Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 26 August 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Maria Clark	Lay Member
Kirsty Irvine (Chair)	IGARD Chair / Lay Representative
Dr Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Prof. Nicola Fear	Specialist Academic Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Michael Ball	Data Access Request Service (DARS)
Dave Cronin	Data Access Request Service (DARS)
Catherine Day	Data Access Request Service (DARS)
Duncan Easton	Data Access Request Service (DARS)
Mujiba Ejaz	Data Access Request Service (DARS)
Kevin Fines-Smith	Digi-Trials
Tania Palmariellodiviney	Data Access Request Service (DARS) (Observer: items 2.1 – 2.3)
Andy Rees	Digi-Trials
Vicki Williams	IGARD Secretariat

1	**Declaration of interests:** Maurice Smith noted a professional link with item 2.1 as part of his role at NHS Liverpool CCG, however it was agreed this did not preclude Maurice from taking part in the discussion. **Review of previous minutes and actions:**

	The minutes of the 19th August 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**
2.1	<u>CCG's sharing commissioning data with members of their Integrated Care System (ICS) (Presenters: Michael Ball / Duncan Easton)</u> This was an NHS Digital executive management team (EMT) paper outlining the need for a smooth transition to the new commissioning landscape to allow Clinical Commissioning Groups (CCGs) to share data with providers and local authorities in the interim period before April 2022. Currently CCG's are prevented from giving access to other organisations within their ICS due to the anonymised small number suppression rule for onward sharing. Noting that ICS's are not legal entities until 1st April 2022, the briefing paper is seeking approval for CCG's, who are already working with the other constituent organisations of the ICS to fulfil their commissioning responsibilities and work collaboratively, to enable them to be able to share NHS Digital data within their ICS group prior to ICS's becoming legal entities. NHS Digital outlined a number of options: **1)** joint data controllership and amend all CCG applications accordingly via a class action and a requirement to update the customer relationship management (CRM) system to allow for many multiples of data controllers to be included on data sharing agreements (DSA); **2)** to allow data controllers to onwardly share data and amend all CCG applications accordingly via a class action; **3)** sub-licencing agreement to allow the CCG to onwardly share the data with other organisations but under specific rules set by NHS Digital as part of the CCG's DSA. IGARD welcomed the draft EMT paper and provided a number of high-level comments including, but not limited to: 1. Given the options put forward in the EMT briefing paper, IGARD were supportive of the sub-licencing option. However, with the sub-licencing option comes significant functional capability risks and for the immediate interim step to flow data to the CCG who would sub-licence to the sub-licencees, NHS Digital would need to ensure additional safeguards were in place, beyond simply only allowing sublicensing within the ICS boundary. 2. The minimum safeguard requirements could include, but not limited to: a. Ensuring adequate training processes were in place, b. a sublicensing oversight board with public involvement from members of the relevant local community, c. developing a pro forma oversight board TOR (to be tabled alongside the updated EMT briefing paper, alongside any other relevant documents), d. adequate transparency and oversight of the sub-licensor. e. ensure record keeping processes were robust to ensure that it was known who had received what data for what purposes and where it was held, f. the need for a Caldicott Guardian who was on the Caldicott Guardian Council, g. a board level CCIO, and h. the need for NHS Digital to keep a watching brief of when the statutory duties and responsibilities were legislated for and to make appropriate changes to arrangements.

	3. More thought should be given to the data used for *"direct care"* and given the risks with direct care and potential misuse of data under a sub-licencing agreement. IGARD noted that the NHS Digital DARS standard for sub-licencing and onward sharing provided that the purpose could be narrower for the sub-licencee than the purpose for the sub-licensor and this could possibly be a useful mechanism to use to ensure only those recipients with a legitimate basis to use data for direct care could do so. 4. Additionally, more thought should be given whether to carve out the direct care data flow to separate DSA's rather than under the one agreement, which would still be in line with NHS Digital's DARS standard for data minimisation. 5. IGARD suggested that NHS Digital speak to their Commercial Legal Team with regard to sub-licencing to ensure that all relevant contractual arrangements had been discussed and were in place before commencing with this option (noting that although discussions with PTE were helpful, the Commercial Team should also be briefed). 6. IGARD noted that the draft EMT briefing was to be circulated internally within NHS Digital and would welcome an updated EMT briefing paper in due course. IGARD would expect the briefing note to be a living document and to be updated and returned to IGARD once the legislation from Government had been approved under the Health & Care Bill 2021.
3	**Data Applications**
3.1	University of Oxford: R1 (D09) Data support to COVID-19 RCT (Presenter: Dave Cronin) NIC-365354-R3M0Q-v7.2 **Background:** This was an amendment application for **1)** Civil Registration (Death) data, Cancer Registration Data, COVID-19 Hospitalisation in England Surveillance System (CHESS), COVID-19 Second Generation Surveillance System (SGSS), COVID-19 UK Non-hospital Antigen Testing Results (Pillar 2), COVID-19 Vaccination Status, Demographics data, Electronic Prescribing & Medicines Administration (EPMA) data in Secondary Care for COVID-19, Emergency Care Data Set (ECDS), GPES Data for Pandemic Planning & Research COVID-19 (GDPPR), Hospital Episode Statistics Admitted Patient Care (HES APC), HES Critical Care, Medicines dispensed in Primary Care (NHSBSA data) and SUS plus – Admitted Patient Care (APC) (beta version) and, **2)** to onwardly share specifically defined datasets with the Infectious Disease Data Observatory (IDDO) at the University of Oxford to enable onward sharing with researchers with a formal affiliation to a health, research, humanitarian, government, inter-government or academic institution with legal status, working in the field relevant to COVID-19. The Randomised Evaluation of COVid-19 thERapY (RECOVERY) trial aims to compare several different treatments that may be useful for patients with COVID-19, that have been recommended by an expert panel that advises the Chief Medical Officer in England. This trial allows reliable assessment of the effects of multiple different treatments (including re-purposed and novel drugs) on major outcomes in COVID-19 NHS Digital noted a number of administrative errors in section 1 (Abstract) which were to be amended including; the history of the approvals did not appear complete; section 1 did not appear to have a comprehensive list of the amendments under this version, or the complete list of additional datasets requested; and the Privacy, Transparency and Ethics (PTE) Directorate advice with regard to sub-licencing had not been provided as a supporting document.

	NHS Digital also noted that providing IGARD with circa 175 complex and lengthy documents as part of the meeting papers pack for this application alone, was not appropriate and that internal discussion would take place to ensure that IGARD were only provided those supporting documents that were vital to the application presented at the time. **Discussion:** IGARD observed that they could not see any analysis from NHS Digital that set out a legal gateway, via the most recent consent materials, for all aspects of the current and proposed onward sharing. IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meetings on 11th June, 30th July and 12th November 2020. IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 21st April, 28th April, 5th May, 12th May, 19th May, 7th July, 21st July, 1st December 2020 and 26th January 2021. IGARD noted that this application had been reviewed by the GPES Data for Pandemic Planning and Research (GDPPR) – Profession Advisory Group (PAG) on the 4th June 2020, and that notes from this meeting had been attached to the IGARD minutes from the 11th June 2020. IGARD also noted that this application had been reviewed at the PAG meeting on the 25th August 2021 (see Appendix B). IGARD noted that PAG generally supported the application but subject to significant conditions, and noted the comments made on the application. Due to the timing of the PAG review, NHS Digital had not prepared a response to the PAG conditions and comments. Separate to this application, IGARD reminded NHS Digital of the process that had been agreed last year, that applications should go to PAG and the PAG minutes should be made available to IGARD, prior to the application being included on the IGARD BAU agenda. Noting that the PAG minutes had been tabled at the meeting, and not provided in a timely fashion, IGARD requested that section 1 be updated to detail how each of the PAG points raised had been addressed. In addition that the application should be updated throughout, and as appropriate, to address each of the points raised. IGARD noted the PAG comment with regard to the applicant's IDDO Terms of Reference (ToR) and suggested that the applicant should consider incorporating some of PAG's requirements alongside those outlined in NHS Digital's DARS Standard for sub-licencing and onward sharing. IGARD noted that it was not usual practice to single out an organisation in such a direct way within published minutes and cautioned against NHS Digital naming specific companies. IGARD suggested that NHS Digital ask PAG to provide broad principles which would be incorporated into any assessment of the data processors. IGARD commended the excellent yielded benefits outlined in section 5(d) (Benefits) (iii) (Yielded Benefits) and noted that these could be used as exemplar wording, and also for further promotion of this ground-breaking work with international impact being undertaken by the team at University of Oxford IGARD noted and supported the verbal update from NHS Digital with regard to the internal administrative errors that would be rectified in section 1 and the work internally to ensure only those documents necessary would be provided to IGARD as part of the meeting papers pack. IGARD suggested that section 1 be updated with a clear narrative to support a future review and audit explaining why the application had not been identified for an independent review (noting the significant risk area noted in the COVID-19 response meeting action notes dated 26/01/21 of ensuring the appropriate legal gateways for different categories of data licencees),

	appropriate communications with the consented cohort and addressing transparency requirements (the application had not been presented at that meeting only sub-licencing documentation)) noting that the Senior Information Risk Owner (SIRO) had approved a significant amendment (the requirement to disclose data to Regulators and Manufacturers of treatments evaluated in the RECOVERY trial) on 23/04/2021, but IGARD had not been notified, as per due process, either at a IGARD BAU meeting or COVID-19 response meeting, and suggested that NHS Digital may wish to review their internal processes. IGARD also noted that section 1 stated that a review by IGARD was not required in response to the question *"review requested by IGARD"* the answer given was *"no"*; and suggested that NHS Digital may wish to review their internal processes and IT systems, for example, to ensure this doesn't incorrectly default to state *"no"* and to update to say *"yes"*. NHS Digital noted that not all the datasets listed in section 3(b) (Additional Data Access Requested) appeared to be listed elsewhere in the application. IGARD were in agreement with this assessment and asked that section 1 fully disclosed all the dataset amendments under this Data Sharing Agreement (DSA); to fully disclose all the datasets outlined in section 3(b) in section 5(a) (Objective for Processing) and as per due process; and to provide a justification in section 5(a) for the inclusion of each of the datasets outlined in section 3(b) and requested under his amendment application. NHS Digital noted that the treatment listed did not appear to include the different types. IGARD were in agreement with this assessment and asked that section 1 and section 5 (Purpose / Methods / Outputs) be updated to accurately describe the different types of treatments under this DSA. In addition a justification should be provided for each treatment type and randomisation in section 5(a). Noting that the application had been approved under the NHS Digital SIRO precedent for an amendment for the requirement to disclose data to Regulators and Manufacturers of treatments evaluated in the RECOVERY trial, IGARD were unclear of the legal gateway for the past or proposed onward sharing of the cohort's data with the manufacturers. (The gateway for regulators is via consent as cohort members consent to access by *"Regulatory Authorities"*.) IGARD suggested that clarification be sought, and that section 1 and section 5 of the application be updated to clearly state the legal gateway, since no analysis had been provided as per usual process. There was a lengthy discussion with regard to the various legal gateways. IGARD noted that the applicant wished to share specifically defined datasets with the IDDO at the University of Oxford, however it was not clear in section 1 or section 5 of the application, the legal gateway for the past and proposed onward sharing of the cohort's data, since no analysis had been provided as per usual process. Furthermore, IGARD noted that the IDDO then wanted to onwardly share the data with researchers with a formal affiliation to a health, research, humanitarian, government, inter-government or academic institution with legal statues working in the fields of COVID-19 however it was not clear in section 1 or section 5 of the application the legal gateway for the past and proposed onward sharing of the cohort's data, since no analysis had been provided as per usual process. In line with NHS Digital DARS standard for sub licencing and onward sharing: and noting NHS Digital's published transparency and GDPR register, IGARD queried the territory of use and whether or not any of the sub-licencees would access the data outside of England and Wales, since it was not clear within the application.

	IGARD noted that in section 5(a) that "*NHS Digital waive the right to audit the regulator or manufacturer of treatment(s) evaluated in the RECOVERY Trial*" and that this was a contractual arrangement between NHS Digital and University of Oxford, however, on the assumption that NHS Digital could audit sub-licencees, IGARD suggested that NHS Digital ensure that there was a clear mechanism for the destruction of GDPPR data at the expiry of The Health Service Control of Patient Information (COPI) Regulations 2002 on the 31/03/22 (as per the special condition in section 6 (Special Conditions) of the DSA). IGARD suggested that reference to "…*improving the health of the whole population*…" be removed from section 5(d), since this seemed an impossible task. IGARD also suggested that the typo in section 5(a) bullet 6(iv) be amended since it altered the meaning of the sentence entirely and to insert the word *"not"* so that that the applicant "*must **not** use the dataset for any purpose other than those defined above*…." 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 significant issues raised by PAG and the queries about the legal gateway. **Outcome**: unable to make a recommendation as not all the necessary information was available in order for IGARD to make a full assessment. 1. In respect of the PAG feedback: a. To update section 1 to detail how each of the points raised by PAG have been addressed; b. To update the application throughout to address each of the points raised by PAG, as appropriate; c. to consider the amendment of the applicant's IDDO TOR to incorporate some of the PAG requirements, as well as ensuring the requirements of NHS Digital's DARS Standard for sub-licencing and onward sharing / agreement were met. 2. In respect of the legal gateway for past and proposed onward sharing of the cohort's data: a. To clarify the legal gateway for onward sharing with manufacturers; b. To clarify the legal gateway to onwardly share with the IDDO; c. To clarify the legal gateway to share data with the IDDO sub-licencees. 3. In respect of sub-licencing and in line with the NHS Digital DARS standard for sub licencing and onward sharing: a. To clarify the territory of use and whether or not any of the sub-licencees will access the data outside of England and Wales. b. On the assumption that NHS Digital can audit sub-licencees, to ensure that there is a clear mechanism for the destruction of GDPPR data at the expiry of the COPI Notice on 31/03/22 (as per the special condition in section 6 of the DSA). 4. To amend section 5(d) to remove reference to "…*improving the health of the whole population*…". 5. To correct the typo in section 5(a) bullet 6(iv) to insert the word "*not*" so that that the applicant "*must **not** use the dataset for any purpose other than those defined above*…." 6. In respect of the data set amendments: a. When describing the amendments under this DSA, to amend section 1 to fully disclose all the dataset amendments; b. To update section 5(a) with to disclose all the datasets being requested under this DSA;

	c. To provide a justification in section 5(a) for the inclusion of each of the datasets requested under this amendment application. 7. In respect of the treatment types: a. When describing the amendments under this DSA, to be clear that this includes the treatment types; b. To provide a justification in section 5(a) of the treatment types and randomisation. The following advice was given: 1. IGARD noted that PAG had specifically named an organisation within their minutes and cautioned against NHS Digital naming specific companies, and instead ask PAG to provide broad principles which would be incorporated into any assessment of the data processors. 2. IGARD noted that section 1 stated that a review by IGARD was not required; and suggested that NHS Digital may wish to review their internal processes and IT systems, for example, to ensure this doesn't incorrectly default to state *"no"* and to update to say *"yes"*. 3. IGARD noted that the SIRO had approved a significant amendment (the requirement to disclose data to Regulators and Manufacturers of treatments evaluated in the RECOVERY trial) on 23/04/2021, but IGARD had not been notified, as per due process, either at a IGARD BAU meeting or COVID-19 response meeting, and suggested that NHS Digital may wish to review their internal processes. 4. IGARD commended the excellent Yielded Benefits outlined in section 5(d)(iii) and noted that these could be used as exemplar wording, and also for further promotion of this ground-breaking work with international impact being undertaken by the team at University of Oxford 5. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the significant issues raised by PAG and the queries about the legal gateway. 6. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the significant issues raised by PAG and the significant queries around the legal gateway.
3.2	Imperial College London: SCAMP – Study of Cognition, Adolescents and Mobile Phones MR1439 (Presenter: Dave Cronin) NIC-27085-C5L5G-V2.9 **Background:** This was an amendment application for Birth Notification data, Bridge file: Hospital Episode Statistics (HES) to Diagnostic Imaging Datasets (DIDs), Bridge file: HES to Mental Health Minimum Data sets (MHMDS), Cancer Registration Data, Civil Registration (Deaths) data, Demographics, DIDs, Emergency Care Data Set (ECDS), HES Accident & Emergency (A&E), HES Admitted Patient Care (APC), HES Critical Care, HES Outpatients, Mental Health & Learning Disabilities Data Set (MHLDDS), and Mental Health Services Data Set (MHSDS). The SCAMP study originally recruited and gathered baseline data from 7,000 year 7 pupils (aged 11 to 12 years) from 39 schools across London, with follow up taking place in year 9 and 10 (aged 13 to 15 years). Of the 7,000 participating pupils, SCAMP has received parental consent parents at age 11 to 12, and subsequently re-consented pupils aged 16+ for 2,500 pupils using individual consent and parental assent. HRA CAG s251 approval has been sought for the proportion of the cohort who left school before age 16 and they are not included in this Data Sharing Agreement (DSA).

	NHS Digital noted a couple of administrative errors in section 1 (Abstract) which were to be amended including the fact that IGARD don't give an *"approval"* they provide a *"recommendation"*, and the history of the approvals did not appear complete and that these would be updated appropriately. **Discussion:** 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. IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meetings on 2nd November 2018, 28th February 2019 and 25th July 2019. IGARD noted and supported the verbal update from NHS Digital with regard to the internal administrative errors that would be rectified in section 1. IGARD noted the Steering Group, outlined in section 5(a) (Objective for Processing), had a membership which comprised of professionals in the field of this research, met twice yearly and provided guidance and feedback on key scientific issues. IGARD suggested that the Steering Group could benefit from the inclusion of members of the cohort and that the applicant look at further patient and public involvement and engagement (PPIE) activities and in line with the HRA guidance on Public Involvement. IGARD also suggested that consideration be given to incorporating PPIE into the designing of and dissemination of results to ensure that the outputs were handled sensitively and so as not to result in potentially upsetting and inappropriate national headlines. IGARD were concerned at the potential for inappropriate attribution of causality pertaining to those with neurodiversity and their use of electronic devices. IGARD and NHS Digital noted that the application referred to "*SCAMP has received consent from parents and pupils aged 15.5+ years…*" and asked that the application be updated throughout to be clear that the data flowing under this application related **only** to those members of the cohort aged 16 and over who had given consent. 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 also include a UK General Data Protection Regulation (UK GDPR) legal basis for dissemination and receipt of data. IGARD noted that a query had been raised on this particular point with the Privacy, Transparency and Ethics (PTE) Directorate and welcomed an update from DARS in due course. IGARD noted the inclusion of a number of technical phrases and words within section 5 (Purpose / Methods / Outputs) such as *"SQL"* and suggested that this was updated to be written in a language suitable for a lay reader and technical terms were either removed, or used only where necessary, and further explained upon first use. IGARD noted that the application was silent on the cohort numbers, and asked that in line with NHS Digital's DARS Standard for Data minimisation, section 3(b) and section 5(b) (Processing Activities) were updated with an indicative cohort size. IGARD suggested that section 5(d) (Benefits) (ii) (Expected Measurable Benefits) be updated to remove reference to "*it will*…" and instead use a form of words such as "*it is expected…"* or *"it is hoped …".* In addition, and noting that no data had flowed under this application, to

	update section 5(d) (iii) (Yielded Benefits) to state the reason why there were no yielded benefit, was because no data had flowed up to that point. IGARD noted that National Institute for Health Research (NIHR) funding was in place under December 2021, but that the DSA end date extended beyond that period. IGARD suggested that section 1, section 5 and section 8 (Period and Funding) be updated to confirm that appropriate funding was still in place and would continue for the life of the DSA. IGARD queried reference to *"…gender…."* data being requested and asked that the datasets requested in the application aligned with the specific NHS Digital data that can flow, as most NHS Digital datasets only contain sex data fields. **Outcome**: recommendation to approve The following amendments were requested: 1. To amend the application throughout to be clear that the data flowing under this application relates only to those members of the cohort aged 16 and over who had given consent. 2. To update section 3 to include a UK GDPR legal basis for those datasets that give information about cohort members who are still living, pending any further advice on this point from PTE. 3. To update section 3(b) and section 5(b) with an indicative cohort size. 4. To amend section 5(b) to ensure statistical terms of art and technical terms are either removed or explained in a manner suitable for a lay audience, for example, "*SQL*" 5. To update section 5(c) to use a form of wording such as "*it is expected…"* or *"it is hoped …"*, rather than "*it will…*". 6. To ensure that the datasets requested align with the specific NHS Digital data that can flow, for example refer to *"sex"* not *"gender"*, if *"sex"* is what is captured in the dataset. 7. Noting that no data had flowed under the application, to update section 5(d)(iii) to state this fact as to the reason why there were no yielded benefits. 8. To update sections 1, 5 and 8 to confirm that appropriate funding was still in place and would continue for the life of this DSA. The following advice was given: 1. IGARD were concerned at the potential for inappropriate attribution of causality pertaining to those with neuro diversity and their use of electronic devices. To address this at the time of dissemination, IGARD suggested that consideration be given to incorporating PPIE into designing the dissemination of results to ensure that the outputs were handled sensitively and so as not to result in potentially upsetting and inappropriate national headlines. 2. IGARD suggested that the steering committee could benefit from the inclusion of members of the cohort and suggested that the applicant look at further PPIE activities, and in line with the HRA guidance on Public Involvement
3.3	Royal Devon and Exeter NHS Foundation Trust (FT): CLARITY IBD Understanding the impact of biologic and immunomodulatory therapy on SARS-CoV-2 infection and immunity in patients with inflammatory bowel disease (Presenter: Catherine Day) NIC-435152-C0H4N-v1.3 **Background:** This was an amendment application to **1)** include COVID-19 vaccination status data and **2)** remove of Public Health England (PHE) as a Data Processor. The aim of the study is to understand the impact of biological and immunomodulatory therapy on SAR-CoV-2 (COVID-19) infection and immunity in patients with inflammatory bowel disease (IBD).

	The Impact of Biologic Therapy on SARS-CoV-2 Infection and Immunity Study (CLARITY) is to investigate the impact of specialist immunomodulatory drugs and shielding on COVID-19 infection and subsequent immunity following infection or vaccination and the results of the study will inform health policy decisions for patients with IBD, alongside other patients treated on immunosuppressant drugs. The request for the COVID-19 vaccination status data for 7,229 patients who are part of CLARITY IBD and have given informed consent will include the date, first or second dose, and type received, and this data will enable a more detailed analysis to be undertaken on SARS-CoV-2 antibody (nucleocapsid and spike) responses and provide a clearer picture of impact of COVID-19 infection and vaccination of patients with IBD on immunosuppressant therapies NHS Digital noted that on review, section 3(c) (Patient Objections) incorrectly referenced "*informed patient consent"* and that this had been updated to correctly reference *"The Health Service Control of Patient Information (COPI) Regulations 2002"*. **Discussion:** IGARD confirmed that they were of the view that the most recent consent materials **did not** provide the appropriate gateway and were incompatible with the processing outlined in the application. However, IGARD noted that the applicant was now relying on COPI as the legal basis in the short term and until the consent materials were updated in line with previous advice given, and were supportive of this approach as an interim measure. In addition, and noting that the applicant plans to transition to the consent model, IGARD noted that there may be significant datasets related to the left-over serum which could be not used under the consent legal gateway and that the applicant may wish to seek Health Research Authority Confidentiality Advisory Group (HRA CAG) s251 support to use this serum data from the study. IGARD noted the verbal update from NHS Digital that the reference to "*informed patient consent*" would be removed from section 3(c) and updated to *"COPI"*. IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 5th August 2021. IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 23rd February 2021. In line with the NHS Digital's DARS Standard for Data Controllers, IGARD queried if any of the other named funders or parties named on the applicant's website or protocol should be included as a joint Data Controller, and if deemed that they should be, that the application be updated throughout. IGARD reiterated they previous comments with regard to the involvement of Imperial College London (ICL) who are named in the study protocol, and as borne of the facts, whether they should be considered a joint Data Controller. In addition, the University of Hull and Hull University Teaching Hospital NHS FT (or others) should also be included within the application, again if the facts lead to that conclusion. If however, the facts do not point to ICL as a joint Data Controller, that the requisite amendments be made to section 5(a) (Objective for Processing). In addition, further narrative should be included in section 5(a) as to why the University of Hull and Hull University Teaching Hospital FT are also not considered joint Data Controllers, given the significant role those parties appeared to play. IGARD reiterated previous comments and in line with NHS Digital's DARS Standard for Data Controllers, that access to the data is **not** a determinative of controllership.

	IGARD suggested that in line with the NHS Digital DARS Standard for Commercial Purpose, that section 5(a) should be updated to outline the potential commercial benefits flowing to each of the funders described in this section, namely: F Hoffman-La Roche AG (Switzerland); Biogen GmbH (Switzerland); Celltrion Healthcare (South Korea); Galapagos NV (Belgium); Takeda UK, noting that benefits may be indirect, delayed or non-financial. In addition, that section 5(e) (is the purpose of the application in any way commercial) was updated to change the "*is the purpose of this application in anyway commercial?*" from "*No*" to *"Yes"* and to include relevant narrative in line with the NHS Digital DARS Commercial Purpose Standard. IGARD noted that the DSP Toolkit for the Royal Devon & Exeter NHS FT DSPT indicated that the latest status was "*standards met*" however had a comment in that section that stated "*20/21 Standards Not Fully Met (Plan Agreed) 29/06/2021*" and noting that an action plan was in place, asked that a special condition be inserted in section 6 (Special Conditions) that only staff who had passed the requisite training could access the data, if that was one of the areas where the requirements had not been met. IGARD queried the benefits outlined in section 5(d) (Benefits), and asked that section 5(d) was updated to remove any outputs and edited to provide examples that reflect the benefits to the Health and Social Care System and in line with NHS Digital's DARS Standard for Expected Measurable Benefits. In line with the NHS Digital DARS Standard for processing activities IGARD suggested removing the word "*deterministic*" from the sentence "*the linkage will be on a deterministic basis…*" in section 5(b) (Processing Activities), since the word was not relevant. In addition, IGARD asked that a clear explanation be provided in section 5(b) how the Royal Devon and Exeter NHS FT would keep the identifiable data and pseudonymised datasets separate. IGARD noted the CLARITY protocol version 7, included detail of the patient and public involvement and engagement (PPIE) undertaken by the applicant, such as Chron's UK and IBD patient group and suggested that a summary of the PPIE undertaken should be included in section 5 (Purpose / Methods / Outputs) , since this formed NHS Digital's data release register. NHS Digital noted that the applicant had not yes published their privacy notice. In respect of the privacy notice and in line with NHS Digital's DARS Standard for transparency (fair processing), IGARD wished to draw the applicant's attention to the statement in section 4 (Privacy Notice) of the application, that a UK General Data Protection Regulation (UK GDPR) compliant, publicly accessible transparency notice was maintained throughout the life of the agreement. 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 change in legal gateway at the expire of the COPI Notice on the 31/03/21. **Outcome:** recommendation to approve subject the following conditions: 1. In respect of the data controllership and in line with NHS Digital's DARS standard for Data Controllers: a. To clarify that none of the other named funders or parties named on the applicant's website or protocol should be considered a joint data controller;

	b. If the facts lead to the Imperial College London, the University of Hull and Hull University Teaching Hospital NHS FT (or others) being considered joint data controllers, to update the application throughout; *OR* c. To make the requisite updates to section 5(a) if Imperial College London are not considered a joint data controller, and to also outline why the University of Hull and Hull University Teaching Hospital NHS FT are also not considered joint data controllers given the significant role those parties appear to play (and noting that access to data is **not** determinative of controllership). 2. In respect of the commercial element, noting that benefits may be indirect, delayed or non-financial, and in line with NHS Digital's DARS standard for Commercial purpose: a. To update section 5(a) to outline the potential commercial benefits flowing to each of the funders described in this section; b. To update section 5(e) in line with the Commercial Standard. The following amendments were requested: 1. Noting the Royal Devon & Exeter NHS FT DSPT indicated that the standards had not been fully met and an action plan was in place, to insert a special condition in section 6 that only staff who had passed the requisite training could access the data, if that was one of the areas where the requirements had not been met. 2. In respect of section 5(b) and in line with the NHS Digital DARS Standard for processing activities: a. To remove the word "*deterministic*" from the sentence "*the linkage will be on a deterministic basis…*" since the word is not relevant b. To clearly explain how the Royal Devon & Exeter NHS FT will keep the identifiable data and pseudonymised datasets separate. 3. Noting the useful PPIE detailed in protocol, to summarise in section 5, since this forms part of NHS Digital's data release register 4. To expand the stated benefits in section 5(d) to ensure they comply with NHS Digital's DARS Standard for Expected Measurable Benefits and are clear as to the benefits to the health care system, and are not simply outputs. The following advice was given: 1. Noting that the applicant plans to transition to the consent model, IGARD noted that there may be significant datasets related to the left-over serum which could be not used under the consent legal gateway and that the applicant may wish to seek s251 to use this serum data from the study. 2. In respect of the privacy notice and in line with NHS Digital's DARS Standard for Transparency (fair processing), IGARD wished to draw to the applicant's attention, the statement in section 4, that a UK GDPR compliant, publicly accessible transparency notice is maintained throughout the life of the agreement, noting that current transparency materials, if they existed, were not easily accessible 3. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the change in legal gateway at the expire of the COPI Notice on the 31/03/21 4. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the change in legal gateway at the expire of the COPI Notice on the 31/03/21 It was agreed the condition would be approved out of committee (OOC) by IGARD Members.

3.4	Sanofi Pasteur: Study of Recombinant Protein Vaccines with Adjuvant as a Primary Series and as a Booster Dose against COVID-19 in Adults 18 years and older (Presenters: Andy Rees / Kevin Fines-Smith) NIC-526363-C3M1K-V0.2 **Background:** This was a new application for Permission to Contact (PtC) data extract for a phase II randomised, single-blind, platform trial to assess the safety, reactogenicity and immunogenicity of the COVID-19 vaccines in pregnant women in the UK (Preg-CoV). The booster vaccine study is looking to recruit up to 900 cohort participants aged 18 to 47 years and between 13 and 34 weeks gestation on the day of the planned vaccination. St George's will be the sole Data Controller, with NHS Digital as the sole Data Processor. NHS Digital will contact the potential participants, in the region of 2,000 to 3,000 people, directly week commencing 6th September 2021, as per the previous permission to contact applications and St George's will have no access to any data provided by NHS Digital. **Discussion:** IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 20th July 2021. IGARD noted that the French parent company, Sanofi Pasteur, was listed as the sole Data Controller and asked that the Data Protection Act (DPA) registration details and Data Security and Protection Toolkit (DSPT) details for Aventis Pharma Limited (the UK subsidiary company) be removed from their listing, since they were two different organisations. IGARD queried the role of Aventis Pharma Ltd, in light of the verbal update from NHS Digital and the inconsistent detail in the application which appeared to state that Aventis Pharma Ltd were acting with Sanofi Pasteur as a Data Controller and were making decision about the work being undertaken. Based on the facts presented and in light of the fact that Aventis Pharma Ltd were a separate entity to Sanofi Pasteur, asked that the application was updated to reflect the factual scenarios, and in line with NHS Digital's DARS Standard for Data Controllers, to list Aventis Pharma Ltd as a joint Data Controller. NHS Digital should also ensure that Data Sharing Framework Contracts (DSFC) were in place for other Sanofi Pasteur and Aventis Pharma Ltd, as per due process and if both organisations were listed as Data Controllers. In line with NHS Digital's DARS standard for Data Processors, IGARD noted in section 1(c) (Data Processor(s)) that PRA Health Sciences was listed as a Data Processor, noting that this was the USA parent company, that as well as correcting the typo in their address, that the DPA registration details and DSPT details for Pharma Research Associates (UK) Ltd should be removed from their listing since they were different organisations. In addition that Pharma Research Associates (UK) Ltd should be included in section 1(c) as a Data Processor, which would also subsequently need reflecting in section 2(b) (Storage Location(s)) and 2(c) (Territory of Use). If Pharma Research Associates (UK) Ltd are processing the data, and it is not the US based PRA Health Sciences, the section 5 (Purpose / Methods / Outputs) of the application should be updated to correctly reference the UK based company and in line with the territory of use restrictions on data, and as cited in section 2(c) of the application (namely: "*UK*"). IGARD suggested that the applicant should give due consideration to the future use of the cohort data and consider explicitly including, but not limited to, in their consent materials: the ability to follow up cohort for significant period of time; link the data held with other health datasets; to allow for sharing of data with NHS Digital and other NHS bodies or Data Controllers; to provide detail of any potential onward sharing with researchers; to ensure a sufficiently wide description of the data fields that may be shared; and to ensure that any

	communications with cohort also complies with UK General Data Protection Regulation (UK GDPR) for example explaining Data Controllers and Data Processors and subject access rights. IGARD noted that section 2(a) (Processing Location(s)) and section 2(b) were blank and in line with the NHS Digital DARS Standard for data processors, should be updated to include the storage and processing locations for the Data Processors listed and in line with the facts of where the data processing was being undertaken. IGARD noted the verbal update that the Research Ethics Committee (REC) favourable opinion had been received but had not been provided as part of the supporting documentation. IGARD noted the verbal update from NHS Digital, that REC opinion was favourable; and asked that a copy of the REC favourable opinion was uploaded to NHS Digital's customer relationship management (CRM) system as future supporting documentation. IGARD noted the benefits in section 5(d) (Benefits) and asked that it was clear as to the benefits to both the patients and the health and social care system more generally for example how this study may reduce mortality and morbidity from COVID-19 through the development of vaccines, and in line with NHS Digital's DARS Standard for Expected Measurable Benefits. Noting this study was being funded by public funds NIHR and Department for Health and Social Care (DHSC)), IGARD advised that when this application returned on renewal, extension or amendment they would expect to see an explanation in section 1 (Abstract) and section 5 why pregnant women were being excluded from the study. IGARD noted that the templated wording used to invite the cohort to take part in the study used the phrasing "*COVID-secure*" and noted that for those most vulnerable to the COVID-19 virus, there was no such place, and that the invite could be updated to more accurately describe that the environment would be following all current health guidance and safety measures. Noting that the application included templated wording, IGARD suggested that section 5(b) (Processing Activities) should be updated to remove reference to the **study** inclusion and exclusion, and to insert the inclusion and exclusion criteria in relation to the **NHS Digital COVID-19 vaccine research registry**. In addition, the paragraph in section 5(a) (Objective for Processing) which started "*New, highly transmissible SARS-CoV-2 variants of concern have emerged and are spreading globally…*" should be removed since this was historical information that contained a lot of unnecessary reference to differing variants of concern which were not relevant for the Data Sharing Agreement (DSA). IGARD noted that the application was silent on the cohort numbers, and asked that in line with NHS Digital's DARS Standard for Data minimisation, section 3(b) (Additional Data Access Requested) and section 5 were updated with an indicative cohort size. IGARD noted that section 3(c) (Patient Objections) should be updated with the usual standard wording to be clear that the basis for handling confidential data was *"consent"*. IGARD noted the inclusion of a number of technical phrases and words within section 5 such as "*monovalent*", "*bivalent*" and suggested that this was updated to be written in a language suitable for a lay reader and technical terms were either removed, or used only where necessary, and further explained upon first use. **Outcome**: recommendation to approve subject to the following condition:

1. In respect of the Data Controllership and in line with NHS Digital's DARS standard for data controllers:
    a. If Aventis Pharma Ltd (subsidiary company of Sanofi Pasteur) also make decisions about the work being undertaken, to update section 1(b) to reflect the factual scenario and include them as a joint Data Controller; **and**
    b. To update section 1(b) to remove the DPA registration details and DSPT details for Aventis Pharma Ltd from Sanofi Pasteur listing;
    c. If both Sanofi Pasteur and Aventis Pharma Ltd are joint data controllers, to ensure the appropriate DSFC is in place for both organisations.

The following amendments were requested:

1. In respect of the data processors and in line with NHS Digital's DARS standard for Data Processors:
    a. To add the UK based PRA Health Sciences as a Data Processor;
    b. To amend the typo in the address for the USA based PRA Health Sciences;
    c. To update section 1(c) to remove the DPA registration details and DSPT details for Pharma Research Associates (UK) Ltd from the PRA Health Sciences listing (USA parent company);
    d. To amend section 5 to reflect the factual scenario that only the UK based PRA Health Sciences will be processing the data (in line with the territory of use restrictions);
    e. To amend section 2, the NHS Digital storage and processing location, in line with the facts and where the data processing will be undertaken.
    2. In respect of the ethical approval
        a. To provide a copy of the REC favourable approval (as verbally updated in-meeting);
        b. to upload a copy of the ethical NHS Digital's CRM system.
3. To update section 3(c) to note that the basis for handling confidential data is "*consent*".
4. To update section 3(b) and section 5 with an indicative cohort size.
5. To amend section 5 to ensure statistical terms of art and technical terms are either removed or explained in a manner suitable for a lay audience, for example, "*monovalent*", "*bivalent*".
6. In respect of the inclusion and exclusion criteria:
    a. To remove from section 5(b) reference to the *study* inclusion and exclusion criteria; **and**
    b. To insert the inclusion and exclusion criteria in relation to the *NHS Digital registry*.
7. In line with the NHS Digital DARS Stand for Expected Measurable Benefits to insert at the start of section 5(d) that the key benefit is to reduce mortality and morbidity from COVID-19 through the development of vaccines.
8. To remove the historical detail in paragraph in section 5(a) with regard to the different variants, since it is not relevant to this DSA.

The following advice was given:

1. The applicant should give due consideration to the future use of the cohort data and consider explicitly including, but not limited to, in their consent materials: the ability to follow up cohort for significant period of time; link the data held with other health datasets; to allow for sharing of data with NHS Digital and other NHS bodies or data controllers; to provide detail of any potential onward sharing with researchers; to ensure a sufficiently wide description of the data fields that may be shared; and to

	ensure that any communications with cohort also complies with UK GDPR for example explaining data controllers and data processors and subject access rights. 2. IGARD advised that when this application returns at renewal, extension or amendment, they would expect to see an explanation as to why pregnant women are being excluded from a study that is being funded by public funds. 3. IGARD noted that the templated wording used to invite the cohort to take part in the study used the phrasing *"COVID-secure"* and noted that for those most vulnerable to the virus , there was no such place, and that the invite could be updated to more accurately describe that the environment would be following all current health guidance and safety measures. It was agreed the condition would be approved out of committee (OOC) by the IGARD Chair **Subsequent to the meeting:** NHS Digital advised that following further discussions with the applicant the queries raised in in the meeting, in respect of the Data Controllers and Data Processors, had been discussed with the applicant. An update had been provided to the IGARD Chair both verbally and in writing out of committee, and the application had been updated accordingly. Further information following the update to the IGARD Chair will be outlined in the minutes of the 16th September 2021 under AOB. IGARD reiterated previous comments: Noting the language used in this and other applications using the NHS Digital COVID-19 permission to contact register (CV19 PtC) (internal process name), consideration should be given to the external name of the registry: *"NHS Digital COVID-19 vaccine research registry"*. Since the vaccine registry was a standalone registry that cannot be linked to any other registry, consideration should be given to its external name, since it could imply that the registry contained all those that had had a vaccine, rather than what the database is; a database of those who have consented to be part of a registry of people who are happy to be contacted about vaccine research. IGARD suggested that in due course the language within this and other permission to contact applications should be updated to ensure that section 5, which forms part of NHS Digital's data release register, contained an accurate description of the registry and what it was.
3.5	<u>King's College London: TRIANGLE HES data application (Presenter: Mujiba Ejaz) NIC-272253-P9X9Y-v0.5</u> **Background:** this was a new application for Emergency Care Data Sets (ECDS), Hospital Episode Statistics (HES) Accident & Emergency (A&E), HES Admitted Patient Care (APC), and Mental Health Service Data Set (MHSDS), This is a multicentre randomised controlled trial (RCT) for individuals aged 16 and over is to examine whether the addition of a patient and carer skills-sharing intervention improves the long term patient wellbeing following hospital inpatient treatment for anorexia nervosa, an eating disorder which has both psychiatric and medical features, which will be known as the HRA TRIANGLE (Health Technology Assessment TRansition care In Anorexia Nervosa through Guidance onLine from per and carer Expertise). The HRA TRIANGLE study began in 2017 and is looking at the impact of ECHOMANTRA*, a digital intervention that aims to augment inpatient care and reduce relapse by providing support for both patients and carers. This work will also contribute to the European Value of Treatment Project for Anorexia Nervosa which began in January 2019. *ECHO – Experienced Carers Helping in Others

	*ECHOMANTRA – Experienced Carers Helping in Others Maudsley Model of Treatment for Anorexia Nervosa for patients **Discussion:** 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. IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 22nd April 2021. IGARD noted that on the applicant's website that a monetary incentive had been citied and asked that for transparency and noting that section 5 (Purpose / Methods / Outputs) forms NHS Digital's public data release register, that section 5(a) (Objective for Processing) be include a brief narrative to explain that a monetary incentive was to all participants; and to also confirm that details of the incentive plan were approved by the relevant Research Ethics Committee (REC). Should the applicant have any additional documentation from REC, this should be provided to NHS Digital and uploaded to NHS Digital's customer relationship management (CRM) system for future reference. In addition, IGARD noted that when referencing *"ECHO"* or *"ECHOMANTRA"* within section 5 of the application, that it should explain clearly that this is a free service and will continue to be free at point of access via the TRIANGLE website. IGARD noted the applicant had taken their previous advice when presented to IGARD business as usual (BAU) meeting on the 22nd April 2021, which was to talk to a small number of the cohort with regard to the nature of the data the cohort members think is flowing and thanked the applicant for providing a detail of the conversation by way of a copy of the transcript, which IGARD thanked the applicant for providing. However, the transcript was silent on whether the discussion had also included the fact that clinical data may flow under this data sharing agreement (DSA), alongside date and time of admission. IGARD suggested that to ensure a clear legal gateway under consent was established, that the applicant undertake to send a newsletter to participants to inform them that the data collected was not simply, for example, stating the date and time of admission, but would include clinical data such as *"x" (the applicant to include an example of the type of sensitive clinical data which may flow under this DSA*). This newsletter should also take the opportunity to update participants of how they can withdraw from the study at any time with no detriment to their care and to be clear that they did not need to pay back the monetary incentive. Confirmation of the dissemination of the newsletter should be provided to NHS Digital and this should be noted in section 1 (Abstract), alongside details of the communication plan which should be uploaded to NHS Digital's CRM system as a future supporting document. IGARD noted in section 5(d) (Benefits) (iii) (Yielded Benefits) reference to *"reducing bed usage"* and although this may be a benefit, suggested that a key benefit would be improving patient outcomes, for those with anorexia nervosa. In addition, section 5(a) should be updated to relate any benefits back to objectives for processing to include all relevant variables the study will be looking at, such as the length of bed days and bed usage etc. IGARD noted the academic papers referenced in section 5(a) (Objective for Processing) and asked that they were either updated to contain the full searchable academic reference or include a link to the website / web page. In addition, any website links in section 5 should be to free webpage and not behind to pay firewalls. In relation to any remote working, as referred to in the application, IGARD suggested that the Data Access Request Service (DARS) should clarify with the NHS Digital Security Advisor,

	what (if any) special conditions should be included within DSA as standard to address any remote working arrangements and particularly during the COVID-19 pandemic and consequent changes in working practices. In addition, and separate to this application, IGARD requested that NHS Digital share a copy the temporary remote access policy, to support the review of future applications. IGARD noted the inclusion of a number of technical phrases and words within section 5(b) (Processing Activities) such as *"protracted"* and suggested that this was updated to be written in a language suitable for a lay reader and technical terms were either removed, or used only where necessary, and further explained upon first use. IGARD noted that there was one processing location and one storage location within section 2 (Locations), and queried if this was correct, for example, was there a back-up or disaster recovery site; and asked that clarification was provided if there were any additional storage locations and to amend section 2(b) (Storage Location(s)) if appropriate. IGARD queried reference to *"…gender…."* data being requested and asked that the datasets requested in the application aligned with the specific NHS Digital data that can flow, for example 'sex' vs 'gender'. IGARD noted that section 1 should be updated to include the previous IGARD minutes or action notes from when last presented to support future audit and / or oversight and assurance (O&A) review. **Outcome**: recommendation to approve The following amendments were requested: 1. To provide confirmation in section 1 that the applicant will commit to disseminating a newsletter to participants and will provide details of this communications plan to NHS Digital. 2. To update section 1 to include the previous IGARD minutes or action notes to support audit and future O&A. 3. In respect of the monetary incentive: a. To update section 5(a) to note the monetary incentive that was paid to all; **and** b. To confirm that the details of this incentive plan were approved by the relevant ethics committee. 4. To amend section 5(b) to ensure statistical terms of art and technical terms are either removed or explained in a manner suitable for a lay audience, for example, "*protracted*" 5. To update the references to academic papers in section 5, to either include a fuller searchable reference or a relevant web link. 6. When referring to "*reducing bed usage*" in section 5(d)(ii) to also be clear that this will also presumably improve patient outcomes 7. To update section 5(a) with all the relevant variables the study will be looking at such as length of bed days / bed usage etc. 8. To update section 5 when referencing *"ECHO"* and *"ECHOMANTRA"* to be clear that the that this service will continue to be free at the point of access via the TRIANGLE website. 9. To amend section 2(b) and section 5(b) to add any additional storage locations, for example back-up or disaster recovery. 10. IGARD suggested that DARS clarify with the NHS Digital Security Advisor, what (if any) special conditions should be included within DSA's as standard to address any remote working arrangements and particularly during the COVID-19 pandemic.

	11. To ensure that the datasets requested align with the specific NHS Digital data that can flow, for example refer to *"sex"* not *"gender"*, if *"sex"* is what is captured in the dataset. The following advice was given 1. IGARD noted the applicant had taken their previous advice to talk to a small number of the cohort with regard to the nature of the data the cohort members think is flowing and thanked the applicant for providing a detail of the conversation by way of a copy of the transcript. IGARD suggested that to ensure a clear legal gateway under consent was established that a newsletter be sent to participants to inform them that the data collected was not simply, for example, stating the date and time of admission, but would include clinical data such as *(the applicant to include an example of the type of sensitive clinical data which may flow under this DSA*). This newsletter should also take the opportunity to update participants of how they can withdraw from the study at any time with no detriment to their care and to be clear that they did not need to pay back the monetary incentive. Separate to this application, IGARD requested that NHS Digital share a copy of the temporary remote access policy, to support the review of future applications.
3.6	<u>London School of Hygiene & Tropical Medicine (LSHTM): Evaluation of community based health and social care multi-disciplinary teams (MDTs) data linkage and controls (Presenter: Mujiba Ejaz) NIC-332870-B6Z4R-v0.5</u> **Background:** this was a new application for Civil Registration (Deaths) data secondary care cut and Hospital Episode Statistics (HES) Critical Care who are seeking to link mortality and HES data for a consented cohort for three key purposes: **1)** to obtain a group of matched comparison patients; **2)** to compare MDT and matched comparison groups on key outcomes; and **3)** to compare these outcomes between patients on the caseloads of different models of community based MDT. The Pioneer Programme (2013/2018) was a national scheme covering 25 geographical and socio-demographically different areas of the country chosen by the Department for Health & Social Care (DHSC) to improve horizontal integration between health and social services. The current research programme, which commenced in 2015 and due to complete in 2021 follows on from earlier evaluation of the Pioneers. **Discussion:** IGARD welcomed the application which had come for advice on and consent, and without prejudice to any additional issues that may arise when the application is fully reviewed. IGARD noted this was an important study 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, noting that "*NHS*" was cited within the consent materials, it also cited *"local NHS*…" which may not correlate to some participants that had signed the form that this referred to data flowing to and from a national NHS body, such as NHS Digital, plus it was not clear if participants were clear on what data was flowing or the nature of the data being shared. Noting that NHS Digital had tabled a further document in meeting, and that the applicant was in contact with the cohort, suggested the applicant test the assumption with a small group of cohort members, that participants would not be surprised at what data they think is flowing and the nature of the data being shared (particularly NHS number). In addition, and noting the application was still in draft, IGARD suggested that further narrative should be included with regard to the Pioneer Programme in section 5(a) (Objective for Processing); that the legal basis should be clearly articulated in section 5(a); and to use a form

	of wording in section 5(d) (Benefits) such as "*it is expected…"* or *"it is hoped …"*, rather than "*it will…*". IGARD noted that aspects of this application had been previously seen at the IGARD – NHS Digital COVID-19 response meeting on the 23rd February 2021 and that all comments previously raised remained live, including the significant risk area. IGARD suggested that a step plan be put in place and provided some high-level suggestions which are included in the outcome below. **Outcome:** IGARD welcomed the application which came for advice on consent and without prejudice to any additional issues that may arise when the application is fully reviewed. IGARD provided some high-level suggestion including, but not limited to: Whilst the additional document tabled in meeting was helpful to support the consent and the proposition that data sharing with NHS Digital may be not be a surprise, IGARD suggested that the applicant took the opportunity to test this assumption and talk to a small number of cohort members (more than 3 but less than 7), with regards to where the cohort members think the data is flowing, and the nature of the data shared (particularly the NHS number).
4	<u>Returning Applications</u> IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. Due to the volume and complexity of applications at today's meeting, IGARD were unable to review any applications as part of their oversight and assurance role.
5	<u>COVID-19 update</u> To support NHS Digital's response to COVID-19, from Tuesday 21st April 2020, IGARD will hold a separate weekly meeting, to discuss COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 urgent applications that have been submitted to NHS Digital. Although this is separate to the Thursday IGARD meetings, to ensure transparency of process, a meeting summary of the Tuesday meeting will be captured as part of IGARD's minutes each Thursday and published via the NHS Digital website as per usual process. The ratified action notes from **Tuesday 23rd August 2021** can be found attached to these minutes as Appendix C.
6 **6.1**	<u>AOB:</u> <u>NIC-148030-Q5N4D UK Haemophilia Centre Doctors' Organisation</u> IGARD noted that this application had been recommended for approval on the 15th April 2021, with conditions, amendments and advice and that the conditions would be approved out of committee by IGARD Members: **Outcome:** recommendation to approve for 1 year subject to the following condition: 1. In respect of the data controllership: a) To provide satisfactory confirmation (in terms of the UK GDPR and NHS Digital's DARS Standard on Data Controllers) why NHS England are **not** considered joint

	Data Controllers, particularly in light of materials in the public domain which indicate that NHS England may be considered a Data Controller for this dataset. b) To provide confirmation (in terms of the UK GDPR and NHS Digital's DARS Standard on Data Controllers) why UKHCDO Ltd are **not** considered joint Data Controllers. c) To update the application throughout, as may be required, to reflect the factual scenario. The following amendments were requested: 1. In respect of the Data Processor: a) To provide confirmation if NHS Greater Manchester Shared Services should be considered a joint Data Processor (in terms of NHS Digital's DARS Standard on Data Processors). b) To update the application throughout, as may be required, to reflect the factual scenario. 2. To update section 5 to remove reference to *"direct patient care"*, and replace with *"management of patient care"* or similar. 3. To update section 1, section 5(a) and section 5(b) to remove reference to CMFT Caldicott Guardian inspecting the registry / database. 4. To update section 5 to ensure it is written in language suitable for a lay reader and that consideration is given to the public audience of NHS Digital's data release register (for example when referring to *"Poisson regression"*). 5. To remove reference in section 1 and section 5(a) to adherence with the Caldicott Guardian principles and instead refer to the HES analysis guidelines. 6. To amend section 5(e) as per the verbal update from NHS Digital, and in line with the NHS Digital DARS Standard for Commercial Purpose. The following advice was given: 1. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment due to the public scrutiny that has been given to the controllership and operation of this dataset. 2. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent. NHS Digital had informed IGARD, via the IGARD Secretariat, that the application had been signed off by the NHS Digital SIRO. IGARD Members thanked NHS Digital for the update, asked that this information be updated to the OOC Report at Appendix A, and reminded NHS Digital that the conditions, amendments and advice remained live until approved by IGARD.
6.2	<u>NIC-172240-R4R0L-v3.2 University of Oxford</u> IGARD noted that this application had been recommended for approval subject to conditions, amendments and advice on the 27th May 2021 and that a SIRO email had been issued on the 30th June 2021, following approval that conditions had been met by the IGARD Chair. NHS Digital had provided updated documentation following the applications recommendation and as discussed previously with IGARD and provided IGARD with a verbal update. IGARD welcomed the update and documentation from NHS Digital and were supportive of the changes and that it was always worthwhile sharing documents with IGARD in order to gain an independent view.

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

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 13/08/21

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-448129-H1V1G -	COVID-19 Vaccine Data for CCGs and Local Authorities	25/03/2021	1. In respect of the legal basis: a. To provide written **justification** from NHS Digital's PTE as to why the pseudonymised data is being disseminated under COPI. b. To ensure a consistent narrative throughout the application to support the identifiability status of the data. c. To upload the written justification from NHS Digital's PTE to NHS Digital's CRM system for future reference. d. to make requisite changes to the special condition wording in section 6, to reflect any changes to the legal basis 2. To remove from the **LA templated wording*** "*ensuring vulnerable individuals and groups are identified and supported through the vaccination process to ensure the maximum possible vaccination uptake*" since this identification is usually	IGARD Chair	OOC by IGARD Chair	IGARD Chair comments: **Significant risk (new) raised:** *I am writing to confirm that condition 2 has been satisfied and condition 1 has been put in abeyance until formal advice on point has been provided by PTE. Accordingly, these templates are ready for use, however, I must stress that the* ***risk to NHS Digital remains and the PTE advice is still urgently needed****.* *Depending on the content of the PTE advice, when received, the template may still need to be changed in accordance with the original condition, or in a different form altogether (again depending on the nature of*

			a role undertaken by the CCG in providing direct care			*the advice). We will need to keep this under review.*
NIC-294590-B6V3F-v0.11	The University of Manchester	22/07/2021	1. In respect of the HRA CAG annual review: a) The applicant to provide written confirmation that they submitted their annual review by December 2020, OR b) b) To otherwise provide express confirmation that the amendment submitted to HRA CAG in October 2020 replaced the annual review in December 2020.	IGARD Chair	OOC by IGARD Chair	IGARD Chair comments: In respect of the written confirmation *"for audit purposes and future reference, could the email with this confirmation be uploaded to CRM".*
NIC-148030-Q5N4D	UK Haemophilia Centre Doctors' Organisation	15/04/2021	1. In respect of the data controllership: a) To provide satisfactory confirmation (in terms of the UK GDPR and NHS Digital's DARS Standard on Data Controllers) why NHS England are **not** considered joint Data Controllers, particularly in light of materials in the public domain which indicate that NHS England may be considered a Data Controller for this dataset. b) To provide confirmation (in terms of the UK GDPR and NHS Digital's DARS Standard on Data Controllers) why UKHCDO Ltd are **not** considered joint Data Controllers. c) To update the application throughout, as may be required, to reflect the factual scenario.	IGARD Members	NHS Digital SIRO	N/A

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

In addition, a number of applications were approved under class action addition of:

Liaison Financial Service and Cloud storage:

- None

Optum Health Solutions UK Limited Class Actions:

- NIC-362208-G8K6D-v2 DSfC – NHS Norfolk and Waveney CCG - Comm, IV, RS

Graphnet Class Actions:

- None

Appendix B

Professional Advisory Group Outcomes
Record of feedback Wednesday, 25 August 2021

Application & version	DARS- NIC-365354-R3M0Q-v7.2
Applicant Organisation	University of Oxford
Data Controller Organisation	University of Oxford
Professional Advisory Group Agenda Item	3

The profession welcomed this application and noted this was an amendment request for the addition of a Sub-licence Agreement for a consented cohort.

The profession noted with regards to the GDPPR data, the only data which will be shared from this dataset is ethnicity of trial participant and requested NHS Digital ensure the applicant utilises the most appropriate dataset available for this request.
The Caldicot Guardian with support of the profession requested that in line with DARS standards the territory of use and any contractual requirements are made clear to the application and highlighted within the Data Sharing Agreement.

The Profession requested that additional Special conditions are included within the application with regards the onward sharing;

The Profession have requested Palantir / Foundry are not a processor for this data or a processor for any sublicensee due to the contentious nature of the organisation as their values are incompatible with those of the professions.

The applicant MUST ensure any sublicensees represent organisations with an established track record for conducting research or analysis on health care datasets or experience in supporting the processing of such research

Should the above conditions be met the profession is happy for this to proceed.

Attendees	Role	Organisation
Arjun Dhillon	Chair and Caldicott Guardian	NHS Digital
Peter Short	NHS Digital Clinical Lead	NHS Digital
Mark Coley	Profession Representative	BMA
Marcus Baw	Profession Representative	RCGP
Liz Gaffney	Head of Data Access	NHS Digital
Dave Cronin	SDAO Presenting	NHS Digital

Appendix C

Independent Group Advising on the Release of Data (IGARD)

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

held via videoconference, Tuesday, 24th August 2021

In attendance (IGARD Members): Kirsty Irvine (IGARD Chair / Lay representative)
Dr. Imran Khan (IGARD Specialist GP Member)
Dr. Geoff Schrecker (IGARD Specialist GP Member)

In attendance (NHS Digital): Kimberley Watson (DARS)
Vicki Williams (IGARD Secretariat)

2	**Welcome** The IGARD Chair noted that this was a weekly meeting convened to support NHS Digital's response to the COVID-19 situation and was separate from the IGARD business as usual (BAU) meetings. IGARD members present would only be making comments and observations on items that were presented, and were not making formal recommendations to NHS Digital. Should an application require a full review and recommendation, then it should go through the usual Data Access Request Service (DARS) process and be presented at a Thursday IGARD meeting. The action notes from the Tuesday meeting will be received out of committee and then published alongside the minutes of the next Thursday BAU meeting as an appendix. **Declaration of interests:** There were no declarations of interest.
2.3	NIC-393650-B7J6F-V4.2 Department for Health & Social Care (DHSC) **Background:** This was an urgent COVID-19 application from the DHSC and Imperial College London for record level identifiable demographic data to flow to Ipsos MORI to support the REACT1 study (Real-time Assessment of Community Transmission 1). V4.2 of the application had been previously discussed at the IGARD business as usual (BAU) meeting on the 12th August 2021. A previous version of this application and relevant supporting document had been discussed at the COVID-19 response meetings on the 4th August 2020, 8th December 2020, and 20th April 2021. The update was in relation to the proposal to add a monetary incentive to participate in the trial known as the "*incentive trial*". When the application had been reviewed at the IGARD BAU Meeting on the 12th August 2021, there was reference in the application to a "*proposed drop 2*" of data for wave 14 which would be subject to an amendment of the data sharing agreement (DSA). NHS Digital confirmed that ethical approval had been confirmed for the second drop of data. The applicant had also confirmed that they were not intending to update their Privacy Notice because Ipsos Market and Opinion Research International (MORI) would administer the voucher (purchase and administer their emailing) and there would be no data transfer to the supplier for the incentive process. DHSC wish to be able to include the incentive trial in the next round (wave 14), due to it being an important pre-Autumn juncture.

	The following observations were made on the basis of the verbal update from NHS Digital, alongside v4.2 of the application and relevant supporting documents. **IGARD Observations:** IGARD members noted that due to the nature of the meeting should a full review of the application and documentation be required, the full suite of documentation should be presented to a IGARD business as usual (BAU) meeting for a recommendation. IGARD members noted that v4.2 of the application and relevant supporting document had been presented to the 12th August 2021 BAU meeting of IGARD and NHS Digital confirmed that the condition and amendments had been satisfactorily updated to the application and prior to its presentation at today's COVID-19 response meeting. IGARD members expressly noted that there were two distinct areas that required ethical support: one being the new offer of an incentive for wave 14; the other being the study to look at the quantum of the incentive and which elicits the better response and in which age group. It was important (noting that neither IGARD nor NHS Digital have had sight of the Research Ethics Committee (REC) application) that ethics were supportive of both limbs. Although IGARD members can take inference from the documentation provided, it should be explicitly clear in section 5 (purpose / methods / outputs) of the application summary which forms NHS Digital data release register that there are two aspects to the incentive trial. IGARD members applauded the applicant's detailed consideration of the wide ranging ethical issues that are raised when introducing incentives for participation in research. On the basis of the detailed analysis provided, IGARD members present were content that all major ethical considerations had been considered and addressed. In particularly, IGARD noted the applicant's decision not to offer the incentive to those in the study aged 5 to 12 years (noting those under 5 years were not part of the study) since it may inadvertently incentivise parents to include their children in the study. IGARD members discussed the Data Controllership element, since Ipsos MORI would be the organisation, as Data Processor, offering the incentive, and were advised by NHS Digital that Ipsos MORI were offering the incentive under direction from DHSC and Imperial College London (the joint Data Controllers). Noting the potential reputational risk of NHS Digital supplying data to the applicant if the vouchers were not deemed appropriate (recent media coverage of NHS voucher incentives refers), IGARD members suggested that a wide range of vouchers be offered to those that are part of wave 14, as noted on Ipsos MORI's Iris Reward webpage, which included the opportunity to donate rewards back to charity. IGARD members also noted that prior to wave 15 and beyond, IGARD would expect the application to be updated with the analysis undertaken of how successful or unsuccessful the incentive trial had been for wave 14 and how, if at all, future waves would be affected as a result of this research (for example, were incentives effective and did they increase participation rates such that the quantum of data from NHS Digital could be minimised further?). IGARD members noted that NHS Digital had indicated that due to the urgency of the application, the application would proceed under NHS Digital's SIRO Precedent and were supportive of this approach, on this occasion, given that a timely response to this research question could improve future response rates and/or reduce the amount of NHS Digital data

	required to reach the appropriate cohort numbers. IGARD noted that the advice points noted in the IGARD BAU minutes from the 12th August 2021 remained live, namely: The following advice was given: 1. IGARD noted the decision not to apply the NDO, due to this being confidential patient information supplied under COPI notice as the legal basis, and suggested that NHS Digital made Ipsos MORI aware of this fact. 2. Ipsos MORI to review the complaints received with regard to NDOs with the Data Controller, and provide an update to NHS Digital, on renewal, extension or amendment. 3. On renewal, IGARD would expect to see an analysis on the number of opt outs from further contact that Ipsos MORI have received. 4. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, given the volume of data, further analysis on the number of opt-outs, and the outputs from the discussion with the Data Controller regarding complaints. **5.** IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, given the volume of data, further analysis on the number of opt-outs, and the outputs from the discussion with the Data Controller regarding complaints. *(IGARD noted that today's support for this urgent review into incentives was an exception to this point of advice which still stood in respect of future amendments).*
3	<u>AOB</u> There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.