

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 28 March 2019

Members: Sarah Baalham, Joanne Bailey, Maria Clark, Kirsty Irvine (Chair), Priscilla McGuire, Eve Sariyannidou.

In attendance: Dave Cronin, Louise Dunn, James Humphries-Hart, Karen Myers.

Apologies: Anomika Bedi, Nicola Fear.

Observers: Dan Goodwin, Geoffrey Schrecker, Maurice Smith (Items 2.1-2.9 and 2.11)

1	<p>Declaration of interests:</p> <p>There were no declarations of interest.</p> <p>Review of previous minutes and actions:</p> <p>The minutes of the 21st March 2019 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record the meeting.</p> <p>Out of committee recommendations:</p> <p>An out of committee report was received (see Appendix B).</p>
2	<p>Data applications</p>
2.1	<p><u>Cardiff University: MR1314: FRAGMATIC: A randomised phase III clinical trial investigating the effect of FRAGMin® Added to standard Therapy In patients with lung Cancer (Presenter: Dave Cronin) NIC-291941-Z2Q1C</u></p> <p>Application: This was an extension and amendment application for identifiable Medical Research Information Service (MRIS) for a study assessing the effect of adding dalteparin (FRAGMIN) for 24 weeks to standard treatment (trial arm) compared to standard treatment alone (control arm). The primary outcome measure of the trial was overall survival. Future objectives include completion of ongoing health economic analysis and further analysis of the data set to further investigate and publish other secondary outcome measures.</p> <p>Discussion: IGARD noted in section 1(b) (Data Controller(s)) that the Data Protect Act (DPA) expiry date had expired for Cardiff University and asked that this was updated with the new date.</p> <p>IGARD noted the reference to Article 9(2)(j) within section 1 (Abstract) and asked that this was updated to reference that the <i>'research is in the public interest'</i>.</p> <p>IGARD suggested information provided in section 5(b) (Processing Activities) on derived data that started <i>"NHS Digital has reviewed the specification and description of the data..."</i> which also included the information on fields and access controls was replicated within section 6 (Special Conditions).</p> <p>IGARD noted the sentence in section 5(b) <i>"Velindre NHS Trust may will not store or process the data."</i> and asked that this was updated to remove the word 'may'.</p> <p>IGARD queried the reference in section 3 (Datasets Held / Requested) under the 'Common Law Duty of Confidentiality' to 'Reasonable Expectations' and asked that this was removed as it was not relevant.</p> <p>IGARD noted that historic phrasing was being used in section 4 (Privacy Notice) and it was suggested that new standard wording be used <i>"All data required under this application is personal data under the GDPR. All Data Controllers are expected to provide a privacy notice"</i></p>

	<p><i>that is compliant with the GDPR notice requirements after obtaining the personal data, but at the latest within one month”.</i></p> <p>IGARD noted that there were inconsistent references to ‘arms’ and ‘groups’ in the application when describing the different groups of the study and asked that the application was updated to consistently use the term ‘arms’ throughout.</p> <p>IGARD queried how the commercial funder was involved in the project and sought confirmation that it was not involved in the design of the study.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To correctly update the Cardiff University DPA expiry date. 2. To update the description of Article 9(2)(j) within section 1 to reference that this <i>‘research is in the public interest’</i>. 3. To replicate information provided in section 5 on derived data, including fields and access controls as a special condition in section 6. 4. To update section 3 to remove the reference to ‘Reasonable Expectations’. 5. To update section 4 with the standard wording “All data required under this application is personal data under the GDPR. All Data Controllers are expected to provide a privacy notice that is compliant with the GDPR notice requirements after obtaining the personal data, but at the latest within one month”. 6. To consistently use the term ‘arms’ when describing the different groups of the study. 7. To remove the word ‘may’ from the first line of section 5(b) (Velindre NHS Trust may...). 8. To confirm how the commercial funder was involved with the project and provide confirmation that they did not influence the design of the study.
2.2	<p><u>NHS Bedfordshire CCG: DSfC - NHS Bedfordshire CCG - IV & Comm (Presenter: Louise Dunn) NIC-49738-Q2B0D</u></p> <p>Application: This was an amendment 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); for the purpose of 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; and to provide intelligence to support the commissioning of health services.</p> <p>NHS Digital noted that the Data Protection Act (DPA) expiry date for NHS Bedfordshire CCG had expired and would need updating in section 1(b) (Data Controller(s)).</p> <p>Discussion: IGARD acknowledged NHS Digital’s observation that the DPA expiry date for NHS Bedfordshire CCG had expired and supported the update that was required to section 1(b) with the correct date.</p> <p>IGARD noted the role of Circle Health Limited outlined in the application and queried the history of their involvement. NHS Digital advised that Circle Health Limited were previously part of the application and had been removed but were now included as part of the application again. It was suggested that this background information was included within section 1 (Abstract) for information.</p>

	<p>IGARD noted the references to Circle Health Limited and RSR Consulting Limited were inconsistent and asked that the application was updated to ensure the correct names are consistently throughout.</p> <p>IGARD noted that within section 3(c) (Patient Objections) the applicant had given the answer 'mixed' to whether patient objections have been applied and asked that this was amended to reflect that there are no applied patient objections.</p> <p>IGARD noted that historic phrasing was being used in section 4 (Privacy Notice) and it was suggested that new standard wording be used "<i>All data required under this application is personal data under the GDPR. All Data Controllers are expected to provide a privacy notice that is compliant with the GDPR notice requirements after obtaining the personal data, but at the latest within one month</i>".</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To provide a further explanation within section 1 on the history of the involvement of 'Circle Health Limited'. 2. To ensure the correct names of Circle Health Limited and RSR Consulting Limited are used consistently throughout the application. 3. To correctly update the NHS Bedfordshire CCG DPA expiry date. 4. To amend section 3(c) to reflect that there are no applied patient objections. 5. To update section 4 with the standard wording "<i>All data required under this application is personal data under the GDPR. All Data Controllers are expected to provide a privacy notice that is compliant with the GDPR notice requirements after obtaining the personal data, but at the latest within one month</i>".
2.3	<p><u>NHS Warrington CCG: DSfC - NHS Warrington CCG: RS, Comm & IV (Presenter: James Humphries-Hart) NIC-47225-D8S4S</u></p> <p>Application: This was an amendment 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) and Civil Registries Data (CRD). 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>NHS Digital advised that the application was returning to IGARD to include Microsoft Azure processing and storage locations and as a Data Processor.</p> <p>Discussion: IGARD noted the application was returning to include Microsoft Azure processing and storage locations and as a Data Processor and that an application with the same request had recently been recommended for approval by IGARD; and asked that the same security assurances wording relating to the use of cloud storage were applied and included within this application. IGARD also asked that due consideration was given of anything additional needed given that identifying data that is being stored.</p> <p>IGARD queried why there was more than one risk stratification provider listed in the application and asked that a further explanation was provided outlining the reasons for this.</p>

	<p>Outcome: recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> 1. To insert appropriate security assurance wording relating to the use of cloud storage and to give due consideration of anything additional needed given that identifying data that is being stored. <p>The following amendment was requested:</p> <ol style="list-style-type: none"> 1. To provide an explanation as to why there is more than one risk stratification provider. <p>It was agreed the condition be approved OOC by IGARD Members.</p>
2.4	<p><u>NHS Arden and Greater East Midlands Commissioning Support Unit: A Class Action for Arden and Greater East Midlands Commissioning Support Unit to amend processing and storage locations to include Cloud locations (Presenter: James Humphries-Hart) NIC-281235-C6T8Z</u></p> <p>Application: This was an amendment Class Action application to update Arden and Greater East Midlands Commissioning Support Units' processing and storage addresses to include Microsoft Azure Cloud addresses. Microsoft supply IT infrastructure and support the system but do not have any access to data.</p> <p>Discussion: IGARD noted that the data in the Cloud included confidential patient information under joint data controllership.</p> <p>IGARD noted that GP data processed by GP system suppliers may increasingly be stored in the cloud.</p> <p>IGARD noted that an application with the same request had recently been recommended for approval by IGARD and asked that the same security assurances assurance wording relating to the use of cloud storage were applied and included within the application; and asked that due consideration was given of anything additional needed given that identifying data that is being stored.</p> <p>Outcome: recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> 1. To insert appropriate security assurance wording relating to the use of cloud storage and to give due consideration of anything additional needed given that identifying data that is being stored. <p>It was agreed the condition be approved OOC by IGARD Members.</p>
2.5	<p><u>NHS Midlands & Lancashire Commissioning Support Unit: A Class Action for Midlands & Lancashire Commissioning Support Unit to amend processing and storage locations to include Cloud locations (Presenter: James Humphries-Hart) NIC-281239-V4X7H</u></p> <p>Application: This was an amendment Class Action application to update Midlands & Lancashire Commissioning Support Units' processing and storage addresses to include Microsoft Azure Cloud addresses. Microsoft supply IT infrastructure and support the system but do not have any access to data.</p> <p>Discussion: IGARD noted that the data in the Cloud included confidential patient information under joint data controllership.</p> <p>IGARD noted that an application with the same request had recently been recommended for approval by IGARD and asked that the same security assurances assurance wording relating to the use of cloud storage were applied and included within the application; and asked that due consideration was given of anything additional needed given that identifying data that is being stored.</p> <p>Outcome: recommendation to approve subject to the following condition(s)</p>

	<p>1. To insert appropriate security assurance wording relating to the use of cloud storage and to give due consideration of anything additional needed given that identifying data that is being stored.</p> <p>It was agreed the condition be approved OOC by IGARD Members.</p>
2.6	<p><u>NHS North East London Commissioning Support Unit: A Class Action for North East London Commissioning Support Unit to amend processing and storage locations to include Cloud locations (Presenter: James Humphries-Hart) NIC-281228-Y3J9J</u></p> <p>Application: This was an amendment Class Action application to update North East London Commissioning Support Units' processing and storage addresses to include Microsoft Azure Cloud addresses. Microsoft supply IT infrastructure and support the system but do not have any access to data.</p> <p>Discussion: IGARD noted that the data in the Cloud included confidential patient information under joint data controllership.</p> <p>IGARD noted that an application with the same request had recently been recommended for approval by IGARD and asked that the same security assurances assurance wording relating to the use of cloud storage were applied and included within the application; and asked that due consideration was given of anything additional needed given that identifying data that is being stored.</p> <p>Outcome: recommendation to approve subject to the following condition(s)</p> <p>1. To insert appropriate security assurance wording relating to the use of cloud storage and to give due consideration of anything additional needed given that identifying data that is being stored.</p> <p>It was agreed the condition be approved OOC by IGARD Members.</p>
2.7	<p><u>North of England Commissioning Support Unit: A Class Action for North of England Commissioning Support Unit to amend processing and storage locations to include Cloud locations (Presenter: James Humphries-Hart) NIC-281222-N3Q1M</u></p> <p>Application: This was an amendment Class Action application to update North of England Commissioning Support Units' processing and storage addresses to include Microsoft Azure Cloud addresses. Microsoft supply IT infrastructure and support the system but do not have any access to data.</p> <p>Discussion: IGARD noted that the data in the Cloud included confidential patient information under joint data controllership.</p> <p>IGARD noted that an application with the same request had recently been recommended for approval by IGARD and asked that the same security assurances assurance wording relating to the use of cloud storage were applied and included within the application; and asked that due consideration was given of anything additional needed given that identifying data that is being stored.</p> <p>Outcome: recommendation to approve subject to the following condition(s)</p> <p>1. To insert appropriate security assurance wording relating to the use of cloud storage and to give due consideration of anything additional needed given that identifying data that is being stored.</p> <p>It was agreed the condition be approved OOC by IGARD Members.</p>

<p>2.8</p>	<p><u>NHS South Central and West Commissioning Support Unit: A Class Action for North East London Commissioning Support Unit to amend processing and storage locations to include Cloud locations (Presenter: James Humphries-Hart) NIC-281231-Y0H3Z</u></p> <p>Application: This was an amendment Class Action application to update South Central and West Commissioning Support Units' processing and storage addresses to include Microsoft Azure Cloud addresses. Microsoft supply IT infrastructure and support the system but do not have any access to data.</p> <p>Discussion: IGARD noted that the data in the Cloud includes confidential patient information under joint data controllership.</p> <p>IGARD noted that an application with the same request had recently been recommended for approval by IGARD and asked that the same security assurances assurance wording relating to the use of cloud storage were applied and included within the application; and asked that due consideration was given of anything additional needed given that identifying data that is being stored.</p> <p>Outcome: recommendation to approve subject to the following condition(s)</p> <ol style="list-style-type: none"> 1. To insert appropriate security assurance wording relating to the use of cloud storage and to give due consideration of anything additional needed given that identifying data that is being stored. <p>It was agreed the condition be approved OOC by IGARD Members.</p>
<p>2.9</p>	<p><u>NHS Bolton CCG: DSfC - NHS Bolton CCG - STP - Comm (Presenter: James Humphries-Hart) NIC-139091-F3T3H</u></p> <p>Application: This was an amendment 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 (CWT) and Civil Registries Data (CRD) (Births and Deaths) to provide intelligence to support the commissioning of health services.</p> <p>Discussion: IGARD noted that where the term 'hosted' was referenced in the application the organisations were referred to inconsistently throughout the application and asked that the correct legal entity is referred to appropriately for the avoidance of doubt.</p> <p>IGARD noted that section 4 (Privacy Notice) incorrectly states that it does meet the criteria set and asked that this was updated to reflect that the privacy notice does not meet the criteria set.</p> <p>IGARD noted that there was a discrepancy with the information provided for the Data Processor 3 (Health Innovation Manchester Utilisation Management Team) in supporting document 1, the data flow diagram and section 5(b) (Processing Activities) and asked that section 5(b) was amended to include a narrative for the Data Processor 3 to reflect the information provided in the Data Flow Diagram.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1 To ensure the correct legal entity is referred to appropriately, for the avoidance of doubt and particularly where the term 'hosted' is used. 2 To update section 4 to reflect that the privacy notice does not meet the criteria set.

	<p>3 To amend section 5(b) to include a narrative for the Data Processor 3 to reflect the information provided in the Data Flow Diagram.</p>
2.10	<p><u>NHS Liverpool CCG: DSfC - NHS Liverpool CCG; RS, IV, Comm (Presenter: James Humphries-Hart) NIC-47191-D9X6J</u></p> <p>Application: This was an amendment 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), Adult Social Care Pilot Data and Civil registration Data (CRD). 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>Discussion: IGARD noted that there were two risk stratification providers referenced in section 1 (Abstract) and asked that this was updated with a further explanation as to why two providers were required.</p> <p>IGARD noted the reference to the Hartree Centre in section 5(a) (Objective for Processing) and asked that for clarity this was updated to include a brief description of who they were.</p> <p>IGARD noted information provided in section 5(b) (Processing Activities) clarifies that LIMA Networks Ltd and Blackpool Royal Hospitals will not access data held under this agreement and asked that this was replicated as a special condition in section 6 (Special Conditions).</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 with an explanation of why there are two risk stratification providers. 2 To update section 5(a) with a brief description of the Hartree Centre. 3 To insert a special condition in section 6 stating that LIMA Networks Ltd and Blackpool Royal Hospitals will not access data held under this agreement.
2.11	<p><u>NHS Manchester CCG: New application to link SUS data to GP and Social Care Data (Presenter: James Humphries-Hart) NIC-272984-V0C5X</u></p> <p>Application: This was a new application for pseudonymised Secondary Uses Service (SUS) for Commissioners data to provide intelligence to support the commissioning of health services. The data is analysed so that health care provision can be planned to support the needs of the population within the CCG area.</p> <p>Discussion: IGARD noted that section 5(b) (Processing Activities) stated that NHS Ilkeston Community Hospital did not access data held under this agreement and asked that this was replicated as a special condition in section 6 (Special Conditions).</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To insert a special condition in section 6 stating that NHS Ilkeston Community Hospital will not access data held under this agreement.

3	<p>AOB</p> <p><u>NIC-368233-L2N0W McKinsey & Co. Inc. UK</u></p> <p>IGARD noted that following the 13th December 2018 meeting, when IGARD recommended for approval subject to conditions. The relevant extract is as follows:</p> <p>“IGARD recommended to approve subject to the following condition(s)</p> <ol style="list-style-type: none"> 1. IGARD to receive written confirmation from NHS Digital that they are content to disseminate the data under this application / data sharing agreement to a company that is a branch of a USA company and, as such, subject to a foreign jurisdiction. 2. To remove any references in the application to geographical restrictions, since it is a branch of a USA company. 3. To clearly set out an analysis within section 5(a) of the application explaining the Legitimate Interests relied on and linked to the purpose outlined. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To amend section 4 to state that the Fair Processing Notice ‘does not’ meet the criteria and to update the abstract checklist to note the current shortcomings. 2. To align and update the abstract to reflect the different types of processing set out in section 5 of the application. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. NHS Digital should work with the applicant to update their Fair Processing Notice. <p>IGARD noted the utility of the work undertaken and the need for the applicant to continue to hold data. IGARD noted that the applicant’s Data Sharing Agreement with NHS Digital was due to expire, and in light of this it was suggested that NHS Digital might wish to consider a short-term extension to permit the applicant to hold but not in any other way process the data while work was undertaken to update the application.</p> <p>It was agreed the conditions be approved OOC by IGARD Members.”</p> <p>NHS Digital had taken the decision to disseminate the data. The IGARD Chair had been informed of this out of committee.</p>
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Independent Group Advising on Releases of Data (IGARD): Out of committee report 22/03/19

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)
NIC-368233-L2NOW	McKinsey & Company, Inc. United Kingdom	13/12/2018	<ol style="list-style-type: none"> 1. IGARD to receive written confirmation from NHS Digital that they are content to disseminate the data under this application / data sharing agreement to a company that is a branch of a USA company and, as such, subject to a foreign jurisdiction. 2. To remove any references in the application to geographical restrictions, since it is a branch of a USA company. 3. To clearly set out an analysis within section 5(a) of the application explaining the Legitimate Interests relied on and linked to the purpose outlined. 	OOO by IGARD Members	Service Director (ai), Data Dissemination (The IGARD Chair noted her contentment that the conditions had been met)	N/A
NIC-302473-K6R0Z	University of Cambridge	17/01/2019	<ol style="list-style-type: none"> 1. To provide confirmation that the work outlined in the application is not part of an EU funded project. 2. To provide confirmation that favourable REC support is continuing as required within the s251 support outlined in the supporting document provided. 3. To replicate the information provided within section 4 (stating that the applicant will work with NHS Digital to ensure the fair 	OOO by IGARD Members	OOO by IGARD Members	N/A

			processing notice is GDPR compliant) in section 6 as a special condition.			
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In addition, the following applications were not considered by IGARD but have been progressed for IAO and Director extension/renewal:

- None