Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 3 June 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker (Chair)	Specialist GP Member / IGARD Deputy Specialist GP Chair
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Prof. Nicola Fear	Specialist Academic Member
Kirsty Irvine (Chair)	IGARD Chair / Lay Representative
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Vicky Byrne-Watts	Data Access Request Service (DARS)
Liz Gaffney	Data Access Request Service (DARS) (Item 6.1 only)
Karen Myers	IGARD Secretariat
Denise Pine	Data Access Request Service (DARS)
Gemma Walker	Data Access Request Service (DARS) (Observer: item 2.1)
Kimberley Watson	Data Access Request Service (DARS)

1	**Declaration of interests:** Dr Maurice Smith declared an interest to NIC-386376-Z1H5J, in that one of the named data processors, AIMES, provided services to Liverpool CCG. It was agreed that there was no conflict of interest. Paul Affleck declared an interest to NIC-386376-Z1H5J, in that AIMES provided services to the UK Colorectal Cancer Intelligence Hub, which he managed. It was agreed that there was no conflict of interest. **Review of previous minutes and actions:**

	The minutes of the 27th May 2021 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 A).
2	
2.1	<u>National Pregnancy in Diabetes Data Set (NPID) Briefing Paper</u> The briefing paper presented on the 3rd September 2020, was to inform IGARD about the NPID Audit data set that is due to be made available through the Data Access Request Service (DARS). Following comments made by IGARD on the 3rd September 2020, the presenter has made the relevant amendments to the briefing paper, and this was circulated to members out of committee by the IGARD Secretariat. IGARD welcomed the updated briefing paper and made no further comments. IGARD looked forward to receiving this finalised briefing paper as a supporting document, alongside a first of type application.
3	**Data Applications**
3.1	<u>University of Leicester: Cardio-oncology: A high resolution national electronic health record investigation of the interplay between cancer and heart disease (Presenter: Denise Pine) NIC-143888-H0W2N1 v1.5</u> **Application:** This was an amendment application to update section 5 throughout, and to permit linkage with an additional data set. The Virtual Cardio-Oncology Research Initiative (VICORI) are requesting to link to Prescription data that is collected by the NHS Business Services Authority (NHS BSA); that is accessible through the National Cancer Registration and Analysis Service (NCRAS) at Public Health England (PHE) to the existing VICORI data resource. The VICORI and NCRAS datasets both contain NHS Digital data supplied to the relevant organisations under separate Data Sharing Agreements (DSA); 1) under NIC-359940-W1R7B, NHS Digital shares data with Barts Health NHS Trust for the purpose of the National Institute for Cardiovascular Outcomes Research (NICOR) audit (which feeds into VICORI); 2) under NIC-343380-H5Q9K, NHS Digital shares data with PHE. VICORI is a 5-year programme with the purpose of undertaking electronic health care record population research into the interplay between heart disease and cancer. The study is relying on s251 of the NHS Act 2006 for the flow of identifiers to NHS Digital. **Discussion:** IGARD noted the additional purpose to the processing of the data, to link NHS Digital data to prescription data collected by the NHS BSA, and queried if the applicant should also submit an amendment request to the Health Research Authority Confidentiality Advisory Group (HRA CAG) in respect of the s251 support. IGARD noted that the HRA CAG Register stated *"29 November 2019: Amendment supported to enable confidential patient information (NHS Number, date of birth, postcode, and sex) to be disclosed to NHS Digital to facilitate linkage with the **HES and ONS datasets** and NHS Wales Informatics to facilitate linkage with the Patient Episodes Database for Wales was supported. Linked data will be made available in the database for use for research purposes.";* and therefore may not cover linkage to

	prescription data that was collected by the NHS BSA. IGARD therefore asked that written confirmation was provided from HRA CAG, that they were content that **no** amendment to the s251 HRA CAG support was required in respect of the additional purpose of processing; or that written evidence was provided, that a suitable amendment had been submitted to, and approved by, HRA CAG; and in either case, the appropriate written evidence was uploaded to NHS Digital's Customer Relationship Management (CRM) system for future reference. IGARD noted that the NHS BSA dataset was flowing directly from the NHS BSA to PHE, and queried what the legal basis for this flow of data was; and if this permitted the processing that was intended within this DSA, noting the constraints placed in the Direction for the collection of NHS BSA medicines data by NHS Digital, specifically *"Providing intelligence about the safety and effectiveness of medicines…"*; and asked that written confirmation was provided that the proposed processing was compatible with the legal basis for the flow of medicines data from NHS BSA to PHE in the relevant agreement. IGARD noted the UK GDPR Article legal basis was referenced in section 3 (Datasets Held / Requested), however asked that as per process and for transparency, section 1 (Abstract) and section 5(a) (Objective for Processing) were updated with a clear justification of the UK GDPR legal basis cited. IGARD queried the information in section 3(a) (Data Access Already Given) that stated pseudonymisation was a data minimisation process, noting that no data was flowing under this DSA, IGARD asked that section 3(a) was updated accordingly. IGARD noted that the VICORI privacy notice stated that *"VICORI will act as data controller"* , and noting that that this was not reflected in the application, asked that section 5 (Purpose / Methods / Outputs) was updated with a statement, explaining why VICORI were **not** considered joint Data Controllers and / or Data Processors; or, if VICORI were considered joint Data Controllers and / or Data Processors, that the application was updated throughout to reflect this. IGARD also noted within the VICORI privacy notice, the statement that patient data could be removed if patients wish; and noting that this was contradictory to the information in section 5(b) (Processing Activities) that data would not be re-identified; asked that further clarification was provided in section 5(b) of how patient data could be removed. IGARD suggested that section 5(d) (Benefits) be updated to remove reference to "*it will*…" and instead use a form of words such as "*it is expected"* or *"it is hoped …".* IGARD noted that some of the information in section 5(d) was not clear and suggested that it was updated to ensure that it was written in a language suitable for a lay reader, and that further consideration was given to the public audience of NHS Digital's data release register. **Outcome:** recommendation to approve subject to the following conditions: 1. In respect of the s251 HRA CAG support: a) To provide written confirmation from HRA CAG that they are content that no amendment to the HRA CAG support is required in respect of the additional purpose of processing; or, b) To provide written evidence that a suitable amendment has been submitted to, and approved by, HRA CAG. c) In either case to upload written evidence to NHS Digital's CRM system. 2. To provide written confirmation that the proposed processing is compatible with the legal basis for the flow of medicines data from NHS BSA to PHE.

	The following amendments were requested: 1. In respect of the information outlined within the VICORI privacy notice that *"VICORI will act as data controller"*: a) To provide a statement in section 5 explaining why VICORI are **not** considered joint Data Controllers and / or Data Processors; or, b) To update the application throughout to reflect that VICORI **are** considered joint Data Controllers and / or Data Processors. 2. Noting the conflicting statement in the VICORI privacy notice that patient data can be removed if patients wish, to clarify in section 5(b) how this is reconciled with the statement that data will not be re-identified. 3. To update the information in section 3(a) that states pseudonymisation is a data minimisation process, noting that no data is flowing under this DSA. 4. To update section 1 and section 5(a) with justification of the UK GDPR Legal basis cited. 5. To update section 5(d) to use a form of wording such as "*it is expected"* or *"it is hoped …"*, rather than "*it will…*". 6. To update section 5(d) to ensure it is written in language suitable for a lay reader and that consideration is given to the public audience of NHS Digital's data release register. It was agreed the condition would be approved out of committee (OOC) by IGARD members.
3.2	<u>UK Biobank: R3 & R5 - MR1109 - UK Biobank (Presenter: Vicky Byrne-Watts) NIC-08472-V9S6K v13.4</u> **Application:** This was a renewal application for identifiable Civil Registration (Deaths) data, Demographics data, Emergency Care Data Set (ECDS), Hospital Episode Statistics (HES) Accident and Emergency (A&E), HES Admitted Patient Care (APC), Improving Access to Psychological Therapies (IAPT) Data Set, Mental Health Services Data Set (MHSDS) and National Diabetes Audit (NDA) data. It was also an amendment to request the following datasets: 1) COVID-19 Vaccination Status data; 2) COVID-19 Hospitalization in England Surveillance System; 3) Medicines dispensed in Primary Care (NHS Business Services Authority (NHS BSA) data). The overall purpose of the research is to create a prospective epidemiological resource of 500,000 people aged 45-69 at the time of recruitment from around the UK. The study cohort consists of 466,818 patients, who have consented to share their information. **Discussion:** IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 1st September 2020 and the 8th September 2020. IGARD noted that this application had been reviewed at the GPES Data for Pandemic Planning and Research (GDPPR) – Profession Advisory Group (PAG) on the 16th September 2020, (notes from that meeting had been attached to the IGARD minutes from the 24th September 2020). IGARD confirmed that they were of the view that the **most recent** consent materials provided the appropriate legal gateway and were broadly compatible with the processing outlined in the application. IGARD noted that the application had previously been to IGARD, for the addition of the GDPPR data, however queried why this was not listed as a dataset within section 3 (Datasets Held / Requested) of the application. NHS Digital advised IGARD, that the applicant had

	confirmed that they no longer required the GDPPR data, and that the GDPPR data already held would be destroyed and a data destruction certificate would be sent to NHS Digital. IGARD noted the verbal update from NHS Digital, and asked that the application was updated throughout to reflect that the GDPPR data was no longer required, and that the applicant would provide a data destruction certificate in due course. IGARD noted the limitations within the Direction amendment letter, dated the 9th August 2019, and queried if this extended to data when disseminated from NHS Digital, for example, in this case, the Medicines dispensed in Primary Care NHS BSA dataset; and asked that NHS Digital clarified with Privacy, Transparency and Ethics (PTE); and if it did extend to data disseminated from NHS Digital, that the application was updated accordingly. IGARD also asked that a special condition was inserted in section 6 (Special Conditions), that any use of the Medicines dispensed in Primary Care NHS BSA data, must be within the parameters of the relevant Direction authorising the collection. IGARD noted that in line with the relevant Direction, the use of the COVID-19 Vaccination Status and COVID-19 Hospitalization in England Surveillance System to COVID-19 dataset, would be restricted; and asked that for transparency, section 5 (Purpose / Methods / Outputs) was updated, to reflect that there may be restrictions on the purpose of use of these datasets. IGARD noted that section 2(c) (Territory of Use) stated that the territory of use was *"worldwide"*, and queried how this would work, noting that as per NHS Digital's public-facing UK General Data Protection Regulation (GDPR) information on its website, some of NHS Digital's datasets had geographical restrictions, such as England and Wales, UK or EEA. IGARD asked that NHS Digital provided written confirmation that the use of the NHS Digital datasets requested that had geographical restrictions, were compatible with the worldwide use as described by the application. IGARD queried if the Data Protection Impact Assessment (DPIA) had been updated to reflect the increased volume of data associated with the dissemination of the additional datasets, noting that they had not had sight of this; and asked that section 1 (Abstract) was updated with confirmation. IGARD suggested that if the DPIA had not been updated, then this should be revised as appropriate, to include the increase in volume of data included with the amendment. IGARD noted that Article 9(2)(j) of the UK General Data Protection Regulation (GDPR) was cited as the legal basis for the processing, however asked that section 1 and section 5 were updated, to correctly list the Data Protection Act (DPA) 2018 Schedule 1 Part 1 references, and to clearly describe how the schedule conditions are met. IGARD noted the statement in section 5(b) (Processing Activities) *that "…primary care data collected from GP system suppliers…"*, and asked that this was updated to correctly state that the primary care data was collected from GP systems, noting that GP system suppliers are Data Processors. IGARD queried the response in section 5(e) (Is the Purpose of this Application in Anyway Commercial) that there was *"no"* commercial element, however noting the applicant does supply data to commercial organisations, asked that section 5(a) (Objective for Processing) was updated to provide details of the commercial element of the application; and in line with the published NHS Digital DARS Standard for Commercial Purpose. IGARD noted the yielded benefits outlined in section 5(d) (Benefits) (iii) (Yielded Benefits), and queried if **all** the information provided was relevant, in light of the significant benefits already highlighted in section 5(d) (ii); and asked that the yielded benefits were reviewed in line with

	the published NHS Digital's DARS Standard for Expected Measurable Benefits, and updated as appropriate. IGARD queried if any of the outputs outlined in section 5(c) (Specific Outputs Expected) had influenced the development of guidelines and public health policy; and if so, that the yielded benefits were updated accordingly. IGARD suggested that section 5(d) be updated to remove reference to "*it will*…" and instead use a form of words such as "*it is expected"* or *"it is hoped …".* IGARD noted that section 7 (Ethics Approval) incorrectly stated that ethics approval was **not** required, and asked that this was updated to correctly note that ethical approval was required, and was in place. IGARD noted the references throughout section 5 to *"mental health disorder"*, and noting that section 5 formed NHS Digital's public data release register, asked that this was updated, with an alternative, more sensitive term, such as *"mental health condition"*. IGARD noted the reference in section 5 to *"lifestyle"*, and noting that this may not be within the control or agency of the patient, asked that, as section 5 formed NHS Digital's public data release register, that this was updated with a different form of words, for example, social or economic determinations of health. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the size and complexity of the datasets. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 1 and section 5 in respect of the UK GDPR Article 9(2)(j) legal basis to correctly list the DPA 2018 Schedule 1 Part 1 references and clearly describe how the schedule conditions are met. 2. To update the application throughout to reflect that GDPPR data is no longer required by the applicant and that the applicant will be providing a data destruction certificate (as per NHS Digital's verbal update). 3. In respect of the Medicines dispensed in Primary Care NHS BSA dataset: a) NHS Digital to clarify with PTE, in respect of the NHS BSA dataset, whether the limitations within the Direction amendment letter (9th August 2019) extend to data when disseminated from NHS Digital, and if so, to update the application accordingly. b) To insert a special condition in section 6, that any use of the Medicines dispensed in Primary Care NHS BSA data must be within the parameters of the relevant Direction authorising that collection. 4. NHS Digital to provide written confirmation that the use of the NHS Digital datasets that have geographical restrictions (as per the NHS Digital public-facing UK GDPR information on its website) are compatible with worldwide use as permitted by the application. 5. To update section 5 to reflect that in respect of the COVID-19 datasets request, there may be restriction on the purpose of use. 6. To update section 5(a) in line with the published NHS Digital DARS Standard for Commercial Purpose, to provide details of the commercial element of the application.

	7. To consider the sensitive use of language section 5 forms NHS Digital's public data release register, for example: a) To update section 5, to amend the references to *"mental health disorder"* to an alternative such as *"mental health condition"*. b) To update reference in section 5 to *"lifestyle"* to another form of wording, since this may not be within the control or agency of the patient, for example, social or economic determinations of health. 8. To update section 7 to note that ethical approval is required and is in place. 9. To confirm in section 1 if the DPIA has been updated to reflect the increased volume of data associated with the dissemination of the additional datasets. 10. To update section 5(b) to state that the primary care data is collected from GP systems (not GP system suppliers who are Data Processors). 11. In respect of the benefits: a) To review the yielded benefits in section 5(d) (iii) in line with the published NHS Digital's DARS Standard for Expected Measurable Benefits, and consider if all the information provided is relevant in light of the significant benefits already highlighted. b) To update section 5(d) (iii) to confirm if the outputs have influenced the development of guidelines and public health policy. c) To update section 5(d) to use a form of wording such as "*it is expected"* or *"it is hoped …"*, rather than "*it will…*". The following advice was given: 1. IGARD advised that the DPIA should be updated to include the increase in volume of data included with this amendment if this has not already been undertaken. 2. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the size and complexity of the datasets. 3. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the size and complexity of the datasets.
3.3	King's College London: Investigating the association between X-ray guided endovascular aortic aneurysm repair and incidence of cancer (Presenter: Vicky Byrne-Watts) NIC-264102-D2X7J V0.12 **Application:** This was a new application for identifiable Hospital Episode Statistics (HES) Admitted Patient Care (APC) data for the purpose of a study aiming to identify the potential association between X-ray guided endovascular aortic aneurysm repairs (EVAR), which expose patients to radiation both during the procedure, and follow-up CT scans, and future incidence of cancer. Defining the risk of cancer after EVAR will contribute to the process of informed consent and decision making between open aneurysm repair and EVAR. The cohort in this study are all patients over 50 years old who have undergone aortic aneurysm repairs between January 2000 and December 2018, and contains approximately 40,000 individuals; and is relying on s251 of the NHS Act 2006 for the flow of data to NHS Digital. NHS Digital advised IGARD that the Data Protection Act (DPA) Registration for King's College London (KCL) had now expired, and that they would need to confirm with them if this had been updated.

	Discussion: IGARD welcomed the application and noted the importance of the study. IGARD noted the verbal update from NHS Digital in respect of the DPA Registration for KCL expiring, and asked that section 1(b) (Data Controller(s)) was updated accordingly to reflect the updated expiry date. IGARD confirmed that they were of the view that the s251 support provided an appropriate legal gateway to support the processing outlined in the application. IGARD queried the references in the application that *"date of surgery"* would flow as an identifier, noting that the s251 Health Research Authority Confidentiality Advisory Group (HRA CAG) approval did not cover the flow of this data and asked that the application was updated throughout to reflect that *"date of surgery"* would not be flowing as an identifier. IGARD noted that the term *"depersonalised"* had been used within section 1 (Abstract) and section 5(b) (Processing Activities), and suggested it was clarified that the data was *"pseudonymised"*. IGARD queried the statement in section 1 and section 5(b) that *"Follow-up on NCRAS will continue to December 2020…"*, and asked that this was reviewed, and amended as appropriate. IGARD noted the statement in section 5(a) (Objective for Processing) *"The pseudonymised data received by KCL will be stored on one password protected university computer…"*, and queried if this was correct, for example, did multiple computers store the data, was encryption as well as a password used to protect access to the university computer, and were there any back-ups held on additional devices. IGARD asked that the statement was reviewed, and amended as appropriate to reflect the correct scenario. In addition, IGARD suggested that if not already in place, that the applicant may wish to consider an appropriate back-up of the NHS Digital data, and in line with their organisation's Data Security and Protection Toolkit (DSPT). IGARD noted the statement in section 5(a) *"The dissemination of the aggregated results of this study pose no risk to the public"*, and asked that this was updated to more accurately reflect that there was *"minimal"* or *"low risk"*. IGARD suggested that section 5(a) be updated to remove reference to "*it will*…" and instead use a form of words such as "*it is expected"* or *"it is hoped …".* IGARD noted the statement in section 5(b) that *"…those under the age of 50 have a different pathology which makes thin unsuitable for this study."*, and asked that the application was reviewed throughout, to ensure there were no grammatical or typographical errors that may alter the sense of what was being said. IGARD queried the target date for completion of analysis in section 5(c) (Specific Outputs Expected), that stated this was Autumn 2021; and asked that this was reviewed and updated if appropriate, ensuring this was realistic and achievable. **Outcome:** recommendation to approve The following amendments were requested: 1. To update the application throughout, to clarify that the *"date of surgery"* is not flowing as an identifier, noting that this is not covered by the HRA CAG approval. 2. To clarify in section 1 and section 5(b) that the *"depersonalised"* data is *"pseudonymised"*.

	3. To review the statement in section 1 and section 5(b) that the follow-up on NCRAS will continue to *"December 2020"* and amend as appropriate. 4. To review the statement in section 5(a) that *"…data received by KCL will be stored on one password protected university computer…"*, and amend as appropriate, for example, to reflect if multiple computers store the data, if encryption as well as a password were used, and if there were any back-ups held on additional devices. 5. To update the statement in section 5(a) from there being *"no risk to the public"* of the dissemination of the aggregated results, to there being *"minimal"* or *"low risk"*. 6. To update section 5(a) to use a form of wording such as "*it is expected"* or *"it is hoped …"*, rather than "*it will…*". 7. To review the application throughout for any grammatical or typographical errors that may alter the sense of what is being said, for example, *"…makes thin unsuitable…"*. 8. To review the target date for completion in section 5(c) which currently states Autumn 2021, and update if appropriate, ensuring this is realistic and achievable. 9. To update section 1(b) to reflect the KCL's updated DPA Registration expiry (as per NHS Digital's verbal update). The following advice was given: 1. IGARD suggested that if not already in place, that the applicant may wish to consider an appropriate back-up of the NHS Digital data, and in line with their organisation's DSPT.
3.4	<u>Manchester University NHS FT: Advanced cardiovascular risk prediction in the acute care setting (Presenter: Vicky Byrne-Watts) NIC-304146-M5F6Y V1.2</u> **Application:** This was an amendment application to add Civil Registration (deaths) data to the existing Data Sharing Agreement (DSA). The purpose is for a study, seeking to improve the short term and long-term treatment of cardiovascular disease by determining whether a diagnostic chest pain algorithm can be updated with machine learning techniques to prevent known loss in accuracy over time. The University of Manchester aim to maintain and improve an existing acute myocardial infarction clinical prediction model currently in clinical use and in the process validate a method for updating all clinical prediction models. In addition, they intend to examine the prognostic value of emergency department data in predicting long term cardiovascular outcomes. The study will consist of two cohorts, the first which will consist of approximately 21,000 (1-10 year outcome) and the second, which will consist of approximately 15,000 (1 year outcome); and is relying on s251 of the NHS Act 2006 for the flow of data to NHS Digital. **Discussion:** IGARD confirmed that they were of the view that the s251 support provided an appropriate legal gateway to support the processing outlined in the application. IGARD noted that NHS Digital's previous review of the University of Manchester's privacy notice discovered deficiencies, and notwithstanding the representation in section 4 (Privacy Notice), it needs to be confirmed that the University of Manchester now had a compliant UK GDPR privacy notice. IGARD noted that the applicant was requesting "*date of registration"* of death data, and queried what the purpose would be of receiving this data; and noting that there was no explanation within the application, asked that section 3(a) (Data Access Already Given) and

	section 5(a) (Objective for Processing) were updated to include a clear justification of the inclusion of this data; in line with NHS Digital's DARS Standard for Data Minimisation. IGARD noted that some of the information in section 5(b) (Processing Activities) was not clear and, noting this formed part of NHS Digital's public data release register suggested that it was updated to ensure that it was written in a language suitable for a lay reader, for example, when referring to *"Cox regression";* and that further consideration was given to the patient audience and how the language could be perceived. IGARD noted that section 5(d) (Benefits) provided details of who would form part of the primary target audience for the study, which included a number of health professionals, including GPs; however the same information in section 5(c) (Specific Outputs Expected) excluded reference to GPs. IGARD asked that for consistency, section 5(c) was updated to align with section 5(d) and reflect that GPs would also be part of the target audience, if this reflected the factual scenario. IGARD suggested that section 5(d) be updated to remove reference to "*it will*…" and instead use a form of words such as "*it is expected"* or *"it is hoped …".* IGARD the statement in section 5(d) *"…it makes efficient use of NHS services maximising each patient encounter for the greatest benefit to patient's health."*, and asked that this was updated, to ensure that the language used is appropriate and realistic in its expectations. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 3(a) and section 5(a), to include a clear justification for the inclusion of the "*date of registration"* of death in line with NHS Digital's DARS standard for Data Minimisation. 2. To update section 5(b) to ensure it is written in language suitable for a lay reader and that consideration is given to the public audience of NHS Digital's data release register (for example when referring to *"Cox regression"*). 3. To update section 5(c) to reflect that *"GPs"* will form part of the primary target audience, as outlined in section 5(d). 4. To update section 5(d) to use a form of wording such as "*it is expected"* or *"it is hoped …"*, rather than "*it will*…". 5. To amend section 5(d), to ensure that the language related to *"patient encounter"* is appropriate and realistic in its expectations. The following advice was given: 1. IGARD noted that NHS Digital's previous review of the University of Manchester's privacy notice discovered deficiencies, and notwithstanding the representation in section 4 (Privacy Notice), it needs to be confirmed that University of Manchester's now have a compliant UK GDPR privacy notice.
3.5	Renal Registry: Commissioning through Evaluation (CtE) Rituximab for Idiopathic Membranous Nephropathy (IMN) (Presenter: Vicky Byrne-Watts) NIC-386376-Z1H5J V0.9 **Application:** This was a new application for pseudonymised Civil Registration (Deaths) data, Emergency Care Data Set (ECDS), Hospital Episode Statistics (HES) Accident and Emergency (A&E), HES Admitted Patient Care (APC), HES Critical Care and HES Outpatients.

	The purpose is to process data from NHS Digital that will be linked to data held by the National Registry of Rare Kidney Diseases (RaDaR) for the purposes of analyses for the Commissioning through Evaluation (CtE) programme: 'Rituximab for the treatment of idiopathic membranous nephropathy (IMN) in adults'. The purpose is for a programme of work to help NHS England decide whether to routinely commission rituximab and its biosimilars for the treatment of IMN. Currently in the UK, rituximab is only prescribed for IMN patients for whom all other options of immunosuppressive treatment have failed, or there is a contraindication for prescribing them. RaDaR is an initiative designed to pull together information from patients with certain rare kidney diseases to develop a better understanding of how these illnesses affect people and to support research into these diseases. The study cohort, consists of 190 patients, who have consented to share their information. **Discussion:** IGARD confirmed that they were of the view that the **most recent** consent materials provided the appropriate legal gateway and was broadly compatible with the processing outlined in the application. IGARD queried the approval role of the National Registry of Rare Kidney Diseases (RaDaR) Operational Management Board (OMB), and were advised by NHS Digital, that approval would only be sought from the OMB if there was to be direct contact with patients, for example, re-consenting, which was not the case for this application. IGARD noted the verbal update from NHS Digital, however noted that in supporting document 2.2, the patient information sheet (PIS) (version 10), there was a clear statement that the sharing of data would be approved by the OMB and the Lead Clinician; and asked that evidence was provided, that the OMB and Lead Clinician, have approved the sharing of data with KiTEC in accordance with the information provided to patients in the PIS. IGARD noted in in section 5 (Purpose / Methods / Outputs), that The Renal Association had worked closely with King's Technology Evaluation Centre (KiTEC), to develop the research questions for the study; and in addition, the National Institute for Health and Care Excellence (NICE), and NHS England had also been involved with the development of the research questions. IGARD therefore queried the information in section 1 (Abstract) and section 1(b) (Data Controller(s)) that the Renal Association was the **sole** Data Controller, and asked that in line with NHS Digital's DARS Standard for Data Controllers, written confirmation was provided that King's College London as the legal entity for KiTEC, NHS England and NICE, were not considered joint Data Controllers, in light of their activities as outlined in section 5. If, however, King's College London as the legal entity for KiTEC, NHS England and NICE, were considered joint Data Controllers, IGARD asked that the application was updated throughout as may be required, to reflect the factual scenario. IGARD also suggested that in respect of the data controllership, the applicant may wish to consider the European Data Protection Board "Guidelines 07/2020 on the concepts of controller and processor in the GDPR"(page 13), in supporting their understanding of the relationships and data controllership within this application. IGARD queried the statement in section 5(a) (Objective for Processing) that *"RaDaR falls under the Renal Association"*, and asked that further clarity was provided on this in section 5(a), as it was not clear what the purpose of the statement was. IGARD queried the statement in section 5(c) (Specific Outputs Expected) *"NICE will also use the findings to consider guidelines for IMN treatment and rituximab"*, and queried what

	relationship the study had with NICE, and asked that section 5(c) was updated with further clarity. IGARD queried the response in section 5(e) (Is the Purpose of this Application in Anyway Commercial) that there was *"no"* commercial element, however queried if KiTEC, or King's Health Partners, have any relevant commercial interests; and were advised by NHS Digital that the applicant had confirmed that KiTEC and King's Health Partners had no commercial interest in the study. NHS Digital noted the verbal update from NHS Digital, and asked that for future reference, section 1 was updated to reflect this. IGARD noted the conflicting information within section 5(b) (Processing Activities) that NHS Digital data would not leave The Renal Association, and also that it would be held on King's College London servers; and asked that further clarity was provided in section 5(b), if the NHS Digital data ever leaves The Renal Association. IGARD noted the statement in section 5(a) that "*there are no moral or ethical issues…"*, and asked that this was amended, to address the recent research indicating the relationship of rituximab to adverse outcomes in COVID-19 and reduced vaccine efficacy. IGARD noted a number of acronyms in section 5 and asked that as this public facing section 5 formed NHS Digital's public data release register, it was updated to ensure that all acronyms and technical terms upon first use were expanded and clearly defined with a supportive explanation in a language suitable for a lay reader, for example, *"GEMRITUX"*, *"MENTOR"* and *"STARMEN"* trials. IGARD suggested that section 5 be updated to remove reference to "*it will*…" and instead use a form of words such as "*it is expected"* or *"it is hoped …".* IGARD noted the benefits outlined in section 5(d) (Benefits), however asked that these were expanded, to explicitly state the benefits of adding another treatment, for example, in terms of improved quality of life or life expectancy. IGARD queried the statement in section 1 *"If a research patient reaches 18 years of age without consenting or withdrawing, their RaDaR record will be frozen…"*, and asked that this was updated to confirm that no data was being requested for the *"frozen"* records. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent; due to the complex relationship between the commissioning and delivering organisations in respect of data controllership. **Outcome:** recommendation to approve subject to the following conditions: 1. In respect of data controllership, and in line with NHS Digital's DARS Standard for Data Controllers: a) To provide written confirmation that King's College London as the legal entity for KiTEC is **not** a joint Data Controller, given KiTEC's activities outlined in the application. r. b) To provide written confirmation that NHS England is **not** a joint Data Controller, given NHS England's activities outlined in the application. c) To provide written confirmation that NICE is **not** a joint Data Controller, given NICE's activities outlined in the application. To update the application throughout, as may be required, to reflect the factual scenario.

	2. To provide evidence that the OMB and Lead Clinician, have approved the sharing of data with KiTEC in accordance with the information provided to patients in the PIS as stated in Section 5. The following amendments were requested: 1. To provide further clarity in section 5(b) if the NHS Digital data ever leaves the Renal Association, in light of information that states it will be held on KCL servers. 2. To update section 5(c) to provide further clarity on the relationship with NICE. 3. To amend the reference to there being *"no moral or ethical issues"* in section 5(a), to address the recent research indicating the relationship of rituximab to adverse outcomes in COVID-19 and reduced vaccine efficacy. 4. To provide further clarity on the statement in section 5(a) that *"RaDaR falls under the Renal Association"*. 5. As section 5 forms NHS Digital's public data release register, to amend section 5 to ensure acronyms be defined upon first use, and technical terms are explained in a manner suitable for a lay audience, for example, *"GEMRITUX"*, *"MENTOR"* and *"STARMEN"* trials. 6. To update section 5 to use a form of wording such as "*it is expected"* or *"it is hoped …"*, rather than "*it will…*". 7. To update section 5(d) to explicitly state the benefits of adding another treatment in terms of improved quality of life or life expectancy. 8. To update section 1 to confirm that no data is being requested for the *"frozen"* records. 9. To update section 1 to reflect the verbal update from NHS Digital, that KiTEC have **no** commercial interest. The following advice was given: 1. IGARD suggested that in respect of the data controllership, the applicant may wish to consider the European Data Protection Board guidelines (page 13), in supporting their understanding of the relationships and data controllership within this application. 2. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the complex relationship between the commissioning and delivering organisations in respect of data controllership. 3. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the complex relationship between the commissioning and delivering organisations in respect of data controllership.
3.6	<u>Public Health England (PHE): D1.1 - PHE Single Data Sharing Agreement (Presenter: Kimberley Watson) NIC-343380-H5Q9K-v10.2</u> **Application:** This was an amended active application, for pseudonymised Civil Registration (Deaths) data, Community Services Data Set (CSDS), Diagnostic Imaging Dataset (DIDs), Emergency Care Data Set (ECDS), Health Survey for England, Hospital Episode Statistics (HES) Accident and Emergency (A&E), HES Admitted Patient Care (APC), HES Critical Care, HES Outpatients, Improving Access to Psychological Therapies (IAPT) Data Set, Mental Health and Learning Disabilities Data Set (MHLDDS), Mental Health Services Data Set (MHSDS), Maternity Services Data Set (MSDS), National Diabetes Audit (NDA), Primary Care Mortality Data; and identifiable NHS 111 Online Dataset, ECDS, Secondary Uses Service (SUS+) data.

	PHE is a direct provider of health protection and health improvement services to patients and the public in England. The successful fulfilment of its remit depends on its ability to process data on the health status of patients and the public, and on the social, economic and environmental factors that determine health. Some of the data it uses it collects directly, but PHE also depends on appropriate and timely access to other sources of health and care data, such as the health status and healthcare provider activity data collected at a national level by NHS Digital. NHS Digital advised IGARD that this Data Sharing Agreement (DSA), is the main DSA for PHE, and superseded the Memorandum of Understanding between NHS Digital and PHE. The imminent transfer of PHE operations to the new UK Health Security Agency (UKHSA), will mean this current DSA will need to be revisited and aligned with the new organisational structure before the end of September 2021. **Discussion:** IGARD welcomed the application which came for advice and without prejudice to any additional issues that may arise when the application is fully reviewed. IGARD noted the verbal update from NHS Digital outlining the purpose of the IGARD review. IGARD noted that previous versions of this application had previously been approved by the Senior Information Risk Owner (SIRO) without IGARD review. IGARD noted the volume of information contained within the overarching DSA, and the substantial number of datasets requested, as outlined in section 3 (Datasets Held / Requested); and discussed whether it was possible for this DSA to be separated into smaller and more manageable DSAs, for example, by purpose, noting that there was wide range of purposes listed within section 5 (Purpose / Methods / Outputs). IGARD queried the legal basis for the dissemination of the data outlined in section 3, and asked that this was reviewed to ensure that the processing outlined, aligned with the legal basis for dissemination, for example, in respect of the Article 6 and Article 9 of the UK General Data Protection Regulation (UK GDPR). IGARD suggested that NHS Digital may wish to consider breaking this application into separate and more manageable DSAs, in light of the volume of information, the wide range of purposes and the forthcoming organisational changes. IGARD asked that the application was reviewed and updated throughout, to reflect the flows of data and the legal bases. In addition, IGARD also asked, that noting the volume of datasets requested, that it would be helpful at a future IGARD review if a data flow diagram was provided that clearly outlined the flow(s) of data. IGARD noted the volume of data fields listed in section 5(a) (Objective for Processing) and suggested that these were removed, as they were not necessary to include. IGARD noted the useful information within section 1 (Abstract) that outlined the version history, however asked that for the purpose of a clear audit trail, this was updated to also include the relevant dates. IGARD noted that section 2(a) (Processing Location(s)) and section 2(b) (Storage Location(s)) only listed one processing and storage location, and, noting that PHE are a large organisation with multiple sites, asked that this was reviewed and updated as necessary to reflect all the processing and storage locations.

	IGARD discussed the merits of NHS Digital carrying out an audit to identify if there were any other significant active DSAs that have not previously been reviewed by IGARD. **Outcome:** IGARD welcomed the application which came for advice and without prejudice to any additional issues that may arise when the application is fully reviewed. 1. IGARD advised that the application should be reviewed and updated throughout, to reflect the flows of data and their legal bases. 2. IGARD suggested that NHS Digital may wish to consider breaking this application into separate and more manageable DSAs, in light of the volume of information, the wide range of purposes and the forthcoming organisational changes. 3. IGARD advised that NHS Digital consider carrying out an audit to identify if there are any other significant historic DSAs that have not previously been reviewed by IGARD.
4	<u>Returning Applications</u> IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. Due to the volume and complexity of applications at today's meeting, IGARD were unable to review any applications as part of their oversight and assurance role.
5	<u>COVID-19 update</u> To support NHS Digital's response to COVID-19, from Tuesday 21st April 2020, IGARD will hold a separate weekly meeting, to discuss COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 urgent applications that have been submitted to NHS Digital. Although this is separate to the Thursday IGARD meetings, to ensure transparency of process, a meeting summary of the Tuesday meeting will be captured as part of IGARD's minutes each Thursday and published via the NHS Digital website as per usual process. IGARD noted that due to the Bank Holiday, and as agreed between IGARD and NHS Digital, the COVID-19 response meeting on Tuesday 1st June 2021 was cancelled.
6 **6.1**	<u>AOB:</u> <u>GP Data Sharing Principles (Presenter: Liz Gaffney)</u> NHS Digital attended the meeting to provide a brief overview of the draft GP Data Sharing Principles. Noting that the IGARD Chair and IGARD Deputy Chair had already provided initial feedback, this was an opportunity to engage other IGARD members in the process. The IGARD members present thanked NHS Digital for the engagement on this issue, and provided some initial verbal feedback, and advised that further written feedback would be shared with NHS Digital once members had reviewed the document provided. There was no further business raised, the Deputy IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 28/05/21

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-408171-X7F8W	University College London (UCL)	22/04/21	1. To provide written confirmation that UCL is **not** a joint Data Controller, particularly noting the reference to them being a research partner, and being involved in the development and operation of the C&I database. 2. In respect to the honorary contracts: a) In line with NHS Digital's policy, to provide further detail of what contractual arrangements are in place to protect the data, when accessed by non-substantive employees. For example, counter signatory by the home research institution and / or employer on relevant honorary contracts. b) To remove the reference to the *"DPA 1998"* and update as appropriate. c) To provide written confirmation that MSc and PhD students from UCL, are covered by the honorary contract arrangements and that they also provide the appropriate coverage for a student.	IGARD Members	Quorum of IGARD Members	*N/A*

In addition, a number of applications were processed by NHS Digital following the Precedents approval route. IGARD carries out oversight of such approvals and further details of this process can be found in the Oversight and Assurance Report.

In addition, a number of applications were approved under class action addition of:

Liaison Financial Service and Cloud storage:

- None

Optum Health Solutions UK Limited Class Actions:

- None

Graphnet Class Actions:

- None