Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 4 August 2022

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Dr. Robert French	Specialist Academic / Statistician Member
Kirsty Irvine	IGARD Chair
Dr. Imran Khan	Specialist GP Member
Dr. Maurice Smith	Specialist GP Member
Jenny Westaway	Lay Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Maria Clark	Lay Member
Prof. Nicola Fear	Specialist Academic Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Chair
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Michael Ball	Data Access Request Services (DARS) (Item 7.1)
Michael Chapman	Director of Research and Clinical Trials (Item 7.2)
Garry Coleman	Associate Director / Senior Information Risk Owner (SIRO) (Item 7.2)
Simone Chung	Information Analysis and Statistics (Observer: item 2.1)
Ayse Depsen	Data Access Request Services (DARS) (Observer: items 2.1, 3 – 3.3)
Duncan Easton	Data Access Request Services (DARS) (**SAT Observer**: item 3.3, 7.1)
Liz Gaffney	Head of Data Access, Data Access Request Service (DARS) (Item 7.2)
Frances Hancox	Data Access Request Services (DARS) (Item 2.2)
Dan Goodwin	Data Access Request Services (DARS) (Observer: item 2.1) (Item 3.4)
Karen Myers	IGARD Secretariat

Tania Palmariellodiviney	Data Access Request Services (DARS) (**SAT Observer**: item 3.1)
Kimberley Watson	Data Access Request Services (DARS) (**SAT Observer**: item 3.2, 3.4)
Emma Whale	Data Access Request Services (DARS) (**Observer**: item 3.1)
Vicki Williams	IGARD Secretariat
Clare Wright	Data Access Request Services (DARS) (**Observer:** item 2.1) (Items 3.1 - 3.3)
Ly-Mee Yu (LMY)	Data Services Directorate (Item 7.3)
***SAT** – Senior Approval Team (DARS)	

1	**Declaration of interests:** Dr. Imran Khan noted a potential conflict with any applications reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) [COVID-19 Therapeutics Programme Dataset – Briefing Presentation], as part of his roles as Deputy Chair of the Health Informatics Group at the RCGP and Co-deputy Chair of the Joint GP IT Committee. It was agreed this did not preclude Dr. Khan from taking part in the discussions about this briefing presentation, however it was agreed that he would not participate in making any observations on the forthcoming application. Dr. Maurice Smith noted professional links to AIMES Management Service (NIC-148128-815J1) but no specific connection with the application or staff involved and it was agreed that there was no conflict of interest. Paul Affleck noted professional links to AIMES Management Service (NIC-148128-815J1) but no specific connection with the application or staff involved and it was agreed that there was no conflict of interest. Paul Affleck noted a professional link with the staff at the University of Oxford (NIC-315419-F3W7K). It was agreed this did not preclude Paul from taking part in the discussions about this application, however agreed that he would not participate in making a recommendation about the application. **Review of previous minutes and actions:** The minutes of the 28th July 2022 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record the meeting **Out of committee recommendations:** An out of committee report was received (see Appendix A).
2	**Briefing Notes**
2.1	COVID-19 Therapeutics Programme Dataset – Briefing Presentation (Presenter: Frances Hancox)

	This briefing presentation was to inform IGARD about the COVID-19 Therapeutics Programme Dataset, which initially will flow to a single applicant, and not be an NHS Digital 'onboarded' dataset made available to DARS applicants to request. The dataset comprises a list of people identified as being most at risk from contracting Covid-19; and it is anticipated that the dataset will contain only a pseudonymised identifier for these individuals, which can be linked to other data previously shared with the recipient. The number of patients identified is approximately 1.2 million. The purpose of the collection is to carry out analyses to determine the uptake, safety and effectiveness of neutralising monoclonal antibodies (nMABs) amongst the high-risk group identified. The list is derived using data from the following datasets: GPES COVID-19 at Risk Patients Collection, GP Data for Pandemic Planning and Research, Personal Demographics Service, COVID-19 UK Non-hospital Antigen Testing Results, COVID-19 Second Generation Surveillance System, NHS BSA Medicines Data, Unique Property Reference Number, Radiotherapy Dataset, Systemic Anti Cancer Therapy and Hospital Episode Statistics data. IGARD noted that a briefing paper had been submitted to the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) in April 2022, and that the briefing paper had been provided as a supporting document; however, IGARD noted that notes from the PAG meeting had not been provided as a supporting document, so IGARD were unclear as to PAG's views. IGARD noted that any forthcoming application should be presented to PAG in line with due process, or the PAG Chair should provide written support that PAG did not want to review any application and that the PAG Chair supported the deviation from the agreed NHS Digital process. **Outcome:** IGARD welcomed the briefing presentation and made no further comments. In respect of a forthcoming application, IGARD made high-level comments on the following themes: 1. To provide the IG Letter of Release and all embedded documents as supporting documents. 2. To provide a copy of the DPIA as a supporting document. 3. To provide a copy of the PAG documents. 4. Transparency. 5. Type-1 Opt-outs (including impact of legal basis). 6. Equality of access to the data. 7. To articulate what NHS Digital's risk is. IGARD welcomed the briefing presentation and asked that it be appended as a supporting document to the single applicant application.
3	**Data Applications**
3.1	<u>Wilmington Healthcare: Hospital Episode Statistics (HES), ECDS, Diagnostic Imaging Dataset (DIDs) and sensitive Mental Health data to assist disease awareness, commissioning, and help to produce longitudinal rare disease analysis and reports (Presenter: Clare Wright) NIC-16016-Y9H1D-v12.2</u> **Application:** This was a renewal and extension application to permit the holding and processing of pseudonymised Diagnostic Imaging Dataset (DIDs), Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC), HES Critical Care,

	HES Outpatients, Emergency Care Data Set (ECDS), Mental Health and Learning Disabilities Data Set (MHLDDS), Mental Health Services Data Set (MHSDS), HES-ID to MPS-ID HES Admitted Patient Care and HES-ID to MPS-ID HES Outpatients. The purpose of the application is to support the NHS either directly through the delivery of tools and bespoke analysis, or indirectly through non-NHS organisations, where solutions are provided with the NHS as the end beneficiary. Wilmington Healthcare will also be working in support of the delivery of New Models of Care and therefore will be required to work with customers and the new NHS bodies, for example, Integrated Care Providers and other bodies that form to provide support or services to the healthcare sector. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meetings on the 5th October 2017, 19th October 2017, 21st December 2017, 26th July 2018 and 16th May 2019. The application was also discussed under 'AOB' on the 11th January 2018; as part of the 'returning applications' section of the IGARD BAU meeting on the 5th November 2020; and as part of the 'applications progressed via NHS Digital's SIRO Precedent route' on the 7th July 2022. IGARD noted that they had previously asked NHS Digital to advise on the s261 legal basis for NHS Digital's dissemination, for example which subsection of s261 of the Health and Social Care Act 2012 was relevant since NHS Digital appeared to be only citing the overarching s261 e.g. "*s261 other dissemination of information*". IGARD asked that section 3 (Datasets Held / Requested) be updated with the most appropriate s261 subsection, in line with the latest advice from NHS Digital's Privacy, Transparency & Ethics (PTE). IGARD also requested sight of the email exchange on this topic between PTE and DARS. IGARD queried the value added by the applicant with regards to processing of data for projects when there were data flows and datasets already available, for example via the *National Institute for Cardiovascular Outcomes Research (NICOR)* and the National Diabetes Audit (NDA) covering the same data; and asked that an explanation was provided as to the additional value provided by Wilmington. IGARD noted the volume of data flowing to the applicant and queried what efforts had been undertaken to ensure that **only** the minimum amount of data was flowing, noting that the application was not clear on this. IGARD asked that in line with NHS Digital DARS standard for data minimisation, written confirmation was provided in section 5(a) (Objective for Processing), of the work undertaken by NHS Digital and the applicant to ensure that only the minimum amount of data necessary for the processing was flowing. In addition, IGARD asked that written confirmation was provided in section 3 and the public facing section 5(a), of the data minimisation undertaken by NHS Digital prior to the data flowing to Wilmington Healthcare; and, if no data minimisation has been undertaken in respect of a particular dataset, that written confirmation was provided in section 3 and an explanation in section 5(a) as to why **all** the data requested were required. IGARD noted references in section 5(c) (Specific Outputs Expected) to "*Each user organisation agrees a legal contract with Wilmington Healthcare stipulating the Terms and Conditions*….", and noting that there was minimal background information in section 5 (Purpose / Methods / Outputs), asked that section 5(a) and section 5(c) was updated with confirmation of which users have a legal contract with Wilmington Healthcare and why this was necessary.

	IGARD noted the information within section 5 in respect of the Quantis portal system, and noting that much of this appeared to be marketing narrative, asked that section 5 was reviewed and updated throughout to remove **all** marketing text. IGARD asked that for clarity and transparency, once the relevant marketing text had been removed, section 5 was updated to provide further clarity on what the Quantis portal system was; and, to provide clarification of the recipients of the Quantis portal system outputs. In addition, and noting that the application was currently not clear, IGARD asked that section 5 was updated to provide further detail about users of the Quantis portal system, by providing quantitative examples, for example, the percentage of users who were pharmaceutical companies. IGARD queried the statement in section 5(c) *"Other Quantis dashboards may be hosted on microsites…"*, and asked that further location clarification was provided on this statement. IGARD noted that when the application was last reviewed on the 16th May 2019, they had asked that a special condition was inserted in section 6 (Special Condition) that a new permanent lay member representative that formed part of the decision-making body would be in place within three months of signing of the agreement and that failing to do this would be a breach of the agreement. IGARD noted that two lay members now formed part of the decision-making body, and that the special condition had therefore been removed. Noting the continued importance of the lay member role on the decision-making body, IGARD asked that the special condition was reinstated (and reworded as necessary) to ensure ongoing / permanent involvement of a lay member. IGARD noted that there did not appear to be any information within the public domain in respect of Wilmington's Advisory Board and suggested that a brief description of the Board and how it operates was published on Wilmington's website. IGARD noted the conflicting information in respect of section 2(c) (Territory of Use) that stated the territory of use was "*England and Wales"* and section 1 (Abstract) that stated "*The Cloud provider will use UK Data Centres only*"; and asked that either section 1 or section 2(c) was updated as appropriate to reflect the correct territory of use. IGARD noted that section 2(b) (Storage Location(s)) noted Snowflake Inc. as a storage location, however the address had not been included; and asked that this was updated accordingly. 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 (Privacy Notice), that a UK General Data Protection Regulation (UK GDPR) compliant, publicly accessible transparency notice is maintained throughout the life of the agreement. IGARD noted that the applicant's published privacy notice, contained incorrect information, in respect of data subjects being able to impact the data flowing to the applicant, by removing consent and exercising their national data opt-out; and asked that In line with NHS Digital's DARS Standard for Transparency (fair processing), the incorrect information was removed. IGARD queried the statement in section 5(a) "…*will be required to work with customers and the new NHS bodies as they form that yet remain unnamed*"; and asked that this was updated to correctly reflect the new NHS bodies, in line with NHS Digital DARS Standard for Objective for Processing. IGARD noted the statement in section 5(a) *"…condition that had not yet been diagnosed…"*, and asked that this was amended as appropriate to provide further clarity on what this meant.

	IGARD made a number of comments on the outputs in section 5(c) and asked that in line with NHS Digital DARS Standard for Expected Outcomes, the following amendments were made: IGARD noted the statement in section 5(c) *"…the burden on social care…"* and asked that this was amended to more accurately state *"patients requiring more social care"* or similar. IGARD queried the statement in section 5(c) *"Quantis has a growing user base, including NHS…"*, and asked that unless this could be objectively demonstrated, this statement was amended, noting that the NHS will not be the primary user. IGARD noted the statement in section 5(c) *"Wilmington Healthcare Customer Service team are responsible for tracking…"*, and noting that it was unclear what was being tracked, asked that further clarification was provided. IGARD queried the statement *"Delphi consensus process"*, and asked that further clarification was provided on what this meant, noting that it was currently unclear. IGARD noted some duplicated text in section 5(c), and asked that this was reviewed, and any duplicated text was removed. IGARD noted and commended the applicant on the excellent yielded benefits provided, for example, in relation to the case studies. IGARD made a number of comments on the yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits) and asked that in line with NHS Digital's DARS Standard for Expected Measurable Benefits, the following amendments were made: IGARD noted references throughout section 5(d) (iii) to financial savings, and asked that this was updated with further clarification on what this referred to, for example, modelled transactional costs versus real cash released. IGARD queried the statements in section 5(d) (iii) to cost effectiveness as a yielded benefit, and noting that it was unclear what this was referring to, asked that was updated with further clarity on the cost effectiveness, for example, providing quantitative information by providing financial figures (£ amounts) and / or percentages of savings. IGARD noted the reference in section 5(d) (iii) to *"…diagnosed with a wound"* and asked that this was updated to correctly state *" …diagnosed with a wound* ***infection****"* if this was correct. As section 5 forms NHS Digital's data uses register, IGARD asked that section 5 was amended, to ensure that all acronyms upon first use be defined and further explained if the meaning was not self-evident, for example *"GIRFT", "OPCS4".* IGARD also noted the inclusion of a number of technical phrases and words within section 5 (Purpose / Methods / Outputs), such as *"Modeller system"*, asked that this public facing section, was amended throughout, to ensure technical terms were explained in a manner suitable for a lay audience. IGARD queried the statement in section 5(b) (Processing Activities) and section 5(c) *"spells break into episodes at record level"* , and asked that this was updated with further clarity on the meaning. IGARD noted that section 5(d) (ii) (Expected Measurable Benefits to Health and/or Social Care) made reference to *"legitimate interest"*, and noting that this was not necessary to include, asked that this was removed.

	NHS Digital noted that the Legitimate Interest Assessment (LIA) had been provided to IGARD as a supporting document, and asked that this was sufficiently addressed in section 5(a) (Objective for Processing) of the application as per process. IGARD noted that the LIA made reference to data subjects removing consent and exercising the Opt-out option; and suggested the applicant may wish to revise and update their LIA to remove the reliance on members of the public exercising opt outs, as this was not relevant in light of the data flow being pseudonymised. In addition, IGARD noted that the LIA minimised the commercial aspect of the use of the NHS Digital data and suggested that this was updated to reflect the factual scenario in respect of the commercial use. IGARD queried the misleading statement(s) in section 5 *"The outputs are not to be used principally for commercial purpose"*, and asked that this was removed as it was not strictly correct. IGARD also noted that there did not appear to be any information within the public domain in respect of Wilmington's customers and suggested that a brief description was published on Wilmington's website, including, but not limited to, the type of customer(s), for example, in quantitative terms, i.e. the percentage of pharmaceutical companies. IGARD noted the helpful supporting document provided, outlining the work undertaken with the data and for what purpose; however, suggested that the applicant could update this with an additional column setting out the project-specific benefits to health and social care. IGARD suggested that if NHS Digital audit this DSA, they may wish to determine whether the controls were sufficient in respect of generating aggregated data with small numbers unsuppressed and how this was shared. 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 commercial aspect / public interest in the application. **Outcome:** recommendation to approve subject to the following condition: 1. In respect of data minimisation and in line with NHS Digital DARS standard for data minimisation: a) To provide written confirmation in section 5(a) of the work undertaken by NHS Digital and the applicant to ensure that only the minimum amount of data, necessary for the processing, is flowing; and, b) To provide written confirmation in section 3 and section 5(a) of the data minimisation undertaken by NHS Digital prior to the data flowing to Wilmington Healthcare; and; c) If no data minimisation has been undertaken in respect of a particular dataset, to provide written confirmation in section 3 and an explanation in section 5(a) as to why **all** the data requested are required. The following amendments were requested: 1. To update section 3 with the relevant subsection of the s261 legal basis for NHS Digital to disseminate data. 2. To provide confirmation in section 5(a) which users have a "legal contract" with Wilmington Healthcare and why that is necessary.

3. To provide an explanation of the value added by the applicant with regards to processing of data for projects when there are NHS data flows already available, for example via NICOR and the NDA covering the same data.
4. To reinstate a special condition in section 6 that there continues to be a permanent lay member representative that forms part of the decision-making body.
5. In line with NHS Digital's DARS Standard for Transparency (fair processing), to update the incorrect information within the privacy notice to remove reference to data subjects being able to impact the data flowing to the applicant by removing consent and exercising their national data opt-out.
6. To update section 1 and / or section 2(c) with the correct territory of use, i.e. "*England and Wales"* or *"UK"*.
7. To update section 2(b) to add the address for Snowflake Inc.
8. In respect of section 5(a) and in line with NHS Digital DARS Standard for Objective for Processing:
    a) To amend section 5(a) to reflect the new NHS bodies.
    b) To amend the statement in section 5(a) *"…condition that had not yet been diagnosed…"*.
9. As section 5 forms NHS Digital's data uses register, to amend section 5 throughout:
    a. To ensure acronyms be defined upon first use, for example *"GIRFT", "OPCS4"*; and
    b. To ensure that technical terms are used only where necessary and explained in a manner suitable for a lay audience, for example *"Modeller system".*
10. In respect of the Quantis portal system:
    a) To remove all marketing narrative from section 5; and
    b) To update section 5 to provide further clarity on what the Quantis portal system is; and,
    c) To update section 5 to provide clarification of the recipients of the Quantis portal system; and
    d) To update section 5 to provide more detail about users of the Quantis portal system, by providing quantitative examples, for example, the percentage of users who are pharmaceutical companies.
    e) To provide further location clarification on the statement in section 5(c) *"Other Quantis dashboards may be hosted on microsites…".*
11. To update section 5 to remove the statement *"The outputs are not to be used principally for commercial purpose"*.
12. To update the statements in section 5(b) and section 5(c) *"spells break into episodes at record level"*
13. In respect of section 5(c) and in line with NHS Digital DARS Standard for Expected Outcomes:
    a) To amend the reference in section 5(c) from *"…the burden on social care…"* to *"patients requiring more social care"* or similar.
    b) To amend the statement in section 5(c) *"Quantis has a growing user base, including NHS…"*, noting that the NHS will not be the primary user (unless this can be objectively demonstrated).
    c) To provide further clarification on the statement in section 5(c) *"Wilmington Healthcare Customer Service team are responsible for tracking…"*.
    d) To provide further clarification on the statement in section 5(c) *"Delphi consensus process"*.
    e) To remove any duplicated text in section 5(c).
14. In respect of the benefits in section 5(d) in line with the NHS Digital's DARS Standard for Expected Measurable Benefits:

	a) To update section 5(d) (iii) to provide further clarity in respect of the financial savings, for example, modelled transactional costs vs real cash released. b) To update section 5(d) (iii) with further clarity on the cost effectiveness, for example, providing quantitative information by providing financial figures (£ amounts) and / or percentages of savings. c) To amend the reference in section 5(d) (iii) from *" …diagnosed with a wound. "* to *" …diagnosed with a wound* ***infection***". 15. In respect of legitimate interest: a) To remove the reference to *"legitimate interest"* from section 5(d) (ii); and b) To ensure the specific Legitimate Interests Assessment is referenced at the beginning of section 5(a). The following advice was given: 1. In respect of transparency: a) IGARD noted that there did not appear to be any information within the public domain in respect of Wilmington's Advisory Board and suggested that a brief description of the Board and how it operates was published on Wilmington's website. b) IGARD noted that there did not appear to be any information within the public domain in respect of Wilmington's customers and suggested that a brief description was published on Wilmington's website, including (but not limited to) the type of customer, for example, in quantitative terms, i.e. the percentage of pharmaceutical companies. 2. In respect of the LIA: a) IGARD noted that the LIA made reference to data subjects removing consent and exercising the Opt-out option; and suggested the applicant revised and updated the LIA to remove the reliance of members of the public exercising opt out as this is not relevant in light of the data flow being pseudonymised. b) IGARD noted that the LIA minimised the commercial aspect of the use of the NHS Digital data and suggested that this was updated to reflect the factual scenario in respect of the commercial use. 3. IGARD noted the helpful supporting document provided outlining the workplan; however, suggested that the applicant should update this with an additional column setting out the project-specific benefits to health and social care. 4. IGARD suggested that if NHS Digital audit this DSA, they may wish to determine whether the controls are sufficient in respect of generating aggregated data with small numbers unsuppressed and how this is shared. 5. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the commercial aspect / public interest in the application. 6. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the commercial aspect / public interest in the application. It was agreed the condition would be approved out of committee (OOC) by IGARD members.
3.2	University of Oxford: Epidemiological and health services research using routine NHS data: work programme of the Unit of Health-Care Epidemiology, Oxford University (Presenter: Clare Wright) NIC-315419-F3W7K-v6.10

	Application: This was a renewal and extension application to permit the holding and processing of pseudonymised Civil Registration (Deaths) - Secondary Care Cut, Hospital Episode Statistics Admitted Patient Care (HES APC), HES Admitted Patient Care, HES:Civil Registration (Deaths) bridge and HES-ID to MPS-ID. It was also an amendment application to add a new purpose for processing, to examine the sociodemographic inequalities in morbidity and mortality. The primary purpose of the application, is the advancement of education and research which are deemed to deliver a public benefit. The database and the research which uses it significantly contributes to the body of evidence and knowledge available which leads to changes in treatment, care and policies which are of benefit to the patient and the health care system; therefore the use of this data in this way is considered to be in the public interest. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the Data Access Advisory Group (DAAG) (IGARD's predecessor) on the 25th March 2015; and the IGARD business as usual (BAU) meetings on the 18th May 2017 and the 3rd October 2019. IGARD noted that section 7 (Ethics Approval) stated "*Ethics approval is not required because only pseudonymised data are processed*", but IGARD queried if all appropriate and necessary internal ethics or other approvals for the continued support for the study had been obtained, for example, the University of Oxford Sponsor Review; and asked that written confirmation was provided. IGARD noted that they had previously asked NHS Digital to advise on the s261 legal basis for NHS Digital's dissemination, for example which subsection of s261 of the Health and Social Care Act 2012 was relevant since NHS Digital appeared to be only citing the overarching s261. NHS Digital's Privacy, Transparency & Ethics (PTE) attended the IGARD BAU meeting on the 7th July 2022, and suggested that the legal basis for NHS Digital to disseminate pseudonymised data to universities under s261 was likely to be: s261(5)(d). IGARD asked that section 3 (Datasets Held / Requested) be updated to reflect the subsection. IGARD noted the request for HES data to produce mother-baby linkage, but queried why the applicant was not requesting the Maternity Services Data Set (MSDS) which contained mother-baby pre-linked pairs. IGARD noted they would be supportive of the applicant requesting and receiving the MSDS dataset. IGARD noted that prior to the meeting, they had raised a query in respect of the outputs in section 5(c) (Specific Outputs Expected) and the benefits in section 5(d) (Benefits); and had asked for clarify which outputs and benefits had been added since the last independent review on the 3rd October 2019, and that all the examples provided have been generated using data from this application and **not** other application(s). NHS Digital advised that they had raised the query with the applicant prior to the meeting, and were awaiting a response. IGARD noted the verbal update from NHS Digital, and asked that section 5(c) and section 5(d) were updated as appropriate following feedback from the applicant. IGARD made a number of comments on the benefits in section 5(d) (iii) (Yielded Benefits) and asked that in line with NHS Digital's DARS Standard for Expected Measurable Benefits, the following amendments to be made: As section 5 forms NHS Digital's data uses register, to amend section 5(d) throughout, so technical terms are used only where necessary and explained in a manner suitable for a lay audience, for example, the medical terms.

	IGARD noted the reference in section 5(d) (ii) to *"pelvic exenteration"*, and asked this was removed, noting the information already referred to "*major operations*" which adequately addressed the benefit provided. IGARD noted the yielded benefit provided in respect of "*valuable population data*" relating to breast cancer; and asked that this was updated with further details on what the specific yielded benefit was. 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 hoped*…". As section 5 forms NHS Digital's data uses register, IGARD asked that section 5(d) was amended, to ensure that all acronyms upon first use be defined and further explained if the meaning was not self-evident, for example *"CMD"*. IGARD noted the data minimisation column in section 3 (Datasets Held / Requested) contained a number of technical terms, and asked that future reference, this was updated with a brief narrative to provide further clarity on the technical language used. IGARD noted that they had been unable to find a published transparency notice for this study; and in line with NHS Digital's DARS Standard for Transparency (fair processing), wished to draw to the applicant's attention the statement in section 4 (Privacy Notice), that a UK General Data Protection Regulation (UK GDPR) compliant, publicly accessible transparency notice was maintained throughout the life of the agreement. IGARD also noted that in addition to the privacy notice, other information that highlights the valuable work undertaken was also difficult to locate within the public domain; and suggested that this was addressed in line with UK GDPR and made easily accessible. **Outcome:** recommendation to approve with a condition by a quorum of 5 members, with one Specialist member present not participating in making a recommendation on the application due to a potential conflict of interest. 1. To provide written confirmation that all appropriate and necessary internal ethics or other approvals for the continued support for the study have been obtained, for example, the University of Oxford Sponsor Review. The following amendments were requested: 1. To update section 3 with the s261(5)(d) legal basis for NHS Digital to disseminate data. 2. To update section 5(c) to clarify which outputs have been added since the last independent review in 2019, and ensure that all the examples provided have been generated using data from this application and **not** other application(s). 3. To update section 5(d) to clarify the benefits that have been added since the last independent review in 2019, and ensure that all the examples provided have been generated using data from this application and not any other application(s). 4. To update the data minimisation column in section 3, to provide a brief narrative description to support the technical terms. 5. In respect of the benefits in section 5(d): a) As section 5 forms NHS Digital's data uses register, to amend section 5(d) throughout, so technical terms are used only where necessary and explained in a manner suitable for a lay audience, for example, the medical terms. b) To remove the reference in section 5(d) (ii) to *"pelvic exenteration"*. c) To update section 5(d) (iii) to provide further detail on the specific yielded benefit ("valuable population data") relating to breast cancer.

	d) To update section 5(d) to use a form of wording such as "*it is hoped* …", rather than "*it will…*". e) To update section 5(d) to ensure acronyms be defined upon first use, for example *"CMD"*. The following advice was given: 1. In respect of transparency and in line with NHS Digital's DARS Standard for Transparency (fair processing): a) 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. b) IGARD noted that in addition to the privacy notice being difficult to locate, other information that highlights the valuable work undertaken was also difficult to locate within the public domain; and suggested that this was addressed in line with UK GDPR that this must be easily accessible. 2. IGARD noted the request for HES data to produce mother-baby linkage, and suggested, and would be supportive of, the applicant requesting and receiving the MSDS dataset which contained mother-baby pre-linked pairs. It was agreed the condition would be approved out of committee (OOC) by IGARD members.
3.3	Neosypher Limited: Pseudonymised record-level HES data for health benefit analysis (Presenter: Clare Wright) NIC-391477-K1P2G-v1.10 **Application:** This was a new application for pseudonymised Emergency Care Data Set (ECDS), Hospital Episode Statistics Admitted Patient Care (HES APC) and Hospital Episode Statistics Outpatients. The purpose of the application, is to undertake numerous ongoing projects using the requested HES data on an annual basis. Neosypher Limited have approximately five clients they have existing workflow with and now require secondary care HES data as they launch their respective drugs and benefit the wider NHS healthcare remit in reducing costs and capacity within the NHS. The main purpose of the data is as follows: **1)** comprehension and quantification of the impact of disease within secondary care; **2)** through robust research, to not only add to the body of healthcare knowledge but reveal key health trends and patterns over time in NHS hospital activity; **3)** application of data to identify key service improvements in terms of the efficiency of service within secondary care and treatment; **4)** to provide solutions to support commissioning, analytical support and outcomes analytics for NHS organisations, ranging from NHS England to regional teams; and **5)** to provide services to commercial organisations within life sciences, social care, charities and healthcare providers who will use the outputs and insights provided by NeoSypher Limited to work collaboratively with NHS organisations to promote health and improve well-being of patients, leading to more patient centric services. NHS Digital advised IGARD that the applicant had previously requested aggregated data with small numbers suppressed under this data sharing agreement (DSA); however that data had not flowed, and the DSA had been amended to reflect the data requested under this version of the DSA.

	Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 5th August 2021. IGARD noted that they had previously asked NHS Digital to advise on the s261 legal basis for NHS Digital's dissemination, for example which subsection of s261 of the Health and Social Care Act 2012 was relevant since NHS Digital appeared to be only citing the overarching s261. IGARD asked that section 3 (Datasets Held / Requested) be updated with the relevant subsection in line with the latest advice from NHS Digital's Privacy, Transparency and Ethics (PTE). IGARD had raised in advance of the meeting with NHS Digital a number of "big picture issues" with regard to commercial applications / applicants, including but not limited to: undertaking due diligence on the applicant and their parent company; DARS comparing this application with other comparable commercial applications in terms of quantum of data requested, information on actual or prospective clients, work plans etc; and whether NHS Digital were supportive of the new commercial application. NHS Digital noted that they did support the application and applicant, due diligence had been undertaken and a comparison with other similar commercial applications had been undertaken. IGARD noted the verbal update. IGARD queried the purpose for processing, in particular in respect of clients and the projects expected to be undertaken, noting that the application was not clear on either of these points. IGARD therefore asked that the application was updated throughout, to be clear that the purpose of the application was for specific projects with specific clients processing the NHS Digital data, as well as the Clarity tool. IGARD asked that if the applicant was unable to provide details on specific clients and specific projects, the application should instead be updated throughout, to be clear that the application was prospective, where the NHS Digital data would be used on a case-by-case basis depending on the clients and work projects secured. In addition, if the application was prospective, the application should be updated throughout, in line with other commercial applications to NHS Digital and NHS Digital DARS Standard for Commercial Purpose; and that **all** appropriate internal governance mechanisms were in place. IGARD queried what, if any specific projects were going to be initiated with this data, and that section 5 (Purpose / Methods / Outputs) was updated throughout with further clarity / information, and in line with NHS Digital DARS Standards. In addition, IGARD asked that all the examples of projects provided in section 5 were removed if speculative; and only those projects that were specific or highly likely to be undertaken were retained, for example, supporting users with NICE submissions and the obesity burden project, and in line with NHS Digital DARS Standards. IGARD queried how the data would be shared across the group of Neosypher organisations, noting that this may have implications on data controllership; and asked that in line with the NHS Digital DARS Standard for Data Controllers, a further explanation was added to section 5(a) (Objective for Processing). In addition, if there were changes to the Data Controllers, IGARD asked that section 1 (Abstract) was updated as may be necessary and as borne of the facts. IGARD noted the end users terms of use contract, that had been provided as a supporting document, however, advised that the document was not consistent with the portal access outlined in the application; and asked that a further explanation was provided as to what access users would get.

	IGARD also noted the reference within the end users terms of use contract, that referred to the *"EEA"*;* and noted that this was inconsistent to the territory of use stated in section 2(c) (Territory of Use) which stated *"England and Wales"*. *European Economic Area IGARD noted the information provided in section 5(e) (Is the Purpose of this Application in Anyway Commercial) outlining the commercial aspect; and queried if the information was a true reflection of what was happening, and could be backed up, for example "*As NeoSypher's company group is involved with NHS projects on a daily basis*…"; and asked that this was reviewed and edited as appropriate to accurately reflect what was happening, in line with the NHS Digital DARS Standard for Commercial Purpose. IGARD noted the useful information in section 5(e) in, in relation to the commercial aspect of the application; and asked that this was replicated in section 5(a) of this application for transparency. IGARD suggested that the applicant should update the Legitimate Interest Assessment (LIA) provided as a supporting document, to ensure it accurately reflects that the data cannot be used for marketing purposes, or for commercial use without benefit to health and social care in England and Wales. IGARD suggested that section 5 be updated throughout to remove reference to "*it will*…", and instead use a form of words such as "*it is hoped*…". IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the applicant having no previous record of processing NHS Digital data, and the commercial aspect / public interest in the application. **Separate to the application:** NHS Digital to advise on the genesis of the commercial conditions in section 6 (Special Conditions), since whilst robust, they may unduly restrict the use of data and go beyond legislative or NHS Digital policy requirements. **Outcome:** Recommendation to defer, pending: 1. In respect of the purpose for processing: a) To update the application throughout, to be clear that the purpose of the application is for specific projects with specific clients processing the NHS Digital data (as well as the Clarity tool); or b) To update the application throughout to be clear that the application is prospective, where the NHS Digital data will be used on a case-by-case basis depending on the clients and work projects secured; and, c) If the application is prospective, to update the application throughout (in line with other commercial applications to NHS Digital), and that all appropriate internal governance mechanisms are in place. 2. In respect of the data controllership and in line with the NHS Digital DARS Standard for Data Controllers: a) To explain in section 5(a) how the data will be shared across the group of organisations; and b) To amend section 1 to reflect the data controllership as may be necessary and as borne of the facts.

	3. To update section 3 with the legal basis for NHS Digital to disseminate data with the relevant subsection of s261 in line with the latest advice from NHS Digital's Privacy, Transparency & Ethics (PTE). 4. To update section 5 throughout, with clarification of any specific projects that are going to be initiated with this data and in line with NHS Digital DARS Standards. 5. For all the examples provided in section 5, to remove if speculative and to only retain those that are specific or highly likely to be undertaken, for example, supporting users with NICE submissions and obesity burden project. 6. To update section 5 to use a form of wording such as "*it is hoped* …", rather than "*it will…*". 7. In respect of the end users terms of use document: a) The document was not consistent with the portal access outlined in the application, and to provide a further explanation as to what access users will get. b) The document refers to the *"EEA"* which is inconsistent to the territory of use in section 2(c). 8. In respect of section 5(e): a) To edit section 5(e) to reflect what is actually happening and ensure all statements can be backed up, for example working with the NHS on a daily basis. b) To replicate in section 5(a) the useful narrative in section 5(e) with regards to the commercial aspect. The following advice was given: 1. IGARD suggested that the applicant should update the LIA to ensure it accurately reflects that the data cannot be used for marketing purposes, or for commercial use without benefit to health and social care in England and Wales. 2. IGARD advised that they would wish to review this application, or any subsidiary or related applications, when it comes up for renewal, extension or amendment, due to the applicant having no previous record of processing NHS Digital data, and the commercial aspect / public interest in the application. 3. IGARD suggested that this application, or any subsidiary or related applications, would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the applicant having no previous record of processing NHS Digital data, and the commercial aspect / public interest in the application. **Separate to the application:** NHS Digital to advise on the genesis of the commercial conditions, since whilst robust, they may unduly restrict the use of data and go beyond legislative requirements.
3.4	<u>University College London (UCL): MR623 – National Mother and Child cohort (Presenter: Dan Goodwin) NIC-148128-815J1-v3.6</u> **Application:** This was a renewal and extension application to permit the holding and processing of identifiable 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 add NHS England as a Data Controller. The National Mother and Child Cohort was established in 1995 as an extension to the National Surveillance of HIV* in Pregnancy and Childhood (NSHPC) that collects data on pregnancies in women living with HIV and their infants. Since 2018 the NSHPC has been absorbed by the Integrated Screening Outcomes Surveillance Service (ISOSS) based at UCL. Monitoring of the

	cohort will provide long term follow up of the cancer and death registration of children born to women living with HIV. ISOSS has collected data on approximately 25,000 pregnancies and their outcome since 1995 and aims to identify any significant health inequalities with a view of informing policies to remove barriers to this population's survival. *Human Immunodeficiency Virus **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 5th August 2021. IGARD noted that the application stated that University College London were the applicant, however asked that this was updated to ensure the Data Uses Register accurately reflected the correct applicant. IGARD noted that at the IGARD meeting on the 5th August 2021, IGARD had discussed Regulation 3(1)(b) and 3(1)(c) of The Health Service Control of Patient Information (COPI) Regulations 2002 and that supporting document 1.2, PHE approval letter for Regulation 3, had been provided but that it did not specifically note the sub-sections of Regulation 3 in the "*legal basis for processing*", but noted the specific text of the relevant sub sections of Regulation 3 in the section "*classification of Regulation 3 support*", namely Regulation 3(1)(b) "*recognising trends in such diseases and risks*" and Regulation 3(1)(c) "*controlling and preventing the spread of such diseases and risks*". IGARD drew to the applicant's attention the narrow scope of Regulation 3(1)(b) and 3(1)(c) COPI and that it did not provide a legal basis for any activity beyond surveillance of communicable disease and other risks to public health. IGARD queried if Regulation 3(1)(b) and 3(1)(c) were still the correct Regulation 3 COPI subsection, in light of the data subjects in fact being the babies exposed in utero; and asked that clarify was provided, if the most appropriate subsection was 3(1)(d)(iv). IGARD noted that the applicant had obtained Research Ethics Committee (REC) approval, which suggested the application was research; plus the UK General Data Protection Regulation (UK GDPR) legal basis put forward in the application also suggested it was a research application; IGARD asked that the application was updated as appropriate to reflect that the application was for research. IGARD queried if all aspects of the processing fitted under Regulation 3 COPI, and was not, for example, carried out under Regulation 5 COPI *"processed for medical purposes in the circumstances set out…by both the Secretary of State and a research ethics committee…"* ; and asked that written confirmation was provided. IGARD noted that PHE's Caldicott Advisory Panel were previously involved in the approval of Regulation 3 COPI as a legal basis; prior to PHE's closure at the end of September 2021. IGARD asked that written confirmation was provided that appropriate support was in place, and all relevant procedures had been carried out, to ensure valid continued support under Regulation 3, for example, in line with NHS England Caldicott Guardian advice. IGARD noted that the special condition in section 6 (Special Conditions) referred to "*Regulation 3(1)(b) and 3(1)(c)*"; and asked that this was updated as appropriate to reflect the appropriate Regulation 3 COPI subsection. IGARD noted the content of the Data Protection Impact Assessment (DPIA) provided as a supporting document, and noting that the DPIA focussed on the mothers who took the drugs, it appeared to lose sight of the fact that the data subjects are those children who were exposed

	to the drugs in utero. IGARD asked that the application and DPIA were updated to address this omission. In addition, IGARD also asked that the application and DPIA were updated to acknowledge that the mothers were not the data subjects. In line with UK GDPR requirements, IGARD queried how the Study Team would provide transparency to the data subjects, noting that the majority of the cohort were uninfected and may not be aware of their mother's status. Noting that this was not clear, IGARD asked that the application and DPIA were updated to clarify, and to acknowledge, any potential harm in contacting data subjects. IGARD noted that they had previously discussed patient and public involvement and engagement (PPIE), noting that this study commenced in 1995. IGARD were surprised at the lack of PPIE over the years but noted that the applicant had confirmed in advance of that meeting that they were going to "explore the possibility" of setting up a patient advisory panel (as noted in section 5(a) (Objective for Processing)) in the first instance with mothers living with HIV, since children born to a women living with HIV may not be aware of their mother's status and were therefore a harder group both to identify and reach out to for involvement. IGARD asked that section 5(c) (Specific Outputs Expected) was updated with a further update of the planned PPIE, for example, what had happened and what was expected to happen, including but not limited to whether there were any established networks or organisations they could partner with that engage children who are uninfected and born to women living with HIV such as the Body & Soul Charity. It should also be noted that the purpose of the application is to identify and track the data subjects so it *would* be possible to directly contact the data subjects or a sample of the cohort. IGARD queried why the children born in Wales had been removed from the cohort, noting that there was no explanation within the application; and asked that confirmation was provided in section 5 (Purpose / Methods / Outputs). In addition, IGARD asked that all references to children born in Wales were removed from the application, noting they were no longer part of the cohort. As section 5 forms NHS Digital's data uses register, to amend section 5(a) throughout, so technical terms were used only where necessary and explained in a manner suitable for a lay audience, for example replacing the reference to *"vertical transmission"* and *"mitochondrial"*. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the novel use of data, sensitive data flowing, complicated history of the application and the extensive extensions and lack of data subject involvement. **Outcome:** recommendation to approve subject to the following conditions: 1. In respect of the reliance on Regulation 3 COPI: a) To clarify if the most appropriate subsection is 3(1)(d)(iv), because the focus of the data subjects is babies exposed in utero. b) Noting the REC approval suggests research, to update the application as may be necessary. c) Noting the UK GDPR legal basis put forward are for research, to update the application as may be necessary. d) To provide confirmation that all aspects of the processing fits under Regulation 3 COPI, and is not carried out under Regulation 5 COPI.

	e) To provide written confirmation that appropriate internal and all procedures have been carried out, to ensure valid continued support under Regulation 3, for example, in line with the NHS England Caldicott Guardian advice. f) To update the special condition in section 6 to reflect the appropriate Regulation 3 subsection. 2. In respect of transparency to the data subjects: a) Noting the DPIA focusses on the mothers who took the drugs and appears to lose sight that the data subjects were those exposed to the drugs in utero, to update the application and DPIA to address this omission. b) To update the application and DPIA to clarify how they will reach out to data subjects, and to acknowledge the potential harm in contacting data subjects. The following amendments were requested: 1. To update the application to ensure the Data Uses Register accurately reflects the correct applicant. 2. As section 5 forms NHS Digital's data uses register, to amend section 5(a) throughout, so technical terms are used only where necessary and explained in a manner suitable for a lay audience, for example replacing the reference to *"vertical transmission"*, *"mitochondrial"*. 3. In respect of Wales: a) To provide confirmation in section 5 why the children born in Wales have been removed from the cohort. b) To ensure all references to children born in Wales are removed from the application. 4. To update section 5(c) with regards to the planned PPIE, for example, what has happened and what is expected to happen. The following advice was given: 1. IGARD advised that they would wish to review this application, or any subsidiary or related applications, when it comes up for renewal, extension or amendment, due to the novel use of data, sensitive data flowing, complicated history of the application and the extensive extensions and lack of participant involvement. 2. IGARD suggested that this application, or any subsidiary or related applications, would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the novel use of data, sensitive data flowing, complicated history of the application and the extensive extensions and lack of data subject involvement. It was agreed the condition would be approved out of committee (OOC) by IGARD members.
4 **4.1**	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). University College London (UCL): MR472A - SABRE: Southall and Brent Revisited - S251 participants not cancer notifiable (No Presenter) NIC-99077-Q0K6Z-v5.4 The purpose of the application was for a population-based cohort study, which is in its 25-year follow-up phase. It is unique as a long-standing tri-ethnic cohort consisting of people of European descent and first-generation migrants of South Asian or African Caribbean descent. This is an academic research study focusing on identifying and understanding the underlying

	reasons for ethnic group and sex differences in cardiometabolic disease and in physical, psychological and cognitive function in older age. IGARD noted that on the 26th July 2022 NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had agreed to authorise an extension to the Data Sharing Agreement (DSA) until the 31st October 2022 to give sufficient time for the applicant to obtain s251 support from Health Research Authority Confidentiality Advisory Group (HRA CAG). IGARD noted and thanked NHS Digital for the written update and asked that the next iteration of the DSA 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 Members noted that they had not yet been updated on the issues raised at the 27th May 2021 IGARD business as usual (BAU) meeting with regard to previous comments made on the IG COVID-19 release registers March 2020 to May 2021. IGARD noted that in addition, they had not been updated on the issues raised on the IG COVID-19 release registers June 2021 to May 2022. IGARD noted that the NHS Digital webpage excel spreadsheet had now been updated for the period March 2020 to April 2022: NHS Digital Data Uses Register - NHS Digital.
6	<u>COVID-19 update</u> *No items discussed*
7 **7.1**	<u>AOB:</u> <u>Integrated Care Board (ICB) Template (Presenter: Michael Ball)</u> IGARD noted that the three first of type ICB applications had previously been presented at the IGARD meetings on the 30th June (NIC-615960-G7W1L), 21st July (NIC-616046-J1Q0N) and the 28th July (NIC-615958-F7Q7Z). In addition, some high-level comments were fed back to NHS Digital on the ICB template at the IGARD meeting on the 28th July. NHS Digital attended the meeting to seek further views on a draft ICB template provided to members in advance of the meeting. IGARD thanked NHS Digital for providing the draft ICB template, however, noted that until the conditions, amendments and advice had been addressed for the three first of type applications, queries still remained on the ICB template application. IGARD suggested that once the three first of type applications, had progressed to SIRO, that NHS Digital update the ICB template accordingly, and bring back to a further IGARD meeting for discussion / finalisation.
7.2	<u>NHS Digital Transition (Presenters: Michael Chapman / Garry Coleman / Liz Gaffney)</u> NHS Digital's Director of Research and Clinical Trials, Associate Director / Senior Information Risk Owner (SIRO) and Head of Data Access, Data Access Request Service (DARS),

7.3	attended the meeting, to provide an update on the ongoing work within NHS Digital in respect of preparation for the transition of NHS Digital into NHS England. NHS Digital had been seeking IGARD's views on the current DARS service including the current applications in the system and predicted applications coming into the DARS service, without increasing the risk to NHS Digital around data disseminations, and following the verbal discussion at IGARD on the 28th July 2022. NHS Digital had provided IGARD with a briefing note outlining the request for advice on NHS Digital's plans to progress existing applications through a revised assurance process focused on risk with immediate plans for consideration, additional plans to work through with IGARD in the near future, and work already supported and agreed with IGARD. IGARD provided a number of verbal overarching high-level comments on the proposals put forward. NHS Digital suggested a standing item on future IGARD BAU meetings to ensure that IGARD were kept in the loop, IGARD were in agreement with this approach. <u>Derived data and data sharing (Presenter: Ly-Mee Yu)</u> NHS Digital attended IGARD to seek their views on what IGARD would expect in a DARS application, where, in some circumstances, it was difficult to have a sub-licence in place for example sharing participant level safety data to an oversight committee. IGARD noted that data should be shared for safety purposes, but that the right approach depends on the nature of the data, the purpose, who it will be shared with, the legal basis, whether consent is in place/is needed, what legislation underpins the safety aspect, etc. IGARD noted that NHS Digital may wish for a follow up discussion at a future IGARD business as usual (BAU) meeting. There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 29/07/22

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-470203-Y2L7J-v0.8	- University of Oxford	23/06/2022	1. The applicant to confirm that study participants (more than 3 but less than 7), who received the earlier consent forms and information sheets, have been consulted and that they agree their consent encompasses NHS Digital supplying medication data.	IGARD members	OOC by quorum of IGARD members	*None*
NIC-155843-0MQMK-v4.17	University of Leeds	30/06/2022	1. In respect of data minimisation: a. To update the application throughout in line with NHS Digital DARS standard for data minimisation, and b. To outline the steps taken to ensure the minimum amount of data possible is used to create the comparison group, and c. To clarify the geographical area (Yorkshire or Yorkshire & Humber) in section 5(a), and d. To provide an estimated size of the comparison cohort in section 5(a), dependent on the clarification of point (c) above.	IGARD members	OOC by quorum of IGARD members	*None*

NIC-05429-H7X6R-v8.3	Device Access UK Ltd	26/05/2022	1. To provide written confirmation in section 5 as to why the clients who *"commission"* the activity are not considered a joint Data Controller, in line with NHS Digital's DARS Standard for Data Controllers, and as borne out of the facts. 2. In respect of the *"contractors"* referenced in section 5(b) and the supporting document(s): a) To provide written confirmation that there are **no** contractors accessing the data: or, b) To update the application throughout to reflect the role of the contractor(s), and as borne out of the facts.	IGARD members	OOC by quorum of IGARD members	*None*
NIC-147843-8NKTW-v5	St George's University of London	17/03/2022	1. In respect of the HRA CAG support: a) To provide written confirmation that the applicant has continued to meet the HRA CAG conditions of support re transparency to the cohort and the steps taken to meet the condition on an ongoing basis. b) To upload a copy of the written confirmation to NHS Digital's CRM system.	IGARD members	OOC by quorum of IGARD members at the IGARD meeting on the 28/07/2022, as per process, noting the period of time that had passed following the initial review.	*None*

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

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

Liaison Financial Service and Cloud storage:

- None

Optum Health Solutions UK Limited Class Actions:

- None

Graphnet Class Actions:

- None