

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 8 November 2018

Members: Sarah Baalham, Joanne Bailey, Kirsty Irvine (Chair),

In attendance: Dave Cronin, Anna Duggan (2.8), Rachel Farrand, James Humphries-Hart, Dickie Langley, Karen Myers, Kimberley Watson, Vicki Williams.

Observers: Stuart Blake, Maria Clark, Priscilla McGuire.

Apologies: Anomika Bedi, Nicola Fear, Eve Sariyiannidou

1	<p>Declaration of interests:</p> <p>There were no declarations of interest.</p> <p>Review of previous minutes and actions:</p> <p>The outcomes of the 1 November 2018 IGARD meeting were reviewed and were agreed as an accurate record of that aspect of the meeting.</p> <p>The minutes of the 1 November 2018 IGARD meeting were reviewed out of committee by IGARD following conclusion of the meeting, and subject to a number of minor changes were agreed as an accurate record of the meetings.</p> <p>Out of committee recommendations</p> <p>An out of committee report was received (see Appendix B).</p>
2	Data applications
2.1	<p><u>Harvey Walsh Ltd: services – data disseminations (Presenter: Dickie Langley) NIC-05934-M7V9K</u></p> <p>Application: This was an amendment application for pseudonymised Hospital Episode Statistics (HES) data, Mental Health Services Data Set (MHSDS) and Civil Registrations Mortality data and a renewal to continue to receive monthly extracts of HES Admitted Patient Care, HES Outpatients, HES Critical Care and HES Accident and Emergency datasets. The purpose was to undertake analysis, develop services and provide solutions to support commissioning, analytical support and outcomes analysis for NHS organisations.</p> <p>Discussion: IGARD noted that Harvey Walsh Ltd had been incorrectly referenced in the abstract and suggested that it be clearly articulated within the abstract that NHS Digital, not Harvey Walsh Ltd, have assessed and deemed the Legitimate Interest Assessment (LIA) satisfactory in order to meet its GDPR obligations.</p> <p>IGARD asked whether the outputs were incorporated into the benefits and asked that this be defined in general terms and to also clarify throughout that the benefits are either current, ongoing or future as this was not currently clear.</p> <p>IGARD queried which of the projects would be using the full ten years of data and asked that this be clearly stated within the application.</p> <p>IGARD noted the special condition in section 6 stating that “The AXON tool will only make use of five years of data” and asked this be included in section 5 for transparency.</p> <p>IGARD noted that section 5(a) should be updated to include clearer examples for processing and how the applicant has been using the data. IGARD also suggested that the applicant provide further details of pathways for disseminating the outputs of the study to the wider public including specific examples of collaboration with patient groups.</p>

	<p>IGARD suggested that NHS Digital may wish to consider auditing this organisation in relation to this application / data sharing agreement, in light of recent updates to the small number suppression (disclosure control) rules in the HES Analysis Guide, given that aggregated data is presented to 3rd parties via an online tool.</p> <p>IGARD noted that Harvey Walsh Ltd had provided an amendment to their privacy notice with regard to the rights available to individuals / national opt out policy.</p> <p>ACTION: To clarify how NHS Digital are advising applicants on appropriate wording within their Privacy Notices with regard to the rights of individuals with regard to the processing of their personal data.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update the abstract to reflect that NHS Digital, rather than Harvey Walsh Ltd, have assessed the LIA and deemed it satisfactory. 2. To define in general terms that the outputs are incorporated in the benefits and to clarify throughout that the benefits are either current, ongoing or future. 3. To clearly state that only one project requires use of a full ten years of data. 4. To amend section 5 (to replicate the Axon special condition) to clearly state that the Axon360 tool will only make use of five years of data. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD suggested on renewal that further details of pathways of dissemination of the outputs to the wider public be provided, including examples of collaboration with patient groups. 2. IGARD suggested that NHS Digital may wish to consider auditing this organisation in relation to this application / data sharing agreement, in light of recent updates to the small number suppression (disclosure control) rules in the HES Analysis Guide, given that aggregated data is presented to 3rd parties via an online tool.
2.2	<p><u>Health IQ Ltd: Benchmarking and reporting (Presenter: Dickie Langley) NIC-15293-R6V2H</u></p> <p>Application: This was a new application for pseudonymised Hospital Episode Statistics (HES) data for research studies which will provide benefit to healthcare by providing some insights from the data. The applicant will produce reports either as a specific data requests, or as part of wider research projects, for example a report on the impact of early diagnostic testing on cardiovascular outcomes or a report on the pre and post-diagnosis burden of Major Depressive Disorder patients, covering Mental Health community contacts as well as related admissions.</p> <p>The application had been previously considered on the 20th September 2018 when IGARD had deferred making a recommendation pending; redrafting the sub-license to incorporate the full terms of the data sharing agreement and data sharing framework contract; confirmation that the NHS Digital Security Adviser is satisfied that the security meets the requisite standard set out in the IG Toolkit; to clarify what is being supplied under the sub-license agreement; provide further information on the legitimate interest and how it relates to the outputs and benefits; provide further information about the customer base, for example the percentage of NHS customers and life science customers; provide further clarity how the work outlined in the application will benefit the wider Health and Social Care system.</p> <p>Discussion: IGARD noted that application had been updated to reflect most of the comments previously raised.</p> <p>IGARD noted the outcomes of the meeting on 20 September and observed that the applicant</p>

	<p>had not directly redrafted the sub-licence to “incorporate the full terms of the data sharing agreement and data sharing framework contract” and that instead various other steps had been taken to incorporate key contractual terms into the subsidiary contract documents and that the users now must meet “HSCIC guidance”. IGARD and NHS Digital discussed at some length the efficacy of these arrangements.</p> <p>IGARD queried if users when accessing the tool are aware of the purposes for which they can use the data they are accessing and asked that section 5 be amended to clearly state this, and that the data use is limited as outlined in the applicant’s Data Sharing Agreement.</p> <p>IGARD suggested that NHS Digital may wish to consider auditing this organisation in relation to this application / data sharing agreement, in light of recent updates to the small number suppression (disclosure control) rules in the HES Analysis Guide, given that aggregated data is presented to 3rd parties via an online tool.</p> <p>IGARD noted that NHS Digital had reviewed the applicant’s privacy notice in particular with regard to the rights available to individuals.</p> <p>ACTION: To clarify how NHS Digital are advising applicants on appropriate wording within their Privacy Notices with regard to the rights of individuals with regard to the processing of their personal data.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To amend section 5 to clearly state that when users access the tool, they are made aware of the purpose they can use the data for which they are accessing, and that it is limited as outlined in the applicant’s DSA. <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, in light of recent updates to the small number suppression (disclosure control) rules in the HES Analysis Guide, given that aggregated data is presented to 3rd parties via an online tool.
2.3	<p><u>Methods Analytics Ltd: Standard Extract Subscription – modification of section 5 (Presenter: Dickie Langley) NIC-09519-D5G0R</u></p> <p>Application: This was an amendment application for pseudonymised Hospital Episode Statistics (HES), Secondary Use Service (SUS), Civil Registrations, Mental Health and Learning Disabilities Data Set (MHLDDS), Diagnostic Imaging Dataset (DIDs) and Mental Health Services Data Set (MHSDS). The data will be used to support the NHS either directly through the delivery of tools and bespoke analysis or indirectly through non-NHS organisations, where analytics are provided to the NHS as the end beneficiary via a non-NHS organisation.</p> <p>Discussion: IGARD noted that further information should be provided on project 2, bespoke tools and analysis, including the appropriate restrictions of use on clinical users (similar to the restrictions outlined in projects 1 and 4 of the applications) and to include a clear description of the users, their employing organisations and their role. IGARD also asked that confirmation be provided that the “clinical leads” are employed by an NHS organisation for access controls currently in place be provided.</p> <p>IGARD queried who the data subjects and users of project 4 (SWORD) outlined in the application are and if the dual functionality are anticipated to be used by the same users and asked for further clarity on this.</p>

IGARD noted that section 5 does not clearly outline that the purpose of the application as an amendment and asked that this be updated to provide consistency with the rest of the application. IGARD queried if users when accessing the tool are aware of the purposes for which they can use the data they are accessing and asked that section 5 be amended to clearly state this, and that the use of data is limited as outlined in the applicant's Data Sharing Agreement.

IGARD suggested that it be clearly articulated within the abstract and section 5 (purpose section) the legitimate interest relied upon and how it relates to the purpose of the research being undertaken, including confirmation within the abstract or as an additional supporting document that NHS Digital have assessed and deemed the Legitimate Interest Assessment (LIA) satisfactory in order to meet its GDPR obligations and to make reference to such assessment in the abstract of the application.

IGARD noted that the section on Article 9(2)(j) in the abstract should be updated to reference the relevant public interest condition under the Data Protection Act 2018.

IGARD noted the special condition that refers to "CONSULT" and asked that section 5 be updated to further outline which products use this.

IGARD suggested that NHS Digital may wish to consider auditing this organisation in relation to this application / data sharing agreement, in light of recent updates to the small number suppression (disclosure control) rules in the HES Analysis Guide, given that aggregated data is presented to 3rd parties via an online tool.

IGARD noted that NHS Digital had reviewed the applicant's privacy notice in particular with regard to the rights available to individuals.

ACTION: To clarify how NHS Digital are advising applicants on appropriate wording within their Privacy Notices with regard to the rights of individuals with regard to the processing of their personal data.

Outcome: recommendation to approve

The following amendments were requested:

1. To include further information on project 2 - bespoke tools and analysis - including appropriate restriction of use on the clinical users (similar to the restrictions outlined in projects 1 and 4 in the application) and to include a clear description of the users, their employing organisations and their role. To also provide confirmation that the "clinical leads" are employed by an NHS organisation and access controls currently in place.
2. To clarify who are the data subjects and users of project 4 (SWORD pathway view) and to clarify if the dual functionality (the two alternative views) are anticipated to be used by same users.
3. To amend section 5(b) to provide consistency with the rest of application.
4. To include narrative within the abstract and section 5(a) of the application explaining the Legitimate Interests relied on as set out in the supporting LIA provided by the applicant.
5. To update the section on Article 9(2)(j) of GDPR to reference the relevant condition under the DPA 2018.
6. To amend section 5 to clearly state that when users access the tool, they are made aware of the purposes for which they can use the data they are accessing, and that it is limited as outlined in the applicants DSA.
7. To clearly state in section 5 which products use "CONSULT".
8. To update section 5(a) to make clear what aspects of the application are an

	<p>amendment.</p> <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, in light of recent updates to the small number suppression (disclosure control) rules in the HES Analysis Guide, given that aggregated data is presented to 3rd parties via an online tool. <p>IGARD advised that they would wish to review this application again when it comes up for renewal.</p>
2.4	<p><u>University College London: Mixed methods evaluation of the Getting it Right First Time (GIRFT) Programme - improvements to NHS orthopaedic care in England (Presenter: Kimberley Watson) NIC-112374-X0T4S</u></p> <p>Application: This was a new application for identifiable Hospital Episode Statistics (HES) data and Patient Reported Outcome Measures (PROMS) data to enhance patient safety by addressing the complex issues of unwarranted variation in elective orthopaedic surgery. The GIRFT programme seeks to change practice in order to improve patient outcomes.</p> <p>The application was been previously considered on the 11th October 2018 when IGARD had deferred making a recommendation pending; HQIP have not provided evidence in law that public task is the appropriate legal basis, particularly in light of documents available in the public domain that state that charities (not covered by the Fol Act) providing public services under contract should be treated in the same way as private contractors; to provide further details of pathways of dissemination of the outputs including any specific examples of public / patient engagement within section 5c; to provide more examples of specific and actual benefits within section 5d of the application; clarification, due to the apparent inconsistencies between the supporting documents provided (Fair Processing Notice and Protocol) and application with regard to the “other parties involved in the project” which suggest joint Data Controllorship may be more appropriate; to update section 4 with the standard wording “All data required by the Data Controller under this application is pseudonymised and therefore is considered as personal data under the GDPR. All Data controllers are expected to provide a privacy notice that is compliant with the GDPR notice requirements within a reasonable period after obtaining the personal data, but at but at the latest within one month”; to update the abstract sections on Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD, including (but not limited to) reference to the public interest condition under the DPA 2018 (reference Article 9(2)(j)).</p> <p>Discussion: IGARD noted that application had been updated to reflect most of the comments previously raised.</p> <p>IGARD noted that Healthcare Quality Improvement Partnership (HQIP) had not provided evidence in law that public task is the appropriate legal basis particularly in light of documents available in the public domain that state that charities (not covered by the Fol Act) providing public services under contract should be treated in the same way as private contractors.</p> <p>IGARD noted the reference to Article 9(2)(i) General Data Protection Regulation in the application and advised that it should be noted how the relevant schedule condition of the Data Protection Act 2018 is met.</p> <p>IGARD queried the employer of the Medical Director referenced in the legal basis and asked for clarification that they are employed by HQIP.</p> <p>IGARD noted that there was reference made to the Higher Education and Research Act 2017 in the application and asked that this be removed since it is not relevant to this application.</p>

	<p>Outcome: Unable to recommend for approval</p> <ol style="list-style-type: none"> HQIP have not provided evidence in law that public task is the appropriate legal basis, particularly in light of documents available in the public domain that state that charities (not covered by the FoI Act) providing public services under contract should be treated in the same way as private contractors. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> IGARD noted that where there is reference to Article 9(2)(i) GDPR, it should also be noted how the relevant schedule condition of DPA 2018 is met. To clarify that the Medical Director referenced in the legal basis explanation is employed by HQIP. To delete the paragraph referencing the Higher Education and Research Act 2017 since it is not relevant to this application.
2.5	<p><u>Clinical Practice Research Database (CPRD): ELAPSE Study – Air Pollution (Presenter: Kimberley Watson) NIC-113074-D9M1C</u></p> <p>Application: This was a new application for pseudonymised Medical Research Information Service (MRIS) data to assess associations between long-term average concentrations of particular matter, nitrogen dioxide, sulphur dioxide, black carbon and ozone and the risk of death and disease incidence in England.</p> <p>Discussion: IGARD noted the collaboration agreement outlined in the application and asked that it be clarified why St George's University of London were not considered as joint Data Controllers and provide relevant justification of this.</p> <p>IGARD noted that the named legal entities listed as the Data Controller(s) and Data Processor(s) within the application needed aligning with contractual documents held by NHS Digital and as per the entities listed HRA CAG s251 support provided as a supporting document.</p> <p>IGARD also queried why NHS Digital is not considered as joint Data Processor and asked for clarification along with relevant justification of this.</p> <p>IGARD queried if it was the geographical postcode that was sent to NHS Digital or the patient's postcode. NHS Digital confirmed that it was the postcodes for the patient at a specific GP Practice that are provided, via the GP patient key. IGARD asked for clarification in section 5 that the postcodes provided by the GP are the patient postcodes only.</p> <p>IGARD asked for clarification that the US funder, The US Health Effects Institute, will not have any influence over the design of the study or have sight of any record level data and asked for this to be updated in section 5 along with a further explanation of the connection between the funder and the funding recipient (at the University of Utrecht) as outlined in supporting document 4 and to confirm that funding is currently in place and provide relevant evidence.</p> <p>IGARD suggested that the applicant provide further details of pathways for disseminating the outputs of the study to patients and the public including specific examples of public / patient engagement.</p> <p>IGARD noted that section 5(a) refers to 'nominal codes' and asked that this be amended to 'nominal pollution code' for clarity.</p> <p>IGARD suggested that reference to identifiable data in the application be updated to 'pseudonymised data'.</p> <p>IGARD noted that in step 1 in section 5(b) it refers to "Transfer of patient identifiers" and asked that this be amended to "Transfer of identifiers".</p>

	<p>Outcome: Recommendation to defer, pending:</p> <ol style="list-style-type: none"> 1. Clarification why St George's University of London are not also considered a Data Controller and provide relevant justification. 2. To further explain within section 5 that the US funder, The US Health Effects Institute, will not influence the design of the study or have sight of the record level data and to explain the connection between the funder and the funding recipient as outlined in supporting document 4 and to confirm that funding is in place and provide relevant evidence. 3. Aligning the named legal entities listed as the Data Controller(s) and Data Processor(s) within the application with contractual documents held by NHS Digital and as per the entities listed in the HRA CAG s251 support provided as a supporting document. 4. Clarify why NHS Digital are not considered a Data Processor and provide relevant justification. 5. To clarify within section 5 that the postcodes provided by the GP is the patient postcode only. 6. To provide further details of pathways of dissemination of the outputs including any specific examples of public / patient engagement. 7. To update section 5(a) from 'nominal codes' to 'nominal pollution codes' 8. To remove any reference in the application to 'anonymised' and replace with 'pseudonymised'. 9. To remove reference to 'patient' from the step 1 statement in section 5(b).
2.6	<p><u>University of Birmingham: MR730 – Bespoke data linkage (Presenter: Dickie Langley) NIC-309500-F4X1B</u></p> <p>Application: This was a renewal application for identifiable Medical Research Information Service (MRIS) data for the BAFTA2 study which is investigating the longer-term effects of anticoagulation in terms of overall mortality and risk of stroke and cardiovascular events.</p> <p>Discussion: IGARD noted that within the abstract section of the application, it states that permission has been given by the Health Research Authority Confidentiality Advisory Group (HRA CAG) for the University of Birmingham to gain access to records without further consent. IGARD asked that this be updated to make it clear that HRA CAG was content that s251 support was not needed.</p> <p>IGARD suggested that the abstract be amended to reference patient consent and the common law duty of confidentiality to: "NHS Digital has determined that the processing in this application is not incompatible with the consent and likely to be within the reasonable expectations to those that have consented".</p> <p>IGARD noted that section 5a should be updated to include clearer examples for processing and how the applicant has been using the data. IGARD also suggested that the applicant provide further details of pathways for disseminating the outputs of the study to patients and the public including specific examples of public / patient engagement.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update the abstract to be clear that HRA CAG was content that s251 support was not needed. 2. To update the abstract to amend references to patient consent and the common law duty of confidentiality to: "NHS Digital has determined that the processing in this application is not incompatible with the consent and likely to be within the reasonable expectations of those that have consented".

	<p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD suggested on renewal that further details of pathways of dissemination of the outputs be provided, including examples of public / patient engagement.
2.7	<p><u>University of Southampton: MR1245: Patient Tracking Service – New EPOC (Presenter: Dickie Langley) NIC-189166-R0Y9Y</u></p> <p>Application: This was a new application for the archiving of pseudonymised Medical Research Information Service (MRIS) data which has been looking at the effect of cancer drugs on progression free survival and whether the introduction of cetuximab makes a difference to the occurrence or rate of the patient's disease progression.</p> <p>Discussion: IGARD welcomed the application and noted the importance of completing the trial.</p> <p>IGARD noted that the abstract refers to “...<i>will not be processing the data during this period.</i>” And suggested this be amended both in the abstract and throughout the application to say “...<i>will not otherwise be processing the data during this period.</i>”</p> <p>Outcome: recommendation to approve</p>
2.8	<p><u>McKinsey & Company Inc: Hospice UK: Hospice-led innovations for end of life care (HOLISTIC) (Presenter: Rachel Farrand) NIC-90989-D6T1T</u></p> <p>Application: This was a new application for pseudonymised Hospital Episode Statistics (HES) and Civil Registrations data for a service evaluation on the effectiveness of end of life care programmes in moving patients out of hospitals at the end of their lives and into other locations of care, such as their homes and hospices, and in their ability to prevent avoidable hospital admissions for these patients. This is a joint evaluation and the organisations involved are NHS England and Hospice UK who are leading the service evaluation, McKinsey and Company Inc who are the contracted data processor and St Giles Medical who are performing qualitative data collection and analysis.</p> <p>Discussion: IGARD queried what the lawful basis is for receipt of, processing and dissemination of the data, and at what point the details of any living individuals are being processed. IGARD also asked for confirmation at what point deceased individuals' data is being processed, and that the legal basis is updated as necessary, to reflect the status of the individual's data being processed.</p> <p>IGARD queried what the contractual arrangements were between NHS England as the data controller and McKinsey and Company Inc as the data processor and asked that further clarification of this be included in section 5.</p> <p>IGARD noted that the applicant was an American company and queried where the data would be processed. NHS Digital confirmed that the data would only be processed in England and Wales and that that Data Processors would be McKinsey and Company Inc]. IGARD asked that a special condition be included to expressly state that the data will only be processed in England and Wales.</p> <p>IGARD noted that within the description of cohort 3 in section 5 it states “...<i>Hospice UK will provide the specific hospital related to each cohort.</i>” and asked for further clarity what is meant by the reference “each cohort”.</p> <p>IGARD queried who the data subjects are, how the cohorts are formed and selected, and in particular for cohort 4 to provide further information on the size and ratios used and asked for further clarification of this in the application and any supporting document.</p> <p>IGARD noted that pending the analysis under the relevant lawful basis, Hospice UK to provide</p>

	<p>a fair processing notice that is compliant with the notice requirements under the GDPR, including but not limited to reference to the data flows and personal data.</p> <p>IGARD suggested on renewal that further details of pathways of dissemination of the outputs be provided including examples of public / patient engagement on the valuable research being undertaken.</p> <p>Outcome: Recommendation to defer, pending:</p> <ol style="list-style-type: none"> 1. To confirm the lawful basis for receipt of, processing of and dissemination of the data, and in particular at what point the details of living individuals (if any) are being processed and at what point data relating to deceased individuals is being processed, and the legal basis to be updated, as may be necessary, to reflect the status of the individual's data being processed. 2. To clarify within section 5 the appropriate contractual arrangements between NHS England (data controller) and McKinsey & Co Inc (data processor). 3. To include a special condition clarifying that the data will only be processed in England and Wales. 4. To provide clarification with regard to who the data subjects are, how the cohorts are formed and selected, and in particular for cohort 4, the size and ratios used. 5. To clarify within section 5 what is meant by the reference "each cohort" within the description for cohort 3. 6. Pending the analysis under the lawful basis, Hospice UK to provide a fair processing notice that is compliant with the notice requirements under the GDPR, including but not limited to reference to the data flows and personal data. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD suggested on renewal that further details of pathways of dissemination of the outputs be provided including examples of public / patient engagement on the valuable research being undertaken.
2.9	<p><u>North South West Lincolnshire CCG: DSfC – NHS South West Lincolnshire CCG IV</u> (Presenter: James Humphries-Hart) NIC-147942-N8J6Y</p> <p>Application: This was a new application for identifiable Secondary Uses Service (SUS) data for Commissioners data covering invoice validation (IV) which is part of a process by which providers of care or services are paid for the work they do.</p> <p>NHS Digital noted that the Data Protection Act 2018 (DPA) date was incorrect and that the s251 support expiry date should be amended to 2020.</p> <p>Discussion: IGARD agreed that the DPA date was showing as expired and the DPA registration number for Optum Health may be incorrect NHS Digital noted that the DPA registration date had been renewed to 2019 and that application would be updated to reflect this, along with checking the DPA registration number for Optum Health.</p> <p>NHS Digital also noted that the section 251 support date noted in the application was incorrect and would need updating to correctly list this as 2020.</p> <p>IGARD noted that there was a reference to 'clear data' within supporting document 1, the data flow diagram and asked that this be removed.</p> <p>IGARD noted that there was reference within the application to "data held in section 3(a)" and asked that this be removed due to this being a new application and therefore no data is held.</p> <p>To remove reference within the application to "data held in section 3(a)" since this is a new application and no data is held.</p>

	<p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To remove reference to 'clear data' from the data flow diagram. 2. To update the DPA expiry date and DPA registration number of Optum Health. 3. To update reference to the s251 expiry date to correctly list the date as 2020. 4. To remove reference within the application to "data held in section 3(a)" since this is a new application and no data is held.
2.10	<p><u>NHS South Lincolnshire CCG: DSfC – NHS South Lincolnshire CCG IV (Presenter: James Humphries-Hart) NIC-148043-R1D0M</u></p> <p>Application: This was a new application for identifiable Secondary Uses Service (SUS) data for Commissioners data covering invoice validation (IV) which is part of a process by which providers of care or services are paid for the work they do.</p> <p>NHS Digital noted that the Data Protection Act 2018 (DPA) date was incorrect and that the s251 should be amended to 2020.</p> <p>Discussion: IGARD agreed that the DPA date was showing as expired and the DPA registration number for Optum Health may be incorrect NHS Digital noted that the DPA registration date had been renewed to 2019 and that application would be updated to reflect this, along with checking the DPA registration number for Optum Health.</p> <p>NHS Digital also noted that the section 251 date noted in the application was incorrect and would need updating to correctly list this as 2020.</p> <p>IGARD noted that there was a reference to 'clear data' within supporting document 1, the data flow diagram and asked that this be removed.</p> <p>IGARD noted that there was reference within the application to "data held in section 3(a)" and asked that this be removed due to this being a new application and therefore no data is held.</p> <p>IGARD noted that there was extraneous wording within the special conditions in section 6 of the application and asked that this be removed as it is not relevant.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To remove reference to 'clear data' from the data flow diagram. 2. To update the DPA expiry date and DPA registration number of Optum Health. 3. To update reference to the s251 expiry date to correctly list the date as 2020. 4. To remove reference within the application to "data held in section 3(a)" since this is a new application and no data is held. 5. To remove extraneous wording with regard to DPA from section 6, special conditions, since it is not relevant to this application.
2.11	<p><u>NHS Medway CCG: DSfC – NHS Medway CCG – RS (Presenter: James Humphries-Hart) NIC-226603-C7K2R</u></p> <p>Application: This was a new application for identifiable Secondary Uses Service (SUS) data for risk stratification 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.</p> <p>NHS Digital noted the s251 date should be amended to 2020</p> <p>NHS Digital also noted that the GDPR legal basis within the abstract should be updated.</p> <p>Discussion: NHS Digital advised that the section 251 date noted in the application was</p>

	<p>incorrect and would need updating to correctly list this as 2020.</p> <p>IGARD noted that NHS Digital had included within the abstract the applicant's legal basis under the General Data Protection Regulation (GDPR) Article 6 and 9, however IGARD suggested that a clear justification for each choice indicated should be given in terms of how the specific criteria and additional requirements would be met since the applicant would need to satisfy the relevant tests associated with the legal basis suggested and as per recent discussions between NHS Digital and IGARD, including to 'no less intrusive to the data subject' wording under Article 9(2)(h) in the Public Task section of the abstract.</p> <p>IGARD noted that there was reference within the application to "data held in section 3(a)" and asked that this be removed due to this being a new application and therefore no data is held.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update the abstract sections on Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD including (but not limited to) reference to 'no less intrusive to the data subject' wording under Article 9(2)(h). 2. To update reference to the s251 expiry date to correctly list the date as 2020. 3. To remove reference within the application to "data held in section 3(a)" since this is a new application and no data is held.
2.12	<p><u>Leicestershire County Council: DSfC – Leicestershire County Council – Comm (Presenter: James Humphries-Hart) NIC-198958-C9G0C</u></p> <p>Application: This was a new application for pseudonymised Secondary Uses Service (SUS) data. The Better Care Together (BCT) Partnership brings together partners from NHS organisations and Local Authorities in Leicestershire and Rutland to commission / provide health and care services for over one million people.</p> <p>NHS Digital confirmed that the NHS West Leicestershire CCG had updated their Data Sharing Framework Contract (DSFC) date to 2021</p> <p>NHS Digital noted that the abstract had been updated to reference nine not 6 organisations</p> <p>Discussion: IGARD noted that the abstract should be updated to correctly reference nine organisations not six were part of this applications</p> <p>It was also noted that the DSFC end date for NHS West Leicestershire CCG should be updated to reflect 2021.</p> <p>IGARD noted that the application should be updated to correctly reference the appropriate use of plurals to reflect the multiple parties involved within this application.</p> <p>IGARD queried the legal basis outlined within the abstract and for the commissioning purposes, the applicant should provide clear basis in law for the Foundation Trusts to receive data in relation to the commissioning proposed under this application.</p> <p>Outcome: recommendation to approve subject to the following condition(s)</p> <ol style="list-style-type: none"> 1. To provide evidence of a clear basis in law for the Foundation Trusts to receive data in relation to the commissioning proposed under this application. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update the application throughout with the appropriate use of plurals to reflect the multiple parties involved in the application. 2. To update the abstract to confirm that 9 organisations are part of this application. 3. To update the DSFC date reference for NHS West Leicestershire CCG with the correct

	<p>date of 2021.</p> <p>It was agreed the conditions be approved OOC by IGARD Members.</p>
2.13	<p><u>Swansea University: MR730 – Bespoke data linkage (Presenter: Dave Cronin) NIC-324116-W0K9R</u></p> <p>Application: This was a new application for pseudonymised Hospital Episode Statistics (HES) and Civil Registrations data for a project that is investigating factors, including the week day of admission, hospital size and services provided that may affect mortality following admission for emergency admissions and various acute conditions in hospitals across England and Wales. NHS Digital noted that a number of typos within the abstract and section 5(a) which had now been amended.</p> <p>Discussion: IGARD queried the funding position of The Wellcome Trust and asked that it be made clear within section 5 that funding had ended, and that they remained supportive and interested in the outcomes of the project.</p> <p>IGARD also asked that section 8(b) is updated to correctly note that The Wellcome Trust funding had expired.</p> <p>IGARD suggested that, given the likely high level of public interest in the valuable research being undertaken, further consideration be given to suitable pathways of dissemination to the wider general public.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To amend section 5 to make clear that the funding from The Wellcome Trust has ended but that they remain supportive and interested in the outcomes. 2. To update section 8(b) to note that The Wellcome Trust funding has now 'expired' <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD suggested that, given the likely high level of public interest in the valuable research being undertaken, further consideration be given to suitable pathways of dissemination to the wider general public.
2.14	<p><u>University of Oxford: MR376 – Ischaemic Stroke and Transient Ischaemic attacks (TIA) (Presenter: Dave Cronin) NIC-33234-C0V1D</u></p> <p>Application: This was a renewal application for pseudonymised Medical Research Information Service (MRIS) data for the purpose of the TIA research study. TIA occurs when there is an interruption to the blood supply to the brain which can result in patients having slurred speech weakness on one side and problems with vision with symptoms resolving fully within 24 hours, however the long-term outcome for patients is not fully understood. NHS Digital noted that the GDPR wording within the abstract had been updated to correctly reference the standard wording.</p> <p>Discussion: IGARD welcomed the application and noted the importance of the study and noted the update to the GDPR wording within the abstract</p> <p>IGARD queried if the identifiable data was going to be held separately and asked that a special condition be included in section 6 making this clear and clearly stating that there must be no attempt to re-identify the data that is held.</p> <p>NHS Digital confirmed that discussions had taken place with the applicant about the pseudonymisation of data already held. IGARD suggested NHS Digital consider asking for</p>

	<p>formal confirmation of this in writing y, possibly by way of a letter from the applicant which should also include the steps that have been taken by the applicant to pseudonymise the data.</p> <p>IGARD noted and endorsed NHS Digital's request for an audit on the organisation in relation to this application / agreement.</p> <p>Outcome: recommendation to approve</p> <p>The following amendment was requested:</p> <ol style="list-style-type: none"> 1. To insert a special condition to make clear the applicant must hold identifiable data separately and that there must be no attempt to re-identify the data held. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD suggested that NHS Digital assure themselves that the applicant has pseudonymised the data and that this may take form of a letter from the applicant which should include the steps taken by the applicant to pseudonymise data. 2. IGARD noted and endorsed NHS Digital's request for an audit on the organisation in relation to this application / agreement.
3.	<p>AOB</p> <p>NIC-15625-T8K6L Medicines and Healthcare Products Regulatory Agency</p> <p>IGARD noted that following the 20th September 2018 meeting, when IGARD had recommended for approval subject to conditions. The relevant extract is as follows:</p> <p>"The application was recommended for approval subject to the following conditions:</p> <ol style="list-style-type: none"> 1. To make reference to pseudonymised data (rather than anonymised data) throughout the application where appropriate. 2. To remove the following paragraph in section 5(b) "The CPRD Policy for Managing Anonymisation and the Risk of Identification in Observational Research sets out the management processes employed to ensure that CPRD appropriately anonymises patient data for observational research purposes and complies with the Information Commissioner's Office (ICO) Code on Anonymisation and with Office of National Statistics (ONS) requirements on use of death registration data. 3. To provide more examples of yielded benefits within section 5 of the application. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To clarify in the abstract and throughout the application that the MHRA is the relevant Executive Agency not CPRD. 2. To update section 4 with the standard wording "All data required by the Data Controller under this application is pseudonymised and therefore is considered as personal data under the GDPR. All Data controllers are expected to provide a privacy notice that is compliant with the GDPR notice requirements within a reasonable period after obtaining the personal data, but at least within 1 month". <p>NHS Digital had taken the decision to disseminate the data. The IGARD Chair had been informed of this out of committee.</p> <p>NIC-311095-K1Q0B Imperial College London</p> <p>IGARD noted that following the 6th September 2018 meeting, when IGARD had recommended for approval subject to conditions. The relevant extract is as follows:</p> <p>"The application was recommended for approval subject to the following condition:</p> <ol style="list-style-type: none"> 1. The applicant to provide a fair processing notice that is compliant with the notice

requirements under the GDPR, and before data can flow.

The following amendments were requested:

1. To clarify the length of the study (28 or 30 years) and confirm that ethics approval is still in place.
2. To clarify that the researcher is requesting 'date of death' data to prevent any communication being issued to deceased participants as well as 'cause of death' to support the analytical part of the work.
3. To explicitly state within section 5(b) that data will not be accessed by any third parties, other than those permitted under this application.
4. Confirmation within section 5(b) of the application that the applicant will not link the data further and the only data linkages are those permitted under this application.
5. To remove the fair processing notice standard wording from section 4 in light of the condition to approval to this application."

NHS Digital had taken the decision to disseminate the data. The IGARD Chair had been informed of this out of committee.

Data in the Cloud

NHS Digital advised IGARD that an application would be presented at a future meeting relating to data in the Cloud and that a briefing paper would be circulated to all IGARD members prior to this with further background information.

Independent Group Advising on Releases of Data (IGARD): Out of committee report 02/11/18

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-15625-T8K6L	Medicines and Healthcare Products Regulatory Agency	20/09/18	<ol style="list-style-type: none"> 4. To make reference to pseudonymised data (rather than anonymised data) throughout the application where appropriate. 5. To remove the following paragraph in section 5(b) "The CPRD Policy for Managing Anonymisation and the Risk of Identification in Observational Research sets out the management processes employed to ensure that CPRD appropriately anonymises patient data for observational research purposes and complies with the Information Commissioner's Office (ICO) Code on Anonymisation and with Office of National Statistics (ONS) requirements on use of 	Quorum of IGARD Members	<p>Quorum of IGARD members agreed conditions 1 and 3 only were met.</p> <p>The Director Data Dissemination, under delegated authority from the SIRO, approved the outstanding condition (2)</p>	Noted under AOB on the 8 November 2018 minutes for transparency

			death registration data. 6. To provide more examples of yielded benefits within section 5 of the application.			
NIC-311095-K1Q0B	Imperial College London	06/09/18	1. The applicant to provide a fair processing notice that is compliant with the notice requirements under the GDPR, and before data can flow.	Quorum of IGARD Members	The Director Data Dissemination, under delegated authority from the SIRO approved the condition	Noted under AOB on the 8 November 2018 minutes for transparency

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

- None notified to IGARD