Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 12 November 2020

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Prof. Nicola Fear	Specialist Academic Member
Kirsty Irvine (Chair)	IGARD Lay Chair
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Dr. Maurice Smith	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Vicky Byrne-Watts	Data Access Request Service (DARS)
Garry Coleman	Data Access Request Service (DARS) (Observer: Item 2.1)
Dave Cronin	Data Access Request Service (DARS)
Louise Dunn	Data Access Request Service (DARS)
Duncan Easton	Data Access Request Service (DARS)
Frances Hancox	Data Access Request Service (DARS)
Richard Hatton	Clinical Informatics and Deputy Caldicott Guardian (Observer: items 2.1 – 2.4)
Karen Myers	IGARD Secretariat
Kimberley Watson	Data Access Request Service (DARS)
Vicki Williams	IGARD Secretariat

1	**Declaration of interests:** Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising on COVID-19.

	Nicola Fear noted a professional link with Kings College London [NIC-144761-Y3X9Y] but noted no specific connection with the application or staff involved and it was agreed that this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 5th November 2020 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	**Data Applications**
2.1	<u>NHS Northamptonshire CCG: DSfC - NHS Northamptonshire CCG - RS, COMM & IV (Presenter: Duncan Easton) NIC-362252-M1X0V</u> **Application:** This was a renewal application for pseudonymised Secondary Uses Service (SUS+), Local Provider Flows, Mental Health Minimum Data Set (MHMDS), Mental Health Learning Disability Data Set (MHLDDS), Mental Health Services Data Set (MHSDS), Maternity Services Data Set (MSDS), Improving Access to Psychological Therapy (IAPT), Child and Young People Health Service (CYPHS), Community Services Data Set (CSDS), Diagnostic Imaging Data Set (DIDS), National Cancer Waiting Times Monitoring Data Set (CWT), Civil Registries Data, National Diabetes Audit (NDA), Patient Reported Outcome Measures (PROMs) and NHS e-Referral Service (e-RS). It was also an amendment to 1) add Newton Europe Limited as a Data Processor for Commissioning purposes; 2) add Prescribing Services Ltd as a Data Processor for Risk Stratification purposes; and 3) to add NHS e-Referral Service (e-RS) data. The overall purpose is for: Invoice Validation (IV) which is part of a process by which providers of care or services are paid for the work they do; Risk Stratification (RS) which is a tool for identifying and predicting which patients are at high risk or likely to be at high risk and prioritising the management of their care, and to provide intelligence to support the commissioning of health services. **Discussion:** IGARD noted that the application stated NHS Northamptonshire CCG was the sole Data Controller, however two senior iCAN individuals were noted within the application and based at *"…the COO at Kettering General Hospital and Deputy CEO at NHFT…"*. IGARD queried if these individuals were leading the 'pillars' that used data from NHS Digital, and if this was compatible with NHS Northamptonshire CCG being the sole Data Controller. IGARD asked that confirmation was provided that the relevant part of the iCAN project, that directly related to the application, was led by an individual from the applicant organisation. IGARD queried the references in section 5(a) to NHS Digital being a joint Data Controller, and were advised by NHS Digital that this was an error. IGARD noted the update and asked that these incorrect references were removed from the application. IGARD noted the statement in section 1 (Abstract) that *"…The partner organisation boards have all individually approved iCAN Phase one…"*, and raised the issues with NHS Digital that this arrangement and these boards were potentially undertaking a data controllership role and that Data Controllership was based on facts, as outlined in NHS Digital's DARS Standard for Data Controllers / Data Processors.

	IGARD queried if NHS Digital were assured that the appropriate protections were in place for the NHS Digital data being disseminated, and asked that section 1 was updated with a statement from the Data Security and Protection Toolkit (DSPT) Team, confirming that they were content. IGARD queried the mismatch between section 5(b) (Processing Activities), and the information provided in supporting document 2, the data flow diagram, for example, in respect of the role of the Prescribing Services Ltd. NHS Digital confirmed that the data flow diagram was incorrect and that this would be updated to correctly align with the information provided in section 5(b) of the application. IGARD noted and endorsed NHS Digital's review that the applicant did not meet NHS Digital's Standard for privacy notices. **Outcome:** recommendation to approve subject to the following condition: 1. To provide confirmation that the relevant part of the iCAN project (directly relating to the application) is led by an individual from the applicant organisation. The following amendments were requested: 1. To remove reference within the application to NHS Digital being a joint data controller. 2. To include in section 1 a statement from the NHS Digital DSPT team that they are assured that the appropriate protections in place for NHS Digital data. It was agreed the condition would be approved out of committee (OOC) by the IGARD Chair.
2.2	Liverpool City Council: DSfC - Liverpool City Council - Comm (Presenter: Duncan Easton) NIC-390508-S4J1N **Application:** This was a new application for pseudonymised Secondary Uses Service (SUS+), Mental Health Minimum Data Set (MHMDS), Mental Health Learning Disability Data Set (MHLDDS), Mental Health Services Data Set (MHSDS), Maternity Services Data Set (MSDS), Improving Access to Psychological Therapy (IAPT), Child and Young People Health Service (CYPHS), Community Services Data Set (CSDS), Diagnostic Imaging Data Set (DIDS), National Cancer Waiting Times Monitoring Data Set (CWT), Civil Registries Data (CRD), National Diabetes Audit (NDA), Patient Reported Outcome Measures (PROMs) and e-Referral Service (eRS). The local authority and CCG have a joint commissioning process established that works alongside GPs, provider market and voluntary organisations to develop an integrated system that meets growing population needs and creates a sustainable health and social care system for the future. The overall purpose is to provide intelligence to support the commissioning of health services. **Discussion:** IGARD welcomed the novel application which came for advice and without prejudice to any additional issues that may arise when the application is fully reviewed. IGARD noted that the application was to support Liverpool City Council with *"…a joint commissioning process…"* with NHS Liverpool CCG, however IGARD noted that NHS Liverpool CCG were not listed as either a Data Controller or a Data Processor, and queried how the processing would work. IGARD suggested that in respect of the data controllership that a number of options could be explored (noting NHS Digital's DARS Standard for Data Controllers / Data Processors) that: NHS Liverpool CCG were added as a Data Controller within this Data Sharing Agreement (DSA); that Liverpool City Council were added as a Data Controller within the overarching CCG's DSA, with the elements of the County Council

	processing added; or, that it was clearly distinguished how Liverpool City Council was carrying out this unique programme of work and was the **sole** Data Controller for this DSA. IGARD noted that the collaboration between the County Council and the CCG was not referenced within the application, and asked that section 5 (Purpose / Methods / Outputs) was updated to accurately reflect this. IGARD queried the references within the application to 'NHS Oldham CCG', and advised NHS Digital that Greater Manchester Shared Services was previously managed under a hosting arrangement by NHS Oldham CCG. However, since the 1st April 2020, this was no longer the arrangement and asked that any references to NHS Oldham CCG was removed, and the application was updated to accurately reflect the current arrangements for Greater Manchester Shared Services. IGARD noted the large volume of data requested and that this was to align with the same levels of data accessed by the CCG. IGARD queried if all the data was in fact required and if so, asked that a clear justification was provided for all the required datasets, both in terms of the proposed processing and the nature of the applicant, for example the request for the Diagnostic Imaging Data Set (DIDS). IGARD queried the statement under the heading 'Contract and Financial Management' in section 5(c*)* (Specific Outputs Expected) *"…The ability to validate claims that are not being made after an individual has died…"*; and asked that further clarity was provided of how claims were validated using pseudonymised data; and how claims were validated after an individual had died, noting that a claim has to be made before it can be validated. IGARD queried the statement in section 3(c) (Patient Objections) "…*National Opt-outs are not applied for pseudonymised data released for the purpose of Commissioning*….", and asked that the reference to the "…*purpose of Commissioning*…" was removed, since it was not relevant. IGARD noted the information in section 5(b) (Processing Activities), in relation to onward sharing for the purpose of direct care, and were advised by NHS Digital that this information was not relevant to this application. IGARD noted the update and asked that this reference was removed from the application. IGARD queried how the reporting was compulsory for the Local Authority to carry out as outlined in the application, noting that most Local Authorities were not in receipt of this data, and would therefore be unable to fulfil the mandatory report, and asked that further clarity was provided of how the reporting was classed as compulsory. IGARD queried the information in section 5(c) in relation to Local Authorities providing analysis on *"…whole system usage…"*, noting that this appeared to suggest that there would be some linkage with social care data; and asked that confirmation was provided in section 5 that linkage with social care data was **not** permitted under this DSA. IGARD noted in section 4 (Privacy Notice) that the privacy notice **did** meet the General Data Protection Regulation (GDPR) criteria, however section 1 (Abstract) indicated the privacy notice **did <u>not</u>** meet GDPR requirements and suggested section 4 be updated appropriately to reflect the correct information. **Outcome:** IGARD welcomed the novel application which came for advice and without prejudice to any additional issues that may arise when the application is fully reviewed. Significant risk areas to address: 1. In respect of the data controllership, to:

	a) Add NHS Liverpool CCG as a joint Data Controller to this DSA; or b) Add Liverpool City Council as a Data Controller within the overarching CCG DSA, with the elements of the County Council processing added; or c) Clearly distinguish how Liverpool City Council is carrying out this unique programme of work and is the sole Data Controller. 2. To provide a justification for all the required datasets, in terms of the proposed processing and nature of the applicant, for example requesting DIDs data. Other suggested amendments / clarifications: 3. To remove the reference to NHS Oldham CCG and to accurately reflect the current arrangements with Greater Manchester Shared Services. 4. To update section 3(c) to remove the reference to *"the purpose of Commissioning"*. 5. To update section 4 to correctly state that *"The Privacy Notice does **not** meet the criteria set"*. 6. To update section 5 to accurately reflect the collaboration between the County Council and the CCG. 7. To remove reference to onward sharing for direct care from section 5(b). 8. In respect of validating claims in section 5(c): a) To clarify how claims are validated using pseudonymised data. b) To clarify how claims are validated after an individual has died. 9. To clarify how the reporting is classed as compulsory. 10. To confirm in section 5 that linkage with social care data is not permitted under this agreement, in reference to *"whole system usage"*.
2.3	University of Oxford: R1 (D09) - Data support to COVID-19 RCT (Presenters: Vicky Byrne-Watts / Louise Dunn) NIC-365354-R3M0Q **Application:** This was an amendment application to 1) amend the frequency of the data disseminated that has already been approved 2) the addition of Cancer Registration Data on an annual basis, 3) the addition of Prescribing Data on a monthly basis, 4) the addition of a new arm added to the study, REGN-COV2, 5) the inclusion of new study documentation, including, new ethical approval, consent forms, Protocol and Patient Information Sheets. This RECOVERY Trial aims to compare several different treatments that may be useful for patients with COVID-19, which have been recommended by an expert panel that advises the Chief Medical Officer in England. This trial allows reliable assessment of the effects of multiple different treatments (including re-purposed and novel drugs) on major outcomes in COVID-19. **Discussion:** IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 21st April, 28th April, 5th May, 12th May, 19th May, 7th July and the 21st July 2020. IGARD noted that this application had been reviewed at the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 4th June 2020, and that notes from this meeting had been attached to the IGARD minutes from the 11th June 2020. IGARD advised NHS Digital that although revised consent materials had been provided with the application, as part of the papers to review, newer versions of the consent materials had already been published by the applicant prior to the meeting, and therefore, the materials received by IGARD were not the latest copies. Any comments would only be made on the materials presented for review.

	IGARD noted the new datasets that had been requested, and noting that they would be linked to the GDPPR data, suggested that NHS Digital made PAG aware of the new datasets and the proposed linkage via a verbal update at the Group's meeting. IGARD also noted that it was not clear within the application that the GDPPR data requested, was underpinned by The Health Service Control of Patient Information (COPI) Regulations 2002, and that once this expired, then the data would no longer flow; and asked that section 5 (Purpose / Methods / Outputs) was updated to clearly reflect this. IGARD suggested the applicant check with their patient and public involvement (PPI) Panel to ensure that the reference to, and explanation of, *"…avoiding live vaccines…"* for babies up to six months, was unequivocally clear to a general public audience, and that this did not detract from the baby immunisation programme. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 5 to make clear that the flow of GDPPR data is underpinned by the COPI Notice, and once this expires then the data will no longer flow. The following advice was given: 1. IGARD suggested that NHS Digital made PAG aware of the new datasets requested and the proposed linkage. 2. IGARD suggested the applicant check with their PPI Panel to ensure that the reference to and explanation of "avoiding live vaccines" for babies up to six months, is unequivocally clear to a general public audience (and does not detract from the baby immunisation programme).
2.4	<u>University of Oxford: RECOVERY Trial - Communications to Participants DSA (Presenters: Vicky Byrne-Watts) NIC-405749-N7T3M</u> **Application:** This was a new application for identifiable Demographics data, for the purpose of co-ordinating a feed of data in order for communications to be sent directly to the RECOVERY Trial Participants. Latest available address details will need to be provided by NHS Digital in order to facilitate this mail out of communications. Two types of communication are planned, one for adult participants in the trial, and the other for parents of children who are participants in the trial. This RECOVERY Trial, which is under Data Sharing Agreement NIC-365354-R3M0Q, aims to compare several different treatments that may be useful for patients with COVID-19, that have been recommended by an expert panel that advises the Chief Medical Officer in England. This trial allows reliable assessment of the effects of multiple different treatments (including re-purposed and novel drugs) on major outcomes in COVID-19. **Discussion:** IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 28th April, 5th May, 12th May, 19th May, 7th July, 21st July and 22nd September 2020. IGARD reviewed the application and noted a number of acronyms in section 5(a) (Objective for Processing) and asked that this public facing section be updated to ensure that all acronyms upon first use were expanded and if necessary, clearly defined with a supportive explanation in a language suitable for a lay reader, for example *"APS Group"*. Consent and Patient Information Sheet Material feedback:

	IGARD had a lengthy discussion on the communication to the cohort. IGARD expressed a concern that the consent materials informed participants that the only people allowed to look at the information about them and their health would be the doctors who are running the study, the staff at the study coordinating centre and regulatory authorities. This could be taken to preclude using an external data processor. In addition, although the materials mention direct contact, they do so only in the specific circumstances of finding out new information that might affect a person's decision to stay in the study. However, IGARD were very supportive of a communication to participants and suggested that NHS Digital may wish to draft a letter to the participants of the study; that included, but was not limited to: being written on the University of Oxford branded paper, and co-branded with NHS Digital, and making it explicitly clear that cohort members can withdraw **both** from receiving future communications, and the study, at any time and for any reason. In addition, IGARD also suggested that a brief explanation was added, that in keeping with the representations made in the consent materials and the patient information sheet, that the University of Oxford have not handled any of the cohort addresses, that this was done by NHS Digital and a trusted third party. IGARD also reiterated previous comments with regard to the *"return to sender"* address and suggested that this address could be either NHS Digital or the third-party mailshot provider. IGARD also suggested that prior to the communication being disseminated to cohort members, that this was taken to the relevant Ethics Committee, for information and / or comments. In addition to the letter, IGARD advised that the applicant's privacy notice was updated, as a matter of urgency, to ensure that role of the trusted third party mailshot provider was added, for transparency (either the name of the provider or a general category of processor; as required by the General Data Protection Regulation (GDPR)). Again, reiterating their support for the communication to the cohort, IGARD also offered NHS Digital additional out of committee support with the letter if required. **Outcome:** recommendation to approve The following amendment was requested: 1. IGARD noted a number of acronyms in section 5(a) (Objective for Processing) and asked that this public facing section be updated to ensure that all acronyms upon first use were expanded (and, if necessary, clearly defined with a supportive explanation in a language suitable for a lay reader). The following advice was given: 1. IGARD suggested that the applicant update their study website and consider the suggestions for the letter as set out in the minutes, to address the use of the mail shot provider (which would go some way to addressing both GDPR requirements and consent issues). 2. IGARD suggested that further iterations of consent and PIS expressly cover the possibility of trusted third parties being involved in communications. 3. IGARD suggested that the applicant considers the implications of the current wording of the materials that consent for access to healthcare records is taken for up to 10 years after the scheduled follow-up period, since the follow-up period will vary depending on individual circumstances (there will not be a single cut-off date for the cohort when requesting follow-up data).

2.5	University Hospitals of Derby and Burton NHS Foundation Trust: Regional variation in epidemiology of COVID-19 in England (Presenter: Kimberley Watson) NIC-391959-Q3C3G **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) and Civil Registrations data for the purpose of determining the regional incidence and case fatality (epidemiology) of hospitalised patients with COVID-19 disease in England, between 1st March 2020 and 30th June 2020 and who meet set criteria. The UHDB will also investigate the association between patient characteristics and patient outcomes in patients admitted with COVID-19 and Acute Kidney Injury (AKI) (previously referred to as Acute renal failure (ARF)) between 1st March 2020 and 30th June 2020 and who meet the set criteria, and explore the various determinants of mortality. The application was been previously considered on the 3rd September 2020 when IGARD had deferred pending: to provide a clearer explanation of the coding and code sets; in particular justification around the ICD-10 ARF codes being used as a proxy for a specific stage of AKI; to provide a clear description of the code sets for conditions with biological plausibility to a COVID outcome; to provide an explanation of the exclusion of maternity data for the data requested, and to add confirmation in section 1(b) that the security requirements for remote access have been deemed satisfactory by NHS Digital's Security Team. In respect of section 5(a): a) to ensure the correct number of COVID-19 deaths in the UK is reflected, b) to include a brief narrative with regard to the code sets, c) to acknowledge the level of interest of the study lead in relation to the key questions, d) to review the language used, for example the *"England, London and West Midlands were overwhelmed"*, 5) to provide a clearer description of AKI and the stages they are referencing. In respect of section 5(c): a) to remove the reference to *"new tools, algorithms and new technology"*, b) to provide narrative for the patient involvement of the dissemination of the outputs. In respect of section 5(d): a) to align the benefits as described with the aims and objectives as described in the protocol, b) to ensure the benefits are expressed in appropriate language that these are realistic and achievable, c) to include relevant target dates. To remove the statement that "the study is not in support of post-graduate research". **Discussion:** IGARD noted that the application had been updated to reflect most of the comments previously made. IGARD discussed deferral point 2, *"To provide a clear description of the code sets for conditions with biological plausibility to a COVID outcome."*; and asked that further justification was provided of how the code sets for conditions with biological plausibility to a COVID outcome were assessed, and how the determination was made. In addition, IGARD also asked that this was aligned with NHS Digital DARS Standard for Data Minimisation. IGARD noted that one of the previous deferral point (point 5d), was to review the language used, for example *"…England, London and West Midlands were overwhelmed…"*, and that the applicant had asked for this information to remain within the application. IGARD therefore suggested that this was amended slightly, to reflect that the *"…**NHS** in England, London and West Midlands…"* were overwhelmed. IGARD noted the reference to *"joint"* Data controller in section 1(b) (Data Controller(s)), and asked that this was removed because it was incorrect. IGARD queried the funding arrangements for the study, noting that the application did not contain any details; and asked that section 5 (Purpose / Methods / Outputs) and section 8(b) (Funding Sources) were updated with the source of the funding; and that confirmation was provided that the funding was ongoing and sufficient. IGARD also asked that any available

	funding documentation was uploaded to NHS Digital's Customer Relationship Management (CRM) system. **Outcome:** recommendation to approve subject to the following condition: 1. In respect of deferral point 2: a) To provide further justification of how the code sets for conditions with biological plausibility to a COVID outcome are assessed, and how the determination is made. b) To ensure this aligns with NHS Digital DARS Standard for Data Minimisation. The following amendments were requested: 1. To amend section 1(b) to remove the reference to *"joint"* Data Controller. 2. In respect of the funding: a) To update the source(s) of funding in section 5 and section 8b. b) To confirm that the funding is ongoing and sufficient. c) To upload any available funding documentation to NHS Digital's CRM system. 3. To amend the application to reflect that the *"**NHS** in England, London and West Midlands"* were overwhelmed. It was agreed the condition would be approved out of committee (OOC) by the IGARD Deputy Chair
2.6	Cegedim Rx Ltd: Cegedim Rx Ltd 2020 (Presenter: Frances Hancox) NIC-355818-H7T3C **Application:** This was a new application for pseudonymised Civil Registration data, Hospital Episode Statistics (HES) and Emergency Care Data Set (ECDS); for the purpose of supporting public health, epidemiological, clinical and health economics research, improvements in healthcare service delivery, treatment, technology appraisals and patient safety monitoring that are complementary to the work performed and products supplied by Cegedim Health Data. The data requested will create a licensed secondary healthcare large scale data resource that will enable research providing insight in important disease areas, with national coverage over patient population, time and space to understand the patient healthcare clinical experience. The objective of the data analysis is to provide a deeper understanding of actual clinical pathways as seen implemented in the data for all disease areas with a view to elicit the clinical phenotypes (categories) of patients as they traverse their care pathway and support understanding the variations in the delivery of care. **Discussion:** IGARD noted that this application was for a one-year agreement, and advised NHS Digital they were supportive of this. IGARD noted the reference in section 5(e) (Is the Purpose of this Application in Anyway Commercial) to the group of *"independent researchers and analysts"* who approved proposals, and asked that a copy of the group's Terms of Reference (ToR) were provided; and that the ToR governed the use of the data in line with NHS Digital's legal obligations in disseminating data, and the terms of the applicant's Data Sharing Agreement (DSA) and Data Sharing Framework Contract (DSFC) with NHS Digital. In addition, IGARD also asked for clarification whether the ToR expressly restricted use of the data to projects for, or engagements with, the limited permitted client list as this would be an essential element for use of NHS Digital data in this way. IGARD also queried if the group of independent researchers or analysts were an advisory or an approval group, and asked that further clarity was provided in section 5.

	IGARD noted the volume of data requested, and asked that in respect of data minimisation, the data requested was aligned with NHS Digital's DARS Data Minimisation Standard; and asked that written justification was provided in section 5 (Purpose / Methods / Outputs), for the requirement of the six years of data that had been requested. In addition, IGARD also asked that confirmation was provided that the applicant would delete the data on a rolling basis. IGARD queried if the applicant had any examples of the specific projects or programmes of work, that had been requested by permitted clients, and asked that section 5 was updated to reflect these; or that section 5 was updated with further details of the specific marketing plan for projects to be marketed to types of permitted clients. IGARD noted that section 5(e) (contained reference to a client list, and asked that this information was also replicated within the published part of section 5. IGARD noted that it was not clear in the application that the research would be carried out by **only** the Cegedim staff researchers, and that only Cegedim staff would have access to the data; and asked that section 1 (Abstract) and section 5 were updated to reflect this point. IGARD noted that the word *"licensed"* was used on multiple occasions in the application, and asked that section 5 was updated to remove any reference or suggestion that Cegedim would be receiving the data under licence or would be permitted to sub-licence further. IGARD noted that NHS Digital had assessed applicant's Legitimate Interest Assessment (LIA) against the Information Commissioner's Officer (ICO) checklist, and were content the requirements were met. IGARD asked that section 5(a) (Objective for Processing) was updated, to ensure that the reference to the specific Legitimate Interests was linked to the processing. IGARD also asked that the LIA was reviewed to make more specific reference to the processing, the nature of the applicant and the activities under this application. IGARD noted that the LIA specifically referenced work relating to "cancer", however the applicant was not requesting any cancer data; and advised that they would support the applicant requesting and receiving the Cancer Registration data, if there was a specific project that could be articulated in section 5. IGARD also noted that the LIA and privacy notice contained misleading statements, for example, that the data subjects could withdraw their consent for the use of this data; and asked that both the LIA and the privacy notice was updated to remove any misleading statements. IGARD noted that the applicant had listed the various datasets requested in section 5(a), and provided the various information they were requesting for each one; and agreed that this was really useful. In respect of this, IGARD queried the fields requested for the ECDS data, particularly the one that related to the *"location"* of the patient's injury; and asked that this was updated to clarify if the location of injury was referring to body site or geographical location. IGARD also noted the reference to *"high risk data"*, and asked that section 5 was updated to clarify what was meant by this. In addition, IGARD queried if waiting time and referral time could be extracted from the HES dataset, and asked for further confirmation. IGARD noted the outputs stated in section 5(c) (Specific Outputs Expected), however asked that further updates were made, to provide a clearer and more detailed description of the work planned. IGARD queried the reference to *"Recital 157"* of the General Data Protection Regulation (GDPR) in section 5(e), and asked that this was removed, since it was not directly relevant to the data that had been requested.

	IGARD noted the information in section 5(e) in respect of commercialisation and publishing the data in an open access manner; and asked that statements in relation to this, were compatible in both section 5(c) and section 5(e). IGARD suggested that, due to the purpose of the work outlined, the applicant may wish to consider whether having a patient or lay representation on the Committee, would be beneficial, particularly in respect of commercialisation of the outputs. IGARD asked that on return, a detailed analysis of the yielded benefits achieved should be provided in section 5(d) (Benefits) (iii) (Yielded Benefits). IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. 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. **Outcome:** recommendation to approve subject to the following conditions: 1. With reference to the group of *"independent researchers and analysts"* who approve proposals: a) To provide a written copy of the ToR. b) To ensure the ToR governs the use of the data in line with NHS Digital's legal obligations in disseminating data and the terms of the applicant's DSA and Data Sharing Framework Contract with NHS Digital. c) To ensure the ToR expressly restricts use of the data to projects for or engagements with the limited permitted client list. d) To clarify whether or not the group of independent researchers or analysts are an advisory or approval group. 2. In respect of data minimisation: a) To ensure alignment with NHS Digital's DARS Data Minimisation Standard. b) To provide a written justification in section 5 for the requirement of the six years of data requested. c) To provide in section 5, examples of the specific projects or programmes of work which have been requested by permitted clients; or the specific marketing plan for projects to be marketed to types of permitted clients. d) To confirm that the applicant will delete the data on a rolling basis. The following amendments were requested: 1. To update section 1 and section 5, to make clear that the research will be carried out by only the Cegedim staff researchers, and only Cegedim staff will have access to the data. 2. To replicate the client list in section 5(e) within the published part of section 5. 3. To remove any reference or suggestion in section 5 that Cegedim would be receiving the data under licence or would be permitted to sub-licence further. 4. In respect of the legitimate interest: a) To update section 5(a) to ensure reference to the specific Legitimate Interests as linked to the processing. b) To review the LIA to make more specific reference to the processing, the nature of the applicant and the activities under this application. 5. To update the LIA and privacy notice to remove misleading statements, such that the data subjects can withdraw their consent for the use of this data.

	6. To update section 5(a) to clarify if the location of injury is physical or geographical. 7. To clarify in section 5 what is meant by "high risk data". 8. To confirm in section 5 if waiting time and referral time can be extracted from HES. 9. To update section 5(c) to provide a clearer and more detailed description of the work planned. 10. To remove the reference to *"Recital 157"* as it is not directly relevant to the data requested. 11. To ensure the statements in section 5(c) and section 5(e) are compatible, in respect of commercialisation and publishing the data in an open access manner. The following advice was given: 1. IGARD noted that on return that a detailed analysis of the yielded benefits achieved should be provided. 2. IGARD suggested that the applicant may wish to consider whether having a patient or lay representation on the Committee, would be beneficial, particularly in respect of commercialisation of outputs. 3. IGARD would support the applicant requesting and receiving the Cancer Registration data, if there was a specific project that could be articulated in section 5. 4. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment. 5. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route. It was agreed the conditions would be approved out of committee (OOC) by IGARD members.
2.7	<u>London School of Hygiene and Tropical Medicine: Emergency Surgery Or noT (the ESORT study) (Presenter: Dave Cronin) NIC-185179-V0B0T</u> **Application:** This was an extension application for pseudonymised Civil Registration data and Hospital Episode Statistics (HES) data; for the purpose of an observational study, which will provide a rigorous evaluation of the relative effectiveness and costs of emergency surgery versus non-operative care for common acute conditions, and inform change to emergency general surgery provision across the NHS. This was also an amendment to 1) to update the application to ensure this aligned with current NHS Digital DARS Standards; 2) the addition of several fields to the HES Admitted Patient Care data, 3) dropping two of the seven conditions from the cohort criteria (acute intestinal ischaemia, peptic ulcer), 4) the addition of HES Critical Care Annual Refresh data for the years 2008/09 to 2019/20, plus the latest available cumulative data for 2020/21, 5) the request of a refresh of previously received Annual Refresh data (due to the additional HES APC fields selected), 6) the date of death is now required (rather than 30/90/365 mortality flags). The aim of the study is to estimate the effectiveness and cost-effectiveness of emergency surgery versus non-operative care for patients with common acute conditions presenting as emergency admissions to NHS trust hospitals. **Discussion:** IGARD queried the information in section 5(b) (Processing Activities) that stated *"…The historic HES records of patients will be used to calculate surgical volume…"*; and asked that further clarity was provided, if the surgeons were identified by pseudonym or directly identifying data; and that in either case, a justification was provided, of the use of this data in the context of this study.

	IGARD noted the brief reference in section 5 (Purpose / Methods / Outputs) to the study's "patient and public involvement (PPI) meetings", and asked that this was updated to include further details of the PPI. IGARD queried the statement in section 7 (Approval Considerations) that *"…Ethics approval is not required because there is no flow of confidential data…"*, and noted that supporting document 1.0, the study protocol stated that they had University ethics approval. IGARD asked that a copy of the positive opinion of the University Ethics Committee was provided and that the appropriate documentation was uploaded to NHS Digital's Customer Relationship Management (CRM) system. IGARD noted that the study protocol specifically referenced international partnerships, and asked that section 5 was updated with further details of this; and that confirmation was provided in section 1 (Abstract) and section 5 that no NHS Digital data would flow to any international partners. IGARD queried the benefits outlined in section 5(d) (Benefits), and noted that some of the information provided were outputs, and / or were not relevant, for example, the information related to the PhD studentship; and asked that section 5(d) was updated to remove any outputs and edit to only leave examples that reflect the benefits to Health and Social Care System. In addition, IGARD also asked that specific outputs removed from section 5(d) were moved to section 5(c) (Specific Outputs Expected). IGARD queried the information within the data minimisation column in section 3(b) (Additional Data Access Requested) that stated *"Please see Additional Production Details"* and asked that this was updated to remove this reference and to replace with a brief lay summary of the data minimisation activities, or to refer to the relevant part of section 5 that detailed this. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of calculating surgical volume by "surgeon": a) To clarify if the surgeons are identified by pseudonym or directly identifying data. b) In either case, provide a justification of the use of this data in the context of this study. 2. To update section 5 to include further details of the PPI which is referred to. 3. In respect of the University Ethics Approval: a) To provide a copy of positive opinion of the University Ethics Committee. b) To upload the appropriate documentation to NHS Digital's CRM system. 4. In respect of the international partnership outlined in the protocol: a) To update section 5 to provide details of the international partnerships. b) To provide confirmation in section 1 and section 5 that no NHS Digital data will flow to any international partners. 5. To remove any specific outputs from section 5(d) and move to section 5(c). 6. To update section 5(d) to remove any outputs and edit to only leave examples that reflect the benefits to Health and Social Care System. 7. To update the data minimisation column in section 3(b) to remove the reference to *"additional production details"* and replace with narrative detail or with a reference to the relevant part of section 5.
3	<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. • NIC-144761-Y3X9Y King's College London • NIC-354267-B4V2G Children's Commissioner • NIC-147437-C9YSC University of Leicester • NIC-195235-Q0B5T University of East Anglia IGARD welcomed the four applications as part of their oversight and assurance role and noted a number of comments to NHS Digital and suggested that further information and comments be provided in an IGARD Oversight and Assurance Report. Moving forward, IGARD agreed that COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 applications may also be included as part of the oversight and assurance review, not just those that were approved via NHS Digital's precedent route.
4	<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. The ratified action notes from Tuesday 10th November 2020 can be found attached to these minutes as Appendix B.
5 **5.1** **5.2**	<u>AOB:</u> <u>IGARD Meeting Quoracy</u> In light of the ongoing situation with COVID-19, and following consideration by IGARD members, it has been agreed with NHS Digital that from the 26th March 2020 meeting, the in-meeting quoracy may be temporarily reduced to three members (from four members), which must include a Chair and at least two specialist members. This is to ensure business continuity in the event that Covid-19 impacts on members ability to dial-in to meetings (due to illness or caring for a household member) and to support those IGARD members who have other roles linked to the Covid-19 response. This will be reviewed as and when required, but no less than monthly, and in response to new guidance that is released. This relates to Covid-19 only. <u>IQVIA / Janssen Pharmaceutical NIC-409290-L1F3L: Permission to Contact</u> An updated was given by NHS Digital, please see the COVID-19 response meeting action notes appended to these minutes at Appendix B There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 06/11/20

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-144568-D7G6V	Royal Brompton and Harefield NHS Foundation Trust	15/10/2020	1. To provide either an analysis plan, funding application update, or similar, which sets out the design of the analysis of the proposed processing for the addition of the COVID-19 purpose. 2. To provide confirmation to NHS Digital that, in light of the significant quantum of data, the applicant has the capacity to deliver the programme of work and fulfil the stated outputs .	IGARD members	Quorum of IGARD members	None

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:

- NIC-362209-B8N9J - NHS Tees Valley CCG
- NIC-55710-W8F8C - NHS West Essex
- NIC-116582-F2F2J - NHS Oxfordshire CCG
- NIC-192767-R0S9V - Suffolk and North East Essex

Appendix B

Independent Group Advising on the Release of Data (IGARD)

Action Notes from the IGARD – NHS Digital COVID-19 Response Meeting

held via videoconference, Tuesday, 10th November 2020

In attendance (IGARD Members):	Kirsty Irvine (IGARD Lay Chair)
	Dr Imran Khan (Specialist GP Member)
	Dr Geoffrey Schrecker (Specialist GP Member / Deputy Specialist Chair)
In attendance (NHS Digital):	Vicky Byrne-Watts (DARS)
	Dave Cronin (DARS)
	Louise Dunn (DARS)
	Duncan Easton (DARS)
	Heather Pinches (DARS)
	Karen Myers (IGARD Secretariat)
	Andy Rees (DARS)
	Bethan Thomas (DARS)
	Vicki Williams (IGARD Secretariat)

2	**Welcome** The IGARD Chair noted that this was a weekly meeting convened to support NHS Digital's response to the COVID-19 situation and was separate from the IGARD business as usual (BAU) meetings. IGARD members present would only be making comments and observations on any items that were presented, and were not making formal recommendations to NHS Digital. Should an application require a full review and recommendation, then it should go through the usual Data Access Request Service (DARS) process and be presented at a Thursday IGARD meeting. The action notes from the Tuesday meeting would be received at the next Thursday meeting of IGARD and published as part of those minutes as an appendix. **Declaration of interests:** Dr Imran Khan noted that he has been part of the recruitment process for patients eligible for the Principle trial through his work as an Out of Hours GP with Berkshire Healthcare NHS Foundation Trust, he has no other professional connection with the work undertaken in NIC-373132-D3Y7P The Nuffield Dept of Primary Health Services, University of Oxford. It was agreed this did not preclude Imran from taking part in the discussions about this application.
2.1	NIC-411813-H0T2W Wellcome Sanger Institute **Background:** This was a verbal briefing about a draft application by the Wellcome Sanger Institute (funded by the Wellcome Trust), in relation to the sequencing as part of the COVID-19 genomic sequencing work and access to Pillar 2 testing data in order to pick up positive test

	results in order to support the wider health system in spotting potential "super spreaders" or outbreaks in a region. NHS Digital noted that no documentation or application was available for review by IGARD members. NHS Digital noted that the Wellcome Sanger Institute was currently acquiring Pillar 2 testing data from Public Health England (PHE), however the applicant required the data flow quicker and on a more frequent basis than what PHE could supply. PHE were aware and happy with this new approach. In addition, the applicant would be gathering data from across the four devolved nations. The following observations were made on the basis of the verbal briefing only. **IGARD Observations:** IGARD members were unclear if the genome sequencing undertaken on specimens acquired from PHE was on the virus genome or human genome, and NHS Digital noted that any application would be clear that this was about the virus genome sequencing only. In addition IGARD members queried the specimens the applicant was receiving from PHE and if they were swabs, which would contain human DNA, or petri dishes (for example) with parts of the human DNA and raised the potential legal and ethical issues around sharing human DNA without consent (not least that that human DNA could be classed as personal data under the General Data Protection Regulation (GDPR)). NHS Digital noted that the applicant would be receiving "*left over tests*" from PHE and that PHE's information governance were content with this approach. IGARD members suggested that the application should be explicit that only the identifier for virus DNA sequence would be linked to any data from NHS Digital and that there would be no attempt by the applicant, or other parties, to use any human DNA or link identifiers associated with the human DNA, which may accompany the virus specimen sample. Noting that the applicant may wish to seek further data at a later time from NHS Digital, which would require linkage, it was evident that the data being disseminated under the initial application could not be classed as "anonymous", and would be better described as "anonymised". IGARD members also noted that consideration should be undertaken by the applicant in to whether they would require the linkage of specimen ID to the patient ID, especially if an individual was to be infected more than once or there were additional sub-strain of the virus. NHS Digital noted that this was a new organisation and IGARD suggested that DARS be clear as to who was/were the Data Controller/s under the agreement, citing the NHS Digital DARS Standard for Data Controllers / Data Processors, and that this should be borne out by the facts presented. NHS Digital noted that the application would be progressed via the NHS Digital SIRO precedent. IGARD members queried why the application would go down the SIRO precedent and noted that for a novel approach and new applicant that NHS Digital may also wish for the assurance of an independent review via a Thursday business as usual (BAU) IGARD meeting. Significant risk areas to address: 1. Data controllership. 2. Addressing human DNA aspects.

2.2	NIC-372791-X0H3Q NHS Blood & Transplant (NHSBT) **Background:** this was a verbal update to verbal presentations to the COVID-19 response meeting on the 28th July and 18th August, and business as usual (BAU) meeting on the 27th August 2020. Previous data releases under v0 and v1 of this this agreement have been facilitated and finalised by signed letters from the Privacy, Transparency and Ethics Directorate (formerly Information Governance (IG) Directorate). The initial request approved under v0 and v1, was to provide contact details for individuals who fit the criteria for collection of convalescent plasma which is being explored as a possible treatment for COVID-19. NHSBT routinely collects plasma from donors who have registered directly as part of their statutory function. The amendments to the application were to access the Pillar 3 and Pillar 4 (when available) data so that NHSBT would get data on those with positive antigen tests and now antibody tests by way of NHS Digital providing the contact details of potential donors from Pillar 3 (and when available Pillar 4). NHSBT were also looking at ways that they can improve the way they prioritise contacts for calling, depending on how likely they are to have high antibody levels. The following observations were made on the basis of the verbal briefing only. **IGARD Observations:** IGARD members welcomed the update from NHS Digital with regard to the amendments that had been made to the application following its last review, and confirmed that they were supportive of the changes made and would also support this going via the NHS Digital SIRO precedent. IGARD noted the update regarding the ongoing efforts to improve transparency and referred to their previously raised detailed comments on this point.
2.3	IQVIA NIC-409290-L1F3L: Permission to Contact **Background:** This was a verbal update to the verbal presentation at the COVID-19 response meetings on the 1st September, 8th September and 3rd November and business as usual (BAU) meeting on the 22nd October 2020. This was a new application to utilise the COVID-19 Permission to Contact (CV19 PtC) dataset for the purpose of recruiting participants in the PROVENT vaccine trial The following observations were made on the basis of the verbal briefing only. **IGARD Observations:** NHS Digital noted that the PROVENT Study Cover Letter and PROVENT Communication Template had been resubmitted to the Research Ethics Committee (REC) last week, however the documentation had not been updated in line with IGARD members out of committee review and comments made subsequent to the meeting held on the 3rd November. IGARD members noted their disappointment that the opportunity to update the materials had not been taken by the applicant. However, IGARD members noted that to support the applicant and NHS Digital on this occasion that they could consider any further documentation out of committee this week, noting the pressure to get invitations sent out to participants in line with the new timeline, which was still to be established with the applicant.

	IGARD members noted the verbal update from NHS Digital and looked forward to further updates in due course. **Subsequent to the meeting:** The IGARD Chair received a copy of the Health Research Authority and Care Research Wales (HCRW) approval letter and the Health Research Yorkshire & the Humber Sheffield Research Ethics Committee (REC) letter for review out of committee. The IGARD Chair noted that the REC favourable approval was subject to a condition, and NHS Digital confirmed that they were satisfied the condition had been met by providing out of committee written confirmation that the grant to Confirmation and Capacity or NHS Management permission from all organisations involved and that these permissions were delivered to all sites. In addition, NHS Digital attended the IGARD business as usual meeting on Thursday, 12th November to update IGARD on the Data Controllership changes that were being applied to the application namely: that Janssen Pharmaceutical would be included as the sole Data Controller and that IQVIA would be the sole Data Processor. IGARD noted the facts of their involvement should align with NHS Digital's DARS standard for Data Controllers / Data Processors and that NHS Digital should satisfy itself that the correct parties were listed on the Data Sharing Agreement (DSA). Given the international nature of the parties, IGARD further suggested that NHS Digital seek confirmation of the appropriate signing authority for the representative individuals to enter into contracts with NHS Digital.
2.4	<u>NIC-411161-G4K7X University of Oxford</u> **Background:** This was an update to the draft application presentation at the COVID-19 response meeting on the 27th October 2020. This was a new application to provide University of Oxford with Pillar 2 testing data in order to aid recruitment into the Platform Randomised trial of Interventions against COVID-19 In older people (PRINCIPLE). The PRINCIPLE study is the only national urgent public health priority trial evaluating therapeutics for COVID-19 in the primary care setting, endorsed by the Chief Medical Officers of the four devolved nations (England, Scotland, Northern Ireland and Wales). The following observations were made on the basis of the draft application only. **IGARD Observations:** NHS Digital noted that the application had progressed via NHS Digital's SIRO precedent, however IGARD members noted reference to the provision of ethics support by way of a special condition in section 6 of the application and queried this approach. NHS Digital noted that ethics had already been in place however it had been implicit, rather than explicit, with regard to recruitment and that on balance, the level of risk was appropriate to add a special condition to section 6, on this occasion only. NHS Digital noted the work undertaken with the applicant to update all relevant privacy notices and that currently they were awaiting the updating of the Department of Health & Social Care privacy notice, and before data could flow. IGARD members noted the verbal update from NHS Digital and looked forward to further updates in due course.
2.5	<u>NIC-373132-D3Y7P The Nuffield Dept of Primary Health Services, University of Oxford</u>

	Background: this was an update to the applications and supporting documentation presented at the COVID-19 response meetings on the 28th April and 22nd September, and the business as usual (BAU) meeting on the 22nd October 2020 The application had been previously presented for advice to the BAU meeting of IGARD on the 22nd October 2020 and since that time had been substantially redrafted. The Platform Randomised trial of INterventions against COVID-19 In older peoPLE (PRINCIPLE) aims to assess the effectiveness of trial treatments in reducing the need for hospital admission or death, for patients aged over 50 years with comorbidity, and aged over 65 years with or without comorbidity and suspected COVID-19 infection. NHS Digital noted that reference to NHS 111 should be removed from the application, that the security details for Public Health England (PHE) should be included and that reference to University of Oxford as a joint Data Controller be amended. IGARD noted the amendments and were supportive of the changes. **IGARD Observations:** IGARD members noted that the application presented had been substantially redrafted since it had been last presented to the BAU meeting of IGARD on the 22nd October. IGARD members noted their thanks to DARS and the applicant for the application presented and how it now reflected only the PRINCIPLE study. IGARD members also noted that the application had been updated to reflect the University of Oxford as the Data Controller, in line with the facts presented. In addition, IGARD members noted that section 5(b) should be updated to be explicit that the SALT key was held by the University of Surrey's IT Department that it was not permissible for them to access the pseudonymised data. NHS Digital noted that the applicant had expressed a wish to add in additional data sets to a future application, and IGARD reiterated previous comments that additional datasets may be possible but must be clearly justified and aligned with the study protocol objectives. IGARD members noted that when the application had been presented previously for advice, they had not given any views on the consent materials presented. IGARD members noted that the consent materials were broadly compatible with the common law duty of confidentiality but that immediate changes were required to the applicant's transparency materials on the website. Moving forward, the consent materials and patient information sheets should be updated in line with current facts. NHS Digital noted that the application would progress under the NHS Digital DARS SIRO Precedent. IGARD were unable to make a formal recommendation since they were not quorate, but were supportive of the proposal outlined to progress via the SIRO precedent, on this occasion. The following advice was given: 1. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment. 2. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent (with the exception of amendments to this application version).

	Significant risk area to address: 1. Applicant to update privacy notice urgently (and as a precursor to updated patient-facing materials as soon as reasonably practicable).
2.6	NIC-402417-N9Z5W UCL Partners **Background:** This was a brief verbal update to the update received on the COVID-19 response meeting 6th October and 13th October 2020 with regard to the NHS Digital Cancer Trusted Research Environment (TRE) and an application from UCL Partners to access the Cancer TRE. The following observations were made on the basis of the verbal briefing only. **IGARD Observations:** NHS Digital noted that further discussions were being undertaken between all parties involved in the Cancer TRE which was supporting the work being undertaken to scope specific applications. IGARD members noted that the applicant, in relation to Data Controllership, should consider the facts of the parties' involvements and as laid out in NHS Digital's DARS Standard for Data Controllers / Data Processors. Noting that a draft application was still to be submitted to DARS, IGARD thanked NHS Digital for the verbal update and reiterated previous comments made and looked forward to further updates in due course. Significant risk area to address: 1. Data controller(s) must match the factual scenario.
	AOB There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.