Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 3 September 2020

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Prof. Nicola Fear	Specialist Academic Member
Kirsty Irvine (Chair)	IGARD Lay Chair
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Garry Coleman	Data Access Request Service (DARS) (Observer: item 2)
Dave Cronin	Data Access Request Service (DARS)
Louise Dunn	Data Access Request Service (DARS)
Carla Howgate	Clinical Audit & Registries Management Service
Ross Jenkins	Clinical Audit & Registries Management Service (Observer: item 2)
Karen Myers	IGARD Secretariat
Denise Pine	Data Access Request Service (DARS) (Observer: item 3.1)
Vicki Williams	IGARD Secretariat

1	**Declaration of interests:** There were no declarations of interest. **Review of previous minutes and actions:** The minutes of the 27th August 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	<u>National Pregnancy in Diabetes Data Set (NPID) Briefing Paper (Presenter: Carla Howgate)</u> The briefing paper was to inform IGARD about the NPID Audit data set that is due to be made available through the Data Access Request Service (DARS). The National Pregnancy in Diabetes (NPID) Audit is a workstream of the National Diabetes Audit (NDA) and is part of the National Clinical Audit Programme. It aims to support clinical teams to deliver better care and outcomes for women with diabetes who become pregnant. The NPID audit collects information about general diabetes care in pregnancy and measures the effectiveness of diabetes healthcare against NICE Clinical Guidelines and NICE Quality Standards, in England and Wales. Potential customers with interest in the data include academic institutions for research purposes and statutory bodies for performance management or future planning of services. IGARD welcomed the briefing paper and looked forward to receiving an updated paper at a future IGARD meeting, and before any first of type applications are submitted. IGARD made the following additional comments: 1. In relation to the legal bases: a) To review the legal bases for NHS Digital to receive, process and disseminate the data. b) To clarify the legal basis for Hospital Trusts in Wales to collect the NPID data. c) To clarify the correct GDPR Article 9 legal bases. d) To ensure that all IG advice is uploaded to NHS Digital's CRM system. e) To review and amend the data flow diagram to ensure the legal basis for each data flow is correct, for example, s251 / consent; and to ensure this aligns with the briefing paper. f) To clarify how the Common Law Duty of Confidentiality is being addressed in terms of the data flows. 2. To review the statement that patient objections will be applied. 3. In relation to the Data Controllers: a) To review and amend where necessary the Data Controllers listed within the briefing paper; b) To further clarify at which point NHS England are considered joint Data Controllers. 4. In relation to HQIP: a) To confirm their role and background in relation to the NPID; b) To clarify why they are not considered a joint Data Controller. 5. To confirm what data the NHS Trusts will have access to. 6. To reflect that the pseudonymised fields will also include information related to the babies born.
3	**Data Applications**
3.1	<u>Compufile Systems Ltd (CSL): ESPRIT tool (Presenter: Dave Cronin) NIC-01207-V9G9P</u> **Application:** This was a renewal and extension application for pseudonymised Hospital Episode Statistics (HES) data; and an amendment to add Microsoft Azure Data Centre as a Cloud storage location.

	The purpose is to provide the NHS and organisations providing goods and services to the NHS, with a tool set to enable them to analyse data, and in some cases consultancy to help them understand the results. The applicant processes the data for statistical purposes and generates cohorts of patients and patient episodes that are relevant to each analysis performed. CSL work with NHS organisations including Clinical Commissioning Groups, NHS England, NHS Supply Chain, Clinical Support Units and NHS Hospital Trusts. Analysis of the data will show aggregated patient pathways through the hospital system and provide an understanding of how patients are treated. The data is also used in the identification of specific high-risk patient groups and development of improved services and patient treatments. NHS Digital advised IGARD that the "Data Summary" information in section 1 (Abstract) had not been updated prior to submission, and would be amended to reflect the correct information. NHS Digital also advised that the 2014/15 data years requested in section 3(a) (Data Access Already given) were incorrect and confirmed that the applicant had confirmed the destruction of the 2014/15 HES data, and that section 3(a) and section 1 would need updating to reflect this, noting they are only permitted to retain a maximum of 5 full years of HES data. NHS Digital also noted that a number of typos had been corrected throughout the application summary. **Discussion:** IGARD welcomed the application and noted the effort that had gone into updating the application following its last review in December 2017. IGARD noted and supported the additional updates outlined by NHS Digital in relation to the "Data Summary" in section 1; and the updates to section 1 and section 3(a) to reflect the correct data years requested. IGARD noted that when the application was last reviewed, IGARD had suggested that, in line with good practice, the applicant may wish to further develop their oversight board to include lay or patient representation. IGARD welcomed the NHS Advisory Board that had been established, which included independent NHS employees, however suggested that the lay representation on the oversight board could be by way of **patient and public** involvement. In addition, IGARD suggested that to further enhance public transparency, the oversight board may wish to publish their minutes of the meetings. IGARD noted the statement in section 1, that there was an outstanding requirement in relation to the applicant's privacy notice, and queried this statement due to the information elsewhere in section 1 and section 4 (Privacy Notice) that stated that the privacy notice **had** met NHS Digital's Standard for privacy notices. NHS Digital advised that the privacy notice had been assessed by NHS Digital on the 5th August 2020 and that section 1 would be updated to accurately reflect that the privacy notice **had** met NHS Digital's Standard for privacy notices and to ensure it accurately aligned with section 4. IGARD queried the outputs stated in section 5(c) (Specific Outputs Expected) and section 5(d) (Benefits), and asked that these were updated to be clearer in terms of both the outputs and the target dates, and that further detailed examples of the outputs were also included. IGARD noted the special condition in section 6 (Special Conditions) that stated *"Compufile Systems Ltd must review and update their *SLSP before the next renewal of this agreement"* (*System Level Security Policy), and queried if this was still relevant, and if it was, then suggested NHS Digital asked for sight of the SLSP, and if not, suggested that this special condition was removed.

	IGARD noted the statement in section 5(d) that *"CSL are not using the data in support of a PhD or post graduate study"*, and asked that this was removed, and advised that information should only be included if the data **was** supporting a PhD or post graduate study. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, with the exception of the notified amendment to the storage location, which would be suitable for the Precedent route. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 1 and section 3(a) to reflect the correct data years requested. 2. To update section 1 to reflect that the privacy notice **has** met NHS Digital's Standard for privacy notices. 3. To update section 5(c) and section 5(d) to have clearer outputs with target dates and examples. 4. To clarify if the SLSP special condition in section 6 is still required, and if not, to remove. 5. To remove reference to the PhD Graduate in section 5(d). The following advice was given: 1. IGARD previously advised that the applicant may wish to develop their oversight board, to include lay representation, by way of patient and public involvement. 2. IGARD suggested that the oversight board may wish to publish their minutes of the meetings for the purpose of transparency. 3. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent (with the exception of the notified amendment to the storage location, which would be suitable for the Precedent route).
3.2	<u>University of Bristol: Outcomes of patients undergoing lower limb vascular procedures in the National Vascular Registry (Presenter: Louise Dunn) NIC-203730-Y4V0Z</u> **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) and Civil Registrations data, for the purpose of a service evaluation project is to investigate patient outcomes after lower limb vascular surgery. This study will look specifically at the time 1st January 2014 - to the 31st December 2016, which covers a total of 40,890 patients who underwent lower limb vascular procedures recorded in the National Vascular Registry (NVR), equivalent to 13,630 procedures per year. Unfortunately, little is known about the longer-term outcomes of this patient group in the 12 months after they leave hospital. The published findings would thus enable clinicians and patients to be better informed and facilitate future research on patient risk prediction for these procedures. **Discussion:** IGARD noted that the purpose of the application was for service evaluation and briefly discussed the overlap between "research" and "service evaluation", and noted that s251 approval had been obtained from Health Research Authority Confidentiality Advisory Group (HRA CAG) for the purpose of service evaluation. IGARD asked that section 5(a) (Objective for Processing) was updated to reflect that the s251 support was not for research purposes. In addition, NHS Digital noted the query from IGARD and advised that this would be discussed further with HRA CAG in a future meeting to seek further clarity on research versus non-research applications. IGARD also discussed that a similar application that had been reviewed, had mixed legal bases, which consisted of consent for the elective procedures on the NVR, and s251 for those

	following emergency procedures. NHS Digital again noted the query and advised that this would also be raised at a future meeting with HRA CAG. **ACTION:** NHS Digital to seek further clarity with HRA CAG on the potential overlap of service evaluation and research purposes; and the mixed legal bases of s251 and consent for a similar application. IGARD noted the legal bases' stated in section 3(b) (Additional Data Access Requested) and asked that this was reviewed to ensure the correct legal basis was stated for the dissemination of each data flow. IGARD noted that section 3(c) (Patient Objections) stated that patient objections were being applied, and asked that this was updated with further narrative stating that patient objections were being applied to the flow of identifiable data into NHS Digital relied on s251. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. NHS Digital noted that the applicant had drafted a privacy notice and that this was to be published on the National Vascular Registry (NVR) website. IGARD noted the draft document and asked that a special condition was inserted in section 6 (Special Conditions), stating that within 1-month of signing the Data Sharing Agreement (DSA), the NVR will have published a General Data Protection Regulation (GDPR) compliant privacy notice. IGARD also queried the statement within the draft privacy notice, that individuals can withdraw consent for their data to be processed, and asked that this statement was reviewed as it was incorrect (once the data has flowed from NHS Digital re-identification will not be permitted). In addition, IGARD asked that for transparency, the NVR privacy notice was either added to the University of Bristol's website, or a link was added to the privacy notice on the NVR website. IGARD suggested that the statement in section 5(a) (Objective for Processing) that stated *"…there are no moral or ethical issues…"* was removed since it was not necessary to include in the application. IGARD noted the outputs stated in section 5(c) (Specific Outputs Expected) and asked that these were reviewed further, for example, giving further consideration to publishing these across more diverse social media channels than the one stated. IGARD also suggested that noting the involvement of patient groups in dissemination of the outputs, the applicant may also wish to consider involving these patient groups in earlier stages of the work. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of the privacy notice: a) To insert a special condition in section 6 that within 1 month of signing the DSA, the NVR will have published a GDPR compliant privacy notice. b) To review the statement within the privacy notice with regards to withdrawal from the study. c) To either add to the University of Bristol website either the NVR Privacy Notice or a link to the notice on the NVR website. 2. To review the legal basis for dissemination in section 3(b). 3. To update section 3(c) to include a narrative outlining that patient objections are being applied as the flow of identifiable data into NHS Digital relies on s251. 4. To remove from section 5(a) reference to '*there are no moral or ethical issues*".

	5. To update section 5(a) to reflect that the s251 support is not for research purposes. The following advice was given: 1. IGARD suggested that the outputs in section 5(c) are reviewed, and consideration was given to publishing across more diverse social media channels. 2. IGARD suggested that noting the involvement of patient groups in dissemination of the outputs, the applicant may wish to consider involving these patient groups in earlier stages of the work.
3.3	<u>University Hospitals of Derby and Burton NHS Foundation Trust (UHDB): Regional variation in epidemiology of COVID-19 in England (Presenter: Louise Dunn) NIC-391959-Q3C3G</u> **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. **Discussion:** IGARD welcomed the application and noted the importance of the research. IGARD had a lengthy discussion on the purpose of the application and what the applicant was trying to achieve across a number of issues, for example, what the national purpose and benefit for the study was, and what the COVID-19 aspect was trying to achieve as this was not clear. IGARD asked that section 5(a) was updated to clarify this, and to acknowledge the level of interest of the specific study lead in relation to the key questions that had been set. IGARD also queried the code sets being used, and specifically queried the 'International Statistical Classification of Diseases and Related Health Problems' (ICD)-10 'Acute Renal Failure' (ARF) codes that were being used as a proxy for a specific stage of AKI, and asked that a clear explanation and justification of this was provided. IGARD also asked that transparency, section 5(a) (Objective for Processing) was updated to include a brief narrative of the code sets. IGARD discussed the various stages of AKI, for example where a patient may or may not require hospital admission, and noted that it was not clear in section 5(a), that where there was reference to AKI, it was not clear at which stages they were referring to, and asked that this was updated with a clearer and more transparent description. In addition, IGARD also noted the statement in section 3(b) (Additional Data Access Requested) "*Only data items with biological plausibility to COVID outcome have been requested*", and asked that a clear description was provided of the code sets for these conditions. IGARD queried why maternity data had been excluded from the application, in light of the questions raised in relation to the maternity risks in relation to COVID-19, and asked that an explanation was provide as to why this was not also requested. IGARD noted the information in section 5(b) (Processing Activities) that outlines the remote access arrangements to the data, and queried if the security requirements for the remote access had been assessed and deemed satisfactory by NHS Digital's Security Team, and asked that section 1(b) (Data Controller(s)) was updated with confirmation.

	IGARD noted that the COVID-19 death figure for the UK stated in section 5(a) was incorrect and asked that this was updated to state the most recent figure. IGARD queried the language used in section 5(a), for example, "*In England, London and the West Midlands were overwhelmed in the early period of the pandemic*", and asked that this was reviewed to ensure the language was not overstated. IGARD queried the statement in section 5(c) (Specific Outputs Expected) *"It is not expected that analysis of this data will produce new tools, algorithm and new technology"*, and asked that this was removed as it was not relevant. IGARD queried the benefits outlined in section 5(d) (Benefits),and noted that the protocol referred to patient involvement with the dissemination of the outputs and asked that section 5(c) was updated to include further narrative for the patient involvement of the dissemination of the outputs. IGARD also asked that the benefits outlined in section 5(d) were updated to align with the aims and objectives as outlined in the protocol, and that the benefits were expressed in appropriate language that were realistic and achievable; and that target dates for the benefits were also included. IGARD noted the statement in section 5(d) "*The study is not in support of postgraduate research*." and asked that this was removed as it was not relevant. **Outcome:** Recommendation to defer, pending: 1. 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. 2. To provide a clear description of the code sets for conditions with biological plausibility to a COVID outcome. 3. To provide an explanation of the exclusion of maternity data for the data requested. 4. To add confirmation in section 1(b) that the security requirements for remote access have been deemed satisfactory by NHS Digital's Security Team. 5. 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"*. e) To provide a clearer description of AKI and the stages they are referencing. 6. 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. 7. 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. d) To remove the statement that "the study is not in support of post-graduate research".
3.4	University of Surrey: Data for NHS hospital workforce retention project (determinants and effects on patients' outcomes) (Presenter: Louise Dunn) NIC-345789-L9Q7J

	Application: This was a new application for pseudonymised Hospital Episode Statistics (HES), Civil Registration (CR) data, Mental Health Services Data Set (MHSDS), Emergency Care Data Set (ECDS), Mental Health Minimum Data Set (MHMDS), Mental Health and Learning Disabilities Data Set (MHLDDS) and Patient Reported Outcome Measures (PROMs). The purpose is for a project with the aim of investigating the determinants and effects of hospital workforce retention (WFR). This project is led by University of Surrey (UoS) and funded by The Health Foundation. The project is of interest for the research team, the Funder, and the wider community of researchers and healthcare policy-makers, with an expected positive impact on the knowledge of the economics of healthcare workforce and its effects on hospital performance and patients' outcomes. The added contribution generated by the project is hoped to help improve the sustainability of the English NHS. The study will focus on two research questions, 1) What are the determinants of variations in NHS WFR, in both acute care (AC) and mental health (MH) hospitals?, and 2) What are the causal effects of WFR on admitted patients' health outcomes (mortality, emergency readmissions, length of stay, waiting times) in emergency, elective and MH care? **Discussion:** IGARD noted the large volume of NHS Digital data requested by the applicant, and asked that a justification was clearly articulated in section 3 (Datasets Held / Requested) and section 5 (Purpose / Methods / Outputs) for the data requested, both in terms of the number of fields and the timescales outline. IGARD queried if the applicant was aware that the NHS Digital data supplied would show associations not causality, and asked that section 1 (Abstract) was updated with confirmation. IGARD had a lengthy discussion on the General Medical Council (GMC) consultant code requested, and queried why this was stated as being an identifiable field, when it was not identifiable but sensitive, and asked that section 3(b) (Additional Data Access Requested) was updated with clarification that GMC consultant code was not treated as an identifiable field. IGARD queried the information within the application that stated the GMC consultant code was required for linkage purposes, and asked that a clear justification was provided in section 5(b) (Processing Activities) of the requirement of the GMC consultant code for linkage purposes. IGARD also queried if the GMC consultant code was removed or replaced with a study ID key once the linkage had taken place, and asked that section 5 was updated with confirmation. IGARD noted the information in section 5(a) (Objective for Processing) that stated "*no ethical issue arises"*, and asked that, in light of the clear ethical issues that arise, for example in relation to the request for GMC consultant codes, asked that this was removed. In addition, IGARD asked that further information was provided in section 5(a) on the ethical issues and how they had been addressed. IGARD noted a number of acronyms in section 5(a) 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, such as *"HHI index".* IGARD queried the statement in section 5(b) that stated *"the first linkage will be by period…the first linkage will be by consultant"*, and asked that further clarity of this was provided. IGARD also queried the statement in section 5(b) *"…the risk of ecological fallacy (i.e. aggregation bias) in the results." and asked that this was updated with a further explanation.* IGARD noted the reference in section 5(b) to "*virtual desktops"* and queried whether these would be used for remote working, and if so, asked that NHS Digital ensured that the appropriate security arrangements were in place.

	IGARD noted the information in section 5(c) (Specific Outputs Expected) and queried if the patient groups would be involved with the dissemination of the outputs, and asked that further confirmation was provided. IGARD also noted in section 5(c) that the research team are seeking to publish the project's findings in "high quality journals", and queried if public access would be available through open access journals, and asked for further clarity. In addition, IGARD noted that specific target dates had not been included in section 5(c) and asked that this was updated with the relevant target dates. IGARD noted some of the language used to describe the benefits in section 5(d) (Benefits), for example "…*as services are overly stretched by a prolonged financial austerity period…*", and asked that this was reviewed to ensure the language used remained objective and neutral. In addition, IGARD also noted that some of the text within section 5(d) had been repeated and asked that any repetitive text was removed if not necessary. IGARD queried the public interest of the study in terms of benefits to the health and care of the population, and asked that section 5(d) was updated clearly articulating this; and that the benefits outlined were realistic and achievable. IGARD suggested that the applicant may wish to consider updating their protocol, to include (but not limited to) the co-investigators not having data access, and to reflect where the study was at now. **Outcome:** recommendation to approve subject to the following conditions: 1. To clearly articulate in section 3 and section 5, the justification for the large volume of data requested both in terms of the number of fields and timescales. 2. In respect of the GMC consultant code: a) To provide clarification in section 3(b) that the GMC consultant code is not treated as an identifiable field. b) To provide a clear justification in section 5(b) of the requirement of the GMC consultant code for linkage purposes. c) To confirm in section 5, if the GMC consultant code is removed or replaced with a study ID key once the linkage has taken place. The following amendments were requested: 1. To update section 1 to confirm the applicant is aware that the data supplied will only show associations. 2. In respect of section 5(a): a) To remove reference to "no ethical issue arises". b) To provide an update on the ethical issues and how they have been addressed. c) To ensure it is written in language suitable for a lay reader. 3. In respect of section 5(b): a) To clarify the sentence *"the first linkage will be by period…the first linkage will be by consultant"*. a) To explain *"…the risk of ecological fallacy (i.e. aggregation bias) in the results"*. b) To clarify whether virtual desktops are used for remote working and if so, to ensure appropriate security arrangements are in place. 4. In respect of section 5(c): a) To confirm if the patient groups will be involved with the dissemination of the outcomes. b) To clarify if public access is available through open access journals. c) To include relevant target dates.

	5. In respect of section 5(d): a) To review the language to ensure it remains objective and neutral. b) To remove any repetitive text. c) To ensure the public interest is clearly articulated in terms of benefits to the health and care of the population. d) To ensure the benefits are realistic and achievable. The following advice was given: 1. IGARD suggested that the applicant consider updating their protocol, to include (but not limited to) the co-investigators not having data access, and to reflect where the study is at now. It was agreed the conditions would be approved OOC by IGARD Members.
3.5	<u>Ignite Data Ltd: INvestigation of TRELEGY Effectiveness: Usual PractIce Design (INTREPID) Exploratory data set (Presenter: Louise Dunn) NIC-297783-V4P6H</u> **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) data. Healthcare resource utilisations (HCRU) is the quantifiable measure of a person's use of services for the purpose of both preventing and curing health problems, the promotion of maintenance of health and wellbeing. Through systematic review the disease burden experienced by both the patient and their healthcare providers can be assessed. The purpose of the study, is 1) to assess the feasibility of using routine healthcare data to collect secondary care healthcare resource utilisation data (all cause and Chronic Obstructive Pulmonary Disease (COPD) related) in clinical trials using HES data for patients consented into the INTREPID study. The study will describe the recording (available in HES, yes/no) and completeness (% non-missing values) of different components of secondary care HCRU and the ability to apply Healthcare Resource Group (HRG) tariffs to these where possible; and 2) to use the HES data to summarise HCRU and costs using HRG tariffs for COPD patients (all cause and COPD related) on inhaled triple therapy for patients consented into the INTREPID study. NHS Digital advised IGARD that all patients were recruited using version 3 of the consent form, and that the consent materials had been revised to align with the General Data Protection Regulation (GDPR) guidance, and that Ethics Approval had been received for these revised materials. NHS Digital also advised that no NHS digital data will leave England and Wales, and that the application had been updated to ensure both these points were accurately reflected. **Discussion:** IGARD noted the update from NHS Digital in relation to version 3 of the consent materials being used for recruitment, and that these had been reviewed by ethics, and asked that section 1 (Abstract) was updated to reflect this, and that a copy of the ethics approval was uploaded to NHS Digital's Customer Relationship Management (CRM) system. IGARD also queried whether any possible issues may arise by possible linkage of NHS Digital data to rival company products, and suggested that NHS Digital confirm with the legal directorate that they were content that there were no issues. In addition, IGARD also noted the clarification from NHS Digital that no NHS Digital data would leave England and Wales, and asked that section 5(b) (Processing Activities) was updated to reflect this information. In addition, IGARD asked that a special condition was inserted in section 6 (Special Conditions), that NHS Digital data must remain within England and Wales. IGARD noted that GlaxoSmithKline (GSK) were funding the study, and discussed the fact that they were also the manufacturer of the device that was being studied, and for the purpose of

	transparency asked that section 5(e) (Is the Purpose of this Application in Anyway Commercial?) was updated further to also reflect this information, and the potential commercial benefit that they may gain. IGARD queried the information in section 1(b) (Data Controller(s)) that stated *"GlaxoSmithKline (GSK)*" were the Data Controller, and asked that this was updated to correctly reflect that *"GlaxoSmithKline Research and Development Limited*", as noted elsewhere in the application were the Data Controller. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. IGARD asked that a special condition was inserted in section 6 (Special Conditions), stating that within 1-month of signing the Data Sharing Agreement (DSA), the applicant will have published a General Data Protection Regulation (GDPR) compliant privacy notice, and before any data flows. In addition, IGARD also suggested that the legal basis for processing the data, and the legitimate interests needs to be accurately described within the privacy notice. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment. **Outcome:** recommendation to approve subject to the following conditions: 1. To update section 5(e) to reflect that GSK who is funding the study, is also the manufacturer of the device being studied and therefore potentially stands to have commercial benefit. 2. To insert a special condition in section 6 that within 1 month of signing the DSA, the applicant will have published a GDPR compliant privacy notice, and before any data flows. The following amendments were requested: 1. To update section 1 to reflect that version 3 of the consent materials has been reviewed by ethics, and a copy has been uploaded to CRM. 2. To update section 1(b) with the correct GSK Data Controller organisation details. 3. With regards to Territory of Use: a. To clarify in section 5(b) that NHS Digital data will not leave England and Wales. b. To insert a special condition in section 6 that NHS Digital data must remain within England and Wales. The following advice was given: 1. IGARD suggested that NHS Digital confirm that they are content that no issues would be raised by the possible linkage of data to rival company products. 2. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment. It was agreed the conditions would be approved OOC by IGARD Members
4	<u>Returning Applications</u> Due to the volume and complexity of applications at today's meeting, IGARD were unable to review any applications as part of their oversight and assurance role.
5	<u>COVID-19 update</u> To support NHS Digital's response to COVID-19, from Tuesday 21st April 2020, IGARD will hold a separate weekly meeting, to discuss COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 urgent applications that have been submitted to NHS Digital. Although this is separate to the Thursday IGARD meetings, to ensure

	transparency of process, a meeting summary of the Tuesday meeting will be captured as part of IGARD's minutes each Thursday and published via the NHS Digital website as per usual process. The ratified action notes from Tuesday 1st September 2020 can be found attached to these minutes as Appendix B.
6	<u>AOB:</u> There was no further business raised, the Deputy 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 28/08/20

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-262908-X5F4Q	University of Leicester	09/04/20	1. To provide justification for the quantum of data requested, in line with NHS Digital's Data Minimisation Standard 3.	IGARD Members	Quorum of IGARD Members	N/A
NIC-170647-Z0B6H	University Hospitals Bristol and Weston NHS Foundation Trust	16/07/20	1. To update the application throughout and the patient information material(s) to be explicitly clear who the Data Controller(s) and Data Processor(s) are, and ensure that all materials are aligned.	IGARD Chair	IGARD Chair	N/A
NIC-49297-Q7G1Q	University College London	06/08/20	1. To provide written confirmation how the applicant has met DARS Standard for Sub Licencing. 2. To update the applicant's TOR provided to reflect the questions on the sub-licensing application, including express consideration of data minimisation and how the data will be of benefit to health and social care. 3.	IGARD Members	Quorum of IGARD Members	N/A

NIC-365354-R3M0Q	University of Oxford	30/07/20	1. IGARD endorsed the comments made by PAG and suggested: a) To confirm whether or not the Professor at the University of Bristol will have access to the primary care data. b) To insert a special condition in section 6 stating that within 1-month a GDPR-compliant Privacy Notice, as assessed by NHS Digital, will be published. 2. To clarify in section 5(a) if the data is being linked to any other application, and if so if this is covered in the study materials and processing activities.	IGARD Members	Quorum of IGARD Members	The special condition states "*The University of Oxford must update their privacy notice to be compliant with the ICO Criteria. The University of Oxford must provide an updated link to NHS Digital to review within 1 one month of signing this agreement*." This wording means that a compliant notice may not be published **within** one month (NHS Digital's review may well take place more than a month after signature and they may judge it requires changes to be compliant). We would suggest the text is revised to more closely follow the condition and usual standard wording which DARS have been using for some considerable time.
NIC-301834-K0S2Y	LA-SER Europe Ltd	30/07/20	1. To provide an explicit statement in section 5 with regard to the relationship between the drug being used, the role of the funder, the condition being studied and the focus of this project. 2. To insert a special condition in section 6 that the findings will be made public within 3-months of the funder receiving them.	IGARD Members	Quorum of IGARD Members	IGARD noted that condition 3 wording had been amended when included as a special condition "*The Data Controller must publish a GDPR compliant Privacy Notice for this study purpose within six weeks of this*

			3. The applicant should publish a GDPR compliant privacy notice and before any data flows.			*agreement becoming active*." NHS Digital confirmed that no data would flow until a GDPR compliant privacy notice had been published and IGARD were content with the amended special condition wording.

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

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, 1st September 2020

In attendance (IGARD Members):	Kirsty Irvine (IGARD Lay Chair)
	Dr. Imran Khan (Specialist GP Member)
	Dr. Geoff Schrecker (Specialist GP Member)
In attendance (NHS Digital):	Cath Day (DARS – item 3.1)
	Louise Dunn (DARS)
	Liz Gaffney (DARS – item 2 and 3.1)
	Karen Myers (IGARD Secretariat – Observer)
	Vicki Williams (IGARD Secretariat)
In attendance (external):	Emily Cross (IBM – item 2 only)

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:** There were no declarations of interest.
2	<u>IBM update</u> IGARD members were given a brief update to the IBM work underway in NHS Digital including improvements to the customer experience and current projects. It was agreed that this would be a weekly update to the COVID-19 response meeting. IGARD members thanked IBM and NHS Digital for the update and reiterated their previous suggestion that IGARD should be included early in any process or drafting changes including, but not limited to, application checklists, standards and precedents.
3.1	<u>NIC-135277-R8M3G Regional Drug & Therapeutic Centre (RDTC)</u> **Background:** This was an amendment to an application from the RDTC (based at the Newcastle-upon-Tyne NHS Foundation Trust) to access the GPES Data for Pandemic Planning & Research (GDPPR) to analyse the medication prescribed both at the time of diagnosis and over time, following a diagnosis to understand and assist with forecasting CCG spend and cost growth. These areas are usually determined through analysis of ePACT2 data,

	however, this data is only available with a 3 month delay and does not provide the level of differentiation needed to understand costs due to COVID-19 infection and short term costs due to changes in prescribing behaviour e.g. stocking up on medicines. NHS Digital noted that the application and supporting documentation would be presented at the Profession Advisory Committee (PAG) next Wednesday, before its inclusion on the IGARD business as usual meeting on Thursday, 17th September 2020. **IGARD Observations:** IGARD members noted the request for GDPPR data but queried why the applicant had not sought out other datasets to achieve this objective such as the NHS Business Services Authority (NHSBSA) data which was currently onboarding to NHS Digital. NHS Digital noted that they were unclear of the timeline for onboarding the NHS BSA dataset. Noting that the applicant would be constrained by the Direction under which the GDPPR data was collected, IGARD suggested that a clear narrative be provided in section 5 (Purpose / Methods / Outputs) in order to justify the use of GDPPR data in the current COVID-19 pandemic. In addition it should be clearly set out how the GDPPR data would be isolated from all other uses and not folded into general processing, since this was not permitted under the Direction. IGARD members noted the questions set out in the application which were to be answered using the GDPPR data, however a narrative should be provided as to how each fitted under the relevant Direction and legal basis applied.
3.2	<u>Permission to Contact (no NIC number available)</u> **Background:** This was a verbal update to an application to be submitted by IQVIA Ltd and AstraZeneca to access the Permission to Contact (PtC) dataset for a potential vaccine trial. NHS Digital noted the discussions were ongoing with the applicant and NHS Digital's information governance (IG) directorate, and that the application had been included as an urgent item on the IGARD business usual meeting on Thursday, 3rd September, noting that if the application was not ready, a verbal update would be given. **IGARD Observations:** IGARD members noted the verbal update and that if documentation was not ready for the Thursday BAU meeting that NHS Digital would take the opportunity to provide another verbal update to members. Noting the privacy notice, published on NHS Digital's website, thought should be given as to updating this urgently to include any new 'categories' of organisations and as set out in Article 14(1)(e) of the General Data Protection Regulations (GDPR). IGARD members noted that a potentially large extract would be required in order to generate the specific exclusion criteria required by the applicant and that thought should be given as to how to find a suitable cohort for both phase 1 (cohort of 48) and phase 2 (cohort of 1550) of the study, since you did not want to cause unnecessary distress or upset to any individual excluded from the trial and who didn't fit the criteria set out by the applicant. IGARD members suggested that due diligence be undertaken to ensure the correct IQVIA legal entity was included on the application summary.

3.3	NIC-390154-Z4M0F Public Health England (PHE) **Background:** this was an update to previous presentations at the COVID-19 response meetings on the 7th July, 28th July and 25th August 2020. This was a new application for GPES Data for Pandemic Planning & Research (GDPPR) and is a priority request with a legal basis of the Health Service (Control of Patient Information Regulations) 2002 (COPI). The broad aim is understanding COVID-19 and risks to public health, trends in COVID-19 and such risks, and controlling and preventing the spread of COVID-19 and such risks, for research and planning purposes. NHS Digital noted that the application and supporting documentation would be presented at the Profession Advisory Committee (PAG) next Wednesday, before its inclusion on the IGARD business as usual meeting on Thursday, 17th September 2020 **IGARD Observations:** IGARD members noted that Amazon Web Services had been referenced in the applicant's Data Protection Impact Assessment (DPIA) and that consideration should be given to including them as a Data Processor (and noting in an appropriate privacy notice/transparency materials), if appropriate and in line with the facts presented. IGARD members noted that the applicant had specified within the application a number of datasets that the GDPPR data would be linked to, and supported NHS Digital's view that any other linkage should be notified to NHS Digital by way of an amendment application, and before that linkage was undertaken. For all the various activities being undertaken, the application should clearly outline how the additional data is related to the COVID-19 purpose, and to provide the relevant justification including, but not limited to, a clear public health use. IGARD members noted that '*service use*' had not been included on the triage form provided as part of the suite of supporting documentation, but was listed in the application, and suggested that it be removed from the application or included on the triage form. Noting that the supporting documentation provided noted that the findings would not be generalisable, IGARD members queried how policy decisions could be made on outcomes that had **not** be generalisable, and suggested that the applicant seek advice from the Health Research Authority (HRA) to get a fast track assessment as to whether Research Ethics Committee (REC) approval was required.
3.4	NIC-394372-G2W3W Department of Health & Social Care (DHSC) **Background:** this was an update to the verbal update at the COVID-19 response meeting on the 25th August 2020. This was a new application from the DHSC requesting data for the National Medical Examiner Review of COVID-19 related deaths of health and social care staff in England. The Office for National Statistics (ONS) will do the work to identify the relevant deaths of care workers and will create a cohort of people to share with NHS Digital who will then link to LEDR-ID's of the identified deaths with NHS Number and existing civil registration data collected and share

	back to DHSC to enable the appropriate regional Medical Examiner to be notified and to accurately identify the deceased. NHS Digital noted that this had been through NHS Digital's prioritisation front door but that an urgent request had been submitted by the information governance (IG) directorate that a Data Sharing Agreement (DSA) be put in place, by way of a DARS application. NHS Digital also noted that they were awaiting written confirmation from the Information Governance (IG) Directorate to support the legal basis cited in the application. **IGARD Observations:** IGARD noted the work undertaken by the applicant and NHS Digital to produce this well-written application. IGARD members noted that the IG advice was in progress to cover the various flows to and from NHS Digital, but were confident that the legal bases were sound. IGARD members noted that the release of this data by ONS could only be for statistical purposes, however since NHS Digital was releasing the same data (since it had been onboarded to NHS Digital from ONS), suggested that a narrative be inserted in section 1 (Abstract) explaining this approach. IGARD members noted that the application was for care workers only, and noting that this may be outside of their Terms of Reference remit, suggested that since some care workers may be third party contractors or through agencies, that it was vitally important to ensure that all care workers were captured and acknowledged in this very important but sensitive study. In addition and noting that a coroners report was produced for each death and that a further investigation was not undertaken when a coroner's report was produced, to clarify in the application why no further information would be flowing after the production of said report. IGARD members noted that acronyms, such as "*LEDR-ID's*", be spelt out on first use and explained where necessary. IGARD members noted the update from NHS Digital on this particularly complex but urgently needed review of COVID-19 related deaths of health and social care staff in England, and supported NHS Digital's assessment that the application would be approved under the DARS SIRO precedent.
3.5	<u>NIC-08472-V9S6K UK BioBank</u> **Background:** This was an amendment application to include GPES Data for Pandemic Planning & Research (GDPPR). The application had been previously considered at the IGARD business as usual meeting on Thursday, 16th January 2020. GDPPR data was being requested to enable a fuller case ascertainment of the disease, given that the majority of people experience mild to moderate symptoms and do not require hospitalisation. The primary care data of over 500,000 participants will enable researchers to answer a wide range of research questions related to COVID-19 including why some people develop severe disease and others do not, it will also enable researchers to better understand how underlying health conditions affect COVID-19 disease severity and to perform research into the longer terms health effects of COVID-19. **IGARD Observations:**

	NHS Digital noted that the Information Governance (IG) directorate had assessed the applicant's legal basis for GDPPR data and supported consent as the legal basis to address the Common Law Duty of Confidentiality. Noting that UK BioBank receive GP data from a number of other sources, IGARD suggested that a justification be provided in section 5 (Purpose / Methods / Outputs) as to why GDPPR data was required, in addition the rich primary care data sources they already held. To address the legal requirement for data minimisation efforts to be addressed, the applicant would need to set out what additional functionality the GDPPR dataset possessed. For example, they may be applying for GDPPR data due to timeliness and the advantage of this timeliness over other datasets should be set out and also clearly linked to the COVID-19 purpose. IGARD members noted that the applicant was requesting the GDPPR data for the entire c. 500,000 cohort, and noting NHS Digital's Data Minimisation Standard, justification should be provided as to why the entire GDPPR dataset was being requested and whether or not it could be minimised to certain code clusters. Noting the good work being undertaken by the applicant to ensure the public facing website was updated regularly, IGARD suggested that the privacy notice and website be updated with the proposed activity outlined in this application and using this dataset. If the applicant was successful in accessing the GDPPR dataset in pseudonymised form, thought should be given as to whether this data would form part of the applicant's "data store" with access by international researchers, and suggested that NHS Digital's IG provide written confirmation of any restrictions that are in place for the use of GDPPR pseudonymised data, particularly in terms of use outside England and Wales and any restriction on the purpose of its use by international researchers (in light of the Direction under which GDPPR data was collected). IGARD members suggested that, in the interests of consistency, NHS Digital ensure the application, approvals, conditions and restrictions on further usage of GDPPR data aligned with other applications previously approved (particularly those similar applications with a consented cohort and potential downstream use of data by researchers). IGARD members noted that this application had previously been approved via SIRO precedent and that a clear history to the approvals of this application (including how conditions and special conditions had been addressed) prior to January 2020 should be provided in section 1 (Abstract) or as a separate supporting document, uploaded to CRM. NHS Digital noted that a verbal update would be provided at next week's COVID-19 response meeting with progress made to date.
4.	<u>AOB</u> There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.