Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 17 June 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark (Chair)	Lay Member / IGARD Alternate Deputy Lay Chair
Prof. Nicola Fear	Specialist Academic Member
Kirsty Irvine	IGARD Chair / Lay Representative (Items 3 and 7)
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
Dr. Maurice Smith	Specialist GP Member (Items 3 and 7)
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Vicky Byrne-Watts	Data Access Request Service (DARS)
Michael Chapman	Director of Research and Clinical Trials (Item 3)
Louise Dunn	Data Access Request Service (DARS) (Items 3 and 6.1)
Liz Gaffney	Data Access Request Service (DARS) (Item 3)
James Gray	Data Access Request Service (DARS)
Nichola Makin	Data Access Request Service (DARS) (Observer: item 2.2)
Karen Myers	IGARD Secretariat
Jonathan Osborn	Deputy Caldicott Guardian (Observer: items 3 and 7)
Denise Pine	Data Access Request Service (DARS)
Dave Roberts	Head of Product for Arm's Length Bodies
Vicki Williams	IGARD Secretariat

GPES DATA FOR PANDEMIC PLANNING AND RESEARCH – PROFESSION ADVISORY GROUP (PAG) MEMBERS IN ATTENDANCE:	
Arjun Dhillon	PAG Chair (Items 3 and 7)
Mark Coley	PAG member (Item 7)

Amir Mehrkar	PAG member (Item 7)
Peter Short	PAG member (Items 3 and 7)

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-309066-X9B9L] and noted a specific connection with the staff involved. It was agreed this did not preclude Nicola from taking part in the discussions about this application, however agreed that she would not participate in making a recommendation about the application. Imran Khan noted a previous educational link to the Clinical Lead in NIC-309066-X9B9L (King's College London) but noted no specific connection with the application and it was agreed this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 3rd June 2021 IGARD meeting were reviewed out of committee by IGARD following conclusion of the meeting, and subject to a number of minor changes were agreed as an accurate record of the meetings. **Out of committee recommendations:** An out of committee report was received (see Appendix A).
2	**Data Applications**
2.1	University of Liverpool: HElping Alleviate the Longer-term consequences of COVID-19 (HEAL-COVID): a national platform trial (Presenter: James Gray) NIC-433257-K6Q2Y-v0.4 **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) Admitted Patient Care (APC), HES Critical Care, HES Outpatients, Civil Registrations (deaths), Emergency Care Data Set (ECDS), Medicines dispensed in Primary Care (NHSBSA data), Medicines dispensed in Primary Care (NHSBSA data) and Secondary Uses Service (SUS) Payment By Results Episodes. The purpose is for a 12-month clinical trial platform study looking at the impact of COVID-19 treatments on mortality and the need for re-hospitalisation following discharge from hospital. Long-term outcomes for COVID-19 are currently unclear, but early data suggests a significant burden of mortality and morbidity; and therefore even treatments with only a moderate impact on survival or on hospital resource are worthwhile. The clinical trial platform will have at most one control and three active arms at any one time, and it is expected that 877 participants will provide consent and will be randomised to each treatment arm. The estimated total cohort size once recruited is approximately 3,500. **Discussion:** IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 9th February and 9th March 2021.

	IGARD confirmed that they were of the view that the **most recent** consent materials provided the appropriate legal gateway and were broadly compatible with the processing outlined in the application. 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 section 5(a) (Objective for Processing) was updated to provide further clarity that the purpose of the study was to look at the safety and effectiveness of the medication in the prevention or management of long COVID, if that was indeed the case. In addition, IGARD 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. IGARD queried the incorrect information within section 3(b) (Additional Data Access Requested) that stated the NHS BSA data, was being disseminated on a *"quarterly basis"*, and asked that this was updated to correctly reflect this would be disseminated on a ***"monthly"*** basis. IGARD noted that section 5(c) (Specific Outputs Expected) and 5(d) (Benefits) contained the same information; and were advised by NHS Digital, this this was an error, and that they did have the correct information to add to section 5(c) in respect of the study outputs. IGARD noted the verbal update from NHS Digital, and asked that the entirety of section 5(c) was replaced to reflect the correct outputs. IGARD noted the paragraph within section 5(a) that referred to the clinical trial being a standalone trial, however also noted the addition information that referred to potential future linkage. IGARD asked that for transparency, this section was updated to reflect that this was a standalone trial, and that any future linkage would come back via the NHS Digital Data Access Request Service (DARS) process for an amendment, as per process. IGARD noted that National Institute for Health Research (NIHR) were funding the research, and asked that, section 5 (Purpose / Methods / Outputs) was updated, which formed NHS Digital's publicly available data release register, to state that the funder would not have influence on the outcomes, nor suppress any of the findings of the research, as borne out of the facts presented. IGARD noted in section 8(b) (Funding Sources) that the NIHR funding was in place *"pending agreement to amendments"*, and asked that either section 1 (Abstract) was updated to address the fact that that the NIHR funding would expire prior to the expiry of the Data Sharing Agreement (DSA), and clarity of how the study would continue without funding; or, that confirmation was provided that the funding from NIHR was ongoing and sufficient, and that any additional funding documentation was uploaded to NHS Digital's customer relationships management (CRM) system for future reference. IGARD noted that there were three processing locations and three storage locations within section 2 (Locations), and queried if this was correct, for example, was there a back-up or disaster recovery site; and asked that clarification was provided if there were any additional storage locations and to amend section 2(b) (Storage Location(s)) and section 5(b) (Processing Activities) if appropriate. IGARD queried the statement in section 1 that started *"Date and cause of death are being released under this agreement…"*, and asked that this was removed as it was not relevant.

	IGARD noted the previous advice provided at one of the IGARD – NHS Digital COVID-19 Response meetings, that the patient information sheet (PIS) should be updated to reflect that data would be requested for the participant's *"lifespan and beyond"* or some other such form of words to make clear that the applicant would be wanting to ascertain cause, date and location of death. IGARD suggested that if the application returned to REC, the applicant may wish to test with a small group of cohort members. more than 3 but less than 7, as to their understanding of this statement. IGARD noted within supporting document 3.1, the GP letter, that there was a request to the GP to prescribe drugs off-licence; and wished to draw to the attention of the clinical trial team, that asking GPs to prescribe an NHS prescription for an off-licence drug, may not be acceptable or supported. IGARD advised that they would wish to review this application when it comes up for amendment, due to the data linkage and data volume. **Outcome:** recommendation to approve subject to the following condition: 1. To update section 5(c) with the correct outputs, noting the current section is a repetition of text from section 5(d). The following amendments were requested: 1. In respect of the Medicines dispensed in Primary Care NHS BSA data: a) 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. b) To amend section 3(b) to remove the incorrect reference to the Medicines dispensed in Primary Care data being disseminated on a *"quarterly basis"*, and update to correctly reflect this will be disseminated on a *"monthly"* basis. c) To update section 5(a) to provide further clarity that the purpose is to look at the safety and effectiveness of the medication in preventing or management of long COVID. 2. To amend section 5(a) to reflect that this is a standalone trial, and that any future linkage would come back via the NHS Digital DARS process for an amendment. 3. In respect of the funding arrangements: a) To update section 5 to state that the funder will not have influence on the outcomes nor suppress any of the findings of the research. b) To update section 1 to address the fact that that the NIHR funding will expire prior to the expiry of the DSA, and how the research will continue without funding; or, c) To confirm that the funding will be ongoing and sufficient. d) To upload any additional funding documentation to NHS Digital's CRM system. 4. To amend section 2(b) and section 5(b) to add any additional storage locations, for example back-up or disaster recovery. 5. To update section 1 to remove the statement that starts *"Date and cause of death are being released…"*, as this is not relevant. The following advice was given: 1. IGARD noted within the GP letter supplied as a supporting document, that there is a request to the GP to prescribe drugs off license. IGARD wished to draw to the attention of the clinical trial team, that asking GPs to prescribe an NHS prescription for an off-license drug, may not be acceptable or supported.

	2. IGARD noted the reference in section 1 to *"lifespan and beyond"* and suggested that if the application returned to REC, the applicant may wish to test with a small group of cohort members (more than 3 but less than 7) as to their understanding of this statement. 3. IGARD advised that they would wish to review this application when it comes up for amendment, due to the data linkage and data volume. It was agreed the condition would be approved out of committee (OOC) by IGARD members
2.2	<u>King's College London: eLIXIR - early LIfe data Cross-linkage In Research (Presenter: Vicky Byrne-Watts) NIC-309066-X9B9L-v0.9</u> **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) Admitted Patient Care (APC), HES Accident and Emergency (A&E) and Emergency Care Data Set (ECDS). The purpose of the project is aiming to support observational research into disorders and other factors measurable across the life course and trans-generationally and to provide a step change in UK research capability in life course research into physical and mental health. The project will assemble a database of clinical data, from patients accessing maternity and neonatal services, which will constitute a unique resource for life-course research. The datasets provided, will provide scope for research in women's health, infant / child health, mental health, implementation science and public health. The study is relying on s251 of the NHS Act 2006, for the flow of data from NHS Digital. NHS Digital advised IGARD that Research Ethics Committee approval was in place, and that the relevant supporting documents for this would be uploaded to NHS Digital's Customer Relationship Management (CRM) system for future reference. **Discussion:** IGARD noted the verbal update from NHS Digital in respect of the REC approval, and that the relevant supporting document would be uploaded to NHS Digital's CRM system for future reference. IGARD confirmed that they were of the view that the relevant s251 support provided the appropriate legal gateway and was broadly compatible with the processing outlined in the application. IGARD queried the conflicting information within supporting document 4.5, the Health Research Authority Confidentiality Advisory Group (HRA CAG) approval letter dated 15th July 2020, that made no reference to participant postcodes being shared for linkage however the HRA CAG register did state that postcode could be shared for linkage. IGARD asked that NHS Digital uploaded a copy of the HRA CAG register as a supporting document on to their NHS Digital's Customer Relationship Management (CRM) system for future reference. IGARD noted that the study website referred to *"opt out consent"*, and queried if mothers could opt themselves and / or their children out of the database, noting that the legal basis for the study was s251 and not consent. IGARD advised that they could not locate an online opt-out form on the website, and asked that further clarification was provided as to **how** patients could opt themselves and / or their children out of the database. IGARD also queried if the patient information materials now included reference to the National Data Opt-out, and asked that, in the absence of any updated materials, that written evidence of this was provided. IGARD advised that there could potentially be an issue in terms of

	whether the interest of the participants had been adequately considered, due to the lack of transparency; and that this could be a potential risk to NHS Digital. IGARD noted the statement in section 3(c) (Patient Objections) that *"Section 251 is in place and so PO will be respected"*, and asked that this was updated to make clear that it was the National Data Opt-out that would be applied and to remove reference to *"PO"*. IGARD noted reference within the supporting documents provided to a *"maternity booking pack"* provided to patients, and in the absence of any further information, asked that information was provided, on the content of the pack, including, but not limited to, details of the materials contained within the packs; clarity of the content of the materials; and confirmation as to when the packs were provided to patients, for example, was this at a pre-natal appointment. IGARD advised that that they were unable to locate a privacy notice on the Data Controllers websites, and asked that the applicant ensured that a project-specific privacy notice was easily accessible and was compliant with the UK General Data Protection Regulation (UK GDPR). IGARD noted that the applicant would be receiving GP data from the Lambeth Data Net (LDN), and reiterated advice previously given to other applicants, that the LDN patient-facing transparency materials stated that they only disseminated *"anonymous" or "anonymised"* data, which, by definition, cannot be linked and the information on LDN's website was misleading and should be updated as a matter of urgency. IGAD noted objective 1 within supporting document 2.0, the protocol, *"To develop robust and innovative processes for effective patient and public involvement including stakeholder consultation, engagement with community groups and roadshows to obtain citizen feedback. Also, to meet NHS England requirements for 'fair processing' of patients' personal and confidential information including producing 'Fair Processing Notices' to inform and consult public about the use of their anonymised data. A steering committee will also be set up as well as an oversight committee to approve research"*. IGARD asked that section 5(a) (Objective for Processing) was updated, to reflect the outputs of objective 1, and how these had been implemented in respect of the application; or, if the data was being used to accomplish objective 1, asked that section 5(c) (Specific Outputs Expected) was updated to clarify how the data was being used and why. IGARD queried the size of the cohort, noting that section 5 (Purpose / Methods / Outputs) was silent on this information, and asked that section 1 (Abstract) and section 5 were updated with an indicative cohort size. IGARD noted that section 5(b) (Processing Activities) contained conflicting statements in respect of who would be accessing the data, for example, *"Any researcher wishing to access eLIXIR data for a project …will be required to have a substantive contract with a *KHP organisation and a KHP Passport."* (*King's Health Partners) and *"Data will only be accessed and processed by substantive employees of King's College".* IGARD asked that section 5(b) was updated with clarity as to who would be accessing the data, and that any conflicting statements were removed. IGARD noted that section 5(e) (Is the Purpose of this Application in Anyway Commercial) stated the purpose of the application was not commercial, however asked that section 5(a) and section 5(e) were updated to clarify that access to the database would be on a cost recovery basis only, and that there would be no profit or commercial benefit made by the applicant.

	IGARD noted that section 5(a) was particularly lengthy, and asked that this was reviewed to remove or edit any duplicate text, to reduce the description of processing, which was potentially too lengthy for NHS Digital's data release register, for example, by moving any relevant processing activities into section 5(b). IGARD queried the reference in section 5(a) to *"patient-level anonym"* used with the eLIXIR data, and noting that it was unclear what this meant, asked that it was reviewed and amended as appropriate. IGARD also noted the reference in section 5(b) to *"Deanonymising"*, and noting that it was unclear what this meant, asked that it was reviewed and amended as appropriate. **Outcome:** unable to make a recommendation as not all the necessary information was available in order for IGARD to make a full assessment. 1. In respect of the opt-out: a) To provide clarification **how** patients can opt themselves and / or their children out of the database. b) To provide written evidence that the patient information materials include reference to the National Data Opt-out. c) To update section 3(c) to remove the reference to *"PO"* and to make clear that the National Data Opt-out will be applied. 2. In respect of the transparency materials: a) To provide clarity of the materials provided within the maternity packs. b) To provide clarity on the content of the maternity pack provided to patients. c) To confirm when the maternity booking packs were provided to patients, for example, at a pre-natal appointment. d) To ensure that the project-specific privacy notice is easily accessible online and is UK GDPR compliant. e) IGARD members reiterated previous points raised with regard to statements made in the LDN patient facing transparency materials, which could be seen as misleading. 3. To update section 1 and section 5 with an indicative cohort size. 4. To update section 5(a) to edit out excessive detail to reduce the description of processing, which is potentially too lengthy for NHS Digital's data release register, for example, by moving processing activities into section 5(b). 5. To review the reference to *"patient-level anonym"* in section 5(a) and amend as appropriate. 6. To review the reference to *"Deanonymising"* in section 5(b) and amend as appropriate. 7. NHS Digital to upload a copy of the HRA CAG register as a supporting document on to their CRM system, due to the mismatch between the register and the HRA CAG approval letter. 8. To update section 5(b) to clarify who will be accessing the data, and remove any conflicting statements, for example, KHP employees and / or KCL employees. 9. In respect of Objective 1 (PPI involvement) within the protocol either: a) To update section 5(a) to reflect the outputs in respect of objective 1 and how these have been implemented in respect of this application; or, b) If the data is being used to accomplish objective 1, to update section 5(c) to clarify how the data is being used and why. 10. To update section 5(a) and section 5(e) to clarify that access to the database will be on a cost recovery basis only, and there will be no profit or commercial benefit made.

2.3	University of Hull: Examining the characteristics and predictors of alcohol withdrawal readmissions and emergency department attendances (Presenter: Denise Pine) NIC-226185-B6C2J-v3.4 **Application:** This was an extension application to the existing Data Sharing Agreement; and an amendment to: 1) increase the scope of the study, to examine routine hospital data, to examine characteristics and predictors of alcohol withdrawal re-admissions and Emergency Department attendances in England; and 2) add permissions for the data to be processed by a PhD student at the University of Hull under honorary contract. The original aim of the study, was to examine routine hospital data to examine characteristics and predictors of alcohol withdrawal re-admissions and Emergent Department attendances in England. The aim of the proposed new purpose, is to characterise the risk of patients experiencing alcohol withdrawal when admitted to acute hospitals, to develop a series of tools to identify 'at risk' individuals which would allow for targeted care and result in better outcomes **Discussion:** IGARD noted that section 1 (Abstract) stated that data was no longer processed or stored at the University of Hull, however section 2 (Locations) stated that the University of Hull was a storage and processing location. IGARD therefore queried if the University of Hull, should be considered a processing location, noting that researcher was working at the University of Hull, and the data was accessed via AIMES Management Services Limited, at the Liverpool Innovation Park. IGARD asked that further clarity was provided, and that the application was updated as appropriate to reflect the correct information. IGARD queried the yielded benefits outlined in section 5(d) (Benefits) (iii) (Yielded Benefits), noting that the benefits outlined appeared to be *"expected"* benefits and not yielded benefits, and asked that a satisfactory update was provided of the yielded benefits to date, and to ensure they complied with the NHS Digital's DARS Standard for Expected Measurable Benefits; or that section 5(d) (iii) was updated with a clear explanation as to why there are currently no yielded benefits. 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 inclusion of a number of technical phrases and words within section 5 (Purpose / Methods / Outputs) such as *"Phillips et al., 2019"* and suggested that this was updated to be written in a language suitable for a lay reader and technical terms used only where necessary, or further explained upon first use. IGARD noted the potentially misleading information in the current privacy notice, including, but not limited to, the storage of the data, and the opt-out options for patients; and suggested that this was reviewed and updated as appropriate. IGARD advised that they would wish to review this application when it comes up for renewal or extension, and that this application would not be suitable for NHS Digital's Precedent route for renewals and extensions; and that upon return, they would expect the privacy notice to be UK General Data Protection Regulation (UK GDPR) compliant. **Outcome:** recommendation to approve. The following amendments were requested: 1. To clarify whether the University of Hull is considered a processing location, when the researcher is working at the University of Hull, and the data is accessed at the Liverpool Innovation Park; and to update the application as appropriate.

	2. To update section 5 to ensure that technical jargon is defined or further explained upon first use. 3. In respect of the yielded benefits: a) To provide a satisfactory update to the yielded benefits in section 5(d) (iii) to ensure they comply with NHS Digital's DARS Standard for Expected Measurable Benefits; or, b) To update section 5(d) (iii) with a clear explanation as to why there are currently no yielded benefits. 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 noted the potentially misleading information in the current privacy notice, including (but not limited to) the storage of the data, and the opt-out options for patients; and suggested that this was reviewed and updated as appropriate. 2. IGARD advised that they would wish to review this application when it comes up for renewal and extension, and would expect the privacy notice to be UK GDPR compliant. 3. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route for renewals and extensions, and would expect the privacy notice to be UK GDPR compliant.
2.4	3M United Kingdom Plc: Data extract to support the continued accuracy of 3M developed quality and performance indicators for commissioners and providers. (Presenter: Denise Pine) NIC-91972-S9W9T-v5.4 3M **Application:** This was an extension application to the existing Data Sharing Agreement (DSA). 3M wish to process five years of pseudonymised Hospital Episode Statistics (HES) in order to validate and refine complex clinical algorithms and ensure they remain tuned as accurately as possible to the NHS experience. The data will be used to anglicise the 3M APR-DRG and 3M CRG (grouper) solutions, specifically by supporting the development of crosswalk tables and algorithms between UK coding classifications (and other NHS Data Dictionary items) and their international equivalents. The quality and performance indicators derived from these 3M solution suites will help the NHS better perform its duties by highlighting actionable areas for clinical and process improvement. NHS Digital advised IGARD that the applicant do not require any new data at the present time. **Discussion:** IGARD noted the verbal update from NHS Digital, that the applicant did not currently require any additional data. In addition, IGARD noted and commended the applicant for reviewing and deleting data held that was no longer required, and for providing NHS Digital with the relevant data destruction certificates. IGARD noted that section 5 (Purpose / Methods / Outputs) stated that five years of data was required to validate and refine complex clinical algorithms, however, section 5(d) (Benefits) stated that this had been completed. IGARD asked that section 5 was updated, to refresh the wording to ensure that the wording reflected the current position and request for the extension. IGARD queried the absence of yielded benefits in section 5(d) (iii) (Yielded Benefits), and acknowledged that the applicant was reliant on securing NHS contracts to be able to provide any yielded benefits, but were unclear what the applicant was using the data for currently, if

	they had completed the data validation. IGARD also queried that if the applicant was continuing to revalidate the tool, why they were not asking for more data. IGARD advised NHS Digital that if, in 12-months, the applicant was not demonstrating effective use of the data, and could not produce / evidence satisfactory yielded benefits, then IGARD may recommended that the data was destroyed. IGARD also asked that for transparency, section 5(d) (iii) was updated with a satisfactory update to the yielded to ensure compliance with NHS Digital's DARS Standard for Expected Measurable Benefits; or, that section 5(d) (iii) was updated with a clear explanation as to why there are currently no yielded benefits. IGARD noted that in the absence of any specific yielded benefits, any future iterations of the application would need to clearly outline the purpose for continued processing of the data, in terms 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; and in line with NHS Digital's DARS Standard for Expected Measurable Benefits. IGARD queried the reference within section 5(a) (Objective for Processing) to *"Article 9(2)(i)"* of the UK General Data Protection Regulation (UK GDPR); and noting that this did not align with the Article 9 legal basis stated elsewhere in the application, asked that section 3(a) (Data Access Already Given) and section 5(a) were reviewed and updated as appropriate to reflect the correct Article 9 legal basis. 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 that upon return, IGARD would expect to see updated yielded benefits. **Outcome:** recommendation to approve for a 1-year extension. 1. To refresh the wording in section 5 to ensure the wording reflects the current position and request for extension. 2. To update section 3(a) and section 5(a) to reflect the correct Article 9 legal basis. 3. In respect of the yielded benefits: a) To provide a satisfactory update to the yielded benefits in section 5(d) (iii) to ensure they comply with NHS Digital's DARS Standard for Expected Measurable Benefits; or, b) To update section 5(d) (iii) with a clear explanation as to why there are currently no yielded benefits. The following advice was given: 1. IGARD noted that in the absence of any specific yielded benefits, any future iterations of the application, would need to clearly outline the purpose for continued processing of the data, in terms 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; and in line with NHS Digital's DARS Standard for Expected Measurable Benefits. 2. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, and IGARD would expect to see updated yielded benefits. 3. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, and IGARD would expect to see updated yielded benefits.

3	<u>GP data for planning & research (Presenters: Dr. Arjun Dhillon, Michael Chapman, Dave Roberts)</u> NHS Digital attended IGARD, to provide a verbal update in respect of the ongoing work with the GP data for planning and research. IGARD thanked NHS Digital for the update and looked forward to further information in due course.
4	<u>Returning Applications</u> IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. Due to the GP data for planning & research discussion and IGARD / GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) Workshop at today's meeting, IGARD were unable to review any applications as part of their oversight and assurance role.
5	<u>COVID-19 update</u> To support NHS Digital's response to COVID-19, from Tuesday 21st April 2020, IGARD will hold a separate weekly meeting, to discuss COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 urgent applications that have been submitted to NHS Digital. Although this is separate to the Thursday IGARD meetings, to ensure transparency of process, a meeting summary of the Tuesday meeting will be captured as part of IGARD's minutes each Thursday and published via the NHS Digital website as per usual process. IGARD noted that as per the request from NHS Digital, the COVID-19 response meeting on Tuesday 8th June 2021 was cancelled. The ratified action notes from **Tuesday 15th June 2021** can be found attached to these minutes as Appendix B.
6 **6.1**	<u>AOB:</u> <u>NHS England / NHS Improvement – Data Sharing Agreement (DSA) alignments (Presenter: Louise Dunn)</u> NHS Digital attended the meeting to advise IGARD of the ongoing work within the Data Access Request Service (DARS), in respect of NHS England and NHS Improvement's Data Sharing Agreement's (DSA). NHS Digital advised that due to organisational restructures and legal changes with NHS England and NHS Improvement, there was ongoing work to merge the currently separate DSAs, and to ensure that duplication of data was not flowing. IGARD thanked NHS Digital for the verbal update. IGARD advised some of the advice / suggestions provided to NHS Digital with regard to the merging applications may also be relevant for this specific programme of work, for example, having separate and more manageable DSAs for each project of work, as opposed to one large general DSA that tried to encompass all the projects undertaken. IGARD looked forward to a further update in due course, and confirmed that they would be happy to provide support as and when required.

6.2	Draft ICO Guidance - Anonymisation, pseudonymisation and privacy enhancing technologies IGARD noted that the Executive Director for Privacy, Transparency and Ethics had advised that an internal working group within NHS Digital was being set-up to discuss the draft ICO guidance, and had requested IGARD's involvement / representation on the working group. IGARD noted that they were very supportive of this request and would await further details from NHS Digital. There was no further business raised, the Alternate Deputy IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.
7	IGARD / GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) Workshop Following conclusion of the IGARD meeting, IGARD and PAG held a workshop, following on from the last one held on the 11th March 2021, to discuss future collaborative working. This part of the meeting was chaired by the PAG Chair, Dr. Arjun Dhillon. It was agreed with PAG and IGARD that, going forward, and starting from the 17th June, a fortnightly placeholder meeting would be held on the afternoon of an IGARD business as usual meeting, and would be coordinated by the IGARD Secretariat. The PAG and IGARD Chairs thanked members for their time.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 11/06/21

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-16656-D9B5T	University of Liverpool	02/06/2021	1. NHS Digital to provide confirmation in the application abstract that NHS Digital's Data Production Team are content that the fullest possible data minimisation has been applied (particularly in light of the additional years of data that have been added to the DSA via the Precedent route since it was last independently reviewed in 2016).	IGARD Chair	OOC by the IGARD Chair	None
NIC-448252-L2R6Q	NHS England (Quarry House)	22/04/2021	1. In respect of the data minimisation and in line with the NHS Digital DARS Standard for Data Minimisation: a) To provide a written justification in section 3 and section 5, as to why there is no data minimisation within each of the datasets requested, for example, why are the fields not minimised to just those drugs relating to AMR. b) To provide a written justification why all conditions within HES are being requested, and not just those conditions relevant to AMR.	IGARD members	OOC by a quorum of IGARD members	*Please could DARS draw the applicant's attention to the special condition that only substantive employees of NHS England may access the data in the TRE.*

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

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

held via videoconference, Tuesday, 15th June 2021

In attendance (IGARD Members):	Paul Affleck (IGARD Specialist Ethics Member)
	Kirsty Irvine (IGARD Chair / Lay Representative)
	Dr. Imran Khan (IGARD Specialist GP Member)
In attendance (NHS Digital):	Dave Cronin (DARS)
	Louise Dunn (DARS)
	Andy Rees (DARS)
	Karen Myers (IGARD Secretariat)
	Vicki Williams (IGARD Secretariat)

2	**Welcome** The IGARD Chair noted that this was a weekly meeting convened to support NHS Digital's response to the COVID-19 situation and was separate from the IGARD business as usual (BAU) meetings. IGARD members present would only be making comments and observations on items that were presented, and were not making formal recommendations to NHS Digital. Should an application require a full review and recommendation, then it should go through the usual Data Access Request Service (DARS) process and be presented at a Thursday IGARD meeting. The action notes from the Tuesday meeting will be received out of committee and then published alongside the minutes of the next Thursday BAU meeting as an appendix. **Declaration of interests:** There were no declarations of interest.
2.1	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.
2.2	<u>NIC-459114-J3C1F-v0.4 AstraZeneca UK Ltd</u> **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.
2.3	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 v0.6 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', 'NHSD TRE Terms Blank 17.05.21', 'AstraZeneca TRE requirements for quote',* and *'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 B'. NHS Digital noted that the application was due to be presented to the Profession Advisory Group (PAG) on the 16th June 2021 and prior to its inclusion on an IGARD business as usual (BAU) agenda due to the significant changes to the study since last presented to PAG on the 26th May (see Appendix C). IGARD noted the verbal update. 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 number of vaccinations carried out in the age group 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 joint Data Controller alongside the University of Oxford, however IGARD Members noted reference

	to 'AstraZeneca UK Ltd' throughout the application and suggested that this was updated accordingly. IGARD Members noted that the applicant did not wish to share with NHS Digital the data processing agreements it had in place 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 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. IGARD members noted the briefing note presented to an IGARD BAU meeting on the 6th May entitled '*Un-curated low latency hospital datasets (Admitted Patient Care, Outpatient and Critical Care*') and the verbal update from NHS Digital that the applicant would have access to this un-curated dataset in the TRE. IGARD noted that while there were advantages of receiving un-curated data quickly, it was not validated, cleaned, or undergone quality checking compared to HES data, and that the applicant should ensure they have the appropriate expertise to manage this novel data set. 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 and contained GDPPR data (which as per process, required PAG and IGARD approval).

	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.
2.4	NIC-264102-D2X7J V0.122 King's College London **Background:** This was a business as usual (BAU) application for identifiable Hospital Episode Statistics (HES) Admitted Patient Care (APC) data for the purpose of a study aiming to identify the potential association between X-ray guided endovascular aortic aneurysm repairs (EVAR), which expose patients to radiation both during the procedure, and follow-up CT scans, and future incidence of cancer had been presented to the IGARD BAU meeting on the 3rd June, where it had been recommended for approval subject to amendments and advice. NHS Digital gave a verbal update to IGARD that due to technical restrictions within NHS Digital's online systems, the application had been split into two separate applications and would therefore have two distinct NIC numbers. The following observations were based on the verbal update only. **IGARD observations** IGARD members noted the verbal update and were supportive of this approach. Members asked that since the original application (NIC-264102) had now split into two distinct applications, to ensure that the customer relationship management (CRM) system linked the two applications, to ensure, for example, both were updated at the same time and both returned to IGARD at the same meeting, since the data products, study and timeline remained the same across both applications.
2.5	NIC-370843-R6V8T Imperial College London **Background:** this was a business as usual (BAU) application for the COSMOS study (cohort study of mobile phone use and health) that had been presented for advice to the IGARD BAU meeting on the 20th May 2021. The follow observations were made on v2.5 of the application summary, '*SD2d COSMOS study protocol letter 2021 06 09'*, and '*SD8 Agreement UKCOSMOST Sweden'*. **IGARD Observations:** The IGARD Chair noted that she and the Deputy Chair had agreed with the Head of Data Access for the BAU application to be discussed at today's meeting. 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 SD2d which was a letter from Imperial College London to IGARD (noting that this was the first time they had seen the letter addressed to them) which provided an addendum to the COSMOS study protocol in response to questions raised by IGARD at their meeting on the 20th May. IGARD members thanked the applicant for providing the letter, however suggested that the study protocol be updated in line with the contents of the letter.

	IGARD reiterated their comments from the IGARD BAU meeting on the 20th May meeting and which were published on line here, especially with regard to the sub-licencing which seemed an appropriate way forward. IGARD noted that SD8 provided as a supporting document was a 'Data Access Agreement' and not suitable for sub-licencing purposes since it did not flow down the contractual arrangements from NHS Digital from the Data Sharing Framework Contract signed by the applicant, including the right to audit all sub-licencees. IGARD members also reiterated previous comments that transparency was very important, especially with regard to the Data Controllership arrangements in Europe and that access to NHS Digital data is controlled by sub-licencing arrangements. NHS Digital queried if the applicant needed a Research Ethics Committee (REC) amendment. IGARD welcomed the query but suggested that it was applicant's responsibility to contact the relevant REC and ascertain if an amendment was required and to ensure all relevant approvals were in place prior to an application being presented to a BAU meeting of IGARD. Finally, IGARD members suggested that the application be checked to ensure that it meets all current NHS Digital published DARS Standards. 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.
3	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.

Appendix B

COVID-19 Action Notes extract 25th May 2021

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).

Appendix C

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 26th May 2021

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

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