

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 15 September 2022

IGARD MEMBERS IN ATTENDANCE:	
Name:	Position:
Paul Affleck	Specialist Ethics Member / Co-Deputy IGARD Chair
Maria Clark	Lay Member
Dr. Robert French	Specialist Academic / Statistician Member
Kirsty Irvine	IGARD Chair
Dr. Imran Khan	Specialist GP Member / Co-Deputy IGARD Chair
IGARD MEMBERS NOT IN ATTENDANCE:	
Prof. Nicola Fear	Specialist Academic Member
Dr. Geoffrey Schrecker	Specialist GP Member
Dr. Maurice Smith	Specialist GP Member
Jenny Westaway	Lay Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	Team:
Dave Cronin	Data Access Request Services (DARS) (Item 3.2) (SAT Observer: items 3.3 – 3.5)
Louise Dunn	Data Access Request Services (DARS) (SAT Observer: item 3.1)
Mujiba Ejaz	Data Access Request Services (DARS) (Items 3.5)
Karen Myers	IGARD Secretariat
Aisha Powell	Data Access Request Services (DARS) (Observer: item 3.2) (Item 3.3)
Charlotte Skinner	Data Access Request Services (DARS) (Item 3.4)
James Watts	Data Access Request Services (DARS) (Items 3.1)
Vicki Williams	IGARD Secretariat
Amanda Young	Data Access Request Services (DARS) (Observer: item 3.2)
*SAT – Senior Approval Team (DARS)	

1	<p>Declaration of interests:</p> <p>There were no declarations of interest.</p> <p>Review of previous minutes and actions:</p> <p>The minutes of the 8th September 2022 IGARD meeting were reviewed and, subject to a number of minor amendments, were agreed as an accurate record the meeting</p> <p>Out of committee recommendations:</p> <p>An out of committee report was received (see Appendix A).</p>
2	<p>Briefing Notes</p>
	<p><i>There were no briefing papers submitted for review.</i></p>
3	<p>Data Applications</p>
3.1	<p><u>The Royal College of Surgeons of England: National Lung Cancer Audit - NCRAS data request (Presenter: James Watts) NIC-663539-G7F9X-v0.6</u></p> <p>Application: This was a new application for pseudonymised National Disease Registration Service (NDRS) Cancer Registry data, NDRS National Radiotherapy Dataset (RTDS), NDRS Rapid Cancer Registrations, NDRS Systemic Anti-Cancer Therapy Dataset (SACT) and Hospital Episodes Statistics Admitted Patient Care (HES APC).</p> <p>The National Lung Cancer Audit (NLCA), is a national clinical audit commissioned by the Healthcare Quality Improvement Partnership (HQIP) on behalf of NHS England, as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP). The NLCA was initially commissioned in 2004 in response to the need for better information about the quality of services and care provided to patients with lung cancer in England. The NLCA supports the NHS in England to improve the length and quality of life of people diagnosed with lung cancer; and is a source of valuable information that supports various quality assurance and improvement activities, both at a local level and a national level. The NLCA activities will drive quality improvement across the country aiming to help lung cancer services reach the highest standards possible.</p> <p>The purpose of the application is to evaluate the performance of NHS lung cancer services against established standards of care, and to encourage NHS hospitals with unexplained levels of variation in areas of clinical practice or patient outcomes to examine their lung cancer service and formulate action plans to improve their clinical performance.</p> <p>NHS Digital noted that some minor amendments had been made to the application following submission to IGARD, which included section 3(b) (Additional Data Access Requested) being updated to reflect the HES APC dataset that had been requested (as outlined in section 5(a) (Objective for Processing)); and an update to section 3(c) (Patient Objections) to reflect that patient objections applied was “mixed”, noting that although the National Data Opt-out did not apply, the NDRS opt-outs would be applied as appropriate.</p> <p>NHS Digital advised IGARD that they had asked the applicant to update the NLCA webpage, to ensure the privacy notice was more visible and accessible to members of the public.</p> <p>Discussion: IGARD noted and commended NHS Digital and the applicant on the quality of the information within the application, which supported the review of the application by Members.</p>

IGARD noted the verbal update from NHS Digital aspect in respect of the updates to the application as outlined, including the update to section 3(b) to reflect the request for HES APC; and the update to section 3(c) to reflect the correct opt-out that would be applied.

IGARD noted and supported the verbal update from NHS Digital, in respect of the applicant updating the NLCA webpage to ensure the privacy notice was more visible and accessible, which is consistent with UK General Data Protection Regulation (UK GDPR) Article 12 *“Transparent information, communication and modalities for the exercise of the rights of the data subject”*.

IGARD suggested that because the purpose of the application was for an ‘audit’, and noting the various outputs outlined in section 5(c) (Specific Outputs Expected), suggested that the applicant ensure there were robust systems in place to ensure that the NDRS datasets were **only** processed for the purpose of audit, and within the terms of the HQIP contract.

IGARD noted that, if this application was ever amended to incorporate processing other than audit, any use of the NDRS datasets for research would require ethical support, even if the data requested was pseudonymised, in line with the [NHS Digital DARS Standard for Ethical Approval](#).

IGARD noted that although the application was a “new” application to NHS Digital, the NDRS datasets for the NLCA had previously flowed from Public Health England (PHE) prior to its closure at the end of September 2021. Noting data had been flowing for this project since 2004, IGARD therefore asked that section 1 (Abstract) was updated with further information on the history of the application, including, but not limited to, the data controllership and the source of the data.

In addition, IGARD asked that the public facing section 5(a) that forms [NHS Digital’s data uses register](#) was updated with further information on the history of the application including, but not limited to, the history of the audit and the sources of data, in line with [NHS Digital DARS Standard for Objective for Processing](#).

IGARD noted that although this was a “new” application, the yielded benefits of the historical data that had flowed from PHE was helpfully outlined in section 5(d) (Benefits) (iii) (Yielded Benefits) and IGARD supported this approach. IGARD asked that, for transparency, this was updated with further information on the history of the source of the data that had produced the yielded benefits, in line with [NHS Digital DARS Standard for Expected Measurable Benefits](#).

ACTION: Where NDRS applications are noted as “new” to NHS Digital, but where data had been previously released from PHE, section 1 should clearly highlight the in-depth history. Within the public facing section 5, a brief narrative for the public should be provided, since it was misleading to suggest that the data was “new” to the applicant if they had previously received it from PHE.

ACTION: Where NDRS applications are noted as “new” to NHS Digital, but where data had been previously released from PHE, the yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits) should be appropriately updated, outlining the benefits accrued to date.

ACTION: When an NDRS application is novel (not just new to NHS Digital), this should be noted in section 1 only.

ACTION: All future NDRS applications should have standard wording in section 3(c) with regard to patient opt outs.

IGARD asked that a special condition was inserted in section 6 (Special Conditions), that, where practicable, outputs cite the source of the data as *“this work uses data provided by*

patients and collected by the NHS as part of their care and support” ([use MY data - our data citation project](#)).

IGARD queried the references in section 5 (Purpose / Methods / Outputs) to “unwarranted”, for example “...to encourage NHS hospitals with unwarranted levels of variation in areas of clinical practice or patient outcomes...”; and asked that this was amended to “unexplained”.

Separate to this application: IGARD noted the concerns that had previously been raised in respect of transparency of the NDRS Datasets, for example, the conflicting information on the data collected, and suggested that NHS Digital set up a further meeting between the NDRS Engagement and Awareness Team and an IGARD member to discuss this further (noting that an initial meeting had taken place on the 27th July 2022).

Outcome: recommendation to approve

The following amendments were requested:

1. In respect of the historical information:
 - a) To update section 1 with further information on the history of the application, including (but not limited to) the data controllership and the source of the data; and,
 - b) To update section 5(a) with further information on the history of the application including (but not limited to) the history of the audit and the sources of data, in line with [NHS Digital DARS Standard for Objective for Processing](#), and,
 - c) To update section 5(d) (iii) with further information on the history of the source of the data that has produced the yielded benefits, in line with [NHS Digital DARS Standard for Expected Measurable Benefits](#).
2. To insert a special condition in section 6, that, where practicable, outputs cite the source of the data as “this work uses data provided by patients and collected by the NHS as part of their care and support”, in line with the [NHS Digital DARS Standard for Special Conditions](#).
3. To amend the references in section 5 from “unwarranted” to “unexplained”.
4. To update section 3(b) to reflect that HES APC data has been requested (as per the verbal update from NHS Digital).
5. To update section 3(c) to reflect that patient objections applied was “mixed” (as per the verbal update from NHS Digital).

The following advice was given:

1. IGARD supported the verbal update from NHS Digital, in respect of the applicant updating their webpage to ensure the privacy notice was more visible / accessible; which is consistent with Article 12 of UK GDPR.
2. IGARD suggested that as the purpose of the application was for an ‘audit’, and noting the various outputs in section 5(c), suggested that the applicant ensure there are robust systems in place to ensure that the NDRS datasets are **only** processed for the purpose of audit, and within the terms of the HQIP contract, noting any use of the NDRS datasets for research would require ethical support, even if the data requested was pseudonymised, in line with the [NHS Digital DARS Standard for Ethical Approval](#).

ACTION: Where NDRS applications are noted as “new” to NHS Digital, but where data had been previously released from PHE, section 1 should clearly highlight the in-depth history. Within the public facing section 5, a brief narrative for the public should be provided, since it was misleading to suggest that the data was “new” to the applicant if they had previously received it from PHE.

	<p>ACTION: Where NDRS applications are noted as “new” to NHS Digital, but where data had been previously released from PHE, the yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits) should be appropriately updated, outlining the benefits accrued to date.</p> <p>ACTION: When an NDRS application is novel (not just new to NHS Digital), this should be noted in section 1 only.</p> <p>ACTION: All future NDRS applications should have standard wording in section 3(c) with regard to patient opt outs.</p> <p>Separate to this application: Noting concerns previously raised in respect of transparency of the Registry Datasets, IGARD suggested that NHS Digital set up a further meeting between the NDRS Engagement and Awareness Team and an IGARD member to discuss progress.</p>
3.2	<p><u>Cegedim Rx Ltd: Cegedim Rx Ltd 2022 (Presenter: Dave Cronin) NIC-355818-H7T3C-v2.3</u></p> <p>Application: This was an extension and renewal application to permit the holding and processing of pseudonymised Civil Registration (Deaths) - Secondary Care Cut, Emergency Care Data Set (ECDS), Hospital Episode Statistics Admitted Patient Care (HES APC), HES Critical Care, HES Outpatients and HES:Civil Registration (Deaths) bridge.</p> <p>The purpose of the application is to create a licensed secondary healthcare, large-scale data resource with national coverage that will enable research providing insight in important disease areas. This could be fundamental to understanding the patient healthcare clinical experience. This type of research will underpin decision-making in the continual improvement of clinical management of patients and service delivery at national and local levels.</p> <p>The geographical coverage of the data set will also provide the actionable evidence required to drive equity in the provision of care and optimise the utilisation of resources. This resource will offer new opportunities to ascertain the strength of previous evidence, providing a test bed for validation of public health, epidemiological and clinical research. It will also aim to measure and improve the quality of the research data stock in the United Kingdom. This processing will be used to perform public health, epidemiological, clinical and health economics research, supporting improvements in healthcare service delivery, treatment, technology appraisals and patient safety monitoring, using statistical, epidemiological and computational methods.</p> <p>The application was previously considered on the 19th May 2022 where IGARD were unable to make a recommendation.</p> <p>NHS Digital advised that following the last IGARD review of the application on the 19th May 2022, further work had been undertaken with the applicant to update the application, to reflect the points raised. NHS Digital noted that the applicant was currently unable to provide any further information on the yielded benefits as the applicant had been unable to process the data for six-months. NHS Digital noted that the applicant had advised that they were confident that progress would be made in this area once they could process the data.</p> <p>NHS Digital advised IGARD that a three-year data sharing agreement (DSA) had been submitted for review, noting that this was to prevent potential future delays to the applicant in accessing / processing the data, for example, if there was a delay in renewing / extending the DSA. IGARD noted that if an extension and renewal was permitted at this time, the yielded benefits could be assessed at the first annual report.</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 12th November 2020 and the 19th May 2022.</p>

IGARD noted that the application had been updated to reflect some of the previous points raised.

IGARD queried the information in section 1 (Abstract) that following the review of the application on the 19th May 2022, the applicant had been only permitted to hold but not otherwise process the data. IGARD noted that this seemed counterproductive since the applicant seemed to be in a similar position now as previously, i.e. they were unable to provide yielded benefits or a detailed plan to achieve them. IGARD advised NHS Digital that this was not what IGARD had recommended (an extension with no such restriction) and noted the impact this had had on the applicant in terms of progressing the data resource.

IGARD raised significant concerns on the Legitimate Interest Assessment (LIA) provided as a supporting document, and suggested that the applicant review and update this document as appropriate, including, but not limited to, the statement that they were **not** processing personal or special category data.

NHS Digital also advised that feedback would be provided to the applicant in respect of their published privacy notice, including, but not limited to, the incorrect references to opt-outs, the Data Protection Officer's comments on the privacy notice that were currently visible to the public, and further refinements to reflect the processing of the HES data. IGARD noted the verbal update from NHS Digital, in respect of the progress / updates to the application since the last IGARD review and supported the feedback to the applicant by NHS Digital in respect of their published privacy notice.

IGARD noted the verbal update in respect of the three-year DSA length, and thanked NHS Digital for providing clarification on this point. IGARD supported the proposal by NHS Digital that the applicant should submit an annual review in twelve months, however suggested that this review was not limited to a review of just the yielded benefits, and should also include **all** aspects of the applicant's information governance, including, but not limited to, the transparency notice and the LIA.

IGARD asked that a special condition was inserted in section 6 (Special Conditions), that, following the signing of the DSA, a detailed annual review was scheduled in twelve-months. The relevant supporting documents should be provided by the applicant to NHS Digital no later than one month prior to the annual review. These documents should be uploaded to NHS Digital's customer relationship management (CRM) system for future reference.

IGARD asked that a special condition was inserted in section 6 (Special Conditions), that, where practicable, outputs cite the source of the data as *"this work uses data provided by patients and collected by the NHS as part of their care and support"* ([use MY data - our data citation project](#)), in line with the [NHS Digital DARS Standard for Special Conditions](#).

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 outstanding actions on yielded benefits.

Separate to this application: IGARD noted that at previous IGARD meetings, for example, on the 16th June (NIC-448252-L2R6Q) and 7th July (NIC-148369-8PPWK), the s261 legal basis had been discussed. IGARD had requested that NHS Digital advised on the s261 legal basis for NHS Digital's dissemination, for example which section of s261 of the Health and Social Care Act 2012 was relevant since NHS Digital appeared to be only citing the overarching s261. IGARD reiterated the request that NHS Digital **urgently** advise IGARD on the s261 legal basis for NHS Digital's dissemination.

	<p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. In respect of the special conditions and in line with the NHS Digital DARS Standard for Special Conditions: <ol style="list-style-type: none"> a) To insert a special condition in section 6, 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>. b) To insert a special condition in section 6, that, following the signing of the DSA, a detailed annual review was scheduled in twelve-months. The relevant supporting documents should be provided by the applicant to NHS Digital no later than one month prior to the annual review. These documents should be uploaded to NHS Digital’s customer relationship management (CRM) system for future reference. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD raised significant concerns on the LIA, and suggested that the applicant should, as a matter of urgency, review and update this document as appropriate, including (but not limited to) the statement that they are not processing personal or special category data. 2. IGARD supported the proposal by NHS Digital that the applicant should submit an annual review in 12-months, however suggested that this review was not limited to a review of just the yielded benefits, and should also include all aspects of the applicants information governance, including (but not limited to) the transparency notice and the LIA. 3. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the outstanding actions on yielded benefits. 4. IGARD suggested that this application would not be suitable for NHS Digital’s Precedent route, including the SIRO Precedent, due to the outstanding actions on yielded benefits. <p>Separate to this application: NHS Digital to urgently advise IGARD on the s261 legal basis for NHS Digital’s dissemination.</p>
3.3	<p><u>University College London Hospitals NHS Foundation Trust: BRIGHTLIGHT: Do specialist cancer services for teenagers and young adults (TYA) add value? (Presenter: Aisha Powell) NIC-384137-V8F6H-v5.3</u></p> <p>Application: This was an extension application to permit the holding and processing of identifiable Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC) and HES Outpatients data.</p> <p>It was also an amendment application to 1) update the funding information; 2) to update the processing activities in section 5(b) and outputs in section 5(c); 3) to update the special conditions in section 6.</p> <p>The purpose of the application is for The Teenage and Young Adult Cancer Specialism Scale (TYA CSS) which has been developed following a previous flow of NHS Digital data under this data sharing agreement (DSA). The preliminary analysis of the data proved to be more complex than had been anticipated, and therefore the study team require additional data to conduct further analysis, to determine if, for example, specialist services for teenagers and young adults add value.</p>

Cancer is the second leading cause of death for young people accounting for 11% of deaths in teenagers and young adults aged 15-24. While potentially curable for many patients, there is evidence that outcomes for some cancers have not improved in line with those achieved for children and older adults. The needs of teenagers and young adults are poorly met by the well-developed cancer services traditionally tailored towards the needs of children and those for older adults with cancer.

The cohort consists of 1,114 young people diagnosed with cancer between July 2012 and December 2014.

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

Discussion: IGARD queried the information provided in some of the Health Research Authority Confidentiality Advisory Group (HRA CAG) documentation provided as supporting document, including the HRA CAG Register, that the s251 support for the study was only in place until the 31st December 2022. Noting that the study and DSA extended beyond this date, IGARD asked that a special condition was inserted in section 6 (Special Conditions), that the applicant would provide written confirmation to NHS Digital that the HRA CAG support was continuing beyond the 31st December 2022 in line with the [NHS Digital DARS Standard for Special Conditions](#). IGARD asked that relevant documentation was uploaded to NHS Digital's customer relationship management (CRM) system for future reference.

In addition, IGARD asked that section 1 (Abstract) and the public facing section 5 (Purpose / Methods / Outputs) that forms [NHS Digital's data uses register](#) were updated, with confirmation that the s251 HRA CAG support was continuing beyond the 31st December 2022; and, that any updated HRA CAG documentation were uploaded to NHS Digital's customer relationships management (CRM) system for future reference.

ACTION: NHS Digital to liaise with the applicant to ensure the s251 support had been progressed with HRA CAG, in advance of December 2022.

IGARD queried what, if any, patient and public involvement and engagement (PPIE) had been undertaken, noting the reference in section 5(d) (Benefits) (ii) (Expected Measurable Benefits to Health and / or Social Care) to the '*James Lind Alliance's recent priority setting exercise*'; and asked that section 5 was updated to provide further details of any PPIE carried out to date; or, that an indicative plan of future PPIE activity was provided for information. IGARD noted that the [HRA guidance on Public Involvement](#) was a useful guide.

IGARD noted that the study website provided some helpful information in respect of the yielded benefits flowing from the use of the data in this DSA; and asked that in addition to the information provided in section 5(d) (iii) (Yielded Benefits), a link to the study website was also provided, in line with [NHS Digital DARS Standard for Expected Measurable Benefits](#).

IGARD asked that a special condition was inserted in section 6 (Special Conditions), that, where practicable, outputs cite the source of the data as "*this work uses data provided by patients and collected by the NHS as part of their care and support*" ([use MY data - our data citation project](#)), in line with the [NHS Digital DARS Standard for Special Conditions](#).

IGARD queried the statement in section 5(b) (Processing Activities) "*There has been a minor update to a previous HES extract in order to rerun the linkage...*"; and asked that for transparency, this was updated to accurately reflect that the linkage will be undertaken by the applicant and **not** NHS Digital.

Outcome: recommendation to approve

The following amendments were requested:

	<ol style="list-style-type: none"> 1. In respect of the HRA CAG support: <ol style="list-style-type: none"> a) To insert a special condition in section 6, that, before 31 December 2022, the applicant will provide confirmation to NHS Digital that the HRA CAG support is continuing beyond the 31st December 2022 in line with the NHS Digital DARS Standard for Special Conditions; and b) To update section 1 and section 5 with confirmation that the s251 HRA CAG support is continuing beyond the 31st December 2022; and, c) To upload any updated HRA CAG documentation to NHS Digital's CRM system for future reference. 2. In respect of PPIE: <ol style="list-style-type: none"> a) To update section 5 to provide details of any PPIE carried out to date; or b) To provide an indicative plan of future PPIE activity. The HRA guidance on Public Involvement is a useful guide. 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. To update the reference to <i>"rerun the linkage"</i> in section 5(b) will be undertaken by the applicant and not NHS Digital. 5. To update the yielded benefits in section 5(d) (iii) to provide further detail or a link to benefits outlined on the study website, in line with NHS Digital DARS Standard for Expected Measurable Benefits. <p>ACTION: NHS Digital to liaise with the applicant to ensure that confirmation of the s251 support has been progressed with HRA CAG, in advance of December 2022.</p>
3.4	<p><u>University of Bristol: Using national-level linked administrative data to explore prevalence of mental health concerns and characteristics of mental health services received by children in State care in England before, during and after the COVID-19 pandemic. (Presenter: Charlotte Skinner) NIC-382333-M5J9W-v0.7</u></p> <p>Application: This was a new application for pseudonymised Emergency Care Data Set (ECDS), Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC), HES Outpatients and Mental Health Services Data Set (MHSDS).</p> <p>At any given time in England, there are around 80,000 children being looked after by the State, the majority of these children are taken into State care due to experiences of severe maltreatment such as abuse or neglect. Research studies indicate that mental health concerns in this vulnerable child population are high with 50% of children in State care having a diagnosable mental health concern, when compared to 12% of children in the general population. Despite this high prevalence of mental health concerns, there is no established evidence base on the characteristics and vulnerabilities of children in care who are referred to mental health services (MHS) and their prognosis and pathways through the MHS system in England, including the impact of the COVID-19 pandemic. This has been flagged by the Children's Commissioner for England and the Education Committee as a serious concern that needs to be addressed.</p> <p>The purpose of the application is for a research project, with the primary objective (phase 1) being to fill this gap in knowledge and to establish new and timely information on the prevalence of mental health concerns in the population of children in care; provision of MHS; and children's prognosis and pathways through the MHS compared with children in the general population before, during and after the COVID-19 pandemic.</p>

NHS Digital noted that a secondary objective (phase 2) of this project, was to be pursued at such time as the required data from the Department for Education (DfE) becomes available, and is to deliver a novel linkage which will demonstrate potential for combining NHS health records with routine social care records. NHS Digital confirmed that this application was **only** for the purpose of the primary objective (as outlined above).

Discussion: IGARD welcomed the application and supported the Children's Commissioner for England comments, in respect of the importance of the research (as outlined within the application).

IGARD noted the verbal update in respect of the purpose of this iteration of the data sharing agreement (DSA) being for phase 1 of the research project only. IGARD queried the significant amount of information in section 5 (Purpose / Methods / Outputs) of the application relating to phase 2, and noting that most of this was currently not relevant, asked that section 5 was updated to provide a brief reference / overview that there was an intention to carry out a phase 2 of the project; and, to remove any suggestion that phase 2 of the research project was confirmed, removing the extensive detail in respect of phase 2 from the application.

IGARD noted that Health Research Authority Research Ethics Committee (HRA REC) approval and been sought and obtained; however, IGARD noted that since HRA REC had reviewed the relevant documentation, there had been an update in respect the storage and processing locations, from the Office for National Statistics' (ONS) Secure Research Service (SRS) to the University of Bristol. IGARD suggested that, for transparency, the applicant notified HRA REC about the change of processing location, and that if HRA REC raised any queries this was notified to NHS Digital.

In addition, IGARD suggested that, assuming the HRA REC support was for the duration of the project, that any aspect **not** covered by the HRA REC, should go through the appropriate University REC channels.

IGARD queried the processing location in section 2(b) (Storage Location(s)) and asked that this was reviewed and updated as may be necessary, in line with [NHS Digital's DARS Standard for processing and storage locations](#), noting that, in this instance, it may need to reflect the storage location in section 2(c) (Territory of Use).

IGARD had a lengthy discussion with regard to data minimisation, noting the volume of data requested in this DSA, for example, the request for data on **all** children and young people in England, aged four to eighteen years, between April 2015 and March 2020. IGARD therefore asked that in line with [NHS Digital DARS standard for data minimisation](#) section 1 (Abstract) was updated with further details of the discussions which had taken place with NHS Digital's Data Production Team and / or the applicant, to ascertain that there were no technical or other options available to reduce the quantity of data requested, for example, but not limited to the fact that some datasets cannot be filtered by ICD10 codes and the entire child and young people population of England would be provided to the applicant.

IGARD also asked that the public facing section 5 that forms [NHS Digital's data uses register](#) was updated, to provide an explanation as to why such a large control cohort was required, which was one hundred times the size of the cohort; and, confirmation as to why the large dataset cannot be filtered by the ICD-10 codes..

In addition, IGARD queried what would happen to the "*clean up*" data, i.e. the data that was filtered out and would not be required for the research project; and asked that section 5 was updated with clarification.

IGARD suggested, that due to the significant volume of data flowing, the type of data being processed, and the data subjects being children and young people, the applicant carried out a Data Protection Impact Assessment DPIA, and before the data was processed, to assure the public that the applicant had thought about the risks and had carried out due diligence, due to the quantum and type of data being processed.

IGARD and NHS Digital noted the language in section 5 in respect of the age groups of the children and young people, for example “*key stages*”; and asked that section 5 was updated to reflect the birth cohort years as outlined in the additional production detail, referenced by NHS Digital in the meeting.

IGARD asked that a special condition was inserted in section 6 (Special Conditions), that, where practicable, outputs cite the source of the data as “*this work uses data provided by patients and collected by the NHS as part of their care and support*” ([use MY data - our data citation project](#)), in line with the [NHS Digital DARS Standard for Special Conditions](#).

Outcome: recommendation to approve

The following amendments were requested:

1. In respect of data minimisation and in line with [NHS Digital DARS standard for data minimisation](#):
 - a) To update section 1 with further details of the discussions that had taken place with NHS Digital’s Data Production Team to ascertain that there were no technical or other options available to reduce the quantity of data requested; and
 - b) To update section 5 to provide an explanation as to why such a large control cohort is required, and
 - c) To update section 5 with confirmation as to why the large dataset requested for children and young people cannot be filtered by the ICD-10 codes; and,
 - d) To update section 5 to clarify what will happen to the “*clean up*” data.
2. To update section 5 to reflect the birth cohort years as outlined in the additional production detail.
3. In respect of ‘phase 2’ of the project:
 - a) To update section 5 with a brief reference / overview, that there is an intention to carry out a phase 2 of the project; and,
 - b) To update section 5 to remove any suggestion that phase 2 of the project is definitely progressing ; and
 - c) To update section 5 to remove the extensive detail in respect of phase 2.
1. To insert a special condition in section 6, that, where practicable, outputs cite the source of the data as “*this work uses data provided by patients and collected by the NHS as part of their care and support*”, in line with the [NHS Digital DARS Standard for Special Conditions](#).
6. To review and update the processing location as may be necessary, in line with [NHS Digital’s DARS Standard for processing and storage locations](#).

The following advice was given:

1. In respect of HRA REC:
 - a) IGARD suggested that the applicant notify HRA REC about the change of processing location.
 - b) IGARD suggested that, assuming the HRA REC support is for the duration of the project, that any aspect not covered by the HRA REC, should go through the appropriate University REC channels.

	<p>2. IGARD suggested the applicant carried out a Data Protection Impact Assessment (DPIA), due to the significant volume of data flowing, the type of data being processed, and the data subjects being children and young people.</p>
3.5	<p><u>University of Kent: Understanding the unpaid carers of people using social care services in England (Presenter: Mujiba Ejaz) NIC-579513-Z7S7N-v0.9</u></p> <p>Application: This was a new application for pseudonymised Personal Social Services Survey of Adult Carers data.</p> <p>The purpose of the application is for a project aiming to understand how carers' satisfaction with services and quality of life change over time, and why.</p> <p>Different patterns and trajectories of caring are likely to influence the way individuals perceive their caring role. Previous research on this topic focused on working age carers of older people, but the way they experience caring may differ compared to retired carers or working age carers of working age individuals. Furthermore, the experiences of carers within these broad groups are likely to vary, for example, intermittent caring associated with a relapsing and recovering relative with a mental health problem has different challenges to the long-term commitment of caring for someone with a severe learning disability.</p> <p>The Equality Act 2014 states that social care organisations should make provision to include carers who may have different values and cultural norms about family care, face particular barriers in accessing services or have particular needs. Ensuring support is accessible, timely, and appropriate for all carers, including those with specific needs is key to enabling the wellbeing of the carers and the service users they support. A recent National Institute for Health and Care Research-School for Social Care Research funded review identified that most research studies do not follow-up the same carers across time, meaning the temporal dimension is rarely captured. The project aims to address these evidence gaps by following up a sample of carers who agreed to be contacted for future research.</p> <p>Discussion: IGARD noted that prior to the meeting, a query had been raised by an IGARD member in respect of whether ethics approval had been sought and obtained, noting the conflicting information in section 1 (Abstract) that stated <i>"NHS Digital note ethical approval is not required to process the pseudonymised data requested..."</i>, and section 7 (Ethics Approval) that stated <i>"Ethics approval is required and in place"</i>. NHS Digital confirmed that ethics approval had been obtained for the wider 'Diverse Experiences of Unpaid Carers Across the Caring Trajectory' (DECAT) project referred to in the application, and not the study for which this data sharing agreement (DSA) related to. IGARD noted and thanked NHS Digital for the verbal update, however asked that section 5(a) (Objective for Processing) was updated, to clarify that ethical issues, for example, the wider ethical aspects of the application, not just related to the sensitivity of the data, had been considered by the University REC.</p> <p>IGARD wished to draw to the attention of the Department of Health and Social Care (DHSC) the potential bias and gaps that the exclusion of an equivalent survey of children and young people who have caring responsibilities may create in the study outputs; and that further consideration should be given as to how these gaps in the research landscape may be mitigated.</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 volunteered by carers and collected by the NHS"</i>, in line with the NHS Digital DARS Standard for Special Conditions.</p>

	<p>IGARD noted the references to the acronym “LD” in section 5 (Purpose / Methods / Outputs), and since this forms NHS Digital’s data uses register, asked that these references were amended to ensure they were all fully expanded to correctly refer to “<i>learning disability</i>”.</p> <p>In addition, IGARD noted that section 5 referred to learning disabilities and autism collectively and asked that section 5 was updated to ensure that all references were separated and distinguished as appropriate, noting that not all individuals with autism would consider that they have a learning disability. IGARD noted that NHS England provide a helpful guide co-produced with autistic people and those with learning disabilities NHS England » Making information and the words we use accessible.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update section 5(a) to clarify that ethical issues have been considered by the University REC. 2. As section 5 forms NHS Digital’s data uses register: <ol style="list-style-type: none"> a) To expand all “LD” references to state “<i>Learning Disability</i>”; and, b) To update section 5 to separate / distinguish all references to learning disabilities and autism. 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 volunteered by carers and collected by the NHS</i>”, in line with the NHS Digital DARS Standard for Special Conditions. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD wished to draw to the attention of DHSC, the gaps that the exclusion of an equivalent survey of children and young people who have caring responsibilities may create in the study outputs; and that further consideration should be given as to how these gaps may be mitigated.
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>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> <p><u>Improving Data Access Programme (No Presenter)</u></p> <p>IGARD noted that at the meeting on the 8th September 2022 a request had been made for the latest copy of the draft DARS Annual Confirmation Report and further clarification as to who was on the Data Access Oversight Board.</p> <p>IGARD reviewed in meeting some of the comments shared with NHS Digital in March 2022 on the draft DARS Annual Confirmation Report, and confirmed that the additional commentary would be sent to NHS Digital following conclusion of the meeting, and for discussion at the IGARD meeting on the 22nd September 2022, where this would be discussed further with NHS Digital.</p> <p>In addition, IGARD noted that the Terms of Reference for the Data Access Oversight Board had been shared by NHS Digital (via the IGARD Secretariat), and again noted that these could be discussed further on the 22nd September 2022 if required.</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 09/09/22

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