

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 13 August 2020

IGARD MEMBERS IN ATTENDANCE:	
Name:	Position:
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Kirsty Irvine (Chair)	IGARD Lay Chair
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	Position:
Paul Affleck	Specialist Ethics Member
Prof. Nicola Fear	Specialist Academic Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	Team:
Garry Coleman	Data Access Request Service (DARS)
Stuart Gunson	Data Access Request Service (DARS)
Karen Myers	IGARD Secretariat
Amy Ogbourne	Information Governance
Bethan Thomas	Data Access Request Service (DARS)
Kimberley Watson	Data Access Request Service (DARS)
Vicky Byrne-Watts	Data Access Request Service (DARS)
Vicki Williams	IGARD Secretariat
Tom Wright	Data Access Request Service (DARS)

1	<p>Declaration of interests:</p> <p>Kirsty Irvine noted a personal link to Genomics England [NIC-12784-R8W7V]. It was agreed this did not preclude Kirsty Irvine taking part in the discussions about this application.</p> <p>Review of previous minutes and actions:</p> <p>The minutes of the 6th August 2020 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record of the meeting.</p>
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	<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>Royal College of Physicians of London (RCP): Chronic Obstructive Pulmonary Disease (COPD) Secondary Care Audit (Presenter: Kimberley Watson) NIC-349273-T3L4K</u></p> <p>Application: This was an amendment application to 1) change the data flow so Crown Informatics Ltd would no longer receive data, 2) change the legal basis for the data flow, and change to fields requested, for use for the purpose of processing 3) To add NHS England as a Data Controller, 4) to remove Crown Informatics Ltd and AIMES Management Services as Data Processors and remove their storage and processing locations.</p> <p>The purpose is for the secondary care Chronic Obstructive Pulmonary Disease (COPD) clinical audit element of the National Asthma and COPD Audit Programme which has been commissioned by the Healthcare Quality Improvement Partnership (HQIP) as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP). The audit programme, including this secondary care audit, supports the Department of Health and Social Care's aims to improve the quality of services for people with COPD, measuring and reporting the delivery of care as defined by guidance standards.</p> <p>Discussion: IGARD noted and endorsed NHS Digital's review that the Health Quality Improvement Partnership (HQIP) did not meet NHS Digital's Standard for privacy notices. IGARD noted that they had previously discussed the privacy notices during the last review on the 26th April 2018, and asked that a special condition was inserted in section 6 (Special Conditions), stating that within 1-month a General Data Protection Regulation (GDPR) compliant Privacy Notice, as assessed by NHS Digital, would be published for HQIP.</p> <p>IGARD queried the yielded benefits outlined in section 5(d) (Benefits) (iii) (Yielded Benefits), noting that there was no information, for example of the improvements that had implemented as a result of the audit, and asked that a satisfactory update was provided of the yielded benefits to date, and to ensure they complied with the NHS Digital DARS Standard 5(d): Expected Measurable Benefits.</p> <p>In addition, IGARD also advised that when this application comes up for renewal, they would expect the yielded benefits to be continually clearly outlined on a rolling basis, and to reflect the work that has been undertaken and the benefits accrued, since the application was last seen by NHS Digital.</p> <p>IGARD noted that the Health Research Authority Confidentiality Advisory Group (HRA CAG) approval letter dated the 12th December 2013, referred specifically to the involvement of the British Thoracic Society, and asked that further clarity was provided of their role, if any.</p> <p>IGARD noted the amendment within the application to add NHS England as a joint Data Controller, however queried if this was also going to be reflected within the s251 support, and asked that confirmation was provided in section 1 (Abstract) of the plans to add NHS England as a Data Controller for the s251 support, noting that this was part a wider programme of work.</p> <p>IGARD noted that section 1 stated that the HQIP was the "<i>sole Data Controller</i>" and asked that this was amended to correctly reflect that they were a "<i>joint Data Controller</i>".</p> <p>IGARD noted that a legal basis for the HES Civil Registration Bridge file had not been included within section 3(a) (Data Access Already Given), and asked that this was updated to include the legal basis.</p>

	<p>In addition, IGARD queried the reference in section 3(a) to the cohort being “<i>expected to grow</i>”, and in light of the request being for a one-off data release, asked that this was removed.</p> <p>Outcome: recommendation to approve subject to the following condition(s)</p> <ol style="list-style-type: none"> 1. To insert a special condition in section 6 stating that within 1-month a GDPR-compliant Privacy Notice, as assessed by NHS Digital, will be published for HQIP. 2. To provide a satisfactory update to the yielded benefits in section 5(d) (iii) to ensure they comply with NHS Digital’s Expected Measurable Benefits Standard 5d. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To provide confirmation in section 1 of the plans to add NHS England as a Data Controller for the s251 support (noting that this is part of a wider programme of work). 2. To provide clarity on the role (if any) of the British Thoracic Society. 3. To update section 3(a) to include the legal basis for the Bridge file. 4. To remove references in section 3(a) to the cohort being “<i>expected to grow</i>”. 5. To amend section 1 to remove the reference to HQIP being the “<i>sole Data Controller</i>”. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD advised that when this application comes up for renewal, they would expect the yielded benefits to be clearly outlined, and to reflect the work that has been undertaken, and the benefits accrued since the application was last seen. <p>It was agreed the conditions would be approved out of committee (OOC) by IGARD Members</p>
2.2	<p><u>University of Bristol: The SIPS study (Presenter: Kimberley Watson) NIC-336857-P6C9Q</u></p> <p>Application: This was a new application for pseudonymised Hospital Episode Statistics (HES) and Civil Registration death data, for the purpose of a study on pressure ulcers, which aims to find out more about how best to conduct research in this area by undertaking three workstreams, 1) literature reviews and interviews with healthcare professionals, 2) retrospective cohort studies, and 3) formal consensus methods with healthcare professionals and patients.</p> <p>The study will analyse data collected routinely in the NHS over a period of 8 years. The study will describe the care that has been provided in England to patients with severe pressure ulcers, the kinds of patients who have been treated in different ways and examine how care is different in different places. To inform whether surgical treatments should be more widely available, the study will identify patients who were similar when admitted to hospital with a severe pressure ulcer and compare health outcomes (such as going back to hospital and death) among those who did and did not have surgery.</p> <p>Discussion: IGARD queried the statement in section 5(a) (Objective for Processing) that stated “<i>*NICE guidance on pressure ulcers makes no recommendations about surgical management</i>” (*The National Institute for Health and Care Excellence), and advised that upon checking the NICE guidelines, surgical procedures were separated into ‘reconstruction’, for example a skin graft, and ‘debriding’, for example removing dead skin tissue; and asked that section 5(a) was updated to make clear that this application was focussed specifically on reconstruction and not debriding.</p> <p>IGARD noted the statement in section 5(c) (Specific Outputs Expected) “<i>members of the Patient and Public Involvement (PPI) forum are actively involved in carrying out activities relating to dissemination and public engagement.</i>”, and queried why there was only PPI involvement at the dissemination stage, and asked that further clarity was provided in section</p>

	<p>5(c) if the existing PPI referenced could be extended to encompass a broader range of involvement through all steps of the study.</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 Manchester University NHS Foundation Trust and the University of Manchester did not meet NHS Digital’s Standard for privacy notices.</p> <p>IGARD queried the benefits outlined in section 5(d) (Benefits) and advised that some of the wording appeared to have been lifted from a National Institute for Health Research (NIHR) application, and in particular noted the declarative statements used, for example <i>“the study will”</i>, rather than the <i>“the study may”</i>; and suggested that the applicant revise the language in section 5(d) to ensure that the benefits were realistic and achievable, and in line with the data flowing.</p> <p>Outcome: recommendation to approve</p> <ol style="list-style-type: none"> 1. To update section 5(a) to make clear that this application is focussed specifically on reconstruction and not debriding. 2. To clarify in section 5(c) if the existing PPI referenced can be extended to encompass a broader range of involvement through all steps of the study. 3. 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:</p> <ol style="list-style-type: none"> 1. IGARD suggested that the applicant revise the language in section 5(d) to ensure that the benefits are realistic and achievable, and in line with the data flowing.
2.3	<p><u>Worcestershire County Council: COVID-19: predicting future adult social care and A&E admissions (Presenter: Bethan Thomas) NIC-385550-Y8T2M</u></p> <p>Application: This was a new application for pseudonymised Mental Health Services Data Set (MHSDS), Secondary Use Service (SUS) for Commissioners, Adult Social Care, Community Services Data Set (CSDS) and Maternity Services Data Set (MSDS), for the purpose of develop a Predictive Model that will answer COVID-19 response related questions, to enable Worcestershire County Council to work better with its' population and target communications and support.</p> <p>Worcestershire County Council have been working with their partner AT Provider and PredictX over the past year to look at how analysing trends can help predict future adult social care and A&E admissions through the way someone uses their assistive technology equipment. In light of COVID-19 and the changes to the way people are living and the support they are receiving the county council have reviewed this project.</p> <p>Discussion: IGARD welcomed the application which came for advice and without prejudice to any additional issues that may arise when the application is fully reviewed.</p> <p>IGARD noted that this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 11th August 2020.</p>

IGARD noted that a query had been raised with NHS Digital's Information Governance (IG) in respect of the legal bases, and that a response was still in progress. IGARD advised that a number of queries in relation to the various legal bases would need clarification, including confirmation if Worcestershire County Council could rely on the COVID-19 Notice issued under The Health Service Control of Patient Information (COPI) Regulations 2002. If COPI could not be relied on, then confirmation would be required as to how Worcestershire County Council could flow Confidential Patient Information (CPI) data to NHS Digital addressing the Common Law Duty of Confidentiality.

IGARD queried the incorrect reference in section 3(b) to "*COPI 2020*" and asked that these were removed and replaced with the correct Notice and Regulations. IGARD also asked that if COPI was being relied upon, that the proposed processing was aligned within the scope of the Notice and Regulations.

In addition, IGARD queried the General Data Protection Regulation (GDPR) legal basis for the flow of data from Worcestershire County Council to NHS Digital and to receive the data back, and advised that confirmation of the GDPR legal basis would be required.

IGARD also queried the legal basis for NHS Digital to process the data and the legal basis for NHS Digital to disseminate the pseudonymised data back to Worcestershire County Council, and asked that confirmation was provided.

IGARD asked that once the correct legal bases had been confirmed with IG, that section 1 (Abstract) and section 3(b) (Additional Data Access Requested) were updated with confirmation of the various legal bases, and that a copy of the IG advice was uploaded to NHS Digital's Customer Relationship Management (CRM) system for future reference as a supporting document.

IGARD noted that Microsoft Limited provided cloud services and were therefore listed as a Data Processor, and asked that section 1 was updated to include confirmation that the Data Processor had met NHS Digital's Standard for Cloud Storage.

IGARD queried the request for Maternity Services Data Set in section 3(b) and why this had been requested in light of the COVID-19 purpose outlined, and asked that a justification was provided in section 3(b) and section 5 (Purpose / Methods / Outputs) of why each of the data sets had been requested.

IGARD queried why the SUS for Commissioners data was required from 2008, and were advised by NHS Digital that the applicant had confirmed that this data was now only requested from January 2019. IGARD noted the update and asked that the application was updated throughout to reflect this new date.

IGARD queried the references within the application to "*gender*" being requested, and asked that the datasets requested in the application aligned with the specific NHS Digital data that can flow, for example 'sex' vs 'gender'.

IGARD noted the information in section 5(b) (Processing Activities) in relation to the role of PI Limited, for example, they will "*use predictive modelling to estimate social care demand*", and asked that further clarification was provided as to their experience with the types of processing outlined and further details of their skills set. In addition, IGARD also asked that should they were handling CPI, and COPI was being relied upon, that further details were provided of how they satisfied Regulation 7, Restrictions and Exclusions, of COPI.

IGARD queried the reference in section 5(c) (Specific Outputs Expected) to "*specific licensed users*" and asked that further information was provided of how the specific licence operated and that confirmation was provided that this was only available to Worcestershire County Council employees, with a specific need to access the data.

IGARD noted the statement in section 5(c) that *“The outputs will be produced around 2-3 months after the initial data has been shared.”* and queried if this timeframe was realistic given the project was for long term health and social care, and asked that this was updated with confirmation if the timeframes set out, aligned with the long-term research goals.

There was a lengthy discussion with regard to the two COVID-19 response related questions that Worcestershire County Council had set out to enable them to work better with their population, and to target communications and support. IGARD queried the benefits outlined in section 5(d), noting they were not related to the questions outlined, and asked that the benefits were updated to be more precise and in line with the two questions asked.

In relation Question 1, *“Is there an identifiable population in Worcestershire that are more likely to be impacted by COVID-19 pandemic through either social care need or acute medical assistance?”*, IGARD queried if there had been any acknowledgement of some of the COVID-19 questions that had already been asked and answered, and asked that section 5(a) (Objective for Processing) was updated to reflect that they had. IGARD also queried what the novel questions were that the applicant wished to be answered, for example how they would use the social care data, noting that this data was not used often, and asked that further information, including the novel question(s) were clearly set out. IGARD also queried how the applicant would tailor the known risk factors for their local community, and asked for further clarity on this.

In relation to Question 2, *“For patients who leave hospital and enter social care, how many will require no further care, how many will need short term care, and how many will need long term care packages?”*, IGARD queried how the long term care packages would be established in light of the COPI timeframe and the limited amount of data the applicant would receive to be able to establish this, and asked that section 5 was updated to acknowledge the COPI timeframe. In addition, IGARD also asked that the impact this may have on the work outlined was addressed.

IGARD noted the reference in section 5(d) (Benefits) that stated *“Worcestershire County Council can support individuals...”* and queried this statement in light of information elsewhere in the application that stated individuals would not be identified; and asked that section 5(d) was updated throughout to clarify that there would be no re-identification and that any reference related to groups of individuals and not any specific individual(s).

IGARD also queried the reference in section 5(d) to *“keeping individuals away from A&E”*, and asked that this was reviewed, noting that individuals should seek support from A&E if and when required.

In addition, IGARD noted the reference to *“intensive care”* in section 5(d) and suggested that this was updated to correctly reference *“intensive social care”*.

IGARD noted and endorsed NHS Digital’s review that the applicant did **not** meet NHS Digital’s Standard for privacy notices, and IGARD suggested that the applicant may wish to submit a draft privacy notice when the application returns for a full review.

Outcome: IGARD welcomed the application which came for advice and without prejudice to any additional issues that may arise when the application is fully reviewed.

1. In respect of the various legal bases and NHS Digital’s forthcoming IG advice:
 - a) To confirm if Worcestershire County Council can rely on the COVID-19 Notice issued under COPI.
 - b) If COPI cannot be relied on, to address how Worcestershire County Council can flow CPI data to NHS Digital addressing the Common Law Duty of Confidentiality.

	<ul style="list-style-type: none"> c) To confirm the GDPR legal basis for the flow of data from Worcestershire County Council to NHS Digital and to receive data back. d) To confirm the legal basis for NHS Digital to process the data. e) To confirm the legal basis for NHS Digital to disseminate the pseudonymised data back to Worcestershire County Council. f) To update section 1 and section 3(b) to confirm the correct legal bases, and to upload a copy of the IG advice to NHS Digital's CRM system. g) To remove the reference(s) to "COPI 2020" and replace with the correct Notice and Regulations. <ol style="list-style-type: none"> 2. If COPI is being relied on, to align the proposed processing within the scope of the Notice and Regulations. 3. To update section 1(c) to include confirmation that the processor meets NHS Digital's standard on Cloud storage. 4. To provide justification in section 3b and section 5 of why each of the Data Sets have been requested, for example the Maternity Services Data Set. 5. To update section 5(d) throughout to clarify that there will be no re-identification and that any reference relates to groups of individuals and not any specific individual(s). 6. To provide further information in section 5(c) of how the specific licence operates and provide confirmation that this is only available to Worcestershire County Council employees with a specific need to access the data. 7. To update the application throughout to reflect the SUS data is only required from January 2019. 8. To ensure that the datasets requested align with the specific NHS Digital data that can flow, for example 'sex' vs 'gender'. 9. In respect of PI Limited: <ul style="list-style-type: none"> a) To provide clarification as to their experience with the type of processing outlined and to provide further details of their skill set. b) If they are handling CPI, and COPI is being relied upon, how they satisfy Reg 7 of COPI. 10. To update section 5(c) to confirm if the timeframes set out align with the long-term research goals. 11. To update the benefits in section 5(d) to be more precise and in line with the Questions asked. 12. To review the reference in section 5(d) to "<i>keeping individuals away from A&E</i>". 13. To update the reference in section 5(d) from "<i>intensive care</i>" to "<i>intensive social care</i>". 14. In respect of Question 1: <ul style="list-style-type: none"> a) To amend section 5(a) to acknowledge some of the COVID-19 questions that have already been answered. b) To set out the novel question(s) that the applicant wishes to answer, particularly how they will use the social care data. c) How they will tailor the known risk factors for their local community. 15. In respect of Question 2: <ul style="list-style-type: none"> a) To update section 5 to acknowledge the limited COPI timeframe b) To address the impact this will have on the work outlined. 16. IGARD suggested that the applicant may wish to submit a draft privacy notice when the application returns for a full review.
2.4	<u>Genomics England: Genomics England (MR1418) - Renewal Request for tranche of data across multiple data sets. (Presenter: Garry Coleman / Victoria Byrne-Watts) NIC-12784-R8W7V</u>

Application: This was an amendment application to add LIFEbit and Amazon Web Services (AWS) as Data Processors. Genomics England will migrate their platforms from the use of UK Cloud to LifeBit and AWS. UK Cloud will remain as a Data Processor to cover the transfer of the data, and UK Cloud will then be removed from future agreements.

In March 2017, the NHS England Board set out its strategic approach to build a national Genomic Medicine Service (GMS), building on the 100,000 Genomes Project. This will include a national Whole Genomic Sequencing provision and supporting informatics infrastructure developed in partnership with Genomics England. Genomics England will therefore undertake genomic sequencing and clinical data collection for the new GMS.

Discussion: IGARD noted that AWS provide cloud services and were therefore listed as a Data Processor, and asked that section 1 (Abstract) was updated to include confirmation that the Data Processor had met NHS Digital DARS Standard on Cloud Storage.

IGARD noted the yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits), and in particular queried how the processing had impacted on the cohort and patient care generally, and asked that the 2019/20 yielded benefits were updated with further examples, including dates.

IGARD also asked that the yielded benefits aligned with the stated projected outputs as detailed in section 5(c) (Specific Outputs Expected). In addition, IGARD asked that the yielded benefits aligned with the stated purpose for processing, since Legitimate Interest was being relied upon.

IGARD discussed the applicant's Data Protection Impact Assessment (DPIA) in relation to the to the transfer of the data to the new research environment, and asked that confirmation was provided in section 1 and section 5(b) (Processing Activities) that a DPIA would be carried out prior to the transfer. In addition, IGARD also asked that a special condition was inserted in section 6 (Special Conditions) that a DPIA would be carried out prior to the transfer of the data to the new environment.

IGARD noted the reference in section 5(a) (Objective for Processing) to *"Mortality data are essential for performing survival analyses and as a metric for success of medical care"*, and advised that whilst this was important, it was not necessarily a useful metric for the success of medical care, and asked that this was amended. IGARD suggested a form of words might be *"Mortality data are essential for performing survival analyses and **may be** an important metric for success of medical care"*

IGARD noted the incorrect reference in section 1 to *"Subject Matter Expert (SME)"* and asked that this was updated to correctly reference *"small medium enterprise"*.

IGARD queried the reference in section 1 to the AWS Data Risk Model, and asked that section 1 was updated to include a brief explanation of this model.

Noting that the applicant had a vibrant and active participant engagement strategy, IGARD suggested that the applicant may wish to liaise with representatives and subsequently communicate with the wider cohort in respect of the changes to data processors, which would satisfy the General Data Protection Regulation (GDPR) transparency requirements.

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 update section 1(c) to include confirmation that the processor meets NHS Digital's standard on Cloud storage.

	<ol style="list-style-type: none"> 2. In respect of the yielded benefits in section 5(d)(iii): <ol style="list-style-type: none"> a) To update the 2019/20 yielded benefits with further examples of how the processing has impacted on the cohort and patient care generally. b) To ensure the yielded benefits align with the stated projected outputs. c) Ensure the yielded benefits align with the stated purpose for processing, in respect of Legitimate Interest being relied upon. 3. In respect of the DPIA: <ol style="list-style-type: none"> a) To provide confirmation in section 1 and section 5(b) to clarify a DPIA will be carried out prior to the transfer of the data to a new environment. b) To insert a special condition in section 6 that a DPIA will be carried out prior to the transfer of the data to a new environment. 4. To amend the reference in section 5(a) to mortality <i>“as a metric for success”</i>. 5. To update section 1 to correctly refer to <i>“small medium enterprise”</i>. 6. To update section 1 to include a brief explanation of the Amazon Web Services Data Risk Model. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. Noting that the applicant has a vibrant and active participant engagement strategy, IGARD suggested that the applicant may wish to liaise with representatives and subsequently communicate with the wider cohort in respect of the changes to data processors, which would satisfy GDPR transparency requirements.
2.5	<p><u>North East Lincolnshire CCG: DSfC - NHS North East Lincolnshire CCG; IV & Comm (Presenter: Bethan Thomas) NIC-59807-V1B8W</u></p> <p>Application: This was an amendment application to 1) add Microsoft Limited and Amazon Web Services as Data Processors as they are providing cloud services to Optum Health Solutions UK Limited, 2) add e-Referral Service data for the purposes of Commissioning. The purpose is for Invoice Validation (IV) which is part of a process by which providers of care or services are paid for the work they do, and to provide intelligence to support the commissioning of health services.</p> <p>Discussion: IGARD noted that Amazon Web Services (AWS) and Microsoft Limited provide cloud services and were therefore listed as a Data Processor, and asked that section 1 (Abstract) was updated to include confirmation that the Data Processor had met NHS Digital DARS Standard on Cloud Storage.</p> <p>IGARD queried the reference in section 1 to the AWS Data Risk Model, and asked that section 1 was updated to include a brief explanation of this model.</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 details this.</p> <p>IGARD noted the statement in section 5(a) (Objective for Processing) in relation to Patient stratification and predictive modelling <i>“to highlight patients at risk of requiring hospital admission”</i> and asked that this was amended, noting it was not possible with the pseudonymised data requested to highlight such patients.</p> <p>IGARD queried the commissioning outputs in section 5(c) (Specific Outputs Expected), in particular the reference to <i>“Patients that are currently in hospital”</i>, and asked that this was amended to ensure that it was clear that the text related only to a cohort of citizens and not individuals.</p>

<p>IGARD queried the references in section 5(b) (Processing Activities) to “NHS Northumberland CCG” and asked that this was updated, for example to remove if not relevant or to update with the correct CCG.</p> <p>IGARD noted the information in section 5 that sets out the role of the commissioners, for example <i>“Demand Management - to improve the care service for patients by predicting the impact on certain care pathways and support the secondary care system in ensuring enough capacity to manage the demand.”</i>, and advised that the role of the commissioner is to commission to meet anticipated demand, rather than work at the operation level in managing demand and asked that section 5 was updated to ensure the role of the commissioners was accurately described.</p> <p>IGARD noted that the expected measurable benefits in section 5(d) appeared to list activities rather than benefits, and asked that this was reviewed to ensure they reflected the actual benefits.</p> <p>IGARD also queried the commissioning benefits outlined in section 5(d), in particular point 15 <i>“Insight to understand the numerous factors that play a role in the outcome for both datasets. The linkage will allow the reporting both prior to, during and after the activity, to provide greater assurance on predictive outcomes and delivery of best practice.”</i>, and asked that confirmation was provided of what the additional support service were.</p> <p>In addition, IGARD also noted the yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits) and asked that further details were provided of the specific 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. In addition, IGARD also advised that when this application comes up for renewal, they would expect the yielded benefits to be updated to also reference the measurable benefits.</p> <p>In relation to point 19, <i>“Assists commissioners to make better decisions to support patients”</i>, IGARD asked that reference was made to commissioning appropriate capacity.</p> <p>In relation to point 20, <i>“Help drive changes in healthcare”</i>, IGARD asked that reference was made to “quantity” or other measure that is possible with pseudonymised data.</p> <p>In relation to point 22, <i>“Inform commissioners and improve services”</i>, IGARD asked that the applicant ensured that this was within the realms of the commissioning activity.</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</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update section 1(c) to include confirmation that the processor meets NHS Digital’s standard on Cloud storage. 2. To update section 1 to include a brief explanation of the Amazon Web Services Data Risk Model. 3. To update the data minimisation column in section 3(b) to remove the reference to <i>“additional production details”</i>. 4. To amend the reference in section 5(a) <i>“to highlight patients at risk of requiring hospital admission”</i> as this is not possible. 5. To amend section 5(c) to ensure it is clear that that the text relates only to a cohort of citizens and not individuals. 6. To update the geographical references in section 5(b).
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	<ol style="list-style-type: none"> 7. To provide further details in section 5(d) of the yielded benefits accrued to date and ensure these are clear as to the benefits to both patients and the health care system more generally. 8. To update section 5 to ensure the role of commissioners is accurately described. 9. Within section 5(d): <ol style="list-style-type: none"> a) Point 15 – to confirm what the additional support services are. b) Point 19 – to refer to commissioning appropriate capacity. c) Point 20 – to refer to “<i>quantity</i>” or other measure that is possible with pseudonymised data. d) Point 22 – to ensure that this is within the realms of commissioning activity. 10. To review the expected measurable benefits in section 5(d) to ensure they reflect actual benefits not activities. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD advised that when this application comes up for renewal, they would expect the yielded benefits to be updated to reference the measurable benefits.
2.6	<p><u>Isle of Man Department of Health & Social Care (DHSC): Isle of Man Department of Health and Social Care – Commissioning purposes (Presenter: Bethan Thomas) NIC-173508-F4X6P</u></p> <p>Application: This was a renewal application for pseudonymised Secondary Use Service (SUS) for Commissioners data for the purpose of providing intelligence to support the commissioning of health services. Currently patients on the Isle of Man that require treatment from services not available on the Isle of Man and have to undertake travel to England / Wales to receive treatment. The Isle of Man Department of Health and Social Care team (IOMHSC) wish to understand the rate of patients being sent to the mainland to assist in understanding what services require commissioning locally.</p> <p>NHS Digital advised that following submission of the application for IGARD review, the applicant had sent further information in relation to the yielded benefits and confirmed that the application would be updated to reflect these.</p> <p>NHS Digital also advised that the Data Sharing Agreement (DSA) would only run until January 2021 due to Brexit and potential changes in law around data sharing.</p> <p>Discussion: IGARD noted the update from NHS Digital in relation to the updated information on the yielded benefits in section 5(d) (Benefits) (iii) Yielded Benefits) to reflect the most recent information.</p> <p>IGARD noted the January 2021 DSA end date due to the potential data sharing laws in relation to Brexit, but queried if NHS Digital had sought internal Information Governance (IG) advice on this application, and were advised by NHS Digital that IG had advised on the January 2021 DSA end date. IGARD noted the update and asked that a clear justification was provided of the DSA end date in light of the Brexit transition phase which was due to end on the 31st December 2020.</p> <p>In addition, IGARD also asked that a copy of the IG advice which supported the timeline set out within the application was provided; and that this was also uploaded to NHS Digital's Customer Relationship Management (CRM) system for future reference.</p> <p>IGARD noted that Microsoft Limited provide cloud services and were therefore listed as a Data Processor, and asked that section 1 (Abstract) was updated to include confirmation that the Data Processor has met NHS Digital DARS standard on Cloud Storage.</p> <p>IGARD queried the reference in section 1 to Amazon Web Services (AWS) Data Risk Model, and asked that section 1 was updated to include a brief explanation of this model.</p>

<p>NHS Digital advised IGARD that the language used in section 5(c) (Specific Outputs Expected) would need reviewing, for example to remove the reference to <i>“high flyers”</i> and <i>“expensive patients”</i>.</p> <p>IGARD queried the commissioning benefits outlined in section 5(d) (Benefits), specifically point 7, <i>“Improved planning by better understanding patient flows through the healthcare system, thus allowing commissioners to design appropriate pathways to improve patient flow and allowing commissioners to identify priorities and identify plans to address these.”</i>, and point 8, <i>“Improved quality of services through reduced emergency readmissions, especially avoidable emergency admissions. This is achieved through mapping of frequent users of emergency services and early intervention of appropriate care.”</i>, and asked that section 5(d) was updated to ensure the role of the commissioner was accurately described.</p> <p>IGARD noted the statement in section 5(a) (Processing Activities) in relation to Patient stratification and predictive modelling <i>“Patient stratification and predictive modelling - to identify specific patients at risk of requiring hospital admission...”</i>, and asked that this was updated to provide further clarity on the activities and whether they were identifying individuals or characteristics of individuals.</p> <p>IGARD noted and endorsed NHS Digital’s review that the applicant did not meet NHS Digital’s Standard for privacy notices. IGARD advised that upon renewal, the applicant should have published a General Data Protection Regulation (GDPR) compliant privacy notice.</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 NHS Digital’s IG advice: <ol style="list-style-type: none"> a) To provide a clear justification of the DSA End Date of the 31st January 2021. b) To provide a copy of NHS Digital’s IG advice which supports the timeline set out in the application. c) To ensure that the IG advice is uploaded to NHS Digital’s CRM system. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update section 1(c) to include confirmation that the processor meets NHS Digital’s standard on Cloud storage. 2. To update section 1 to include a brief explanation of the Amazon Web Services Data Risk Model. 3. To review the language used in section 5(c) and remove for example, reference to <i>“high flyers”</i> and <i>“expensive patients”</i>. 4. To review and revise point 7 and point 8 in section 5(d) (ii). 5. To update section 5 to provide further clarity on the activities and whether they are identifying individuals or characteristics of individuals. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD advised that upon renewal, the applicant should have published a GDPR compliant privacy notice. 2. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment. 3. IGARD suggested that this application would not be suitable for NHS Digital’s Precedent route. <p>It was agreed the conditions would be approved out of committee (OOC) by the IGARD Chair</p>
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3	<p><u>Clinical Registries Workshop</u></p> <p>NHS Digital have previously presented the Clinical Registries for Commissioners Briefing Paper to IGARD, the paper was accepted with suggested amendments and used to support the NHS England application to flow the Clinical Registries into NCDR.</p> <p>Due to staffing changes within NHS Digital, the workshop was held to discuss and resolve any outstanding issues with the paper and to progress as appropriate.</p> <p>IGARD thanked NHS Digital for attending to discuss this in more detail, and looked forward to receiving an updated documentation in due course.</p>
4	<p><u>Returning Applications</u></p> <p>Due to the volume and complexity of applications at today's meeting, IGARD were unable to review any applications as part of their oversight and assurance role.</p>
5	<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 11th August can be found attached to these minutes as Appendix B.</p> <p>IGARD noted that there were no additional COVID-19 related items to discuss at this week's meeting.</p>
6	<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 application section of the meeting.</p>

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 07/08/20

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-148364-RHMHS	Society of Endocrinology	21/05/20	1. NHS Digital to provide written confirmation that the applicant has provided a suitable communication plan for the next 12 months, which includes (but not limited to) updating the Protocol, revising and refreshing the PPI, and ensuring participants are aware of their ongoing ability to withdraw from the study.	IGARD Chair	IGARD Chair	To insert the date the communications plan was written and to upload the finalised copy to CRM as a future supporting document
NIC-357479-S6C7T	Royal College of Physicians of London	30/07/20	1. To confirm if date of death data is covered by HRA CAG approval.	IGARD Alternate Deputy Chair	IGARD Alternative Deputy Chair	N/A

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

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, 11 August 2020

In attendance (IGARD Members): Prof. Nicola Fear (Specialist Academic Member)
Kirsty Irvine (IGARD Lay Chair)
Dr. Geoff Schrecker (Special GP Member)

In attendance (NHS Digital): Vicky Byrne-Watts (DARS – item 2.2)
Dan Goodwin (DARS – item 2.1)
Karen Myers (IGARD Secretariat – Observer)
Vicki Williams (IGARD Secretariat)

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> <p>Nicola Fear noted a professional link with King's College London [NIC-381719-L6D2H King's College Hospital NHS Foundation Trust London and Guys & St Thomas'] but noted no specific connection with the application, and it was agreed that this was not a conflict of interest at the COVID-19 response meeting.</p>
2.1	<p><u>NIC-385550-Y8T2M Worcestershire County Council</u></p> <p>Background: this was a verbal update to the application which was due to be presented to the business as usual (BAU) meeting of IGARD on Thursday, 13th August 2020. This was a new application for the County Council to receive data in support of the COVID-19 emergency in order for them to develop a Predictive Model that may answer COVID-19 response related questions to enable the County Council to work better with its population, and target communications and support.</p> <p>IGARD Observations:</p>

	<p>IGARD members noted that the application was to be presented to the IGARD BAU Meeting on Thursday, 13th August 2020 with a copy of this minute extract appended to IGARD's published minutes</p> <p>IGARD Members noted that the discussion today was not to pre-empt discussions that would take place at the BAU meeting on Thursday and thanked NHS Digital for their verbal update.</p>
2.2	<p><u>NIC-381719-L6D2H King's College Hospital NHS Foundation Trust London and Guys & St Thomas'</u></p> <p>Background: Guy's & St Thomas' (GSTT) and King's College Hospital NHS Foundation Trust (KCL) have set up the King's Health Partners (KHP) COVID Data Analytics & Modelling Group. The purpose of the group is to utilise the electronic health records (EHRs) to identify patients tested for COVID-19, influenza or other respiratory pathogens from 1 October 2016, and describe the phenotyping, allowing tracking and comparison of disease progression, care and outcomes.</p> <p>NHS Digital noted that the data linkages would occur in GSTT's data warehouse, a secure environment.</p> <p>NHS Digital noted the applicant was relying on COPI and that this had been queried with NHS Digital's Information Governance (IG) directorate to ensure it met the relevant criteria.</p> <p>NHS Digital also noted that they had advised the applicant that both GSTT and KCL should be joint Data Controllers and joint Data Processors for this Data Sharing Agreement (DSA).</p> <p>IGARD Observations:</p> <p>IGARD members noted that this was potentially a very worthwhile study into phenotyping and noting that London and in particular GSTT was a particular focal point for COVID-19 patients during wave 1 of the pandemic, welcomed the approach.</p> <p>IGARD members agreed with NHS Digital's analysis that both KCL and GSTT be considered joint Data Controllers and Data Processors.</p> <p>IGARD members noted that General Data Protection Regulation (GDPR) compliant transparency materials would be required, and especially due to the high profile patients that had been admitted to GSTT during wave 1 of the pandemic, and suggested the applicant work with NHS Digital on a GDPR compliant publishable Privacy Notice and other transparency initiatives.</p> <p>IGARD members queried how the applicant was keeping pseudonymised data separate from the identifying data.</p> <p>Noting this was a relatively novel initiative, IGARD members suggested that NHS Digital may wish to explore other applications where the data warehouse approach had been used within a hospital environment. IGARD suggested that NHS Digital's Data Access Environments (DAEs) or Trusted Research Environments (TREs) alternatives may be worth exploring with the applicant.</p> <p>IGARD noted the reference to the 'data access committee' and suggested that further exploration be undertaken as to the level of supervision and suitable terms of reference with equivalent applicants to ensure consistency across all applicants with similar committees.</p>

	<p>IGARD members queried the legal basis for the applicant to send data to NHS Digital and suggested that this be clearly stated in any future application. In addition, consideration should be given, if relying on COPI, as to how the research questions within the secure environment were linked with the managing of the pandemic, which may be a consideration and until any move to another legal basis, such as S251.</p> <p>IGARD members noted that the applicant would be receiving GP data from the Lambeth Data Net (LDN), but suggested that in addition to this data, the applicant may wish to consider the GPES Data for Pandemic Planning & Research (GDPPR), which may supplement any gaps in the GP data received from LDN. IGARD members suggested it should be clearly established the type of data the applicant was receiving from LDN and ensure there was a clear legal basis, since the supporting documents suggesting linking of data with data from LDN, but the LDN transparency materials state that they only disseminate “anonymous” data, which, by definition, cannot be linked.</p> <p>IGARD members noted the protocol stated (emphasis added): “Where unstructured data, for example CT scan reports, are required, identifiers will be removed where possible. However, due to the time critical nature of the work it may not be possible to completely remove all confidential patient information. For example, a patient name might be included in the comments on a CT scan report.” and noting this potentially identifiable data would flow into the “pseudonymised” dataset to be linked, this may raise significant issues with the status of the data. IGARD suggested that notwithstanding the time pressure on the applicant that further consideration be given to all identifiers being removed OR stripping out all unstructured data prior to its inclusion in the data warehouse - or some other suitable workaround.</p>
3.	<p>AOB</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>