

**Independent Group Advising on the Release of Data (IGARD)**

**Minutes of meeting held via videoconference 3 March 2022**

<b>IGARD MEMBERS IN ATTENDANCE:</b>	
<b>Name:</b>	<b>Position:</b>
Paul Affleck	Specialist Ethics Member
Prof. Nicola Fear	Specialist Academic Member
Maria Clark	Lay Member
Dr. Robert French	Specialist Academic / Statistician Member (Observer)
Kirsty Irvine	IGARD Chair
Dr. Imran Khan	Specialist GP Member
<b>IGARD MEMBERS NOT IN ATTENDANCE:</b>	
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Chair
Dr. Maurice Smith	Specialist GP Member
Jenny Westaway	Lay Member
<b>NHS DIGITAL STAFF IN ATTENDANCE:</b>	
<b>Name:</b>	<b>Team:</b>
Imran Basser	Data Access Request Services (DARS) (Observer: items 3.1 - 3.4)
Vicky Byrne-Watts	Data Access Request Services (DARS) (SAT* Observer: item 3.3)
Garry Coleman	Associate Director / Senior Information Risk Owner (SIRO) (Observer: item 3.2) (Item 4.1)
Dave Cronin	Data Access Request Services (DARS) (items 5, 7.1, 7.2)
Louise Dunn	Data Access Request Service (DARS) (SAT* Observer: item 3.2)
Duncan Easton	Data Access Request Service (DARS) (SAT* Observer: item 3.1)
Suzanne Hartley	Data Access Request Services (DARS) (Observer: item 4.1)
Dan Goodwin	Data Access Request Services (DARS) (item 3.1)
James Gray	Digi-Trials (Item 3.5)
Dickie Langley	Privacy, Transparency and Ethics (PTE) (Observer: item 3.2)
Sara Lubbock	Data Access Request Services (DARS) (Observer: item 3.3)

Karen Myers	IGARD Secretariat
Dr. Jonathan Osborn	Deputy Caldicott Guardian (Observer: 3.1 – 3.4)
Tania Palmariellodiviney	Data Access Request Service (DARS) (Item 7.2)
Frances Perry	DigiTrials (Item 3.2)
Emma Russell	Data Access Request Services (DARS) (Item 5)
Charlotte Skinner	Data Access Request Services (DARS) (Item 3.4)
Joanna Warwick	Data Access Request Services (DARS) (Item 5)
Kimberley Watson	Data Access Request Services (DARS) (SAT* Observer: items 3.4 - 3.5)
Anna Weaver	Data Access Request Services (DARS) (item 7.2)
Vicki Williams	IGARD Secretariat
Clare Wright	Data Access Request Services (DARS) (Items 3.3)
<b>SAT – Senior Approval Team (DARS)</b>	

<b>1</b>	<p><b>Declaration of interests:</b></p> <p>Prof. Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising the Scientific Advisory Group for Emergencies (SAGE) on COVID-19.</p> <p>Prof. Nicola Fear noted a professional and personal link to the staff involved with NIC-17218-B0W9X (University College London) and NIC-121849-W0T5C (University of Birmingham), but noted no specific connection with these applications and it was agreed this was not a conflict of interest.</p> <p>Dr. Imran Khan noted a potential conflict with any applications reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) [NIC-411161-G4K7X], 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 application, however it was agreed that he would not participate in making a recommendation about the application.</p> <p><b>Review of previous minutes and actions:</b></p> <p>The minutes of the 23<sup>rd</sup> February 2022 IGARD meeting were reviewed out of committee by IGARD following conclusion of the meeting, and subject to a number of minor changes were agreed as an accurate record.</p> <p><b>Out of committee recommendations:</b></p> <p>An out of committee report was received (see Appendix A).</p>
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2	<b>Briefing Notes</b>
2.1	<p><u>Un-curated Low Latency Hospital Data Sets - Emergency Care – Briefing Paper (No Presenter)</u></p> <p>This briefing paper, for information only, was to inform IGARD about the Un-curated Low Latency Hospital Data Sets - Emergency Care, which is an asset onboarded by the Data Access Request Services (DARS), as a slimmed down cut of the baseline Emergency Care Dataset (ECDS) asset with no curation / validation taking place before dissemination. It is not a unique dataset, all fields within Un-curated Low Latency Hospital Data Sets - Emergency Care are already within the baseline ECDS asset.</p> <p>Unlike the Un-curated Low Latency Hospital Data Products, Un-curated Low Latency Hospital Data Sets - Emergency Care contains no derived fields bar Master Person Service ID for cohort linkage.</p> <p>IGARD thanked NHS Digital for providing a copy of the briefing paper as per process and confirmed that they had no further comments.</p>
3	<b>Data Applications</b>
3.1	<p><u>NHS Nottingham &amp; Nottinghamshire CCG: DSfC - Nottinghamshire Joint Data Controller - Commissioning (Presenter: Dan Goodwin) NIC-274291-Q5T1S</u></p> <p><b>Application:</b> This was an amendment application to <b>1)</b> add the following pseudonymised datasets for the purpose of Commissioning: e-Referral Service for Commissioning, Personal Demographics Service (PDS), Summary Hospital-level Mortality Indicator (SHMI), Medicines Dispensed in Primary Care NHS Business Services Authority (NHSBSA) data and Adult Social Care; <b>2)</b> add NHS North of England Commissioning Support Unit (CSU) as a Data Processor for the purpose of Commissioning; <b>3)</b> the addition of Optum Health Solutions UK Limited as a Data Processor for the purpose of Commissioning; <b>4)</b> the addition of Microsoft Limited and Amazon Web Services Limited as Data Processors for the purpose of Cloud Storage Service providers; <b>5)</b> amendment to add Nottingham Health Informatics Service (NHIS) as a Data Processor. The Data Processor and processing remain the same, however as NHIS is hosted by Sherwood Forest Hospitals NHS Foundation Trust, the trust are included as a Data Processor.</p> <p>The purpose of the application, is to ensure that analysis of health care provision can be completed to support the needs of the health profile of the population within each CCG area based on the full analysis of multiple pseudonymised datasets.</p> <p><b>Discussion:</b> IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 23<sup>rd</sup> May 2019; and had been discussed under “AOB” at the IGARD BAU meeting on the 16<sup>th</sup> December 2022.</p> <p>IGARD noted that the dissemination of data by NHS Digital was regarded as pseudonymous when the recipient <b>does not</b> hold the identity of the pseudonyms, however, for this specific application, the recipient <b>does</b> hold the identity of some of the pseudonyms, and therefore queried if the flow of data must therefore be considered identifiable noting that it contained identifying data. IGARD queried if Privacy, Transparency and Ethics (PTE) believed that contractual controls could take the data outside the common law duty of confidentiality (CLDoC) and if there was any case law that would support such a position. NHS Digital advised that this point has been raised with PTE, who had confirmed that the CLDoC would</p>

not be an issue, if the appropriate contractual controls were in place. IGARD noted the verbal update from NHS Digital, and asked that a copy of the written confirmation was provided from PTE, outlining their assessment that the contractual controls adequately addressed the CLDoC.

In addition to the written confirmation from PTE, IGARD asked that NHS Digital provided written confirmation that the Caldicott Guardian, in light of case law such as *R. v. Department of Health ex parte Source Informatics Ltd.* Court of Appeal: Simon Brown, Aldous and Schiemann L.J.J.; [2000] 1 All E.R. 786), was content that the CLDoC was not an issue that needed to be addressed in this application.

IGARD asked that for future reference, and audit purposes, the written confirmation from the Caldicott Guardian **and** PTE were uploaded to NHS Digital's customer relationships management (CRM) system; and for transparency, section 1 and section 5 (Purpose / Methods / Outputs) were updated with an explanation of the assessment that contractual controls were sufficient to render the data non confidential.

IGARD queried how NHS Sherwood Forest Hospitals NHS FT's technical and organisational controls would keep the data separate from the identifiers, and noting that this had not been addressed in the application, asked that this was clearly explained for transparency in section 5, and in line with Article 25 of the UK General Data Protection Regulation (UK GDPR) in order to meet the requirements of the Regulation and protect the rights of data subjects.

IGARD queried the statement in section 3(b) (Additional Data Access Requested) that "*GDPR does not apply to data solely relating to deceased individuals*", however, noting that the status of those patients that are still alive would be revealed, asked that, this was updated to include a UK General Data Protection Regulation (UK GDPR) legal basis for dissemination and receipt of data; if in accordance with the latest advice from the Privacy, Transparency and Ethics (PTE) Directorate.

IGARD noted the statement in the data minimisation column in section 3 (Datasets Held / Requested) "*See Additional Production Detail*"; and asked that for ease of future reference, this was removed, and a replaced with a statement to refer to the data minimisation outlined in section 5, or similar.

IGARD noted the examples provided in section 5(b) (Processing Activities) of A&E usage and polypharmacy, however asked that prior to this information, and for transparency, it was made clear these were generic examples and not necessarily linked to the applicant CCG, and as discussed at the workshop at the IGARD BAU meeting on the 18<sup>th</sup> November 2021. In addition, IGARD asked that section 5(b) was updated with an example of programmatic re-identification that could be substituted for the generic examples; or, if they **have** taken part in A&E / polypharmacy, section 5(b) was updated with further clarification.

IGARD queried the statement in section 1 that the data may need to be "*...downloaded and stored temporarily...*", and asked that a justification was provided in section 1.

**Outcome:** recommendation to approve subject to the following condition:

1. In respect of the contractual controls which are asserted render the data non-confidential:
  - a) NHS Digital to provide written confirmation that the Caldicott Guardian, in light of case law such as *R. v. Department of Health ex parte Source Informatics Ltd.* Court of Appeal: Simon Brown, Aldous and Schiemann L.J.J.; [2000] 1 All E.R. 786), is content that CLDoC is not an issue that needs to be addressed in this application.

	<ul style="list-style-type: none"> <li>b) To provide a copy of the written confirmation from PTE outlining their assessment that the contractual controls adequately address the CLDoC.</li> <li>c) To upload the written confirmation from the Caldicott Guardian <b>and</b> PTE to NHS Digital's CRM system.</li> </ul> <p>The following amendments were requested:</p> <ul style="list-style-type: none"> <li>1. To update section 1 and section 5 with an explanation of the assessment that contractual controls are sufficient to render the data non confidential.</li> <li>2. In respect of section 3: <ul style="list-style-type: none"> <li>a) 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.</li> <li>b) To remove the statements in section 3 "<i>See Additional Production Detail</i>"; and replace with a statement to refer to the data minimisation outlined in section 5, or similar.</li> </ul> </li> <li>3. To clearly explain in section 5 NHS Sherwood Forest Hospitals NHS FT's technical and organisational controls that will keep the data separate from the identifiers.</li> <li>4. In respect of A&amp;E / polypharmacy in section 5(b): <ul style="list-style-type: none"> <li>a) To update section 5(b) prior to the information on A&amp;E / polypharmacy, to make it clear these are generic examples and not necessarily linked to the applicant CCG.</li> <li>b) To update section 5(b) with an example of programmatic re-identification that could be substituted for the generic examples; or,</li> <li>c) If they have taken part in A&amp;E / polypharmacy, to update section 5(b) with further clarification.</li> </ul> </li> <li>5. To provide a justification for the statement in section 1 that the data may need to be stored temporarily.</li> </ul> <p>It was agreed the conditions would be approved out of committee (OOC) by IGARD members</p>
<p><b>3.2</b></p>	<p><u>University of Oxford: PRINCIPLE: 'Platform Randomised Trial of Treatments in the Community for Epidemic and Pandemic Illnesses' (Presenter: Frances Perry) NIC-411161-G4K7X</u></p> <p><b>Application:</b> This was a renewal and extension application to permit the holding and processing of pseudonymised Civil Registration (Deaths), Hospital Episode Statistics Admitted Patient Care (HES APC), HES Critical Care and identifiable Covid-19 UK Non-hospital Antigen Testing Results (pillar 2), GPES Data for Pandemic Planning and Research (COVID-19) (GDPPR) data.</p> <p>It was also an amendment to <b>1)</b> add the Medicines Dispensed in Primary Care NHS Business Services Authority (NHSBSA) data to the data sharing agreement (DSA); <b>2)</b> to extend the current DSA end date of the 31<sup>st</sup> March 2022 for a further 12 months; <b>3)</b> to amend the legal basis for the Common Law Duty of Confidentiality.</p> <p>The purpose of the application is to support the PRINCIPLE trial, which is the only national Urgent Public Health priority clinical trial evaluating potential therapeutics for COVID-19 in the primary care setting, endorsed by the four Chief Medical Officers. The trial aims to find out whether early treatment in the community speeds recovery and reduces the need for hospital admission for those with COVID-like-illness.</p>

The primary objective, is to assess the effectiveness of trial treatments in reducing the need for hospital admission or death, for patients aged 18 years and over, with confirmed COVID-19 infection during time of prevalent COVID-19 infections.

The legal basis for processing, is a mixture of The Health Service Control of Patient Information (COPI) Regulations 2002, and consent; and following the expiry of COPI on the 30<sup>th</sup> June 2022, the data would be processed in line with s251.

NHS Digital noted that the application referred to just over 8,500 participants having been recruited to the trial, however advised that this number had now increased, and confirmed that the application would be updated to accurately reflect the revised figure.

NHS Digital advised that prior to the meeting, IGARD had raised a query in respect of the Health Research Authority Confidentiality Advisory Group (HRA CAG) conditions of support, and whether these had all been met, as set out supporting document (SD) 1.10, the HRA CAG letter of support dated the 16<sup>th</sup> September 2021. NHS Digital confirmed that the applicant had confirmed that the HRA CAG conditions of support had been met, and had provided the relevant supporting evidence, which had been shared with members prior to the meeting, and had been saved to NHS Digital's customer relationships management (CRM) system.

**Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 25<sup>th</sup> February 2021.

IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 27<sup>th</sup> October 2020, 10<sup>th</sup> November 2020, 9<sup>th</sup> February 2021 and 28<sup>th</sup> September 2021.

IGARD noted that this application had been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 9<sup>th</sup> February 2022 (see Appendix B).

IGARD noted that, separate to this application, IGARD wished to discuss with the PAG Chair the special conditions requested by PAG on applications containing GDPR data; and, alongside the SIRO, asked that NHS Digital carefully reviewed any special conditions PAG had required on earlier reviews since it was for NHS Digital to form a view as to whether they were required or not, and to check that they were also content previous points had been suitably addressed.

IGARD noted the verbal update from NHS Digital, in respect of the revised number of cohort members recruited, and supported the update to the application to reflect the revised figure.

IGARD also noted the verbal update in respect of the HRA CAG conditions of support, and thanked NHS Digital for providing the additional supporting evidence to support the applicant's confirmation that the conditions of support had been met. IGARD asked that for transparency, section 1 (Abstract) and section 5(a) (Objective for Processing) were updated, to confirm that the HRA CAG conditions of support had been met and that any relevant supporting documentation was uploaded to NHS Digital's CRM system for future reference.

IGARD queried the yielded benefit in section 5(d) (Benefits) (iii) (Yielded Benefits) *"PRINCIPLE has successfully identified budesonide as the first widely available, inexpensive COVID-19 treatment, which the Chief Medical Officer has recommended on a case-by-case basis."*, and noting that this was now incorrect, asked that this statement was updated to make clear that the current guidance ([NICE COVID-19 rapid guideline: Managing COVID-19 section 7.11 Page 219](#)) is that the drug only be administered to treat COVID-19 as part of a clinical

trial, and is therefore not “widely available”, noting the importance of having factually correct publicly available information in section 5 which forms [NHS Digital’s data uses register](#).

IGARD also suggested that the trial website was updated to acknowledge the work undertaken, and to ensure all the information was accurate, including, but not limited to, removing the reference to budesonide being “widely available”.

IGARD noted that when the application was last reviewed on the 25<sup>th</sup> February 2021, they had queried whether the applicant would find the NHSBSA data more timely and complete to achieve their research goals outlined, instead of the GPPR data requested, or as well as the GPPR data requested. Any request for NHSBSA data would need the appropriate justification added to the public facing section 5 (Purpose / Methods / Outputs). Noting that the NHSBSA data had now been added to the application, IGARD reiterated that an appropriate justification for the NHSBSA **and** the GPPR datasets, which were datasets that contained similar data, should be added to section 5(a), in line with the [NHS Digital DARS standard for data minimisation](#) and the [NHS Digital’s DARS Standard for Objective for Processing](#).

IGARD noted that following submission of the initial application, there had been significant changes, for example in respect of COVID-19 testing and access to polymerase chain reaction (PCR) tests etc; and asked that a clear statement was provided at the start of section 5(a), acknowledging how the researchers will be reviewing, how the study would be run in light of the Government’s recent policy changes to PCR testing in the community and whether this would impact on the data requested, the processing and the expected outcomes.

Separate to this application, IGARD recommended that NHS Digital pro-actively contacted **all** applicants who were using Covid-19 UK Non-hospital Antigen Testing Results (pillar 2) data to ask them to consider how the testing policy changes impact how their study / trial is run, the datasets requested, the processing and the expected outputs; and advised that, where relevant, applicants should submit an amended application to NHS Digital.

IGARD queried the statement in section 5(a) “*In addition, we will collect information from your GP records and data held by central NHS bodies (such as NHS Digital) for long-term follow-up for up to 10 years, to help us better understand the long-term effects of COVID-19 and the trial treatments.*”; and asked that this was updated to clarify what would be followed up in the future, for example, just COVID-19 **or** COVID-19 **and** the treatments.

IGARD suggested that this application would be suitable for NHS Digital’s Precedent route, including the SIRO Precedent, until the legal basis changed to s251. Once the legal basis changes, IGARD would wish to review this application when it comes up for renewal, extension or amendment.

**Outcome:** IGARD were supportive of the application but unable to make a formal recommendation as there was not a quorum of members available to make a recommendation (potential conflict on the part of the GP Specialist member present). Members forming part of the quoracy suggested the following condition:

1. To amend the yielded benefit that states “...*budesonide as the first widely available, inexpensive COVID-19 treatment*...”, to make clear that this drug should only be administered as part of a clinical trial and is not “widely available”.

The following amendments were requested:

1. To update the application throughout to reflect the current number of cohort members (as per the verbal update from NHS Digital).
2. To update section 1 and section 5(a) to confirm that the HRA CAG conditions of support have been met (as per the verbal update from NHS Digital).

	<ol style="list-style-type: none"> <li>3. To update section 5(a) with an appropriate justification for the similar NHSBSA <b>and</b> the GDPR datasets, in line with the <a href="#">NHS Digital DARS standard for data minimisation</a></li> <li>4. To provide a clear statement at the beginning of section 5(a) acknowledging how the researchers will be reviewing: <ol style="list-style-type: none"> <li>a) how the study will be run in light of the Government's recent policy changes to PCR testing in the community; and,</li> <li>b) whether this will impact on the data requested, the processing and the expected outcomes.</li> </ol> </li> <li>5. To clarify in section 5(a) what will be followed up in the future, for example, just COVID-19 <b>or</b> COVID-19 and the treatments.</li> </ol> <p>The following advice was given:</p> <ol style="list-style-type: none"> <li>1. IGARD suggested that the trial website was updated to acknowledge the work undertaken, and to ensure all the information is accurate, including (but not limited to) removing the reference to budesonide being widely available as a COVID-19 treatment.</li> <li>2. IGARD advised NHS Digital to carefully review any special conditions PAG have placed on earlier reviews and checking that they are content that previous points have been suitably addressed.</li> <li>3. IGARD suggested that this application would be suitable for NHS Digital's Precedent route, including the SIRO Precedent, until the legal basis changes to s251. Once the legal basis changes IGARD would wish to review this application when it comes up for renewal, extension or amendment.</li> </ol> <p><b>ACTION:</b> Separate to this application: IGARD recommended that NHS Digital pro-actively contact all applicants who are using testing data to ask them to consider how the testing policy changes impact how their study / trial is run, the datasets requested, the processing and the expected outputs; and advised that, where relevant, applicants should submit an amended application to NHS Digital.</p> <p><b>ACTION:</b> Separate to this application: IGARD wished to discuss with the PAG Chair the special conditions requested by PAG.</p> <p>It was agreed the condition would be approved out of committee (OOC) by the IGARD Chair.</p>
3.3	<p><u>University of Oxford: The Oxford Risk Factors And Non Invasive Imaging Study (ORFAN) Arm 4 (Presenter: Clare Wright) NIC-409610-J6L1F-v1.9</u></p> <p><b>Application:</b> This was an amendment application to add additional variables classed as 'sensitive' or 'identifiable' which were not authorised under previous iterations of the data sharing agreement (DSA). The amendments are as follows: <b>1)</b> Ethnic category, gender and sex variables (9 extra variables in total) have been added in the following databases: <b>a)</b> Emergency Care Data Set (ECDS): Ethnic category – Sensitive; <b>b)</b> Hospital Episodes Statistics (HES) Outpatients: Ethnic category and Sex of patient; <b>c)</b> HES Admitted Patient Care (APC): Ethnic category and Sex of patient; <b>d)</b> HES A&amp;E: Sex of patient; <b>e)</b> COVID-19 Hospitalization in England Surveillance System: Ethnicity and Sex – Sensitive; <b>f)</b> Medicines Dispensed in Primary Care NHS Business Services Authority (NHSBSA) data: Gender; <b>2)</b> to increase the size of the initial cohort from 75,000 to 200,000.</p> <p>The purpose is for the ORFAN 'Arm 4' retrospective study arm, which is a multi-centre observational cohort study including up to 100,000 adult participants (75,000 in the UK and 25,000 internationally) and concerns only patients located in England and Wales who have had a computed tomography (CT) angiography or CT chest scan. The aim is to develop new</p>



and better biomarkers of cardiovascular disease risk, using novel approaches to the analysis of CT scans; to reduce the large burden of morbidity and mortality that cardiovascular disease such as heart attack and stroke.

A further purpose is to understand the cardiovascular disease ramifications of COVID-19 by identifying novel biomarkers that are able to predict cardiovascular disease pathogenesis and extent of pre-existing vascular disease, including in those with COVID-19 infection.

The study is relying on s251 of the NHS Act 2006 for the flow of data into NHS Digital.

NHS Digital advised IGARD that section 6 (Special Conditions) contained a special condition relating to IT infrastructure for ICNARC, and confirmed that this would be removed, noting that this was not relevant to this application.

**Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 18<sup>th</sup> March 2021.

IGARD confirmed that they were of the view that the relevant s251 support provided the appropriate legal gateway and was broadly compatible with the processing outlined in the application.

IGARD noted the verbal update from NHS Digital, in respect of the incorrect special condition in section 6 relating to IT infrastructure for ICNARC, and supported the update to the application to remove this special condition.

IGARD noted the amendments to the application, specifically relating to the request for sex and gender fields. IGARD asked that NHS Digital advise the applicant to carefully review the full definition for each dataset requested, because the applicant may not be receiving what they think they are getting, for example “*gender*” and “*sex*” are used interchangeably or incorrectly which will have impact on the research. IGARD also asked that, for transparency, section 5(b) (Processing Activities) was updated, to acknowledge that the inconsistent recording of sex and gender fields by NHS Digital may have a significant negative impact on the research and the expected benefits.

IGARD noted the constraints placed in the [Direction](#) for the collection of NHSBSA data, specifically, “*Providing intelligence about the safety and effectiveness of medicines...*”; and asked that in line with [NHS Digital's DARS Standard for Objective for Processing](#), when referencing processing of NHSBSA data to ensure a clear narrative is provided linking the purposes and processing to the relevant Direction.

In addition, IGARD asked that a special condition was inserted in section 6, that any use of the NHSBSA data must be within the parameters of the relevant Direction authorising that collection.

IGARD noted a risk to NHS Digital, in that the NHSBSA dataset was being used for purposes beyond the scope of the Direction, namely “*to deliver comprehensive data about the medicines dispensed, and drive the linkage of data to provide intelligence about the safety and effectiveness of medicines*”.

IGARD advised that the NHS Digital Information Asset Owner (IAO) for the NHSBSA dataset should confirm that use of NHSBSA in this study was within scope of the Direction authorising collection of the data, noting that computerised tomography (CT) scans were not a medication, and the dataset appeared to be being used to generate / populate gender and sex data fields and identify gaps in data collection, rather than check the efficacy of treatment on a particular sex as such.

IGARD queried the statement in section 5(b) *“The ORFAN study team will also request data from national registries...such as National Institute for Cardiovascular Outcomes Research (NICOR) and the Sentinel Stroke National Audit Programme (SSNAP)...and will link the pseudonymised NHS Digital data to ORFAN study participants events recorded in these national registries”*; and asked that this was updated to be clear, that any linkage to the NICOR / SSNAP data, would be subject to an amendment of the DSA as per process.

IGARD noted the scale, nature and scope of the processing. Since it includes ethnicity data, which would have a wide scale impact on all members of the community, IGARD suggested the applicant should complete an Equality and Health Inequalities Impact Assessment, if not already done so; and that, for transparency, section 5(a) (Objective for Processing) should be updated with the output of any Equality and Health Inequalities Impact Assessment completed.

IGARD also suggested that the applicant carry out a Data Protection Impact Assessment (DPIA), due to the scale, nature and scope of the processing. If a DPIA had already been produced, IGARD suggested that this was updated to reflect the amendments outlined within the application and before the processing took place.

IGARD noted the large number of international organisations listed in the protocol provided as a supporting document, and asked that confirmation was provided in section 5(a), that none of the international organisations were considered joint Data Controllers, in line with [NHS Digital's DARS Standard for Data Controllers](#). In addition, IGARD asked that clarity was provided in section 1 (Abstract), as to the work undertaken to determine that none of the international organisations were considered joint Data Controllers.

IGARD also asked that for transparency, section 5 (Purpose / Methods / Outputs) was updated, to clarify that **none** of the international parties would have access to the data, as outlined in the protocol.

IGARD noted that the weblinks provided in section 5(d) (Benefits) (iii) (Yielded Benefits) were behind a pay wall, and asked that the links were reviewed, and where possible to be updated to ensure links were to an open-source page, to allow accessibility, since section 5 forms [NHS Digital's data uses register](#).

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, for example, adding the data fields and processing being undertaken.

IGARD reiterated their previous advice from the 18<sup>th</sup> March 2021, in respect of the level of detail and breadth of information included within section 5, and reminded the applicant that because this section formed the dual purpose of a contract and public-facing [NHS Digital's data uses register](#), that brevity and simplicity were preferred. Should the applicant wish to provide this level of technical detail, this could either be included in the protocol or as a stand-alone supporting document, but it was not necessary in order to meet NHS Digital's Standards.

IGARD queried the statement in section 3(b) (Additional Data Access Requested) that *“GDPR does not apply to data solely relating to deceased individuals”*, however, noting that the status of those patients that are still alive would be revealed, asked that, this was updated to include a UK General Data Protection Regulation (UK GDPR) legal basis for dissemination and receipt of data; if in accordance with the latest advice from the Privacy, Transparency and Ethics (PTE) Directorate.

**Outcome:** recommendation to approve

The following amendments were requested:

1. To remove the special condition in section 6 relating to the IT infrastructure for ICNARC (as per the verbal update from NHS Digital).
2. To update section 3 to include a UK GDPR legal basis for those datasets that give information about cohort members who are still living, if this accords with the latest advice from PTE.
3. To update section 5(b) to acknowledge that the inconsistent recording of sex and gender fields by NHS Digital may have a significant negative impact on the research and the expected benefits.
4. In respect of the large number of international organisations listed in the protocol:
  - a) To provide confirmation in section 5(a) that none of the international organisations are considered joint Data Controllers, in line with [NHS Digital's DARS Standard for Data Controllers](#).
  - b) To provide clarity in section 1 as to the work undertaken to determine that none of the international organisations are considered joint Data Controllers.
  - c) To update section 5 to clarify that none of the international parties will have access to the data, as outlined in the protocol.
5. To update section 5(b) that any linkage with NICOR / SSNAP data, would be subject to an amendment of the DSA as per process.
6. To review and update the weblinks in section 5(d) (iii) where possible, to ensure links to an open-source page are provided and not behind a pay wall.
7. In respect of the NHSBSA dataset:
  - a) To update section 5(a) and in line with [NHS Digital's DARS Standard for Objective for Processing](#), when referencing processing of NHSBSA dataset to ensure a clear narrative is provided linking the purposes to the relevant Direction
  - b) To insert a special condition in section 6, that any use of the NHSBSA dataset must be within the parameters of the relevant Direction authorising that collection.
8. To update section 5(a) with the output of any Equality and Health Inequalities Impact Assessment completed.

The following advice was given:

1. 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, for example, adding the data fields and processing being undertaken.
2. IGARD reiterated their previous advice, in respect of the level of detail and breadth of information included within section 5, and reminded the applicant that because this section forms the dual purpose of a contract and public-facing data release register, that brevity and simplicity were preferred. Should the applicant wish to provide this level of technical detail, this could either be included in the protocol or as a stand-alone supporting document, but it was not necessary in order to meet NHS Digital's Standards.
3. Given the scale, nature and scope of the processing, which includes ethnicity data, and will have a wide scale impact on all members of the community, IGARD suggested that the applicant should complete an Equality and Health Inequalities Impact Assessment, if not already done so.

	<ol style="list-style-type: none"> <li>4. IGARD suggested the applicant carried out a Data Protection Impact Assessment (DPIA), due to the scale, nature and scope of the processing. If a DPIA has already been produced, IGARD suggested that this was updated to reflect the amendments outlined.</li> <li>5. NHS Digital to advise the applicant to carefully review the full definition for each dataset requested, because the applicant may not be receiving what they think they are getting, for example, “<i>gender</i>” or “<i>sex</i>”, are used interchangeably or incorrectly which will potentially have impact on the research.</li> <li>6. The NHS Digital IAO for the NHSBSA dataset should confirm that use of NHSBSA in this study is within scope of the Direction authorising collection of the data, noting that CT scans are not medication, and the dataset appears to be being used to generate/populate gender and sex data fields and identify gaps in data collection, rather than check the efficacy of treatment by sex.</li> </ol> <p><b>Risk area:</b> the NHSBSA dataset is being used for purposes beyond the scope of the Direction, namely “<i>to deliver comprehensive data about the medicines dispensed, and drive the linkage of data to provide intelligence about the safety and effectiveness of medicines</i>”.</p>
3.4	<p><u>London School of Hygiene &amp; Tropical Medicine (LSHTM): Evaluation of community-based health and social care multi-disciplinary teams (MDTs) - data linkage and comparison patients (Presenter: Charlotte Skinner) NIC-332870-B6Z4R-v0.10</u></p> <p><b>Application:</b> This was a new application for pseudonymised Civil Registration (Deaths) - Secondary Care Cut, Hospital Episode Statistics Admitted Patient Care (HES APC) and HES Critical Care.</p> <p>The purpose of the application is for a long-term programme of research on the Integrated Care and Support Pioneers in order to identify factors that enable or inhibit progress towards the integration of health and social care services and to assess whether such integrated services lead to better outcomes for patients in a more patient-centered and cost-effective way.</p> <p>The current research programme, which is due to be completed in Autumn 2022, follows on from an earlier evaluation of the Pioneers which was undertaken by the same research team (2014-15), and involves three work packages: <b>Work package 1:</b> Implementation and progress – Pioneer level process evaluation and (limited) impact evaluation in all 25 Pioneers via interviews, web based panel surveys and analysis of performance indicators relevant to integrated health and social care; <b>Work package 2:</b> Impacts, costs and patient outcomes – impact and economic evaluations of selected Pioneer initiatives using mixed methods, and designed to follow patients, carers and staff over the longer-term; <b>Work package 3:</b> Lessons learned – Working with Pioneers, national policy makers and partners, patient/user organisations and experts to derive and spread learning on improving integrated care.</p> <p>The cohort comprises of 441 consented patients and a comparison group.</p> <p><b>Discussion:</b> IGARD welcomed the application and noted the importance of the research in looking at survey data and the patient perspective.</p> <p>IGARD noted that the application and relevant supporting documents had previously been presented for advice at the IGARD business as usual (BAU) meeting on the 26<sup>th</sup> August 2021.</p> <p>IGARD noted the efforts made by the applicant to address issues / comments made previously on the consent materials, and confirmed that, although not ideal, IGARD were of the view that the most recent consent materials provided the appropriate gateway and were broadly</p>

compatible with the processing outlined in the application, and were content to proceed on this basis.

IGARD noted that the data requested was “*pseudonymised*” and queried if any of the data was identifiable. NHS Digital advised that although the applicant held the identifiers, the data flowing back to the applicant was pseudonymised and the applicant had confirmed that the identifiers were kept separate and there would not be any attempts to re-identify individuals by the applicant. IGARD noted the verbal update from NHS Digital, and advised that in this scenario, data was flowing under consent, and was therefore not an issue; however, separate to this application, IGARD asked that the Senior Approval Team (SAT) within the Data Access Request Service (DARS), followed-up how identifiability is recorded, where there are confidential and pseudonymised data flows out from NHS Digital.

IGARD queried the statement in section 5(b) (Processing Activities) “*For the comparison patients, NHS Digital is asked to provide the data items requested for all patients born before 1st October 1964 (and who were still alive on 1st October 2018 when the study started data collection).*”; noting the volume of data that would potentially be flowing if this statement was correct. IGARD asked that the application was updated throughout, in line with [NHS Digital DARS standard for data minimisation](#) to outline the steps taken to ensure the minimum amount of data possible was used to create the comparison group. IGARD asked that any data not required was destroyed and that the applicant provided a data destruction certificate, as per NHS Digital’s process.

IGARD noted the inclusion criteria outlined in section 5 (Purpose / Methods / Outputs), for example those who “*...are aged 55 years and over, have multiple chronic conditions, live at a private residential address, and were added to the caseload during the recruitment period...*”; and asked that a justification was provided in section 3(b) and section 5 as to why these exclusions had been made.

IGARD queried the funding arrangements for the programme, noting that publicly available information, for example, the programme website referred to the Department of Health and Social Care (DHSC) “*commissioning*” the programme. IGARD asked that section 5(a) (Objective for Processing) was updated with clarification, that even though publicly available information referred to DHSC “*commissioning*” the programme, they did not carry out data controllership activities, as borne out of the facts and in line with the [NHS Digital’s DARS Standard for Data Controllers](#).

IGARD noted the reference to “*gender*” in section 5; and asked that it was clarified if it was actually “*sex*”, since they are not interchangeable data fields.

IGARD noted the inclusion of a number of technical phrases and words within section 5(a), such as “*horizontal integration*”, asked that this public facing section, that forms [NHS Digital’s data uses register](#), was amended throughout, to ensure technical terms are defined upon first use, and explained in a manner suitable for a lay audience.

IGARD noted the minimal information within the application in relation to patient and public involvement and engagement (PPIE), and suggested that the applicant consider involving relevant public and patient groups throughout the life cycle of the study in line with [HRA guidance on Public Involvement](#).

IGARD queried the statement in section 3(b) (Additional Data Access Requested) that “*GDPR does not apply to data solely relating to deceased individuals*”, however, noting that the status of those patients that are still alive would be revealed, asked that, this was updated to include a UK General Data Protection Regulation (UK GDPR) legal basis for dissemination and receipt

	<p>of data; if in accordance with the latest advice from the Privacy, Transparency and Ethics (PTE) Directorate.</p> <p>IGARD suggested that this application would be suitable for NHS Digital's Precedent route, including the SIRO Precedent.</p> <p><b>Outcome:</b> recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> <li>1. In respect of data minimisation: <ol style="list-style-type: none"> <li>a) To update the application throughout in line with <a href="#">NHS Digital DARS standard for data minimisation</a>; and</li> <li>b) To outline the steps taken to ensure the minimum amount of data possible is used to create the comparison group;</li> <li>c) To ensure that any data not required is destroyed and that the applicant has provided a data destruction certificate.</li> </ol> </li> </ol> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To update section 5(a) with clarification that even though publicly available information refers to DHSC “<i>commissioning</i>” the programme, they do not carry out data controllership activities, as borne out of the facts and in line with the <a href="#">NHS Digital's DARS Standard for Data Controllers</a>.</li> <li>2. To update section 3 to include a UK GDPR legal basis for those datasets that give information about cohort members who are still living, if this accords with the latest advice from PTE.</li> <li>3. As section 5 forms <a href="#">NHS Digital's data uses register</a>, 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 “<i>horizontal integration</i>”.</li> <li>4. To update section 5 to clarify if “<i>gender</i>” or “<i>sex</i>” is required, since they are not interchangeable data fields.</li> <li>5. To provide a justification in section 3(b) and section 5 as to why significant exclusions in the data fields have been made.</li> </ol> <p>The following advice was given:</p> <ol style="list-style-type: none"> <li>1. IGARD that the applicant may wish to consider involving the relevant public and patient groups throughout the life cycle of the study in line with <a href="#">HRA guidance on Public Involvement</a>.</li> <li>2. IGARD suggested that this application would be suitable for NHS Digital's Precedent route, including the SIRO Precedent.</li> </ol> <p><b>ACTION:</b> Separate to this application: SAT to follow-up how identifiability is recorded where there are confidential and pseudonymised data flows out from NHS Digital.</p> <p>It was agreed the conditions would be approved out of committee (OOC) by IGARD members.</p>
3.5	<p><u>University Hospital Southampton NHS FT: A randomised, phase II UK multi-centre study to determine reactogenicity and immunogenicity of booster vaccination against ancestral and novel variants of SARS-CoV-2 Short Title: Evaluating COVID-19 Vaccine Boosters (Covboost) (Presenter: James Gray) NIC-456088-R0H0V v0.1</u></p> <p><b>Application:</b> This was an amendment application to utilise the Permission to Contact Service (PtC) for the purpose of a second sub-study called ‘Cov-Boost Omicron Variant Fourth Dose Booster’.</p>



This purpose of the second sub-study is to determine the side effect profile, safety and immune response of giving a fourth COVID-19 vaccine booster doses of Pfizer and Moderna, to people who have previously received three doses of COVID-19 vaccine; and is aiming to recruit a further 200-400 people 30 years or older.

The initial purpose of this Data Sharing Agreement (DSA), was to determine the immune responses provided from different booster vaccinations given a minimum of 3-months from the second dose of an initial course of AstraZeneca or Pfizer vaccines.

The PtC Service is where members of the public can register their details and give their permission to be contacted by researchers working on National Institute of Health Research (NIHR) approved UK coronavirus vaccine trials about participating in those trials. This PtC Service, which is called 'Sign Up to be Contacted about Coronavirus Vaccine Studies' on the nhs.uk website was launched as a national service on 20th July 2020.

**Discussion:** IGARD noted that they had received a **verbal** update on aspects of this application at the IGARD – NHS Digital COVID-19 Response meeting on the 18<sup>th</sup> May 2021, but had not received an application or any supporting documents to review.

IGARD noted that this was an **active** DSA and advised NHS Digital that as this was out of process, and they would be unable to provide a recommendation, and would instead make observations for when the application returned for renewal, extension or amendment.

IGARD noted that although the consent materials had **not** been subject to a full review, the consent materials appeared to be very limited in scope and preclude future further follow-up and linkage to NHS Digital data; and NHS Digital should ensure the applicant is aware of this, as per previous advice given on this topic.

IGARD noted the new data fields in section 5(b) (Processing Activities), for example ethnicity and sex at birth. IGARD queried, noting that this information was not referred to in the "*identifiable fields*" in section 3 (Datasets Held / Requested), what was happening with the new data fields. IGARD asked that, for transparency, section 5 (Purpose / Methods / Outputs) was updated, with an explanation of what was happening with the new data fields, for example to ensure an appropriate sample was being created.

IGARD noted that a Data Protection Impact Assessment (DPIA) had been completed, but suggested that this was updated to reflect the processing of ethnicity and sex at birth data, in accordance with the UK General Data Protection Regulation (UK GDPR).

IGARD observed that the most recent amendments to the application were mid-way down section 5(a) (Objective for Processing), and asked that, for ease of reference, this was re-ordered to ensure the current amendments were at the beginning of section 5(a), before outlining the other historical amendments.

IGARD noted the inclusion and exclusion criteria in section 5(b) that would be used by the recruitment sites during the screening phase, and queried the reasons for the exclusions, for example pregnant women and those who are immunosuppressed, IGARD asked that for transparency, section 5 was updated with a brief explanation / justification of the various exclusion criteria, for example, was this on documented safety grounds and had this been approved by a research ethics committee.

IGARD noted that the yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits) had been addressed by providing a weblink to an article; and asked that this was updated, in line with [NHS Digital DARS Standard for Expected Measurable Benefits](#), to provide a brief summary of the yielded benefits accrued, rather than providing a link.

	<p><b>Outcome:</b> IGARD were supportive of the application with regard to the data flows that had already occurred, and made the following observations:</p> <p>When the application comes up for renewal, extension or amendment, the following updates to the application should be made:</p> <ol style="list-style-type: none"> <li>1. To update section 5 with an explanation of what is happening with the new data fields (e.g. ethnicity and sex at birth); for example to ensure an appropriate sample is being created.</li> <li>2. To update section 5 to lead with the current amendments, before outlining other historical amendments.</li> <li>3. To update section 5 with a brief explanation / justification of the various exclusion criteria, for example, is this on documented safety grounds and has this been approved by a research ethics committee.</li> <li>4. To update section 5(d) (iii), in line with <a href="#">NHS Digital DARS Standard for Expected Measurable Benefits</a>, to provide a brief summary of the yielded benefits accrued, rather than just a link to an article.</li> </ol> <p>The following advice was given:</p> <ol style="list-style-type: none"> <li>1. IGARD noted that although the consent materials had not been subject to a full review, the consent materials appeared to be very limited in scope and preclude future further follow-up and linkage to NHS Digital data; and NHS Digital should ensure the applicant is aware of this, as per previous advice given on this topic.</li> <li>2. IGARD noted that a DPIA had been completed, but suggested that this was updated to reflect the processing of ethnicity and sex at birth data (in accordance with UK GDPR).</li> </ol>
4	<p><u>Applications progressed via NHS Digital's Precedent route, including the SIRO Precedent</u></p> <p>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).</p>
4.1	<p><u>NIC-382794-T3L3M-v4.2 – University of Oxford (Garry Coleman)</u></p> <p>The purpose of this application was to support QResearch's urgent COVID-19 research. QResearch is a database of linked medical records that has been used and continues to be used by a variety of research projects undertaken by UK universities; and consists of the coded pseudonymised electronic health records from primary care patients registered with approximately 1,500 general practices spread throughout the UK.</p> <p>IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 12<sup>th</sup> January 2021, 19<sup>th</sup> January 2021 and the 2<sup>nd</sup> March 2021.</p> <p>NHS Digital's Associate Director / Senior Information Risk Owner (SIRO) attended the meeting to provide a verbal update, and advised that a 2-month renewal would be approved, allowing the data to flow, and for the application to be reviewed at an IGARD BAU meeting.</p> <p>In addition, IGARD were advised that as this was the second time the application had proceeded down the SIRO approval route, this was exceptional and did not set a precedent for other applications.</p>



	<p>IGARD noted the verbal updated and advised that although observations had been provided by IGARD members at the IGARD – NHS Digital COVID-19 Response meetings in 2021, this did not replace a full review of the application and supporting documents by a quorum of IGARD members at an IGARD BAU meeting.</p> <p>IGARD thanked the Associate Director / SIRO for attending the meeting, and looked forward to receiving the application in due course. IGARD advised that when the application was ready for review, this should be accompanied by a copy of the other application (NIC-240279-Y2V2N), and would require a double slot on the IGARD BAU meeting agenda, to allow sufficient time for review / discussion.</p>
5	<p><u>Oversight &amp; Assurance</u></p> <p>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.</p> <ul style="list-style-type: none"> <li> <p><b>NIC-10123-M5K5H University of Oxford</b> (class action)</p> <p>IGARD noted that whilst they were briefed on a proposed ‘class action’ approach, there is no agreed “class action precedent”.</p> <p>IGARD were unable to say if the application had proceeded under the correct precedent route.</p> <p>IGARD queried the versioning of the application, noting that when last seen it was version 3 and in the pack for review was version 5, and queried the precedent used for version 4 and that section 1 (Abstract) should clearly note the application history.</p> <p>IGARD noted that in section 1 there was no narrative, as per usual process, with regard to the NHS Digital review of consent materials relating to the sub-groups.</p> <p>IGARD noted that they had still not seen the risk matrix and scoring, and which had not been included as a supporting document because it had not been labelled as an “SD”.</p> </li> <li> <p><b>NIC-17218-B0W9X University College London</b> (class action)</p> <p>IGARD noted that whilst they were briefed on a proposed ‘class action’ approach, there is no agreed “class action precedent”.</p> <p>IGARD were unable to say if the application had proceeded under the correct precedent route.</p> <p>IGARD noted that, as per due process, the action plan requested by NHS Digital had not been included as a special condition.</p> </li> <li> <p><b>NIC-121849-W0T5C University of Birmingham</b> (extensions &amp; renewals)</p> <p>IGARD noted the excellent yielded benefits accrued to date and updated within the application summary.</p> <p>IGARD noted that a prior simple amendment to include a missing data field was not included in the history of the application in section 1 (Abstract)</p> </li> <li> <p><b>NIC-184951-D1G8R ICNARC</b> (SIRO)</p> <p>IGARD noted the inappropriate statement in section 1 (Abstract) which noted that the application had been ready to proceed to IGARD but due to the Christmas break had been subsequently given a one-year extension. NHS Digital noted this was out of process and should have been given a short-term extension and the application put on the next available IGARD agenda after the holiday period.</p> </li> </ul>

	<ul style="list-style-type: none"> <li>• <b>NIC-184980-J5B6C Cardiff University (SIRO)</b> IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, and that the focused areas would be the meeting of the NHS Digital DARS Standards (which had still not been met) and the HRA CAG approval.</li> <li>• <b>NIC-253220-Q1X8H University of Manchester (simple amendment)</b> 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 nature of the application and in line with previous advice given.</li> </ul> <p>IGARD Members noted that they had not yet been updated on the issues raised at the 27<sup>th</sup> 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 October 2021.</p> <p>IGARD noted that the IG COVID-19 Release Register November 2021 to January 2022 had been circulated and reviewed out of committee by members, discussed in-meeting and agreed the comments that would be shared with the Privacy, Transparency and Ethics Directorate.</p>
6	<p><u>COVID-19 update</u></p> <p><i>No items discussed</i></p>
7 7.1	<p><u>AOB:</u></p> <p><u>NIC-243790-Y8K8C Carnall Farrar Limited (Presenter: Dave Cronin / Anna Weaver)</u></p> <p>This application was previously reviewed at the IGARD business as usual (BAU) meeting on the 26<sup>th</sup> September 2019, where IGARD had made a recommendation to approve, with a number of amendments, including:</p> <ol style="list-style-type: none"> <li>1. To add a special condition in section 6 stating that a report will be provided to NHS Digital in 12-months; including (but not limited to) how many NHS organisations the applicant is working for as a result of receiving this data and examples of work done demonstrating the requirement for the extent of data provided.</li> </ol> <p>IGARD noted that at the IGARD BAU meeting on the 4<sup>th</sup> November 2021, NIC-243790-Y8K8C Carnall Farrar Limited was discussed under 'Applications progressed via NHS Digital's Precedent route'; and noted that this amendment was still outstanding. IGARD therefore requested that confirmation was provided in March 2022 that the report had been received by NHS Digital, and that that failure to submit this would be a breach of the Data Sharing Agreement.</p> <p>IGARD noted and thanked NHS Digital for providing a copy of the report (via the Secretariat) for information, in advance of the meeting. IGARD noted that it was an informative report which indicated appropriate processing in line with the applicant's DSA.</p> <p><u>NIC-400304-S1P1B-v4 ONS (Presenter: Dave Cronin / Tania Palmariellodiviney )</u></p>

<p><b>7.2</b></p>	<p>This application was previously reviewed at the IGARD business as usual (BAU) meeting on the 27<sup>th</sup> January 2022, where IGARD had made a recommendation to approve with the following conditions:</p> <ol style="list-style-type: none"> <li>1. To provide a satisfactory procedure for the <b>prospective</b> review and approval of new projects under this agreement. To include the outline membership of the review committee (unless NSDEC is utilised), and to set out its terms of reference (which accord with similar oversight committee terms of reference for controllers holding large stores of NHS Digital data for programmatic access).</li> <li>2. To upload a copy of the procedure for the prospective oversight to NHS Digital's CRM system for future reference.</li> </ol> <p>Following an out of committee (OOC) review by members as per process, NHS Digital were notified (via the IGARD Secretariat) on the 15<sup>th</sup> February 2022, that the conditions had not been met; and IGARD had requested additional information from NHS Digital, as part of any future out of committee review.</p> <p>Noting that IGARD had not been asked to undertake any further OOC reviews, and noting the importance of the data required by ONS, IGARD requested that NHS Digital attended the meeting, to provide a verbal update on progress.</p> <p>IGARD and NHS Digital discussed the ongoing / outstanding issues with the OOC review, and noted that a further OOC review would be undertaken as per process, following the additional information being sent to the Secretariat, and once the application had been updated as appropriate, in line with <a href="#">IGARD's Out of Committee Process Standard Operating Procedure</a>.</p> <p>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.</p>
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## Appendix A

### Independent Group Advising on Releases of Data (IGARD): Out of committee report 25/02/22

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-258079-G7W1Y-v0.10	University College London (UCL)	07/10/21	1. In respect of the security arrangements: <ol style="list-style-type: none"> <li>To provide written confirmation (such as an e-mail) that NHS Digital's Security Advisor has expressed satisfaction that the appropriate security is in place.</li> <li>To upload the written confirmation from NHS Digital's Security Advisor to NHS Digital's CRM system for future reference.</li> </ol>	Quorum of IGARD Members	IGARD members	<p><b>IGARD made the following additional comments:</b></p> <p>IGARD noted that when the application was reviewed on the 7<sup>th</sup> October 2021, they had suggested the applicant carried out a DPIA, due to the possible contentious nature of the processing, and the sensitivities around the data. As part of this review, IGARD suggested that NHS Digital request a copy of the DPIA once completed, and upload it to NHS Digital's customer relationships management (CRM) system for future reference.</p> <p>IGARD also reiterated advice in respect of the PPIE undertaken to date within the application, and strongly suggested that the applicant undertakes PPIE, in some</p>

						form and throughout the lifetime of the DSA, given the significant amount of data flowing, public interests and wide scope of the application, and in line with the <a href="#">HRA guidance on Public Involvement</a> .
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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

## Appendix B

### GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 9<sup>th</sup> February 2022

<b>Application &amp; application version number: DARS-NIC-411161-G4K7X-v5.3</b>
<b>Organisation name: University of Oxford</b>
<b>Profession Advisory Group Agenda item: 2</b>
PAG notes that the amendment does not materially change the existing terms of use for the GDPR data; specifically, that the processing of the GDPR data will cease when the Covid-19 COPI notice ends.

Attendees	Role	Organisation
Jonathan Osborn	Deputy Caldicott Guardian	NHS Digital
Amir Mehrkar	GP, Clinical Researcher	RCGP
Mark Coley	Deputy IT Policy Lead	BMA
Liz Gaffney	Head of Data Access	NHS Digital
Garry Coleman	Senior Information Risk Owner (SIRO)	NHS Digital
Pam Soorma	Secretariat	NHS Digital
Frances Perry	Senior Case Officer	NHS Digital