Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 24 June 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Prof. Nicola Fear	Specialist Academic Member
Kirsty Irvine (Chair)	IGARD Chair / Lay Representative
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Catherine Day	Data Access Request Service (DARS)
Louise Dunn	Data Access Request Service (DARS)
Chris Dyson	Privacy, Transparency and Ethics (PTE) (Observer: items 2.1 – 2.4)
Duncan Easton	Data Access Request Service (DARS) (Item 6.1)
Dan Goodwin	Data Access Request Service (DARS)
James Gray	Data Access Request Service (DARS)
Frances Hancox	Data Access Request Service (DARS)
Karen Myers	IGARD Secretariat
Sam Olusoji	Data Access Request Service (DARS)
Jonathan Osborn	Deputy Caldicott Guardian (Observer: items 2.1 – 2.4)
Andy Rees	Data Access Request Service (DARS)
Charlotte Skinner	Data Access Request Service (DARS)
Kimberley Watson	Data Access Request Service (DARS)

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 to King's College London [NIC-456778-J0G3H], but noted no connection with the application. It was agreed this did not preclude Nicola from taking part in the discussions about this application. It was agreed this did not represent a substantive conflict of interest. Nicola Fear noted a personal link to staff at the University College London [NIC-408892-F1R1Y]. It was agreed this did not preclude Nicola from taking part in the discussion about this application, however agreed that she would not participate in making a recommendation about the application. **Review of previous minutes and actions:** The minutes of the 17th 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	NHS England (Quarry House): NHS England - Infections & Antimicrobial Resistance (AMR) Trusted Research Environment (Presenter: Kimberley Watson) NIC-448252-L2R6Q-v1.2 **Application:** This was an amendment application for NHS England for access to the Trusted Research Environment (TRE) for the project - Infections & Antimicrobial Resistance (AMR) and to include General Practice Extraction Service (GPES) Data for Pandemic Planning and Research (COVID-19) (GDPPR) and Electronic Prescribing and Medicines Administration (EPMA) data in Secondary Care for COVID-19 data. The World Health Organization (WHO) has declared that Antimicrobial Resistance (AMR) is one of the top 10 global public health threats facing humanity; as a result, in January 2019 the UK Government published a 5 Year UK AMR National Action Plan (NAP) alongside a UK AMR 20 Year Vision Paper. The amendment is to enable the AMR programme to understand the impact that the COVID-19 pandemic has had on the utilisation of antimicrobial agents and associated resistance changes versus patterns pre-pandemic, taking into account the indications that there have been significant changes in primary prescribing patterns, in order to inform the key actions to ensure effective antimicrobial stewardship and appropriateness of clinical prescribing going forward as the country starts to come out of the pandemic. NHS Digital advised IGARD, that following the review of the application at the GPES Data for Pandemic Planning and Research (GDPPR) – Profession Advisory Group (PAG), on the 23rd June 2021 (Please see Appendix B); the application would be updated to add the three points raised by PAG as special conditions.

	Discussion: IGARD noted the request to amend the application to include the EPMA data, and confirmed that they were content with this amendment, and that there was a clear justification for this additional data within the application. IGARD noted that this application had been reviewed at the PAG meeting on the 21st April 2021, (notes from that meeting had been attached to the IGARD minutes from the 22nd April 2021); and the 23rd June 2021. IGARD noted and supported the comments made by PAG on the 23rd July 2021 (Please see Appendix B); and supported the amendment outlined verbally by NHS Digital, to include the additional three points raised by PAG, as special conditions in section 6 (Special Conditions). IGARD queried how the applicant was planning to use the GDPPR data for the purpose of COVID-19, noting that the application referred to *"research"*, and that the use of GDPPR data was not permitted for general research; and also in light of the fact that the application stated the purpose was *"service evaluation"*. IGARD also queried what the GDPPR data was offering, beyond, for example, what the Medicines Dispensed in Primary Care – NHS Business Services Authority (NHS BSA) Data was providing. IGARD asked that an appropriately detailed justification was provided in section 5 (Purpose / Methods / Outputs) for the use of the GDPPR data requested, that aligned with both the service evaluation scope of the application and the narrowly permitted use of the GDPPR data collection. IGARD noted that GDPPR data had been requested for individuals under the age of 18 years, and queried what the reason for this was, noting that this age group had not been as affected by the COVID-19 pandemic as those aged over 18 years. IGARD asked that in line with NHS Digital DARS Standard for Data Minimisation, the GDPPR data was filtered out for those under the age of 18 years; or that a justification was provided in section 5, as to why **all** children and young people's GDPPR data was required, in order to achieve the COVID-19 outputs. IGARD queried the paragraph in section 5(a) (Objective for Processing) *"…there is an emerging threat of pan-antibiotic resistance…"*, and asked that this was reviewed and amended as appropriate, to avoid any misinterpretation. IGARD noted the reference in section 5(b) (Processing Activities) to *"human healthcare ambitions"*, and noting that section 5 formed NHS Digital's public data release register, asked that either a relevant weblink was added to the reference, or that this was amended to include a brief lay summary. IGARD noted that the processing of the requested data, would be within NHS Digital's Trusted Research Environment (TRE), however queried why this could not be processed in NHS England's COVID-19 datastore. IGARD asked that confirmation was provided in section 5, that the applicant could not carry out this work in the NHS England COVID-19 datastore, and that the NHS Digital TRE was the most appropriate place for the processing. 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 data requested, the use of the COVID-19 specialist datasets and to review the yielded benefits. **Outcome:** recommendation to approve subject to the following condition: 1. To provide an appropriately detailed justification in section 5 for the use of the GDPPR data requested that aligns with both the service evaluation scope of the application and the narrowly permitted use of the GDPPR data collection. The following amendments were requested:

	1. To provide confirmation in section 5 that the applicant cannot carry out this work in the NHS England COVID-19 datastore, and that the NHS Digital TRE is the most appropriate place for the processing. 2. In respect of data minimisation and in line with NHS Digital DARS Standard for Data Minimisation: a) To filter out the GDPPR data for those aged under 18; or, b) To provide a justification why **all** children and young people's GDPPR data is required, in order to achieve the COVID-19 outputs. 3. To review the paragraph in section 5(a) *"…there is an emerging threat of pan-antibiotic resistance…"*, and amend as appropriate. 4. To review the reference in section 5(b) to *"human healthcare ambitions"* and either add a relevant weblink, or amend to add a brief lay summary. 5. To update section 6 to insert the relevant special conditions, in line with the PAG feedback. The following advice was given: 1. IGARD advised that when this application comes up for renewal, they would expect the yielded benefits to be clearly outlined, and to reflect the work that has been undertaken, and the benefits accrued since the application was last seen. 2. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the quantum of data requested, the use of the COVID-19 specialist datasets and to review the yielded benefits. 3. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the quantum of data requested, the use of the COVID-19 specialist datasets and to review the yielded benefits. It was agreed the condition would be approved out of committee (OOC) by IGARD members
2.2	GRAIL Bio UK Ltd: GRAIL-009: A randomized, comparator-controlled trial to assess the clinical utility of a multi-cancer early detection (MCED) test for population screening in the United Kingdom (UK) when added to standard of care (Presenter: James Gray / Andy Rees / Sam Olusoji) NIC-456778-J0G3H-v0.2 **Application:** This was a new application for identifiable Demographics data, for the purpose of a clinical trial called 'NHS-Galleri'; specifically supporting the recruitment of a cohort for this trial by contacting individuals who meet the required eligibility criteria. A new Multi-Cancer Early Detection (MCED) test (Galleri) has been developed, that can detect many types of cancer from a single blood sample. The trial aims to determine, whether it is better at discovering cancer early, compared to other tests that the NHS currently uses; and to demonstrate the clinical utility of the MCED blood test for individuals in a general screening population in a real-world NHS setting. The trial will be conducted throughout England, and patients will be recruited from eight Cancer Alliances, with the aim is to recruit around 140,000 patients, with approximately 70,000 per arm. The study is relying on s251 of the NHS Act 2006, for the flow of data from NHS Digital. NHS Digital advised IGARD, that when the application was submitted to IGARD for review, the Health Research Authority Confidentiality Advisory Group (HRA CAG) letter of support was still outstanding, and that this had been received and shared with members prior to the meeting.

	Discussion: IGARD welcomed the application and noted the importance and potentially ground-breaking purpose of the study. IGARD noted and commended NHS Digital on quality of the information provided in section 1 (Abstract), which provides historical and additional background information which supported the review of the application by Members. IGARD noted the verbal update from NHS Digital, in respect of the late submission of the HRA CAG letter of approval to members, and thanked them for sharing this with members once it had been received. 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 that in the various Health Research Authority Confidentiality Advisory Group (HRA CAG) and the Research Ethics Committee letters, provided as supporting documents, referred to the University of Leeds and University College London (UCL); however, advised that neither of these organisations were referred to within the application. IGARD asked that a satisfactory explanation was provided of the involvement of the University of Leeds and UCL, and why they were not noted as Data Controllers or Data Processors. IGARD noted that section 1(b) (Data Controller(s)) did not reflect that GRAIL Bio UK Ltd was a commercial organisation, and that they were a *"joint"* Data Controller, and asked that this was updated accordingly to reflect this information. 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). In addition, further transparency should be provided in section 5 (Purpose / Methods / Outputs), as appropriate, in terms of King's College London's (KCL) commercial arrangement with GRAIL Bio UK Ltd. IGARD queried the UK General Data Protection Regulation (UK GDPR) Article 6 and 9 legal basis for KCL, which was *"public task"*; and asked if legitimate interest would be a more suitable legal basis, noting the commercial aspect of the study and asked that confirmation was provided, as to whether KCL should note legitimate interest, rather than public task, as their legal basis. If, however, legitimate interest was more appropriate, to ensure reference to the specific Legitimate Interests Assessment (LIA) was referenced at the beginning of section 5(a), as per usual process. IGARD also suggested that Grail Bio UK Ltd's LIA should be finalised, and the wording in section 5(a) and section 5(d) (Benefits) was updated to reflect the legitimate interests described, and in accordance with the relevant NHS Digital Standards. IGARD suggested that given the scope of processing of identifiable data, the Data Controllers may wish to carry out a Data Protection Impact Assessment (DPIA), on the Information Commissioner's Office (ICO) template available via the ICO website. IGARD queried the territory of use, noting that GRAIL Bio UK Ltd has a parent company based in the United States of America, and asked that section 6 (Special Conditions) was updated, to state that the territory of use was England and Wales. In addition, IGARD asked that section 5 was updated, to make clear that while NHS Digital's data may not go outside the permitted territory of use, other non-NHS Digital data may be sent to the USA. IGARD noted that NHS DigiTrials had discussed the issue of explaining the National Data Opt-outs (NDO) with HRA CAG. IGARD applauded the reference to the s251 support within the letter to prospective participants, however, advised that best practice would be to explain the operation of the NDO in the mailout letter for transparency. In addition, IGARD noted the

	suggestion that a trial-specific opt out could be applied, however advised, that this would **not** be a satisfactory substitute for explaining the availability of the NDO to participants. IGARD suggested that the lack of transparency in respect of the NDO in the invitation letter could undermine public trust and confidence in NHS Digital, and that further advice / guidance may wish to be sought from NHSX, who are sponsor and holder of the NDO policy, and the Office of the National Data Guardian. IGARD thought it was useful to have 4-week lead up promotion period and suggested that during this time citizens could learn about exercising the NDO, and also how they could still join the trial, such as signing up directly, even if they had already exercised their NDO. IGARD noted the references throughout the application to *"demonstrate",* for example when describing the purpose of the study; and asked the application was updated, to amend this reference to *"determine whether there is"*, to allay concerns regarding pre-determination of research outputs. IGARD noted the references within the application to *"Kings College London"*, and asked that they were updated to correctly reference *"**King's** College London"*. **Outcome:** recommendation to approve subject to the following condition: 1. To provide a satisfactory explanation of the involvement of the University of Leeds and UCL and why they are not noted as Data Controllers or Data Processors. The following amendments were requested: 1. To update section 1(b) to reflect that GRAIL Bio UK Ltd is a commercial organisation and a joint Data Controller. 2. In respect of KCL's legal basis for processing: a) To confirm if KCL should note legitimate interest (rather than public task) as their legal basis, noting the commercial aspect of this study. b) If legitimate interest is appropriate, to ensure reference to the specific Legitimate Interests Assessment is referenced at the beginning of section 5(a). 3. To replicate the information in section 5(e) into section 5(a), and provide any further transparency as appropriate, in terms of KCL commercial arrangement with GRAIL Bio UK Ltd. 4. To update the application throughout, to amend the reference from *"demonstrate"* to *"determine whether there is"*, to allay concerns regarding pre-determination of research outputs. 5. To ensure that the reference to *"King's College London"* is correct throughout the application. 6. In respect of the territory of use: a) To insert a special condition in section 6, to state that the territory of use is England and Wales (noting GRAIL Bio UK Ltd has a US parent company). b) To update section 5 to make clear that while NHS Digital's data may not go outside the permitted territory of use, other non-NHS Digital data may be sent to the USA. The following advice was given: 1. IGARD suggested that Grail Bio UK Ltd's LIA should be finalised and the wording in section 5(a) and section 5(d) updated to reflect the legitimate interests described and in accordance with the relevant NHS Digital Standards. 2. IGARD suggested that the Data Controllers may wish to carry out a DPIA, on the ICO template, given the scope of processing of identifiable data.

	3. IGARD noted that DigiTrials have discussed the issue of explaining NDO's with HRA CAG. While IGARD applauded the reference to section 251 support in the letter to prospective participants, IGARD maintained that best practice would be to explain the operation of the NDO in the mailout letter. 4. IGARD was of the view that a trial-specific opt out would not be a satisfactory substitute for explaining the availability of the NDO. 5. IGARD thought it was useful to have 4-week lead up promotion period and suggested that during this time citizens could learn about exercising NDO's (and also how they could still join the trial, such as signing up directly, even if they had already exercised their NDO). **Significant Risk Area:** 1. IGARD suggested that the lack of transparency in respect of the NDO in the invitation letter could undermine public trust and confidence in NHS Digital. It was agreed the condition would be approved out of committee (OOC) by IGARD members
2.3	<u>University of Bristol: Inequalities in stillbirth and preterm birth and their risk factors (Presenter: Charlotte Skinner) NIC-430380-F7L4Z-v0.4</u> **Application:** This was a new application for a one-off report of pseudonymised Maternity Services Data Set (MSDS) for all births that occurred in England from April 2015 until March 2019; for the purpose of a study, investigating inequalities in rates of stillbirth (SB) and preterm birth (PTB) and their risk factors in England. There has been an increased national focus on improving maternity outcomes, with a range of initiatives developing from the Government, the NHS and professional bodies. Wide variations of SB and PTB have been identified throughout the UK, with some NHS Trusts having SB rates of more than 15% lower than the national average, but other units have rates more than 5% higher than the national average. These inequalities remain after accounting for patient case-mix and some Trust characteristics. Inequalities in PTB have been identified in England and Wales by maternal residential area, but there is no data on variations between NHS Trusts and over time. The risk factors that contribute to these geographical variations remain unclear, therefore identifying and understanding the variations in SB and PTB should help care providers to identify best and poor practices and evaluate the effectiveness of intervention or guidelines aiming to improve care practices and clinical outcomes. However, clinicians and mothers need to be able to identify the risk of PTB and SB as early as possible to prevent these outcomes. NHS Digital advised IGARD that the funding end data stated within the application was 2022, however and noted this did not align with the Data Sharing Agreement (DSA) end date of 2024. NHS Digital confirmed that the applicant had confirmed that funding was in place until 2024, however it was allocated on an annual basis, hence the stated date of 2022. NHS Digital confirmed that that a study protocol was in the process of being developed, and it was hoped that this would be completed and published by September 2021. **Discussion:** IGARD welcomed the application and noted the importance of the study. IGARD noted and thanked NHS Digital for the verbal update, in respect of the funding arrangements and the study protocol that was in the process of being developed. IGARD noted that data had been requested from the period 2015 – 2019, however, queried what the size of the cohort would be, noting that this was not clear within the application; and

	asked that for transparency, section 3(b) (Additional Data Access Requested) and section 5(a) (Objective for Processing) was updated to include an indicative size of the cohort. IGARD queried the references within the application to the data for *"all births"* between 2015 and 2019 being required, and asked that further clarity was provided on what was meant by this, and did this refer to the babies born or the Mothers who had given birth. IGARD queried if all the live births data was required to provide an appropriate control cohort (more than 3 but less than 7), and asked that confirmation was required; and that if the entire datasets were required, then an appropriate justification should be provided in line with the UK General Data Protection Regulation (UK GDPR) and in line with NHS Digital DARS Standard for Data Minimisation. IGARD suggested that the researchers may wish to consider if they required data on neonatal deaths, i.e. those babies who had died within 30-days of being born; and confirmed that they would be supportive of the applicant receiving this data, with the appropriate amendments and justifications made to the application, and without the need to return to IGARD for review on this specific point. IGARD noted in section 5(b) (Processing Activities) the reference to the timing of the birth, and asked that this was updated, to provide further clarity as to why this information was so important; or that it was removed if deemed not necessary. IGARD noted that small numbers would not be suppressed, and asked that section 5 (Purpose / Methods / Outputs) was updated, to expressly state that, because the data was at Trust level; that the ethical issue, in terms of the remote risk of inadvertent reidentification, had been considered and outline what steps would be taken to mitigate this. IGARD queried the narrative in section 5 when referring to the UK GDPR Article 9(2)(j) legal basis, and noting that this was incorrect, asked that section 5 was updated with the correct narrative for the legal basis cited. IGARD noted the inclusion of a number of terms of art and technical terms within the application, such as *"change agents"*, and asked that these were either remove, or, written in a manner suitable for a lay audience. IGARD queried the outputs **and** benefits in section 5(c) (Specific Outputs Expected) and section 5(d) (Benefits), and asked that they were reviewed and amended as appropriate, to ensure that they were realistic and achievable, for example, in reference to the outputs disseminated to healthcare professionals. 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 the language used within the paper in respect of the definition of the legal entities, for example, the Clinical Commissioning Groups (CCGs), and in light of the forthcoming system changes across healthcare, suggested that the paper was updated to future-proof it, for example, referencing the Integrated Care Systems (ICSs); which are new partnerships between the organisations that meet health and care needs across an area, to coordinate services and to plan in a way that improves population health and reduces inequalities between different groups. **Outcome:** recommendation to approve subject to the following conditions: 1. In respect of data minimisation and in line with NHS Digital DARS Standard for Data Minimisation: a) To provide in section 3(b) and section 5(a) an indicative size of the cohort.

	b) To clarify reference to *"all births"* and whether this is in reference to the babies born or the Mothers giving birth. c) To confirm if **all** live births data is required to provide an appropriate cohort control. d) If the entire datasets are required, then an appropriate justification should be provided in line with the UK GDPR and in line with NHS Digital DARS Standard for Data Minimisation. The following amendments were requested: 1. To expressly state in section 5, that because small numbers will not be supressed, and the data is at Trust level, that the ethical issue of the remote risk of inadvertent reidentification has been considered and what steps will be taken to mitigate this. 2. To amend the application throughout to ensure terms of art and technical terms are either removed or explained in a manner suitable for a lay audience, for example, *"change agents"*. 3. To insert the correct narrative in section 5 in relation to the Article 9(2)(j) legal basis. 4. To update section 5(b) to clarify why the timing of birth is so important, or remove if not necessary. 5. In respect of the outputs and benefits: a) To review the outputs in section 5(c), to ensure that they are realistic and achievable; and amend as appropriate. b) To review the benefits in section 5(d), to ensure that they are realistic and achievable; and amend as appropriate. c) To update section 5(d) to use a form of wording such as "*it is expected"* or *"it is hoped …"*, rather than "*it will…*". d) To update the application to future-proof it in relation to the system changes across healthcare, for example, in relation to the CCGs. The following advice was given: 1. IGARD suggested that the researchers may wish to consider if they require data on neonatal deaths (within 30-days of being born), and IGARD would be supportive of them asking for and receiving this data (with the appropriate amendments and justifications made to the application) and without the need to return to IGARD for review on that specific point. It was agreed the condition would be approved out of committee (OOC) by IGARD members
2.4	IQVIA Ltd: Using Patient Data in Amyloidosis to Understand Complex Diagnosis Pathways and Treatment Patterns (Presenter: Frances Hancox) NIC-60624-B1R2Q-v4.4 **Application:** This was an extension application to the existing Data Sharing Agreement; and an amendment, to 1) to reflect the newly obtained funding from Alnylam Pharmaceuticals Inc. and to remove references to the previous funder GlaxoSmithKline (GSK); 2) to update section 2 (Locations) to reflect a change in storage and processing locations due to a server move. Amyloidosis is a rare disease that occurs when a substance called amyloid builds up in the body's organs. Amyloid is an abnormal protein that is produced in bone marrow and can be deposited in any tissue or organ, affecting their normal function. The disease consists of many different sub-types and the type of protein that is misfolded along with the organ or tissue in which the misfolded proteins are deposited determines the clinical manifestations of amyloidosis. The purpose of the application is for research aiming to: 1) Understand the amyloidosis patient's diagnostic pathway and outcomes. This includes the implications of going through

	different routes to diagnosis, which can be used to develop materials which can help educate physicians on how to diagnose patients earlier; 2) Identify barriers in the patient pathways to receiving diagnosis; 3) Understand current coding in HES for different subtypes of amyloidosis, which can be used to support applications to change current ICD-10 coding practices in the UK and therefore enable capturing of more clinically accurate patient information nationally, which can support future research efforts in this understudied condition; 4) Develop a predictive algorithm which would be able to flag patients with a high probability of having amyloidosis (and subtypes) from their data fingerprint, which will support finding undiagnosed patients. The study is relying on s251 of the NHS Act 2006, for the flow of data from NHS Digital. **Discussion:** IGARD noted that this application had previously been discussed as part of the 'returning applications' section of the IGARD business as usual (BAU) meeting on the 13th 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 noted that the applicant was silent on the commercial aspect of the study, namely that the commercial funder of the research, Alnylam Pharmaceuticals Inc, manufactured medicine specifically for the treatment of amyloidosis. IGARD asked that in line with NHS Digital DARS Standard for Commercial Purpose, section 5(a) (Objective for Processing) and section 5(e) (Is the Purpose of this Application in Anyway Commercial) was updated with a written explanation of the commercial aspect, for transparency. In addition, IGARD asked that section 5(d) (Benefits) was updated, to provide details of the potential commercial benefits accruing to the pharmaceutical company, for example, that they are the manufacturer of the relevant drug, and in line with NHS Digital DARS Standard for Commercial Purpose. IGARD queried the response in section 5(e) that stated there was **no** commercial purpose to the application; and asked that this was updated to 'Yes', and to refer to the commercial purpose of Alnylam Pharmaceuticals Inc. 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 that section 5(d) should be updated to expand on the benefits accruing directly to the Health and Social Care System and the NHS, noting that this was not clear. IGARD noted the yielded benefits in section 5(d) (iii) (Yielded Benefits) and asked that further details were provided of the specific yielded benefits accrued to date, and asked that it was clear as to the benefits to both the patients and the health and social care system more generally, and in line with NHS Digital's DARS Standard for Expected Measurable Benefits. IGARD advised that when this application comes up for renewal, they would expect the yielded benefits to be clearly outlined, and to reflect the work that had been undertaken, and the benefits accrued, since the application was last seen. 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; in light of the commercial link and the need to assess the yielded benefits against the expected outcomes.

	Outcome: recommendation to approve subject to the following condition(s) 1. In respect of Alnylam Pharmaceuticals Inc and in line with NHS Digital DARS Standard for Commercial Purpose: a) To provide a written explanation in section 5(a) and section 5(e) that the commercial funder of the research manufactures medicine specifically for the treatment of amyloidosis. b) To update section 5(d), to provide details of the potential commercial benefits accruing to the pharmaceutical company, for example, that they are the manufacturer of the relevant drug. The following amendments were requested: 1. In respect of the benefits and in line with NHS Digital's DARS Standard for Expected Measurable Benefits: a) To update section 5(d) to use a form of wording such as "*it is expected"* or *"it is hoped …"*, rather than "*it will…*". b) To provide further details in section 5(d) of the yielded benefits accrued to date and ensure these are clear as to the benefits to both patients and the health care system more generally c) To update section 5(d) to expand on the benefits accruing directly to the Health and Social Care System and the NHS. 2. To update section 5(e) to remove the incorrect reference to there being *"no"* commercial purpose, and update as per Condition 1. The following advice was given: 1. IGARD advised that when this application comes up for renewal and amendment, they would expect the yielded benefits to be clearly outlined and to reflect the work that has been undertaken, and the benefits accrued since the application was last seen. 2. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment; in light of the commercial link and the need to assess the yielded benefits against the expected outcomes. 3. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent; in light of the commercial benefit and need to assess the yielded benefits. It was agreed the condition would be approved out of committee (OOC) by IGARD members
2.5	University College London (UCL): Millennium Cohort Study (also known as Child of the New Century) - Tracing (Presenter: Catherine Day) NIC-408892-F1R1Y-v0.8 **Application:** This was a new application for identifiable Demographics data; for the purpose of contacting participants to take part in the upcoming The Millennium Cohort Study (MCS), also known as the 'Child of the New Century'. This is to ensure that 'untraced' cohort members are not contacted if they have died The MCS is following the lives of around 19,000 young people born across England, Scotland, Wales and Northern Ireland in 2000-02. The ongoing success of the study depends on maintaining contact with as large a number of study members as possible. The Centre for Longitudinal Studies (CLS) at University College London (UCL) is an academic centre responsible for producing and disseminating data resources for the scientific community. It is responsible for four of Britain's internationally renowned longitudinal studies,

	which provides a wealth of information used in the policy decisions affecting society's health and well-being. NHS Digital data for the MCS cohort flows under a separate Data Sharing Agreement (DSA) NIC-147860-0RSHN, where under a s251 legal basis, they periodically receive notifications of deaths and exits; and NIC-384504-N2V5B for a proportion of the cohort that have consented to have their details linked to Hospital Episode Statistics (HES) data, which is then sub-licenced under the DSA. The study is relying on s251 of the NHS Act 2006, for the flow of data from NHS Digital. **Discussion:** IGARD noted and applauded the excellent published transparency notice, and advised that this was an exemplar to other researchers, in terms of transparent communication with a cohort. 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 reference within the application to two cohort figures, 19,000 and 14,100, and that the Health Research Authority Confidentiality Advisory Group (HRA CAG) correspondence stated the cohort figure was 19,000. IGARD therefore queried which figure was correct; and asked that section 3(b) (Additional Data Access Requested) and section 5 (Purpose / Methods / Outputs) were updated with the correct cohort size, and that this aligned with the HRA CAG support. IGARD asked that if the cohort was smaller than the figure specified in the HRA CAG support, that for transparency, section 5(b) (Processing Activities) was updated, with a clear explanation of the discrepancy. IGARD suggested that the applicant may wish to approach HRA CAG to seek support in setting aside the National Data Opt-out (NDO) in this instance, to avoid distress to the families of deceased cohort members; and confirmed that they would be supportive of this approach, noting the strong case for not applying the NDO. IGARD noted the benefits outlined in section 5(d) (Benefits), however asked that further details were provided, of how the outputs accrued to date have translated into actual benefits to patients or the healthcare system more generally, for example, was the recent research, reinforcing the benefits of breastfeeding, now included in information provided to expectant mothers. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of the cohort size: a) To update section 3(b) and section 5 with the correct cohort size, and ensure this aligns with the HRA CAG support. b) If the cohort is smaller than the figure specified in the HRA CAG support, to update section 5(b) with a clear explanation of the discrepancy. 2. To provide further details in section 5(d) of how the outputs accrued to date have translated into actual benefits to patients or the healthcare system more generally, For example, is the recent research reinforcing the benefits of breastfeeding now included in information provided to expectant mothers. The following advice was given:

	1. IGARD suggested that the applicant may wish to approach HRA CAG to seek support in setting aside the NDO in this instance, to avoid distress to the families of deceased cohort members.; IGARD confirmed that they would be supportive of this approach.
2.6	University of Oxford: Models of Resilience – COVID-19 and Non-COVID-19 Contexts (Presenter: Louise Dunn) NIC-378657-B8F3K-v0.16 **Application:** This was a new application for pseudonymised Civil Registrations (deaths) data, Emergency Care Data Set (ECDS), Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (HES APC), HES Critical Care and HES Outpatients. The purpose is for a study to inform policy decisions by the Department of Health and Social Care (DHSC) and NHS England, regarding resilience of the healthcare system during and after peaks of COVID-19. The surge of COVID-19 has had a profound impact on the management and delivery of acute healthcare, and as a result, NHS Trusts have redesigned organisational models with changes in processes of assessment and care delivery, redeployment of staff, new pathways of care, and different prescribing strategies. These changes have been implemented to provide a rapid increase in acute care assessment and treatment capacity across a system of care for patients with COVID-19-related symptoms, whilst also trying to maintain delivery of care for patients with non-COVID-19 healthcare needs. The study that is subject of this agreement is part of a broader project, which has three operational tiers, however NHS Digital data will only be used for one of the tiers, to support the empirical analysis of hospital resilience. NHS Digital advised IGARD that although the application states that the applicant is the University of Oxford, this was in fact and error, and the applicant is the University of Birmingham. NHS Digital confirmed that discussions had taken place with the various legal teams, and it had been agreed that the University of Oxford were not joint Data Controllers; and that the University of Oxford were acting strictly under the instruction of the University of Birmingham. NHS Digital advised that the application would need updating throughout to reflect this information, including (but not limited to), the special condition in section 6 (Special Conditions), where reference was made to there being joint data controllership. **Discussion:** IGARD noted the verbal update from NHS Digital in respect of the roles of the University of Oxford and the University of Birmingham, and supported the update of the application throughout, to reflect this information. IGARD noted that the Chief Investigator held an honorary contract with the University of Birmingham, but were a substantive employee of the University of Warwick, and queried if the University of Warwick should also be considered a joint Data Controller. NHS Digital advised that there was no involvement from the University of Warwick as an establishment, and therefore they were not considered joint Data Controllers. IGARD noted the verbal update from NHS Digital, and asked that section 5(a) (Objective for Processing) was updated, with an express statement, that the University of Warwick was not carrying out joint data controllership activities, in light of the Chief Investigator holding an honorary contract with the University of Birmingham, but being a substantive employee of the University of Warwick. IGARD queried why the proposed processing could not be carried out within NHS Digital's Research Environment (TRE), and asked that section 5(a) was updated with a written justification, as this was not clear.

	IGARD noted the information within the application, in respect of the ethnicity data, for example, section 5(a) stated that the risk of identifying patients through the ethnicity data was very remote; and asked that for transparency, section 1 (Abstract) and section 5(b) (Processing Activities) were updated with clarification that ethnicity data was not identifiable but was a sensitive field. IGARD noted the volume of information within section 5(a), and noting that this formed NHS Digital's data release register, asked that the provided information was reduced, and any duplicate text removed. IGARD noted a number of acronyms and technical terms in section 5(a), and asked that this public facing section be updated to ensure that all acronyms upon first use were defined; and technical terms were either removed, or explained in a manner suitable for a lay audience, for example, *"regression coefficients"*. IGARD queried the outputs **and** benefits in section 5(c) (Specific Outputs Expected) and section 5(d) (Benefits), and asked that they were reviewed and amended as appropriate, to ensure that they were realistic and achievable, for example, in reference to the outputs disseminated to healthcare professionals. 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 advised NHS Digital that there was a potential area of risk to NHS Digital's reputation, in terms of undermining public trust and confidence, if un-measurable, potentially hyperbolic and non-specific outputs were outlined, and then not realised with the data received. IGARD noted the potential valuable outputs coming from the work outlined in the application, and suggested the applicant may wish to review the datasets requested, for example, in respect of the COVID-19 objectives. IGARD advised that they would be supportive of the applicant receiving additional flows of data if required, and if the appropriate legal basis could be satisfied, to ensure they were working with as full set of relevant data as possible; and that an appropriate justification for this additional data should be added in section 5 (Purpose / Methods / Outputs). IGARD advised that when this application comes up for renewal, they would expect the yielded benefits to be clearly outlined, and to reflect the work that had been undertaken, and the benefits accrued, since the application was last seen. 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; and upon return, IGARD would expect to see the outputs clearly mapped against the expected benefits. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 5(a) with a written justification as to why the proposed processing cannot be carried out within NHS Digital's TRE. 2. To update section 5(a) to make an express statement that the University of Warwick is not carrying out joint data controllership activities, in light of the Chief Investigator holding an honorary contract with the University of Birmingham, but being a substantive employee of the University of Warwick. 3. To update section 1 and section 5(b) with clarification that ethnicity data is not identifiable but is a sensitive field.

	4. In respect of section 5(a) and noting that this forms NHS Digital's data release register: a) To remove any duplicated text in section 5(a). b) To amend section 5(a) to ensure acronyms be defined upon first use, and technical terms are either removed, or explained in a manner suitable for a lay audience, for example, *"regression coefficients"*. 5. In respect of the outputs and benefits: a) To review the outputs in section 5(c), to ensure that they are realistic and achievable; and amend as appropriate. b) To review the benefits in section 5(d), to ensure that they are realistic and achievable; and amend as appropriate. c) 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 advised that when this application comes up for renewal, they would expect the yielded benefits to be clearly outlined, and to reflect the work that has been undertaken, and the benefits accrued since the application was last seen. 2. IGARD noted the potential valuable outputs coming from the work outlined in the application, and suggested the applicant may wish to review the datasets requested, for example in respect of the COVID-19 objectives. IGARD advised that they would be supportive of the applicant receiving additional flows of data if required, and if the appropriate legal basis could be satisfied, to ensure they were working with as full set of relevant data as possible; and that an appropriate justification for this additional data should be added in section 5. 3. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, where IGARD would expect to see the outputs clearly mapped against the expected benefits. 4. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, where IGARD would expect to see the yielded benefits mapped against the outputs. **Significant Risk Area:** 1. IGARD advised NHS Digital that there was a potential area of risk to NHS Digital's reputation, in terms of undermining public trust and confidence, if un-measurable, potentially hyperbolic and non-specific outputs are outlined , and then not realised with the data received.
2.7	NHS Lincolnshire CCG and Lincolnshire County Council: DSfC - Lincolnshire CCG and Lincolnshire County Council - Comm (Presenter: Dan Goodwin) NIC-454217-D9J5X-v0.3 **Application:** This was a new application for pseudonymised Secondary Uses Service (SUS+), Local Provider Flows, Mental Health Minimum Data Set (MHMDS), Mental Health Learning Disability Data Set (MHLDDS), Mental Health Services Data Set (MHSDS), Maternity Services Data Set (MSDS), Improving Access to Psychological Therapy (IAPT), Child and Young People Health Service (CYPHS), Community Services Data Set (CSDS), Diagnostic Imaging Data Set (DIDS), National Cancer Waiting Times Monitoring Data Set (CWT), Civil Registration data (births and deaths), National Diabetes Audit (NDA), Patient Reported Outcome Measures (PROMs), e-Referral Service (eRS), Personal Demographics Service (PDS), Summary Hospital-level Mortality Indicator (SHMI) and Medicines Dispensed in Primary Care (NHSBSA Data).

	The purpose is to provide intelligence to support the commissioning of health services, and analysed so that health care provision can be planned to support the needs of the population within the CCG and local authority area. **Discussion:** IGARD queried why data had been requested from 2008, and advised that if this was for the purpose of identifying *"trends"*, this would still be achievable with less years of data, for example, 5-years. IGARD therefore asked that the application was amended throughout to ensure that the date range for the datasets requested was **only** from 2016 onwards at the earliest. IGARD noted the constraints placed in the Direction for the collection of NHS BSA Medicines dispensed in Primary Care data, by NHS Digital, specifically *"Providing intelligence about the safety and effectiveness of medicines…"*; and asked that a special condition was inserted in section 6 (Special Conditions), that any use of the NHS BSA data must be within the parameters of the relevant Direction authorising that collection. In addition, IGARD remained concerned that there may be widespread use of the NHS BSA dataset despite the narrow scope of the relevant Direction. IGARD noted that this was a *"new"* application and was therefore silent on the yielded benefits achieved to date; however, noting that data had flowed via previous incarnations of the CCG application asked that section 5(d) (Benefits) (iii) (Yielded Benefits) was updated with further details of the yielded benefits accrued to date from previous incarnations of the CCG application, and to ensure these were clear as to the benefits to both patients and the health care system more generally. IGARD noted the reference in section 5(a) (Objective for Processing) to *"Using value as the redesign principle"* when referring to the purpose of the data, and asked that this was removed as it was not relevant. IGARD noted the reference in section 5(c) (Specific Outputs Expected) to *"reidentification for direct care"* when noting the commissioning outputs, and asked that this was removed as it was incorrect. **Outcome:** recommendation to approve The following amendments were requested: 1. To amend the application throughout to ensure that the date range for the datasets requested is **only** from 2016 onwards at the earliest. 2. To provide further details in section 5(d) (iii) of the yielded benefits accrued to date from previous incarnations of the CCG application, and ensure these are clear as to the benefits to both patients and the health care system more generally. 3. To amend section 5(a) to remove reference to *"Using value as the redesign principle"*. 4. To update section 5(c) to remove references to the application permitting *"reidentification for direct care"*. 5. To insert a special condition in section 6, that any use of the Medicines Dispensed in Primary Care NHS BSA data must be within the parameters of the relevant Direction authorising that collection. **Significant Risk Area:** 1. IGARD remained concerned that there may be widespread use of the NHS BSA dataset the narrow scope of the relevant Direction.

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. 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	IG COVID-19 Release Register April and May 2021 IGARD noted that the IG COVID-19 Release Register April and May 2021 had been circulated and reviewed out of committee by members, and discussed and agreed the comments that would be shared with the Privacy, Transparency and Ethics Directorate.
5	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 22nd June 2021** can be found attached to these minutes as Appendix C.
6 **6.1**	AOB: New Data Processors to the organisation (Presenter: Duncan Easton) NHS Digital queried, following a brief discussion at the 27th May 2021 business as usual meeting, if IGARD would want to see returning applications where a brand-new Data Processor was to be included in the agreement. Noting that IGARD had discussed due diligence with NHS Digital over the last four years, and that Data Access Request Service (DARS) had in place a risk matrix in order to assess such queries, IGARD suggested that that DAO discuss further with the Head of Service for DARS, since adding a new Data Processor without relevant due diligence may impact on the reputation of NHS Digital. 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 18/06/21

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-125783-W2W3P	NHS Wakefield CCG	11/03/2021	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.	IGARD members	OOC by quorum of IGARD members	N/A

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-438547-B6Y8V-v0.5 DSfC- NHS Hampshire, Southampton and Isle of Wright CCG and NHS Portsmouth CCG- COMM

Graphnet Class Actions:

- None

Appendix B

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 23rd June 2021

Application & application version number: DARS-NIC-448252-L2R6Q-v1.2

Organisation name: NHS England

Profession Advisory Group Agenda item: 3

PAG supports the application and that it is tailored to analysis related to Covid-19 purposes.

PAG refer to various points in the BMA/RCGP standard and ask that they are addressed within the application:

3. For service evaluation or audit (which do not usually require ethical approval), the applicant **MUST** provide evidence of a National or Regional **Senior Clinical** NHS England and Improvement sponsor.

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.

7. Any results that are not published in the public domain, for example for closed circulation to SAGE or used to inform policy papers, **MUST** be shared with the BMA/RCGP (via DARS) at the same time as they are circulated; this includes all related content, such as, executive summaries, recommendation on changes in policy, appendices, etc. Nevertheless NHS Digital should continue to encourage all applicants to publish their findings; this not only supports the benefits realisation strand around the use of GP Data but also transparency with the public.

Attendees	Role	Organisation
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
Kimberley Watson	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, 22nd June 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):	Louise Dunn (DARS)
	Dan Goodwin (DARS)
	Chloe Newbigging (DARS) (item 3)
	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-386720-C3X1B V0.2 Wakefield Metropolitan District Council **Background:** This was a new application for GP data for pandemic planning & research (GDPPR). Under this application the Council are seeking approval to link GDPPR data to other pseudonymised datasets which the Council holds under a joint CCG / Local Authority (the Council) data sharing agreement (DSA) NIC-125783-W2W3P, and which may also be linked to COVID-19 testing data the council receives from a separate DSA they hold with NHS England. The following observations were made on the basis of the draft v0.2 application summary and relevant draft supporting documents. **IGARD Observations:** IGARD members noted that due to the nature of the meeting and when papers were disseminated, they had not conducted a full review of the application and supporting documents provided. Should a full review of the application and documentation be required

	including the consent materials and patient information leaflets, the full suite of documentation should be presented to a IGARD business as usual (BAU) meeting for a recommendation.
	
	IGARD members noted the update from NHS Digital and that the application was to be presented at PAG on Wednesday, 23rd June and an IGARD business as usual (BAU) yet to be determined. IGARD members noted that the discussion today was not to pre-empt discussions that would take place at the BAU meeting and gave the following high-level comments:
	
	• Given the novel use of the GDPPR data, IGARD members suggested that the current 3-year DSA be amended to 1-year in order to ensure the relevant checks and balances could be undertaken, including but not limited to,
	  ○ ensuring that section 5(d) had been updated in line with the NHS Digital DARS Standard for Expected Measurable Benefits and in particular that the Yielded Benefits clearly aligned to the work being undertaken by the Council.
	  ○ Ensuring the section 5(c) had been updated in line with the NHS Digital DARS standard for Expected Outcomes and that they clearly aligned with the work being undertaken by the Council
	• IGARD members suggested that NHS Digital explore whether this was indeed a standalone application or whether NIC-125783-W2W3P could be appropriately amended to clearly set out what the Council was doing separately to the CCG and the Council be added to that DSA as a joint Data Controller.
	• IGARD members noted that NHS Digital should proactively raise with PAG on the 23rd June that the GDPPR data may be linked to other datasets held under a separate DSA held between the Council and NHS England.

2.2	NIC-459114-J3C1F-v0.4 AstraZeneca UK Ltd **Background:** this was a new urgent public health priority application to assess the real-world effectiveness and safety of the Oxford / AstraZeneca COVID-19 vaccine in England (ORCHID linkage). Civil Registration (Deaths) data, COVID-19 Second Generation Surveillance System (SGSS), COVID-19 UK Non-Hospital Antibody Testing Results (pillar 3), COVID-19 UK Non-Hospitalisation Antigen Testing Results (pillar 2), COVID-19 Vaccination Status, Hospital Episode Statistics (HES) Admitted Patient Care (APC), and HES Critical Care datasets have been requested to be used to build algorithms for analysis in a smaller cohort to which they will be linked, prior to these algorithms being deployed in the national level data within the NHS Digital Trusted Research Environment (TRE) under the Data Sharing Agreement (DSA) NIC-445543-W0D4N NIC-445543-W0D4N v0.3 AstraZeneca UK Limited **Background:** this was a new urgent public health priority application to assess the real-world effectiveness and safety of the Oxford / AstraZeneca COVID-19 vaccine in England – Trusted Research Environment (TRE) analysis. Civil Registration (Deaths) data, Hospital Episode Statistics (HES) Admitted Patient Care (APC), and HES Critical Care datasets will be accessed via NHS Digital's TRE. The purpose of the processing the requested data is to run a retrospective, non-interventional study to assess the effectiveness of the COVID-19 vaccination to reduce severe COVID-19 infection and mortality in the population of England and the study will define a cohort of patients who have received a COVID-19 vaccination and define matched controls from non-vaccinated populations. No data will be extracted out of

	NHS Digital under this Data Sharing Agreement (DSA) and all processing will be conducted within the NHS Digital TRE. The following observations were made on the basis of the verbal update from NHS Digital only. **IGARD observations:** IGARD members noted 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. NHS Digital noted the applications would be presented to the IGARD BAU Meeting on Thursday, 1st July. IGARD noted the update and noted that the discussion today was not to pre-empt discussion that would take place at the BAU meeting. NHS Digital noted that the University of Oxford had written to NHS Digital to request if data they held currently under another data sharing agreement (DSA) and being used for other purposes could be reused on a temporary basis and until the two DSA's were in place and data flowing under the two DSA's. NHS Digital had discussed with the Privacy, Transparency and Ethics (PTE) Directorate to explore options to permit the University of Oxford to reuse data under another DSA and where they are the Data Processor, not the Data Controller, in order to start to build the algorithms for analysis. PTE were of the opinion that this could be undertaken but that a separate new DSA be put in place for 3 months. NHS Digital noted that this application would proceed under the SIRO precedent. IGARD members noted that all comments and significant risk areas previously raised at the 25th May and 15th June COVID-19 response meeting for both applications, remained live and these were appended to these notes as 'appendix A'. IGARD members agreed that the proposed short-term solution had a sound contractual basis and understood that NHS Digital may wish to proceed under the SIRO precedent. Notwithstanding the fact that this approach appeared technically sound, IGARD raised again the significant risks relating to transparency in terms of: a. complying with the legal requirements for transparency about this re-use of data (Legal Risk) and; b. the potential reputational risk to NHS Digital and potential damage to public trust if said transparency materials were not sufficient (Risk to NHS Digital's reputation/Public Trust). **Significant Risk Areas:** IGARD members noted that all previously raised significant areas of risks and points were still live including: transparency; volume of GP data being used; and extension of cohort to include children.
3	<u>Uses Release Register – business as usual (BAU)</u> **Background:** NHS Digital provided a brief overview of the new beta Uses Release Register, which was not currently live on the NHS Digital website but was in final sign off stages. NHS Digital noted that the new release register build had commenced in October 2020 and would show all data sharing agreements with an end date after January 2020. **IGARD Observations:**

	Noting this was a BAU item and that not all members had reviewed the content of materials provided and noting this was the first time those present had viewed the beta release register, IGARD reserved the right to produce a position statement on the new Uses Release Register, and provided the following high level comments: • Generally and visually, the new look release register was a good step forward and noted the hard work undertaken by NHS Digital, but suggested that NHS Digital have a formal consultation in place to ensure the release register was what users and the public wanted. IGARD members also noted the proposed feedback mechanism incorporated and applauded its inclusion. • Noting the ICO Code of Practice was defunct, IGARD suggested that reference should be removed before publication. • Noting the use of the word "anonymised" throughout the register, IGARD suggested that an explanatory note be included to be clear this was "pseudonymised" data. • IGARD members noted that some single legal entities had multiple entries for example "Office for National Statistics" and "Office for National Statistics (ONS)" and that if searching for "ONS" the search engine would only provide the one entity with "ONS" in its title, which may be misleading. If this cannot be fixed on the release register, then appropriate explanatory notes should be included, via the mouseover box which was enabled on the beta release register. • IGARD members noted that legal terms such as "sensitive" and "non-sensitive" be described via the mouseover box which was enabled on the beta release register. • IGARD members noted that although National Data Opt Outs were discoverable, suggested that they be displayed in a more user-friendly fashion with an explanatory note as how the public are able to search for those applications that have NDO applied, or not applied. • IGARD members noted that a number of applications were listed as "expired" however noting that for the vast majority of those applications they would however be in the process of being "renewed" that a clear explanatory note be included via the mouseover box, which was enabled, to explain the DARS process, this was especially relevant to a number of high-profile applications. • IGARD members noted that explanatory notes across the release register were essential for the user experience and offered to support NHS Digital with a review, if they felt it appropriate, and before the release register went live on the NHS Digital website. • IGARD members also requested that they be informed when the release register went live, by way of an email to IGARD@nhs.net. • Noting that the release register would be part of a regular cycle of updating and refresh, IGARD members suggested that commercial aspects of applications be drawn out so that members of the public could search solely for commercial applications, funding arrangements be a searchable function, involvement of pharmaceutical companies be a searchable function, the number of data processors per application be a searchable function (for example some CCG applications have a plethora of Data Processors). Noting that the type of data was searchable via the Excel spreadsheet, IGARD suggested that this interesting feature was brought to the "front" of the search function.

4	AOB There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.

Appendix A

COVID-19 Action Notes extract 25th May 2021

NIC-459114-J3C1F v0.1 AstraZeneca UK Limited

Background: this was a new urgent public health priority application to assess the real-world effectiveness and safety of the Oxford / AstraZeneca COVID-19 vaccine in England (ORCHID linkage). Civil Registration (Deaths) data, COVID-19 Second Generation Surveillance System (SGSS), COVID-19 UK Non-Hospital Antibody Testing Results (pillar 3), COVID-19 UK Non-Hospitalisation Antigen Testing Results (pillar 2), COVID-19 Vaccination Status, Hospital Episode Statistics (HES) Admitted Patient Care (APC), and HES Critical Care datasets have been requested to be used to build algorithms for analysis in a smaller cohort to which they will be linked, prior to these algorithms being deployed in the national level data within the NHS Digital Trusted Research Environment (TRE) under the Data Sharing Agreement (DSA) NIC-445543-W0D4N (see item 2.3 below)

The following observations were made on the basis of v0.1 application summary and version 1.0 *Real-world effectiveness of the Oxford/AstraZeneca COVID-19 vaccine in England Observational Study Protocol 22-Mar-21 – CSP 26Apr21_clean*

NHS Digital noted that they had not undertaken a review of the documentation including the DPA, security etc.

IGARD Observations:

IGARD members noted that due to the nature of the meeting and when papers were disseminated, they had not conducted a full review of the application and supporting documents provided, noting that not all the supporting documents available had been provided for consideration. 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 AstraZeneca had cited Article 6(1)(e) (public task) of the UK General Data Protection Regulations (UK GDPR) and that this should be reviewed, since legitimate interests Article 6(1)(f) may be a more appropriate legal basis. It was agreed that a UK GDPR legal basis was not required for the date of death but NHS Digital should provide confirmation in section 1 (Abstract) that the flow of date of death data is in line with NHS Digital's policy assessment and would not increase the likelihood of re-identification of data subjects.

IGARD suggested NHS Digital should receive confirmation that AstraZeneca has carried out a Data Protection Impact Assessment (DPIA) which addresses the significant volume of data, the flow of data and the processing outlined in the application. IGARD members noted that the DPIA is not a public-facing document and does not need to published but that NHS Digital should have the appropriate assurances, noting widespread media coverage regarding DPIAs (see, for example, a recent BMJ article (BMJ 2021;372:n587 http://dx.doi.org/10.1136/bmj.n587 Published: 01 March 2021)).

IGARD members noted previous lengthy discussions with regard to the different legal entities of AstraZeneca and noting that section 1(b) (Data Controllers) was currently blank

suggested that the correct legal entity be cited. IGARD members suggested that in alignment with the definition of Controller in Article 4(7) UK GDPR, the Data Protection Officer (DPO) of AstraZeneca UK Limited provided written confirmation, that AstraZeneca UK Limited was the **sole** legal person determining the purposes and means of processing of the NHS Digital data, such processing as outlined in the application in line with NHS Digital's DARS Standard for Data Controllers; and that the written confirmation was uploaded to NHS Digital's customer relationships management (CRM) system for future reference. However, noting the facts available in the application summary and protocol provided, IGARD members suggest that the University of Oxford appeared to be a joint Data Controller, alongside AstraZeneca UK Limited, and suggested that the parties involved should be assessed in line with NHS Digital's DARS standard for Data Controllers and in line with the factual scenario.

IGARD members noted that the 'Oxford Royal College of General Practitioners Clinical Informatics Hub' (ORCHID) platform outlined in section 5 had been cited in other applications presented to IGARD, where the University of Oxford had been assessed as being a joint Data Controller, asked that further clarification was provided in section 5 (purpose / method / outputs) of the platform and its use, noting that the ORCHID transparency page on their webpage was still "*under construction*"

IGARD members noted that the requested datasets would be used to build algorithms for analysis in a smaller cohort before the algorithms were deployed at national level data (under NIC-445543) and suggested that further narrative should be included in section 5 as to how these algorithms and their outputs are likely to be used, since section 5 forms part of NHS Digital's data release register.

In addition, IGARD members noted that as per NHS Digital's published 'register of processing activities' that some datasets have specific territories of use and cannot, for example, be transferred outside of England and Wales. In addition, noting that this application was concerned with England, section 5 should remove any reference to 'Wales', since it was not relevant.

IGARD members suggested that an indicative cohort size or number of records flowing under this DSA should be included in section 5, for transparency.

In addition, and noting the useful narrative included in the protocol provided as a supporting document, IGARD members suggested that some of this narrative be included in section, since section 5 forms part of NHS Digital's published data release register, and that it should be clearly articulated within section 5 why NHS Digital's Trusted Research Environment (TRE) could not be used for the research being undertaken in this application.

IGARD members noted that the specific outputs noted in section 5(c) (specific outputs expected, including target dates) appeared to be internal facing, and since the application was looking at the real world effectiveness for the COVID-19 vaccine in England, suggested that further detail be included in section 5(c) setting out how the benefits translated into benefits for patients and the public, by way of for example a communications plan, public engagement and appropriate communications with relevant national and international bodies such as the Joint Committee on Vaccinations & Immunisation (JCVI), and in line with NHS Digital's DARS standard for Expected Outputs. In addition, section 5 should clearly state that any "unfavourable" results would not be supressed and given equal prominence and widespread dissemination, given the other vaccines being studied under this DSA, since

NHS Digital was legally obliged to ensure that the data was not used solely for the commercial benefit of Astra Zeneca.

Finally, IGARD members suggested that the application be checked to ensure that it meets all current NHS Digital published DARS Standards.

IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the high profile and impactful nature of the application.

IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent (with the exception of this application which would progress under SIRO due to the urgency of the request).

NHS Digital noted that due to the urgency of the application that it would be progressed under NHS Digital's SIRO Precedent, on this occasion only, IGARD were supportive of this approach.

NIC-445543-W0D4N v0.3 AstraZeneca UK Limited

Background: this was a new urgent public health priority application to assess the real-world effectiveness and safety of the Oxford / AstraZeneca COVID-19 vaccine in England – Trusted Research Environment (TRE) analysis. Civil Registration (Deaths) data, Hospital Episode Statistics (HES) Admitted Patient Care (APC), and HES Critical Care datasets will be accessed via NHS Digital's TRE. The purpose of the processing the requested data is to run a retrospective, non-interventional study to assess the effectiveness of the COVID-19 vaccination to reduce severe COVID-19 infection and mortality in the population of England and the study will define a cohort of patients who have received a COVID-19 vaccination and define matched controls from non-vaccinated populations. No data will be extracted out of NHS Digital under this Data Sharing Agreement (DSA) and all processing will be conducted within the NHS Digital TRE.

The following observations were made on the basis of v0.3 application summary and version 1.0 *Real-world effectiveness of the Oxford/AstraZeneca COVID-19 vaccine in England Observational Study Protocol 22-Mar-21 – CSP 26Apr21_clean*

NHS Digital noted that they had not undertaken a review of the documentation including the DPA, security etc.

IGARD Observations:

IGARD members noted that due to the nature of the meeting and when papers were disseminated, they had not conducted a full review of the application and supporting documents provided, noting that not all the supporting documents available had been provided for consideration. 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 this application was linked to NIC-459114-J3C1F v0.1 AstraZeneca UK Limited (item 2.2 above).

IGARD members noted that AstraZeneca had cited Article 6(1)(e) (public task) of the UK General Data Protection Regulations (GDPR) and that this should be reviewed, since legitimate interests Article 6(1)(f) may be a more appropriate legal basis. It was agreed that a UK GDPR legal basis was not required for the date of death but NHS Digital should provide confirmation in section 1 (Abstract) that the flow of date of death data is in line with NHS

Digital's policy assessment and would not increase the likelihood of re-identification of data subjects.

In addition, IGARD members noted that the datasets outlined in section 5 (purpose / methods / outputs) were not reflected in the additional data requested tables in section 3b (additional data access requested), and that this section should be updated with the relevant datasets requested under this DSA.

IGARD suggested NHS Digital should receive confirmation that AstraZeneca has carried out a Data Protection Impact Assessment (DPIA) which addresses the significant volume of data, the flow of data and the processing outlined in the application. IGARD members noted that the DPIA is not a public-facing document and does not need to published but that NHS Digital should have the appropriate assurances, noting widespread media coverage regarding DPIAs (see, for example, a recent BMJ article (BMJ 2021;372:n587 http://dx.doi.org/10.1136/bmj.n587 Published: 01 March 2021)).

IGARD members noted previous lengthy discussions with regard to the different legal entities of AstraZeneca and noting that section 1(b) (Data Controllers) was currently blank suggested that the correct legal entity be cited IGARD members suggested that in alignment with the definition of Controller in Article 4(7) UK GDPR, the Data Protection Officer (DPO) of AstraZeneca UK Limited provided written confirmation, that AstraZeneca UK Limited was the **sole** legal person determining the purposes and means of processing of the NHS Digital data, such processing as outlined in the application in line with NHS Digital's DARS Standard for Data Controllers; and that the written confirmation was uploaded to NHS Digital's customer relationships management (CRM) system for future reference. However, noting the facts available in the application summary and protocol provided, IGARD members suggest that the University of Oxford appeared to be a joint Data Controller, alongside AstraZeneca UK Limited, and suggested that the parties involved should be assessed in line with NHS Digital's DARS standard for Data Controllers and in line with the factual scenario.

IGARD members noted that further narrative with regard to the datasets requested under NIC-459114-J3C1F to build algorithms for analysis in a smaller cohort before deployed at national level data should be included in section 5 as to how these algorithms and their outputs are likely to be used, since section 5 forms part of NHS Digital's data release register.

In addition, IGARD members noted that as per NHS Digital's published 'register of processing activities' that some datasets have specific territories of use and cannot, for example, be transferred outside of England and Wales.

IGARD members suggested that an indicative cohort size or number of records flowing under this DSA should be included in section 5, for transparency.

IGARD members noted that the specific outputs noted in section 5(c) (specific outputs expected, including target dates) appeared to be internal facing, and since the application was looking at the real world effectiveness for the COVID-19 vaccine in England, suggested that further detail be included in section 5(c) setting out how the benefits translated into benefits for patients and the public, by way of for example a communications plan, public engagement and appropriate communications with relevant national and international bodies such as the Joint Committee on Vaccinations & Immunisation (JCVI), and in line with NHS Digital's DARS standard for Expected Outputs. In addition, section 5 should clearly state that

any “unfavourable” results would not be supressed and given equal prominence and widespread dissemination, given the other vaccines being studied under this DSA, since NHS Digital was legally obliged to ensure that the data was not used solely for the commercial benefit of Astra Zeneca.

Finally, IGARD members suggested that the application be checked to ensure that it meets all current NHS Digital published DARS Standards.

NHS Digital noted that due to the inclusion of GP Data for Pandemic Planning and Research (GDPPR), that the application would be presented to a Profession Advisory Group (PAG) meeting and before it was presented to an IGARD business as usual meeting (BAU), as per due process for applications for GDPPR data.

IGARD further advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the high profile and impactful nature of the application.

IGARD suggested that this application would **not** be suitable for NHS Digital’s Precedent route, including the SIRO Precedent, since this application was relying on the outputs from NIC-459114-J3C1F v0.1 (which would not be subject to independent review) and contained GDPPR data (which as per process, required PAG and IGARD approval).

COVID-19 Action Notes extract 15th June 2021

AstraZeneca UK Ltd (No NIC Number)

Background: NHS Digital provided a verbal update with regard to a “permission to contact” application from AstraZeneca for a phase 2 / 3 clinical trial “*Vaccine for the Prevention of COVID-19 caused by variant strains of SARS-CoV-2*”.

The phase 2 / 3 double blinded randomised clinical trial is looking to recruit up to 900 cohort participants aged 30 years and older, via the registry who had had both vaccinations of either the AstraZeneca vaccine, Pfizer vaccine or Moderna vaccine.

NHS Digital noted that AstraZeneca would be the Data Controller, with NHS Digital as the Data Processor (NHS Digital will contact registry participants directly). In addition IQVIA would be a Data Processor on the application to undertake the pre-screening requirements.

The following observations were made on the basis of the verbal update only.

IGARD Observations:

IGARD members noted that due to the nature of the meeting and the fact that they had received no draft application or supporting documents, 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 noted the verbal update from NHS Digital with regard to this variant booster trial, noting that NHS Digital had determined that there was nothing novel or distinct from previous booster trials using the “permission to contact” registry, such as NIC-456088-R0H0V v0.1 University Hospital Southampton NHS FT (seen at the CV19 meeting on the 18th May 2021).

IGARD Members queried if NHS Digital had had sight of the ethics and consent materials and NHS Digital confirmed they had not. IGARD members noted the importance of ensuring

a careful review of the ethics and consent materials to ensure they aligned with the processing outlined in the application and protocol, and that the materials did not preclude the applicant from, for example, receiving further additional datasets, linking to other datasets, and carrying out long term follow up due to the nature of the disease and scientific interest in long-term effects.

IGARD members noted that the trial was looking at participants aged 30 years and over, and drew to the attention of NHS Digital and the applicant to the guidance from the MHRA with regard to the AstraZeneca vaccine for people aged under 40. Noting that this aspect was outside of IGARD's scope in reviewing use of the permission to contact registry, IGARD nonetheless suggested that MHRA and the appropriate ethics committee were expressly consulted on the aspect of the trial which was proactively targeting potential cohort members aged 30-39 and to ensure the consent materials in due course fairly and transparently reflected the latest JCVI/MHRA advice.

Noting the language used in this and other applications using the permission to contact register (internal process name), consideration should be given to the external name of the registry: "vaccine registry". Since the vaccine registry was a standalone registry that cannot be linked to any other registry, consideration should be given to its external name, since it could imply that the registry contained all those that had had a vaccine, rather than what the database is; a database of those who have consented to be part of a registry of people who are happy to be contacted about vaccine research. NHS Digital noted that the permission to contact / vaccine registry had nearly ½ million cohort members. IGARD suggested that in due course the language within this and other permission to contact applications should be updated to ensure that section 5, which forms part of NHS Digital's data release register, contained an accurate description of the registry and what it was.

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, assuming full ethical support had been received alongside a review of the consent materials in due course.

ACTION: Separate to this application, IGARD members asked for an update with regard to the number of participants who had withdrawn from the permission to contact / vaccine registry since its inception and NHS Digital agreed to provide an update at a future COVID-19 response meeting.

NIC-459114-J3C1F-v0.4 AstraZeneca UK Ltd

Background: this was a new urgent public health priority application to assess the real-world effectiveness and safety of the Oxford / AstraZeneca COVID-19 vaccine in England (ORCHID linkage). Civil Registration (Deaths) data, COVID-19 Second Generation Surveillance System (SGSS), COVID-19 UK Non-Hospital Antibody Testing Results (pillar 3), COVID-19 UK Non-Hospitalisation Antigen Testing Results (pillar 2), COVID-19 Vaccination Status, Hospital Episode Statistics (HES) Admitted Patient Care (APC), and HES Critical Care datasets have been requested to be used to build algorithms for analysis in a smaller cohort to which they will be linked, prior to these algorithms being deployed in the national level data within the NHS Digital Trusted Research Environment (TRE) under the Data Sharing Agreement (DSA) NIC-445543-W0D4N (see item 2.3 below).

The following observations were made on the basis of v0.4 application summary, version 1.0 '*Real-world effectiveness of the Oxford/AstraZeneca COVID-19 vaccine in England*

Observational Study Protocol 22-Mar-21 – CSP 26Apr21_clean', 'favourable London Bromley Research Ethics Committee (REC) approval (IRAS Project ID: 300259) dated 23 May 2021', and *'Legitimate Interest Assessment (LIA) Vaccine Effectiveness 10.06.2021'*

NHS Digital tabled a document 45 minutes before the start of the meeting entitled '*why data all ages 20210607*'.

The following observations were made on the basis of v0.4 of the application and relevant supporting documents.

IGARD Observations:

IGARD members noted that due to the nature of the meeting and when papers were disseminated, they had not conducted a full review of the application and supporting documents provided, noting that not all the supporting documents available had been provided for consideration. 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 reiterated their comments from the 25th May meeting and these were appended to these notes as 'appendix A'.

NHS Digital noted that since the previous discussion at the 25th May COVID-19 response meeting, the applicant had requested "all ages" – extending the cohort to under 16s. IGARD members noted that both the public and public health institutions were waiting for this type of research on children and young people, however, the applicant had not provided a robust justification for the inclusion of all those aged under 16 at this time given the limited numbers of vaccinations carried out in this age group (approximately 200 within the ORCHID cohort) and with the question mark over whether living arrangements would be able to be inferred from the data requested.

In addition, IGARD members suggested that the applicant should consider rewriting their protocol to align with the new proposed processing, noting the significant change to the study to include all ages, including children and young people under 16 years of age.

IGARD noted that if text was to be transferred from the document provided entitled *'why data all ages 20210607*', that a careful review be undertaken to ensure the points reflect the current situation. For example, bullet point 3 of the document does not reflect current facts: *'Vaccination age **may** be extended to children and young people age 12 to 15 years old with comorbidities"* (emphasis added), as vaccination has already been extended to a limited group of children in that age group with comorbidities.

NHS Digital noted that it would be AstraZeneca AB (based in Sweden) who would be the Data Controller, however IGARD Members noted reference to 'AstraZeneca UK Ltd' throughout the application and suggested that this was updated accordingly. It is also unclear if the Royal College of General Practitioners is a joint data controller.

IGARD Members noted that the applicant did not wish to share with NHS Digital the data processing agreements between AstraZeneca and University of Oxford, and University of Oxford and Momentum Data, however IGARD members noting that Momentum Data would be accessing data under honorary contracts, suggested that further discussions take place between NHS Digital and the applicant in order for NHS Digital to be assured appropriate arrangements are in place.

IGARD members queried, for the flow of GP data, if the applicant observed the Type 1 opt outs or had another process in place, since type 1 opt outs enabled patients to object to any confidential patient information about them being extracted from their GP records, and therefore this data would not flow to NHS Digital.

IGARD members noted reference in sections 3(a) and 3(b) to COPI and suggested that this be amended to reflect the correct legal basis since this was pseudonymised data.

IGARD noted the lack of transparency on the website. IGARD noted the Legitimate Interest Assessment (LIA) had been provided as part of the supporting documents and it had stated that they did not process personal data or process special category data, and since both these statements were at odds with the application, suggested that the LIA was updated accordingly.

As previously requested, IGARD suggested that section 5 should be updated to include an indicative cohort size, since the figure may be quite large.

IGARD members noted a Data Protection Impact Assessment was underway and applauded the applicant for carrying this out.

Finally, IGARD members suggested that the application be checked to ensure that it meets all current NHS Digital published DARS Standards.

IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the high profile and impactful nature of the application.

IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent and withdraw their previous support from the 25th May for this application to proceed under NHS Digital's SIRO Precedent.

Significant Risk Areas: IGARD members noted that all previously raised significant areas of risks and points were still live including: transparency; volume of GP data being used; and following today's meeting, extension of cohort to include children.