Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 4 March 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Prof. Nicola Fear	Specialist Academic Member
Kirsty Irvine (Chair)	IGARD Chair / Lay Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Dr. Imran Khan	Specialist GP Member
Dr. Maurice Smith	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Vicky Byrne-Watts	Data Access Request Service (DARS)
Dave Cronin	Data Access Request Service (DARS)
Catherine Day	Data Access Request Service (DARS)
Louise Dunn	Data Access Request Service (DARS)
Mujiba Ejaz	Data Access Request Service (DARS) (Observer: item 2.1)
James Gray	Data Access Request Service (DARS)
Richard Hatton	Clinical Informatics and Deputy Caldicott Guardian (Observer: item 1 - 2.4)
Karen Myers	IGARD Secretariat
Heather Pinches	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 on COVID-19.

	Nicola Fear noted a professional link to King's College London [NIC-188499-K4G0M] but noted no specific connection with the application or staff involved. It was agreed this did not preclude Nicola from taking part in the discussions about this application. **Review of previous minutes and actions:** The minutes of the 25th February 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	**Briefing Papers**
2.1	<u>COVID-19 Vaccination assets – Briefing Paper</u> The briefing paper was in respect of two COVID-19 products, 1) the COVID-19 Vaccination Status, and 2) the COVID-19 Vaccination Adverse Reactions. The vaccination status and adverse reactions data sets are collected from a variety of sources responsible for administering COVID-19 vaccinations. It is collected for the purposes of service monitoring, planning and research in response to the spread of the COVID-19 pandemic in the UK. The vaccination data sets have been introduced as a DARS asset with additional prioritisation due to the relevance of this data, to support the response to the COVID-19 pandemic. These data sets are collected and analysed as required by the Department of Health and Social Care, as what is required to support the COVID-19 Public Health Directions 2020, from the Secretary of State for Health and Social Care to NHS Digital. IGARD welcomed the briefing paper and made no further comments. IGARD looked forward to receiving the finalised briefing paper as a supporting document, alongside a first of type application.
3	**Data Applications**
3.1	<u>University of Bristol: University of Bristol - Longitudinal Linkage Collaboration (Consent) (Presenter: Louise Dunn) NIC-420168-K4N1F-v0.9</u> **Application:** This was a new application for a pseudonymised Hospital Episode Statistics to Mental Health Minimum Data Set Bridge File, Cancer Registration, Civil Registration, Community Service Data Set (CSDS), COVID-19 Hospitalization in England Surveillance System, COVID-19 UK Non-hospital Antibody Testing Results (Pillar 3), COVID-19 UK Non-hospital Antigen Testing Results (pillar 2), Demographics, Emergency Care Data Set (ECDS), Hospital Episode Statistics (HES), Improving Access to Psychological Therapies Data Set (IAPT), Medicines dispensed in Primary Care (NHS Business Services Authority data), Mental Health Minimum Data Set (MHMDS), Mental Health Services Data Set (MHSDS), Maternity Services Data Set (MSDS), Personal Social Services Adult Social Care Survey and Personal Social Services Survey of Adult Carers. The UK Chief Scientific Advisor has established a programme of National Core Studies (NCS) for COVID-19 research as a coordinated, long-term, national research initiative. This will consider COVID-19 in terms of a viral pandemic and in terms of the health and social impacts of behavioural restrictions designed to mitigate the harms of the pandemic. The NCS has six different sub-programmes which are addressing major COVID-19 research areas; the following

	of which will be linked to NHS Digital data within the UK LLC Trusted Research Environment (TRE): 1) The National Study of Health and Development (NSHD); which is owned by University College London, 2) The Southall And Brent REvisited (SABRE); which is owned by University College. NHS Digital advised IGARD that following discussions, and in agreement with the applicant, the data requested was deemed 'pseudonymised'. NHS Digital noted that due to time constraints, the application had **not** been reviewed by GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG), as per process when requesting GPES Data for Pandemic Planning and Research (GDPPR) data; and confirmed that the application would therefore be updated to remove all references to the GDPPR data, until the application had been reviewed / supported by PAG. NHS Digital advised that following a future PAG review, they would be happy to also return to IGARD for a further review of the application, should IGARD wish to see it. NHS Digital advised that in addition to this application, the applicant was intending to submit a further application to secure s251 support, and was currently working with HRA CAG on this. **Discussion:** IGARD noted that the application had previously been discussed at the IGARD meeting on the 4th February 2021, when NHS Digital had brought it for advice. IGARD noted that aspects of this application had last been seen by the IGARD – NHS Digital COVID-19 Response meeting on the 21st January 2021. IGARD noted the update from NHS Digital in respect of the data being classed as 'pseudonymised'. IGARD queried the conflicting information within the application, that suggested the data was deemed not personal, and supporting document 13.1, the data flow diagram, that showed separate flows of *"de-identified"* data and *"anonymous"* data indicating that they were not seen as pseudonymised. In addition, IGARD asked that the application was updated throughout, to reflect that the data was considered *"personal"* within the TRE; and to make any consequential amendments to any supporting documents that were being **relied** on for this application, to ensure they reflected that the data was *"personal"*. IGARD noted the update from NHS Digital, in respect of the application having not been review by PAG, and, in light of the GDPPR not relevant at the present time, asked that section 3(b) (Additional Data Access Requested) was updated to remove the reference to *"GDPPR"*. However, IGARD confirmed that they were supportive of the GDPPR data being re-included in the application as an amendment without further referral back to IGARD, subject to PAG being supportive of the inclusion, and if there were no conditions or amendments requested by PAG that would impact on this inclusion. IGARD asked that if PAG did raise concerns, the usual DARS process would be followed, for example, that the application would return to IGARD for a further review. IGARD queried the statement in supporting document 15, the fair processing briefing *"We note that some contributing studies have some information points that might be seen as incompatible. We commit to resolving these by providing clarifications where necessary and set a new clear expectation, rather than providing detail about specific communications".* IGARD asked that in respect of assessing that the consent taken from the cohorts was a sound legal gateway in terms of compatibility with the processing of the data in the TRE, suggested that a small representative sample of the two cohorts were approached and the relevant wording in the consent highlighted to them and the proposed new processing explained. IGARD asked that if the sample of cohort members **was content** with the proposed processing, that this be confirmed in writing to NHS Digital, and a copy uploaded to NHS

	Digital's customer relationships management (CRM) system for future reference; or if the cohort representatives **were surprised** by the proposed processing, then the applicant would need to address this potential incompatibility with additional measures or an alternative legal gateway. Overall, IGARD were content that the consent was broadly compatible with the processing outlined in the application as the legal gateway, subject to the above proposal to speak to a representative sample of the cohorts. IGARD noted the helpful explanation of the role of the University of Edinburgh in section 1 (Abstract), and asked that for transparency, the public facing section 5 (Purpose / Methods / Outputs) was updated to also include this information. IGARD queried the information in section 3(c) (Patient Objections) that stated *"Data will be processed in line with the reasonable expectations of the data subjects."*, and asked that this was updated to include the standard *"informed consent"* wording. IGARD queried the references in section 5(a) (Objective for Processing) to *"breach of confidentiality"*, and noting that the data flowing was relying on consent as a legal gateway, asked that the references were removed as they were not relevant. IGARD suggested that section 5(d) (Benefits) be updated to remove reference to "*it will*…" and instead use a form of words such as "*it is hoped*…" IGARD queried the references in section 1 to *"ensured"*, for example, *"The applicant has ensured…"*; and asked that this was updated to correctly refer to *"assured"*, if relevant. **Outcome:** recommendation to approve subject to the following condition: 1. In respect of assessing that the consent taken from the cohorts was a sound legal gateway in terms of compatibility with the processing of the data in the TRE, IGARD suggested that a small representative sample of the two cohorts were approached and the relevant wording in the consent highlighted to them and the proposed new processing explained: a) If the sample cohort **is content** with the proposed processing, that this be confirmed in writing to NHS Digital, and a copy uploaded to NHS Digital's CRM system; or b) If the cohort representatives **are surprised** by the proposed processing, then the applicant would need to address this potential incompatibility with additional measures or an alternative legal gateway. The following amendments were requested: 1. In respect of the data requested: a) To update the application throughout to reflect that the data is considered *"personal"* within the TRE. b) To make any consequential amendments to any supporting documents that are being **relied** on for this application, to ensure they reflect that the data is *"personal"*. 2. To update section 5 to include the helpful explanation of the role of the University of Edinburgh as outlined in section 1. 3. To amend section 3(c) to include the standard *"informed consent"* wording. 4. To remove the reference(s) to *"breach of confidentiality"* in section 5(a) as this is not relevant. 5. To update section 5(d) to use a form of wording such as "*it is hoped* …", rather than "*it will…*" 6. To remove the reference to *"GDPPR"* data in section 3(b).

	7. To update section 1 to amend the reference from *"ensured"* to *"assured"* where appropriate. The following advice was given: 1. IGARD were supportive of the GDPPR data being re-included in the application as an amendment without further referral back to IGARD, subject to PAG being supportive of the inclusion (and if there were no conditions or amendments requested by PAG that would impact on this inclusion). If PAG did raise concerns, the usual DARS process would be followed. It was agreed the condition would be approved out of committee (OOC) by the IGARD Chair.
3.2	<u>Imperial College London: patient choices and provider quality, why patients change GPs (Presenter: Louise Dunn) NIC-218380-R8L2R-v0.17</u> **Application:** This was a new application for pseudonymised record level extract of England patients listed in the Personal Demographics Service (PDS) dataset data over a 5-year period (2015/16 to 2019/20) to try to understand why an individual moves their GP practice. The research team, based in the Economics and Public Policy Department within the Business School at Imperial College, are requesting data as part of a wider programme of research investigating patient choices over GP providers and the project is looking specifically at how patients choose their GP, and when and why they switch their GP over time, in order to try to understand the factors involved with a change of GP. The application was previously considered on the 3rd December 2020 when IGARD had been unable to recommend: NHS Digital to liaise further with internal colleagues to ascertain if this is a project they would like to actively support. If NHS Digital support the application, IGARD would be happy to support the project, be it working directly with the applicant and NHS Digital to refine the application to meet NHS Digital DARS Standards, or supporting an internal project by the use of an honorary contract. To update the source(s) of funding in section 8b. To update the study protocol to provide further meaningful information and background to the study as outlined in the application. To provide further clarity on the references to *"English patients"* throughout the application and what is meant by this term. NHS Digital advised IGARD that following the last review of the application, further discussions had been held internally with NHS Digital colleagues, who had confirmed that they were broadly supportive of the application. NHS Digital noted that as per IGARD's previous advice, the applicant had updated the study protocol to provide further meaningful information and background to the study. **Discussion:** IGARD noted the updates from NHS Digital, in respect of the broad support of the application by NHS Digital; and the updates to the study protocol by the applicant, following the last review of the application by IGARD. IGARD advised NHS Digital that a full review of the application would not be undertaken within the meeting, due to the issues and concerns about the application that had previously been raised, for example, in respect of potential risks to NHS Digital's reputation; and the misleading and / or incorrect information stated within the application about the online GP rating system. IGARD did however note that, based on the evidence presented, they did **not** identify any problems with the legal basis or any other data protection issues.

	IGARD noted the extensive updates made to the study protocol, and specifically highlighted that parts of the protocol provided more transparency than the information contained within the application, in terms of the study rationale and the objectives. IGARD were therefore unable to recommend the application for approval, on the grounds of the potential reputational risk to NHS Digital of being associated with this research as currently summarised in section 5 (Purpose / Methods / Outputs), which formed the basis of NHS Digital's Data Release Register. Notwithstanding this, IGARD advised that NHS Digital may choose to flow the data, and reiterated the point that IGARD did not identify any problems with the legal basis or any other data protection problems. If NHS Digital did choose to flow the data, IGARD suggested replacing the current section 5(a) (Objective for Processing) with sections 1, 2 and 3 of the protocol provided as a supporting document. **Outcome:** Unable to recommend for approval 1. IGARD were unable to recommend for approval, on the grounds of the potential reputational risk to NHS Digital of being associated with this research as currently summarised in section 5, which forms the basis of NHS Digital's Data Release Register. Notwithstanding this, NHS Digital may choose to flow the data, (noting that IGARD did not identify any problems with the legal basis or any other data protection problems), and if NHS Digital did choose to do so, IGARD would suggest replacing the current section 5(a) with sections 1, 2 and 3 of the protocol provided as a supporting document.
3.3	<u>Nuffield Department of Primary Health Sciences: Establishing predictors of long-term health outcomes in the NewKI CKD cohort (Presenter: Vicky Byrne-Watts) NIC-384326-R9V7S-v0.8</u> **Application:** This was a new application for pseudonymised Civil Registration (deaths) data and pseudonymised Hospital Episodes Statistics (HES) data; for the purpose of a longitudinal observational study, seeking to establish predictors of long-term health outcomes in the New Onset Kidney Impairment Study (NewKI) Chronic Kidney Disease (CKD) cohort. The aim of this study is to identify predictors of adverse health outcomes in an older primary care population with chronic kidney disease or transiently impaired renal function; the aim is to identify which people with CKD are most likely to develop health problems, to help to plan preventive treatments, were admitted to hospital or died. This study is a subsidiary of, and follows on from, the Oxford Renal Longitudinal cohort study (OxRen) which commenced in 2013 and closed in 2017 and recruited 3,200 primary care participants aged 60 years and older from 13 GP practices across the Thames Valley region. NHS Digital advised IGARD that section 5(c) (Specific Outputs Expected) contained information in respect of the funders having *"expectations"* for data sharing, and confirmed that any data shared would be aggregated with small numbers supressed, and that data would not be shared with the funder. **Discussion:** IGARD welcomed the application and noted the importance of the study and commended both the applicant and NHS Digital on the quality of the application presented. IGARD noted the update from NHS Digital in respect of the statement in relation to the funders expectations for data sharing; and supported the update to section 5(c) to reflect that any NHS Digital data shared would be aggregated with small numbers supressed, and that data would **not** be shared with the funder. IGARD thanked NHS Digital for providing the consent review form as a supporting document, that formed part of the review for this application; and confirmed that they were of the view that

	the consent provided the appropriate legal gateway and was compatible with the processing outlined in the application. IGARD noted and commended the applicant in offering the results of the study to cohort members, as outlined within the consent materials provided and noted the positive patient and public involvement (PPI) involvement, for example, within the study protocol, and asked that section 5(c) was updated to include further details of the PPI involvement. IGARD noted that section 2(b) (Storage Location(s)) only listed one storage location, and queried if this was correct, for example, was the data being backed-up to a different storage location, since other University of Oxford applications had this facility; and asked that clarification was provided if there were any additional storage locations and to amend section 2(b) if appropriate. IGARD queried the information in section 3(c) (Patient Objections) that stated *"Data will be processed in line with the reasonable expectations of the data subjects"*, and asked that this was updated to include the standard *"informed consent"* wording. IGARD queried the inconsistent cohort numbers quoted throughout the application, for example, 902 versus 861, and asked that the application was updated to align the correct cohort numbers accurately and consistently; and that if the differing cohort numbers stated were correct, to update section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) to provide a further explanation of the difference between the cohort numbers. IGARD also noted the reference to *"approximate"* when referring to the cohort numbers, and asked that this was removed, unless the cohort numbers were subject to further changes, in which case, this should be made clear. IGARD queried the reference within the application to managing *"patients"* and asked that this was amended to refer to managing the *"conditions"*. IGARD noted the references within the application to *"trial"* and noting that the evidence presented appeared to confirm that it was in fact a *"study"*, asked that the application was updated throughout to reflect that it was a study (if that accurately reflected the factual scenario). IGARD noted and wished to draw to the attention of the applicant, in respect of future studies only, that supporting document 3.2, the participant information booklet (version 2.0), and supporting document 3.4, the participant information booklet (version 3.0) referred to the data **only** being used for this study, however elsewhere it was indicated that the data may be used for future studies. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 5(c) to reflect that any NHS Digital data being shared will be aggregated with small numbers supressed. 2. To amend section 2(b) to add any additional storage locations, for example back-up or disaster recovery. 3. To amend section 3(c) to include the standard *"informed consent"* wording. 4. In respect of the cohort numbers: a) To ensure the correct cohort numbers are accurately and consistently aligned throughout the application, for example, 902 vs 861. b) If the differing cohort numbers stated are correct, to update section 1 and section 5 to provide a further explanation of the difference between the cohort numbers.

	c) To remove the reference to *"approximate"* when referring to the cohort numbers, unless they are subject to further changes. 5. To update section 5(d) to ensure any references to managing *"patients"* is amended to managing the *"condition"*. 6. To update the end of section 5(c) to include further details of the positive PPI involvement. 7. To update the application throughout to amend the reference from *"trial"* to *"study"* (if that accurately reflects the factual scenario). The following advice was given: 1. IGARD noted and wished to draw to the attention of the applicant (re future studies, not the application at hand), that SD 3.2 and SD 3.4 referred to the data **only** being used for this study, however elsewhere it was indicated that the data may be used for future studies.
3.4	<u>University of Nottingham: Aspirin To Target Arterial Events in Chronic Kidney Disease (ATTACK) (Presenter: James Gray) NIC-327369-T1M7M-v0.14</u> **Application:** This was a new application for identifiable Hospital Episodes Statistics Admitted Patient Care (HES APC), Civil Registration (deaths) data, Cancer Registration data, and Emergency Care Data Set (ECDS); which will then be linked to a randomised cohort of 25,210 cohort members, taken from the ATTACK study database. The purpose of the trial, which commenced on 1st January 2018 and is due to finish in July 2025 is aiming to demonstrate whether the addition of low-dose (75mg non-enteric coated) aspirin to usual care, reduces the risk of major vascular events (excluding confirmed intracranial haemorrhage) in people with Chronic kidney disease (CKD), who do not have pre-existing cardiovascular disease (CVD), and whether, and to what extent the benefits outweigh any harms due to an increased risk of bleeding. **Discussion:** IGARD confirmed that they were of the view, that the consent provided the appropriate legal gateway and was compatible with the processing outlined in the application. An IGARD clinician noted the incorrect statement in section 5(a) (Objective for Processing) *"Aspirin thins the blood so reduces the chance that clots will form…"*, and asked that this was updated to accurately reflect that aspirin reduced the risk of blood clots and does **not** thin blood. IGARD queried the statement in section 5(a) that potential eligible adults, would be "*identified from GP records"* wand invited to participate in the study, and asked that for transparency, this was updated to clarify that the GP data referenced was **not** flowing from NHS Digital. IGARD noted the references in section 5(a) to *"authorised individuals"* and *regulatory authorities*", when referring to permissions given in respect of accessing data, and asked that those references were removed, as they were not necessary, in support of the processing outlined in the application. IGARD noted the reference in section 5(b) (Processing Activities) to the data flowing on patients from the date of their consent, and asked that the application was updated throughout to reflect when the data was actually flowing, for example, a set timeframe or date range rather than individual flows from each individual date of consent.

	IGARD noted and commended the approach by the applicant, as outlined in section 5(d) (Benefits), to look at both the use **or** avoidance of aspirin for the primary prevention of CVD in CKD. IGARD noted that one of the Data Processors was hosted by Sherwood Forrest NHS Trust, and suggested that consideration should be given as to whether they should be listed as the Data Processor as the host trust and legal entity, instead of Health Informatics, noting that Health Informatics did have their own submitted Data Security and Protection Toolkit (DSPT). IGARD commended the applicant with regard to the outputs outlined in section 5(c) (Specific Outputs Expected) and the statistical power used in calculating their figures to know when to stop. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 5(a) to accurately reflect that aspirin reduces the risk of blood clots and does **not** thin blood. 2. To clarify in section 5(a) that the GP data referenced in this study is **not** flowing from NHS Digital. 3. To remove the references to *"authorised individuals"* and "*regulatory authorities*" in section 5(a) as the reference is not necessary in support of the processing outlined in the application. 4. To update the application throughout to reflect when the data is actually flowing, for example, a set timeframe or date range rather than individual flows from each individual date of consent.
3.5	University College London (UCL): NIHR Children and Families Policy Research Unit (Presenter: Catherine Day) NIC-393510-D6H1D-v6.9 **Application:** This was an amendment application to 1) increase the frequency of the Hospital Episodes Statistics (HES) data from annual to quarterly; 2) to include the additional datasets; Community Services Dataset (CSDS), Maternity Services Dataset (MSDS), Mental Health Services Dataset (MHSDS) (and predecessors), Civil Registrations (Births) data, Second Generation Surveillance System (SGSS) and, National Pathology Exchange (NPeX) (Pillar 2); 3) to replace the HES Accident and Emergency data with Emergency Care Data Set (ECDS). As a response to COVID-19, UCL, the applicant, has added an additional objective to examine the risk of confirmed COVID-19 infection according to demographic, clinical and ethnic risk groups in children and young people under the age of 25. The purpose is for a programme of research to determine variation in use of secondary care services by children and young people over time and their transition to adult services; to determine risk factors for emergency use of secondary care and risk factors for recurrent use; and to conduct prognostic analyses for children and young people based on diagnosis and procedure codes to identify risk factors for emergency hospital care and for subsequent long-term adverse outcomes into adulthood. **Discussion:** IGARD noted that Civil Registration (death) data had been requested, and highlighted that where this specific data was flowing, that NHS Digital would review on a case-by-case basis, to determine if there was an increased risk of identification. IGARD agreed that, in this particular case, there was less risk due to NHS Digital undertaking the linkage. IGARD asked that section 1 (Abstract) was updated confirming that the flow of date of death data was

	in line with NHS Digital's policy assessment and would not increase the likelihood of re-identification of data subjects. IGARD noted the information within the data minimisation columns for all data requested in section 3(b) (Additional Data Access Requested) where it stated *"records will be limited to people under the age of 56",* in light of the data flows requested and the new processing aim of looking at COVID-19 data **specifically relating to children and young people under 25**, IGARD asked that the COVID-19 data was minimised to citizens aged 25 and under; or otherwise, to provide a further explanation for the discrepancy between the target study age, which was under 25, and the data range in the data minimisation column in table 3b, which was under 56. In addition, in respect of other non-COVID datasets, to provide a clear explanation in section 5 (Purpose / Methods / Outputs) of the rationale for the upper age limit of 56, as this was not clear within the application. IGARD queried the reference in section 5(a) (Objective for Processing) to *"shielding status"*, and noting that it was unclear who this was referring to, asked that confirmation was provided, for example, was it in relation to the child, the mother or family members. IGARD also asked that further clarity was provided as to where the shielding status data was being obtained from, noting that it is not available in the data sets and fields requested; and that if the shielding status was being obtained from another source, to clarify the source, the legal basis for such use envisaged by this application, and to provide a relevant justification. IGARD noted that the references to *"pillar 2"* data were inconsistent, for example *"NPeX (pillar 2)"*; and asked that the application was updated throughout, to ensure the references to *"pillar 2"* were correct, consistent and align with the terminology outlined in section 3 *"Covid-19 UK Non-hospital Antigen Testing Results (pillar 2)"* (Datasets Held . Requested). IGARD noted that section 5 was mainly silent on the patient and public involvement (PPI), and asked that for transparency, section 5 as updated to provide further examples of the PPI. In addition, IGARD noted that the outputs would be mainly disseminated to policy and academic targets, and asked that section 5(c) (Specific Outputs Expected) was updated to provide further details of how the outputs will be accessible to a wider audience beyond those policy and academic targets. IGARD noted that the privacy notice was available under the 'Child Health Informatics Group' page, and suggested that this was **also** made available on the Children and Families Policy Unit' page on the website. IGARD also noted the reference to the data subjects contacting NHS Digital if they did not want their data to be used as outlined, and suggested that this was removed, as the National Data Opt-out (NDO) would **not** impact on the flow of pseudonymised data. In addition, IGARD noted that technically the data subject would be able to provide further information in order to de-pseudonymise themselves, in order to have their data removed; and suggested that the applicant most likely did not want to provide this service, but if they did, then data subjects should be referred to the Data Controller and **not** NHS Digital. IGARD noted that there would be no automatic flow of NHS Digital data from this application to the other linked applications and should any of the other linked applications wish to utilise the data under this application, those other linked applications would need to be amended as per the usual process. IGARD noted that the yielded benefits stated, appeared to be more outputs than actual yielded benefits, and that given the number of years the applicant has held the data, **and** the quantum

	of data they had received, IGARD advised that they would expect detailed yielded benefits, to be set out in section 5(d) (Benefits), since this is essential for NHS Digital to demonstrate its legal basis to flow the data. In addition, IGARD advised that the yielded benefits should comply with various relevant policies, including, but not limited to, NHS Digital's DARS Standard for Benefits. Accordingly, on return, IGARD would expect to see further details in section 5(d) as to the benefits expected and accrued to patients and/or the health and social care system more generally; or to provide a brief explanation as to why there were no yielded benefits to date. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment; to review the yielded benefits, what has been done with the data, and how it has impacted on the patient experience due to the quantum of data provided. IGARD advised that this application would **not** be suitable for NHS Digital's Precedent route, including the SIRO Precedent. **Outcome:** recommendation to approve The following amendments were requested: 1. NHS Digital to confirm in section 1 that the flow of date of death data is in line with NHS Digital's policy assessment and will not increase the likelihood of re-identification of data subjects. 2. In respect of the cohort age limits and data minimisation: a) Noting the new data flows and new processing aim of looking at COVID-19 data relating to children and young people under 25, to minimise the COVID-19 data to citizens aged 25 and under, or otherwise provide a further explanation for the discrepancy between the target study age (under 25) and the data range in the data minimisation column in table 3b (under 56). b) In respect of other non-COVID datasets, to provide a clear explanation in section 5 of the rationale for the upper age limit of 56. 3. In respect of the reference to *"shielding status"* in section 5(a): a) To confirm who the shielding status relates to, for example, the child, mother or family members. b) To provide clarity as to where the shielding status data is being obtained from (noting that it is not available in the data sets and fields requested). c) If the shielding status is being obtained from another source, to clarify the source, the legal basis for such use envisaged by this application, and to provide a relevant justification. 4. To amend the application throughout to ensure the references to *"pillar 2"* are correct, consistent and align with the terminology outlined in section 3. 5. In respect of PPI and dissemination to the general public: a) To provide further examples in section 5 of the PPI. b) To update section 5(c) as to how the outputs will be accessible to a wider audience beyond policy and academic targets. The following advice was given: 1. In respect of the privacy notice:

	a) IGARD noted that the privacy notice is available under the 'Child Health Informatics Group' page, and suggested that this was **also** made available on the Children and Families Policy Unit' page on the website. b) IGARD noted the reference to the data subjects contacting NHS Digital if they do not want their data to be used as outlined, and suggested that this was removed, as the NDO would **not** impact on the flow of pseudonymised data. c) IGARD noted that technically the data subject would be able to provide further information in order to de-pseudonymise themselves, in order to have their data removed; and suggested that the applicant most likely did not want to provide this service, but if they did, then data subjects should be referred to the Data Controller and not NHS Digital. 2. IGARD noted that there would be no automatic flow of data from this application to the other linked applications and should any of the other linked applications wish to utilise the data under this application, those other linked applications would need to be amended. 3. In respect of the stated expected benefits and yielded benefits: a) Given the number of years the applicant has held the data, and the quantum of data they have received, IGARD would expect detailed yielded benefits, to be set out in section 5(d), since this is essential for NHS Digital to demonstrate its legal basis to flow the data. b) In addition, the yielded benefits should comply with various relevant policies, including (but not limited to) NHS Digital's DARS Standard for Benefits. c) Accordingly, on return, IGARD would expect to see further details in section 5(d) as to the benefits expected and accrued to patients and/or the health and social care system more generally; or to provide a brief explanation as to why there are no yielded benefits to date. 4. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, to review the yielded benefits, what has been done with the data, and how it has impacted on the patient experience due to the quantum of data provided. 5. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent.
3.6	<u>London School of Hygiene and Tropical Medicine: Using medical-detection dogs to identify people with SARS-CoV-2. Phase I-III studies. Application for participant results details. (Presenter: Catherine Day) NIC-426830-M1C1K-v0.2</u> **Application:** This was a new application for pseudonymised COVID-19 UK Non-hospital Antigen Testing Results (pillar 2); for the purpose of a study, that will assess the sensitivity and specificity of medical detection dogs in identifying COVID-19. Following the changing path of the epidemic in the UK, the Department of Health and Social Care (DHSC) has made a request for evidence that 1) the medical detection dogs can detect COVID-19 in people with new viral strains, and 2) the dogs can detect COVID-19 in people with low viral loads, and asymptomatic individuals. Recruitment to the study of approximately 800 study participants was conducted between August 2020 and January 2021 who sought a COVID-19 test for reasons of symptoms or probable disease exposure, and who provided informed consent to participate in the trial, and are aged 16 years or older and provided odour samples to the trial. At 30 days participant involvement in the study ends.

	The success of this study would aid in preventing future outbreaks of the virus, as the medical detection dogs could provide a high-throughput screening tool in key public risk areas such as airports. NHS Digital advised IGARD that following previous IGARD advice, a newsletter was in the process of being sent out to participants, where they were also given the option of withdrawing consent from the study; and that to date, there had been no requests to withdraw. **Discussion:** IGARD noted that aspects of this application had been seen by the IGARD – NHS Digital COVID-19 Response meeting on the 19th January 2021. IGARD confirmed that they were of the view that the consent provided the appropriate legal gateway and was compatible with the processing outlined in the application; and noting the update from NHS Digital in respect of the newsletter, supported the continued distribution to participants. IGARD noted the reference within the study protocol and newsletter to *"ARCTEC"*, and asked that section 5 (Purpose / Methods / Outputs) was updated to outline the role of ARCTEC, noting that it was silent on this. In addition, IGARD also asked that if the facts supported ARCTEC being considered a joint Data Controller or Data Processor, that the application was updated throughout to reflect this. IGARD noted that the references to *"pillar 2"* data were inconsistent, and asked that the application was updated throughout, to ensure the references to *"pillar 2"* were correct, consistent and align with the terminology outlined in section 3 *"Covid-19 UK Non-hospital Antigen Testing Results (pillar 2)"* (Datasets Held / Requested); and in addition that the reference to *"NHS Digital DARS Pillar 2 Dataset"* was removed from section 5(a) (Objective for Processing) and section 5(b) (Processing Activities) as it was incorrect. IGARD queried the statement in section 5(c) (Specific Outputs Expected) that *"…anonymised study data may be published in a data repository."*, and asked that further clarity was provided in respect of the data repository, and if the data would be *"published"*, as the application would only permit publication of aggregated data with small numbers suppressed. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of ARCTEC: a) To update section 5 to outline the role of ARCTEC (as referred to in the newsletter and protocol). b) If the facts support ARCTEC being considered a joint Data Controller or Data Processor, to update the application throughout to reflect this. 2. In respect of the pillar 2 dataset: a) To amend the application throughout to ensure the references to *"pillar 2"* are correct, consistent and align with the terminology outlined in section 3. b) To remove the reference in section 5(a) and section 5(b) to ***"DARS"*** pillar 2. 3. To provide further clarity in respect of the data repository, if the data will be published, as the application would only permit publication of aggregated data with small numbers suppressed.
4	<u>Returning Applications</u>

	IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. • NIC-148437-C9YSC-v4.6 University of Leicester • NIC-158754-R5T3V-v3.4 The Brain Tumour Charity • NIC-147834-LHQ2R-v5.2 Nuvia Ltd • NIC-206314-N1N7K-v1.2 University of Manchester • NIC-188499-K4G0M-v1.7 King's College London IGARD welcomed the five applications as part of their oversight and assurance role and noted a number of comments to NHS Digital and suggested that further information and comments be provided in an IGARD Oversight and Assurance Report. Moving forward, IGARD agreed that COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 applications may also be included as part of the oversight and assurance review, not just those that were approved via NHS Digital's precedent route.
5.1	<u>COVID-19 update</u> To support NHS Digital's response to COVID-19, from Tuesday 21st April 2020, IGARD will hold a separate weekly meeting, to discuss COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 urgent applications that have been submitted to NHS Digital. Although this is separate to the Thursday IGARD meetings, to ensure transparency of process, a meeting summary of the Tuesday meeting will be captured as part of IGARD's minutes each Thursday and published via the NHS Digital website as per usual process. The ratified action notes from **Tuesday 2nd March 2021** can be found attached to these minutes as Appendix B.
5.2	<u>NIC-381634-X8H0H-v1.2 Public Health England (PHE) (Presenters: Heather Pinches / James Gray)</u> **Background:** This was an amendment application to receive COVID-19 Hospitalisation in England Surveillance System (CHSS), COVID-19 Second General Surveillance System (SGSS), COVID-19 Vaccination Status, Personal Demographics Service and Secondary Uses Service Payments by Results Episodes (SUS PbR) data and a renewal application until the 30th September 2021 to receive this data and in line with the current COPI expiry date. IGARD had previously discussed at the COVID-19 response meetings on the 5th May, 12th May and 2nd June application NIC-372789-B6Q2B PHE. The purpose of this application is to support PHE surveillance system on household transmission of COVID-19 to enhance the national public surveillance of COVID-19 infections in the population of England. The following observations were based on v1.2 of the application and relevant supporting documents. **IGARD Observations:** IGARD members noted that the application had been updated in line with all previous comments made at the COVID-19 response meetings with regard to NIC-372789-B6Q2B PHE

	IGARD gave a positive statement of support and noting the urgency of the application noted that the application would be progressing under SIRO precedent. IGARD had no further observations on the application or supporting documentation, noting that due to the nature of this session and when papers were received, they had not conducted a full review of the documentation provided. Should a full review of the application and documentation be required, the full suite of documentation should be presented to the IGARD business as usual meeting for a recommendation.
6	<u>AOB:</u> There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 26/02/21

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

NIC Reference	Applicant	IGARD meeting date	Recommendation conditions as set at IGARD meeting	IGARD minutes stated that conditions should be agreed by:	Conditions agreed as being met in the updated application by:	Notes of out of committee review (inc. any changes)
None						

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

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

- None

Optum Health Solutions UK Limited Class Actions:

- None

Appendix B

Independent Group Advising on the Release of Data (IGARD)

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

held via videoconference, Tuesday, 2nd March 2021

In attendance (IGARD Members):	Kirsty Irvine (IGARD Lay Chair)
	Dr. Imran Khan (IGARD Specialist GP Member)
	Dr. Geoff Schrecker (IGARD Specialist GP Member)
In attendance (NHS Digital):	Louise Dunn (DARS)
	James Gray (DARS)
	Karen Myers (IGARD Secretariat)
	Vicki Williams (IGARD Secretariat)

1	**Welcome** The IGARD Chair noted that this was a weekly meeting convened to support NHS Digital's response to the COVID-19 situation and was separate from the IGARD business as usual (BAU) meetings. IGARD members present would only be making comments and observations on any items that were presented, and were not making formal recommendations to NHS Digital. Should an application require a full review and recommendation, then it should go through the usual Data Access Request Service (DARS) process and be presented at a Thursday IGARD meeting. The action notes from the Tuesday meeting would be received at the next Thursday meeting of IGARD and published as part of those minutes as an appendix. **Declaration of interests:** There were no declarations of interest.
2.1	NIC-420105-M8Y5X-v1.1 Novavax Inc **Background:** This was v1.1 application and v 4.1.0 Main Participant Information Sheet (PIS) and Consent Form UK following a verbal briefing at the COVID-19 response meeting on the 8th December 2020. Since the verbal update to IGARD on the 8th December 2020, the application had been updated to include changes to the proposed processing activities and inclusion of a special condition that a Legitimate Interest Assessment (LIA) would be completed within two weeks of the data sharing agreement (DSA) being signed – this special condition had been completed and the special condition removed. IGARD members noted the update. The amendment to the current application v1.1 was to include a regular flow of one extra item 'Specimen Processed Data' into NHS Digital from PPD Global Ltd (Data Processor), with matching undertaken by NHS Digital; and, to regularly flow one extra data item 'Specimen Processed Date' in addition to those already being provided, with additional detail added in sections 3(b) and 5(b).

	Novavax are conducting a Phase 3 clinical trial of SARS-CoV-2 recombinant spike protein nanoparticle vaccine (SARS-CoV-2 rS) with Matrix-M1Tm Adjuvant with the primary objective to demonstrate the efficacy of SARS-CoV-2 rS with Matrix-M1 adjuvant in the prevention of virologically confirmed (by PCR) symptomatic COVID-19, when given as a 2-dose vaccination regimen as compared to a placebo, in serological negative (to SARS-CoV-2) adult participants. The trial originally recruited its cohort of 15,000 members through NHS Digital's Permission to Contact service The following observations were made on v1.1 of application and v4.1.0 of the PIS and consent form UK **IGARD Observations:** IGARD members noted that section 1 of the application should be updated to be clear that on the 8th December 2020, IGARD did **not** review this or any previous iteration of the application and that the briefing had been verbal. IGARD noted that this was the first time they had seen the application and consent materials and that due to the nature of the meeting and when papers were disseminated, they had not conducted a full review of the two documents provided. 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 meeting for a recommendation. IGARD members noted reference to "*NIC-411171*" within section 5 of the application and suggested that this was checked to reference the full NIC reference, for transparency since this section formed part of NHS Digital's data release register. NHS Digital noted that the applicant wished to reconsent the 15,000 participants on the trial, noting that they were presently relying on the Health Services Control of Patient Information (COPI) Regulation 2002 and that the COPI Notice was in place until the 30th September 2021. IGARD were unclear why the applicant would wish to move to the reconsent model whilst COPI was still in place and since it was still unclear at this early stage whether COPI would be extended further, noting that the trial would end on the 31st January 2022. IGARD suggested that further discussions be undertaken with the applicant with regard to Health Research Authority Confidentiality Advisory Group (HRA CAG) s251 support, since them being a US based organisation did not necessarily preclude them from applying for s251 in respect of confidential information pertaining to English patients. In addition, and noting that the future of COPI had not been outlined by the UK Government, IGARD suggested that the applicant may wish to wait to reconsent, alongside other applicants who were also relying on COPI as their legal basis, as to the decision that may come as to whether COPI would be extended beyond the end of September 2021. In addition IGARD members suggested that NHS Digital discuss this application with the Caldicott Guardian, as there may be other avenues to explore, other than consent and s251 support. IGARD members noted that should the applicant now wish to store blood samples, for example, that reconsenting would certainly be required. However, without knowing the other changes to the study protocol, it was difficult to opine on whether consenting was necessary in this instance. If the reconsenting was *only* to facilitate NHS Digital handling confidential patient information, then IGARD would urge an alternative approach to minimise loss of cohort members.

	Notwithstanding these queries, IGARD members noted the update from NHS Digital that the applicant thought that reconsenting was the best option. Consent material review comments including, but not limited to: • IGARD members were unclear what changes had been made to this version, since it was standard practice for any amendments to be noted at the start of a reconsenting document for example the inclusion of reference to NHS Digital, how the consent document had changed since the signing of the previous iteration etc. • IGARD members noted that the first paragraph of v4.1.0 stated "*you are being asked to consider whether you would like to participate in a clinical trial study*…" and suggested the language be updated appropriately to reflect a reconsent process. • IGARD members noted reference to the participant being able to withdraw from the study, however there were no explicit details in v4.1.0 of ***how*** the participant could withdraw such as a telephone number, email address or postal address. • IGARD members noted that NHS Digital had been referred to in v4.1.0 as a "*vendor*", noting that the Oxford English Dictionary definition of "*vendor*" was "*a person or company offering something for sale…*" suggested this was a Americanism, but should be updated to accurately reflect NHS Digital did not sell data and clearly detail the role they were undertaking in this important clinical trial including, but not limited to, their role, the data flowing to and from NHS Digital and any data linkages being undertaken by NHS Digital etc. • IGARD members queried reference within v4.1.0 to "*the Public Health of England (PHE)*" and if this was the health body Public Health England (PHE) or just the public health of England in general. • IGARD reiterated their previous comment that the applicant take the opportunity to inform the cohort of any possible long term follow up and any possible linkage to health data held by NHS Digital (since there appeared to be none outlined) • While amendments were required throughout the document, the key pages were the "consent form" at the back of v4.1.0 which contained tick boxes for the participant to acknowledge. NHS Digital's involvement – both current and potential in the future – should be clearly articulated here. IGARD members noted that on balance anyone consented on v4.1.0 was not incompatible with the flow of confidential data as there is no express bar with sharing the data, and NHS Digital are mentioned in the document, however further transparency materials should be provided to all those consented on this v4.1.0 to update on points outlined above. In addition to the above comments relating to the compatibility of the materials with the common law duty of confidentiality (the legal gateway for NHS Digital to handle the data), there were additional reviews that should take place to ensure compliance with UK General Data Protection Regulations (UK GDPR) /Data Protection Act 2018 – in particular, appropriate transparency about the handling and use of data – and any additional relevant UK legislation relating to clinical trials. IGARD members suggested that a verbal update be given at next week's COVID-19 response meeting with progress to date in order for IGARD to give support to both NHS Digital and the applicant.

	Significant area(s) of risk: loss of a statistically significant proportion of the cohort due to reconsenting; particularly if reconsenting is not necessary due to other available avenues. **Subsequent to the meeting:** The IGARD Chair raised the query if PPD Global Ltd should be noted as a Data Processor in the DARS application or was their handling of data separate from the handling of NHS Digital data? Notwithstanding this, "PPD" should be referred to by its full legal name on first use in the public facing section of the application and its involvement in the processing should be clearly articulated in the DARS application.
2.2	NIC-433176-J8Q2S-v1.1 AstraZeneca UK Ltd **Background:** This was a business as usual discussion with regard to v2 of the Study Information and Informed Consent Form and DAPA MI data flow diagram (unknown version number). This was a registry based randomised double-blinded placebo-controlled cardiovascular outcomes trial to evaluate the effect of Dapagliflozin on the incidence of heath failure or cardiovascular death in patients without diabetes with acute myocardial infarction at increased risk for subsequent development of heart failure. Dapagliflozin is a drug that was originally developed for the treatment of type 2 diabetes. The following observations were made on v2 of the Study Information and Informed Consent Form and DAPA MI data flow diagram only. **IGARD Observations:** NHS Digital noted that the data flow diagram provided did not include reference to AstraZeneca or the flow of data back to NHS Digital. IGARD members noted that without the application, the study protocol and proposed processing outlined therein, it was not possible to ascertain whether the consent materials provided were compatible or incompatible with the processing being undertaken. In addition, IGARD noted that this was the first time they had seen the consent document and that due to the nature of the meeting and when papers were disseminated, they had not conducted a full review of the two documents provided. 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 meeting for a recommendation or advice. NHS Digital confirmed that although v2 had been presented to the Research Ethics Committee in July 2020, they had not commenced recruitment on v2 of the consent materials. Consent material review comments including, but not limited to: • IGARD members noted that it was unclear in the documentation what the role of NHS Digital was with regard to what they were undertaking, which should be clearly outlined, including but not limited to, what they were doing, the data flowing, and any data linkages etc. • IGARD Members suggested that the applicant may wish to consult the terminology used on the Understanding Patient Data website in order to describe the categories of data handled by the researcher. • IGARD members noted the tick boxes on page 17 of v2 (Part III: consent form) and in particular point 9 which referred to "*regulatory authorities*" and noted that this did not cover NHS Digital, since they were not a regulatory body and suggested that an

	additional tick box be included that clearly and succinctly describes NHS Digital's role now and with regard to any possible follow up or linkage in the future. In addition to the above comments relating to the compatibility of the materials with the common law duty of confidentiality (the legal gateway for NHS Digital to handle the data), there were additional reviews that should take place to ensure compliance with UK GDPR/Data Protection Act 2018 – in particular, appropriate transparency about the handling and use of data - and any additional relevant UK legislation relating to clinical trials. The involvement of the Swedish research partners also needed to be clearly explained, as per GDPR requirements, including any flow of data outside of the UK. IGARD members suggested that a full review of the suite of consent materials be undertaken by NHS Digital, as per usual practice, and an assessment provided as a supporting document and that following that review, REC approval be sought (if appropriate) on the updated documentation and before the consenting of participants began. If however, consenting had already started, then further transparency work would need to be undertaken by the applicant to ensure the cohort were not surprised (as per the new Caldicott Principle 8) by any of the processing being undertaken. IGARD members suggested that a verbal update be given at next week's COVID-19 response meeting with progress to date in order for IGARD to give support to both NHS Digital and the applicant.
2.3	<u>NIC-382794-T3L3M-v3.1 University of Oxford</u> **Background:** This was an amendment application (V3.1) to request the COVID-19 Vaccination Adverse Reaction data and COVID-19 Vaccination Status data to be added to data already flowing under this data sharing agreement (DSA). The work had been funded by the rapid national core study grant and there was some urgency in getting the flow approved and in place to support the rapid COVID-19 response work being undertaken by the team at University of Oxford. V2.4 of this application and relevant supporting documentation had been previously discussed at the COVID-19 response meetings on the 19th January and 12th January 2021. The following observations were made on the basis of the updated v3.1 application and supporting documentation only. **IGARD Observations:** NHS Digital noted that section 4 incorrectly referenced that "*the Data Controllers listed within this agreement in section 1* ***WILL NOT*** *be required to ensure that a GDPR compliant, publicly accessible transparency notice is maintained throughout the life of this agreement*…" and that this would be updated to correctly not that the Data Controllers "….***will be required***…" IGARD members suggested that the data minimisation column in section 3b be updated to expressly state that free text fields were not flowing as part of the vaccine adverse reactions dataset, since this free text could not be quantified or cleansed to remove any identifiers. Notwithstanding the above points, IGARD members supported NHS Digital's assessment that the application would be approved under the NHS Digital SIRO precedent.
3	<u>AOB</u>

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