Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 7 February 2019

Members: Anomika Bedi, Maria Clark, Nicola Fear, Kirsty Irvine (Chair), Priscilla Maguire.

In attendance: Stuart Blake, Dave Cronin, Louise Dunn, Karen Myers, Vicki Williams.

Apologies: Sarah Baalham, Joanne Bailey, Eve Sariyiannidou.

Observer: Frances Hancox (Items 2.1 – 2.2)

1	**Declaration of interests:** Nicola Fear noted professional links to King's College London [NIC-44383-L6C0X] but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest. Kirsty Irvine noted a personal link to Genomics England [NIC-12784-R8W7V]. It was agreed this did not preclude Kirsty Irvine taking part in the discussions about this application. Maria Clark noted professional links to the University of Sheffield [NIC-194387-K3H5K] but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 31st January 2019 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record of the meeting. **Out of committee recommendations** An out of committee report was received (see Appendix B).
2	**Data applications**
2.1	<u>Kings College London: HES/Mortality data for the analysis of alcohol related frequent attenders to hospitals (Presenter: Louise Dunn) NIC-44383-L6C0X</u> **Application:** This was an amendment application for pseudonymised Hospital Episode Statistics and Civil Registrations data for a study to ascertain the nature, natural history and characteristics of alcohol-related frequent attenders (ARFAs). The project has two specific aims; 1) to explore a sample of hospital attenders, which medical and socio-demographic characteristics are associated with alcohol-related frequent attendance. Different patterns of health service utilisation and health outcomes including death; 2) to explore the costs of health service use by ARFAs. **Discussion:** IGARD noted that the information provided in the application in respect of data minimisation was inconsistent with the filters applied in section 3(b) (Additional Data Access Requested) and asked that this be updated for consistency. IGARD asked that the reference to the STATA MP Software Tool in section 5(b) (Processing Activities) be amended to explicitly state that a local version of this is being used and not cloud. IGARD noted that the applicant's privacy notice did not meet NHS Digital's criteria and queried when the applicant's privacy notice was to be published and were advised by NHS Digital that this was going to be done imminently. IGARD advised that the applicant should ensure the privacy notice is published forthwith.

	IGARD noted that section 5a (Objective for Processing) 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 in particular consideration should be given to how best to engage with the population of interest. IGARD noted that the contract of employment provided as supporting document 7 was due to expire in March 2019 and were advised by NHS Digital that this was in the process of being renewed. **Outcome:** recommendation to approve The following amendments were requested: 1. The data minimisation table in section 3(b) should be updated to clearly outline the filters applied to reflect the data minimisation outlined elsewhere within the application. 2. To amend section 5(b) to explicitly state that a local version of the STATA MP Software Tool is being used and not cloud. The following advice was given: 1. IGARD advised that the applicant should ensure the privacy notice is published forthwith. 2. IGARD suggested on renewal that further details of pathways of dissemination of the outputs be provided including examples of public / patient engagement in particular consideration should be given to how best to engage with the population of interest.
2.2	<u>Guys & St Thomas NHS FT: Cancer Alliance access to National Cancer Waiting Times Monitoring Data Set (NCWTMDS) from the Cancer Wait Times (CWT) System (Presenter: Louise Dunn) NIC-204554-Y7F3H</u> **Application:** This was a new application for pseudonymised National Cancer Waiting Times Monitoring Dataset (CWT) to both monitor and improve performance against the Cancer Waiting Time standards and to inform wider Cancer pathways improvements. **Discussion:** NHS Digital noted that any relevant information from the recently disseminated briefing paper with regard to Cancer Alliances would be incorporated into future applications. NHS Digital noted that the application followed a template application that was previously brought to IGARD and advised that the section 1 (Abstract) needed updating to note this and to make it clear that this is not a 'template application'. IGARD noted that section 1 needed amending to include the name of the lead organisation in the Cancer Alliance. IGARD queried why the yielded benefits which had been carried out by the Royal Marsden Partners were noted within the abstract and were advised by NHS Digital that this would be removed since it was not relevant to this application. IGARD noted that section 5(b) (Processing Activities) needed updating to clearly describe in the actual outputs that will be shared including the level of data. **Outcome:** recommendation to approve The following amendments were requested: 1. To update the abstract with the name of the lead organisation in the Cancer Alliance. 2. To remove the paragraph on yielded benefits from the abstract referencing the Royal Marsden Partners.

	3. To update the abstract to be clear that this application follows a template and that it is not a "template application". 4. To clearly describe in section 5(b) the actual outputs that will be shared including the level of data.
2.3	<u>Genomics England: Genomics England (MR1418) - Amendment and Updated Request for tranche of data across multiple data sets (Presenter: Louise Dunn) NIC-12784-R8W7V</u> **Application:** This was a renewal and amendment application for identifiable Hospital Episode Statistics (HES), Medical Research Information Service (MRIS), Mental Health and Learning Disability Data Set (MHLDDS), Mental Health Services Data Set (MHSDS), Patient Reported Outcome Measures (PROMs), Mental Health Minimum Data Set (MHMDS) and Diagnostic Imaging Dataset (DIDS). In March 2017, the NHS England Board set out its strategic approach to build a national Genomic Medicine Service (GMS), building on the 100,000 Genomes Project. This will include a national Whole Genomic Sequencing provision and supporting informatics infrastructure developed in partnership with Genomics England. Genomics England will therefore undertake genomic sequencing and clinical data collection for the new GMS. NHS Digital advised that the protocol was currently in the process of being signed off and that NHS Digital would share with IGARD once available. NHS Digital also advised that the Consent forms and related Patient Information Sheet (PIS) were in the process of being updated to reflect the GMS but had not been finalised and would be shared with IGARD once available. **Discussion:** IGARD welcomed and supported the application and noted the importance of the research. IGARD noted the ongoing work in relation to the protocol, consent forms and PIS and advised that they would like to have sight of these documents once they are available for consistency and transparency. IGARD noted the reference within the application to Genomics England being "owned" by the Department of Health and Social Care and asked for further explanation within section 1 (Abstract) as to why the applicant has selected legitimate interests as a legal basis. IGARD also asked that NHS Digital provide confirmation that they were content with this analysis and to provide confirmation of this within the abstract. IGARD also asked that section 5(a) (Objective for Processing) be amended to clearly set out what the legitimate interests were and how they related to the legal basis for processing. IGARD noted that consent was being relied upon to address the duty of confidentiality only and asked that this be made explicitly clear throughout the application for clarity and advised that the consent materials should be explicit that the consent was being used to address the duty of confidentiality (as opposed to data protection). IGARD noted that Article 9(2)(d) was incorrectly referenced within section 1 (Abstract) and asked that the application is updated with the correct legal basis under Article 9. IGARD noted that under section 5(e) (Is the Purpose of this Application in Anyway Commercial?) was answered as 'yes' but did not contain enough information to support this. IGARD therefore asked that further clarity was provided to explain how these activities were commercial, or if they are not commercial to capture the current wording in section 5(e) and reproduce under the body of the agreement. It was also noted that the application stated that PROMs data cannot be used for commercial purposes and queried what controls were in

	place and asked that a special condition be included stating that PROMs data cannot be used for commercial use within the research environment. IGARD queried what would happen to the data if consent was withdrawn by the participant and asked for section 1 (Abstract) to be updated clarifying this. IGARD noted that UKCloud Limited is listed as a Data Processor and asked that further information be provided within the application on the organisation; and that section 5 (Purpose / Methods / Outputs) is updated to clarify that UKCloud Limited is not being used for Cloud storage. IGARD noted that the applicant's fair processing notices stated that data may be taken outside the territory of use and advised that this should be updated to clearly state that territory of use was England and Wales to reflect the terms of the data sharing agreement. IGARD were unable to make a recommendation in respect of the Genomic Medical Service due to the Consent forms and related Patient Information Sheet (PIS) being unavailable to review, such documents being necessary to allow IGARD to make an informed recommendation, and as per usual practice. **Outcome:** IGARD recommended to approve in respect of the data refresh and sub-licencing aspects of the application only. IGARD was unable to make a recommendation in respect of the Genomic Medical Service as the relevant supporting documents, essential to IGARD's review, were not available. The following amendments were requested: 1. Given that the applicant is described in some instances as being "owned" by the Department of Health and Social Care, the applicant to set out in the abstract reasoning why they have selected legitimate interest as a legal basis and for NHS Digital to confirm they are content with that analysis and confirm within the abstract. 2. To amend section 5(a) to clearly set out what the legitimate interests are and how they relate to the processing. 3. To make it explicitly clear throughout the application that consent is being relied on to address the duty of confidentiality only. 4. The applicant to review the correct legal basis under Article 9. 5. To provide clarity in section 5(e) to explain how these activities are commercial, or if not commercial to capture the wording in section 5(e) and reproduce under the body of agreement. 6. To amend the abstract to clarify what would happen if consent was withdrawn by the participant and to clarify what happens to their data. 7. To amend section 5 to clarify that UKCloud Limited is not being used for Cloud storage. 8. To insert a special condition stating that PROMs data cannot be used for commercial use within the research environment. The following advice was given: 1. IGARD suggested that the privacy notice should be updated to clearly state that territory of use is England and Wales. 2. IGARD suggested that the consent materials should be explicit that the consent is being used to address the duty of confidentiality (as opposed to data protection).
2.4	University of York: Economic Analyses of Health and Social Care -Evaluation of differences in the performance of health care providers in terms of the amount and cost of provision and in patient outcomes including mortality and self-reported morbidity (Presenter: Louise Dunn) NIC-84254-J2G1Q

	Application: This was a renewal and amendment application for pseudonymised Patient Reported Outcome Measures (PROMs), Hospital Episode Statistics (HES), Mental Health Services Data Set (MHSDS), Mental Health Minimum Data Set (MHMDS), Mental Health and Learning Disability Data Set (MHLDDS) and Civil Registrations (Mortality) data. The data is required for a number of projects which all involve economic analyses of health and social care, the aim being to study the way in which services are provided and the outcomes of those services in order to improve health and healthcare services in the NHS. **Discussion:** IGARD queried the reference to the University of York holding a number of Mental Health datasets within the application and asked that it be made clear that these were NHS Digital datasets. IGARD noted the reference to 'software' in section 5 (Purpose / Methods / Outputs) and asked that for clarity, this be amended to explicitly state that the applicant is using a local version of the software and this is not accessed by the cloud. IGARD queried the sentence in section 5(b) (Processing Activities) *"…will only be accessible to individuals who are substantively employed by or enrolled at the University of York."* and were advised by NHS Digital that the reference to "enrolled" would need to be removed. IGARD also queried the sentence in section 5(b) *"…will not be accessed or processed by any other third parties not mentioned in this agreement."*. NHS Digital confirmed there was no third-party involvement and IGARD suggested that reference to "third" should be removed. IGARD noted that supporting document 3, relating to a contract with a named individual with the Department of Health, was due to expire in February 2019. IGARD asked that confirmation be provided that this had been extended and suggested the new document be uploaded to NHS Digital's Customer Relationship Management System (CRM). IGARD noted that section 5(a) (Objective for Processing) should be updated to include further details of pathways for disseminating the outputs of the study to the public. **Outcome:** recommendation to approve The following amendments were requested: 1. Where there is reference to the applicant holding a number of mental health datasets, to clarify that these are NHS Digital datasets. 2. To amend section 5 to explicitly state that the applicant is using the local versions of the software referred to and this is not accessed by the Cloud. 3. To amend section 5 to remove reference to 'enrolled'. 4. To amend section 5(b) to remove reference to 'third' (parties). 5. To provide confirmation that the contract set out in supporting document 3 has been extended and the new document has been uploaded to CRM. The following advice was given: 1. IGARD suggested on renewal that further consideration be given to pathways of dissemination of the outputs to the public.
2.5	NHS England: Cancer Alliance access to National Cancer Waiting Times Monitoring Data Set (NCWTMDS) from the Cancer Wait Times (CWT) System (Presenter: Louise Dunn) NIC-204575-V7X8H The application was withdrawn by the presenter.
2.6	IQVIA Solutions UK Limited: NIC-373563 - IQVIA Solutions UK Limited & IQVIA Technology Services Ltd (Presenter: Louise Dunn) NIC-373563-N8Z9J

	Application: This was an amendment and renewal application for (1) pseudonymised Hospital Episode Statistics (HES) data to perform two types of service: (a) Data visualisation and benchmarking tools which includes Care Pathway Analyser, Hospital Feedback services and Visualise Healthcare Data, E360™ Platform and Healthcare Optimisation Benchmarking; and (b) Advanced Statistical Analysis (2) removal of a storage location and (3) replacement of a software tool. **Discussion:** IGARD suggested that previous points raised with regard to IQVIA applications should be crossed referenced to ensure that all previous universally applicable comments had been reflected and that previous NIC numbers and dates of approval be included within section 1 (Abstract) for background information. IGARD noted that section 1 (Abstract) incorrectly references the 'E330 Tool' and asked that that be amended to correctly refer to the 'E360 Tool'. IGARD asked when the applicant had been audited and NHS Digital noted that IQVIA Solutions UK Limited had been audited in August 2018 and there were no areas of concern. IGARD noted the role of the Independent Scientific and Ethics Advisory Committee (ISEAC) and asked that a special condition be included that the applicant will provide a record of ISEAC decisions for the preceding 6 months and within 1 month of the agreement being signed. IGARD noted the ethics approval wording in section 7 (Ethics Approval) was incorrect in that it referenced approval by ISEAC. NHS Digital agreed that this needed updating to reflect that ethical approval was not needed because it was pseudonymised data. IGARD queried the reference to "CTSI" in section 6 (Special Conditions) and were advised by NHS Digital that this paragraph was incorrect and would be removed. **Outcome:** recommendation to approve The following amendments were requested: 1) To update the abstract to refer to the correct E360 tool. 2) To include a special condition that the applicant will provide a record of ISEAC decisions for the preceding 6 months and within 1 month of the agreement being signed. 3) To amend the ethics approval wording in section 7 to reflect that ethical approval is not needed because it is pseudonymised data. 4) To remove the paragraph in the special conditions referring to "CTSI".
2.7	University College London (UCL): Extended follow-up of the TARGIT A Trial (Presenter: Stuart Blake) NIC-126676-G1X4M **Application:** This was a new application for identifiable Civil Registration data for a cohort of UK breast cancer patients who are participating in the TARGIT A trial, which measures the effectiveness of targeted intraoperative radiotherapy treatment, where the patient's entire local treatment (lumpectomy plus radiation therapy) is completed at the time of the operation. The extended follow-up study will enable timely recording of additional local recurrences and deaths. NHS Digital noted that the cohort numbers referred to in section 5(a) were incorrect and needed updating to accurately reference the correct number of UK participants. **Discussion:** IGARD noted and supported the amendment to Section 5(a) to update the cohort number to accurately reflect 608 participants, not 3451.

	IGARD welcomed the application and noted the importance of the study and its far reaching impact. IGARD queried how the duty of confidentiality owed to the patient identifiers flowing to NHS Digital was satisfied (prima facie, the original consent form and Patient Information Sheet) and asked that the original documentary evidence was provided. IGARD noted that section 5(a) (Objective for processing) 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. IGARD queried the role of Carl Zeiss Surgical had in the study, as outlined in supporting document 2, the National Institute for Health Research funding letter, and asked that a special condition be added to clarify and to also provide confirmation that they will not have influence on the outcomes nor suppress any of the findings of the research. **Outcome:** recommendation to approve subject to the following condition: 1) To provide documentary evidence of how the duty of confidentiality owed to the patient identifiers flowing to NHS Digital is satisfied (prima facie, the original consent form and Patient Information Sheet). The following amendments were requested: 1) To add a special condition clarifying the role Carl Zeiss has in the study and provide confirmation that they will not have influence on the outcomes nor suppress any of the findings of the research. 2) To update the section 5(a) with the correct number of UK participants. The following advice was given: 1) IGARD suggested on renewal that further details of pathways of dissemination of the outputs be provided including examples of public / patient engagement. It was agreed the condition be approved OOC by IGARD Members.
2.8	<u>University College London Hospitals NHS FT: Cancer Alliance access to National Cancer Waiting Times Monitoring Data Set (NCWTMDS) from the Cancer Wait Times (CWT) System – UCLH Cancer Collaborative (Presenter: Stuart Blake) NIC-204565-L5J5F</u> **Application:** This was a new application for pseudonymised National Cancer Waiting Times Monitoring Dataset (CWT) to both monitor and improve performance against the Cancer Waiting Time standards and to inform wider Cancer pathways improvements. **Discussion:** IGARD noted that the application followed a template application that was previously brought to IGARD and advised that the section 1 (Abstract) needed updating to note this and to make it clear that this is not a 'template application'. IGARD also noted the recent generic amendments that were discussed on previous applications of this type and asked that the application be updated to reflect these. IGARD noted the reference to NHS England as the lead organisation within section 1 (Abstract) and asked that this be removed since it is not relevant to this application. IGARD queried the reference to 'West Essex' in section 5(a) (Objective for Processing) and were advised by NHS Digital that this would be removed as it was not relevant to this application.

	IGARD noted that the reference to 'North Central and East London' was referred to differently throughout the application and asked that this is updated to ensure the correct names of the parties are used consistently throughout the application. IGARD noted that section 5(b) (Processing Activities) needed updating to clearly describe in the actual outputs what will be shared including the level of data. **Outcome:** recommendation to approve The following amendments were requested: 1) To ensure all recent generic amendments discussed on previous applications of this type to be uplifted to this application. 2) To remove reference to NHS England within the application since this is not relevant. 3) To remove reference to West Essex within the application since this is not relevant. 4) To ensure the correct names of the parties are used consistently throughout the application. 5) To update the abstract to be clear that this application follows a template and that it is not a "template application". 6) To clearly describe in section 5(b) the actual outputs that will be shared including the level of data.
2.9	University of Sheffield: MR1466 - Life and Bladder Cancer: The Yorkshire Cancer Research Bladder Cancer Patient Reported Outcomes Survey (Longitudinal Study) (Presenter: Dave Cronin) NIC-194387-K3H5K **Application:** This was a new application for identifiable Medical Research Information Service (MRIS) List Cleaning Report which will be used to carry out mortality checks and retrieve current patient addresses for those people in the Life and Bladder Cancer (LABC) survey cohort for the purpose of administering a Patient Reported Outcome Measures (PROMs) survey of people diagnosed with bladder cancer in Yorkshire, Humber, North Derbyshire and South Tees. **Discussion:** IGARD noted that supporting document 1.1, the study protocol, stated that patient objections had been applied and asked that section 3(c) (Patient Objections) of the application be updated to align with this document. NHS Digital advised that previous versions of this application did not have the University of Leeds listed as a Data Controller and that as a result they currently do not have a fair processing notice. IGARD agreed that as University of Leeds was now a Data Controller, it may be expedient for University of Leeds to work with NHS Digital on a fair processing notice that is GDPR compliant. IGARD noted that section 5(d) (Benefits) may not be fully reflective of the good work that will come from this trial and suggested that on return the applicant consider how best to set out the benefits flowing from the valuable research undertaken. NHS Digital and IGARD were in agreement that using the term "status" in the consent was not best practice when the data being sought was death or mortality related data (it would usually be expected that the type of "status" would be qualified – e.g. "health status" or "vital status"). However, NHS Digital noted that the purpose of this application was solely to clarify if the participants were still alive and living at the same address in order to send them further material and on balance was prepared to accept that use of the term "status" in the consent form was acceptable in this instance in light of the clarifying information in the Participant Information Sheet. IGARD concurred. NHS Digital observed that if more detailed mortality data (such as cause of death details) or other health data was required in future, the consent

	materials would not evidence sufficiently informed consent for those purposes and again IGARD members agreed with this analysis. **Outcome:** recommendation to approve The following amendments were requested: 1) To update section 3(c) to reflect whether patient objections are being applied, and in alignment with the study protocol. The following advice was given: 1) IGARD suggested that the University of Leeds should work with NHS Digital on a fair processing notice that is GDPR compliant. 2) IGARD suggested that on return the applicant to set out the benefits flowing from the valuable research undertaken and to consider further routes of dissemination to the public.
2.10	<u>Clatterbridge Cancer Centre NHS Foundation Trust: Cancer Alliance access to National Cancer Waiting Times Monitoring Data Set (NCWTMDS) from the Cancer Wait Times (CWT) System (Presenter: Dave Cronin) NIC-204580-F5B0C</u> **Application:** This was a new application for pseudonymised National Cancer Waiting Times Monitoring Dataset (CWT) to both monitor and improve performance against the Cancer Waiting Time standards and to inform wider Cancer pathways improvements. NHS Digital noted that the application followed a template application that was previously brought to IGARD and advised that the section 1 (Abstract) needed updating to note this and to make it clear that this is not a 'template application'. NHS Digital noted that section 5(b) (Processing Activities) needed updating to clearly describe in the actual outputs that will be shared including the level of data. **Discussion:** IGARD noted and supported the amendment that needed making to the application in respect of noting that the application followed a template application and also the update to the outputs. IGARD also noted the recent generic amendments that were discussed on previous applications of this type and asked that the application be updated to reflect these. **Outcome:** recommendation to approve The following amendments were requested: 1) To ensure all recent generic amendments discussed on previous applications of this type to be uplifted to this application. 2) To update the abstract to be clear that this application follows a template and that it is not a "template application". 3) To clearly describe in section 5(b) the actual outputs that will be shared including the level of data.
3 **3.1**	**AOB** **<u>NHS Sunderland CCG - NIC-250326-W3F1B</u>** IGARD noted that following the 31st January 2019 meeting, when IGARD were unable to recommend for approval. The relevant extract is as follows: **"**IGARD were unable to recommend for approval. 1. IGARD did not have a complete position from NHS Digital with regard to cloud storage in order to confidently acknowledge the risks involved and mitigation taking place.

	2. To update the data flow diagram provided with the pseudonymised GP data as described in the application." NHS Digital advised that the Cloud storage locations have been removed from the application and all non-related cloud amendments addressed, and NHS Digital had taken the decision to disseminate the data. The IGARD Chair had been informed of this out of committee.
3.2	**<u>NHS Barnsley CCG - NIC-90647-G3Q4S</u>** IGARD noted that following the 31st January 2019 meeting, when IGARD were unable to recommend for approval. The relevant extract is as follows: **"**IGARD were unable to recommend for approval. 1. IGARD did not have a complete position from NHS Digital with regard to cloud storage in order to confidently acknowledge the risks involved and mitigation taking place. 2. To update the data flow diagram provided with the pseudonymised GP data as described in the application. 3. To include a special condition in section 6 that no other company within the Kier Group will have access to the data other than the Kier entity listed in the agreement. 4. To use the full and correct names for each of consortium members outlined throughout the application. 5. To clarify if Yeadon Community Health Centre should be part of the agreement, and if so, to clarify if they should be listed as a processing and storage location address and to amend accordingly, or remove the reference. 6. To amend the incorrect reference to Nexent Data Centre to the correct name of Pulsant." NHS Digital advised that the Cloud storage locations have been removed from the application and all non-related cloud amendments addressed, and NHS Digital had taken the decision to disseminate the data. The IGARD Chair had been informed of this out of committee.

Independent Group Advising on Releases of Data (IGARD): Out of committee report 01/02/19

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-14340-R7G1F	Meditrends Ltd	17/01/19	1. To justify within section 5 the number of years of data requested for study 1 purpose 2 and the breadth of data requested. 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.	IGARD Members	Quorum of IGARD Members	N/A
NIC-88623-F2H1Q	Royal College of Anaesthetists	13/12/18	1. To provide clarification of whether it is all UK hospitals or is it just those hospitals who have patients in critical care during that one week outlined in the application and who participated in the study. 2. Section 5 of the application should be updated to provide a more detailed description of the study or studies and the cohorts, details of who is accessing the data and what data they are accessing which aligns with the information provided in the HRA CAG approval and Protocol supporting documents. The update regarding the data and access to data should also reflect the joint controllership outlined in the application. 3. Provide clarification in section 5 of how the medical PhD referenced in supporting	IGARD members	Quorum of IGARD Members	N/A

			document 8 fits with the wider study outlined in the application. 4. To update the abstract to reflect that NHS Digital, rather than the Royal College of Anaesthetists, have assessed the LIA and deemed it satisfactory.			

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

- None