Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 16 December 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member
Kirsty Irvine	IGARD Chair
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Chair
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Prof. Nicola Fear	Specialist Academic Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Michael Ball	Data Access Request Service (DARS) (Item 3.6, 3.7, 7.1)
Garry Coleman	Associate Director / Senior Information Risk Owner (SIRO) (Item 7.2)
Catherine Day	Data Access Request Service (DARS) (Item 3.3)
Faris Dean	Data Access Request Service (DARS) (Item 3.5)
Louise Dunn	Data Access Request Service (DARS) (Items 3.2, 3.3, 4.2) (Observer: item 3.1 – 7.2)
Mujiba Ejaz	Data Access Request Service (DARS) (Item 3.2)
Dan Goodwin	Data Access Request Service (DARS) (Item 3.6) (Observer: 3.7)
James Gray	DigiTrials (Item 3.4)
Dickie Langley	Privacy, Transparency & Ethics (PTE) (Observer: items 3.1 – 3.4)
Magda Martinez-Queipo	NHS Digital TRE (Observer: items 3.1 – 3.3)
Karen Myers	IGARD Secretariat (3.4 – 7.2)
Rahima Oliver	Privacy, Transparency & Ethics (PTE) (Observer: items 3.1 – 3.3)
Jonathan Osborn	Deputy Caldicott Guardian (Observer: 3.1 – 3.3)

Frances Perry	DigiTrials (Item 3.4)
Andy Rees	DigiTrials (Item 3.4)
Charlotte Skinner	Data Access Request Service (DARS) (Item 3.1)
Kimberley Watson	Data Access Request Service (DARS) (Item 3.3)
Vicki Williams	IGARD Secretariat

1	**Declaration of interests:** Dr. Maurice Smith noted a professional link with NHS Liverpool CCG (NIC-140059-P1J9L) and would not be part of the discussion. It was agreed that Dr. Smith would not remain in the room for the discussion of that application. Dr. Maurice Smith noted professional links to AIMES Management Service (NIC-612092-Q0Y6F, NIC-604847-S4B5L and NIC-140059-P1J9L National Institute for Health Research (NIHR)) but no specific connection with the application or staff involved and it was agreed that there was no conflict of interest. Paul Affleck noted professional links to AIMES Management Service (NIC-612092-Q0Y6F, NIC-604847-S4B5L and NIC-140059-P1J9L National Institute for Health Research (NIHR)) but no specific connection with the application or staff involved and it was agreed that there was no conflict of interest. Kirsty Irvine noted a personal link to Genomics England [NIC-12784-R8W7V]. It was agreed this did not preclude Kirsty from taking part in the discussions about this application. Dr. Imran Khan noted a professional link to the North of England Commissioning Support Unit (NIC-183870-V0T3Y) but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 9th December 2021 IGARD meeting were reviewed, and subject to a number of minor amendments were agreed as an accurate record of the meeting. **Out of committee recommendations:** An out of committee report was received (see Appendix A).
2	**Briefing Notes**
	There were no briefing papers submitted for review.
3	**Data Applications**
3.1	Home Office: Hospitalisation from serious violence (Presenter: Charlotte Skinner) NIC-612092-Q0Y6F-v0.2 **Application:** This was a new application for aggregated – small numbers not suppressed Hospital Episode Statistics Admitted Patient Care (HES APC) data.

	Reducing Serious Violence is a key aims that the Prime Minister has set the Home Office as outlined in the Beating Crime Plan published early in 2021. The requested data is the key metric through which the Home Office measures its performance against this Prime Ministerial (PM) ambition on Serious Violence. The purpose of this application is to monitor and evaluate serious violence in England, with the aim of identifying areas with high levels (of serious violence), to develop policies and programmes to reduce serious violence, and target these policies and funding at the areas that need it the most. The data will allow greater, more accurate detail in supporting the Home Office demonstrate the extent to which it is achieving the ambitions set by the Prime Minister. **Discussion:** IGARD members noted that the analysis had been commissioned by the Home Office and that one of the Prime Minister's (PM) key aims was to reduce serious crime and that the 'No10 Delivery Unit' monitor the 'under 25 sharp object' hospitalisation admissions and regularly update the PM. Noting that the No10 Delivery Unit is part of the Cabinet Office, IGARD asked that the Cabinet Office be included as a joint Data Controller and in line with NHS Digital's DARS Standard for Data Controllers and in line with the UK General Data Protection Regulations (UK GDPR); or to provide a clear narrative in section 5 (Purpose / Methods / Outputs) as to why the Cabinet Office's commissioning role does not create a data controllership role, as borne of the facts. In addition, IGARD queried why the University of Hull who were only listed as a Data Processor, were not also considered a joint Data Controller since the Violence Reduction Unit (VRU) are the evaluation partner of the Home Office. IGARD asked that a clear narrative be included in section 5 why the University of Hull were not considered, nor fulfil the criteria, of a Data Controller under UK GDPR and in line with the NHS Digital DARS Standard for Data Controllers. IGARD noted that reducing serious crime is a key aim of the PM, but noting that NHS Digital's legal obligation is to disseminate data under s261 of the Health & Social Care Act for the benefit of health and / or care, that a clear statement be inserted in section 5(a) (Objective for Processing) as to why this study was important from a public health perspective; for example, the application could mention that knife crime is a serious public health problem and that knife crime can impact on the provision of health services. In addition, section 5(d) (Benefits) should be updated and in line with the NHS Digital DARS Standard for expected measurable benefits to ensure that the benefits are also in line with NHS Digital's legal obligation to disseminate data under s261 of the Health & Social Care Act for the benefit of health and / or care. IGARD clinicians noted that not all serious crime or knife crime victims would be captured in HES APC since some victims would be dealt with in the accident and emergency (A&E) department or unfortunately die in A&E whilst being treated and before admission to hospital. IGARD were therefore supportive of the applicant receiving Emergency Care Data Set (ECDS) data to capture those serious crime victims. IGARD also queried the statement in section 3 (Datasets Held / Requested) with regard to data minimisation: "*no maternity or neonatal or unborn child data is included*", and why maternity data was being excluded. IGARD noted that this data may include pregnant women or those who had recently given birth where it is a well-known public health issue that they are at higher risk of violent assault. IGARD were therefore supportive of the applicant receiving maternity data and it being reinstated to the application to ensure those groups were not excluded from public health research.

	IGARD queried why the Home Office had cited Article 6(1)(f) (legitimate interest) as their UK GDPR legal basis and suggested that the application be updated throughout to correctly reference Article 6(1)(e) (public task). IGARD noted in section 3 that it clearly stated that the application did not include the flow of confidential data, however suggested justification be included in section 1 (Abstract) and section 5, as aggregate data without small number suppression can be identifying data. IGARD advised that NHS Digital draw the applicant's attention to the contractual obligation in section 4 (Privacy Notice), in respect of maintaining a UK GDPR compliant, publicly accessible transparency notice throughout the life of this agreement, in order to maintain public trust in using health data from national datasets. In addition, IGARD noted that NHS Digital may wish to promote the research and use of health data given the importance of transparency. IGARD noted, and separate to this application, that the NHS Digital data security toolkit (DSPT) webpage stated that "*all organisations that have access to NHS patient data and systems **must*** use this toolkit to provide assurance that they are practising good data security and that personal information is handled correctly*" and suggested that the DSPT webpage, which makes it mandatory for organisations accessing health data to have a DSPT in place matches the information on the NHS Digital DARS webpage which states organisations may have a System Level Security Policy or ISO27001 certification as a viable alternative to DSPT. *emphasis added Due to the nature of the research and nature of the applicant, IGARD noted that there was no ethics support which may be a significant risk to public trust and confidence and given the potential impact of the research findings, noted this was a potential reputational risk to NHS Digital. IGARD also suggested that, along with DARS, they discuss with the National Data Guardian (NDG) as to how public bodies assure themselves that ethical issues have been considered and addressed. **Outcome:** recommendation to approve subject to the following conditions: 1. In respect of Data Controllers: a. To add the Cabinet Office as a joint Data Controller, in line with the NHS Digital DARS Standard for Data Controllers / UK GDPR or otherwise clarify why their commissioning role does not create a controllership role. b. Where the University of Hull are described in section 5, to be clear that they are not considered, nor fulfil the criteria of, a Data Controller under UK GDPR. 2. In respect of the dissemination of data under s261 of the Health & Social Care Act: a. To insert a clear statement in section 5(a) as to why this study is important from a public health perspective for example to mention that knife crime is a **serious public health problem** that can impact on the **provision of health services**. b. To update section 5(d) to be clear that the benefits are in line with the NHS Digital DARS Standard for Expected Measurable Benefits and satisfy the legal obligations to disseminate data under s261 of the Health and Social Care Act for the benefit of health and / or care. The following amendments were requested: 1. To add clear statements in section 1 and 5 that the data will not be identifiable in the hands of the recipient and why that is the case. 2. To amend the legal basis throughout the application from legitimate interest to public task.

	The following advice was given: 1. IGARD were supportive of the applicant receiving ECDS data to capture those serious crime victims which may be dealt with in the A&E without admission or die in A&E whilst being treated and before admission to the hospital. 2. IGARD queried why as part of data minimisation, maternity data was being excluded, which may exclude those pregnant women or those who had recently given birth where it is a well-known public health issue that they are at higher risk of violent assault. IGARD were supportive of the applicant receiving maternity data and it being reinstated to the application to ensure those groups are not excluded from public health research. 3. In respect of the privacy notice, and in line with NHS Digital's DARS Standard for Transparency (fair processing): a. IGARD wished to draw the applicant's attention to the statement in section 4, that a UK GDPR compliant, publicly accessible transparency notice is maintained throughout the life of the agreement, in order to maintain public trust in using health data from national datasets. b. IGARD noted that NHS Digital may wish to promote the research and use of health data, given the importance of transparency. **Significant Risk Area:** due to the nature of the research, and nature of applicant, IGARD noted that there was no ethics support which may be a significant risk to public trust and confidence, given the potential impact of the research findings. **ACTION:** IGARD suggested that along with NHS Digital that a discussion with NDG should be undertaken as to how public bodies assure themselves that ethical issues have been considered and addressed. **ACTION:** NHS Digital to ensure that the DSPT toolkit webpage, which makes it mandatory for organisations accessing health data to have a DSPT in place, matches information on the NHS Digital DARS webpage which states that organisation may have a SLSP or ISO27001 certification as a viable alternative to the DSPT. It was agreed the conditions would be approved out of committee (OOC) by IGARD members.
3.2	Genomics England: R26 – Genomics England: GenOMICC COVID-19 Study (Presenter: Louise Dunn / Mujiba Ejaz) NIC-374190-D0N1M-v4.1 **Application:** This was a renewal application for a further 12-months, to permit the holding and processing of identifiable Mental Health Services Data Set (MHSDS), Community Services Data Set (CSDS), Civil Registration (death), Demographics, COVID-19 Hospitalization in England Surveillance System (CHESS), Hospital Episode Statistics Accident & Emergency (HES A&E), HES Admitted Patient Care (APC), HES Critical Care, HES Outpatients, Diagnostic Imaging Dataset (DIDs), Emergency Care Data Set (ECDS), COVID-19 Second Generation Surveillance System (SGSS), Secondary Uses Service Payment by Result (SUS PBR), Cancer Registration Data, Bridge file: Hospital Episode Statistics (HES) to Diagnostic Imaging Dataset (DIDs), Bridge file: HES to Mental Health Minimum Data Set (MHMDS), GPES Data for Pandemic Planning and Research (GPDPPR) and pseudonymised HES-ID to MPS-ID HES Accident and Emergency and HES-ID to MPS-ID HES Outpatients. It was also an amendment is to change the way the Common Law Duty of Confidentiality is addressed within the application, moving from The Health Service Control of Patient Information (COPI) Regulations 2002 to consent; and to add pseudonymised COVID-19 Vaccination Status data.

	The purpose is for a national study aiming to provide detailed whole genome sequencing to 35,000 participants affected by COVID-19 and it is the aim to concurrently add high quality clinical data to aid the research effort; and would be available for analysis alongside the extant Genomics England data set of the 100,000 Genomes Project. **Discussion:** IGARD welcomed the application and noted it was of huge public importance. IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meetings on the 25th June 2020 and the 6th August 2020. IGARD noted that this application had been previously seen at the IGARD – NHS Digital COVID-19 Response meetings on the 28th April , 5th May, 12th May, 16th June, 23rd June, 14th July, 21st July, 6th October 2020; and the 30th March 2021. IGARD also noted that this application had been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 17th June 2020, and that notes from this meeting had been attached to the IGARD BAU minutes from the 25th June 2020; and the 29th July 2020, and that notes from this meeting had been attached to the IGARD BAU minutes from the 6th August 2020. IGARD confirmed that they were of the view that the most recent consent materials provided the appropriate gateway and were broadly compatible with the processing outlined in the application. However, IGARD requested that the NHS Digital provide written analysis of the 100,000 Genome Project consent assessment which establishes there was appropriate legal basis through consent for the use of data as a control group for this research and a written copy of the written analysis be uploaded to NHS Digital's customer relationship management (CRM) system as a future supporting document. IGARD noted that the special conditions in section 6 (Special Conditions) with regard to territory of use that stated, "*remote access by any 3rd party must ensure that they are physically based within the territory of use as set out in the agreement*", and "*access to data internationally is restricted to the territory of use as set out in the agreement*" and noting that section 2(c) (Territory of Use) listed the territory of use as *"UK"* queried the SGSS and CHSS datasets which are UK use only and as outlined on NHS Digital's transparency note: register of processing activities. IGARD asked that confirmation was provided on whether those requirements from the disbanded Public Health England (PHE) still applied. Noting that data may have been potentially accessed by researchers not physically based in the UK, to provide confirmation that the NHS Digital SIRO had been notified of a potential breach of the DSA in relation to the access of data from outside the permitted territory of use. In addition, IGARD suggested that the special conditions be updated or deleted, as may be necessary, to reflect the current restrictions on the use of CHSS / SGSS data. IGARD queried why the applicant had not provided a copy of the sub-licence register and in line with NHS Digital's DARS Standard for sub-licencing and onward sharing. IGARD asked that a special condition be inserted in section 6 that the register be made available on the applicant's website for participants to view and accessible within 3 months of signing the DSA and in addition that the copy of the register by sent to NHS Digital and a copy uploaded to NHS Digital's CRM as a future supporting document. In addition, and noting the published PHG Foundation 'how does personal data apply to genomics and what does that mean for researchers and healthcare?' which states that the whole genome can be commonly assessed as an identifier, asked that section 5 (Purpose /

	Methods / Outputs) be updated to clearly describe what aspects of the participants' genome were available to sub-licencees. IGARD noted reference in section 5 to "*consultee consent*" and suggested that this was amended to "*consultee advic*e", and also asked that further clarification was provided for the legal basis for retaining the information relating to those who are part of the cohort which consultee advice was relied upon. IGARD also noted a possible concern that those participants who had consented under original documentation were not informed that identifiable information would flow **to** NHS Digital, however it was clear to IGARD that the applicant was very proactive in communicating with the cohort and were content on this aspect. 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 would be revealed, asked that, this was updated to include a UK General Data Protection Regulation (UK GDPR) legal basis for dissemination and receipt of data; in accordance with the latest advice from the Privacy, Transparency and Ethics (PTE) Directorate. 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 to the Health and Social Care System. IGARD noted the yielded benefits in section 5(d) (iii) (Yielded Benefits) and, in line with NHS Digital's DARS Standard for Expected Measurable Benefits, asked that further details were provided of two or three 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, to ensure the processing activities as outlined in section 5(a) (Objective for Processing) are reflected in yielded benefits. IGARD noted references in section 5 to academic papers and asked that this public facing section, which forms NHS Digital's data uses register, was reviewed and either updated to include a relevant weblink or fuller searchable reference. In addition, IGARD noted that weblinks within section 5 should be accessible across a range of internet browsers. IGARD asked that section 5(a) was updated and in line with NHS Digital's DARS standard for commercial purpose, to provide a brief summary in section 5(a) of the commercial aspect of the application and as outlined in section 5(e) (Is the Purpose of this Application in Anyway Commercial). NHS Digital noted that they would update the Profession Advisory Group with regard to the updated application and IGARD were in agreement of this approach. **Outcome:** recommendation to approve subject to the following conditions: 1. In respect of the consent: a. To provide a written analysis of the 100,000 Genomes Project consent assessment which establishes there is appropriate legal basis through consent for the use of the data as a control group for this research. b. To upload a copy of the written analysis to NHS Digital's CRM. 2. In respect of the territory of use: a. Noting that the special condition section 6 notes that users of the data must be physically based in the UK, and that SGSS / CHSS datasets are UK use only, to provide confirmation that those requirements from the disbanded PHE still apply.

	b. To notify the SIRO that there may have been a breach of the DSA in relation to the access of data from outside the permitted territory of use. c. To update or delete the special condition in section 6, as may be necessary, to reflect any current restrictions on the use of CHSS / SGSS data. The following amendments were requested: 1. To update section 3 to include a UK GDPR legal basis for those datasets that give information about cohort members who are still living, if this accords with the latest advice from PTE. 2. In respect of the sub licence register, and in line with the NHS Digital DARS Standard for sub-licencing and onward sharing: a. To insert a special condition that the sub licence register is available on the applicant's website for participants to view and ensure it is accessible within 3 months of signing of the DSA. b. The applicant to provide the sub licence register to NHS Digital and a copy uploaded to NHS Digital's CRM. 3. To update section 5 to clearly describe what aspects of the participants' genome are available to sub-licencees, noting that the whole genome is commonly assessed as an identifier. 4. In respect of section 5d Benefits and in line with the NHS Digital DARS Standard for expected measurable benefits: a. To remove any specific outputs from section 5(d) and move to section 5(c), b. To update section 5(d) (iii) to provide 2 or 3 specific yielded benefits accrued to date, to ensure the processing activities as outlined in section 5(a) are reflected in the yielded benefits. 5. To update the references to academic papers in section 5, to either include a fuller searchable reference or a relevant web link. 6. To update the weblink provided in section 5 to ensure they are accessible across a range of internet browsers. 7. In line with the NHS Digital DARS Standard for commercial purpose, to provide a brief summary in section 5(a) of the commercial aspect of this application. 8. To clarify the legal basis for retaining the information relating to those who are part of the cohort where consultee advice was relied upon. The following advice was given: 1. IGARD suggested NHS Digital inform PAG of the updated application. It was agreed the conditions would be approved out of committee (OOC) by IGARD members.
3.3	Imperial College London / HSCIC: Mass evaluation of lateral flow immunoassays for the detection of SARSCoV-2 antibody responses in immunosuppressed people (MELODY) (Presenter: Catherine Day, Louise Dunn, Kimberley Walsh) NIC-609903-V6Q7S-v0.4 **Application:** This was a new application for identifiable Demographics data; for the purpose of supporting the mass evaluation of lateral flow immunoassays for the detection of SARS-CoV-2 antibody responses in immunosuppressed people (MELODY) Study, funded by the Medical Research Council. The study includes two parallel arms: **1)** where a cohort of people who are immunosuppressed due to autoimmune diseases and cancers are identified by the National Disease Registration Service (NDRS), and **2)** another parallel arm and methodologically similar arm where a cohort of people who are immunosuppressed due to solid organ transplants are included through

	NHS Blood and Transplant. This application relates only to the arm involving NDRS and the patients with autoimmune diseases and cancers. The MELODY study will invite up to 40,000 immunosuppressed people with either an autoimmune disease or haematological malignancy, aged 18 years of age and over, who have received 3 doses of a COVID-19 vaccine. The aim is to receive consent from approximately 24,000 participants. NHS Digital noted that this was an urgent application and thanked IGARD for receiving additional clarity and information up to the start of the meeting. **Discussion:** IGARD noted that this application had been previously seen at the IGARD – NHS Digital COVID-19 Response meeting on the 14th December 2021. IGARD confirmed that they were of the view that the most recent consent materials provided the appropriate gateway and were broadly compatible with the processing outlined in the application. NHS Digital verbally noted that NHS Digital had not been included as a Data Processor and IGARD suggested that section 1(c) (Data Processor(s)) be updated to reflect this additional information, including any other relevant amendments throughout the application, in line with NHS Digital's DARS Standard for Data Processors. IGARD queried what databases would be updated with the survey answers to the questionnaires sent to participants, since it was not clear within the application. NHS Digital verbally noted that the survey answers would populate both the Melody study and permanent NDRS data asset. Noting that the NDRS dataset held by NHS Digital is a permanent data asset for use by other DARS applicants, IGARD stated the applicant should update their transparency materials to be clear that the survey answers provided would not only be used in respect of the Melody Study but would also populate the permanent NDRS data asset. IGARD were unclear with regard to the contractual arrangements between the data controller and data processors, and between the data processors, and suggested that NHS Digital assure itself of the contractual arrangements in place, and to include a brief summary in section 1 (Abstract). Noting the current SARS-CoV-19 variant was affecting a large number of younger people and children, IGARD queried why that part of the population were being excluded from the research, and noting that this was not necessarily an invasive procedure (e.g. a questionnaire where the young person could answer or not the survey questions) that an explanation be provided in section 5 (Purpose / Methods / Outputs) as to why they were excluded. In addition, IGARD members noted the concerns of the wider community and as raised in the national news of the inaccurate recording of the booster vaccine as a primary dose at injection 3, and the qualifying criterion of becoming a cohort participant, as outlined in the application. IGARD suggested that the applicant may wish to consider this point. IGARD also noted that the applicant had only requested 40,000 data records in order to receive consent from approximately 24,000 participants, which would require a response rate of 60%. Noting the holiday period and in light of the current push for vaccine and boosters which may reduce the eligible pool, IGARD were supportive of the applicant receiving further data records beyond the initial request of 40,000 to ensure that appropriate cohort members were gathered. IGARD noted that the study protocol provided as a supporting document may be of interest to the wider community and suggested that the applicant publish it on their public facing website.

	IGARD noted the engagement of charities and other interested groups, including the letters of support which had been provided as supporting documents, but suggested that the applicant include further public and patient involvement and engagement (PPIE) and in line with the HRA guidelines for Public Involvement. IGARD noted a number of acronyms and technical terms in section 5, and asked that this public facing section, that forms NHS Digital's data uses register, was amended throughout, to ensure acronyms be defined upon first use, and technical terms are explained in a manner suitable for a lay audience, for example "*immunoassay*". IGARD suggested that section 5(d) (Benefits) be updated to remove reference to "*it will*…", and instead use a form of words such as "*it is hoped*…". IGARD 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 of the data flows, use of international data processors and the importance of this study, (with the exception of the addition of further data beyond the initial 40,000 requested which had IGARD support). **Outcome:** recommendation to approve The following amendments were requested: 1. To add to section 1c NHS Digital as a Data Processor, as per the verbal update. 2. To update the transparency material to be clear that the survey answers provided would not only be used in respect of the Melody study but would also populate the permanent NDRS data asset held by NHS Digital for use by other DARS applicants. 3. For NHS Digital to assure itself that the appropriate contractual arrangements are in place between the data controller and data processors, and between the data processors. 4. IGARD noted a number of technical terms in section 5, and asked that this public facing section, that forms NHS Digital's data uses register, was amended throughout so technical terms are explained in a manner suitable for a lay audience, for example *"immunoassays"*. 5. To provide an explanation in section 5 as to why children and young people under 18 have been excluded from the research. 6. To update section 5(d) to use a form of wording such as "*it is hoped* …", rather than "*it will…*". The following advice was given: 1. IGARD noted that concerns raised in the wider community of the inaccurate recording of the booster vaccine as a primary dose at injection 3 and the qualifying criterion of becoming a cohort participant. 2. IGARD were supportive of the applicant receiving further data records beyond the initial 40,000 requested to ensure that the appropriate cohort members were gathered (in light of the current push for vaccines and boosters which may reduce the eligible pool). 3. IGARD Members noted that the study protocol may be of interest to the wider community and that the applicant may wish to publish on the public facing website. 4. IGARD members noted the engagement with charities and other interested groups but suggested that the applicant include further PPIE and in line with the HRA guidelines on public involvement. 5. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the complexity of the data flows, use of

	international data processors and importance of this study, (with the exception of the addition of further data records beyond the initial 40,000 requested which already had IGARD support). 6. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the complexity of the data flows, use of international data processors and the importance of this study, (with the exception of the addition of further data flows beyond the 40,000 requested which already had IGARD support). **Risk area:** NHS Digital should update their NDRS DPIA to clearly outline the additional processing taking place for the NDRS dataset.
3.4	<u>GRAIL Bio UK Ltd: GRAIL's NHS Galleri Clinical Trial Outcomes Data Request (Presenter: James Gray, Frances Perry, Andy Rees) NIC-604847-S4B5L-v0.4</u> **Application:** This was a new application for pseudonymised Cancer Registration Data, Cancer Waiting Times (CWT) Data Set, Diagnostic Imaging Dataset (DID), Emergency Care Data Set (ECDS), Hospital Episode Statistics Admitted Patient Care (HES APC), HES Outpatients, Radiotherapy Data Set, Rapid Cancer Registrations Data Set and Systemic Anti-Cancer Therapy Dataset (SACT). The purpose is to carry out follow-up analysis based on a cohort of patients who are being recruited to a clinical trial called 'NHS-Galleri' following being invited to participate if they are found to meet the required eligibility criteria. A new Multi-Cancer Early Detection (MCED) test has been developed that can detect many types of cancer from a single blood sample. This test is called Galleri, and will aim to find out whether it is better at discovering cancer early, compared to other tests that the NHS currently uses. The purpose of NHS-Galleri is to demonstrate the clinical utility of the MCED blood test for individuals in a general screening population in a real-world NHS setting. The rationale behind this trial is that MCED is a novel screening paradigm, and assessment of the use and impact of test results is necessary to enable integration into clinical practice. This will be the first randomised, double blind, controlled trial statistically powered to assess clinical utility of a MCED test. Recruitment to the trial is being undertaken via a separate Data Sharing Agreement (DSA) NIC-456778-J0G3H, and is taking place over a period of 10-12 months from August 2021 with the aim of consenting 140,000 participants. NHS Digital advised IGARD that a thorough review had been undertaken of the consent materials, and confirmed that they were content that the consent materials were compatible with the flow of data. NHS Digital noted that the Global Transfer Assessment for the transfer of pseudonymised record-level data to the United States of America, was currently with Privacy, Transparency & Ethics (PTE). **Discussion:** IGARD noted that NHS Digital had provided a verbal update in respect of this application at the IGARD business as usual (BAU) meeting on the 25th November 2021. IGARD noted and commended NHS Digital, in respect of the review undertaken on the consent materials, as per the verbal update provided. IGARD confirmed that they were also of the view that the most recent consent materials provided the appropriate gateway and were broadly compatible with the processing outlined in the application.

	IGARD also noted and commended NHS Digital on the quality of the information provided within section 1 (Abstract) of the application, which supported the review of the application by Members. IGARD noted the verbal update from NHS Digital in respect of the outstanding Global Transfer Assessment; and asked that written confirmation was provided from PTE that the appropriate documentation had been approved and was in place and that a copy be uploaded to NHS Digital's customer relationship management (CRM) as a future supporting document. IGARD noted that there was a mismatch between the applicant's various transparency materials in terms of how long the data would be held for, and suggested that the published privacy notice, which currently stated that the data may be held *"indefinitely"*, was updated, to align with the consent materials. IGARD asked that NHS Digital ensured that all of their public facing transparency materials were updated to reflect which datasets may be used worldwide, for example, Radiotherapy data which still stated that it can only be used within the UK. IGARD noted that the datasets listed within section 3(b) (Additional Data Access Requested) were all *"pseudonymised"*, however asked that this was updated to correctly reflect the identifiability of the datasets, including, but not limited to, the Cancer Registration data; noting that the cohort had consented and that identifiable data would be handled. IGARD noted that the discussion in respect of the identifying data does not in any way take away from the requirement that the USA entity will only have access to pseudonymised data. IGARD noted the incorrect reference in section 5(a) (Objective for Processing) to *"Clinical Trials Prevention Unit"*, and asked that this was updated to correctly state *"Clinical Prevention Trials Unit"*. IGARD noted a number of technical terms in section 5(a), and asked that this public facing section, that forms NHS Digital's data uses register, was amended throughout, to ensure technical terms are explained in a manner suitable for a lay audience, for example *"…ICD-O-3.2"*. **Outcome:** recommendation to approve The following amendments were requested: 1. To provide confirmation from NHS Digital's PTE that the appropriate Global Transfer Assessment documentation has been approved and in place. 2. To update section 3(b) to correctly reflect the identifiability of the datasets, including (but not limited to) the Cancer Registration data. 3. As section 5 forms NHS Digital's data uses register, to amend section 5(a) throughout, so technical terms are used only where necessary and explained in a manner suitable for a lay audience, for example *"…ICD-O-3.2"*. 4. To amend the incorrect reference in section 5(a) from *"Clinical Trials Prevention Unit"* to *"Clinical Prevention Trials Unit"*. The following advice was given: 1. IGARD noted a mismatch between the various transparency materials in terms of how long the data will be held for, and suggested that the published privacy notice, which currently states that the data may be held indefinitely, is updated, to align with the consent materials.

	2. IGARD asked that NHS Digital ensured that all of their public facing transparency materials are updated to reflect which datasets may be used worldwide, for example, Radiotherapy data which still states it can only be used within the UK.
3.5	London School of Economics and Political Science (LSE): Investigating the impact of the Health in Pregnancy Grant on birth outcomes in England, 2009-2011 (Presenter: Farris Dean) NIC-309029-P7H1D-v1.4 **Application:** This was a renewal and extension application, to permit the holding and processing of pseudonymised Hospital Episode Statistics Admitted Patient Care (HES APC) data; and an amendment to include additional data fields within the HES dataset requested, which are two bespoke weeks of birth variables. The purpose is for a stand-alone research project, building on previous work conducted by the London School of Economics (LSE) evaluating the Health in Pregnancy Grant (2009-2011). This grant was a lump sum of £190.00 given to all pregnant women in the UK from the third trimester of pregnancy, regardless of income or work status. The aims of the grant were to reduce low birthweight; and to reduce prematurity. Both low birthweight and prematurity are associated with low-income and lack of funds during pregnancy for healthy nutrition and lifestyle. The rationale of the grant, therefore, was that boosting women's incomes during pregnancy, would facilitate the purchase and consumption of healthier food, invest in healthy lifestyle choices and reduce any financial stress caused by having a baby. The cohort to be generated by NHS Digital could be approximately 5.7 million records. NHS Digital advised that the previous Data Sharing Agreement (DSA) had expired on the 30th April 2021; and suggested that a 1-year extension to the DSA was recommended, for example, to review the progress made to date with the outcomes and benefits of the research. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 28th May 2020. IGARD noted the verbal update from NHS Digital in respect of the DSA having expired on the 30th April 2021; and confirmed that they agreed with the proposal made by NHS Digital in respect of a 1-year extension to the DSA. IGARD noted that section 1 (Abstract) stated that a review by IGARD was not required; and again requested that NHS Digital review their internal processes and IT systems to ensure this doesn't incorrectly default to state *"no"*. NHS Digital confirmed that work was ongoing to resolve this issue, and a verbal update would be provided by a member of the Data Access Request Service (DARS), at an IGARD BAU meeting in early 2022. IGARD queried why there was no reference within the application to the National Institute for Health Research (NIHR) funded study, as reported in The Lancet, which was to assess the effectiveness of the Health in Pregnancy (HiP) Grant in Scotland; and determine whether mothers who received HiP had babies with a different birthweight and had different health behaviours compared with mothers who did not receive HiP. IGARD asked, that noting the broadly similar scope, that section 5(a) (Objective for Processing) as updated to acknowledge the research and why further research was necessary given the similarities in methodology. IGARD noted that following the end of the Health in Pregnancy programme, there was a more targeted Sure Start Maternity Grant, that was only eligible to be claimed within 11-weeks of the baby's due date (or within 6 months after the baby's birth), which was a different timeframe from the Health in Pregnancy programme. IGARD asked that section 5(a) was updated, with

	assurance that the study was sufficiently powered to reflect both grants, and how the final cohort would be processed to take account of the fact whilst some of the cohort not be in receipt of the Health in Pregnancy Grant, some may have received the targeted Sure Start Maternity Grant. IGARD suggested that the applicant check with their University ethics committee, as to whether or not ethics support was required, noting that even though it was using pseudonymised data, the research may have negative repercussions for a specific group, for example, informing decisions about the provision or withdrawal of grants to pregnant women. IGARD suggested that the applicant may wish to discuss plans for disseminating the outputs, with relevant patient-focussed charities, including, but not limited to, BLISS, who provide emotional and practical support to families who have low birth weight babies. IGARD noted the reference within the applicants published privacy notice to data not being collected under contract, and suggested that this was removed as it was not necessary. IGARD advised that they would wish to review this application when it comes up for renewal, to check how the benefits had progressed and how any confounding factors such as the subsequent Sure Start Maternity Grant would be accounted for in processing the data**.** **Outcome:** recommendation to approve for a 1-year extension. The following amendments were requested: 1. To update section 5(a) to acknowledge the NIHR funded research of a broadly similar scope, as reported in The Lancet. 2. To update section 5(a) with assurance that the study is sufficiently powered to reflect that following the end of the Health in Pregnancy programme, there was a more targeted Sure Start Maternity Grant; and how will the final cohort be processed to take account of the fact whilst some of the cohort not be in receipt of the Health in Pregnancy Grant may have received the Sure Start Maternity Grant. *3.* IGARD noted that section 1 stated that a review by IGARD was not required; and again requested that NHS Digital review their internal processes and IT systems to ensure this doesn't incorrectly default to state *"no"*. The following advice was given: 1. IGARD supported NHS Digital's suggestion of a 1-year DSA extension. 2. IGARD suggested that the applicant may wish to discuss plans for disseminating the outputs with relevant patient-focussed charities, including (but not limited to) BLISS, who work with families who have low birth weight babies. 3. IGARD suggested that the applicant updates the published privacy notice to remove the reference to data not being collected under contract. 4. IGARD suggested that the applicant check with the University ethics committee as to whether or not ethics support is required because even though it is pseudonymised data, it may have negative repercussions for a specific group, for example, informing decisions about the provision or withdrawal of grants to pregnant women. 5. IGARD advised that they would wish to review this application when it comes up for renewal, to check how the benefits have progressed and how any confounding factors such as the subsequent Sure Start Maternity Grant will be accounted for in processing the data**.**
3.6	NHS Cheshire CCG: DSfC Cheshire CCG - STP - Comm (Presenter: Dan Goodwin) NIC-140059-P1J9L-v4.2

	Application: This was an amendment application to **1)** add Optum Health Solutions Limited for population health management; **2)** to add Graphnet Health Ltd who will provide outputs of the Optum programme; **3)** to add Amazon Web Services who supply Cloud services to Optum; **4)** to add 9 Local Authorities as Data Controllers; **5)** to change Oldham CCG to Salford Royal NHS Foundation Trust (IT Supplier); **6)** to add linkage to GP, Social Care, Mental Health, Community and Acute data; **7)** to add Medicines Dispensed in Primary Care and Adult Social Care data. The purpose is to provide intelligence to support the commissioning of health services. The data is analysed so that health care provision can be planned to support the needs of the population within the CCG area. NHS Digital advised IGARD that Liverpool City Council and Sefton Metropolitan Borough Council had not been included within all the right sections within the application, and advised that this would be reviewed and updated as appropriate. IGARD noted the large number of storage and processing locations in section 2 (Locations), and noting this may cause difficulty for NHS Digital in respect of auditing, suggested that NHS Digital worked with the applicant to review and consider if the locations could be consolidated, noting the discussion at the workshop at the business as usual (BAU) meeting on the 18th November 2021. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 15th March 2018. IGARD noted the verbal update from NHS Digital in respect of Liverpool City Council and Sefton Metropolitan Borough Council not being captured within the relevant sections; and supported the update to the application to amend as necessary. IGARD noted the advice provided from NHS Digital's Privacy, Transparency &Ethics (PTE), that specifically stated that pseudonymised data should **not** be re-identified for purposes relating to housing data. IGARD suggested that NHS Digital asked for further confirmation from PTE as to why this this outcome had been distinguished specifically for housing data, and not in other applications where there were potential sensitivities and similar ethical issues. IGARD noted the forthcoming system changes across healthcare, in respect of the Integrated Care Systems (ICSs); which are new partnerships between the organisations that meet health and care needs across an area, to coordinate services and to plan in a way that improves population health and reduces inequalities between different groups; and therefore asked that section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) were updated with a reference to the forthcoming CCG / ICS transition. **Outcome:** recommendation to approve The following amendments were requested: 1. IGARD noted the large number of storage and processing locations, and, noting this may cause difficulty for NHS Digital in respect of auditing, suggested that NHS Digital worked with the applicant to review and consider if the locations could be consolidated, noting fewer storage locations are needed, due to the fact the processing involves linkage in a shared cloud. 2. To update section 1 and section 5 with a reference to the forthcoming CCG / ICS transition. The following advice was given:

	1. IGARD noted the PTE advice provided that specifically stated that pseudonymised data should not be re-identified for purposes relating to housing data. IGARD suggested that NHS Digital asked for further confirmation from PTE as to why this this outcome has been distinguished specifically for housing data, and not in other applications where there are potential sensitivities and similar ethical issues.
3.7	NHS North and East London Commissioning Support Unit: DSfC - Pseudo Person-Household Analytics to assess wider social determinants of health (Presenter: Michael Ball) NIC-183870-V0T3Y-v0.22 Application: This was a new application for pseudonymised Improving Access to Psychological Therapies (IAPT) Data Set, Personal Demographic Service (PDS), Secondary Uses Service (SUS) for Commissioners data, Mental Health Services Data Set (MHSDS), Community Services Data Set (CSDS), Children and Young People Health Services (CYPHS) Data Set. The London Borough of Islington requires pseudonymised data for use in the Islington Advancing Applied Analytics project to improve public health in Islington, and the targeted commissioning of services relevant to the needs of the population in the borough. This project aims to achieve this by linking health records with local authority council records (including social care, education and housing), at a household level, using pseudonymised Unique Property Reference Number (UPRN) to create a pseudonymised dataset of linked health and social records for households in Islington. The application was previously considered on the 22nd October 2020 where IGARD had deferred making a recommendation. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 22nd October 2020. IGARD noted that the application had been updated to reflect all the previous deferral points except for clarity regarding this being a pilot project. IGARD queried the role of the Health Foundation, noting that information about the study was seemingly published on the Health Foundation website; and noting that there was no reference with the application to the Health Foundation, asked that written confirmation was provided of any link and / or funding arrangements with the Health Foundation; and that the written confirmation be added to NHS Digital's customer relationships management (CRM) system for future reference. IGARD noted that the last paragraph in section 5(d) (Benefits) that started "*Housing plays a central role in the conditions of daily life of each individual…"* was in fact an output, and asked that this was removed from section 5(d) and added to the outputs in section 5(c) (Specific Outputs Expected), in line with NHS Digital's DARS Standard for Expected Outcomes. IGARD also asked that for transparency, the references to the proof-of-concept pilot within section 5 (Purpose / Methods / Outputs) were updated to accurately reflect that was a proof of concept of evidence-based commissioning. Following the update to section 5, IGARD asked that the benefits in section 5(d) were updated to state what the expected benefit to commissioning would be, in line with NHS Digital DARS Standard for Expected Measurable Benefits, for example, how it has worked and how it would be demonstrated. IGARD asked that the application was reviewed to ensure that it reflected a commissioning application, for example, updating section 5 to state that ethical support was not required if this was a commissioning application.

	IGARD noted that given the developments in understanding about the impact of air pollution on public health, they advised that they would be supportive of expanding the investigation of evidence-based commissioning, linking to air pollution data that could subsequently inform commissioning decisions. IGARD advised that when this application comes up for renewal, they would expect the yielded benefits to be clearly outlined, and to reflect the work that has been undertaken, and the benefits accrued since the application was last seen. IGARD advised that they would wish to review this application when it comes up for renewal; and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the novel linkage with housing data. **Outcome:** recommendation to approve subject to the following conditions: 1. In respect of the Health Foundation: a) To provide written confirmation of any link and / or funding arrangements with the Health Foundation, in light of the information published about this study on the Health Foundation website. b) To upload the written confirmation to NHS Digital's CRM system for future reference. 2. In respect of the proof-of-concept pilot: a) To remove the last paragraph of section 5(d) and move to section 5(c). b) To update section 5 to state that it is a proof of concept of evidence-based commissioning. c) To update section 5(d) to state what the expected benefit to commissioning will be. The following amendments were requested: 1. To update section 5 that ethical support is not required if this is a commissioning application. The following advice was given: 1. Given the developments in understanding about the impact of air pollution on public health, IGARD advised that they would be supportive of expanding the investigation of evidence-based commissioning linking to air pollution data that could subsequently inform commissioning decisions. 2. IGARD advised that when this application comes up for renewal, they would expect the yielded benefits to be clearly outlined, and to reflect the work that has been undertaken, and the benefits accrued since the application was last seen. 3. IGARD advised that they would wish to review this application when it comes up for renewal, due to the novel linkage with housing data. 4. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the novel use of data. It was agreed the conditions would be approved out of committee (OOC) by IGARD members.
4	<u>Applications progressed via NHS Digital's Precedent route, including the SIRO Precedent</u> Applications that have been progressed via NHS Digital's Precedent route, including the SIRO Precedent, and NHS Digital have notified IGARD in writing (via the Secretariat).
4.1	<u>NIC-343380 Public Health England (PHE)</u>

	The purpose of this application was for this Data Sharing Agreement (DSA), to be the main DSA for PHE, which superseded the Memorandum of Understanding (MoU) between NHS Digital and PHE. IGARD noted that this application was last reviewed at the IGARD business as usual meeting on the 3rd June 2021 for advice only; and was previously seen at the IGARD – NHS Digital COVID-19 Response meeting on the 27th July 2021. IGARD noted that on the 3rd December 2021, NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had agreed to authorise a renewal for a period of 6-months, while PHE's functions were fully transferred to the receiver organisations following the closure of PHE. During this time this current PHE Single DSA will be reviewed and replaced by separate DSAs between NHS Digital and each receiver organisation, with a review by IGARD. IGARD noted and thanked NHS Digital for the written update and confirmed that they supported NHS Digital's assessment that the next iteration(s) should be brought to a future IGARD BAU meeting. In addition, and noting the complexity of the application, IGARD advised that they would welcome a discussion at an IGARD BAU meeting with colleagues from the Data Access Request Service (DARS) and, if appropriate, Privacy, Transparency & Ethics (PTE) in advance of the application being submitted to IGARD for review.
4.2	NIC-15814-C6W9R - Monitor (NHS England / NHS Improvement) (Presenter: Louise Dunn) The purpose of this application, was to request data for the NHS Trust Development Agency, NHS England / NHS Improvement, and Monitor as join Data Controllers and will be used to support the delivery of the applicant's statutory function and support direct improvement and / or oversight of Trusts. IGARD noted that this application was last reviewed at the IGARD business as usual meeting on the 2nd July 2020, where the application was recommended for approval with conditions, by way of a majority vote of four members to one member, with one specialist member dissenting. NHS Digital attended the meeting to advise IGARD that as this DSA was due to expire on the 31st December 2021, the SIRO had agreed to authorise a renewal for a period of 3-months, up to the 31st March 2022. In addition, NHS Digital have confirmed that the next iteration of the application would be presented at a future IGARD BAU meeting. IGARD noted and thanked NHS Digital for the verbal update and confirmed that, noting the complexities of the application, they supported NHS Digital's assessment that the next iteration should be brought to a future IGARD BAU meeting.
5	Oversight & Assurance IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. Due to the volume and complexity of applications at today's meeting, IGARD were unable to review any Data Access Request Service (DARS) applications as part of their oversight and assurance role. IGARD noted that they had requested, an IG COVID-19 release register suite of documents on a particular data release for review by IGARD as part of their oversight and assurance, and as agreed in June 2020 with the Executive Director Privacy, Transparency and Ethics (PTE) when it had been agreed that IGARD review an agreed number per month, by way of a review of all documentation revised by PTE, and as part of continuous improvement and quality.

	IGARD Members noted that they had not yet been updated on the issues raised at the 27th May 2021 IGARD business as usual (BAU) meeting with regard to previous comments made on the IG COVID-19 release registers. IGARD Members noted that the last IG COVID-19 release register that they had reviewed and provided comments on was July 2021.
6	<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 14th December 2021** can be found attached to these minutes as Appendix B.
7 **7.1**	<u>AOB:</u> <u>CCG DSA Amendment (Presenter: Michael Ball)</u> NHS Digital attended IGARD for some advice, in relation to an urgent amendment to a CCG DSA, to change its Data Processor to an NHS Trust. NHS Digital advised that the NHS Trust also had access to other datasets, which included local patient identifiers; and that it was therefore technically possible for them to re-identify individuals. IGARD had a brief discussion with NHS Digital, and advised that they were unable to provide a formal response on the query raised, noting that as the item was a late addition to the meeting agenda, no written information had been provided to support the discussion. Several members of IGARD were broadly supportive *in principle* of an NHS hospital trust acting as a data processor for another NHS body, (e.g. a CCG or other commissioning body) provided appropriate contractual, organisational, and technical controls were in place. IGARD did however ask that NHS Digital seek written support from Privacy, Transparency & Ethics (PTE); and that this was uploaded on to NHS Digital's CRM system for future reference. IGARD also noted that they would be happy to provide formal advice at a future IGARD BAU meeting, following submission of the appropriate supporting documentation as per process.
7.2	<u>SIRO Attendance</u> NHS Digital's Senior Information Risk Owner (SIRO) attend the meeting, to thank IGARD members for their valuable support to NHS Digital over the last 12-months, and in advance of the imminent Christmas break. IGARD noted and thanked the SIRO for attending the meeting.
7.3	<u>IGARD Meeting Quoracy</u> In light of the ongoing situation with COVID-19, and following consideration by IGARD members, it has been agreed with NHS Digital that from the 26th March 2020 IGARD business

	as usual meeting, the in-meeting quoracy may be temporarily reduced to three members (from four members), which must include a Chair and at least two specialist members. This is to ensure business continuity in the event that COVID-19 impacts on members ability to dial-in to meetings (due to COVID-19 illness or caring for a household member with COVID-19) and to support those IGARD members who have other roles linked to the COVID-19 response. This will be reviewed as and when required, but no less than monthly, and in response to new guidance that is released. This relates to COVID-19 only and the next formal update in IGARD minutes will be at the end of June 2022. 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 10/11/21

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-379653-W3G5Q-v0.14	Royal College of Physicians of London	14/10/2021	1. In respect of the one year of data (2020-2021) not covered in the application: a) To provide a satisfactory and robust explanation in section 1 and section 5 as to why the one year of data during the height of the COVID-19 pandemic is not included within the DSA; and, b) To provide confirmation of how and who this was *"agreed"* with. c) To expressly acknowledge in section 5(c) that the audit will be missing one year of data at the height of the COVID-19 pandemic and the potential impact this may have on the outputs.	IGARD members	Quorum of IGARD members	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, 14th December 2021

In attendance (IGARD Members):	Prof. Nicola Fear (IGARD Specialist Academic Member)
	Kirsty Irvine (IGARD Chair)
	Dr. Imran Khan (IGARD Specialist GP Member)
In attendance (NHS Digital):	Dave Cronin (DARS)
	Cath Day (DARS)
	Louise Dunn (DARS)
	Dickie Langley (PTE – Observer) (Item 2.1)
	Kimberley Watson (DARS)
	Vicki Williams (IGARD Secretariat)

3	**Welcome** The IGARD Chair noted that this was a weekly meeting convened to support NHS Digital's response to the COVID-19 situation and was separate from the IGARD business as usual (BAU) meetings. IGARD members present would only be making comments and observations on items that were presented, and were not making formal recommendations to NHS Digital. Should an application require a full review and recommendation, then it should go through the usual Data Access Request Service (DARS) process and be presented at a Thursday IGARD meeting. The action notes from the Tuesday meeting will be received out of committee and then published alongside the minutes of the next Thursday BAU meeting as an appendix. **Declaration of interests:** Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising the Scientific Advisory Group for Emergencies (SAGE) on COVID-19
2.1	NIC-609903-V6Q7S-v0.4 Imperial College London / HSCIC **Background:** This was a new application requesting demographic data to support the mass evaluation of lateral flow immunoassays for the detection of SARS-CoV-2 antibody responses in immunosuppressed people (MELODY) Study, funded by the Medical Research Council. The application relates only to the arm involving the National Disease Registration Service (NDRS) and the patients with autoimmune diseases and cancer. NHS Digital noted that the study had been originally submitted to Public Health England's (PHE) Office of Data Release (ODR) and that as part of the transition, DARS had been asked to progress the application as per due process. NHS Digital noted the data from PHE (now NHS Digital) NDRS would be linked to Personal Demographic Data (PDS) and the contact

	details provided to Ipsos MORI who would send invitations to approximately 40,000 in order to recruit 24,000 participants. NHS Digital noted that the application and relevant supporting documentation was to be presented to the IGARD business as usual (BAU) meeting on Thursday, 16th December 2021. The following observations were made on the basis of the verbal update from NHS Digital and relevant documentation provided for the BAU meeting on Thursday. **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 documentation. Should a full review of the application and any supporting documentation be required, the full suite of documentation should be presented to a IGARD BAU meeting for a recommendation. IGARD members noted the verbal update from NHS Digital and that the application was to be presented at an IGARD BAU meeting on the 16th December 2021. IGARD members noted that the discussion today was not to pre-empt discussions that would take place at the BAU meeting and thanked NHS Digital for the verbal update.
2.2	<u>NIC-599458-Y5Y8X Office for National Statistics (ONS)</u> **Background:** the new application had been brough to IGARD for advice. ONS and the University of Oxford are data controllers for the COVID-19 infection survey (CIS) and they will be applying for approval to use Hospital Episode Statistics (HES), Emergency Care Data set (ECDS), GP data for pandemic planning and research (GDPPR) and Vaccination data linked to participants who consented to be in the CIS. The application had been brought to IGARD on the appropriateness of the proposed opt-out model to permit the collection of and use of the data that was outside the scope of the original consent materials. NHS Digital noted that the application was still in draft, and that further work needed to be undertaken before it could progress further. The following observations were made on the basis of the verbal update from NHS Digital alongside the draft application v0.3, '*Protocol COVID-19 infection survey v13.7 2021-12-03*', '*16yr+ Parent Carer COVID-19 Infection Survey v9.9 2021-12-03*' and '*All participation communications v0.2 2021-12-03*'. **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 documentation. Should a full review of the application and any supporting 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 the verbal update from NHS Digital and that the application may be presented at an IGARD BAU meeting, date yet to be determined. IGARD members noted that the discussion today was not to pre-empt discussions that may take place at a future BAU meeting and thanked NHS Digital for the update and looked forward to receiving the full suite of documentation at the BAU meeting in due course. IGARD members present made the following high-level comments: • IGARD noted that this was an incredibly important study.

	• The change in follow up timing from 1 year to 15 years was a substantive change to the study. • IGARD strongly suggested that the applicant speaks informally to Health Research Authority Confidentiality Advisory Group (HRA CAG) to ask them whether an application should be submitted for s251. If HRA CAG said that an application was not required, to ask HRA CAG to clarify if this was on the grounds that reconsenting was necessary or if the consent was sound (but additional transparency, such as a detailed communication to all cohort members, was needed). • It was acknowledged that reconsenting the entire cohort may lead to significant loss to the cohort so section 251 support would be the likely route to address any deficiencies in consent. • IGARD noted that the communication drafted by the application to send out to all cohort members consented for this study, should be updated from "…*we would like to **ask you** to allow us to link your data*…" (emphasis added). Written in this way it suggested that consent was being sought and a response was required- but there was no mechanism for cohort members to respond to indicate that they agreed with the question. • Any communication to the cohort needed to have a clear, transparent pathway for cohort members to withdraw their consent (e.g. several modes of contacting the study team etc). NHS Digital noted that due to the holiday period that this and other Office for National Statistics (ONS) applications may be progressed via SIRO precedent for minor amendments, however work was ongoing to update all ONS applications to present to a future IGARD BAU meeting. NHS Digital also noted that they were progressing the action raised at the 9th December BAU meeting with regard to the applicant attending an IGARD BAU meeting prior to the application(s) being submitted for review, for further discussions to support the progression of the application(s) and as a general fact-finding meeting.
3	<u>AOB</u> The IGARD Chair thanked all the IGARD members who had attended since April 2020 for their participation and Secretariat for providing support to the meetings. The IGARD Chair also thanked NHS Digital staff for their contributions to the meetings and noted that this was the last meeting of the COVID-19 response meeting, at this time. The IGARD Chair suggested that the IGARD Secretariat team update the NHS Digital IGARD webpages accordingly to remove reference in particular to IGARD running two meetings per week. There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.