Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 18 March 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Kirsty Irvine (Chair)	IGARD Chair / Lay Representative
Dr. Imran Khan	Specialist GP Member
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Prof. Nicola Fear	Specialist Academic Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist Chair
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Dave Cronin	Data Access Request Service (DARS)
Catherine Day	Data Access Request Service (DARS)
Louise Dunn	Data Access Request Service (DARS)
Mujiba Ejaz	Data Access Request Service (DARS)
Liz Gaffney	Data Access Request Service (DARS)
James Gray	Data Access Request Service (DARS)
Richard Hatton	Clinical Informatics and Deputy Caldicott Guardian (Observer: item 3.1 - 3.4)
Karen Myers	IGARD Secretariat
Charlotte Skinner	Data Access Request Service (DARS)
Kimberley Watson	Data Access Request Service (DARS)
Vicki Williams	IGARD Secretariat

1	**Declaration of interests:**

	There were no declarations of interest. **Review of previous minutes and actions:** The minutes of the 11th March 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	<u>Covid Oximetry @ Home (CO@h) Data Set – Briefing Paper</u> The briefing paper was to inform IGARD of the COVID Oximetry @home (CO@h) Programme, which is to detect earlier deterioration in the community of COVID diagnosed cases silent hypoxia (a condition when oxygen levels in the body are abnormally low) and reduce hospital length of stay, including potentially freeing up critical care beds. The data collected for COVID Oximetry @home is required to support the COVID-19 Public Health Directions issued to NHS Digital. There are 2 phases of data flow; Phase 1 (data dissemination to CCGs) and Phase 2 (data collection from providers). Only Phase 2 is in scope of this briefing as it is these data flows which are used to create the COVID Oximetry @home (CO@h) data set. The CO@h data set is patient data for those patients who have agreed to take part in the CO@h monitoring programme. They will have met the CO@h standard operating procedures; those who have been diagnosed with COVID and who are either (a) over 65, or (b) under 65 at high COVID risk, drawing on the Clinical Extremely Vulnerable list, with clinical judgement; AND symptomatic. IGARD noted that this briefing paper had been reviewed by members out of committee (OOC), and comments had been shared (via the IGARD Secretariat) with the presenters on the 10th March 2021. In addition to the OOC comments provided, IGARD noted that an emerging issue, regarding pulse oximetry at home, is that readings in people with dark colour skin may underestimate low oxygen levels (hypoxaemia), and as discussed in The British Medical Journal (BMJ) article "Pulse oximetry may underestimate hypoxaemia in black patients, study finds". IGARD welcomed the briefing paper and made no further comments. IGARD looked forward to receiving the finalised briefing paper as a supporting document, alongside a first of type application.
3	**Data Applications**
3.1	<u>University Hospitals Birmingham NHS Foundation Trust (UHB): Long-term Follow Up of Patients in the Birmingham and Lambeth Liver Evaluation Strategies (BALLETS) Study (Presenter: Charlotte Skinner) NIC-386178-Y2S6V-v0.8</u> **Application:** This was a follow-up application of the original BALLET study, requesting identifiable Civil Registrations (deaths) data, and pseudonymised Hospital Episodes Statistics (HES) Admitted Patient Care (APC) and HES Outpatient data; for the purpose of a 10-year standalone follow-up study, with the aim of describing the risk of progression to severe liver disease in patients with non-alcoholic fatty liver disease (NAFLD), and understand whether this cohort is at an increased risk of death.

	The original Birmingham and Lambeth Liver Evaluation Strategies (BALLETS) study was a prospective study of people in General Practice who had abnormal Liver Function Tests (LFTs); with a cohort recruited between 2005 and 2008. The standalone follow-up study will follow-up 1,237 patients who received an abnormal result in their LFT and specific, severe causes of liver disease were ruled out. The cohort size is anticipated to be 1,237 patients, and is relying on s251 of the NHS Act 2006, for the flow of data from NHS Digital. **Discussion:** IGARD confirmed that they were of the view that the relevant s251 support provided the appropriate legal gateway and was broadly compatible with the processing outlined in the application. IGARD noted the proposed flow of data within the application and supporting document 1.0, that the data would be flowing from University Hospitals Birmingham NHS Foundation Trust (UHB) to the University of Birmingham (UoB), **before** flowing to NHS Digital; and queried why the data was not flowing directly from the UoB to NHS Digital; and asked that section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) were updated with a brief explanation. IGARD noted the statement in section 5(b) (Processing Activities) that *"No data will be taken off site for analysis"*, however this potentially contradicted additional information, for example, that statistical analysis would be carried out remotely by UHB employees; and asked that section 5(b) was updated to clarify the potential inconsistencies. In addition, and in relation to remote working, IGARD suggested that the Data Access Request Service (DARS) should clarify with the NHS Digital Security Advisor, what (if any) special conditions should be included within Data Sharing Agreements (DSA) as standard to address any remote working arrangements and particularly during the COVID-19 pandemic and consequent changes in working practices. IGARD noted the useful information in section 1, outlining the data minimisation efforts for data flowing from NHS Digital to UHB, and asked that this information was replicated in the public facing section 5(b) for transparency. IGARD noted a number of acronyms in section 5, for example *"NIHR ARC WM"*, and asked that this public facing section be updated to ensure that all acronyms upon first use were expanded and clearly defined with a supportive explanation in a language suitable for a lay reader. IGARD suggested that section 5(d) (Benefits) be updated to remove references to "*it will*…" and instead use a form of words such as "*it is hoped*…" IGARD noted that the application was for a follow-up of the original BALLET study, between 2005 and 2008, and asked that for section 5(d) (iii) (Yielded Benefits) was updated to briefly reference the yielded benefits that flowed from the original study using NHS Digital data. IGARD commended the applicant on their engagement with the public and patients as outlined in the application. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 1 and section 5 with a brief explanation as to why the data is flowing from UoB to UHB and then to NHS Digital, instead of directly flowing from the UoB to NHS Digital.

	2. To update section 5(b) to clarify the potential inconsistencies between the reference to remote access and the statement that data cannot be taken off-site. 3. To replicate the data minimisation efforts as outlined in section 1 within section 5(b). 4. To amend section 5 to ensure that all acronyms upon first use be defined and further explained if the meaning is not self-evident. 5. To update section 5(d) to use a form of wording such as "*it is hoped* …", rather than "*it will…*" 6. To update section 5(d) (iii) to briefly reference the yielded benefits that flowed from the original study using NHS Digital data. The following advice was given: 1. IGARD suggested that DARS clarify with the NHS Digital Security Advisor, what (if any) special conditions should be included within DSAs as standard to address any remote working arrangements and particularly during the COVID-19 pandemic and consequent changes in working practices.
3.2	<u>University of Bristol: Impact of the COVID-19 pandemic on outcomes following cardiac surgery (Presenter: Louise Dunn) NIC-419173-Z1G3C-v0.5</u> **Application:** This was a new application for identifiable Hospital Episode Statistics (HES) Admitted Patient Care (APC), HES Critical Care (CC), pseudonymised Civil Registration (Deaths) data and the National Adult Cardiac Surgery Audit (NACSA) data, to look at the impact of the COVID-19 pandemic on outcomes following cardiac surgery. NACSA collects data on all major heart operations carried out in NHS hospitals and a selection of private hospitals throughout the UK. The data is not yet onboarded to NHS Digital's Data Access Request Service (DARS) but is in the process of being onboarded for COVID-19 related research only. The purpose of the study is assessing the impact of COVID-19 on outcomes following cardiac surgery. The study will compare national surgical outcomes during the pre-COVID pandemic (April 2016-January 2020) period and COVID-19 pandemic (February 2020-Present date) period. In addition, the study would also like to determine the clinical impact on operated patients who have a perioperative diagnosis of COVID-19. It is hoped these findings will be able to inform clinicians and patients undergoing both routine / elective and emergency surgery and allow them to more accurately gauge the risks involved. This is turn may impact the provision of such services during the pandemic period. The cohort of patients for the study, are all patients above 18 years of age, that have undergone cardiac surgery in England, excluding surgery for congenital heart disease. **Discussion:** IGARD noted that aspects of this application had been seen by the IGARD – NHS Digital COVID-19 Response meeting on the 9th March 2021. IGARD noted that this application was a request for an extract of data for a stand-alone research project, however, queried why the research could not be conducted via the cardiovascular Trusted Research Environment (TRE). NHS Digital advised that discussion had taken place with the applicant to clarify this particular point, and had been advised by the applicant that there were a number of factors for requesting the extract of data, including, but not limited to, the funding arrangements, the set-up of the study team, and the urgency of the data request. IGARD noted the verbal update from NHS Digital, and asked that for transparency a brief explanation was provided in section 5(a) (Objective for Processing).

	In addition, IGARD wished to draw to NHS Digital's attention that they may come under scrutiny for providing an extract of data directly to an applicant and not facilitating the data linkage through the cardiovascular TRE. IGARD suggested that NHS Digital should satisfy themselves that this issue has been fully explored and that there were genuine timing issues which would be appropriately addressed via the bespoke extract / linkage. IGARD noted that Civil Registration (death) data had been requested, and highlighted that where this specific data was flowing, that NHS Digital would review on a case-by-case basis, to determine if there was an increased risk of identification. IGARD agreed that, in this particular case, there was less risk due to NHS Digital undertaking the linkage. IGARD asked that section 1 (Abstract) was updated confirming that the flow of date of death data was in line with NHS Digital's policy assessment and would not increase the likelihood of re-identification of data subjects. IGARD noted that in section 3(b) (Additional Data Access Requested) it was unclear whether flows were identifiable or pseudonymised and asked for the information to be updated. IGARD also noted a UK General Data Protection Regulation (GDPR) basis was given for the Civil Registration (death) data, however IGARD advised that this was incorrect since the UK GDPR does not cover those that have died. In addition, IGARD also noted the data fields were listing incorrect detail, for example, requesting *"postcode"* data; and asked that the requisite changes in section 3(b) were made to the requested data fields. IGARD queried the statement in section 5(b) (Processing Activities) *"Only staff with honorary NHS contracts, and as such an equivalent duty of confidentiality to a health professional, who are directly involved in the project will be given access to such data by the chief investigator."*; and asked that, for clarity, this was amended to clearly define that the contract must be with the Data Controller and not any NHS body. IGARD noted that section 5(a) was quite lengthy in detail, and asked that excessive detail was edited to reduce the description of the processing, which was potentially too lengthy for NHS Digital's data release register, for example reference to having gone to the Research Ethics Committee (REC) to seek ethical approval which the applicant does not need for this application. IGARD queried the references in section 5 (Purpose / Methods / Outputs) to *"consent"* and COVID-19 research policy, when referring to the NACSA dataset; and asked that the references were removed as they were not relevant. IGARD noted within the application, that over 18s who have undergone congenital heart surgery would not be included in the cohort for the study, and asked that section 5 was updated to include a brief rationale for this exclusion. IGARD noted a number of acronyms in section 5, for example *"HES ID"*, and asked that this public facing section be updated to ensure that all acronyms upon first use were expanded and clearly defined with a supportive explanation in a language suitable for a lay reader. IGARD queried the statement in section 5(a) *"Should surgery be offered or is the combined risk of salvage/life-saving surgery…"*, and asked that the reference to *"salvage"* was removed as it was not necessary to include. IGARD queried whether the researchers would have the full breadth of data they required to achieve the research aims; and advised that they would be supportive of the applicant receiving required additional flows of data, and would support the addition of pseudonymised Covid-19 UK Non-hospital Antigen Testing Results (Pillar 2) data without an additional IGARD review; and that an appropriate justification for this additional data should be added in section

	5. In addition, IGARD also confirmed that they were supportive of the pseudonymised NACSA dataset extract flowing to the applicant, without additional IGARD review, and when the data was onboarded to DARS. IGARD suggested that that the applicant updated the application to reflect any patient and public involvement (PPI) that has been undertaken, and as noted as a placeholder within the protocol. IGARD commended the applicant on the description of the project outputs in section 5(d) (Benefits). **Outcome:** recommendation to approve The following amendments were requested: 1. To provide a brief explanation in section 5(a) why there is a request for this extract of data for this stand-alone research project and why the research could not be conducted via the cardiovascular TRE. 2. In respect of the Civil Registration (deaths) data: a) To update section 3(b) to reflect that the data is pseudonymised. b) To make the requisite changes in section 3(b) to the legal basis and the requested data fields. c) NHS Digital to confirm in section 1 that the flow of date of death data is in line with NHS Digital's policy assessment and will not increase the likelihood of re-identification of data subjects. 3. To amend section 5(b) to ensure that the reference to *"honorary NHS contracts"* states that the contract must be with the Data Controller and not any NHS body. 4. To edit section 5(a) to remove excessive detail and reduce the description of processing, which is potentially too lengthy for NHS Digital's data release register. 5. To update section 5 to remove references to *"consent"* and COVID-19 research policy. 6. To amend section 5 to include a brief explanation of the rationale of the exclusion of over-18s who have undergone congenital heart surgery. 7. To update section 5 to either expand acronyms, or provide a supportive explanation upon first use, for example, *"HES ID"*. 8. To remove the reference to *"salvage"* in section 5(a). The following advice was given: 1. IGARD wished to draw to NHS Digital's attention that they may come under scrutiny for providing an extract of data directly to an applicant and not facilitating the data linkage through the cardiovascular TRE; and suggested that NHS Digital should satisfy themselves that this issue has been fully explored and that there are genuine timing issues which would be appropriately addressed via the bespoke extract/linkage. 2. IGARD queried whether the researchers would have the full breadth of data they required to achieve the research aims; and advised that they would be supportive of the applicant receiving additional flows of data (for example pseudonymised pillar 2 data without additional IGARD review); and that an appropriate justification for this additional data should be added in section 5. 3. IGARD were supportive of the pseudonymised NACSA dataset extract flowing to the applicant (without additional IGARD review) when the data was onboarded. 4. IGARD suggested that that the applicant updated the application to reflect any PPI that has been undertaken, and as noted as a placeholder within the protocol.

3.3	University of Oxford: The Oxford Risk Factors And Non-Invasive Imaging Study (ORFAN) Arm 4 (Presenter: Catherine Day) NIC-409610-J6L1F-v0.3 **Application:** This was a new application for pseudonymised Civil Registrations (deaths) data, Hospital Episodes Statistics (HES), Emergency Care Data Set (ECDS), Medicines dispensed in Primary Care (NHSBSA data) and COVID-19 Hospitalization in England Surveillance System. The NHS Digital datasets requested will be linked to the ORFAN Arm 4, noting that Arms 1, 2 and 3 do not form part of this application. The purpose is for the ORFAN 'Arm 4' retrospective study arm, which is a multi-centre observational cohort study including up to 100,000 adult participants (75,000 in the UK and 25,000 internationally) and concerns only patients located in England and Wales who have had a computed tomography (CT) angiography or CT chest scan. The aim is to develop new and better biomarkers of cardiovascular disease risk, using novel approaches to the analysis of CT scans; to reduce the large burden of morbidity and mortality that cardiovascular disease such as heart attack and stroke. A further purpose is to understand the cardiovascular disease ramifications of COVID-19 by identifying novel biomarkers that are able to predict cardiovascular disease pathogenesis and extent of pre-existing vascular disease, including in those with COVID-19 infection. The study is relying on s251 of the NHS Act 2006 for the flow of data into NHS Digital. **Discussion:** IGARD confirmed that they were of the view that the relevant s251 support provided the appropriate legal gateway and was broadly compatible with the processing outlined in the application. IGARD noted the references in section 5(c) (Specific Outputs Expected) to various *"tools"*, and queried if there was any anticipated commercial nature or intention to monetise / generate income. IGARD asked that section 5(c) was updated accordingly, with further clarity; or, that if this was no intention to monetise / generate income, this was clearly stated. In addition, IGARD asked that if there were any commercial aspects, that this was clearly reflected in section 5(e) Is the Purpose of this Application in Anyway Commercial). IGARD queried the reference in section 5(a) (Objective for Processing) to *"radiomics"*, and noting that this was not a commonly used term, asked that this was either replaced with a non-technical term, or provide a supportive explanation. IGARD noted the inclusion of a number of technical phrases and words within section 5(c), for example, *"perivascular Fat Attenuation"*, and asked that, these were updated as necessary with further supportive text. IGARD noted the benefits outlined in section 5(d) (Benefits), however asked that as the benefits were not yet known, that the applicant revised some of the language, for example, the definitive references to *"will"*. IGARD noted the references within the application to an *"award"*, and asked that the yielded benefits in section 5(d) (iii) (Yielded Benefits) were updated to reference this, and to also reflect the basis of previous work with NHS Digital, if any. IGARD noted the level of detail and breadth of information included within section 5 (Purpose / Methods / Outputs), but reminded the applicant that because this section formed the dual purpose of a contract and public-facing data release register, that brevity and simplicity were preferred. Should the applicant wish to provide this level of technical detail this could either be included in the protocol or as a stand-alone supporting document, but it was not necessary in order to meet NHS Digital's Data Access Request Service (DARS) Standards. IGARD suggested that as a starter, the applicant may wish to consider removing the paragraphs in

	section 5(d) that started *"ORFAN Arm 4 compliments [sic] the other arms…"* and *"Such synergy within the Ox-HVF projects facilitates…"*. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 5(a) to either replace with a non-technical term, or provide a supportive explanation for the reference to *"radiomics"*. 2. To update the yielded benefits in section 5(d) (iii) to reflect the reference to the *"award"* referenced elsewhere in the application, and the basis of previous work with NHS Digital (if any). 3. To revise the references to any technical language used within section 5(c), including (but not limited to) *"perivascular Fat Attenuation"*, and update as necessary with further supportive text. 4. In respect of any potential commercial element: a) To update the references to the *"tool"* in section 5(c) to clarify any anticipated commercial nature or intention to monetise / generate income; or b) If there is no intention to monetise / generate income, to clearly state this; and c) To update section 5(e) to reflect any commercial aspects. 5. To revise the language in section 5(d) to reflect that the exact benefits are not yet known; for example references to *"will"*. The following advice was given: 1. IGARD noted the level of detail and breadth of information included within section 5, but reminded the applicant that because this section forms the dual purpose of a contract and public-facing data release register, that brevity and simplicity were preferred. Should the applicant wish to provide this level of technical detail this could either be included in the protocol or as a stand-alone supporting document, but it was not necessary in order to meet NHS Digital's Standards.
3.4	<u>London North West University Healthcare NHS Trust: Route of myomectomy (Fibroid surgery) (Presenter: Kimberley Watson / Mujiba Ejaz) NIC-361800-N8R5G-v0.11</u> **Application:** This was a new application for pseudonymised Hospital Episodes Statistics (HES) Admitted Patient Care. Over the past 2 decades, gynaecological surgery has progressed to include minimally invasive techniques including laparoscopic myomectomy, which is a surgical procedure to remove uterine fibroids. Uterine fibroids, which are non-cancerous growths that develop in or around the womb. The current hypothesis is that laparoscopic procedures would be superior to abdominal surgery where possible due to reduced length of stay, improved recovery rates and fewer complications. To perform laparoscopic myomectomy, compared to the open abdominal approach, additional training and skill is required, since techniques have significantly evolved; however, many practising gynaecologists would not have the skill set required to offer it to women The aim of the project is to ascertain current practice with variation according to diagnosis, patient demographics, and geography, which would allow the description of current practice and how this has evolved over the last few years. It will allow identification of inequity in this practice and allow the appropriate promotion and provision training. NHS Digital advised IGARD that following submission of the application and supporting document for review, the applicant had confirmed that 'Tommy's The Baby Charity' were

	funding the project, and that they would not acting as a Data Controller. In addition, NHS Digital noted that they were still awaiting a copy of the funding letter. **Discussion:** IGARD noted that the research was being undertaken by a sole researcher, and queried the capacity and capability of a lone researcher in respect of handing the large volume of data requested, and achieving the potential outputs and benefits stated. However, IGARD were supportive of the potential benefits to women outlined in both the application and protocol. IGARD noted the verbal update from NHS Digital in respect of 'Tommy's The Baby Charity' funding the project, and that they were not acting as a Data Controller; and asked that section 8(b) (Funding Sources) was updated to ensure the correct funder was reflected. In addition, IGARD asked that the written funding evidence was uploaded to NHS Digital's customer relationships management (CRM) system for future reference when received from the applicant. IGARD noted that data was required for all women aged 18 and over in England, and section 3(b) (Additional Data Access Requested) stated that only the required fields were selected; and asked that this was updated to specify the specific diagnosis codes, or, that if there were too many to list, to provide a narrative of the codes, that directly related to myomectomy. In addition, IGARD asked that written justification was provided, as to why data for **all** of England was required, and not a representative geographical strata, and that this complied with NHS Digital's Data Access Request Service (DARS) Data Minimisation Standard. IGARD queried why the 10-years of data had been requested by the applicant, and not a shorter timeframe, and asked that a justification was provided, and that this complied with NHS Digital's DARS Data Minimisation Standard. IGARD noted the outputs outlined in section 5(c) (Specific Outputs Expected), however asked that as the outputs were not yet known, that the applicant revised some of the language, for example, the definitive references to *"will"*. IGARD also queried the statement in section 5(c) *"Data is requested so London North West University NHS Trust can make the data available to both an international journal (BJOG - British journal of obstetrics and gynaecology- in the first instance) as well as RCOG (Royal College of Obstetrics and Gynaecology)…"*, and asked that the outputs in section 5(c) were revised to reflect realistic aspirations that may flow from a piece of research that had not been specifically commissioned by any national bodies. Also, to make it clear the data itself will not flow to a journal or professional body. IGARD noted the outputs outlined in section 5(c), however asked that as the outputs were not yet known, that the applicant revised some of the language, for example, the definitive references to *"will"*. IGARD commended the applicant for the clear breakdown on the benefits within section 5(d) (Benefits), however, again, asked that as the benefits were not yet known, that the applicant revised some of the language, for example, the definitive references to *"will"*. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment due to the large quantum of data flowing to a single individual not seemingly supported by a wider study team or research institute; and that this application would not be suitable for NHS Digital's Precedent route, including the Senior Information Risk Owner (SIRO) Precedent. **Outcome:** recommendation to approve subject to the following condition(s)

	1. In respect of data minimisation: a) To update section 3(b) to specify the specific diagnosis codes; or if there are too many to list, to provide a narrative of the codes, directly related to myomectomy. b) To provide a written justification that data for **all** of England is required, and not a representative geographical strata. c) To provide a justification why 10-years of data has been requested and not a shorter timeframe. The following amendments were requested: 1. In respect of the funding: a) To update section 8(b) to ensure the correct funder is reflected. b) To upload the written funding evidence to NHS Digital's CRM system. 2. In respect of the outputs in section 5(c): a) To revise the language to reflect that the exact outputs are not yet known; for example references to *"will"*. b) To revise the outputs to reflect realistic aspirations that may flow from a piece of research that has not been specifically commissioned by any national bodies. 3. To revise the language in section 5(d) to reflect that the exact benefits are not yet known; for example references to *"will"*. 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 due to the large quantum of data flowing to a single individual not supported by a wider study team or research institute. 2. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent. It was agreed the condition would be approved out of committee (OOC) by IGARD members.
3.5	<u>Public Health England (PHE): D24 - Request to share data for Covid-19 purposes – HOSTED Project (Presenter: James Gray) NIC-381634-X8H0H-v2.2</u> **Application:** This was an amendment application to 1) receive pseudonymised Hospital Episodes Statistics (HES) Outpatients, Accident and Emergency (A&E) and Admitted Patient Care (APC) data, GPES Data for Pandemic Planning and Research (COVID-19), COVID-19 Hospitalisation in England Surveillance System (CHSS), COVID-19 Second General Surveillance System (SGSS), COVID-19 Vaccination Status, Personal Demographics Service, Secondary Uses Service Payments by Results Episodes (SUS PbR) data; and 2) to amend the output from the Second Generation Surveillance System (SGSS) dataset to include the spike gene target failure (SGTF) field. This was a renewal application until the 30th September 2021 to receive this data and in line with the current COPI expiry date. The purpose of this application is to support the PHE surveillance system on household transmission of COVID-19 to enhance the national public health surveillance of COVID-19 infections in the population of England. COVID-19 laboratory and case data from PHE will be linked to NHS Digital controlled data sets using a one-way encrypted versions of NHS number and unique property reference number to identify the household contacts of COVID-19 patients. This linked dataset is called "HOSTED" and is used to establish the COVID-19 status and associated outcomes of these household contacts.

	The HOSTED data sets will be used to identify: a) the testing status of household contacts b) secondary cases of COVID-19 infection among household contacts c) hospital admissions for COVID-19 among household contacts d) risk factors for Covid-19 among household contacts e) deaths from COVID-19 among household contacts. **Discussion:** IGARD noted that the application had previously been discussed at the IGARD meeting on the 4th March 2021, when NHS Digital had brought it for advice under the 'COVID-19' section of the meeting. IGARD noted that aspects of this application had last been seen by the IGARD – NHS Digital COVID-19 Response meeting on the 6th June 2020 (NIC-372789-B6Q2B PHE). **I**GARD also noted that this application had been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) (see Appendix B) on the 17th March 2021. IGARD noted and supported the comments made by PAG. In line with PAG's comments, IGARD asked that written clarification and justification was provided in section 5 (Purpose / Methods / Outputs), as to why s-flags (sensitive status) were being used to exclude individuals, as this was not evident in the application provided. IGARD queried if the data flowing was pseudonymised or if any confidential data was flowing, noting that there was conflicting information within the application, and in light of the legal basis stated, the Health Services Control of Patient Information (COPI) Regulation 2002. NHS Digital advised that the data flowing was pseudonymised. IGARD noted the verbal update from NHS Digital, and asked that the legal basis for dissemination was updated to reflect that the data flowing was pseudonymised; and that in addition, section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) were updated to clarify if at any point confidential data would be flowing; and that in either case, a consistent narrative was provided as to what level of data was being disseminated and processed, and under what legal basis. IGARD noted the statement in section 5(b) (Processing Activities) *"Records will be extracted by interrogating the fields PERSON_ID, DATE_AND_TIME…"*, in respect of the vaccination data, and queried if the vaccination data / person ID was identifying data in the hands of the recipient; and asked that this was clarified in section 5(b). IGARD noted the references within section 1 and section 5(a) (Objective for Processing) of the application to managing *"patients"* and asked that this was amended to refer to managing the *"condition"*. IGARD queried the cohort figure stated in section 5, and that this was a rough estimate as of the 22nd April 2020, and asked that this was updated to reflect the current cohort size, and that the latest information was reflected in respect of other data points that have moved on since 2020. IGARD noted the reference to the SHSS amendment in section 5 and queried if this should be SGSS. IGARD also advised that it was not clear that this was to provide focus on new COVID-19 variants, and asked that section 5 was amended to clarify this, and that it was in language suitable for a lay reader. IGARD queried the statement in section 5(a) *"…vaccine efficacy (protection) has been established in trials (at around 90%)…"*, and noting that there was no additional information as to where this figure had come from, asked that this was removed. IGARD noted that no yielded benefits had been populated in section 5(d) (Benefits) (iii) (Yielded Benefits) of the application, and noting that the applicant already held NHS Digital

	data, asked that a satisfactory update was provided, and that this complied with NHS Digital's Data Access Request Service (DARS) Expected Measurable Benefits Standard. IGARD noted that routine reports would be produced for inclusion in the PHE surveillance report and for the PHE Sitrep (Public Health Emergency Situation Reports) on a weekly basis, and asked that section 5(c) (Specific Outputs Expected) was updated, with further information of the output feeding into the Sitrep, since they were unable to locate a public record of this on PHE's website. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the high profile and impactful nature of the application; and that this application would not be suitable for NHS Digital's Precedent route, including the Senior Information Risk Owner (SIRO) Precedent. **Outcome:** recommendation to approve subject to the following conditions: 1. To provide written clarification and justification as to why S flags are being used to exclude individuals. 2. In respect of the legal basis for dissemination: a) To update the legal basis for dissemination to reflect that the data flowing is pseudonymised. b) To clarify in the abstract and section 5 if at any point confidential data is flowing. c) In either case, to provide a consistent narrative as to what level of data is being disseminated and processed, and under what legal basis. d) To clarify in section 5(b) if the vaccination data / person ID is identifying data in the hands of the recipient. The following amendments were requested: 1. To update section 1 and section 5(a) to ensure any references to managing *"patients"* is amended to managing the *"condition"*. 2. To update section 5 to update the cohort size and any other data points that have moved on since 2020. 3. To amend section 5 to provide a clarity that the SGSS amendment is to provide focus on new variants, and is in language suitable for a lay reader. 4. To amend section 5(a) to remove reference to *"90% efficacy"*. 5. To provide a satisfactory update to the yielded benefits in section 5(d) (iii) to populate NHS Digital's data release register and ensure compliance with NHS Digital's Expected Measurable Benefits Standard. 6. To provide more information in section 5(c) with reference to the output feeding into PHE's Sitrep since IGARD could not find a public record of this on PHE's website. 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, due to the high profile and impactful nature of the application. 2. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent. It was agreed the condition would be approved out of committee (OOC) by IGARD members.
3.6	Methods Analytics Ltd: Standard Extract Subscription - Amendment to purpose section (Presenter: Dave Cronin) NIC-09519-D5G0R-v15.2

	Application: This was an amendment application to 1) receive pseudonymised Hospital Episodes Statistics (HES) Outpatients, Critical Care and Admitted Patient Care (APC) data, Civil Registrations (deaths) data, Diagnostic Imaging Dataset (DIDs), Mental Health Services Data Set (MHSDS), Emergency Care Data Set (ECDS) and Secondary Uses Service Payment By Results; 2) add a new purpose for processing for The NHS Improvement Getting It Right First Time Programme (GIRFT); 3) to remove Stethoscope (a quality variation tool which provided local and national benchmarking of indicators derived from NHS Digital and other data) from the purpose section; 4) NHSX, Integrated Care Systems (ICS) and Sustainability and Transformation Partnerships (STP) have been added to the list of organisations who would be considered as supporting the NHS directly. The aim is for data to be used to help inform improvement in NHS services. The effect of using this data, analysed securely and then provided to NHS decision makers / providers to the NHS in Methods' tools which helps decision makers visualise and understand what changes they need to make to their organisations and services to enhance the quality, safety and efficiency of health and care. NHS Digital advised that section 1 (Abstract) of the application stated the incorrect start date of the Data Sharing Agreement (DSA), and that this would need updating to reflect the correct date. NHS Digital also highlighted to IGARD, that the previous version of the application did not state that NHS Digital data would be used for research purposes, however although the version presented to IGARD did clearly highlight this, it had not been listed as an 'amendment' within the application. NHS Digital confirmed that they did not view this as being problematic, they wanted to highlight for transparency. **Discussion:** IGARD noted that this application had previously been discussed as part of the 'returning applications' section of the IGARD business as usual (BAU) meeting on the 23rd January 2020, and that as part of this review, IGARD had specifically requested that that they would wish to review this application when it comes up for renewal, extension or amendment. IGARD noted the verbal update from NHS Digital in respect of the incorrect DSA start date, and supported the amendment to reflect the correct date. IGARD also noted the additional information highlighted by NHS Digital, in respect of the data requested being used for research purposes, and that although this was noted within the application reviewed, it had not been flagged as a specific amendment. IGARD noted that Civil Registration (death) data had been requested, and highlighted that where this specific data was flowing, that NHS Digital would review on a case-by-case basis, to determine if there was an increased risk of identification. IGARD agreed that, in this particular case, there was less risk due to NHS Digital undertaking the linkage. IGARD asked that section 1 was updated confirming that the flow of date of death data was in line with NHS Digital's policy assessment and would not increase the likelihood of re-identification of data subjects. IGARD noted the reference to *"professional bodies"* in section 5 (Purpose / Methods / Outputs), when referring to who the applicant works with, and asked that this was updated, to stipulate that the this referred to professional bodies who directly support the NHS; and if possible, to provide examples of such organisations. IGARD also noted in section 5(c) (Specific Outputs Expected) and section 5(d) (Benefits) the potentially hyperbolic statements made in terms of the money that will be saved from the research, and asked that section 5(c) and 5(d) were reviewed and updated where necessary,

	to reflect that the potential benefits may be more effective utilisation of resources, rather than money *"saved"*. In addition, IGARD also asked that the expected outputs and benefits in section 5(c) and 5(d) were refined and provide further details, for example, on projected savings; or that any references no longer relevant were removed. IGARD noted the reference throughout section 5 (Purpose / Methods / Outputs) to NHS Improvement's Getting It Right First Time Programme (GIRFT), and asked, that since GIRFT receive their own flow of data from NHS Digital, that section 5(d) was updated to clearly articulate the specific benefits that had been generated by work with GIRFT. IGARD suggested that NHS Digital may wish to draw to the applicant's attention the following two misleading statements within their published transparency materials: 1) to amend their assertion that they are not handing personal data, as pseudonymised data is personal under the UK General Data Protection Regulation (UK GDPR); and 2) to remove the reference to *"purchasing"* NHS Digital data, as NHS Digital does **not** sell NHS data. IGARD advised that when this application comes up for amendment, extension or renewal, they would expect the yielded benefits to be clearly outlined, and to reflect the work that has been undertaken, and the benefits accrued since the application was last seen; since this was essential for NHS Digital to demonstrate its legal basis to flow the data and to populate the NHS Digital data release register. IGARD advised that they would wish to review this application when it comes up for renewal or extension, to review the yielded benefits and the privacy notice; and that this application would not be suitable for NHS Digital's Precedent route for renewals or extensions. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 1 to reflect the correct start date of the DSA. 2. NHS Digital to confirm in section 1 that the flow of date of death data is in line with NHS Digital's policy assessment and will not increase the likelihood of re-identification of data subjects. 3. To update section 5 to stipulate that the *"professional bodies"* referred to directly support the NHS, and if possible, to provide some examples of such organisations. 4. In respect of section 5(c) and section 5(d): a) To review any hyperbolic statements made in section 5(c) and section 5(d), for example, in relation to projected savings. b) To refine the expected outputs and benefits, and provide further details, for example, on projected savings, or remove any references no longer relevant. 5. To update section 5(d) to clearly articulate the specific benefits that have been generated by work with GIRFT, since GIRFT receive their own flow of data from NHS Digital. The following advice was given: 1. IGARD advised that when this application comes up for amendment, extension or renewal, they would expect the yielded benefits to be clearly outlined, and to reflect the work that has been undertaken, and the benefits accrued since the application was last seen; since this is essential for NHS Digital to demonstrate its legal basis to flow the data and to populate the NHS Digital data release register.

	2. IGARD suggested that NHS Digital may wish to draw to the applicant's attention the following two misleading statements within their published transparency materials: 1) to amend their assertion that they are not handing personal data (as pseudonymised data is personal under UK GDPR); and 2) to remove the reference to *"purchasing"* NHS Digital data, as NHS Digital does not sell NHS data. 3. IGARD advised that they would wish to review this application when it comes up for renewal or extension, to review the yielded benefits and the privacy notice. 4. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route for renewals or extensions.
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. • NIC-66034-M7B8W-v3.2 Rand Europe Ltd • NIC-411813-H0T2W-v0.7 Wellcome Sanger Institute • NIC-427822-X5G6N-v0.2 NHS England (Quarry House) • NIC-428459-V7Q8M-v0.3 University of Oxford • NIC-49164-R3G5K-v1.8 University of Leeds IGARD welcomed the five 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. IGARD noted the Data Access Request Service (DARS) had been running a pilot in respect of a low-risk Senior Information Risk Owner (SIRO) Precedent; NHS Digital advised that the pilot had ended on the 31st January 2021, and was currently in the process of being evaluated.
5	<u>IG Covid-19 Release Register February 2021</u> IGARD noted that the IG Covid-19 Release Register February 2021 had been circulated and reviewed out of committee by members, and discussed and agreed the comments that would be shared with the Privacy, Transparency and Ethics Directorate.
6	<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 16th March 2021** can be found attached to these minutes as Appendix C.

7	AOB:
7.1	NIC-55679-K9X4J-v6 – NHS East and North Hertfordshire CCG IGARD noted that NHS Digital had notified them out of committee that NIC-55679-K9X4J-v6 – NHS East and North Hertfordshire CCG had been approved by NHS Digital, under the commissioning precedent; however, it had since been noted that they will use Microsoft Azure Cloud, and that this should have come to IGARD for review. NHS Digital had advised IGARD this was approved under SIRO on the basis that the duration was shortened to a 3-month duration and the application is taken to IGARD as soon as possible. In addition, NHS Digital provided reassurance to IGARD that their Security Team have reviewed and approved the use of MS Cloud for Outcome Based Healthcare. IGARD noted and thanked NHS Digital for providing an update and acknowledged the forthcoming review of the application at a future IGARD meeting. 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 12/03/21

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-356234-W2K8R	University of Cambridge	25/02/2021	1. In respect of the data controllership: a) To provide a written explanation (in terms of the UK GDPR and NHS Digital's DARS Standard on Data Controllers) why the University of Cambridge are **not** considered joint Data Controllers, particularly in light of the information provided in the supporting documents, for example the protocol. b) If the University of Cambridge are considered joint Data Controllers, to update the application throughout to reflect this.	IGARD members	Quorum of IGARD members	*"IGARD are content that condition 1a is met and therefore condition 1b does not apply."*

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:

- NIC-422195-G1Y7D-v0.3 NHS Frimley CCG

Optum Health Solutions UK Limited Class Actions:

- NIC-422195-G1Y7D-v0.3 NHS Frimley CCG

Graphnet Class Actions:

- NIC-422195-G1Y7D-v0.3 NHS Frimley CCG

Appendix B

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 17th March 2021

Application & application version number: DARS-NIC-381634-X8H0H-v2.2 **Organisation name: Public Health England** **Profession Advisory Group Agenda item: 3**
PAG support this application. PAG would like clarification on why S flags are being upheld? PAG recommend that S flags are not upheld unless there is justification for this.

Attendees	Role	Organisation
Arjun Dhillon	Chair and Caldicott Guardian	NHS Digital
Peter Short	Clinical Lead	NHS Digital
Amir Mehrkar	GP, Clinical Researcher	RCGP
Mark Coley	Deputy IT Policy Lead	BMA
Liz Gaffney	Head of Data Access	NHS Digital
Pam Soorma	Secretariat	NHS Digital
James Gray	Senior Case Officer	NHS Digital

Appendix C

Independent Group Advising on the Release of Data (IGARD)

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

held via videoconference, Tuesday, 16th March 2021

In attendance (IGARD Members): Paul Affleck (IGARD Specialist Ethics Member)
Kirsty Irvine (IGARD Chair, Lay representative)
Dr. Imran Khan (IGARD Specialist GP Member)

In attendance (NHS Digital): Cath Day (DARS)
Louise Dunn (DARS)
James Gray (DARS)
Kimberley Watson (DARS)
Vicki Williams (IGARD Secretariat)
Tom Wright (DARS)

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 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:** There were no declarations of interest.
2.1	NIC-420168-K4N1F-v0.9 University of Bristol **Background:** this was a verbal update following previous discussions at the COVID-19 response meetings on 8th December, 15th December 2020, 12th January, 26th January and 2nd February 2021, and at the IGARD business as usual (BAU) meetings on the 4th March and 4th February 2021. The following observations were made on the basis of the verbal update only. **IGARD Observations:** IGARD members thanked NHS Digital for their brief verbal update following the application's latest presentation at the IGARD BAU meeting on the 4th March 2021 and looked forward to reviewing the updated application out of committee as per due process and in due course.
2.2	NIC-431881-N8B0N-v0.1 University of Oxford

	Background: This was a new application v0.1 from the University of Oxford requesting new data for the National Core Studies (NCS) "*can phenotypes developed from enhanced remove primary care assessments of COVID-19 be used to identify a cohort of community cases, and enable comparison of recovered and long-COVID?*" study. The study is being funded by the Health Data Research UK (HDR UK). NHS Digital explained that no data was proposed to be flowed under this data sharing agreement (DSA) and that the data that would be accessed to support this study would be via NIC-381683-R6R6K and NIC431355-B1L8W. The data under the above two DSAs will be linked to the cohort of patients registered within the Royal College of General Practitioners (RCGP) Research and Surveillance Centre (RSC) network. The following observations were made on the basis of the draft v0.1 application summary and relevant draft supporting documents. **IGARD Observations** IGARD members noted that due to the nature of the meeting and when papers were disseminated, they had not conducted a full review of the application and supporting documents provided. Should a full review of the application and documentation be required, the full suite of documentation should be presented to a IGARD business as usual (BAU) meeting for a recommendation. IGARD members noted that they were supportive of the National Core Studies and thanked NHS Digital for the overview. IGARD members suggested that the applicant may wish to update relevant transparency materials and provide updated copies to participating general practitioners reflecting recent developments and the proposed purpose of the processing outlined within this application. Noting that the GPs are the Data Controllers, it is still for the applicant to ensure the practices have all the relevant and up to date information about the processing. In addition, the public facing materials for the RSC and this research project should be clear as to the data controllership and processing responsibilities of each of the parties involved and that there should be a distinction between the surveillance and the research projects. IGARD members noted that the size of the cohort was circa 5.4 million and noting the NHS Digital standard for Data Minimisation, suggested that further consideration be given to whether the applicant could minimise further, for example to only those patients with a positive COVID-19 test result. IGARD members noted reference with the application to "*patients being managed*" and suggested that this was further clarified as to whether this referred to those patients being managed in the current climate via telephone, or those patients that were being managed out of a hospital setting. Noting that NHS Digital had developed and published on its website a tool for use by physicians in predicting COVID-19 morbidity and mortality (COVID-19 Clinical Risk Assessment Tool - NHS Digital), IGARD suggested that the applicant clearly articulate what additional or different benefits or impact could be generated from this apparently similar physician tool.

	IGARD members noted that the proposal for this application was for the University of Oxford (who are the Data Processor under applications NIC-381683-R6R6K and NIC431355-B1L8W) to be the Data Controller for this DSA and would use the data under NIC-381683-R6R6K and NIC431355-B1L8W in order to run this study. IGARD were supportive of this approach, but asked that section 5 of the application clearly articulate the role of the University of Oxford, their responsibility and what data would be used, and in line with the relevant published NHS Digital DARS standards. NHS Digital should ensure there was a clearly transparent audit trail that also detailed which organisation held what data, for what purpose and who had responsibility at each part of the processing. **Significant risk areas:** Data Controllership, data minimisation and transparency.
2.3	NIC-431355-B1L8W-v0.3 University of Oxford **Background:** This was a new application v0.3 from the University of Oxford requesting new data for the National Core Studies (NCS) "*data and connectivity: COVID-19 vaccines pharmacovigilance (DaC-VaP)*" study. The study is being funded by the Health Data Research UK (HDR UK). NHS Digital explained that no data was proposed to be flowed under this data sharing agreement (DSA) and that the data that would be accessed to support this study would be via NIC-381683-R6R6K. The data will be linked to the cohort of patients registered within the Royal College of General Practitioners (RCGP) Research and Surveillance Centre (RSC) network. The following observations were made on the basis of the draft v0.3 application summary and relevant draft supporting documents. **IGARD Observations** IGARD members noted that due to the nature of the meeting and when papers were disseminated, they had not conducted a full review of the application and supporting documents provided. Should a full review of the application and documentation be required, the full suite of documentation should be presented to a IGARD business as usual (BAU) meeting for a recommendation. IGARD members noted that they were supportive of the National Core Studies and thanked NHS Digital for the overview. IGARD members suggested that the applicant may wish to update relevant transparency materials and provide updated copies to participating general practitioners reflecting recent developments and the proposed purpose of the processing outlined within in this application. Noting that the GPs are the Data Controllers, it is still for the applicant to ensure the practices have all the relevant and up to date information about the processing. In addition the public facing materials for the RSC and this research project should be clear as to the data controllership and processing responsibilities of each of the parties involved and that there should be a distinction between the surveillance and research projects. IGARD members noted that the size of the cohort was circa 5.4 million and asked that consideration be given to addressing the questions posed in the NHS Digital standard for Data Minimisation.

	IGARD members noted that the proposal for this application was for the University of Oxford (who are the Data Processor under applications NIC-381683-R6R6K) would be the Data Controller for this DSA and would use the data under NIC-381683-R6R6K in order to run this study. IGARD were supportive of this approach, but asked that section 5 of the application clearly articulate the role of the University of Oxford, their responsibility and what data would be used, and in line with the relevant published NHS Digital DARS standards. NHS Digital should ensure there was a clearly transparent audit trail that also detailed which organisation held what data, for what purpose and who had responsibility at each part of the processing. IGARD members noted reference to "…*to conduct observational epidemiological studies that inform the national public health response to COVID-19*…" and asked that section 5 be updated to clarify the beneficial aspect, since the application seemed to be a mixture of outcome and real time observations. In addition IGARD noted that section 5(c) referenced "*to measure the outcome of the COVID-19 vaccine*" and suggested that for each of the bulleted outputs listed, that a clearer narrative be included in line with NHS Digital's DARS Standard for Expected Outcomes. IGARD also noted in section 5(c) that given the potentially detailed information with regard to GP practices that may be available as part of the outputs from this study, that the applicant consider whether the GP would be surprised by any of the details and if further context should be given alongside the practice level data. In addition, and noting the plethora of detail in the '*DaC VaP Protocol'* (no version number), that the detail with regard to the datasets be included in section 5 of the application, since this formed part of NHS Digital's data release register, and noting the request for maternity data, and that current clinical trials were not recruiting pregnant women, that, for example, what valuable and high impact data could be derived from processing the maternity services dataset. **Significant risk areas:** Data Controllership, data minimisation and transparency.
2.4	NIC-431352-G7F1M-v0.3 Imperial College London **Background:** this was a new application v0.3 from Imperial College London for new data for the National Core Studies (NCS) "*REACT data and connectivity national core studies*" study. The study is being funded by the HDR UK. The Real-Time Assessment of COVID Transmission (REACT) study was established in May 2020 and to date there are over 1.5 million people in the REACT cohort and over 90% have provided consent for linkage of their study data to records held by NHS Digital. This new application is requesting linkage between the participant's REACT study data and a number of NHS Digital held datasets. The following observations were made on the basis of the draft v0.3 application summary and the verbal update provided by NHS Digital. No consent materials were reviewed. **IGARD Observations** IGARD members noted that due to the nature of the meeting and when papers were disseminated, they had not conducted a full review of the application and had not been provided with any additional supporting document, such as the consent materials. Should a full

	review of the application and documentation be required, the full suite of documentation should be presented to a IGARD business as usual (BAU) meeting for a recommendation. NHS Digital provided a verbal update with regard to the consent materials reviewed, however IGARD members suggested (without sight of the relevant consent materials) that an analysis be undertaken by NHS Digital of the consent materials utilising the published NHS Digital DARS Standard for Duty of Confidentiality which has been worked up with the NHS Digital Caldicott Guardian and the Health Research Authority Confidentiality Advisory Group (HRA CAG) to assess the data linkage being proposed; any retrospective data access the applicant may be seeking now or in the future; any prospective data access the applicant may be seeking now or in the future; how to convert the current studies into longitudinal studies; who the parties involved were under this application and the relevant REACT data sharing agreement (DSA) etc. IGARD suggested that this analysis by NHS Digital be undertaken before the applicant submitted any further documentation to a Research Ethics Committee (REC) since they did not want to unduly burden the applicant if they had had to resubmit documentation to REC. IGARD members also suggested that the UK General Data Protection Regulation (UK GDPR) Article 6 legal basis be reviewed to ensure the correct Article 6 had been cited in the DSA. IGARD members further suggested that they would be supportive of working with DARS and the applicant on progressing the materials for this application. **Significant risk area:** Common law duty of confidentiality and scope of consent.
2.5	NIC-359937-L8N3F-v0.8 University College London (UCL) **Background:** This was a new business as usual (BAU) application v0.8 to complete a feasibility study using the Bring Your Own Data (BYOD) mechanism to the NHS Digital Trusted Research Environment (TRE), with request for Hospital Episode Statistics (HES) Admitted Patient Care (APC) linked to a cohort of approximately 10,000 people. NHS Digital noted that they had undertaken a limited review of the consent materials provided against the proposed purpose of the application, but were seeking further advice from IGARD. The following observations were made on the basis of the draft v0.8 application summary and some of the relevant supporting documents. **IGARD Observations:** IGARD members noted that due to the nature of the meeting and when papers were disseminated, they had not conducted a full consent review, or full review of the application and supporting documents provided. Should a full review of the application and documentation be required, the full suite of documentation should be presented to a IGARD business as usual (BAU) meeting for a recommendation as per usual practice. IGARD members queried if the feasibility study could utilise “dummy” data, since the purpose of the application was to bring your own data into the TRE, and if no ingested data was being used queried how the feasibility study would achieve its purpose. If the applicant could not use dummy data, this should be clearly articulated in section 5 of the application. Noting that the applicant had informed NHS Digital that they did not know the number of cohort members that had consented on each version of the consent materials, IGARD suggested that NHS Digital put the onus on the applicant to ensure that all relevant materials were provided in

	order to support the application, and that any documentation not relevant to this application be removed from the NHS Digital customer relationship management (CRM) holder. Notwithstanding this, IGARD noted this was potentially a national Stroke TRE and that NHS Digital further support the applicant in analysing the relevant consent and PIS materials and that an analysis grid be set up that could reference each of the relevant versions of consent and PIS and whether the materials were sufficient, and if not, what the gaps were. Noting the limited documentation provided, IGARD members observed potentially ambiguous wording within the consent materials such as "…*with your agreement*…" and "…*that is, with my permission*…" since these phrases could be open to interpretation whether the permission/agreement is being given at the time consent is being taken, or will be sought at some time in the future. On balance, and with regard to other statements and the "easy read" version of the materials, IGARD thought that the proposed processing was consistent with the consent taken. However, given the potential national significance and impact of this proposed TRE, IGARD suggested that the applicant may wish to seek the assurance of approaching a small sample of the cohort and highlighting the relevant wording in the consent to them. If the cohort representatives **were surprised** by the proposed processing then the applicant may need to undertake further consultation with the cohort and address this potential incompatibility with additional measures or an alternative legal gateway. IGARD members noted that '*v2.2 Consultee Declaration form* 'had been provided and noted that it was important that the applicant knew who within the cohort had been included via this consultee form, by virtue of the fact that this group would require a separate legal basis to address the common law duty of confidentiality, for example Health Research Authority Confidentiality Advisory Group (HRA CAG) s251 support or NHS Digital's Caldicott Guardian to invoke the public interest legal gateway. Further discussion should be undertaken by NHS Digital once the number of cohort members added to the study under the consultee form had been established, since they may adversely affect the study outcomes. In addition, the applicant should also provide the number of cohort members who had been added under the consultee form but had subsequently given consent if they regained capacity to do so.
2.6	<u>COVID-19 Vaccine Data for CCGs and Local Authorities (No NIC number)</u> **Background:** This was a verbal update in response to NHS England who had been commissioned by the Secretary of State for Health and Social Care to operate the COVID-19 vaccination programme and for that data to be made available to a number of organisations for COVID-19 purposes such as Local Authorities and CCGs. The Vaccine data is identifiable patient data and contains patient demographics, source organisation (where the vaccination data originated), vaccination appointment and outcome details, and vaccine batch details. The following observations were made on the basis of the verbal update and background paper provided by NHS Digital. **IGARD Observations:** IGARD members noted that the application(s) was potentially to be presented to the IGARD BAU Meeting on Thursday, 25th March 2020. IGARD members noted that the discussion today was not to pre-empt discussions that would take place at the BAU meeting on Thursday, thanked NHS Digital for their verbal update but offered the following limited commentary.

	IGARD members suggested that a templated application be put in place, one for a Local Authority and one for a CCG and that within that templated application that key areas be drawn out in section 5, including, but not limited to: • Outlining the different use cases, particular for the local authorities, and the expertise that they have and what they are proposing to do with this identifiable data. • Information should be drawn out to highlight, in particular for local authorities, any work they are currently doing with regard to the annual flu vaccination programme and any experience they can draw from that. • Since this may be a long term project, how the local authorities / CCGs are planning for this long term project and any learning or expertise they are wishing to propose. • Reference should be made to transparency and how the local authorities / CCGs would address this aspect (noting NHS Digital DARS standard for transparency (fair processing). This may be a **key area of risk to address,** particularly if the data is being handled in a way or by parties, that may surprise citizens. • Since the local authorities and CCGs may be linking to other sensitive datasets, such as the Shielded Patient List, that further investigation be undertaken with regard to what each are doing with the raw data, any linkages they are undertaking, how they are keeping the data secure and any transparency measures they are taking. • Since some aspects of this request may be for direct care, for example to support vulnerable people in their community, IGARD members suggested the National Data Guardian's Excel flow chart be used as a useful ready reckoner for whether "direct care" can be relied on for access to confidential patient data for some access to, or sharing of, the data. • Further consideration should also be undertaken for when COPI ends, currently 30th September 2021, and any other legal gateways that the local authorities for example could rely on such as other public health provisions.
2.7	NIC-433176-J8Q2S-v1.1 AstraZeneca UK Ltd **Background:** This was an update to the business as usual (BAU) item which had been previously discussed at the COVID-19 response meeting on 2nd and 9th March 2021. This was a registry based randomised double-blinded placebo-controlled cardiovascular outcomes trial to evaluate the effect of Dapagliflozin on the incidence of heart failure or cardiovascular death in patients without diabetes with acute myocardial infarction at increased risk for subsequent development of heart failure. Dapagliflozin is a drug that was originally developed for the treatment of type 2 diabetes. The following observations were made on the basis of a number of draft supporting documents including the '*DAPA MI K Flow Split 15032021*', '*DAPA MI Subject ICF UK 16 July 2020 Master Local v2*' and '*DAPA MI Subject ICF UK 16 July 2020 Master Local V2 Edits 030321 v3*' IGARD did not receive a copy of the application or the full suite of relevant supporting documentation. **IGARD Observations** IGARD members noted that the application was to be presented to the IGARD BAU Meeting on Thursday, 25th March 2020. IGARD members noted that the discussion today was not to

	pre-empt discussions that would take place at the BAU meeting on Thursday, thanked NHS Digital for their verbal update but offered the following limited commentary. IGARD members reiterated their previous comments that due to the nature of the meeting and when papers were disseminated, they had not conducted a full consent review nor had they reviewed the application and any other pertinent supporting documentation. Should a full review of the application and documentation be required, the full suite of documentation should be presented to a IGARD business as usual (BAU) meeting for a recommendation. IGARD noted the helpful amendments to the consent materials which addressed a number of comments previously made by IGARD. Noting the glossary of terms the applicant had helpfully provided, IGARD suggested that any acronyms or definitions that were not part of the consent materials could be removed, such as "*HQIP*" but that key terms such "*anonymised*" be defined and explained for the lay reader. IGARD noted that without sight of the application and the full suite of documentation they were unable to state unequivocally if the consent was compatible with the proposed processing and reiterated their previous comment that consent would be assessed in line with NHS Digital's published standards and in particular the published NHS Digital DARS Duty of Confidentiality Standard which had been developed with the Health Research Authority Confidentiality Advisory Group (HRA CAG) and NHS Digital's Caldicott Guardian. IGARD reiterated previous comments made that the applicant may wish to consider "future proofing" their consent materials with regard to gaining consent for any retrospective (for example, 10 years of historical data) data access the applicant may be seeking now or in the future; any prospective data access the applicant may be seeking now or in the future (for example following the cohort for a number of years); how to convert the current studies into a longitudinal study, etc. However, without reference to the protocol or the application, IGARD made these speculative suggestions based on their experience of reviewing consent materials for clinical trials of a similar nature. Finally, IGARD noted that a number of points had been previously raised, and that they had not been provided with a copy of the updated application summary, and that all previous points raised remained outstanding until fully addressed.
3	AOB There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.