

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 22 September 2022

IGARD MEMBERS IN ATTENDANCE:	
Name:	Position:
Paul Affleck	Specialist Ethics Member / Co-Deputy IGARD Chair
Prof. Nicola Fear	Specialist Academic Member (Items 3.1 to 3.4)
Kirsty Irvine	IGARD Chair (Items 1 to 3.1, 3.4 to 7.3)
Dr. Imran Khan	Specialist GP Member / Co-Deputy IGARD Chair (Chaired items 3.2 and 3.3)
Dr. Maurice Smith	Specialist GP Member
Jenny Westaway	Lay Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Maria Clark	Lay Member
Dr. Robert French	Specialist Academic / Statistician Member
Dr. Geoffrey Schrecker	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	Team:
Garry Coleman	Associate Director, Deputy SIRO & Audit Services (Item 7.3)
Dave Cronin	Data Access Request Services (DARS) (SAT Observer: items 3.2, 3.4) (Item 3.3)
Louise Dunn	Data Access Request Services (DARS) (SAT Observer: item 3.5)
Duncan Easton	Data Access Request Services (DARS) (SAT Observer: item 3.1)
James Gray	Digi-Trials (Item 3.5)
Dickie Langley	Privacy, Transparency, Ethics and Legal (PTEL) (Observer: item 7.1)
Abigail Lucas	Data Access Request Services (DARS) (Item 3.2)
Susan Main	Data Access Request Services (DARS) (Item 7.1) (Observer: item 7.3)
David Morris	Data Access Request Services (DARS) (Item 3.1)
Karen Myers	IGARD Secretariat

Anna Weaver	Data Access Request Services (DARS) (Item 3.4)
Vicki Williams	IGARD Secretariat
Ly-Mee Yu	Data Service Directorate (Item 7.2)
*SAT – Senior Approval Team (DARS)	

1	<p>Declaration of interests:</p> <p>Paul Affleck noted he was a public contributor to the Blood and Transplant Research Unit (BTRU) in Donor Health and Genomics at the University of Cambridge (relevant to NIC-241585-H9F8C); and also noted a personal connection to the cohort study. It was noted that he had no specific connections with the application or staff involved and it was agreed that this was not a conflict of interest.</p> <p>Prof Nicola Fear noted a professional link to the staff involved with NIC-169971-Z9M1C (Institute of Occupational Medicine), it was agreed this did not preclude Prof. Fear from taking part in the discussions about this application, however agreed that she would not participate in making a recommendation about the application.</p> <p>Review of previous minutes and actions:</p> <p>The minutes of the 22nd September 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><u>NHS England: DSfC - NHS England Data Platform (Presenter: David Morris) NIC-139035-X4B7K-v12.2</u></p> <p>In line with the new process, as per the discussion at the IGARD meeting on the 8th September 2022 and agreed by NHS Digital via email, this application is being brought to IGARD for advice only and would then proceed under NHS Digital's SIRO precedent if appropriate. The new process, implemented from the 1st September 2022, was made in line with IGARD's published Terms of Reference and to support NHS Digital / NHS England ahead of the transition of NHS Digital into NHS England on 1st April 2023, where both organisations will become one entity.</p> <p>Application: This was an extension application to NHS England's National Commissioning Data Repository agreement for pseudonymised Children and Young People's Health Services (CYPHS), Secondary Use Service (SUS) for Commissioners, Demand for Service-Local Provider Flows, Community-Local Provider Flows, Acute Local Provider Flows, Ambulance-Local Provider Flows, Diagnostic Services-Local Provider Flows, Emergency Care-Local</p>

Provider Flows, Experience, Quality and Outcomes-Local Provider Flows, Mental Health-Local Provider Flows, Population Data-Local Provider Flows, Other Not Elsewhere Classified (NEC)-Local Provider Flows, Community Services Data Set (CSDS), Diagnostic Imaging Data Set (DIDs), Improving Access to Psychological Therapies (IAPT), Mental Health Minimum Data Set (MHMDS), Mental Health and Learning Disabilities Data Set (MHLDDS), Maternity Services Data Set (MSDS), Civil Registration (Births), Civil Registration (deaths), Mental Health Services Data Set (MHSDS), National Cancer Waiting Times Monitoring Data Set (NCWTMDS), National Diabetes Audit (NDA), Assuring Transformation Flows (AT), Patient Reported Outcome Measures (PROMs), Medicines dispensed in Primary Care (NHSBSA data), Summary Hospital-level Mortality Indicator and e-Referral Service for Commissioning.

It was also an amendment application to **1)** update the purpose of the application in section 5(a); **2)** to add in the additional yielded benefits in section 5(d) (iii); **3)** to remove NHS Improvement (Comprised of NHS Trust Development Authority and Monitor) as a Data Controller; **4)** to add Hospital Episodes Statistics Admitted Patient Care (HES APC), HES Accident & Emergency (A&E), HES Outpatients and HES Critical Care datasets; and **5)** to add the Emergency Care Dataset (ECDS).

The purpose of the application is to ensure that NHS England can meet their statutory duties as per the NHS Act 2006 and the Health and Social Care Act 2012, and to meet the requirements of the Five Year Forward View.

Discussion: IGARD noted that in line with the new process outlined to NHS Digital via email on the 22nd August 2022, and as discussed at the IGARD meeting on the 8th September 2022, this application was being brought to IGARD for advice only and would then proceed under NHS Digital's SIRO precedent if appropriate.

IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD meetings on the 25th April 2019, 15th August 2019, 17th October 2019, 12th December 2019, 13th February 2020, 19th July 2020, 17th November 2020, 17th December 2020, 28th January 2021, 19th August 2021, 27th January 2022 and the 12th May 2022.

IGARD noted that this application had been previously seen at the IGARD – NHS Digital COVID-19 Response meeting on the 7th January 2021.

The application was discussed under 'AOB' on the 19th May 2022 and 26th May 2022; and as part of the 'applications progressed via NHS Digital's SIRO Precedent route on the 10th March 2022.

It was also discussed as part of the discussion for NIC-384608-C9B4L on the 25th August 2022.

IGARD expressed concern that the applicant did **not** seem to have a publicly available privacy notice covering this processing and noted that they'd been unable to find any publicly available information on the website about the activities generally, noting that NHS Digital had also agreed with this point in-meeting IGARD wished to draw to the attention of the applicant and NHS Digital's Senior Information Risk Owner (SIRO), the statement in section 4 (Privacy Notice), that a UK General Data Protection Regulation (UK GDPR) compliant, publicly accessible transparency notice will be maintained throughout the life of the agreement, in line with [NHS Digital's DARS Standard for Transparency \(fair processing\)](#). IGARD noted there was a significant reputational and legal risk factor to NHS Digital, in respect of the lack of transparency to the public in the form of a privacy notice.

IGARD noted that in addition to the significant point raised on the privacy notice, other information that highlighted the work undertaken with NHS Digital data covered by this data

sharing agreement (DSA), was also difficult to locate within the public domain; and suggested that, as a matter of urgency, this was addressed in line with UK GDPR, i.e. that this must be easily accessible. IGARD suggested that there was a risk that public trust and confidence would be undermined by this lack of information generally.

IGARD noted that prior to the meeting, a query had been raised by an IGARD member in respect of whether the University of Manchester had confirmed whether local ethical approval was required. NHS Digital confirmed that they had received verbal confirmation, that the work carried out was **not** research, and therefore local ethical approval was not required. IGARD noted the verbal update from NHS Digital, and asked for written confirmation from the relevant ethics body that ethical support from the University of Manchester was not required; and that the written confirmation was uploaded to NHS Digital's customer relationships management (CRM) system for future reference.

IGARD queried the statement in section 5(a) (Objective for Processing) under the heading 'Practical priorities will drive NHS Digital transformation' – *"Protect patients' privacy and give them control over their medical record"*; and asked that this was amended to provide further information, for example, were there future plans to update the NHS app; or remove, if it could not be linked to a current or future planned workstream using this data.

IGARD noted the references to *"*CCGs"* in section 5 (Purpose / Methods / Outputs), and following the dissolution of CCGs and the formation of Integrated Care Boards (ICBs) from the 1st July 2022, asked that references to *"CCGs"* were removed throughout the application and replaced with *"ICBs"*.

*Clinical Commissioning Groups

Separate to this application: IGARD noted that to support the new process for NHS England applications, it had been agreed with NHS Digital that a mid-pilot progress report would be produced in December 2022. Following the review of this application, IGARD highlighted a number of points to feed into the mid-pilot progress report, which are as follows:

IGARD suggested that an internal benefits register was created for the following purposes: **1)** to demonstrate compliance with the forthcoming National Data Guardian (NDG) public benefit guidance; **2)** to enable ready records and sharing of best practice to support the health and social care system; and **3)** for transparency to the public, which will build public trust and would likely be an important limb of the forthcoming NDG public benefit guidance.

IGARD suggested consideration was given to breaking down large former applications into more manageable workstreams, and to link to specific datasets, to enable scrutiny of NHS England's use of data to support delivery of its statutory duties.

IGARD suggested that a process was devised and agreed to identify when SIRO input would be required once NHS Digital became part of NHS England, for example, for use of significant flows of data.

Advice Outcome: IGARD confirmed that they were broadly supportive of the extension to the application and amendment points, but wished to draw to the attention of the SIRO the following significant issue:

1. In respect of the privacy notice and in line with [NHS Digital's DARS Standard for Transparency \(fair processing\)](#), IGARD wished to draw to the applicant's attention to the statement in section 4, that a UK GDPR compliant, publicly accessible transparency notice will be maintained throughout the life of the agreement.

	<p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. In respect of University REC support: <ol style="list-style-type: none"> a) To provide written confirmation from the relevant ethics body that ethical support from the University of Manchester is not required (as per the verbal update from NHS Digital). b) To upload the written confirmation to NHS Digital's CRM system for future reference. 2. To amend or remove the statement in section 5(a) <i>"Protect patients' privacy and give them control over their medical record"</i>. 3. To update section 5 to remove references to "CCGs" and replace with "ICBs". <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD noted that in addition to the significant point raised on the privacy notice, other information that highlights the work undertaken with the NHS Digital data, was also difficult to locate within the public domain; and suggested that, as a matter of urgency, this was addressed in line with UK GDPR, i.e. that this must be easily accessible. <p>Significant Risk Factor: Reputational and legal risk to NHS Digital in respect of the lack of transparency to the public in the form of a privacy notice.</p> <p>Separate to this application: IGARD noted points which would feed into the NHS England new process mid-pilot progress report.</p>
3.2	<p><u>Institute of Occupational Medicine (IOM): Cancer Incidence and Mortality Experience of a British and an International Cohort of Workers Occupationally Exposed to Styrene (Presenter: Abigail Lucas) NIC-169971-Z9M1C-v0.31</u></p> <p>Application: This was a new application for identifiable Cancer Registration Data, Civil Registration (Deaths) and Demographics data.</p> <p>Styrene is a high-production high-volume chemical with about eighteen thousand tonnes produced annually in the manufacture of plastic and synthetic rubber products worldwide. The general population is exposed to very low levels of styrene while occupationally exposed workers may encounter much higher levels of exposure. Around forty years ago, findings among workers in the synthetic rubber industry suggested an increased risk of leukaemia and lymphoma; however, interpretation of this finding was hampered by co-exposure to other chemicals.</p> <p>The purpose of the application is for a research project based on a cohort of workers occupationally exposed to styrene aiming 1) to understand which participants have died or contracted cancer, what the cause of death or type of cancer was and when these events occurred; 2) to understand whether cancer is occurring in this study population at a rate that is consistent with expectations after adjusting for age, sex and calendar year; and 3) to compare cancer rates, after the same adjustments, among those with higher and those with lower (or zero) exposure to styrene. This will hopefully increase the understanding of whether occupational exposure to styrene increases a person's risk of cancer.</p> <p>The cohort consists of approximately 1,800 workers in the glass reinforced plastics manufacturing industry, originally assembled by the Health and Safety Executive (HSE).</p> <p>The study is relying on s251 of the NHS Act 2006, for the flow of data in and out of NHS Digital.</p>

Discussion: IGARD noted that, prior to the meeting, a query had been raised by an IGARD member in respect of what specific steps have been taken to avoid past breaches reoccurring with this data sharing agreement (DSA), noting that information had been provided in section 1 (Abstract). NHS Digital advised that the past breaches fell into two primary categories; **1)** onward sharing of NHS Digital data where not permitted; and **2)** retaining data beyond the end of the DSA / Data Sharing Framework Contract (DSFC). NHS Digital advised that there had been ongoing discussions over recent months with the applicant, their Data Protection Officer and the NHS Digital Data Security Team; and that the DSA had been updated to make it explicit that onward sharing of data was not permitted; that all NHS Digital data must be destroyed when this DSA expires, and that the DSA must be extended and remain in line with the information standards in order to retain NHS Digital data. In addition, NHS Digital advised that NHS Digital could mark this DSA for the attention of NHS Digital's Audit team when it becomes an active DSA. IGARD noted and thanked NHS Digital for the update provided, and IGARD supported NHS Digital's proposal in respect of the audit of this organisation in relation to this DSA.

IGARD confirmed that they were of the view that the relevant s251 support was broadly compatible with the processing outlined in the application; however noting that the Health Research Authority Confidentiality Advisory Group (HRA CAG) annual review was due by the 15th September 2022, asked that written confirmation was provided that this had been submitted and accepted by HRA CAG, and that the written confirmation was uploaded to NHS Digital's customer relationships management (CRM) system for future reference. In addition, IGARD asked that section 1 was updated, to reflect that the HRA CAG annual review had been submitted and accepted.

IGARD suggested that NHS Digital contacted HSE **and** HRA CAG to discuss several issues including, but not limited to, the identifying information held by HSE on cohort members, whether they had previously given any consent, and the legal basis for holding confidential data; in addition to any other aspects of informing the cohort.

IGARD queried the reference in section 5(a) (Objective for Processing) to "*type 2*" opt-outs, and noting that this had now been replaced with the National Data Opt-out (NDO), asked that section 5(a) was updated to remove the reference to "*type 2*" opt-outs and replace with the NDO, if applicable.

IGARD noted references within the protocol and HRA CAG documentation to discussions held with Trade Unions and asked that section 5(a) was updated to reference the patient and public involvement and engagement (PPIE) undertaken.

IGARD noted the information in section 5(d) (Benefits) (ii) (Expected Measurable Benefits to Health and / or Social Care) relating to "*medico-legal cases*" brought against employers; and asked that this was removed, noting that this was not a benefit in line with the [NHS Digital DARS Standard for Expected Measurable Benefits](#). IGARD asked that, noting the possible medico-legal implications, section 5(a) was updated to briefly refer to the consideration of this.

IGARD suggested that section 5 (Purpose / Methods / Outputs) be updated to remove reference to "*it will...*", and instead use a form of words such as "*it is hoped...*".

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 DSA breaches by the applicant.

	<p>Outcome: recommendation to approve by a quorum of 4 members, with one Specialist member present not participating in making a recommendation on the application due to a potential conflict of interest.</p> <ol style="list-style-type: none"> In respect of the s251 support: <ol style="list-style-type: none"> To provide written confirmation that the HRA CAG annual review, due 15th September 2022, had been submitted and accepted, and To upload the written confirmation from HRA CAG to NHS Digital's CRM system for future reference; and, To update section 1 to reflect that the HRA CAG annual review has been submitted and accepted. To update the application to remove reference to "<i>type 2 objections</i>" and update to "<i>NDO</i>", if applicable. In respect of the reference to "<i>medico-legal cases</i>": <ol style="list-style-type: none"> To remove reference to "<i>medico-legal cases</i>" in section 5(d) (ii). To update section 5(a) to briefly refer to the consideration of possible medico-legal implications. To update section 5(a) with a reference to the PPIE, for example, the discussions held with Trade Unions as highlighted in the protocol and HRA CAG documentation. To update section 5 to use a form of wording such as "<i>it is hoped ...</i>", rather than "<i>it will...</i>". <p>The following advice was given:</p> <ol style="list-style-type: none"> IGARD suggested that NHS Digital contacted HSE and HRA CAG to discuss several issues including (but not limited to) the identifying information held by HSE on cohort member, whether they had previously given any consent, and the legal basis for holding confidential data; in addition to any other aspects of informing the cohort. IGARD supported NHS Digital's verbal update in respect of the audit of this organisation in relation to this DSA, due to previous breaches. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the history of DSA breaches by the applicant. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the history of DSA breaches by the applicant.
3.3	<p>University of Cambridge: STRategies to Improve Donor ExperienceS (STRIDES) (Presenter: Dave Cronin) NIC-241585-H9F8C-v0.5</p> <p>Application: This was a new application for pseudonymised Civil Registration (Deaths), Diagnostic Imaging Dataset (DIDs) and Hospital Episode Statistics Admitted Patient Care (HES APC) data.</p> <p>Vasovagal reactions (VVRs) are the most common acute complication related to blood donation and cause the greatest degree of donor injury. These reactions are highly disruptive and costly for blood services, for example, moderate to severe VVRs reduce the likelihood of repeat donations by more than 50%. They are also the second most frequent reason for donor claims; however, the evidence base for interventions to prevent VVRs is extremely limited.</p> <p>The purpose of the application is for a study, with the primary objective being to demonstrate effectiveness of interventions or combination of interventions to prevent vasovagal reactions</p>

(VVRs) in whole blood donors, through conduct of a cluster-randomised trial embedded within NHS Blood and Transplant (NHSBT).

The secondary objective of the study, is to develop prevention strategies tailored to specific sub-populations and identify predictors of VVRs, including demographic, biological, psychosocial and lifestyle factors. The study's endpoints are in-session VVRs, delayed VVRs and any in-session non-VVR adverse events or reactions. Endpoints will be collected using NHSBT's national recording systems for all donor adverse events or reactions. Delayed VVRs will be recorded by donors directly contacting NHSBT to report the VVRs and through linkage to electronic health records.

The trial is ongoing from November 2019 and is expected to finish in November 2022. All donors attending NHSBT donation sites and fulfilling all criteria for routine blood donation during the study period will receive interventions. It will involve approximately 1.3 million blood donors across the study period.

Discussion: IGARD noted that the application was coming for advice on the consent for the study cohort, due to concerns within NHS Digital, that the proposed cohort would not be sufficiently informed about the processing proposed under this application; and without prejudice to any additional issues that may arise when the application is fully reviewed.

IGARD noted that prior to the meeting, they had sought the views of NHS Digital's Deputy Caldicott Guardian in relation to the consent obtained for this study. The NHS Digital Deputy Caldicott Guardian had expressed concerns on the validity of the consent, however agreed that it was broadly compatible with the reasonable expectations of participants.

IGARD discussed the timing of the consent obtained, i.e. at the same time as donors were attending / consenting to donate blood, and noted that information was sent out to donors via an e-mail the week prior to this, and agreed that although this provided some reassurance in terms of transparency, however, there was a risk that this information may be lost / not read etc.

IGARD judged that the consent was insufficient but the data flow was compatible with the consent, in line with the [NHS Digital DARS Standard for Duty of Confidentiality](#). The consent form for blood donation was being relied upon with the key information about linkage and secondary uses of data being a brief statement in the 'Donor consent booklet'. However, the donation safety check/consent form was not explicit about such usage. IGARD therefore suggested that the applicant review the consent materials to ensure information to potential participants was clear and transparent with regard to data linkage and use.

To aid transparency, IGARD also suggested that the applicant should consider widening the method of communication to the potential participants of the cohort, for example, via newsletter, updating the website and / or text message etc; and that the applicant not just rely on e-mail and information provided on the day of blood donation.

IGARD noted that when blood donors attended blood donation centres, the consent undertaken by NHS Blood and Transplant, prior to donating, was very thorough. IGARD asked that section 5 (Purpose / Methods / Outputs) of the application was updated to clearly articulate and evidence this for transparency to the public.

IGARD queried what data minimisation had been undertaken on the datasets requested, including, but not limited to, the DIDs dataset; and noting that this was not clear in the application, asked that further clarification was provided in section 5, in line with [NHS Digital DARS standard for data minimisation](#).

	<p>IGARD noted the reference to the international collaborators in the protocol provided as a supporting document, and noting that the application was silent on this, asked that further clarification was provided in section 5.</p> <p>IGARD suggested the applicant explore with blood donors whether those donors believed their consent covered the intended linkage and use of data. Another suggestion was for NHS Digital and the applicant to explore ways of linking data without sharing personal identifiers via the use of a shared cryptographic SALT.</p> <p>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.</p> <ol style="list-style-type: none"> 1. To review and update any future consent materials. 2. To update the application to articulate and evidence the thorough process undertaken by NHS B&T when consenting donors for blood donation. 3. IGARD suggested that the applicant should also consider widening the method of communication to potential participants of the cohort. 4. To provide further clarification in the application of the data minimisation, including (but not limited to) the DIDs dataset, in line with NHS Digital DARS standard for data minimisation 5. To update the application to provide further clarification on the international collaborators, as outlined in the protocol. 6. IGARD suggested the applicant explore with blood donors whether those donors believed their consent covered the intended linkage and use of data. 7. IGARD suggested NHS Digital and the applicant explore ways of linking data without sharing personal identifiers via the use of a shared cryptographic SALT.
3.4	<p><u>Intensive Care National Audit & Research Centre (ICNARC): Risk modelling in the critically ill (Presenter: Anna Weaver) NIC-379807-P3R7Z-v5.18</u></p> <p>Application: This was an extension application to permit the holding and processing of identifiable Civil Registration (Deaths) - Secondary Care Cut, Hospital Episode Statistics Admitted Patient Care (HES APC), HES:Civil Registration (Deaths) bridge and National Diabetes Audit (NDA) data.</p> <p>It was also an amendment application to 1) add Exponential-e Ltd as a Cloud Storage Provider; 2) to add Babble Cloud (SUI) Limited as a Data Processor; 3) to remove ICNARC, Napier House, 24 High Holborn, London, WC1 6AZ as a processing and storage location; 4) to update the application to reflect that pseudonymisation of the data currently held by ICNARC will take place on or before 31st December 2022 in line with s251 support which expires on the same date; 5) to add a new study aim: to include secondary analysis and a PhD study.</p> <p>The purpose of the application is for a study that follows a previous study conducted by ICNARC, entitled “<i>Ensuring comparisons of health-care providers are fair: risk modelling for quality improvement in the critically ill</i>”, that addressed risk prediction modelling in three clinical areas: 1) adult general critical care; 2) adult cardiothoracic critical care; and 3) in-hospital cardiac arrest.</p> <p>This study aims to better understand the following: 1) epidemiology of critical illness, and 2) risk factors for and consequences of critical illness. Increased understanding of these areas and using data linkage with other routinely collected data sources will lead to improvements the risk models used to underpin national clinical audits for: 1) adult general critical care; 2) cardiothoracic critical care; and 3) in-hospital cardiac arrest.</p>

The cohort consist of approximately 800,000 patient records (cohort 1) in the initial linkage for 2009/10 - 2014/15, with a further cohort of approximately 200,000 (cohort 2) for the update to 2015/16.

The study is relying on s251 of the NHS Act 2006, for the flow of data in and out of NHS Digital.

Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the Data Access Advisory Group (DAAG) (IGARD's predecessor) meetings on the 12th July 2016 and 19th July 2016; and the IGARD meeting on the 8th June 2017.

IGARD noted and commended NHS Digital on the quality of some of the information within section 1 (Abstract) of the application, which supported the review of the application by Members.

IGARD queried, however, the history of the application since the last IGARD review in 2017 and were advised by NHS Digital that the application had proceeded via the Senior Information Risk Owner (SIRO) Precedent route. Internal issues meant this application had been out of contract since December 2021. NHS Digital advised that work had been undertaken to prevent this issue occurring again with this or other applications. IGARD noted and thanked NHS Digital for the verbal update, and asked that for future reference, the historical information was added to section 1.

IGARD queried if there had been a breach of the data sharing agreement (DSA) in respect of the processing and storage location, noting that it appeared the location address had changed and prior to notification to NHS Digital, despite this application noting this as an 'amendment' to an existing DSA. NHS Digital advised that the applicant had breached the DSA as the processing and storage location had been changed before the DSA had been updated, and that NHS Digital should have been notified prior to this. NHS Digital advised IGARD that the breach would be a reasonable justification for NHS Digital undertaking an audit on this DSA. IGARD noted and thanked NHS Digital for the verbal update, and were supportive of the suggested audit of this organisation in relation to this DSA.

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

IGARD queried if favourable ethical approval was still in place, noting that the supporting documentation provided did not clarify this point; and asked that written confirmation was provided that favourable ethical approval was in place, in particular supporting the extended length of the DSA; and, asked that the written confirmation was uploaded to NHS Digital's customer relationships management (CRM) system for future reference. IGARD also asked that once written confirmation was provided, section 1 was updated to reflect that favourable ethical approval was in place.

IGARD noted the benefits provided in section 5(d) (Benefits), however asked that these were reviewed in line with [NHS Digital DARS Standard for Expected Measurable Benefits](#), noting that some of the benefits outlined seemed to be for the applicant rather than for the benefit to the health system generally or patients specifically. IGARD also asked that section 5(d) was updated to ensure the benefits were clear to patients or the health and social care system or to remove the narrative from that section.

IGARD queried the references to "cost" in section 5(d), and asked that this was updated to further articulate, for example, whether this refers to the cost to an individual or financial costs to the NHS.

	<p>IGARD suggested that section 5(d) be updated to remove reference to “<i>it will...</i>”, and instead use a form of words such as “<i>it is hoped...</i>”.</p> <p>IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application, including spin-off or successor 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> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. In respect of ethical approval: <ol style="list-style-type: none"> a) To provide written confirmation that favourable ethical approval is in place, in particular supporting the extended length of the DSA; and, b) To update the written confirmation to NHS Digital’s CRM system for future reference; and, c) To update section 1 to reflect that favourable ethical approval is in place. 2. In respect of the benefits in section 5(d): <ol style="list-style-type: none"> a) To update the benefits in section 5(d) in line with NHS Digital DARS Standard for Expected Measurable Benefits; and, b) To update the benefits in section 5(d) to ensure they are clear as to the benefits to both the patients and the health and social care system; and, c) To update section 5(d) to further articulate the reference to “<i>cost</i>”, for example, whether this refers to a cost to an individual and/or financial costs to the NHS. d) To update section 5 to use a form of wording such as “<i>it is hoped ...</i>”, rather than “<i>it will...</i>”. 3. To update section 1 with clarity on the history of the application, i.e. since the last IGARD review in 2017. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD supported NHS Digital’s verbal update in respect of the audit of this organisation in relation to this DSA, due to previous breaches. 2. 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. 3. IGARD suggested that this application (including spin-off or successor applications) would not be suitable for NHS Digital’s Precedent route, including the SIRO Precedent, due to the history of the breach in the DSA.
3.5	<p><u>Our Future Health: Our Future Health Outcomes Data Linkage Application (Presenter: James Gray) NIC-411795-X5N2V-v0.3</u></p> <p>Application: This was a new application for pseudonymised Civil Registration (Deaths) data, Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC), HES Critical Care, HES Outpatients, National Disease Registration Service (NDRS) Cancer Pathway, NDRS Cancer registration (pre-1995), NDRS Cancer Registry, NDRS National Radiotherapy Dataset (RTDS), NDRS Somatic Molecular Dataset, NDRS Systemic Anti-Cancer Therapy Dataset (SACT); and identifiable Demographics data, Emergency Care Data Set (ECDS).</p> <p>Our Future Health was formed as part of the UK Life Sciences Industrial Strategy; and is designed to be the UK’s largest ever health research programme with the goal to recruit up to</p>

<p>5 million adult participants from across the UK to create a detailed picture that reflects the whole of the population.</p> <p>The purpose of the application is to 1) obtain pseudonymised record-level data linked to a cohort of consenting participants held by Our Future Health. Linkage to health records is a central component of the Our Future Health programme, forming part of the core cohort dataset. This application seeks to enable the high priority data linkages that will include secondary care, cancer data, and death data; and 2) seek permission to sub-licence the linked data with the global research community within the Our Future Health Trusted Research Environment (TRE).</p> <p>Our Future Health has a sister Data Sharing Agreement (DSA) NIC-414067-K8R6J to facilitate recruitment.</p> <p>Discussion: IGARD noted that the application and relevant supporting documents for NIC-414067-K8R6J had previously been presented at the IGARD meeting on the 5th May 2022. It was also discussed under 'AOB' at the IGARD meeting on the 26th May 2022.</p> <p>IGARD noted that the application was coming for advice before this was submitted to IGARD for a full review; and the proposed future amendment to the DSA - for record-level pseudonymised data to be shared with worldwide sub-licensees, via a defined access application process; who can access and analyse the data from the Our Future Health TRE and extract record level pseudonymised data to their own TREs, potentially situated in worldwide locations. The advice is without prejudice to any additional issues that may arise when the application is fully reviewed.</p> <p>IGARD had a lengthy discussion on the proposal within the data sharing agreement (DSA) for sub-licensing, and asked that in line with NHS Digital DARS standard for sub-licencing and onward sharing, NHS Digital should review the model for sub-licences for TRE access, for example, noting that NHS Digital would presumably not need to audit the sublicensee if data was only accessed via the Our Future Health TRE, as any data removed from that environment would be aggregated data.</p> <p>In addition, IGARD noted concern on the enormous volume of possible sub-licence applicants, i.e. "200 – 1000 over a five-year period", most of whom would be based outside of the UK, and suggested that NHS Digital gave this further consideration from a policy and practicality perspective. IGARD also queried how NHS Digital and the applicant would maintain appropriate oversight of so many sublicensees, and asked that further consideration was given to this.</p> <p>IGARD noted that for the future proposal in terms of worldwide sublicensees this would need engagement with other areas within NHS Digital, including, but not limited to Privacy, Transparency, Ethics and Legal PTEL).</p> <p>Separate to this application: IGARD suggested that NHS Digital review / update the NHS Digital DARS standard for sub-licencing and onward sharing to reflect recent sub-licensing special conditions, including, but not limited to, the Integrated Care Board (ICB) template.</p> <p>Separate to this application: IGARD suggested that NHS Digital considered having a separate Sub-licence Standard or an additional section within the existing NHS Digital DARS standard for sub-licencing and onward sharing specifically for data access via a TRE.</p> <p>IGARD noted that although the applicant had consent to hold the genomic data, further thought should be given to describing this as "<i>pseudonymised</i>" data, noting that unless this</p>

	<p>data had been partially redacted or further refined, current thinking in this area is that the data would in fact be identifiable.</p> <p>IGARD asked that a special condition was inserted in section 6 (Special Conditions), that, where practicable, outputs cite the source of the data as <i>"this work uses data provided by patients and collected by the NHS as part of their care and support"</i> (use MY data - our data citation project).</p> <p>IGARD advised that they would be content to provide further support to NHS Digital separate to the IGARD meeting, for example, an IGARD member attending a high-level policy meeting with NHS Digital only, to discuss further.</p> <p>IGARD also suggested and welcomed the application returning to a future IGARD meeting for further advice, prior to this being submitted for a full IGARD review.</p> <p>IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent.</p> <p>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.</p> <ol style="list-style-type: none"> 1. In respect of the sub-licences and in line with NHS Digital DARS standard for sub-licencing and onward sharing: <ol style="list-style-type: none"> a) NHS Digital to review the model of sub-licences for TRE access and to consider alternatives. b) NHS Digital to consider the enormous volume of possible sub-licence applicants'; and, c) To consider how NHS Digital and the applicant will maintain appropriate oversight of so many sublicensees. 2. In respect of the genomic data that will be held by the applicant, to consider the status of this data, noting that it unlikely to be <i>"pseudonymised"</i>. 3. To insert a special condition in section 6, that, where practicable, outputs cite the source of the data as <i>"this work uses data provided by patients and collected by the NHS as part of their care and support"</i>, in line with the NHS Digital DARS Standard for Special Conditions. 4. IGARD advised that they would be content to provide further support to NHS Digital separate to the IGARD meetings, for example, an IGARD member attending a high-level policy meeting with NHS Digital to discuss further. 5. IGARD suggested and welcomed the application returning to a future IGARD meeting for further advice, prior to this being submitted for a full IGARD review. 6. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent. <p>Separate to this application: IGARD suggested that NHS Digital review / update the NHS Digital DARS standard for sub-licencing and onward sharing to reflect recent sub-licensing special conditions, including (but not limited to) the ICB template.</p> <p>Separate to this application: IGARD suggested that NHS Digital considered having a separate Sub-licence Standard or an additional section within the existing NHS Digital DARS standard for sub-licencing and onward sharing specifically for access to data via a TRE.</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>

	<i>No items discussed</i>
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>The NHS Digital SIRO was currently reviewing the feedback provided on the IG release registers by IGARD for the period March 2020 to May 2022, alongside the process of review, and as discussed on the 11th August 2022, would come back to IGARD in due course with any feedback or response.</p> <p>IGARD noted that the NHS Digital webpage Excel spreadsheet had now been updated for the period March 2020 to April 2022: NHS Digital Data Uses Register - NHS Digital. IGARD noted that May 2022 appeared to be outstanding, following them returning their comments on the May 2022 release register on 1st July 2022.</p>
6	<p><u>COVID-19 update</u></p> <p><i>No items discussed</i></p>
7	<p><u>AOB:</u></p>
7.1	<p><u>Improving Data Access Programme (Presenter: Susan Main)</u></p> <p>Following the last update at the IGARD meeting on the 8th September 2022, this was a further update by NHS Digital with regard to the improving data access programme workstream; and other relevant areas of work linked to the programme.</p> <p>NHS Digital provided an update on four key areas: update on the improvement data access programme, how this work is building on the IBM programme of work, the DARS annual confirmation report and due diligence.</p> <p>a) <u>Update on the Improving Data Access Programme</u></p> <p>NHS Digital advised IGARD that a number of separate workstreams with their own agendas were in the process of being created as part of the Improving Data Access Programme and that further information on the workstreams would be shared with IGARD at a future IGARD meeting in due course.</p> <p>IGARD noted that at the meeting on the 8th September 2022, a verbal update was provided in respect of the ongoing work within NHS Digital to update NHS Digital DARS Standards 5(a) and 5(b); however queried what the process was for updating this and other NHS Digital DARS Standards. NHS Digital advised that work was ongoing to prioritise the updates to the Standards. IGARD noted the verbal update, and asked that NHS Digital engaged with IGARD and other key internal stakeholders, as per the agree DARS standard process, at the earliest opportunity on this programme of work, for example, before engagement commenced outside NHS Digital.</p> <p>b) <u>DARS Annual Confirmation Report</u></p> <p>IGARD noted that following the 8th September 2022 meeting, they had provided collated comments on the DARS Annual Confirmation Report via email on the 15th September 2022 to</p>

<p>7.2</p>	<p>NHS Digital, noting that comments had previously been provided on the 31st March 2022 to NHS Digital and which IGARD were still awaiting feedback on.</p> <p>NHS Digital advised that further information would be shared with IGARD in due course and after the draft annual confirmation report had been shared with external users.</p> <p>c) <u>Due diligence</u></p> <p>NHS Digital advised IGARD that due diligence was not part of the Improving Data Access Programme of work, and advised that this was currently within the remit of NHS Digital's Commercial Team. IGARD noted and thanked NHS Digital for the verbal update.</p> <p>d) How this work is building on previous improvement work</p> <p>NHS Digital noted that this programme was building on some past improvement work, but noted that it was not building on any outputs from the IBM improvement work which IGARD had inputted into. IGARD noted the verbal update from NHS Digital.</p> <p><u>Derived data and data sharing (Presenter: Ly-Mee Yu)</u></p> <p>NHS Digital attended the meeting, following the discussion at the IGARD meeting on the 4th August 2022, where IGARD provided views on what they would expect in a DARS application, where, in some circumstances, it was difficult to have a sub-licence in place, for example sharing participant level safety data to an oversight committee.</p> <p>NHS Digital advised IGARD that following the meeting on the 4th August 2022, further work had been undertaken in collaboration with NHS Digital's Data Access Request Service (DARS), to update the application template as appropriate.</p> <p>NHS Digital also advised that they would be happy to provide a further update to IGARD on progress at a future meeting.</p> <p>IGARD noted the verbal update from NHS Digital and advised they would welcome a further discussion at a future IGARD meeting.</p> <p>7.3</p> <p><u>Sections 97, 99, 100 of the Health and Social Care Act (Presenter: Garry Coleman)</u></p> <p>NHS Digital attended the meeting to discuss the recent notification from the Department of Health and Social Care, that amendments to sections 97, 99 and 100 of the Health and Care Act 2012 are to be commenced from 1st October.</p> <p>NHS Digital advised that amendment 97 enables NHS Digital to share data for purposes connected with (a) the provision of health care or adult social care, or (b) the promotion of health (<i>emphasis added</i>). IGARD noted that it seemed that the Care Act 2014 explanatory notes had not changed.</p> <p>NHS Digital advised that further work was ongoing to determine what this would mean in practice; and that this remit of work would form part of the Improving Data Access Programme.</p> <p>NHS Digital noted that further information would be presented to IGARD in due course.</p> <p>IGARD noted and thanked NHS Digital for the verbal update, and welcomed further information in due course.</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 16/09/22

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)
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