

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 10 February 2022

IGARD MEMBERS IN ATTENDANCE:	
Name:	Position:
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member (Item 8)
Dr. Robert French	Specialist Academic / Statistician Member (Observer)
Kirsty Irvine	IGARD Chair
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Chair
Dr. Maurice Smith	Specialist GP Member
Jenny Westaway	Lay Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Prof. Nicola Fear	Specialist Academic Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	Team:
Michael Ball	Data Access Request Service (DARS) (Item 3.3 - 3.4)
Natalie Brewer	Data Services Directorate (Item 8)
Dave Cronin	Data Access Request Service (DARS) (Item 8)
Stuart Crook	Data Access Request Service (DARS) (Item 8)
Louise Dunn	Data Access Request Service (DARS) (SAT Observer: item 3.2) (Observer: item 3.3)
Duncan Easton	Data Access Request Service (DARS) (SAT Observer: items 3.3 - 3.4)
Mujiba Ejaz	Data Access Request Service (DARS) (Item 8)
Liz Gaffney	Head of Data Access, Data Access Request Service (DARS) (Item 8)
Florence Geut	Data Access Request Service (DARS) (Observer: items 3.1 – 3.3)
Suzanne Hartley	Data Access Request Service (DARS) (Item 8)

Dickie Langley	Privacy, Transparency & Ethics (PTE) (Item 8)
Wendy Lee	DCSRO South Collaborative (Item 3.3)
Karen Myers	IGARD Secretariat
Dr. Jonathan Osborn	Deputy Caldicott Guardian (Observer: 3.1 – 3.3)
Tania Palmariellodiviney	Data Access Request Service (DARS) (SAT Observer: item 3.1) (Item 8)
Katharine Robbins	Data Access Request Service (DARS) (Item 8)
Gemma Walker	Data Access Request Service (DARS) (Item 8)
Kimberley Watson	Data Access Request Service (DARS) (Item 8)
Anna Weaver	Data Access Request Service (DARS) (Items 3.1 - 3.2)
Emma Whale	Data Access Request Service (DARS) (Observer: item 3.1)
Vicki Williams	IGARD Secretariat
SAT – Senior Approval Team (DARS)	
UK STATISTICS AUTHORITY / OFFICE FOR NATIONAL STATISTICS STAFF IN ATTENDANCE:	
Name:	Position:
Jonny Tinsley	Head of Data, Health Analysis and Life Events Division, Office for National Statistics (ONS) (Item 8 only)
Simon Whitworth	Head of Data Ethics, UK Statistics Authority (UKSA) (Item 8 only)

1	<p>Declaration of interests:</p> <p>Maurice Smith noted a professional link with NHS Liverpool CCG [396095-H1P1D] and would not be part of the discussion. It was agreed that Maurice 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 3rd February 2022 IGARD meeting were reviewed out of committee by IGARD following conclusion of the meeting, and subject to a number of minor changes were agreed as an accurate record 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
	<i>There were no briefing papers submitted for review.</i>

3	Data Applications
3.1	<p data-bbox="256 221 1461 293"><u>University of Oxford: MR360 - Early Breast Cancer Trialists' Collaborative Group (Presenter: Anna Weaver) NIC-148204-7B1XT-v8.4</u></p> <p data-bbox="256 315 1445 427">Application: This was a renewal and extension application to permit the holding and processing of identifiable Medical Research Information Service (MRIS) - Cause of Death Report, MRIS - Flagging Current Status Report and MRIS - Members and Postings Report.</p> <p data-bbox="256 450 1481 562">It was also an amendment to 1) add quarterly disseminations of identifiable Civil Registration (Deaths) data, Cancer Registration Data, and Demographics data; and 2) to add an additional purpose for data processing, for use in eight more clinical trials.</p> <p data-bbox="256 584 1493 730">The purpose of the application is for a study for women who have been diagnosed with operable breast cancer (or breast cancer which might become operable through the use of neo-adjuvant therapy) and enrolled in one of seven randomised trials comparing treatments for breast cancer, with recurrence or death as a principal outcome.</p> <p data-bbox="256 752 1485 864">The Early Breast Cancer Trialists' Collaborative Group (EBCTCG) was created in 1985 and its membership share their trial data for the purpose of the meta-analysis that assesses the benefits and risks of treatments for early breast cancer.</p> <p data-bbox="256 887 1477 999">The original cohort consisted of 9,029 individuals, of which 1,385 are still alive. The University of Oxford will receive data on the remaining 1385 individuals, as well as the same data for a further 17,638 participants from eight more randomised trials.</p> <p data-bbox="256 1021 1430 1088">The study is relying on s251 of the NHS Act 2006, for the flow of data into and out of NHS Digital.</p> <p data-bbox="256 1111 1465 1223">Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 5th August 2021.</p> <p data-bbox="256 1245 1425 1357">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 13th February 2020.</p> <p data-bbox="256 1379 1493 1872">IGARD queried at what point the Clinical Trial Service Unit - Clinical Trials Follow-up Service (CTSU-ctfs) deleted identifiers, noting that the information varied across the various supporting documents provided. NHS Digital advised that identifiers would be deleted once the correct linkage was confirmed. IGARD noted the verbal update from NHS Digital, however noted that supporting document 4.2, the s251 letter of support from the Health Research Authority Confidentiality Advisory Group (HRA CAG), dated the 10th August 2021, did not provide support for identifiable data to flow to the CSU from NHS Digital. IGARD therefore asked that written confirmation was provided from HRA CAG, that either the existing s251 support provided a gateway for NHS Digital to flow identifiable data to the CTSU-ctfs; or, that written confirmation was provided from HRA CAG that the s251 support had been extended to cover this flow of data. IGARD asked that in either scenario, written confirmation from HRA CAG was uploaded to NHS Digital's customer relationships management (CRM) system for future reference.</p> <p data-bbox="256 1895 1477 2007">In addition, IGARD asked that section 5(b) (Processing Activities) was updated, to ensure this public facing section that formed <u>NHS Digital's data uses register</u>, accurately aligned with the HRA CAG support. In line with <u>NHS Digital's DARS Standard for processing activities</u>.</p>

IGARD also noted that as part of the HRA CAG support accurate transparency was essential, and suggested that the applicant discussed the proposed Opt-out procedures with HRA CAG, to ensure it aligned with the HRA CAG support.

IGARD advised that NHS Digital should ensure they were able to provide the service referenced within the applicant's privacy notice, in relation to removing participants who opt out of the follow-up; and if not, to suggest that updates were made to the transparency materials as appropriate.

IGARD noted that at the last review on the 5th August 2021, they had advised that they would expect to see significant patient and public involvement and engagement (PPIE) having taken place, and plans for ongoing PPIE, given the study's importance, that it commenced in 1985, the history of the application and previous HRA CAG advice with regard to PPIE. IGARD noted the helpful update within the application in respect of the three current patient members of the Early Breast Cancer Trialists' Collaborative Group (EBCTCG) steering committee, however suggested that further thought was given to wider engagement, for example, in developing communications with the cohort, wider public communications about the research, and that a clear narrative was provided of the PPIE undertaken to date and in line with the [HRA guidance on Public Involvement](#).

IGARD noted that a Data Protection Impact Assessment (DPIA) was not necessary because of the aged processing, however noted [guidance](#) from the Article 29 Working Party, that strongly recommended DPIAs for processing already underway before May 2018 or where risks had changed. IGARD suggested that the [DPIA template](#) provided by the ICO would provide helpful guidance and consideration for transparency and engagement with the cohort as well as providing useful information for patients with similar needs.

IGARD queried the benefits outlined in section 5(d) (Benefits), and noted that some of the information provided were outputs, and asked that section 5(d) was updated to remove any outputs, and edited to only leave examples that reflect the benefits to Health and Social Care System, in line with the [NHS Digital's DARS Standard for Expected Measurable Benefits](#).

IGARD noted the yielded benefits in section 5(d) (iii) (Yielded Benefits) and, in line with [NHS Digital's DARS Standard for Expected Measurable Benefits](#), asked that the outputs were moved to section 5c and that the section retain the details provided of two or three 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, to ensure the processing activities as outlined in section 5(a) (Objective for Processing) were reflected in the excellent and wide-ranging yielded benefits achieved.

IGARD noted that section 1 (Abstract) stated that a review by IGARD was not required; and again requested that NHS Digital review their internal processes and IT systems to ensure this doesn't incorrectly default to state "no" and until this was corrected in the IT system, that it was manually corrected when the DSA was prepared.

IGARD noted the reference to "CMS products" in section 1, and asked that for ease of reference, the acronym was defined upon first use.

IGARD asked that section 1 was amended, to correctly reflect that **only** the identifiers would be destroyed for the relevant cohort, not "the data".

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 s251 support queries.

Outcome: recommendation to approve subject to the following conditions:

1. In respect of the HRA CAG support:
 - a) To provide written confirmation from HRA CAG that the existing s251 support provides a gateway for NHS Digital to flow identifiable data **to** the CTSU-ctfs; or,
 - b) To provide written confirmation from HRA CAG that the s251 support has been extended to cover this flow of data.
 - c) To upload the written confirmation from HRA CAG to NHS Digital's CRM system for future reference.
 - d) To update section 5(b) to ensure this section accurately aligns with the HRA CAG support.

The following amendments were requested:

1. In respect of the benefits and in line with the [NHS Digital's DARS Standard for Expected Measurable Benefits](#):
 - a) To remove any specific outputs from section 5(d) and move to section 5(c).
 - b) To update section 5(d) (iii) to provide 2 or 3 specific yielded benefits accrued to date, to ensure the processing activities as outlined in section 5(a) are reflected in the excellent and wide-ranging yielded benefits achieved.
2. In respect of section 1:
 - a) IGARD noted that section 1 stated that a review by IGARD was not required; and again requested that NHS Digital review their internal processes and IT systems to ensure this doesn't incorrectly default to state "*no*" and until this is corrected in the IT system, that it is manually corrected when the DSA is prepared.
 - b) To update section 1 to ensure the "*CMS products*" acronym is defined upon first use.
 - c) To amend section 1 to correctly reflect that **only** the identifiers will be destroyed for the relevant cohort, not "*the data*".

The following advice was given:

1. In respect of transparency to the cohort:
 - a) IGARD noted that, as part of the HRA CAG support, accurate transparency was essential and suggested the applicant discussed the proposed Opt-out procedures with HRA CAG to ensure it aligned with the HRA CAG support; and,
 - b) IGARD advised that NHS Digital should ensure they were able to provide the service referenced within the privacy notice; and if not, to suggest updates to the transparency materials as appropriate.
2. IGARD noted the helpful update within the application in respect of the three current patient members of the EBCTCG steering committee and suggested that, given the scope, scale and importance of the study, that further thought was given to wider engagement, for example, in developing communications with the cohort.
3. IGARD noted that a DPIA may not necessary because of the aged processing, however noted guidance that made clear that the date of processing was not determinative. IGARD also suggested that the DPIA template provided by the ICO would provide helpful guidance and consideration for transparency and engagement with the cohort as well as providing useful information for patients with similar needs.
4. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the s251 support queries.
5. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the s251 support queries.

	It was agreed the conditions would be approved out of committee (OOC) by IGARD members.
3.2	<p><u>GlaxoSmithKline Research & Development Limited: Investigation of TRELEGY Effectiveness: Usual Practice Design (INTREPID) Exploratory data set (Presenter: Anna Weaver) NIC-297783-V4P6H-v2.2</u></p> <p>Application: This was an extension application to permit the holding and processing of pseudonymised Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC), HES Critical Care and HES Outpatients data.</p> <p>It was also an amendment to 1) remove Ignite Data Limited as a Data Processor; 2) to remove Microsoft Limited as a Data Processor, and their associated storage and processing locations.</p> <p>Healthcare resource utilisations (HCRU) is the quantifiable measure of a person's use of services for the purpose of both preventing and curing health problems, the promotion of maintenance of health and wellbeing. Through systematic review the disease burden experienced by both the patient and their healthcare providers can be assessed.</p> <p>The purpose is for a study, to 1) assess the feasibility of using routine healthcare data to collect secondary care healthcare resource utilisation data (all cause and Chronic Obstructive Pulmonary Disease (COPD) related) in clinical trials using NHS Digital data for patients consented into the INTREPID study. The study will describe the recording and completeness of different components of secondary care HCRU and the ability to apply Healthcare Resource Group (HRG) tariffs to these where possible; and 2) to use the NHS Digital data to summarise HCRU and costs using Healthcare Resource Group (HRG) tariffs for COPD patients on inhaled triple therapy for patients consented into the INTREPID study.</p> <p>The trial consists of 629 consented individuals from England only.</p> <p>NHS Digital noted, that as outlined in section 1 (Abstract), the applicant had breached the current data sharing agreement (DSA) by remotely accessing data from a location outside the territory of use, i.e. from the United States of America (USA).</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 3rd September 2019 and the 7th October 2021.</p> <p>IGARD confirmed that they were of the view that the most recent consent materials provided the appropriate gateway and were broadly compatible with the processing outlined in the application.</p> <p>IGARD noted the information in section 1 in respect of the breach of the DSA, where the NHS Digital data had been remotely accessed from the USA. NHS Digital advised IGARD that following discussions and ongoing work with the applicant, it had been established that no further breaches had occurred under this DSA, other than the one highlighted in the application, and there was therefore no need to contact the Information Commissioner's Office (ICO) in terms of UK General Data Protection Regulation (UK GDPR), and there was low risk to the cohort members / patients. IGARD noted and thanked NHS Digital for the verbal update; however advised, that there was still a risk to public trust and confidence in the use of their data and given the breach by a commercial company of its contract with NHS Digital, and that that breach involved processing data in the USA, that narrative be included within the application summary. IGARD also noted that while access to the data from the USA was a breach of the DSA, IGARD reviewed the consent material and observed that this did appear to be in line with the consent given by participants. This review did not appear to have happened</p>

during the assessment of the breach and IGARD noted that it is important that NHS Digital should check the perspective of a consented cohort where a DSA breach occurs.

IGARD asked that section 5(b) (Processing Activities) was updated, to ensure this public facing section that formed [NHS Digital's data uses register](#), was updated to note that there was a period where processing of the NHS Digital data was taking place in breach of the DSA and outside the permitted territory of use and in line with [NHS Digital's DARS Standard for processing activities](#).

IGARD also suggested, that in **all** cases, a copy of the Breach Report should be provided to the Caldicott Guardian by NHS Digital's Data Protection Office (DPO) and that separate to this application, Breach Reports were included as a supporting document for IGARD to review as part of the application pack.

IGARD noted the potential benefit of having publicly available information on the applicant's website, along with a paper copy of patient information provided at consent, to support public trust and confidence in pharmaceutical company use of health data. Noting that the applicant only provides a paper copy of the privacy notice at consent, IGARD suggested that an online notice would have the additional benefit of keeping the cohort updated on developments, since they may not be attending GP practices.

IGARD noted the helpful information provided in section 5(e) (Is the Purpose of this Application in Anyway Commercial) in respect of the commercial activities, however asked that the second sentence "...wider service improvement..." was removed since it was not necessary.

IGARD noted the Legitimate Interest information in section 5(a) (Objective for Processing), and asked that the Legitimate Interest information was further developed, with narrative in line with the [NHS Digital DARS Standard for Objective for Processing](#) and additional detail added about the commercial activities, as outlined within section 5(e), since the current narrative was describing the therapy not what legitimate interest was.

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 the breach in the DSA.

Outcome: recommendation to approve

The following amendments were requested:

1. To update section 5(b) to note that there was a period where processing of the NHS Digital data was taking place in breach of the DSA and outside the permitted territory of use.
2. To update the Legitimate Interest information in section 5(a) with a more developed narrative in line with the NHS Digital DARS Standard and additional detail added about the commercial activities (as outlined within section 5(e).
3. To amend section 5(e) to remove the second sentence as this is not necessary.

The following advice was given:

1. IGARD noted that in respect of the breach, NHS Digital have worked with the applicant to establish that there is no other breach of the DSA and there is no need to contact the ICO in terms of UK GDPR, and there is low risk to the cohort members / patients. In addition, IGARD suggested, that in all cases, a copy of the Breach Report should be provided to the NHS Digital Caldicott Guardian.

	<ol style="list-style-type: none"> 2. Separate to this application, IGARD suggested Breach Reports are included as a supporting document for IGARD reviews by NHS Digital. 3. IGARD noted the potential benefit of having publicly available information on the applicant's website, along with a paper copy of patient information provided at consent, to support public trust and confidence in pharmaceutical companies use of health data. Noting that the applicant only provides a paper copy of the privacy notice at consent, suggested that an online notice would have the additional benefit of keeping the cohort updated on developments, since they may not be attending GP practices. 4. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the history of the breach in the DSA. 5. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the history of the breach in the DSA. <p>Significant Risk Area: There is a risk to public trust and confidence in the use of their data, given the breach by a commercial company of its contract with NHS Digital and that that breach involved processing data in the US.</p>
3.3	<p><u>NHS Bristol, North Somerset and South Gloucestershire CCG: (Presenters: Michael Ball / Wendy Lee) NIC-186885-Q1T3D-v6.2</u></p> <p>Application: This was an amendment application to 1) add Medicines Dispensed in Primary Care (NHSBSA Data) and Adult Social Care data for commissioning purposes; 2) to add COVID-19 Mapping and Mitigation in Schools (CoMMins) project which is led by University of Bristol, this will involve linkage to an external dataset; 3) to add details for Bristol, North Somerset and South Gloucestershire CCG project, that evaluates the key deliverables from 5 sub-projects, around hip and knee osteoarthritis patients within the CCG's area (Evaluation of the key deliverables for Keeping People Healthy subgroup of the MSK programme board); this will involve linkage to an external dataset; 4) to add details for a second independent part of the Evaluation project, conducted by University of Bristol on behalf of the CCG. Service users who are part of the Keeping People Healthy programme will be invited to take part in a Health Improvement Opportunities (HIO) for Joint Arthritis Patients Study via Questionnaire. If the patient consents and completes the questionnaire, this will be linked to the data via Study ID.</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>Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 21st November 2019, 8th October 2020 and 2nd December 2021.</p> <p>IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 19th January 2021.</p> <p>IGARD noted that prior to the meeting, and due to the complexity of the application, a number of queries had been raised with NHS Digital in respect of the amendments outlined, particularly in respect of amendments 1, 2 and 4. The queries raised by IGARD, included the data controllership arrangements for example, were NHS Bristol, North Somerset and South Gloucestershire CCG the sole data controller for this particular activity, noting the supporting documents did not appear to support this position. IGARD advised that this aspect would</p>

need reviewing, in line with the consent materials, which would need assessing in line with usual NHS Digital processes and [NHS Digital's DARS Standard for Data Controllers](#), to ensure there was nothing in the CoMMins consent materials that would preclude the data from being linked, processed or onwardly shared by the Data Controller for that study; and that the study was aligned with the ethical support provided. IGARD noted that the application would need updating as appropriate to ensure this reflected the correct information.

IGARD also asked that NHS Digital provide a satisfactory written assessment of the data controllership underpinning the MSK data request.

IGARD also advised that if the Data Controller(s) were looking to establish a Programme Level Agreement, then the applicant should consider a separate DSA, which should include (but not limited to) strong governance for instance by a local NHS system mandated oversight Committee, and a clear description of the broad parameters, under which programmatic applications would progress.

Noting the number of outstanding queries raised on the amendments, IGARD asked that the application was updated throughout to remove **all** references to any new prospective project work. In addition, IGARD asked that the application was updated throughout to remove references to the CoMMins study.

IGARD noted that should the amendments, which were not recommended for approval at this time, be added back in to the DSA, and presented at a future IGARD BAU meeting, that NHS Digital and the applicant should ensure that they read the full minute extract from this meeting, which would outline a number of key points that relate to the amendments not being recommended for approval; and that these points should be fully addressed.

IGARD asked that a satisfactory written assessment of the consent materials was provided and in line with usual NHS Digital processes, underpinning the MSK data set and other related materials which demonstrates NHS Digital's view that the processing was not incompatible with the consent participants provided.

IGARD noted that Article 9(2)(h) of the UK General Data Protection Regulation (GDPR) Article was being relied on for the processing of the NHS Digital data however asked that this was revised to align with the new processing outlined, and to correctly list the DPA 2018 Schedule 1 Part 1 references and clearly describe how the schedule conditions were met.

IGARD noted the benefits in section 5(d) (Benefits), however asked that these were updated further, to ensure the benefits reflect the additional processing being undertaken, in line with the [NHS Digital DARS Stand for Expected Measurable Benefits](#).

IGARD queried point 23 of the benefits outlined in section 5(d) *"Insight to understand the numerous factors that play a role in the outcome for **both datasets**."*; and asked that this was updated with further clarity on the reference to *"both datasets"*, since it was not clear what this referred to.

IGARD noted that Section 5(d) (iii) (Yielded Benefits) did not appear to be in line with the [NHS Digital DARS Stand for Expected Measurable Benefits](#), and asked that this section was updated accordingly. In addition, IGARD asked that confirmation was provided in section 5(d) (iii) that the yielded benefits were achieved using the data under this DSA, noting that this was currently unclear.

IGARD noted the statement to the actual savings made in section 5(d) (iii), however asked that statements to actual savings that would be made were avoided, unless these could reasonably be justified, and instead, refer to, for example, *"modelled"* savings.

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

Noting the forthcoming CCG / Integrated Care System (ICS) transition that was due to be completed later this year, prior to the end date of the agreement and the data retention period, IGARD asked that section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) were updated to also include a reference to this for information.

IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the novel processing.

Outcome: unable to recommend for approval for amendment points 1, 2 and 4

Outcome: recommendation to approve subject to the following conditions in respect of amendment point 3 only.

1. To update the application throughout to remove **all** references to any new prospective project work.
2. To update the application throughout to remove **all** references to the CoMMins study.
3. NHS Digital to provide a satisfactory written assessment of the consent materials underpinning the MSK data set and other related materials which demonstrates NHS Digital's view that the processing is not incompatible with the consent participants provided.
4. NHS Digital to provide a satisfactory written assessment of the data controllership underpinning the MSK data request.

The following amendments were requested:

1. To update section 1 and section 5 with a reference to the forthcoming CCG / ICS transition.
2. IGARD asked that the UK GDPR legal basis was revised to align with the new processing outlined, and to correctly list the DPA 2018 Schedule 1 Part 1 references and clearly describe how the schedule conditions are met.
3. IGARD noted a number of technical terms in section 5, and asked that this public facing section, that forms [NHS Digital's data uses register](#), was amended throughout, to ensure acronyms be defined upon first use, and technical terms are explained in a manner suitable for a lay audience, for example, “ARC Bite”.
4. In respect of the benefits in section 5(d):
 - a) To ensure the yielded benefits are updated in line with the [NHS Digital DARS Stand for Expected Measurable Benefits](#).
 - b) To update section 5(d) to ensure the benefits reflect the additional processing being undertaken.
 - c) To confirm that the yielded benefits in section 5(d) (iii) were achieved using the data under this DSA.
 - d) To update point 23 in section 5(d) to provide further clarity on the reference to “both datasets”.
 - e) To avoid statements that actual savings will be made and instead refer to, for example, “modelled” savings.

The following advice was given:

1. IGARD noted that should the amendments which were not recommended for approval at this time be added back in to the DSA, and presented at a future IGARD BAU

	<p>meeting, that NHS Digital and the applicant should ensure that they read the full minute extract, which will outline a number of key points that relate to the amendments not being recommended for approval; and that these points should be fully addressed.</p> <ol style="list-style-type: none"> 2. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the novel processing. 3. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the novel processing.
3.4	<p>NHS Liverpool CCG: DSfC - CIPHA - CV19 (Presenter: Michael Ball) NIC-396095-H1P1D-v3.4</p> <p>Application: This was an amendment application to update the description of the data within the Data Sharing Agreement (DSA), specifically the description of the data being transferred to Graphnet Health Ltd being changed from pseudonymised to identifiable.</p> <p>The purpose of the application, is to support a set of COVID-19 related population health analytics, designed to inform both population level planning for COVID-19 recovery and to support the targeting of direct care to vulnerable populations across the Cheshire and Merseyside Sustainable Transformation Partnership.</p> <p>The proposal is to make a set of person level pseudonymised data available to CCG and Local Authorities, which will enable them to support the local system including the COVID-19 recovery cells, public health teams, Hospital and Out of Hospital cells across the Cheshire and Merseyside patch as well as with local COVID-19 planning; which includes support to General Practice and Primary Care Networks in intelligence required. A further example of analysis is a set of automated dashboards in the areas of COVID sit rep reporting, Capacity and Demand, Epidemiology, and Population Stratification.</p> <p>The CCGs named within this DSA already receive commissioning data from NHS Digital under data sharing agreement (DSA) NIC-140059-P1J9L.</p> <p>NHS Digital noted, that as outlined in section 1 (Abstract), the applicant had breached the current data sharing agreement (DSA) through the process of re-identification for direct care performed by the Data Controllers / Data Processors.</p> <p>Discussion: IGARD noted that this application had been previously seen at the IGARD – NHS Digital COVID-19 Response meetings on the 29th September 2020, 1st October 2020, 6th October 2020 and 20th October 2020.</p> <p>IGARD noted and commended NHS Digital, on the response to previous issues and queries raised by IGARD, which had been addressed within the updated application.</p> <p>IGARD noted the information in section 1, in respect of the breach of the DSA, through the process of re-identification for direct care performed by the Data Controllers / Data Processors. IGARD thanked NHS Digital for providing a copy of the Breach Report had been provided as a supporting document, however suggested that this was also shared with NHS Digital's Caldicott Guardian.</p> <p>IGARD noted that the amendment was to allow the activity which led to the breach to become part of the DSA, as opposed to the re-identification being undertaken by the Data Services for Commissioners Regional Office (DSCRO), and queried if Graphnet had equivalent, robust re-identification processes in place; and, noting that this was unclear, asked that satisfactory written confirmation was provided.</p> <p>IGARD queried the information in section 1 that stated version 1 of the application was amended due to Microsoft (MS) locations being omitted from the previous version; and asked</p>

that clarity was provided in section 1 if the MS locations being omitted also resulted in a breach of the DSA, with narrative included for future reference.

IGARD suggested that NHS Digital consider a full audit of Graphnet Health Ltd in respect of **all** data usage under **all** live DSAs with NHS Digital, where Graphnet was recorded as a Data Processor, to ensure it was in line with the specific purposes of the data flows and the legal basis put forward for each data flow.

IGARD noted that, since The Health Service Control of Patient Information (COPI) Regulations 2002 was being relied upon, the special condition in section 6 (Special Conditions) was updated with confirmation that all Data Processors processing confidential patient information, would comply with Regulation 7(2) COPI, and must be a health professional or person who in the circumstance owes a duty of confidentiality which is equivalent to that which would arise if that person were a health professional, citing the Regulation 7(2) wording: *"No person shall process confidential patient information under these Regulations unless he is a health professional or a person who in the circumstances owes a duty of confidentiality which is equivalent to that which would arise if that person were a health professional."*. In addition, IGARD also suggested an audit review, to ensure the appropriate contracts were in place, to fulfil Regulation 7(2) of COPI.

IGARD queried the reference in section 1 to pseudonymised data flowing under COPI, and asked that this was removed as it was incorrect.

IGARD noted that Section 5(d) (iii) (Yielded Benefits) did not appear to be in line with the NHS Digital DARS Standard for Expected Measurable Benefits and asked that this section was updated accordingly. In addition, IGARD asked that applicant provided two or three specific yielded benefits accrued to date in section 5(d) (iii) and to ensure these are clear about the benefits to both patients and the health care system more generally, that justified the continued use of the re-identification data outlined in the DSA.

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.

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 suggested audit.

Outcome: recommendation to approve subject to the following conditions:

1. NHS Digital to provide satisfactory written confirmation that Graphnet have robust re-identification processes in place, comparable to the DSCRO's re-identification processes.
2. In respect of the Yielded Benefits in section 5(d)(iii):
 - a. To update the yielded benefits in line with the NHS Digital DARS Standard for Expected Measurable Benefits, and
 - b. Given the significant volume of data, to provide 2 or 3 specific yielded benefits accrued to date and ensure these are clear as to the benefits to both patients and the health care system more generally, that justifies the continued use of the re-identification data outlined in the DSA.

The following amendments were requested:

1. To update section 1 to remove reference to pseudonymised data flowing under COPI.
2. To amend the special condition in section 6 to provide confirmation that all Data Processors, processing confidential patient information under COPI, comply with the

	<p>obligations of those processing data (not just the obligations of the controller) as per Regulation 7(2) COPI.</p> <ol style="list-style-type: none"> To clarify in section 1 if the earlier iteration of the DSA, that was amended in light of the MS locations being omitted, resulted in a breach of the DSA. 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"> IGARD noted the Breach Report provided as a supporting document and suggested that this was shared with NHS Digital's Caldicott Guardian. In respect of a request to audit: <ol style="list-style-type: none"> IGARD suggested that NHS Digital consider a full audit of Graphnet Health Ltd in respect of all data usage under all live DSAs with NHS Digital where Graphnet is recorded as a processor to ensure it is in line with the specific purposes of the data flows and the legal basis put forward for each data flow. IGARD suggested an audit review to ensure the appropriate contracts are in place, to fulfil Regulation 7(2) of COPI. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the suggested audit. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the suggested audit. <p>It was agreed the conditions would be approved out of committee (OOC) by IGARD members.</p>
4	<p><u>Applications progressed via NHS Digital's Precedent route, including the SIRO Precedent</u></p> <p>Applications that have been progressed via NHS Digital's Precedent route, including the SIRO Precedent, and NHS Digital have notified IGARD in writing (via the Secretariat).</p> <p><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 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 register June to July 2021.</p> <p>IGARD noted that the IG COVID-19 Release Register July to October 2021 had been circulated and reviewed out of committee by members, discussed in-meeting and agreed the comments that would be shared with the Privacy, Transparency and Ethics Directorate. IGARD noted that no new major issues had been raised in respect of the IG COVID-19 release register July to October 2021.</p>

6	<p><u>COVID-19 update</u></p> <p><i>No items discussed.</i></p>
<p>7</p> <p>7.1</p>	<p><u>AOB:</u></p> <p><u>Updated PAG Notes – 400304-S1P1B-v4.1</u></p> <p>IGARD noted that at the BAU meeting on the 27th January 2022, 400304-S1P1B-v4.1, the Office for National Statistics (ONS) application had been presented; and that meeting notes from the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) held on the 26th January 2022 had been provided to support the discussion.</p> <p>IGARD noted that PAG had not supported the application in its current form; and that the notes from the PAG meeting were in the process of being updated and ratified by PAG members, to ensure the reason for this was clear and transparent. IGARD confirmed that although out of process, the revised PAG notes would be included in the IGARD BAU minutes on the 10th February 2022 for transparency.</p> <p>IGARD noted and thanked PAG colleagues for the updated notes that had been received prior to the meeting (please see appendix B).</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>
8	<p><u>IGARD / ONS – Meet and Greet Session</u></p> <p>Following conclusion of the IGARD business as usual (BAU) section of the meeting, IGARD held a meet and greet session with colleagues from the Office for National Statistics (ONS), which was also attended by a number of NHS Digital colleagues.</p> <p>The <u>UK Statistics Authority</u> is an independent body at arm's length from government and has a statutory objective of promoting and safeguarding the production and publication of official statistics. Their remit covers three principal elements of the UK official statistics system:</p> <ul style="list-style-type: none"> • The <u>Government Statistical Services</u> (GSS) • The <u>Office for National Statistics</u> (ONS) • The <u>Office for Statistics Regulation</u> (OSR) <p>IGARD thanked ONS for attending and for providing a briefing paper which gave an overview of ONS and addressed some of the points raised previously by IGARD, during review of ONS applications at IGARD BAU meetings.</p> <p>IGARD and ONS agreed that moving forward, it may be beneficial to meet on an ad-hoc basis in order to keep each other informed and up to date.</p> <p>In addition, IGARD advised that they would be pleased to meet with the National Statistician's Data Ethics Advisory Committee (NSDEC), or NSDEC Chair, to further understand their operation and share ideas.</p> <p>IGARD also advised ONS that they would be happy to discuss specific subject matters with ONS colleagues, for example, transparency of information provided to the public.</p> <p>The IGARD Chair thanked colleagues within the Data Access Request Service (DARS) for arranging the session; and thanked ONS, IGARD members and NHS Digital colleagues for</p>

	their time. The IGARD Chair noted that the discussion had also raised a number of issues that it would be useful for IGARD to discuss with NHS Digital colleagues.
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Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 04/02/22

These applications were previously recommended for approval with conditions by IGARD, and since the previous Out of Committee Report the conditions have been agreed as met out of committee.

NIC Reference	Applicant	IGARD meeting date	Recommendation conditions as set at IGARD meeting	IGARD minutes stated that conditions should be agreed by:	Conditions agreed as being met in the updated application by:	Notes of out of committee review (inc. any changes)
NIC-604847-S4B5L	GRAIL's NHS Galleri Clinical Trial	13/01/2022	1. In relation to the Global Transfer Assessment: a) To provide written confirmation from NHS Digital's PTE that the appropriate Global Transfer Assessment documentation has been approved and in place. b) To upload the written confirmation to NHS Digital's CRM system.	IGARD Chair	OOO by the IGARD Chair	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:

- NIC-90647-G3Q4S-v7.2 - DSfC – NHS Barnsley CCG – Comm, RS & IV

Graphnet Class Actions:

- None

Appendix B

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 26th January 2022

Application & application version number: DARS-NIC-400304-S1P1B-v4.1
Organisation name: ONS
Profession Advisory Group Agenda item: 2
<p>PAG do not support the application in its current form:</p> <ol style="list-style-type: none">1. The applicant should outline a list of additional projects associated with other linkages for PAG to consider as there may be unintended consequences that we need to consider from a professional and patient perspective.2. PAG feel that the current Covid-19 related scope should provide quite a broad range of analyses that the organisation can conduct. What specific analysis does the currently approved DARS application not allow ONS to carry out?

Attendees	Role	Organisation
Jonathan Osborn	Deputy Caldicott Guardian	NHS Digital
Amir Mehrkar	GP, Clinical Researcher	RCGP
Mark Coley	Deputy IT Policy Lead	BMA
Liz Gaffney	Head of Data Access	NHS Digital
Pam Soorma	Secretariat	NHS Digital
Dave Cronin	Data Approvals Officer	NHS Digital