

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 24 March 2022

IGARD MEMBERS IN ATTENDANCE:	
Name:	Position:
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member
Dr. Robert French	Specialist Academic / Statistician Member (Observer)
Kirsty Irvine	IGARD Chair
Dr. Imran Khan	Specialist GP Member
Dr. Maurice Smith	Specialist GP Member
Jenny Westaway	Lay Member (Observer)
IGARD MEMBERS NOT IN ATTENDANCE:	
Prof. Nicola Fear	Specialist Academic Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Chair
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	Team:
Michael Ball	Data Access Request Services (DARS) (Items 3.4 - 3.5)
Ricky Brooks	Data Access Request Services (DARS) (Observer: items 3.1 - 3.3)
Michael Chapman	Director of Research and Clinical Trials (Observer: item 3.1)
Dave Cronin	Data Access Request Services (DARS) (Item 3.1) (SAT* Observer: items 3.2)
Louise Dunn	Data Access Request Services (DARS) (SAT* Observer: items 3.3)
Dickie Langley	Privacy, Transparency & Ethics (Observer: item 3.1)
Karen Myers	IGARD Secretariat
Dr. Jonathan Osborn	Deputy Caldicott Guardian (Observer: 3.1 - 3.3)
Tania Palmariellodiviney	Data Access Request Services (DARS) (SAT* Observer: items 3.4 - 3.5)
Stuart Richardson	Data Access Request Services (DARS) (Items 2.1)
Charlotte Skinner	Data Access Request Services (DARS) (Item 3.3)

Gemma Walker	Data Access Request Services (DARS) (Observer: item 3.2)
Anna Weaver	Data Access Request Services (DARS) (Item 3.2)
Vicki Williams	IGARD Secretariat
NHS ENGLAND / IMPROVEMENT STAFF IN ATTENDANCE:	
Raj Bhatt	NHS England / Improvement (Item 2.1)
*SAT – Senior Approval Team (DARS)	

1	<p>Declaration of interests:</p> <p>Maurice Smith noted professional links to AIMES Management Service [NIC-94250-L8W8T] but no specific connection with the application or staff involved and it was agreed that there was no conflict of interest.</p> <p>Paul Affleck noted professional links to AIMES Management Service [NIC-94250-L8W8T] but no specific connection with the application or staff involved and it was agreed that there was no conflict of interest.</p> <p>Dr. Imran Khan noted a professional link to NHS Buckingham CCG [NIC-400077-T4C4V-v1.4]. It was agreed that Dr. Khan would not remain in the room for the discussion of that application.</p> <p>Review of previous minutes and actions:</p> <p>The minutes of the 17th March 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 of 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>NHS Continuing Health Care Patient Level Data Set Briefing Paper (Presenters: Stuart Richardson / Raj Bhatt)</u></p> <p>The briefing paper was to inform IGARD about the NHS Continuing Healthcare (NHS CHC) data set, which is a patient level, output based, secondary uses data set, which aims to deliver robust, comprehensive, nationally consistent, and comparable person-based information for people (over the age of 18 years) accessing NHS CHC services and NHS-funded Nursing Care located in England.</p> <p>NHS CHC means a package of ongoing care that is arranged and funded solely by the NHS where the individual has been assessed and found to have a 'primary health need' as set out in the National Framework for NHS Continuing Healthcare and NHS-funded Nursing.</p> <p>The benefits of implementing this dataset will allow a much richer patient level dataset to fully understand the patient pathway from initial checklist to care package. The move to this dataset will provide opportunities to determine if there are health inequalities, how long patients are waiting for their package of care, are care package reviews taking place as scheduled etc.</p>

	<p>IGARD welcomed the draft briefing paper.</p> <p>IGARD looked forward to receiving a copy of the finalised briefing paper, and any relevant supporting documents, at a future meeting of IGARD alongside the first of type application at IGARD, as per usual practice.</p> <p>Separate to the briefing paper, IGARD provided high-level comments including, but not limited to:</p> <ol style="list-style-type: none"> 1. NHS Digital to update their website for enhanced transparency about the legal basis for the data flow to NHS Digital and to make clear that the data flow is not based on consent. 2. IGARD agreed to provide comments out of committee on the NHS England consent materials (which will be couched as advice and not impacting on the onboarding of the dataset or its use).
3	Data Applications
3.1	<p><u>Office for National Statistics (ONS): ONS Longitudinal Study (Presenter: Dave Cronin) NIC-194340-D6F3B-v1.2</u></p> <p>Application: This was an extension and renewal application to permit the holding and processing of identifiable Demographics data; for the purpose of a Longitudinal Study (LS), which is the largest longitudinal data resource in England and Wales, and contains linked census and life events data for an approximate 1% sample of the population of England and Wales.</p> <p>The study has linked records at each census since the 1971 Census, for people born on one of four selected dates in a calendar year. These four dates were used to update the sample at the 1981, 1991, 2001 and 2011 Censuses. Life events data are also linked for LS members including births to sample mothers, deaths and cancer registrations. The LS now holds data relating to approximately 1.2 million people.</p> <p>The data requested will be used for three purposes: 1) maintenance of the LS Research Database; 2) providing access to the LS Research database; 3) adding 2021 Census data to the LS.</p> <p>Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 22nd October 2020 and 11th February 2021.</p> <p>IGARD welcomed the application and noted the importance of this long running study.</p> <p>IGARD noted that the application was coming for advice on 1) ethics; 2) the right to be informed / transparency and 3) the legal basis for processing special category data; and without prejudice to any additional issues that may arise when the application is fully reviewed. IGARD noted that, as part of the meeting pack, NHS Digital had provided a briefing paper outlining further details on each of the advice points.</p> <p>IGARD reiterated their previous advice point from the 11th February 2021 where they had suggested that if the National Statistician's Data Ethics Advisory Committee (NSDEC) had not yet discussed the ethical support for the Longitudinal Study, that NHS Digital confirm with the applicant that this was on the next Advisory Board's meeting agenda, scheduled for the 17th February 2021; and if this item was not on the agenda, that confirmation was provided by the applicant that this would be on the next available agenda slot. IGARD noted that the Longitudinal Study had not been presented to NSDEC as per their previous advice, and that</p>

ONS had completed an Ethics Self-Assessment form. Given the magnitude and nature of the study, IGARD suggested that a self-assessment was not the appropriate pathway and that, as a minimum, NSDEC should review the Longitudinal Study. IGARD also noted that since the study involved processing identifiable healthcare data it may fall within the remit of the Health Research Authority.

IGARD noted that as the role of the Health Research Authority (HRA) was to protect and promote the interests of patients and the public in health research, the applicant should consult the HRA to see if the Longitudinal Study requires a review by a HRA Research Ethics Committee.

IGARD noted that the applicant has undertaken to furnish a UK General Data Protection Regulation (UK GDPR) compliant privacy notice, and reiterated previous advice from the 11th February 2021 that it would aid transparency if the flow of data to NHS Digital was also noted in the privacy notice. In addition, IGARD noted the importance of transparency in respect of being clear to the data subjects of the long running study, what rights they have, and that this should be done in collaboration with the Information Commissioner's Office (ICO).

IGARD suggested that ONS could consult with the Information Commissioner's Office about what information should be provided to the public to enable data subjects included in this study to exercise their UK GDPR rights.

IGARD noted that NHS Digital data was limited to identifying demographic data and does not involve any special category data. However, giving consideration to the further linkage to special category data (including cancer registration), IGARD suggested that for the purpose of transparency, a UK GDPR Article 9 legal basis should be cited within a study privacy notice.

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 significant amount of data flowing and the national importance of the processing.

Outcome: IGARD welcomed the application which came for advice and without prejudice to any additional issues that may arise when the application is fully reviewed.

1. IGARD noted the NHS Digital briefing note provided, and endorsed its content, including, but not limited to:
 - a) Ethics,
 - b) The Right to be informed / transparency,
 - c) Legal basis for processing special category data.

IGARD reiterated their previous advice given:

1. IGARD noted that the applicant has yet to meet its undertaking to furnish a UK GDPR compliant privacy notice, and reiterated previous advice that it would aid transparency if the flow of data to NHS Digital was also noted in the privacy notice.
2. IGARD noted that the Longitudinal Study had **not** been presented to NSDEC as per their previous advice, and, given the magnitude of and nature of the study, suggested that a self-assessment was not the appropriate pathway and that as a minimum, NSDEC should review the Longitudinal Study.
3. IGARD advised that they would wish to review this application when it comes up for amendment, renewal or extension, due to the significant amount of data flowing and the national importance of the processing.

	<p>4. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the significant amount of data flowing and the national importance of the processing.</p> <p>IGARD also gave the following new advice:</p> <ol style="list-style-type: none"> 1. Given that the role of the Health Research Authority (HRA) is to protect and promote the interests of patients and the public in health research, the applicant should consult the HRA to see if the Longitudinal Study requires a review by a HRA Research Ethics Committee. 2. The ONS could consult with the Information Commissioner's Office about what information should be provided to the public to enable data subjects included in this study to exercise their UK GDPR rights.
3.2	<p><u>IQVIA Ltd: Hospital Treatment Insights (Presenter: Anna Weaver) NIC-13925-Q7R2D-v10.2</u></p> <p>Application: This was a renewal and extension application to permit the holding and processing of pseudonymised Emergency Care Data Set (ECDS), Hospital Episode Statistics Admitted Patient Care (HES APC), HES Critical Care, HES Outpatients and IQVIA Data Quality Reports.</p> <p>This is also an amendment to include details of three proposed uses of the data 1) Feedback report to Hospital Treatment Insights (HTI) hospitals - the HTI database will be used to generate a feedback report for participating hospitals. The feedback report is provided on an annual basis and is usually based on a therapy of interest to chief pharmacists. It provides them with a view of the use of the therapy in their own hospital compared with all hospital contributing data to HTI; 2) Assessing the utility of the Hospital Treatment Insights (HTI) database for the development of an algorithm for identification and mitigation of cardiotoxicity related to cancer treatments; 3) Investigation into the switching dynamics between reference biological medicines and biosimilars of biological disease modifying agents in England.</p> <p>The HTI contains unique information on diagnosis, treatment and drug usage across secondary care in England and has been linked to primary care data in the past. HTI is currently the only routinely collected population-based database available for monitoring the safety of medicines used in the secondary care setting.</p> <p>The study is relying on s251 of the NHS Act 2006, for the flow of contact details into NHS Digital.</p> <p>NHS Digital advised IGARD that although this application had been submitted to IGARD for a review and a recommendation, further work would need to be undertaken in line with IGARD's comments, to ensure that application was in line with NHS Digital's Data Access Request Services (DARS) Standards.</p> <p>NHS Digital advised IGARD that an audit of this organisation / data sharing agreement (DSA) was due to take place within the coming weeks.</p> <p>Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 15th November 2016, 20th December 2016, 8th June 2017 and 29th April 2021.</p> <p>It was also discussed under 'AOB' at the IGARD BAU meeting on the 2nd December 2021.</p> <p>IGARD noted and commended NHS Digital on the quality of the information provided within section 1 (Abstract) of the application, which supported the review of the application by Members.</p>

IGARD noted and supported the verbal update from NHS Digital, in respect of the ongoing work on this DSA, to ensure that the application was in line with [NHS Digital's Data Access Request Services \(DARS\) Standards](#).

IGARD noted and supported the verbal update from NHS Digital in respect of the forthcoming audit of this organisation as a matter of urgency in relation to this application / DSA, and any other live DSAs and in line with [NHS Digital's published policy](#).

IGARD noted the update to the application to include three specific projects, however asked that the application was updated throughout, to ensure that the three projects were suitably explained in sufficient detail, in accordance with [NHS Digital's standards](#). In addition, IGARD asked that section 5(c) (Specific Outputs Expected) was updated to reflect the outputs of the three projects, since no detail was currently provided.

IGARD noted that IQVIA's Independent Scientific Ethical Advisory Committee (ISEAC), did not appear to have fulfilled its function as described in the DSA and as per their Terms of Reference (ToR), which may undermine NHS Digital's confidence that IQVIA would ensure data was used for purposes which NHS Digital would be content to approve. IGARD noted that, at previous review, they had flagged the importance of transparency to the public. They had also asked that the minutes be provided to NHS Digital and to IGARD when the applicant returned to IGARD and that any useful work contained in the minutes be added to NHS Digital's publicly available release register. IGARD noted that the minutes may contain commercially sensitive information, however advised that did not stop IQVIA from sharing, for example, redacted minutes. IGARD noted a reputational risk to NHS Digital and risk to other commercial users of data that the applicant's non-compliance with the contractual terms (and requests from previous reviews) would significantly undermine the public's trust and confidence in use of their health data by commercial applicants.

IGARD noted references to "ISEAC" within the applicant's published transparency notice, and advised that any references would need reviewing to ensure the references to ISEAC reflected the factual scenario, and were not misleading or incorrect.

IGARD also asked that the application was reviewed and updated throughout to remove reference to programmatic access; and to remove reference to ISEAC having oversight of programmatic access, since there will be no mechanism for programmatic access.

Separate to this application, IGARD suggested that NHS Digital should review **all** IQVIA DSAs which are reliant on ISEAC undertaking oversight.

IGARD queried if IQVIA Ltd were the sole Data Controllers as outlined in section 1(b) (Data Controller(s)), for example, noting the reference within 5(a) to a collaboration with the University of Hertfordshire; noting the absence of any documentation for which the use of the data had been approved, which may provide further information in relation to data controllership. IGARD therefore asked that in line with the [NHS Digital DARS Standard for Data Controllers](#); the application was amended to confirm that the Data Controller(s) were appropriately described in the application reflecting the three projects outlined; and that the application was amended as may be required to ensure the correct Data Controllers were reflected as may be relevant, and as borne of the facts.

IGARD confirmed that they were of the view that the relevant s251 was broadly compatible with the processing outlined in the application; however queried if the applicant had continued to meet the Health Research Authority Confidentiality Advisory Group (HRA CAG) conditions of support; and asked that written confirmation was provided of the steps taken to meet the conditions, set out on HRA CAG's register, on an ongoing basis; and that the written

confirmation was uploaded to NHS Digital's customer relationship management (CRM) system for future reference.

IGARD also queried if the applicant has continued to meet the HRA Research Ethics Committee (HRA REC) conditions of support, for example, a publicly available register of research projects, and the steps taken to meet the conditions on an ongoing basis, and asked that written confirmation was provided. IGARD also noted that that last review by HRA REC was in 2020, and asked that for clarity, written confirmation was provided of the last HRA REC annual report from 2021. IGARD asked that the report was uploaded to NHS Digital's CRM system.

IGARD noted in section 5(a) that "*Sub-licencing of data is not permitted under this Agreement*", and references throughout the application to IQVIA sub-licensing. In addition, IGARD noted the special condition in section 6 (Special Conditions) "*Honorary contracts must not be used to grant external access as an alternative to sublicensing arrangements.*"; and also noted references within the application to researchers working under an honorary contract. IGARD therefore asked that the application was reviewed and updated throughout to remove references to "*sub-license*", and in line with the [NHS Digital DARS Standard for Sub-Licencing and Onward Sharing of Data](#), and "*honorary contract*".

IGARD queried the benefits outlined in section 5(d), and noted that some of the information provided were outputs, and asked that section 5(d) was updated to remove any outputs, and that these were moved to correctly sit in section 5(c); in line with the [NHS Digital's DARS Standard for Expected Measurable Benefits](#) and [NHS Digital DARS Standard for Expected Outcomes](#).

In addition, IGARD noted the yielded benefits in section 5(d) (iii) (Yielded Benefits), however asked that it was clear as to the benefits to both the patients and the health and social care system more generally, in line with the [NHS Digital's DARS Standard for Expected Measurable Benefits](#).

IGARD queried the statement in section 5(c) "*ALBs such as NICE, NHS Digital and NHS England will be able to access the pseudonymised, non-sensitive record level database...*"; and noting that it was unclear, suggested that for transparency, further investigative work was undertaken to determine what data NHS Digital receive; and that the application was updated accordingly.

IGARD noted that section 2(c) (Territory of Use) stated that the territory of use was "*England and Wales*", and in line with the [NHS Digital DARS Standard for Territory of Use](#) asked that the application was reviewed throughout, to remove any suggestion that data is accessed outside England or Wales, for example, the statement in section 5(a) "*...the data must be accessible across all 4 countries within the UK.*".

IGARD noted the reference within the application to the previous collaboration with the Clinical Practice Research Datalink (CPRD), and asked that for background / future reference, a brief narrative was added to section 1 clarifying why IQVIA's relationship with CPRD has now concluded.

IGARD noted the inclusion of a number of technical phrases and words within section 5 (Purpose / Methods / Outputs), such as "*attrition analysis*", asked that this public facing section, which forms [NHS Digital's data uses register](#), was amended throughout, to ensure technical terms are explained in a manner suitable for a lay audience.

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 history of non-compliance with requests; breach of contractual terms, and the sensitivity around commercial uses of data.

Outcome: unable to recommend for approval

1. In respect of the three projects outlined:
 - a) To update the application throughout to ensure the three projects are suitably explained in sufficient detail, in accordance with [NHS Digital's standards](#), and
 - b) To update section 5(c) to reflect the outputs of the three projects.
2. In respect of programmatic access:
 - a) To update the application throughout to remove reference to programmatic access, and
 - b) To update the application throughout to remove reference to ISEAC having oversight of programmatic access.
3. To update the application throughout to remove reference to "*sub-license*".
4. To update the application throughout to remove reference to "*honorary contract*".
5. To update the application throughout to ensure the territory of use is correctly stated as "*England and Wales*" and that there is no suggestion that data is accessed outside England or Wales.
6. In respect of the HRA REC conditions of support:
 - a) To provide written confirmation that the applicant has continued to meet the HRA REC conditions of support, for example, a publicly available register of research projects, and the steps taken to meet the condition on an ongoing basis, and
 - b) To provide written confirmation of the last HRA REC annual review, and
 - c) To upload a copy of the written confirmation to NHS Digital's CRM system.
7. In respect of the HRA CAG conditions of support:
 - a) To provide written confirmation that the applicant has continued to meet the HRA CAG conditions of support, and the steps taken to meet the conditions, set out on HRA CAG's register, on an ongoing basis, and
 - b) To upload a copy of the written confirmation to NHS Digital's CRM system.
8. To review the published transparency notice, to ensure the references to ISEAC reflect the factual scenario.
9. In respect of the data controllership and in line with the [NHS Digital DARS Standard for Data Controllers](#); to amend the application:
 - a) To confirm that the Data Controller(s) are appropriately described in the application reflecting the three projects outlined, and
 - b) To amend the application as may be required to ensure the correct Data Controllers are reflected as may be relevant.
10. As section 5 forms [NHS Digital's data uses register](#), to amend section 5 throughout to ensure that technical terms are used only where necessary and explained in a manner suitable for a lay audience, for example "*attrition analysis*".
11. In respect of section 5(d) benefits:
 - a) To remove any specific outputs from section 5(d) and move to section 5(c), and
 - b) To update the yielded benefits in section 5(d) (iii) in line with the [NHS Digital DARS Standard for expected measurable benefits](#).
12. To provide a brief narrative in section 1 as to why IQVIAs relationship with CRPD has now concluded.
13. IGARD suggested that NHS Digital should review **all** IQVIA DSA's, which are reliant on ISEAC undertaking oversight.
14. IGARD noted the reference within the application to NHS Digital receiving outputs as a result of this processing, and suggested that further investigative work was undertaken

	<p>to determine what data NHS Digital receive; and that the application was updated accordingly.</p> <p>15. IGARD supported NHS Digital's verbal update in respect of the audit of this organisation as a matter of urgency in relation to this application and any other live DSAs.</p> <p>16. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the history of non-compliance with requests and breach of contractual terms and the sensitivity around commercial uses of data.</p> <p>17. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the history of non-compliance with requests and breach of contractual terms and the sensitivity around commercial uses of data.</p> <p>Significant Risk Factor: Reputational risk to NHS Digital and risk to other commercial users of data that the applicant's non-compliance with the contractual terms (and requests from previous reviews) will significantly undermine the public's trust and confidence in use of their health data by commercial applicants.</p>
3.3	<p><u>North Bristol NHS Trust: The Renal Association, UK Renal Registry - audit application (Presenter: Charlotte Skinner) NIC-94250-L8W8T-v2.4</u></p> <p>Application: This was a renewal application to permit the holding and processing of identifiable Civil Registration (Deaths) - Secondary Care Cut, HES:Civil Registration (Deaths) bridge, Hospital Episode Statistics Admitted Patient Care (HES APC), HES Critical Care and HES Outpatients data.</p> <p>It was also an amendment to 1) to amend the Renal Association processing location; 2) to update the data minimisation to reflect the increase in cohort size and additional data years requested; 3) to update section 5 to provide further clarifying statements on the objective for Processing, Processing Activities, outputs and benefits; 4) to update the special condition in section 6 in relation to the Data Security and Protection Toolkit (DSPT).</p> <p>The UK Renal Registry was set up as a National Audit in 1995, reaching full coverage of the UK in 2007, its primary purpose remains national audit. Initially the UK Renal Registry collected data on people receiving dialysis treatment or a kidney transplant, but extended its audit remit in recent years to include: 1) all cases of acute kidney injury (AKI) in primary and secondary care from 2015 (following a level 3 Patient Safety Alert issued by NHS England); 2) all cases of advanced, pre-dialysis chronic kidney disease (stages 2 to 5) in secondary care from 2016.</p> <p>The purpose of the application is to perform the audit and quality improvement function of the UK Renal Registry.</p> <p>The study is relying on s251 of the NHS Act 2006, for the flow of contact details out of NHS Digital; and the cohort size for all patients (new and existing) is currently about 2.5 million.</p> <p>NHS Digital noted that the s251 support referenced linkage to National Institute for Cardiac Outcomes Research (NICOR), however confirmed that there was no linkage as part of this data sharing agreement (DSA).</p> <p>Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 1st March 2018.</p>

IGARD noted that the application incorrectly stated that 'North Bristol NHS Trust' were the applicant, and asked that the application was updated to correctly state that the applicant was 'The Renal Association'.

IGARD noted and commended the applicant on the patient and public involvement and engagement (PPIE), in particular the Patient Council, which IGARD noted had an excellent public facing [website](#), which was an exemplar to others.

IGARD confirmed that they were of the view that the relevant s251 was broadly compatible with the processing outlined in the application. IGARD noted the verbal update in respect of the NICOR linkage within the s251 support, and that this was not taking place under this DSA.

IGARD noted the amendment to the legal basis for flowing the data, and stated that although they felt the new legal basis was appropriate, queried whether consideration had been given to the UK General Data Protection Regulation (UK GDPR) implications of changing the Article 9 legal basis once processing was underway. IGARD noted the [ICO guidance](#) on this specific point, for example "*...retrospectively switching lawful basis is likely to be inherently unfair to the individual and lead to breaches of accountability and transparency requirements*". IGARD asked that the applicant provide written confirmation to NHS Digital that they had considered the UK GDPR implications of changing the Article 9 condition once processing was underway and that the relevant conditions in Schedule 1 Part 1 of the DPA 2018 had been satisfied; and that copy of the written confirmation was uploaded to NHS Digital's customer relationships management (CRM) system for future reference.

IGARD queried the yielded benefits outlined in section 5(d) (Benefits) (iii) (Yielded Benefits), and noted that some of the information provided were outputs, and asked that section 5(d) (iii) was updated to remove any outputs, and that these were moved to correctly sit in section 5(c) (Specific Outputs Expected); in line with the [NHS Digital's DARS Standard for Expected Measurable Benefits](#).

In addition, IGARD noted that the yielded benefits in section 5(d) (iii) contained expected benefits, and, in line with [NHS Digital's DARS Standard for Expected Measurable Benefits](#), asked that the expected were moved to section 5(d) (ii); and that the section retain the details provided on the specific yielded benefits accrued to date, and asked that it was clear as to the benefits to both the patients and the health and social care system more generally.

IGARD noted and commended the applicant on the plethora of benefits to patients that had been outlined within section 5(d).

IGARD suggested that the applicant may wish to apply for additional datasets, for example, BadgerNet; and that they would be supportive of this flow of data should the applicant wish to apply for it. If this dataset were added to the application, or was sourced from another controller and linked to the data in this application, IGARD would not need to re-review but would ask that an appropriate description of this additional data and processing should be added in section 5 for transparency.

Outcome: recommendation to approve

The following amendments were requested:

1. In respect of the legal basis:
 - a) The applicant to confirm to NHS Digital that they have considered the UK GDPR implications of changing the Article 9 condition once processing is underway and that the relevant conditions in Schedule 1 Part 1 of DPA 2018 have been satisfied, and

	<p>b) To upload a copy of the written confirmation to NHS Digital's CRM system.</p> <p>2. In respect of the benefits and in line with the NHS Digital's DARS Standard for Expected Measurable Benefits:</p> <p>a) To remove any specific outputs from section 5(d) (iii) and move to section 5(c), and</p> <p>b) To remove the expected benefits from section 5(d) (iii) and move to section 5(d) (ii), and</p> <p>c) To provide further details in section 5(d) (iii) of the specific yielded benefits accrued to date.</p> <p>The following advice was given:</p> <p>1. IGARD suggested that the applicant may wish to apply for additional datasets, for example, BadgerNet. IGARD would be supportive of this flow of data should the applicant wish to apply for it. If this dataset were added to the application, or was sourced from another controller and linked to the data in this application, IGARD would not need to re-review but would ask that an appropriate description of this additional data and processing should be added in section 5 for transparency.</p>
3.4	<p><u>NHS North West London CCG: DSfC - NHS North West London CCG - Comm, RS & IV (Presenter: Michael Ball) NIC-422205-F2Y2V-v2.2</u></p> <p>Application: This was an amendment application to 1) to add the following CCGs as Data Processors: NHS South West London CCG, NHS South East London CCG, NHS North West London CCG, NHS North East London CCG and NHS North Central London CCG; 2) the addition of GP Data linkage for the purposes of Commissioning; 3) the addition of Adult Social Care dataset for the purposes of commissioning; and 4) the addition of Mental Health Services Dataset.</p> <p>The overall purpose for this application is for: Invoice Validation (IV) which is part of a process by which providers of care or services are paid for the work they do; Risk Stratification (RS) which is a tool for identifying and predicting which patients are at high risk or likely to be at high risk and prioritising the management of their care; and to provide intelligence to support the commissioning of health services.</p> <p>NHS Digital advised IGARD that an audit of this organisation was due to take place within the coming weeks.</p> <p>Discussion: NHS Digital noted that the application had not previously been presented at an IGARD business as usual (BAU) or at a Data Access Advisory Group (DAAG) meeting (IGARD's predecessor).</p> <p>IGARD noted and supported the verbal update from NHS Digital in respect of the forthcoming audit of this organisation in relation to a separate flow of data and in line with NHS Digital's published policy.</p> <p>IGARD noted that section 5(a) (Objective for Processing) stated "<i>The One London CCGs will fulfil CSU responsibilities</i>" and that whilst this transition was ongoing, NHS North East London CSU would still need to be named within the application; and asked that clarity was provided on the governance arrangements, for example, for the former members of the CSU, which Data Protection Act (DPA) registration are they working under and which Data Security and Protection Toolkit (DSPT) submission were they adhering to. In addition, IGARD also asked that clarity was provided of how the responsibility for the data would be assigned.</p>

	<p>IGARD noted the reference in section 5(b) (Processing Activities) to a pseudo key provided by the DSCRO, however asked that this was updated to make clear that different pseudo keys are being utilised, that do not allow cross linkage.</p> <p>IGARD queried the yielded benefits outlined in section 5(d) (Benefits) (iii) (Yielded Benefits), and asked that these were reviewed and updated in line with the NHS Digital DARS Stand for Expected Measurable Benefits. In addition, IGARD asked that conformation was provided, that the yielded benefits in section 5(d) (iii) were achieved using the data under this data sharing agreement (DSA), for example, by providing specific examples from the CCG's annual report.</p> <p>IGARD noted the large number of storage and processing locations in section 2 (Locations), and noting this may cause difficulty for NHS Digital in respect of auditing, suggested that NHS Digital worked with the applicant to review and consider if the locations could be consolidated and in line with the NHS Digital DARS Standard for Processing and Storage Locations.</p> <p>IGARD advised that NHS Digital draw the applicant's attention to the contractual obligation in section 4 (Privacy Notice), in respect of maintaining a UK GDPR compliant, publicly accessible transparency notice throughout the life of this agreement, in order to maintain public trust in using health data from national datasets; and in line with NHS Digital's DARS Standard for Transparency (fair processing); and suggested that all parties ensured that their privacy notices had been updated to reflect the changes with the CSU.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. In respect of the NEL CSU dissolution: <ol style="list-style-type: none"> a) To clarify what the governance arrangements will be, and b) To clarify how the responsibility for the data will be assigned. 2. To update section 5(b) to clarify that different pseudo keys are being utilised. 3. In respect of the benefits in section 5(d): <ol style="list-style-type: none"> a) To ensure the yielded benefits are updated in line with the NHS Digital DARS Stand for Expected Measurable Benefits, and b) To confirm that the yielded benefits in section 5(d) (iii) were achieved using the data under this DSA. 4. IGARD noted the large number of storage and processing locations, and, noting this may cause difficulty for NHS Digital in respect of auditing, suggested that NHS Digital worked with the applicant to review and consider if the locations could be consolidated. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD supported NHS Digital's verbal update in respect of the audit of this organisation in relation to a separate flow of Secondary Uses Service (SUS) data for direct care and secondary purposes. 2. In respect of the privacy notice and in line with NHS Digital's DARS Standard for Transparency (fair processing), IGARD wished to draw to the applicant's attention to the statement in section 4, that a UK GDPR compliant, publicly accessible transparency notice is maintained throughout the life of the agreement, and suggested that all parties ensure that their privacy notices have been updated to reflect the changes with the CSU.
3.5	<p><u>NHS Buckinghamshire CCG: DSfC - Oxfordshire County Council, NHS Buckinghamshire, NHS Oxfordshire and NHS Berkshire West CCGs - Comm (Presenter: Michael Ball) NIC-400077-T4C4V-v1.4</u></p>

	<p>Application: This was an amendment application to 1) add Oxfordshire Council as a Data Controller to receive outputs; and 2) to add the following datasets: Personal Demographics Service (PDS), Summary Hospital-level Mortality Indicator (SHMI), Medicines Dispensed in Primary Care (NHSBSA Data) and Adult Social Care Data.</p> <p>The overall purpose for this application is to provide intelligence to support the commissioning of health services. The data is analysed so that health care provision can be planned to support the needs of the population within the Data Controller geographical areas.</p> <p>Discussion: NHS Digital noted that the application had not previously been presented at an IGARD business as usual (BAU) or at a Data Access Advisory Group (DAAG) meeting (IGARD's predecessor).</p> <p>IGARD noted the examples that had been provided in section 5(b) (Processing Activities), of instances where the CCG has used the re-identification process, however queried if the statements that "GPs have requested a list of patients registered with them..."; and asked the statements were reviewed and amended if appropriate, for example, was it in fact one or more Primary Care Networks (PCNs) who had requested the data.</p> <p>In addition, IGARD queried if the recipient of the data, following the reidentification request, would be a person with the direct care responsibilities; and asked that as this was currently unclear it was clarified in section 5 (Purpose / Methods / Outputs).</p> <p>IGARD queried the yielded benefits outlined in section 5(d) (Benefits) (iii) (Yielded Benefits), and asked that these were reviewed and updated in line with the NHS Digital DARS Stand for Expected Measurable Benefits. In addition, IGARD asked that confirmation was provided, that the yielded benefits in section 5(d) (iii) were achieved using the data under this data sharing agreement (DSA), for example, by providing specific examples from the CCG's annual report.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To review the statement in section 5(b) "GPs have requested..." and amend if appropriate, for example, is it in fact one or more PCNs who have requested the data. 2. To clarify in section 5 that the recipient of the data following the reidentification request will be a person with the direct care responsibilities. 3. In respect of the benefits in section 5(d): <ol style="list-style-type: none"> a) To ensure the yielded benefits are updated in line with the NHS Digital DARS Stand for Expected Measurable Benefits, and b) To confirm that the yielded benefits in section 5(d) (iii) were achieved using the data under this DSA.
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><i>No items discussed.</i></p>
5	<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>IGARD Members noted that they had not yet been updated on the issues raised at the 27th May 2021 IGARD business as usual (BAU) meeting with regard to previous comments made on the IG COVID-19 release registers March 2020 to May 2021. IGARD noted that in addition, they had not been updated on the issues raised on the IG COVID-19 release registers June 2021 to January 2022.</p> <p>IGARD Members noted that the last IG COVID-19 release register that they had reviewed and provided comments on was January 2022.</p> <p>IGARD also noted that the NHS Digital webpage Excel spreadsheet was for the period March 2020 to May 2021 and that they had queried for some considerable time with PTE why the COVID-19 (non-DARS) data release register was not being updated in a timely fashion: NHS Digital Data Uses Register - NHS Digital</p>
6	<p><u>COVID-19 update</u></p> <p><i>No items discussed</i></p>
7	<p><u>AOB:</u></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>

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 18/03/22

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-610798-N0G8Z-v0.4	National Institute for Health and Care Excellence (NICE)	24/02/2022	<ol style="list-style-type: none"> 1. In respect of the purpose of the application (service evaluation/audit): <ol style="list-style-type: none"> a. To remove any reference to research from section 5 for example “<i>driving the research agenda</i>”, and b. To clearly explain in section 5 how this application, using a TRE, will be limited solely to service evaluation and audit. 	IGARD members	Quorum of IGARD members	Comments / advice to the applicant <ul style="list-style-type: none"> • With regard to amendment point 2 it would be sensible to inform the applicant that since the TRE team cannot keep the data separate they should maintain records that would enable them to demonstrate they have not used the COVID-19 datasets for non-COVID-19 purposes. • With regard to amendment point 5 we note this amendment has not been made. We accept the justification but the applicant should bear the wording in mind when the yielded benefits come to be populated with how NICE has delivered improvements.

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