the significant risk to NHS Digital in respect of public trust; and the lack of further information supporting this statement, for example, why this policy decision had been taken by NHS Digital and how the University of Oxford would manage the use of the data by the manufacturers. IGARD queried who had oversight on the access to, and onward sharing of, the data; for example, was this the responsibility of The Trial Steering Committee, discussed at the meeting on the 14th October 2021; and asked that the public facing section 5(a) that forms NHS Digital's data uses register, was updated with clarification. IGARD noted that as part of the communication between NHS Digital and PAG following the PAG meeting on the 20th July 2022, PAG had advised that "*It would also be helpful to understand if best practice guidelines exist regarding the sharing of data with manufactures [sic] (as part of safety studies) that encourage a log to be kept of what data and volumes (in summary), have been shared and when"*. IGARD noted and supported the advice / query raised by PAG and noted a risk to NHS Digital that if there were best practice guidelines that existed regarding the sharing of data with manufacturers, then NHS Digital should take them into consideration. IGARD noted that some of the information within section 5(a) was not reflective of the current status of the COVID-19 pandemic, including, but not limited to, the statement *"Given the high mortality rate among patients hospitalised with acute COVID-19…"*, which would have been relevant to a previous version of this application. IGARD therefore asked that section 5(a) was reviewed throughout, and update as appropriate to ensure this reflected the current status of the COVID-19 pandemic. IGARD queried the content of the paragraph in section 5(a) that stated *"Quarterly Demographics data is being requested for the purpose of…"*; and asked that this was amended to simplify the language in a manner suitable for a lay reader. IGARD noted the references in section 5(b) (Processing Activities) to *"Public Health Scotland (PHS)"*; and noting that PHS were not currently involved with any aspect of the trial or part of this application at the current time, asked that all references to *"PHS"* were removed. IGARD applauded the applicant for following previous IGARD advice and consulting with the patient and public involvement and engagement (PPIE) group / cohort members. IGARD noted the reference to some PPIE in section 1, however noting that this was not public facing, asked that section 5(a) which forms NHS Digital's data uses register was updated to provide details of any PPIE carried out to date; or that an indicative plan was provided of future PPIE activity. The HRA guidance on Public Involvement is a useful guide. IGARD noted that the COVID-19 datasets in the DSA, for example the COVID-19 Hospitalization in England Surveillance System (CHESS) (now called *"SARI Watch"*) and COVID-19 Vaccination Status datasets, were restricted to COVID-19 related research only; and asked that in line with NHS Digital DARS Standard for Special Conditions that a special

	condition outlining any restrictions was inserted in section 6 (Special Conditions), i.e. processing must be for the purpose of COVID-19 related research **only**. IGARD asked that a special condition was inserted in section 6, that, where practicable, outputs cite the source of the data as *"this work uses data provided by patients and collected by the NHS as part of their care and support"* (use MY data - our data citation project). IGARD noted in section 10 (Sub-Licensing), section 5 and section 6 that the term(s) of the sub-license had been aligned with the term of the 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; due to the high-profile nature of the application and complexity related to onward sharing. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 5(a) to clarify who has oversight on access to, and onward sharing of, the data. 2. To review section 5(a) and update as appropriate to ensure this reflects the current status of the COVID-19 pandemic, for example, the narrative about current mortality rates. 3. To amend section 5(a) to simplify the *"Quarterly Demographics data"* paragraph in language suitable for a lay reader. 4. To remove reference(s) to *"Public Health Scotland"* from section 5(b). 5. In respect of PPIE: a) To update section 5 to provide details of any PPIE carried out to date; or b) To provide an indicative plan of future PPIE activity. The HRA guidance on Public Involvement is a useful guide. 6. In respect of section 6 and in line with NHS Digital DARS Standard for Special Conditions: a) To insert a special condition in section 6 outlining the restrictions on the COVID-19 datasets, i.e. processing must be for the purpose of COVID-19 related research **only;** and, b) To insert a special condition in section 6, that, where practicable, outputs cite the source of the data as *"this work uses data provided by patients and collected by the NHS as part of their care and support"*, in line with the NHS Digital DARS Standard for Special Conditions. The following advice was given: 1. IGARD expressed concern that the previous comments made, in respect of the consent for the trial, did not appear to have been taken in the manner intended; for example, previous versions of the application had proceeded via NHS Digital's SIRO Precedent approval route without NHS Digital's SIRO being notified of the issues raised. 2. IGARD reiterated advice from the 14th October 2021, that the applicant update the relevant REC about the onward sharing of data. 3. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the high-profile nature of the application and complexity related to onward sharing.

	4. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the high-profile nature of the application and complexity related to onward sharing. **Significant Risk Area:** NHS Digital waiving its rights to audit manufacturers in the RECOVERY trial. **Risk Area:** In response to the PAG point raised, if best practice guidelines exist regarding the sharing of data with manufacturers, NHS Digital should take them into consideration.
3.2	University of Warwick: PreFIT trial (Prevention of Falls Injury Trial) (Presenter: Anna Weaver) NIC-302792-X4T6B-v4.4 **Application:** This was an extension application to permit the holding and processing of pseudonymised Hospital Episode Statistics Admitted Patient Care (HES APC) and HES Accident & Emergency (A&E) data. It was also an amendment application to permit the retention of data for ten years for archiving purposes in line with University of Warwick policy for clinical trial data retention. The purpose of the application was for a large complex intervention trial, to investigate alternative strategies to prevent falls and fractures in older adults. The applicant was involved with earlier research that identified gaps in evidence in this area; thus leading to a grant award to investigate alternative interventions to prevent falls: **1)** advice alone, versus **2)** exercise; versus **3)** multifactorial falls prevention (MFFP) intervention in older adults. The aim of the trial was to identify which falls prevention intervention were the most clinically effective and cost-effective, on outcomes of falls and fractures, in adults aged over 70 years. The trial is the largest trial ever conducted on community-based fall prevention on outcomes of fractures. The study cohort consisted of 9,803 consented participants; selected from 63 GPs throughout five regions in England and included people aged 70 years or older, male, female, and who lived in the community. NHS Digital advised IGARD that section 5(a) (Objective for Processing) contained a number of references to *"General Data Protection Regulation (GDPR)"*, and that this would need updating to correctly refer to the **UK** GDPR. NHS Digital noted that prior to the meeting, an IGARD member had raised a query in respect of point ten on the University of Warwick's published Research Data Management Policy, that stated *"Data deemed to be of interest to future research, including data that substantiate research findings, will normally be offered for deposit in an appropriate external data service or repository and/or a Warwick repository"*. IGARD had queried whether the data was purely being archived in case the original findings were challenged; or, if there was a possibility of future research by researchers at the University or elsewhere; and whether the funder had any requirements in this regard. NHS Digital advised IGARD that the applicant had confirmed that the data was only being held for the purpose of any future challenges, and that the data would not be processed / shared further. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the Data Access Advisory Group (DAAG) (IGARD's predecessor) meeting on the 13th August 2015; and at the IGARD meetings on the 24th August 2017 and 28th September 2017. IGARD noted the verbal update from NHS Digital in response to the queries raised in advance of the meeting, relating to what purposes were covered under 'archiving'. IGARD queried why the data was required for archiving if many future queries could be answered using existing

	outputs containing aggregated data with small numbers suppressed (what further clarification could be sought from the archived data). NHS Digital advised that further clarification would be sought from the applicant. IGARD confirmed that they were of the view that the **most recent** consent materials provided the appropriate legal gateway and were broadly compatible with the processing outlined in the application. IGARD noted the verbal update from NHS Digital in respect of the updated to section 5(a) to correctly refer to *"**UK** GDPR"*; and supported the proposed update. IGARD noted the second sentence in section 5(a) that stated *"The University of Warwick requires access to NHS Digital data for the purpose of the following clinical trial"*; and asked that this public facing section that forms NHS Digital's data uses register was amended to be clear that the clinical trial was now complete. In addition, IGARD also asked that for transparency, section 5(a) was updated with further clarity as to what has happened, and what will happen under the archiving arrangement. IGARD noted the information in section 5(d) (Benefits) (ii) ((Expected Measurable Benefits to Health and / or Social Care) relating to the updates to the National Institute for Health and Care Excellence (NICE) guidelines in 2024; and noting that the rest of the application was silent on this point; asked that section 5 (Purpose / Methods / Outputs) was updated throughout to clarify if and how the NICE guidelines have been, or will be, influenced by the outcome of this research. IGARD noted the information in section 1 (Abstract) that referred to this version of the application being structured on a draft template and that consideration was sought for a future DARS Archiving Standard. IGARD advised that any discussion on a draft template or DARS Arching Standard would need to be discussed separately to this application and suggested that an agenda item be included at a future IGARD meeting. IGARD asked that to avoid any future misunderstanding, all references to an archiving template or DARS Archiving Standard were removed from section 1. **Separate to this application:** Noting the ongoing work within NHS Digital in respect of designing a template for *"archiving"* applications and a new DARS Archiving Standard, IGARD suggested that NHS Digital may wish to consider a number of key elements for the template and DARS Archiving Standard, including, but not limited to: retaining the original purpose section but topping and tailing to be clear the application was now for archiving; retaining the expected benefits which would enable the applicant to map these to the yielded benefits; and including a brief additional expected benefits with regard to the benefits of archiving, possibly using templated / standard wording. IGARD advised that they would be happy to discuss this at a future IGARD meeting. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of section 5(a) and in line with NHS Digital DARS Standard for Objective for Processing: a) To update section 5(a) to ensure "**UK** GDPR" is correctly referenced (as per the verbal update from NHS Digital). b) To amend the second sentence in section 5(a) to be clear that the clinical trial has now completed. c) To update section 5(a) to distinguish what has happened and will happen under this archiving arrangement.

	2. In respect of section 5(d) (iii) and in line with NHS Digital DARS Standard for Expected Measurable Benefits, to ensure that the yielded benefits align with: a) The original purpose of the study; and, b) The outputs in section 5(c); and. c) The expected benefits in section 5(d) (ii). 3. To update section 5 throughout to clarify if and how the NICE guidelines have been, or will be influenced by the outcome of this research. 4. To update section 1 to remove all references to a "template" and / or "standard" being used for this archiving DSA. 5. To update section 1 and section 5(a) with further clarification of the purpose for archiving and any future use of the archived data (as per the query raised in advance of the meeting). The following advice was given: 1. Applicant to confirm to NHS Digital that the proposed activities match what is permitted under this DSA. **Separate to this application:** Noting the ongoing work within NHS Digital in respect of designing a template for *"archiving"* applications, IGARD suggested that NHS Digital may wish to consider a number of points, including (but not limited to) not editing the expected benefits and developing specific "archiving" benefits. IGARD advised that they would be happy to discuss this at a future IGARD meeting.
3.3	Barts Health NHS Trust: Barts structural Interventional Registry (BSIR) (Presenter: Aisha Powell) NIC-496149-M6P7P-v0.4 **Application:** This was a new application for identifiable Civil Registration (Deaths) and Hospital Episode Statistics Admitted Patient Care (HES APC) data. Valvular heart disease (VHD) affects a significant proportion of the global population. With advances in technology, treatments and Barts Heath NHS Trust understanding of cardiac disease, Barts Heath NHS Trust can now treat VHD using new therapies; however, the trials that have introduced these therapies have strict inclusion and exclusion criteria, resulting in many patients being excluded. Consequently, there is a great deal of uncertainty about the safety and efficacy of treatments for many patient populations. Real-world evidence of treatments among patients with VHD is increasingly recognised as an important part of providing safety and efficacy data and improving the care that Barts Heath NHS Trust provide. The purpose of the application is for a study aiming to **1)** understand the impact of disease and treatments on the mortality of patients with valvular heart disease; **2)** to compare demographic and clinical characteristics, biomarkers, therapies, their complications on quality of life, hospitalisation and mortality among patients with valvular heart disease; and **3)** to validate simulations of procedures which have been undertaken in real patients and to correlate numerical results with retrospective clinical measurements. The overall study population is approximately 10,000 people; with patients largely elderly with a mean age of 75 years. The study is relying on s251 of the NHS Act 2006, for the flow of data out of NHS Digital. NHS Digital noted the statement in section 5(c) (Specific Outputs Expected) "*The Study aims to produce outputs from its work at the end of the first year of obtaining data from NHS Digital in June 2023"*; and advised IGARD that this would be updated with a more attainable deadline.

	Discussion: IGARD confirmed that they were of the view that the relevant s251 support was broadly compatible with the processing outlined in the application. IGARD suggested that if the applicant wishes to continue to expand the BSIR and add patients in the future, that the most appropriate way of doing this would be via a consent model. IGARD noted the verbal update from NHS Digital in respect of the update to the study output date; and supported the update to section 5(c) to amend this. IGARD queried the statistics provided in section 5(a) (Objective for Processing), for example *"…valvular heart disease is common affecting 1 in 2 adults in the UK…"*, and asked that this was updated to correctly align with the statistics referenced in the protocol provided as a supporting document, that VHD affects 1 in 2 adults **over** the age of 65 years. IGARD queried the statement in section 5(a) *"…Bart's Health provides care to a large population of ethnic minorities (of African and Asian heritage). These ethnicities are often less presented in clinical trials, making this study even more important"*; and asked that further information was provided in section 5(a) as to why certain ethnic minority groups were less represented in clinical trials. IGARD noted the reference in section 5 (Purpose / Methods / Outputs) to first person statements, for example *"I can confirm…"*; and asked that these were removed or updated as appropriate. IGARD noted a number of references in section 5 to *"literature"*, for example *"This study will add to that void in literature…"*; and asked that further clarification was provided as to what each reference to *"literature"* was specifically referring to. IGARD noted that not all of the objectives of the study would be achieved using NHS Digital data, for example, data from Bart's Heath NHS Trust may also be used; and asked that section 5(a) was updated to clarify this point. IGARD queried the statement in section 5(b) (Processing Activities) that *"…only persons with a valid GDPR will have access to this data…"*; and asked that this was amended with further clarification as to the meaning of this. IGARD noted the final paragraph in section 5(d) (Benefits) (ii) (Expected Measurable Benefits to Health and / or Social Care) that outlined an expected benefit of how Barts Heath NHS Trust hope to treat patients with valvular heart disease following conclusion of the study; and asked in line with NHS Digital DARS Standard for Expected Measurable Benefits that this was updated to also reflect the expected national **and** international benefits of the study. IGARD noted the patient and public involvement and engagement (PPIE) study previously undertaken by Bart's Heath NHS Trust, and the lessons that had been learnt from that study, however suggested that the applicant gave consideration to the ongoing study specific PPIE involvement for this application. The HRA guidance on Public Involvement is a useful guide. IGARD suggested that the PPIE group should be representative of the local community, and the population affected by VHD. IGARD advised that the applicant may wish to engage with the PPIE group in respect of a number of issues, including (but not limited to) the language used around the various participants of the study, the dissemination of outputs and any future consent model. IGARD noted that a supporting document had been provided as part of the meeting pack, that was an honorary contract request form for Queen Mary University of London. Noting that there was no mention within the application of honorary contracts and that this application did not cover those under honorary contracts, IGARD advised NHS Digital that they had not reviewed

	this document; and that an amendment to the DSA to include honorary contracts would need submitting by the applicant to NHS Digital as per due process. IGARD asked that for future reference, section 1 (Abstract) was updated to reflect this. IGARD queried the reference to *"substantive staff"* in section 5, and asked that this was updated with further clarification, elucidating that it would not encompass honorary staff. 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 complexity of the study and the scope for further PPIE, **Outcome:** recommendation to approve The following amendments were requested: 1. To update the study output date in section 5(c) (as per verbal update from NHS Digital). 2. To amend the VHD statistics in section 5(a) to align with VHD statistics referenced in the protocol, i.e. VHD affects 1 in 2 adults **over** the age of 65 years, not all adults. 3. To amend section 5 to remove / amend first person statements, for example *"I"*. 4. To provide further clarification in section 5 on the references to *"literature"*. 5. To provide clarification in section 5(a) as to why certain ethnic minority groups were less represented in clinical trials. 6. To update section 5(a) to clarify that not all objectives will be achieved using NHS Digital data. 7. To amend the reference in section 5(b) to *"valid GDPR"*. 8. To update section 5(d) (ii) in line with NHS Digital DARS Standard for Expected Measurable Benefits, to outline the national and international benefits of the study. 9. To update section 1 to clarify that IGARD have not assessed any honorary contracts as part of this review. 10. To update section 5 with further clarification on the reference to *"substantive staff"* elucidating that it would not encompass honorary staff. The following advice was given: 1. IGARD suggested that if the applicant wishes to continue to expand the Registry, and add patients in the future, that the most appropriate way of doing this would be via a consent model. 2. In respect of PPIE: a) IGARD noted the PPIE study, however suggested that the applicant give consideration to the ongoing study specific PPIE. The HRA guidance on Public Involvement is a useful guide. b) IGARD suggested that the PPIE group should be representative of the local community and population affected by VHD. c) IGARD advised that the applicant may wish to engage with the PPIE group in respect of a number of issues, including (but not limited to) the language used around the various participants of the study, the dissemination of outputs and any future consent model. 3. IGARD advised that they would wish to review this application when it comes up for renewal or extension, 4. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent,

3.4	Care Quality Commission (CQC): CQC agreement for HES, MHSDS, MSDS, CSDS and ECDS and associated datasets (Presenter: Charlotte Skinner) NIC-359603-D2Q6M-v9.8 **Application:** This was a renewal and extension application to permit the holding and processing of identifiable Civil Registration (Deaths) - Secondary Care Cut, Community Services Data Set (CSDS), Emergency Care Data Set (ECDS), HES: Civil Registration (Deaths) bridge, Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care(APC), HES Critical Care, HES Outpatients, Mental Health and Learning Disabilities Data Set (MHLDDS), Mental Health Services Data Set (MHSDS), Maternity Services Data Set (MSDS) v1.5; and pseudonymised HES-ID to MPS-ID HES A&E, HES-ID to MPS-ID HES APC and HES-ID to MPS-ID HES Outpatients. It was also an amendment to add monthly Mental Health Services Data Set (MHSDS) v5.0 data to the data sharing agreement (DSA). CQC's remit is to make sure health and social care services provide people with safe, effective, compassionate, high-quality care and CQC encourages them to improve. It does this through effective monitoring and inspection activity underpinned by an Intelligence insight programme that draws together risk and bench marking metrics at a core service level. The data directly influences risk and benchmarking models and helps determine both when inspections take place and where they should focus. They also help with CQC's statutory responsibility to monitor the use of the Mental Health Act. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the Data Access Advisory Group (DAAG) (IGARD's predecessor) meeting on the 8th September 2015, 27th September 2016, 25th October 2016; and at the IGARD meetings on the 1st June 2017, 4th July 2019, 7th May 2020 and 27th May 2021. IGARD noted the removal of the following statement in the applicant's draft Data Protection Impact Assessment (DPIA): *"NHS Digital, in turn, have their independent governance committee, IGARD (Independent Group Advising on the Release of Data) that considers all requests for the dissemination of confidential information. IGARD ensures that our applications meet sufficient governance obligations, have the necessary legal bases, and can fulfil minimum security requirements"*. To support the justification of this text removal, IGARD noted the following statement "*The removal of IGARD as a control has been taken on the recommendation of NHS Digital Applications team. It has been deemed as unnecessary to include in this DPIA and will cause delays to processing DSA applications with NHS Digital in the future"*. IGARD suggested NHS Digital liaise with the applicant to ensure that the draft DPIA was updated to reinstate the original information relating to IGARD, noting that current text was factually correct; and that in addition, the text be expanded to include the description of IGARD's remit, which extends to oversight of NHS Digital's Precedent route for minor amendments and in line with IGARD's published Terms of Reference. IGARD noted in section 1 (Abstract) that NHS Digital had asked the applicant to provide examples of the confidentiality clauses within the contracts of the non-substantive employees; and were advised by NHS Digital that, prior to the meeting, the applicant had provided a copy of a confidentiality statement contract, which NHS Digital shared with members in-meeting. IGARD asked that, following a quick review of the confidentiality statement contract shared in-meeting via screen sharing, the references to *"non-substantive employees (contractors)"* in section 5(a) (Objective for Processing) **and** section 5(b) (Processing Activities) of the

	application, were updated to clarify that these references were specifically referring to contractors who had signed the appropriate confidentiality statement contract. IGARD queried the reason why the applicant was requesting identifiable data and not pseudonymised data, and noting that this was not clear in the application, asked that for transparency, the public facing section 5(a) which forms NHS Digital's data uses register was updated with a justification for identifiable data. In addition, IGARD queried what data minimisation had been undertaken; and asked that written confirmation was provided in section 5(a) of the work undertaken by NHS Digital and the applicant to ensure that only the minimum amount of data, necessary for the processing, was flowing, in line with NHS Digital DARS standard for data minimisation. IGARD queried the statement in section 5(a) *"Future analyses using birth date, death date, and **unique restrictive intervention incident ID** from the MHSDS data set will support work related to mortality and for monitoring **Use Of Force Act 2018**"*; and asked that further clarification was provided on the meaning of this, in particular the reference to *"unique restrictive intervention incident ID"* and *"Use Of Force Act 2018*", in language suitable for a lay reader, and in line with NHS Digital DARS Standard for Objective for Processing. IGARD noted in section 5(d) (Benefits) (iii) (Yielded Benefits) that there had been a delay with identifying some of the yielded benefits, due to the COVID-19 pandemic; however, asked that this section was linked to the expected benefits in section 5(d) (ii) (Expected Measurable Benefits to Health and / or Social Care) and in line with the NHS Digital DARS Standard for Expected Measurable Benefits. IGARD noted that there was some text missing from section 11 (Charges) in their view of the application; and asked that this was reviewed by NHS Digital to ensure that the version of the DSA shared with the applicant contained the full text. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of the data requested: a) To update section 5(a) with a justification for requesting identifiable data; and, b) To provide written confirmation in section 5(a) of the work undertaken by NHS Digital and the applicant to ensure that only the minimum amount of data, necessary for the processing, is flowing, in line with NHS Digital DARS standard for data minimisation. 2. To provide further clarification in section 5(a) as to what is meant by *"unique restrictive intervention incident ID"* and *"Use Of Force Act 2018*". 3. In respect of the reference to "non-substantive employees (contractors)": a) To update section 5(a) to make clear that the reference to *"non-substantive employees (contractors)"* is referring to contractors who have signed the appropriate confidentiality statement contract. b) To update section 5(b) to make clear that the reference *to "non-substantive employees (contractors)"* is referring to contractors who have signed the appropriate confidentiality statement contract. 4. To update section 5(d) (iii) to link the delay with the yielded benefits to the expected benefits in section 5(d) (ii). 5. To update section 11 with the missing text. The following advice was given:

	1. IGARD suggested that NHS Digital liaise with the applicant to ensure that the DPIA is updated to reinstate information relating to IGARD; and to expand the description of IGARD's remit which extends to oversight of NHS Digital's Precedent route for minor amendments.
3.5	University of Cambridge: The EMBED Study: Early Markers for Breast Cancer Detection (Presenter: Mujiba Ejaz) NIC-602345-C6S4M-v0.15 **Application:** This was a new application for identifiable Cancer Registration Data; and pseudonymised Civil Registration (Deaths) data. The last few years have seen progress towards the ability to detect cancer minimally invasively using circulating tumour DNA (ctDNA); which is released into the blood from tumour cells and is now in widespread use in research studies of advanced disease and in clinics. Researchers have demonstrated the capability to monitor disease recurrence and study tumour evolution in a variety of cancer types; and a major advantage of ctDNA is that it may be applicable to a wide range of cancers. There are significant challenges in applying this approach to the detection of early disease however, particularly where the levels of ctDNA (and other markers) are expected to be very low, and in many cases will be below detection thresholds of current methodologies. Several recent studies have used a range of high-sensitivity sequencing-based methods and have been able to detect ctDNA in the plasma of 40% to 50% of stage I cancer patients. Despite increasingly powerful and expensive sequencing methodologies, detection of ctDNA in early-stage cancer patients has been limited. The purpose of the application, is for the EMBED study, to support the University of Cambridge's existing research into ctDNA; building on the existing resources of the Epidemiological Study of Familial Breast Cancer (EMBRACE) study (under a separate data sharing agreement (DSA) NIC-302473-K6R0Z); which is a prospective cohort study which has recruited and followed individuals with mutations through clinical genetics centres in the UK since 1998 to facilitate the establishment of a new cohort of women at an increased risk of breast cancer. The aims of the EMBED study are: **1)** to further develop and use sensitive state-of-the art assays to detect small amounts of ctDNA, with increased sensitivity, in the blood of women with breast cancer and before current screen detection or clinical presentation; **2)** to retrospectively measure ctDNA in blood samples prospectively collected before cancer diagnosis; initially in the sample most proximal to cancer diagnosis and if successful in annual samples from the years before; and **3)** to assess the value of new methods for early detection. There are two consented cohorts: **Cohort 1** is expected to comprise of approximately 2,700 women at recruitment end (currently 1449), consisting of participants who have a strong family inherited history of breast cancer, have an increased lifetime risk of developing the disease and are hence undergoing more intensive (annual) screening; and **Cohort 2** is expected to comprise of 200 women age 50 to 69 at recruitment end (currently 43), consisting of participants who have been re-called to the Cambridge Breast Unit due to abnormal mammograms. These women will have attended mammographic screening as part of the NHS breast screening programme, but an abnormality in the image has been detected which requires further investigation. **Discussion:** IGARD welcomed the application and noted the importance of the potentially ground-breaking research. IGARD confirmed that they were of the view that the **most recent** consent materials provided the appropriate legal gateway and were broadly compatible with the processing outlined in the

	application. IGARD noted and thanked NHS Digital for providing a review of the consent materials, which supported the review of the application by Members. IGARD noted that the study was jointly sponsored by Cambridge University Hospitals NHS Foundation Trust; and that there was a statement in section 1 (Abstract) that the applicant had confirmed to NHS Digital that this organisation did not have responsibility for determining the purposes and means of the processing of NHS Digital data, nor could they access or process the NHS Digital data required. IGARD asked that an express statement was added to section 1 explaining that, notwithstanding the NHS Health Research Authority guidance, which states *"It is the sponsor who determines what data is collected for the research study through the protocol, case report form and/or structured data fields in a database. The sponsor therefore acts as the controller in relation to the research data."*; in this instance, it had been determined that Cambridge University Hospitals NHS Foundation Trust was **not** a joint Data Controller. IGARD noted that mammograms were not always easily accessible for patients of certain age groups; and asked that, for transparency, section 5(a) (Objective for Processing) was updated with information on the inclusion and exclusion criteria for mammograms, for example, to remove any suggestion that mammograms were more easily accessible for those aged 30 to 49, when this was not correct, the NHS advises that the first invitation for a mammogram is between the ages of 50 and 53. IGARD noted complex / technical information within section 5(a), and asked that although this was relevant, a simple introductory paragraph was also included at the beginning of section 5(a) in language suitable for a lay reader, in line with NHS Digital DARS Standard for Objective for Processing. IGARD suggested that section 5(c) Specific Outputs Expected, be updated, where appropriate, to remove reference to "*hope*", and instead use a word such as "*will*" when the output is within the control of the applicant (for example, making interim reports available to the funder and listing progress on the EMBED website). IGARD noted that there was some text missing from section 11 (Charges) in their view of the application; and asked that this was reviewed by NHS Digital to ensure that the version of the DSA shared with the applicant contained the full text. IGARD suggested that, if not already happening, the applicant involve relevant patient and public involvement and engagement (PPIE) groups for the lifecycle of the project. The HRA guidance on Public Involvement is a useful guide. IGARD noted and commended NHS Digital for providing advice to the applicant in respect of a newsletter to participants, and the subsequent work by the applicant in sending a newsletter to all participants notifying them of the change in responsibility in respect of PHE transferring confidential patient information, to NHS Digital; which had also been uploaded to the study website. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 1 to clarify that although Cambridge University Hospitals NHS Foundation Trust are a study sponsor, they are not a joint Data Controller. 2. To update section 5 to provide further clarity on the inclusion and exclusion criteria for mammograms. 3. To add a simple introductory paragraph Section 5(a) in language suitable for a lay reader, in line with NHS Digital DARS Standard for Objective for Processing.

	4. To update section 5(c) to use "*will*", rather than "*hope*", where the action is within the control of the applicant. 5. To update section 11 with the missing text. The following advice was given: 1. IGARD suggested that, if not already happening, the applicant involve relevant public and patient groups for the lifecycle of the project. The HRA guidance on Public Involvement is a useful guide.
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).
4.1	ICB Template (No Presenter) IGARD noted that the three first of type ICB applications had previously been presented at the IGARD meetings on the 30th June (NIC-615960-G7W1L), 21st July (NIC-616046-J1Q0N) and the 28th July (NIC-615958-F7Q7Z). In addition, some high-level comments were fed back to NHS Digital on the ICB template at the IGARD meeting on the 28th July 2022. IGARD noted that they had received further iterations of the draft ICB template from NHS Digital, which included version 11 reflecting amendments following previous comments made by IGARD; version 13, reflecting amendments following comments from NHS Digital's Deputy SIRO; and NIC-615890-Q8N9R-v0.2 (NHS Hertfordshire, and West Essex ICB), which had been provided as an example of a live DSA that had used an earlier version of the ICB template. IGARD thanked NHS Digital for providing the updated ICB template for information, and confirmed that they had no further comments to make. IGARD advised that NIC-615890-Q8N9R-v0.2 did not appear to contain the version 13 wording, and suggested that NHS Digital discuss how they will manage those applications that may contain wording from older versions of the ICB template, and update as and when appropriate.
4.2	University College London (UCL): MR623 – National Mother and Child cohort (No Presenter) NIC-148128-815J1-v3.6 The purpose of the application was for The National Mother and Child Cohort, which was established in 1995 as an extension to the National Surveillance of HIV in Pregnancy and Childhood (NSHPC) that collects data on pregnancies in women living with HIV and their infants. IGARD noted that this application was last reviewed at the IGARD business as usual meeting on the 4th August 2022 where IGARD had recommended for approval with conditions, amendments and advice. IGARD noted that on the 26th September 2022 NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had agreed to authorise an extension to the Data Sharing Agreement (DSA) until the 31st March 2023. IGARD noted that that the IGARD Chair would contact the Deputy SIRO out of committee in respect of this application progressing via the NHS Digital's SIRO Precedent route.

4.3	Institute of Cancer Research: MR1211 - UK Genetic Prostate Cancer Study (No Presenter) NIC-148118-VCXW9-v3.2 The purpose of this application was for a study aiming to find genetic changes which are associated with prostate cancer risk. If the study can find alterations in genes that increase the chances of getting prostate cancer, it may be possible in the future to use this knowledge: to 1) screen other family members to see if they are also at a higher risk of developing prostate cancer; and 2) to develop new prostate cancer treatments for the future. IGARD noted that this application was last reviewed by the Data Access Advisory Group (DAAG) *(IGARD's predecessor)* in 2011. IGARD noted that on the 26th September 2022 NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had agreed to authorise an extension to the Data Sharing Agreement (DSA) until mid-November 2022. IGARD noted and thanked NHS Digital for the written update and asked that the next iteration of the DSA should be brought to a future IGARD meeting. IGARD noted and thanked NHS Digital for the written update and asked that the next iteration of the DSA should be brought to a future IGARD meeting before mid-November.
4.4	NHS England (Quarry House): Access to HES via NHS Digital online portal - NIC-09042-L9M1K (No Presenter) NIC-18798-V2J6C-v10.1 The purpose of this application was to support NHS England, who have a wide spectrum of responsibilities to support health and social care within England, to access data via the NHS Digital Portal, to support the following areas; commissioning, policy, finance and economic development. IGARD noted that this application was last reviewed by the Data Access Advisory Group (DAAG) (IGARD's predecessor) on the 29th November 2016; where DAAG had recommended for approval with conditions and amendments. IGARD noted that on the 26th September 2022 NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had agreed to authorise an extension to the Data Sharing Agreement (DSA) until mid-November 2022. IGARD noted and thanked NHS Digital for the written update and asked that the next iteration of the DSA should be brought to a future IGARD meeting, in line with the new process outlined to NHS Digital via email on the 22nd August 2022, and as discussed at the IGARD meeting on the 8th September 2022, whereby NHS England applications were being brought to IGARD for advice only and would then proceed under NHS Digital's SIRO precedent if appropriate. IGARD also advised that as per the new process, they would welcome the attendance of an NHS England colleague, if available, to discuss this application.
5	Oversight & Assurance IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. Due to the volume and complexity of applications at today's meeting, IGARD were unable to review any Data Access Request Service (DARS) applications as part of their oversight and assurance role.

	The NHS Digital SIRO was currently reviewing the feedback provided on the IG release registers by IGARD for the period March 2020 to May 2022, alongside the process of review, and as discussed on the 11th August 2022, would come back to IGARD in due course with any feedback or response. IGARD noted that the NHS Digital webpage Excel spreadsheet had now been updated for the period March 2020 to April 2022: NHS Digital Data Uses Register - NHS Digital. IGARD noted that May 2022 appeared to be outstanding, following them returning their comments on the May 2022 release register on 1st July 2022.
6	COVID-19 update *No items discussed*
7 **7.1**	AOB: Information Governance A member of NHS Digital's Privacy, Transparency and Ethics, attended the meeting to provide a brief update / overview of ongoing information governance (IG) work. IGARD noted and thanked NHS Digital for the verbal update and looked forward to further relevant updates at a future IGARD meeting. 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 30/09/22

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 20 July 2022

Application & application version number: DARS-NIC-365354-R3M0Q-v9.2 **Organisation name: University of Oxford** **Profession Advisory Group Agenda item: 2**
PAG supports the amendment. PAG would like clarification as to why the research cannot be conducted within the Oxford analysis environment to prevent further dissemination to Edinburgh. PAG would like to clarify if consent continues to be the basis by which ISARIC data is being linked (in terms of common law duty of confidence).

Attendees	**Role**	**Organisation**
Jonathan Osborn	Deputy Chair, Caldicott Guardian	NHS Digital
Amir Mehrkar	GP, Clinical Researcher	RCGP
Mark Coley	Deputy IT Policy Lead	BMA
Florence Geut	Secretariat	NHS Digital
Duncan Easton	Senior Approvals Team	NHS Digital
Frances Perry	Data Services	NHS Digital
Laura Evans	Data Services	NHS Digital