

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 15 October 2020

IGARD MEMBERS IN ATTENDANCE:	
Name:	Position:
Paul Affleck	Specialist Ethics Member
Prof. Nicola Fear	Specialist Academic Member (Chair 2.6 onwards)
Kirsty Irvine (Chair)	IGARD Lay Chair (Chair 2.1 - 2.5)
Dr. Imran Khan	Specialist GP Member
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	Position:
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	Team:
Dave Cronin	Data Access Request Service (DARS) (Item 3)
Catherine Day	Data Access Request Service (DARS)
Duncan Easton	Data Access Request Service (DARS)
Richard Hatton	Clinical Informatics and Deputy Caldicott Guardian (Observer: items 2.1 – 2.4)
Dickie Langley	Information Governance
Karen Myers	IGARD Secretariat
Kimberley Watson	Data Access Request Service (DARS)
Vicki Williams	IGARD Secretariat

1	<p>Declaration of interests:</p> <p>Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising on COVID-19.</p> <p>Review of previous minutes and actions:</p>
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	<p>The minutes of the 8th October 2020 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	Data Applications
2.1	<p><u>Manchester University NHS Foundation Trust: Advanced cardiovascular risk prediction in the acute care setting (Presenter: Kimberley Watson) NIC-304146-M5F6Y</u></p> <p>Application: This was a new application for pseudonymised Hospital Episode Statistics (HES) Admitted Patient Care (APC) data, for the purpose of a study, seeking to improve the short term and long term treatment of cardiovascular disease by determining whether a diagnostic chest pain algorithm can be updated with machine learning techniques to prevent known loss in accuracy over time.</p> <p>The University of Manchester aim to maintain and improve an existing acute myocardial infarction clinical prediction model currently in clinical use and in the process validate a method for updating all clinical prediction models. In addition, they intend to examine the prognostic value of emergency department data in predicting long term cardiovascular outcomes.</p> <p>Discussion: IGARD noted that Manchester University NHS Foundation Trust was the applicant and listed as one of the funders of the study, and queried if they should also be considered a joint Data Controller or Data Processor, and were advised by NHS Digital that this had been assessed and it had been determined that they were not considered a Data Controller or Data Processor. IGARD noted the update from NHS Digital and asked that section 1 (Abstract) was amended to clarify that the activities of Manchester University NHS Foundation Trust had been assessed by NHS Digital and it was not considered to be a Data Controller or Data Processor.</p> <p>IGARD queried the reference in section 1(b) (Data Controller(s)) to “<i>joint</i>” Data Controller, and asked that this was removed, noting that only The University of Manchester were a Data Controller.</p> <p>IGARD queried the statement in section 5(a) (Objective for Processing) “<i>University of Manchester are currently amending the relevant Confidentiality Advice Group Materials and Ethics Materials to apply for the Civil Registration Data that NHS Digital hold. University of Manchester will submit a subsequent amendment to this agreement to obtain the Civil Registration Data set and corresponding HES bridge file once those permissions are in place</i>”. Noting that the Civil Registration data was mortality data, IGARD advised that s251 would not be required and asked that this statement was reviewed or removed if deemed unnecessary.</p> <p>IGARD noted the reference in section 5(a) to including patients over the age of 16, noting that supporting document 2.1, the Health Research Authority Confidentiality Advisory Group (HRA CAG) letter of support, dated the 5th February 2020 stated that patients would be aged 18 and older; asked that section 5(a) was amended to remove any reference to patients aged 16 and over to make it explicitly clear the HRA CAG approval and the data flow only applied to a cohort comprising of patients aged 18 and over.</p> <p>IGARD noted the reference in section 3(b) (Data Access Already Given) to the overall size of the cohort consisting of 24,000 patients, and asked that the application, where relevant was updated to note the individual sizes of the respective cohorts.</p>

IGARD noted that section 5(a) made specific reference to an academic paper, however the full title of the paper had not been completed, and asked that section 5(a) was updated with the full title of the academic paper, or that the reference was removed.

IGARD queried the information in section 5(d) (Benefits), specifically in relation to the patient and public involvement (PPI), and asked that, in light of the information in supporting document 2.0, the HRA CAG form, which detailed more specific PPI involvement, asked that section 5(d) was updated to include the PPI engagement that is already underway; and that this was aligned with the HRA CAG form and supporting document 1.0, the study protocol. In addition, IGARD also asked that section 5(d) was updated with any details of future PPI engagement plans.

IGARD noted that section 5 (Purpose / Methods / Outputs) referred to “*target audiences*” for the study, however queried why GPs were not listed as part of this in light of the study topic, and asked that section 5(d) was updated to include a reference to GPs being part of the interested audience.

IGARD noted the statement in section 5(b) (Processing Activities) “*On receipt the data will be linked back to the clinical data set with unique study ID numbers, on completion of this final local linkage the data key will be deleted and the data anonymised*”, and asked that the end of the sentence “... *and the data anonymised*” to avoid giving the impression the dataset would be anonymous.

IGARD noted the reference within the protocol, to the applicant holding the anonymised dataset for 7 years, and advised that they would need to ensure they have a live Data Sharing Agreement (DSA) with NHS Digital during that period.

IGARD noted and endorsed NHS Digital’s review that the applicant did **not** meet NHS Digital’s Standard for privacy notices.

Outcome: recommendation to approve

The following amendments were requested:

1. To review the reference in section 5(a) to the HRA CAG application being amended for the purpose of applying for the Civil Registration mortality data and remove if deemed unnecessary.
2. To amend section 5(a) to remove any reference to patients aged **16** and over to make it explicitly clear the HRA CAG approval and the data flow only applies to a cohort comprising of patients aged **18** and over.
3. To amend section 1(b) to remove the reference to “*joint*” Data Controller.
4. To update the application, where relevant, to note the size of the respective cohorts.
5. To complete the reference to the academic paper in section 5(a) or remove the reference.
6. To update section 5(d) to include reference to GPs being part of the interested audience.
7. To remove the reference in section 5(b) to “... *and the data anonymised*”.
8. In respect of PPI:
 - a) To update section 5(d) to include the PPI engagement that is already underway.
 - b) To align with the PPI engagement outlined in the HRA CAG form and the protocol.
 - c) To include any future PPI engagement plans.
9. To amend section 1 to clarify that the activities of Manchester University NHS Foundation Trust have been assessed by NHS Digital and is not a Data Controller **or** Data Processor.

	<p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD noted the reference within the supporting document to the applicant holding the anonymised dataset for 7 years, and advised that they would need to ensure they have a live DSA with NHS Digital during that period.
2.2	<p><u>Royal Brompton and Harefield NHS Foundation Trust: Epidemiology and Prognosis in Acute Myocarditis (Presenter: Kimberley Watson) NIC-144568-D7G6V</u></p> <p>Application: This was a renewal application for pseudonymised Hospital Episode Statistics (HES) Admitted Patient Care (APC) data and Civil Registrations data; an extension for a further 1-year; and an amendment to add an additional purpose, to improve the national understanding of the implications of COVID-19 on the heart and cardiovascular system.</p> <p>The purpose is for a study aims to describe the longitudinal epidemiological trends of acute myocarditis to provide a contemporary, population-level assessment of the burden of disease and how this may have changed over the last 23 years.</p> <p>Myocarditis (inflammation of the heart muscle) is known to predominantly affect young adults aged between 19- 35 years. It is usually related to a recent viral infection, patients often present with severe, sudden-onset chest pain mimicking a heart attack, difficulty breathing due to weakened heart muscle, and/or palpitations due to electrical rhythm disturbances within the heart. However, myocarditis also affects infants and older adults where causative factors and clinical outcomes are poorly characterised. In the long-term, up to one third of patients are at risk of developing heart failure, known as dilated cardiomyopathy, or experiencing a sudden cardiac arrest.</p> <p>NHS Digital advised IGARD that following the observations made by IGARD at the IGARD – NHS Digital COVID-19 Response meeting on the 5th May 2020 in relation to the upper age limit on the data flows from the age of 80, that the age restriction had been removed and now included all age groups.</p> <p>NHS Digital also advised that the application previously requested a bridging file, linking APC data to death data, and that this had not been included within the application submitted to IGARD for review, and confirmed that this had now been added into section 3(a) (Data Access Already Given).</p> <p>Discussion: IGARD noted that this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 5th May 2020.</p> <p>IGARD queried the references in section 1 (Abstract) when referring to the IGARD – NHS Digital COVID-19 Response meeting, for example, referring to it as a “<i>Board</i>” and a “<i>panel</i>”; and asked that section 1 was updated to accurately describe the role of the IGARD – NHS Digital COVID-19 Response meeting and as set out by its published Terms of Reference.</p> <p>IGARD noted and supported the update from NHS Digital in respect of the upper age limit being removed but noted that some text still remained and asked that the application was further updated throughout to reflect this. In addition, IGARD noted the update from NHS Digital and asked for the inclusion of the historical bridging file be added to section 3(a) (Data Access Already Given).</p> <p>IGARD noted the British Heart Foundation-funded cardiovascular Trusted Research Environment (TRE), and suggested that the applicant may wish to consider whether the work outlined could be carried out within the TRE now or in future, or whether there was any</p>

synergy that could be achieved through collaborating with the research design or outputs, now or in the future.

IGARD queried why the study did not appear to have a study protocol, especially in light of the additional COVID-19 purpose, and asked that in the absence of a protocol, that either an analysis plan, funding application update, or similar was provided; that set out the design of the analysis, of the proposed processing for the addition of the COVID-19 purpose.

IGARD noted and commended the applicant's efforts in respect of the data minimisation that had been undertaken; however noted the significant quantum of data still being requested and queried whether the applicant had the capacity to deliver the programme of work and fulfil the stated outputs, in light of the study lead undertaking the work as part of a PhD and the other commitments that this entails; and asked that the applicant provide confirmation to NHS Digital.

IGARD queried if any additional datasets would be required, to support the additional COVID-19 purpose, for example 'COVID-19 Hospitalisation in England Surveillance System' (CHESS) or 'The Second Generation Surveillance System' (SGSS); and asked that confirmation was provided in section 1.

IGARD noted that some of the information in section 5 (Purpose / Methods / Outputs) was not clear and suggested that it was updated to ensure that it was written in a language suitable for a lay reader including reference to "*thrombogenicity*" and that further sensitive consideration was given to the patient audience.

IGARD noted that section 5(a) made specific reference to an academic paper, however the full title of the paper had not been completed, and asked that section 5(a) was updated with the full title of the academic paper, or that the reference was removed.

IGARD queried the outputs stated in section 5(c) (Specific Outputs Expected), and asked that these were updated to be clearer in terms of the target dates.

IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices and suggested that the privacy notice was updated to reflect the change in processing as outlined in the application.

Outcome: recommendation to approve subject to the following conditions:

1. To provide either an analysis plan, funding application update, or similar, which sets out the design of the analysis of the proposed processing for the addition of the COVID-19 purpose.
2. To provide confirmation to NHS Digital that, in light of the significant quantum of data, the applicant has the capacity to deliver the programme of work and fulfil the stated outputs.

The following amendments were requested:

1. To provide confirmation in section 1 and section 5 if additional data sets would be required, for example CHESS or SGSS.
2. To update section 3 to ensure all the datasets requested are noted.
3. To update section 5 to ensure it is written in language suitable for a lay reader and that consideration is given to a patient audience (for example when referring to "*thrombogenicity*").
4. To complete the reference to the academic paper in section 5(a) or remove the reference.

	<ol style="list-style-type: none"> 5. To update the application throughout to ensure the references to the upper age limit of 80 are removed. 6. To update section 5(c) to include relevant target dates. 7. To update section 1 to accurately describe the role of the IGARD – NHS Digital COVID-19 Response meeting. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD noted the British Heart Foundation-funded cardiovascular TRE, and suggested that the applicant may wish to consider whether the work outlined could be carried out within the TRE now or in future or whether there was any synergy that could be achieved through collaborating with the research design or outputs, now or in the future. 2. IGARD suggested that applicant's privacy notice is updated to reflect the change in processing. <p>It was agreed the conditions would be approved out of committee (OOC) by IGARD Members.</p>
2.3	<p><u>Health Data Research UK: R14.2 - CVD-COVID-UK. Cardiovascular disease and COVID-19: using UKwide linked routine healthcare data to address the impact of cardiovascular disease on COVID-19 and the impact of COVID-19 on cardiovascular diseases. (Presenter: Catherine Day) NIC-381078-Y9C5K</u></p> <p>Application: This was an amendment application to 1) add The Medicines Dispensed in Primary Care (NHS Business Services Authority (BSA) data); and 2) to increase the number of Data Controllers from 6 to 7, with the addition of The National Institute for Health and Care Excellence (NICE).</p> <p>The British Heart Foundation (BHF) Data Science Centre, which is embedded within Health Data Research UK (HDR UK), is working in partnership with NHS Digital to establish a Cardiovascular Disease Trusted Research Environment (CVD TRE) [service] for England, to enable analyses of linked, nationally collated healthcare datasets. This project is entitled 'CVD COVID UK', and will enable timely research on the effects /impacts of cardiovascular disease on COVID-19, and the direct and indirect impacts of COVID-19 on cardiovascular diseases; coordinate similar approaches across the four nations of the UK; and future proof an enduring CVD TRE service post-COVID-19.</p> <p>Discussion: IGARD welcomed the application and noted the importance of the research.</p> <p>IGARD noted that this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 26th May, 2nd June, 9th June, 16th June and 23rd June 2020.</p> <p>IGARD noted that when this application was last reviewed and recommended for approval on the 23rd July 2020, a number of amendments were requested, however it did not appear as though they had all been addressed within the application presented for review. IGARD advised that this application would be reviewed on the new amendment requests only, and that further discussions would take place separately with NHS Digital, to discuss any additional issues relating to the last review / amendment requests.</p> <p>IGARD noted the request to add NICE as a Data Controller, and queried what their role within the TRE was, and asked that additional documentation or confirmation was provided, that all of the appropriate documentation as required of a Data Controller TRE was in place, including, but not limited to; the joint Data Controller Agreement as per Article 26 of the General Data Protection Regulation (GDPR); the appropriate transparency notice published; and</p>

	<p>confirmation that NICE had acknowledged and was compliant with the relevant Special Conditions to the DSA.</p> <p>IGARD queried if the CVD-COVID-UK Oversight Committee had provided NHS Digital with the first quarterly report detailing the projects undertaken in the Data Sharing Agreement (DSA) as requested in a special condition in section 6 (Special Conditions); and were advised by NHS Digital that the first CVD-COVID-UK Oversight Committee meeting would take place on the 30th October 2020 and NHS Digital representation would form part of the committee, and it was expected that the first report would be produced following this.</p> <p>IGARD noted a number of acronyms in section 5(a) (Objective for Processing) and asked that this public facing section be updated to ensure that all acronyms upon first use were expanded and clearly defined with a supportive explanation in a language suitable for a lay reader.</p> <p>IGARD noted that section 1 referred to questions that the CVD COVID UK research group were looking to address, however noted that the questions had not been included; and asked that section 1 (Abstract) was updated to include the missing questions.</p> <p>IGARD queried the reference in section 1 and section 5(a) to “<i>Future proof an enduring CVD TRE service post-Covid19</i>” when describing the CVD COVID UK project objectives; and asked for further clarity of this, including the plan for future proofing in light of the data being provided under The Health Service Control of Patient Information (COPI) Regulations 2002.</p> <p>IGARD queried the references in section 1 and section 5 to “<i>TRE Secondary Care</i>”, noting that they had not seen this reference previously, and were advised by NHS Digital that this was the umbrella data set for the Secondary Uses Service (SUS) products; IGARD noted the update from NHS Digital and asked that section 1 and section 5 were both updated with a more detailed explanation.</p> <p>IGARD noted and endorsed NHS Digital’s review that the applicant did not meet NHS Digital’s Standard for privacy notices.</p> <p>Outcome: recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> 1. In respect of the addition of NICE as a Data Controller, to provide or confirm that all of the appropriate documentation as required of a Data Controller TRE is in place, including (but not limited to); <ol style="list-style-type: none"> a) The joint Data Controller Agreement as per Article 26 of GDPR; b) The appropriate transparency notice published; c) Confirmation that NICE has acknowledged and is compliant with the relevant Special Conditions to the DSA. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To amend section 5 to ensure that all acronyms upon first use be defined and further explained if the meaning is not self-evident. 2. To update section 1 to include the missing questions. 3. To clarify the wording “<i>future proof an enduring CV19 TRE service post-covid19</i>”. 4. To update section 1 and section 5 to provide an explanation of what is meant by “<i>TRE Secondary Care</i>”. <p>It was agreed the conditions would be approved out of committee (OOC) by IGARD Members.</p>
2.4	<p><u>Royal Devon and Exeter NHS Foundation Trust: An exploratory descriptive analysis of the 5-year survivorship of total ankle replacements compared with equivalent rates in administrative datasets with further adjusting for co-varieties (Presenter: Catherine Day) NIC-178836-V1G3V</u></p>

Application: This was a new application for ten years of pseudonymised Hospital Episode Statistics (HES) Admitted Patient Care (APC) data and Civil Registrations (death) data, on a cohort of approximately 5,000 individuals, for the purpose of a study which will analyse data from the UK National Joint Registry (NJR) and HES data, to find out how many ankle replacements fail within five years of the surgery.

This will be the largest study looking at outcomes of these operations, by analysing this data it will give both surgeons and patients more information on the expected outcomes and risks of complications following ankle replacements. The study hopes to improve knowledge of ankle replacements, and complications arising from them, that will improve future patient outcomes, and has support from the National Joint Registry and the British Orthopaedic Foot and Ankle Surgery Society (BOFAS).

Discussion: IGARD queried if the purpose outlined in the application was service evaluation or research, and were advised by NHS Digital that the application submitted to the Health Research Authority Confidentiality Advisory Group (HRA CAG) clearly determined that it was service evaluation. IGARD noted the update from NHS Digital, however asked that a summary of the outlier policy was included, or, if there was no such policy, that an explanation was provided as to why an outlier policy was not needed.

IGARD queried if the study would include patients who had stated that they did not consent to their data being recorded with the NJR, and asked that confirmation was provided of the percentage of patients who did not consent and were not included within the dataset; and in addition, if there were any service evaluation implications in respect of the patients who were not included within the dataset.

In addition, IGARD also queried if there was a significant number of patients missing from the dataset, and whether the applicant could carry out the service evaluation using **only** NHS Digital data.

IGARD noted in section 3(c) (Patient Objections) that patient objections were not being applied as the data requested in the Data Sharing Agreement (DSA) was not considered confidential under the Health and Social Care Act 2012; and asked that justification was provided of why NHS Digital were not applying National Data Opt-outs.

IGARD noted the reference in section 5(b) (Processing Activities) to a supporting document listing the operation codes, and asked that this was amended to either remove the reference to the supporting document, noting that the wider public would not have sight of this, or to include the operating codes noted within the supporting document into the application.

IGARD queried the funder that was referenced in section 8(b) (Funding Sources) 'Gwen Fish Orthopaedic Trust', noting that this was the first time they had seen this funder within an application. IGARD asked that a copy of the funding agreement was provided, if available, and that a copy was uploaded NHS Digital's Customer Relationship Management (CRM) system. In addition, IGARD asked that section 5 (Purpose / Methods / Outputs) was updated with confirmation that the funder would not have influence on the outcomes nor suppress any of the findings of the research.

IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices and that further significant work was required, and in addition, IGARD highlighted the special condition in section 6 (Special Conditions) that stated "*All Data Controllers are expected to provide a privacy notice that is compliant with the GDPR notice requirements within one month after obtaining the personal data*".

Outcome: recommendation to approve subject to the following condition:

	<ol style="list-style-type: none"> 1. In respect of the patients not consented: <ol style="list-style-type: none"> a) To provide confirmation what percentage of patients did not consent and are not included within the dataset. b) To provide confirmation if there are any service evaluation implications in respect of the patients not included within the dataset. c) If there is a significant number of patients missing from the dataset, to confirm if the applicant can carry out the service evaluation, using only NHS Digital data. 2. To provide justification why NHS Digital are not applying National Data Opt-outs. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To include a summary of the outlier policy or, if there is no such policy, to explain why this is not needed. 2. To amend section 5(b) to either remove the reference to the supporting document, or to include the operating codes noted within the supporting document. 3. In respect of the funding: <ol style="list-style-type: none"> a) To provide a copy of the funding agreement, if available, and upload a copy of the funding agreement to NHS Digital's CRM system; b) To confirm within section 5 that the funder will not have influence on the outcomes nor suppress any of the findings of the research. <p>It was agreed the conditions would be approved OOC by IGARD Members.</p>
2.5	<p><u>Group Application 6 x CCG's¹: DSfC - STP - NHS Staffordshire and Stoke on Trent CCGs - Commissioning (Presenter: Duncan Easton) NIC-234915-J3K4V</u></p> <p>Application: This was a renewal application for pseudonymised Secondary Uses Service (SUS+), Local Provider Flows, Mental Health Minimum Data Set (MHMDS), Mental Health Learning Disability Data Set (MHLDDS), Mental Health Services Data Set (MHSDS), Maternity Services Data Set (MSDS), Improving Access to Psychological Therapy (IAPT), Child and Young People Health Service (CYPHS), Community Services Data Set (CSDS), Diagnostic Imaging Data Set (DIDS), National Cancer Waiting Times Monitoring Data Set (CWT), Civil Registration (CRD), National Diabetes Audit (NDA) and Patient Reported Outcome Measures (PROMs). This was also an amendment to 1) remove Blackpool Teaching Hospitals as a Data Processor, and 2) to include Microsoft Limited as they provide Cloud services for NHS Midlands and Lancashire Commissioning Support Unit.</p> <p>The purpose of the application is to provide intelligence to support the commissioning of health services.</p> <p>NHS Digital advised IGARD that this application had been brought to IGARD for a recommendation due to NHS Digital having determined that a risk applied to the application following a breach that had been highlighted following an audit in 2018 and reported on in 2019.</p> <p>Discussion: IGARD noted the update from NHS Digital in respect of the breach that had been highlighted following the audit in 2018 and reported on in 2019 in relation to NHS East Staffordshire CCG, and suggested to NHS Digital that this was referenced within the application, noting that there was minimal information referring to this.</p>

¹ NHS North Staffordshire CCG, NHS East Staffordshire CCG, NHS South East Staffordshire and Seisdon Peninsula CCG, NHS Stoke on Trent CCG, NHS Stafford and Surrounds CCG and NHS Cannock Chase CCG

	<p>IGARD also asked that NHS Digital provided confirmation that they were satisfied with the audit findings in respect of the parties involved, and that any remedial actions recommended by the audit team had been undertaken to NHS Digital's satisfaction.</p> <p>In addition, IGARD also asked that a copy of the audit information was provided in relation to NHS East Staffordshire CCG and a copy uploaded to NHS Digital's customer relationship management (CRM) system.</p> <p>IGARD queried the information within the data minimisation column in section 3(b) (Additional Data Access Requested) that stated <i>"Please see Additional Production Details"</i> and asked that this was updated to remove this reference and to replace with a brief lay summary of the data minimisation activities, or to refer to the relevant part of section 5 (Purpose / Methods / Outputs) that detailed this.</p> <p>IGARD noted and endorsed NHS Digital's review that the applicant did not meet NHS Digital's Standard for privacy notices.</p> <p>IGARD suggested that they would wish to review this application again when it comes up for renewal, extension or amendment; and that this application would not be suitable for NHS Digital's Precedent route.</p> <p>Outcome: recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> 1. In respect of the audit carried out in 2018 and reported on in 2019: <ol style="list-style-type: none"> a) To provide conformation that NHS Digital is satisfied with the audit findings in respect of the parties and that any remedial actions recommended have been undertaken to NHS Digital's satisfaction. b) To provide a copy of the audit information in relation to East Staffordshire. <p>The following amendment were requested:</p> <ol style="list-style-type: none"> 1. To update the data minimisation column in section 3(b) to remove the reference to <i>"additional production details"</i> and replace with narrative detail or with a reference to the relevant part of section 5. <p>The following advice was given, if the above condition was not satisfied:</p> <ol style="list-style-type: none"> 1. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment. 2. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route. <p>It was agreed the condition would be approved OOC by IGARD members.</p>
2.6	<p><u>Group Application 3 x CCG's²: CCG - Commissioning (Presenter: Duncan Easton) NIC-338789-M0T3Q</u></p> <p>Application: This was a renewal application for pseudonymised Secondary Uses Service (SUS+), Local Provider Flows, Mental Health Minimum Data Set (MHMDS), Mental Health Learning Disability Data Set (MHLDDS), Mental Health Services Data Set (MHSDDS), Maternity Services Data Set (MSDS), Improving Access to Psychological Therapy (IAPT), Child and Young People Health Service (CYPHS), Community Services Data Set (CSDS), Diagnostic Imaging Data Set (DIDS), National Cancer Waiting Times Monitoring Data Set (CWT), Civil Registries Data (CRD), National Diabetes Audit (NDA) and Patient Reported Outcome</p>

² NHS Bedfordshire CCG, NHS Luton CCG and NHS Milton Keynes CCG

Measures (PROMs). This was also an amendment to add Amazon Web Services as a cloud provider for Optum Health Solutions UK Ltd

The purpose of the application is to provide intelligence to support the commissioning of health services.

Discussion: IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices; and asked that a special condition was inserted in section 6 (Special Conditions) that within 1 month of signing the Data Sharing Agreement (DSA), the applicant will have published a General Data Protection Regulation (GDPR) compliant privacy notice.

IGARD noted that section 3(c) (Patient Objections) that patient objections had not been applied, however queried the reference in supporting document 2, the data flow diagram, that Type 2 Objections had been applied with the linking of the GP data, and asked that the data flow diagram was updated with reference to patient Data Opt-outs and aligned with the application.

IGARD queried the reference to Interxion UK listed as a processing location in section 2 (Locations), and noted that elsewhere in the application it referred to them as being an entity in their own right, and asked that clarification was provided as to why they were listed as a processing location, or if not relevant, to remove.

IGARD noted that the application referenced two cloud storage platforms, Microsoft Limited and Amazon Web Services, and asked that section 1(b) (Data Controller(s)) was updated with the reference to the agreed cloud storage security assurances.

IGARD noted within the application and supporting documents provided that the data risk model ranking for the Cloud Storage was assessed as class 4, for Microsoft Azure and class 5, for Amazon Web Services, both of which were high risk; and asked that in light of this, a brief statement was provided in section 1 (Abstract), confirming that NHS Digital's Security Advisor was satisfied with the security arrangements.

ACTION: IGARD suggested that NHS Digital may wish to consider the number of storage locations, when reviewing this application, particularly noting that there is cloud based storage.

IGARD discussed the data risk model categories and suggested that a further discussion was held with NHS Digital to determine where there was a high risk, how this conclusion had been reached and what assurances, if any, had been put in place.

ACTION: IGARD to discuss data risk model categories and any additional assurance that could be included within the application with NHS Digital.

IGARD noted a number of acronyms in section 5(a) (Objective for Processing) and asked that this public facing section be updated to ensure that all acronyms upon first use were expanded and clearly defined with a supportive explanation in a language suitable for a lay reader.

IGARD noted the large amount of storage locations within the application and suggested that NHS Digital may wish to consider the number of storage locations, when reviewing this application, particularly noting that there is cloud based storage.

Outcome: recommendation to approve

The following amendments were requested:

1. To insert a special condition in section 6 that within 1 month of signing the DSA, the applicant will have published a GDPR compliant privacy notice.

	<ol style="list-style-type: none"> 2. To update the data flow diagram with reference to patient Data Opt-outs and align with the application. 3. To provide clarification why Interxion UK is listed as a processing location, and if not relevant, to remove. 4. To update section 5 to ensure it is written in language suitable for a lay reader and that consideration is given to the lay audience. 5. To insert the reference to the cloud storage security assurances, in section 1(b).
3	<p><u>Returning Applications</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.</p> <ul style="list-style-type: none"> • NIC-20951-D2K6S Office for National Statistics (ONS) • NIC-389320-R4M6Z University of Nottingham <p>IGARD welcomed the two applications as part of their oversight and assurance role and noted a number of comments to NHS Digital and suggested that further information and comments be provided in an IGARD Oversight and Assurance Report.</p> <p>Moving forward, IGARD agreed that COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 applications may also be included as part of the oversight and assurance review, not just those that were approved via NHS Digital's precedent route.</p>
4	<p><u>COVID-19 update</u></p> <p>To support NHS Digital's response to COVID-19, from Tuesday 21st April 2020, IGARD will hold a separate weekly meeting, to discuss COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 urgent applications that have been submitted to NHS Digital. Although this is separate to the Thursday IGARD meetings, to ensure transparency of process, a meeting summary of the Tuesday meeting will be captured as part of IGARD's minutes each Thursday and published via the NHS Digital website as per usual process.</p> <p>The ratified action notes from Tuesday 13th October 2020 can be found attached to these minutes as Appendix B.</p>
5 5.1	<p><u>AOB:</u></p> <p><u>Information Governance</u></p> <p>A member of NHS Digital's Information Governance – COVID-19 Response Team, attended the meeting to provide a brief update / overview of ongoing work.</p> <p>There was no further business raised, the acting IGARD Chair 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 09/10/20

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-178135-HJSFF -	University of Birmingham	02/07/2020	1. With reference to PAG point 4, to update section 5(e) to include reference to 'Prior Principle'.	IGARD Chair	OOC by IGARD Chair	None
NIC-374190-D0N1M	Genomics England	06/08/2020	1. With reference to PAG point 4, to update section 5(e) to include reference to 'Prior Principle'.	IGARD Chair	OOC by IGARD Chair	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):

- NIC-41525-H2P4B NHS Chorley and South Ribble CCG
- NIC-47184-P3G4K NHS South Sefton CCG
- NIC-54764-N1C1J NHS Portsmouth CCG

Appendix B

Independent Group Advising on the Release of Data (IGARD)

Action Notes from the IGARD – NHS Digital COVID-19 Response Meeting

held via videoconference, Tuesday, 13th October 2020

In attendance (IGARD Members):	Paul Affleck (Specialist Ethics Member) Prof Nicola Fear (Specialist Academic Member) Kirsty Irvine (IGARD Lay Chair)
In attendance (NHS Digital):	Dave Cronin (DARS – item 3.1) Louise Dunn (DARS – item 3.3) Liz Gaffney (DARS) Fran Hancox (DARS – item 3.2) Karen Myers (IGARD Secretariat) Kimberly Watson (DARS) Vicki Williams (IGARD Secretariat)
In attendance (external):	Emily Cross (IBM – item 2 only) Jerome Greutmann (IBM – item 2 only)

1	<p>Welcome</p> <p>The IGARD Chair noted that this was a weekly meeting convened to support NHS Digital's response to the COVID-19 situation and was separate from the IGARD business as usual (BAU) meetings. IGARD members present would only be making comments and observations on any items that were presented, and were not making formal recommendations to NHS Digital. Should an application require a full review and recommendation, then it should go through the usual Data Access Request Service (DARS) process and be presented at a Thursday IGARD meeting. The action notes from the Tuesday meeting would be received at the next Thursday meeting of IGARD and published as part of those minutes as an appendix.</p> <p>Declaration of interests:</p> <p>Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising on COVID-19.</p>
2	<p><u>IBM update</u></p> <p>IGARD members were given a brief update to the IBM work underway in NHS Digital including improvements to the customer experience and current projects. It was agreed that this would be a weekly update to the COVID-19 response meeting.</p> <p>IGARD members thanked IBM and NHS Digital for the update and noted that further updates from IBM would be on an ad-hoc basis.</p>
3.1	<p><u>NIC-402417-N9Z5W UCL Partners</u></p>

	<p>Background: This was a brief verbal update to the update received on the COVID-19 response meeting 6th October with regard to the NHS Digital Cancer Trusted Research Environment (TRE) and an application from UCL Partners to access the Cancer TRE.</p> <p>The following observations were made on the basis of the verbal briefing only.</p> <p>IGARD Observations:</p> <p>NHS Digital noted that further discussions were being undertaken between all parties involved in the Cancer TRE which was supporting the work being undertaken to scope specific applications. IGARD thanked NHS Digital for the update and reiterated their comments made at last week's COVID-19 response meeting, particularly with regard to Cancer Alliances.</p>
3.2	<p><u>Joint Biosecurity Centre (no NIC number available)</u></p> <p>Background: This was a verbal briefing by NHS Digital with regard to a request from the Department of Health & Social Care (DHSC) Test and Trace programme which had been through NHS Digital's prioritisation front door and prioritised as an urgent request. The application, which was still in draft, was to support the analysis work being undertaken in relation to COVID-19 and supporting the UK Government's response to the pandemic by providing rapid response analysis at local, regional and national level.</p> <p>NHS Digital noted that the application would progress under the NHS Digital DARS SIRO Precedent, following a comprehensive review by Information Governance (IG) and that an updated application would be brought back to next week's COVID-19 response meeting, but not a formal IGARD business as usual meeting for a recommendation.</p> <p>The following observations were made on the basis of the verbal briefing only.</p> <p>IGARD Observations:</p> <p>IGARD members welcomed the verbal update and the urgent request for data.</p> <p>IGARD Members queried the legal basis for the Joint Biosecurity Centre (a new organisation, sitting within the DHSC) to receive the data. Noting the analysis which would be undertaken by IG, IGARD members suggested that the legal basis be clearly documented, since the new organisation may be relying, in part, on DHSC statutory powers.</p> <p>IGARD members noted the description of the work being undertaken but suggested that section 5 of the application clearly articulate how this would be different from other work in this area to address the urgent public health response (to assuage any concerns about duplication of effort or excessive handling of data).</p> <p>Noting that a number of datasets were being requested under this application and that not all the datasets had been onboarded to DARS, IGARD suggested that it be clearly articulated within the application how the anticipated future datasets would be onboarded and disseminated.</p> <p>IGARD members welcomed sight of an application at next week's meeting and asked that it be clearly articulated within section 5 what the applicant was doing with the data. Given the scope, sensitivities and nature of the data being requested - which could be combined with sensitive non-health data – Section 5 also needs to articulate the governance and oversight arrangements in place.</p>

	<p>IGARD members noted the verbal update from NHS Digital that due to the urgency of the request the application would ultimately be approved under the DARS SIRO precedent and were supportive of that approach in the circumstances. However, IGARD would expect that a future amendment or renewal would go through the usual DARS - IGARD process to allow a full review.</p>
3.3	<p><u>NIC-15625-T8K6L CPRD / MHRA</u></p> <p>Background: This was a brief verbal update to updates received at the 6th October, 26th May, 19th May and 12th May 2020 COVID-19 Response meetings.</p> <p>The following observations were made on the basis of the verbal briefing only.</p> <p>IGARD Observations:</p> <p>NHS Digital noted that the applicant's overarching Data Sharing Agreement (DSA) was due to expire and IGARD suggested that NHS Digital consider a short term 3-month extension while work was undertaken to address the outstanding concerns raised by both NHS Digital and IGARD. It was also noted that the COVID-19 response meeting could not make formal recommendations to NHS Digital and that should an application require a full review and recommendation, then it should go through the usual DARS process and be presented at a Thursday IGARD meeting.</p> <p>Noting the imminent publication of the 2nd edition of the UK Anonymisation Network's '<i>Anonymisation Decision Making Framework</i>' (which may be endorsed by the Information Commissioner's Office (ICO) as per the 2016 edition), IGARD suggested that a full independent information governance (IG) review by NHS Digital's IG Directorate be undertaken of the applicant's suite of documentation which had been presented to NHS Digital, including but not limited to, the full IGARD minutes for each time the overarching application (NIC-15625) was presented to IGARD, and, if relevant, any time the application was presented to its predecessor the Data Access Advisory Group (DAAG), since a number of previously raised points remain open.</p> <p>IGARD noted the brief verbal update from NHS Digital that in due course an updated application would be coming to a future IGARD BAU meeting for a full review.</p>
4.	<p><u>AOB</u></p> <p>There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.</p>