Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 14 October 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member (Item 3.1)
Maria Clark	Lay Member
Prof. Nicola Fear	Specialist Academic Member
Kirsty Irvine (Chair)	IGARD Chair
Dr. Imran Khan	Specialist GP Member
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Michael Chapman	Director of Research and Clinical Trials (Observer: item 3.1)
Dave Cronin	Data Access Request Service (DARS) (Item 7.1)
Louise Dunn	Data Access Request Service (DARS) (Observer: item 3.1)
James Gray	DigiTrials
Dickie Langley	Privacy, Transparency & Ethics (PTE) (Observer: item 3.1)
Karen Myers	IGARD Secretariat
Jonathan Osborn	Deputy Caldicott Guardian (Observer: items 1- 3.1)
Tania Palmariellodiviney	Data Access Request Service (DARS)
Fran Perry	Data Access Request Service (DARS)
Heather Pinches	DigiTrials
Denise Pine	Data Access Request Service (DARS)
Andy Rees	DigiTrials
Vicki Williams	IGARD Secretariat

Clare Wright	Data Access Request Service (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. **Review of previous minutes and actions:** The minutes of the 7th October 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	Statutory Commissioners Applications - Yielded Benefits Briefing Paper (Presenter: Tania Palmariellodiviney) The briefing paper, was to inform IGARD about the proposal from NHS Digital, in respect of the content of the yielded benefits section for statutory commissioners applications; and to support the Data Access Request Service (DARS) with work planning going forward. At the IGARD business as usual (BAU) meeting on the 5th November 2020, IGARD discussed "*the quantum of data that CCGs were getting under their various Data Sharing Agreements (DSA) and how the yielded benefits for CCG applications were being updated and subsequently reviewed by DARS, noting that this section was not always updated within the renewals submitted to IGARD. It was agreed that going forward, where a CCG application was recommended for approval without having provided transparent yielded benefits or that proceeded via NHS Digital's DARS precedent route that IGARD would review these applications as part of the Oversight and Assurance work.".* There are currently 201+ statutory commissioning applications. The applications are templated since statutory commissioning responsibilities are written in statute and do not change. The risk of not publishing the yielded benefits may result in a reduction of public confidence due to not being transparent on each individual case in the data release register, this however would be mitigated by copying in the link that points to the public webpage with the examples of yielded benefits for each data set. Covid-19 and the formation of Integrated Care Systems (ICS) have added additional strain to statutory commissioners. In addition, CCGs are adversely affected due to the high volume of amendments during the life of a DSA. In order to manage the concerns of the CCGs, the risks of using local data and the recommendations from IGARD a possible solution is to work together with the CCGs at a national coordinated level. This would require the DARS and the Data Services for Commissioners (DSfC) Team to work together with the CCGs to capture yielded benefits that can be published on the NHS Digital public facing webpage for each of the Datasets flowing from NHS Digital to the statutory commissioners.

	IGARD welcomed the draft briefing paper and reiterated comments previously made about why NHS Digital needed to undertake a benefits assessment and referred to recent training provided by IGARD on this topic, including key developments which will come into effect later this year. IGARD noted the action to arrange a future workshop. IGARD noted that CCGs cannot be treated any differently to any other body carrying out statutory functions but would be happy to explore detailed guidance that might help CCGs fulfil the requirements which other public body applicants for NHS Digital data undertake without undue burden. Critically, IGARD noted that the NDG will be issuing guidance this year on public benefit assessments, and NHS Digital must have regard to this new guidance. CCGs (or ICSs from the 1st April 2022) will also need to have due regard to demonstrating the specific benefits flowing to the public from the use of health data. In order to fulfil their obligations, CCGs may wish to explore the use of documents already prepared and in the public domain, such as their statutory annual report. IGARD looked forward to discussing possible solutions to help CCGs meet their obligations at a workshop to be scheduled.
3	**Data Applications**
3.1	University of Oxford: R1 (D09) - Data support to COVID-19 RCT (Presenters: James Gray / Andy Rees / Heather Pinches) NIC-365354-R3M0Q-v7.3 **Application:** 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; **3)** to include details of additional treatment types C, D, E and F in section 5(a) (Objective for Processing). The Randomised Evaluation of COVid-19 thERapY (RECOVERY) trial aims to compare 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. The application was previously considered on the 26th August 2021 where IGARD were unable to make a recommendation as not all the necessary information was available in order to make a full assessment. NHS Digital provided a brief overview of the history of the application for the benefit of IGARD members and observers, including the number of previous reviews made by IGARD at both the IGARD business as usual (BAU) and the IGARD – NHS Digital COVID-19 Response

	meetings; and in addition, the reviews and comments made by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG). **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meetings on the 11th June 2020, 30th July 2020, 12th November 2020 and 26th August 2021. IGARD noted that aspects of this application had been previously seen at the IGARD – NHS Digital COVID-19 Response meetings on the 21st April 2020, 28th April 2020, 5th May 2020, 12th May 2020, 19th May 2020, 7th July 2020, 21st July 2020, 22nd September 2020, 1st December 2020 and 26th January 2021. IGARD noted that they had reviewed an early version of the consent materials in March 2020 and had provided a paper with suggestions and comments to NHS Digital. IGARD also noted that this application had been reviewed by the GPES Data for Pandemic Planning and Research – 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; and the 25th August 2021 and that notes from this meeting had been attached to the IGARD minutes from the 26th August 2021. It was agreed by IGARD and NHS Digital that the discussion would be separated in to three sections; **1)** providing a recommendation on the additional flows of data requested and the additional treatment arms, **2)** providing advice on the proposed onward sharing of data with researchers, and **3)** providing advice on the past / ongoing sharing of data with manufacturers. **In respect of the additional flows of data requested and the additional treatment arms:** IGARD noted that NHS Digital's UK GDPR transparency pages set out geographical restrictions on where various datasets may be used. Depending on the source of the data and nature of collection, there may also be restrictions contained in the relevant Direction which denote in which jurisdictions data may be shared. IGARD suggested that the level of data for each dataset shared was reviewed to ensure that NHS Digital data did not leave the permitted geographical area (including via the IDDO and flow of data to manufacturers). IGARD noted the amendment to add the treatment types, however queried the information provided for *"Randomisation Part E"*, in particular the reference to data subjects in *"non-UK countries"*, and, noting that it was not clear, asked that section 5(a) was updated to clarify that this would **not** involve the use of NHS Digital data. IGARD noted the constraints placed in the Direction for the collection of NHS BSA Medicines dispensed in Primary Care data, specifically, *"Providing intelligence about the safety and effectiveness of medicines…"*; and asked that in line with NHS Digital's DARS Standard for Objective for Processing, when referencing processing of Medicines Dispensed in Primary Care NHS BSA data to ensure a clear narrative is provided linking the purposes and processing to the relevant Direction. In addition, IGARD asked that a special condition was inserted in section 6 (Special Conditions), that any use of the NHS BSA data must be within the parameters of the relevant Direction authorising that collection. IGARD noted the excellent yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits), however asked that some minor amendments were made to the information provided, including, updating the reference to the "4th June", to also include the year; and to review the statement *"…reduced the significantly reduced deaths…"*, and amend as appropriate.

	In respect of the proposed onward sharing of data with researchers: IGARD noted at the IGARD BAU meeting on the 26th August 2021, that the IDDO 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. IGARD noted that as highlighted in section 1 (Abstract), a draft sub-license for onward sharing of data, had been seen by those IGARD members present at the IGARD – NHS Digital COVID-19 Response meetings on the 1st December 2020 and 26th January 2021; where IGARD had provided some brief high-level comments, as per the nature of that Response meeting. IGARD noted in section 1 that the points previously raised had been addressed and the draft sub-licence now included the use of the IDDO's clinical data platform, with a robust governance and ethical framework, to enable onward sharing of data, and the requirement for a Data Transfer Agreement (which will constitute a sub-license agreement) and ensured NHS Digital's requirement to audit and destruction of data upon expiry or termination of the sub-licence. IGARD reiterated their concern (first raised in March 2020) that the consent materials were very specific about what would happen with the cohort data and did not give cohort members an indication that their data, albeit pseudonymised, may be onwardly shared with either researchers or manufacturers. IGARD acknowledged that the updated privacy notice referred to additional detail about sharing data with researchers and commercial companies but noted that the privacy notice could not be used to disclose such substantive issues which contradicted the express consent taken from participants. See also the analysis of the HRA guidance under the sharing of data with manufacturers discussion below. IGARD outlined the potential ethical issues with the onward sharing and further noted the relevance of the Caldicott principle of *"no surprises"*. NHS Digital advised IGARD that the applicant continued to maintain contact with the consented cohort. The applicant had offered to provide further information to participants, via a newsletter, within the next few weeks in order to ensure further transparency in respect of how the participants' data was currently being processed and shared and how it may be processed and shared going forward. IGARD noted the verbal update from NHS Digital and supported the proposal from the applicant to send a newsletter to participants; however, IGARD suggested that prior to circulating the newsletter the applicant consulted with a group of cohort members, for example, by utilising the existing cohort patient and public involvement and engagement (PPIE) committee. As part of this engagement, IGARD suggested that the applicant sought the PPIE committee's views on several points, including, but not limited to, the onward sharing of data with researchers, how the applicant was proposing to update the cohort (for example, via a newsletter), and the design and language used within the newsletter. IGARD also suggested that in order to seek the views of the PPIE group, the applicant may wish to consider delaying the distribution of the newsletter to allow sufficient time to consult with the PPIE group and make any requisite changes as appropriate. IGARD noted that the newsletter would reference the privacy notice, and asked that the applicant ensured that the privacy notice aligned with the newsletter, and that it did not add any additional detail about the onward sharing of data, beyond what would be in the newsletter update; noting that not all participants may view the privacy notice in addition to the newsletter so the key information needed to be in the hard copy newsletter. NHS Digital agreed with IGARD that it was essential that the newsletter clearly set out how participants could withdraw their consent if they no longer wanted to take part. Good practice

	would suggest offering at least two ways of contacting the study team (for example both a phone number and email address). IGARD noted the statement within supporting document 1.11, the protocol that "*The Trial Steering Committee will also establish a process by which proposals for additional publications (including from independent external researchers) are considered by the Trial Steering Committee. The Trial Steering Committee will facilitate the use of the study data and approval will not be unreasonably withheld. However, the Trial Steering Committee will need to be satisfied that any proposed publication is of high quality,* ***honours the commitments made to the study participants in the consent documentation*** *and ethical approvals, and is compliant with relevant legal and regulatory requirements (e.g. relating to data protection and privacy).".* IGARD therefore strongly suggested that the applicant demonstrated compliance with their own published protocol and update the Trial Steering Committee on the proposed onward sharing of data via the IDDO mechanism. This update should include details about the level of data to be shared and how this aligns with the consent taken from participants. IGARD also suggested that the applicant ensured that the necessary positive support from the Trial Steering Committee was appropriately documented for future reference and a copy uploaded to NHS Digital's customer relationship management (CRM) system for future reference. IGARD noted that Research Ethics Committee (REC) approval was in place, however, advised that it was unclear if the applicant had advised REC on the proposed onward sharing of data with researchers, and that this may be beyond the scope of the original REC approval. IGARD suggested that the applicant updated the REC about the onward sharing of data to researchers and that if the REC wished to update the support, that the positive support was appropriately documented for future reference and a copy uploaded to NHS Digital's CRM system for future reference. IGARD referred to the geographical restrictions on where NHS Digital data could be used, as detailed above. IGARD noted the information within the application that stated the data shared with researchers by the IDDO would be *"anonymous"*, and queried if this was correct, noting the sublicensing arrangements between the University of Oxford and the IDDO. If the data was truly anonymous then it would no longer be NHS Digital data and a sublicensing agreement would not be required and the data could simply be released into the public domain. NHS Digital advised IGARD that the description of the data as *"anonymous"* was incorrect, and that the data shared by the IDDO was either *"anonymous in context"* or *"pseudonymised"*. IGARD noted the verbal update from NHS Digital, and asked that the application was updated throughout, to ensure that **all** references to the data being *"anonymous"* were removed; and replaced with a more accurate description of the data, depending on the context, for example, *"pseudonymised"* or *"anonymised in context"*, including (but not limited to) the statement within the special conditions in section 10 (Sub-licensing) that stated *"Data accessed via IDDO may be shared worldwide, as it is rendered anonymous."*. Noting the significance of the points raised, IGARD suggested that NHS Digital's Caldicott Guardian reviewed all the actions undertaken by the applicant, and document this review and the pertinent factors in approving any flows of data to the applicant via the NHS Digital SIRO approval route. **In respect of the existing / ongoing sharing of data with manufacturers:**

	IGARD noted that they had previously raised concerns on the 26th August 2021, that they were unclear of the legal gateway for the past or ongoing onward sharing of the cohort's data with the manufacturers following the approval under NHS Digital Senior Information Risk Owner (SIRO) precedent for an amendment for the requirement to disclose data to Regulators and Manufacturers of treatments evaluated in the RECOVERY trial in April 2021. IGARD noted the update from NHS Digital in section 1, that stated, that onward sharing with manufacturers was in line with information provided to participants; and that although manufacturers were not explicitly mentioned in any version of the consent form, NHS Digital noted that the trial had taken a layered approach to consent and how information was provided to participants. In addition, NHS Digital noted that this approach, was in line with Health Research Authority (HRA) guidance, in that providing a layered approach to consent, whereby participants were provided with limited information within the participant information leaflet and consent form, and were directed to more detailed information; which was relevant for patients providing informed consent who may have been acutely unwell at the time of consent. IGARD were not in agreement with this interpretation since the supporting documentation provided did not provide the relevant facts to support the claim of a layered approach. For a layered approach to work **no new consent items or information that contradicts the first layer should be included within deeper layers**. IGARD noted that the Patient Information Sheet (PIS) that had been provided as a supporting document did not mention such onward sharing, but did in fact state "*All information about you and your health will be kept private. The only people allowed to look at the information will be the doctors who are running the study, the staff at the study coordinating centre, and the regulatory authorities who check that the study is being carried out correctly. A privacy notice is on the study website*." (RECOVERY PIS+ICF V1.0 2020-03-13.pdf). The consent form expressly noted sharing data with NHS national bodies and regulatory authorities so the sharing with NHS Digital and the flow of data to regulators was not in question. The consent form was silent on any other sharing. IGARD referred to the geographical restrictions on where NHS Digital data could be used, as detailed above. IGARD noted that NHS Digital data had already been shared with manufacturers, and pragmatically suggested that similar steps were taken as outlined above, in respect of the sharing of data with researchers, for example, updating the REC, seeking support from the Trial Steering Committee, consulting with the PPIE group and updating the cohort via the newsletter. IGARD suggested ensuring full transparency in the application and in communication with the cohort, in respect of any use of the data that may have a commercial benefit, for example, the marketing of a COVID-19 treatment or development of a non-COVID-19 related drug; in line with NHS Digital DARS Standard for Commercial Purpose. IGARD queried the statement 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 queried if this was a contractual arrangement between NHS Digital and the University of Oxford. IGARD were advised by NHS Digital that a Data Sharing Agreement (DSA) had already been signed by the manufacturer(s) with the University of Oxford, and due to the pace and urgency of the trial it had been assessed by NHS Digital that as the data flowing to the manufacturer was anonymous in context the need for an audit was considered low risk. IGARD noted the verbal update from NHS Digital, however suggested that NHS Digital considered their position on this going forward, noting the audit requirement in NHS Digital's DARS Standard for Sublicensing

	and Onward Sharing of Data, and asked that section 5(a) was updated to reflect that NHS Digital's decision to waived the right to audit was under review. 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 high-profile nature of the application and complexity related to onward sharing. **Outcome:** recommendation to approve for the additional flows of data requested and the additional treatment arms only. The following amendments were requested: 1. To update the application throughout to remove all references to the data being *"anonymous"*, and replace with a more accurate description, depending on the context, for example, *"pseudonymised"* or *"anonymised in context"*. 2. In respect of the NHS BSA dataset: a) In respect of section 5(a) and in line with NHS Digital's DARS Standard for Objective for Processing, when referencing processing of Medicines Dispensed in Primary Care NHS BSA data to ensure a clear narrative is provided linking the purposes to the relevant Direction. b) To insert a special condition in section 6, that any use of the Medicines dispensed in Primary Care NHS BSA data must be within the parameters of the relevant Direction authorising that collection. 3. To amend the statement in section 5(a) *"NHS Digital waive the right to audit…"*, to reflect that this is under review. 4. To update *"Randomisation Part E"* in section 5(a), to clarify that this will not involve the use of NHS Digital data. 5. In respect of the yielded benefits in section 5(d) (iii): a) To update the reference to the *"4th June"* to include the year. b) To review the statement *"…reduced the significantly reduced deaths…"*, and amend as appropriate. 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 high-profile nature of the application and complexity related to onward sharing. 2. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the high-profile nature of the application and complexity related to onward sharing. **Outcome:** IGARD provided the following advice with regards to the proposed onward sharing of data with researchers, and without prejudice to discussions on this aspect at any future reviews. 1. In respect of the onward sharing of data with researchers: a) IGARD suggested that the applicant consulted with a group of cohort members, for example, by utilising the existing cohort PPIE committee. b) In respect of the newsletter, IGARD suggested that the applicant seek the views of the PPIE group on several points, including (but not limited to) the onward sharing of data with researchers, how they are proposing to update the cohort (for example, via a newsletter), the content and language used within the newsletter, and the ability to withdraw consent.

	c) IGARD suggested that in order to seek the views of the PPIE group, the applicant may wish to consider delaying the distribution of the newsletter to allow sufficient time to consult with the PPIE group and make any requisite changes. 2. In respect of the Trial Steering Committee: IGARD strongly suggest demonstrating compliance with the applicant's own published protocol in updating the Committee of the onward sharing of data via the IDDO mechanism, including (but not limited to), the level of data to be shared and how this aligns with the consent taken from participants; IGARD suggested ensuring that the necessary support from the Steering Committee is appropriately documented. 3. IGARD suggested that the applicant update REC about the onward sharing of data to researchers. 4. NHS Digital should ensure that no NHS Digital data will be shared beyond any geographical boundaries that may exist for particular datasets. 5. To ensure that the privacy notice aligns with the newsletter and does not add any additional detail about the onward sharing beyond what will be in the newsletter update. 6. IGARD suggested that NHS Digital review all the actions undertaken by the applicant, in respect of the advice points raised above, and document this review and the pertinent factors in approving flows of data to the applicant. The following advice was given in respect of the existing sharing of data with manufacturers: 1. IGARD noted that NHS Digital data had already been shared with manufacturers. IGARD suggested that the same steps were taken as per the sharing with researchers above (updating REC, Trial Steering Committee, consulting with PPIE group and updating the cohort via the newsletter). IGARD suggested ensuring full transparency in the application and in communication with the cohort in respect of any use of the data that may have a commercial benefit, for example, the marketing of COVID-19 treatment or development of a non-COVID-19 related drug. This advice was made in line with NHS Digital DARS Standard for Commercial Purpose.
3.2	Royal College of Physicians of London: National Asthma & COPD Audit Programme (NACAP): Outcomes of patients in the 2019/20 children and young people (CYP) asthma clinical audit. CYP admitted for asthma attacks discharged from acute hospitals between 1) 01/06/2019 and 31/01/2020 and 2) CYP discharged between 01/04/2021 and 31/03/2022. (Presenter: Clare Wright) NIC-379653-W3G5Q-v0.14 **Application:** This was a new application for pseudonymised Civil Registration (Deaths) - Secondary Care Cut, Hospital Episodes Statistics (HES):Civil Registration (Deaths) bridge and HES Admitted Patient Care (APC). This application relates to the secondary care children and young people asthma clinical element of the National Asthma and chronic obstructive pulmonary disease (COPD) Audit Programme (NACAP). The children and young people asthma audit has been running since the 1st June 2019 and reports on care processes provided in the acute hospital setting such as, the provision of personalised asthma action plans, inhaler technique checking, smoking and specialist review and follow-up. The NACAP aims to improve the quality of services for children and young people between the ages of 1-18 years old, with asthma by measuring and reporting on the delivery of care as defined by national guidelines and standards. During the first round of data collection (1 June

	2019 – 31 January 2020) 152 hospitals participated in the audit and 8,506 records were included in the first audit cycle. There are two cohorts, **cohort 1**, with approximately 8,500 children and young people aged 1-18 years old who were admitted to hospital paediatric services with a primary diagnosis of asthma attack on or after 1st June 2019 and discharged by 31st January 2020, whose details have been entered into the children and young people asthma clinical audit data collection; and, **cohort 2**, children and young people aged 1-18 years old who were discharged from hospital paediatric services with a primary diagnosis of asthma attack between 1st April 2021 and 31st March 2022, whose details will be entered into the children and young people asthma clinical audit data collection (the cohort size is unknown until mid-2022). NHS Digital noted in section 1(c) (Data Processor(s)), that the Royal College of Physicians (RCP) and Imperial College London (ICL) Data Protection Act (DPA) Registration had expired or was about to expire, and advised that this would be updated to reflect the correct DPA Registration expiry date. The study is relying on s251 of the NHS Act 2006, for the flow of data out of NHS Digital. **Discussion:** IGARD noted the verbal update from NHS Digital in respect of the expired DPA dates currently noted within section 1(c) for the RCP and ICL; and supported the update to the application to reflect the correct DPA expiry date. 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 also confirmed that they were content that supporting document 1.5, the Health Research Authority Confidentiality Advisory Group (HRA CAG) amendment form, dated the 12th April 2021, covered the s251 support throughout the lifetime of this DSA. IGARD noted the statement in section 1 (Abstract) that the applicant had advised, that as an audit programme, they had agreed not to report on any COVID-19 impacted data, so the period covering children and young people discharged between the 1st February 2020 and the 31st March 2021, was not included in cohort 1 or 2. IGARD queried the reason for this exclusion of data, noting the potential importance of this period through the core COVID-19 pandemic, and how the data may provide valuable information, for example, by undertaking an analysis comparison, pre-COVID-19 and during. IGARD asked that a satisfactory and robust explanation was provided in section 1 and section 5 (Purpose / Methods / Outputs), as to why the one year of data during the height of the COVID-19 pandemic was not included within the DSA; and to provide confirmation of how and who this was *"agreed"* with. In addition, noting the potential impact the missing data may have on the outputs of the audit, IGARD asked that for transparency, it was expressly acknowledged in section 5(c) (Specific Outputs Expected) that the audit would be missing one year of data at the height of the COVID-19 pandemic and the potential impact of this. IGARD noted within the application that the size of cohort 2 was currently unknown, however asked that for transparency, section 3(b) (Additional Data Access Requested) and section 5(b) (Processing Activities) were updated with an 'indicative' size of cohort 2. IGARD queried the statement in section 3(b) that *"GDPR does not apply to data solely relating to deceased individuals"*, however, noting that the status of those patients that are still alive would be revealed, asked that this was updated to include a UK General Data Protection Regulation (UK GDPR) legal basis for dissemination and receipt of data. 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 queried the role of ICL, in light of the information within the application that referred to ICL undertaking analysis on the datasets on behalf of the RCP; and asked that clarity was provided in section 5, as to whether ICL, when undertaking work on behalf of RCP were acting as a sub-Data Processor. In addition, IGARD asked that an analysis was provided in section 1 as to why ICL were **not** considered a joint Data Controller or Data Processor; and in line with NHS Digital's DARS Standard for Data Controllers and NHS Digital's DARS Standard for Data Processors, and as borne of the facts. IGARD noted the information within section 5(a) in relation to the role and membership of the *"patient panel"*, however asked that this was updated further to also include information of the recent activities of the patient and public involvement (PPI), as this was not clear. IGARD noted the benefits in section 5(d) (Benefits), for example, *"Awareness of what patients should expect from their care provider, and how their local provider Trust/Board is performing, can help people with asthma to insist on better quality care."*; and asked that the applicant consulted with the PPI group (patient panel), with regards to the stated benefits to patients / the public to see if they agreed with the assessment, and / or could suggest any additional benefits that may flow. IGARD noted a number of statistical terms of art and technical terms in section 5(d), and asked that this public facing section, that formed NHS Digital's data uses register, was amended throughout, to ensure these are explained in a manner suitable for a lay audience, for example *"AOR: 1.97 [95% CI: 1.71 – 2.29]"*. IGARD suggested that section 5(d) be updated to remove reference to "*it will*…" and instead use a form of words such as "*it is expected"* or *"it is hoped …".* IGARD queried the reference in section 5(d) *"The reports must be addressed by all NHS provider services…"*, and asked that this was removed, and, for example, replaced with the benefits to patients and / or the health and care system. IGARD noted the reference in section 5(a) to the *"Office **of** National Statistics"*, and asked that this was updated to correctly refer to the *"Office **for** National Statistics"*. **Outcome:** recommendation to approve subject to the following conditions: 1. In respect of the one year of data (2020-2021) not covered in the application: a) To provide a satisfactory and robust explanation in section 1 and section 5 as to why the one year of data during the height of the COVID-19 pandemic is not included within the DSA; and, b) To provide confirmation of how and who this was *"agreed"* with. c) To expressly acknowledge in section 5(c) that the audit will be missing one year of data at the height of the COVID-19 pandemic and the potential impact this may have on the outputs. The following amendments were requested: 1. To update section 3 to include a UK GDPR legal basis for those datasets that give information about cohort members who are still living, if this approach is supported by advice on this point from PTE. 2. In respect of ICL: a) To update section 5 to clarify when ICL is undertaking work on behalf of RCP, are they acting as a sub-Data Processor. b) To provide an analysis in section 1 as to why ICL are not considered a joint Data Controller or Data Processor; and in line with NHS Digital's DARS Standard for

	Data Controllers and NHS Digital's DARS Standard for Data Processors, and as borne of the facts. 3. To update section 3(b) and section 5(b) with an indicative size of cohort 2. 4. In respect of the PPIE: a) To update section 5(a) with further information of the recent activities of the PPI group. b) To consult with the PPI group with regards to the stated benefits to patients/the public to see if the agree with the assessment (and/or can suggest any additional benefits that may flow). 5. To update section 5(a) to ensure that ONS is referenced correctly as the Office **for** National Statistics. 6. In respect of the benefits in section 5(d): a) To amend section 5(d) to ensure statistical terms of art and technical terms are either removed or explained in a manner suitable for a lay audience. b) To update where appropriate in section 5(d) to use a form of wording such as "*it is hoped* …", rather than "*it will…*". *c)* To remove the reference in section 5(d) to *"NHS service providers".* It was agreed the conditions would be approved out of committee (OOC) by IGARD members.
3.3	The University of Manchester: MR1102 - British Association of Dermatologists' Biologic and Immunomodulators Register (BADBIR) (Presenter: Denise Pine) NIC-147941-XX4JP-v4.5 **Application:** This was a renewal and extension application to permit the holding and processing of identifiable Cancer Registration Data, Civil Registration (Deaths) data, Demographics data, Hospital Episode Statistics Admitted Patient Care (HES APC), Medical Research Information Service (MRIS) - Cause of Death Report, MRIS Cohort Event Notification Report, MRIS - Flagging Current Status Report and MRIS - Members and Postings Report. It was also an amendment to **1)** add British Association of Dermatologists (BAD) as a joint Data Controller and making the relevant updates to the application; **2)** following the previous IGARD review and comments made on the patient information sheet, version 5.2 has been updated accordingly and has been reviewed and received Research Ethics Committee (REC) approval; **3)** to amend the data frequency for Civil Registration (Deaths) and Cancer Registration data, from a 4-monthly basis to annually **4)** to update the objectives for processing (section 5(a)) and the processing activities (section 5(b)) to ensure compliance with NHS Digital Standards **5)** to update the output dates in section 5(c); **6)** to update the yielded benefits in section 5(d) (iii). The purpose is to support the British Association of Dermatologists Biologics and Immunomodulators Register (BADBIR) study's aim of assessing the long-term safety of new treatments for psoriasis. Since its inception in 2007, BADBIR seeks to address the previously described limitations by systematically and prospectively evaluating safety in large numbers of "real world" patients receiving new treatments for psoriasis over a prolonged period compared to a comparator/control cohort. This type of register is considered to be the current gold standard in evaluating long-term treatment safety, which is achieved by following consented, registered participants and collecting information on drug exposure and adverse events (AEs). Therefore, a more reliable and valid picture of long-term safety can be provided to clinicians and patients.

	The study is funded by BAD and based at the University of Manchester. The data requested has been minimised, to a cohort, currently of around 14,500 participants, although this is added to on an annual basis as more participants consent to the study. The study is relying on both consent **and** s251 of the NHS Act 2006, for the flow of data out of NHS Digital. NHS Digital advised IGARD that supporting document 1.6, the latest patient information sheet (PIS) that was provided with the papers for IGARD to review alongside the application, contained further information outlining how participants could withdraw from the study, as per previous IGARD advice. NHS Digital noted in section 1 (Abstract), that the University of Manchester does not have specific authority to access NHS Digital data; and advised that this was incorrect, and would be amended to align with the PIS, that stated the University of Manchester does have specific authority to access NHS Digital data. NHS Digital advised that the applicant had advised that those participants who had turned 16 years of age, and not reconsented to remain in the study, would be removed, once the Data Sharing Agreement (DSA) had been renewed. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 4th October 2018. IGARD noted the verbal updates from NHS Digital, in respect of the updated PIS with additional information outlining how participants could withdraw from the study; and the incorrect statement in section 1 that would be updated to reflect that the University of Manchester does have specific authority to access NHS Digital data. IGARD also noted the verbal update from NHS Digital, in respect of the removal of those participants who had turned 16, and not reconsented, from the study; and queried, what steps had been undertaken to reconsent those participants, for example, had attempts been made to reconsent and failed, or had it not been possible to contact those individuals. IGARD asked that it was clearly outlined in section 1 and section 5 (Purpose / Methods / Outputs), what steps had been undertaken to reconsent those participants that have turned 16. In addition, IGARD noted that it was important to endeavor to retain those who had turned 16 as part of the cohort; and that if the applicant had lost contact with members of that particular group, IGARD suggested that the applicant may wish to seek s251 support from the Health Research Authority Confidentiality Advisory Group (HRA CAG). 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 queried the statement in section 5(b) (Processing Activities) *"Some study data will be shared with pharmaceutical companies, some of which are outside the EEA"*, and asked that section 1 and section 5 were updated, to confirm that where there was reference to the sharing of data with pharmaceutical companies outside of the EEA, that this did not include any NHS Digital data. IGARD queried the statement in section 3(b) (Additional Data Access Requested) that *"GDPR does not apply to data solely relating to deceased individuals"*, however, noting that the status of those patients that are still alive would be revealed, asked that this was updated to include a UK General Data Protection Regulation (UK GDPR) legal basis for dissemination and receipt

	of data. 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 queried the reference in section 1 to *"type 2"* patient objections, and noting that this had now been replaced with the National Data Opt-out (NDO), asked that section 1 was updated to remove the reference to "*type 2"* objections and replace with the NDO. IGARD noted that the NDO was applied to the entire cohort, regardless of whether they had consented, or they were under the s251 support; and queried why, notwithstanding that this was a consented cohort, that the NDO would be applied, and why the decision was taken, not to respect the cohorts consent; and asked that an explanation was provided in section 5. In addition, IGARD asked that for transparency, the privacy notice was updated, to explain, that the NDO would be applied, even though this was a consented cohort. IGARD queried the UK General Data Protection Regulation (UK GDPR) Article 6 legal basis for BAD, which was Article 6(1)(e) and Article 9(2)(j) *"public task"*; and asked that this was reviewed and updated as appropriate, if it was considered to not be the most appropriate legal basis. IGARD noted the primary end points for evaluations within supporting document 4.1, the protocol, and asked that this useful information was added to section 5 of the application for transparency. IGARD suggested that section 5(d) (Benefits) be updated to remove reference to "*it will*…" and instead use a form of words such as "*it is expected"* or *"it is hoped …".* IGARD noted a number of acronyms in section 5(d) and asked that as this formed NHS Digital's data uses register, section 5(d) be updated to ensure that all acronyms be defined upon first use, and technical terms are explained in a manner suitable for a lay audience, for example *"survival"* in the context of the drugs. **Outcome:** recommendation to approve subject to the following conditions: 1. To clearly outline in section 1 and section 5 what steps have been undertaken to reconsent those participants that have turned 16 years of age. 2. To confirm in section 1 and section 5, where referring to the sharing of data with pharmaceutical companies outside of the EEA, that this does not include any NHS Digital data. The following amendments were requested: 1. To update section 3 to include a UK GDPR legal basis for those datasets that give information about cohort members who are still living, if this approach is supported by advice on this point from PTE. 2. In respect of the NDO: a) To update the terminology in section 1 from *"Type 2 Opt-outs"* to *"NDO"*. b) Notwithstanding that this is a consented cohort, to provide an explanation in section 5, that the NDO will be applied, and why the decision was taken, not to respect the cohorts consent. c) To update the privacy notice, to explain, that the NDO will be applied, even though this is a consented cohort. 3. To review the BAD UK GDPR legal basis, and update as appropriate. 4. To update section 5 with the list of primary end points as outlined in the protocol. 5. In respect of section 5(d):

	a) To update section 5(d) to use a form of wording such as "*it is hoped* …", rather than "*it will…*". b) As section 5(d) forms NHS Digital's data uses register, to amend section 5(d) throughout, to ensure acronyms be defined upon first use, and technical terms are explained in a manner suitable for a lay audience, for example *"survival"* in the context of the drugs. The following advice was given: 1. IGARD noted that it was important to endeavour to retain those who had turned 16 years of age as part of the cohort. If the applicant had lost contact with members of that particular group, IGARD suggested that the applicant may wish to seek s251 support. It was agreed the condition would be approved out of committee (OOC) by IGARD members.
3.4	Royal Free London NHS Foundation Trust: Phenotyping individuals with elevated mean pulmonary arterial pressure and elevated pulmonary vascular resistance in the United Kingdom (Presenter: Fran Perry) NIC-306849-M2N0X **Application:** This was a new application for pseudonymised Civil Registration (Deaths), Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC) and HES Outpatients. Pulmonary hypertension is when there is increased pressure in the blood vessels of the lungs, which increases the strain that is placed on the right side of the heart, ultimately leading to failure of the right side of the heart to pump against increased pressures. It is diagnosed by haemodynamics obtained by an invasive procedure known as a right heart catheterisation. This is where a catheter is inserted through the vessels and directly measures the pressures in the right side of the heart and arteries in the lung, known as the pulmonary artery. Under the current guidelines a diagnosis of Pulmonary Hypertension is made when the mean pulmonary artery pressure of greater than 25mmHg, and carries a risk of high mortality and morbidity. It is known that a mean pulmonary artery pressure of >20mmHg is abnormal, however this does not meet the criteria for Pulmonary Hypertension; and these patients are often not formally followed up however, remain symptomatic, some may even progress to pulmonary hypertension by its current definition. It is important to understand this group of patients who have a mean pulmonary artery pressure less than 25mmHg, however still have abnormal haemodynamics, looking specifically at their baseline characteristics, how the population behaves, progression and most importantly if they demonstrate increased attendances to hospital settings whilst still undiagnosed. This is a retrospective study looking at all right heart catheters done between the 1st January 2009 – 31st December 2016. Patients will be selected for the cohort according to their pulmonary artery pressure; and by peripheral vascular resistance (i.e. the resistance in the pulmonary vessels against blood flow). The primary objectives for this study are to look at mortality and admission to hospital for treatment in this population against a control population. The study is relying on s251 of the NHS Act 2006, for the flow of data out of NHS Digital. NHS Digital advised IGARD that there were several organisations referred to in the protocol that were not referenced as joint Data Controllers and / or Data Processors within the application. NHS Digital confirmed that following further discussions with the applicant, they were content, that the organisations were not deemed joint Data Controllers / Data Processors.

	Discussion: IGARD noted and commended both the applicant and NHS Digital, on the quality of the information provided within the application, in particular highlighting the information provided in section 1 (Abstract), section 5 (Purpose / Methods / Outputs) and the transparency of the commercial aspect in section 5(e) (Is the Purpose of this Application in Anyway Commercial), 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 noted that there was an outstanding query raised with the Privacy, Transparency and Ethics (PTE) Directorate by colleagues in Data Access Request Service (DARS), in respect of Civil Registration (death) and whether UK General Data Protection Regulation (UK GDPR) applied. IGARD therefore queried the misleading information in section 1, that stated the *"current policy"* should be followed pending the outcome of the query; and asked that this was removed. IGARD also queried the statement in section 3(b) (Additional Data Access Requested) that *"GDPR does not apply to data solely relating to deceased individuals"*, however, noting that the status of those patients that are still alive would be revealed, asked that this was updated to include a UK GDPR legal basis for dissemination and receipt of data. IGARD reiterated that a query had been raised on this particular point with PTE Directorate and welcomed an update from DARS in due course. IGARD noted the references within the application to *"The Royal Brompton Hospital"*, and asked that these were updated to correctly reflect that The Royal Brompton Hospital was now Guy's and St Thomas' NHS Foundation Trust. IGARD members noted and applauded the applicant for the published study specific web page, however asked if further information could be added to section 5(a) outlining any prior and ongoing patient and public involvement and engagement (PPIE), noting that this was not clearly outlined; and in line with HRA guidance on Public Involvement. IGARD queried the statement in section 5(c) *"The study is supporting one full-time postgraduate research degree MD (res)…"*, and asked that this was updated, to ensure an accurate and consistent description of the post-graduate research qualification. IGARD suggested that section 5(d) (Benefits) be updated to remove reference to "*it will*…" and instead use a form of words such as "*it is hoped*…" IGARD queried why the applicant had requested Welsh data, noting the references in section 5(a), and asked that an explanation was provided in section 5, noting that there were no Welsh hospitals involved, for example, was this for patients residing in Wales, who were admitted to a study hospital in England? IGARD noted the information provided in section 5 in respect of the arterial pressures, however asked that for additional context, section 5 was updated to include reference range of the arterial pressures. IGARD suggested that any future update to the PIS should be updated to clearly explain that the study have support for the flow of data, where National Data Opt-outs (NDO) have been applied, via the Health Research Authority Confidentiality Advisory Group (HRA CAG). **Outcome:** recommendation to approve The following amendments were requested:

	1. In respect of the Civil Registration (death) data: a) To update section 1 to remove the misleading information in respect of the Civil Registration (death) data. b) To update section 3 to include a UK GDPR legal basis for those datasets that give information about cohort members who are still living, if this approach is supported by advice on this point from PTE. 2. To update the application to reflect that The Royal Brompton Hospital is now Guy's and St Thomas' NHS Foundation Trust. 3. To update section 5(a) to outline any prior and ongoing PPIE, and in line with HRA guidance on Public Involvement. 4. To update section 5(c) to ensure an accurate and consistent description of the post-graduate research qualification. 5. To update section 5(d) to use a form of wording such as "*it is hoped* …", rather than "*it will*…". 6. To provide an explanation in section 5 as to why the applicant has requested Welsh data (presumably for patients residing in Wales admitted to a study hospital in England), noting that there are no Welsh hospital involved. 7. To update section 5 to include a reference range of the arterial pressures. The following advice was given: 1. IGARD suggested that any future update to the PIS should be updated to clearly explain that they have support for the flow of data, where NDOs have been applied, via HRA CAG.
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. Due to the volume and complexity of applications at today's meeting, IGARD were unable to review any Data Access Request Service (DARS) applications as part of their oversight and assurance role. IGARD noted that they had requested, but had not as yet been provided with, an Information Governance (IG) COVID-19 release register suite of documents on a particular data release for review by IGARD as part of their oversight and assurance, and as agreed in June 2020 with the Executive Director Privacy, Transparency and Ethics (PTE) when it had been agreed that IGARD review an agreed number per month, by way of a review of all documentation revised by PTE, and as part of continuous improvement and quality.

6	COVID-19 update To support NHS Digital's response to COVID-19, from Tuesday 21st April 2020, IGARD will hold a separate weekly meeting, to discuss COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 urgent applications that have been submitted to NHS Digital. Although this is separate to the Thursday IGARD meetings, to ensure transparency of process, a meeting summary of the Tuesday meeting will be captured as part of IGARD's minutes each Thursday and published via the NHS Digital website as per usual process. IGARD noted that at the request of DARS, and as agreed between IGARD and NHS Digital, the COVID-19 response meeting on Tuesday, 12th October 2021 was cancelled.
7 **7.1**	AOB: Data Access Request Service (DARS) Processes (Presenter: Dave Cronin) IGARD were provided with a verbal update in respect of ongoing internal changes within Data Access Request Service (DARS), including (but not limited to), the roles and responsibilities of senior DARS colleagues and the process for reviewing and progressing applications to IGARD business as usual (BAU) meetings. IGARD were advised that this was an ongoing project of work, and that IGARD would be updated as this progressed. IGARD noted the verbal update, and thanked NHS Digital for the updated information, and looked forward to additional information being presented in due course. 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 08/10/21

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-407274-Q4N0X-v2.4	NHS East Leicestershire and Rutland CCG	19/08/2021	1. In respect of the PAG review: a) To prove written evidence of PAG support from the meeting on the 25th August 2021 (as per the verbal update from NHS Digital). b) To upload the written PAG support to NHS Digital's CRM system for future reference.	IGARD members	Quorum of IGARD members	**Condition 1(a)** – NHS Digital to confirm that DARS will notify PAG about the 6-week timeframe. **Condition 1(b) –** To confirm the PAG support has been uploaded to CRM. **Amendment 1 – "***All existing GDPPR templates use the existing wording. This is due to NHS Digital's current position on pseudonymised GDPPR data requiring to be treated as confidential. Discussions are currently ongoing (as per advice) and therefore until resolved all GDPPR applications need to maintain consistent wording.*" **IGARD were unaware that NHS Digital's position is that pseudonymised GDPPR data requires being treated as confidential.**

						Could we please have clarification on this point?
NIC-55752-D6X5Y-v9	NHS Herts Valley CCG	15/07/2021	1. To update section 5(c) to remove references to the application permitting *"reidentification for direct care"* as not relevant OR add justification of how this is necessary if there are incidental findings from carrying out commissioning. 2. In respect of the yielded benefits: a) To provide a satisfactory update to the yielded benefits in section 5(d) (iii) to ensure they comply with NHS Digital's DARS Standard for Expected Measurable Benefits; or, b) To update section 5(d) (iii) with a clear explanation as to why there are currently no yielded benefits. 3. To provide written confirmation within section 5(a) as to how the Social Prescribing Data will be handled, including the free text field.	IGARD members	Quorum of IGARD members	In respect of condition 2a: IGARD requested that further information and evidence was provided on the updates to the yielded benefits.
NIC-422971-B8P2V	Imperial College London	29/07/2021	1. In respect of the data controllership and in line with NHS Digital's DARS Standard for Data Controllers: a) To clarify which legal entities should be considered a Data Controller, as borne out of the facts presented with particular reference to NHS Improvement (Monitor and NHS TDA), noting that the Head of Screening confirmed in an email that "NHSEI" are to be joint data controllers. b) To update the application and any relevant supporting documents with a clear justification.	IGARD members	Quorum of IGARD members	The application abstract should be updated with the PAG addendum.

NIC-394285-D0L6M	Suffolk County Council	01/07/2021	1. To provide a clear justification in section 5(a) of what Suffolk County Council will be doing with the GDPPR data, beyond what the relevant CCG(s) are already doing; or how they are working in collaboration with the relevant CCG(s) to deliver the objectives outlined.	IGARD Chair and 1 IGARD Specialist member	OOC by the IGARD Chair and IGARD Specialist member	Members were content that this condition has been met if the reference to "Public Health" could be explained throughout that it (presumably??) is a division of the Suffolk County Council. That would then make clear what the Council is doing, separate from the CCG. eg "Public Health do not currently have access to line level vaccination data, or vaccination data linked to GPs"

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