

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 7 April 2022

IGARD MEMBERS IN ATTENDANCE:	
Name:	Position:
Maria Clark	Lay Member (Chair)
Prof. Nicola Fear	Specialist Academic Member
Dr. Robert French	Specialist Academic / Statistician Member
Dr. Imran Khan	Specialist GP Member
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Paul Affleck	Specialist Ethics Member
Kirsty Irvine	IGARD Chair
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Chair
Jenny Westaway	Lay Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	Team:
Garry Coleman	Associate Director / Senior Information Risk Owner (SIRO) (Observer: item 3.1)
Dave Cronin	Data Access Request Service (DARS) (SAT Observer: items 3.1)
Catherine Day	Data Access Request Service (DARS) (Item 3.2)
Dan Goodwin	Data Access Request Service (DARS) (Item 3.3)
Frances Hancox	Data Access Request Service (DARS) (Items 2.1 - 2.2)
Suzanne Hartley	Data Access Request Service (DARS) (Observer: item 3.1)
Sara Lubbock	Data Access Request Service (DARS) (Observer: item 3.1)
Karen Myers	IGARD Secretariat
Lizz Paley	National Disease Registration Service (Items 2.1 - 2.2)
Sarah Stevens	Deputy Director, National Disease Registration Service (Items 2.1 - 2.2)

Kimberley Watson	Data Access Request Service (DARS) (SAT Observer: items 3.2 - 3.3)
Vicki Williams	IGARD Secretariat
Clare Wright	Data Access Request Service (DARS) (Item 3.1)
Tom Wright	Data Services for Commissioners (DSfC) (Item 7.1)
*SAT – Senior Approval Team (DARS)	

1	<p>Declaration of interests:</p> <p>Maria Clark noted professional links to the Royal College of Surgeons [NIC-72064-V5V2X] via her work with The College of General Dentistry (previously the Faculty of General Dental Practice (UK)); 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 professional link to Liverpool University [NIC-382794-T3L3M] through his role as Liverpool CCG Chief Clinical Informatics Officer (CCIO) and Caldicott Guardian; but noted no specific connection with the application or staff involved and it was agreed that there was no conflict of interest.</p> <p>Dr. Maurice Smith noted a professional link with Egton Medical Information Systems (EMIS) [NIC-382794-T3L3M] as a practising GP partner at the Mather Avenue Surgery; but noted no specific connection with the application or staff involved and it was agreed that there was no conflict of interest.</p> <p>Review of previous minutes and actions:</p> <p>The minutes of the 31st March 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.</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 Disease Registration Service (NDRS) Cancer Registration: Non-Routine Collections – Briefing Paper (Presenters: Frances Hancox / Lizz Paley / Sarah Stevens)</u></p> <p>This briefing paper is to inform IGARD of the onboarding of the National Disease Registration Service (NDRS) cancer registration data products. The NDRS is split into two disease registers:</p> <ul style="list-style-type: none"> • National Cancer Registration and Analysis Service (NCRAS) • National Congenital Anomaly and Rare Disease Registration Service (NCARDRS) <p>NDRS were formerly managed by Public Health England (PHE) prior to its closure, and have now been brought into NHS Digital. The NDRS systems are hosted by the UK Health Security Agency (UKHSA), who act as a Data Processor on behalf of NHS Digital.</p>

	<p>The NDRS datasets within scope of this briefing paper and to be onboarded in this first phase are the following non-routine collections of cancer data managed by the National Cancer Registration and Analysis Service (NCRAS):</p> <ul style="list-style-type: none"> • National Cancer Diagnosis Audit (NCDA) • Lung Cancer Data Audit (LUCADA) • National Lung Cancer Audit (NLCA) • National Cancer Patient Experience Survey (CPES) • Quality of Life of Cancer Survivors in England: (Breast, Colorectal, Prostate, Non-Hodgkin's Lymphoma) • Quality of Life of Colorectal Cancer Survivors in England: Patient Reported Outcome Measures Survey (PROMS) • Somatic Molecular dataset <p>NCRAS is responsible for population-based cancer registration in England. Anyone referred, diagnosed or treated for cancer in England is registered. People with certain conditions that may lead to cancer are also registered.</p> <p>The collection aims to provide the following benefits to patients and the public: increase prevention and early diagnosis of cancer; improve the management of NHS cancer services; improve NHS cancer treatment and care; and improve patient outcomes, including better quality of life and longer survival.</p> <p>Outcome: IGARD welcomed the briefing paper and made the following high-level comments:</p> <ol style="list-style-type: none"> 1. In respect of the opt outs: <ol style="list-style-type: none"> a) To update the briefing paper throughout, to clarify any contradictory text in respect of the opt out. b) When using the term "<i>opt out</i>", to clarify which opt out is being referred to, for example, NDO*, Type-1, collection or study specific. 2. IGARD noted that the team were in the process of updating the transparency documents and website, and suggested that it was made clear how patient data would end up in the Registry, noting the different avenues that someone can end up in the database. 3. IGARD suggested that further consideration should be given to removing historical or out of date websites from internet search engines, and that all current websites should reference the appropriate body and contact details, to opt out of the Registry. <p>IGARD welcomed the draft briefing paper and looked forward to receiving the updated briefing paper, either out of committee (OOC) or at a future meeting, and before any first of type applications were received by IGARD.</p> <p>*National Data Opt Out</p>
<p>2.2</p>	<p><u>National Disease Registration Service (NDRS) Cancer Registration – Briefing Paper (Presenters: Frances Hancox / Lizz Paley)</u></p> <p>This briefing paper is to inform IGARD of the onboarding of the National Disease Registration Service (NDRS) cancer registration data products.</p> <p>The NDRS is split into two disease registers:</p>

	<ul style="list-style-type: none"> • National Cancer Registration and Analysis Service (NCRAS) • National Congenital Anomaly and Rare Disease Registration Service (NCARDRS) <p>NDRS were formerly managed by Public Health England (PHE) prior to its closure, and have now been brought into NHS Digital. The NDRS systems are hosted by the UK Health Security Agency (UKHSA), who act as a Processor on behalf of NHS Digital.</p> <p>The NDRS datasets within scope of this briefing paper and to be onboarded in this first phase are the five core cancer registration data collections managed by the National Cancer Registration and Analysis Service (NCRAS):</p> <ul style="list-style-type: none"> • Cancer registration (pre-1995) • Cancer registry • Systemic Anti-Cancer Therapy Dataset (SACT) • National Radiotherapy Dataset (RTDS) • Rapid Cancer Registrations Dataset (RCRD) <p>NCRAS is responsible for population-based cancer registration in England. Anyone referred, diagnosed or treated for cancer in England is registered. People with certain conditions that may lead to cancer are also registered.</p> <p>The collection aims to provide the following benefits to patients and the public: increase prevention and early diagnosis of cancer; improve the management of NHS cancer services; improve NHS cancer treatment and care; and improve patient outcomes, including better quality of life and longer survival.</p> <p>Outcome: IGARD welcomed the briefing paper and made the following high-level comments:</p> <ol style="list-style-type: none"> 1. In respect of the opt outs: <ol style="list-style-type: none"> a) To update the briefing paper throughout, to clarify any contradictory text in respect of the opt out. b) When using the term “<i>opt out</i>”, to clarify which opt out is being referred to, for example, NDO*, Type-1, collection or study specific. 2. IGARD noted that the team were in the process of updating the transparency documents and website, and suggested that it was made clear how patient data would end up in the Registry, noting the different avenues that someone can end up in the database. 3. IGARD suggested that further consideration should be given to removing historical or out of date websites from internet search engines, and that all current websites should reference the appropriate body and contact details, to opt out of the Registry. <p>IGARD welcomed the draft briefing paper and looked forward to receiving the updated briefing paper, either out of committee (OOC) or at a future meeting, and before any first of type applications were received by IGARD.</p> <p>*National Data Opt Out</p>
3	Data Applications
3.1	<u>University of Oxford: QResearch - COVID-19 Risk Stratification project (Presenter: Clare Wright) NIC-382794-T3L3M-v5.4</u>

Application: This is a renewal application to permit the holding and processing of pseudonymised Civil Registration (Deaths) data, COVID-19 Hospitalization in England Surveillance System (CHESS), COVID-19 Second Generation Surveillance System (SGSS), COVID-19 UK Non-hospital Antigen Testing Results (pillar 2), COVID-19 Vaccination Adverse Reactions and Secondary Uses Service (SUS+) data Admitted Patient Care (beta version).

It is also an amendment to update the application throughout to ensure it meets NHS Digital's [Data Access Request Service \(DARS\) Standards](#).

QResearch is a database of linked medical records that has been used and continues to be used by a variety of research projects undertaken by UK Universities; and consists of the coded pseudonymised electronic health records from primary care patients registered with approximately 1,500 general practices spread throughout the UK.

The purpose of this application is for QResearch's urgent COVID-19 research projects to support the COVID-19 pandemic, for example, the development and maintenance of a COVID-19 risk stratification tool commissioned by the Chief Medical Officer (CMO).

The applicant continues to use Hospital Episode Statistics (HES) and Emergency Care Data Set (ECDS) data under this data sharing agreement (DSA) which flows under NIC-240279-Y2V2N.

Discussion: IGARD welcomed the application and noted the importance of the research.

IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD – NHS Digital COVID-19 response meetings on the 12th January 2021, 19th January 2021 and 2nd March 2021.

It was also discussed under 'AOB at the IGARD BAU meeting on the 3rd March 2022.

IGARD noted that section 1 (Abstract) of the application contained an analysis by NHS Digital on a number of areas, including, but not limited to data controllership / data processing, sub-licensing and the noted urgency of the work outlined within the application.

IGARD noted that the University of Oxford was currently the sole Data Controller, and supported NHS Digital's analysis in section 1, that statements within section 5(a) (Objective for Processing) were conflicting on this issue, for example *"Requests to use the linked NHS Digital data come from researchers within University of Oxford and/or its Data Processing organisations."* and *"The University of Oxford is the sole Data Controller who also process data. The University of Oxford are solely responsibility for determining the purpose for which, or the manner in which NHS Digital data will be processed."* IGARD asked that in respect of the Data Controllers and the Data Processors, the application was reviewed throughout, to align with [NHS Digital's DARS Standard for Data Controllers](#) and [NHS Digital's DARS Standard for Data Processors](#) and as borne out of the facts, and that updates were made to the application as appropriate. IGARD also agreed with NHS Digital's analysis that organisations named as Data Processors in the DSA who determine the purpose for processing, were in fact Data Controllers in such scenarios, which conflicted with statements in section 5(a), and asked that this be amended accordingly.

IGARD noted and agreed with NHS Digital's analysis in section 1, that the use of honorary contracts by the University of Oxford, to cover all legal responsibilities, was **not** an appropriate mechanism for sharing data with the Data Processor; and asked that NHS Digital work with the applicant to determine another pathway, for example, by using a sub-licensing model, in line with [NHS Digital DARS Standard for Sub-licensing and Onward Sharing of Data](#).

IGARD noted that section 1 referred to a future audit, following the previous SIRO approval of the application, and queried if an audit had taken place. NHS Digital advised that an audit had not yet taken place, and confirmed that this would take place within the next six-months, and that specific points raised by the SIRO would be addressed as part of the audit. IGARD noted the verbal update from NHS Digital, and asked that for future reference, section 1 was updated with clarification that NHS Digital would undertake an audit, as advised to the SIRO, within six-months.

IGARD noted the references throughout the application to the “urgency” of the work, and asked that, notwithstanding the importance of the research, that a justification was provided in section 1 and section 5 (Purpose / Methods / Outputs) as to the “urgency” of the application, for example, by including relevant timescales or evidence from funders that they were requesting outputs within a certain period of time and giving details of the time period specified.

IGARD noted the yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits) and, in line with [NHS Digital's DARS Standard for Expected Measurable Benefits](#), asked that given the significant volume of data flowing, this was updated to provide two or three specific **urgent** yielded benefits accrued to date, and asked that it was clear as to the benefits to both the patients and the health and social care system more generally, for example, in relation to the shielded patient list.

IGARD queried the statement in section 5(b) (Processing Activities) “*EMIS and TPP have given permission for the GP data it supplies to be linked with the data from NHS Digital...*”, and noting that this was incorrect, asked that it was amended to correctly state that the GP is the Data Controller and gives permission for the GP data to be linked with the data from NHS Digital.

IGARD noted the statement in section 5(b) “*Regular reviews will be undertaken to ensure that all appropriate controls are in place to minimise any risk of reidentification.*”, and asked that confirmation was provided that regular reviews had taken place, and asked that evidence and examples are provided as appropriate.

IGARD queried the statement in the data minimisation column in section 3 (Datasets Held / Requested) “*In 2016 the applicant reviewed the data held to determine whether all fields continued to be necessary for research.*”, and asked that this was reviewed and that confirmation was provided of a more recent review date, noting that the DSA was created in June 2020, in line with [NHS Digital DARS standard for data minimisation](#).

IGARD noted the information in section 5(e) (Is the Purpose of this Application in Anyway Commercial) outlining the commercial aspect of the application, and noted that section 5(a) was not clear on the commercial aspect, and since section 5 forms [NHS Digital's data uses register](#) asked that a brief summary was added to section 5(a) of the commercial aspect of this application, as outlined in section 5(e) and in line with [NHS Digital DARS Standard for Commercial Purpose](#).

IGARD noted the references throughout section 5(a) to the various committees and boards, for example, the QResearch Scientific Committee; and suggested that there was more transparency, including, but not limited to, ensuring that minutes were published in a timely manner and the website was updated regularly.

IGARD advised that NHS Digital draw the applicant's attention to the contractual obligation in section 4 (Privacy Notice), in respect of maintaining a UK GDPR compliant, publicly accessible transparency notice throughout the life of this agreement, in order to maintain public trust in

using health data from national datasets; and in line with [NHS Digital's DARS Standard for Transparency \(fair processing\)](#); and suggested that the correct processing was accurately reflected.

IGARD queried the reference to "*departmental laptops*" in the special condition in section 6 (Special Conditions), and asked that further clarity was provided as to what this meant.

IGARD noted a number of technical terms in section 5(b), and asked that this public facing section, that forms [NHS Digital's data uses register](#), was amended throughout, to ensure acronyms be defined upon first use, and technical terms are explained in a manner suitable for a lay audience, for example, "*TPP*".

IGARD suggested that NHS Digital put in place a short-term extension until the deferral points had been addressed.

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 outstanding queries with regards to data controllership.

Outcome: recommendation to defer, pending:

1. In respect of the Data Controllers / Data Processors:
 - a) To align with [NHS Digital's DARS Standard for Data Controllers](#) and [NHS Digital's DARS Standard for Data Processors](#) and as borne out of the facts.
 - b) IGARD agreed with NHS Digital's analysis that organisations named as Data Processors in the DSA, can determine the purpose for processing, and are in fact Data Controllers in such scenarios, which conflicts with statements in section 5(a), and this should be amended accordingly.
 - c) IGARD agreed with NHS Digital's analysis that the use of honorary contracts by the University of Oxford, to cover all legal responsibilities, is **not** an appropriate mechanism for sharing data with the Data Processor; and that NHS Digital should work with the applicant to determine another pathway, for example, by using a sub-licensing model.
2. To update section 1 with clarification that NHS Digital will undertake an audit, as advised to the SIRO, within six-months.
3. To provide a justification as to the "*urgency*" of the application, for example, by including relevant timescales or evidence from funders.
4. To review the statement in section 3 that the data fields were reviewed in 2016, and provide confirmation of a more recent review date, in line with [NHS Digital DARS standard for data minimisation](#).
5. To amend the statement in section 5(b) that EMIS and TPP have given permission for the GP data it supplies to be linked, to correctly reference that the GP is the Data Controller and gives permission.
6. In line with the [NHS Digital DARS Standard for commercial purpose](#), to provide a brief summary in section 5(a) of the commercial aspect of this application, as outlined in section 5(e).
7. To provide confirmation in section 5(b) that regular reviews to minimise any risk of reidentification have taken place, and provide evidence and examples as appropriate.
8. Given the significant volume of data, to provide 2 or 3 specific urgent yielded benefits accrued to date and ensure these are clear as to the benefits to both patients and the health care system more generally.

	<p>9. IGARD noted a number of technical terms in section 5(b), and asked that this public facing section, that forms NHS Digital's data uses register, was amended throughout, to ensure acronyms be defined upon first use, and technical terms are explained in a manner suitable for a lay audience, for example, "TPP".</p> <p>10. To clarify what is meant by "<i>departmental laptops</i>" in section 6.</p> <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD suggested more transparency with regards to the committees and boards, including (but not limited to), ensuring that minutes are published in a timely manner. 2. In respect of the privacy notice and in line with NHS Digital's DARS Standard for Transparency (fair processing), IGARD wished to draw to the applicant's attention to the statement in section 4, that a UK GDPR compliant, publicly accessible transparency notice is maintained throughout the life of the agreement; and that the correct processing is accurately reflected. 3. IGARD suggested that NHS Digital put in place a short-term extension until the deferral points above had been addressed. 4. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the outstanding queries with regards to data controllership. 5. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the outstanding queries with regards to data controllership.
3.2	<p><u>Department of Health and Social Care (DHSC): TRE access - Enabling Policy Analysis (Presenter: Catherine Day) NIC-484452-H8S1L-v1.5</u></p> <p>Application: This is an amendment application to permit access to the following pseudonymised datasets via NHS Digital's Trusted Research Environment (TRE): Civil Registration (Deaths), Emergency Care Data Set (ECDS), Improving Access to Psychological Therapies Data Set (IAPT), Medicines dispensed in Primary Care (NHSBSA data), Maternity Services Data Set (MSDS), Secondary Uses Service Payment By Results Episodes (SUS PBR) (available through tactical Uncurated Low Latency Hospital Episode Statistics (HES) Admitted Patient Care (APC), Outpatients and Critical Care).</p> <p>DHSC currently holds an active Data Sharing Agreement (DSA) under NIC-365132-V5S8H, which includes access to NHS Digital's Data Access Environment (DAE) for the same purpose. This purpose of this DSA is to replace the existing DAE agreement as the datasets currently held under NIC-365132-V5S8H-v1.2 that are still required, become available within the TRE.</p> <p>DHSC will use the data within NHS Digital's TRE for the analysis of data, in support of the Secretary of State for Health & Social Care in delivery of their duties set out within the National Health Service Act 2006.</p> <p>NHS Digital advised IGARD that section 5(b) (Processing Activities) stated "<i>Only registered users will have access to record level or aggregate data containing small numbers downloaded from the system.</i>", and confirmed that this was incorrect and would need amending.</p> <p>NHS Digital noted that at the last review of the application, IGARD had strongly suggested that the applicant undertakes patient and public involvement and engagement (PPIE), in some form and throughout the lifetime of the agreement. NHS Digital confirmed that the applicant</p>

had advised that there was ongoing work with individual teams using the data within DHSC, for example, the maternity team, as to how PPIE could be undertaken.

Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 16th September 2021.

IGARD noted that this application had been reviewed by the GPES Data for Pandemic Planning and Research (GDPPR) – Profession Advisory Group (PAG) on the 25th August 2021 and 15th September 2021, and that notes from this meeting had been attached to the IGARD BAU minutes from the 16th September 2021. IGARD also noted that further PAG reviews had taken place on the 3rd November 2021 and 24th November 2021, however, as the applicant was not currently requesting GDPPR data under this version of the DSA, these notes had not been reviewed by IGARD. IGARD advised that if GDPPR data was requested in the future, the notes would be reviewed as supporting documentation and attached to the published IGARD meeting minutes as per process.

IGARD noted and thanked NHS Digital for the verbal updates, and confirmed that they were supportive of the update to the incorrect statement in section 5(b), relating to the download of aggregated data with small number suppressed, to reflect the factual scenario.

In addition, IGARD noted the verbal update from NHS Digital in respect of how the applicant was addressing the PPIE advice previously suggested, and asked that for transparency, this was updated within section 5(a) (Objective for Processing).

IGARD queried why the applicant was requesting Uncurated Low Latency Hospital Data Sets, noting that these datasets were usually only requested where there was an urgency for the data, and the data contained within the Uncurated Low Latency datasets would also be available within the other data requested, albeit with a small time lag. IGARD therefore asked that section 5 (Purpose / Methods / Outputs) was updated with a justification for the requirement of the Uncurated Low Latency HES APC, HES Outpatients and HES Critical Care Data Sets.

IGARD noted the constraints placed in the [Direction](#) for the collection of NHSBSA data, specifically, *“Providing intelligence about the safety and effectiveness of medicines...”*, and asked that in line with [NHS Digital DARS Standard for Objective for Processing](#), when referencing processing of NHSBSA data, including in section 5(a), to ensure a clear narrative is provided linking the purposes and processing to the relevant Direction.

Separate to this application, IGARD suggested that the Data Access Request Service (DARS) update their relevant onboarding documentation to ensure DARS staff are aware of the constraints placed in the Direction for the collection of NHSBSA data and the relevant updates required within the DSA.

IGARD noted the incorrect references throughout the application to *“Public Health England (PHE)”*, and asked that the application was updated to correctly reference the *“UK Health Security Agency (UKHSA)”* and that all references to *“PHE”* were removed, noting the functions of PHE were merged into UKHSA (and other organisations) in October 2021.

IGARD queried the special condition in section 6 (Special Conditions) relating to The Health Service Control of Patient Information (COPI) Regulations 2002, that stated *“...all data must be destroyed when COPI expires...”*, and asked that this was updated to be clear that it is the *“COPI Notice”* that will be expiring and not COPI Regulations.

IGARD noted the references within section 1 (Abstract) and section 5 to *“7 Day Services”*, and noting that healthcare was already available seven days a week, asked that this was either

updated, for example, to refer to *“improved access to health services”* or similar; or asked that the references were removed.

IGARD noted the yielded benefits outlined in section 5(d) (Benefits) (iii) (Yielded Benefits), however asked that this were reviewed and amended to ensure they were correctly referenced in the past tense, in line with [NHS Digital DARS Standard for Expected Measurable Benefits](#).

IGARD noted that Section 5(d) (iii) did not appear to be in line with the [NHS Digital DARS Stand for Expected Measurable Benefits](#), and asked that this section was updated accordingly. In addition, IGARD asked that confirmation was provided in section 5(d) (iii) that the yielded benefits were achieved using the data under this DSA, noting that this was currently unclear.

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...”*.

As section 5 forms [NHS Digital’s data uses register](#), IGARD asked that section 5(a) **and** section 5(b) was amended, to ensure that all acronyms upon first use be defined and further explained if the meaning is not self-evident, or example *“ALB”*, *“R Studio”* and *“SQL”*, in line with [NHS Digital DARS Standard for Objective for Processing](#) and [NHS Digital DARS Standard for processing activities](#).

IGARD noted the inclusion of a number of technical phrases and words within section 5(a), such as *“tooling and functionality”*, asked that this public facing section, that forms [NHS Digital’s data uses register](#), was amended throughout, to ensure technical terms were explained in a manner suitable for a lay audience, in line with [NHS Digital DARS Standard for Objective for Processing](#).

IGARD noted the references throughout the application to the urgency of the work, for example *“urgent data requirements”*, and asked that for clarity, section 5(a) was updated with a definition of the term *“urgent”*.

IGARD queried the reference in section 5(a) to *“85 year old diabetic men”*, and asked that this was amended to *“men living with diabetes”* or similar.

IGARD noted the reference in section 5(a) **and** section 5(c) (Specific Outputs Expected) to *“false”* dichotomy, and asked that this was amended to remove reference to *“false”*.

IGARD queried the paragraph in section 5(b) *“All possible ways of data minimisation have been considered and undertaken where possible, therefore, the applicant have met their legal obligations under UK General Data Protection Regulation (UK GDPR).”*; and asked that this was removed as it was not relevant.

IGARD queried the reference in section 5(b) to *data uploads*”, and noting that this function does not exist within the TRE, asked that it was removed.

IGARD noted the statement in section 5(b) *“Users are not permitted to link data extracted from the TRE system.”*; and asked that this was removed as this was not relevant.

IGARD queried the content within section 5(b), and noted that some of the information provided were outputs, for example, the Chief Medical Officer briefings; and asked that section 5(b) was updated to remove any outputs, and that these were moved to correctly sit in section 5(c); in line with [NHS Digital DARS Standard for Expected Outcomes](#).

Outcome: recommendation to approve subject to the following condition:

1. To provide a justification in section 5, for the requirement of the Uncurated Low Latency Hospital Data Sets.

The following amendments were requested:

1. To update section 5(a) and in line with [NHS Digital's DARS Standard for Objective for Processing](#), when referencing processing of NHSBSA dataset to ensure a clear narrative is provided linking the purposes to the relevant Direction.
2. To amend the sentence in section 5(b) in relation to aggregated data with small number suppressed, to reflect the factual scenario (as per the verbal update from NHS Digital).
3. To update section 5(a) with further information of the PPIE (as per the verbal update from NHS Digital).
4. To review the reference in section 1 and section 5 to "7 Day Services" and either update for example, to "improved access to health services" or similar, or remove.
5. As section 5 forms [NHS Digital's data uses register](#), to amend section 5(a):
 - a. to ensure acronyms be defined upon first use, for example "ALB"; and
 - b. technical terms are used only where necessary and explained in a manner suitable for a lay audience, for example "tooling and functionality".
 - c. To define what is meant by the term "urgent".
 - d. To amend the reference from "85 year old diabetic men" to "men living with diabetes".
 - e. To remove the reference to "false" dichotomy.
6. In respect of section 5(b):
 - a) IGARD noted a number of technical terms in section 5(b), and asked that this public facing section, that forms [NHS Digital's data uses register](#), was amended throughout, to ensure technical terms are explained in a manner suitable for a lay audience, for example, "R Studio" and "SQL".
 - b) To remove the paragraph in section 5(b) that starts "All possible ways of data minimisation...", as this is not relevant.
 - c) To remove reference to "data uploads" since this function does not exist in the TRE.
 - d) To remove the statement "Users are not permitted to link data extracted from the TRE system.", as this is not relevant.
 - e) To remove any specific outputs from section 5(b) and move to section 5(c).
7. To update the application throughout, to correctly reference the UKSHA and remove all references to PHE.
8. To explain in section 5(c) what is meant by "Alcohol Attributable fractions".
9. In respect of the yielded benefits in section 5(d) and in line with [NHS Digital DARS Standard for Expected Measurable Benefits](#):
 - a) To update the yielded benefits to ensure they are referenced in the past tense.
 - b) To update section 5(d) to use a form of wording such as "it is hoped ...", rather than "it will...".
 - a) To confirm how the yielded benefits in section 5(d) (iii) were achieved using the data under this DSA.
10. To update the special condition in section 6 to be clear it is the "COPI Notice" that expires.

Separate to this application: IGARD suggested that DARS update their relevant onboarding documentation to ensure DARS were aware of the constraints placed in the Direction for the collection of NHSBSA data and the relevant updates required within the DSA.

It was agreed the conditions would be approved out of committee (OOC) by IGARD members.

London School of Hygiene and Tropical Medicine (LSHTM): Liver transplantation as treatment for patients with hepatocellular carcinoma; a study using existing electronic data (Presenter: Dan Goodwin) NIC-72064-V5V2X-v5.8

Application: This is 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 Critical Care, HES Outpatients and HES: Civil Registration (Deaths) bridge.

The application is also an amendment to remove The Royal College of Surgeons of England (RCS) as a Data Controller.

Hepatocellular carcinoma (HCC) is the most common liver cancer, with more than 4,000 patients are being diagnosed with HCC in the UK each year. The incidence of HCC has increased four-fold in the last 30 years. Liver diseases such as obesity and hepatitis c lead to liver cirrhosis and eventually cancer. There is often a lag time of two decades between the acquisition of liver disease and the development of HCC.

The purpose of the application is to maximise the benefit of liver transplantation as a treatment option for patients with liver cancer. There are five separate work packages (WP), each with specific objectives: **WP1** - Identifying the rising incidence and mortality of Hepatocellular carcinoma (HCC) in England and worldwide; **WP2** - Assessing the validity of the linked national databases as a data source for HCC research; **WP3** - Assessing the impact of sociodemographic and clinical factors on treatment selection and survival of patients with HCC; **WP4** - Analysing outcomes of liver transplantation in patients with HCC; and **WP5** - Analysing outcomes of liver transplantation in patients with HCC who receive a cardiac death donor liver.

The data will be limited to patients in either the liver cancer or liver transplant cohorts, the cohort will consist of 84,000 patients.

Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 10th August 2017 and 21st September 2017.

IGARD noted in section 1 of the application, that the study had previously had s251 support from Health Research Authority Confidentiality Advisory Group (HRA CAG), to allow the transfer of confidential patient information without the discloser being in breach of the Common Law Duty of Confidentiality (CLDoC); however, as there were no further data flows required and all organisations specified within the DSA only held pseudonymised data with no confidential information, NHS Digital stated that there was no requirement to maintain the s251 support. IGARD noted the information provided by NHS Digital, however, asked that the applicant liaised with HRA CAG, to clarify if s251 support was still required for this application, since they were of the opinion that s251 support was required.

IGARD asked that following confirmation from HRA CAG, that if the s251 support was **not** required, that the applicant provided the appropriate written confirmation from HRA CAG. Or if the s251 support **was** required, written confirmation from HRA CAG should be provided showing how the applicant had continued to meet the HRA CAG conditions of support, by way of annual reports for example; and that written confirmation was provided that HRA CAG continued to support the application. IGARD asked that in all instances, the written confirmation was uploaded to NHS Digital's Customer Relationship Management (CRM) system for future reference.

IGARD queried the cohort numbers referenced within the supporting documents provided and the application, and noting the conflicting numbers, asked that the application was reviewed and updated throughout, to ensure the cohort numbers were correct and consistent.

IGARD noted the reference to “*gender*” in section 5(b); and asked that it was clarified if it was actually “*sex*”, since they are not interchangeable data fields, in line with [NHS Digital DARS Standard for processing activities](#).

Noting that the public facing section 5 forms [NHS Digital’s data uses register](#), IGARD noted the following in respect of the language throughout section 5, and asked that the relevant updated below were made in line with [NHS Digital DARS Standard for Objective for Processing](#), [NHS Digital DARS Standard for processing activities](#), [NHS Digital DARS Standard for Expected Outcomes](#) and [NHS Digital DARS Standard for Expected Measurable Benefits](#).

IGARD noted the statements in section 5(a) that HCC was the most common liver cancer, and asked that this was updated to further reflect that it was the most common “*primary*” liver cancer.

IGARD queried the statement in section 5(a) “*They accept that transplant outcomes...*”, and asked that it was amended to state “*it is understood that transplant outcomes...*”.

IGARD noted the statement in section 5(a) “*The National Cancer Registration and Analysis Service (NCRAS) is responsible for cancer registration and was previously run by Public Health England before coming under the **ownership** of NHS Digital.*”; and asked that this was amended to the data coming under “*controllership*”, noting that the data is not owned by NHS Digital.

IGARD noted the references in section 5(a) and section 5(b) to “*post-op*”, and asked that this was updated to clearly refer to “*post-operative*”.

IGARD queried the statement in section 5(a) “*LSHTM know the development of HCC*”, and noting that this knowledge was not specific to LSHTM, asked that this was amended, to more accurately state “*it is known*” or similar.

IGARD queried the reference in section 5(b) to “*deterministic linkage of data*”, and noting that it was currently unclear what this meant, asked that the reference was updated with further clarity.

IGARD noted the inclusion of a number of technical phrases and words within section 5(b), such as “*ICD10 code of ‘C22’*” and “*OPCS4 code of ‘J01’*”, asked that this public facing section, which forms [NHS Digital’s data uses register](#), was amended throughout, to ensure technical terms are explained in a manner suitable for a lay audience.

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

IGARD queried the statements in section 5(a) and section 5(d) to “*patients falling off the waiting list due to spread of their cancer*”, and asked that this was reviewed and updated in a more sensitive and appropriate language.

IGARD noted the reference in section 5(d) (iii) to “*equivocal*” results, and suggested that this was updated to state “*equivalent*” *provided that was what the applicant had intended*.

IGARD advised that NHS Digital draw the applicant’s attention to the contractual obligation in section 4 (Privacy Notice), in respect of maintaining a UK GDPR compliant, publicly accessible transparency notice throughout the life of this agreement, in order to maintain public trust in

using health data from national datasets; and in line with [NHS Digital's DARS Standard for Transparency \(fair processing\)](#); and that the legal basis was referenced.

IGARD noted the reference to patient and public involvement and engagement (PPIE) in the application, however suggested that the applicant may wish to consider involving the relevant public and patient groups throughout the lifecycle of the project in line with [HRA guidance on Public Involvement](#).

Outcome: recommendation to approve subject to the following condition:

1. In respect of the s251 support:
 - a) The applicant to liaise with HRA CAG to clarify if s251 support is still required for this application.
 - b) If the s251 support is **not** required, to provide written confirmation from HRA CAG; or,
 - c) If the s251 support is required, to provide written confirmation that the applicant has continued to meet the HRA conditions of support, by way of annual reports; and,
 - d) To provide written confirmation that HRA CAG continue to support the application.
 - e) To upload all the written confirmation to NHS Digital's CRM system for future reference.

The following amendments were requested:

1. To update the application throughout to ensure the cohort numbers are correct and consistent throughout.
2. In respect of the language in section 5 that forms [NHS Digital's data uses register](#):
 - a) To update the statement that HCC is the most common liver cancer, to reflect that it is the most common "*primary*" liver cancer.
 - b) To amend the statement "*They accept that transplant outcomes...*", to "*it is understood that transplant outcomes...*".
 - c) To remove reference to NCRAS data coming under the "*ownership*" of NHS Digital, to "*controllership*".
 - d) To amend the reference from "*post-op*" to "*post-operative*".
 - e) To update section 5(a) to use a form of wording such as "*it is hoped ...*", rather than "*it will...*".
 - f) To amend the statement "*LSHTM know the development of HCC*" to "*it is known*" or similar, as this not knowledge specific to the school.
 - g) To provide further clarity in section 5(b) regarding the reference "*deterministic linkage of data*".
 - h) IGARD noted a number of technical terms in section 5(b), and asked that this public facing section, that forms [NHS Digital's data uses register](#), was amended throughout, to ensure technical terms are explained in a manner suitable for a lay audience, for example, "*ICD10 code of 'C22'*" and "*OPCS4 code of 'J01'*".
3. To update section 5(b) to refer to "*sex*" rather than "*gender*" as the former is what will be disseminated, and they are not interchangeable data fields.
4. In respect of the benefits in section 5(d):
 - a) To update section 5(d) to use a form of wording such as "*it is hoped ...*", rather than "*it will...*".
 - b) To update the reference from "*equivocal*" to "*equivalent*".
 - c) To review and update the reference to "*patients falling of the waiting list due to spread of their cancer*", to reflect more appropriate language.

The following advice was given:

	<p>1. In respect of the privacy notice and in line with NHS Digital's DARS Standard for Transparency (fair processing), IGARD wished to draw to the applicant's attention to the statement in section 4, that a UK GDPR compliant, publicly accessible transparency notice is maintained throughout the life of the agreement; and that the legal basis is referenced.</p> <p>2. IGARD noted the reference to PPIE in the application, however suggested that the applicant may wish to consider involving the relevant public and patient groups for the lifecycle of the project in line with HRA guidance on Public Involvement.</p> <p>It was agreed the conditions would be approved out of committee (OOC) by IGARD members.</p>
4	<p><u>Applications progressed via NHS Digital's Precedent route, including the SIRO Precedent</u></p> <p>Applications that have been progressed via NHS Digital's Precedent route, including the SIRO Precedent, and NHS Digital have notified IGARD in writing (via the Secretariat).</p> <p><i>No items discussed.</i></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>IGARD Members noted that they had not yet been updated on the issues raised at the 27th May 2021 IGARD business as usual (BAU) meeting with regard to previous comments made on the IG COVID-19 release registers March 2020 to May 2021. IGARD noted that in addition, they had not been updated on the issues raised on the IG COVID-19 release registers June 2021 to January 2022.</p> <p>IGARD Members noted that the last IG COVID-19 release register that they had reviewed and provided comments on was January 2022.</p> <p>IGARD noted that the NHS Digital webpage excel spreadsheet had now been updated for the period March 2020 to February 2022: NHS Digital Data Uses Register - NHS Digital</p>
6	<p><u>COVID-19 update</u></p> <p><i>No items discussed</i></p>
7 7.1	<p><u>AOB:</u></p> <p><u>Clinical registries for Health and Social Care Commissioners (Presenter: Tom Wright)</u></p> <p>NHS Digital attended the meeting to provide a verbal update in respect of commissioners now wanting to access the Clinical registries for Health and Social Care; and to make members aware that a briefing paper would be presented at a future IGARD BAU meeting.</p> <p>IGARD noted and thanked NHS Digital for notifying them in advance; and looked forward to receiving a briefing paper in due course.</p> <p>There was no further business raised, the Chair of the meeting thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.</p>

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 01/04/22

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)
NIC-411161-G4K7X	University of Oxford	03/03/2022	1. To amend the yielded benefit that states “... <i>budesonide as the first widely available, inexpensive COVID-19 treatment</i> ...”, to make clear that this drug should only be administered as part of a clinical trial and is not “ <i>widely available</i> ”.	IGARD Chair	IGARD Chair	None
NIC-381972-Q5F0V-v1.3	University College London (UCL)	25/11/2022	1. In respect of the “ <i>vulnerable</i> ” cohort(s): a) To provide confirmation as to what definition of “ <i>vulnerable</i> ” applies to the 25 - 37-year-old cohort, for whom the Children’s Act definition of ‘vulnerable’ does not cover (it is only relevant up to age 24). b) To provide an explanation as to how the applicant has identified the cohort of vulnerable parents and what is the criteria for inclusion in that cohort. c) To provide an explanation of how “ <i>previous birth</i> ” contributes to the vulnerable characteristics of the cohort of vulnerable mothers. d) To note if at any point ethnicity data will be used as a determinant of vulnerability. e) To update section 5 with a clear definition of what is meant by children who were	IGARD members	Quorum of IGARD members at the IGARD BAU meeting on the 31/03/2022.	None

			<i>“otherwise vulnerable”</i> as part of the cohort, including (but not limited to) what factors would lead a child to be defined as <i>“otherwise vulnerable”</i> .			
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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