Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 28 January 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 Lay Chair
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 GP Chair
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Nicola Bootland	Data Access Request Service (DARS) (Observer: item 2)
Catherine Day	Data Access Request Service (DARS)
Louise Dunn	Data Access Request Service (DARS)
Duncan Easton	Data Access Request Service (DARS)
Dan Goodwin	Data Access Request Service (DARS)
Richard Hatton	Clinical Informatics and Deputy Caldicott Guardian (Observer: items 1 - 3.3)
Dickie Langley	Privacy, Transparency and Ethics
Christina Munns	Privacy, Transparency and Ethics
Karen Myers	IGARD Secretariat
Denise Pine	Data Access Request Service (DARS)
Alyson Whitmarsh	Workforce Statistics, Data, Information and Statistics Directorate
Vicki Williams	IGARD Secretariat

1	**Declaration of interests:** Maurice Smith highlighted his roles as a GP partner working in a Liverpool GP practice in relation to the GP Workforce Data Set Briefing Paper (item 2). This was not considered a conflict of interest and Maurice remained in the room for the discussion. Maria Clark noted professional links to the British Medical Association in relation to the GP Workforce Data Set Briefing Paper (item 2). This was not considered a conflict of interest and Maria remained in the room for the discussion. Maria Clark noted professional links to the Royal College of Surgeons (NIC-136916-B7D5C), but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 21st January 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>General Practice Workforce Data Set - Briefing Paper (Presenters: Christina Munns / Alyson Whitmarsh)</u> The briefing paper was to inform IGARD about the General Practice (GP) Workforce data set, which contains data on individual staff members providing services at a General Practice in England. The Department for Health and Social Care (DHSC) and other Arms-Length Bodies (ALBs) use the data for policy formulation and workforce planning. The General Practice (GP) Workforce Data Set is currently being onboarded into NHS Digital's Data Access Request Service (DARS) at the request of stakeholders. This data has been collected by NHS Digital via the National Workforce Reporting System (NWRS), formally known as the Primary Care Web Tool, since Sept 2015. Prior to that, an annual GP workforce census used information provided by National Health Applications and Infrastructure Services (NHAIS). This briefing paper was previously presented to IGARD on the 26th March 2020, where IGARD made a number of comments. IGARD welcomed the revised briefing paper and made the following additional comments: IGARD noted within the briefing paper, that data would be collected, processed and published, under the Workforce Information Directions 2019 from the Department of Health and Social Care; however, queried what the legal gateway was for NHS Digital to share the data with researchers, and asked that narrative was included within the briefing paper clarifying this, notwithstanding the wording of the relevant Direction. IGARD queried the statement *"All requests for dissemination of data will be considered on a case by case basis depending on the application and data minimisation will be upheld as standard."*; and asked that further information was provided in the briefing paper outlining, the data minimisation efforts, and in addition, that this was also aligned with NHS Digital's DARS Data Minimisation Standard.

	IGARD had a lengthy discussion in respect of the transparency arrangements, to the affected workforce; and suggested that the categories of possible data recipients were expanded to give indicative categories, and in particular to highlight researchers. IGARD noted the three transparency notices that had been provided, and suggested that NHS Digital may wish to consider requesting *"soft"* feedback from the stakeholders they were working with, as opposed to formal consultation, for example, from the Royal College of General Practitioners (RCGP). IGARD also advised that NHS Digital should produce an indicative plan for transparency communication which addressed how to effectively reach **all** staff in practices, beyond general NHS websites, for example posters that could be e-mailed to staff and made visible within GP practices. It was suggested that transparency information could be presented automatically to GP practice managers or similar, when uploading data to the National Workforce Reporting System (NWRS). Summary of IGARD comments: 1) To include a narrative of what the legal gateway is for NHS Digital to share the data with researchers, notwithstanding the wording of the relevant Direction. 2) To provide further information outlining the data minimisation efforts and to ensure alignment with NHS Digital's DARS Data Minimisation Standard. 3) IGARD suggested that in relation to transparency to the affected workforce: a) That the categories of recipients are expanded to give indicative categories (and particularly to highlight researchers). b) To request *"soft"* feedback from the stakeholders that NHS Digital are working with, for example, the RCGP in respect of the transparency notices. c) To produce an indicative plan for transparency communication which addresses how to effectively reach all staff in practices, beyond general NHS websites. IGARD looked forward to receiving a finalised paper and update on transparency plans at a future IGARD business as usual meeting, or out of committee, and before any first of type applications are submitted.
3	**Data Applications**
3.1	University College London: Evaluating the Family Nurse Partnership in England (Presenter: Catherine Day) NIC-136916-B7D5C **Application:** This was an amendment application to include Department for Education (DfE) as a Data Processor in relation to linking Hospital Episode Statistics (HES) and the Family Nurse Programme (FNP) to the National Pupil Database (NPD). The purpose of the application, is for a longitudinal research study aiming to evaluate the real-world implementation of the FNP in England. FNP is an intensive early home visiting programme for first time young mothers, delivered by trained nurses aiming to improve maternal and child outcomes by providing support throughout pregnancy and until the child's second birthday. The study aims to evaluate the real-world implementation of FNP in England with findings from the study helping policy makers decide whether FNP should be offered to families in their local setting. NHS Digital advised IGARD that the applicant's data sharing framework contract had been signed and was in place until July 2021.

	NHS Digital noted that supporting document 1, the data flow diagram, did not show the flow of data from University College London (UCL) to NHS Digital, and confirmed that this could be updated to reflect this flow. In addition, NHS Digital also noted that one of the Health Research Authority Confidentiality Advisory Group (HRA CAG) conditions of support, was to produce a Patient and Public Involvement (PPI) and Engagement Report, at the time of first annual review which centred around the activity which had been undertaken in this area, together with any feedback. NHS Digital confirmed that the report had been produced and sent to HRA CAG by the applicant, alongside their annual review in December 2020. NHS Digital also advised that the National Institute for Health Research (NIHR) funding, referred to in the HRA CAG documentation, was in place until March 2022. **Discussion:** IGARD noted the updates from NHS Digital, in relation to the data sharing framework contract that had been signed and was in place until July 2021; and the funding arrangements which were in place until March 2022. IGARD also noted from NHS Digital that there was incorrect information within the data flow diagram, and suggested that if the applicant intended to use the data flow diagram in the future, that this should be updated as appropriate and uploaded to NHS Digital's customer relationships management (CRM) system for future reference; or that the data flow diagram was removed from CRM if no future use was envisaged. In addition, IGARD also noted that, in relation to the HRA CAG conditions of support, that the PPI plan had been shared with HRA CAG, and asked that for transparency, section 5(a) (Objective for Processing) was updated to include a narrative that summarised the PPI plan. IGARD noted that when this application was previously reviewed by IGARD on the 17th October 2019, they had requested that a clear narrative was provided as to why the large control group (975,000) was necessary rather than a significantly smaller stratified sample for comparison; for example, as outlined in the HRA CAG supporting documents. IGARD reiterated their previous comment that section 5(a) was updated, to provide a clear narrative. In addition, IGARD queried what the approximate cohort numbers involved were at each stage of the processing since it was not clear, and asked that section 5(a) was updated to provide further clarity, and for transparency. IGARD noted that the reference throughout section 5(a) to *"HESIDs"*, and asked that this was either expanded to provide further clarity; or that a supportive explanation was provided for the acronym upon first use. IGARD noted that section 1(b) (Data Controller(s)) made reference to *"joint"* Data Controller, and asked that this was removed as it could be misleading in light of the fact that only the UCL were a Data Controller. IGARD reiterated a previous suggestion, that the applicant may wish to consider replacing all the references to *"delivery*" with *"birth"* in section 5(a). IGARD noted and applauded the thought and effort made by the applicant, when describing the potential moral and ethical issues, and how they were attempting to address them. IGARD advised NHS Digital that they were aware that DfE was subject to an audit by the Information Commissioner's Office (ICO) in 2020, which raised a number of concerning issues regarding data handling. IGARD suggested that NHS Digital should consider whether they wish to include additional measures to monitor DfE's handling of NHS Digital data, such as additional special conditions, relating to DfE; or that the NHS Digital Security Advisor had

	reviewed and provided contentment with regard to the handling of identifying information. In addition, IGARD also suggested that the Caldicott Guardian was consulted. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 5(a) to provide a clear narrative why the large control group (975,000) is necessary rather than a significantly smaller stratified sample for comparison (for example as explained in the HRA CAG supporting documents). 2. To update section 5(a) to provide the approximate cohort numbers involved at each stage of the processing. 3. To update section 5(a) to include a narrative summarising the PPI plan, as furnished to HRA CAG. 4. To update section 5(a) to either expand, or provide a supportive explanation for, the *"HESIDs"* acronym upon first use. 5. To update section 1(b) to remove the reference to *"joint"* Data Controller. The following advice was given: 1. As previously noted, and partially actioned, IGARD suggested that the applicant may wish to consider replacing all the references to *"delivery*" with *"birth"* in section 5(a). 2. IGARD suggested that if the applicant intends to use the data flow diagram in the future, to update as appropriate and upload to NHS Digital's CRM system; or to remove, as it does not accurately reflect the data flowing. 3. IGARD is aware that DfE was subject to an ICO audit in 2020, which raised a number of concerning issues regarding data handling. IGARD suggested that NHS Digital should consider whether they wish to include additional measures to monitor DfE's handling of NHS Digital data, such as additional special conditions, relating to DfE or that the NHS Digital Security Advisor has reviewed and provided contentment with regard to the handling of identifying information. IGARD also suggested that the Caldicott Guardian is consulted.
3.2	Isle of Man Department of Health & Social Care: Isle of Man Department of Health and Social Care - Commissioning purposes (Presenter: Dan Goodwin) NIC-173508-F4X6P **Application:** This was a renewal application for pseudonymised Secondary Use Service (SUS) for Commissioners data for the purpose of providing intelligence to support the commissioning of health services. Currently patients on the Isle of Man that require treatment from services not available on the Isle of Man and have to undertake travel to England / Wales to receive treatment. The Isle of Man Department of Health and Social Care team (IOMHSC) wish to understand the rate of patients being sent to the mainland to assist in understanding what services require commissioning locally. NHS Digital advised IGARD that any potential changes in law and data sharing, due to Brexit, were being continuously monitored, for example in respect of the UK General Data Protection Regulation (UK GDPR); however, advised that currently, this did not have any implications on this Data Sharing Agreement (DSA). In addition, NHS Digital also confirmed that a special condition had been included within section 6 (Special Conditions), that covered any event in regard to the UK Government's position, should it affect the DSA.

	NHS Digital noted that the Isle of Man Cabinet Office had been inadvertently removed from the application, and that this would be updated to correctly reinstate, noting they served as the legal entity for Government Technology Services (GTS). **Discussion:** IGARD noted and supported the update to the application, to correctly reinstate the Isle of Man Cabinet Office. IGARD **also** noted the update from NHS Digital in respect of the latest position with potential changes in law and data sharing, due to Brexit, however queried the wording of the special condition in section 6 that stated *"Should the UK Government's position on the Commissions adequacy decisions change at any time during this Agreement*…", and suggested that NHS Digital amend this to remove the work *"Commissions"*, noting that the agreement was between the UK and the Isle of Man, and not the EU. IGARD queried the role of Manx Telecom and Netcetera, and were advised by NHS Digital that they **only** provided infrastructure and would **not** have any access to NHS Digital data; IGARD noted this update and asked that section 1 (Abstract) and Section 5(b) (Processing Activities) were updated to make this explicitly clear. IGARD queried the reference in section 5(a) (Objective for Processing) to *"Using value as the redesign principle",* when outlining why the Secondary Uses Service (SUS) data was required; and asked that this was removed as it was not relevant. IGARD noted and applauded the specific and focused yielded benefits outlined in section 5(d) (Benefits) (iii) (Yielded Benefits); however, asked that the long list of examples, of the 'specialties' supported for Outpatient activity on UK mainland were either removed, or that a brief summary was included of **specific** yielded benefit(s) that flowed from each of the 'specialities'. In addition, IGARD suggested that the applicant reviewed the language in section 5(d), for example, listing a series of process descriptions, and before submitting for any future amendment, extension or renewal. IGARD advised NHS Digital that to further support this, they would provide some additional written support wording out of committee. IGARD noted that section 5(e) (Is the Purpose of this Application in Anyway Commercial?) incorrectly stated "*yes"*, and asked that this was amended to reflect the application was **not** commercial. IGARD advised that they would wish to review this application when it comes up for renewal. **Outcome:** recommendation to approve The following amendments were requested: 1. To amend the special condition in section 6, to remove the reference to *"**Commissions**"* adequacy decisions. 2. To remove the reference to *"Using value as the redesign principle"* in section 5(a). 3. In respect of the Yielded Benefits in section 5(d) (iii), to remove the long list of 'specialities' or remove and include a brief summary of specific yielded benefit(s) that flow from the list of 'specialities'. 4. To update section 1 and Section 5(b) to make it explicitly clear that Manx Telecom and Netcetera are only providing infrastructure and will not have access to NHS Digital data. 5. To update the application to reinstate the Isle of Man Cabinet Office, which serves as the legal entity for the Government Technology Services. 6. To amend section 5(e) to reflect the application is **not** commercial.

	The following advice was given: 1. IGARD suggested that the applicant review the language in section 5(d), for example, listing a series of process descriptions, and before submitting for any future amendment, extension or renewal. (suggested wording provided by IGARD) 2. IGARD advised that they would wish to review this application when it comes up for a renewal.
3.3	<u>NHS England (Quarry House): NHS England - DSfC - NCDR amendment (Presenter: Duncan Easton) NIC-139035-X4B7K</u> **Application:** This was an renewal application to NHS England's National Commissioning Data Repository agreement for pseudonymised Clinical Registry data; Children and Young People's Health Services (CYPHS), Secondary Use Service (SUS) for Commissioners, Local Provider Flows, Community Services Data Set (CSDS), Mental Health Learning Disability Data Set (MHLDDS), Diagnostic Imaging Data Set (DIDs), Improving Access to Psychological Therapies (IAPT), Mental Health Minimum Data Set (MHMDS), Maternity Services Data Set (MSDS), Civil Registration, Mental Health Services Data Set (MHSDS), National Cancer Waiting Times (CWT), National Diabetes Audit (NDA), Assuring Transformation (AT), Patient Reported Outcome Measures (PROMs) and e-Referral Service for Commissioning. It was also an amendment to 1) add Monitor and The Trust Development Authority (TDA) as joint Data Controllers, 2) to add Outcomes Based Healthcare (OBH) as a Data Processor, 3) the addition of Summary Hospital-Level Mortality Indicator (SHMI) and 111 Pathways Data Medicines Prescribed in Primary Care datasets, 4) the addition of ANS Group Limited as a Data Processor. NHS England requires access to data collected within Clinical Registries, Databases and Audits. Part of NHS England's responsibility is to oversee the budget, planning, delivery and day-to-day operation of the commissioning side of the NHS in England as set out in the Health and Social Care Act 2012. **Discussion:** IGARD noted and thanked NHS Digital for providing a supporting document, that contained a clear outline of the updates / amendments to this lengthy Data Sharing Agreement (DSA). IGARD noted that this application was last seen by the IGARD – NHS Digital COVID-19 Response meeting on the 7th January 2021. IGARD discussed the specific points raised at this meeting, in respect of the 'Medicines Prescribed in Primary Care data', and the Direction which was very specific; and asked that section 5 (Purpose / Methods / Outputs) was updated, to ensure that all the outputs related to the permitted activities within the Direction, for example, *"assessing stock levels"*. NHS Digital advised IGARD, that the public facing section 5(a) (Objective for Processing), did not provide substantive details of the relationship between NHS England and NHS Improvement; and agreed that to not add to the current volume of information within this section, that a brief description should be added, for example by way a weblink to existing information already published. IGARD noted that section 5(a) referred to processing by NHS England and NHS Improvement, done at a patient level; and asked that this was amended to ensure this reflected the overarching powers of the two organisations. In addition to provide confirmation that any processing done at patient level, would be strictly within NHS England and NHS Improvement's remit.

	IGARD queried the datasets listed in section 3(a) (Data Access Already Given) and section 3(b) (Additional Data Access Requested), and advised NHS Digital that some of the datasets were not familiar to IGARD members; and asked that sections 3(a) and section 3(b) were updated to ensure that the datasets were appropriately described. In addition, and separate to this application, IGARD asked that NHS Digital provided further information on the newer datasets contained within this application. **ACTION:** NHS Digital to provide further information on any new datasets, for example, including (but not limited to) the new datasets contained within this DSA. IGARD also reiterated their previous action point that NHS Digital may wish to consider convening a working group, to review the process of assuring and onboarding of the additional datasets. In addition, IGARD reiterated their previous advice, that this overarching application, should be broken up into relevant bespoke project applications. IGARD also noted that they would want to be involved in early-stage work on the rationalisation of the applications, as appropriate, in order to support both NHS Digital and the applicant. IGARD advised that they would wish to review this overarching application **and** any spin-off applications when it comes up for renewal, extension or amendment; and that this overarching application **and** any spin-off applications would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent. **Outcome:** recommendation to approve The following amendments were requested: 1. To insert a description, such as a weblink in section 5(a) that provides further details of the relationship between NHS England and NHS Improvement. 2. To amend section 5(a) to ensure this reflects the overarching powers of NHS England and NHS Improvement, and confirm that the processing will be done at patient level and will be strictly within NHS England and NHS Improvement's remit. 3. In respect of the 'Medicines dispensed in Primary Care' dataset, to update section 5, to ensure that all the outputs relate to the permitted activities within the Direction, for example, *"assessing stock levels"*. 4. In respect of the datasets requested: a) To update section 3(a) and section 3(b) to ensure the datasets are appropriately described. b) NHS Digital to provide further information on the newer datasets contained. The following advice was given: 1. IGARD reiterated their previous advice, that this overarching application, should be broken up into relevant bespoke project applications. IGARD noted that they would want to be involved in early-stage work on the rationalisation of the applications, as appropriate, in order to support both NHS Digital and the applicant. 2. IGARD reiterated their previous action point that NHS Digital convene a working group, to review the process of assuring and onboarding of the additional datasets. 3. IGARD advised that they would wish to review this overarching application and any spin-off applications when it comes up for renewal, extension or amendment. 4. IGARD suggested that this overarching application and any spin-off applications, would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent.

3.4	Norfolk and Norwich University Hospitals NHS Foundation Trust: Outcomes of Percutaneous Coronary Intervention at Norfolk & Norwich University Hospital (Presenter: Louise Dunn) NIC-303785-L3K3Z **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) and Civil Registration data. Coronary artery disease refers to the *"furring up"* of the inside of the coronary arteries (the arteries that supply heart muscle with blood), and remains the leading cause of mortality worldwide and the death rate continues to increase. The purpose of the application, is for a study comparing the outcomes of patients treated with drug coated balloon (DCB) and Drug eluting stent (DES) at the Norfolk and Norwich Hospital. The comparison will be based on three main patient outcomes, which are, cause of death, rehospitalisation and cause for rehospitalisation after the PCI. NHS Digital advised that the study team at Norfolk and Norwich University Hospital' at Norfolk and Norwich University Hospitals NHS Foundation Trust, had not yet submitted a **Standards Met** Data Security and Protection Toolkit (DSPT) for 2019/20; and confirmed that no NHS Digital would flow until this had been achieved. **Discussion:** IGARD welcomed the application and noted the importance of the study. IGARD noted and supported the update from NHS Digital in respect of the applicant's DSPT; and asked that a special condition was inserted in section 6 (Special Conditions), that this must be in place before any NHS Digital data can flow, and supported this approach. IGARD queried the reference within the data minimisation column in section 3(b) (Additional Data Access Requested) to *"excess of 10,000 patients…",* and asked that this was amended to be more precise, for example to *"…in the region of…"*. In addition, IGARD noted that the data would be narrowed by age, with the minimum age of entry being 18; and suggested that the applicant considered minimising this further, by amending the minimum age to 25 instead of 18, noting that coronary heart disease was uncommon in the younger age bracket; and if appropriate asked that the application was amended throughout to reflect any change. IGARD noted and commended the applicant for the clear and lay friendly description of the two procedures in section 5(a) Objective for Processing). IGARD noted the statement in section 5(a) that *"The Norfolk and Norwich University Hospital (NNUH) has one of the largest DCB implantation cohorts in the UK…"*, and asked that this was updated to provide a further explanation as to why. IGARD queried how the study statistician would adjust for the fact that patients may have been allocated DCB or DES, due to the features of their heart disease or particular health problem, and that some presentations will always respond better to DCB or DES; and asked that this was explored further in section 5 (Purpose / Methods / Outputs). IGARD queried if the study statistician would only receive aggregated numbers with small numbers supressed, and asked that confirmation was provided in section 5.; Alternatively, if the study statistician was receiving pseudonymised data, that confirmation was provided that they either have an honorary contract with the Data Controller, or that the study statistician's home institution were added as a Data Processor. IGARD noted the statement in section 5(b) (Processing Activities) *"…all patients with left main stem coronary artery disease) and propensity matched…"*; and asked that this was updated to

	provide a further explanation of what was meant by *"propensity matched"*, as this was not clear. IGARD queried the statement in section 5(b) that stated *"Data provided by the data controller…to NHS Digital will include…"*; and asked that this was amended to specifically state the list of identifiers going to NHS Digital; and to remove the word *"include"* as this could be misleading. IGARD noted the opening statement in section 5(d) (Benefits) that started *"The anonymisation of the patient data…"*, as this does not add any value to the narrative. IGARD suggested that the applicant may wish to consider the involvement of a national charity, for example, but not limited to, the British Heart Foundation, in respect of disseminating any outputs of the study and developing patient communication of the results, as may be relevant and appropriate. **Outcome:** recommendation to approve The following amendments were requested: 1. To insert a special condition in section 6 that the applicant's DSPT **must be** in place before any data can flow. 2. In respect of data minimisation in section 3(b): a) To amend the refence to …*"excess of 10,000 patients…"* , for example to *"…in the region of…"*. b) To consider minimising by way of entry age, for example, by amending the minimum age to 25 instead of 18; and if appropriate to amend the application throughout to reflect any change. 3. To update section 5(a) to provide a further explanation as to why the Norfolk and Norwich University Hospital (NNUH) has *"one of the largest DCB implantation cohorts in the UK"*. 4. To explore in section 5 how the study statistician will adjust for the fact that patients may have been allocated DCB or DES due to the features of their heart disease or particular problem and that some presentations will always respond better to DCB or DES, as they case may be. 5. To update section 5(b) to provide a further explanation of what is meant by *"propensity matched"*. 6. In respect of the study statistician: a) To provide confirmation in section 5 that the study statistician will only receive aggregated numbers with small numbers supressed; or b) If they are receiving pseudonymised data, to confirm they either have an honorary contract with the Data Controller or add the study statistician's home institution as a Data Processor. 7. To amend section 5(b), to specifically state the list of identifiers going to NHS Digital and to remove the word *"include"*. 8. To remove the first sentence from section 5(d) as this does not add any value to the narrative. The following advice was given: 1. IGARD suggested that the applicant may wish to consider the involvement of a national charity, for example (but not limited to) the British Heart Foundation, in respect of disseminating any outputs of the study and developing patient communication of the results, as may be relevant and appropriate.

3.5	IQVIA Ltd: NIC-373563 - IQVIA Ltd & IQVIA Technology Services Ltd (Presenter: Denise Pine) NIC-373563-N8Z9J **Application:** This was a renewal and extension application for pseudonymised Hospital Episode Statistics (HES), Emergency Care Data Set (ECDS), Civil Registrations data; and an amendment to, 1) to add a new storage / processing location to be used by both Data Controllers, 2) to remove a storage / processing location that will no longer be used, 3) to include the newly requested data periods for previously requested datasets, 4) to reflect the Data Controllers request to receive monthly Summary Hospital Mortality Indicators (SHMI) data, 5) to update the Processing Activities to include details of how data will be migrated between existing and new storage locations, 6) to add information about newly generated outputs, 7) to add information regarding new yielded benefits. The purpose is to perform two types of services: 1) Data Visualisation and Benchmarking (the *"Service 1"* services). This is a suite of software tools into which the relevant Data is loaded, which enables users to view metrics using tables, maps and charts; 2) Advanced Statistical Analysis (the *"Service 2"* services) is bespoke analysis for external organisations on a project by project basis. NHS Digital advised that the application did not reflect the new storage locations and would be updated following the meeting, to include this information. NHS Digital noted that section 3(a) (Data Access Already Given) still included 2014/15 data, and that this would need to be removed from the application; and that the applicant had been notified by NHS Digital, that this data would need to be destroyed, and that a data destruction certificate should be provided as soon as possible. NHS Digital also noted the special condition in section 6 (Special Conditions) relating to IQVIA Ltd's and IQVIA Technology Services Ltd's security arrangements, that stated *"Upon its expiry…this should be renewed."*, and asked that this was updated to more clearly state it ***"must"*** be renewed upon expiry. **Discussion:** IGARD noted and supported the update from NHS Digital, in respect of the update to the application to reflect the new storage locations; section 3(b) (Additional Data Access Requested) being updated to remove reference to the 2014/15 data, in addition to the data destruction certificate being provided by the applicant; and the re-wording of the special conditions in respect of the security arrangements. IGARD noted the monthly dissemination of the Summary Hospital Mortality Indicators (SHMI) data, that had been requested, and queried whether IQVIA had work packages from its clients specifically to use this data. If, however, the data was being received on a speculative basis, with the intention of offering improved products for its clients, asked that further narrative was provided confirming this. In addition, IGARD asked that section 5(c) (Specific Outputs Expected) was updated to also include any specific outputs that were anticipated with the use of the SHMI dated. IGARD noted the volume of yielded benefits provided in section 5(d) (Benefits) (iii) (Yielded Benefits), however asked that for ease of reference, this was updated to **only** include the most recent projects, for example, the last 2 years. IGARD advised that they were appreciative of the breadth of detail provided, but also suggested that when IQVIA edit the yielded benefit list to only include the most recent projects, that the historical work was archived, noting historical information could be added as a supporting document should it be required.

	IGARD also asked that when the yielded benefits were updated that they were clear as to the benefits to health and / or Social Care; and that any reference to *"potential savings"* was removed as this was not necessarily accurate. IGARD noted the role of the IQVIA Independent Scientific and Ethics Advisory Committee (ISEAC) within the application, and suggested that for transparency, the committee considered making a summary of approved projects publicly available. In respect of future project updates to NHS Digital, and any public disclosures, IGARD suggested that, to ensure it was transparent, when pharmaceutical company clients supplied the drug that was being studied; or an illness or disease that was being researched for, which they produced relevant treatment or medical devices. IGARD advised that they would wish to review this application when it comes up for renewal. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of the SHMI data: a) To provide a further narrative whether IQVIA has work packages from its clients specifically to use this data; or b) If the data is being received on a speculative basis, with the intention of offering improved products for its clients; and c) To update section 5(c) with any specific outputs anticipated with the use of SHMI data. 2. In respect of the yielded benefits in section 5(d) (iii): a) To update to limit the yielded benefits to **only** include the most recent projects, for example, the last 2-years. b) To ensure the yielded benefits are clear as to the benefits to the health and / or Social Care. c) To remove any reference to *"potential savings"*. The following advice was given: 1. IGARD suggested that the IQVIA ISEAC oversight committee consider making a summary of approved projects publicly available. 2. In respect of future project updates to NHS Digital (and any public disclosures), to ensure it is transparent when pharmaceutical company clients supply the drug that is being studied or an illness or disease is being researched for which they produce relevant treatment or medical devices. 3. IGARD noted and was grateful for the breadth of detail provided in the yielded benefits, but suggested that when IQVIA edit the list to the most recent projects they archived the historical work. 4. IGARD advised that they would wish to review this application when it comes up for renewal.
3.6	<u>King's College London: Survival and recovery after hip fracture surgery, overall and by timing of mobilisation (Presenter: Denise Pine) NIC-164830-L7L7C</u> **Application:** This was an amendment application to 1) add additional information to the Processing Activities, confirming as well as the study team being substantive employees of King's College London, there are also graduate students enrolled at King's College London who access the NHS Digital data, and that the students are subject to King's College London's policies, procedures and sanctions. 2) to update the application to reflect the additional

	analysis for the development of multi variable prognostic models for survival and recovery after hip fracture. The purpose is for a study, looking at the most effective rehabilitation after hip fracture, to determine the association between early mobilisation (as a care delivery related factor) on outcomes, as well as to identify patients with different risk of poor outcomes (as patient related factors). The application was been previously considered on the 20th September 2018 when IGARD had deferred pending: to confirm the HQIP GDPR legal basis; to provide confirmation that HQIP are authorising the use of data; to clarify who the additional Data Controllers are and to provide fair processing notices which are GDPR compliant; to delete the existing text in section 4 and replace with the standard wording *"All data required by the Data Controller under this application is pseudonymised and therefore is considered as personal data under the GDPR. All Data controllers are expected to provide a privacy notice that is compliant with the GDPR notice requirem*ents within a reasonable period after obtaining the personal data, but at least within 1 month". **Discussion:** IGARD noted that the application had been updated to reflect **all** of the comments previously made. IGARD noted the addition of the graduate students within the Data Sharing Agreement (DSA), and asked that conformation was provided in section 5 (Purpose / Methods / Outputs), of the number of King's College London (KCL) students involved with the study, and confirmation that they were all graduate students of KCL. In addition, IGARD asked that confirmation was provided that they were accessing the data **only** to carry out processing directly related to the processing permitted by the application. IGARD queried the references in section 5(a) (Objective for Processing) to *"compete for resources"*, and asked that this was re-worded, for example to *"limited resources"*, as this could be misinterpreted. IGARD noted the references in section 5(d) (Benefits) to *"savings"*, and asked that this was updated throughout to removes these references, as this information was not necessarily accurate. In addition, IGARD noted that the benefits outlined were updated to ensure they reflected the patient experience or direct impact on patient care; and that further narrative was added to the yielded benefits in section 5(d)(iii) (Yielded Benefits), to explain how the outputs translated into benefits for patients and patient care, for example, how the valuable research on mobilisation practice in hospital had resulted in changes to practice which has improved survival and recovery for patients. IGARD suggested that the applicant liaise with the Health Research Authority Confidentiality Advisory Group (HRA CAG), in order to ensure the HRA CAG Register, which was visible to the public, addressed the fact that this data was also used for research as well as audit purposes. IGARD also suggested that the applicant feeds back to the controllers of the FAPP in respect of the web pages, that only referred to the research undertaken by the University of Oxford, to either, specifically mention this research project; or, to expand, so that it reflects that it was not only the University of Oxford carrying out research; and to accurately describe the level of data the researchers have access to. **Outcome:** recommendation to approve

	The following amendments were requested: 1. In respect of the graduate students referred to: a) To provide confirmation in section 5 of the number of King's College London students involved with the study and that they are all graduate students of KCL. b) To confirm that they are accessing the data only to carry out processing directly related to the processing permitted by the application. 2. To re-word the reference to *"compete for resources"* in section 5(a). 3. In respect of section 5(d): a) To update throughout to remove reference to *"savings"*. b) To update to ensure the benefits reflect the patient experience or direct impact on patient care. c) To provide a further narrative in the yielded benefits to explain how the outputs translated into benefits for patients and patient care, for example, how the valuable research on mobilisation practice in hospital has resulted in changes to practice which has improved survival and recovery for patients. The following advice was given: 1. IGARD suggested that the applicant liaise with HRA CAG in order to ensure the HRA CAG Register, which is visible to the public, addresses the fact that this data is also used for research as well as audit purposes. 2. IGARD suggested that the applicant feeds back to the controllers of the FAPP in respect of the web pages, that only refer to the research undertaken by the University of Oxford, to either a) Specifically mention this research project; or b) To expand that it is not only the University of Oxford carrying out research; and c) To accurately describe the level of data the researchers have access to.
4	<u>Returning Applications</u> IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. Due to the volume and complexity of applications at today's meeting, IGARD were unable to review any applications as part of their oversight and assurance role.
5	<u>COVID-19 update</u> To support NHS Digital's response to COVID-19, from Tuesday 21st April 2020, IGARD will hold a separate weekly meeting, to discuss COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 urgent applications that have been submitted to NHS Digital. Although this is separate to the Thursday IGARD meetings, to ensure transparency of process, a meeting summary of the Tuesday meeting will be captured as part of IGARD's minutes each Thursday and published via the NHS Digital website as per usual process. The ratified action notes from Tuesday 18th January 2021 can be found attached to these minutes as Appendix B.
6 **6.1**	<u>AOB:</u> <u>Information Governance</u>

	A member of NHS Digital's Privacy, Transparency and Ethics – COVID-19 Response Team, attended the meeting to provide a brief update / overview of ongoing work. 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 22/01/21

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)
None						

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

In addition, a number of applications were approved under class action addition of Liaison Financial Service and Cloud storage:

- None

Optum Health Solutions UK Limited Class Actions:

- 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, 26th January 2021

In attendance (IGARD Members):	Prof Nicola Fear (IGARD Specialist Research Member)
	Kirsty Irvine (IGARD Lay Chair)
	Dr. Imran Khan (IGARD Specialist GP Member)
In attendance (NHS Digital):	Louise Dunn (DARS)
	Phil Durkin (DARS – Item 3.1)
	Duncan Easton (DARS)
	Liz Gaffney (DARS – item 3.1)
	James Gray (DARS – Observer item 2.1)
	Suzanne Hartley (DARS)
	Karen Myers (IGARD Secretariat)
	Vicki Williams (IGARD Secretariat)

2	**Welcome** The IGARD Chair noted that this was a weekly meeting convened to support NHS Digital's response to the COVID-19 situation and was separate from the IGARD business as usual (BAU) meetings. IGARD members present would only be making comments and observations on any items that were presented, and were not making formal recommendations to NHS Digital. Should an application require a full review and recommendation, then it should go through the usual Data Access Request Service (DARS) process and be presented at a Thursday IGARD meeting. The action notes from the Tuesday meeting would be received at the next Thursday meeting of IGARD and published as part of those minutes as an appendix. **Declaration of interests:** Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising on COVID-19. Nicola Fear noted a professional link with King's College London [NIC-381719-L6D2H] but noted no specific connection with the application, and it was agreed that this was not a conflict of interest
2.1	NIC-365354-R3M0Q University of Oxford RECOVERY Trials / Sub-License Standard **Background:** this was an update with regard to the Randomised Evaluation of COVID-19 Therapy (RECOVERY) Trial amendment for sub-licensing which had previously been discussed in detail at the 1st December 2020 COVID-19 response meeting. For background, the application and relevant supporting documentation had been previously discussed at the COVID-19 response meetings on the 21st April, 28th April, 5th May, 12th May, 19th May, 7th July, 21st July, 22nd September, 20th October and 1st December 2020. The

	application had previously been discussed at the IGARD business as usual (BAU) meeting on the 11th June, 30th July and 12th November 2020. IGARD members noted that no updated amendment application had been provided as part of the review. The following observations were made on the basis on the four documents provided only: 1) proposed "standard 10b – sub-license and onward sharing of data for clinical trials; 2) comparison of the existing standard and the new standard; 3) proposed text for inclusion in the sub-license section (section 10) of NIC-365354 to show how compliance with the standard is met and 4) IGARD briefing document dates 2020-10-27 – appendix 1 of this document provides more detail on standards applied to the RECOVERY trial dataset. NHS Digital noted that the reason the application was being cited alongside a draft Standard was in order to work through a live example of how the documentation would work moving forward, IGARD were supportive of this approach. **IGARD Observations:** IGARD noted that they had last commented on the Oxford RECOVERY Trials and draft Data Sharing Sub-License Standard documentation at the COVID-19 response meeting on the 1st December 2020. IGARD also noted that this discussion, as previously, was in advance of any formal discussion at an IGARD BAU meeting and due process for NHS Digital DARS Standards. IGARD members reiterated their previous suggestion that since GPES Data for Pandemic Research & Planning (GDPPR) data was included, that DARS discuss the proposed sub-licensing agreements with the Profession Advisory Group (PAG). As arrangements currently stand, when the CV-19 Direction (issued under the emergency National Health Service (Control of Patient Information Regulations) 2002 (COPI)) expires at some point in the future, the data would have to be destroyed. IGARD members noted that when they had previously seen the documentation, they had been under the impression that the materials were primarily focussed on addressing the desire to share with other research organisations. Sharing data with UK Regulators, such as the Medicines & Healthcare products Regulatory Agenda (MHRA), is permitted by a clear statutory gateway and is further helped by the Health Research Authority (HRA) standard consent wording being designed to allow sharing with relevant regulatory authorities. IGARD was unsure what the outstanding issue was in relation to regulators and queried the jurisdiction (e.g.: England / Wales, UK, European Union, worldwide) in which case the consent would need to be assessed for jurisdiction and relevant legislative gateway. Finally, the sharing of some datasets would need to be line with any geographical restrictions which may be present for certain of the datasets such as Public Health England (PHE) Second Generation Surveillance System (SGSS) and PHE COVID-19 Hospitalisations in England Surveillance System (CHESS). IGARD members made a number of general points with reference to the materials provided including, but not limited to: • IGARD suggested that a detailed inclusive list (cf. an exclusive list), be provided with regard to the list of organisations who may sub-license data and that it more clearly articulated with regard to each organisation or category who wanted the data, home jurisdiction, level of data requested (eg identifying, pseudonymised, anonymous/non personal, aggregate), the legal gateway to receive the data (addressing both

	confidentiality as may be relevant depending on the status of the data and data protection) and the purpose, including benefits to the health and social care in England. • Consideration should be given to any commercial aspects to the sub-licensing and this should be in line with the published NHS Digital DARS Standard for Commercial Purpose and again reflected in the governance terms of reference, including expanding the potential commercial use. • Consideration should be given if an organisation is transferring data outside of England and Wales and the legal gateway for that transfer. • Referring to the "Legal Basis" paragraph in the briefing paper, reference should be made to the Data Protection Act (DPA) 2018 and UK General Data Protection Regulations (GDPR), and acknowledge that a duty of confidentiality is owed to the trial participants as this is a consented cohort. It would be helpful to note that there may also be other statutory gateways such as COPI or other regulatory mechanisms for the safety of medicines which may be an alternative way to address the duty of confidence. • The audit section outlined should also link back to NHS Digital DARS Standard for Sub-Licensing and Onward Sharing of Data, including the reporting of breaches, noting this is an NHS Digital policy position and that the relevant Executive Director for Audit may wish to be made aware of identifying / identifiable data in a sub-license that cannot be audited. • Careful consideration should be given to communication with the cohort. In addition to ensuring compatibility with the consent materials and UK GDPR transparency requirements, there were ethical and public perception reasons why the cohort should be kept up to date. Given the high profile of this research project, it is particularly important to ensure continued public trust in clinical trials and their management. IGARD suggested consulting with patient representatives about the tone and nature of any update. • IGARD noted that any definitions cited in documentation should be updated to more accurately reflect current legislation such as the reference to "personal data" in document 1, referring to DPA 1998 in the proposed standard (noting these definitions had been drawn across from NHS Digital's Data Sharing Framework Contract (DSFC)). **Significant areas of risk:** ensuring appropriate legal gateways for different categories of data and sub-licensee. Appropriate communication with consented cohort to maintain public trust in clinical trial management (and also addressing transparency requirements).
2.2	<u>NIC-406871-Q9G2Q Department of Health & Social Care (DHSC)</u> **Background:** This was a verbal update to a verbal presentation at the COVID-19 response meeting on the 13th October 2020 under the Joint Bio-Research Centre. This was an urgent COVID-19 related request for data to support the NHS Test and Trace work carried out by the DHSC's Joint Biosecurity Centre (JBC). NHS Digital noted that the amendment was to clarify the production details, update the agreement in line with recommended wording form the Information Asset Owner (IAO) and add further detail in line with NHS Digital's DARS standards. The following observations were made on the basis of a verbal update only.

	IGARD Observations: IGARD members noted that although version 1.3 of the application and supporting documentation was available on NHS Digital's customer relationship management (CRM) system, they had not been provided for review at this meeting and their observations were based on the verbal update by NHS Digital only. IGARD welcomed the verbal update and noted the urgent request for data as outlined by NHS Digital. Noting that they had not had sight of the current Data Sharing Agreement (DSA), IGARD members reiterated their previous query from the 13th October 2020 COVID-19 response meeting with regard to the legal basis for the Joint Biosecurity Centre (a new organisation sitting within the DHSC) to receive data, noting that they had not had sight of the analysis that should have been undertaken by the Privacy, Ethics and Transparency Directorate (formerly the Information Governance Directorate), and where therefore unclear if NHS Digital had entered into a Data Sharing Framework Contract (DSFC) with the correct legal entity. IGARD also reiterated their previous comments from the 13th October 2020 COVID-19 response meeting that section 5 should clearly articulate how the work being undertaken differed from other work in this area to address the public health response (to assuage any concerns about duplication of effort or excessive handling of data), noting NHS Digital's comments that this application would also be looking at the effectiveness of the vaccine programme. But since the vaccination statistics were already in the public domain and cited by the Prime Minister at his regular press briefings, queried the public perception and transparency of this new purpose verbally outlined by NHS Digital. As noted previously, IGARD members would welcome sight of both the application and relevant supporting documentation and would expect that a future amendment or renewal would go through the usual DARS – IGARD process to allow for a full independent review. **Significant areas of risk:** transparency and public perception (there had been no independent review of the application or supporting documentation).
2.3	<u>NIC-381719-L6D2H King's Health Partners / Guys' & St Thomas' NHS Foundation Trust</u> **Background:** This was an amendment application for the King's Health Partners (a partnership consisting of King's College Hospital NHS Foundation Trust (KCL NHS FT), Guys' & St Thomas' NHS Foundation Trust (GSTT) and King's College London (KCL)) for pseudonymised Hospital Episode Statistic (HES) Critical Care (CC) data. The applicant will provide a cohort of approximately 4,000 patient identifiers which will be linked to HES CC which would allow for tracking repeat admissions into GSTT, post and prior to COVID-19 diagnosis, influenza and other respiratory pathogens while providing information on admissions to critical care used besides GSTT. Linkage will enable a better understanding on long term healthcare, utilisations, and outcomes and will allow for a better understanding and prediction of future healthcare requirements. The application and relevant supporting documentation had been previously presented the COVID-19 response meetings on the 11th August and 25th August 2020. The following observations were made on the basis of the amendment application and relevant supporting documents provided only.

	IGARD Observations: IGARD members reiterated their previous comments that this was potentially a very worthwhile study and welcomed the innovative approach. IGARD members noted that they would be supportive of a wider or alternative data flow rather than restrict the data to only those that resided in the Lambeth area, since it was a geographically small area, but that those accessing the GSTT may be from outside this specific geographical area of Lambeth. IGARD members reiterated their previous comment from the COVID-19 response meetings on 11th August and 25th August 2020, that the applicant would be receiving GP data from the Lambeth Data Net (LDN), since the LDN patient-facing transparency materials still stated that they only disseminated "anonymous" or "anonymised" data, which, by definition, cannot be linked and the information on LDN's website was misleading. In addition, the LDN website stated that they would not be sharing data with any 3rd parties, but elsewhere do state they are receiving data from 3rd parties, and reference to "linkage", which again could be seen as misleading. IGARD members noted that NHS Digital had assessed the facts in line with the NHS Digital DARS Standard for Data Controllers / Data Processors and were content with the Data Controllers and Data Processors cited in the application. **Comments previously raised but not discussed in this meeting:** • The abridged Data Protection Impact Assessment (DPIA) (submitted as a supporting document at 25th August COVID-19 response meeting) stated that "*none of the data constitutes 'patient confidential data' nor 'personal data', nor 'patient identifiable data*'" which appeared to be factually incorrect on the supporting documents provided (as pseudonymised data is personal data under UK General Data Protection Regulations (GDPR)) and suggested that the applicant reconsider this assessment and complete a full DPIA. • Re opt outs: care should be taken since when the notice issued under the emergency legislation falls away, and should the applicant not have applied opt outs, an amendment Integrated Research Application System (IRAS) form would need to be submitted to note that opt outs had **not** been applied. **Significant areas of risk:** None (based on the documentation presented at today's meeting).
2.4	<u>NIC-387291-B3M4Z Dudley Metropolitan Borough Council</u> **Background:** This was a new application for GP Data for Pandemic Planning & Research (GDPPR) in support of the management of the COVID-19 emergency. NHS Digital noted this was a first of type application and that it would be presented to a future Profession Advisory Group (PAG) before coming back to an IGARD business as usual (BAU) meeting for a full independent review. The following observations were made on the basis of the draft application summary only. **IGARD Observations:** While there appeared to a legal gateway, IGARD members noted that the language in section 1 appeared to be the National Health Service (Control of Patient Information Regulations)

	2002 (COPI) standard form text for other bodies, and queried if the Privacy, Ethics and Transparency Directorate (formerly the Information Governance Directorate) had expressly considered whether a Metropolitan Borough Council can be regarded as being engaged for the purpose of the "health service" and whether all processing activities had been considered and mapped to Regulation 3 of COPI. Noting that greater responsibility for Public Health now sits within Local Authorities and those Public Health staff are employed by the Local Authority, IGARD advised that the application should be updated throughout to develop this narrative further which should align the applicant with the activities intended to be covered by COPI . IGARD members noted the clear public health reasons for the Public Health Team at the Council to be requesting the GDPPR data, but that section 5 should clearly outline how this GDPPR data would be used for pandemic response planning (not for generic council use) and how this differed from the data flow they would be getting from the local Clinical Commissioning Group (CCG), who also received the GDPPR dataset. In addition, that the stated purposes, objectives for processing, outputs and benefits should all link back to the specific pandemic-response related health purposes. IGARD members also noted the language used with reference to COVID-19 (the pandemic) and that a single term be used throughout the application, rather than mixing "COVID-19", "Covid", "coronavirus" and "the virus" terminology throughout the application. IGARD members noted that the territory of use section 2(c) appeared to be blank and should be updated appropriately and to also update section 2(b) which appeared to cite the same storage location for the Council and remove the duplication, or amend the second address appropriately. IGARD members noted that Article 6(1)(c) of the UK GDPR appeared to be listed in section 1, but that section 3 listed Article 6(1)(e); the applicant should clarify which legal basis they were advancing. **Significant areas of risk:** None (based on the discussion and documentation presented at today's meeting).
2.5	<u>NIC-402116-G1T7V NHS England</u> **Background:** This was a verbal update to a verbal presentation at the COVID-19 response meeting on the 15th September 2020. The amendment is to add Palantir Technologies UK Limited ("Palantir") as a Data Processor and Amazon Web Services (AWS) who host the data for Palantir. Due to the urgency of the request, data is already flowing to Palantir in agreement with the NHS Digital SIRO. Palantir are being added to support NHS England as a processor for vaccination reporting only and the data sharing agreement (DSA) limits their role to that purpose. NHS Digital noted that the Profession Advisory Group (PAG) would be updated on Wednesday 3rd February 2021 to the amendment, and that the amendment falls under the relevant NHS Digital DARS Precedent. The following observations were made on the basis of a verbal update only. **IGARD Observations:**

	IGARD members noted that although version 1.2 of the application and supporting documentation was available on NHS Digital's customer relationship management (CRM) system, they had not been provided for review at this meeting and their observations were based on the verbal update by NHS Digital only. IGARD members noted that NHS Digital should be assured that NHS England have been fully transparent in public-facing materials about their use of Palantir and their involvement in the processing of the data requested for the purposes outlined in the application. IGARD members also queried if Palantir was a legal entity in its own right (noting the parent company was a United States ("US") based company under US jurisdiction) or if it was a branch office off the larger company where it could be obliged to share data with its parent company due to the operation of foreign law. In addition, NHS Digital should be assured that AWS, who are hosting the data for Palantir in their agreement, have no ability for any resilience services to hold the data outside of the UK. IGARD members noted that NHS Digital should also be assured that NHS England have an appropriate data processing agreement in place for Palantir for the work they are undertaking, and that they explicitly set out how they satisfy Regulation 7 (1) and (2) of COPI. IGARD members also advised that the agreement should be updated to clearly state that the Data Processor had access to the data from "X" date and that this agreement had been updated from "Y" data and that all parties were in agreement with this reflection of the facts (in light of the position that no DSA should be retrospectively amended). **Significant areas of risk:** Based on the verbal update at today's meeting only, IGARD suggested that there was a potential public perception risk related to the involvement of Palantir that could be mitigated by appropriate General Data Protection Regulation (GDPR)-compliant transparency by NHS England. The home jurisdiction, company structure and any intra-company data sharing issues regarding Palantir should also be explored and addressed, as necessary.
2.6	<u>NIC-420168-K4N1F University of Bristol</u> **Background:** this was a verbal update of the progress made to update the application following its presentation at the COVID-19 slot on the business as usual (BAU) IGARD meeting on the 22nd January 2021. The application had also been discussed at the COVID-19 response meetings on the 8th December, 15th December 2020 and 15th January 2021. The following observations were made on the basis of a verbal update only. **IGARD Observations:** IGARD members noted that although v0.6 of the application and supporting documentation was available on NHS Digital's customer relationship management (CRM) system, they had not been provided for review at this meeting and their observations were based on the verbal update by NHS Digital only. IGARD members noted that the application was to be presented to the IGARD BAU Meeting on Thursday, 4th February 2021, following a review by the Profession Advisory Group (PAG) on Wednesday, 3rd February 2021, with an extract of the PAG minutes appended to IGARD's published minutes.

	IGARD members noted that the discussion today was not to pre-empt discussions that would take place at the BAU meeting on Thursday and thanked NHS Digital for their verbal update. **Significant areas of risk:** No new issues raised by the verbal update at today's meeting but all previously raised significant areas of risk were still live.
3	AOB
3.1	Tracked Change Documentation for IGARD Liz Gaffney and Phil Durkin (DARS) presented an update to business as usual (BAU) work that was being undertaken by NHS Digital to provide IGARD members with tracked change versions of the application summaries. IGARD members welcomed the brief update and asked that a presentation be made to the IGARD BAU meeting and before the system went "live" so that any further comments could be captured. IGARD members thanked NHS Digital on the work undertaken to date. There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.