Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 3 February 2022

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member
Prof. Nicola Fear	Specialist Academic Member
Dr. Robert French	Specialist Academic / Statistician Member (Observer)
Kirsty Irvine	IGARD Chair
Dr. Imran Khan	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Chair
Dr. Maurice Smith	Specialist GP Member
Jenny Westaway	Lay Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Michael Ball	Data Access Request Service (DARS) (Item 3.6)
Catherine Day	Data Access Request Service (DARS) (Item 3.2)
Louise Dunn	Data Access Request Service (DARS) (SAT Observer: item 3.1)
Duncan Easton	Data Access Request Service (DARS) (SAT Observer: items 3.5 - 3.6)
Dan Goodwin	Data Access Request Service (DARS) (Item 3.5)
James Gray	Data Access Request Service (DARS) (Item 3.1)
Suzanne Hartley	Data Access Request Service (DARS) (Observer: 3.1 - 3.4)
Karen Myers	IGARD Secretariat
Dr. Jonathan Osborn	Deputy Caldicott Guardian (Observer: 3.1 – 3.4)
Tania Palmariellodiviney	Data Access Request Service (DARS) (SAT Observer: items 3.3 - 3.4)
Denise Pine	Data Access Request Service (DARS) (Item 3.4)

Joanna Warwick	Data Access Request Services (DARS) (Item 5)
Kimberley Watson	Data Access Request Services (DARS) (Item 5) (SAT Observer: item 3.2)
Anna Weaver	Data Access Request Services (DARS) (Item 3.3)
Vicki Williams	IGARD Secretariat
SAT – Senior Approval Team (DARS)	

1	**Declaration of interests:** Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising the Scientific Advisory Group for Emergencies (SAGE) on COVID-19. Nicola Fear noted professional links to the University of Manchester [NIC-147811-YTH88] but noted no specific connections with the application or staff involved and it was agreed that this was not a conflict of interest. Nicola Fear noted professional links to National Centre for Social Research (NatCen) [NIC-175989-M9T7B] and the applicant, but noted no specific connections with the application and it was agreed that this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 27th January 2022 IGARD meeting were reviewed out of committee by IGARD following conclusion of the meeting, and subject to a number of minor changes were agreed as an accurate record of the 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	Moderna Therapeutics, Inc: A Phase 2/3, Randomized, Stratified, Observer-blind Study to Evaluate the Immunogenicity and Safety of mRNA-1273.529 (B.1.1.529, Omicron variant) in Comparison with mRNA-1273 (prototype) Booster Vaccine (Presenter: James Gray) NIC-623799-T2J4F-v0.2 **Application:** This was a new application for identifiable Permission to Contact (PtC) data, for the purpose of a vaccine trial. Participants who previously received two or three doses of a COVID-19 vaccine will receive a single booster dose of the Moderna mRNA-1273 or Moderna mRNA-1273.529 vaccines. The aim is to recruit a total of 3,000 participants; therefore, the initial mailout will aim for around four / five times the number of potential participants to be recruited and the estimate is

	for around 12,000 - 15,000 individuals to be contacted via the Permission to Contact (PtC) Service. The PtC Service is where members of the public can register their details and give their permission to be contacted by researchers working on National Institute of Health Research (NIHR) approved UK coronavirus vaccine trials about participating in those trials. This PtC Service, which is called *"Sign Up to be Contacted about Coronavirus Vaccine Studies"* on the nhs.uk website was launched as a national service on 20th July 2020. The contact details obtained via the PtC data, will be used to invite potentially eligible individuals to undertake an eligibility assessment and, if eligible, to give informed consent to participate in this trial. NHS Digital advised IGARD that ethics approval for the study was awaited, due to some outstanding queries that had been raised by The Medicines and Healthcare products Regulatory Agency (MHRA). NHS Digital noted that, as per process, no data would flow until ethical approval was in place. NHS Digital also noted that Informa UK Ltd had submitted a Data Security and Protection Toolkit (DSPT) assessment, and that this was in the process of being reviewed by NHS Digital's Security Advisor, and that security assurance was currently still outstanding. It was also noted that the DSPT for Moderna Therapeutics, Inc. seemingly relate to Moderna Biotech UK limited not the US entity. **Discussion:** IGARD noted the verbal update from NHS Digital that ethical approval was currently not in place. IGARD asked that in line with NHS Digital's DARS Standard for Ethical Approval, written evidence was subsequently provided that ethical support was in place and that the written confirmation provided confirmed that **all** outstanding MHRA queries had been addressed. IGARD asked that a copy of the written ethical support was uploaded to NHS Digital's customer relationships management (CRM) system for future reference. IGARD noted the verbal update from NHS Digital in respect of the outstanding DSPT assessment and that security was currently not in place. IGARD asked that written confirmation was provided, that the DSPT assessment has been finalised, for example by way of an e-mail, and that NHS Digital's Security Advisor had expressed satisfaction that the appropriate security was in place for both Moderna Therapeutics Inc and Informa UK Ltd. IGARD asked that the written confirmation from NHS Digital's Security Advisor was uploaded to NHS Digital's CRM system for future reference. IGARD noted that prior to the meeting, a query had been raised with NHS Digital in respect of the various legal entities of Moderna, for example, Moderna TX Inc, Moderna Therapeutics Inc and Moderna Tx Ltd (now Moderna Biotech UK Ltd), and that they had queried if Moderna Therapeutics Inc were the sole Data Controller, as outlined in the application. NHS Digital advised IGARD that prior to the meeting, they had received written confirmation from the Assistant Secretary of Moderna Therapeutics Inc, confirming that Moderna Therapeutics Inc were the sole Data Controller, and had provided further background information in respect of the study's relationship with the other entities. IGARD noted the verbal update from NHS Digital, and asked that a copy of the document referred to, from the Assistant Secretary of Moderna Therapeutics Inc, was provided, that outlined the descriptions of the entities. In addition, IGARD asked that NHS Digital ensured that the document aligned with the description of the entities in the application, the processing described and data controllership arrangements in line with NHS Digital DARS Standard for Data Controllers and the supporting documents provided. IGARD asked that a copy of the documentation was uploaded to NHS Digital's CRM system for future reference.

	IGARD noted the Professor named within supporting document 1.1, NHS Digital's Preliminary Application Checklist, and queried the role of the Professor in terms of data controllership responsibilities. IGARD asked that written confirmation was provided, that the Professor has not, and does not, carry out any controllership activities, for example, by taking any action that may determine the purposes or the means of using the PtC dataset, and therefore their employer was **not** considered, nor fulfils the criteria of, a Data Controller under UK General Data Protection Regulation (UK GDPR) in respect of the PtC dataset, and in line with NHS Digital's DARS Standard for Data Controllers. In addition, IGARD also asked that for future reference, an analysis was provided in section 1 (Abstract), as to why the Professor was not carrying out any data controllership level activities and therefore their employer was not considered a joint Data Controller. IGARD noted that potentially eligible individuals would be invited to give informed consent to participate in this trial, however, IGARD noted that there was no provision in the current version of the consent materials for future linkage of trial data to NHS Digital data or ongoing follow up of health status. NHS Digital advised that communication with the applicant(s) was undertaken via the National Institute for Health Research (NIHR), who were communicating key messages on behalf of NHS Digital to applicants. IGARD noted the verbal update from NHS Digital, and asked that an example was provided of the correspondence from NIHR to the applicant(s) accessing the PtC, setting out the concerns IGARD have expressed about the risks of limited and restricted consent; and that a copy of such example was uploaded to NHS Digital's CRM system for future reference. IGARD noted that Article 9(2)(j) of the UK General Data Protection Regulation (UK GDPR) was cited as the legal basis for the processing, however asked that section 1 and section 5 (Purpose / Methods / Outputs) were updated, to correctly list the Data Protection Act (DPA) 2018 Schedule 1 Part 1 references, and to clearly describe how the schedule conditions are met. IGARD noted the inclusion and exclusion criteria in section 5(b) (Processing Activities) that would be used by the recruitment sites during the screening phase, and queried the reasons for the exclusions, for example pregnant women and those that are immunosuppressed, IGARD asked that for transparency, section 5 was updated with a brief explanation / justification of the various exclusion criteria, for example, was this on documented safety grounds and had this been approved by a research ethics committee. In addition, noting current discussions nationally and internationally around systemic health inequalities and the dearth of research into the safety of medicines for pregnant women, and consequent impact on women's health, IGARD suggested that NHS Digital raised with NIHR the extensive exclusion criteria in the PtC applications and what steps were being taken to reassure the public that there were ethically sound and scientifically robust justifications for each exclusion, for example as discussed at the IGARD BAU meeting on the 13th January 2022 (item 3.3) it was a known fact of complications during pregnancy for those women who remained unvaccinated. IGARD also noted a significant risk to NHS Digital, who may be seen as being complicit in enabling systematic bias, in terms of not challenging exclusion criteria for clinical trials using NHS Digital data. **Outcome:** recommendation to approve subject to the following conditions: 1. In respect of the ethical approval and in line with NHS Digital's DARS Standard for Ethical Approval: a) To provide written evidence that ethical support is in place.

b) To provide written confirmation that all outstanding MHRA queries have been suitably addressed (as per the verbal update from NHS Digital).
c) To upload a copy of the written ethical confirmation to NHS Digital's CRM system.

2. In respect of the security arrangements:
   a) To provide written confirmation (such as an e-mail) that the DSPT assessment has been finalised for Informa UK Ltd; and
   b) To confirm that NHS Digital's Security Advisor has expressed satisfaction that the appropriate security is in place for Moderna Therapeutics Inc.
   c) To confirm that NHS Digital's Security Advisor has expressed satisfaction that the appropriate security is in place for Informa UK Ltd.
   d) To upload the written confirmation from NHS Digital's Security Advisor to NHS Digital's CRM system for future reference.
3. In respect of the description of the entities in relation to data controllership:
   a) To provide a copy of the document from the Assistant Secretary of Moderna Therapeutics Inc that outlines the descriptions of the entities (as per the verbal update from NHS Digital).
   b) To ensure the document aligns with the description of the entities in the application, the processing and controllership arrangements and the supporting documents provided.
   c) To upload a copy of the document from the Assistant Secretary of Moderna Therapeutics Inc to NHS Digital's CRM system for future reference.
4. In respect of the Professor named within supporting document 1.1:
   a) To provide written confirmation that the Professor has not and does not carry out any controllership activities (e.g. taking any action that may determine the purposes or the means of using the PtC dataset) and therefore their employer is **not** considered, nor fulfils the criteria of, a Data Controller under UK GDPR in respect of the PtC dataset (and in line with NHS Digital's DARS Standard for Data Controllers).
   b) To provide an analysis in section 1 as to why the Professor is not carrying out any controllership level activities and therefore their employer is not considered a joint Data Controller.

The following amendments and actions were requested:

1. In respect of the correspondence from NIHR to the applicant(s):
   a) To provide to IGARD an example of the correspondence from NIHR to the applicant(s) accessing the PtC setting out the concerns IGARD have expressed about the risks of limited and restricted consent.
   b) To upload a copy of such example to NHS Digital's CRM system for future reference.

2. To update section 5 with a brief explanation / justification of the various exclusion criteria, for example, is this on documented safety grounds and has this been approved by a research ethics committee.

3. To update section 1 and section 5 in respect of the UK GDPR Article 9(2)(j) legal basis to correctly list the DPA 2018 Schedule 1 Part 1 references and clearly describe how the schedule conditions are met.

The following advice was given:

1. Noting current discussions nationally and internationally around systemic health inequalities and the dearth of research into the safety of medicines for pregnant women, and consequent impact on women's health, IGARD suggested that NHS

	Digital raised with NIHR the extensive exclusion criteria in the PtC applications and what steps were being taken to reassure the public that there are ethically sound and scientifically robust justifications for each exclusion. **Significant Risk Area:** NHS Digital may be seen as being complicit in enabling systematic bias, in terms of not challenging exclusion criteria for clinical trials. It was agreed the conditions would be approved out of committee (OOC) by IGARD members.
3.2	<u>NHS Blood and Transplant (NHSBT): MELODY Study (Mass evaluation of lateral flow immunoassays for the detection of SARS-CoV-2 antibody responses in immunosuppressed people) - Transplant Patients (Presenter: Catherine Day) NIC-619023-C7K5V-v0.6</u> **Application:** This was a new application for identifiable Demographics data from NHS Digital's Personal Demographic Service (PDS). The purpose is for the MELODY study, which aims to determine **1)** the proportion of immunosuppressed people who have detectable SARS-CoV-2 antibodies following a primary vaccine course (at least 3 doses), and the demographic, disease, and treatment characteristics that influence antibody status; and **2)** if the detection of antibodies inversely correlates with subsequent risk of SARS-CoV-2 infection and / or severity of disease in immunosuppressed people. The MELODY study also has a parallel arm, where a cohort of people who are immunosuppressed due to autoimmune diseases and cancers which are identified by the National Disease Registration Service (NDRS); data for this arm flows under a separate data sharing agreement (DSA) NIC-609903-V6Q7S-v0.2. The study is funded by the Medical Research Council (MRC). The study will invite up to 40,000 participants to consent to take part in the study, with the aim of recruiting 10,000. The study is relying on s251 of the NHS Act 2006, for the flow of contact details out of NHS Digital. **Discussion:** IGARD noted and commended the applicant and NHS Digital on the quality of the information provided within the application, which supported the review of the application by Members. IGARD confirmed that they were of the view that the relevant s251 support provided the appropriate legal gateway and was broadly compatible with the processing outlined in the application. IGARD queried the statement in section 5(b) (Processing Activities) that further linkage *"…will be done without consent from participants …"*, and asked that this was updated, to make clear that further consent would be taken or that s251 support would be requested. IGARD noted the location of Tivian GmbH who were listed as a storage location in section 2(b) (Storage Location(s)) was Koln, German and queried where the PDS data would be handled. Noting that it was currently unclear, IGARD asked that clarity was provided if the PDS data would be processed in Germany; or to clarify if only the data supplied directly by the consented cohort members would be processed in Germany. IGARD asked that section 5 (Purpose / Methods / Outputs) was amended as appropriate, with relevant narrative confirming the processing being undertaken in Germany. In addition, IGARD asked that any necessary amendments were made to the listed data processors and storage locations; and that the

territory of use aligned with the processing of the PDS data as outlined on the NHS Digital transparency notice for PDS data.

IGARD also noted that following the confirmation, in terms of the processing / data flowing to Germany; that NHS Digital should review and update NIC-609903-V6Q7S throughout as appropriate, noting this DSA was for the parallel arm of the study.

Noting a significant risk to NHS Digital, IGARD asked that NHS Digital confirmed whether the Spine service (no 2) 2014 Direction, which underpins PDS, allowed the use of PDS in this research context, since a Direction, for example, may have territory or recipient restrictions.

IGARD reiterated their request, raised consistently throughout 2021, that NHS Digital ensured that **all** of their public facing transparency materials were updated to reflect which datasets may be used outside England and Wales, for example, the PDS data, which still stated that it can only be used within the UK. IGARD noted that it would be a significant risk to NHS Digital, in terms of UK General Data Protection Regulation (UK GDPR), for transparency information on its website being inaccurate as to the territory of use for a number of datasets.

In addition, IGARD suggested that NHS Digital updated their transparency materials around PDS, for example, to explain where the Local Provider Flows were coming from.

IGARD noted the information provided in supporting document 7, the patient information sheet, in relation to the data controllership arrangements, and noting that this could be open to misinterpretation, suggested that the applicant update their transparency materials to provide a list of the Data Controllers in each limb of the study, and make a general overarching point about data controllership responsibilities.

IGARD reiterated advice provided on NIC-609903-V6Q7S; that the study protocol may be of interest to the wider community and that the applicant may wish to publish this on a public facing website.

IGARD noted the reference to patient and public involvement and engagement (PPIE) in the application, however suggested that the applicant may wish to consider involving the relevant public and patient groups throughout the lifecycle of the project in line with HRA guidance on Public Involvement.

IGARD noted the references in section 1 and section 5(a) to *"…immunoassays…"*, and asked that further clarity was provided on this, for example, by amending to refer to *"at home finger prick blood test"* or similar.

IGARD suggested that this application would be suitable for NHS Digital's Precedent route, including the SIRO Precedent.

Outcome: recommendation to approve subject to the following conditions:

1. In respect of the data handled in Germany:
   a) To clarify if the PDS data will be processed in Germany; or
   b) To clarify if only the data supplied by the cohort will be processed in Germany; and
   c) To amend section 5 with relevant narrative explaining the above;
   d) To make any necessary amendments to the listed data processors and storage locations; and
   e) To ensure the territory of use aligns with the processing of the PDS data.
2. NHS Digital to confirm that the Spine service (no 2) 2014 Direction which underpins PDS, allows the use of PDS in this research context.

The following amendments were requested:

	1. To provide further clarity on the reference in section 1 and section 5(a) to *"…immunoassays…"*, for example, amending to refer to *"at home finger prick blood test"* or similar. 2. To amend the statement in section 5(b) that further linkage *"…will be done without consent from participants …"*, to make clear that further consent will be taken or that s251 support will be requested. The following advice was given: 1. IGARD reiterated their request (raised consistently throughout 2021) that NHS Digital ensured that all of their public facing transparency materials are updated to reflect which datasets may be used outside England and Wales (for example, PDS data which still states it can only be used within the UK). 2. IGARD reiterated advice provided on NIC-609903-V6Q7S; 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. 3. IGARD noted the reference to PPIE in the application, however suggested that the applicant may wish to consider involving the relevant public and patient groups for the lifecycle of the project in line with HRA guidance on Public Involvement. 4. IGARD noted that following the confirmation in terms of the processing / data flowing to Germany; that NHS Digital should review and update NIC-609903-V6Q7S throughout as appropriate. 5. IGARD suggested that NHS Digital updated their transparency materials around PDS, for example, to explain where the Local Provider Flows are coming from. 6. IGARD suggested that the applicant update their transparency materials to provide a list of the Data Controllers in each limb of the study, and make a general overarching point about data controllership responsibilities. 7. IGARD suggested that this application would be suitable for NHS Digital's Precedent route, including the SIRO Precedent. **Significant Risk Area:** The open query of whether Spine service (no 2) 2014 Direction allows PDS to be used in a research context. **Significant Risk Area:** NHS Digital's UK GDPR transparency information on its website is inaccurate as to the territory of use for a number of datasets (see Advice point 2 above). It was agreed the conditions would be approved out of committee (OOC) by IGARD members.
3.3	United Kingdom Plc: Data extract to support the continued accuracy of 3M developed quality and performance indicators for commissioners and providers. (Presenter: Anna Weaver) NIC-91972-S9W9T-v6.3 3M **Application:** This was an extension application to permit the holding and processing of pseudonymised Hospital Episode Statistics Admitted Patient Care (HES APC) and HES Outpatients data. 3M wish to process five years of pseudonymised Hospital Episode Statistics (HES), received under previous iterations of this data sharing agreement (DSA), in order to validate and refine complex clinical algorithms and ensure they remain tuned as accurately as possible to the NHS experience. The data will be used to anglicise the 3M APR-DRG and 3M CRG (grouper) solutions, specifically by supporting the development of crosswalk tables and algorithms between UK

	coding classifications (and other NHS Data Dictionary items) and their international equivalents. The quality and performance indicators derived from these 3M solution suites will help the NHS better perform its duties by highlighting actionable areas for clinical and process improvement. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on 1st February and 1st November 2018, 17th January and 14th March 2019, 9th April 2020, and 17th June 2021. It was also discussed under "AOB" at the IGARD BAU meeting on 30th April 2020. IGARD noted that when this application was last reviewed in 2021, they had advised NHS Digital that if, in 12-months, the applicant was not demonstrating effective use of the data, and could not produce / evidence satisfactory yielded benefits, then IGARD may recommend that the data was destroyed. IGARD noted that this iteration of the application was still unclear on a number of issues. IGARD noted that, upon return, and in addition to the usual review of the application as per process and in line with the NHS Digital DARS Standards, the following criteria should be adequately addressed, including, but not limited to, substantial development in terms of forward planning on prospective customers for this work. IGARD asked that a subject matter expert on the innovative use of health data within NHS Digital should undertake an objective assessment and provide a view of the programme, including current status and potential benefit(s) to health and care, and with reference to the NHS Digital DARS Standard for Commercial Purpose and NHS Digital's requirements vis à vis benefit to health and care. IGARD requested that a copy of the report(s) that the applicant provided to NHS Digital on a quarterly basis, regarding the progress on the benefits realised, should continue and be provided as a supporting document to IGARD at the next / any future review(s). IGARD noted that if the criteria outlined above were **not** adequately addressed upon return, they would be likely to recommend that NHS Digital issue a data destruction notice. 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 novel processing and commercial nature of the application. **Outcome:** recommendation to approve for six months only. The following advice was given: 1. IGARD noted that upon return, and in addition to the usual review of the application as per process, the following criteria should be adequately addressed, including (but not limited to): a) There should be a substantial development in terms of forward planning on prospective customers for this work. b) A subject matter expert on the innovative use of health data within NHS Digital should undertake an objective assessment, and provide a view of the programme (current status and potential benefit to health and care, with reference to the NHS Digital DARS Standard for Commercial Purpose and NHS Digital's requirements vis à vis benefit to health and care).

	c) A copy of the report(s) that the applicant provides to NHS Digital on a quarterly basis, regarding progress on the benefits realised, should continue and be provided as a supporting document to IGARD. 2. IGARD noted that if the criteria outlined were not adequately addressed, they would be likely to recommend that NHS Digital issue a data destruction notice. 3. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the novel processing and commercial nature of the application. 4. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the novel processing and commercial nature of the application.
3.4	Barts Health NHS Trust: MR1486 - International Surgical Outcomes Study: Long-term survival & healthcare utilisation (Presenter: Denise Pine) NIC-68740-X7R2N-v2.5 **Application:** This was an extension application to permit the holding and processing of identifiable Medical Research Information Service (MRIS) - Cause of Death Report and MRIS - Flagging Current Status Report. It was also an amendment application to add a one-off dissemination of pseudonymised Hospital Episode Statistics Admitted Patient Care (HES APC) data for 2013/14 - 2015/16. The International Surgical Outcomes Study (ISOS) was a separate study and was completed in 2014. The purpose of this application is for a three-year follow up of the ISOS UK cohort, which is estimated to be approximately 7,045 participants. The study team are performing a survival analysis of patients recruited in the UK during ISOS. This study will be exploring the long-term survival of those who have had surgery and will provide further evidence to support ongoing research in this field. The study is relying on consent (for the first year of follow up) and s251 of the NHS Act 2006 for the flow of data out of NHS Digital for years 2 and 3. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meetings on the 6th July 2017 and the 1st August 2019. 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 12th December 2019. IGARD confirmed that they were of the view that the most recent consent materials provided the appropriate gateway and was broadly compatible with the processing outlined in the application for year 1. 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 for years 2 and 3. IGARD noted that the HES APC data requested was listed as *"pseudonymised"* in the application, however queried if this was correct, noting that the applicant also held a separate flow of identifiable data which would therefore make the pseudonymised data identifiable if the two datasets were linked. IGARD asked that the application was updated where relevant to reflect that the data requested would effectively be *"identifiable"* and not "*pseudonymise*d". IGARD queried the information in section 1 (Abstract) that the honorary contract for the Chief Investigator at Queen Mary University of London (QMUL), and Barts Health NHS Trust was an

	ongoing contract with no end date; and noted that this did not align with the information in supporting document 8.0, Barts Health NHS Trust honorary letter of attachment, which stated the honorary contract would be valid / reviewed after three years. IGARD asked that confirmation was provided that the honorary contract had been extended; and that all appropriate documentation was uploaded to NHS Digital's customer relationships management (CRM) system for future reference. IGARD noted the reference in section 1 to the *"COVID-19 Inquiry"*, which prevented NHS Digital from requesting data destruction at the current time. Noting the discussion at the IGARD business as usual (BAU) meeting on the 2nd December 2021, IGARD had received a verbal update from NHS Digital to confirm that the retention of data **only** applied where the application was related to COVID-19, and that the blanket cessation had been removed. IGARD asked that section 1 was updated, to reflect the latest information, and that the application was reviewed throughout, to remove reference(s) to the *"COVID-19 Inquiry"* as it was not relevant to this application. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 1 and review the application throughout to remove reference(s) to the *"COVID-19 Inquiry"* as it is not relevant to this application. 2. To update the application where relevant to reflect that the data requested will effectively be *"identifiable"* and not "*pseudonymise*d". 3. In respect of the honorary contract: a) To provide confirmation that the honorary contract has been extended. b) To upload all appropriate documentation to NHS Digital's CRM system for future reference. 4. IGARD suggested that this application would be suitable for NHS Digital's Precedent route, including the SIRO Precedent.
3.5	<u>NHS Oldham CCG: DSfC - Oldham CCG - Comm (GP and Social Care Linkage) (Presenter: Dan Goodwin) NIC-580886-S2M3Z-v0.3</u> **Application:** This was a new application for pseudonymised Secondary Uses Service (SUS+), Local Provider Flows, Mental Health Minimum Data Set (MHMDS), Mental Health Learning Disability Data Set (MHLDDS), Mental Health Services Data Set (MHSDS), Maternity Services Data Set (MSDS), Improving Access to Psychological Therapy (IAPT), Child and Young People Health Service (CYPHS), Community Services Data Set (CSDS), Diagnostic Imaging Data Set (DIDS), National Cancer Waiting Times Monitoring Data Set (CWT), Civil Registration (Births), Civil Registration (Deaths), National Diabetes Audit (NDA), Patient Reported Outcome Measures (PROMs), e-Referral Service (eRS), Personal Demographics Service (PDS), Summary Hospital-level Mortality Indicator (SHMI), Medicines Dispensed in Primary Care (NHSBSA Data) and Adult Social Care Data. The purpose of the application is to receive data 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. This data sharing agreement (DSA) will allow Oldham CCG to link the commissioning datasets received from NHS Digital to a local collection of Adult Social Care Data and GP Data. NHS Oldham CCG already receives commissioning data from NHS Digital under data sharing agreement (DSA) NIC-139091-F3T3H, however this is a sustainability and transformation

	partnership agreement between 11 CCGs within the North West England region and therefore localised Adult Social Care data and localised GP data cannot be used in that DSA. **Discussion:** IGARD noted that local providers of Adult Social Care Data and GP Data, flow patient identifiers to the CCG, and queried how the common law duty of confidentiality (CLDoC) was being met, noting that these flows of data would also be combined with NHS Digital data. IGARD asked that satisfactory confirmation was provided in section 1 (Abstract) of how the CLDoC was satisfied by the CCG when receiving Adult Social Care data **and** GP data. In addition, IGARD asked that NHS Digital provided a copy of the analysis of how the CLDoC was satisfied in respect of the receipt of GP data and Adult Social Care data; and that moving forward, a brief explanation should be included in section 1 of relevant applications as standard practice. IGARD also asked that a brief explanation was provided in section 1, of the legal basis relied upon for the various uses of confidential data, as this was currently unclear. IGARD queried the number of processing locations in section 2(a) (Processing Location(s)) and storage locations in section 2(b) (Storage Location(s)), noting that Microsoft Azure were providing cloud storage (which is typically a way of reducing the number of storage locations), and asked that they were reviewed and updated as necessary, to ensure they are all in use and relevant. IGARD noted the reference in section 5(a) (Objective for Processing) to *"expensive services"* and asked that this was amended to a more sensitive form of wording, for example *"understanding the cohort's use of different levels of care"* or similar. IGARD suggested that this application would be suitable for NHS Digital's Precedent route, including the SIRO Precedent. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of the CLDoC: a) To provide satisfactory confirmation in section 1 concerning how the CLDoC is satisfied by the CCG when receiving Adult Social Care data. b) To provide satisfactory confirmation in section 1 concerning how the CLDoC is satisfied by the CCG when receiving GP data. 2. To review the processing locations in section 2(a) and storage locations in section 2(b) to ensure they are all in use and relevant, particularly in light of the utilisation of cloud storage. 3. To amend the reference in section 5(a) from *"expensive services"* to *"understanding the cohort's use of different levels of care"* or similar. 4. To provide a brief explanation in section 1 of the legal basis relied upon for the various uses of confidential data. 5. IGARD suggested that this application would be suitable for NHS Digital's Precedent route, including the SIRO Precedent. **ACTION:** NHS Digital to provide IGARD with a copy of the analysis of how the CLDoC is satisfied in respect of the receipt of GP data and Adult Social Care data; and that moving forward, a brief explanation should be included in section 1 of relevant applications as standard practice (see amendment points 1(a), 1(b) and 4).

3.6	NHS North Central London CCG: DSfC - NHS North Central London CCG - RS, COMM & IV (Presenter: Michael Ball) NIC-362253-J5V8L-v3.2 **Application:** This was an amendment application to add GP Data linkage for the purposes of Commissioning, which will be processed with existing flows of data. The overall purpose of the application is for Invoice Validation (IV), which is part of a process by which providers of care or services are paid for the work they do, Risk Stratification (RS) which is a tool for identifying and predicting which patients are likely to be at high risk and prioritising the management of their care; and to provide intelligence to support the commissioning of health services. NHS Digital noted, that as outlined in section 1 (Abstract), the applicant had breached the current data sharing agreement (DSA) by linking GP data for the purpose of commissioning, and this was therefore the purpose of the amendment. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on 29th October 2020. IGARD noted that the previous amendments requested by IGARD, had been addressed in section 1, however noted that one of the responses did not align with the amendment point; and asked that this was reviewed to ensure that all previous requested amendments for this application were accurately replicated and answered in section 1, for ease of reference in the future. IGARD noted that, under this DSA, both pseudonymised **and** identifiable data would be flowing for the Secondary User Services (SUS+) data and Mental Health Services Dataset (MHSD) to enable commissioning and risk stratification respectively. However, the commissioning purpose would seem to encompass risk stratification activities. IGARD therefore asked that section 5(b) (Processing Activities) was updated to provide a justification as to why, in effect, the same data was flowing twice. Also, why support under Section 251 of the NHS Act 2006 is not needed for risk stratification under commissioning. IGARD noted and commended NHS Digital on the information provided within the Breach Report, provided as a supporting document, in relation to linkage of the GP data that was not currently permitted under this DSA. IGARD suggested however, that it was edited to be clear that any potential breach of the CLDoC would be discussed with NHS Digital's Caldicott Guardian; and separately any data protection issues would be raised with the Information Commissioner's Office (ICO). IGARD suggested that noting the potential breach under this DSA, the SIRO considered the other DSAs entered into with the applicant, alongside all flows of data, and consider whether, in that wider context, an NHS Digital audit may be appropriate at this time. Separate to this application, IGARD provided advice to NHS Digital's Caldicott Guardian, regarding the legal basis for a Commissioning Support Unit (CSU) to receive and process confidential data. IGARD suggested that NHS Digital may wish to document advice from the Caldicott Guardian whether they agree with the stated position in respect of the duty of confidence that the CSU can rely on as the GP's direct care gateway to satisfy this duty, in order to receive and process the data (which, when pseudonymised, will be used for reasons other than direct care). IGARD suggested that a file note be held on NHS Digital's CRM for future reference, and a brief summary added to section 1 of applications where this was the case.

	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 work with the applicant to review and consider if the locations could be consolidated; and noting the discussion at the workshop at the business as usual (BAU) meeting on 18th November 2021. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 5(b) to provide a justification as to why, in effect, the same data is flowing twice to enable commissioning and risk stratification. 2. To update section 5(b) to provide a justification as to why support under Section 251 of the NHS Act 2006 is not needed for risk stratification under commissioning. 3. To ensure all previously requested amendments for this application requested by IGARD are accurately replicated and answered in section 1. The following advice was given: 1. IGARD noted the Breach Report provided as a supporting document and suggested that it is edited to be clear that any potential breach of CLDoC would be discussed with NHS Digital's Caldicott Guardian; and separately any data protection issues would be raised with the ICO. 2. 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. 3. Advice to NHS Digital SIRO: IGARD suggested that the SIRO consider the other DSAs entered into with the applicant, alongside all flows of data, and consider whether, in that wider context, an audit may be appropriate at this time. **Separate to this application:** *Advice to the NHS Digital Caldicott Guardian regarding the legal basis for a CSU to receive and process confidential data*: IGARD suggested that NHS Digital may wish to document advice from the Caldicott Guardian whether they agree with the stated position in respect of the duty of confidence that the CSU can rely on the GP's direct care gateway to satisfy this duty in order to receive and process the data (which, when pseudonymised, will be used for reasons other than direct care). IGARD suggested that a file note be held on NHS Digital's CRM for future reference, and a brief summary added to section 1 of applications where this was the case.
4	Applications progressed via NHS Digital's Precedent route, including the SIRO Precedent 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). *No items discussed.*
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. • **NIC-140981-R5N6Z University College London (UCL)**

	IGARD queried if there was current valid ethical support for this sensitive study about children and young people, noting that SD1 provided stated that University ethics committee chair's approval for proposed amendments must be sought. IGARD asked that reference to the defunct ICO code of anonymisation be removed from this application, and all others. 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 novel processing and commercial nature of the application. • **NIC-15335-H0D1F The Royal College of Surgeons (RCS)** IGARD reiterated previous comments that changes to applications should be "date stamped" so that it was clear when updates had been made to the application summary. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, and that the outputs, data minimisation, data destruction, duplication of data and transparency should be addressed. • **NIC-121483-R8P9F University Hospitals Birmingham NHS Trust** IGARD reiterated previous comments that changes to applications should be "date stamped" so that it was clear when updates had been made to the application summary. IGARD noted that just because wording was suitable for other application it did not mean that it would be suitable for this application and that the wording in the application should reflect the relevant facts. • **NIC-147811-YTH88 The University of Manchester** • **NIC-175989-M9T7B National Centre for Social Research** IGARD noted that the governance pathway for APMS data had not been updated to correctly reference when applications for APMS should come via IGARD. IGARD reiterated previous requests made that internal processes be updated accordingly. • **NIC-301834-K0S2Y LA-SER Europe Ltd** 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 as per previous review by IGARD on 30th July 2020. • **NIC-177392-B8T1Z University of Oxford** IGARD members noted that no yielded benefits had been provided. • **NIC-303785-L3K3Z Norfolk & Norwich University Hospitals NHS Foundation Trust** • **NIC-147907-MLK7R Derbyshire Healthcare NHS Foundation Trust** IGARD noted that whilst they were briefed on a proposed 'class action' approach, there is no agreed "class action precedent". IGARD were unable to say if the application had proceeded under the correct precedent route. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, and that the focus areas would be ongoing HRA CAG support evidence and review of the shared database outputs and arrangements.

	• **NIC-147901-2XMLG University Hospitals Bristol & Weston NHS Foundation Trust** IGARD noted there is no agreed "class action precedent". IGARD were unable to say if the application had proceeded under the correct precedent route. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, and that data minimisation and follow up with the audit team should be addressed. 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 March 2020 to May 2021. IGARD noted that in addition, they had not been updated on the issues raised on the IG COVID-19 release register June to July 2021. 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> <u>NIC-604851- W0M3S-v0.4 GRAIL Bio UK Ltd</u> NHS Digital attended the meeting to discuss the above application that was presented at the IGARD business as usual (BAU) meeting on the 13th January 2022, where IGARD had recommended for approval, with the following condition: 1. In relation to the Global Transfer Assessment: a) To provide written confirmation from NHS Digital's PTE that the appropriate Global Transfer Assessment documentation has been approved and in place. b) To upload the written confirmation to NHS Digital's CRM system. NHS Digital advised that there were ongoing discussions with Privacy, Transparency & Ethics (PTE) colleagues in relation to the applicant's transparency materials. IGARD noted the verbal update in respect of the outstanding condition, and the ongoing discussions with PTE; and it was agreed that the OOC would be progressed in line with the published OOC standard operating procedure and IGARD looked forward to receiving all relevant documentation in due course with any additional narrative with regard to how the conditions had been met.
7	<u>AOB:</u> **<u>General Practice Data for Planning and Research (GPDPR)</u>** **Significant Risk Area:** IGARD members discussed the lack of communication and transparency for the public relating to the GPDPR programme. IGARD suggested that the absence of any update risked undermining public trust and confidence in what was already a controversial programme. While noting that there were now several parties who needed to be involved in decisions about communications, IGARD were concerned that, by way of example, the NHS Digital website had not been updated with any news on the programme for approximately six months. <u>NIC-402116-G1T7V NHS England</u> IGARD noted that at the IGARD – NHS Digital COVID-19 Response meeting on the 26th January 2021, NHS Digital provided a verbal update to a verbal presentation at the COVID-19

	response meeting on the 15th September 2020. The amendment was to add Palantir Technologies UK Limited (*"Palantir"*) as a Data Processor and Amazon Web Services (AWS) who host the data for Palantir. Due to the urgency of the request, data was already flowing to Palantir in agreement with the NHS Digital SIRO. Palantir were added to support NHS England as a processor for vaccination reporting only and the data sharing agreement (DSA) limited their role to that purpose. NHS Digital noted that the Profession Advisory Group (PAG) were updated on Wednesday 3rd February 2021, and that the amendment falls under the relevant NHS Digital DARS Precedent. IGARD provided several comments in response to the verbal update, around transparency and public perception around Palantir and its involvement in this instance. It has been brought to the attention of IGARD that PAG had reported they had not been updated regarding this application on the 3rd February 2021, and that they had particular concerns regarding this data flow. IGARD suggested that DARS may wish to consider the following: 1. The GPES approval process "https://digital.nhs.uk/services/data-access-request-service-dars/gpes-data-for-pandemic-planning-and-research-covid-19-agreed-process-document point 11" Renewals, extensions and amendments to existing applications may be agreed by the Associate Director of Data Access, who in turn reserves the right to pass applications back into the process for additional comment or review if they wish". IGARD strongly suggest that in the interests of transparency that for all GPES agreement renewals, extensions and amendments, SIRO authorisations are formally notified to both PAG and IGARD, who can then decide if they wish to comment. 2. Verbal updates with high profile applications under COPI come with associated risks as in this case where one of the parties was not notified. It is vital in these instances that the action points of the verbal discussions are carried though and evidenced, noting the PAG agenda and minutes are not easily accessible. IGARD agreed that given the nature of the application, members would review this under Oversight and Assurance at a future meeting. 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 28/01/22

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