

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 6 December 2018

Members: Sarah Baalham, Nicola Fear, Kirsty Irvine (Chair), Eve Sariyiannidou (application 2.1 only)

In attendance: Dave Cronin, Louise Dunn, Rachel Farrand, Dickie Langley, Karen Myers, Kimberley Watson, Vicki Williams

Observers: Stuart Blake, Priscilla McGuire

Apologies: Joanne Bailey, Anomika Bedi

1	<p>Declaration of interests:</p> <p>Nicola Fear noted a professional link with staff involved with NIC-121849-W0T5C University of Birmingham and would not be part of the discussion. It was agreed Nicola would not remain in the meeting for the discussion of this application.</p> <p>Review of previous minutes and actions:</p> <p>The minutes of the 29 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	<p>Data applications</p>
2.1	<p><u>University of Birmingham: Long term impact of giving antibiotics before skin incision versus after cord clamping on children born by caesarean section: longitudinal study based on UK electronic health records (Presenter: Dickie Langley) NIC-121849-W0T5C</u></p> <p>Application: This was a new application for pseudonymised Hospital Episode Statistics (HES) data to determine whether there is an association between the change in antibiotic prophylaxis in caesarean delivery and the incidence of subsequent admission to hospital of the child for a number of diseases.</p> <p>Discussion: IGARD welcomed the application and noted the importance of this worthwhile study noting that the overarching purpose was clearly outlined.</p> <p>IGARD queried details on the control group and the cohort and asked that a clear description was provided in section 5 of the application outlining what data was gathered on the mothers and babies as well as providing further information on how the data was gathered, including details of the years sought and a clear justification for the years of data for both mothers and babies in both the control group and cohort.</p> <p>IGARD noted that the data requested for the mothers could be from 2005 and queried why this amount of data was required noting that in some instances the baby may not have been born until 2018. IGARD also noted that the study would only monitor infection rates in mothers for up to 56 days post-delivery and therefore asked for further justification for the amount of data being requested pre and post birth.</p>

	<p>IGARD noted that the application stated that the primary outcomes of interest in the study were asthma and eczema and asked for a clear exposition of other health conditions that are being captured.</p> <p>IGARD queried why this particular study was different from other clinical trials that already had published findings and which were easily accessible. NHS Digital advised that this study was looking at health outcomes for both mothers and babies and IGARD suggested that this point of difference should be clearly described within the application to explain that the study focused on health outcomes for babies and mothers, not just mothers.</p> <p>IGARD noted that National Institute for Health Research (NIHR) funding was in place for this study and asked that relevant evidence was provided, such as a funding letter.</p> <p>IGARD noted that supporting document 1, the Study Protocol, that was provided outlined data linkages and asked that section 5 be updated to clearly describe how the data linkages aligned with those set out in the Study Protocol.</p> <p>IGARD queried to what age or period of time the mother and / or baby would be followed as part of this study and asked for this to be clearly outlined in the application.</p> <p>Outcomes: Recommendation to defer, pending:</p> <ol style="list-style-type: none"> 1. To provide a clear description of the control group and the cohort within section 5(a), and for each, to clearly describe what data is gathered on the mothers, what data is gathered on the babies and to clearly describe how the data is gathered, including the years of data sought and a clear justification for the years of data for both mothers and babies in both the control group and cohort. 2. To clearly describe and provide a justification for the number of years of data being requested for the mother prior to birth, which could be from 2005 (even if the birth is in 2018), and the data being gathered after birth (56 days) 3. To clearly define which other health conditions are being captured since only eczema / asthma are expressly outlined. 4. To clearly describe how this study is different from other clinical trials with published findings, drawing out the fact that this study is focused on health outcomes for both babies and mothers. 5. To provide evidence of funding. 6. To clearly describe within section 5 how the data linkages align with those data linkages set out in the protocol document provided. 7. To clearly outline up to what age or time period will the mother and / or baby be followed.
2.2	<p><u>University College London (UCL): Variation in Healthy Life Expectancy Throughout Childhood and Adulthood in England DSA (Presenter: Kimberley Watson) NIC-06527-J1Q6T</u></p> <p>Application: This was a new application for pseudonymised Hospital Episode Statistics (HES) data and Civil Registrations data for four studies looking at variation in healthy life expectancy throughout childhood and adulthood investigating the relationship between age at which people develop morbidities or disability requiring hospital admission and subsequent survival.</p> <p>Discussion: IGARD noted that the Farr Institute that were previously involved with this study was no longer in operation and asked for further clarification on the role of Health Data Research UK outlined within the abstract and section 5, along with a brief outline of how they had taken over from the Farr Institute and a brief explanation of what the Farr Institute was. IGARD also discussed how this linked with the UCL institute for Health Informatics Research.</p>

	<p>IGARD noted that the data minimisation column within section 3(b) of the application references 'recruit' and suggested this was amended to 'identify subjects' and that this was also amended throughout the application, as required.</p> <p>IGARD noted that the data minimisation efforts were clearly outlined within supporting document 4, the data minimisation table, and asked that section 5 of the application be updated to summarise the data minimisation efforts undertaken.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To provide clarity within the abstract and section 5 of the application on the role of Health Data Research UK and how they have taken over from the Farr Institute (with a very brief explanation of what the Farr Institute is). 2. To amend the reference to 'recruit' in the data minimisation column to 'identify subjects' within section 3(b) and throughout the application as necessary. 3. To summarise the data minimisation efforts outlined in supporting document 4 within section 5 of the application.
2.3	<p><u>Health and Social Care Information Centre: National Gastro Intestinal Cancer Audit comprising MR1368 National Bowel Cancer Audit and MR1281 National Oesophago-Gastric Cancer Audit (Presenter: Kimberley Watson) NIC-376603-K2J9R</u></p> <p>Application: This was an amendment application for identifiable Hospital Episode Statistics (HES) data and Medical Research Information Service (MRIS) data for the National Bowel Cancer Audit and the National Oesophago-Gastric Cancer Audit which have been amalgamated into one programme, the aim being to assess the quality of care received by patients.</p> <p>The National Oesophago-Gastric Cancer Audit [NIC-376599-X4H8Y] was previously recommended for approval on the 1st June 2017.</p> <p>The National Bowel Cancer Audit was previously deferred on the 19th October 2017, pending: providing evidence that appropriate approvals are in place for the use of data under section 42(4) of the SRSA 2007; confirmation of whether the applicant has acted on advice from HRA CAG to update the statement of use provided to CPES respondents; amending the abstract to state that the request for ONS data is an amendment rather than a renewal.</p> <p>NHS Digital advised that supporting document 5, 'Section 251' Approval – Annual Review' contained information relating to planned linkages (in italics) and confirmed that no supporting documents had been provided to IGARD due to these linkages being planned for the future.</p> <p>NHS Digital noted that there were a large number of supporting documents and this was due to the number of CAG approvals linked to this application. It was agreed with NHS Digital and IGARD that for future applications, the most recent CAG approval documents would be provided, along with a table outlining the other available documents highlighting any conditions for information.</p> <p>Discussion: IGARD noted that the application had been updated to reflect the comments previously made, however IGARD noted that Healthcare Quality Improvement Partnership (HQIP) had not provided adequate evidence to substantiate that public task is the appropriate legal basis.</p>

	<p>IGARD noted that application outlined the benefits of the audit to clinical staff, however asked that section 5 be updated to demonstrate that consideration has also been given to the needs of patients, including whether there was any less intrusive way to process the data.</p> <p>IGARD noted that it was not clear that the two audits were running separately, and overseen by one board for cost savings and that for transparency section 5 be updated to provide a very brief overview to aid the lay reader.</p> <p>IGARD noted that the National Emergency Laparotomy Audit (NELA) Dataset was just for the Bowel Cancer Audit and asked that for clarity section 5(b) be updated to clarify this as it was noted elsewhere in the application.</p> <p>IGARD noted that legal basis in the abstract was incorrectly referenced as 9(2)(i) and should be updated with the correct legal basis which is 9(2)(j).</p> <p>Outcome: Unable to recommend for approval</p> <ol style="list-style-type: none"> 1. HQIP have not provided adequate evidence to substantiate that public task is the appropriate legal basis. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To include within section 5 that as well as the audit resulting in efficiencies for staff, consideration has been given to the needs of patients including whether there is any less intrusive way to process the data. 2. To provide a very brief and simple introduction to section 5(a) to aid the lay reader. 3. To explain within section 5(b) that NELA is just for the bowel cancer audit 4. To update the abstract to correctly reference the legal basis.
2.4	<p><u>The Christie NHS Foundation Trust: Cancer Alliance access to National Cancer Waiting Times Monitoring Data Set (NCWTMDS) from the Cancer Wait Times (CWT) System (Presenter: Rachel Farrand) NIC-204548-T8H8P</u></p> <p>Application: This was a new application for pseudonymised National Cancer Waiting Times Monitoring Dataset (NCWTMDS). Cancer Alliances have been set up across England and are key to driving the change needed to achieve The Independent Cancer Taskforce's vision for improving services, care and outcomes for everyone with cancer, fewer people getting cancer, more people surviving cancer, more people having a good experience of their treatment and care and more people being supported to live as well as possible after treatment has finished. Cancer Alliances provide the opportunity for a different way of working to improve and transform Cancer services.</p> <p>NHS Digital advised it was hoped this application would be used as a template for Cancer Alliances going forward.</p> <p>Discussion: IGARD queried who the Data Controller and Data Processor would be as this was not clear in the application and asked that this be clearly set out, along with further clarity on who would be accessing the data on behalf of the relevant Cancer Alliance and suggested that this should also be documented in table format.</p> <p>IGARD noted that it was not clear in section 5 of the application what the legal entity was for this application and asked that this be updated to clarify this.</p> <p>IGARD also queried who the lead organisation is as there are references to the 'Cancer Alliance' accessing the data, however this needs to be more specific due to the number of organisations that form the Cancer Alliance.</p>

	<p>IGARD noted that although supportive of the template for Cancer Alliances application, that it should follow the correct path and be forwarded as a precedent to the Project Board and ask that Rachel Farrand progress on behalf of NHS Digital.</p> <p>Outcome: recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> 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. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update section 5(b) to include the legal entity. 2. To clarify within the abstract and section 5(a) who the lead organisation is. <p>It was agreed the conditions would be approved OOC by IGARD Members.</p>
2.5	<p><u>Doncaster CCG: Cancer Alliance access to National Cancer Waiting Times Monitoring Data Set (NCWTMDS) from the Cancer Wait Times (CWT) System (Presenter: Rachel Farrand)</u> <u>NIC-204562-J5W0T</u></p> <p>Application: This was a new application for pseudonymised National Cancer Waiting Times Monitoring Dataset (NCWTMDS). Cancer Alliances have been set up across England and are key to driving the change needed to achieve The Independent Cancer Taskforce's vision for improving services, care and outcomes for everyone with cancer, fewer people getting cancer, more people surviving cancer, more people having a good experience of their treatment and care and more people being supported to live as well as possible after treatment has finished. Cancer Alliances provide the opportunity for a different way of working to improve and transform Cancer services.</p> <p>NHS Digital advised it was hoped this application would be used as a template for Cancer Alliances going forward.</p> <p>Discussion: IGARD queried who the Data Controller and Data Processor would be as this was not clear in the application and asked that this be clearly set out, along with further clarity on who would be accessing the data on behalf of the relevant Cancer Alliance and suggested that this should also be documented in table format.</p> <p>IGARD noted that it was not clear in section 5 of the application what the legal entity was for this application and asked that this be updated to clarify this.</p> <p>IGARD also queried who the lead organisation is as there are references to the 'Cancer Alliance' accessing the data, however this needs to be more specific due to the number of organisations that form the Cancer Alliance.</p> <p>IGARD noted that although supportive of the template for Cancer Alliances application, that it should follow the correct path and be forwarded as a precedent to the Project Board and ask that Rachel Farrand progress on behalf of NHS Digital.</p> <p>Outcome: recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> 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. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update section 5(b) to include the legal entity. 2. To clarify within the abstract and section 5(a) who the lead organisation is.

	It was agreed the conditions would be approved OOC by IGARD Members.
2.6	<p><u>NHS England: Cancer Alliance access to National Cancer Waiting Times Monitoring Data Set (NCWTMDS) from the Cancer Wait Times (CWT) System (Presenter: Rachel Farrand) NIC-204557-F0N1T</u></p> <p>Application: This was a new application for pseudonymised National Cancer Waiting Times Monitoring Dataset (NCWTMDS). Cancer Alliances have been set up across England and are key to driving the change needed to achieve The Independent Cancer Taskforce's vision for improving services, care and outcomes for everyone with cancer, fewer people getting cancer, more people surviving cancer, more people having a good experience of their treatment and care and more people being supported to live as well as possible after treatment has finished. Cancer Alliances provide the opportunity for a different way of working to improve and transform Cancer services.</p> <p>NHS Digital advised it was hoped this application would be used as a template for Cancer Alliances going forward.</p> <p>Discussion: IGARD queried who the Data Controller and Data Processor would be as this was not clear in the application and asked that this be clearly set out, along with further clarity on who would be accessing the data on behalf of the relevant Cancer Alliance and suggested that this should also be documented in table format.</p> <p>IGARD noted that it was not clear in section 5 of the application what the legal entity was for this application and asked that this be updated to clarify this.</p> <p>IGARD also queried who the lead organisation is as there are references to the 'Cancer Alliance' accessing the data, however this needs to be more specific due to the number of organisations that form the Cancer Alliance.</p> <p>IGARD noted that although supportive of the template for Cancer Alliances application, that it should follow the correct path and be forwarded as a precedent to the Project Board and ask that Rachel Farrand progress on behalf of NHS Digital</p> <p>Outcome: recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> 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. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update section 5(b) to include the legal entity. 2. To clarify within the abstract and section 5(a) who the lead organisation is. <p>It was agreed the conditions would be approved OOC by IGARD Members.</p>
2.7	<p><u>NHS England: Cancer Alliance access to National Cancer Waiting Times Monitoring Data Set (NCWTMDS) from the Cancer Wait Times (CWT) System (Presenter: Rachel Farrand) NIC-204535-L4S1P</u></p> <p>Application: This was a new application for pseudonymised National Cancer Waiting Times Monitoring Dataset (NCWTMDS). Cancer Alliances have been set up across England and are key to driving the change needed to achieve The Independent Cancer Taskforce's vision for improving services, care and outcomes for everyone with cancer, fewer people getting cancer, more people surviving cancer, more people having a good experience of their treatment and care and more people being supported to live as well as possible after treatment has finished.</p>

	<p>Cancer Alliances provide the opportunity for a different way of working to improve and transform Cancer services.</p> <p>NHS Digital advised it was hoped this application would be used as a template for Cancer Alliances going forward.</p> <p>Discussion: IGARD queried who the Data Controller and Data Processor would be as this was not clear in the application and asked that this be clearly set out, along with further clarity on who would be accessing the data on behalf of the relevant Cancer Alliance and suggested that this should also be documented in table format.</p> <p>IGARD noted that it was not clear in section 5 of the application what the legal entity was for this application and asked that this be updated to clarify this.</p> <p>IGARD also queried who the lead organisation is as there are references to the 'Cancer Alliance' accessing the data, however this needs to be more specific due to the number of organisations that form the Cancer Alliance.</p> <p>IGARD noted that the storage location entity name was not included within section 1 of the application and asked that this be updated.</p> <p>IGARD noted that although supportive of the template for Cancer Alliances application, that it should follow the correct path and be forwarded as a precedent to the Project Board and ask that Rachel Farrand progress on behalf of NHS Digital</p> <p>Outcome: recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> 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. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update section 5(b) to include the legal entity. 2. To clarify within the abstract and section 5(a) who the lead organisation is. 3. To include the storage location entity name within Section 1 (storage location) <p>It was agreed the conditions would be approved OOC by IGARD Members.</p>
2.8	<p><u>NHS England: Cancer Alliance access to National Cancer Waiting Times Monitoring Data Set (NCWTMDS) from the Cancer Wait Times (CWT) System (Presenter: Rachel Farrand) NIC-204550-N7M4D</u></p> <p>Application: This was a new application for pseudonymised National Cancer Waiting Times Monitoring Dataset (NCWTMDS). Cancer Alliances have been set up across England and are key to driving the change needed to achieve The Independent Cancer Taskforce's vision for improving services, care and outcomes for everyone with cancer, fewer people getting cancer, more people surviving cancer, more people having a good experience of their treatment and care and more people being supported to live as well as possible after treatment has finished. Cancer Alliances provide the opportunity for a different way of working to improve and transform Cancer services.</p> <p>NHS Digital advised it was hoped this application would be used as a template for Cancer Alliances going forward.</p> <p>Discussion: IGARD queried who the Data Controller and Data Processor would be as this was not clear in the application and asked that this be clearly set out, along with further clarity on who would be accessing the data on behalf of the relevant Cancer Alliance and suggested that this should also be documented in table format.</p>

	<p>IGARD noted that it was not clear in section 5 of the application what the legal entity was for this application and asked that this be updated to clarify this.</p> <p>IGARD also queried who the lead organisation is as there are references to the 'Cancer Alliance' accessing the data, however this needs to be more specific due to the number of organisations that form the Cancer Alliance.</p> <p>IGARD noted that there is reference to 'Joint Data Controller' in section 1(b) and asked that this be removed as it is not relevant to this application.</p> <p>IGARD noted that although supportive of the template for Cancer Alliances application, that it should follow the correct path and be forwarded as a precedent to the Project Board and ask that Rachel Farrand progress on behalf of NHS Digital</p> <p>Outcome: recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> 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. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update section 5(b) to include the legal entity. 2. To clarify within the abstract and section 5(a) who the lead organisation is. 3. To remove reference to the joint data controller from section 1(b), since it is not relevant to this application. <p>It was agreed the conditions would be approved OOC by IGARD Members.</p>
2.9	<p><u>NHS England: Cancer Alliance access to National Cancer Waiting Times Monitoring Data Set (NCWTMDS) from the Cancer Wait Times (CWT) System (Presenter: Rachel Farrand) NIC-204559-J4H7T</u></p> <p>Application: This was a new application for pseudonymised National Cancer Waiting Times Monitoring Dataset (NCWTMDS). Cancer Alliances have been set up across England and are key to driving the change needed to achieve The Independent Cancer Taskforce's vision for improving services, care and outcomes for everyone with cancer, fewer people getting cancer, more people surviving cancer, more people having a good experience of their treatment and care and more people being supported to live as well as possible after treatment has finished. Cancer Alliances provide the opportunity for a different way of working to improve and transform Cancer services.</p> <p>NHS Digital advised it was hoped this application would be used as a template for Cancer Alliances going forward.</p> <p>Discussion: IGARD queried who the Data Controller and Data Processor would be as this was not clear in the application and asked that this be clearly set out, along with further clarity on who would be accessing the data on behalf of the relevant Cancer Alliance and suggested that this should also be documented in table format.</p> <p>IGARD noted that it was not clear in section 5 of the application what the legal entity was for this application and asked that this be updated to clarify this.</p> <p>IGARD also queried who the lead organisation is as there are references to the 'Cancer Alliance' accessing the data, however this needs to be more specific due to the number of organisations that form the Cancer Alliance.</p>

	<p>IGARD noted that although supportive of the template for Cancer Alliances application, that it should follow the correct path and be forwarded as a precedent to the Project Board and ask that Rachel Farrand progress on behalf of NHS Digital.</p> <p>Outcome: recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> 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. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update section 5(b) to include the legal entity. 2. To clarify within the abstract and section 5(a) who the lead organisation is. <p>It was agreed the conditions would be approved OOC by IGARD Members.</p>
2.10	<p><u>Royal Liverpool and Broadgreen University Hospitals NHS Trust: Investigation of Aneurysm Repair Decision Aid (ARDA) for Management of Abdominal Aortic Aneurysms: Safety Validation and Impact Assessment (Presenter: Dave Cronin) NIC-170867-M5Q6W</u></p> <p>Application: This was a new application for pseudonymised Civil Registrations Mortality Data for support the development of a clinical decision tool based on Aneurysm Repair Decision Aid (ARDA) and to conduct external validation among Abdominal Aortic Aneurysm Repair (AAA) to achieve optimum survival advantage for individual patients and to assess the cost-effectiveness of elective repair at a particular aneurysm diameter.</p> <p>NHS Digital noted that there were incorrect references to Hospital Episode Statistics (HES) data in the abstract and section 5 and this would need to be amended since it is not relevant to this application.</p> <p>Discussion: IGARD noted reference in the application to section 251 support and asked that evidence is provided that the applicant had submitted its annual review for section 251 support to the Health Research Authority Confidentiality Advisory Group (HRA CAG).</p> <p>IGARD noted that HRA CAG had previously requested that the research results should be widely disseminated to consolidate and increase public involvement and asked that section 5 be updated to clearly define the benefits, how they link to health and social care, including any examples of work undertaken with patient representatives.</p> <p>Outcome: recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> 1. To provide evidence that the applicant has submitted its annual renewal for s251 support to HRA CAG. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To remove any reference to HES data from the abstract and section 5 since it not relevant to this application. 2. To update section 5 to clearly define the benefits, how they link to health and social care, including any examples of work undertaken with patient representatives. <p>It was agreed the condition would be approved OOC by the IGARD Chair.</p>
2.11	<p><u>Imperial College London: Renewal and amendment of Imperial DSA for research into UK Health Policy Reform (Presenter: Louise Dunn) NIC-366210-V2H5M</u></p> <p>Application: This was an amendment application for pseudonymised Hospital Episodes Statistics (HES) data and Patient Reported Experience Measures (PROMs) to investigate the effects of greater private and voluntary provision of publicly funded care on outcomes for NHS</p>

	<p>patients, equity of access to care and overall NHS costs and will concentrate on the elective procedures most commonly done by private providers, specifically hip and knee replacements</p> <p>Discussion: IGARD noted that the application incorrectly referenced the awarding institution as being the Economics and Social Research Council (ESRC) and asked that this is amended to correctly reference the European Research Council (ERC).</p> <p>IGARD queried the lack of outputs, a defined process within section 5 along with yielded benefits with examples of patient and public engagement in order to be transparent for the general public when this was published within NHS Digital's data release register and suggested on renewal further information would be expected to be provided.</p> <p>Outcome: recommendation to approve</p> <p>The following amendment was requested:</p> <ol style="list-style-type: none"> 1. To amend the funding source to correctly reference ERC. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD advised when the application returns for renewal, IGARD would expect to see further information and evidence with regard to expected benefits and yielded benefits for the public and patients.
2.12	<p><u>IQVIA Technology Services Ltd: HES data for IQVIA clinical trial site identification (Presenter: Louise Dunn) NIC-210151-K9C7G</u></p> <p>Application: This was a new application to use pseudonymised record-level Hospital Episode Statistics (HES) data already held under a data sharing agreement (NIC-373563) for an additional purpose which is for IQVIA and its Affiliates to use Visualise Healthcare Data (VHD) to provide a further permitted services. VHD provides users with a role-based access to the applications and allows users to perform analyses on aggregated HES data and data from other sources and then view graphs and tables.</p> <p>Discussion: IGARD queried if record level data would be made available to any organisation within the IQVIA group of companies including for IQVIA Technology Services Ltd and IQVIA Solutions UK Ltd and asked that a special condition be added stating data would not be made available to any organisation within IQVIA group of companies except for IQVIA Technology Services Ltd and IQVIA Solutions UK Ltd, as well as setting this out within section 5 of the application.</p> <p>IGARD also queried if only substantive employees of IQVIA Technology Services Ltd and IQVIA Solutions UK Ltd would have access to record level data and asked that a special condition be added stating this, as well as setting this out within section 5 of the application.</p> <p>IGARD asked for further information on OneKey including how the data for participating physicians is collected, stored and disseminated and evidence of the fair processing material provided to physicians participating in the OneKey dataset.</p> <p>IGARD noted that reference was made to 'affiliates' in the application and asked that this reference be removed unless referencing aggregated HES data with small numbers suppressed.</p> <p>IGARD noted that the history of the applicant and related applications was unclear, particularly in relation to the change of company names and asked that Section 1(a) be updated to clearly outline this.</p> <p>IGARD noted that some of the references to 'IQVIA' were incorrect in the application and asked that these be corrected throughout to correctly state the company name.</p>

	<p>IGARD suggested that NHS Digital may wish to consider auditing this organisation in relation to this application / data sharing agreement.</p> <p>Outcome: recommendation to approve subject to the following conditions:</p> <ol style="list-style-type: none"> 1. Adding a special condition that record level data will not be made available to any organisation within the IQVIA group of companies except for IQVIA Technology Services Ltd and IQVIA Solutions UK Ltd (and to also set out this restriction in part 5 of the application). 2. Adding a special condition that only substantive employees of IQVIA Technology Services Ltd and IQVIA Solutions UK Ltd will have access to record level data (and to also set out this restriction in part 5 of the application). 3. To provide further information about OneKey, particularly for transparency how the data for participating physicians is collected, stored and disseminated and evidence of the fair processing material provided to physicians participating in the OneKey dataset. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To remove reference to 'affiliates' from the application unless referencing aggregated HES data with small numbers suppressed. 2. To update the abstract to clearly set out the history of the application, particularly how the company names have changed. 3. To correctly reference the IQVIA name throughout the application. <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. <p>It was agreed the conditions would be approved OOC by IGARD Members.</p>
3.	<p>AOB</p> <p>None</p>

Independent Group Advising on Releases of Data (IGARD): Out of committee report 30/11/18

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-315716-L0F4M	Imperial College London	01/11/18	<ol style="list-style-type: none"> 1 To clearly explain within section 5 that projects 1, 3 and 4 have now completed and that this application is for project 2, and additionally to confirm funding is in place for the continuation of project 2 and provide relevant evidence. 2 To explicitly state within section 5 the applicable controls to ensure that data will only be accessed by the researchers for project 2 and to clarify that their access to data will be restricted so they only access that subset of data that is necessary for project 2. Furthermore to update the application to clarify that access to data for the three completed projects is restricted so that this data can only be accessed for the purpose of answering queries and that there are appropriate controls in place to achieve this. 3 To provide further examples of measurable and yielded benefits within section 5 of the application for the completed projects 1, 3 and 4. 	IGARD Members	Quorum of IGARD Members	N/A

NIC-67398-K2Y3T	Imperial College London	01/11/18	<ol style="list-style-type: none"> 1 To provide further details of pathways of dissemination of the outputs including any specific examples and also provide a clear plan of public / patient engagement 2 To clarify within section 5 why maternity data is required, and bearing in mind that the data is to be used by the Department of Surgery and Cancer, to clearly describe how the use of maternity data in the research being undertaken aligns with the remit of the Department of Surgery and Cancer. 	IGARD Members	Quorum of IGARD Members	N/A
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In addition, the following applications were not considered by IGARD but have been progressed for IAO and Director extension/renewal:

- None notified to IGARD