Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 12 January 2023

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member / Co-Deputy IGARD Chair
Prof. Nicola Fear	Specialist Academic Member
Kirsty Irvine	IGARD Chair
Dr. Geoffrey Schrecker	Specialist GP Member
Jenny Westaway	Lay Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Maria Clark	Lay Member
Dr. Robert French	Specialist Academic / Statistician Member
Dr. Imran Khan	Specialist GP Member / Co-Deputy IGARD Chair
Dr. Maurice Smith	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Michael Ball	Data Access Request Services (DARS) (**Presenter**: item 3.7)
Vicky Byrne-Watts	Data Access Request Services (DARS SAT) (**SAT Observer**: item 3.7)
Garry Coleman	Associate Director / Senior Information Risk Owner (SIRO) (**Observer**: item 3.7)
Dave Cronin	Data Access Request Services (DARS SAT) (**SAT Observer**: item 3.6)
Louise Dunn	Data Access Request Services (DARS SAT) (**SAT Observer**: items 3.1 to 3.2)
Elizabeth Flaherty	Data Access Request Services (**Observer**: items 3.1 to 3.4)
Dan Goodwin	Data Access Request Services (DARS) (**Presenter**: items 3.4 to 3.5)
Karen Myers	IGARD Secretariat Team
Frances Perry	Digi-Trials (**Presenter**: item 3.1)
Charlotte Skinner	Data Access Request Services (DARS) (**Presenter:** item 3.2)

Kimberley Watson	Data Access Request Services (DARS SAT) (**SAT Observer**: items 3.3 to 3.5)
Anna Weaver	Data Access Request Services (DARS) (**Presenter**: item 3.3)
Vicki Williams	IGARD Secretariat Team
Clare Wright	Data Access Request Services (DARS) (**Presenter:** item 3.6)
***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 15th December 2022 IGARD meeting were reviewed out of committee by IGARD following conclusion of the meeting, and subject to a number of minor changes 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: Frances Perry) NIC-365354-R3M0Q-v10.2 **Application:** This was an amendment application to **1)** add a sub-study to section 5(a); **2)** to add Public Health Scotland (PHS) as a Data Processor, as they will be facilitating analyses for a RECOVERY trial sub-study; **3)** to add Atos IT Services UK Limited as a Data Processor, as they host and supply the IT infrastructure on which the PHS secure network sits and the data will be processed through on route to the National Safe Haven; **4)** to add the University of Edinburgh as a Data Processor. The University of Edinburgh's supercomputing centre (the UK's leading centre of Supercomputing and Data Science expertise) operates the National Safe Haven for Public Health Scotland under a separate IT services agreement between PHS and University of Edinburgh and will store the resting data once linked. 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. The sub-study (amendment point 1) aims to further explore the clinical and biological effects of immunomodulatory therapies within the RECOVERY trial in order to: understand the full spectrum of host and pathogen risk factors which predict outcomes and modify the effects of immunomodulatory therapy in COVID-19; describe the long-term clinical effects of

	immunomodulatory therapy in COVID-19; and identify potential causal pathways through which the beneficial effects of immunomodulatory treatment for COVID-19 are mediated. **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, 14th October 2021 and 6th October 2022. 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 (*notes from that meeting had been attached to the IGARD minutes from the 6th October 2022*). IGARD welcomed the application and noted the national and global importance of the trial. IGARD noted that prior to the meeting, and following discussions with the applicant, NHS Digital had provided further supporting information, in respect of the movement of the NHS Digital data to PHS, and to ensure this was minimised. NHS Digital advised that following discussions with the applicant, it had been agreed that the methodology for the linkage proposed within the data sharing agreement (DSA) would be updated to reflect that **1)** the University of Oxford would **only** send RECOVERY Study ID and identifiers to PHS / electronic Data Research and Innovation Service (eDRIS) for linkage (not NHS Digital data); **2)** the eDRIS link and extract ISARIC4C data, to remove identifiers and add the resultant pseudonymised dataset to the National Safe Haven Trusted Research Environment (TRE); and **3)** the University of Oxford to upload to the TRE the RECOVERY extended analysis dataset only for those participants who feature in the ISARIC4C dataset as well, and undertake linkage between the two sets of data for analysis. IGARD noted the written update from NHS Digital and supported the relevant amendments to the application to reflect the revised information. IGARD queried the statement within the patient information sheet (PIS) dated the 7th April 2020 *"All information about you and your health will be kept private. The only people allowed to look at the information will be the doctors who are running the study, the staff at the study coordinating centre, and the regulatory authorities who check that the study is being carried out correctly. A privacy notice is on the study website".* IGARD noted that individuals outside the study coordinating centre would be permitted to access the data, for example, the data flow diagram provided as a supporting document, stated that PHS eDRIS would receive identifiable NHS Digital data. IGARD therefore queried how the transfer of information was compatible with the RECOVERY Trial PIS. NHS Digital advised that PHS eDRIS were receiving identifiers, in order to link and extract study participant data, to provide the study team with a RECOVERY extended analysis dataset. NHS Digital also advised that access to NHS Digital data would be restricted to named researchers approved by the University of

	Oxford RECOVERY team, who were all substantive employees of the University of Oxford, and system administrators only; and that an appropriate Data Controller / Data Processor agreement was in place between the University of Oxford and PHS prior to any data transfer. IGARD noted the verbal update from NHS Digital, however asked that the transparency materials were reviewed, to ensure they do **not** give the incorrect impression of the data being solely held by the University of Oxford. IGARD also asked that the transparency materials, including, but not limited to, the privacy notice, were reviewed and updated as appropriate, to clarify **all** aspects of the processing taking place outside the University of Oxford, to satisfy the UK General Data Protection Regulation (UK GDPR), in terms of alignment with the consent, maintaining the trust of the cohort and the Caldicott Principle 8 of *"no surprises"*. IGARD noted that the transparency materials do not make reference to the onward sharing of data with manufacturers; and asked that the transparency materials were updated as appropriate. IGARD suggested that, for transparency, the applicant provided an update to the study cohort, for example, in respect of the sub-study, via newsletters or other regular communication(s). IGARD noted the special condition in section 6 (Special Conditions) relating to the 'use of COVID-19 datasets'; and asked that this was updated further in line with NHS Digital DARS Standard for Special Conditions to specifically list the datasets that this special condition related to; and in alignment with the datasets requested in section 3 (Datasets Held / Requested). IGARD also noted that the special condition in section 6 relating to the 'use of COVID-19 datasets', stated *"…which are expected to be reviewed annually with the first review anticipated in **December 2022**"*; and noting that this date had now passed, asked that the review date was updated as appropriate. IGARD noted the excellent yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits); however, asked that in line with NHS Digital DARS Standard for Expected Measurable Benefits, further information was provided, to reflect the latest usage and impact statistics. IGARD queried whether the existing Research Ethics Committee (REC) approval also covered the amendment to the application in respect of the additional sub-study; and noting that this was currently unclear, asked that for clarification / future reference, section 1 (Abstract) was updated with confirmation. 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 application, the expiring timeframes in the consent, the international importance and the magnitude of the study. **Outcome:** recommendation to approve The following amendments were requested: 1. To update the application with the revised methodology for the linkage proposed. 2. In respect of transparency: a) To review the transparency materials to ensure they do **not** give the incorrect impression of the data being solely held by the University of Oxford. b) To update the transparency materials, as appropriate, to clarify **all** aspects of the processing taking place outside the University of Oxford

	c) To update the transparency materials as appropriate to refer to the onward sharing of data with manufacturers. 3. In respect of the special conditions: a) To update the 'use of COVID-19 datasets special condition in section 6, to list the specific datasets. b) To amend the review date in the 'use of COVID-19 datasets special condition in section 6. 4. To update the yielded benefits in section 5(d) (iii) to reflect the latest usage and impact statistics, in line with NHS Digital DARS Standard for Expected Measurable Benefits. 5. To update section 1 with confirmation that the amended activities are covered under the existing REC support. The following advice was given: 1. IGARD suggested that, for transparency, the applicant update the study cohort via newsletters or other regular communications. 2. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the complexity of the application, the expiring timeframes in the consent, the international importance and the magnitude of the study. 3. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the complexity of the application, the expiring timeframes in the consent, the international importance and the magnitude of the study.
3.2	London School of Hygiene and Tropical Medicine: (MR1355) The MANCHESTER and (MR1016) ARTISTIC COHORTS (HPV and Cervical Cancer) (Presenter: Charlotte Skinner) NIC-58603-S6Z1B-v6.8 **Application:** This was a renewal and extension application to permit the holding and processing of identifiable Cancer Registration Data, Civil Registrations (Death), Demographics, Medical Research Information Service (MRIS) - Cause of Death Report, MRIS - Cohort Event Notification Report and MRIS - Flagging Current Status Report. It was also an amendment application to address the NHS Digital DARS Standard for Expected Measurable Benefits and NHS Digital DARS Standard for Transparency. Human papillomavirus (HPV) infection is known to cause cervical cancer, but it is a relatively common infection, especially in young women, and usually clears without any symptoms or long-lasting effects. There are different strains (known as genotypes) of HPV, and some are more likely to cause pre-cancer or cancer than others. The purpose of the application is to follow-up existing cohorts in order to determine long-term risks associated with HPV infection. It is hoped that the research can help the national screening committee decide whether changes to national screening policy are necessary. A balance must be achieved so that most of the women with abnormal cells are identified but unnecessary referral and anxiety for women are minimised. Questions this research aims to influence are: **1)** is it safe to leave a longer interval between screening tests when a woman has a negative HPV test? **2)** what follow-up tests should be done in women who test positive for HPV? The study can evaluate cytology, genotyping (identifying the strain of HPV) or new testing methods; and **3)** what age is it safe to stop screening? Future risks can be determined in women who tested negative for HPV at various ages. There are two cohorts who serve as the subjects for the data linkage requested in this data sharing agreement (DSA). The first cohort is the Manchester Study Cohort, and the second is

	the '(A Randomised Trial In Screening To Improve Cytology' (ARTISTIC) Trial Cohort. The cohorts have previously been merged for administrative purposes. The cohort for this follow-up study is restricted to the 49,549 women recruited between 1989-1993. The study is relying on s251 of the NHS Act 2006. NHS Digital advised IGARD, that the Data Protection Act (DPA) registration expiry date for the London School of Hygiene and Tropical Medicine in section 1(b) (Data Controller(s)) was incorrect, and would need updating from the 22nd December 2022, to correctly state the 22nd December **2023**. **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 16th August 2016; and the IGARD meetings on the 31st October 2019 and the 5th March 2020. IGARD noted that this application had previously been discussed as part of the 'returning applications' section of the IGARD meeting on the 20th January 2022. IGARD noted the verbal update from NHS Digital in respect of the incorrect DPA registration expiry date for the London School of Hygiene and Tropical Medicine in section 1(b); and supported the update to the 22nd December **2023**. IGARD noted the Health Research Authority Confidentiality Advisory Group (HRA CAG) condition of support, in relation to engagement with the cohort; and that prior to the meeting, an IGARD member had submitted a query to NHS Digital, in respect of the statement in section 1 (Abstract) *"As part of a CAG application for a new project, the applicant has recently run a PPI activity to test processing confidential patient data without consent".* IGARD noted that the PPIE referred to was for a different project, and that the HRA CAG application for this new project, may not yet have been finalised. IGARD therefore asked that the applicant updated HRA CAG on the PPIE activities undertaken and how they fulfil the relevant conditions of support for the activity in **this** study. IGARD noted that when the application was reviewed on the 31st October 2019, they had *"…welcomed the applicant's engagement with the wider community including the team's aim to work with Jo's Cervical Cancer Trust and / or the Eve Appeal,* ***but suggested that a more concrete plan for the involvement of these two cervical cancer charities*** *be included with the steps outlined for engagement with the cohort and wider community…".* IGARD also noted that when the application was reviewed on the 5th March 2020, they had discussed the applicant's transparency arrangements, and stated *"This should also include (but not limited to) updating their Privacy Notice; and in light of the fact that the applicant is not in contact with the cohort, engaging with relevant local women's health charities who may be representative of the cohort. The detailed plan should also* ***include a timeframe for engaging with such charities*** *and providing updated transparency information materials and incorporate the view of the women's health charity/ies of how to communicate with the cohort".* IGARD noted that subsequent engagement with the relevant charities appeared to be limited, and asked that, in line with the HRA CAG support, the applicant considered other ways of raising awareness for those cohort members unaware that they are in the study, for example, promoting it on the research pages of relevant charities. IGARD queried whether the s251 support covered the Manchester study cohort, noting that the supporting documents were not explicit on this point; and asked that the applicant confirmed with HRA CAG that there was a clear evidentiary trail, that documented the s251 support for the Manchester study cohort / limb of the study; and that any additional written

	evidence on this query was uploaded to NHS Digital's customer relationships management (CRM) system for future reference. IGARD queried the statement in the HRA CAG letter of support dated the 19th May 2015 *"Patients would be flagged for 20 years"*; and asked that, for transparency, section 1 and section 5(a) (Objective for Processing) were updated, with confirmation of when the twenty years run from / to. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 1 to reflect the updated DSA expiry date of 22nd December 2023 (as per the verbal update from NHS Digital). 2. In respect of the HRA CAG support / liaison: a) To update HRA CAG on the PPIE activities undertaken and how they fulfil the relevant conditions of support. b) In line with the HRA CAG support, to consider other ways of raising awareness for those cohort members unaware they are in the study, for example, promoting it on the research pages of relevant charities. c) To confirm with HRA CAG that there is a clear evidentiary trail, documenting the s251 support for the Manchester study cohort / limb of the study; and d) To upload any additional written evidence of the s251 support for the Manchester study cohort / limb of the study to NHS Digital's CRM system for future reference. 3. In respect of the 20-year retention of the data: a) To update section 1 with confirmation of when the 20 years run from / to; and, b) To update section 5(a) with confirmation of when the 20 years run from / to.
3.3	<u>Imperial College London: The Power Of Connections: Mapping the Behaviour of Health Care Networks (Presenter: Anna Weaver) NIC-67398-K2Y3T-v4.9</u> **Application:** This was a renewal application to permit the holding and processing of pseudonymised Hospital Episode Statistics (HES) Accident and Emergency (A&E), HES Admitted Patient Care (HES APC) and HES Outpatients. It was also an amendment application to 1) extend the scope of approval to create new databases that aim to provide information on the flow of patients between hospitals; 2) to update the processing activities to include remote access to the current storage location for substantive employees of the data controller; and 3) to request the Emergency Care Dataset (ECDS) dataset. The purpose of the application is to extend the scope of approval and to use data previously disseminated, alongside newly requested data, to create databases that aim to provide information on the flow of patients between hospitals; by investigating the extent to which providers of hospital care in England are connected to one another, and the extent to which clinical care for patients is fragmented between providers. The databases created using the NHS Digital data will allow Imperial College London to ensure outputs closely reflect current practice, in a healthcare environment where care pathways and networks are constantly evolving. The data will also allow the study to analyse how health networks have evolved over the periods of data received and explore reasons for this; and will also allow the study to better understand current trends in health networks and predict future trends more accurately which is important for health policy.

	NHS Digital advised IGARD that the application submitted for review stated that it was for a renewal and amendment; however, advised that it had also been submitted for an extension, and confirmed that section 1 (Abstract) would be updated to reflect this. **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 31st January 2017; and the IGARD meeting on the 1st November 2018. IGARD noted the verbal update from NHS Digital, in respect of the application being submitted for a renewal, amendment **and extension**; and supported the update to section 1 to accurately reflect this. IGARD queried the statement in section 7 (Ethics Approval) *"Ethics approval is not required because this study does not include the flow of confidential data"*; and the statement in the protocol provided as a supporting document *"The Principal Investigator has obtained approval from the Head of Department and favourable opinion from Imperial College Research Ethics Committee (ICREC)"*. IGARD asked that section 7 was updated to reflect that **HRA** Ethics was **not** required as there was no confidential flow of data; and, to reflect that **University** ethics support had been obtained. IGARD asked that the University ethics support was uploaded to NHS Digital's customer relationships management (CRM) system for future reference. IGARD queried the yielded benefits within section 5(d) (Benefits) (iii) (Yielded Benefits), and noted that some of the information provided were outputs and not yielded benefits, asked that these were moved to correctly sit in section 5(c) (Specific Outputs Expected); in line with NHS Digital DARS Standard for Expected Outcomes. IGARD also asked that the yielded benefits in section 5(d) (iii) (not moved to section 5(c)) were updated further, to provide clarification of the **specific** yielded benefits accrued to date in line with NHS Digital DARS Standard for Expected Measurable Benefits. IGARD noted that a number of "papers" were referred to in section 5(d) (iii), for example *"Defining Integrated Care Systems Through Patient Data From Referral Networks in the English National Health Service: A Graph-Based Clustering Study"*; and asked that further clarity was provided outlining what the papers were contributing to, in respect of yielded benefits, and in line with NHS Digital DARS Standard for Expected Measurable Benefits. IGARD queried the references in section 5 (Purpose / Methods / Outputs) to *"patient sharing network"*; and noting that it was unclear exactly what this was, asked that further clarity was provided in section 5. IGARD wished to draw to the attention of the applicant that the existing data sharing agreement (DSA) does **not** permit sharing of / access to the databases to anyone other than ICL staff. IGARD suggested that any future plans to allow such access or sharing of the databases should be explored now; and that the relevant amendments were made to the application as per process and in line with NHS Digital DARS Standards. IGARD noted that prior to the meeting, an IGARD member had queried what NHS Digital's current policy was on enabling remote access to data within DSAs, i.e. was this permitted as standard; or if not, what criteria was applied. IGARD noted that NHS Digital had advised that NHS Digital DARS Standard for processing activities stated *"[This section of the application shall provide detail on the following:] Detail of how the data is being accessed by anyone accessing the data (secure environment/system access/**remote access** etc)"* and the (now retired) NHS Digital DARS Standard for Processing and Storage Location had stated *"Remote access 1. Where the processing of the data is only carried out at the storage location and only*

	a screen view of the data is provided to the remote device then ***the remote device location need not be listed as a processing location*** *2. In all other situations all locations must be explicitly stated within the agreement 3.* ***In both cases data can only be accessed/viewed within the stated territory of use****".* IGARD noted and thanked NHS Digital for the update, however, and separate to this application**, asked that** NHS Digital examined how the existing Data Sharing Framework Contract (DSFC) addresses the requirements and controls for remote access. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 1 to reflect that the application had been submitted for a renewal, amendment **and extension** (as per the verbal update from NHS Digital). 2. In respect of the ethical support: a) To update section 7 to reflect that **HRA** Ethics is **not** required as there is no confidential flow of data; and, b) To update section 7 to reflect that University ethics support has been obtained; and. c) To upload the University ethics support to NHS Digital's CRM system for future reference. 3. In respect of the Yielded Benefits in section 5(d) (iii): a) To remove any specific outputs from section 5(d) (iii) and move to section 5(c). b) To update section 5(d) (iii) to clarify the specific yielded benefits accrued to date in line with NHS Digital DARS Standard for Expected Measurable Benefits; and c) To clarify what the papers referred to, are contributing to in terms of yielded benefits. 4. To provide further clarity in section 5 on the references to 'patient sharing network'. The following advice was given: 1. IGARD wished to draw to the attention of the applicant that the existing DSA does **not** permit sharing of / access to the databases to anyone other than ICL staff. IGARD suggested that any future plans to allow such access or sharing of the databases, should be explored now; and that the relevant amendments are made to the application as per process, and in line with NHS Digital DARS Standards. **Separate to this application:** NHS Digital to examine how the existing DSFC addresses the requirements and controls for remote access.
3.4	The University of Manchester: MR1135 - Manchester self-harm project - Mortality and suicide after self-harm- a cohort study (Presenter: Dan Goodwin) NIC-147916-DPQ3Q-v6.3 **Application:** This was a renewal and extension application to permit the holding and processing of identifiable Civil Registrations (Death), Demographics, Medical Research Information Service (MRIS) – Bespoke, MRIS - Cause of Death Report, MRIS - Cohort Event Notification Report, MRIS - Flagging Current Status Report and MRIS - Members and Postings Report. It was also an amendment application to **1)** apply National Data Opt-out exemption to all disseminations going forward following support from the Health Research Authority Confidentiality Advisory Group (HRA CAG); and **2)** following an amendment to the scope of support under s251, the University of Manchester wish to expand the cohort of those who present to hospital* due to Self-Harm between 2000 to 2018 and 2000 to 2021. *(*Restricted to three general hospitals within the Manchester area: Manchester Royal Infirmary (Manchester*

	University NHS Foundation Trust), Wythenshawe Hospital (Manchester University NHS Foundation Trust) and North Manchester General Hospital (Northern Care Alliance NHS Group)). The purpose of the application is for the Manchester Self-Harm project (MaSH) and the Multicentre Study of Self-Harm in England; the core remit of these projects is to monitor self-harm presentations to general hospitals and to investigate associated risks, such as death by suicide. MaSH was established in 1997 as a stand-alone self-harm monitoring study. At the time, people who attended hospital for self-harm accounted for some of the highest rates of people being admitted to hospital beds in English NHS Trusts, and investigation of this group was of great interest. The success of the study led to a number of extensions beyond the original funding period that enabled the study to continuously collect data on self-harm in the City of Manchester from 1997 onwards. From April 2012 MaSH has been funded directly from the Department of Health and Social Care budget, under the umbrella of the Multicentre Study of Self-harm in England. However, MaSH continues to be a separate project with a separate identity and continues to audit self-harm in Manchester and to conduct studies and produce outputs focused on the Manchester-based cohort. The University of Manchester also collaborates with the other sites in the Multicentre Study. The Multicentre Study of Self-harm in England is a collaboration between three separate self-harm monitoring projects based in different areas of England (University of Oxford, the University of Manchester, and Derbyshire Healthcare NHS Foundation Trust), that conducts studies on the epidemiology, causes, clinical management, outcome and prevention of self-harm. By combining data on self-harm from different areas, the Multicentre Study of Self-harm in England provides more representative and reliable data on self-harm in England than could be achieved by each site individually. The Multicentre Study contributes to the National Suicide Prevention Strategy for England (2002, 2012, 2017, 2019), and prevention and service initiatives, including NICE guidance on self-harm. This application is linked to **NIC-147907-MLK7R** (Derbyshire Healthcare NHS Foundation Trust) and **NIC-147957-4444C** (University of Oxford). The study is relying on s251 of the NHS Act 2006, for the flow of data out of NHS Digital. NHS Digital advised IGARD that section 1 (Abstract) would need updating to reflect that **NIC-147907-MLK7R** had been reviewed at the IGARD meeting on the 12th January 2023 (Item 3.5). NHS Digital noted that section 1 would also need updating to remove reference to the latest identifiers being removed, when referring to the data minimisation for Demographics and Civil Registrations (Death); noting that this was not relevant. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD meetings on the 18th October 2018 and the 22nd November 2018. IGARD noted that this application had previously been discussed as part of the 'returning applications' section of the IGARD meeting on the 28th November 2019. IGARD noted that **NIC-147907-MLK7R** (item 3.5) was previously discussed at the IGARD meeting on the 22nd November 2018; and as part of the 'returning applications' section of the IGARD meeting on the 3rd February 2022.

	IGARD noted that **NIC-147957-4444C** was previously discussed at the IGARD meetings on the 1st November 2018 and the 22nd November 2018. IGARD noted the verbal update from NHS Digital in respect of the review history for **NIC-147907-MLK7R**, and supported the update to section 1 to state that this application had been reviewed at the IGARD meeting on the 12th January 2023 (Item 3.5). IGARD also noted the verbal update from NHS Digital, in respect of the reference to the latest identifiers being removed, when referring to the data minimisation for Demographics and Civil Registrations (Death); and supported the update to section 1. IGARD noted the special condition in section 6 (Special Conditions), in relation to the HRA CAG support; and asked that this was amended, in line with NHS Digital DARS Standard for Special Conditions to reflect that the HRA CAG support for the revised HRA CAG application must have been accepted and provided by the 7th June 2023, otherwise no further processing was permitted. IGARD queried whether the existing HRA CAG support was for both the surveillance **and** the research limbs of the study, and asked that the applicant confirmed this with HRA CAG; and that section 5 (Purpose / Methods / Outputs) of the application was updated accordingly; and that any written confirmation relating to this query was uploaded to NHS Digital's customer relationships management (CRM) system for future reference. IGARD noted that prior to the meeting, an IGARD member had submitted a query in respect of a statement on the study website that stated *"You have the right to opt out of having your personal data processed by The Manchester Self-Harm Project for tasks in the public interest. **Any request to opt out must be made on grounds relating to your particular situation**";* and asked that further clarification was provided on this, noting that an individual does **not** have to provide any *"grounds"* for opting out. NHS Digital advised that this clause related to the fact that not all individuals appear on the database and therefore there needed to be a reason to suspect they were included in the database, to enable the study team, to identify and remove an individual. NHS Digital advised that the applicant had agreed that this wording was misleading and had agreed to update the wording to make it clear that no *"grounds"* would need to be provided when requesting the removal of data by an individual. IGARD noted the verbal update from NHS Digital and supported the update to the study website by the applicant. IGARD queried why Derbyshire Healthcare NHS Foundation Trust **and** University of Oxford were **not** considered Data Processors, noting that both receive data from The University of Manchester; and noting that this was not clear, asked that a justification was provided in section 1 and section 5(a) (Objective for Processing), in line with NHS Digital DARS Standard for Data Processors. IGARD noted that Greater Manchester Mental Health Trust was referred to in the data flow diagram provided as a supporting document; and noting that no reference was made to them within the application, asked that section 5 was updated to clarify the role of Greater Manchester Mental Health Trust or its data. IGARD queried the statement in section 5(a) *"The University of Manchester envisions there are **minimal** moral or ethical issues raised by this proposed dissemination…"*; and asked that the reference to *"…minimal…"*; was removed, as this was incorrect. IGARD also asked that section 5(a) was updated with further clarity as to how the moral and ethical issues of the study had been considered, including, but not limited to, whether University ethical approval has been provided. If University ethical approval had been

	obtained, IGARD asked that written evidence was uploaded to NHS Digital's CRM system for future reference. IGARD also asked that if University ethical approval had been obtained, that written confirmation was provided that the ethics committee had been updated on the non-application of the NDO (as per amendment point 1). 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. IGARD queried the statement in section 5(d) (ii) ((Expected Measurable Benefits to Health and / or Social Care) *"…is key to understanding the **burden** of self-harm…"*; and asked that this was amended to more sensitively refer to the *"…**impact** of self-harm…"*. 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 issues raised on the HRA CAG and ethical supports. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 1 with further information on the review history of NIC-147907-MLK7R (as per the verbal update from NHS Digital). 2. To update section 1 to remove reference to the latest identifiers being removed for Demographics and Civil Registrations (Death) (as per the verbal update from NHS Digital). 3. To provide a justification in section 1 and section 5(a) as to why Derbyshire Healthcare NHS Foundation Trust **and** University of Oxford are not considered Data Processors; in line with NHS Digital DARS Standard for Data Processors. 4. To clarify in section 5 the role of Greater Manchester Mental Health Trust or its data (as per the data flow diagram). 5. In respect of ethics: a) To amend section 5(a) to remove the reference to *"…minimal…"* . b) To clarify in section 5(a) how the moral and ethical issues have been considered; and, c) To clarify in section 5(a) if University ethical approval has been provided; and / or, d) If University ethical approval has been obtained, to upload written evidence to NHS Digital's CRM system for future reference; and, e) To provide written confirmation that the University ethics committee have been updated on the non-application of the NDO. 6. In respect of HRA CAG support: a) To amend the special condition in section 6, to reflect that the HRA CAG support for the revised HRA CAG application must have been accepted and provided by the 7th June 2023, otherwise no further processing is permitted. b) To clarify with HRA CAG that the existing s251 support is for both the surveillance **and** the research limbs; and, c) To clarify in section 5 that the existing s251 support is for both the surveillance **and** the research limbs; and, d) To upload any written confirmation from HRA CAG on to NHS Digital's CRM system for future reference. 7. To remove the reference to *"burden"* in section 5(d) and replace with *"impact"*.

	The following advice was given: 1. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the issues raised on the HRA CAG and ethical supports. 2. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the issues raised on the HRA CAG and ethical supports.
3.5	Derbyshire Healthcare NHS Foundation Trust: MR1142 - Self Harm Monitoring Project - Mortality Following Self-Harm (Presenter: Dan Goodwin) NIC-147907-MLK7R-v7.4 **Application:** This was a renewal and extension application to permit the holding and processing of identifiable Civil Registrations (Death), Demographics, MRIS - Cause of Death Report, MRIS - Cohort Event Notification Report, MRIS - Flagging Current Status Report and MRIS - Members and Postings Report; and pseudonymised Medical Research Information Service (MRIS) – Bespoke. It was also an amendment application to **1)** to remove special conditions section 6 to allow the processing of data; and **2)** to update the Purpose / Methods / Outputs in section 5 to meet all applicable NHS Digital DARS Standards. Since 1989 the South Derbyshire Liaison team (formerly named the deliberate self-harm team and then the Mental Health Liaison Team) of Derbyshire Healthcare NHS Foundation Trust based at the Royal Derby Hospital (formerly the Derby Royal Infirmary and Derby City General) have monitored self-harm attendances to the Emergency Department as part of everyday clinical practice. The aim of the Derby monitoring system is to: **1)** Monitor local self-harm and suicide numbers; **2)** examine the association between self-harm, suicide and other causes of premature death; and **3)** help inform service planning, policy development, local service provision, deliver training to clinical staff and local suicide prevention strategies. The purpose of the application is for the monitoring of self-harm attendances to general hospitals and the linkage with mortality data; the processing of the data therefore leads to increased knowledge and understanding around risk of premature death and effective clinical management for people who self-harm. The Multicentre Study of Self-harm in England is a collaboration between three separate self-harm monitoring projects based in different areas of England (University of Oxford, the University of Manchester, and Derbyshire Healthcare NHS Foundation Trust), that conducts studies on the epidemiology, causes, clinical management, outcome and prevention of self-harm. By combining data on self-harm from different areas, the Multicentre Study of Self-harm in England provides more representative and reliable data on self-harm in England than could be achieved by each site individually. The Multicentre Study contributes to the National Suicide Prevention Strategy for England (2002, 2012, 2017, 2019), and prevention and service initiatives, including NICE guidance on self-harm. This application is linked to **NIC-147916-DPQ3Q** (The University of Manchester) and **NIC-147957-4444C** (University of Oxford). The study is relying on s251 of the NHS Act 2006, for the flow of data out of NHS Digital. NHS Digital advised IGARD that section 1 (Abstract) would need updating, to refer to the HRA CAG annual review report in September 2022.

	NHS Digital also advised IGARD, that the NHS Digital data citation special condition in section 6 (Special Conditions), would need updating, to include the relevant quotation marks. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD meeting on the 22nd November 2018. IGARD noted that this application had previously been discussed as part of the 'returning applications' section of the IGARD meeting on the 3rd February 2022. IGARD noted that **NIC-147916-DPQ3Q** (item 3.4) was previously discussed at the IGARD meeting on the 18th October 2018 and the 22nd November 2018; and as part of the 'returning applications' section of the IGARD meeting on the 28th November 2019. IGARD noted that **NIC-147957-4444C** was previously discussed at the IGARD meetings on the 1st November 2018 and the 22nd November 2018. IGARD confirmed that they were of the view that the relevant s251 support was broadly compatible with the processing outlined in the application. IGARD noted and supported the verbal update from NHS Digital, in respect of the update to section 1, to make reference to the HRA CAG annual review report in September 2022. IGARD also noted and supported the update to the NHS Digital data citation special condition in section 6, to include the relevant quotation marks. IGARD queried whether any members of the cohort had used the study specific opt-out, and were advised by NHS Digital that one person had done so. IGARD noted the verbal update from NHS Digital and queried whether this indicated that few cohort members were aware of the study or whether cohort members were under the impression that the National Data Opt-out (NDO) would be sufficient and prevent their data from flowing. IGARD asked that further information was provided in section 5 (Purpose / Methods / Outputs), outlining the activities planned to increase awareness of the study specific opt-out to the cohort. IGARD suggested that if not already done so, the applicant advised HRA CAG if the patient study leaflet has **not** been updated in respect of the study website and the study specific opt-out. IGARD noted in section 7 (Ethics Approval) that ethics approval was in place, however noted that that the most recent ethical support appeared to have been obtained in 2006 and queried if more recent ethical support had been sought. IGARD asked that if more recent ethical support had been obtained, that written confirmation from this ethical review, was uploaded to NHS Digital's NHS Digital's customer relationships management (CRM) system for future reference. IGARD queried why the University of Manchester **and** University of Oxford were **not** considered Data Processors, and asked that a justification was provided in section 1 and section 5(a) (Objective for Processing), in line with NHS Digital DARS Standard for Data Processors. IGARD noted the statement in section 5(d) (Benefits) (iii) (Yielded Benefits) *"Derbyshire have also found through the **morality** data linkage…"*; and asked that this was updated to refer to *"…**mortality** data linkage…"*. **Outcome:** recommendation to approve The following amendments were requested: 1. To update the s251 information in section 1, to note the annual review report in September 2022 (as per the verbal update from NHS Digital).

	2. To amend the NHS Digital citation special condition in section 6, to include the relevant quotation marks (as per the verbal update from NHS Digital). 3. To upload the **most recent** ethical support written confirmation to NHS Digital's CRM system for future reference. 4. To provide further information in section 5 outlining the activities planned to increase awareness of the study specific opt-out. 5. To provide a justification in section 1 as to why the University of Manchester **and** University of Oxford are not considered Data Processors; in line with NHS Digital DARS Standard for Data Processors. 6. To remove the reference in section 5(d) to *"morality"* and replace with *"mortality"*. The following advice was given: 1. IGARD suggested that the applicant advised HRA CAG if the study leaflet has **not** been updated in respect of the study specific opt-out.
3.6	Epsom and St Helier University Hospitals NHS Trust: Maternal and fetal variables associated with term stillbirths (Presenter: Clare Wright) NIC-239092-Q9Q3X-v0.15 **Application:** This was a new application for pseudonymised Maternity Services Data Set (MSDS) v1.5 and Maternity Services Data Set (MSDS) v2. The purpose of the application is for a study aiming to improve outcomes for women and babies from black, Asian and minority ethnic (BAME) backgrounds. Previous studies have shown differences in stillbirth rates for women and babies from BAME backgrounds and differences in gestational age duration between different ethnic groups, as a possible contributor to term stillbirths. The study aims to add to the existing 'Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK' (MBRRACE-UK) work by looking specifically into stillbirths and identify risk factors cohort. The focus of the study is more precise than other dataset studies to enable informed decision-making processes by analyses of parameters that have not been addressed in other studies. **Discussion:** IGARD noted and commended the supporting information provided by NHS Digital for this application, in particular the application assessment process undertaken by NHS Digital, and detailed information outlining the discussions with the applicant, which supported the review of the application by members. IGARD noted that an honorary contract had been provided as a supporting document, for the clinician from an NHS Trust, to enable them to undertake data analysis on the study, within Epsom and St Helier University Hospitals NHS Trust. IGARD noted that the honorary contract had been signed by the individual, however had not been counter-signed by the employing body (the clinician's employing NHS Trust). IGARD therefore asked that written confirmation was provided that the honorary research fellow contract has been counter-signed by the employing body; and that the written confirmation was uploaded to NHS Digital's customer relationships management (CRM) system for future reference. IGARD queried the references in section 5(b) to *"…agents…"*; and asked that the second reference to *"agents"* was removed from section 5(b) as this was not necessary to include. IGARD noted the helpful information within the assessment form provided by NHS Digital as a supporting document, in relation to patient and public involvement and engagement (PPIE); and noting that the application was silent on the PPIE activities carried out to date, asked that for transparency, section 5 was updated as appropriate to include further information on PPIE.

	IGARD also suggested that the applicant undertakes ongoing study specific PPIE. The HRA guidance on Public Involvement is a useful guide. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of the honorary contract: a) To provide written confirmation that the honorary research fellow contract has been counter-signed by the employing body; and, b) To upload the written confirmation to NHS Digital's CRM system for future reference. 2. To remove the second reference to *"agents"* in section 5(b). 3. To update section 5 to provide details of any PPIE carried out to date. The following advice was given: 1. IGARD suggested that the applicant undertake ongoing study specific PPIE. The HRA guidance on Public Involvement is a useful guide.
3.7	NHS Lincolnshire Integrated Care Board (ICB): Lincolnshire Wearables Project - Consented (Presenter: Michael Ball) NIC-687867-Y7L9P-v0.2 **Application:** This was a new application for pseudonymised Secondary Use Services (SUS) for Commissioners dataset. The purpose of the application is to determine: *"If information about patient behaviour, conditions and events, captured from wearables and other smart technologies can predict demand for services, then providing these technologies to patients and using the data generated, will enable providers to pre-empt and redirect demand or design new services".* The hypothesis will be tested by deploying smart technologies with sensor-based wearables, software sensors using the camera on a smart phone or tablet, and web-based questionnaires to study data from the participants. This will then be linked to SUS data for these participants. Data scientists and researchers will perform data analysis and model development within the collaborative development environment with tools that manage the end-to-end process of analytics, analytics asset creation, deployment and support. The analytics will seek to understand whether the use of such technologies and the data gathered from them, can indeed provide useful information in predicting adverse healthcare events and therefore inform the transformation of health services to make interventions sooner to achieve better outcomes. The cohort consist of approximately 500 consented individuals. NHS Digital advised IGARD that points one to five of the consent review, provided as a supporting document, would be removed as they were not necessary. **Discussion:** 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 that, prior to the meeting, an IGARD member has raised a query with NHS Digital in respect of the data controllership, noting that the application stated that NHS Lincolnshire Integrated Care Board (ICB) were the **sole** Data Controller; and the consent form stated that the Chief Investigator was the Chief Medical Officer at Helicon Health. NHS Digital advised that as per the responsibilities set out in the contract between Philips Ltd and the ICB,

	the ICB is the sole Data Controller and the research team were Data Processors, which includes Helicon Health as a subcontractor to Philips Ltd. NHS Digital advised that the Chief Investigator has a formal relationship with the ICB by virtue of the contract, and was selected to undertake the role based on their specialist academic / clinical credentials and experience as being essential to perform the role. IGARD expressed surprise that the Chief Investigator was not, to some extent, determining the purpose and the means of processing. IGARD queried whether there were wider commercial benefits for Philips Healthcare or Helicon Health, noting that Chief Investigator is the Chief Medical Officer at Helicon Health; and noting that section 5(e) (Is the Purpose of this Application in Anyway Commercial) stated that there was *"no"* commercial purpose to the application. IGARD asked that further information was obtained from the applicant, on the wearables provided, and whether they were provided on a commercial arm's-length basis; **or** if there were any additional commercial benefits to the commercial partners; and that clarification was provided in section 5(a) (Objective for Processing) in line with NHS Digital DARS Standard for Objective for Processing. IGARD noted the statement in the protocol, provided as a supporting document "Each Commercial Partner was selected via an open and competitive procurement process across the EU, in-line with the requirements of the Public Contract Regulations; this approach and the procurement strategy were approved by NHS England prior to publication". IGARD asked that, for transparency, section 5(a) in line with NHS Digital DARS Standard for Objective for Processing and section 5(e) in line with NHS Digital DARS Standard for Commercial Purpose were updated to refer to the commercial partners appointed following procurement process as outlined in the protocol. IGARD noted the statement in section 5(a) outlining the role of the GPs *"…the GPs will be asked to select patients who meet the required selection criteria for the study from the information already available to them. GPs will then make the final decision on their patients' suitability for the study… If deemed suitable the GP Practice will send potential participants an Invitation Letter, a Participant Information Sheet, a Consent Form…"*. IGARD queried if the commercial partners had any involvement in terms of supporting the GPs to identify patients, including, but not limited to, a payment, practical support, payment in kind etc; and asked that for transparency, section 5(a) was updated with further clarification, in line with NHS Digital DARS Standard for Objective for Processing and section 5(e) in line with NHS Digital DARS Standard for Commercial Purpose. IGARD also asked if any other resources were used to undertake identifying patients, for example, Academic Health Science Networks (AHSN) or other research networks; and that clarification was provided in section 5(a). IGARD noted that the NHS Digital citation special condition had been added in section 6 (Special Conditions), however asked that this was updated to also include the relevant quotation marks and capitals, i.e. *"This work uses data provided by patients and collected by the NHS as part of their care and support"*. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of the commercial aspect of the application: a) To obtain further information on the wearables provided and whether they were provided on a commercial arm's-length basis; or if there were any additional

	commercial benefits to the commercial partners; and to update section 5(a) as appropriate. b) To update section 5(a) to refer to the commercial partners appointed following procurement process (protocol); and, c) To update section 5(e) to refer to the commercial partners appointed following procurement process (protocol); and, d) To update section 5(a) to clarify **any** involvement of the commercial partners in terms of supporting GPs to identify patients (payment/practical support/payment in kind); and, e) To update section 5(e) to clarify **any** involvement of the commercial partners in terms of supporting GPs to identify patients (payment/practical support/payment in kind) f) To update section 5(a) to clarify if any other resources were used to undertake identifying patients, for example, an AHSN. 2. To amend the NHS Digital citation special condition in section 6, to include the relevant quotation marks.
4	<u>Applications progressed / to be progressed via NHS Digital's SIRO Precedent route</u> Applications that have been progressed or will / may be progressed via NHS Digital's Precedent route, including the SIRO Precedent, and NHS Digital have notified IGARD in writing (via the Secretariat).
4.1	<u>University College London (UCL): SUMMIT Study: Cancer screening study with or without low-dose lung CT to validate a multi-cancer early detection test (Previously ODR1718_316) (No Presenter) NIC-656813-F4H5W-v1.3</u> The purpose of the application is for a prospective cohort study of approximately 13,000 participants from London, designed to investigate how cancer screening can be improved and delivered. The study will recruit individuals at high risk for cancer, especially lung cancer, due to significant smoking history. The study has two main aims: **1)** to develop and evaluate the performance of the GRAIL blood test for the detection of multiple cancer types and the identification of tissue of cancer origin; and **2)** to examine the performance and feasibility of delivering a low dose CT (LDCT) screening service for lung cancer to a high-risk population in London and the surrounding area. IGARD noted that this application was last reviewed at the IGARD business as usual meeting on the 10th November 2022; where, IGARD had recommended for approval with amendments and advice. It was also discussed under 'AOB' at the IGARD meeting on the 15th December 2022. IGARD noted that on the 19th December 2022 NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had approved authorisation for this application to progress via NHS Digital's SIRO Precedent route. 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.
4.2	<u>GRAIL Bio UK Ltd: GRAIL's SYMPLIFY Study Clinical Trial Outcomes Data Request (No Presenter) NIC-604851-W0M3S-v0.4</u>

	The purpose of the application, is to request access to pseudonymised record level data, linked against a cohort of individually consented patients recruited to 'SYMPLIFY', a study designed to assess GRAIL's Galleri multi-cancer early detection (MCED) test in individuals referred with signs and symptoms of cancer. The Primary objective of the study is to evaluate the performance of GRAIL's *"GALLERI"* MCED test for the detection of invasive cancer. The Secondary objectives of the study are to evaluate the: performance and yield of the MCED test by referral pathway (i.e. lung, upper Gastrointestinal (GI), lower GI, gynae, and Rapid Diagnostic Centres (RDC)) and cancer type and stage; and performance of the MCED test for the identification of cancer signal origin (CSO) by referral pathway. IGARD noted that this application was last reviewed at the IGARD business as usual meeting on the 13th January 2022; where, IGARD had recommended for approval for one-year, with conditions, amendments and advice. It was also discussed under 'AOB' at the IGARD meeting on the 15th December 2022. IGARD noted that on the 19th December 2022, NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had approved authorisation for this application to progress via NHS Digital's SIRO Precedent route. 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.
4.3	<u>University of Sheffield: A comparison of the effectiveness of different treatment regimens for pancreatic cancer using English cancer registry data (No Presenter) NIC-656862-L4M7T-v1.2</u> The purpose of the application is for a project, which aims to investigate whether or not English cancer registry data is sufficient for reliably comparing the effectiveness of different cancer treatments given in the NHS. This is an important first step in showing whether registry data can be relied upon to compare the effectiveness of different cancer treatments. If it can, registry data can be used to compare the effectiveness of different treatments in real world populations – going beyond the highly selected patient groups usually included in clinical trials. IGARD noted the National Disease Registration Service (NDRS) datasets requested under this DSA, had previously flowed from Public Health England (PHE) prior to its closure at the end of September 2021; and therefore, had not had a previous IGARD review. IGARD noted that on the 14th December 2022, NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had approved authorisation for this application to progress via NHS Digital's SIRO Precedent route. IGARD noted that an individual researcher was named in section 5 of the application, and advised NHS Digital that this should be removed. IGARD also noted references to "I" in section 5, and suggested that this was update to refer to the study team. 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.
4.4	<u>Barts Health NHS Trust: Retinoblastoma gene mutations and risk of secondary primary tumours (ODR1819_191) (No Presenter) NIC-656834-N7Z3Q-v1.6</u>

	The purpose of the application is for a research study, to investigate how the type of RB1 gene mutation that predisposes to retinoblastoma might affect the risk of developing a second primary tumour in another part of the body later in life. The study will include RB1 mutation carriers who have not developed retinoblastoma due to incomplete penetrance but nevertheless may also be at increased risk of developing other cancers. It is also proposed to take into account details of the therapy used in the treatment of the initial retinoblastoma. IGARD noted the NDRS datasets requested under this DSA, had previously flowed from Public Health England (PHE) prior to its closure at the end of September 2021; and therefore, had not had a previous IGARD review. IGARD noted that on the 14th December 2022, NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had approved authorisation for this application to progress via NHS Digital's SIRO Precedent route. 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.
4.5	<u>University College London (UCL): Cancer Registry-wide study in infants with neuroblastoma; Task 11.4 of the ENNCCA Network of Excellence (ODR1516_119) (No Presenter) NIC-656760-F8Y3C-v0.2</u> The purpose of the application is for a project, to understand the outcomes of current treatments for neuroblastoma in infants in relation to the success of first-line therapy (event-free survival) and the burden of treatment received by the individual child and reasons for any differences between countries. This project will develop mechanisms and methods of collaborative work between the population-based cancer registries and the clinical databases across the participating European countries and clinical registries. The aim will be to link the series of cases arising in a well-defined (by age at diagnosis) population of infants with neuroblastoma and registered in cancer registries, enhanced with the detailed information held in the clinical databases/hospital records at the patient's treatment centres. IGARD noted the NDRS datasets requested under this DSA, had previously flowed from Public Health England (PHE) prior to its closure at the end of September 2021; and therefore, had not had a previous IGARD review. IGARD noted that on the 14th December 2022 NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had approved authorisation for this application to progress via NHS Digital's SIRO Precedent route. IGARD noted the query with regard to data controllership and whether there was a joint controller. IGARD felt it was appropriate to resolve this issue via a special condition. However, data controllership questions may well be a concern with other former Public Health England agreements and will need attention. 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.
5	<u>Oversight & Assurance</u> IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. Due to the volume and complexity of applications at

	today's meeting, IGARD were unable to review any Data Access Request Service (DARS) applications as part of their oversight and assurance role. 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: IGARD Meeting Quoracy IGARD noted that following consideration by IGARD members, it had been agreed with NHS Digital that from the 26th March 2020 IGARD business as usual (BAU) meeting in-meeting quoracy may be temporarily reduced to three members (from four members), which must include a Chair and at least two specialist members. This was to ensure business continuity in the event that COVID-19 impacted on members ability to dial-in to meetings (due to COVID-19 illness or caring for a household member with COVID-19) and to support those IGARD members who had other roles linked to the COVID-19 response. Noting that membership had now increased to 9 members, it was agreed that this requirement was no longer required and that quoracy would revert to pre-pandemic and in line with the published IGARD Terms of Reference and Standard Operating Procedures which was 4 members including a Chair and at least 2 specialist members. 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 06/01/23

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

NIC Reference	Applicant	IGARD meeting date	Recommendation conditions as set at IGARD meeting	IGARD minutes stated that conditions should be agreed by:	Conditions agreed as being met in the updated application by:	Notes of out of committee review (inc. any changes)
NIC-234297-P4M5G-v3.3 -	University College London (UCL)	15/12/2022	1. In respect of The Health Foundation and in line with NHS Digital's DARS Standard for Data Controllers: a) To clarify in section 5(a) that The Health Foundation has no involvement in determining the purpose and means of processing and is **not** carrying out any data controllership activities; or, b) To update the application throughout to add The Health Foundation as a joint Data Controller, as borne out of the facts.	Co-Deputy IGARD Chair	OOC by the Co-Deputy IGARD Chair	*N/A*
NIC-148411-Q64H8-v4.4 -	University College London (UCL)	03/11/2022	1. In respect of the HRA CAG s251 support: a) To provide written confirmation from HRA CAG that the current s251 support maps to the processing outlined in the application; b) To upload the written confirmation from HRA CAG to NHS Digital's CRM system for future reference.	IGARD Chair	OOC by the Co-Deputy IGARD Chairs	*"…it would be sensible for the applicant keep under review whether a refreshed CAG application becomes necessary in the future"*

NIC-315419-F3W7K-v6.10	University of Oxford	04/08/2022	1. To provide written confirmation that all appropriate and necessary internal ethics or other approvals for the continued support for the study have been obtained, for example, the University of Oxford Sponsor Review.	Quorum of IGARD members	In-meeting on the 15/12/2022 by a quorum of IGARD members.	*"IGARD noted that the letter provided referred to two conditions of support and suggested that DARS may wish to clarify further with the applicant what this means, since ethics was not usually conditional"*

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