

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 20 June 2019

In attendance (IGARD Members): Anomika Bedi, Eve Sariyannidou, Geoffrey Schrecker (Deputy Chair), Maurice Smith.

In attendance (NHS Digital): James Humphries-Hart, Dickie Langley, Karen Myers, Kimberley Watson, Vicki Williams.

Not in attendance (IGARD Members): Sarah Baalham, Maria Clark, Nicola Fear, Kirsty Irvine (Chair), Priscilla McGuire.

1	<p>Declaration of interests:</p> <p>Geoff Schrecker noted professional links to the Royal College of General Practitioners [NIC-195793-R5Y3H University of Surrey] but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest.</p> <p>Maurice Smith noted professional links to the Royal College of General Practitioners [NIC-195793-R5Y3H University of Surrey] but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest.</p> <p>Eve Sariyannidou noted professional links to the Healthcare Quality Improvement Partnership (HQIP) [NIC-359940-W1R7B National Institute for Cardiovascular Outcomes Research] but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest.</p> <p>Review of previous minutes and actions:</p> <p>The minutes of the 13th June 2019 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>NHS Barnsley CCG: DSfC - NHS Barnsley CCG - Comm, RS & IV to add Outcomes based Healthcare as a Data Processor (Presenter: James Humphries-Hart) NIC-90647-G3Q4S</u></p> <p>Application: This was an amendment application for pseudonymised Secondary Use Service (SUS) for Commissioners data, 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). The data required is for Risk Stratification (RS) which is a tool for identifying and predicting which patients are at high risk or likely to be at high risk and prioritising the management of their care; 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>The application was been previously considered on the 31st January 2019 when IGARD had been unable to make a recommendation pending: IGARD did not have a complete position from NHS Digital with regard to cloud storage in order to confidently acknowledge the risks involved and mitigation taking place; to update the data flow diagram provided with the pseudonymised GP data as described in the application; to include a special condition in</p>

	<p>section 6 that no other company within the Kier Group will have access to the data other than the Kier entity listed in the agreement; to use the full and correct names for each of consortium members outlined throughout the application; to clarify if Yeadon Community Health Centre should be part of the agreement, and if so, to clarify if they should be listed as a processing and storage location address and to amend accordingly or remove the reference; to amend the incorrect reference to Nexent Data Centre to the correct name of Pulsant.</p> <p>NHS Digital advised that a selection of security documentation to support the use of Cloud storage was reviewed by NHS Digital Security who were satisfied that the documentation demonstrated the level of security and governance in place. NHS Digital advised that section 1 (Abstract) of the application would need to be updated with a list of the documentation supplied by the applicant.</p> <p>Discussion: IGARD noted that the application had been updated to reflect all of the comments previously made.</p> <p>IGARD noted the update from NHS Digital on the security documentation provided by the applicant to support the use of cloud and also the review given to this by NHS Digital Security; and supported the update to section 1 of the application to reflect this.</p> <p>IGARD queried information in section 3(b) (Additional Data Access Requested) noting that the application was for an 'amendment'; and were advised by NHS Digital that section 1 of the application would require updating to confirm that it was also a 'renewal' and 'extension' application in addition to it being an amendment.</p> <p>IGARD noted the timeframe for the period of the datasets requested in section 3(b) was not in line with the Data Sharing Agreement (DSA) and asked that this section was updated to reflect information in the DSA.</p> <p>IGARD queried conflicting information in the application and supporting document 1, the Data Flow Diagram in relation to the flow of data for Invoice Validation; and asked that section 5(b) (Processing Activities) (point 3) was updated to correctly reference NHS Rotherham CCG and to remove the reference to the North of England Commissioning support Unit (CSU).</p> <p>Outcome Summary: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update section 5(a) to include the Cloud security evidence supplied by the CCG. 2. To update section 1(a) 'agreement type' to confirm that it is a renewal and extension, in addition to it being an amendment 3. To update section 3(b) to extend the timeframe for period of the datasets requested, in line with the DSA. 4. To update section 5(b) (point 3) to correctly reference NHS Rotherham CCG for Invoice Validation and remove reference to the North of England CSU.
2.2	<p><u>NHS Cambridgeshire and Peterborough CCG: DSfC - NHS Cambridgeshire and Peterborough CCG - Comm (Presenter: James Humphries-Hart) NIC-95040-Y0P3W</u></p> <p>Application: This was an amendment and 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</p>

	<p>Outcome Measures (PROMs); to provide intelligence to support the commissioning of health services as part of NHS England's five year forward plan.</p> <p>NHS Digital advised that a selection of security documentation to support the use of Cloud storage was reviewed by NHS Digital Security who were satisfied that the documentation demonstrates the level of security and governance in place. NHS Digital advised that section 1 (Abstract) of the application would need to be updated with a list of the documentation supplied by the applicant.</p> <p>Discussion: IGARD noted the update from NHS Digital on the security documentation provided by the applicant to support the use of cloud and also the review given to this by NHS Digital Security; and supported the update to section 1 of the application to reflect this.</p> <p>IGARD queried the reference within the application to the linkage to 'consented data' and queried what was meant by this, who had given consent and under what circumstances consent was given. NHS Digital advised that further information would need to be sought and that this reference would be removed from throughout the application and if necessary, would be brought back to a future IGARD meeting as a future amendment application.</p> <p>IGARD had a lengthy discussion on why the applicant required the additional dataset linkage as outlined in section 5(a) (Objective for Processing) and queried why the linkage was required and how the data was to be used; and asked that section 5(a) was updated to provide a clearer explanation.</p> <p>IGARD noted the information provided in section 5(b) (Processing Activities) that stated "<i>All access to data is managed under Role-Based Access Controls</i>" and asked that section 5(a) was updated and a special condition was added to section 6 (Special Conditions) confirming that role based access controls to access the data were "task based".</p> <p>IGARD asked that for clarity a special condition was included in section 6 (Special Conditions) clarifying that individual level risk stratification data can only be used for direct care.</p> <p>Outcome Summary: recommendation to approve subject to the following conditions:</p> <ol style="list-style-type: none"> 1. To remove from throughout the application reference to the linkage to consented data. 2. To update section 5(a) to provide a clearer explanation of why the applicant requires the additional datasets linkage. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update section 5(a) to include the Cloud security evidence supplied by the CCG. 2. To update section 5(a) and include a special condition in section 6 confirming that role-based access controls to access the data are "task based". 3. To include a special condition in section 6 clarifying that individual level risk stratification data can only be used for direct care. <p>It was agreed the conditions be approved OOC by IGARD Members.</p>
2.3	<p><u>Department for Transport: HES and STATS19 One-to-one linkage project (Presenter: James Humphries-Hart) NIC-381383-Z9F2P</u></p> <p>Application: This was an amendment application for pseudonymised Hospital Episode Statistics (HES) data to understand the types of injuries sustained by people injured in road traffic accidents. The amendments is to remove the following special condition: condition 'The Department for Transport will securely destroy the historic HES data (1997 to 2011) once the new matching exercise that requires this data is completed, and no later than January 2019'; and to add a new processing and storage address.</p>

	<p>Discussion: IGARD queried the basis in law that supported the request and the processing of the data under this application and asked that section 1 (Abstract) was amended to correctly list the applicant's legal basis under the General Data Protection Regulation (GDPR).</p> <p>IGARD queried why the applicant still required the data and asked that section 5(a) (Objective for Processing) was updated with a clear narrative outlining this, along with clarity on what was being done with the data and how long the applicant needed the data going forward.</p> <p>Outcome Summary: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To amend section 1 to correctly list the applicant's legal basis. 2. To update section 5(a) to provide a clear narrative why the data is still required, what is being done with the data and how long the applicant will need the data.
2.4	<p><u>National Institute for Cardiovascular Outcomes Research: Barts Health NICOR NCAP (Previously known as CCAD - Central Cardiac Audit Database - MR1233) (Presenter: James Humphries-Hart) NIC-359940-W1R7B</u></p> <p>Application: This was a renewal, extension and amendment application for identifiable Medical Research Information Service (MRIS), Hospital Episode Statistics (HES) and Civil Registrations data for six national cardiovascular audits. The aim of the audits is to measure and report delivery of care against defined guidance standards and to enable the improvement of the quality of care and outcomes of patients with a range of cardiac conditions.</p> <p>Discussion: IGARD noted that the Healthcare Quality Improvement Partnership (HQIP) had not provided adequate evidence to substantiate that public task is the appropriate legal basis.</p> <p>IGARD noted the information provided in section 1 (Abstract) under the General Data Protection Regulation (GDPR) narrative that described how the work undertaken is in fulfilment of NHS England's statutory functions; and asked for further clarification why, in light of this that NHS England were not considered as joint Data Controller.</p> <p>IGARD queried information provided in section 5(a) (Objective for Processing) and section 5(b) (Processing Activities) in relation to the purpose(s) and were advised by NHS Digital that both sections needed further updates so that the three purposes of the application and their objectives were clearly identified. IGARD also asked that for each of the three purposes outlined, section 1 and section 5(a) were updated ensuring the legal gateway was in place along with the relevant supporting documents to support the flow of data.</p> <p>IGARD noted that data disseminated under this agreement would be linked to other audits and asked that a clear narrative was inserted in section 5 (Purpose / Methods / Outputs) explaining that data disseminated under this application can only be used for different purposes after those different purposes have been approved by NHS Digital under separate applications and a live DSA was in place.</p> <p>IGARD queried information provided in section 1 outlining the purpose of the application and were advised by NHS Digital that this was a renewal, extension and amendment application and that section 1 would be updated to clearly reflect this.</p> <p>Outcome Summary: Recommendation to defer, pending:</p> <ol style="list-style-type: none"> 1. To provide adequate evidence to substantiate that public task is the appropriate legal basis for HQIP. 2. To clarify why NHS England is not considered joint data controller as the narrative around the GDPR legal basis provided by the applicant clearly describes how the work undertaken is in fulfilment of NHS England's statutory functions.

	<ol style="list-style-type: none"> 3. To update section 5(a) and 5(b) to clearly identify the three purposes and their objectives. 4. To update section 1 and section 5(b) to ensure that for each of the 3 purposes outlined, the legal gateway is in place along with the relevant supporting documents to support the flow of data. 5. To insert in section 5 a clear narrative explaining that data disseminated under this application can only be used for different purposes after those different purposes have been approved by NHS Digital under separate applications and a live DSA is in place. 6. To update section 1 to clearly explain the purpose(s) of this application.
2.5	<p><u>University of Surrey: Establishing the impact of the national VTE prevention programme on post-operative VTE rates in England (Presenter: Kimberley Watson) NIC-195793-R5Y3H</u></p> <p>Application: This was a new application for Civil Registration and pseudonymised Hospital Episode Statistics (HES) for a study looking at comparable sized population of about 3 million individuals from the Royal College of General Practitioners Research and Surveillance Centre (RCGP RSC) data centre; looking at preventing venous thromboembolism (VTE also known as blood clots) by examining the impact of mandatory VTE risk assessments on the incidence of VTE after general surgery and major orthopaedic surgery.</p> <p>NHS Digital noted that section 1 (Abstract) would need updating to correctly list the correct legal basis for both the RCGP and the University of Surrey.</p> <p>Discussion: IGARD noted and supported the amendment outlined by NHS Digital in relation to section 1 being updated to correctly list the correct legal basis for the RCGP and the University of Surrey.</p> <p>IGARD suggested that it be clearly articulated within section 1 and section 5 (Purpose / Methods / Outputs) the legitimate interest relied upon and how it relates to the processing of the research being undertaken; and also asked that the first paragraph in section 5(a) (Objective for Processing) was updated with further information of the legitimate interest.</p> <p>IGARD noted the information in the supporting documents provided that referenced the involvement of King's College London and University of Leiden in the study; and asked that a written explanation was provided clarifying why they were not considered joint Data Controllers, in light of this information provided.</p> <p>IGARD queried the response given in section 5(e) (Is the Purpose of this Application in anyway Commercial) that stated the purpose of the application was not commercial and asked for further clarity on this given the funding involvement and commercial interest of 'Sanofi-Aventis'; and that they would not use the data to undertake sales and / or marketing activities to the healthcare or any other sector.</p> <p>IGARD noted the special condition in section 6 (Special Conditions) <i>"The RCGP must supply evidence of due diligence regarding security within 3 months of the signing of this agreement."</i> and asked that written evidence was provided that NHS Digital were satisfied that the RCGP had appropriate security in place and that due diligence regarding security was in place.</p> <p>IGARD noted the sentence in section 5(a) <i>"The GDPR legal basis for the study is public interest..."</i> and asked that this was removed since it was not relevant to this application.</p> <p>IGARD queried which parties would have access to the data and asked that section 5(b) (Processing Activities) was updated to provide further clarification of this and how they would handle the data. IGARD also asked that a special condition was inserted in section 6 (Special Conditions) and for the avoidance of doubt that neither 'Sanofi-Aventis' or 'Apollo Medical Software Solutions' could access the data under this agreement, and further if King's College</p>

	<p>London and University of Leiden were not considered joint Data Controllers to include them also.</p> <p>Outcome Summary: recommendation to approve subject to the following condition(s)</p> <ol style="list-style-type: none"> 1. To provide a written explanation why King's College London and University of Leiden are not considered joint data controllers, in light of the supporting documents provided. 2. Given the funding involvement and commercial interest of 'Sanofi-Aventis', why this application is not considered in any way commercial. 3. To provide written evidence that NHS Digital are satisfied that the RCGP has appropriate security and that due diligence regarding security is in place. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To amend section 1 to correctly list the RCGP's legal basis. 2. To amend section 1 to correctly list the University of Surrey's legal basis. 3. To amend section 1 and section 5(a) to clearly set out what the legitimate interests relied on are and how they relate to the processing; and to update the first paragraph in section 5(a) to provide further detailed information on the legitimate interest 4. To update section 5(a) to remove reference to the legal basis in the paragraph starting "<i>the GDPR legal basis for the study is public interest...</i>" since it is not relevant to this application. 5. To update section 5(b) to provide further clarification of which parties will have access to the data and how they will handle the data. 6. To insert a special condition in section 6 and for the avoidance of doubt that neither 'Sanofi-Aventis' or 'Apollo Medical Software Solutions' can access the data under this agreement, and further if King's College London and University of Leiden are not considered joint Data Controllers to include them also. <p>It was agreed the conditions be approved Out of committee (OOC) by IGARD Members.</p>
2.6	<p><u>Imperial College London: Imperial College London/Dr Foster Limited Standard Extract Service Feed (HES Amendment, Renewal/Extension) (Presenter: Dickie Langley) NIC-12828-M0K2D</u></p> <p>Application: This was an amendment application to add Civil Registrations Data for the purpose of identifying measures of quality and safety in healthcare. Research themes are around developing and validating indicators of quality and safety of healthcare particularly by GP practice, consultant, and NHS Trust, showing variations in performance by unit, patient risk subgroups and risk prediction, risk adjustment and outlier detection for such indicators and variations and any other methodological aspects as they arise.</p> <p>Discussion: IGARD queried whether s251 support was in place for both the research database and the patient re-identification service for all Trusts and asked that the applicant provide documentary evidence, since it was noted that the Health Research Authority Confidentiality Advisory Group (HRA CAG) register had not been updated to reflect that the applicant had submitted their annual review.</p> <p>IGARD noted the references to the legitimate interest being the "direct care" (of patients) and asked that this reference was removed throughout the application.</p> <p>IGARD also noted the references to "sub-licence" and asked they were removed from throughout the application, including the special condition in section 6 (Special Conditions) that references this since it is not relevant.</p> <p>IGARD queried the information provided in section 1 (Abstract) point 1(i) in accordance with the General Data Protection Regulation (GDPR) 89(1) that states "<i>The data will only be used in identifiable form for the specific purpose of data linkage and quality assurance of that</i></p>

<p><i>linkage – for which purpose use of identifiable data is necessary – and measures are taken to ensure subsequent uses of the data will involve only data that has been appropriately pseudonymised.</i>” and asked that this was updated to clarify the re-identification service for Trusts.</p> <p>IGARD noted the language and acronyms used throughout section 5 (Purpose / Methods / Outputs) and asked that this was updated to ensure the use of technical jargon were only used where necessary and that it was also written in language suitable for a lay reader.</p> <p>IGARD noted the sentence in section 5(a) (Objective for Processing) that states <i>“Understanding referral rates by GP practice and consultant can help to identify issues of quality of primary care.”</i> and asked that the reference to ‘primary’ was removed as it was not relevant.</p> <p>IGARD also noted the sentence in section 5(a) that states <i>“These data are extremely critical because mortality information is a surrogate metric for success of medical care.”</i> and asked that the word “is” was more accurately updated to “may be”.</p> <p>IGARD noted the error in the sentence in section 5(b) (Processing Activities) that states <i>“There will be not data linkage undertaken with NHS Digital...”</i> and asked that this was updated to remove ‘not’ and replace with ‘no’.</p> <p>IGARD queried if any record level data would be shared with Dr Foster Limited’s parent company or group of companies and asked that section 5(b) was updated to clearly state that no record level data would be shared.</p> <p>Outcome Summary: recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> 1. The applicant to provide documentary evidence that s251 support is in place for both the research database and the patient re-identification service for all Trusts. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To remove reference to “direct care” from throughout the application. 2. To remove reference to “sub-license” from throughout the application and to remove the special condition referencing this, since it is not relevant. 3. To update section 1 point 1(i) in accordance with GDPR 89(1) to clarify the re-identification service for Trusts. 4. To update section 5(a) to remove ‘primary’ from the sentence <i>“...can help to identify issues of quality in primary care...”</i>. 5. To update the sentence in section 5(a) starting <i>“These (sic) data are extremely critical because mortality information is a surrogate metric for success of medical care”</i> to remove ‘is’ and replace with ‘may be’. 6. To update section 5 to ensure the use of technical jargon is used only where necessary; and where it is necessary, to be also written in language suitable for a lay reader. 7. To update the sentence in section 5(b) starting <i>“There will be not data linkage undertaken...”</i> to remove ‘not’ and replace with ‘no’. 8. To update section 5(b) to be clear that no record level data will be shared its parent company or group of companies <p>The following advice was given</p> <ol style="list-style-type: none"> 1. IGARD suggested that NHS Digital may wish to consider auditing this organisation in relation to this application / data sharing agreement 2. IGARD advised that they would wish to review this application again when it comes up for renewal.
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	<p>3. IGARD suggested that the applicant may wish to update their privacy notice (including but not limited to) reference to direct care.</p> <p>It was agreed the condition be approved Out of committee (OOC) by the IGARD Deputy Chair.</p>
2.7	<p><u>Dr Foster Ltd: Dr Foster Standard Extract Service Feed (Presenter: Dickie Langley) NIC-68697-R6F1T</u></p> <p>The application was withdrawn by the presenter.</p>
3	<p>AOB:</p> <p>There was no further business raised, the IGARD Acting 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 14/06/19

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)
N/A						

In addition, the following applications were not considered by IGARD but have been progressed for IAO and Director extension/renewal:

- None