

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 15 December 2022

IGARD MEMBERS IN ATTENDANCE:	
Name:	Position:
Paul Affleck	Specialist Ethics Member / Co-Deputy IGARD Chair (Chair: items 1 to 3.6 and 4 to 8)
Maria Clark	Lay Member
Dr. Imran Khan	Specialist GP Member / Co-Deputy IGARD Chair (Chair: item 3.7)
Dr. Maurice Smith	Specialist GP Member
Jenny Westaway	Lay Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Dr. Robert French	Specialist Academic / Statistician Member
Kirsty Irvine	IGARD Chair
Prof. Nicola Fear	Specialist Academic Member
Dr. Geoffrey Schrecker	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	Team:
Michael Ball	Data Access Request Services (DARS) (Presenter: items 2.2 and 3.6)
Kate Bedford	Data Services Directorate (Presenter: item 2.1)
Vicky Byrne-Watts	Data Access Request Services (DARS SAT) (Presenter: item 2.1)
Garry Coleman	Associate Director, Deputy SIRO & Audit Services (Observer: item 7.2) (Presenter: item 8)
Dave Cronin	Data Access Request Services (DARS SAT) (SAT Observer: item 3.5)
Cath Day	Data Access Request Services (DARS SAT) (Presenter: items 3.1 to 3.2) (SAT Observer: item 3.4)
Louise Dunn	Data Access Request Services (DARS SAT) (Presenter: item 3.1 and 7.3)
Duncan Easton	Data Access Request Services (DARS SAT) (SAT Observer: items 3.6) (Presenter: item 2.2)

Dan Goodwin	Data Access Request Services (DARS) (Presenter: item 3.4)
James Gray	Digi-Trials (Presenter: item 7.2)
Dickie Langley	Privacy, Transparency, Ethics and Legal (PTEL) (Observer: items 7.1 and 8)
Susan Main	Data Access Request Services (DARS) (Presenter: item 7.1)
Shaista Majid	Data Access Request Services (DARS) (Presenter: item 3.5)
Karen Myers	IGARD Secretariat Team
Dr. Jonathan Osborn	Deputy Caldicott Guardian (Observer: item 3.6)
Frances Perry	Digi-Trials (Presenter: item 7.2)
Andy Rees	Digi-Trials (Presenter: item 7.2)
Kimberley Watson	Data Access Request Services (DARS SAT) (SAT Observer: items 3.2 to 3.3)
Anna Weaver	Data Access Request Services (DARS) (Presenter: item 3.3)
Vicki Williams	IGARD Secretariat Team
*SAT – Senior Approval Team (DARS)	

1	<p>Declaration of interests:</p> <p>Dr. Imran Khan noted a potential conflict with any applications reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) (NIC-431352-G7F1M), as part of his roles as Deputy Chair of the Health Informatics Group at the RCGP and Co-deputy Chair of the Joint GP IT Committee. It was agreed this did not preclude Dr. Khan from taking part in the discussions about this application, however, it was agreed that he would not participate in making a recommendation about the application.</p> <p>Dr. Imran Khan noted a potential conflict with NHS Buckinghamshire, Oxfordshire, and Berkshire West ICB (NIC-616007-R3H0G), as part of his role as Clinical Digital Place Lead for Buckinghamshire, Oxfordshire and Berkshire West Integrated Care Board. It was agreed that Dr. Khan would not remain in the room for the discussion of that application.</p> <p>Paul Affleck noted a professional link with the staff at the University of Oxford (NIC-315419-F3W7K). It was agreed that he would not form part of the quoracy for the OOC review.</p> <p>Maria Clark noted professional links to the Royal College of Obstetricians and Gynaecologists (NIC-359651-H3R1P) but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest.</p> <p>Dr. Maurice Smith noted a potential conflict with regard to the Research for Commissioners Briefing given his role as a contracted employee of Cheshire and Merseyside Integrated Care</p>
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	<p>Board (ICB). It was agreed that this did not preclude Dr. Smith from taking part in the discussion.</p> <p>Review of previous minutes and actions:</p> <p>The minutes of the 8th December 2022 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record of the meeting.</p> <p>Out of committee recommendations:</p> <p>An out of committee report was received (see Appendix A).</p>
2	Briefing Notes
2.1	<p><u>National Child Measurement Programme – Briefing (Presenters: Vicky Byrne-Watts / Kate Bedford)</u></p> <p>This briefing paper was to inform / seek the views of IGARD, in relation to a new request for linking aggregate National Child Measurement Programme (NCMP) data to Free School Meals data at school level (NIC-693605-B9G9D).</p> <p>The National Child Measurement Programme (NCMP) measures the height and weight of children in reception class (aged 4 to 5) and year 6 (aged 10 to 11), to assess underweight, healthy weight, overweight and obesity levels in children within primary schools. Data has been collected since 2006/07.</p> <p>Essex University would like to request NHS Digital to link some of their data on Free School Meals (FSM) to aggregated National Child Measurement Programme (NCMP) data with the Local Authority (LA) flag attached. The aggregate data does not include any personally identifiable data at the child level.</p> <p>A version of the letter sent to parents, which was seen by an IGARD member, states, “<i>NHS Digital only ever shares information for research with the approval of an independent group of experts</i>”. This is factually incorrect since IGARD is advisory and NHS Digital can disseminate data without its recommendation.</p> <p>Outcome: IGARD welcomed the briefing paper and made the following high-level comments:</p> <ol style="list-style-type: none"> 1. To seek written confirmation from PTEL that the proposed dissemination is compatible with the relevant regulations. 2. To clarify the second sentence under “<i>Data Request</i>” that the data is disseminated at school level. 3. To amend the language to refer to “<i>living with obesity</i>”. 4. Suggest amending the minimum number of children in a school year to no fewer than 20 (not 10). 5. IGARD suggested that the wording of the letter sent to parents is reviewed. <p>IGARD welcomed the draft and looked forward to receiving the finalised briefing paper, either out of committee (OOC) or tabled at a future meeting (before, or contemporaneously with, any first of type applications received by IGARD).</p>
2.2	<p><u>Research for Commissioners Briefing (Presenter: Michael Ball / Duncan Easton)</u></p> <p>This briefing paper was to inform IGARD of the proposal by NHS Digital to add research as an additional purpose and term to the sub-licensing, to allow Integrated Care Boards (ICB), to conduct and share health and social care data with research organisations, such as universities for the purpose of local research.</p>

	<p>The use of sub-licensing will allow NHS Digital to retain control and audit rights of the onward sharing and additional uses of the data. Local research has the potential to provide vital analysis of health and social care issues affecting ICB areas that could result in key changes to how the local health and social care system is run and improve patient outcomes. Requests for national research will continue to be handled by NHS Digital.</p> <p>Outcome: IGARD welcomed the briefing paper and made the following high-level comments:</p> <ol style="list-style-type: none"> 1. To amend the reference from “GDPR” to “UK GDPR”. 2. IGARD recognised the potential benefits of enabling research. 3. IGARD stressed the need for ICBs to engage their populations, and widely consult on their plans to use and disseminate data for research. 4. IGARD cautioned that as worded an ICB could charge more than cost recovery for providing data and to make a profit for providing data for research, in contrast to NHS Digital’s practice. 5. IGARD cautioned that ICBs would need to address the same governance and ethical issues as a research application to NHS Digital. 6. IGARD commented that it would be sensible for ICBs to share best practice and align their processes to ensure consistency. <p>IGARD welcomed the draft and looked forward to receiving the finalised briefing paper, tabled at a future meeting.</p>
3	Data Applications
3.1	<p><u>Medicines and Healthcare Products Regulatory Agency (MHRA) / Clinical Practice Research Datalink (CPRD): R23 - Clinical Practice Research Datalink (CPRD) Routine Linkages Application (Presenter: Cath Day / Louise Dunn) NIC-15625-T8K6L-v12.4</u></p> <p>Application: This was a renewal and extension application to permit the holding and processing of pseudonymised Medical Research Information Service (MRIS) – Bespoke; Hospital Episode Statistics Accident and Emergency (A&E), HES Admitted Patient Care (APC), HES Critical Care, HES Outpatients, Emergency Care Data Set (ECDS), Diagnostic Imaging Dataset Bridge file: HES to Mental Health Minimum Data Set (MHMDS), Civil Registration (Deaths) and COVID-19 Hospitalization in England Surveillance System (CHESS) (now called “SARI Watch”).</p> <p>It was also an amendment application to 1) tidy up of the data sharing agreement (DSA); 2) to add Maternity Services Data Set (MSDS) v2.0; 3) to add Medicines Dispensed in Primary Care (NHSBSA data); 4) to add Civil Registration data; 5) the removal of Civil Registration (Deaths) secondary Care cut; 6) the removal of storage and processing locations as these are no longer required; 7) the removal of COVID-19 Second Generation Surveillance System (SGSS) and CHESS COPI conditions as these now have Section 251 support for CPRD; 8) the removal of the Patient Reported Outcome Measures (PROMs) terms and conditions; 9) the addition of Microsoft Azure as a Data Processor; and 10) for all datasets to be provided as latest available to CPRD as a 'one-off' in September 2023.</p> <p>CPRD is a government not for profit research service delivered by the MHRA, with support from the National Institute of Health and Care Research (NIHR), that provides access to pseudonymised health data for studies to safeguard and improve patient and public health.</p> <p>CPRD provides data to researchers under sublicense agreements, access to primary care data linked to secondary health care datasets for both observational research and to supplement clinical trial data. Linked data greatly increases the scale, depth, completeness</p>

and value of data available for public health and clinical research. Linked data are also used to assess study feasibility and create lists of eligible patients who could potentially be included in clinical trials. In addition, linked data are used by CPRD to generate derived fields that improve the quality of the primary care data for e.g. ethnicity records. The outputs of such research based on linked data inform clinical guidance and best practice for patients in the UK.

NHS Digital advised IGARD that as per process, a task had been raised with NHS Digital's Privacy, Transparency, Ethics and Legal (PTEL), to review the ongoing position for worldwide sharing in relation to the CPRD data sharing agreement (DSA). NHS Digital advised that PTEL have noted that there was a requirement to review all sharing of NHS Digital data, outside of the UK, on a case-by-case basis but as yet do not have a process in place to manage this. NHS Digital's Data Access Request Services (DARS) were content to continue under the existing arrangements because the data being shared under sublicense worldwide was considered effectively anonymised.

NHS Digital advised IGARD that section 3(b) (Additional Data Access Requested) incorrectly stated that the frequency of the data dissemination was "quarterly"; and that this would be updated correctly state that the data flow would be "one-off".

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 24th January 2017; and at the IGARD meetings on the 22nd June 2017, 20th September 2018, 17th October 2019, 6th February 2020, 27th February 2020 (application withdrawn by presenter), 19th March 2020, 16th July 2020, 28th April 2022 and the 10th November 2022.

IGARD noted that a CPRD briefing paper had been submitted for review at the IGARD meeting on the 27th January 2022, that provided IGARD with an update on previous points raised on this application.

IGARD noted that this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 12th May 2020, 19th May 2020, 26th May 2020, 6th October 2020 and 13th October 2020.

It was also discussed as part of the 'applications progressed via NHS Digital's SIRO Precedent route' on the 8th November 2018; and as part of 'AOB' on the 27th August 2020.

IGARD noted and commended NHS Digital on the updated information provided within the application, which supported the review of the application by members.

IGARD noted the verbal update from NHS Digital in respect of the worldwide sharing of data, the outstanding PTEL query raised; and the update in respect of how this would be managed in the interim, prior to PTEL confirming the process for reviewing this on a case-by-case basis.

IGARD noted and supported the verbal update from NHS Digital in respect of the update to section 3(b) to reflect correct the frequency of the data requested.

IGARD noted in section 3(b) that the correct legal basis was not cited for some of the datasets, for example, the COVID-19 Hospitalization in England Surveillance System dataset (now called "SARI Watch") would flow under "*Coronavirus (COVID-19) notices under reg 3(4) of the Health Service Control of Patient Information Regulations 2002*". IGARD asked that section 3(b) was updated to ensure the correct legal basis was cited for each dataset.

IGARD queried the statement in section 5(a) (Objective for Processing) "*CPRD considers the pseudonymised data it holds, to be effectively anonymised and therefore, not personal data*"; and asked that this incorrect information was removed. IGARD asked that section 5(a) was

updated to clearly reflect that the data was considered personal and within the UK General Data Protection Regulation (UK GDPR), in line with [NHS Digital DARS Standard for Objective for Processing](#).

IGARD noted a risk to NHS Digital, in that the Information Commissioner's Office (ICO) anonymisation, pseudonymisation and privacy enhancing technologies guidance was still draft; so the status of 'effectively anonymised' data as outside UK GDPR may not be confirmed.

IGARD noted that at the IGARD meeting on the 10th November 2022, they had suggested that that CPRD listed the participating GP Practices on the CPRD website for transparency. IGARD noted that, prior to the meeting, NHS Digital had provided further information from the applicant on this point, suggesting it may increase the risk of patients being identified if there was a data breach. IGARD suggested that the applicant seek further guidance on this issue from the Health Research Authority Confidentiality Advisory Group (HRA CAG) and their HRA Research Ethics Committee (REC).

IGARD noted the content of the GP letter provided as a supporting document, that GPs used to sign-up to CPRD; in particular the reference to giving consent and suggested that this was amended to make it clear that GP practices give agreement **not** consent.

IGARD noted that prior to the meeting, an IGARD member had raised a query in respect of the Diagnostic Imaging Dataset (DIDs) and whether this was covered by the HRA CAG support, noting that it was not on the HRA CAG publicly available register. NHS Digital advised IGARD that DIDs was included, and that the applicant had been advised that HRA CAG would need notifying of this omission on the register. IGARD noted and thanked NHS Digital for the verbal update and suggested that both the applicant **and** NHS Digital asked HRA CAG to update the register.

IGARD queried the information in section 5(b) (Processing Activities) in relation to "*linkage*"; and were advised by NHS Digital that this was referring to third-party linkage under a previous version of the DSA, and confirmed that this was no longer happening. IGARD noted the verbal update from NHS Digital, and asked that in line with [NHS Digital DARS Standard for processing activities](#), section 5(b) was updated to clarify that the third party linkages happened under earlier versions of the DSA, and were **not** part of this DSA.

IGARD noted and commended the applicant on the valuable yielded benefits outlined in section 5(d) (Benefits) (iii) (Yielded Benefits); however, asked that further information was provided on the yielded benefits accrued from the published "*paper*" referred to, in line with [NHS Digital DARS Standard for Expected Measurable Benefits](#).

IGARD suggested that section 5(d) be updated to remove reference to "*it will...*", and instead use a form of words such as "*it is hoped...*".

IGARD asked that a special condition was inserted in section 6 (Special Conditions), that any use of the NHSBSA data must be within the parameters of the relevant [Direction](#) authorising that collection, in line with [NHS Digital DARS Standard for Special Conditions](#).

IGARD reiterated a previous point from the 10th November 2022; where they had queried if there was a greater risk of re-identification of women with children, for example, if a recipient of data had requested maternity datasets **and** other datasets that would increase the risk of re-identification. IGARD suggested that this example was addressed when considering whether data that was disseminated by CPRD was "effectively anonymised". IGARD observed that the risk of reidentification in such an instance would be disproportionately borne by women.

As section 5 (Purpose / Methods / Outputs) forms [NHS Digital's data uses register](#), IGARD asked that section 5(b) was amended throughout, to ensure acronyms be defined upon first use.

IGARD noted that some of the datasets requested under previous versions of the application, were not included in this version, for example, Patient Reported Outcome Measures (PROMs); and were advised by NHS Digital that these had been removed from the DSA as they were currently not required. IGARD noted the verbal update from NHS Digital, and commended the data minimisation efforts undertaken.

IGARD suggested that CPRD undertake further, and wider, patient and public involvement and engagement (PPIE), outside the GP patient groups that they had already engaged with.

Separate to the application, IGARD suggested that there was further transparency on the NCRAS dataset within the public domain.

Outcome: recommendation to approve

The following amendments were requested:

1. In respect of section 3(b):
 - a) To amend section 3(b) to reflect the correct frequency of the data (as per the verbal update from NHS Digital).
 - b) To update section 3(b) to ensure correct legal basis is cited.
2. In respect of section 5(a) and in line with [NHS Digital DARS Standard for Objective for Processing](#):
 - a) To remove the text “CPRD considers the pseudonymised data it holds, to be effectively anonymised and therefore, not personal data”; and,
 - b) To update section 5(a) to reflect that the data is considered personal and within UK GDPR.
3. In respect of section 5(b) and in line with [NHS Digital DARS Standard for processing activities](#):
 - a) To update section 5(b) to clarify that the third-party linkages happened previously and are **not** part of this DSA.
 - b) As section 5 forms [NHS Digital's data uses register](#), to amend section 5(b) throughout, to ensure acronyms are defined upon first use.
4. In respect of section 5(d) and in line with [NHS Digital DARS Standard for Expected Measurable Benefits](#):
 - a) To update section 5(d) to use a form of wording such as “it is hoped ...”, rather than “it will...”.
 - b) To update section 5(d) (iii) with further yielded benefits from the “paper” referenced.
5. In respect of re-identification:
 - a) To confirm if there is an increased risk of re-identification for women with children; and,
 - b) To address any gender inequality issues if there is an increased risk of re-identification for women with children.
6. To insert a special condition in section 6, that any use of the NHSBSA dataset must be within the parameters of the relevant Direction authorising that collection.

The following advice was given:

1. IGARD suggested that the letters that GPs use to sign-up to CPRD is amended to make clear that the GPs do not give consent, they give agreement.

	<ol style="list-style-type: none"> 2. IGARD reiterated previous advice and suggested that the participating GP Practices were listed on the CPRD website for transparency. IGARD also suggested that the applicant seek further advice on this point from HRA CAG and their HRA REC. 3. IGARD suggested that the applicant and NHS Digital draw to the attention of HRA CAG that the DIDs dataset is not on the publicly available HRA CAG register and ask them to update. 4. IGARD suggested that CPRD undertake further, and wider PPIE, outside the GP patient groups that they had already engaged with. <p>Risk Area: the ICO anonymisation, pseudonymisation and privacy enhancing technologies guidance is still draft so the status of 'effectively anonymised' data as outside UK GDPR may not be confirmed.</p> <p>Separate to the application: further transparency on the NCRAS dataset within the public domain.</p>
3.2	<p><u>Department for Education: ECHILD - Education and Child Health Insights from Linked Data (Presenter: Cath Day) NIC-578994-N0J1X-v0.7</u></p> <p>Application: This was a new application for pseudonymised Birth Notification Data, Civil Registration (Deaths), Community Services Data Set, Emergency Care Data Set (ECDS), Hospital Episode Statistics Accident and Emergency (HES A&E), HES Critical Care, HES Admitted Patient Care (APC), HES Outpatients, Mental Health and Learning Disabilities Data Set (MHLDDS), Mental Health Services Data Set (MHSDS), Mental Health Minimum Data Set (MHMDS), Bridge file: HES to MHMDS, HES:Civil Registration (Deaths) bridge, Maternity Services Data Set (MSDS) v1.5 and MSDS (Maternity Services Data Set) v2.0.</p> <p>This application will re-use the data disseminated under NIC-381972-Q5F0V.</p> <p>The purpose of this application is for the Department for Education (DfE) to gain access to the Education and Child Health Insight Linked Data (ECHILD), which is stored on the Office for National Statistics (ONS) Secure Research Service (SRS); and consists of education records and health records. ECHILD, is a pseudonymised longitudinal linked dataset obtained from matching the HES dataset, plus death registration to administrative data contained in the datasets collectively supplied within the National Pupil Dataset (NPD), including education, Children in Need (CiN), and Children Looked After (CLA). The ECHILD Database also includes the mental health services data set (MHSDS), the community services data set and maternity services data set (MSDS) for the age range of the education records to be matched from the 1st September 1984.</p> <p>This data sharing agreement (DSA) will permit DfE to gain access to ECHILD in the ONS SRS, for the purpose of fulfilling their own independent function of promoting the well-being of children in England.</p> <p>Discussion: IGARD noted that NIC-381972-Q5F0V was previously discussed at the IGARD meetings on the 25th June 2020, 21st October 2021, 25th November 2021 and the 17th November 2022.</p> <p>NIC-381972-Q5F0V was discussed as part of University College London (UCL) application for 'Education and Child Health Insights from Linked Data' (ECHILD) Dataset Sub-Licensing – Briefing on the 26th May 2022.</p> <p>NIC-381972-Q5F0V was discussed under 'AOB at the IGARD meeting on the 20th October 2022.</p>

IGARD noted that prior to the meeting, an IGARD member had raised a query in respect of the Department for Education (DfE), who are responsible for children's services and education and not providing insights on the effects of education on health and social care; and how the use of eCHILd would enable DfE to exercise its function as a Government Department. NHS Digital confirmed that the responsibilities of DfE was wider than just education, for example, [section 7 of the Children and Young Persons Act 2008](#) places a general duty on the Secretary of State to promote the "well-being" of children in England. IGARD noted the verbal update from NHS Digital, and confirmed that they were broadly satisfied that the purposes were encompassed.

IGARD queried the references in section 5(a) (Objective for Processing) to "...*Middle Layer Super Output Areas*..." and "...*Lower Layer Super Outputs Area (LSOA)*..."; and asked that these references were updated with a clear indication of the size of each of the area outputs, in line with [NHS Digital DARS Standard for Objective for Processing](#).

IGARD queried the statement in section 5(a) "...*44% are ever referred to children's social care before the age of 16 years*"; and asked that further clarity was provided on this statement to be clear what the statement / figure was referring to and to align with NIC-381972-Q5F0V.

IGARD noted that not all vulnerable children were necessarily captured by the criteria being used and that potentially some children may be excluded from the research who may benefit from it; and it was agreed that an IGARD member would provide further information / clarity on this issue out of committee (OOC), for NHS Digital to share with the applicant.

IGARD noted a risk factor to NHS Digital, in respect of the Department for Education (DfE) being recently reprimanded by the Information Commissioner's Office (ICO); and that, although the data would be held within the ONS, the reprimand may be relevant to the processing. IGARD suggested that this concern could be mitigated via a Data Protection Impact Assessment (DPIA) specific to this application.

IGARD noted the reference in section 5(a) to "...*synthetic control groups*..."; and asked that this was updated / simplified as appropriate for a lay audience, for example, to refer to "*appropriate control groups*" or similar.

IGARD suggested that section 5(a) be updated to remove reference to "*it will...*", and instead use a form of words such as "*it is hoped...*".

To remove reference in section 5(b) to "...*VPN tunnel and Remotely Access (RA) the SRS*..." and replace with plainer language.

IGARD advised that this application would be suitable for NHS Digital's Precedent route if all qualifying [NHS Digital DARS Standards](#) were met.

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) with an indication of the size of the area outputs.
 - b) To simplify the language for a lay reader in section 5(a) around "...*synthetic control groups*...".
 - c) To update section 5(a) to use a form of wording such as "*it is hoped ...*", rather than "*it will...*".
 - d) To clarify in section 5(a) reference to "*44%*" of children.

	<p>2. To remove reference in section 5(b) to “...VPN tunnel and Remotely Access (RA) the SRS...” and replace with plainer language.</p> <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD noted that not all vulnerable children are necessarily captured by the criteria being used; and it was agreed that an IGARD member would provide further detail for the applicant, in respect of information / clarity on this issue OOC. 2. IGARD advised that this application would be suitable for NHS Digital's Precedent route if all qualifying NHS Digital DARS Standards were met. <p>Risk Factor: IGARD is aware that DfE was recently reprimanded by the ICO. Although the data here will be held within the ONS, the reprimand may be relevant to the processing; this concern could be mitigated via a DPIA.</p>
3.3	<p><u>Imperial College London: Imperial College London - REACT Data and Connectivity National Core Studies (Presenter: Anna Weaver) NIC-431352-G7F1M-v1.10</u></p> <p>Application: This was a renewal and extension application to permit the holding and processing of pseudonymised Civil Registration (Deaths), COVID-19 Hospitalization in England Surveillance System (CHESS) (now called “SARI Watch”), COVID-19 Second Generation Surveillance System (SGSS), COVID-19 Vaccination Adverse Reactions, COVID-19 Vaccination Status, GPES Data for Pandemic Planning and Research (COVID-19) (GDPPR), Hospital Episode Statistics Admitted Patient Care (HES APC), HES Outpatients; and identifiable Covid-19 UK Non-hospital Antibody Testing Results (Pillar 3) and Covid-19 UK Non-hospital Antigen Testing Results (pillar 2) data.</p> <p>It was also an amendment application to 1) extend the duration of the project from 12 months to 3 years; 2) to receive historic data dating back from 2014/15, previously the study only required historic data dating back to one year before entry to the cohort; 3) to expand the study cohort to include adult participants recruited between June 2021 and February 2022 (Rounds 11-19 of REACT I); 4) to update section 5(b) to reflect the request that Students and Honorary Contract holders be permitted to process NHS Digital data on behalf of ICL; 5) to update section 3 to reflect the request to receive HES Critical Care data for the entire cohort.</p> <p>The Real-Time Assessment of COVID-19 Transmission (REACT) Study was established in May 2020 and provides monthly estimates of the prevalence of SARS-CoV-2 virus and bi-monthly estimates of the prevalence of antibodies to SARS-CoV-2 virus in the general population of England. Under this iteration of the Agreement a further 638,299 participants have been added to the cohort with the overall cohort totalling 2,774,600.</p> <p>This overarching purpose of this application is to enhance the existing REACT study research cohorts by linking the study data from participants (who have provided consent) to their health records held by the NHS. This enhanced dataset will then be used to advance understanding of the risks of infection and reinfection with COVID and people's future health following a COVID infection.</p> <p>NHS Digital advised IGARD that Article 9(2)(j) as the UK General Data Protection Regulation (UK GDPR) was cited as the legal basis for the processing; however noted that section 5(a) (Objective for Processing) would need updating to ensure the relevant section of the Data Protection Act (DPA) was also cited.</p> <p>NHS Digital also advised IGARD, that section 3(b) (Additional Data Access Requested) would need updating to state the correct overall cohort number.</p>

Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD meeting on the 25th March 2021.

IGARD noted that this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 16th March 2021.

IGARD also noted that the application had also been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) meetings on the 24th March 2021 (*the notes from this meeting had been attached to the IGARD minutes from the 25th March 2021*); and the 7th December 2022 (*please see appendix B*).

IGARD noted and supported the verbal update from NHS Digital, in respect of the update to section 5(a), to cite the relevant section of the DPA in respect of the UK GDPR Article 9 legal basis.

IGARD also noted and supported the verbal update from NHS Digital, in respect of the update to section 3(b), to state the correct overall cohort number.

IGARD noted the information in section 5(b) (Processing Activities) in relation to the students; however, asked that for transparency this was updated in line with [NHS Digital DARS Standard for processing activities](#), to also include further information on the role of the students. IGARD also noted that section 5(b) stated that the number of students involved with the study would be “*circa 5 at any time*”, and asked that to allow some flexibility, this was updated, for example, to state “*fewer than ten*”. In addition, IGARD asked that section 5(b) was updated to be clear that the students would have honorary contracts.

IGARD noted the technical security information in section 5(b), for example “...*encrypted to AES-256 standards...*”, “...*pulse secure VPN software...*” and “...*Pulse Secure uses ESP with 256bit strength (split tunnel)*”; and noting that section 5 forms [NHS Digital's data uses register](#), asked that this was amended or removed, and replaced with less technical / restrictive wording in line with NHS Digital DARS Standard for processing activities.

IGARD noted the statement in section 5(c) (Specific Outputs Expected) “*The key study output is expected to be produced by Q2 of 2023*”; and asked that this was updated, to refer to specific months.

IGARD noted the engagement undertaken with the REACT Patient Advisory Group, particularly in terms of exploring what participants understood they had consented to. Separately, IGARD suggested that the applicant considered the impact of Long-COVID and how this may be a barrier to some individuals fully participating in future patient and public involvement and engagement (PPIE).

IGARD noted the IPSOS Mori privacy notice web address cited in some patient information material(s) currently stated “*page not found*”. IGARD suggested it was reinstated with a holding message and a link to the current privacy notice.

IGARD advised that this application would be suitable for NHS Digital's Precedent route if all qualifying [NHS Digital DARS Standards](#) were met.

Separate to this application, IGARD suggested that NHS Digital may wish to discuss the optimal wording in consent forms and patient information sheets (PIS) with the Health Research Authority (HRA) in respect of access to retrospective **and** future data.

Outcome: recommendation to approve

The following amendments were requested:

	<ol style="list-style-type: none"> 1. To update section 5(a) to clarify the relevant section of the DPA (as per the verbal update from NHS Digital). 2. To amend section 3 with the correct cohort numbers (as per the verbal update from NHS Digital). 3. In respect of the students: <ol style="list-style-type: none"> a) To provide further clarity in section 5(b) of the role of students; and, b) To update section 5(b) to reflect the approximate number of students involved; and, c) To update section 5(b) to make clear that the students will have honorary contracts. 4. To remove reference in section 5(b) to "...pulse secure VPN software..." and ".... Pulse Secure uses ESP with 256bit strength..." and replace with plainer language. 5. To amend the reference in section 5(c) "Q2 of 2023". <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD suggested that the applicant consider the impact of Long-COVID, which may impair some people's ability to participate in relevant PPIE. 2. IGARD suggested that the IPSOS Mori privacy notice web address was reinstated with a holding message and a redirection link to the current privacy notice. 3. IGARD advised that this application would be suitable for NHS Digital's Precedent route if all qualifying NHS Digital DARS Standards were met. <p>Separate to this application: NHS Digital may wish to discuss the optimal wording in consent forms and PIS with the HRA in respect of access to retrospective and future data.</p>
3.4	<p><u>University College London (UCL): LAUNCHES QI: Linking AUdit and National datasets in Congenital HEart Services for Quality Improvement. Congenital Heart Audit: Measuring Progress In Outcomes Nationally (CHAMPION) (Presenter: Dan Goodwin) NIC-234297-P4M5G-v3.3</u></p> <p>Application: This was an extension application to permit the holding and processing of pseudonymised Civil Registration (Deaths) - Secondary Care Cut, Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC), HES Outpatients, HES:Civil Registration (Deaths) bridge, HES-ID to MPS-ID HES A&E, HES-ID to MPS-ID HES APC and HES-ID to MPS-ID HES Outpatients.</p> <p>It was also an amendment application to 1) add an additional purpose and processing to the CHAMPION study to recalibrate the Partial Risk Adjustment in Surgery (PRAiS) risk model for mortality after paediatric cardiac surgery with new diagnostic and procedure codes; and 2) to submit an updated cohort of patients to NHS Digital to link to, and receive, pseudonymised Civil Registration Mortality life status data.</p> <p>This application initially only covered a study called 'Linking Audit and National datasets in Congenital Heart Services for Quality Improvement (LAUNCHES QI). In 2019 this was amended to reuse the LAUNCHES QI dataset for a new study called 'Congenital Heart Audit: Measuring Progress in Outcomes Nationally' (CHAMPION).</p> <p>The CHAMPION study will provide information on a) which cases of adults undergoing surgery or interventional cardiology should be included in the reporting and comparing of adult CHD outcomes; establish which outcomes are feasible and appropriate for routine monitoring and which factors influence outcomes; develop the analytical methods for taking account of differences in risk across case-mix; and b) Key diagnoses for which outcomes should be reported, establish which outcome metrics can be routinely measured for these diagnoses, and develop the analytical means to do so (including exploring non-diagnostic factors that can influence outcomes).</p>

LAUNCHES QI is a dataset analysis of five linked audit and national datasets which includes 143,862 patients with congenital heart disease that have been captured by the National Congenital Heart Disease Audit (NCHDA) since 2000.

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 following an update from the Privacy, Transparency, Ethics and Legal (PTEL) Team; the application would be amended to remove reference to “s261(5)(d)” and instead cite s261(2)(a) of the Health and Social Care Act 2012, as the legal basis for NHS Digital to disseminate the data.

NHS Digital advised IGARD that the reference to “*Senior Approvals Manager*” in section 1 (Abstract) would be updated, to clearly specify that this was referring to Data Access Request Services (DARS) Senior Approval Team (SAT).

Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD meeting on the 3rd October 2019, 1st July 2021 and the 7th July 2022.

IGARD noted the verbal update from NHS Digital, in respect of the update from PTEL on the s261 legal basis; and asked that the relevant updates were made to the application to ensure the correct legal basis was cited.

IGARD also noted the verbal update from NHS Digital, in respect of the update to section 1, and supported the amendment, to clearly reflect that the “*Senior Approvals Manager*” was referring to the DARS SAT.

IGARD confirmed that they were of the view that the relevant s251 support was broadly compatible with the processing outlined in the application.

IGARD queried the statement in section 5(a) (Objective for Processing) “*The sole funder, The Health Foundation, are involved in the study only to provide the award, as grant-funding. They will also oversee progress of the project through annual reports and award meetings*”; and asked that in line with [NHS Digital's DARS Standard for Data Controllers](#), section 5(a) was updated, to clarify that The Health Foundation has **no** involvement in determining the purpose and means of processing and was **not** carrying out any data controllership activities; or, if the Health Foundation were a Data Controller, that the application was updated throughout, to add The Health Foundation as a joint Data Controller, as borne out of the facts.

IGARD noted the references in section 5(a) to “*CHD*”; and advised that although in this instance this was referring to ‘congenital heart disease’, that CHD was also the commonly used acronym for ‘coronary heart disease’. IGARD therefore asked that either congenital heart disease was referred to throughout the application in full or further information was added to section 5(a) acknowledging that the acronym was also the acronym for ‘coronary heart disease’, whilst clearly stating that in this instance it was **only** referring to ‘congenital heart disease’.

IGARD noted the duplicate text in section 5(a) “*Measuring, reporting and learning from outcomes...*”; and asked that the second time this statement was used, was removed from section 5(a).

IGARD suggested that section 5(d) (Benefits) be updated to remove reference to “*it will...*”, and instead use a form of words such as “*it is hoped...*”.

	<p>As section 5 (Purpose / Methods / Outputs) forms NHS Digital's data uses register, IGARD asked that section 5(d) was amended throughout, to ensure acronyms be defined upon first use, for example “(BCCA, SCTS, RCSEd) and HQIP”.</p> <p>Outcome: recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> 1. In respect of The Health Foundation and in line with NHS Digital's DARS Standard for Data Controllers: <ol style="list-style-type: none"> 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. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update the application throughout with the correct legal basis (as per the verbal update from NHS Digital). 2. To amend the reference to “<i>Senior Approvals Manager</i>” in section 1 (as per the verbal update from NHS Digital). 3. To provide further clarification on the reference to “<i>CHD</i>” in section 5(a). 4. To remove the duplicate text from section 5(a). 5. To update section 5(d) to use a form of wording such as “<i>it is hoped ...</i>”, rather than “<i>it will...</i>”. 6. As section 5 forms NHS Digital's data uses register, to amend section 5 throughout, to ensure acronyms be defined upon first use, for example “(BCCA, SCTS, RCSEd) and HQIP”. <p>It was agreed the condition would be approved out of committee (OOC) by Co-Deputy IGARD Chair</p>
3.5	<p><u>University of Oxford: MBRRACE-UK - Delivering the National Maternal, Newborn and Infant Clinical Outcome Review Programme - National Surveillance of Maternal and Perinatal Deaths (Presenter: Shaista Majid) NIC-359651-H3R1P-v6.5</u></p> <p>Application: This was a renewal and extension application to permit the holding and processing of identifiable Birth Notification Data.</p> <p>It was also an amendment application to 1) add the Health Research Authority Confidentiality Advisory Group (HRA CAG) support to permit the exemption of the National Data Opt-out; 2) the removal of 'purpose 2' (related to producing aggregated data that was then supplied to the National Neonatal Audit Programme (NNAP)) as referred to in previous versions, as this purpose is not pursued anymore and is therefore not relevant to the application.</p> <p>The purpose of the application is for the MBRRACE-UK and 'National Maternal, Newborn and Infant clinical Outcome Review Programme' (MNI-CORP) programme, which aim to provide robust national information to support the delivery of safe, equitable, high quality, women and person-centred maternal, newborn and infant health services. The aim is to systematically assess quality and stimulate improvement in safety and effectiveness of maternal, newborn and infant healthcare by enabling clinicians, commissioners and policy makers to learn from adverse events and good practice.</p> <p>The purpose of the programme is to: 1) monitor, through population surveillance, the frequency of maternal, perinatal and infant deaths; and 2) review clinical practice and assess quality of care for women and babies who have died and those who are seriously ill (mortality</p>

and morbidity) through confidential enquiries, with the aim of identifying factors that can be attributed to suboptimal clinical care and be improved in the future, and also examples of good practice.

The cohort for this Agreement is all women giving birth and their babies born (live born, stillbirth and those who die in the neonatal period (first 28 days after birth) from 1st January 2013 on an ongoing basis, subject to contract extension for the project, in England and Wales.

The study is relying on s251 of the NHS Act 2006, for the flow of data out of NHS Digital.

Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the Data Access Advisory Group (*IGARD's predecessor*) meeting on the 14th June 2016; and the IGARD meeting on the 9th December 2021.

IGARD noted that this application had previously been discussed as part of the 'returning applications' section of the IGARD business as usual (BAU) meeting on the 11th June 2020.

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 the content of the patient information poster dated June 2022, that was provided as a supporting document. IGARD noted issues with the weblinks provided within the poster, for example, one of the web links is incorrect and the other web link did not provide any information on the ability to opt-out. IGARD therefore asked that the poster was updated with the correct weblink; and that the linked webpages provide relevant information on the ability to opt-out.

IGARD also suggested that the applicant liaise with HRA CAG as appropriate, with regard to any significant updates to the poster and websites.

IGARD queried the references in section 5(a) (Objective for Processing) to "*NN4B*"; and asked that these references were either removed or updated as appropriate; noting that NN4B (NHS Numbers for Babies) was an historic service used to allocate NHS Numbers; and was decommissioned in 2015, and replaced with equivalent facilities that sit within the Personal Demographics Service, and on the Spine.

IGARD noted some technical terms within section 5(b) (Processing Activities), for example, "*logistic regression*"; and noting section 5 (Purpose / Methods / Outputs) forms [NHS Digital's data uses register](#), asked that section 5(b) was amended, to ensure that technical terms were used only where necessary and explained in a manner suitable for a lay audience.

IGARD queried the statement in section 5(d) (Benefits) (ii) (Expected Measurable Benefits to Health and / or Social Care) "*This demonstrates the magnitude of the benefits expected...*"; and asked that this was reviewed and amended as appropriate, in line with [NHS Digital DARS Standard for Expected Measurable Benefits](#).

IGARD noted the references in section 5(d) (ii) and section 5(d) (iii) (Yielded Benefits) to the national initiative "*Saving Babies' Live Care Bundle, versions 1 and 2 in 2016*"; and asked that the relevant weblinks were added to these statements for further support / transparency to this specific benefit / yielded benefit.

IGARD queried the statement in section 5(d) (iii) "*...the national ambition to reduce the maternal and perinatal mortality rate by half by 2030; this was subsequently redefined in 2016 to achieve this ambition by 2025, with a 20% reduction by 2020*"; and asked that further clarification was provided on what had been achieved or was projected in terms of statistics.

	<p>IGARD queried the content of the last sentence in section 5(d) (iii) “...one small district general hospital introduced a new referral form...”; and asked that this was expanded if it was being used as a model for other hospitals. IGARD also noted that the end of this sentence had some text missing and asked that this was updated as appropriate.</p> <p>Separate to this application: IGARD asked that NHS Digital provide a briefing on current work to increase the reliability and granularity of ethnicity data in datasets; noting that with this application, and others, the ethnicity information was a vital variable.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update or remove the reference to “<i>NN4B</i>” in section 5(a). 2. As section 5 forms NHS Digital’s data uses register, to amend section 5(b) to ensure that technical terms are used only where necessary and explained in a manner suitable for a lay audience, for example, “<i>logistic regression</i>”. 3. In respect of the benefits in section 5(d) and in line with NHS Digital DARS Standard for Expected Measurable Benefits: <ol style="list-style-type: none"> a) To update the reference in section 5(d) (ii) “...the magnitude of the benefits...” b) To add a relevant weblink(s) to further support the benefits / yielded benefits. c) To update the yielded benefit in section 5(d) (iii) to clarify what has been achieved or is projected in terms of statistics. d) To update the last sentence in section 5(d) (iii), if it is an example for wider implementation; and, e) To update the last sentence in section 5(d) (iii) to add the missing text. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. In respect of the patient information poster: <ol style="list-style-type: none"> a) IGARD suggested that the poster was updated with the correct / working web links; and, b) IGARD suggested that the linked webpages provide further information on the ability to opt out. c) IGARD suggested that the applicant liaise with HRA CAG, as appropriate, in relation to any significant updates to the poster or websites. <p>Separate to this application: NHS Digital to provide a briefing on current ethnicity recording in datasets in terms of increasing reliability and granularity.</p>
3.6	<p><u>NHS Buckinghamshire, Oxfordshire, and Berkshire West ICB: DSfC - NHS Buckinghamshire, Oxfordshire And Berkshire West Integrated Care Board- IV, RS & Comm (Presenter: Michael Ball) NIC-616007-R3H0G-v0.2</u></p> <p>Application: This was an application for pseudonymised Commissioning Datasets; and identifiable Invoice Validation Datasets and Risk Stratification Datasets.</p> <p>The purpose of the application is for 1) Invoice Validation, which is part of a process by which providers of care or services get paid for the work they do 2) Risk Stratification, which is a tool for identifying and predicting which patients are at high risk (of health deterioration and using multiple services) or are likely to be at high risk and prioritising the management of their care in order to prevent worse outcomes; and 3) Commissioning, to provide intelligence to support the commissioning of health services. The data (containing both clinical and financial information) is analysed so that health care provision can be planned to support the needs of the population within the ICB area.</p>

	<p>The application includes a new linkage to 'Better Housing Better Health Plus' data for commissioning purposes. The existing 'Better Housing Better Health' service is a longstanding telephone support service (delivered by the National Energy Foundation) working to reduce and prevent the number of people in fuel poverty, and so improve health and wellbeing. The Council has put a pilot in place extending this service as the 'Better Housing Better Health Plus' service, which is for vulnerable residents in the area. A consented home visit takes place, which offers an integrated holistic assessment to better identify the range of the service users' needs and enable them to access relevant support services such as signposting to social prescribing. The Council and ICB now wishes to evaluate the service to understand the impact of the service on the health and wellbeing of the participants.</p> <p>Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD meeting on the 24th November 2022, where IGARD had recommended for approval, for the templated aspects of the application only; and had been unable to recommend for approval, for the 'Better Housing Better Health' linkage.</p> <p>IGARD noted that the Deputy Caldicott Guardian was in attendance for this item as an observer.</p> <p>IGARD noted and thanked NHS Digital and the applicant, in respect of the previous comments raised on the 'Better Housing Better Health' linkage; and the work undertaken to resolve these issues.</p> <p>IGARD noted and supported the three options for action outlined in section 1 (Abstract) to be undertaken by the applicant prior to the linkage of any data, for those who had consented via the previous consent model. 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.</p> <p>IGARD asked that the words "...to ensure they receive the services that would be of benefit to them, and to" was removed, noting that it was unnecessary and not in line with the most recent consent materials.</p> <p>IGARD advised that this application would be suitable for NHS Digital's Precedent route if all qualifying NHS Digital DARS Standards were met.</p> <p>Outcome: recommendation to approve the 'Better Housing Better Health' linkage</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update section 5(a) to remove the words "<i>to ensure they receive the services that would be of benefit to them, and to...</i>". <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD advised that this application would be suitable for NHS Digital's Precedent route if all qualifying NHS Digital DARS Standards were met.
3.7	<p><u>University of Oxford: Epidemiological and health services research using routine NHS data: work programme of the Unit of Health-Care Epidemiology, Oxford University (Presenter: Clare Wright) NIC-315419-F3W7K-v6.10</u></p> <p>Application: This was a renewal and extension application to permit the holding and processing of pseudonymised Civil Registration (Deaths) - Secondary Care Cut, Hospital Episode Statistics Admitted Patient Care (HES APC), HES Admitted Patient Care, HES:Civil Registration (Deaths) bridge and HES-ID to MPS-ID.</p>

	<p>It was also an amendment application to add a new purpose for processing, to examine the sociodemographic inequalities in morbidity and mortality.</p> <p>The primary purpose of the application is the advancement of education and research which are deemed to deliver a public benefit. The database and the research which uses it significantly contributes to the body of evidence and knowledge available which leads to changes in treatment, care and policies which are of benefit to the patient and the health care system; therefore, the use of this data in this way is considered to be in the public interest.</p> <p>Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD BAU meeting on the 4th August 2022; where the application had been recommendation for approval with a condition, by a quorum of 5 members, with one Specialist member present not participating in making a recommendation on the application due to a potential conflict of interest.</p> <p>IGARD noted that, as outlined in the Out of Committee (OOC) Standard Operating Procedure, any applications returned to the IGARD Secretariat for review OOC by the IGARD Chair or quorum of IGARD Members which were over three months old, would be automatically placed on the next available BAU meeting agenda for review by IGARD Members as per the current standard processes. Members would only review if the conditions have been met or not, and would not re-review the application, unless significant legislative or policy changes had occurred since last reviewed by a full meeting of IGARD or the application had been significantly updated, in which case the conditions may be updated to reflect such changes which will be noted for transparency in the published minutes and a full review of the application undertaken.</p> <p>The condition from the 4th August 2022 meeting was as follows:</p> <ol style="list-style-type: none"> 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. <p>A quorum of IGARD members were content that the condition had been met, however noted that the letter provided outlined that the support was conditional upon any amendments to or extension of the study being sent to the sponsor. IGARD suggested that DARS may wish to confirm with the applicant that that this condition was complied with.</p>
4	<p><u>Applications progressed / to be progressed via NHS Digital's SIRO Precedent route</u></p> <p>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).</p>
4.1	<p><u>Office for National Statistics (ONS): Maternity Services Data Set (MSDS) Legal Notice (No Presenter) NIC-631605-F2H3M-v0.11</u></p> <p>ONS as the executive arm of the UK Statistics Authority (UKSA), requires access to administrative data held by NHS Digital for the production of official statistics.</p> <p>The purpose of the application, is to enable ONS' health analysts to use information about who has accessed maternity services, including, when, where, and why maternity services have been accessed for a range of statistical purposes in line with ONS' function to produce statistics for the public good. All uses of the MSDS data for health and social care analysis hope to improve the availability and quality of statistics.</p>

<p>4.2</p>	<p>This application has not previously been reviewed by IGARD.</p> <p>IGARD noted that on the 5th December 2022 NHS Digital had advised in writing (via the IGARD Secretariat) that following the statutory notice from ONS to NHS Digital, mandating disclosure of the MSDS; the SIRO had approved authorisation for this application to progress via NHS Digital's SIRO Precedent route.</p> <p>IGARD noted this was a new application which had bypassed an independent review and suggested that NHS Digital should carefully document the process for legal notice applications for transparency to the public. It was not clear to IGARD why a legal notice removed the need for an independent review.</p> <p>IGARD also noted that use of the word "<i>permissive</i>" in section 1 (Abstract) did not align with the s45(c) mandatory request, which was not permissive.</p> <p>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.</p> <p><u>Cancer Research UK: Cancer Stats Future: Incidence Data Request (ODR1819_060) (No Presenter) NIC-656826-M3Y6C-v1.8</u></p> <p>The purpose of the application is to use de-personalised cancer registration data to produce statistics for a range of stakeholders, including the public, health professionals and teams within Cancer Research UK, about cancer in the UK.</p> <p>The datasets requested 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.</p> <p>IGARD noted that on the 5th 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.</p> <p>IGARD noted that the UK GDPR Article 9 legal basis and NHS Digital citation special condition in section 6 (Special Conditions) were missing from the application.</p> <p>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.</p> <p>4.3</p> <p><u>Erasmus University: Metastatic cutaneous Squamous Cell Carcinoma (cSCC) in England 2013- 2015– assessment of staging systems and histological risk factors for metastasis. (ODR1819_225) (No Presenter) NIC-656837-J7G8S-v1.2</u></p> <p>The purpose of the application is to review known cases of metastatic cSCC tumours with comparison to non-metastatic cSCC tumour characteristics such as thickness and diameter and comparison of current staging systems. Primary outcome will be risk of metastasis, secondary outcome will be risk of death in metastatic cases and potential improvements to current staging systems.</p> <p>The datasets requested 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.</p> <p>IGARD noted that on the 5th December 2022 NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had approved this application to progress via NHS Digital's SIRO Precedent route.</p>
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4.4	<p>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.</p> <p><u>Royal Marsden NHS Foundation Trust: A National Study Of Breast Cancer And A Range Of Late Effects Of Hodgkin Lymphoma Treatments In Women (ODR1516_470) (No Presenter) NIC-659282-H1F7C-0.3</u></p> <p>The purpose of the application is to improve understanding of the risks of the wide range of long-term fatal and non-fatal morbidities in women treated for Hodgkin Lymphoma (HL) at young ages; and to create a unique risk profile of incidence and severity of multiple long-term comorbidities, in order to enable clinicians and patients to understand patients' personalised risk profile when deciding on and consenting for treatment, and when managing follow-up and screening for late effects.</p> <p>The datasets requested 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.</p> <p>IGARD noted that on the 5th 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.</p> <p>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.</p> <p><u>London School of Hygiene and Tropical Medicine: CONCORD Programme (ODR1617_033) (No Presenter) NIC-659283-N1S1H-v0.4</u></p> <p>The purpose of the application is for the CONCORD programme, which provides the information required to assess the effectiveness of healthcare systems around the world in managing cancer patients and allows the assessment of how individual countries compare on the 25 indicators and global targets set by the World Health Assembly.</p> <p>The datasets requested 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.</p> <p>IGARD noted that on the 5th 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.</p> <p>IGARD suggested that the NDRS citation special condition be included in section 6 (special conditions) of the application.</p> <p>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.</p>
5	<p><u>Oversight & Assurance</u></p> <p>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.</p> <p>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,</p>

	<p>and as discussed on the 11th August 2022, would come back to IGARD in due course with any feedback or response.</p> <p>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.</p>
6	<p><u>COVID-19 update</u></p> <p><i>No items discussed</i></p>
7	<p><u>AOB:</u></p>
7.1	<p><u>Improving Data Access Programme (Presenter: Sue Main)</u></p> <p>Following the last update at the IGARD meeting on the 27th October 2022, this was a further update by NHS Digital with regard to the improving data access programme workstream, and other relevant areas of work linked to the programme.</p> <p>NHS Digital updated IGARD on the DARS annual confirmation report which was being updated in line with IGARD's comments made in March and July 2022; DARS Standard Territory of Use which was in final draft and would be circulated to IGARD Members for final comments ahead of the festive break; and the standard rationalisation work which starts as a pilot in December 2022 with a proposed end date of June 2023.</p> <p>IGARD thanked NHS Digital for attending and looked forward to further updates in the New Year.</p>
7.2	<p><u>University College London (UCL) (SUMMIT Study) NIC-656813-F4H5W-v1.3 and GRAIL Bio UK Ltd (SYMPLIFY Study) NIC-604851-W0M3S-v0.4 (Presenter: Frances Perry / Andy Rees / James Gray)</u></p> <p>IGARD noted that NIC-656813-F4H5W was last reviewed at IGARD on the 10th November 2022; and that NIC-604851-W0M3S progressed via NHS Digital's SIRO Precedent route, and was noted in the IGARD minutes on the 5th May 2022.</p> <p>IGARD noted that prior to the meeting, they had been provided with some written background information, in respect of a discrepancy in both data sharing agreements (DSA), relating to the period of data that can be shared, specifically if any data prior to the consent date can be shared.</p> <p>Colleagues from NHS Digital's Digi-Trials and the Associate Director, Deputy SIRO & Audit Services; attended the meeting to provide a further verbal update on this, including proposed amendments to the DSAs prior to them proceeding via NHS Digital's SIRO Precedent route.</p> <p>IGARD noted and thanked NHS Digital for the written information provided prior to the meeting; and the verbal update provided in-meeting.</p>
7.3	<p><u>National Disease Registration Service (NDRS) Congenital Anomalies Data Sets – Briefing Paper (Louise Dunn)</u></p>

	<p>NHS Digital advised IGARD, that the updated National Disease Registration Service (NDRS) Congenital Anomalies Data Sets – Briefing Paper (tabled at IGARD 20th October 2022) was still in progress; and that an update would be provided in the New Year.</p> <p>IGARD noted and thanked NHS Digital for the verbal update from NHS Digital; and as previously agreed, noted that this would be appended to a future set of IGARD minutes as per process.</p> <p>There was no further business raised, the Co-Deputy IGARD Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.</p>
8	<p><u>NHS Digital / NHS England merger (Presenter: Garry Coleman)</u></p> <p>NHS Digital's Deputy SIRO and Audit Services attended the meeting to further discuss the latest developments on NHS Digital's merger with NHS England and the possible future of IGARD, or its successor, up to and beyond the merger.</p> <p>As advised at the IGARD meeting on the 24th November 2022, this was part of the ongoing engagement with IGARD; and to provide further updates as this area of work develops.</p> <p>IGARD noted that following first consultation with IGARD at the BAU meeting on the 24th November 2022; IGARD had provided NHS Digital with written feedback / queries in respect of the verbal information provided at that meeting. The Deputy SIRO reiterated that a response would be provided as soon as possible.</p> <p>The Deputy SIRO also reiterated that work was ongoing to the draft guidance and was not considered ready to be shared with IGARD.</p> <p>IGARD thanked the Deputy SIRO for attending the meeting, and it was agreed that this item would be a weekly item on the IGARD meeting agenda.</p>

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 16/12/22

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: 7 December 2022

Application & application version number: DARS-NIC-431352-G7F1M-v1

Organisation name: Imperial College London

Profession Advisory Group Agenda item: 2

PAG understands that participants of the REACT study consent to their data being processed.

Acknowledging that consent materials will address the location of processing, PAG continues to seek to minimise the dissemination of GP data as part of ongoing measures to limit disclosure and privacy risks; this is especially important now that the Health and Social Care system-wide COPI regulations have now been withdrawn.

Accepting a COVID-19 “emergency” is no longer recognised by the government (i.e. there are no longer any restrictions to individual’s activities) and despite the consent of patients for this study, PAG strongly encourages NHS Digital (soon to be NHS England) to rapidly invest in ensuring studies using GP data are conducted inside the NHS D TRE as a priority.

PAG recognises that NHS Digital has discussed with the applicant the feasibility of conducting the study within NHS Digital’s TRE, and understands that the NHS Digital TRE is unable to currently deal with cohorts. PAG would encourage NHS Digital to continue to improve their TRE offering.

PAG advises NHS Digital that applicants adopt best practice around open science, specifically meaning applicants make public their finalised protocols, analysis code, and codelists. Can the applicant support such best practice?

Attendees	Role	Organisation
Jonathan Osborn	Deputy Chair, Caldicott Guardian	NHS Digital
Amir Mehrkar	GP, Clinical Researcher	RCGP
Mark Coley	Deputy IT Policy Lead	BMA
Duncan Easton	Senior Approvals Team	NHS Digital
Joanna Warwick	Secretariat	NHS Digital
Kimberley Watson	Senior Approvals Team	NHS Digital

David Morris	Senior Case Manager	NHS Digital
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