

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 25 August 2022

IGARD MEMBERS IN ATTENDANCE:	
Name:	Position:
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member
Kirsty Irvine (Chair)	IGARD Chair
Dr. Imran Khan	Specialist GP Member (attended for Item 8.1)
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Chair
Dr. Maurice Smith	Specialist GP Member
Jenny Westaway	Lay Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Prof. Nicola Fear	Specialist Academic Member
Dr. Robert French	Specialist Academic / Statistician Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	Team:
Dani Breitingner-Blatt	Associate Director of Research and Clinical Trials at NHS Digital, (item 8.1)
Catherine Day	Data Access Request Services (DARS) (SAT Observer: item 8.1)
Dave Cronin	Data Access Request Services (DARS) (SAT Observer: item 3.4) (Item 8.2)
Louise Dunn	Data Access Request Services (DARS) (SAT Observer: item 3.2)
Liz Gaffney	Head of DARS (Observer: Item 8.1)
Russell Healy	Senior Delivery Manager, Data Services (Item 8.1)
Shaista Majid	Data Access Request Services (DARS) (Item 3.4)
Magda Martinez-Queipo	Programme Manager, Data Services (Item 8.1)
David Morris	Data Access Request Services (DARS) (Items 2.1, 3.1, 3.2)
Denise Pine	Data Access Request Services (DARS) (item 3.3)
Kimberley Watson	Data Access Request Services (DARS) (SAT Observer: items 2.1, 3.1, 3.3)

Vicki Williams	IGARD Secretariat Team
Tom Wright	Head of Data Services for Commissioners (DSfC) (item 2.1)
*SAT – Senior Approval Team (DARS)	

1	<p>Declaration of interests:</p> <p>Dr Maurice Smith noted a professional link to the Combined Intelligence for Population Health Action (CIPHA) data hub at Cheshire & Mersey Integrated Care System (ICS) (NIC-577815-R9L1J) by virtue of membership of Cheshire & Merseyside Integrated Care Board (ICB) committees connected with overseeing access to data held in CIPHA. It was agreed this did not preclude Dr. Smith from taking part in the discussions about this application, however that he would not participate in making a recommendation about the application.</p> <p>Review of previous minutes and actions:</p> <p>The minutes of the 18th August 2022 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record the meeting.</p> <p>Out of committee recommendations:</p> <p>An out of committee report was received (see Appendix A).</p>
2	Briefing Notes
2.1	<p><u>COVID Data Store – additional datasets briefing paper (Presenter: Tom Wright / David Morris)</u></p> <p>NHS England currently have two Data Sharing Agreements (DSA) with NHS Digital, the first being the National Commissioning Data Repository (NCDR) DSA (NIC-139035 -X4B7K) and the second, the COVID Data Store DSA (NIC-384608-C9B4L).</p> <p>The NCDR includes data to support NHS England in its commissioning responsibilities and the COVID Data Store DSA is specifically relating to NHS England's response to COVID-19 (see item 4.1 below)</p> <p>NIC-384608-C9B4L permits data from the NCDR to be linked to data in the COVID Data Store for the purposes listed within NIC-384608-C9B4L. However, data released under NIC-384608-C9B4L cannot be used for the purposes listed within the NCDR DSA.</p> <p>During the pandemic, several datasets flowed directly into NHS England from suppliers using the Notice issued by the Secretary of State for Health and Social Care under the Control of Patient Information (COPI) Regulations Regulation 2002 4(3) of which required the organisations to process data to support the response to COVID-19. The datasets that flowed directly into NHS England from suppliers were:</p> <ul style="list-style-type: none"> - Children and Young People – National Child Mortality Database (NCMD) - Intensive Care National Audit and Research Centre (ICNARC) - Vaccinations and Immunisations - Covid Therapeutics/Blueteq - Key Worker Tests - COVID Patient Notification System (CPNS)

- COVID-19 Hospitalisation in England Surveillance System (CHESS) / Severe Acute Respiratory Infection Watch (SARI-Watch)

Of these, DARS have onboarded the following datasets:

- ICNARC
- Key Worker Tests
- CHESS/SARI-Watch

Four of the datasets are not currently onboarded into DARS. NHS England require these datasets to continue their work relating to COVID-19. NHS England wish to move from receiving these datasets directly from suppliers to receiving the data from NHS Digital (via DSCRO). The datasets are yet to be onboarded into the DARS system as products. These are:

- Children and Young People – National Child Mortality Database (NCMD)
- Vaccinations and Immunisations
- COVID Therapeutics/Blueteq
- COVID Patient Notification System (CPNS)

NHS England have requested NHS Digital to disseminate this data via Data Services for Commissioners Regional Offices (DSCRO) and release to NHS England using the same pseudonymisation key as the NCDR. The data will be used for the purposes stipulated under the NIC-384608-C9B4L and permissions to link will only be to those listed within NIC-384608-C9B4L.

IGARD noted that NHS Digital may wish to review its internal processes to ensure that briefing notes to IGARD are approved by relevant approvers, and prior to submission to the IGARD agenda.

Separately, the IGARD briefing note template would be updated to include a new section which outlined any restrictions on processing for example legal basis, consent materials, or what is in the public domain.

Outcome: IGARD welcomed the briefing paper and made the following high-level comments:

1. IGARD noted that they had not been provided with a copy of the draft DPN which would have allowed them to give a fuller review of each of the data collections, and that a copy of the DPN should be provided with each individual dataset briefing paper.
2. IGARD suggested that NHS Digital produce a briefing paper for each new dataset, in line with usual practice and following the template of other onboarded datasets.
3. IGARD suggested that particular focus should be given to what the relevant data subjects had been told about a data collection (especially if there is limited transparency about the particular collection), and what mitigating steps might need to be taken to address any information gap. For example, what (family members of) data subjects have been told with regard to the use of data in the [National Child Mortality Database](#) (NCMD).
4. IGARD queried what happened to the flow of data already collected – would it cease, or would there be a period of dual running?
5. IGARD noted that there was no requirement to rely on COPI for the flow of pseudonymised data, as the data would not be subject to the Common Law Duty of Confidentiality (CLDoC).
6. Noting that NHS Digital may progress an application under the NHS Digital SIRO precedent due to perceived urgency, IGARD noted that they would be prepared to provide a retrospective assurance of the briefing papers (per dataset) and DPNs.

	IGARD welcomed the draft briefing paper and looked forward to receiving the finalised briefing paper, either out of committee (OOC) or tabled at a future meeting (before, or contemporaneously with, any first of type applications received by IGARD).
3	Data Applications
3.1	<p><u>NHS England (Quarry House): COVID-19 (Presenter: David Morris) NIC-384608-C9B4L-v6.2</u></p> <p>Application: This was an extension to NHS England's Data Sharing Agreement (DSA) which is due to expire on the 30th September 2022.</p> <p>It was also an amendment to 1) remove NHS Improvement (NHS Trust Development Authority and Monitor) as a Data Controller following the merger with NHS England on 1st July 2022, 2) to add the following datasets: COVID-19 UK Non-Hospital Antigen Testing Results (pillar 2), Intensive Care National Audit & Research Centre (ICNARC), and COVID-19 Hospitalisation in England Surveillance System (CHESS), 3) to update section 5 to justify the inclusion of the new datasets, and 4) to update the legal basis for dissemination in line with advice from Privacy, Transparency, Ethics & Legal (PTEL) to section s261(d) of the Health & Social Care Act 2012.</p> <p>COVID-19 has led to a change in demand on general practices (GPs), including an increasing number of requests to provide patient data to inform planning and support vital insights on the cause, effects, treatments and outcomes for patients of the virus. To support the response to the COVID-19 outbreak, NHS Digital has been legally directed to collect and analyse healthcare information about patients, including from their GP record, for the duration of the COVID-19 emergency period, under the COVID-19 Public Health Directions 2020 (COVID-19 Direction). All GP practices in England are legally required to share data with NHS Digital for this purpose under the Health and Social Care Act 2012. This collection will reduce burden on general practices, allowing them to focus on patient care and support the COVID-19 response. NHS Digital noted that the application was coming for advice.</p> <p>Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meetings on the 23rd July 2020, 6th August 2020, 27th May 2021, 23rd September 2021. It was also discussed under 'AOB on the 23rd June 2022.</p> <p>IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 21st July 2020, 4th August 2020 and 23rd March 2021.</p> <p>IGARD noted that this application had been reviewed at the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 22nd July 2020, (notes from that meeting had been attached to the IGARD minutes from the 23rd July 2020); the 5th August 2020 (notes from that meeting had been attached to the IGARD minutes from the 6th August 2020); the 31st March, 5th May, and 27th May 2021 (notes from that meeting had been attached to the IGARD minutes from the 27th May 2021); and 9th February 2022 (notes from that meeting are attached at Appendix B).</p> <p>IGARD noted that as part of the introduction, NHS Digital had stated that the application was coming for advice and would be proceeding down NHS Digital's SIRO precedent. Noting that this had not been notified to IGARD, they suggested that NHS Digital may wish to review their internal processes to ensure that section 1 (Abstract) clearly articulated that the application was coming to IGARD for advice alongside relevant narrative, and that the "<i>for recommendation</i>" be changed to "<i>for advice</i>".</p>

Noting the application was coming for advice, IGARD agreed with NHS Digital that they would provide a number of high-level comments for the NHS Digital SIRO.

IGARD noted the information in section 5(d) (Benefits) (iii) (Yielded Benefits) and suggested that the narrative was updated in line with the [NHS Digital DARS Standard for Expected Measurable Benefits](#), noting that Palantir had built analytical dashboards for access by NHS England plus expertise of data processors such as Faculty AI, McKinsey and Deloitte's staff who would access the large volume of pseudonymised data.

Noting the [Data Sharing in a Pandemic: Three Citizens' Juries](#) published recently, IGARD suggested that the benefits in section 5(d) be updated to reflect the public feedback on the transparency they would like to see about this data, and as set out in the publication.

IGARD suggested that the expected benefits outlined in section 5(d) (ii) (Expected Benefits) be moved to section 5(d)(iii) since those benefits should have been realised, and that new expected benefits be outlined in section 5(d)(ii), including target dates, based on what they expect those expected benefits to be, and based on the new data collections outlined in the application.

IGARD noted a number of benefits that had not happened or may not happen in section 5(d) and suggested that the applicant review and remove if necessary.

IGARD had a lengthy discussion with regard to the [NHS England COVID Data Store Privacy Notice](#) and in line with [NHS Digital DARS Standard for Transparency \(Fair Processing\)](#) suggested that it be updated to specifically mention the retention of data and remove reference to, for example but not limited to, "*emergency powers*". IGARD noted NHS England's [COVID 19 Data Dissemination Register](#) and were unclear what COVID-19 data was being disseminated by NHS England and whether that data linked to the Data Store and suggested that the COVID Data Store Privacy Notice be updated with further detail. In addition, and in line with the [Data Sharing in a Pandemic: Three Citizens' Juries](#) publication, suggested that more explanation be provided to the public for the ongoing need of the COVID Data Store.

IGARD noted there is a risk of a loss of public trust if NHS England are seen not to be acting on the outcomes from the recently published [Data Sharing in a Pandemic: Three Citizens' Juries](#), commissioned by the National Institute for Health Research (NIHR) Applied Research Collaboration Greater Manchester (ARC-GM), NHS England and National Data Guardian (NDG).

IGARD also noted that the lack of transparency with regard to what the data subjects had been told about the data collections (see briefing note points item 3.1 above) and that this was a risk to NHS Digital.

Noting the publicly available information on [NHS Digital's website](#) that at the expiry of the COPI notice (on 30 June 2022) organisations who received the NHS Shielded Patient List (SPL) needed to securely delete the information held, except where it formed part of the patient's medical record, IGARD asked that any reference to SPL within the application was checked to ensure it was still accurate, noting that section 5 (Purpose / Methods / Outputs) of the DSA forms part of [NHS Digital's data use register](#). In addition, IGARD suggested that if retaining SPL data, it be clearly articulated in section 5 what the permitted use of this was.

IGARD noted the large number of storage and processing locations (over 20) in section 2 (Locations), and, noting this may cause difficulty for NHS Digital in respect of auditing, suggested that NHS Digital worked with the applicant to review and consider if the locations could be consolidated, in line with [NHS Digital's DARS Standard for processing and storage locations](#).

IGARD queried the data access already given and data access requested in sections 3(a) (Data Sets Held) and 3(b) (Additional Data Access Requested) and suggested that the tables be updated to accurately reflect the factual scenario.

In line with the [NHS Digital DARS Standard for Data Minimisation](#), IGARD suggested that section 5 be updated to clearly articulate why no data minimisation was possible, noting that there was currently no narrative in the public facing section of the application which formed NHS Digital's data uses register.

IGARD noted reference in section 5(a) (Objective for Processing) and 5(b) (Processing Activities) to the Trusted Research Environment (TRE) and suggested that this was updated to reflect the latest status.

Noting that both NHSX and NHS Improvement (comprising of Monitor and TDA) had merged with NHS England as from 1st July 2022, IGARD suggested that the application be reviewed throughout to remove any 'retired' NHS entities and replace with "*NHS England*".

Outcome: IGARD were unable to make a recommendation as not all the necessary information was available in order for IGARD to make a full assessment. However, noting this application would proceed down the NHS Digital SIRO Precedent, IGARD made a number of high-level comments for the SIRO:

1. In respect of Yielded Benefits
 - a. To update the yielded benefits in line with [NHS Digital DARS Standard for Expected Measurable Benefits](#), and
 - b. To update the benefits to reflect the public feedback on the transparency they would like to see about this data use as set out in the [Data Sharing in a Pandemic: Three Citizens' Juries](#), and
 - c. To move the expected benefits in section 5(d)(ii) to the yielded benefits section 5(d)(iii) since those benefits should have already been realised, and
 - d. To insert new expected benefits in section 5(d)(ii), including targets dates, based on what they expect those to be, based on the new data collections, and
 - e. To remove any benefits from section 5(d) that have not happened or will happen.
2. In respect of Transparency and in line with the [NHS Digital DARS Standard for Transparency \(Fair Processing\)](#):
 - a. To update the COVID Data Store privacy notice to specifically mention the retention of the data, and
 - b. To update the COVID Data Store privacy notice to remove reference, for example but not limited to, "emergency powers", and
 - c. To clarify in the COVID Data Store privacy notice what data is being disseminated and how that data links to the uses register, and
 - d. To explain the ongoing need for the COVID Data Store in line with the comments made in the [Data Sharing in a Pandemic: Three Citizens' Juries](#) publication.
3. In respect of the SPL and in line with the [NHS Digital DARS Standards](#):
 - a. To update section 5(a) to remove any dated references, including but not limited to, SPL, and
 - b. If retaining the SPL data, to clearly articulate what the permitted use of this is, and
 - c. To ensure that any reference to SPL is accurate with regard to what is or is not happening with the SPL data, noting that section 5 of the DSA is published in the data uses register.
4. In line with the [NHS Digital DARS Standard for Data Minimisation](#), to update section 5 to clearly articulate why no data minimisation is possible.
5. To update the narrative in section 5 with regard to Trusted Research Environments to reflect the latest status.

	<p>6. IGARD noted the large number of storage and processing locations (over 20), and, noting this may cause difficulty for NHS Digital in respect of auditing, suggested that NHS Digital worked with the applicant to review and consider if the locations could be consolidated, in line with NHS Digital's DARS Standard for processing and storage locations</p> <p>7. To update the application to remove reference to any former NHS entities.</p> <p>8. To update section 3a / 3b to reflect data access already given and data access requested.</p> <p>Risk area: There may be a loss of public trust if NHS England are seen not to be acting on the outcomes from the recently published Data Sharing in a Pandemic: Three Citizens' Juries, commissioned by the NIHR, NHS England and NDG.</p> <p>Risk area: lack of transparency with regard to what the data subjects have been told about the data collections (see briefing note points).</p>
3.2	<p><u>NHS North & East CSU: HES data for all CSUs and NHS England 2020/21 (Presenter: David Morris) NIC-371243-H1P5T-v8.3</u></p> <p>Application: This was a renewal and extension to NHS England's Data Sharing Agreement (DSA) which expires on the 2nd September 2024.</p> <p>It was also an amendment to the purpose section of the DSA to include the further scope of the services provided to "<i>other CSU* clients</i>" through sharing aggregated data with small numbers suppressed in line with the HES analysis guide.</p> <p>*CSU – Clinical Support Units</p> <p>The purpose of the application is to allow CSUs, which are part of NHS England, to provide comprehensive business intelligence (BI) services to a wide range of organisations, this includes both standard analytics and reporting, deep-dives and diagnostic exercises to offer insight and intelligence on a commissioner's health economy. In addition, CSUs offer business intelligence applications allowing self-service access to a range of dashboards and configurable reports. Tools are available on a subscription-basis to NHS organisations, internally within the CSUs through specialist support teams, by Integrated Care Board (ICB) member practices, local authorities and other CSU clients. Other CSU clients will consist of organisations within a health and social care setting or companies where there is clear evidence of engagement with Organisations that reside in a health and social care setting, both within the UK and internationally. Other CSU clients will only consist of Organisations where there is the intention to enhance health and social care outcomes for patients under the jurisdiction of the associated health and social care organisation. The CSU will ensure direct engagement with local Health boards is implemented, including those residing outside the UK, or with partners supporting their initiatives.</p> <p>The application was previously considered on the 20th January 2022 where IGARD had deferred making a recommendation.</p> <p>Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the Data Access Advisory Group (IGARD's predecessor) / IGARD business as usual (BAU) meetings on the 10th November 2015, 30th August 2018, 29th August 2019, and the 20th January 2022.</p> <p>IGARD noted that the application had been updated to address most of the previous deferral points.</p> <p>IGARD noted that NHS Digital had shared with the IGARD Chair (via the IGARD Secretariat) written confirmation of the verbal update provided in meeting on the 20th January 2022 in</p>

relation to “*other CSU clients*” and noting the significant information contained within the correspondence the IGARD Chair had asked that section 1 (Abstract) be updated with this information. However, in respect of transparency and in line with the [NHS Digital DARS Standard for Transparency \(fair processing\)](#) IGARD noted that the CSU’s privacy notice(s) and application lacked clarity. IGARD suggested that the applications and CSU’s privacy notice(s) be updated to include a list of the recipient categories who may receive the data. In addition, that the application and CSU’s privacy notice(s) be updated to develop the category of “*other*” outlined, and to provide an indicative, but not exhaustive, list of who fell into the category of “*other*”.

IGARD noted that for those CSUs who were carrying out this activity, that they should ensure their privacy notice(s) were updated to reflect and that relevant documentary evidence was provided, and copies uploaded to NHS Digital’s customer relationship management (CRM) system.

IGARD also noted that for those CSUs carrying out this activity, that they should ensure their privacy notice(s) were updated to provide an overview of the governance processes, so that the public and anyone applying was aware of the process.

IGARD noted that there appeared to be no publicly available information either in the application or on the CSU website(s) with regard to the governance process and asked that section 5 (Purpose / Methods / Outputs) provided an indicative government process through which applications received and handled by the CSU would be assured that the processing undertaken, and outputs, would be used for the benefit of health and social care.

IGARD also suggested that the application be updated throughout with assurance that the CSU had the legal basis to process the data for all classes of applicants for the purposes outlined in the application, and in line with UK General Data Protection Regulations (UK GDPR).

IGARD noted that section 1 appeared to be missing crucial approval history information which would be helpful to IGARD as part of their review of the application and asked that this was reviewed.

IGARD reiterated previous advice that NHS Digital should consider auditing this organisation in relation to this application / DSA, due to the quantum of national data flowing and the unique processing arrangements

Outcome: recommendation to approve subject to the following conditions:

1. In respect of the governance process:
 - a. To update section 5 with an indicative governance process through which applications received and handled by the CSU will be assured that the processing undertaken, and outputs, will be used for the benefit of health and social care, and
 - b. To update the application with assurance that the CSU has the legal basis to process data for all classes of applicants for the purposes outlined in the DSA.
2. In respect of transparency and in line with the [NHS Digital DARS Standard for Transparency \(fair processing\)](#):
 - a. To update the application and CSU privacy notice(s) with a list of the recipient categories who may receive the data, and
 - b. To update the application and CSU privacy notice(s) to develop the category of “*other*” and provide an indicative, but not exhaustive, list of who falls into the category “*other*”, and
 - c. For those CSUs carrying out the activity, to ensure their privacy notice(s) are updated to reflect this activity, and

	<p>d. For those CSUs carrying out the activity, to ensure their privacy notice(s) provide an overview of the governance processes so that the public and anyone applying is aware of the process.</p> <p>The following amendment was requested:</p> <ol style="list-style-type: none"> 1. To update section 1 with the history of approvals. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD reiterated previous advice that NHS Digital should consider auditing this organisation in relation to this application / DSA, due to the quantum of national data flowing and the unique processing arrangements. <p>It was agreed the condition would be approved out of committee (OOC) by IGARD members.</p>
<p>3.3</p>	<p><u>University Hospital Birmingham (UHB) NHS Foundation Trust (FT): COVID-19 vaccination and disease and the risk of events and complications including major venous and arterial vascular events (Denise Pine) NIC-577815-R9L1J-v0.6</u></p> <p>Application: This was a new National Core Study (NCS) application for pseudonymised COVID-19 Vaccination Adverse Reaction data and COVID-19 Vaccination Status data on a monthly basis for a cohort of 27,200 individuals.</p> <p>The request for COVID-19 Vaccine data is supported by the Scientific Group for Emergencies (SAGE) and Sir Patrick Valance, UK Government Chief Scientific Adviser.</p> <p>The data obtained under this application will provide information about adverse events for the Birmingham population, who have attended the UHB emergency department or been admitted to one of the UHB hospital sites. The aim of the project is to explore the added value of enabling regional, acute care admissions and proxy data flows linked to key data sets such as Vaccination Status to enable surveillance and research on the COVID-19 vaccination programme – specifically to evaluate the safety and effectiveness of the vaccination programme and answer key questions of clinical, regulatory and policy importance, including the incidence of rare adverse events such vaccine-induced immune thrombocytopenia and thrombosis (VITT).</p> <p>The study is funded by the HDR UK Rapid funding programme.</p> <p>The study is relying on s251 of the NHS Act 2006, for the flow of data out of NHS Digital.</p> <p>Discussion: IGARD confirmed that they were of the view that the relevant s251 support was broadly compatible with the processing outlined in the application.</p> <p>Separate to this application, IGARD suggested that NHS Digital may wish to review their internal processes to ensure that applications were given adequate time on the agenda for review, especially if it was a new application with a sublicensing model.</p> <p>There was a lengthy discussion with regard to the sublicense model and IGARD asked that the terms and / or specific terms documentation provided as supporting documentation were compliant with the NHS Digital DARS Standard for Sub Licencing & Onward Sharing.</p> <p>IGARD noted that in line with the NHS Digital DARS Standard for Sub Licencing & Onward Sharing, that the terms and / or specific terms should be updated to clearly state that the territory of use was the United Kingdom (UK) and matched the territory of use outlined in section 2(c) (Territory of Use) of the data sharing agreement (DSA). In addition, IGARD suggested that supporting document 100 (DARS sub licence assessment) be updated to correctly reference the territory of use.</p>

<p>IGARD suggested that the terms and / or specific terms documentation be updated to remove reference to any international sharing, since the DSA did not allow for data to be shared internationally.</p> <p>IGARD noted that a query had been raised on supporting documents with regard to whether or not the NHS Digital DSA should be attached to the sub licensing documentation. IGARD noted that the terms and / or specific terms be updated to be clear that the DSA must be included as a schedule to the sub licence.</p> <p>IGARD thanked the applicant for providing a copy of the Data Trust Committee Terms of Reference (ToR). IGARD suggested that the TOR be updated to be clear that the committee should ensure that the territory of use was the UK only (in line with the DSA), that the use of data was non-commercial (in line with the DSA), and that the benefit must be for the benefit of health and social care.</p> <p>Noting the NHS Digital DARS Standard for Special Conditions IGARD suggested that the third party sub licensee special conditions in section 10 (Sub-Licensing) be inserted in section 6 (Special Conditions) repeating the sub licensing special condition that the applicant will publish a sublicense register. IGARD also noted that if practicable, that any outputs will cite the source of the data as “<i>this work uses data provided by patients and collected by the NHS as part of their care and support</i>” (https://www.usemydata.org/citation.php)</p> <p>IGARD noted the third-party sub licensee special condition listed in section 10 that “<i>PIONEER provide lay summaries of successful applications on the PIONEER website...</i>” and suggested that reference to “<i>as requested by NHS Digital</i>” be removed.</p> <p>IGARD suggested that section 5 (Purpose / Methods / Outputs) be updated to remove reference to “<i>it will...</i>”, and instead use a form of words such as “<i>it is hoped...</i>”.</p> <p>IGARD asked that as section 5 forms NHS Digital's data uses register, section 5(a) (Objective for Processing) was amended throughout, so technical terms were used only where necessary and explained in a manner suitable for a lay audience, for example “<i>enumerated population denominator</i>”.</p> <p>IGARD noted the projected dates for publication within the application, for example dates that were imminent, and asked that these were reviewed and updated as necessary to reflect the current position.</p> <p>IGARD asked that section 3(b) (Additional Data Access Requested) be updated to reflect the identifiability of the data and the correct s261 legal basis.</p> <p>IGARD noted the excellent patient and public involvement and engagement (PPIE) carried out and stressed the need for PPIE across the whole research cycle and beyond feedback and dissemination, in line with the HRA guidance on Public Involvement. Noting the continued public interest in outputs from this study, IGARD encouraged the applicant with the continuing dialogue on their website and through their online blogs.</p> <p>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 sublicensing arrangements.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. In respect of sublicensing: <ol style="list-style-type: none"> a. To ensure the application and supporting documents (terms and specific terms) are compliant with the NHS Digital DARS Standard for Sub Licencing & Onward Sharing, and
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	<ol style="list-style-type: none"> b. As required in the above Standard, to update the terms and / or specific terms to clearly state the territory of use is United Kingdom (i.e. matches that which is outlined in the DSA), and c. To remove any reference to international sharing from the terms and / or specific terms, since the DSA does not allow for data to be shared internationally, and d. to amend the terms and / or specific terms to be clear that this DSA must be included as a schedule to the sublicense, and e. to correct the analysis undertaken in SD100 with regard to territory of use. <ol style="list-style-type: none"> 2. In respect of the Data Trust Committee's ToR: <ol style="list-style-type: none"> a. To update the TOR to be clear that the territory of use is UK only, and b. To update the TOR to be clear that the use of data is non-commercial, and c. To update the TOR be explicit that the benefit must be for health and social care in the UK. 3. In respect of special conditions and in line with the NHS Digital DARS Standard for Special Conditions: <ol style="list-style-type: none"> a. To insert a special condition in section 6 repeating the amended (see 4 below) sublicense conditions in section 10 that the applicant will publish a sublicense register, and b. If practicable, any outputs will cite the source of the data as "this work uses data provided by patients and collected by the NHS as part of their care and support" (https://www.usemydata.org/citation.php) 4. In respect of the sublicensing special condition with regard to PIONEER publishing a register of approved applications, to remove "<i>as requested by NHS Digital</i>" 5. In respect of section 3(b): <ol style="list-style-type: none"> a. To update the identifiability of the data, and b. To update the s261 legal basis. 6. As section 5 forms NHS Digital's data uses register, to amend section 5 throughout, so technical terms are used only where necessary and explained in a manner suitable for a lay audience, for example, "<i>enumerated population denominator</i>". 7. To review the projected dates for publication within the application and update as necessary to reflect the current position. 8. To update section 5 to use a form of wording such as "<i>it is hoped ...</i>", rather than "<i>it will...</i>". <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. In respect of PPIE: <ol style="list-style-type: none"> a. IGARD noted the excellent patient and public involvement and engagement (PPIE) carried out and stressed the need for PPIE across the whole research cycle and beyond feedback and dissemination, in line with the HRA guidance on Public Involvement, and b. Noting the continued public interest in outputs from this study, IGARD encouraged the applicant with the continuing dialogue on their website and through their online blogs. 2. IGARD advised that they would wish to review this application when it comes up for renewal or extension, due to sublicensing arrangements. 3. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the sublicensing arrangements.
3.4	<p><u>Private Healthcare Information Network (PHIN): Acute Data Alignment programme (ADAPt) pilot 2 – SUS private healthcare APC data extract (participating NHS PPUs) (Shaista Majid) NIC-592501-J1M1X-v0.9</u></p>

Application: This was a new application for identifiable Secondary Uses Service (SUS) Admitted Patient Care (APC) (beta version). The data requested is related to The Acute Data Alignment Programme (ADAPt) which is a programme jointly run by PHIN and NHS Digital, in partnership with observers from the Department of Health & Social Care (DHSC), NHS England (NHSE), the Care Quality Commission (CQC), NHS Resolution, Getting It Right First Time (GIRFT), National Consultant Information Programme (NCIP) and the Independent Healthcare Providers Network (IHPN).

The application relates to Pilot 2 which will examine whether Private Healthcare APC data submitted by NHS providers (including private patient units) to NHS Digital via SUS could be used as an alternative to replace the existing need for NHS providers to submit almost identical data to PHIN to meet the Competition and Markets Authority (CMA) Private Healthcare Market Investigations Order 2014. This would reduce the burden upon NHS providers by removing an existing and duplicate data flow.

For background: Pilot 1 is the collection and processing of private healthcare APC data from PHIN and linkage to NHS funded activity and mortality data to demonstrate the feasibility of meeting customer needs. This is under a Secretary of State Direction; and Pilot 3 is the collection of private healthcare APC data directly from private healthcare providers via SUS to demonstrate that comparable data could be collected via NHS systems.

Discussion: IGARD had raised in advance of the meeting with NHS Digital a “big picture” issue in relation to the legal basis and if there were any relevant NHS Digital documents to support the legal basis outlined in the application. NHS Digital noted that they had discussed PHIN’s legal basis with Privacy, Transparency, Ethics & Legal (PTEL) but that these documents had not been provided to IGARD. Noting [IGARD’s Terms of Reference](#) that stated that NHS Digital would provide confirmation of the legal basis underpinning each application, IGARD asked that the full legal advice from PTEL which outlined the legal basis for PHIN to receive the data, including but not limited to any supplemental questions or answers between DARS and PTEL be provided. In addition, that written confirmation be provided that the legal basis cited as s261(4) was the correct subsection for NHS Digital’s dissemination.

In line with [NHS Digital’s DARS Standard for Data Controllers](#), IGARD asked that written analysis was provided as to why the CMA was not considered a joint Data Controller, as borne out of the facts. A copy of the written analysis should also be uploaded to NHS Digital’s customer relationship management (CRM) system for future reference.

Noting the [Private Healthcare Market Investigation Order 2014](#), IGARD asked that the incorrect references were removed from the quoted excerpt article 21.1, and in particular remove reference to “PHIN” as the Order does not reference “PHIN” but references “*information organisation*”, for example: “...Every operator of a private healthcare facility shall, subject to article 21.3 and article 21.5, supply the **information organisation**...”. If reference to “PHIN” was required, then it should be included in any quoted wording from the Order in square brackets, for example “...Every operator of a private healthcare facility shall, subject to article 21.3 and article 21.5, supply the **[PHIN]**...”.

IGARD asked that the application be updated to clearly articulate how PHIN was operating as the named “*information organisation*” as outlined in the Order, since it was not clear.

IGARD noted reference within the application to “*using their existing legal powers*” or “*having legal powers*” and asked that these references were removed, since they were incorrect.

IGARD noted that the Moorfield Eye Hospital was part of pilot 2, however they were not flowing any private patient data to NHS Digital via SUS and asked that an explanation be

<p>provided in section 5 (Purpose / Methods / Outputs) of why they had been chosen as one of the three pilot 2 sites.</p> <p>IGARD had raised in advance of the meeting with NHS Digital a query with regard to pilots 1 and 3 outlined in the application, since it was unclear how the pilots had impacted on, or would impact, on pilot 2 (this application), and to provide an update in section 5 of the application.</p> <p>Noting the benefits outlined in section 5(d) (Benefits) and in line with the NHS Digital DARS Standard for Expected Measurable Benefits, IGARD asked that the benefits for pilot 2 were clearly delineated.</p> <p>IGARD noted that private patients may be surprised that their data was flowing to NHS Digital, and noting there appeared to be no transparency to private patients at the sites who were part of pilot 2 with regard to the flow of data to NHS Digital or the purpose of the pilot, suggested that the applicant communicate this to the pilot sites for them to address.</p> <p>IGARD also suggested that any generic text relating to the other PHIN projects and not relating to pilot 2 was removed, since they were not relevant to this application.</p> <p>IGARD also suggested that consideration be given with regard to opt outs and whether or not there was a case for upholding the National Data Opt-out (NDO), noting there was a precedent for applying the NDO even if legal obligation was used for the flow of data.</p> <p>Noting that NHS Improvement (comprising of Monitor and TDA) had merged with NHS England as from 1st July, IGARD suggested that the application be reviewed to remove any retired NHS entities and replace them with “<i>NHS England</i>”.</p> <p>As section 5 forms NHS Digital’s data uses register, IGARD asked that section 5(a) (Objective for Processing) was amended, to ensure that all acronyms upon first use be defined or technical terms of art explained if the meaning was not self-evident, for example “ADMICAT”, “R1K”, “RP6”, “RX1”.</p> <p>IGARD suggested that any colloquialisms such as “<i>get rid of</i>” be removed from section 5(a).</p> <p>IGARD also suggested that section 5 be revised to remove any duplicate text or wording.</p> <p>IGARD suggested that the section 5 be revised to use a lower case “<i>p</i>” when referring to “<i>NHS providers</i>” or use a different phrase, and to remove reference to “NHS PPU’s” or change to “<i>NHS providers</i>” if that is more accurate.</p> <p>Noting that section 5(e) (Is the purpose of this application in anyway commercial?) stated “<i>no</i>”, IGARD suggested that a brief explanation be provided, and in line with the NHS Digital DARS Standard for Commercial Purpose to note that this DSA will support private healthcare.</p> <p>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 legal basis (via a time-limited Order) and nature of processing (a time-limited pilot).</p> <p>Outcome: recommendation deferred as not all the necessary information was available in order for IGARD to make a recommendation:</p> <ol style="list-style-type: none"> 1. In respect of the reference to the Private Healthcare Market Investigation Order 2014 <ol style="list-style-type: none"> a. To update section 1 and section 5 to remove reference to “<i>PHIN</i>” when referencing the Private Healthcare Market Investigation Order 2014, article 21.1, since the Order does not reference “<i>PHIN</i>” but references “<i>information organisation</i>”, or b. To place “<i>PHIN</i>” in square brackets within the quoted wording from Order, for example “[<i>PHIN</i>]”. 2. In respect of PHIN

- a. To remove reference to PHIN “*using their existing legal powers*” or “*having legal powers*” since that is incorrect, and
- b. To explain how PHIN is operating as the named “*information organisation*” as outlined in the Order.
3. To provide a written analysis and in line with the [NHS Digital DARS Standard for Data controllers](#) as to why the CMA are **not** considered a joint Data Controller.
4. In respect of the legal basis:
 - a. To provide the full legal advice from PTEL which outlines the legal basis for PHIN to receive the data, including but not limited to, any supplemental questions or answers between DARS and PTEL.
 - b. To confirm that the legal basis cited as s261(4) is the correct subsection for NHS Digital’s dissemination.
5. To provide an explanation why Moorfield Eye Hospital is part of the pilot if they are not flowing any private patient data to NHS Digital via SUS.
6. To provide an update as to how pilot 1 and pilot 3 have impacted, or will impact, on pilot 2 (this application).
7. As section 5 forms [NHS Digital’s data uses register](#),
 - a. To remove any generic text relating to other PHIN projects and not relating to pilot 2, and
 - b. to amend section 5 throughout, to ensure acronyms or terms of art be defined upon first use, for example “ADMICAT”, “R1K”, “RP6”, “RX1”, and
 - c. to remove colloquialisms such as “*get rid of*” from section 5(a), and
 - d. To remove all duplicate text, and
 - e. To use a lower case “*p*” when referring to “*NHS providers*” or use a different phrase, and
 - f. To remove reference to “NHS PPU’s” or change to “*NHS providers*” if that is more accurate.
8. To briefly update section 5(e) and in line with the [NHS Digital DARS Standard for Commercial Purpose](#) to note that this DSA will support private healthcare.
9. To update the section 5(d) and in line with the [NHS Digital DARS Standard for Expected Measurable Benefits](#) to delineate what the benefits are for pilot 2.
10. To update the application to remove reference to “NHS Improvement”, noting it had merged with NHS England.

The following advice was given:

1. IGARD noted that there appeared to be no transparency to private patients at the sites who were part of pilot 2 with regard to the flow of data to NHS Digital or the purpose of the pilot.
2. IGARD suggested that consideration be given with regard to opt outs and whether or not there was a case for upholding the NDO, noting there was a precedent for applying the NDO even if legal obligation was used for the flow of data.
3. IGARD advised that they would wish to review this application when it comes up for renewal or extension, due to the novel legal basis (via a time-limited Order) and nature of processing (a time-limited pilot).
4. IGARD suggested that this application would not be suitable for NHS Digital’s Precedent route, including the SIRO Precedent, due to the novel legal basis (via a time-limited Order) and nature of processing (a time-limited pilot).

Application: This was a renewal application to permit the holding and processing of pseudonymised COVID-19 Hospitalization in England Surveillance System, COVID-19 Second Generation Surveillance System, COVID-19 Vaccination Status, Hospital Episode Statistics Accident and Emergency (HES A&E), Personal Demographic Service and Secondary Uses Service Payment By Results Episodes (SUS PBR).

It was also an amendment to **1)** remove the following datasets: HES Admitted Patient Care (APC), HES Outpatients, Emergency Care Dataset (ECDS); **2)** to add COVID-19 Ethnic Category dataset / Management Information Ethnic Category (MIECC) Dataset; **3)** to add COVID-19 UK Non-hospital Antigen Testing Results (Pillar 2 data); **4)** to add additional wording in section 5(b) (Processing Activities) to allow for receipt of all COVID-19 vaccines and boosters within 'Covid Vaccination Status' product (previously just first and second vaccine); **5)** to add UKHSA as a joint Data Controller.

The purpose of this application is to support the UK Health Security Agency (UKHSA) (previously PHE) surveillance system on household transmission of COVID-19 to enhance the national public health surveillance of COVID-19 infections in the population of England. COVID-19 laboratory and case data from UKHSA will be linked to NHS Digital controlled data sets using a one-way encrypted versions of NHS number and unique property reference number to identify the household contacts of COVID-19 patients. This linked dataset is called “HOSTED” and is used to establish the COVID-19 status and associated outcomes of these household contacts.

The HOSTED data sets will be used to identify: **a)** the testing status of household contacts **b)** secondary cases of COVID-19 infection among household contacts **c)** hospital admissions for COVID-19 among household contacts **d)** risk factors for Covid-19 among household contacts **e)** deaths from COVID-19 among household contacts.

Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD BAU meeting on the 17th March 2022; where the application had been recommended for approval with conditions and amendments.

IGARD noted that, as outlined in the Out of Committee (OOC) Standard Operating Procedure, any applications returned to the IGARD Secretariat for review OOC by the IGARD Chair or quorum of IGARD Members which were over three months old, would be automatically placed on the next available BAU meeting agenda for review by IGARD Members as per the current standard processes. Members would only review if the conditions have been met or not, and would not re-review the application, unless significant legislative or policy changes had occurred since last reviewed by a full meeting of IGARD or the application had been significantly updated, in which case the conditions may be updated to reflect such changes which will be noted for transparency in the published minutes and a full review of the application undertaken.

The multi-limbed conditions from the 17th March 2022 BAU meeting was as follows:

1. In respect of the security assurance:
 - a) To provide written confirmation (such as an e-mail) that NHS Digital’s Security Advisor has expressed satisfaction that the activities in this DSA have appropriate security in place.
 - b) To upload a copy of the written confirmation to NHS Digital’s CRM system for future reference.

	<ol style="list-style-type: none"> 2. To confirm that the Data controller(s) are appropriately described in the application reflecting, as may be required, the publicly available framework document between DHSC and UKHSA. 3. In respect of the COVID-19 Ethnic Category dataset / MIECC: <ol style="list-style-type: none"> a. To provide written confirmation that PAG have reviewed the data and are content, as per the review process notified to IGARD; or, b. That the policy pathway has changed, and to provide written confirmation to IGARD of what that policy is now; and c. To upload a copy of the written confirmation to NHS Digital's CRM system for future reference. 4. In respect of PPIE <ol style="list-style-type: none"> a) To explain why it was not deemed appropriate to seek the views of the data subjects or their representatives prior to processing and include that narrative in the DPIA as per UK GDPR Article 35(9): b) To provide an indicative plan of future PPIE activity, in line with HRA guidance on Public Involvement. <p>A quorum of IGARD members were content that the multi-limbed conditions had been met.</p>
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> <p><u>North West EHealth Limited NIC-290527-P5C0Y-v2.2 (No presenter)</u></p>
4.1	<p>The purpose of this application was for a feasibility study aiming to increase the understanding of the profile and characteristics of patients with unexplained Refractory Chronic Cough by understanding the healthcare resource utilisation and treatment patterns of these patients.</p> <p>IGARD noted that this application was last reviewed at the IGARD business as usual meeting on the 15th April 2021 where IGARD had recommended for approval the flow of data in accordance with the timeframes set out within the patient consent.</p> <p>IGARD noted that on the 17th August 2022, NHS Digital had advised in writing (via the IGARD Secretariat) that this application had proceeded via NHS Digital's SIRO Precedent, for a three-month extension to hold but not process the data only and to allow the applicant to submit an application for a long-term agreement for archiving purposes only.</p> <p>IGARD noted and thanked NHS Digital for the written update and reiterated their previous advice, namely:</p> <ol style="list-style-type: none"> 1. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment due to the speculative and commercial nature of the application, save for this particular SIRO approval. 2. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, save for this particular SIRO approval. 3. IGARD drew to the attention of NHS Digital, the specific requirement in the consent materials, that the data would only flow from 5 years before and 2 years after the date of diagnosis, and to ensure that the data flow is in accordance with the express consent given by participants.
6	<p><u>Oversight & 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. Due to the volume and complexity of applications at</p>

	<p>today's meeting, IGARD were unable to review any Data Access Request Service (DARS) applications as part of their oversight and assurance role.</p> <p>The NHS Digital SIRO was currently reviewing the feedback provided on the IG release registers by IGARD for the period March 2020 to May 2022, alongside the process of review, and as discussed on the 11th August 2022, would come back to IGARD in due course with any feedback or response.</p> <p>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. IGARD noted that May 2022 appeared to be outstanding, following them returning their comments on the May 2022 release register on 1st July 2022.</p>
7	<p><u>COVID-19 update</u></p> <p><i>No items discussed</i></p>
8	<p><u>AOB:</u></p>
8.1	<p><u>Trusted Research Environment (TRE) programme of work and engagement with IGARD (Presenters: Magda Martinez-Queipo / Russell Healey / Dani Breitingner-Blatt)</u></p> <p>NHS Digital attended to provide an update on the TRE programme of work and their plans for engaging with IGARD.</p> <p>The discussion covered a wide range of topics including, but not limited to, how the NHS Digital TRE sits alongside other TREs within the NHS and wider data landscape, the accreditation of TREs, how much data the TRE would hold, what data it currently holds, an overview of the pilot / beta stage, transparency to the public, the difference between a TRE and a Secure Data Environment (SDE), opt-outs, consultation with stakeholders (internal and external), use cases and the future, communications, governance, preferred partners for research, limitation or exclusion of commercial organisations, whether GP data would be held in the TRE and timescales.</p> <p>NHS Digital suggested that Nicola Brassington be invited to a future IGARD meeting to discuss TREs.</p> <p>IGARD thanked NHS Digital for attending and looked for to a more focused agenda and discussion in approximately 6 weeks' time and 6 weekly thereafter, as a standing item.</p>
8.2	<p><u>Imperial College London (Presenter: Dave Cronin) NIC-283774-B9Z6K-v0.19</u></p> <p>A member of the Senior Approvals Team (SAT) attended IGARD to request the "recommendation to approve for 1 year subject to the following condition" be amended to "recommendation to approve subject to the following condition".</p> <p>Although NHS Digital had proposed at last week's IGARD meeting a one-year Data Sharing Agreement (DSA), they noted that based on current timescales relating to a Data Production that it would only give the applicant a small window to receive and work on the NHS Digital data before having to come back to NHS Digital for an extension.</p> <p>Noting that a justification had already been provided in the application for the three-year DSA and that IGARD had only recommended for one year based on advice from NHS Digital, IGARD agreed to remove "1 year" from the 18th August 2022 recommendation and prior to ratification of the minutes, and to include a "subsequent to the meeting" as an explanation to tie it to these minutes.</p>

8.3	<p><u>UK Health Security Agenda (HAS) Data Controllership</u></p> <p>NHS Digital provided a written update to IGARD with regard to UKHSA's Data Controllership, following the Public Health England (PHE) Data Sharing Agreement (DSA) transition to UKSHA and Office for Health Improvement & Disparities (OHID) briefing at IGARD on the 23rd June 2022.</p> <p>Privacy, Ethics, Transparency & Legal (PTEL) had confirmed to the SIRO that as the UKHSA are an executive agency of the Department of Health & Social Care (DHSC) and not a legal entity they cannot be a Data Controller. NHS Digital noted that relevant appropriate wording had been included on all UKSHA DSAs.</p> <p>IGARD thanked NHS Digital for the written update.</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 19/08/22

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-615960-G7W1L-v0.3	NHS Kent & Medway Integrated Care Board (ICB)	30/06/22	<ol style="list-style-type: none"> In respect of terminology around the initialisms CCG / ICB <ol style="list-style-type: none"> To update the application throughout to remove reference to “CCG” and replace with “ICB”, and To remove reference to “merger” to clearly articulate the legislative framework, timeframes, the dissolution of CCGs and the formation of the new ICB entities, and To clearly articulate the ICB’s legal responsibility in section 5 that the ICB can identify cohorts of patients for service providers to provide the most appropriate care, but the ICB cannot provide direct care, and To be clear in section 5 that the re-identification of individuals and cohorts are different processes and recognised as such. 	IGARD Members	Quorum of IGARD Members	<p>We believe condition 1f would be met, for this application, with this wording: <i>“Their organisation / department has completed the latest available version of the DSPT assessment or has produced the previous version of the DSPT within the last 12 months; or if the organisation is an ICB, the former CCG completed the latest available version of the DSPT assessment and the ICB commits to abide by it,”</i></p> <p>This will only work where the ICB footprint is the same as a previous CCG. If there were multiple CCGs it will need further thought. Such a situation needs to be</p>

			<p>e) To update section 5 to be clear that the DSPT for the year 2021/2022 was submitted by the CCG, and that the ICB will submit a DSPT for the year 2022/23 onwards, and</p> <p>f) To update section 6 to ensure that the DSPT covers the relevant bodies and is in line with point (c) above.</p>			<p>discussed with the NHS Digital Security Advisor to determine what wording/approach would be appropriate.</p> <p>In addition to the comments above in respect of condition 1f, we have also received the following comments on the amendments / template:</p> <p>a) Section 1b. It is still stated "The ICB has submitted the 21/22 DSPT in the former CCG name". This is incorrect. The ICB will be relying on the DSPT submission of the former CCG. This does seem to have changed in the template (SD1.0).</p> <p>b) Section 5b. The agreement erroneously states "This Agreement novates the CCG's DSA." This statement needs to be deleted. It also appears in the template.</p>
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NIC-616046-J1Q0N-v0.2	NHS Norfolk and Waveney Integrated Care Board	21/07/22	<ol style="list-style-type: none"> 1. In respect of the ICP / ICP Constituent data controllership and in line with the NHS Digital DARS Standard for Data Controllers: <ol style="list-style-type: none"> a) To provide written confirmation in section 5(a) that the ICP (save for the ICB) do not carry out data controllership activities; and b) To provide written confirmation in section 5(a) that the ICPs constituent members (save for the ICB) do not carry out data controllership activities; and c) To update section 5(a) with confirmation that the ICP / ICP Constituent members (save for the ICB) will not make any decisions on sub-licensing; and d) To add a special condition in section 6 that the ICP and / or the ICPs constituent members (save for the ICB) do not carry out data controllership activities, that they will not make any decisions on sub-licensing. e) Should the ICP or any constituent of the ICS wish to undertake data controllership activities then they will need to apply for an amendment as per DARS processes. 2. In respect of transparency: <ol style="list-style-type: none"> a) To update the application in line with NHS Digital's DARS Standard for Transparency (fair processing); and, b) To update the special condition in section 6, to state that they must have a UK GDPR compliant, publicly accessible 	IGARD members	Quorum of IGARD Members	We agree that both conditions have been MET or addressed via suitable wording, however 1(e) has been left off the response (possibly because the draft outcomes were referred to, not the ratified ones?) but note that the wording in 1a covers the situation. Please ensure that the abstract contains the ratified published IGARD Minutes and that responses to OOC's are based on the ratified published outcomes (SAT – internal process review please).
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			<p>transparency notice that is maintained throughout the life of the agreement; and,</p> <p>c) To update section 5(b) to state that they will have a UK GDPR compliant, publicly accessible transparency notice that is maintained throughout the life of the agreement.</p> <p>d) To update the application in line with NHS Digital DARS standard for sub-licencing and onward sharing; and,</p> <p>e) To add a special condition in section 6 that a sub-licence register will be published in the public domain on a quarterly basis; and,</p> <p>3. To update section 5(a) to confirm that a sub-licence register will be published on a quarterly basis.</p>			
NIC-486044-S3T0J-v0.16	London School of Hygiene and Tropical Medicine	21/07/22	<p>1. In respect of the data requested:</p> <p>a) To provide written confirmation in section 5(a) as to how the Study Team are determining who has had Norovirus; and</p> <p>b) To provide written confirmation in section 5(a) of any data linkage to the UKHSA data; or</p> <p>c) To provide written confirmation in section 5(a) if it is an ecological study; and</p> <p>2. If it is an ecological study, to provide confirmation in section 5(a) as to why aggregated data would not be sufficient and why patient level data is required.</p>	IGARD Members	Quorum of IGARD Members	N/A

NIC-615958-F7Q7Z	NHS Bristol, North Somerset and South Gloucestershire ICB	28/07/22	<ol style="list-style-type: none"> 1. In respect of the ICP / ICP Constituent data controllership and in line with the NHS Digital DARS Standard for Data Controllers: <ol style="list-style-type: none"> a) To provide written confirmation in section 5(a) that the ICP (save for the ICB) do not carry out data controllership activities; and b) To provide written confirmation in section 5(a) that the ICPs constituent members (save for the ICB) do not carry out data controllership activities; and c) To update section 5(a) with confirmation that the ICP / ICP Constituent members (save for the ICB) will not make any decisions on sub-licensing; and d) To add a special condition in section 6 that the ICP and / or the ICPs constituent members (save for the ICB) do not carry out data controllership activities, that they will not make any decisions on sub-licensing. e) Should the ICP or any constituent of the ICS wish to undertake data controllership activities then they will need to apply for an amendment as per DARS processes. 2. In respect of the University data controllership and in line with the NHS Digital DARS Standard for Data Controllers: <ol style="list-style-type: none"> a) To provide written confirmation in section 5(a) that the Universities do not carry out data controllership activities; and 	IGARD Members	Quorum of IGARD Members	<p>The abstract gives responses to the draft conditions not the ratified conditions (although these are included later in the abstract). Please ensure that the abstract contains the ratified published IGARD Minutes ONLY and that responses to OOC's are based on the ratified published outcomes (SAT – internal process review please).</p> <p>Amendment: "<i>To explain the data processing roles of the University of Bristol and the University of the West of England in section 5(a).</i>" - the roles of the two universities have not been explained (it has simply been restated that they are data processors) – please <u>explain</u> the roles. <i>Background:</i> The concern is that the line between commissioning and research will be blurred as will the data controllership. We are reassured by the related special condition. We would ask that the special condition is brought to the</p>
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			<p>b) To add a special condition in section 6 that if the Universities do not carry out data controllership activities</p> <p>3. In respect of transparency:</p> <p>a) To update the application in line with NHS Digital's DARS Standard for Transparency (fair processing); and,</p> <p>b) To update the special condition in section 6, to state that they must have a UK GDPR compliant, publicly accessible transparency notice that is maintained throughout the life of the agreement; and,</p> <p>c) To update section 5(b) to state that they will have a UK GDPR compliant, publicly accessible transparency notice that is maintained throughout the life of the agreement.</p> <p>d) To update the application in line with NHS Digital DARS standard for sub-licencing and onward sharing; and</p> <p>e) To add a special condition in section 6 that a sub-licence register will be published in the public domain on a quarterly basis; and</p> <p>4. To update section 5(a) to confirm that a sub-licence register will be published on a quarterly basis.</p>			<p>attention of the applicant for them to share with the universities in addition to explaining the data processing roles of the Universities in the public facing section of the application.</p>
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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, 9th February 2022

Application & application version number: DARS-NIC-384608-C9B4L-v5.2
Organisation name: NHS England
Profession Advisory Group Agenda item: 4 AOB
<p>PAG understands that NHS England will add a derived data item (a simple yes flag) for individuals with a severe mental illness to add to the vaccine analysis to be processed by Foundry/Palantir. That no other data will flow into Foundry.</p> <p>Please could NHS England clarify the purpose of this dataset and will the dataset update if it changes in the GDPR.</p> <p>PAG support this application.</p>

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
Duncan Easton	Data Approvals Officer	NHS Digital
Michael Ball	Case Officer	NHS Digital