Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 1 July 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Prof. Nicola Fear	Specialist Academic Member
Kirsty Irvine (Chair)	IGARD Chair / Lay Representative
Dr. Imran Khan	Specialist GP Member
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Ben Cromack	Data Access Request Service (DARS) (Observer: item 2.4)
Louise Dunn	Data Access Request Service (DARS)
Karen Myers	IGARD Secretariat
Jonathan Osborn	Deputy Caldicott Guardian (Observer: items 2.2)
Frances Perry	Data Access Request Service (DARS) (Observer: items 2.1 – 2.2)
Denise Pine	Data Access Request Service (DARS)
Andy Rees	Clinical Trials Service
Bethan Thomas	Data Access Request Service (DARS)
Joanna Warwick	Data Access Request Service (DARS) (Item 3)
Vicki Williams	IGARD Secretariat

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

	Nicola Fear noted a professional link with King's College London [NIC-174740-C0H0L] but noted no specific connection with the application or staff involved and it was agreed that this was not a conflict of interest. Maurice Smith noted a professional link to Alder Hey Children's NHS Foundation Trust [NIC-406632-X0L2M] by virtue of his previous role on the Governing Body of Liverpool CCG which commissions services from Alder Hey, 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 24th June 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	AstraZeneca UK Limited: Real-world effectiveness and safety of the Oxford/AstraZeneca covid-19 vaccine in England: ORCHID linkage (Presenter: Louise Dunn) NIC-459114-J3C1F-v0.5 **Application:** This was a new urgent public health priority application for pseudonymised Civil Registrations (deaths) data, COVID-19 Second Generation Surveillance System, Covid-19 UK Non-hospital Antibody Testing Results (Pillar 3), Covid-19 UK Non-hospital Antigen Testing Results (pillar 2), COVID-19 Vaccination Status, Hospital Episode Statistics Admitted Patient Care (HES APC) and HES Critical Care. The requested datasets will be linked to a cohort and used to develop analysis code and algorithms prior to being deployed in the national level data within the NHS Digital Trusted Research Environment (TRE) under Data Sharing Agreement (DSA) NIC-445543-W0D4N (item 3.2). The primary objective of this study is to assess the real-world effectiveness of the Oxford/AstraZeneca COVID-19 vaccine among people who receive one dose of the vaccine, overall and by age group and time period after 1 dose. The secondary objectives of the study are to: a) assess the vaccine effectiveness in people who have received the two doses; the timing after the 1st and 2nd dose, interval between the two doses and comorbidity status b) replicate the above analyses in people receiving the Pfizer COVID-19 vaccine. **Discussion:** IGARD welcomed the application and noted the importance of the study. IGARD noted that this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 25th May, 15th June and 22nd June 2021. IGARD noted that the application stated that AstraZeneca UK Limited were a joint Data Controller, however, noting supporting document 3.1, the Integrated Research Application System form, gave a sponsor contact located in the United States of America, IGARD queried if the USA entity had any data controllership responsibility, in light of the published guidance regarding sponsors being Data Controllers from the Health Research Authority (HRA). NHS Digital advised IGARD that despite the location of the sponsor contact, the USA entity would have no data controllership responsibilities. IGARD noted the verbal update from NHS Digital, and asked that for future reference, section 1 (Abstract) was updated to note that no US entity was taking on any Data Controller responsibilities.

	In addition, IGARD asked that a special condition was inserted in section 6 (Special Conditions), to make clear that the permitted territory of use was England and Wales, as stated in section 2(c) (Territory of Use). IGARD noted that the same data in the Oxford-Royal College of General Practitioners Clinical Informatics Digital Hub (ORCHID) would have a different Data Controller depending on the purpose; and advised that it might be the case that the data has joint controllers (the University of Oxford and the Royal College of General Practitioners). IGARD suggested that that the joint named Data Controller(s) in this application consider this issue within their Data Protection Impact Assessment (DPIA) for transparency. In addition, IGARD advised that, in line with the Information Commissioner's Office (ICO) guidance, the DPIA **must** be completed before the applicant commences processing of the data. IGARD noted that section 3(c) (Patient Objections) stated that patient objections were **not** observed, however queried the information within the draft privacy notice that stated *"You can withdraw your consent at any time by contacting your General Practitioner or using the NHS national data opt out service…"*; and queried if this was an error, and whether type one objections only should be featured. NHS Digital advised IGARD that prior to the meeting, they had received three revised privacy notices that had also been published, for the users / researchers, patients / participants / public, and a study specific privacy notice. IGARD noted the verbal update from NHS Digital (noting that they had not seen nor reviewed the revised privacy notices) and their concern that the revised privacy notice(s), still gave the impression that the National Data Opt-out would be effective in stopping the data reaching the data resource; when in fact **only** data subjects who have registered a Type 1 opt-out would prevent their data being used this way. NHS Digital also verbally advised that the privacy notice(s) still referred to *"consent"*, which was not being taken. IGARD noted the verbal update from NHS Digital that this was misleading and there would be a legal risk to the Data Controllers, and a significant reputational risk to NHS Digital, disseminating data where the opt-out arrangements are incorrectly described. IGARD queried the reference in section 5(a) (Objective for Processing) that stated *"…each individual's address will be used to link individuals to a household."*, and for further transparency, asked that this was amended to provide further clarity on where the household linkage had taken place, as this was not clear. IGARD noted that supporting document 1.1, the revised study protocol, still does not refer to research into the vaccination of under 16s, and that it only established the use of under 16s data for the household transmission research. IGARD suggested that the protocol was revised further, to explicitly cover the use of the data for research into vaccinations carried out to date in under 16s; and that there was a risk that the research into under 16 vaccination was not in line with a protocol with ethical support. IGARD noted the information provided in section 5(e) (Is the Purpose of this Application in Any Way Commercial), that outlined the commercial aspects of the application, and asked that for transparency, this was replicated in section 5(a); along with any further transparency as appropriate, regarding the commercial aspects of the application. IGARD noted the information in section 3 (Datasets Held / Requested) that stated that the common law duty of confidentiality was addressed by *"Statutory exemption to flow confidential data without consent"*; and asked that this was amended to reflect that the data requested was pseudonymised. IGARD queried the references in section 3(b) (Additional Data Access Requested) and section 5 (Purpose / Methods / Outputs) to *"records"*, for example, *"22 million records"*; and asked that

	this was updated to refer to *"patients"*, and, if appropriate, the patient figures stated were amended, noting these may differ. IGARD noted the information provided in section 5(b) in respect of the SALTing methodology, however asked that for transparency, this was updated further, to include a brief lay summary of the SALTing methodology. IGARD queried the statement in section 5(b) (Processing Activities) *"The data is controlled and processed by a group of staff who are all substantive employees of the University of Oxford."*, and asked that this was reviewed and amended as appropriate, noting that this could be misleading. IGARD noted the statement in section 5(d) (Benefits), that the vaccine had *"…helped save tens of thousands of lives…"*, and asked that this was amended, to make clear that the vaccine had been proven to be effective in clinical trials, and that this study was now necessary to conclude on a scientific basis how, and to what extent, the vaccine was effective in real world terms. IGARD suggested that section 5(d) be updated to remove reference to "*it will*…" and instead use a form of words such as "*it is expected…"* or *"it is hoped …".* IGARD suggested that consideration was given to patient and public involvement and engagement (PPIE), given the significant amount of data flowing and the public interest in the topic. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent; due to the quantum of national data flowing. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 1 to note that, notwithstanding published guidance regarding sponsors being Data Controllers, that no US entity has Data Controller responsibilities. 2. To amend section 5(a) to clarify where the household linkage has taken place. 3. To replicate the information in section 5(e) into section 5(a), and provide any further transparency as appropriate, regarding the commercial aspects of the application. 4. To update section 3 to amend the common law duty of confidentiality wording to reflect that the data is pseudonymised. 5. To update the references in section 3(b) and section 5 from *"records"* to *"patients"* and amend the figures if appropriate. 6. To update section 5(b) to include a brief lay summary of the SALTing methodology. 7. To amend the references in section 5(b) to a group of staff *"controlling"* the data and re-word as appropriate. 8. To insert a special condition in section 6 to make clear the permitted territory of use. 9. In respect of section 5(d): a) To amend section 5(d) to make clear that the vaccine has been proven to be effective in trials, and that this study is now necessary to conclude on a scientific basis how and to what extent it is effective in real world terms. b) To update section 5(d) to use a form of wording such as "*it is expected…"* or *"it is hoped …"*, rather than "*it will…*". The following advice was given: 1. IGARD noted that there is a risk that the RCGP may be deemed a Data Controller, as the data is held in a single resource. IGARD suggested that that the joint named Data Controller(s) in this application consider this issue in their DPIA(s).

	2. IGARD advised that, in line with the ICO guidance, the DPIA must be completed before the applicant commences processing the data. 3. IGARD noted concern that the revised (not seen by IGARD) privacy notice, still gives the impression that the National Data Opt-out will be effective in stopping the data reaching the data resource; when in fact **only** Type 1 opt-outs will prevent data being used this way. NHS Digital also verbally advised that the privacy notice still referred to *"consent"*, which was not given in this factual scenario. IGARD noted this was misleading and there would be a legal risk to the Data Controllers, and a reputational risk to NHS Digital, disseminating data where the opt-out arrangements are incorrectly described. 4. IGARD noted that the revised protocol still does not refer to research into the vaccination of under 16s (it only establishes the use of under 16s data for the household transmission research). IGARD suggested that the protocol is revised further, to explicitly cover the use of the data for research into vaccinations carried out to date in under 16s. Accordingly, there is a risk that the research into under 16 vaccination is not in line with a protocol with ethical support. 5. IGARD suggested that consideration was given to PPIE, given the significant amount of data flowing and the public interest in the topic. 6. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment; due to the quantum of national data flowing. 7. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent; due to the quantum of national data flowing. **Significant Risk Area:** 1. IGARD advised NHS Digital that there was a potential area of risk to NHS Digital's reputation with regards to the revised privacy notice which was potentially misleading with regards to NDOs (see advice above).
2.2	<u>AstraZeneca UK Limited: Real-world effectiveness of the Oxford/AstraZeneca covid-19 vaccine in England - TRE Analysis (Presenter: Louise Dunn) NIC-445543-W0D4N-v0.7</u> **Application:** This was a new application for pseudonymised Civil Registrations (deaths) data, COVID-19 Second Generation Surveillance System, Covid-19 UK Non-hospital Antibody Testing Results (Pillar 3), Covid-19 UK Non-hospital Antigen Testing Results (pillar 2), COVID-19 Vaccination Status, Hospital Episode Statistics Admitted Patient Care (HES APC), HES Critical Care, Uncurated Low Latency Hospital Data Sets APC and GPES Data for Pandemic Planning and Research (COVID-19) (GDPPR). The datasets are also being requested as an extract to flow to University of Oxford under Data Sharing Agreement (DARS) NIC-459114-J3C1F (item 3.1) to be linked to the data in the ORCHID resource to develop code and algorithms for analyses in a cohort to which they will be linked, prior to the analysis code and algorithms being deployed in the national level data. The primary objective of this study is to assess the real-world effectiveness of the Oxford/AstraZeneca COVID-19 vaccine, among people who receive one dose of the vaccine, overall and by age group and time period after 1 dose. The secondary objectives of the study are to: a) assess the vaccine effectiveness in people who have received the two doses; the timing after the 1st and 2nd dose, interval between the two doses and comorbidity status b) replicate the above analyses in people receiving the Pfizer COVID-19 vaccine. **Discussion:** IGARD welcomed the application and noted the importance of the study.

	IGARD noted that this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 25th May, 15th June and 22nd June 2021. IGARD noted that this application had been reviewed at the GPES Data for Pandemic Planning and Research (GDPPR) – Profession Advisory Group (PAG) meeting on the 26th May and the 16th June 2021 (Please see Appendix B). IGARD noted and supported the comments made by PAG. IGARD noted that the application stated that AstraZeneca UK Limited were a joint Data Controller, however, noting supporting document 3.1, the Integrated Research Application System form, gave a sponsor contact located in the United States of America, IGARD queried if the USA entity had any data controllership responsibility, in light of the published guidance regarding sponsors being Data Controllers from the Health Research Authority (HRA). NHS Digital advised IGARD that despite the location of the sponsor contact, the USA entity would have no data controllership responsibilities. IGARD noted the verbal update from NHS Digital, and asked that for future reference, section 1 (Abstract) was updated to note that no US entity was taking on any Data Controller responsibilities. IGARD noted that supporting document 1.1, the revised study protocol, still does not refer to research into the vaccination of under 16's, and that it only established the use of under 16s data for the household transmission research. IGARD suggested that the protocol was revised further, to explicitly cover the use of the data for research into vaccinations carried out to date in under 16s; and that there was a risk that the research into under 16 vaccination was not in line with a protocol with ethical support. NHS Digital advised IGARD that prior to the meeting, they had received a published study specific privacy notice. IGARD noted the verbal update from NHS Digital (noting that they had not seen nor reviewed the revised privacy notice) and their concern that it may contain an inaccurate description of the processing, and suggested that NHS Digital undertake a review, and raise any risks. IGARD noted the information provided in section 5(e) (Is the Purpose of this Application in Any Way Commercial), that outlined the commercial aspects of the application, and asked that for transparency, this was replicated in section 5(a) (Objective for Processing); along with any further transparency as appropriate, regarding the commercial aspects of the application. IGARD noted that section 2(c) (Territory of Use) stated that the territory of use was England and Wales, however, queried the references elsewhere in the application, that Amazon Web Services would store NHS Digital data on **UK** based servers, noting that could include Scotland and Northern Ireland. In addition, IGARD noted that some of NHS Digital's datasets had transparency notices giving geographical restrictions, such as England and Wales, UK or EEA. IGARD asked that the NHS Digital TRE Team check that the territory of use in section 2(c) aligned with the location of the Data Processors, and the geographical restrictions on the datasets; and that this was confirmed in section 1 for future reference. IGARD queried the size of the cohort, for example, would this include every citizen registered with a GP practice in England who had not registered a Type 1 opt-out; and asked that section 5 (Purpose / Methods / Outputs) was updated with further clarity. IGARD queried the reference to the *"RCGP Surveillance Centre"*, and asked this this was removed as it was not relevant to this application. IGARD noted the inclusion of a number of technical terms within section 5(a), such as *"ontological algorithms"*, and asked that these were either removed, or written in a manner suitable for a lay audience.

	IGARD noted the statement in section 5(d) (Benefits), that the vaccine had *"…helped save tens of thousands of lives…"*, and asked that this was amended, to make clear that the vaccine had been proven to be effective in clinical trials, and that this study was now necessary to conclude on a scientific basis how and to what extent the vaccine was effective in real world terms. IGARD suggested that section 5(d) be updated to remove reference to "*it will*…" and instead use a form of words such as "*it is expected…"* or *"it is hoped …".* IGARD queried the special condition in section 6 (Special Conditions), that referred to a data deletion clause, and asked that this was removed, noting this would not technically be possible for the applicant to undertake. IGARD noted that the application requested access to household key, and NHS Digital commented that this was not available in the TRE. IGARD confirmed that they would be open to the addition of this functionality; however, any addition of this, would require approval through the appropriate channels, including, but not limited to, PAG support and a briefing to IGARD, since the creation would require the re-identification of GP data. NHS Digital advised IGARD, that although the application currently stated that the Uncurated Low Latency Hospital Data Set was being requested, NHS Digital were currently unable to flow this data, and that the application would be amended to remove it. IGARD noted the verbal update from NHS Digital, and advised that they would be supportive of the Uncurated Low Latency Hospital Data Set being added as an amendment in the future, without coming back for IGARD approval, and that a clear justification would need to be included in section 5(a), noting this data was unfiltered with no data minimisation. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent; due to the quantum of national data flowing, and with the exception of the inclusion of the Uncurated Low Latency Hospital Data Set. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 1 to note that, notwithstanding published guidance regarding sponsors being Data Controllers, that no US entity has Data Controller responsibilities. 2. To replicate the information in section 5(e) into section 5(a), and provide any further transparency as appropriate, regarding the commercial aspects of the application. 3. In respect of section 5(d): a) To amend section 5(d) to make clear that the vaccine has been proven to be effective in trials, and that this study is now necessary to conclude on a scientific basis how and to what extent it is effective in real world terms. b) To update section 5(d) to use a form of wording such as "*it is expected…"* or *"it is hoped …"*, rather than "*it will…*". 4. The NHS Digital TRE Team to confirm that the territory of use in section 2(c) aligns with the location of the Data Processors, and the geographical restrictions on the datasets; and to confirm in section 1. 5. To update section 1 and section 5a to remove reference to the *"RCGP Surveillance Centre"*, as it is not relevant to this application. 6. To amend section 5(a) throughout to ensure technical terms are either removed or explained in a manner suitable for a lay audience, for example, *"ontological algorithms"*. 7. To amend section 5, to clarify if the size of the cohort is every citizen registered with a GP practice in England who have not registered a Type 1 opt-out.

	8. To remove the special condition in section 6 that refers to the data deletion clause, as this is not technically possible. The following advice was given: 1. IGARD advised that, in line with the ICO guidance, the DPIA must be completed before the applicant commences processing the data. 2. IGARD noted concern that the revised (not seen by IGARD) privacy notice, may contain an inaccurate description of the processing, and suggested that NHS Digital undertake a review, and raise any risks. 3. IGARD noted that the revised protocol still does not refer to research into the vaccination of under 16s (it only establishes the use of under 16s data for the household transmission research). IGARD suggested that the protocol is revised further, to explicitly cover the use of the data for research into vaccinations carried out to date in under 16s. Accordingly, there is a risk that the research into under 16 vaccination is not in line with a protocol with ethical support. 4. Noting that the application requested access to household key, and this was not available in the TRE, IGARD would be open to the addition of this functionality. Any addition, however, would require approval through the appropriate channels, including (but not limited to) PAG support and a briefing to IGARD, since the creation would require the re-identification of GP data. 5. IGARD advised that they would be supportive of the Uncurated Low Latency Hospital Data Set being added as an amendment in the future, without coming back for IGARD approval, and that a clear justification would need to be included in section 5(a), because this data is unfiltered with no data minimisation. 6. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment; due to the quantum of national data flowing, and with the exception of the inclusion of the Uncurated Low Latency Hospital Data Set. 7. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent; due to the quantum of national data flowing, and with the exception of the inclusion of the Uncurated Low Latency Hospital Data Set.
2.3	University College London (UCL): **L**inking **AU**dit and **N**ational datasets in **C**ongenital **HE**art **S**ervices for **Q**uality **I**mprovement(LAUNCHES QI). **C**ongenital **H**eart **A**udit: **M**easuring **P**rogress **I**n **O**utcomes **N**ationally (CHAMPION). (Presenter: Denise Pine) NIC-234297-P4M5G-v1.12 **Application:** This was an amendment application to the existing Data Sharing Agreement (DSA), to 1) add the Congenital Heart Audit: Measuring Progress In Outcomes Nationally (CHAMPION) study as a new purpose for processing; 2) to amend the DSA to reflect that 'Only UCL substantive employees and clinical researchers on an honorary contract with UCL are working with the data. Clinical researchers will not have access to data until the signed contract/addendum letter is in place.'; 3) to provide a full resupply of the data previously provided, which includes pseudonymised Civil Registrations (deaths) data, Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC) and HES Outpatients. UCL are requesting permission to use the LAUNCHES QI data for the purpose of a new project, "CHAMPION"; which aims to indirectly improve services for congenital heart disease (CHD), by developing tools for routinely measuring CHD outcomes that can inform the delivery and commissioning of CHD services.

	LAUNCHES QI is a dataset analysis of five linked audit and national datasets which includes a cohort of patients with congenital heart disease that have been captured by the National Congenital Heart Disease Audit (NCHDA) since 2000, the core dataset defining the study CHD population. The study aims to indirectly improve services for CHD by providing the first description of how CHD patients interact with the NHS acute sector and where variation in outcomes or service use exist. This information is the first crucial step in supporting service improvement by building the evidence base on which aspects of the current service offer the most potential for improvement programmes. The study is relying on s251 of the NHS Act 2006, for the flow of data into NHS Digital. **Discussion:** IGARD confirmed that they were of the view that the relevant s251 support provided the appropriate legal gateway and was broadly compatible with the processing outlined in the application. IGARD noted the divergence between the approximate cohort numbers in the Health Research Authority Confidentiality Advisory Group (HRA CAG) support (122,000) and the current cohort size in the application (144,362), and suggested that the applicant should proactively make HRA CAG aware of the change in the cohort size as part of their annual review. IGARD noted that section 3 (Datasets Held / Requested) stated that s251 was the legal basis for the dissemination of the NHS Digital data. However, noting that this was the legal basis for the data flowing **into** NHS Digital, the data being disseminated out of NHS Digital was pseudonymised and would not require s251 support. IGARD asked that section 3 was updated to remove all references to s251 being the legal basis for the dissemination of the NHS Digital data. IGARD queried the reference in section 3, to *"GDPR does not apply to data solely relating to deceased individuals"*, in respect of the Civil Registration data; noting that the data would also provide information on the entire cohort, including those who were still alive. IGARD asked that section 3 was updated to include a UK GDPR legal basis for those datasets that relate to cohort members still alive. IGARD noted that section 3(c) (Patient Objections) stated that patient objections would be applied, however asked that this was updated with confirmation that NHS Digital would apply National Data Opt-outs (NDO), in line with NHS Digital's NDO policy. IGARD noted that some of the information relating to the benefits in section 5(d) (Benefits) were repetitive, for example *"…approximately 200,000 people currently living with CHD in the UK and services are expensive, high profile…"*; and asked that this section was reviewed, and any duplication of information was removed. IGARD noted that some of the information in section 5(d) was not clear and suggested that it was updated to ensure that it was written in a language suitable for a lay reader, and that consideration was given to the patient audience. In addition, IGARD noted the statement *"…UCL work will enable commissioners to put the outcomes achieved by centres in the context of the outcomes predicted for that centre and the outcomes achieved by other centres, and clinical teams to target service improvements"*; and asked that this was amended, to simplify the language. IGARD suggested that section 5(d) be updated to remove reference to "*it will*…" and instead use a form of words such as "*it is expected…"* or *"it is hoped …".* IGARD noted in section 5(d) (iii) that no yielded benefits had been achieved to date, however asked that this was updated, to provide a clear explanation as to **why** no yielded benefits have

	been achieved to date; and in line with NHS Digital DARS Standard for Expected Measurable Benefits. IGARD suggested that this application may not be suitable for NHS Digital's Precedent route, including the SIRO Precedent; due to the s251 support and multiple datasets requested. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of the legal basis for dissemination: a) To update section 3 to remove all references to s251 being the legal basis for the dissemination of the NHS Digital data. b) To update section 3 to include a UK GDPR legal basis for those datasets that give information about cohort members who are still living. 2. To update section 3(c) with confirmation that NHS Digital will apply NDOs in line with NHS Digital's NDO policy. 3. In respect of section 5(d): a) To update section 5(d) to remove any duplication of information. b) To update section 5(d) to ensure it is written in language suitable for a lay reader and that consideration is given to the patient audience. c) To amend section 5(d) where relevant, to simplify the language. d) To update section 5(d) to use a form of wording such as "*it is expected…"* or *"it is hoped…"*, rather than "*it will…*". e) To update section 5(d) (iii) to provide a clear explanation as to why no yielded benefits have been achieved to date; and in line with NHS Digital DARS Standard for Expected Measurable Benefits. The following advice was given: 1. IGARD suggested that given the divergence between the approximate cohort numbers in the HRA CAG support and the current cohort size in the application that the applicant should proactively make HRA CAG aware of the change in the cohort size as part of their annual review. 2. IGARD suggested that this application may not be suitable for NHS Digital's Precedent route, including the SIRO Precedent; due to the s251 support and multiple datasets requested.
2.4	Suffolk County Council: GDPPR Template for Local Authority (Presenter: Bethan Thomas) NIC-394285-D0L6M-v0.2 **Application:** This was a new application for pseudonymised GPES Data for Pandemic Planning and Research for Commissioning (COVID-19) (GDPPR) data; for the purpose of providing intelligence to support the local response to the COVID-19 emergency. The data will be analysed so that health care provision can be planned to support the needs of the population within the local authority area for COVID-19 purposes. Some of the data uses include: the analysis of missed appointments, patient risk stratification and predictive modelling, the analysis of vaccination data, analysis to support the operational response to COVID-19 as part of the Local Outbreak Control Plan and analysis to understand the long-term direct and indirect impacts of COVID-19 on health and health inequalities. **Discussion:** IGARD noted that this application had been reviewed at the GPES Data for Pandemic Planning and Research (GDPPR) – Profession Advisory Group (PAG) meeting on the 30th June 2021 (Please see Appendix B). NHS Digital verbally advised IGARD that PAG

	were supportive of the application. IGARD noted the comments made by PAG and the verbal update from NHS Digital in respect of the PAG support. IGARD noted and supported the point raised by PAG, that references to *"direct care"* should be removed from the application, noting that GDPPR data had not been designed for this purpose. IGARD noted that section 5(a) (Objective for Processing) had been updated to provide additional information in respect of the request for the GDPPR data, however queried what Suffolk County Council would be doing with the GDPPR data, beyond what the relevant CCG(s) were already doing in their geographical area; or how they were working in collaboration with the relevant CCG(s) to deliver the objectives outlined, because this was not clear. IGARD asked that for transparency, section 5(a) was updated to provide a clear justification for the request for GDPPR data beyond what was being undertaken by relevant CCG(s). IGARD noted the benefits outlined in section 5(d) (Benefits) with regard to the GDPPR data, however asked that further clarity was provided of how the benefits could be realised by Suffolk County Council. IGARD also asked for confirmation, that there was a separate benefit, to what would be delivered, beyond what the relevant CCG(s) were already doing, and already had the data to deliver. In addition, IGARD asked that section 5(c) (Specific Outputs Expected) was updated with clarity, of how the outputs would work with any parallel CCG activity using the GDPPR data, as this was not clear. IGARD queried the output in section 5(c) in relation to *"Patient Stratification in relation to COVID-19"*, and asked that further clarity was provided as to what outputs would be achieved from patient stratification for example any interplay with the CCG(s), since they already had GDPPR data to undertake patient stratification relating to COVID-19. IGARD noted the output in section 5(c) in relation to *"Patients with prescriptions related to COVID-19"*, and noting that there was currently no specific coded category of prescriptions that related to COVID-19; asked that this either removed, or that a further explanation to support this output was provided. IGARD noted the paragraph in section 5(a) *"The health and care system is facing an unprecedented challenge and we want to ensure that health organisations, arm's length bodies and local authorities are able to process and share the data they need to respond to COVID-19 , for example by treating and caring for patients and those at risk, managing the service and identifying patterns and risks."*; and asked that this was either removed, if deemed not necessary; or that the general wording was revised, to reflect that this was in respect of the aims of Suffolk County Council. **Outcome:** recommendation to approve subject to the following condition: 1. To provide a clear justification in section 5(a) of what Suffolk County Council will be doing with the GDPPR data, beyond what the relevant CCG(s) are already doing; or how they are working in collaboration with the relevant CCG(s) to deliver the objectives outlined. The following amendments were requested: 1. In respect of the outputs: a) To update section 5(c) to clarify how the outputs will work with any parallel CCG activity. b) To clarify in section 5(c) what outputs will be achieved from patient stratification.

	c) To remove the reference in section 5(c) *to "Patients with prescriptions related to COVID-19"*; or to provide a further explanation as to what this is, as there is currently no specific coded category of prescriptions that relate to COVID-19. 2. To update the application throughout to remove any reference to the data being used for *"direct care"* (as per the PAG point raised). 3. To clarify in section 5(d) how the benefits can be realised by Suffolk County Council, with the GDPPR data; and that they are a separate benefit to what will be delivered, beyond what the relevant CCG(s) are already doing (and have the data to deliver). 4. To remove the paragraph in section 5(a) that starts "The health and care system is facing an unprecedented challenge…"; or revise the general wording, to reflect that this is in respect of the aims of Suffolk County Council. It was agreed the condition would be approved OOC by the IGARD Chair and one Specialist GP member.
2.5	University of Warwick: R18 - Recovery - RS Trial: (Consented Cohort) (Presenter: Andy Rees) NIC-378066-D9S8P-v0.7 **Application:** This was a new application for identifiable Civil Registrations (deaths) data, Emergency Care Data Set (ECDS), Hospital Episode Statistics Admitted Patient Care (HES APC) and HES Critical Care data. The purpose is for inclusion of the data in the RECOVERY-RS Trial which is an adaptive, pragmatic, randomised controlled, open label, multi centred, effectiveness trial investigating the ventilation strategies in COVID-19, continuous positive airway pressure (CPAP), high flow nasal oxygen (HFNO) and standard care. The objective for processing data from NHS Digital is to collect data on survival, intubation rates, critical care of stay and hospital length of stay, which forms part of the primary and secondary trial outcomes. The trial is funded by the National Institute for Health Research (NIHR). This application relies upon patient consent or consultee advice; where neither is in place for a patient, data will flow under a different agreement (NIC-379982-F8G4M, item 2.6). **Discussion:** IGARD noted that this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 23rd February and 19th May 2021. IGARD confirmed that they were of the view that the **most recent** consent materials were compatible with the processing outlined in the application. IGARD queried how many participants fell under each category, consent, consultee advice, and where The Health Service Control of Patient Information (COPI) Regulations 2002 were being relied upon. NHS Digital verbally advised IGARD that 1,175 participants had provided consent, 90 participants were recruited via consultee advice, and COPI was being relied on for 35 participants and this was covered via NIC-379982-F8G4M. IGARD noted and thanked NHS Digital for the verbal update in respect of the cohort numbers, and asked that section 5(a) (Objective for Processing) was updated with a summary of the cohort numbers and brief explanation provided in-meeting. IGARD noted and commended the applicant for obtaining consent/consultee advice for the large number of participants, as outlined verbally by NHS Digital. IGARD noted the references in section 5(b) (Processing Activities) to consultees providing *"consent"*, and asked that this was amended to accurately state that consultees give *"advice"*, since they do not give consent. IGARD queried why National Data Opt-outs (NDO) would not be upheld for those individuals where consultee advice was being relied upon*;* and asked that written confirmation was

	provided from NHS Digital, that **not** upholding the National Data Opt-out was in accordance with NHS Digital's NDO policy. In addition, IGARD suggested that NHS Digital may wish to seek advice from the Caldicott Guardian on this issue. IGARD queried supporting document 3.0, the data flow diagram, which showed recipients of the pseudonymised data who were not listed in the application. IGARD asked that for transparency, section 5 (Purpose / Methods / Outputs) was reviewed and updated, to ensure that **all** of the recipients of the pseudonymised data were referenced, and in alignment with the diagram provided, and if the diagram was incorrect to update it accordingly. IGARD also asked that confirmation was provided by the applicant, that none of the recipients of the pseudonymised data, as outlined on the data flow diagram, were considered joint Data Controller(s) / Data Processor(s); and if any of the recipients of the pseudonymised data were considered joint Data Controller(s) / Data Processor(s), IGARD asked that the application was updated accordingly. IGARD queried if the sharing of the pseudonymised data, with the recipients outlined on the data flow diagram, was in accordance with the consent obtained from the participants; and asked that further clarity was provided in section 5 for transparency. IGARD noted the statement in section 5(a) that *"No NHS Digital data is transferred to the funder"*, however advised that this did not align with the information provided in the data flow diagram. NHS Digital advised that the data flow diagram was incorrect, and that the application was correct, that no NHS Digital data would be transferred to the funder. IGARD noted the verbal update from NHS Digital, and asked that the data flow diagram was reviewed and updated where necessary, to ensure it accurately reflected the factual scenario and was in line with the application. IGARD queried the statement in section 1 (Abstract) and section 5(a) "…. **QUB are not responsible for dictating the processing activity of the data disseminated by NHS Digital*…" (*Queens University Belfast), and asked that the reference to "*dictating"* was removed, and this was aligned with the wording within the UK General Data Protection Regulations (UK GDPR), for example, no control over the purpose or means of processing the data. IGARD noted the reference in section 5(b) to *"…PGP Encryption…",* and suggested it was simplified to simply say data would be encrypted. IGARD queried the statement in section 5(b) that the data would be *"downloaded to portable laptops"*, and asked that further information was provided on this statement within the application or amended as appropriate. In addition, confirmation should be provided in section 5 that this was in accordance with NHS Digital's temporary remote access policy / guidance. IGARD noted the statement in section 5(d) (Benefits) that *"The most significant results will be communicated to the public…"*, and asked that this was amended to state that **all** results will be communicated to the public, irrespective of significance. IGARD noted the benefits outlined in section 5(d), however asked further clarity was provided, that the benefits were to reduce morbidity and mortality, and may reduce hospital stays; and to clearly outline the consequential benefit(s) that would flow from this. **Outcome:** recommendation to approve subject to the following condition: 1. To provide written confirmation that **not** upholding the National Data Opt-out for those cohort members present in the cohort via consultee advice, but who had previously registered a National Data Opt-out, is in accordance with NHS Digital's National Data Opt-out policy. The following amendments were requested:

	1. To update section 5(a) with a summary of the cohort numbers, as per the verbal update from NHS Digital. 2. In respect of the pseudonymised data: a) To review and update section 5, to ensure this section clearly notes **all** of the recipients of the pseudonymised data, and in alignment with the data flow diagram provided. b) The applicant to confirm that none of the recipients of the pseudonymised data are considered joint Data Controller(s) / Data Processor(s). c) If any of the recipients of the pseudonymised data are considered joint Data Controller(s) / Data Processor(s), to update the application accordingly. d) To update section 5 to clarify that the sharing of the pseudonymised data is in accordance with the consent obtained from the participants. 3. To review and update the data flow diagram to ensure this accurately reflects the factual scenario and is in line with the application. 4. To update section 1 and section 5(a) to remove reference to QUB *"dictating"* and to align the wording with the UK GDPR (no control over the purpose or means of processing the data). 5. To amend section 5(b) to be clear that the consultee(s) gives advice and does **not** provide consent. 6. To amend the reference *"…PGP Encryption…"* in section 5(b) to more clearly reflect that the data will be encrypted. 7. To provide further information on the statement in section 5(b) that the data will be "downloaded to portable laptops", and to confirm that that this is in accordance with NHS Digital's temporary remote access policy / guidance. 8. To amend the statement in section 5(c) *"The most significant results will be communicated to the public…"*, to state that **all** results will be communicated to the public. 9. To clarify in section 5(d) that the benefits are to reduce morbidity and mortality, and may reduce hospital stays and clearly outline the consequential benefit(s) that would flow from this. The following advice was given: 1. IGARD suggested that NHS Digital may wish to seek advice from the Caldicott Guardian, that **not** upholding the National Data Opt-out for those cohort members present in the cohort via consultee advice, but who had previously registered a National Data Opt-out, is in accordance with NHS Digital's National Data Opt-out policy. It was agreed the condition would be approved out of committee (OOC) by the IGARD Chair.
2.6	<u>University of Warwick: R18 - Recovery - RS Trial: (COPI/ S251 Cohort) (Presenter: Andy Rees) NIC-379982-F8G4M-v0.6</u> **Application:** This was a new application for identifiable Civil Registrations (deaths) data, Emergency Care Data Set (ECDS), Hospital Episode Statistics Admitted Patient Care (HES APC) and HES Critical Care data. The purpose is for inclusion of the data in the RECOVERY-RS Trial which is an adaptive, pragmatic, randomised controlled, open label, multi centred, effectiveness trial investigating the ventilation strategies in COVID-19, continuous positive airway pressure (CPAP), high flow nasal oxygen (HFNO) and standard care. The objective for processing data from NHS Digital is to collect data on survival, intubation rates, critical care of stay and hospital length of stay,

	which forms part of the primary and secondary trial outcomes. The trial is funded by the National Institute for Health Research (NIHR). The study cohort, consists of patients who have either consented to share their information, or have positive consultee advice (please refer to NIC-378066-D9S8P – item 2.5); and the remaining cohort which will flow via The Health Service Control of Patient Information (COPI) Regulations 2002 / s251 of the NHS Act 2006, for the flow of data from NHS Digital. **Discussion:** IGARD noted that this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 23rd February and 19th May 2021. 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 asked that, for transparency, section 5(a) was updated, to clarify that the data flowing for the 35 patients referred to in section 3(b), would be combined with the data in NIC-378066-D9S8P. IGARD queried information provided within supporting document 3.0, the data flow diagram, which showed some recipients of the pseudonymised data who were not listed in the application. IGARD asked that for transparency, section 5 (Purpose / Methods / Outputs) was reviewed and updated, to ensure that **all** of the recipients of the pseudonymised data were referenced, and in alignment with the diagram provided, and if the diagram was incorrect to update it accordingly. IGARD also asked that confirmation was provided by the applicant, that none of the recipients of the pseudonymised data, as outlined on the data flow diagram, were considered joint Data Controller(s) / Data Processor(s); and if any of the recipients of the pseudonymised data were considered joint Data Controller(s) / Data Processor(s), IGARD asked that the application was updated accordingly. IGARD queried if the sharing of the pseudonymised data, with the recipients outlined on the data flow diagram, was in accordance with the consent obtained from the participants; and asked that further clarity was provided in section 5 for transparency. IGARD noted the statement in section 5(a) that *"No NHS Digital data is transferred to the funder"*, however advised that this did not align with the information provided in the data flow diagram. NHS Digital advised that the data flow diagram was incorrect, and that the application was correct, that no NHS Digital data would be transferred to the funder. IGARD noted the verbal update from NHS Digital, and asked that the data flow diagram was reviewed and updated where necessary, to ensure it accurately reflected the factual scenario and was in line with the application. IGARD queried the statement in section 1 (Abstract) and section 5(a) "…. ***QUB are not responsible for dictating the processing activity of the data disseminated by NHS Digital**…" (*Queens University Belfast), and asked that the reference to "*dictating"* was removed, and this was aligned with the wording with the UK General Data Protection Regulations (UK GDPR), for example, no control over the purpose or means of processing the data. IGARD noted the reference in section 5(b) to *"…PGP Encryption…",* and suggested it was simplified to simply say data would be encrypted. IGARD queried the statement in section 5(b) that the data would be *"downloaded to portable laptops"*, and asked that further information was provided on this statement within the application or amended as appropriate. In addition, confirmation should be provided in section 5 that this was in accordance with NHS Digital's temporary remote access policy / guidance.

	IGARD noted the statement in section 5(d) (Benefits) that *"The most significant results will be communicated to the public…"*, and asked that this was amended to state that **all** results will be communicated to the public, irrespective of significance. IGARD noted the benefits outlined in section 5(d), however asked further clarity was provided, that the benefits were to reduce morbidity and mortality, and may reduce hospital stays; and to clearly outline the consequential benefit(s) that would flow from this. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent; upon expiry of the COPI notice and at the point of transition to HRA CAG s251 support being the legal basis for the flow of NHS Digital data. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 5(a) with a summary of the cohort numbers, as per the verbal update from NHS Digital. 2. In respect of the pseudonymised data: a) To review and update section 5, to ensure this section clearly notes **all** of the recipients of the pseudonymised data, and in alignment with the data flow diagram provided. b) The applicant to confirm that none of the recipients of the pseudonymised data are considered joint Data Controller / Data Processor. c) If any of the recipients of the pseudonymised data are considered joint Data Controller / Data Processor, to update the application accordingly. 3. To review and update the data flow diagram to ensure this accurately reflects the factual scenario and is in line with the application. 4. To update section 1 and section 5(a) to remove reference to QUB *"dictating"* and to align the wording with the UK GDPR (no control over the purpose or means of processing the data). 5. To amend the reference *"…PGP Encryption…"* in section 5(b) to more clearly reflect that the data will be encrypted. 6. To provide further information on the statement in section 5(b) that the data will be "downloaded to portable laptops", and to confirm that that this is in accordance with NHS Digital's temporary remote access policy. 7. To amend the statement in section 5(c) *"The most significant results will be communicated to the public…"*, to state that **all** results will be communicated. 8. To clarify in section 5(d) that the benefits are to reduce morbidity and mortality, and may reduce hospital stays and clearly outline the consequential benefit(s) that would flow from this. 9. To update section 5(a) to clarify that the data flowing for the 35 patients referred to in section 3(b), will be combined with the data in NIC-378066-D9S8P. The following advice was given: 1. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment; upon expiry of the COPI notice and at the point of transition to HRA CAG s251 support being the legal basis for the flow of NHS Digital data. 2. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent; upon expiry of the COPI notice and at

	the point of transition to HRA CAG s251 support being the legal basis for the flow of NHS Digital data.
3	Returning Applications IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. • NIC-15226-X7Z9R University College London • NIC-113025-X7Z3L Clinical Practice Research Datalink (CPRD) • NIC-174740-C0H0L King's College London • NIC-193518-T5K7C Children's Commissioner IGARD welcomed the four applications as part of their oversight and assurance role and noted a number of comments to NHS Digital and suggested that further information and comments be provided in an IGARD Oversight and Assurance Report. Moving forward, IGARD agreed that COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 applications may also be included as part of the oversight and assurance review, not just those that were approved via NHS Digital's precedent route.
4	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 29th June 2021** can be found attached to these minutes as Appendix C.
5 **5.1**	AOB: NIC-370843-R6V8T Imperial College London At the IGARD - NHS Digital COVID-19 Response meetings on the 15th June 2021, NIC-370843-R6V8T Imperial College London, was discussed by the three IGARD members present, and observations were discussed with NHS Digital as per process. On the 24th June 2021, NHS Digital queried (via the IGARD Secretariat), if IGARD would be content for NHS Digital to renew and extend the Data Sharing Agreement (DSA), for the UK arm of the study **only** via the SIRO route. NHS Digital advised that in line with the observations made on the 15th June, the application would be brought back for a review at an IGARD Business as Usual meeting in the future, and with the relevant updates addressed on all other aspects of the application, which include (but are not limited to) an updated study protocol, advice / approval from the Research Ethics Committee and a new sublicense agreement. Noting the that the DSA expired on the 31st December 2020, IGARD discussed the proposal from NHS Digital, and thanked NHS Digital for their written update and confirmed that they

	were content with the approach outlined that only the UK arm of the study would be renewed and extended via the SIRO precedent.
5.2	NIC-388794-Z9P3J – Office for National Statistics (ONS) At the IGARD Business as usual meeting on the 17th December 2020, IGARD reviewed and recommended for approval, the above application (subject to amendments), noting that this had an end date of the 31st March 2021. On the 22nd June 2021, NHS Digital advised IGARD (via the IGARD Secretariat), that this application had been extended for a further 3-months in March 2021, subject to a number of actions within that period, that would support a further review at the end of June 2021, as per process. NHS Digital confirmed that although the application has now been submitted, there was not sufficient time to process this via the necessary review stages prior to the DSA expiring on the 30th June 2021. Noting the importance of the work, the impact of any disruption, and in light of the research directly feeding into the Scientific Advisory Group for Emergencies (SAGE) (via the National Statistician); NHS Digital confirmed that a further 6-week extension / renewal had been approved by NHS Digital. The extension / renewal, was subject to the same terms as the current DSA, and on the strict condition that this was immediately followed by an application for a longer renewal which will be reviewed by both IGARD and the GPES Data for Pandemic Planning and Research – Profession Advisory Group. IGARD noted and thanked NHS Digital for the written update, and confirmed that this application would be reviewed as part of the returning applications section of the meeting, on Thursday 8th July.
5.3	NIC-362239-F6V0N-v2 - NHS South West London CCG This was an amendment application, to 1) add Medicines Dispensed in Primary Care (NHSBSA Data), 2) to add Optum Health Solutions UK limited, and 3) to add linkage to GP data. The purpose of the application is for: Risk Stratification, which is a tool for identifying and predicting which patients are at high risk or likely to be at high risk and prioritising the management of their care; and to provide intelligence to support the commissioning of health services. IGARD noted that on the 28th June 2021, NHS Digital had advised in writing (via the IGARD Secretariat) that the above Data Sharing Agreement, had been progressed via the SIRO Precedent, due to the urgency of the date requested, and the assessment made by NHS Digital that the DSA was considered “low risk”. IGARD noted and thanked NHS Digital for the written update.
5.4	IGARD Webpage Refresh The IGARD Secretariat confirmed to members that the refreshed IGARD webpage had been signed off by the Caldicott Guardian, and was published on Wednesday 30th June. The Secretariat thanked members for their support in provided feedback and reviewing iterations of the draft webpage, prior to publishing; and NHS Digital’s Web Team for their support and guidance.

	IGARD members noted the update and thanked the IGARD Secretariat for their work in undertaking this important refresh of the webpages. There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 25/06/21

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-422044-Z5K5Q	Health IQ Limited	20/05/2021	1. In respect of the benefits and in line with NHS Digital's Expected Measurable Benefits Standard: a) To provide written confirmation in section 5(d) of how the benefits will be achieved, for example, further specific details about which channels of communication will be utilised and how. b) To clarify in section 5(d) how the research will benefit health and social care in England and Wales (as per NHS Digital's requirements). c) To clarify in section 5(d) if the research will benefit the NHS (as per the DHSC guidance). d) To update section 5(d) to confirm if only Bristol-Myers Squibb will be receiving the outputs of the research, or if Health IQ Ltd will also generate other outputs and benefits from the research. e) To update section 5(c) and section 5(d) to reflect the latest dates for the projected outputs and benefits.	IGARD members	Quorum of IGARD members	IGARD requested that: 1. The response to condition 1c was updated to state *"This is hoped to be of significant benefit to newly diagnosed and existing NHS patients with beta-thalassaemia and myelodysplasia syndrome".* *2.* Noting that section 5 forms part of NHS Digital's public facing release register, please could you update amendment point 2 to ensure the meaning is clear, for example: *"Bristol-Myers Squibb is the manufacturer of Reblozyl and as such would stand to gain by*

						way of commercial profit if the drug is adopted for use in the UK and in other healthcare systems around the world."

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

In addition, a number of applications were approved under class action addition of:

Liaison Financial Service and Cloud storage:

- None

Optum Health Solutions UK Limited Class Actions:

- NIC-362255-K5D1H-v1.4 - DSfC - NHS Kent and Medway CCG - IV, RS & Comm
- NIC-362252-M1X0V-v2.2 - DSfC - NHS Northamptonshire CCG - RS, COMM & IV
- NIC-362237-Y5K7L-v2.2 - DSfC - NHS Bath and North East Somerset, Swindon and Wiltshire CCG - Comm/RS/IV

Graphnet Class Actions:

- None

Appendix B

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 26th May 2021

Application & application version number: **DARS-NIC-445543-W0D4N-v0.3 Astra Zeneca** **Organisation name: Astra Zeneca** **Profession Advisory Group Agenda item: 3**
PAG are strongly supportive of the purpose of the research and particularly that it is occurring within NHS Digitals TRE. We recognise that the application when reviewed was not in its finished state due to the urgency and priority of the work. Of note PAG would like to emphasise that all outputs from this research are published (not just positive outcomes for any particular vaccine). We note that Astra Zeneca is a joint controller with Oxford University. PAG support this application as long as it completes the full complete DARS IGARD Process.

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

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 16th June 2021

Application & application version number: DARS-NIC-445543-W0D4N-v0.6 **Organisation name: University of Oxford and Astra Zeneca** **Profession Advisory Group Agenda item: 4**
PAG are supportive of this application noting that the application will be progress through the full DARS assurance process. PAG note the broadening of inclusion of all ages is important. PAG support IGARD's view that the data processing agreement between the data controllers and their processors is scrutinised and assurance by NHS Digital is complete.

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
Louise Dunn	Data Approvals Officer	NHS Digital
Pam Soorma	Secretariat	NHS Digital
Garry Coleman	Associate Director	NHS Digital

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 30th June 2021

Application & application version number: DARS-NIC-394285-D0L6M-v0.2

Organisation name: Suffolk County Council

Profession Advisory Group Agenda item: 2

PAG welcome the application and note that the reference to direct care should be removed. The applicant should be advised that GP data for pandemic planning and research has not been designed for this purpose.

PAG require the following points within the BMA/RCGP standard to be addressed within the application:

4. For all commissioner/ICS/Local authority led applications, the applicant **MUST** provide evidence that the relevant clinical director or clinical lead for the commissioner/ICS endorses the application, that the GP practices and relevant LMCs have been informed of (and have voiced no concerns with) the application, and provide copies of the patient / transparency communications relating to the application.
5. Pertaining to the creation, publication or circulation of results:
   a) All efforts **MUST** be made to ensure **no** individual (including a health care professional) can be identified (i.e. any published/shared results are statistically non-disclosive).
   b) All efforts **MUST** be made to ensure **no** GP practice or Primary Care Network (PCN) can be identified, unless there is written evidence that their CCG or LMC have obtained such permission from practices; or similar agreement from the BMA/RCGP.
   c) Results **MUST NOT** be used for performance management of GP practices or PCNs, unless it has been **explicitly agreed, and in writing,** through normal negotiating routes with the BMA.

PAG would like to review this application again.

Attendees	Role	Organisation
Arjun Dhillon	Chair, Caldicott Guardian	NHS Digital
Jonathan Osborn	Deputy Chair, Caldicott Guardian	NHS Digital
Peter Short	Clinical Lead	NHS Digital
Amir Mehrkar	GP, Clinical Researcher	RCGP
Mark Coley	Deputy IT Policy Lead	BMA
Louise Dunn	Data Approvals Officer	NHS Digital
Garry Coleman	Associate Director	NHS Digital
Duncan Easton	Data Approvals Officer	NHS Digital
Pam Soorma	Secretariat	NHS Digital

Appendix C

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

held via videoconference, Tuesday, 29th June 2021

In attendance (IGARD Members):	Prof Nicola Fear (IGARD Specialist Academic Member)
	Kirsty Irvine (IGARD Chair / Lay Representative)
	Dr. Imran Khan (IGARD Specialist GP Member)
In attendance (NHS Digital):	Cath Day (DARS)
	Louise Dunn (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 will be received out of committee and then published alongside the minutes of the next Thursday BAU meeting as an appendix. **Declaration of interests:** Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising the Scientific Advisory Group for Emergencies (SAGE) on COVID-19
2.1	NIC-381078-Y9C5K-v4.4 Health Data Research UK (HDRUK) **Background:** This was a verbal update to amend the application for the inclusion of King's College London as a joint Data Controller. In addition, a document had been provided as to how the applicant was addressing the condition and amendments from the 25th February 2021 meeting, noting that due to the urgency of the application, the application had progressed under the SIRO precedent, rather than being returned out of committee for the IGARD Chair to approve the condition, as per due process. The application has been previously presented to the COVID-19 response meetings on 19th January 2021, 24th November, 23rd June, 16th June, 9th June, 2nd June and 26th May 2020. The application has been previously presented to the IGARD business as usual (BAU) meetings on the 25th February 2021, 3rd December, 15th October, 23rd July and 25th June 2020. The following observations were made on the basis of the verbal update from NHS Digital and a copy of the data sharing agreement (DSA) v4.4 and '*CVD TRE* outstanding LM 20210609*' documents provided as background documents.

	*Cardiovascular Disease Trusted Research Environment (CVD TRE) **IGARD Observations:** IGARD members noted that due to the nature of the meeting, that should a full review of the application and documentation be required, the full suite of documentation should be presented to a IGARD business as usual (BAU) meeting for a recommendation. IGARD members noted that a number of project leads, for example the University of Edinburgh, were described as carrying out activities in the TRE but had not been listed as a joint Data Controller on the privacy noticed on the HDRUK website. IGARD members suggested that if the projects had commenced, that the privacy notice should be updated as per due process and these parties added to the DSA as data controllers, or if the projects were yet to commence to include a small narrative note. IGARD members commended the applicant on the revisions made to their privacy notice and website and thanked HDRUK for the work they had undertaken over the last year. IGARD noted the references within the application to *"Kings College London"*, and asked that they were updated to correctly reference *"**King's** College London"*. NHS Digital verbally updated IGARD members on the outstanding points from when last presented to IGARD on the 25th February including, but not limited to: • Data Controllership agreement which was still in draft. IGARD members noted that the full agreement need not be provided to IGARD or published, however the "essence" of the agreement should be included for transparency to data subjects on the applicant's website, including the role of each Data Controller and how they relate, as per UK GDPR requirements. • IGARD Members suggested that any reference to post-COVID work to improve the TRE for system wide change should be removed from the DSA, since the applicant was relying on the Health Service (Control of Patient Information) Regulations 2002 (COPI) which was for a pandemic response not for developing a new system. Useful learning using the TRE should be fed back to NHS Digital as a matter of course. • IGARD members suggested that a brief paragraph be included in section 5 that notes that all possible ways of data minimisation had been considered and undertaken where possible and that the applicant had met their legal obligations under UK General Data Protection Regulation (UK GDPR). • Noting that one dataset requested was for data years from 1989 IGARD suggested that a use case was prepared that justified the date range of that data (not necessarily to be published but as evidence if the breadth of data was ever challenged). • Noting the oversight committee should be publishing full or redacted minutes on the applicant's website, IGARD members suggested that NHS Digital may wish to have sight of a spreadsheet from the applicant that detailed each project, when it was approved etc. • NHS Digital noted that the benefits provided by the applicant were outputs, and IGARD members were in agreement with that analysis. IGARD members welcomed the verbal update and noted that due to the urgency of the application that it would be progressed under NHS Digital's SIRO Precedent and were supportive of this approach.

	IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the high profile and novel use of data, with the exception of amendments where the parties listed in the DSA and having involvement in the projects were being added formally to the DSA as joint Data Controllers (and assuming NHS Digital had undertaken due process in vetting those Controllers). IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent with the exception of amendments where the parties listed in the DSA and having involvement in the projects were being added formally to the DSA as joint Data Controllers and assuming NHS Digital had undertaken due process.
3	<u>AOB</u> There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.