Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 11 March 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Kirsty Irvine (Chair)	IGARD Chair / Lay Member
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
Dr. Maurice Smith	Specialist GP Member (Item 6 only)
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Prof. Nicola Fear	Specialist Academic Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Vicky Byrne-Watts	Data Access Request Service (DARS)
Louise Dunn	Data Access Request Service (DARS) (Observer: item 2.2)
Duncan Easton	Data Access Request Service (DARS)
Liz Gaffney	Data Access Request Service (DARS) (item 6 only)
Dan Goodwin	Data Access Request Service (DARS)
Richard Hatton	Clinical Informatics and Deputy Caldicott Guardian (Observer: item 1 - 2.4)
Shaista Majid	Data Access Request Service (DARS) (Observer: item 2.1)
Karen Myers	IGARD Secretariat
Kimberley Watson	Data Access Request Service (DARS)
Vicki Williams	IGARD Secretariat
GPES DATA FOR PANDEMIC PLANNING AND RESEARCH – PROFESSION ADVISORY GROUP (PAG) MEMBERS IN ATTENDANCE: (Item 6 only)	
Arjun Dhillon	PAG Chair

Amir Mehrkar	PAG member
Mark Coley	PAG member

1	**Declaration of interests:** Dr. Geoff Schrecker noted that he had a potential professional conflict with OptimizeRx (NIC-253220-Q1X8H), but noted no specific connection with the application or staff involved. It was agreed this did not preclude Dr Geoff Schrecker from taking part in the discussions about this application, however agreed that he would not participate in making a recommendation about the application. **Review of previous minutes and actions:** The minutes of the 4th March 2021 IGARD meeting were reviewed, and subject to a number of minor amendments were agreed as an accurate record of the meeting. **Out of committee recommendations:** An out of committee report was received (see Appendix A).
2	**Data Applications**
2.1	Dudley Metropolitan Borough Council: GDPPR Data Request for Dudley Metropolitan Borough Council (Presenter: Dan Goodwin) NIC-387291-B3M4Z-v0.3 **Application:** This was a new application for pseudonymised GPES Data for Pandemic Planning and Research (GDPPR) data, for the purpose of supporting the response to COVID-19; which has led to a change in demand on general practices, including an increasing number of requests to provide patient data to inform planning and support vital insights on the cause, effects, treatments and outcomes for patients. To support the response to COVID-19 NHS Digital has been legally directed to collect and analyse healthcare information about patients, including from their GP record, for the duration of the COVID-19 emergency period, under the COVID-19 Public Health Directions 2020 (COVID-19 Direction). All GP practices in England are legally required to share data with NHS Digital for this purpose under the Health and Social Care Act 2012. More information about this requirement is contained in the Data Provision Notice issued by NHS Digital to GP practices. This collection will reduce burden on general practices, allowing them to focus on patient care and support the COVID-19 response. NHS Digital advised IGARD that the application had been reviewed at the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) meeting, on the 10th March 2021, where PAG had asked that a special condition was added to the application, in relation to the applicant obtaining support from their local clinical lead. NHS Digital noted that following the PAG meeting, the applicant had confirmed that they had received a positive expression of support from their local clinical lead. NHS Digital advised IGARD that the incorrect UK General Data Protection Regulation (GDPR) Article 6 legal basis had been referenced in section 1 (Abstract), and confirmed that this would need updating to correctly align with the Article 6 legal basis referenced elsewhere in the application.

	NHS Digital noted for background information, that the applicant currently had access to NHS Digital data via the following Data Sharing Agreements (DSA); NIC-392001-G1C3D – LAPH, NIC-41001 – PCMD and NIC-218988-L5K0G (from the 1st April 2021, this will become NIC-433163-Y2V0K due to CCG merger)*;* however advised that none of the existing DSAs contained GDPPR data. **Discussion:** IGARD noted that aspects of this application had been seen by the IGARD – NHS Digital COVID-19 Response meeting on the 26th January 2021. IGARD noted that this application had also been reviewed by PAG (see Appendix B) on the 17th February 2021 and 10th March 2021. IGARD noted the verbal update from NHS Digital confirming that, as per the PAG request on the 10th March 2021, the applicant **had** received a positive expression of support from their local clinical lead for the project; and asked that a copy of this written evidence was uploaded to NHS Digital's customer relationship management (CRM) system for future reference. IGARD noted the additional updates from NHS Digital, in respect of other DSAs currently held by the applicant; and the incorrect UK GDPR Article 6 legal basis, and the update to section 1 to ensure it aligned with the rest of the application. IGARD queried a statement in section 1 and section 3(c) (Patient Objections) in relation to National Data Opt-outs (NDO) *"…national data opt-out does not apply to disclosure of confidential patient information in such circumstances."*, and asked that it was updated to expressly state that the NDO was **not** applicable to pseudonymised data; and that any references to *"confidential data"* were removed as they were not relevant. IGARD noted one of the special conditions in section 6 (Special Conditions), referred to the end date of *"31st March 2021"* in respect of The Health Service Control of Patient Information (COPI) Regulations 2002; and asked that this was updated to reflect the extension of the COPI Notice to the 30th September 2021. IGARD noted the statement in section 5(a) (Objective for Processing), that *"The Recipients are health organisations covered by Regulation 3(3) of COPI…"*; and advised that this definition of a Local Authority was incorrect, and that although Local Authorities do have some responsibility for public health, it was incorrect to state that they were a *"health organisation"*. IGARD therefore asked that this was updated to remove the statement to the applicant being a health organisation and to simply state that Regulation 3(3) of COPI applied to the recipients. IGARD noted that Dudley Metropolitan Borough Council, had been added as a storage location twice in section 2(b) (Storage Location(s)), and asked that this was updated to remove one of the duplicated addresses. In addition, IGARD queried, why Dudley Metropolitan Borough Council was noted as a storage location, but not as a processing location in section 2(a) (Processing Location(s)); and asked that a clear explanation was provided as to why they were storing but not processing the data; or that section 2 (Locations) was amended as necessary. IGARD queried the statements in section 1 and section 5(a) *"The Recipients…will not generate copies of their cuts of the disseminated data unless this is strictly necessary."*; and asked that the applicant provide a justification **and** further details of recipients if the dissemination was happening; or that the reference to *"…generate copies of their cuts of the disseminated data…"* was removed if it was incorrect. IGARD noted the objectives for processing, which were extensive and should be of benefit to the public, however, were of the opinion that the one dataset requested did not contain the full coverage for the entire population, and may have particular gaps and may hinder the

	applicant's ability to meet these objectives. IGARD suggested that as a minimum, the applicant may also wish to consider requesting Covid-19 UK Non-hospital Antigen Testing Results (Pillar 2) data and, if this data were added to the application, IGARD would be supportive of it progressing without it coming back for an IGARD review. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 1 correct the Article 6 legal basis. 2. To update section 1 and section 3(c): a) To expressly state that the NDO is **not** applicable to pseudonymised data. b) To remove any references to *"confidential data"*. 3. To update section 5(a) to remove the statement that the applicant is a health organisation and simply state that Regulation 3(3) of COPI applies to the recipient. 4. In respect of the storage and processing locations in section 2: a) To provide a clear explanation as to why the Council is storing but not processing the data; or amend as necessary. b) To remove the duplicate storage location in section 2(b). 5. To update section 1 and section 5(a) to remove the reference to *"…generate copies of their cuts of the disseminated data…"* ; or to provide a justification **and** details of recipients if this dissemination is happening. 6. To update the special condition in section 6 to reflect the extension of the COPI Notice to the 30th September 2021. 7. In respect of the PAG point raised: to upload the written evidence of the positive expression of support from the applicant's local clinical lead to NHS Digital's CRM system (as per NHS Digital's verbal update). The following advice was given: 1. IGARD noted the objectives for processing, which are extensive and should be of benefit to the public, however, were of the opinion that the one dataset requested does not contain the full coverage for the entire population, and may have particular gaps, and may hinder the applicant's ability to meet these objectives. IGARD suggested that, as a minimum, they may also wish to consider requesting pillar 2 data and, if this data were added to the application, IGARD would be supportive of it progressing without it coming back for an IGARD review.
2.2	Royal College of Paediatrics & Child Health (RCPCH): National Paediatric Diabetes Audit (NPDA) HES extract 2019 (Presenter: Vicky Byrne-Watts) NIC-252024-D7R9W-v0.14 **Application:** This was a new application for identifiable Hospital Episodes Statistics Admitted Patient Care (HES APC) data; for the purpose of establishing whether hospital admission rates reported in previous NPDA publications have improved or worsened over time, and whether there has been year on year progress towards fewer admissions. A cohort of approximately 30,000 will be supplied to NHS Digital. The primary aims of the NPDA are to facilitate health providers and commissioners to measure and improve quality of care, and to contribute to the continuing improvement of outcomes for children and young people with diabetes and their families receiving care within paediatric diabetes units, up to the age of 24.

	The audit is managed by the Royal College of Paediatrics and Child Health (RCPCH), and commissioned by the Healthcare Quality Improvement Programme (HQIP) as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP). NHS Digital confirmed that the Health Research Authority Confidentiality Advisory Group (HRA CAG) had been made aware of the addition of NHS England as a joint Data Controller, not just for this application, but all other relevant HQIP commissioned applications, and that the formal application to amend the s251 support had not yet been submitted. NHS Digital also advised IGARD that the relevant privacy notice had not been updated to reflect that NHS England were a joint Data Controller, and that this had been highlighted to the applicant, who had advised that this would be updated as part of the regular website update. **Discussion:** IGARD noted the verbal updates from NHS Digital in respect of the amendment application that needed submitting to HRA CAG in respect of the joint data controllership arrangements with NHS England. IGARD asked that a special condition was inserted in section 6 (Special Conditions), that the applicant **will**, without delay, submit the amendment request form to HRA CAG to formally make them aware of the additional joint Data Controller. IGARD acknowledged the wider discussions that were ongoing, in respect of adding NHS England as a joint Data Controller on all other relevant HQIP commissioned applications. In addition, IGARD noted and supported the amendment highlighted by NHS Digital, that the applicant should update the privacy notice to reflect the addition of NHS England as a Data Controller. IGARD queried if the application presented to IGARD was in fact a *"new"* application, noting that it appeared to be a replication of NIC-34964-S2V0M (Royal College of Paediatrics & Child Health (RCPCH) , that had previously been reviewed by IGARD; and were advised by NHS Digital that the Data Sharing Agreement (DSA) for NIC-34964-S2V0M had expired and that the data under that agreement had been destroyed NHS Digital noted that although this was a new application, with a new NIC number, it was a continuation of the previous historical DSA. IGARD noted the verbal update from NHS Digital, and asked that for transparency and future reference, section 1 (Abstract) was updated to reflect the previous audit that was carried out with NHS Digital data under NIC-34964-S2V0M. In addition, and in light of the historical audit that had been carried out with NHS Digital data, IGARD asked that section 5(d) (Benefits) (iii) (Yielded Benefits) was updated to briefly reference the yielded benefits that flowed from the previous audit using NHS Digital data and in line with NHS Digital's DARS standard for Expected Measurable Benefits IGARD queried how the identifying data and the pseudonymised data was being segregated, by the Data Processor(s) the processes that were in place to ensure the data was kept separate, and to avoid the data being re-identified since it was not clear; and asked that section 5(b) (Processing Activities) was updated with clarification. IGARD noted the references within section 5 (Purpose / Methods / Outputs) to the *"Study Team"*, and asked that, to avoid any confusion as to the remit of the team, a special condition was inserted in section 6, that stipulated that NHS Digital data may only be used by the Data Processor to answer the audit questions as posed by the Data Controllers. IGARD noted the incorrect reference in section 5(c) (Specific Outputs Expected) to a *"five year comparative report"*, and asked that this was updated to only reference the **four**-year comparative report. IGARD suggested that, in light of The Health Service Control of Patient Information (COPI) Regulations 2002 expiring on the 30th September 2021; the Data Controllers and Data

	Processors consider how they were going to respond to the projected rollout of the National Data Opt-out. Due to the public interest in this dataset, IGARD also suggested that HQIP may wish to consider how other researchers could access the data, potentially on a sub licensing model or other platform, given the breadth and quality of the data and the time and expertise that had gone into creating the dataset. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of the special conditions in section 6: a) To insert a special condition, that the applicant will, without delay, submit the amendment request form to HRA CAG to formally make them aware of the additional joint Data Controller. b) To insert a special condition that stipulates that NHS Digital data may only be used by the Data Processor to answer the audit questions as posed by the Data Controllers. 2. In respect of the previous audit: a) To update section 1 to reflect the previous audit that was carried out with NHS Digital data (NIC-34964). b) To update section 5(d) (iii) to briefly reference the yielded benefits flowing the previous audit using NHS Digital data. 3. To update section 5(b) to clarify how the identifying data and the pseudonymised data will be segregated by the Data Processor(s), and the processes in place to ensure the data is kept separate. 4. To amend section 5(c) to only reference the **four**-year comparative report. The following advice was given: 1. IGARD suggested that the Data Controllers and Data Processors consider how they are going to respond to the projected rollout of the NDO on the 30th September 2021. 2. IGARD suggested that HQIP may wish to consider how other researchers could access the data, potentially on a sub licensing model or other platform, given the breadth and quality of the data and the time and expertise that has gone into creating the dataset.
2.3	<u>Northgate Public Services (UK) Limited: National Joint Registry (NJR) Annual Extract 2020 (Presenter: Vicky Byrne-Watts) NIC-07289-G8J6C-v8.8</u> **Application:** This was an amendment application to 1) to permit the NJR to sublicense NHS Digital data linked with NJR data; 2) to include the legal basis for dissemination for the consented cohort; 3) to update section 5(d) (Benefits) to outline the potential benefits of sublicensing. The National Clinical Audit and Patient Outcomes Programme (NCAPOP) is a large programme of circa 35 projects consisting of National Clinical Audits. The National Joint Registry (NJR) is commissioned by the Healthcare Quality Improvement Partnership (HQIP) on behalf of NHS England (NHSE) as part of the NCAPOP; and its purpose is to collect high quality and relevant data about joint replacement surgery in order to provide an early warning of issues relating to patient safety. The study relies on patient consent to link patient identifying information for around 93% of the NJR cohort to HES data; and s251 provides support for the cohort of patients for whom the consent status is unknown.

	Discussion: IGARD confirmed that they were of the view that the **most recent** consent materials and the relevant s251 support provided the appropriate legal gateway and was broadly compatible with the processing outlined in the application. IGARD did however, query the statement in supporting document 2.0, version 1.4 of the NJR patient consent form, that stated before any onward sharing *"Research projects are subject to ethical review…"*, and asked that the applicant established or evidence a procedure that would meet the requirement of providing an ethical review. IGARD advised, that as the process was currently structured, there was no scope for an ethical review, and further suggested that this was incorporated into HQIP's Data Access Review Group (DARG) review, or into the Terms of Reference (ToR) of the NJR Research Committee. Until such procedures were put into place, IGARD were of the opinion that there appeared to be no legal gateway for the data of those data subjects who had consented on the earlier versions of consent materials. IGARD also suggested that the NJR ToR was amended in a similar fashion to other sub-licence ToRs reviewed by NHS Digital, which as a minimum would require the establishment of a clear benefit to health and / or care, and that any commercial benefit would be proportionate to demonstrable benefits to health and care. In terms of the composition of the NJR Research Committee: IGARD suggested that this would greatly benefit from at least one additional patient representative drawn from the existing NJR Patient Representative Committee; and that they would benefit from an external independent member(s) outside the NJR sphere; and suggested that the committee may benefit from a member with Information Governance or Ethics expertise to satisfy the ethical review component, and provide the ability to assess applications for the benefit to health and care. IGARD queried, in light of the amendment request to sub-license the data, which data this specifically applied to and were advised by NHS Digital that only the flow of data flowing under consent and under s251 where consent status was recorded as unknown in the NJR would be part of the sub-licensing dataset. IGARD noted the confirmation from NHS Digital and asked that for transparency, an express statement was inserted in section 5 (Purpose / Methods / Outputs), that the flow of data relying on s251 related to safety data (covering individuals with no record in the NJR), where the data subjects were potentially asked for consent but did not give it, would not be part of the sub-licence dataset. IGARD queried if the NJR would be charging a cost for the sub-licenses, and were advised by NHS Digital that sub-licences would be on a cost recovery basis only; IGARD noted this verbal update and asked that section 5(a) (Objective for Processing) and section 5(e) (Is the Purpose of this Application in Anyway Commercial) were updated to reflect this statement. IGARD noted that section 5(e) stated that the application was not commercial, however, asked that this was updated to reflect that commercial bodies can apply for sub-licences and that if they did, they would be required to go through the Research Committee approval process. IGARD queried the statement in section 5(a) "…*not for marketing or sales*…" which meant that potential sub-licensees such as for Orthopaedic device manufactures may be restricted, and asked that the reference to the restriction to *"marketing and sales"* was removed and include an express statement that any potential commercial gain must be proportionate to potential health and or care gains, as outlined in the NHS Digital DARS standard for commercial purpose. IGARD noted the references to *"supported project"* and *"partnership project"* in section 5(a), and queried what the difference was since it was not clear and were advised by NHS Digital

	that a *"supported project"* was an NJR supported project by a third party applicant, that would typically require aggregate or summary data, pseudonymised or anonymised patient level data; and that a partnership project had an identified collaborator from the NJR and required sensitive data items, flows of identifiable data, or data linked to external datasets. IGARD noted the verbal update from NHS Digital, and asked that section 5(a) was updated, with a clear distinction of the difference between the two projects. IGARD queried the reference in section 5(a) to *"real time"* monitoring and in light of the fact that NHS Digital data being disseminated on an annual basis asked that the reference was either removed, or that a further explanation was provided as to how this real time monitoring was being undertaken with annual date from NHS Digital. IGARD noted the statement and web link in section 5(a) that stated "*A public register of NJR data releases is available here…"*, however, IGARD advised that as no information was available via the web link as yet; this was amended to state that a public register of NJR data releases *"…will be populated in due course…"*. IGARD noted the references throughout section 5 to the term *"survival"*, and asked that for clarity, section 5 was updated to make it clear that this was referring to survival of prosthesis and not survival of the patient. IGARD noted and commended the applicant on the excellent yielded benefits summary in section 5(d) (iii) (yielded benefits) gained from the recent flows of NHS Digital data. **Outcome:** recommendation to approve subject to the following condition: 1. In respect of the cohort members consented on the older versions of consent materials (expressly referencing an ethical review before any onward sharing), the applicant to establish or evidence a procedure that would meet the requirement of providing an ethical review. The following amendments were requested: 1. To insert an express statement in section 5 that the flow of data relying on s251 related to safety data, where the data subjects potentially did not consent to their data being used, would not be part of the sub-licence dataset. 2. To update section 5(a): a) To make a clear distinction of the difference between *"partnership projects"* and *"supported projects"*. b) To either remove the reference to *"real time"* monitoring; or to provide a further explanation as to how this real time monitoring is being undertaken. c) To amend to state a public register of NJR data releases *"…will be populated in due course…"*. 3. In respect of the commercial sublicences in section 5(a): a) To remove the reference to the restriction to *"marketing and sales"*. b) To make an express statement that commercial sublicensees must evidence potential benefit to health and care, proportionate to any commercial gain that may be derived from receiving the sublicensed data. 4. In respect of the sub-licensing arrangements: a) To update section 5(a) and section 5(e) to clarify that sub-licences will be granted on a cost recovery basis only. b) To update section 5(e) to make clear that commercial bodies can apply for sub-licences and all research projects will be required to go through an ethics review process.

	5. To update section 5 to make clear that the references to *"survival"* is referring to survival of prosthesis and not survival of the patient. The following advice was given: 1. In terms of the composition of the Research Committee: a) IGARD suggested that this would greatly benefit from at least 1 additional patient representative drawn from the existing NJR Patient Representative Committee. b) IGARD also suggested that they would benefit from an external independent member(s) outside the NJR sphere. c) IGARD suggested that the committee may benefit from a member with Information Governance or Ethics expertise to satisfy the ethical review component, and provide the ability to assess applications for the benefit to health and care. 2. IGARD suggested that the ToR were amended in a similar fashion to other sub-licence ToR reviewed by NHS Digital, which as a minimum would require the establishment of a clear benefit to health and / or care and that any commercial benefit would be proportionate to demonstrable benefits to health and care. 3. In respect of the data being sub-licenced relying on consent: the earlier versions of the consent material refer to *"onward sharing"* being subject to ethical review; as the process is currently structured, there is no scope for ethical review, and IGARD suggested that this was incorporated into HQIP's DARG review, or into the ToR of the NJR Research Committee; and until such procedures were put into place, there appeared to be no legal gateway for the data of those data subjects who consented on the earlier versions of consent. It was agreed the condition would be approved out of committee (OOC) by IGARD members.
2.4	<u>The University of Manchester: Evaluating prescribing safety indicators embedded in computerised clinical decision support software (Presenter: Vicky Byrne-Watts) NIC-253220-Q1X8H-v0.5</u> **Application:** This was a new application for Hospital Episodes Statistics Admitted Patient Care (HES APC) and Critical Care data, and Civil Registrations (deaths) data; for the purpose of evaluating two large-scale interventions in English general practices that employ prescribing safety indicators to reduce hazardous prescribing and avoidable harm to patients, 1) the clinical decision support software OptimiseRx, and 2) a pharmacist-led IT based intervention (PINCER). The cohort size is anticipated to be between 500,000 - 1,000,000 patients, and is relying on s251 for the flow of data. This study aims to assess the effect of the implementation of OptimiseRx on potentially hazardous prescribing and associated adverse outcomes including hospitalisation and death; and to evaluate the cost-effectiveness of OptimiseRx to NHS England. **Discussion:** IGARD confirmed that they were of the view that the relevant s251 support provided the appropriate legal gateway and was broadly compatible with the processing outlined in the application. IGARD queried the information in section 1 (Abstract), that stated *"The economic evaluation of OptimiseRX will…form part of a journal publications covering the qualitative, quantitative and economic evaluation…"*; and noting that this statement could potentially be misleading, asked that both section 1 and section 5 (Purpose / Methods / Outputs) were updated to clarify that

	the study related to the economic evaluation of point of prescription decision support and **not** just one commercial product. IGARD noted that in section 5(e) (Is the Purpose of this Application in Anyway Commercial) there were no commercial aspects to the application, and queried if this was correct in light of the statement in section 5(c) (Specific Outputs Expected) *"Each party within the programme is however granted an irrevocable, non-transferable, royalty-free right to use all arising IP generated in the course of the project for academic teaching, research purposes and for non-commercial clinical purposes."* IGARD asked that section 5(e) was updated accordingly and to reflect any commercial aspects, for example the intellectual property (IP) rights. IGARD noted specific Health Research Authority Confidentiality Advisory Group (HRA CAG) conditions of support in supporting document 3.7, the s251 register index sheet, and asked that a special condition was inserted in section 6 (Special conditions) replicating the relevant conditions, and with the requisite amendments. IGARD queried the role of the key Co-Investigators, referred to in supporting document 1.0, the study protocol, and asked that section 1 was updated, confirming that they did not exercise any influence over the study as borne out of the facts, such as they may be deemed joint Data Controllers and as set out in the NHS Digital DARS standard for Data Controllers. IGARD noted the statement in section 1 "*The University of Manchester are the delegated leads…"*, and asked that the reference to *"delegated"* was removed to avoid any misinterpretation of this word, which could be seen as Data Controllership. IGARD commended the applicant on their engagement with the public and patients and as outlined in the application. IGARD advised that they would wish to review this application when it comes up for amendment due to the novel nature of the study. **Outcome:** recommendation to approve subject to the following condition: 1. To update section 1 and throughout section 5 to clarify that this study relates to the economic evaluation of point of prescription decision support and not just one commercial product. The following amendments were requested: 1. To update section 5(e) to reflect any commercial aspects, for example, the IP rights. 2. To insert a special condition in section 6, to replicate the HRA CAG condition (as set out in SD 3.7), and with the requisite amendments. 3. To confirm in section 1 that the key Co-Investigators (as set out in the protocol), do not exercise any influence over the study, such that they may be deemed joint Data Controllers. 4. To remove the reference to *"delegated"* in section 1. The following advice was given: 1. IGARD advised that they would wish to review this application when it comes up for amendment due to the novel nature of the study. It was agreed the condition would be approved out of committee (OOC) by the IGARD Chair.
2.5	NHS Wakefield CCG: DSfC - NHS Wakefield CCG & Wakefield Council - Comm (Presenter: Duncan Easton) NIC-125783-W2W3P-v1.4

	Application: This was a new application to 1) add Wakefield Council as a joint Data Controller; 2) to add NHS E-Referral Service (e-RS) data set, Personal Demographic Service (PDS) data set, Summary Hospital-level Mortality Indicator (SHMI), National Diabetes Audit (NDA) dataset and Patient Reported Outcome Measures (PROMS) data set; 3) to remove eMBED as a Data Processor; and 4) to update the processing and storage locations. The purpose is to determine the impact the Population Health Management interventions are having on different elements of an individual's care. This evidence will support future service delivery, but also provide the national new models of care team with information to enable them to determine the optimum design that should be used for national roll out. This will support Primary Care Networks in their development and service planning, having the deeper insight about the population that they service will allow for better planning. **Discussion:** IGARD noted the amendment to add Wakefield Metropolitan District Council as a joint Data Controller, and queried what their role was, noting that the application was not clear on this point. IGARD asked that section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) were updated, to provide a clear justification of why Wakefield Council were considered a joint Data Controller, in terms of their direct involvement in the decision making regarding the processing of the data. In addition, the relationship between the Data Controllers should be clearly explained throughout section 5 to make clear how the joint Data Controllers were working together and dividing the Data Controllership responsibilities, as set out the NHS Digital DARS Standard for Data Controllers. In addition, IGARD also asked that written confirmation was provided in section 1 and section 5, of the legal gateway for the Council to handle the data and the safeguards that were in place. IGARD suggested that in respect of transparency and noting NHS Digital's DARS standard for transparency (fair processing), NHS Digital may wish to draw the applicant's attention to Article 26(2) of the UK General Data Protection Regulation (GDPR), which states that they must convey the essence of the joint data controllership arrangements to their data subjects. IGARD noted the amendment to add the SHMI dataset to the Data Sharing Agreement (DSA), and queried what the benefit was of this since there was no reference to how the SHMI data was being used in section 5, and asked that section 5(b) (Processing Activities) was updated with a further explanation of the benefits, for example, how this was improving the quality of the outputs or producing a new output. IGARD queried what the yielded benefits were of the work outlined within the application, noting that this was an amendment application, and the applicant was already in receipt of NHS Digital data. IGARD asked that section 5(d) (Benefits) (iii) (Yielded Benefits) was updated, to add further examples as per NHS Digital's DARS Standard for Expected Measurable Benefits. IGARD noted the statement in section 5(b) *"Data will be stored within a single platform…"*, and queried the accuracy of this, in light of the multiple storage and processing locations listed in section 2 (Locations); and asked that section 5(b) was updated to reconcile this statement. **Outcome:** recommendation to approve subject to the following condition: 1. In respect of Wakefield Council: a) To update section 1 and section 5 to provide a clear justification of why Wakefield Council are considered a joint Data Controller (in terms of their direct involvement in the decision making regarding the processing of the data).

	b) To provide written confirmation in section 1 and section 5 of the legal gateway for Wakefield Council to handle the data and the safeguards that are in place. c) To update section 5 throughout to make clear how the joint Data Controllers are working together and dividing data controllership responsibilities. The following amendments were requested: 1. To update section 5(b) to reconcile the reference to the data being hosted on a *"single platform"*, with the multiple storage and processing locations listed in section 2. 2. To update section 5(b) to provide a further explanation as to the benefits of adding the SHMI data to the DSA, for example, how this is improving the quality of the outputs or producing a new output. 3. To update the yielded benefits in section 5(d) (iii) to add further examples. The following advice was given: 1. IGARD suggested that NHS Digital may wish to draw the applicant's attention to Article 26(2) UK GDPR, which states that they must convey the essence of the joint data controllership arrangements to their data subjects. It was agreed the condition would be approved out of committee (OOC) by IGARD members.
2.6	<u>Office for National Statistics (ONS): ONS / NHS Digital TRE Public Health Asset (Presenter: Kimberley Watson) NIC-420710-X0H1P-v1.2</u> **Application:** This was an amendment application to add the GPES Data for Pandemic Planning and Research (GDPPR) (COVID-19) to the Public Health Research Database. The objective of this application is to seek permission for ONS to make an anonymised version of an existing dataset it holds containing NHS Digital data available for use by approved researchers in its Trusted Research Environment (TRE). ONS are requesting to use Hospital Episodes Statistics (HES) data, already disseminated (to ONS) under active NHS Digital Data Sharing Agreements (DSA), to link to ONS 2011 Census data to create a new data asset. The HES data will be used to enrich the 2011 Census data with additional health characteristics. This new data asset will be referred to as the 'Public Health Data Asset'. The Public Health Research Database will be created from the Public Health Data Asset. NHS Digital advised IGARD that following discussions between the applicant, NHS Digital's Data Access Request Service (DARS), and Privacy, Transparency and Ethics (PTE) (formerly Information Governance) the legal basis for the GDPPR data has changed from The Health Service Control of Patient Information (COPI) Regulations 2002, to section 45A of the Statistics and Registration Services Act (SRSA) (2007). NHS Digital also noted that the applicant had published their updated privacy notice. **Discussion: I**GARD noted that this application had been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) (see Appendix B) on the 10th March 2021. IGARD noted and supported the comments made by PAG on the 10th March 2021. IGARD noted that this review was specifically to look at the amendment aspect of the application for inclusion of the GDPPR data and they were not providing any contentment or otherwise on the wider application as a whole.

	IGARD noted the verbal update from NHS Digital in respect of the change to the legal basis for collecting and use of the data and therefore asked that a special condition was inserted in section 6 (Special Conditions), that all GDPPR derived data **shall** be destroyed on the expiry of the COPI Notice, which is currently the 30th September 2021. IGARD queried the transparency to the public in terms of the National Data Opt-out (NDO), and asked that all public facing transparency materials for NHS Digital and ONS, had an express statement that the NDO was **not** applied to the data going into the TRE. IGARD noted the sub-license arrangements outlined within the application, and asked that a special condition was inserted in section 6, that if any sub-licensee wished to ingest data into the Public Health Research Database (PHRD), the research or accreditation panel **must** satisfy themselves that the PHRD data in the hands of that researcher would still be anonymous in terms of the UK General Data Protection Regulation (UK GDPR). IGARD noted the special condition in section 6, in relation to the research, and asked that a new special condition was added to state the data can only be used for statistical research where permitted by the Statistics and Registration Service Act 2007 (SRSA). IGARD reiterated previous advice that there were significant areas of risk with regard to the concept of *"functionally anonymous"*; specifically, there was a risk that the assessments relating to whether the data in the hands of researchers was anonymous in terms of the UK GDPR may come down on the wrong side of the Information Commissioners Officer (ICO) guidance, once this was produced. IGARD made reference to the recent observation by the European Data Protection Board that *"anonymisation of personal data should be approached with caution in the context of scientific research."* IGARD noted with regards to ethical review, that this would be done on a case-by-case basis, however, in practice, this appeared to enable a researcher to self-certify their own ethical review, and suggested the rigour of the National Statistician's Data Ethics Advisory Committee (NSDEC) would be more appropriate and in line with public expectations. IGARD suggested that the applicant, give further consideration to the current website communications with the public relating to the 2021 census; and suggested that the applicant took the opportunity to inform the public in terms of current and future linkage of health data, since it would be accessed by a good proportion of the population during this period. IGARD noted several references to *"IGARD"* within supporting document 3.1, the Data Protection Impact Assessment (DPIA), and politely requested that all references were removed, since IGARD **do not** approve flows of data, nor did they have any input into the applicant's DPIA. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, given the quantum of NHS Digital data involved in this project of national significance; and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent. **Outcome:** recommendation to approve **for the addition of GDPPR amendment only** The following amendments were requested: 1. To ensure that all public facing transparency materials for NHS Digital and ONS, have an express statement that the NDO is **not** applied to the data going into the TRE. 2. In respect of the special conditions in section 6:

	a) To insert a special condition, that if any sub-licensee wishes to ingest data into the PHRD, the research or accreditation panel must satisfy themselves that the PHRD data in the hands of that researcher will still be anonymous in terms of the UK GDPR. b) To insert a special condition, that all GDPPR derived data shall be destroyed on the expiry of the COPI Notice (currently the 30th September 2021). c) To insert a special condition to state the data can only be used for statistical research where permitted by the Statistics and Registration Service Act 2007 (SRSA). The following advice was given: 1. IGARD reiterated previous advice that there are significant areas of risk with regard to the concept of *"functionally anonymous"*; specifically, there is a risk that the assessments relating to whether the data in the hands of researchers is anonymous in terms of UK GDPR may come down on the wrong side of ICO guidance, once this is produced. IGARD made reference to the recent observation by the European Data Protection Board that *"anonymisation of personal data should be approached with caution in the context of scientific research."* 2. IGARD noted with regards to ethical review, that this would be done on a case-by-case basis, however, in practice, this appears to enable a researcher to self-certify their own ethical review, and suggested the rigour of NSDEC would be more appropriate and in line with public expectations. 3. IGARD suggested that consideration be given to the current website communications with the public, relating to the 2021 census, and suggested that the applicant takes the opportunity to inform the public in terms of current and future linkage of health data, since it would be accessed by a good proportion of the population. 4. IGARD requested that all references to *"IGARD"* are removed from the applicant's DPIA, as IGARD do not approve flows of data, nor do they have any input into the applicant's DPIA. 5. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment given the quantum of NHS Digital data involved in this project of national significance. 6. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent.
3	<u>Returning Applications</u> IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. 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.

4	COVID-19 update 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 9th March 2021** can be found attached to these minutes as Appendix C.
5	AOB: 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.
6	IGARD / GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) Workshop Following conclusion of the IGARD business as usual section of the meeting, IGARD and PAG held a workshop, to discuss future collaborative working, and this part of the meeting was chaired by the PAG Chair, Dr. Arjun Dhillon. The PAG and IGARD Chair's thanked members for their time and it was agreed that further discussions would be held on any future joint working.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 05/03/21

These applications were previously recommended for approval with conditions by IGARD, and since the previous Out of Committee Report the conditions have been agreed as met out of committee.

NIC Reference	Applicant	IGARD meeting date	Recommendation conditions as set at IGARD meeting	IGARD minutes stated that conditions should be agreed by:	Conditions agreed as being met in the updated application by:	Notes of out of committee review (inc. any changes)
NIC-390749-C4P0X	University of York	14/01/2021	1. In respect of Hull University Teaching Hospitals NHS Trust: a) The applicant to expressly notify REC that Hull University Teaching Hospitals NHS Trust is a joint Data Controller. b) To provide a copy of any relevant documentation to NHS Digital for uploading onto NHS Digital's CRM system.	IGARD Chair	IGARD Chair	None
NIC-06759-X5V7P	University of York	14/01/2021	1. In respect of HRA CAG: a) To provide evidence of unconditional HRA CAG support, including all relevant application documentation. b) That the unconditional HRA CAG support aligns with the proposed processing set out in this application. c) That the NDO questions have been addressed to IGARD's satisfaction, and amendments made as appropriate to the application.	IGARD members	Quorum of IGARD members	**Condition 1a** Set Aside *"This agreement is not receiving information based on s251 (that only applies to NIC-346859-C9J6J)"* **Condition 1b** Set aside *"This agreement is not receiving information based on s251 (that only applies to NIC-346859-C9J6J)"* **Condition 1c** Set Aside

						"This agreement is not receiving confidential patient information based on s251 (that only applies to NIC-346859-C9J6J) and is not flowing any confidential patient information."

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

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

- NIC-422211-Q0Y4D-v0.2 - NHS Black Country and West Birmingham CCG

Optum Health Solutions UK Limited Class Actions:

- None

Appendix B

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 17th February 2021

Application & application version number: **DARS-NIC-387291-B3M4Z-v0.3** **Organisation name: Dudley Local Authority** **Profession Advisory Group Agenda item: 2**
PAG supports the application with the following points: PAG noted that COPI was used for this application to disseminate data, but it is not identifiable data, therefore it would be helpful to know why COPI was used in this instance? PAG requires assurance that the local authority involves relevant healthcare professionals in their work including CCG GP Lead for Covid-19 local response and clinical chair. This is to ensure collaboration and minimise any unintentional consequences. The application makes reference to: *the Recipients will keep their cut of the electronic disseminated data in an encrypted form and take all required security measures to protect the disseminated data and they will not generate copies of their cuts of the disseminated data unless this is strictly necessary.* PAG queried the reference to 'strictly necessary' which is somewhat vague and does not state when this may be the case. PAG requests NHS Digital to explore these criteria with applicants with a view of updating the templates.

Attendees	**Role**	**Organisation**
Peter Short	Deputy Chair	NHS Digital
Amir Mehrkar	GP, Clinical Researcher	RCGP
Mark Coley	Deputy IT Policy Lead	BMA
Pam Soorma	Secretariat	NHS Digital
Duncan Easton	Data Approvals Officer	NHS Digital
Daniel Goodwin	Senior Case Officer	NHS Digital
David Morris	Case Officer	NHS Digital

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 10th March 2021

Application & application version number: **DARS-NIC-387291** **Organisation name: Dudley Local Authority** **Profession Advisory Group Agenda item: 7a**
PAG received a verbal update from the case officer. The response from the local authority was slightly unclear. In order to move the application forward PAG request that a special condition is added into the application: PAG supports this application once the applicant have support from their local clinical lead.

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

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 10th March 2021

Application & application version number: **DARS-NIC-420710-X0H1P-v1.2** **Organisation name: Office of National Statistics (ONS)** **Profession Advisory Group Agenda item: 3**
PAG is supportive of the ONS work related to Covid-19 analysis and the restriction as identified in the DSA. PAG understand there is a change in the legal basis but are not clear why this proposed, this needs to be clearly outlined. PAG recommend that the final written summary is incorporated into the application (including to ensure IGARD oversight). PAG wish to highlight to the applicant the limitations of the collection of this data which remains under COPI i.e this dataflow will end when COPI ends. The policy around data retention for data collected is under COPI which is owned by NHSX. NHSX have stated its current position that data will need to be deleted. The change in legal basis requires the purpose to be statistics. ONS must have controls in place to ensure all use of the data is compatible with that legal basis.

Attendees	**Role**	**Organisation**
Arjun Dhillon	Chair, Caldicott Guardian	NHS Digital
Peter Short	Clinical Lead	NHS Digital
Amir Mehrkar	GP, Clinical Researcher	RCGP
Mark Coley	Deputy IT Policy Lead	BMA
Liz Gaffney	Head of Data Access	NHS Digital
Pam Soorma	Secretariat	NHS Digital
Kimberley Watson	Data Approval Officers	NHS Digital

Appendix C

Independent Group Advising on the Release of Data (IGARD)

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

held via videoconference, Tuesday, 9th March 2021

In attendance (IGARD Members):	Prof. Nicola Fear (IGARD Specialist Academic Member)
	Kirsty Irvine (IGARD Chair, Lay representative)
	Dr. Geoff Schrecker (IGARD Specialist GP Member)
In attendance (NHS Digital):	Dave Cronin (DARS)
	Louise Dunn (DARS)
	James Gray (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 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.
2.1	<u>Specific Risk Criteria</u> **Background:** This was a business as usual (BAU) proposal which proposes to replace the reference to the Specific Risk Criteria in the exclusion criteria of several of NHS Digital DARS Precedents used for extensions, renewals and amendments with a Specific Exclusion Criteria document which is more focused on when those Precedents should not be used and which gives more clarity to staff in DARS about those scenarios. This document does not include the scenario where IGARD in its meetings specifically requests under "advice" that it wishes to see it again on renewal, amendment or extension, since that is already listed in the Exclusion Criteria section of all Precedents. **IGARD Observations:**

	IGARD members noted a number of comments to NHS Digital and that the documentation would be circulated as per due process out of committee to IGARD and other key stakeholders in due course.
2.2	NIC-419173-Z1G3C-v0.4 University of Bristol **Background:** this was a new draft application (v0.4) and relevant supporting documents requesting Hospital Episode Statistics (HES) Admitted Patient Care (APC), HES Critical Care (CC), Civil Registration (Deaths) data and the National Adult Cardiac Surgery Audit (NACSA) data to look at the impact of the COVID-19 pandemic on outcomes following cardiac surgery. NACSA collects data on all major heart operations carried out in NHS hospitals and a selection of private hospitals throughout the UK. The data is not yet onboarded to NHS Digital's DARS but is in the process of being for COVID-19 related research only. The draft application (v0.4) and relevant supporting documents was being presented at the COVID-19 response meeting ahead of any formal presentation to the IGARD business as usual (BAU) meeting for a recommendation. The application had been through NHS Digital's COVID-19 front door prioritisation meeting. NHS Digital noted that the NACSA data had not yet onboarded to NHS Digital's DARS and that this data product was not listed in section 3(b) (Additional Data Access Requested). The following observations were made on the basis of the draft v0.4 of the application and relevant supporting documents only. **IGARD Observations:** IGARD members noted the important work and were supportive of the work being undertaken, they also noted that the application had been well constructed and thanked NHS Digital and applicant for the open ended questions it was asking and trying to address. IGARD members noted that the University of Bristol was part of the consortium of members which made up the cardiovascular trusted research environment (CV TRE) and queried why the applicant was not utilising the TRE, and that a justification should be included in the abstract (section 1) for this standalone application. IGARD members noted that the application should clearly reference that this was pseudonymised data and the application updated throughout to remove reference to COPI or statutory exemptions for handling confidential data, since they were not relevant. Noting the standard special conditions outlined in section 6 (special conditions) highlighting the negotiated position reached between NHS Digital and the University of Bristol, that a brief narrative be included in section 1 (abstract) or added as a preface to the special condition wording. IGARD members noted reference within section 8(b) (Funding Sources) of the application and SD1.0 *study protocol v1.0* to the NIHR Bristol Biomedical Research Centre as a funder and IGARD members suggested that section 5(a) (Objective for Processing) be updated with a brief description of the involvement of the funders and any vested interest they may have in the research being undertaken. IGARD members suggested that section 5 (Purpose / Methods / Outputs) should be updated that the sharing of aggregated data was in line with the HES analysis guidelines

	IGARD members noted reference in section 5(c) (Specific Outputs Expected, including targets dates) to "*The findings may be published on a secure website…*" and suggested that this was clarified if it was intended to be generic wording to reference relevant security certificates, rather than an actual secure website. Noting that the data minimisation wording in section 3(b) had already been included in section 5 which is publicly available, that consideration be given to reducing the text in section 3(b). IGARD noted that the applicant on the NHS Digital customer relationship management (CRM) system was the 'Doctors.UK.Net', however the documentation provided clearly indicated that this was not the case. NHS Digital noted that CRM would be updated to clearly identify the correct applicant as the University of Bristol.
2.3	NIC-433257-K6Q2Y-v0.4 University of Liverpool **Background:** This was a new application (v0.4) and relevant supporting documents for the Helping Alleviate the Longer-term Consequence of COVID-19 (HEAL-COVID) which was a national platform trial and was requesting Civil Registration (Deaths) data, Hospital Episode Statistics Accident & Emergency (HES A&E), HES Admitted Patient Care (APC), HES Critical Care (CC), HES Outpatients, Medicines dispensed in Primary Care (NHSBSA) data and Secondary Uses Service Payment by Results (SUS PbR) episodes. The '*HEAL-COVID Adult Participation Information Sheet v0.7_05022021*' and '*HEAL-COVID website data processing statement draft v0.2*' had been previously discussed at the COVID-19 response meeting on 9th February 2021. This is a NIHR funded urgent public health trial and would be progressed via the SIRO precedent. HEAL-COVID is a platform trial comparing treatment for the long term consequences of COVID-19. The University of Cambridge and Cambridge University Hospitals NHS Foundation Trust jointly sponsor the trial with the day to day running of the trial carried out by the team based at the Liverpool Clinical Trials Centre at the University of Liverpool and researchers at the University of Cambridge. The following observations were made on the basis of the draft v0.4 of the application and relevant supporting documents only. **IGARD Observations:** IGARD members noted the work the applicant had undertaken since its previous limited review to update the consent materials from previously reviewed v0.7 to current v1.1. IGARD members noted reference to a number of funders outlined in SD5.1 *Protocol Draft v0.11* which did not appear in section 8 (Funding Sources) of the application and suggested that the application be updated as appropriate to reflect the factual information. In addition, to check if any funder listed had any commercial interests (for example: a manufacturing interest in any of the drugs being studied) and to update section 5 (Purpose / Methods / Outputs), as per the NHS Digital DARS standard for commercial use. In addition and noting the number of organisations listed in SD5.1 *Protocol Draft v0.11*, that an assessment be undertaken in relation to the Data Controllership and consideration be given to the facts of the parties' involvement and as laid out in NHS Digital's DARS Standard for Data Controllers / Data Processors.

	IGARD Members noted the special condition in section 6 that "*The data received by the University of Liverpool (UoL), University of Cambridge and Cambridge University Hospitals NHS Foundation Trust will not be used for any purpose other than to meet objectives as stated in this Data Sharing Agreement and will not be shared with any other third party or organisation*." However, this would preclude any other organisation listed in the application and suggested the wording be updated to include "*except the handling by the named Data Processors within this application…*", or other such words. IGARD members noted the special condition in section 6 (Special Conditions) to "*The University of Liverpool (UoL), University of Cambridge and Cambridge University Hospitals NHS Foundation Trust must subsequently maintain their DSPT (or subsequent versions / successors) during the period of this DSA…*" but that section 1(b) (Data Controllers) clearly stated that Cambridge University Hospitals NHS Foundation Trust had not fully met its DSPT and that a plan had been agreed. IGARD members suggested that these two statements be aligned to the facts and the special condition amended as may be necessary. IGARD members noted that the consent materials had been re-presented to Research Ethics Committee (REC) and that approvals should be in place before data flowed under this agreement. IGARD did not need to see the ethics approval, but that NHS Digital should undertake a review of the materials, in line with its usual processes. Notwithstanding the above points, IGARD members supported NHS Digital's assessment that the application would be approved under the NHS Digital SIRO precedent.
2.4	<u>NIC-420105-M8Y5X-v1.1 Novavax Inc</u> **Background:** This was a verbal update having been previously discussed at the 2nd March 2021 and 8th December 2020 COVID-19 response meetings. Novavax are conducting a Phase 3 clinical trial of SARS-CoV-2 recombinant spike protein nanoparticle vaccine (SARS-CoV-2 rS) with Matrix-M1Tm Adjuvant with the primary objective to demonstrate the efficacy of SARS-CoV-2 rS with Matrix-M1 adjuvant in the prevention of virologically confirmed (by PCR) symptomatic COVID-19, when given as a 2-dose vaccination regimen as compared to a placebo, in serological negative (to SARS-CoV-2) adult participants. The trial originally recruited its cohort of 15,000 members through NHS Digital's Permission to Contact service NHS Digital noted that reconsenting had commenced on the 5th February 2021 and was due to be completed by the 5th April 2021 and that it was the applicant updating their protocol regarding unblinding, rather than any advice received from NHS Digital, that had prompted them to reconsent their cohort. NHS Digital noted that 7,500 members of the cohort had been unblinded and that no further data would flow from NHS Digital to the applicant for those cohort members who had been withdrawn from the study. In addition, NHS Digital noted that the applicant had taken on board comments previously made by IGARD on the consent materials. The following observations were made on v3.0 (dated 20 December 2020) of the *Clinical Study Protocol* and verbal update only. IGARD did not receive a copy of the application or any other relevant supporting documentation. **IGARD Observations:**

	IGARD members noted the update from NHS Digital with regard to the updated consent materials, and reiterated their previous comments that due to the nature of the meeting and when papers were disseminated, they had not conducted a full consent review. Should a full review of the application and documentation be required, the full suite of documentation should be presented to a IGARD business as usual (BAU) meeting for a recommendation. IGARD members noted the substantial numbers of unblinded trial participants and hoped that this would not unduly affect the validity of the ongoing trial, noting this was a multinational trial across a number of countries and required 15,000 participants. NHS Digital noted that there were a number of orphaned bar codes which were positive tests taken by the trial member but had no identifiers and the applicant had requested this data. IGARD members were supportive of the applicant receiving this data but to clarify the nature of the bar code as an identifier, who could re-identify, the legal basis to flow this from NHS Digital to the applicant and the legal basis for the applicant to receive this data from NHS Digital. IGARD reiterated their point previously made that an assessment of whether PPD Global Ltd should be noted as a Data Processor in the DARS application should be undertaken, or was their handling of data separate from the handling of NHS Digital data and in line with NHS Digital's DARS Standard for Data Controllers / Data Processors. In addition, "PPD" should be referred to by its full legal name on first use in the public facing section of the application and its involvement in the processing should be clearly articulated in the DARS application. Finally, IGARD noted that a number of points had been previously raised, and that they had not been provided with a copy of the updated application summary, and that all previous points raised remained outstanding until fully addressed. IGARD members advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent. Notwithstanding the above points, IGARD members supported NHS Digital's assessment that the application would be approved under the NHS Digital SIRO precedent for a 6 month extension and in line with the Health Service (Control of Patient Information) 2002 (COPI) Notice end date.
2.5	NIC-433176-J8Q2S-v1.1 AstraZeneca UK Ltd **Background:** This was a verbal update to the business as usual (BAU) item which had been previously discussed at the COVID-19 response meeting on 2nd March 2021. This was a registry based randomised double-blinded placebo-controlled cardiovascular outcomes trial to evaluate the effect of Dapagliflozin on the incidence of heart failure or cardiovascular death in patients without diabetes with acute myocardial infarction at increased risk for subsequent development of heart failure. Dapagliflozin is a drug that was originally developed for the treatment of type 2 diabetes. The following observations were made on the verbal update only. IGARD did not receive a copy of the application or any other relevant supporting documentation. **IGARD Observations:**

	NHS Digital noted that the applicant had taken on board comments previously made by IGARD on the consent materials and had updated and resubmitted the consent materials to the Research Ethics Committee (REC). IGARD members reiterated their previous comments that due to the nature of the meeting and when papers were disseminated, they had not conducted a full consent review nor had they seen the redrafted material. Should a full review of the application and documentation be required, the full suite of documentation should be presented to a IGARD business as usual (BAU) meeting for a recommendation. In addition, IGARD reiterated to NHS Digital that comments made with regard to the consent materials were in line with NHS Digital's published standards and in particular the published NHS Digital DARS Duty of Confidentiality Standard which had been developed with the Health Research Authority Confidentiality Advisory Group (HRA CAG). Finally, IGARD noted that a number of points had been previously raised, and that they had not been provided with a copy of the updated application summary, and that all previous points raised remained outstanding until fully addressed. IGARD noted that this application would be presented to a future IGARD BAU meeting for a full review of the application and suite of documentation.
3	AOB There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.