Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 13 January 2022

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member
Kirsty Irvine	IGARD Chair
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Chair
IGARD MEMBERS NOT IN ATTENDANCE:	
Prof. Nicola Fear	Specialist Academic Member
Dr. Maurice Smith	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Vicky Byrne-Watts	Data Access Request Service (DARS) (Observer: items 3.1 – 3.7)
Dave Cronin	Data Access Request Service (DARS) (Observer: items 3.1 – 3.2)
Faris Dean	Data Access Request Service (DARS) (SAT Observer: item 3.7)
Louise Dunn	Data Access Request Service (DARS) (Item 3.3) (SAT Observer: items 3.1 – 3.2)
Duncan Easton	Data Access Request Service (DARS) (SAT Observer: item 3.6)
Dan Goodwin	Data Access Request Service (DARS) (items 3.5 – 3.7)
James Gray	DigiTrials (Item 3.1)
Karen Myers	IGARD Secretariat
Dr. Jonathan Osborn	Deputy Caldicott Guardian (Observer: 3.1)
Frances Perry	DigiTrials (Item 3.2)
Denise Pine	Data Access Request Service (DARS) (Item 3.4)
Andy Rees	DigiTrials (Item 3.1)
Kimberley Watson	Data Access Request Service (DARS) (SAT Observer: Items 3.3 – 3.5)

Vicki Williams	IGARD Secretariat
SAT – Senior Approval Team (DARS)	

1	**Declaration of interests:** Paul Affleck noted professional links to AIMES Management Service (NIC-604847-S4B5L) National Institute for Health Research (NIHR)) but no specific connection with the application or staff involved and it was agreed that there was no conflict of interest. Dr. Imran Khan noted a professional link to the North of England Commissioning Support Unit (NIC-423341-T5F3T), but no specific connection with the application or staff involved and it was agreed this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 16th December 2021 IGARD meeting were reviewed out of committee by IGARD following conclusion of the meeting, and subject to a number of minor changes were agreed as an accurate record of the meeting. **Out of committee recommendations:** An out of committee report was received (see Appendix A).
2	**Briefing Notes**
2.1	ICNARC Case Mix Programme for Adult Critical Care data set – Briefing Paper (No Presenter) The briefing paper was to inform IGARD about the ICNARC Case Mix Programme (CMP) for Adult Critical Care data set, which will be made available via NHS Digital's Trusted Research Environment (TRE), and extract, for COVID-19 purposes only. IGARD noted that this briefing paper had previously been presented at the IGARD business as usual (BAU) meeting on the 12th August 2021, where they had made a number of high-level comments; and that the updated briefing paper had been submitted to IGARD for information only. IGARD thanked NHS Digital for providing a copy of the updated briefing paper as per process and confirmed that they had no further comments.
3	**Data Applications**
3.1	GRAIL Bio UK Ltd: GRAIL's NHS Galleri Clinical Trial Outcomes Data Request (Presenter: James Gray / Andy Rees) NIC-604847-S4B5L-v0.4 **Application:** This was a new application for pseudonymised Cancer Registration Data, Cancer Waiting Times (CWT) Data Set, Diagnostic Imaging Dataset (DID), Emergency Care Data Set (ECDS), Hospital Episode Statistics Admitted Patient Care (HES APC), HES Outpatients, Radiotherapy Data Set, Rapid Cancer Registrations Data Set and Systemic Anti-Cancer Therapy Dataset (SACT). This application was presented at the IGARD business as usual (BAU) on the 16th December 2021, however, following this meeting, there were high-level discussions between NHS Digital

	and GRAIL Bio UK Ltd; and as a result the application was returning to IGARD for the purpose of extending the Data Sharing Agreement from a one-year agreement to three years. The purpose is to carry out follow-up analysis based on a cohort of patients who are being recruited to a clinical trial called 'NHS-Galleri'. A new Multi-Cancer Early Detection (MCED) test has been developed for use with a single sample of blood. The purpose of the NHS-Galleri study is to test the clinical utility of the MCED blood test in a general screening population in a real-world NHS setting. The rationale behind this trial is that MCED is a novel screening paradigm, and assessment of the use and impact of test results is necessary to enable integration into clinical practice. This will be the first randomised, double blind controlled trial statistically powered to assess clinical utility of a MCED test. Recruitment to the trial is being undertaken via a separate Data Sharing Agreement (DSA) NIC-456778-J0G3H and is taking place over a period of 10-12 months from August 2021 with the aim of consenting 140,000 participants. NHS Digital advised IGARD that work was currently ongoing to update the relevant NHS Digital DARS Standard(s) to permit commercial entities to hold and process NHS Digital data for a period of three years (currently one year), where there was clear and informed participant consent. NHS Digital noted that the draft revised Standard(s) had not yet been shared with IGARD members, or other key internal stakeholders, for comments, however, confirmed that this would be done in the near future as per process. NHS Digital also noted that the amendment request to extend the DSA to three years was supported by both the NHS Digital Chief Executive and the NHS England Chair. NHS Digital noted that the Global Transfer Assessment for the transfer of pseudonymised record-level data to the United States of America (previously with Privacy, Transparency & Ethics (PTE) when the application was reviewed by IGARD on the 16th December 2021) had been received by the Digi-Trials team and was due to be discussed internally the following day (14th January 2021). IGARD noted that they had not received a copy of this document. **Discussion:** IGARD noted that NHS Digital had provided a verbal update in respect of this application at the IGARD business as usual (BAU) meeting on the 25th November 2021; and that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 16th December 2021. IGARD noted the verbal update from NHS Digital in respect of the update to the relevant NHS Digital DARS Standard(s), to permit commercial entities to hold and process data for a period of three years; and the acknowledgement that the updated draft Standard(s) had not been shared with IGARD or other internal stakeholders as per process. IGARD noted that whilst they were certainly supportive in principle of longer DSAs, in the appropriate circumstances, to allow commercial entities to hold and process data, they would be unable to recommend approval for this specific application until such time the NHS Digital DARS Standard(s) had been through the correct and agreed process, updated and published transparently on the NHS Digital website. Separate to this application, IGARD suggested that NHS Digital update the relevant NHS Digital DARS Standards to reflect a three-year DSA for commercial organisations; that they include information on their website with regard to the changes to the relevant NHS Digital DARS Standards; that they may wish to proactively write to other commercial organisations with regard to the proposed change to the NHS Digital DARS Standard(s) since it may be of interest to them; and for NHS to provide IGARD with a copy of the pro forma draft annual

	report that commercial organisations would have to provide under the proposed change to the NHS Digital DARS standard(s). IGARD noted the verbal update from NHS Digital in respect of the outstanding Global Transfer Assessment; and that a response had been received from NHS Digital's PTE and would be discussed internally the following day. However, as discussed at the 16th December 2021 BAU meeting of IGARD, IGARD reiterated their request that written confirmation was provided from PTE, that the appropriate Global Transfer Assessment documentation had been approved and was in place; and that a copy be uploaded to NHS Digital's customer relationship management (CRM) as a future supporting document. IGARD reiterated their previous point of advice from the 16th December 2021, that there was a mismatch between the various transparency materials in terms of how long the data would be held for, and suggested that the published privacy notice, which currently stated that the data may be held indefinitely, was updated, to align with the consent materials. IGARD also reiterated their request, that had been raised consistently throughout 2021, that NHS Digital ensured that **all** of their public facing transparency materials were updated to reflect which datasets may be used worldwide, for example, Radiotherapy data which still stated that it can only be used within the UK. NHS Digital advised IGARD that in addition to the specific benefits outlined in section 5(d) (Benefits), if successful, the study would enable the NHS to have early access to the MCED tests, at a competitive price that would benefit UK citizens. IGARD noted the verbal update from NHS Digital and asked that for transparency, this important and helpful information be added to section 5(a) (Objective for Processing) and section 5(e) (Is the Purpose of this Application in Anyway Commercial), with a relevant weblink to further details, if available. IGARD queried the funding arrangements for the study, in light of the information within supporting document 2.0, the patient information sheet (version 3.), that stated GRAIL Bio UK Ltd would be the *"main"* funder; and asked that section 8(b) (Funding Sources) was updated to outline who the funder(s) of this study are, and to provide an indicative proportion contributed by each funder. In addition, IGARD asked that any pertinent funding documentation was uploaded to NHS Digital's CRM system for future reference. IGARD noted the useful information in section 5(e) in relation to marginalised groups, for example, in relation to *"…equity of access…"*; and asked that this was replicated in section 5(a) for transparency. IGARD advised that this application would be suitable for NHS Digital's Precedent route if all qualifying DARS Standards are met. **Outcome:** unable to recommend for approval for a three-year DSA, until such time the NHS Digital DARS Standard(s) has been updated. **Outcome:** recommendation to approve subject to the following condition for one year 1. In relation to the Global Transfer Assessment: a) To provide written confirmation from NHS Digital's PTE that the appropriate Global Transfer Assessment documentation has been approved and in place. b) To upload the written confirmation to NHS Digital's CRM system. The following amendments were requested: 1. To amend section 5(a) and section 5(e) to include information with regard to the NHS being able to have early access to the MCED tests, at a competitive price that would benefit UK citizens; including a relevant weblink to further details, if available.

	2. To replicate in section 5(a) the useful narrative in section 5(e) with regards to marginalised groups. 3. In respect of the funding: a) To update section 8(b) to outline who the funder(s) of this study are. b) To provide an indicative proportion contributed by each funder. c) To upload any pertinent funding documentation to NHS Digital's CRM system for future reference. The following advice was given: 1. IGARD reiterated their previous point of advice (December 2021) that there was a mismatch between the various transparency materials in terms of how long the data will be held for, and suggested that the published privacy notice, which currently states that the data may be held indefinitely, is updated, to align with the consent materials. 2. IGARD reiterated their request (raised consistently throughout 2021) that NHS Digital ensured that all of their public facing transparency materials are updated to reflect which datasets may be used worldwide (for example, Radiotherapy data which still states it can only be used within the UK). 3. IGARD advised that this application would be suitable for NHS Digital's Precedent route if all qualifying DARS Standards are met. 4. Separate to this application, IGARD suggested that NHS Digital may wish to update their relevant NHS Digital DARS Standards to reflect a three-year DSA for commercial organisations; that they include information on their website with regards to the changes to the relevant NHS Digital DARS Standards, that they may wish to proactively write to other commercial organisations to the proposed change to the NHS Digital DARS Standards since it may be of interest to them; and for NHS to provide IGARD with a copy of the pro forma draft annual report that commercial organisations would have to provide under this proposed change. **Significant Risk Area:** NHS Digital's UK GDPR transparency information on its website is inaccurate as to the territory of use for a number of datasets (see Advice point 2 above). It was agreed the condition would be approved out of committee (OOC) by the IGARD Chair.
3.2	<u>GRAIL Bio UK Ltd: GRAIL's SYMPLIFY Study Clinical Trial Outcomes Data Request (Presenter: Frances Perry) NIC-604851-W0M3S-v0.4</u> **Application:** This was a new application for Cancer Registration Data, Cancer Waiting Times (CWT) Data Set, Diagnostic Imaging Dataset (DIDs), Emergency Care Data Set (ECDS), Hospital Episode Statistics Admitted Patient Care (HES APC), HES Outpatients and Rapid Cancer Registrations Data Set. The purpose of the application, is to request access to pseudonymised record level data, linked against a cohort of individually consented patients recruited to the 'SYMPLIFY', a study designed to assess GRAIL's Galleri multi-cancer early detection (MCED) test in individuals referred with signs and symptoms of cancer. The Primary objective of the study is to evaluate the performance of GRAIL's *"GALLERI"* MCED test for the detection of invasive cancer. The Secondary objectives of the study are to evaluate the: performance and yield of the MCED test by referral pathway (i.e. lung, upper Gastrointestinal (GI), lower GI, gynae, and Rapid Diagnostic Centres (RDC)) and cancer type and stage; and performance of the MCED test for the identification of cancer signal origin (CSO) by referral pathway.

	The data requested will be linked to a cohort of approximately 6,240 consented individuals. NHS Digital advised IGARD that work was currently ongoing to update the relevant NHS Digital DARS Standard(s) to permit commercial entities to hold and process NHS Digital data for a period of three years (currently one year), where there was clear and informed consent to add the additional years. NHS Digital noted that the draft revised Standard(s) had not yet been shared with IGARD members or other key internal stakeholders for comments, however, confirmed that this would be done in the near future as per process. NHS Digital also noted that the amendment request to extend the DSA to three years was supported by both the NHS Digital Chief Executive and the NHS England Chair. NHS Digital noted that the Global Transfer Assessment for the transfer of pseudonymised record-level data to the United States of America, that was previously with Privacy, Transparency & Ethics (PTE) when NIC-604847-S4B5L GRAIL Bio UK Ltd application (item 3.1) was reviewed by IGARD on the 16th December 2021, was also relevant to this application; and confirmed that written confirmation had been received from PTE and was due to be discussed internally the following day (14th January 2021). **Discussion:** IGARD noted that NHS Digital had provided a verbal update in respect of this application at the IGARD business as usual (BAU) meeting on the 25th November 2021. IGARD 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 did however note that the in respect of the data controllership arrangements, the information in the application did not align with the consent materials, for example, the application stated that GRAIL Bio UK Ltd and the University of Oxford were joint Data Controllers, and the consent materials state that the University of Oxford were the sole Data Controller. NHS Digital confirmed that there were different Data Controller roles for the University of Oxford and Bio UK Ltd depending on the stage of the study, however confirmed that the application was correct in that both were joint Data Controllers. NHS Digital noted and thanked NHS Digital for the verbal update, and suggested that the cohort were updated, for example, via a published privacy notice / newsletter. IGARD noted the verbal update from NHS Digital in respect of the update to the relevant NHS Digital DARS Standard(s), to permit commercial entities to hold and process data for a period of three years; and the acknowledgement that the updated draft Standard(s) had not been shared with IGARD or other internal stakeholders as per process. IGARD noted that whilst they were supportive in principle of longer DSAs, in the correct circumstances, to allow commercial entities to hold and process data, they would be unable to recommend for approval for this specific application, until such time the NHS Digital DARS Standard(s) had been through the correct and agreed process, updated and published on the NHS Digital website. Separate to this application, IGARD suggested that NHS Digital update their relevant NHS Digital DARS Standards to reflect a three-year DSA for commercial organisations; that they include information on their website with regards to the changes to the relevant NHS Digital DARS Standards; that they may wish to proactively write to other commercial organisations with regard to the proposed change to the NHS Digital DARS Standard(s) since it may be of interest to them; and for NHS to provide IGARD with a copy of the pro forma draft annual report that commercial organisations would have to provide under the proposed change to the NHS Digital DARS Standard(s).

	IGARD noted the verbal update from NHS Digital in respect of the outstanding Global Transfer Assessment; and that a response had been received from NHS Digital's PTE and would be discussed internally the following day. However, as discussed at the 16th December BAU meeting of IGARD, IGARD reiterated their request that written confirmation was provided from PTE, that the appropriate Global Transfer Assessment documentation had been approved and was in place; and that a copy be uploaded to NHS Digital's customer relationship management (CRM) as a future supporting document. IGARD reiterated their point of advice from the 16th December 2021 for NIC-604847-S4B5L, that there was a mismatch between the various transparency materials in terms of how long the data would be held for, and suggested that the published privacy notice, which currently stated that the data may be held indefinitely, was updated, to align with the consent materials. IGARD also reiterated their request, that had been raised consistently throughout 2021, that NHS Digital ensured that **all** of their public facing transparency materials were updated to reflect which datasets may be used worldwide, for example, the Rapid Cancer Registrations Data Set which still stated that it can only be used within the UK. IGARD advised that NHS Digital draw the applicant's attention to the contractual obligation in section 4 (Privacy Notice), in respect of maintaining a UK GDPR compliant, publicly accessible transparency notice throughout the life of this agreement, in order to maintain public trust in using health data from national datasets; and in line with NHS Digital's DARS Standard for Transparency (fair processing). IGARD noted the update provided for NIC-604847-S4B5L by NHS Digital, that in addition to the specific benefits outlined in section 5(d) (Benefits), if successful, the study would enable the NHS to have early access to the MCED tests, at a competitive price that would benefit UK citizens; and asked that for transparency, this important information be added to section 5(a) (Objective for Processing) and section 5(e) (Is the Purpose of this Application in Anyway Commercial), with a relevant weblink to further details, if available. IGARD noted the useful information in section 5(e) in NIC-604847-S4B5L, in relation to marginalised groups, for example, in relation to *"…equity of access…"*; and asked that this was replicated in section 5(a) of this application for transparency. IGARD advised that this application would be suitable for NHS Digital's Precedent route if all qualifying DARS Standards are met. **Outcome:** unable to recommend for approval for a 3-year DSA, until such time the NHS Digital DARS Standard(s) has been updated. **Outcome:** recommendation to approve subject to the following condition for 1-year 1. In relation to the Global Transfer Assessment: a) To provide written confirmation from NHS Digital's PTE that the appropriate Global Transfer Assessment documentation has been approved and in place. b) To upload the written confirmation to NHS Digital's CRM system. The following amendments were requested: 1. To amend section 5(a) and section 5(e) to include information with regard to the NHS being able to have early access to the MCED tests, at a competitive price that would benefit UK citizens; including a relevant weblink to further details, if available. 2. To include in section 5(a) and section 5(e) the useful narrative with regards to marginalised groups as outlined in NIC-604847-S4B5L. 3. In respect of section 3(b):

	a) To update section 3(b) to ensure the data production aligns with the years of data and the consent taken. b) To populate the *"identifiability"* column in section 3(b). The following advice was given: 1. IGARD reiterated their request (raised consistently throughout 2021) that NHS Digital ensured that all of their public facing transparency materials are updated to reflect which datasets may be used worldwide (for example, the Rapid Cancer Registration Data Set which still states it can only be used within the UK). 2. IGARD advised that NHS Digital draw the applicant's attention to the contractual obligation in section 4, in respect of maintaining a UK GDPR compliant, publicly accessible transparency notice throughout the life of this agreement. IGARD also advised that the publicly accessible transparency notice should reflect the correct joint data controllership arrangements. 3. IGARD suggested that in the next iteration of the newsletter, the applicant should consider updating participants on the joint data controllership arrangements. 4. IGARD advised that this application would be suitable for NHS Digital's Precedent route if all qualifying DARS Standards are met. 5. Separate to this application, IGARD suggested that NHS Digital may wish to update their relevant NHS Digital DARS Standards to reflect a three-year DSA for commercial organisations; that they include information on their website with regards to the changes to the relevant NHS Digital DARS Standards, that they may wish to proactively write to other commercial organisations to the proposed change to the NHS Digital DARS Standards since it may be of interest to them; and for NHS to provide IGARD with a copy of the pro forma draft annual report that commercial organisations would have to provide under this proposed change. **Significant Risk Area:** NHS Digital's UK GDPR transparency information on its website is inaccurate as to the territory of use for a number of datasets (see Advice point 1 above). It was agreed the condition would be approved out of committee (OOC) by the IGARD Chair. **Subsequent to the meeting:** IGARD noted the statement in section 1 of the application *"The cohort is linked to secondary data sources including…RTDS Radiotherapy and SACT Chemotherapy"*; and noting that these datasets were not included within section 3(b) of the application, suggested that should these datasets need adding to the Data Sharing Agreement, this application should return to IGARD as an 'amendment' as per process.
3.3	<u>AstraZeneca UK Limited: Real-world effectiveness and safety of the Oxford/AstraZeneca covid-19 vaccine ***and investigation of the epidemiology of thrombotic thrombocytopenia and other adverse events of interest following COVID-19 vaccination*** in England: ORCHID linkage (Presenter: Louise Dunn) NIC-459114-J3C1F-v1.4</u> **Application:** This was a renewal and amendment application to **1)** extend the expiry date to the 12th January 2023; **2)** to add a second and third Purpose to the use of the data; **3)** to add non-sensitive pseudo fields to the Hospital Episode Statistics (HES) and Vaccination data; **4)** the addition of the following datasets: Emergency Care Data Set (ECDS) (April 2019 to latest available), Secondary Uses Service Payment By Results Spells (SUS PbR) (April 2019 to latest available), SUS PbR Episodes (April 2019 to latest available), COVID-19 Vaccination Adverse Reactions (December 2020 to latest available), HES Outpatients (April 2019 to latest

	available) and HES Accident and Emergency (Annual Refresh for 2019/20 only) (plus HES: Deaths Bridging file); 5) a request for five further bi-monthly drops of data. The datasets will be linked to a cohort and used to develop analysis code and algorithms prior to being deployed in the national level data within the NHS Digital Trusted Research Environment (TRE) under Data Sharing Agreement (DSA) NIC-445543-W0D4N. The primary objective of this study is to assess the real-world effectiveness of the Oxford/AstraZeneca COVID-19 vaccine among people who receive one dose of the vaccine, overall and by age group and time period after 1 dose. The secondary objectives of the study are to: a) assess the vaccine effectiveness in people who have received the two doses; the timing after the 1st and 2nd dose, interval between the two doses and comorbidity status b) replicate the above analyses in people receiving the Pfizer COVID-19 vaccine. The new / additional purposes (amendment point 2) are to **1)** Estimate occurrence of thrombotic thrombocytopenia, thromboembolism, and thrombocytopenia; and **2)** additional analyses in light of the rapidly changing nature of the COVID-19 pandemic. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 1st July 2021. IGARD noted that this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 25th May, 15th June and 22nd June 2021. IGARD noted that there was a linked TRE DSA (NIC-445543-W0D4N) and suggested that this was updated and aligned, where relevant, with this application as soon as possible. IGARD noted that section 5 (Purpose / Methods / Outputs) stated *"…the analyses will consider all individuals 16 years and over…"*, and queried why the primary interest was specifically on those aged 16 years and above, given the current wide age range of recipients of the vaccines, which included those under the age of 16; and asked that a further explanation was provided in section 5 for transparency. IGARD also reiterated the advice given at the IGARD BAU meeting on the 1st July 2021, that that the revised protocol still does not refer to research into the vaccination of under 16s, it only establishes the use of under 16s data for the household transmission research. IGARD suggested that the protocol was revised further, to explicitly cover the use of the data for research into vaccinations carried out to date in under 16s. Accordingly, there was a risk that the household transmission research into under 16 vaccination was not in line with a protocol with ethical support. IGARD queried why significant data fields had been excluded from the study, for example, maternity and mental health; and noting that the reason for this had not been made clear within the application, asked that a justification was provided in section 3(b) (Additional Data Access Requested) and section 5 (Purpose / Methods / Outputs). In addition, IGARD noted that as per the advice provided at the IGARD BAU meeting on the 1st July 2021, a Data Protection Impact Assessment (DPIA) had been completed, but suggested that this was also updated to outline the rationale for excluding both mental health and maternity data, and the risk(s) associated with such exclusions, for example it was a known fact of complications during pregnancy for those women who remained unvaccinated. 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 if in accordance with the latest advice from the Privacy, Transparency and Ethics (PTE) Directorate. IGARD noted in section 5(a) (Objective for Processing) that data would be acquired through the COVID-19 Genomics UK Consortium (COG-UK), and queried if this would provide details of variants, and asked that section 5 was updated with confirmation; or, if this was not the same, asked that a further explanation was provided on what data they were receiving and how it was used. IGARD noted the other datasets that were held by the Data Controllers, and asked that for clarity, section 5 was amended, to be clear that they would not be linked to NHS Digital data, or used in this research. IGARD queried the statements in section 5(a) and section 5(e) (Is the Purpose of this Application in Anyway Commercial) *"The studies are not conducted with the intention of generating profit"*, and, noting that this no longer accurate, asked that the statements were removed. IGARD noted that the application was not clear as to the new purpose of analysing healthcare costs, and asked that, for transparency, section 5(a) and section 5(d) (Benefits) were updated with a further explanation, and in line with NHS Digital's DARS Standard for Objective for Processing and NHS Digital DARS Standard for Expected Measurable Benefits. IGARD noted that the language and definitions used within the application, were no longer correct, for example, the statement *"…the introduction of booster vaccines in late 2021 for groups most as risk of the disease…"* and the reference to *"long COVID-19"*, which needed updating in line with the National Institute of Health and Clinical Excellence (NICE) guidelines; and asked that the application was reviewed throughout, to ensure that the language and definitions used match the current position. IGARD noted the references to *"gender"* in section 5(a); and asked that this was updated to refer to *"sex"* rather than "*gender*" as the former is what will be disseminated, and they were not interchangeable data fields. IGARD queried the statement in section 5(a) *"This project requires only pseudonymised data and* ***no identifiable or "high risk" variable****."*; and asked that further information was provided on this, as it was currently unclear. **Outcome:** recommendation to approve The following amendments were requested: 1 To provide an explanation in section 5 as to why there is a primary interest in those aged 16 and above, given the current wide age range of recipients of vaccines. 2 To remove the statement in section 5(a) and section 5(e): *"The studies are not conducted with the intention of generating profit"*. 3 To explain why the new purpose of analysing healthcare costs has been added, in section 5(a) and section 5(d). 4 To update section 3 to include a UK GDPR legal basis for those datasets that give information about cohort members who are still living, if this accords with the latest advice from PTE. 5 To confirm in section 5 if the COG-UK data is providing details of variants, or, if this is not the case, to explain what data they are receiving and how it is used. 6 To provide a justification in section 3(b) and section 5 as to why significant exclusions in the data fields have been made, for example, maternity and mental health.

	7 To amend section 5 to be clear that other datasets held by the Data Controllers will not be linked to NHS Digital data or used in this research. 8 To update section 5(a) to refer to *"sex"* rather than "*gender*" as the former is what will be disseminated, and they are not interchangeable data fields. 9 To review the entire application to ensure that the language and definitions used match the current position, for example, defining the booster doses, defining long COVID-19 as per the NICE guidelines. 10 To provide further information on the reference in section 5(a) to *"…no identifiable or "high risk" variable"*. The following advice was given: 1 IGARD suggested that the linked TRE application (NIC-445543-W0D4N) is updated and aligned (where relevant) with this application as soon as possible. 2 IGARD noted that a DPIA had been completed, but suggested that this was updated to outline the rationale for excluding both mental health and maternity data, and the risk associated with such exclusions. 3 IGARD noted that the revised protocol still does not refer to research into the vaccination of under 16s (it only establishes the use of under 16s data for the household transmission research). IGARD suggested that the protocol is revised further, to explicitly cover the use of the data for research into vaccinations carried out to date in under 16s. Accordingly, there is a risk that the household transmission research into under 16 vaccination is not in line with a protocol with ethical support. **Significant Risk Area:** the exclusion of mental health and maternity data from the research.
3.4	University of Birmingham: MR785 - PD MED Trial- A randomised assessment of the cost effectiveness of different classes of drugs for Parkinson's Disease (Presenter: Denise Pine) NIC-147927-8K193-v5.4 **Application:** This was an amendment application to add the latest available Cancer Registration data and Civil Registration (Deaths) data to the existing Data Sharing Agreement (DSA). Parkinson's Disease Medicines (PD MED) is a randomised, pragmatic, open label trial that is one of the largest (1,896 UK patients) and longest running trials (20 years) around the world. Its purpose is to compare the long-term cost-effectiveness of four different classes of PD medicines, which are currently prescribed to improve Early (newly or less than 6 months diagnosis) and Later (has PD diagnosis plus motor complications unresponsive to LD dosing changes or timings) patients' Parkinsonian symptoms. The medications being assessed are levodopa (LD), dopamine agonists (DA), monoamine oxidase type B inhibitors (MAOBI) and catechol-O-methyltransferase inhibitors (COMTI). The purpose of the application is to allow researchers to complete their time to event analyses as part of the PD MED clinical trial. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 26th September 2019; and the 21st January 2021. It was also discussed as part of oversight and assurance at the IGARD BAU meeting on the 13th May 2021. IGARD noted that the application specifically made reference to the cost effectiveness of the drug being studied, however the study protocol referred to both the cost effectiveness **and** the efficacy of the drug; and asked that section 5 (Purpose / Methods / Outputs) was updated throughout to ensure that this was reflected in the purpose and benefits and in-line with NHS

	Digital's DARS Standard for Expected Outcomes and NHS Digital's DARS Standard for Expected Measurable Benefits. In addition, IGARD asked that section 5 was updated to make clear, that patients were benefitting from the fact that the drug was more effective, and not just because it was more cost-effective. In addition, IGARD asked that the yielded benefits were updated to reflect that the drug was the most cost effective **and** most beneficial to patients; and in-line with NHS Digital DARS Standard for Expected Measurable Benefits. IGARD queried the potentially misleading statement in section 5(d) (Benefits) *"The results of these analyses are expected to benefit Parkinson's disease patients because it is possible that one of these classes of medicines can delay dementia…"*; and asked that this was updated to remove suggestion that all individuals with Parkinson's will go on to develop dementia, for example, noting that 30 per cent of patients will not develop dementia. IGARD noted that the information provided in section 5(a) (Objective for Processing) in relation to the University of Birmingham's Steering Committee was not correct, for example, the reference to *"Radcliffe Infirmary in Oxford"*, which closed in 2007; and asked that this was updated with the latest and most accurate information; or if no longer relevant, asked that it was removed. IGARD suggested that the application was updated with additional information in respect of any patient and public involvement and engagement (PPIE) activities, including, but not limited to, how they are keeping in touch with the cohort and updating participants. IGARD drew the applicant's attention to their obligations under the UK General Data protection Regulation (UK GDPR) in maintaining appropriate transparency for cohort members. IGARD noted the statement in section 5(a) *"**Should the results of this analysis be significant…**"*, and asked that this was removed, and instead updated to note that all results have been, and will be, provided to NICE. IGARD queried some of the language used in section 5(d), for example, when referring to the *"institutionalisation"* of patients; and asked that this was revised as appropriate, and that further sensitive consideration was given to the patient audience and how this type of language could be perceived. In addition, IGARD also noted the reference to *"onset of death"* in section 5(d); and asked that be revised and replaced with an alternate form of wording, for example *"extending the years of good health"* or similar. IGARD advised that NHS Digital draw the applicant's attention to the contractual obligation in section 4 (Privacy Notice), in respect of maintaining a UK GDPR compliant, publicly accessible transparency notice throughout the life of this agreement, in order to maintain public trust in using health data from national datasets; and in line with NHS Digital's DARS Standard for Transparency (fair processing). **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 5 throughout to ensure that the purpose and benefits reflect both the cost effectiveness **and** the efficacy of the drug, as outlined in the study protocol. 2. To update section 5 to make clear that patients are benefitting from the fact the drug is more effective (and not just because it is a more cost-effective drug). 3. To update section 5(d) (iii) to reflect that the drug was the most cost effective **and** beneficial to patients.

	4. To update the reference to the steering committee in section 5(a) to provide the latest information; or remove if no longer relevant. 5. To update section 5(d) to remove suggestion that all individuals with Parkinson's will go on to develop dementia, for example, noting that 30 per cent will not. 6. In respect of the language used: a) To revise the references to *"institutionalisation"* in section 5(d). b) To revise the reference to *"onset of death"* in section 5(d) and replace with an alternate form of wording, for example *"extending the years of good health"* or similar. 7. To remove the statement in section 5(a) ***"Should the results of this analysis be significant…"***. and instead note that all results have been, and will be, provided to NICE. The following advice was given: 1. IGARD suggested that the application was updated with additional information in respect of any PPIE activities, including (but not limited to) how they are keeping in touch with the cohort, updating participants. IGARD drew the applicant's attention to their obligations under UK GDPR in maintaining appropriate transparency for cohort members. 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 to the statement in section 4, that a UK GDPR compliant, publicly accessible transparency notice is maintained throughout the life of the agreement.
3.5	East Midlands Cancer Alliance: Cancer Alliance access to National Cancer Waiting Times Monitoring Data Set (NCWTMDS) from the Cancer Wait Times (CWT) System (Presenter: Dan Goodwin) NIC-204535-L4S1P-v2.5 **Application:** This was a renewal and extension application, to permit the holding and processing of pseudonymised National Cancer Waiting Times Monitoring DataSet (NCWTMDS). It was also an amendment to **1)** remove Nottingham University Hospital NHS Trust as a Data Controller; **2)** the addition of Nottingham University Hospital NHS Trust as a Data Processor; **3)** the addition of West Midlands Cancer Alliance as one of the Cancer Alliances NHS England represents as the legal entity and Data Controller (noted as *"West Midlands Cancer Alliance & East Midlands Cancer Alliance"* under this Data Sharing Agreement (DSA)). The independent Cancer Taskforce set out an ambitious vision for improving services, care and outcomes for everyone with Cancer: fewer people getting Cancer, more people surviving Cancer, more people having a good experience of their treatment and care, whoever they are and wherever they live, and more people being supported to live as well as possible after treatment has finished. Cancer Alliances, which have been set up across England, are key to driving the change needed across the country to achieve the Taskforces vision. Bringing together local clinical and managerial leaders from providers and commissioners who represent the whole Cancer pathway, Cancer Alliances provide the opportunity for a different way of working to improve and transform Cancer services. Cancer Alliance partners will take a whole population, whole pathway approach to improving outcomes across their geographical footprints building on their relevant Sustainability and Transformation Plans (STPs).

	Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 6th December 2018. It was also discussed as part of oversight and assurance at the IGARD BAU meeting on the 19th March 2020. IGARD noted the statement in section 5 (Purpose / Methods / Outputs) *"…outputs may be shared with national/regional bodies including NHS Improvement and NHS England."*; and noting that NHS England were the Data Controller, asked that the references were removed as they were no longer relevant. IGARD noted the incorrect references in section 1 (Abstract) and section 5, to staff being *"substantially employed"* and asked that these references were updated to correctly state they were "*substantively employed".* IGARD queried the statement in section 5(a) (Objective for Processing) *"iView Plus uses **cube functionality**…"*; and asked that for transparency, further information was provided, as it was currently unclear what was meant by *"cube functionality"*; and in line with NHS Digital DARS Standard for Objective for Processing. IGARD also queried the statement in section 5(a) *"…the aggregation categories are such that the data is not at a **lesser granular level**…"*, and asked that for transparency, further information was provided; and in line with NHS Digital DARS Standard for Objective for Processing. To provide further details in section 5(d) (Benefits) (iii) (Yielded Benefits) of the yielded benefits accrued to date, for example, what has the Cancer Alliance achieved with the data which has impacted the community covered by the flow of data; and in line with NHS Digital's DARS Standard for Expected Measurable Benefits. IGARD advised that this application would be suitable for NHS Digital's Precedent route if all qualifying NHS Digital's DARS Standards are met. Separate to this application, IGARD suggested that any other Cancer Alliance which was switching data controllership to NHS England would be suitable for the precedent route, if all other aspects of NHS Digital's DARS Standards are met. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 5 to remove reference to the outputs being shared with NHS England. 2. To update section 1 and section 5 to amend the reference from *"substantially employed"* to "*substantively employed".* 3. To provide further information in section 5(a) to the reference to *"cube functionality"*. 4. To provide further information in section 5(a) to the reference *"lesser granular level"*. 5. To provide further details in section 5(d) (iii) of the yielded benefits accrued to date, for example, what has the Cancer Alliance achieved with the data which has impacted the community covered by the flow of data. The following advice was given: 1. IGARD advised that this application would be suitable for NHS Digital's Precedent route if all qualifying NHS Digital's DARS Standards are met.

	2. Separate to this application, IGARD suggested that any other Cancer Alliance which is switching data controllership to NHS England would be suitable for the precedent route, if all other aspects of NHS Digital's DARS Standards are met.
3.6	Department of Health and Social Care (DHSC) - Adult Social Care Data Department of Health and Social Care (DHSC) (Presenter: Dan Goodwin) NIC-463165-H3R4K-v0.2 **Application:** This was a new application for pseudonymised record level Adult Social Data. The purpose of this application is to support the Secretary of State for Health and Social Care in delivery of their duties set out within the National Health Service Act 2006 (and as subsequently amended), the Health and Social Care Act 2012 and the Care Act 2014. The DHSC analysts and officials will use data accessed via this Data Sharing Agreement (DSA) to explore and analyse these data to identify and provide actionable insights that will inform policy decisions. They will also use the data and evidence to respond rapidly to emergent challenges and issues, for example analysing in detail the impact on services from any pandemic contagious illnesses; providing actionable evidence and briefing to decision makers. **Discussion:** IGARD queried, in line with usual process, if there had been an assessment of the quantum of national data requested, and whether it was proportionate to the proposed processing and outputs outlined in the application; for example, ensuring that the minimum volume of data was flowing, whilst ensuring the proposed activities would be successful; and asked that a statement was added to section 1 (Abstract) for clarity / future reference. IGARD noted that Article 9(2)(j) of the UK General Data Protection Regulation (GDPR) was cited as the legal basis for the processing, however asked that section 1 and section 5 (Purpose / Methods / Outputs) were updated, to correctly list the Data Protection Act (DPA) 2018 Schedule 1 Part 1 references, and to clearly describe how the schedule conditions are met. IGARD noted the large number of storage and processing locations in section 2 (Locations), and noting this may cause difficulty for NHS Digital in respect of auditing, suggested that NHS Digital work with the applicant to review and consider if the locations could be consolidated, noting fewer storage locations should be needed, due to utilisation of cloud storage; and noting the discussion at the workshop at the business as usual (BAU) meeting on the 18th November 2021. IGARD queried the references in section 5(b) (Processing Activities) to *"identifiable"* data, and noting that the data requested was pseudonymised, asked that the incorrect templated wording was removed. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 1 with a statement that NHS Digital have undertaken an analysis of the quantum of data requested, and that this is proportionate to the proposed processing and outputs. 2. To update section 1 and section 5 in respect of the UK GDPR Article 9(2)(j) legal basis to correctly list the DPA 2018 Schedule 1 Part 1 references and clearly describe how the schedule conditions are met. 3. IGARD noted the large number of storage and processing locations, and, noting this may cause difficulty for NHS Digital in respect of auditing, suggested that NHS Digital

	worked with the applicant to review and consider if the locations could be consolidated, noting fewer storage locations should be needed, due to utilisation of cloud storage. 4. To amend section 5(b) to remove the templated wording relating to identifiable data.
3.7	London Borough of Islington: DSfC - Adult Social Care Free Text analysis (Presenter: Dan Goodwin) NIC-423341-T5F3T-v0.4 **Application:** This was a new application for pseudonymised Adult Social Data and Secondary Uses Service (SUS) for Commissioners data. The purpose is for a project with the aim of building a novel and comprehensive dataset that makes use of structured NHS and Adult Social Care (ASC) data and free text data from adult social care case notes, to identify need, escalating need and predict demand for adult social care. The high level aims of the project are to **a)** identify methods for sufficiently de-personalising ASC free-text data and using AI to extract systematically structured indicators from free-text data into structured data that can support the description and analyses of the care needs; **b)** to assess quality/validity of the new variables formed e.g. through expert discussions with care professionals and refine models/variables accordingly; **c)** to proactively explore clients' and residents' views on the use of data in this way and the ethics of this, and agree information governance protocols. d) Link structured NHS data with structured ASC data and structured free text data. **Discussion:** IGARD welcomed the application and noted the importance of this project in light of the minimal research into adult social care. IGARD queried if the research outlined within the application, was linked to the Free text data for Adult Social Care Prevention and Intervention Case Study, noting that this involved the same applicant and the work outlined on the web page was very similar to the information provided within the application. Noting that the application was silent on the Case Study, IGARD asked that the application was updated throughout, to ensure the Case Study was referenced, including, but not limited to, the *"lessons learned"* and how they have been addressed. IGARD discussed whether the data requested was effectively *"pseudonymised"*, or if there was any risk that the free text rendered the data '*identifying'*, noting the risk to the NHS Digital if the pseudonymised **and** identifying data were linked. IGARD also noted that this may in effect, have an implication for the legal basis currently cited in the application. In addition, IGARD asked that, for transparency, the application include an analysis, to establish that the data had been sufficiently deidentified to render it truly *"pseudonymised"*. IGARD noted that the application stated that the purpose was for *"commissioning"*, however queried if this was correct based on the evidence provided, as the first three high level aims appear as research question. IGARD asked that if the research limb of the NHS Digital sponsored project was over, then the application was updated to make clear what those outputs were, and to explain how the research questions had been answered; and to provide clarification this was now purely a commissioning application. IGARD queried how the relevant cohort had been made aware of the project, noting that one of the outputs of the Case Study was in relation to developing materials to describe the project for public consumption; and asked that further details were provided clarifying this. IGARD asked that the transparency materials were also updated, in line with the lessons learned from the Case Study. IGARD noted that the materials provided to IGARD for review,

	did not address the automated de-personalisation process, and suggested that the transparency materials would need updating accordingly. IGARD queried how the UK General Data Protection Regulation (UK GDPR) requirements of potential automated decision making had been addressed; the use of artificial intelligence to depersonalise the data; and how any biases had been addressed, and asked that section 5 (Purpose / Methods / Outputs) was updated with clarification. IGARD also asked that section 5 was updated with confirmation as to whether a Data Protection Impact Assessment (DPIA) had been carried out, as it was unclear. IGARD noted that National Data Opt-outs would apply, however queried if a local opt-out would be applied as noted in the patient information leaflet; and asked that confirmation was proved as to how the local opt-out would be applied. IGARD queried the references in section 1 (Abstract) and section 5(a) (Objective for Processing) to one of the high-level aims of the project was to *"…agree information governance (IG) protocols"*; and asked that written confirmation was provided, that the *"IG protocols"* had been finalised, agreed and adopted. IGARD noted that only social care users over 65 were covered in this project, and queried why it was focussed on this specific age group, given that social care impacts on a wide age range, including under 65s; and asked that the application was updated with further clarity. IGARD noted the large number of storage and processing locations in section 2 (Locations), and noting this may cause difficulty for NHS Digital in respect of auditing, suggested that NHS Digital worked with the applicant to review and consider if the locations could be consolidated; and noting the discussion at the workshop at the business as usual (BAU) meeting on the 18th November 2021. IGARD noted the information published on The London School of Economics and Political Science (LSE) (Data Processor) research ethics webpage, that appeared to indicate that the project would need University ethics support; and therefore asked that written confirmation was provided as to why the project had not obtained University ethics support. IGARD advised NHS Digital, that they would be content for this application to return to a future IGARD BAU meeting for advice, prior to it returning for a full review. **Outcome:** IGARD were unable to make a recommendation as not all the necessary information was available in order for IGARD to make a full assessment. 1. To update the application throughout to reference the Free text data for Adult Social Care Prevention and Intervention Case Study, including (but not limited to), the *"lessons learned"* and how they have been addressed. 2. To clarify if the data is effectively pseudonymised, or is there any risk that the free text renders the data identifying; and if this has any implication for the legal basis. 3. The application should include an analysis to establish that the data has been sufficiently deidentified to render it truly pseudonymised. 4. If the research limb of the NHS Digital sponsored project is over, then to make clear what those outputs were, and to explain how the research questions have been answered and this is a purely commissioning application. 5. In respect of transparency: a) To provide details as to how the relevant cohort have been made aware of the project (see the outputs from the Case Study referred to in point 1 above). b) To develop the materials for the project in line with the lessons learned from the Case Study.

	c) The materials reviewed did not address the automated de-personalisation process, and would need updating accordingly. d) To update section 5 to clarify how the UK GDPR requirements of potential automated decision making have been addressed, and the use of artificial intelligence to depersonalise the data, how any biases have been addressed, and to confirm if a DPIA has been carried out. 6. To provide confirmation of how the local opt-out process is applied. 7. To provide written confirmation that *"IG protocols"* have been finalised, agreed and adopted. 8. To provide an explanation as to why only social care users over 65 are covered in this project. 9. IGARD noted the large number of storage and processing locations, and, noting this may cause difficulty for NHS Digital in respect of auditing, suggested that NHS Digital worked with the applicant to review and consider if the locations could be consolidated. 10. Noting LSE's Ethics Policy, to provide written confirmation why the project does not require University ethics support.
4	<u>Applications progressed via NHS Digital's Precedent route, including the SIRO Precedent</u> Applications that have been progressed via NHS Digital's Precedent route, including the SIRO Precedent, and NHS Digital have notified IGARD in writing (via the Secretariat).
4.1	<u>NIC-15814-C6W9R Monitor (NHS England / Improvement) (No Presenter)</u> The purpose of this application was to request data for the NHS Trust Development Agency, NHS England / NHS Improvement, and Monitor as join Data Controllers, and is used to support the delivery of the applicant's statutory function and support direct improvement and / or oversight of Trusts. IGARD noted that this application was last reviewed at the IGARD business as usual meeting on the 2nd July 2020; and was previously seen at the IGARD – NHS Digital COVID-19 Response meeting on the 6th August 2020. IGARD noted that on the 24th December 2021, NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had agreed to authorise a short-term renewal for a period of 3-months. In addition, IGARD noted that the SIRO had approved the flow of Patient Level Costing Data (PLICS) under this DSA. IGARD noted and thanked NHS Digital for the written update and confirmed that they supported NHS Digital's assessment that the next iteration(s) should be brought to a future IGARD BAU meeting.
4.2	<u>NIC-49297-Q7G1Q-v3 University College London (UCL) (No Presenter)</u> The purpose of this application was for the '1958 National Child Development Study' (NCDS) study, that follows the lives of over 17,000 people born in England, Scotland and Wales in a single week of 1958, and collects information on physical and educational development, economic circumstances, employment, family life, health behaviour, wellbeing, social participation and attitudes. IGARD noted that this application was last reviewed at the IGARD business as usual meeting on the 6th August 2020.

4.3	IGARD noted that on the 20th December 2021, NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had agreed to authorise a short-term extension for a period of 4-months. IGARD noted and thanked NHS Digital for the written update and confirmed that they supported NHS Digital's assessment that the next iteration(s) should be brought to a future IGARD BAU meeting. <u>NIC-49826-T0J7C-v3 University College London (UCL)</u> The purpose of this application was for the '1970 British Cohort Study' (BCS70), that was created in response to concerns about the health and life changes of babies being born at that time and information was collected on about 17,000 babies born in a single week in 1970 and this became the first wave of BCS70. Since birth there have been nine further studies at ages 5, 10, 16, 2, 30, 34, 38, 42, 46 and 50. IGARD noted that on the 20th December 2021, NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had agreed to authorise a short-term extension for a period of 4-months. IGARD noted and thanked NHS Digital for the written update and confirmed that they supported NHS Digital's assessment that the next iteration(s) should be brought to a future IGARD BAU meeting.
5	<u>Oversight & Assurance</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 Data Access Request Service (DARS) applications as part of their oversight and assurance role. IGARD noted that they had requested, an IG COVID-19 release register suite of documents on a particular data release for review by IGARD as part of their oversight and assurance, and as agreed in June 2020 with the Executive Director Privacy, Transparency and Ethics (PTE) when it had been agreed that IGARD review an agreed number per month, by way of a review of all documentation revised by PTE, and as part of continuous improvement and quality. IGARD Members noted that they had not yet been updated on the issues raised at the 27th May 2021 IGARD business as usual (BAU) meeting with regard to previous comments made on the IG COVID-19 release registers. IGARD Members noted that the last IG COVID-19 release register that they had reviewed and provided comments on was July 2021.

6	COVID-19 update To support NHS Digital's response to COVID-19, from Tuesday 21st April 2020, IGARD held a separate weekly meeting, to discuss COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 urgent applications that had been submitted to NHS Digital. Although this was separate to the Thursday IGARD meetings, to ensure transparency of process, a summary of the Tuesday meeting was captured as part of IGARD's minutes each Thursday and published via the NHS Digital website as per usual process. As noted in the IGARD – NHS Digital COVID-19 Response Meeting notes from the 14th December 2021 (published in the IGARD meeting minutes from the 16th December 2021), this was the last meeting of the COVID-19 response meeting, at this time. The IGARD Chair thanked all the IGARD members who had attended since April 2020 for their participation and Secretariat for providing support to the meetings; and NHS Digital staff for their contributions. As per process since April 2020, the IGARD meeting each Thursday, will continue to hold an allocated slot each week for any COVID-19 related items that NHS Digital wish to discuss.
7 **7.1**	AOB: National Cancer Registration and Analysis Service (NCRAS) and the National Congenital Anomaly and Rare Disease Registration Service (NCARDRS) IGARD noted that at the IGARD BAU meeting on the 9th December 2021, the above briefing papers were provided to IGARD for review, where a number of high-level comments were provided (please see the published minutes for further information); including a request to see relevant Data Protection Impact Assessment(s) (DPIA) in advance of any applications being submitted to an IGARD BAU for review. Subsequent to the meeting, IGARD noted the DPIAs requested, were shared with members by DARS (via the IGARD Secretariat), with additional information, namely that Privacy, Transparency & Ethics (PTE) had advised that the documents were still in draft form and were awaiting further review by the Data Protection Officer and then a security team review; and that once the reviews, and any changes were complete, an *"owner"* of the DPIAs would be identified, who would be responsible for updating. IGARD thanked DARS for sharing the documents with members, and for the updated information. 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 07/01/22

These applications were previously recommended for approval with conditions by IGARD, and since the previous Out of Committee Report the conditions have been agreed as met out of committee.

NIC Reference	Applicant	IGARD meeting date	Recommendation conditions as set at IGARD meeting	IGARD minutes stated that conditions should be agreed by:	Conditions agreed as being met in the updated application by:	Notes of out of committee review (inc. any changes)
NIC-158754-R5T3V	Brain Tumour Charity	21/10/2021	1. To provide written confirmation, confirming TBTC's relationship with the Data Partners, Research Partners and Technology Partners; as outlined on the TBTC website. 2. To provide written confirmation of the enduring relationship between TBTC and BrightSparks Innovations Limited. 3. To provide a clear justification in section 5(a) as to why the consultant code has been requested.	IGARD members	Quorum of IGARD members	None
NIC-402963-P0Y5D-v1.8 -	University of Liverpool	23/09/2021	1. To provide confirmation in section 5 that NHS Digital data is not included in the resource overseen by IDAMAC.	IGARD Chair	IGARD Chair	To update the application to state that: *"NHS Digital data will not be included or made available for access to external researchers…"* *"NHS Digital to note in CRM that the yielded benefits should be substantially developed on renewal"*
NIC-403870-H8L5B-v0.7 -	London School of Economics and Political	25/11/2021	1. To provide a satisfactory indicative plan for the development and implementation of PPIE initiatives, in line with the HRA guidance on Public Involvement.	IGARD members	Quorum of IGARD members	None

	Science (LSE)		2. In respect of the Ethics: a) To provide written confirmation that the University ethics committee were aware of the quantum of data flowing and the sensitive nature of the data, including (but not limited to) disability, ethnicity and religion fields; or, b) If the University ethics committee were not aware (as above), the applicant to resubmit an application for review, with the additional information; and, c) To provide written confirmation that the re-submitted application has been reviewed by the University ethics committee, who have provided ethical support; or, d) To provide written confirmation that the re-submitted application has been reviewed by the University ethics committee, who support their original decision, that ethics support is not required. e) In all cases, to upload the written confirmation to NHS Digital's CRM system for future reference.			
NIC-368477-C9Q1X -	University College London	09/12/2021	1. In respect of the consultee advice: a) To provide written confirmation that the applicant has contacted HRA / REC, to check with them whether consultee advice can be relied upon in this factual scenario; specifically whether there is a qualifying *"impairing condition"* that falls under the Mental Capacity Act 2005. b) Following discussion with HRA / REC, to make any necessary changes, as may be requested, to the application.	IGARD Chair	IGARD Chair	None

			c) To upload the written confirmation from HRA / REC to NHS Digitals CRM system, for future reference.			

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