Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 22 July 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Prof. Nicola Fear	Specialist Academic Member
Kirsty Irvine (Chair)	IGARD Chair / Lay Representative
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Maria Clark	Lay Member
Dr. Imran Khan	Specialist GP Member
Dr. Maurice Smith	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
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)
Frances Hancox	Data Access Request Service (DARS)
Karen Myers	IGARD Secretariat
Frances Perry	Data Access Request Service (DARS)
Joanna Warwick	Data Access Request Service (DARS) (Item 3)
Kimberley Watson	Data Access Request Service (DARS) (Item 3)
Vicki Williams	IGARD Secretariat
Tom Wright	Data Services for Commissioners (Item 5.1)
EXTERNAL OBSERVER(S) IN ATTENDANCE:	
Dr. Nicola Byrne	National Data Guardian (Item 2.1 – 2.2)

1	**Welcome and Introductions:** IGARD welcomed the National Data Guardian, Dr. Nicola Byrne, who had been invited to observe the IGARD meeting by the IGARD Chair. **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. **Review of previous minutes and actions:** The minutes of the 15th July 2021 IGARD meeting were reviewed, and subject to a number of minor amendments were agreed as an accurate record of the meeting. **Out of committee recommendations:** An out of committee report was received (see Appendix A).
2	**Data Applications**
2.1	Office for National Statistics (ONS): Provision of data via PDS to ONS (Presenter: Dave Cronin) NIC-20951-D2K6S-v7.4 **Application:** This was an amendment application to add additional variables to the Personal Demographic Service (PDS) Periodic Movers Extract and the Annual mid-year PDS Stock Extract File. The additional variables are required to help ONS to understand how migrants interact with services and to allow analyses to meet the 2023 recommendation of the future of the Census. The data will be used in conjunction with other administrative data for estimating internal and international migration, the local authority distribution of international migrants component of change for the mid-year estimates and small area population estimates within England and Wales and estimating migration between England and Wales, Scotland and Northern Ireland. ONS is responsible for producing statistics on a range of key economic, social and demographic topics in order to inform the needs of Government, society, academia and business to enable better decisions to be made. Using administrative data such as PDS allows ONS to produce statistics which are more granular and timelier at a lower cost to the public, therefore enabling better decisions and resource allocation. **Discussion:** IGARD and NHS Digital had a lengthy discussion with regard to the legal gateway to disseminate the data, noting that s261(7) of the Health and Social Care Act 2012 was cited and had been the legal gateway since version 3 of the application. IGARD noted that its published Terms of Reference stated that "*NHS Digital…shall include inter alia confirmation on the legal basis underpinning each application…*" and requested that in addition to s261(7), there should also be an additional legal gateway that sat alongside this, for example, an express statutory reference or Direction for NHS Digital to disseminate the data. IGARD asked that section 1 (Abstract) and section 3 (Datasets Held / Requested) were updated accordingly to reflect the additional legal gateway. IGARD queried the statement in section 1 that ONS *"…are effectively only asking for data they already have which was approved by NHS England."*, and asked that this was reviewed and amended as necessary, noting it was unclear why the data would be requested if it was already disseminated and held by the applicant.

	IGARD noted the volume of data requested and queried what, if any, linkage was taking place between the flow of data in the application, and other datasets held by ONS since this was not clear; and asked that section 5(a) (Objective for Processing) was updated with further clarity. IGARD also noted the references in section 5(b) (Processing Activities) to the data potentially being linked with other organisations, for example, the Department for Work and Pensions (DWP) and Her Majesty's Revenue and Customs (HMRC); and asked that section 5(b) was updated to provide confirmation as to what data linkage was taking place, as this was not clear within the application. IGARD noted that both identifying and pseudonymised data would be held by the applicant, and queried how the applicant was keeping this data separate; and asked that confirmation was provided in section 5 (Purpose / Methods / Outputs). IGARD suggested that in respect of the sharing of data with the National Records of Scotland (NSR), that the statement that demographic data was not personal data was reconsidered, particularly in light of recent discussions on this topic between various relevant parties and the resulting paper published in June 2021 Disclosing_personal_demographic_data_0621.pdf (aomrc.org.uk). In addition, NHS Digital commented it may be advisable to stop sharing record level data with the NSR until such time that classification of the data was clarified, i.e. whether it is confidential patient information or not. IGARD noted the suggestion from NHS Digital and confirmed that they were supportive of this approach, and until an appropriate contractual arrangement was put in place to reflect the nature of the data, for example, a Data Sharing Agreement. IGARD noted in Section 5(b) that *"ONS will keep a record of any processing of Personal Data and will provide a copy of such record to NHS Digital on request."*; and asked that the applicant provided this record to NHS Digital as a future supporting document, to provide further understanding of how the data would be used. IGARD noted that section 3(c) (Patient Objections) stated that National Data Opt-outs (NDO) would not be applied as *"The Statistics and Registration Service Act 2007 provides an exemption"*, and asked this was amended, to correctly state that NDOs were not applied, in line with NHS Digital's NDO policy, in respect of date shared for production of official statistics. IGARD noted that under the UK General Data Protection Regulation (UK GDPR), it was a transparency requirement for individuals to be informed about the collection and use of their personal data. IGARD noted the concerns raised by its predecessor the Data Access Advisory Group (DAAG) in 2016, in respect of the privacy notice, and wished to draw the applicant's attention to the statement in section 4 (Privacy Notice) of the application, that a UK GDPR compliant, publicly accessible transparency notice was maintained throughout the life of the agreement. In addition, IGARD suggested that ONS may wish to refresh the advice previously received from the Information Commissioner's Office (ICO) in respect of transparency to the public. IGARD noted the statement in section 5(a) that there were no *"moral or ethical issues*", and, noting the number of issues outlined, for example with regard to the use of data assessing *"migrants' interaction with services"*; asked that this incorrect statement was removed. IGARD queried the reference to various activities within section 5(a), and noting that it was not clear what this was referring to, asked that further clarity was provided, including, but not limited to, the references to *"migrants"*, for example, are they only internal migrants, or internal migrants *and* international migrants.

	IGARD queried the benefits outlined in section 5(d) (Benefits), and noted that some of the information provided were outputs, and asked that section 5(d) was updated to remove any outputs and edit to only leave examples that reflect the benefits of the research. IGARD noted the yielded benefits in section 5(d) (iii) (Yielded Benefits) and, noting these were more aligned with *"outputs"*, asked that further details were provided of the specific yielded benefits accrued to date, and asked that it was clear as to the benefits to both the patients and the health and social care system more generally, and in line with NHS Digital's DARS Standard for Expected Measurable Benefits. IGARD noted a number of statistical terms of art and technical terms in section 5(b), and asked that this public facing section be updated to, either remove or explained in a manner suitable for a lay audience, for example *"NHAIS"*. IGARD noted the outdated references in section 5, for example, reports that should have already been produced / published a number of years ago; and asked that these were removed if no longer relevant / necessary. IGARD queried the references in section 5 to the census being a *"…denominator for numerous other statistics…"*, and asked that this was reviewed and revised as appropriate. IGARD noted that section 2(c) (Territory of Use) stated that the territory of use was *"England and Wales"*, however noting that the data was being shared with Northern Ireland, asked that this was updated to correctly state that the territory of use was the *"UK"*. IGARD noted in section 1(b) (Data Controller(s)), that ONS' Data Protection Act (DPA) Registration had expired, and asked that this was updated to reflect the correct DPA Registration expiry date. IGARD suggested that ONS table the processing under this application for consideration by the National Statistician's Data Ethics Advisory Committee; and advised that they would like to receive a copy of the minutes of any such consideration, and that a copy should be uploaded to NHS Digital's customer relationships management (CRM) system for future reference. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the cumulative effect of updating the application and proceeding under precedent and not having an independent review for 5 years. IGARD advised that separate to this application, IGARD would welcome an information sharing session with ONS. **Outcome:** unable to make a recommendation as not all the necessary information was available in order for IGARD to make a full assessment. 1. To update section 1 and section 3 to clarify the legal gateway that sits alongside s261(7) Health and Social Care Act 2012 (for example, an express statutory reference or direction) for NHS Digital to disseminate the data. 2. To review the statement in section 1, that states the requested flow of data is already held (disseminated by NHS England), and amend as necessary. 3. To amend section 3(c) to make clear that NDOs are not applied, in line with the NDO policy in respect of data shared for the production of official statistics. 4. In respect of section 5(a): a) To remove from section 5(a) the statement that there are no *"moral or ethical issues*", as there are a number of such issues (for example with regard to the use of data assessing *"migrants' interaction with services"*).

b) To update section 5(a) to clarify if any linkage will take place between this flow of data and other datasets held by ONS.
c) To update section 5(a) to provide further clarity of the various activities, including (but not limited to) the references to *"migrants"*, for example, are they only internal migrants, or internal migrants *and* international migrants.

5. In respect of section 5(b):
   a) To amend section 5(b) to ensure statistical terms of art and technical terms are either removed or explained in a manner suitable for a lay audience, for example *"NHAIS"*.
   b) To update section 5(b) to provide confirmation as to what data linkage is taking place.
6. To provide confirmation in section 5 as to how identifying and pseudonymised data are kept separate.
7. To update section 5 to remove any outdated references, for example, reports that should have already been produced / published a number of years ago.
8. To review the references in section 5 to the census being *a "…denominator for numerous other statistics…"* and revise as appropriate.
9. To remove any specific outputs from section 5(d) and move to section 5(c).
10. In line with NHS Digital's DARS Standard for Expected Measurable Benefits, to provide further details in section 5(d) of the yielded benefits accrued to date and ensure these are clear as to the benefits to both patients and the health care system more generally.
11. To update section 2(c) to reflect that the territory of use is *"UK"* and not England and Wales.
12. To update section 1(b) to reflect the ONS' updated DPA Registration expiry date.

The following advice was given:

1. IGARD noted the concerns raised by DAAG in 2016, in respect of the privacy notice, and wished to draw to the applicant's attention, the statement in section 4, that a UK GDPR compliant, publicly accessible transparency notice is maintained throughout the life of the agreement. IGARD suggested that ONS may wish to refresh the advice previously received from the ICO in respect of transparency to the public.
2. IGARD suggested that ONS table this processing for consideration by the National Statistician's Data Ethics Advisory Committee. IGARD advised that they would like to receive a copy of the minutes of any such consideration, and that a copy should be uploaded to NHS Digital's CRM system for future reference.
3. IGARD suggested that in respect of the sharing of data with the National Records of Scotland, that the statement that demographic data is not confidential patient data, is reconsidered, particularly in light of recent discussions on this topic between various relevant parties and the resulting paper published in June 2021– see: Disclosing_personal_demographic_data_0621.pdf (aomrc.org.uk).
4. IGARD supported the verbal update from NHS Digital that it would be advisable to stop sharing record level data with National Records of Scotland until such time that classification of the data is clarified; and an appropriate contractual arrangement is put in place to reflect the nature of the data, for example, a Data Sharing Agreement.
5. IGARD noted in Section 5(b) that *"ONS will keep a record of any processing of Personal Data and will provide a copy of such record to NHS Digital on request."*, and asked that the applicant provide this record to NHS Digital as a future supporting document, to provide further understanding of how the data will be used.
6. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the cumulative effect of updating the

	application and proceeding under precedent and not having an independent review for 5 years. 7. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the cumulative effect of updating the application and proceeding under precedent and not having an independent review for 5 years. Separate to this application, IGARD would welcome an information sharing session with ONS.
2.2	<u>University of Oxford: National Core Studies - Data and Connectivity: COVID-19 Vaccines Pharmacovigilance (DaC-VaP) (Presenter: Louise Dunn) NIC-431355-B1L8W-v0.9</u> **Application:** This was a new application for pseudonymised COVID-19 Hospitalization in England Surveillance System, Diagnostic Imaging Dataset (DIDs), Emergency Care Data Set (ECDS), Mental Health Services Data Set (MHSDS), Secondary Uses Service (SUS+), Civil Registration (Deaths), COVID-19 Second Generation Surveillance System, Covid-19 UK Non-hospital Antigen Testing Results (pillar 2), COVID-19 Vaccination Adverse Reactions, COVID-19 Vaccination Status and Maternity Services Data Set (MSDS). The application is part of the urgent public health study that is funded by Health Data Research UK (HDR UK), to investigate the pharmacovigilance of the COVID-19 vaccine. The purpose is to link data held by NHS Digital to support the University of Oxford to conduct observational epidemiological studies that inform the national public health response to COVID-19 and the COVID-19 vaccine. The objectives are to: measure variation in vaccine uptake in relation to a) population characteristics; b) assess vaccine effectiveness (VE) against infection, transmission, severe outcomes, and deaths; and c) identify the risk of adverse events following immunisation (AEIs). NHS Digital advised IGARD that the difference with this application, was that the four nations would be collaborating. Data that is already being disseminated under the main route Data Sharing Agreement (DSA) (NIC-381683-R6R6K) will be accessed for this study. **Discussion:** IGARD noted that this application had previously been discussed as part of the 'returning applications' section of the IGARD business as usual (BAU) meeting on the 15th October 2020. IGARD noted that they had recently seen other applications from the University of Oxford for data to look at COVID-19 vaccines, for example *"Real-world effectiveness and safety of the Oxford/AstraZeneca covid-19 vaccine in England"* (NIC-459114-J3C1F); and queried how this project was different or novel to those other applications, and how the applicant would keep track of what data is to be used for what purpose, and how data deletion would be managed when Data Sharing Agreements (DSA) expired. NHS Digital advised IGARD that the four home nations (England, Scotland, Wales and Northern Ireland) would be sharing their analysis with the University of Oxford for further analysis, and this element differed to other previous DSA's reviewed by IGARD. IGARD noted the verbal update from NHS Digital, and asked that in respect of the proposed processing, written confirmation was provided that the processing under this DSA was not excessive processing when aligned with other uses of data by the applicant. In addition NHS Digital should ensure that this DSA and / or the main route agreement (NIC-381683-R6R6) were amended as required. IGARD suggested that NHS Digital checked and took appropriate action, as may be necessary, to confirm that the main route agreement permitted the use of the data outlined in this DSA; and that the data controllership of the main route agreement aligned with the statements in this agreement around permissions to share, and use of the data for this purpose.

	IGARD expressed concern about what appeared to be identical processing with identical outputs, and was concerned that this may be excessive processing under the UK General Data Protection Regulation (UK GDPR), with a reputational risk to NHS Digital if it enabled such duplication. IGARD noted in section 1 (Abstract), that the University of Edinburgh had been removed as a joint Data Controller with the explanation being that they were not making any decisions about the processing under this DSA for the England arm of the study. IGARD however, queried the role of the investigator named within the supporting documents who was located at the University of Edinburgh; and asked that confirmation was provided in section 1, that the investigator was **not** undertaking any activities which may attribute data controllership responsibilities to their employer, the University of Edinburgh. IGARD reiterated their comments previously made about the transparency relating to this study, for example, the generic privacy notice that contained incorrect information. NHS Digital advised IGARD that the applicant had confirmed updated transparency materials would be published by the end of the week. IGARD noted the verbal update from NHS Digital and advised that an IGARD specialist member had offered support in reviewing the updated material. IGARD queried the processing and storage locations noted in section 2 (Locations), noting the addresses appeared to be institutional ones as opposed to exact processing and storage locations; and asked that NHS Digital confirmed that the description of the processing locations provided sufficient granular detail for NHS Digital audit purposes. IGARD noted that section 5(a) (Objective for Processing) did not contain any information in relation to the size of the cohort, which was circa 5.5 million, and asked that this was updated to provide an indicative size of the cohort. IGARD queried the statement in section 5(a) *"data of death to report excess mortality, both overall"*, and asked that this was amended to include further information, or removed if deemed unnecessary. IGARD noted and commended the applicant for the involvement of the Patient and Public Involvement and Engagement (PPIE) members, that had been involved since the beginning of the project, as outlined in section 5(c) (Specific Outputs Expected); however asked that this was updated with further clarity of what effect the patient and public involvement (PPI) had on the study, as this was not clear. **Outcome:** recommendation to approve subject to the following condition: 1. In respect of the proposed processing: a) To provide written confirmation that the processing under this DSA, is not excessive processing when aligned with other uses of data by the applicant. or b) To amend this DSA and / or the main route agreement (NIC-381683-R6R6) as required. The following amendments were requested: 1. To provide confirmation in section 1 that the investigator at the University of Edinburgh is not undertaking any activities which may attribute data controllership responsibilities to their employer (noting the University of Edinburgh had been removed from the DSA). 2. NHS Digital to confirm that the description of the processing locations provides sufficient granular detail for NHS Digital audit purposes. 3. To update section 5(a) to provide an indicative size of the cohort.

	4. To review the statement in section 5(a) *"data of death to report excess mortality, both overall"* and amend as appropriate, or remove if deemed unnecessary. 5. To amend section 5(c) to clarify what effect the PPI input had on the study. The following advice was given: 1. IGARD suggested that NHS Digital checked and took appropriate action as may be necessary, to confirm that: a) The main route agreement permits this use of the data. b) The data controllership of the main route agreement aligns with the statements in this agreement around permissions to share and use of the data for this purpose. 2. IGARD reiterated the comments previously made about the transparency relating to this study. IGARD noted the verbal update from NHS Digital that the transparency communications would be updated by the end of the week, and advised that an IGARD specialist member had offered support in reviewing the updated material. **Significant Risk Area:** 1. IGARD expressed concern about what appeared to be identical processing with identical outputs, and was concerned that this may be excessive processing under UK GDPR, with a reputational risk to NHS Digital if it enabled such duplication. It was agreed the condition would be approved out of committee (OOC) by IGARD members.
2.3	<u>University of Bristol: Improving Medicines use in People with Polypharmacy in Primary Care (Presenters: Louise Dunn / Frances Perry) NIC-263738-V6V9N-v0.7</u> **Application:** This was a new application for pseudonymised Emergency Care Data Set (ECDS), Hospital Episode Statistics Admitted Patient Care (HES APC) and HES Outpatients. The purpose is for a study, aiming to develop, implement and evaluate an intervention to optimise medication use for patients with polypharmacy in a general practice setting. The study objectives are: Development study (Phase 1): To learn from NHS work in Scotland in order to develop a complex organisational intervention to improve medication review for people with polypharmacy. Pilot-feasibility study (Phase 2): To optimise the implementation of the IMPPP intervention for use in the NHS in England in a pilot-feasibility study. Main trial (Phase 3): To evaluate the clinical effectiveness and cost effectiveness of the intervention in a cluster randomised controlled trial; and to examine the implementation of the intervention in the trial using a mixed methods process evaluation. The University of Bristol will be supplying a cohort of 2,700 individuals in October 2022 who have provided direct consent for Phase 3 of the study. **Discussion:** IGARD noted and commended the applicant and NHS Digital on the quality of the application presented. IGARD noted that aspects of this application had been previously seen at the IGARD – NHS Digital COVID-19 Response meetings on the 16th March and 23rd 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 also noted and thanked NHS Digital for the helpful supporting document that contained a good analysis by NHS Digital of the consent materials provided IGARD noted the references to *"explicit"* consent within the application, and asked that this was removed as it was not relevant to the legal basis cited. IGARD queried the content of the paragraph in section 5(c) (Specific Outputs Expected) that contained *"PPI advisers were not involved in discussion or decision making with respect to*

	collection of data or processing", and advised that that this was reviewed and amended as appropriate, noting that it incorrectly appeared to imply that PPI had been excluded. IGARD noted that section 5(b) (Processing Activities) stated that data *"…will not be shared with any other third party or organisation unless first aggregated with small number suppression applied…"*; however queried the statement in supporting document 4.0, the patient consent form, that data would be shared with *"authorised researchers";* and asked if there was any intention to share NHS Digital data with other researchers. NHS Digital advised that there was no intention of sharing NHS Digital data, which was not first aggregated and suppressed, with authorised researchers at the end of the study. IGARD noted the verbal update from NHS Digital, and asked that a special condition was inserted in section 6 (Special Conditions), to reflect the current factual arrangement, that there would be no onward sharing of NHS Digital data. **Outcome:** recommendation to approve The following amendments were requested: 1. To update the application throughout to remove references to *"explicit"* consent. 2. To review the statement in section 5(c) relating to the PPI advisors and their involvement with the study, and amend as appropriate. 3. To insert a special condition in section 6 to reflect the current factual arrangement, in that there will be no onward sharing of NHS Digital data.
2.4	<u>University College London (UCL): Extended follow-up of the TARGIT A Trial (Presenters: Dave Cronin / Frances Hancox) NIC-126676-G1X4M-v1.14</u> **Application:** This was an amendment application to 1) permit additional access to Hospital Episode Statistics (HES) and Cancer Registration data, 2) to permit the use of that data for comparing health records with self-reported information from participants *"to determine if direct patient contact is an effective way of obtaining outcome data from patients participating in a randomised clinical trial"*. Breast cancer remains the most common female malignancy and its incidence continues to rise. The TARGIT-A randomised clinical trial, compared a risk-adapted approach with use of single dose targeted intra-operative radiotherapy (TARGIT IORT) versus conventional external beam radiotherapy (EBRT) given as a daily course over 3 to 6 weeks. The initial and 5 year results have been published and found that TARGIT-IORT is non-inferior to EBRT. The purpose of the application is for an extended follow-up study, which will enable timely recording of additional local recurrences and deaths. With a higher number of events, it would be possible to perform meaningful subgroup analysis using predictive factors such as hormone receptors, tumour grade and lymph node involvement that would allow fine tuning of patient selection criteria. Furthermore the effect on non-breast-cancer and overall mortality will also be ascertained. The study cohort consists of 382 participants, aged 18 and over, who consented in the TARGIT-A randomised clinical trial**.** **Discussion:** IGARD welcomed the application which came for advice and without prejudice to any additional issues that may arise when the application is fully reviewed. IGARD noted that section 1 (Abstract) contained an assessment of the application by NHS Digital, that outlined ongoing issues and concerns with the application in its current form; and thanked NHS Digital for providing this thorough information, and confirmed that they agreed with the assessment undertaken.

	IGARD noted that the analysis would be undertaken by a statistician employed by the University of Notre Dame in Australia who would remotely access the data in UCL's Safe Haven from Australia, and that this individual would process the data as an Honorary Professor of UCL. NHS Digital advised IGARD that this information was not made clear previously, and therefore had not been noted within previous iterations of the application. IGARD noted the verbal update from NHS Digital, however shared concerns about the remote access of the data from Australia. IGARD queried the international component of the study, in that eleven countries had participated in the trial; and queried how this data would be shared, for example, would the data be shared with the ten other countries. NHS Digital advised that the application was silent on this point, and that further discussions would need to take place with the applicant to determine this. IGARD noted that the application did not contain a strong justification for the project being undertaken, and advised that the application would need to be updated to provide further detail, for any future review and for transparency to the public, since section 5 forms NHS Digital's public data release register. IGARD supported NHS Digital's assessment that there was no evidence of approval from the Research Ethics Committee (REC) of the proposed processing of the HES data. IGARD also supported NHS Digital's assessment that there was no evidence, that the study protocol had been revised, to reflect the proposed processing and the necessary REC support required. In addition to the comprehensive analysis undertaken by NHS Digital, IGARD further noted that there were geographical restrictions on the use of the datasets, as noted in NHS Digital's UK General Data Protection Regulation (UK GDPR) transparency pages. IGARD also suggested that further analysis was undertaken, and a policy position formed by NHS Digital, as to whether access to data in a secure data access environment (DAE) constituted processing the data in the jurisdiction of the DAE or the jurisdiction of the researcher accessing that DAE. IGARD confirmed that they were of the view that the **most recent** consent materials were broadly compatible with the processing outlined in the application, notwithstanding the queries raised. **Outcome:** IGARD welcomed the application which came for advice and without prejudice to any additional issues that may arise when the application is fully reviewed.
2.5	Ignite Data Limited: The Extended Salford Lung Study Data Access Project (Presenter: Mujiba Ejaz) NIC-115298-L5X4V-v1.4 **Application:** This was an amendment application to add Adelphi Group Limited (trading as Adelphi Real World) as an additional Data Processor, to carry out research on the Extended-Salford Lung Study (SLS) data to answer some of the Asthma specific research questions. The Extended-SLS is a follow-on study to the original Salford Lung Studies, two landmark effectiveness trials of fluticasone furoate / vilanterol (an inhaled corticosteroid combined with a long-acting-b2-agonist [LABA] in a single inhaler device) in patients with Chronic Obstructive Pulmonary Disease (COPD) and asthma which ran from March 2012 to December 2016. The data will be used to form a longitudinal patient record, over the lifetime of the study, and will answer questions in the Extended-SLS relating to, 1) Healthcare resource utilisation and costs (HRG); 2) Severe exacerbation's of COPD and asthma; 3) Frailty and disease severity defined based on prior hospitalisations (all-cause) and comorbidities not managed in primary

	care. 4) Potential, treatment-related adverse events resulting in hospitalisation; 5) the impact of treatments and / or disease severity / subtypes on all-cause or COPD- and asthma- related mortality; primary care. The study cohort consists of 382 participants, aged 18 and over, who have a current diagnosis of COPD or asthma and were previously consented to be on the SLS. NHS Digital advised IGARD that the applicant was in the process of obtaining approval from the Health Research Authority Research Ethics Committee (HRA REC), for the addition of the Data Processor. **Discussion:** IGARD noted the verbal update from NHS Digital, in respect of the HRA REC approval being sought for the addition of the new Data Processor; and asked that a special condition was inserted in section 6 (Special Conditions), that no data would flow to Adelphi Group Limited, until HRA REC had confirmed support. IGARD noted the new Data Processor's links to the USA, and asked that a special condition was inserted in section 6, specifically noting the permitted territory of use of England and Wales, and that Adelphi Group Limited cannot send data outside the permitted territory of use. 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 reiterated advice previously given at the review at the IGARD business as usual meeting on the 14th January 2021, in respect of a newsletter provided to the consented cohort, that the 10 years of data referred to in the consent materials referred to the data flowing from the date of consent and that historical data was also being requested from NHS Digital. IGARD noted the update in section 1 (Abstract), that the applicant had committed to sending a newsletter at the time of the previous IGARD review, IGARD suggested that confirmation was provided as to when this was sent, or to provide a timeframe for circulation. IGARD noted that the link provided in section 1 to the privacy notice, was incorrect, and asked that this was updated, to remove the link to the incorrect privacy notice and review to ensure there were no other incorrect references not related to this application. In addition, IGARD suggested that it may be preferable to have **one** privacy notice, and that the relevant GP practices provided a link to this on their individual websites, as opposed to disseminating multiple privacy notices, and that this would, for example, address concerns with version control. IGARD queried the statement in section 5(e) (Is the Purpose of this Application in Anyway Commercial) that the data will be used as a commercial entity, but that this was "…*incidental to the processing…"*; and asked that this was removed. IGARD also asked that the commercial element outlined within the application was reviewed and updated as required, and to ensure it was in line with NHS Digital DARS Standard for Commercial Purpose. IGARD noted that the protocol was not currently published and asked that section 5 (Purpose / Methods / Outputs) was updated to reflect the commitment from GlaxoSmithKline Research & Development Limited (GSK) to publish the protocol, or to update the clinical trials website in advance of the processing, to enable the public to ascertain whether or not the research undertaken was in alignment with the protocol. IGARD noted that section 3(c) (Patient Objections) stated that that National Data Opt-out (NDO) would be applied, however asked that this was updated to correctly reflect that NDO would **not** be applied, as this was a consented study.

	IGARD queried the content of the statement in section 5(b) (Processing Activities) relating to *"Methodology"*, that started *"Pseudonymisation is defined as using a code…"*, and asked that this was amended to remove the misleading text, that suggested pseudonymised data was no longer sensitive or personal. IGARD could not see within the application any sharing of outputs with relevant organisations, and suggested that the applicant may wish to share the outputs with relevant patient-focussed charities, including, but not limited to, Asthma UK. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent; due to the complexity, and commercial element of the application. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 1 to remove the link to the incorrect privacy notice and review to ensure there are no other incorrect references. 2. To update section 3(c) to reflect that NDO will **not** be applied as this is a consented study. 3. To amend the *"Methodology"* information in section 5(b), to remove the text that suggests pseudonymised data is no longer sensitive or personal. 4. In respect of section 6: a) To insert a special condition in section 6, specifically noting the permitted territory of use and that Adelphi Group Limited cannot send data outside the permitted territory of use. b) To insert a special condition in section 6, that no data will flow to Adelphi Group Limited, until HRA REC have confirmed support. 5. In respect of the commercial element: a) To amend section 5(e) to remove reference to the data being *"incidental to the processing"*. b) To ensure the commercial element outlined within the application is in line with NHS Digital DARS Standard for Commercial Purpose, and update as required. 6. To update section 5 to reflect the commitment from GSK, to publish the protocol or to update the clinical trials website in advance of the processing, to enable the public to ascertain whether or not the research undertaken is in alignment with the protocol. The following advice was given: 1. IGARD suggested that it would be preferable to have **one** privacy notice, and that the relevant GP practices provide a link to this on their individual websites, as opposed to disseminating multiple privacy notices (to address concerns with version control). 2. IGARD reiterated advice previously given, in respect of a newsletter provided to the consented cohort, that the 10 years of data referred to in the consent materials referred to the data flowing from the date of consent and that historical data was also being requested from NHS Digital. Noting the applicant had committed to sending a newsletter at the time of the previous IGARD review, IGARD suggested that confirmation was provided as to when this was sent, or to provide a timeframe for circulation. 3. IGARD suggested that the applicant may wish to share the outputs with relevant patient-focussed charities, including (but not limited to) Asthma UK.

	4. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment; due to the complexity, and commercial element of the application. 5. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent; due to the complexity, and commercial element of the application.
2.6	<u>The University of Manchester: Naevoid melanoma: Comparing prognosis of two subtypes (Presenter: Catherine Day) NIC-294590-B6V3F-v0.11</u> **Application:** This was a new application for pseudonymised Civil Registration (deaths) data; for the purpose of a longitudinal observational study, with the aim of increasing the precision of diagnosis and positively influence the different managements of subtypes of melanoma (skin cancer). The study has shown that two different subtypes of naevoid melanomas have distinct clinical, histopathological and immunochemical profiles that may be prognostically significant. These comprise of papillomatous and maturing naevoid melanomas, and begin when the melanocytes in the skin grow out of control and form tumours. Melanocytes are the cells responsible for making melanin, the pigment that determines the colour of the skin. A cohort of 151 patients that were identified at Royal Surrey County Hospital NHS Foundation Trust as having melanomas that have been classified as naevoid melanomas. The study is relying on s251 of the NHS Act 2006, for the flow of data into NHS Digital. **Discussion:** IGARD confirmed that they were of the view that the relevant s251 support provided the appropriate legal gateway and was broadly compatible with the processing outlined in the application. IGARD noted that section 1 (Abstract) contained incorrect references to the HRA CAG letters for this application, and asked that this was updated to include the correct references for audit purposes. IGARD noted that supporting document 5.1, the Health Research Authority Confidentiality Advisory Group (HRA CAG) approval letter dated the 3rd December 2019, stated that the annual review should be provided no later than the 3rd December 2020, and queried if this had been done. NHS Digital advised that they were unsure and would need to discuss with the applicant to seek confirmation. IGARD noted the verbal update from NHS Digital, and asked that the applicant provided written confirmation that they had submitted their annual review by the 3rd December 2020; or otherwise provided express confirmation that the amendment submitted to HRA CAG in October 2020 replaced the annual review in December 2020. IGARD also noted in supporting document 5.1, the specific HRA CAG condition of support, that *"all staff involved in processing data under this section 251 support must have successfully completed local security awareness training before processing any data"*; and asked that a special condition was inserted in section 6 (Special Conditions) to reflect this. IGARD queried the statement in section 3(b) (Additional Data Access Requested) that *"GDPR does not apply to data solely relating to deceased individuals"*, however, noting that the status of those patients that are still alive will be revealed, asked that this was updated to also include a UK General Data Protection Regulation (UK GDPR) legal basis for dissemination and receipt of data. IGARD noted the proforma wording in section 1, in respect of NHS Digital having assessed the identifiability of the death data; and asked that this was removed, as it was not relevant.

	IGARD noted the academic papers referenced in section 5(a) (Objective for Processing), such as *"Cook et al. 2017"*, and asked that they were either updated to contain the full searchable academic reference or include a link to the website / web page. IGARD queried the references in section 5(a) and section 5(b) (Processing Activities) to *"informed consent"*, and asked that these were removed, noting there was no consent limb to this application. IGARD noted the volume of information within section 5(b), and asked that this was edited, to remove excessive detail to reduce the description, which was potentially too lengthy for NHS Digital's data release register, for example, the text that *"…patients will not be able to give their consent if they have died"*. IGARD suggested that if there was ongoing patient and public involvement (PPI), that the application was updated to reflect these activities; and that if there was no PPI activity, IGARD suggested that the applicant may wish to give consideration to such involvement. IGARD noted the HRA CAG application referred to engagement with Melanoma UK, and suggested that any involvement with the charity was referenced within the application. **Outcome:** recommendation to approve subject to the following condition: 1. In respect of the HRA CAG annual review: a) The applicant to provide written confirmation that they submitted their annual review by December 2020. or b) To otherwise provide express confirmation that the amendment submitted to HRA CAG in October 2020 replaced the annual review in December 2020. The following amendments were requested: 1. To update section 3(b) to include a UK GDPR legal basis for dissemination and receipt of data. 2. In respect of section 1: a) To include the correct references to the HRA CAG letters for audit purposes. b) To remove the proforma wording in respect of NHS Digital having assessed the identifiability of the death data, as it is not relevant. 3. To insert a special condition in section 6, to reflect the HRA CAG condition of support relating to local security awareness staff training. 4. To update the references to academic papers in section 5, to either include a fuller searchable reference or a relevant web link. 5. To amend section 5(a) and section 5(b) to remove references to *"informed consent"* as there is no consent limb to this application. 6. To review section 5(b) to remove any excessive or unnecessary information, for example, *"…patients will not be able to give their consent if they have died"*. The following advice was given: 1. In respect of PPI: a) IGARD suggested that if there was ongoing PPI, that the application was updated to reflect these activities. b) If there was no PPI activity, IGARD suggested that the applicant may wish to give consideration to such involvement. c) IGARD noted the HRA CAG application referred to engagement with Melanoma UK, and suggested that any involvement with the charity was referenced within the application.

	It was agreed the condition would be approved out of committee (OOC) by the IGARD Chair
3	<u>Returning Applications</u> IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. IGARD agreed, that from the 22nd July 2021, where substantial issues / significant risks are raised in respect of the returning applications, that a high level summary of these points would be included within the published minutes for transparency and audit purposes • NIC-148247 University of Manchester • NIC-148341 University of Oxford • NIC-389914 Department of Health and Social Care – IGARD noted that when this application had been brought to the COVID-19 response meeting on the 14th July 2020 they had given the following observation "*IGARD members queried why the application would go down the SIRO precedent and noted that for potentially repercussive application that NHS Digital may also wish for the assurance of an independent review via a Thursday BAU IGARD meeting";* and requested an update under a future AOB item, as to why the application had been progressed under the NHS Digital Simple Amendment precedent. • NIC-433629 NHS England – IGARD requested an update under a future AOB item, as to why this **new** application had been progressed under the NHS Digital SIRO precedent, since it was not clear within the application and supporting documentation provided. IGARD welcomed the four applications as part of their oversight and assurance role and noted a number of comments to NHS Digital and suggested that further information and comments be provided in an IGARD Oversight and Assurance Report. Moving forward, IGARD agreed that COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 applications may also be included as part of the oversight and assurance review, not just those that were approved via NHS Digital's precedent route.
4	<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 20th July 2021** can be found attached to these minutes as Appendix B.
5 **5.1**	<u>AOB:</u> <u>Class action for diabetes data and Clinical Registries Workshop (Presenter: Tom Wright)</u> NHS Digital attended the meeting, to notify IGARD that a 'Class Application for Diabetes Footcare and Diabetes In-Patients' and a Clinical Registries Workshop would be discussed at a future IGARD business as usual (BAU) meeting.

	IGARD noted the update from NHS Digital in respect of the two items that would be on a future IGARD BAU agenda, and requested that the appropriate information was sent to the IGARD Secretariat in advance of the meeting, for example, an overview of the purpose of the clinical registries workshop, the goals and outcomes of the workshop, and any relevant supporting documents for IGARD to review. 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 16/07/21

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

Graphnet Class Actions:

- None

Appendix B

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

held via videoconference, Tuesday, 20th July 2021

In attendance (IGARD Members):	Prof Nicola Fear (IGARD Specialist Academic Member)
	Kirsty Irvine (IGARD Chair / Lay Representative)
	Dr. Geoff Schrecker (IGARD Specialist GP Member)
In attendance (NHS Digital):	Dave Cronin (DARS)
	Cath Day (DARS)
	Kevin Fines-Smith (Digi-Trials)
	James Gray (Digi-Trials)
	Dickie Langley (Privacy, Transparency & Ethics)
	Karen Myers (IGARD Secretariat)
	Vicki Williams (IGARD Secretariat)

2	**Welcome** The IGARD Chair noted that this was a weekly meeting convened to support NHS Digital's response to the COVID-19 situation and was separate from the IGARD business as usual (BAU) meetings. IGARD members present would only be making comments and observations on items that were presented, and were not making formal recommendations to NHS Digital. Should an application require a full review and recommendation, then it should go through the usual Data Access Request Service (DARS) process and be presented at a Thursday IGARD meeting. The action notes from the Tuesday meeting will be received out of committee and then published alongside the minutes of the next Thursday BAU meeting as an appendix. **Declaration of interests:** Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising the Scientific Advisory Group for Emergencies (SAGE) on COVID-19. Nicola Fear noted a professional link to the team at the University College London (NIC-372269-N8D7Z), but noted no specific connection with the application, and it was agreed this was not a conflict of interest.
2.1	NIC-372269-N8D7Z University College London (UCL) **Background:** this was an amendment application to include vaccine data to an application that was previously recommended for approval subject to conditions at a business as usual (BAU) meeting on the 30th July 2020. The applicant wishes to re-use the consent as a legal basis to cover the common law duty of confidentiality and use this consent to link the participants' data to vaccine data.

	The application had been previously discussed at the COVID-19 response meetings on the 26th May 2020 and 30th June 2020, before discussion at the BAU meeting on the 30th July 2020. The following observations were made on the basis of the verbal update from NHS Digital and a copy of the data sharing agreement (DSA) v0.3 and older versions of supporting documents, including the consent and patient information leaflets, as provided at last year's BAU meeting. **IGARD Observations:** IGARD members noted that due to the nature of the meeting, that should a full review of the application and documentation be required, the full suite of documentation should be presented to an IGARD business as usual (BAU) meeting for a recommendation. IGARD members noted that members had not been in agreement that the conditions had been met following its review at the BAU meeting of IGARD on the 30th July 2020, and the IGARD Chair had taken 'chair's authority' following due process outlined in IGARD's Terms of Reference and relevant standard operating procedures had agreed the conditions had been met subject to advice and amendments, namely: to align the assent materials more closely with the adult consent materials, the assent materials should explicitly state that a hospital visit related to a respiratory illness could be any visit within a certain number of days following report of a respiratory symptom or following serological evidence of respiratory infection, and to check the wording *"up to 5 years after the end of the study"* to ensure it aligned with the adult consent materials. NHS Digital noted that the advice had been conveyed to the applicant and that this application would be updated in line with the IGARD Chair's advice given at the time. IGARD members noted that, given the subject matter and far-ranging scope of the original study, members of the study would most likely **not** be surprised at the request for the vaccine data under the amendment DSA. It was suggested that this additional data flow and linkage could be communicated to cohort members via a newsletter or other direct communication. Members present were not of the view that re-consenting would be necessary on the basis of this amendment only. Members noted the reference in both the 'Participant Information Sheet Children aged 10-15 years v8' and 'Adult Participant (Age 16+) Information Sheet V6', provided as supporting documents, that under the header "*How long will this study go for?*" that it specifically stated "*this study will run until spring next year (2021)*", and queried what communication there been with the cohort about the extension to the study. IGARD also queried how the IGARD Chair's advice regarding the assent materials had been actioned. NHS Digital noted that they had recently received an updated consent form, but they had not provided this to IGARD as part of today's meeting. In summary, IGARD members noted the current consent materials were broadly compatible with the inclusion of the vaccine data if supplemented by appropriate communication with the cohort. However ,IGARD members could not comment further on whether the consent materials (new or old) would be compatible with the processing, should the application have been updated significantly or there had been other significant changes to the protocol or proposed processing. IGARD suggested that the application was updated with how the conditions and points of advice from the previous BAU meeting had been addressed and that

	a review was undertaken regarding communication with the cohort and informing them of the study's end date.
2.2	NIC-526384-M3T5R St George's University Hospitals NHS Foundation Trust (PTC) **Background:** this was a new application for a phase II randomised, single-blind, platform trial to assess the safety, reactogenicity and immunogenicity of the COVID-19 vaccines in pregnant women in the UK (Preg-CoV). The study is looking to recruit up to 900 cohort participants aged 18 to 47 years and between 13 and 34 weeks gestation on the day of the planned vaccination. St George's will be the sole Data Controller, with NHS Digital as the sole Data Processor. NHS Digital will contact the potential participants directly as per the previous permission to contact applications and St George's will have no access to any data provided by NHS Digital. The following observations were made on the basis of the verbal update from NHS Digital 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 members noted this was incredibly important research into vaccination and pregnancy. IGARD noted the verbal update from NHS Digital with regard to this trial, noting that NHS Digital had determined that there was nothing novel or distinct using the "permission to contact" registry and that all women in the age group would be targeted with relevant communications from NHS Digital. IGARD members noted in principal that they were supportive of using the templated approach. However, IGARD members noted that this was a novel and potentially sensitive use of the database, since some of those women who had signed up to the database may have suffered a miscarriage, still birth or neonatal death, and IGARD suggested that in addition to sign off of any communications going out from NHS Digital to a large number of women, that the contact letter proactively sign post the recipients to relevant national charities who would be able to offer support if they were distressed by a communication asking if they were pregnant such as the Miscarriage Association and SANDS (still birth and neonatal death charity). IGARD members queried the availability of a suitable sized cohort of women yet to be vaccinated and pregnant in the database, and that further thought should be given by the applicant to other avenues of recruiting women to the study, such as through booked ante-natal services whereby a midwife could provide with those attending with a leaflet about the study. IGARD members were not clear via the verbal update if the study was looking at women who were already vaccinated or to be vaccinated whilst pregnant and that if the study was not looking at the former, that the applicant may wish to include this as a limb of their study. IGARD noted there was already a number of research studies in the global public arena with regard to vaccination of pregnant women. 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 welcomed the verbal update and noted that NHS Digital had indicated that due to the urgency of the application that it would be progressed under NHS Digital's SIRO Precedent, however IGARD were **not** supportive of this approach given the potential sensitivity and outstanding ethical support and asked that the application and relevant supporting documents (if available) be brought back to a future COVID-19 response meeting on the 3rd August 2021, alongside the full unconditional ethical support. **Subsequent to the meeting:** IGARD reiterated comments made previously (see 22nd June CV19 action notes): Noting the language used in this and other applications using the NHS Digital COVID-19 permission to contact register (CV19 PtC) (internal process name), consideration should be given to the external name of the registry: "NHS Digital COVID-19 vaccine research 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. 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.
2.3	<u>NIC-526363-C3M1K Sanofi Pasteur</u> **Background:** This was a new application for the study of recombinant protein vaccines with adjuvant as a primary series and as a booster dose against COVID-19 in adults 18 years of age and older. The trial is looking to recruit up to 550 cohort participants aged 18 years and older. Sanofi Pasteur will be the sole Data Controller, with NHS Digital and Pharmaceutical Research Associates Health Sciences (PRA HS) as the Data Processors. NHS Digital will contact the potential participants directly as per previous permission to contact applications and Sanofi Pasteur and PRA HS will have no access to any data provided by NHS Digital. The following observations were made on the basis of the verbal update from NHS Digital 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 trial, noting that NHS Digital had determined that there was nothing novel or distinct using the "permission to contact" registry.

	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 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 unconditional ethical support had been received (and noting the importance of a review of the consent materials in due course). **Subsequent to the meeting:** IGARD reiterated comments made previously (see 22nd June CV19 action notes): Noting the language used in this and other applications using the NHS Digital COVID-19 permission to contact register (CV19 PtC) (internal process name), consideration should be given to the external name of the registry: "NHS Digital COVID-19 vaccine research 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. 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.
2.4	<u>Expired & Expiring DSA's (Business as Usual (BAU))</u> DARS provide an update to IGARD and PTE with regard to expiring and expired Data Sharing Agreements (DSA) and noted the project last year at the height of the pandemic, which extended all DSA's expiring at the time by 6 months. DARS noted that they were looking to introduce principles and after discussion with NHS Digital's legal team, and that further work was being undertaken across directorates and with the SIRO. IGARD suggested that NHS Digital may benefit from some input into the risk assessment, particularly around medium and high risk decisions, and that DARS may wish to utilise the skills, knowledge and expertise of the independent group for borderline cases. DARS thanked IGARD for their high-level comments and noting that this was not a quorate IGARD BAU Meeting and only three members were present, would come to a future IGARD BAU or provide a briefing note to share with all members.
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.