

## Independent Group Advising on the Release of Data (IGARD)

### Minutes of meeting held 17 January 2019

**Members:** Sarah Baalham, Maria Clark, Nicola Fear, Kirsty Irvine (Chair), Priscilla Maguire, Eve Sariyannidou.

**In attendance:** Stuart Blake, Dave Cronin, Louise Dunn, Rachel Farrand, James Humphries-Hart, Karen Myers, Katharine Robbins, Sharon Thandie, Vicki Williams.

**Apologies:** Joanne Bailey, Anomika Bedi.

**Observer:** Frances Hancox (Item 2.14)

1	<p><b>Declaration of interests:</b></p> <p>Nicola Fear noted a professional link with Kings College London [NIC-156409-F4P2D] and would not be part of the discussion. It was agreed Nicola would not remain in the meeting for the discussion of that application.</p> <p>Priscilla McGuire noted close professional links with NHS North Kirklees CCG (NIC-241634-Z3F2L) and would not be part of the discussion. It was agreed Priscilla would not remain in the meeting for the discussion of that application</p> <p>Priscilla McGuire noted a professional link with NHS Wakefield CCG (NIC-125783-W2W3P), but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest.</p> <p><b>Review of previous minutes and actions:</b></p> <p>The minutes of the 10<sup>th</sup> January 2019 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record of the meeting.</p> <p><b>Out of committee recommendations</b></p> <p>An out of committee report was received (see Appendix B).</p>
2	<p><b>Data applications</b></p>
2.1	<p><u>Community Services Data Set Briefing (CSDS) Paper (Presenters: Katharine Robbins / Sharon Thandie)</u></p> <p>This briefing was to inform IGARD of the onboarding to DARS of the Children's and Young People Health Services Dataset (CYPHS) and the Community Services Dataset (CSDS).</p> <p>The CSDS is a patient-level data set providing information relating to publicly funded community services for children, young people and adults. These services can include health centres, schools, mental health trusts, and health visiting services. The data collected includes personal and demographic information, diagnoses including long-term conditions and disabilities and care events plus screening activities.</p> <p>The CSDS has the same structure as CYPHS. It was first collected in respect of October 2017 and patients of all ages and all publicly funded community health services are in scope.</p> <p>IGARD welcomed the briefing note and confirmed that written feedback would be provided to NHS Digital.</p>
2.2	<p><u>Monitor: NHS Improvement DSA extension, add CSDS and purpose amendments for GIRFT (Presenter: Louise Dunn) NIC-15814-C6W9R</u></p> <p><b>Application:</b> This was an amendment and renewal application for pseudonymised Hospital</p>

	<p>Episode Statistics (HES), Improving Access to Psychological Therapies Data Set, Secondary Use Service (SUS), Patient Reported Outcome Measures (PROMs), Diagnostic Imaging Dataset (DIDs), Civil Registrations, Mental Health Services Data Set (MHSDS), Mental Health Minimum Data Set (MHMDS), Community Services Data Set (CSDS) and National Cancer Waiting Times Monitoring Data Set (CWT). The data will be used to support the delivery of their statutory function and support direct improvement and / or oversight of Trusts. The original application had previously been recommended for approval by IGARD on the 13<sup>th</sup> September 2018.</p> <p><b>Discussion:</b> IGARD noted that the data that was being processed was personal data and that General Data Protection Regulation (GDPR) was therefore applicable and asked that this be made explicitly clear within section 1(a) (Abstract).</p> <p>IGARD noted that Advanced 365 Limited were previously only listed as a Data Processor, however the application now listed them as a Data Processor, NHS Digital advised this was a new amendment to the application. IGARD asked that for clarity a further explanation be provided within section 1(a) (Abstract) with a further explanation on the role of Advanced 365 Limited.</p> <p><b>Outcome:</b> recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To amend the abstract to make it explicitly clear that personal data is being processed and that GDPR is applicable.</li> <li>2. To provide a further explanation within the abstract on the role of Advanced 365 Limited due to them being listed as a data processor.</li> </ol>
2.3	<p><u>University of Cambridge: MR699 – Epidemiological Study of BRCA1 and BRCA2 Mutation Carriers (Presenter: Louise Dunn) NIC-302473-K6R0Z</u></p> <p><b>Application:</b> This was an amendment and renewal application for identifiable Medical Research Information Service (MRIS) data for a study evaluating the long-term cancer incidence and mortality in BRCA1 and BRCA2 carriers and to examine associations with other risk factors, both environmental and genetic.</p> <p><b>Discussion:</b> IGARD noted the valuable research being undertaken.</p> <p>IGARD noted the changes to the amendment and renewal application presented, however asked that section 1(a) (Abstract) be updated to ensure that the proposed changes were clear.</p> <p>IGARD noted that the application was for the retrospective cohort only, as outlined in section 5(b) however asked that for clarity that section 5(a) (Objective for Processing) was amended to clearly state this and for transparency.</p> <p>IGARD noted that within the protocol supporting document provided it noted they received EU funding and therefore queried if the work outlined in the application was or was not part of an EU funded project and asked for confirmation of this.</p> <p>IGARD noted that supporting document 9, the s251 approval notes that favourable Research Ethics Committee (REC) support is required and asked that confirmation that this support is continuing be provided.</p> <p>IGARD asked that the statement in section 4 (Privacy Notice) <i>“All Data Controllers are expected to provide a privacy notice that is compliant with the GDPR notice requirements”</i> be replicated in section 6 (Special Conditions) and suggested that the applicant work with NHS Digital to amend their current privacy notice</p>

	<p>IGARD noted that section 5a should be updated to include clearer examples of 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 and how the results will be disseminated to the wider public.</p> <p><b>Outcome:</b> recommendation to approve subject to the following conditions:</p> <ol style="list-style-type: none"> <li>1. To provide confirmation that the work outlined in the application is not part of an EU funded project.</li> <li>2. To provide confirmation that favourable REC support is continuing as required within the s251 support outlined in the supporting document provided.</li> <li>3. To replicate the information provided within section 4 (stating that the applicant will work with NHS Digital to ensure the fair processing notice is GDPR compliant) in section 6 as a special condition.</li> </ol> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To amend the abstract to ensure that it is clear what all the changes to the application are.</li> <li>2. To amend section 5(a) to clearly state that the application is for the retrospective cohort only.</li> </ol> <p>The following advice was given:</p> <ol style="list-style-type: none"> <li>1. The applicant should work with NHS Digital on a fair processing notice that does not contain misleading statements, is GDPR compliant and this should be noted as part of any audit.</li> <li>2. IGARD suggested on renewal that further details of pathways of dissemination of the outputs be provided including examples of public / patient engagement and how the results will be disseminated to the wider public.</li> </ol> <p>It was agreed the conditions be approved OOC by IGARD Members.</p>
<p><b>2.4</b></p>	<p><u>3M United Kingdom Plc: Data extract to support the continued accuracy of 3M developed quality and performance indicators for commissioners and providers (Presenter: Louise Dunn) NIC-91972-S9W9T</u></p> <p><b>Application:</b> This was an extension application for pseudonymised Hospital Episode Statistics (HES) data which will be used to anglicise the 3M APR-DRG and 3M CRG (grouper) solutions, specifically by supporting the development of crosswalk tables and algorithms between UK coding classifications (and other NHS Data Dictionary items) and their international equivalents.</p> <p><b>Discussion:</b> IGARD noted that the applicant needed to understand and articulate the formal requirements that have to be met before it can use 'legitimate interest' as a legal basis and then to assess the legitimate interest in the context of the purpose of this application.</p> <p>IGARD noted that as "pseudo-anonymised" data does not exist as a category and as outlined in the application and that the applicant should evaluate the type and level of data it processes in the context of the General Data Protection Regulations (GDPR) requirements.</p> <p>IGARD suggested that it be clearly articulated within section 5(a) (Objective for Processing), 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.</p>

	<p>IGARD noted that a GDPR compliant fair processing notice should be provided, as the 'legitimate interest' legal basis was most appropriate where you use people's data in ways they would reasonably expect.</p> <p>IGARD noted that the applicant should provide more detailed evidence of a project with (an) NHS organisation(s) which is proposed to start in the near future and define the purpose of this application in the context of that project.</p> <p>IGARD noted that there are several references in the application to 'NHS Clients' and asked that further information be provided on these within section 5(a).</p> <p>IGARD noted that the language used in section 5(c) (Specific Outputs Expected, Including Target Date) may not be accessible to a lay reader and asked that this be amended and to also include clearly defined timescales.</p> <p>IGARD noted that the applicant had answered 'yes' to the question in section 5(e) (Is the purpose of this application in anyway commercial?) and asked that the information provided be amended to clearly explain which aspect of the project was commercial.</p> <p><b>Outcome:</b> Unable to recommend for approval</p> <ol style="list-style-type: none"> <li>1. The applicant needs to understand and articulate the formal requirements that have to be met before it can use 'legitimate interest' as a legal basis and then to assess the legitimate interest in the context of the purpose of this application.</li> <li>2. Since pseudo – anonymised data does not exist as a category, the applicant is to evaluate the data they use in connection to the GDPR requirements.</li> <li>3. To provide a GDPR compliant fair processing notice as the 'legitimate interest' legal basis is most appropriate where you use people's data in ways they would reasonably expect.</li> <li>4. To provide more detailed evidence of a project with (an) NHS organisation(s) which is proposed to start in the near future and define the purpose of this application in the context of that project.</li> <li>5. Confirmation in the abstract or a supporting document that NHS Digital have assessed the Legitimate Interest Assessment and deemed it satisfactory.</li> <li>6. To amend section 5(a) to include the legitimate interest relied on and how it relates to the processing outlined within the application.</li> <li>7. To amend section 5(a) to provide further information on NHS clients referred to within the application.</li> <li>8. To amend section 5(c) to make the language more accessible to a lay reader with clearly defined timescales.</li> <li>9. To amend section 5(e) to clearly explain which aspect of the project is commercial.</li> </ol> <p>IGARD noted that the applicant's Data Sharing Agreement with NHS Digital had expired, 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 address the queries raised by IGARD.</p>
2.5	<p><u>NHS Dorset CCG: DSfC – NHS Dorset CCG: RS (Presenter: James Humphries-Hart) NIC-252496-Z7M8H</u></p> <p><b>Application:</b> This was a new application for identifiable Secondary Use Service (SUS) for Commissioners data 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.</p>

	<p><b>Discussion:</b> IGARD noted the incorrect reference to 'Prescribing Services Ltd' in section 6 (Special Conditions) and asked that this be amended to correctly reference 'The Bunker Secure Hosting Ltd'.</p> <p>IGARD noted the special condition in section 6 clearly outlining when the identifiable data will be disclosed and asked that this; along with the seven points of criteria were replicated within section 5.</p> <p><b>Outcome:</b> recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To amend the special condition in section 6 to correctly refer to 'The Bunker Secure Hosting Ltd' not 'Prescribing Services Ltd'.</li> <li>2. To replicate the Special Condition in section 6 relating to 'identifiable data' (including the 7 points of criteria) within section 5.</li> </ol>
2.6	<p><u>NHS Wakefield CCG: DSfC – NHS Wakefield CCG – VAN (Presenter: James Humphries-Hart) NIC-125783-W2W3P</u></p> <p><b>Application:</b> This was a new application for pseudonymised Community Services Data Set (CSDS), Diagnostic Imaging Dataset (DIDs), Mental Health Services Data Set (MHSDS), Mental Health and Learning Disabilities Data Set (MHLDDS), Other Not Elsewhere Classified (NEC) Local Provider Flows, Mental Health Minimum Data Set (MHMDS), Maternity Services Data Set (MSDS), Children and Young People's Health Service (CYPHS), Improving Access to Psychological Therapies Data Set (IAPT), Secondary Use Service (SUS) for Commissioners and National Cancer Waiting Times Monitoring Dataset (CWT). The objective is to enable a robust evaluation of the Multi-Speciality Community Provider Vanguard interventions, in order to inform future service planning and resource allocation.</p> <p>NHS Digital noted that the Data Protection Act (DPA) 2018 for the Kier Business Service Limited had expired and would be updated to show the correct expiry date.</p> <p>NHS Digital noted that supporting document 1, the data flow diagram was incorrect and would need updating to correctly align with the application.</p> <p><b>Discussion:</b> IGARD noted that the Kier Business Service Limited DPA expiry date needed to be updated and that the data flow diagram should be updated to accurately reflect the application.</p> <p>IGARD noted that the standard geographical data minimisation wording was not included in section 5(b) (Processing Activities) and asked that this be updated clearly stating which CCG's are relevant to the application.</p> <p>IGARD noted that the eMBED consortium members are referred to differently throughout the application and asked that for consistency the full and correct names are used throughout the application.</p> <p>IGARD noted that that unless listed as a Data Processor or Data Controller, that other eMBED consortium members will not have access the data under this application or Data Sharing Agreement and asked that a special condition be included within section 6 (Special Conditions) stating this and for this to be also replicated in section 5 (Purpose / Methods / Outputs).</p> <p>IGARD queried why Pulsant were noted in section 5(b) and section 6 and queried their role. NHS Digital advised that Pulsant needed reinstating as a storage and processing location and that section 2 (Processing Location(s)) would be amended to accurately reflect this.</p> <p>IGARD noted that section 5(b) refers to 'data processor 2' and asked that for transparency this</p>

	<p>be amended to clarify which eMBED consortium members are receiving data.</p> <p><b>Outcome:</b> recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> <li>1. To update section 5(b) with the standard geographical data minimisation wording, clearly stating which CCG's are relevant to the application.</li> </ol> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To use the full and correct names for each of the eMBED consortium members outlined throughout the application.</li> <li>2. To include a special condition within section 6, clearly stating that unless listed as a Data Processor or Data Controller, other eMBED consortium members will not have access the data under this application / Data Sharing Agreement, and to replicate this statement in section 5.</li> <li>3. To amend section 2 to reinstate Pulsant as a storage and processing location.</li> <li>4. To clarify within section 5(b) which eMBED consortium members are receiving data for transparency, rather than stating 'data processor 2'.</li> <li>5. To correctly update the Kier DPA expiry date.</li> <li>6. To update the data flow diagram to correctly reflect information provided in the application.</li> </ol> <p>It was agreed the condition would be approved OOC by the IGARD Chair.</p>
2.7	<p><u>Kent County Council: Optum Application – Comm (Presenter: James Humphries-Hart) (NIC-174337-X0N1L</u></p> <p><b>Application:</b> This was a new application for pseudonymised Mental Health Minimum Data Set (MHMDS), Mental Health Services Data Set (MHSDS), Community Services Data Set (CSDS), Maternity Services Data Set (MSDS), Mental Health and Learning Disabilities Data Set (MHLDDS), Diagnostic Imaging Dataset (DIDs), Children and Young People's Health Service (CYPHS), Secondary Use Service (SUS) for Commissioners and Improving Access to Psychological Therapies Data Set (IAPT). The objective is to ensure that analysis of health and social care provision can be completed to support the needs of the population within the County Council area.</p> <p><b>Discussion:</b> IGARD noted the legal basis provided, Article 9(3) Section 11 of the Data Protection Act (DPA) 2018 and asked for further clarity on how the applicant meets the requirements.</p> <p>IGARD noted the reference to the Clinical Commissioning Groups within the legal basis section of section 1(a) (Abstract) and asked that this be removed since it was not relevant to the application.</p> <p>IGARD noted the references to 'non-sensitive' and 'sensitive' in the application and asked that this reference be removed because all health data is considered 'sensitive' (special categories of data).</p> <p><b>Outcome:</b> recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> <li>1. To clarify how the applicant meets the requirements under Article 9(3) GDPR and section 11 of DPA 2018.</li> </ol> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To remove reference to 'non-sensitive' and 'sensitive' throughout the application since it is not relevant.</li> <li>2. To amend the legal basis within the abstract and remove reference to the CCG, since it is not relevant to this application.</li> </ol>

	It was agreed the condition would be approved OOC by the IGARD Chair.
2.8	<p><u>NHS North Kirklees CCG: Shared Acute Commissioning Data Sharing Agreement between NHS North Kirklees Clinical Commissioning Group and NHS Wakefield Clinical Commissioning Group (Presenter: James Humphries-Hart) NIC-241634-Z3F2L</u></p> <p><b>Application:</b> This was a new application for pseudonymised Local Provider Flows and Secondary Use 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>NHS Digital noted that supporting document 1, the data flow diagram was incorrect and would need updating to correctly align with the application.</p> <p>NHS Digital noted that the additional processing activities in section 5 (Purpose / Methods / Outputs) needed updating to reflect the usual template wording.</p> <p><b>Discussion:</b> IGARD noted that the data flow diagram should be updated to correctly align with the application and that section 5 should be updated to correctly reflect the agreed template wording.</p> <p>IGARD noted that the standard geographical data minimisation wording was not included in section 5(b) (Processing Activities) and asked that this be updated clearly stating which CCG's are relevant to the application.</p> <p>IGARD queried the roles undertaken by Kier Business Service Limited and Dr Foster Limited in their role as data processors and asked that differentiate this in section 5(b), along with clarity on how this differentiates from the CCG's role as a data processor; and to provide further clarity on what service each data processor provides.</p> <p>IGARD noted that the consortium members are referred to differently throughout the application and asked that for consistency the full and correct names are used throughout the application.</p> <p>IGARD noted that the reference to Dr Foster Limited within the Data Controller / Data Processor within section 1(a) (Abstract) was not listed correctly and asked this be corrected.</p> <p>IGARD noted that Calderdale and Huddersfield NHS Trust would be processing the data via storage activity but will not in any other way access the data and asked that a separate special condition be listed in section 6 (Special Conditions) for clarity and that is separate from the last special condition listed that refers to Calderdale and Huddersfield NHS Trust and for this new special condition to be also replicated in section 5.</p> <p><b>Outcome:</b> recommendation to approve subject to the following condition(s)</p> <ol style="list-style-type: none"> <li>1. To update the geographical data minimisation wording in section 5(b) to specify which CCG's are relevant to this application.</li> <li>2. To differentiate within section 5(b) the different roles undertaken by Kier Business Service Limited and Dr Foster Limited in their role as data processors, and in addition, how this also differentiates from the CCG's role as a data processor to provide clarity on what services each data processor provides.</li> </ol> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To use the full and correct names for each of consortium members outlined throughout the application.</li> <li>2. To ensure the description of Dr Foster Limited is correctly named in Data Controller / Data Processor section within the abstract.</li> </ol>

	<ol style="list-style-type: none"> <li>3. To include a special condition (separate from the last one in section 6) and within section 5 that Calderdale and Huddersfield NHS Trust will be processing the data via storage activity but will not in any other way access the data.</li> <li>4. To update section 5 with the additional processing activities to reflect the usual template wording.</li> <li>5. To align the description of activities described within the application with the data flow diagram provided.</li> </ol> <p>It was agreed the condition would be approved OOC by the IGARD Chair</p>
2.9	<p><u>King's College London: Practice level Primary Care Mortality Data (Presenter: Stuart Blake) NIC-156409-F4P2D</u></p> <p><b>Application:</b> This was a new application for aggregated Primary Care Mortality Data Tabulation for a research study aiming to investigate the relationship between general practice funding, staffing and healthcare outcomes. The six primary healthcare outcomes include primary care mortality, secondary care utilisation, patient safety, patient experience, clinical achievement / quality and outcomes framework and health reported quality of life.</p> <p><b>Discussion:</b> IGARD welcomed this interesting application and noted the sensitive issues it raised and the steps taken by the applicant to consider those sensitivities. IGARD noted that under their Terms of Reference it may be more appropriate to give advice, rather than a recommendation per se and also suggested that NHS Digital seek a formal view from the Caldicott Guardian, or their deputy.</p> <p>IGARD did not align with NHS Digital's assessment that the data requested was not personal data for the GPs since it might be possible to identify GPs in single handed, small or geographically isolated practice, especially as the applicant expressly stated its intention to link the requested data to a number of NHS administrative data sets. IGARD referred to the ICO guidance on personal data supporting its alternative assessment. In addition, it was unclear whether the additional linkage of the datasets to HES data would result to the potential identifiability of groups or categories of living individuals. Nonetheless, IGARD thought that this issue would not prevent NHS Digital from disseminating the data and suggested that a Data Sharing Agreement (DSA) and Data Sharing Framework Contract (DSFC) were put in place, and any dissemination was in compliance with the GDPR .</p> <p>IGARD agreed to provide additional written comments following the meeting and without prejudice to further comments from the Caldicott Guardian, or their deputy.</p> <p><b>Outcome:</b> IGARD welcomed the application which came for advice and without prejudice to any additional issues which may arise should the application return to IGARD.</p>
2.10	<p><u>University of Leicester: MR1275 – the United Kingdom Aneurysm Growth Study (UKAGS) (Presenter: Louise Dunn) NIC-148437-C9YS</u></p> <p><b>Application:</b> This was a renewal application for identifiable Medical Research Information Service (MRIS) data for use in a study aiming to find out more about aortic aneurysms. The UKAGS is a prospective cohort study of men attending the NHS aneurysm screening programmes in the UK, who are recruited to the study after they have been screened for abdominal aortic aneurysm (AAA) and are followed for up to five years. It is necessary to identify participants who have died during the follow up period to prevent questionnaires being sent to deceased individuals, it is also necessary to establish date and cause of death.</p> <p>The application was been previously considered on the 25<sup>th</sup> January 2018 when IGARD had deferred making a recommendation pending; Confirmation of whether the applicant will be undertaking list cleaning to ensure they have up to date address details for all patients or what</p>



other steps had been taken to ensure address details were up to date. If list cleaning is undertaken, information about this should be included in the applicant's patient information leaflets and consent materials and to explicitly state that they were sending identifiers to NHS Digital; clarification whether the applicant required date of death for research purposes in addition to fact of death for patients; clarification of the consent process for the control group and evidence of any consent materials provided to the control group; to clarify which consent materials were used for each recruitment wave of the cohort group and what percentage of the cohort group each of these represent; to clarify which patient information sheet and consent form the applicant is currently using as part of ongoing recruitment; the legal basis within section 3 of the application be updated to include the relevant sections of the Health & Social Care Act 2012 and Statistics & Registration Service Act 2007; the processing location be updated to correctly list the University of Leicester; the governance path within the summary be corrected to "for independent review". The application was also withdrawn by the presenter at the IGARD meeting on the 6<sup>th</sup> September 2018.

**Discussion:** IGARD queried the structure of the application and asked that for clarity the group of participants and control group outlined in the application were separated into (i) those who the applicant is in active contact with and who have been recruited within the last 5 years, and (ii) those who the applicant is no longer in contact with.

IGARD noted that for those where the applicant is in contact (group (i)), a number of steps should be taken with regard to setting out a clear timeline of the most recent consent forms with the most recent Patient Information Leaflets for the participants (cohort) and the control groups and to confirm how many were consented with the most recent consent form and Patient Information leaflet and a review should be undertaken of the materials to ascertain if the consent is either "incomplete" or "incompatible". For those where the applicant is NOT in contact with the group (group (ii)) IGARD suggested that s251 support is sought for the use of their data because the consent materials used for this group would appear to be incompatible with the reasonable expectations of the study participants, inter alia because participants would not expect their data to be linked with other data, including data held by NHS Digital, and would be unlikely to expect researchers to be using their data past the stated five year follow up period.

IGARD suggested that future steps would be to reconsent those participants and members of the control group who the applicant continues to be in contact (group (i)) with via an updated consent form along with the October 2017 Patient Information Sheet, depending on whether the consent was "incomplete" or "incompatible".

**Outcome:** Unable to recommend for approval

1. To separate the group of participants and the control group outlined in the application into (i) those who the applicant is in active contact with and recruited in last 5 years, and (ii) those who the applicant is not in contact with.
2. In respect of those where the applicant is in contact with (group (i)), a number of steps should be taken with regard to setting out a clear timeline of the most recent consent forms with the most recent Patient Information Leaflets for the participants (cohort) and the control groups and to confirm how many were consented with the most recent consent form and Patient Information leaflet and a review should be undertaken of the materials to ascertain if the consent is either "incomplete" or "incompatible".
3. In respect of those where the applicant is NOT in contact with (group (ii)) suggest s251 support is sought for the use of their data.
4. IGARD suggested that future steps would be to reconsent those participants and members of the control group who the applicant continues to be in contact (group (i)) with via an updated consent form along with the October 2017 Patient Information Sheet, depending on whether the consent was "incomplete" or "incompatible".

	<p>IGARD noted the importance of the study being undertaken and the need for the applicant to continue to hold data. IGARD noted that the applicant's Data Sharing Agreement with NHS Digital had expired, 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 address the queries raised by IGARD.</p>
2.11	<p><u>University of Oxford: MR1164 – The Asymptomatic Carotid Surgery Trial (ACST-2) (Presenter: Dave Cronin) NIC-10123-M5K5H University of Oxford</u></p> <p><b>Application:</b> This was an extension and renewal application for identifiable Medical Research Information Service (MRIS) data for a large international clinical trial comparing the long-term benefits of carotid endarterectomy (CEA) and carotid artery stenting (CAS) for stroke prevention. The longitudinal study benefits will help inform clinicians and patients of the long-term effects of surgery to help them make informed treatment decisions.</p> <p>NHS Digital highlighted to IGARD that the applicants current Data Sharing Agreement (DSA) expires on the 20<sup>th</sup> January 2019.</p> <p><b>Discussion:</b> IGARD queried the role of St George's University of London and were advised by NHS Digital that they have no ongoing involvement with the project and would not be accessing any data. IGARD asked that for clarity section 5(a) (Objective for Processing) was updated making this explicitly clear.</p> <p>IGARD noted that section 5(a) should be updated to include clearer examples for processing and how the applicant had 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>IGARD queried the purpose of supporting document 3.2, ACST-2 Personal Data Privacy Notice and noted that it did not support the use of this document as it did not reflect what was happening to patient data.</p> <p>It was noted that the applicant's fair processing notice did not comply with GDPR, including being published and accessible.</p> <p><b>Outcome:</b> The application was recommended for approval for a period of 3 months and upon return IGARD would expect a fair processing notice to be provided that meets all relevant legal requirements. IGARD extended their support to assess the FPN OOC if requested by NHS Digital.</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1) To amend section 5(a) to make it explicitly clear that St George's University of London has no ongoing involvement with the project and is not accessing any data.</li> </ol> <p>The following advice was given:</p> <ol style="list-style-type: none"> <li>1) IGARD suggested on renewal that further details of pathways of dissemination of the outputs be provided including examples of public / patient engagement.</li> <li>2) IGARD noted that it did not support the use of supporting document 3.2 provided as it did not reflect what was happening to patient data.</li> </ol> <p>IGARD noted the importance of the study being undertaken and the need for the applicant to continue to hold data. IGARD noted that the applicant's Data Sharing Agreement with NHS Digital had expired, 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 address the queries raised by IGARD.</p>

2.12	<p><u>University of Oxford: QResearch-Oxford Data Linkage Project (Presenter: Dave Cronin) NIC-240279-Y2V2N</u></p> <p><b>Application:</b> This was a new application for pseudonymised Civil Registrations data and Hospital Episode Statistics (HES) data, for QResearch which is a database of linked medical records what is used by a variety of research projects undertaken by UK universities, from reviewing the safety of antidepressant medicines to studying factors to predict variation in survival rates for cancer patients. The database is widely used for medical research into the causes of disease, its natural history, treatment and outcomes.</p> <p>NHS Digital noted that section 1(a) (Abstract) needed updating to correctly state the legal basis for the University of Oxford and to correctly reference two Data Processors</p> <p><b>Discussion:</b> IGARD noted the updates to the abstract and supported.</p> <p>IGARD queried contractual arrangements between the University of Oxford and the University of Nottingham and asked that by the 1<sup>st</sup> March 2019 the applicant provide NHS Digital with an updated Data Processor agreement, meeting NHS Digital's requirements.</p> <p>IGARD noted that a special condition should be included in section 6 (Special Conditions) confirming for clarity that the applicant will provide confirmation from the University of Nottingham that they no longer hold a copy of any data or an extract of the data.</p> <p>IGARD noted reference in the application to 'anonymised' data and asked that this be removed and replaced with 'pseudonymised' throughout the application</p> <p>IGARD noted the last paragraph on page 1 in section 1(a) (Abstract) starting "no identifying fields are received by..." be removed since reference to linkage was not relevant in this application.</p> <p>IGARD asked that a copy of the latest Research Ethics Approval (REC) Approval document be added to NHS Digital's CRM holder and for future reference.</p> <p>IGARD noted the historic funding outlined within the application and queried if the funding as described in the application was ongoing and would transfer to the University of Oxford and asked for further clarification of this or to remove reference if no longer relevant.</p> <p><b>Outcome:</b> recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1) To update the abstract to correctly state the legal basis for the University of Oxford.</li> <li>2) To include a special condition stating that by the 1<sup>st</sup> March 2019 the applicant will provide NHS Digital with an updated Data Processor agreement between itself and the University of Nottingham meeting NHS Digital's requirements.</li> <li>3) To insert a special condition that the applicant will provide confirmation from the University of Nottingham that they no longer hold a copy of any data or an extract of the data.</li> <li>4) To remove any reference to 'anonymised' data throughout the application and replace it with 'pseudonymised'.</li> <li>5) To remove the last paragraph of the abstract since it is not relevant.</li> <li>6) To update the CRM holder to include a copy of the latest REC approval document and for future reference.</li> <li>7) To clarify that the funding as described in the application is ongoing and will transfer to the University of Oxford.</li> </ol>
2.13	<p><u>Bangor University: Nerve Root Block Versus Surgery (NERVES) Trial (Presenter: Dave Cronin) NIC-139741-D9Y1C</u></p>

	<p>Eve Sariyiannidou and Sarah Baalham were not present for the consideration of this application</p> <p><b>Application:</b> This was a new application for pseudonymised Hospital Episode Statistics (HES) data for a study assessing the clinical and cost effectiveness of transforaminal epidural steroid injection to surgical microdiscectomy for treatment of sciatica caused by a prolapsed intervertebral disc.</p> <p><b>Discussion:</b> IGARD noted that the Data Protection Act (DPA) 2018 registration expiry dates for The Walton Centre NHS Foundation Trust and Bangor University had expired and should be updated with the new expiry dates within the application.</p> <p><b>Outcome:</b> recommendation to approve</p> <p>The following amendment was requested:</p> <ol style="list-style-type: none"> <li>1. The Walton Centre NHS Foundation Trust and Bangor University should update their DPA registration expiry date within the application.</li> </ol>
2.14	<p><u>Meditrends Ltd: Information intermediary specialising to produce outputs for use in health and social care (Presenter: Rachel Farrand) NIC-14340-R7G1F</u></p> <p><b>Application:</b> This was an amendment and renewal application for pseudonymised Hospital Episode Statistics (HES) and Civil Registrations data for two purposes, the first purpose is for Meditrends online which aims to improve the ease with which key stakeholders in the commissioning cycle can access and use important health measures. The second purpose is to custom analyses requested as part of projects led by NHS organisations which can be complex and are required in rapid timeframes to achieve NHS and social care objectives.</p> <p>NHS Digital noted that the HES data set usage percentages in section 3 (Datasets Held / Requested) needed updating to correctly list the percent per field.</p> <p><b>Discussion:</b> IGARD queried the number of years of data requested for study 1 purpose 2 outlined in the application and asked that this be justified within section 5 (Purpose / Methods / Outputs) including the breadth of data requested.</p> <p>IGARD queried the proposed custom analysis and asked that further details be provided in section 5, including clearly describing the specific project being undertaken and how the relevant Life Science Company is going to use the data outputs to the benefit of and support of the NHS.</p> <p>IGARD noted that mortality data was requested in section 3 and asked for further clarity on the number of years required.</p> <p>IGARD queried the number of years of data that can be accessed through the Meditrends online reporting tool for purpose 1, since it was not clear if 5 years was standard, and asked for further clarity of this.</p> <p>IGARD noted the title of the application did not refer specifically to the project and asked for this to be amended to reflect the application submitted.</p> <p><b>Outcome:</b> recommendation to approve subject to the following conditions:</p> <ol style="list-style-type: none"> <li>1. To justify within section 5 the number of years of data requested for study 1 purpose 2 and the breadth of data requested.</li> <li>2. To provide further detail within section 5 with regard to the proposed custom analysis and to clearly describe the specific project being undertaken and how the relevant Life Science Company is going to use the data outputs to benefit the NHS.</li> </ol> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To update section 3 to include the HES data set usage percentages.</li> <li>2. To clarify the number of years required for the mortality data requested within section 3.</li> </ol>

	<p>3. To clarify for purpose 1 the number of years of data that can be accessed through the Meditrends online reporting tool.</p> <p>4. To amend the application title to refer specifically to this project.</p> <p>It was agreed the conditions be approved OOC by IGARD Members.</p> <p>IGARD noted the importance of the study being 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 at the end of January 2019, 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 address the queries raised by IGARD.</p>
<b>3</b>	<p><b>AOB</b></p> <p>None.</p>

### Independent Group Advising on Releases of Data (IGARD): Out of committee report 11/01/19

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-25007-J9M9P	Birmingham City Council	13/12/18	<ol style="list-style-type: none"> <li>To further minimise the data for the mental health dataset by geographical reduction to align with the smaller number of comparator geographies referenced in the application and supporting documentation.</li> <li>To expressly state within section 5(b) that the data held will be segregated from any identifying data already held by the applicant and that no attempt to re-identify will be undertaken by the applicant or any third party.</li> </ol>	OOC by IGARD Chair	OOC by IGARD Chair	
NIC-68697-R6F1T	Dr Foster Limited	13/12/18	<ol style="list-style-type: none"> <li>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.</li> <li>To update the abstract to reflect that NHS Digital, rather than Dr Foster Limited, have assessed the LIA and deemed it satisfactory.</li> </ol>	OOC by IGARD Chair	OOC by IGARD Chair	
NIC-204535-L4S1P	NHS England	06/12/18	<ol style="list-style-type: none"> <li>To clearly set out who is the Data Controller, who is the Data Processor and who is accessing the data on behalf of the relevant Cancer Alliance and suggested this was also documented in a table format.</li> </ol>	OOC by IGARD Members	OOC by IGARD Members	
NIC-204557-F0N1T	NHS England	06/12/18	<ol style="list-style-type: none"> <li>To clearly set out who is the Data Controller, who is the Data Processor and who is accessing the data on behalf of the relevant</li> </ol>	OOC by IGARD Members	OOC by IGARD Members	

			Cancer Alliance and suggested this was also documented in a table format.			
NIC-204559-J4H7T	NHS England	06/12/18	1. To clearly set out who is the Data Controller, who is the Data Processor and who is accessing the data on behalf of the relevant Cancer Alliance and suggested this was also documented in a table format.	OOC by IGARD Members	OOC by IGARD Members	
NIC-204562-J5W0T	NHS Doncaster CCG	06/12/18	1. To clearly set out who is the Data Controller, who is the Data Processor and who is accessing the data on behalf of the relevant Cancer Alliance and suggested this was also documented in a table format.	OOC by IGARD Members	OOC by IGARD Members	
NIC-204548-T8H8P	The Christie NHS Foundation Trust	06/12/18	1. To clearly set out who is the Data Controller, who is the Data Processor and who is accessing the data on behalf of the relevant Cancer Alliance and suggested this was also documented in a table format.	OOC by IGARD Members	OOC by IGARD Members	
NIC-204550-N7M4D	NHS England	06/12/18	1. To clearly set out who is the Data Controller, who is the Data Processor and who is accessing the data on behalf of the relevant Cancer Alliance and suggested this was also documented in a table format.	OOC by IGARD Members	OOC by IGARD Members	

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

None