

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 16 June 2022

IGARD MEMBERS IN ATTENDANCE:	
Name:	Position:
Paul Affleck	Specialist Ethics Member
Dr. Robert French	Specialist Academic / Statistician Member
Kirsty Irvine	IGARD Chair
Dr. Imran Khan	Specialist GP Member
Jenny Westaway	Lay Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Maria Clark	Lay Member
Prof. Nicola Fear	Specialist Academic Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Chair
Dr. Maurice Smith	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	Team:
Michael Ball	Data Access Request Services (DARS) (Items 7.3)
Helen Buckles	Data Access Request Services (DARS) (Observer: Item 3.2)
Michael Chapman	Director of Research and Clinical Trials (Item 7.1)
Garry Coleman	Associate Director / Senior Information Risk Owner (SIRO) (Item 4.2) (Observer: item 7.1)
Dave Cronin	Data Access Request Services (DARS) (SAT Observer: Item 3.1) (Item 3.2, 7.1)
Duncan Easton	Data Access Request Services (DARS) (SAT Observer: item 3.5)
Mujiba Ejaz	Data Access Request Services (DARS) (Observer: item 3.2) (Item 3.3)
Dan Goodwin	Data Access Request Services (DARS) (Item 7.3)
Mary Kisanga	Data Access Request Services (DARS) (Observer: items 3.1 - 3.4)
Karen Myers	IGARD Secretariat

Frances Perry	Digi-Trials (Item 3.4)
Andy Rees	Digi-Trials (Item 7.1)
Charlotte Skinner	Data Access Request Services (DARS) (Item 3.5)
Kimberley Watson	Data Access Request Services (DARS) (SAT Observer : item 3.3, 3.4)
Anna Weaver	Data Access Request Service (DARS) (Item 3.1)
Vicki Williams	IGARD Secretariat
Tom Wright	Data Services for Commissioners (DSfC) (Item 2.1)
*SAT – Senior Approval Team (DARS)	

1	<p>Declaration of interests:</p> <p>Dr. Imran Khan noted a potential conflict with any applications reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) [NIC-448252-L2R6Q], as part of his roles as Deputy Chair of the Health Informatics Group at the RCGP and Co-deputy Chair of the Joint GP IT Committee. It was agreed this did not preclude Dr. Khan from taking part in the discussions about this application, however, it was agreed that he would not participate in making a recommendation about the application.</p> <p>Review of previous minutes and actions:</p> <p>The minutes of the 26th May 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>Clinical Registries for Commissioners Briefing Paper (Presenters: Tom Wright)</u></p> <p>This briefing paper was to inform IGARD that Commissioners are requesting to receive the pseudonymised Clinical Registry data already approved to flow to NHS England.</p> <p>NHS Digital has been directed by NHS England to establish and operate an information system for the collection and analysis of local commissioning data, clinical registry data and historic Primary Care Trust data to deliver data services for commissioners.</p> <p>Commissioners require access to the Clinical Registry data collected within Clinical Registries, Databases and Audits in order to fulfil their functions as set out in the Health and Social Care Act 2012.</p> <p>Health commissioners continually commission, recommission and procure health services from health service providers. It is a complex process, involving the assessment and understanding of a local population's health needs, the planning of services to meet those</p>

	<p>needs and securing services on a limited budget, then monitoring the services procured. When a service is procured, this is done through a contract. This NHS Standard Contract sets out the type of service, how much the service will cost, how much the health provider will be paid, what the data requirements are, why the data is being collected and what it will be used for.</p> <p>Clinical Registry data can in some cases be used as the main source of information for contract planning to improve the consistency and delivery of quality care. There are also instances where the content of a Clinical Registry requires cross-referencing with commissioning Service Level Agreement monitoring information, to ensure that patients who are recognised in core data flows as being specialised are treated for appropriately.</p> <p>The Data Services for Commissioners Regional Office (DSCRO) will obtain the Clinical Registry data from central NHS Digital. Data quality management, data linkage to other approved commissioning flows, and pseudonymisation is completed within the DSCRO and is then disseminated in line with existing Data Sharing Agreements.</p> <p>Outcome: IGARD welcomed the briefing paper and made the following high-level comments:</p> <ol style="list-style-type: none"> 1. IGARD suggested a number of minor edits to the briefing note, including (but not limited to): <ol style="list-style-type: none"> a) Updating the executive summary to reflect that IGARD make “<i>recommendations for approval</i>”. b) To provide further details of the role of the DSCRO. c) When citing UK GDPR to be clear how it is being complied with, not just citing the regulation. d) To remove reference to “<i>the four criteria above</i>”. 2. Separate to the briefing paper, IGARD suggested that NHS Digital contact PICA Net to ask them to update their published privacy notice, in line with comments made, for example, updating it to state that it regularly shares data with NHS Digital not just “<i>very occasionally</i>”. 3. Separate to the briefing paper, IGARD suggested that NHS Digital contact NICOR to ask them to update their published privacy notice, in line with comments made, for example, to make reference to NHS Digital and NHS England processing data for commissioning. 4. Separate to this application, IGARD advised they would welcome a further discussion about setting parameters or expectations about transparency, given the fact this is an ongoing process, and there are still a number of registries to onboard. IGARD noted that clear guidance for the registries may be helpful since neither IGARD, nor NHS Digital has time to undertake a review of each privacy notice. <p>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).</p>
2.2	<p><u>Surgical Devices & Implants Data Set Briefing Paper (No Presenter)</u></p> <p>This briefing paper was to inform IGARD about the Surgical Devices and Implants Data Set (SDIDS) collected and processed by NHS Digital within a single system known as the Surgical Device and Implant Information System (SDIIS); which will be made available for customers to request through the Data Access and Request Service (DARS); and had been previously discussed at the IGARD business as usual meeting on the 5th May 2022.</p> <p>The main aim of the collection of SDIDS is to improve patient safety so that patients can be traced in the event of a product recall or safety concern relating to a specific type of implant or</p>

	<p>treatment. Outcomes data collected will also be used to improve procedures offered to future patients and facilitate the national reporting of activity relating to any surgical device or implant across both the NHS and independent health care sector.</p> <p>IGARD welcomed the finalised briefing paper and made no further comments.</p> <p>As per due process, a copy of the finalised briefing paper should be provided as a supporting document alongside any first of type applications to IGARD.</p>
2.3	<p><u>NHS Continuing Health Care Patient Level Data Set Briefing Paper (Presenters: No Presenters)</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; and had been previously discussed at the IGARD business as usual meeting on the 24th March 2022.</p> <p>IGARD welcomed the finalised briefing paper and made no further comments.</p> <p>As per due process, a copy of the finalised briefing paper should be provided as a supporting document alongside any first of type applications to IGARD.</p> <p>Separate to the briefing paper, IGARD noted that they had provided comments OOC on the NHS England consent materials, and asked that NHS Digital provide a further update at a future IGARD BAU meeting.</p>
3	Data Applications
3.1	<p><u>Office for National Statistics (ONS): Provision of data via PDS to ONS (Presenter: Anna Weaver) NIC-20951-D2K6S-v9.4</u></p> <p>Application: This was an extension application to permit the holding and processing of identifiable Personal Demographic Service (PDS) data.</p> <p>It was also an amendment application to 1) add new variables for the PDS Weekly Update File; 2) add Crown Hosting Data Centres (CHDC) Limited as a Data Processor; 3) to add CHDC processing and storage locations; 4) add in details of a data sharing model permitting ONS to share record level data with National Records Scotland (NRS).</p> <p>The purpose of the application is to use the data in conjunction with other administrative data for estimating internal and international migration, the local authority distribution of international migrants component of change for the mid-year estimates and small area population estimates within England and Wales and estimating migration between England and Wales, Scotland and Northern Ireland.</p> <p>ONS is responsible for producing statistics on a range of key economic, social and demographic topics in order to inform the needs of Government, society, academia and business to enable better decisions to be made. Using administrative data such as PDS allows ONS to produce statistics which are more granular and timelier at a lower cost to the public, therefore enabling better decisions and resource allocation.</p> <p>The application was previously considered on the 22nd July 2021 where IGARD were unable to make a recommendation as not all the necessary information was available in order for IGARD to make a full assessment.</p>

NHS Digital noted the concerns previously raised by its predecessor the Data Access Advisory Group (DAAG) in 2016, in respect of the privacy notice, which were also raised at the IGARD meeting on the 22nd July 2021; and confirmed that work was ongoing with ONS to ensure that transparency about all the data flowing from NHS Digital to ONS was clearly and accurately described on both organisations' published privacy notices.

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 March 2016 and 22nd July 2021.

IGARD noted that this application had previously been discussed as part of the 'returning applications' section of the IGARD business as usual (BAU) meeting on the 15th October 2020.

IGARD noted the concerns raised by DAAG in 2016, in respect of the privacy notice, and wished to draw to the applicant's attention the statement in section 4 (Privacy Notice) that a UK General Data Protection Regulation (UK GDPR) compliant, publicly accessible transparency notice was maintained throughout the life of the agreement. IGARD noted the verbal update from NHS Digital in respect of the positive steps / ongoing work with ONS to update the transparency materials, and strongly suggested that this was updated as a matter of urgency. IGARD also reiterated its advice on the 22nd July 2021 that ONS may wish to refresh the advice previously received from the Information Commissioner's Office (ICO) in respect of transparency to the public.

IGARD noted on the population statistics page on the ONS website that NHS Digital was not cited as a source of data and suggested that this was updated as soon as possible, to ensure transparency to the public.

Separate to this application, IGARD noted that the NHS Digital transparency pages suggested that the use of all data was only for health and social care purposes, and suggested that the NHS Digital transparency pages were updated to reflect special cases, where data is used for non-health and social care purposes, for example, ONS using NHS Digital data for population statistics.

IGARD noted the previous advice provided on the 22nd July 2021, that *"ONS table this processing for consideration by the National Statistician's Data Ethics Advisory Committee (NSDEC)"*. IGARD noted the update provided in section 1 (Abstract), and the emphasis on assessing requests to access data after it had been obtained rather than at the acquisition stage. Notwithstanding this, and following a lengthy discussion, IGARD maintained that onboarding this data, particularly with a view to new uses and linkages, would benefit from NSDEC oversight. It would also provide public reassurance, for example with regard to the use of the data for migrant statistics.

IGARD noted the risk to NHS Digital, in respect of flowing extensive population-wide data to ONS, who have an ethics committee but were not utilising it.

IGARD noted the use of primary care identifiers and, given these could be used to infer information on GP practice performance, queried what ONS would use this identifier for, and suggested NHS Digital considered if it was appropriate to flow this data for this specific Data Sharing Agreement (DSA).

IGARD noted the proposed flow of data to the devolved nations via a DSA; and noted the draft DSA provided as a supporting document contained an express statement that it was not a legally binding agreement. IGARD therefore suggested NHS Digital investigated whether this was an appropriate way of regulating those data flows. IGARD suggested that NHS Digital evaluate this potential risk.

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 quantum of data flowing and the outstanding NSDEC query.

Outcome: recommendation to approve

The following advice was given:

1. IGARD noted the concerns raised by DAAG in 2016, in respect of the privacy notice, and wished to draw to the applicant's attention the statement in section 4 that a UK GDPR compliant, publicly accessible transparency notice is maintained throughout the life of the agreement. IGARD noted the verbal update from NHS Digital in respect of the positive steps / ongoing work with ONS to update the transparency materials, and strongly suggested that this was updated as a matter of urgency. IGARD also reiterated its advice on the 22nd July 2021 that ONS may wish to refresh the advice previously received from the ICO in respect of transparency to the public.
2. IGARD noted on the population statistics page on the ONS website that NHS Digital was not cited as a source of data and suggested that this was updated as soon as possible.
3. IGARD noted the use of primary care identifiers and, given these could be used to infer information on GP practice performance, queried what ONS would use this identifier for, and suggested NHS Digital considered if it was appropriate to flow this data for this specific DSA.
4. IGARD noted the previous advice provided on the 22nd July 2021, that "*ONS table this processing for consideration by the National Statistician's Data Ethics Advisory Committee (NSDEC)*". IGARD noted the update provided on this, and the emphasis on assessing requests to access data after it had been obtained rather than at the acquisition stage. Notwithstanding this, IGARD maintained that onboarding this data, particularly with a view to new uses and linkages, would benefit from NSDEC oversight. It would also provide public reassurance, for example with regard to the use of the data for migrant statistics.
5. IGARD noted the proposed flow of data to the devolved nations via a data sharing agreement. The draft provided as a supporting document contains an express statement that it is not a legally binding agreement. IGARD therefore suggested NHS Digital investigate whether this is an appropriate way of regulating those data flows.
6. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the quantum of data flowing and the outstanding NSDEC query.
7. IGARD suggested that this application, would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the quantum of data flowing and the outstanding NSDEC query.

Risk Factor: NHS Digital are flowing extensive population-wide data to ONS, who have an ethics committee but are not utilising it.

Risk Factor: IGARD noted the proposed flow of data to the devolved nations via a supporting document, which contains an express statement that it is not legally enforceable, and this is a potential risk for NHS Digital to evaluate.

ACTION: Separate to this application, IGARD noted that the NHS Digital transparency pages suggested that the use of all data was for health and social care purposes, and suggested that

	they were updated to reflect special cases, where data is used for non-health and social care purposes, for example, ONS using NHS Digital data for population statistics.
3.2	<p><u>Evidera Ltd: Health Burden of COVID-19 and Healthcare Resource Utilisation in England (Presenter: Dave Cronin) NIC-561357-X0F3N-v0.16</u></p> <p>Application: This was a new application for pseudonymised Civil Registration (Deaths) data, COVID-19 Hospitalization in England Surveillance System, COVID-19 Second Generation Surveillance System, COVID-19 Vaccination Status, Diagnostic Imaging Dataset (DIDs), Emergency Care Data Set (ECDS), GPES Data for Pandemic Planning and Research (COVID-19) (GDPPR), Hospital Episode Statistics (HES) Accident and Emergency (A&E), HES Admitted Patient Care (APC), HES Critical Care, HES Outpatients and Medicines dispensed in Primary Care (NHSBSA data).</p> <p>The purpose of the application is for a study to generate the evidence necessary to understand unmet need in the prevention and treatment of COVID-19 following the deployment of vaccination campaigns. This may also help inform the assessment and usage guidance of EVUSHELD, a long-acting antibody combination for prevention against, and treatment of, COVID-19 in the most vulnerable people.</p> <p>The core study objectives are to: 1) estimate the size of populations (pre-defined) in England that potentially are ineligible for vaccines or are at risk of inadequate response to COVID-19 vaccines; 2) estimate incidence of COVID-19 by age group, disease severity, and selected comorbidities; 3) estimate incidence of long-COVID-19 by age, disease severity, and selected comorbidities; 4) describe patterns of healthcare resource utilisation and costs associated with an episode of COVID-19, stratified by age, selected comorbidities, disease severity, and the occurrence (vs. absence) of long-COVID-19.</p> <p>Discussion: IGARD noted that the application was coming for advice on 1) the expected benefits to the health and social care system and to the public; 2) the importance of the proposed study; 3) the specific data requested and the data minimisation efforts; 4) whether the application achieves a transparent and credible assessment of how the commercial interests are proportionately balanced with the benefits to the health and social care system and the interests of the data subjects; 5) if there was a satisfactory explanation of the roles of AstraZeneca UK Ltd and Evidera to support the proposition that Evidera is a Data Processor and is not a joint Data Controller.</p> <p>IGARD expressed concern that the applicant took action and investigated various points based on GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) verbal advice, when the PAG feedback was not formally recorded at the meeting on the 9th February 2022, and was therefore unable to be provided at IGARD today, and appended to the IGARD minutes, in line with due process.</p> <p>IGARD broadly supported the public benefit aspects of the application, and were of the view that this type of research should be a high priority so as to protect the most vulnerable in society who were not afforded the same protection as those who were able to benefit more from the COVID-19 vaccinations, which would then allow those that were most vulnerable to live more openly in a pandemic.</p> <p>IGARD noted the efforts undertaken in respect of data minimisation which the applicant had undertaken following the verbal advice received from PAG, however, IGARD suggested that it may be possible to justify the national data set in line with the NHS Digital DARS standard for data minimisation, and that if the applicant wished to have national data they provide a robust justification for its use. If the applicant was confident that requesting data for a subset of data</p>

subjects from nine regions in England would give a representative outcome for the whole of England, then narrative should be provided within the application that there would be no risk of bias by using such sampling.

IGARD noted that section 5(a) (Objective for Processing) could be updated further to provide clarity on the purpose of the application.

IGARD noted the commercial aspect of the application in section 5(e) (Is the Purpose of this Application in Anyway Commercial), however, noting that this was not public facing, asked that for transparency, and in line with [NHS Digital DARS Standard for commercial purpose](#), a brief summary was also provided in section 5(a).

IGARD noted that the NHS Digital had raised a query on data controllership, and noting that the Principal Investigator (PI) was based in Sweden, that it would be unusual for the PI not to have data controllership responsibilities. IGARD asked that confirmation was provided that the Data Controller(s) were appropriately described in the application, in line with the [NHS Digital DARS Standard for Data Controllers](#), and as borne out of the facts.

In addition, IGARD asked that the territory of use was aligned with the processing and the location of the Data Controller(s), especially relevant if the PI was to become a Data Controller.

IGARD asked that section 5 (Purpose / Methods / Outputs) was updated to clarify any onward sharing of the data, in line with [NHS Digital DARS Standard for sub-licencing and onward sharing](#).

IGARD suggested the applicant carried out a Data Protection Impact Assessment (DPIA), due to the scale, nature and scope of the processing, for example, in light of the machine learning and the volume of data.

IGARD also suggested that the applicant involved relevant public and patient groups for the lifecycle of the project in line with [HRA guidance on Public Involvement](#).

IGARD noted the Legitimate Interests Assessment provided as a supporting document, however asked that this was reviewed, including (but not limited to), the statement that children's data would **not** be processed, noting that this was incorrect; and the statement "*All individuals in the UK have the opportunity to opt out for providing their data to NHS digital*", which was also incorrect.

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 General Data Protection Regulation (UK GDPR) compliant, publicly accessible transparency notice was maintained throughout the life of the agreement.

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 broadly supported the application presented in terms of public benefit and were of the view that this type of research should be a high priority so as to protect the most vulnerable in society.
2. In line with [NHS Digital DARS Standard for commercial purpose](#), to provide a brief summary in section 5(a) of the commercial aspect of this application, as outlined in section 5(e).
3. To update section 5(a) with further clarity of the purpose of the application.

	<ol style="list-style-type: none"> 4. To confirm that the Data Controller(s) are appropriately described in the application, in line with the NHS Digital DARS Standard for Data Controllers, and as borne out of the facts. 5. To ensure the territory of use aligns with the processing and the location of the Data Controller(s). 6. To update section 5 to clarify any onward sharing of the data, in line with NHS Digital DARS Standard for sub-licencing and onward sharing. 7. IGARD suggested the applicant carried out a Data Protection Impact Assessment (DPIA), due to the scale, nature and scope of the processing. 8. IGARD suggested that the applicant involve relevant public and patient groups for the lifecycle of the project in line with HRA guidance on Public Involvement. 9. In respect of the Legitimate Interests Assessment: <ol style="list-style-type: none"> a) To review the statement that children's data will not be processed. b) To review the incorrect statement(s) relating to the Opt-out. 10. 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. 11. In respect of data minimisation: <ol style="list-style-type: none"> a) IGARD noted the efforts undertaken in respect of data minimisation, however suggested that it may be possible to justify the national data set in line with the NHS Digital DARS standard for data minimisation, and that if the applicant wished to have national data they provide a robust justification for its use. b) If the applicant is confident that the nine regions chosen will give a representative outcome for the whole of England, to provide a narrative that there would be no risk of bias by using such sampling. 12. IGARD expressed concern that the applicant took action and investigated various points based on PAG advice, when the PAG feedback was not formally recorded at the time (9th February 2022) and was therefore unable to be provided at IGARD today, and appended to the IGARD minutes, in line with due process.
3.3	<p><u>Imperial College London: MR1108: CT colonography, colonoscopy, or barium enema for diagnosis of colorectal cancer in older symptomatic patients: SIGGAR1 (Special Interest Group in Gastrointestinal and Abdominal radiology). Plus SOCCER (Symptoms of Colorectal Cancer Evaluation Research). (Presenter: Mujiba Ejaz) NIC-291981-Y7J2F-v6.11</u></p> <p>Application: This was an extension application to permit the holding and processing of identifiable Medical Research Information Service (MRIS) Cause of Death Report, MRIS - Cohort Event Notification Report and MRIS - Flagging Current Status Report.</p> <p>The purpose is for the SOCCER study, which follows on from an earlier study on bowel cancer symptoms (the Special Interest Group Gastrointestinal and Abdominal Radiology (SIGGAR) study), with the aim of providing evidence that is needed to show whether flexible sigmoidoscopy (a technique which examines only the last [distal] part of the colon) is an effective and safe alternative to whole colon examinations for many people; which may change how doctors diagnose bowel cancer in their patients based on their symptoms.</p> <p>The size of the cohort is 7,472 patients; and the study is relying on consent <u>and</u> s251 of the NHS Act 2006, for the flow of data into NHS Digital.</p> <p>The application was previously considered on the 9th September 2021 where IGARD were unable to make a recommendation as not all the necessary information about the SIGGAR</p>

	<p>database was available to enable IGARD to make a full assessment of the Health Research Authority Confidentiality Advisory Group (HRA CAG) correspondence.</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 10th November 2015, 31st January 2019, 20th August 2020 and 9th September 2021.</p> <p>IGARD noted that this application had previously been discussed as part of the ‘returning applications’ section of the IGARD business as usual (BAU) meeting on the 4th February 2021.</p> <p>IGARD noted that prior to the meeting, an IGARD member had raised a query in respect of supporting document 19, that had been provided by the applicant, outlining whether or not the SIGGAR database currently contained any confidential patient information about the SOCCER cohort, that stated that some of the patients who consented to SIGGAR were not, in fact, asked to consent to future research. In addition, it also stated <i>“An application was also submitted to CAG in early 2021, on the advice of IGARD, to change this legal basis from consent to section 251. After extensive review of the application, CAG however found that there was no requirement for their support, and the application (21/CAG/0059) was withdrawn”</i>. IGARD advised that they were not asking for the legal basis to change from consent to s251 as such, but had made the point that consent for SOCCER only covered a subset of those who consented to SIGGAR.</p> <p>In addition, supporting document 15.5, the e-mail from HRA CAG dated the 18th May 2021, stated <i>“However, I could not work out where the breach in confidentiality was, as you had confirmed to me that you do not retain any items of confidential patient information, and the dataset retained regarding the randomised consented cohort was pseudonymised.”</i>. IGARD noted that the potential breach in confidentiality related to those that consented to SIGGAR but were not asked to consent to further research; and that the research group still had the means to identify these individuals, therefore it was still confidential patient information.</p> <p>IGARD asked that written confirmation was provided from the Health Research Authority Confidentiality Advisory Group (HRA CAG) that there was an appropriate legal gateway for all members of the cohort; and that the written confirmation was uploaded to NHS Digital’s Customer Relationship Management (CRM) system for future reference. IGARD members said that they would welcome the opportunity to review the query to be sent by NHS Digital to HRA CAG.</p> <p>IGARD noted that there was an agreed process in place between NHS Digital and HRA CAG and that NHS Digital would approach HRA CAG before an applicant submitted any application for s251 based on NHS Digital feedback (for example if NHS Digital was concerned that consent was insufficient). IGARD suggested that NHS Digital review their internal processes.</p> <p>Outcome: recommendation to approve by a quorum of 4 members, with one specialist member dissenting, subject to the following condition:</p> <ol style="list-style-type: none"> 1. In respect of the HRA CAG support: <ol style="list-style-type: none"> a) To provide written confirmation from HRA CAG that there is an appropriate legal gateway for all members of the cohort. b) To upload the written confirmation from HRA CAG to NHS Digital’s CRM system. <p>It was agreed the conditions would be approved out of committee (OOC) by IGARD members.</p>
3.4	<p><u>University of Oxford: PANORAMIC: Platform Adaptive trial of NOvel antiViRals for eArly treatMent of covid-19 In the Community (Presenter: Frances Perry) NIC-605115-L0W3V-v3.2</u></p>

Application: This was a renewal application to permit the holding and processing of Civil Registration (Deaths), identifiable Covid-19 UK Non-hospital Antigen Testing Results (pillar 2), Hospital Episode Statistics Admitted Patient Care (HES APC), HES Critical Care, HES Outpatients, Medicines dispensed in Primary Care (NHSBSA data), Uncurated Low Latency Hospital Data Sets - APC, Uncurated Low Latency Hospital Data Sets - Critical Care, COVID-19 Access to Summary Care Records, Emergency Care Data Set (ECDS).

It was also an amendment application to **1)** extend the current Data Sharing Agreement end date until the 30th June 2023; and **2)** amend the legal basis for common-law duty of confidentiality from The Health Service Control of Patient Information (COPI) Regulations 2002 to s251; **3)** to add four additional data fields in the existing ECDS dataset.

The purpose is for the PANORAMIC trial, which is the only national priority clinical trial evaluating potential novel antivirals for COVID-19 in the primary care setting, endorsed by the Chief Medical Officers (CMOs) of all four devolved nations. The primary aim is to determine the effectiveness of selected antiviral agents in preventing hospitalisation and / or death in higher-risk patients with a confirmed positive SARS-CoV-2 PCR test result.

This is a sister application to the 'Platform Randomised Trial of Treatments in the Community for Epidemic and Pandemic Illnesses' (PRINCIPLE) trial (NIC-411161-G4K7X).

This DSA covers both the recruitment of participants to the trial, and the request for follow-up data after recruitment and consent.

NHS Digital advised that prior to the meeting, IGARD had raised a query in respect of the Health Research Authority Confidentiality Advisory Group (HRA CAG) support, noting that there was no supporting information provided that confirmed s251 was in place. NHS Digital confirmed that the applicant had not yet received the HRA CAG letter to confirm the s251 support including any detailed conditions; however advised that NHS Digital had confirmed verbally with HRA CAG that s251 approval for this agreement was in place once the Health Service Control of Patient Information (COPI) Regulations 2002 expired on the 30th June 2022.

NHS Digital advised that prior to the meeting, IGARD had also raised a query in respect of the legal representative cover letter provided as a supporting document, and queried if consultees were being used in this project. NHS Digital noted that the applicant had confirmed that five cohort members were recruited under consultee advice, however the applicant had advised that they would be removed from the cohort.

Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 2nd December 2021 and the 17th March 2022; and was also discussed under 'AOB' at the IGARD BAU meeting on the 24th February 2022.

IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 23rd November 2021.

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.

IGARD noted the verbal update from NHS Digital in respect of the HRA CAG support, and asked that evidence was provided of unconditional HRA CAG support, including all relevant documentation; and that the unconditional HRA CAG support aligned with the proposed processing set out in this application; and that the written confirmation from HRA CAG was

uploaded to NHS Digital's Customer Relationship Management (CRM) system for future reference.

IGARD noted the verbal update from NHS Digital in respect of the five cohort members recruited under consultee advice; and advised that, if the consultee advice was compliant, they would be supportive of these individuals being included back in the cohort.

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

Noting that the event rate is currently lower than 1% (the lowest value used in their power calculations) , IGARD queried whether or not the applicant may need to rethink the study design. This point was made with reference to NHS Digital needing to ensure it complies with data protection principles and that it was sharing data for the right reasons with the right justifications proportionate to the volume of data requested.

IGARD reiterated comments that they had made on the 21st November 2021: *"Those that had "opted out" of being contacted for participation in the trials, appeared to being contacted via the test and trace website and NHS Digital should ensure it has a clear policy decision and has ascertained from the applicant the number of complaints that have been received in relation to a participant being contacted by the trial teams when they have specifically ticked the "do not contact" box on the test and trace website"* . IGARD noted that the applicant had advised that they discuss complaints in operational meetings, but do not capture them systematically. IGARD suggested that the applicant should monitor complaints carefully, and in a robust manner, and provide an update to NHS Digital on amendment or renewal. IGARD noted that it was important to validate the mode of contact to inform recruitment methods for future projects.

IGARD noted a significant risk factor to NHS Digital, if there were significant complaints not being tracked, addressed or mitigated it would undermine public trust and confidence in the handling of NHS Digital data.

Outcome: recommendation to approve subject the following condition:

1. In respect of HRA CAG:
 - a) To provide evidence of unconditional HRA CAG support, including all relevant documentation.
 - b) That the unconditional HRA CAG support aligns with the proposed processing set out in this application.
 - c) To upload the written confirmation from HRA CAG to NHS Digital's CRM system.

The following amendments were requested:

1. To provide a clear statement at the beginning of section 5(b) acknowledging how the researchers will be reviewing:
 - a) how the study will be run in light of the Government's recent policy changes to PCR / LFT testing in the community; and,
 - b) whether this will impact on the data requested, the processing and the expected outcomes.

	<p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD advised that the applicant should consider if the Government's recent policy changes to PCR / LFT testing in the community, will affect the validity of the outcomes; and if it will introduce a bias, and if this has been addressed and / or acknowledged. 2. Noting that the current event rate is lower than 1%, IGARD queried whether or not the applicant may need to rethink the study design. This point was made with reference to NHS Digital needing to ensure it complies with data protection principles and that it is sharing data for the right reasons with the right justifications proportionate to the volume of data requested. 3. In respect of complaints received: <ol style="list-style-type: none"> a) IGARD reiterated comments that they had made on the 21st November 2021: <i>"Those that had "opted out" of being contacted for participation in the trials, appeared to being contacted via the test and trace website and NHS Digital should ensure it has a clear policy decision and has ascertained from the applicant the number of complaints that have been received in relation to a participant being contacted by the trial teams when they have specifically ticked the "do not contact" box on the test and trace website"</i> . b) IGARD noted that the applicant had advised that they discuss complaints in operational meetings, but do not capture them systematically. IGARD suggested that the applicant should monitor complaints carefully, and in a robust manner, and provide an update to NHS Digital on amendment or renewal. IGARD noted that it is important to validate the mode of contact to inform recruitment methods for future projects. 4. IGARD advised that, if the consultee advice is compliant, they would be supportive of these individuals being included back in the cohort. <p>Significant Risk Factor: If there are significant complaints not being tracked, addressed or mitigated it will undermine public trust and confidence in the handling of NHS Digital data.</p>
3.5	<p><u>NHS England (Quarry House): NHS England - Infections & Antimicrobial Resistance (AMR) Trusted Research Environment - renewal application for the same data fields and datasets and an amendment to the data processor (Presenter: Charlotte Skinner) NIC-448252-L2R6Q-v3.4</u></p> <p>Application: This was a renewal application to permit the holding and processing of pseudonymised Civil Registration (Deaths), Community Services Data Set (CSDS), Electronic Prescribing and Medicines Administration (EPMA) data in Secondary Care for COVID-19, Emergency Care Data Set (ECDS), GPES Data for Pandemic Planning and Research (COVID-19), Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC), HES Critical Care, HES Outpatients and Medicines dispensed in Primary Care (NHSBSA data).</p> <p>It was also an amendment application to 1) update the application throughout to amend the references from the Trusted Research Environment (TRE) or Data Access Environment (DAE) to 'NHS Digital's Online Portal'; 2) to amend section 1 to remove HSCIC (NHS Digital) as a Data Processor; 3) to update section 2 to amend the processing location from NHS Digital to NHS England; 4) to update section 3 to reflect that Community Services Data Set (CSDS) is now in the new 'package' structure rather than reflecting individual fields. In addition, Emergency Care Data Set (ECDS) added as a proxy for the HES A&E data that remains available on the DAE but for which formal 'associated product years' do not exist; 5) to amend section 5(a) to a) add descriptions of the key stakeholders and other parties involved in the</p>

broader project scope added for transparency; **b)** add description of the data requested and how it will achieve the identified aims moved from section 5(b) to 5(a); **c)** to move detail of data minimisation efforts from section 5(b) to section 5(a); **d)** to add a justifications for the level of data and number of years requested, plus confirmation that there are no alternative, less intrusive ways of achieving the purpose in line with the relevant [NHS Digital DARS Standard](#). e) to described why NHS Digital are no longer a Data Processor; **6)** to amend section 5(b) to **a)** align with [NHS Digital DARS Standard for processing activities](#); **b)** to remove reference to "Registered NHSE employees... will be supported in their use of the data by NHS Digital staff..." as this related to the 'discovery phase' only; **7)** to amend section 5(c) to **a)** remove reference to the collaboration of NHS Digital developers as this related to the 'discovery phase' only; **b)** to add further details of the stakeholders with whom the outputs are shared; 8) to amend section 5(d) to includes some preliminary benefits achieved to date and intentions for the coming financial year; **8)** to amend section 7 - the 'reason for no ethics approval' has been updated from 'does not include flow of confidential data' to 'this is not a research project'.

The World Health Organization (WHO) has declared that Antimicrobial Resistance (AMR) is one of the top 10 global public health threats facing humanity; as a result, in January 2019 the UK Government published a 5 Year UK AMR National Action Plan (NAP) alongside a UK AMR 20 Year Vision Paper.

The amendment is to enable the AMR programme to understand the impact that the COVID-19 pandemic has had on the utilisation of antimicrobial agents and associated resistance changes versus patterns pre-pandemic, taking into account the indications that there have been significant changes in primary prescribing patterns, in order to inform the key actions to ensure effective antimicrobial stewardship and appropriateness of clinical prescribing going forward as the country starts to come out of the pandemic.

Discussion: 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.

IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 22nd April 2021 and 24th June 2021.

IGARD noted that this application had been reviewed at the General Practice Extraction Service (GPES) Data for Pandemic Planning and Research (COVID-19) (GDPPR) (PAG) meeting on the 21st April 2021 (notes from that meeting had been attached to the IGARD minutes from the 22nd April 2021); and the 23rd June 2021 (notes from that meeting had been attached to the IGARD minutes from the 24th June 2021).

IGARD asked that NHS Digital provide an update to PAG on the status of this application, noting that the last review was on the 23rd June 2021, and in light of the amendments to the application considered at today's meeting.

IGARD queried the special condition in section 6 (Special Conditions) relating to the COVID-19 Public Health Directions 2020, and asked that this was amended to be clear that the use of GDPPR and EPMA data are restricted to COVID-19 purposes as set out in the relevant Direction.

IGARD noted that section 6 had a special condition at the request of PAG, relating to the sharing of documents with the British Medical Association (BMA) and the Royal College of General Practitioners (RCGP); and asked that this special condition was removed, since no justification had been provided for the inclusion of it.

In addition, IGARD queried the inclusion of the special condition at the request of PAG, relating to the performance management of GP practices, and asked that this was also removed, since no justification had been provided for the inclusion of it.

IGARD noted a number of risk factors for NHS Digital, in that the applicant may be inadvertently breaching the terms of their DSA with the inclusion of the PAG standard conditions, especially when no justification had been provided for their inclusion, for example by including the PAG standard condition, consideration did not appear to be being given to NHS England's duty to monitor GP performance.

IGARD reiterated their request to speak to the PAG Chair about the standard PAG conditions. IGARD reiterated their concerns about the blanket ban on performance management. IGARD further noted the special condition may be impossible to comply with, for example, identification of practices, due to the nature of the data being disseminated and processed.

IGARD queried why this processing could not be carried out in the NHS COVID-19 Data Store, as it appeared that there is an extensive overlap of data flowing under this data sharing agreement (DSA) and what is in the NHS COVID-19 Data Store; and asked that a robust explanation was provided at the apparent duplication of data sets.

IGARD noted that on amendment, renewal or extension, the applicant should update any placeholders in the application with regard to data minimisation, in order to continue to justify such a large quantum of data and why they cannot further minimise, and in line with [NHS Digital DARS standard for data minimisation](#).

IGARD noted that, on amendment or renewal, they would expect to see an explanation by the applicant of how those datasets within the programme had only been used for COVID-19 purposes, and in line with the Direction.

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 data minimisation compliance and the large quantum of data.

Separate to this application, IGARD asked that NHS Digital advised on the s261 legal basis for NHS Digital's dissemination, for example, which section of s261 is relevant, since NHS Digital appeared to be only citing the overarching s261.

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

The following amendments were requested:

1. To amend the special condition relating to the COVID-19 Public Health Directions 2020, to be clear that the use of GDPR and EPMA data is restricted to COVID-19 purposes as set out in the relevant Direction.
2. In respect of the special condition inserted at the request of PAG:
 - a) To remove the special condition relating to the sharing of documents with the BMA and RCGP, since no justification has been provided.
 - b) To remove the special condition relating to the performance management of GP practices, since no justification has been provided.
3. To provide a robust explanation why this processing cannot be carried out in the NHS England data store as it appears there is an extensive overlap of data flowing under this DSA and what is in the data store.

	<p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD noted that the applicant should update any placeholders in the application with regard to data minimisation, in order to continue to justify such a large quantum of data, and in line with NHS Digital DARS standard for data minimisation. 2. IGARD noted that on amendment or renewal, they would expect to see an explanation by the applicant, of how those datasets within the programme, had only been used for COVID-19 purposes. 3. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to data minimisation compliance and the large quantum of data. 4. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to data minimisation compliance and the large quantum of data. <p>Risk Factors: Applicant may be inadvertently breaching the terms of their DSA with the inclusion of the PAG standard conditions.</p> <p>Risk Factors: By including PAG standard conditions, consideration is not being given to NHS England's duty to monitor GP performance.</p> <p>ACTION: IGARD reiterated the request to speak to the PAG Chair about the standard PAG conditions. IGARD reiterated concerns about the blanket ban on performance management. IGARD further noted that aspects of the special conditions may be impossible to comply with, for example, identification of practices, due to the nature of the data being disseminated and processed.</p> <p>ACTION: NHS Digital to provide an update to PAG on the status of this application.</p> <p>ACTION: Separate to this application, NHS Digital to advise on the s261 legal basis for NHS Digital's dissemination.</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>
4.1	<p><u>NIC-382794-T3L3M-v5.4 University of Oxford (No Presenter)</u></p> <p>The purpose of this application is for QResearch's urgent COVID-19 research projects to support the COVID-19 pandemic, for example, the development and maintenance of a COVID-19 risk stratification tool commissioned by the Chief Medical Officer (CMO).</p> <p>IGARD noted that this application was last reviewed at the IGARD business as usual meeting on the 7th April 2022 where IGARD had deferred.</p> <p>IGARD noted that on the 31st May 2022, NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had agreed to authorise a 4-month extension to the Data Sharing Agreement (DSA).</p> <p>IGARD noted and thanked NHS Digital for the written update and asked that the next iteration of the DSA should be brought to a future IGARD BAU meeting.</p>
4.2	<p><u>NIC-197669-K8J6D-v5.2 NHS Basildon and Brentwood CCG (Presenter: Garry Coleman)</u></p> <p>The purpose of this application is to permits access to data for the purpose of Commissioning.</p>

	<p>IGARD noted that this application was last reviewed at the IGARD business as usual meeting on the 17th May 2018.</p> <p>NHS Digital's Associate Director / Senior Information Risk Owner (SIRO) attended the meeting, to discuss the applicants request to add an additional Data Processor to the data sharing agreement (DSA), noting that as per process, this would usually be submitted to IGARD for review. IGARD were advised by the SIRO that a number of data breaches had been identified in respect of this DSA, however noting that the applicant brought this to the attention of NHS Digital, and a number of actions were taken to mitigate any further breaches, the SIRO advised this would be proceeding down the SIRO Precedent route for the addition of the Data Processor, thus minimising any impact on the CCG and the service it provides.</p> <p>IGARD noted and thanked the SIRO for attending the meeting and noted the verbal update provided.</p> <p>As a separate process point, IGARD noted and thanked NHS Digital's Associate Director / Senior Information Risk Owner (SIRO), for ensuring that IGARD were informed in a timely manner of the progress of applications proceeding down NHS Digital's SIRO Precedent route and advised that this process was working well and ensuring transparency to the public via the published IGARD minutes.</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 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 April 2022.</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.</p>
6	<p><u>COVID-19 update</u></p> <p><i>No items discussed</i></p>
7 7.1	<p><u>AOB:</u></p> <p><u>Inclusion of the IGARD comments in Grail's version of the draft "DARS Annual Confirmation Report" (Presenters: Andy Rees / Dave Cronin / Michael Chapman)</u></p> <p>IGARD noted that at the IGARD BAU meeting on the 31st March 2022, NHS Digital attended to discuss the comments IGARD had shared with regards to the updated DARS Standard for Length of Data Sharing Agreement (DSA) and Draft DARS Annual Confirmation Report. As part of this discussion, it was agreed that the NHS Digital Clinical Trials Head of Business Operation attend a future IGARD meeting to provide an update and discuss the inclusion of the IGARD comments on Grail's version of the Draft Annual Confirmation Report.</p> <p>NHS Digital attended the meeting to provide a verbal update to IGARD on progress since the 31st March 2022. NHS Digital advised IGARD that a final version of the latest Annual</p>

7.2	<p>Confirmation Report would be shared with members as soon as possible , which would also be made available to the public.</p> <p>IGARD noted and thanked NHS Digital for attending the meeting to provide a verbal update.</p> <p><u>COPI Notice (Presenter: Kimberley Watson)</u></p> <p>Noting the expiry of the Health Service Control of Patient Information (COPI) Regulations 2002 COVID-19 notices on the 30th June 2022, NHS Digital attended the meeting to provide a verbal update on the progress taken to date with the data sharing agreements (DSA) which are currently using this legal basis. NHS Digital noted that all relevant DSAs would be migrated to their new legal basis by the 30th June 2022, or relevant actions taken, for example issuing of data destruction notices.</p> <p>IGARD noted the verbal update provided and thanked NHS Digital for attending the meeting.</p>
7.3	<p><u>NHS Oldham CCG NIC-580886-S2M3Z-v0.3 (Presenters: Dan Goodwin / Michael Ball)</u></p> <p>IGARD noted that at the IGARD BAU meeting on the 3rd February 2022, this application was discussed, and that an action had been raised for <i>“NHS Digital to provide IGARD with a copy of the analysis of how the CLDoC is satisfied in respect of the receipt of GP data and Adult Social Care data...”</i>.</p> <p>NHS Digital attended the meeting to discuss this outstanding action, however IGARD noted that the legal advice provided on this action had not been circulated to members as part of this discussion, and it was therefore agreed that this would be discussed at a future IGARD meeting, with all the relevant supporting information made available as part of the agenda papers pack.</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 10/06/22

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-64474-V4B2D-v1.5	St. George's Hospital Medical School	18/11/2021	<ol style="list-style-type: none">1. In respect of the HRA CAG support:<ol style="list-style-type: none">a) To provide written evidence of the continuing HRA CAG support.b) To upload the written evidence of this to NHS Digital's CRM system.2. In respect of the PPIE advice point previously made on the 28th May 2020: to provide a satisfactory indicative plan for the development and implementation of PPIE initiatives.	IGARD members	Quorum of IGARD members at the IGARD BAU meeting on the 26/05/2022.	None

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

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

Liaison Financial Service and Cloud storage:

- None

Optum Health Solutions UK Limited Class Actions:

- None

Graphnet Class Actions:

- None