

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 12 May 2022

IGARD MEMBERS IN ATTENDANCE:	
Name:	Position:
Paul Affleck	Specialist Ethics Member
Dr. Robert French	Specialist Academic / Statistician Member
Kirsty Irvine	IGARD Chair
Dr. Imran Khan	Specialist GP Member
Jenny Westaway	Lay Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Maria Clark	Lay Member
Prof. Nicola Fear	Specialist Academic Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Chair
Dr. Maurice Smith	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	Team:
Michael Ball	Data Access Request Services (DARS) (Items 3.1 - 3.2)
Vicky Byrne-Watts	Data Access Request Services (DARS) (SAT Observer: items 2.1, 3.2 - 3.3)
Dave Cronin	Data Access Request Services (DARS) (Item 5, 7.1)
Duncan Easton	Data Access Request Services (DARS) (SAT Observer: items 3.1 - 3.2)
Frances Hancox	Data Access Request Service (DARS) (Item 2.1)
Gavin Harrison	Data Access Request Services (DARS) (Observer: items 3.1 - 3.3)
Karen Myers	IGARD Secretariat
Dr. Jonathan Osborn	Deputy Caldicott Guardian (Observer: items 3.1 - 3.3)
Tania Palmariellodiviney	Data Access Request Services (DARS) (SAT Observer: item 3.4)
Denise Pine	Data Access Request Services (DARS) (Item 3.3)
Charlotte Skinner	Data Access Request Services (DARS) (Item 3.5)

Joanna Warwick	Data Access Request Services (DARS) (Item 5)
Vicki Williams	IGARD Secretariat
*SAT – Senior Approval Team (DARS)	

1	<p>Declaration of interests:</p> <p>Dr. Imran Khan noted a potential conflict with NIC-397618-T8L8Z, as part of his roles as Deputy Chair of the Health Informatics Group at the RCGP and Co-deputy Chair of the Joint GP IT Committee. It was agreed this did not preclude Dr. Khan from taking part in the discussions about this application, however it was agreed that he would not participate in making a recommendation about the application.</p> <p>Review of previous minutes and actions:</p> <p>The minutes of the 5th May 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	Briefing Notes
2.1	<p><u>Clinical and Translational Radiotherapy (CTRad): COVID Radiotherapy (COVID-RT) Study dataset – Briefing Presentation (Presenter: Frances Hancox)</u></p> <p>This briefing presentation was to inform IGARD about the CTRad COVID-RT Study dataset, which initially will flow to a single applicant, and not be an NHS Digital ‘onboarded’ dataset made available to DARS applicants to request.</p> <p>COVID-RT data has been captured by radiotherapy providers (centres/hospitals) and provides a detailed description of clinical decisions and radiotherapy treatment delivery across the UK during the COVID-19 pandemic and was collected from providers for the time period 1st March 2020 to 31st December 2020.</p> <p>The purpose of the collection is to understand the impact of COVID-19 on both radiotherapy patients and the radiotherapy service at a national scale.</p> <p>Outcome: IGARD welcomed the briefing presentation and made the following high-level comments:</p> <ol style="list-style-type: none"> 1. IGARD noted that the collection and dissemination appeared to have a sound legal basis. However, using a bespoke Data Provision Notice with the intention of flowing data to a single recipient does set a precedent and there is a reputational risk to NHS Digital that it might be seen to be giving some organisations preferential treatment. Such a risk could be mitigated by NHS Digital publicising this data asset to make other researchers aware, and to provide researchers with a mechanism to apply for access. 2. IGARD noted that it appeared that the general policy of equality of access to data is not being adhered to, in that this was a bespoke collection for a single charity. IGARD suggested that a clear audit trail is maintained and that there is an acknowledgement of this bespoke data for a single applicant and how the policy issues have been considered and addressed.

	<p>3. IGARD suggested that the application have a mechanism in place, that there are purpose limitations as set out in the Direction and DPN, and the purpose can only be related to COVID-19, notwithstanding the dataflow will be pseudonymised.</p> <p>4. IGARD asked that when the application is presented, that NHS Digital provide an indicative timescale as to when other applicants can apply for this data.</p> <p>5. IGARD noted the briefing presentation was presented for this single applicant and reminded NHS Digital that due process should be followed in that a briefing paper should be provided to IGARD and before any first of type applications for wider data access.</p> <p>IGARD welcomed the briefing presentation and asked that it be appended as a supporting document to the single applicant application.</p>
2.2	<p><u>National Disease Registration Service (NDRS) Cancer Registration: Non-Routine Collections – Briefing Paper (No Presenter)</u></p> <p>The briefing paper was to inform IGARD of the onboarding of the National Disease Registration Service (NDRS) Cancer Registration: Non-Routine Collections dataset and had been previously discussed at the IGARD business as usual meeting on the 7th April 2022.</p> <p>The collection aims to provide the following benefits to patients and the public: increase prevention and early diagnosis of cancer; improve the management of NHS cancer services; improve NHS cancer treatment and care; and improve patient outcomes, including better quality of life and longer survival.</p> <p>IGARD welcomed the finalised briefing paper and made no further comments.</p> <p>As per due process, a copy of the finalised briefing paper should be provided as a supporting document alongside any first of type applications to IGARD.</p>
2.3	<p><u>National Disease Registration Service (NDRS) Cancer Registration – Briefing Paper (No Presenter)</u></p> <p>The briefing paper was to inform IGARD of the onboarding of the National Disease Registration Service (NDRS) Cancer Registration: Non-Routine Collections dataset and had been previously discussed at the IGARD business as usual meeting on the 7th April 2022.</p> <p>The collection aims to provide the following benefits to patients and the public: increase prevention and early diagnosis of cancer; improve the management of NHS cancer services; improve NHS cancer treatment and care; and improve patient outcomes, including better quality of life and longer survival.</p> <p>IGARD welcomed the finalised briefing paper and made no further comments.</p> <p>As per due process, a copy of the finalised briefing paper should be provided as a supporting document alongside any first of type applications to IGARD.</p>
3	Data Applications
3.1	<p><u>NHS England (Quarry House): NHS England - DSfC - NHS England & Improvement Data Platform (Presenter: Michael Ball) NIC-139035-X4B7K-v10.2</u></p> <p>Application: This was an amendment application to 1) add the University of Manchester as a Data Processor; and 2) add Greater Manchester Academic Health Science Network (HInM) (hosted by Manchester University NHS Foundation Trust), and Wessex Academic Health</p>

Science Network Limited (WAHSN) – (hosted by University Hospital Southampton NHS Foundation Trust) as Data Processors.

The purpose of the application is to ensure that NHS England and NHS Improvement can meet their statutory duties as per 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 the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meetings on the 25th April, 15th August, 17th October, 12th December 2019, 13th February, 19th July, 17th November, 17th December 2020, 28th January 2021, 19th August 2021 and the 27th January 2022.

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

IGARD noted that all previous comments made on this application at either an IGARD business as usual (BAU) or IGARD – NHS Digital COVID-19 Response meeting remained live and that they were only focusing on the two amendments only.

IGARD reiterated their previous advice, that this overarching application should be broken up into relevant bespoke project applications. IGARD noted that they would want to be involved in early-stage work on the rationalisation of the applications, as appropriate, in order to support both NHS Digital and the applicant.

IGARD also reiterated their previous action point, that NHS Digital convene a working group, to review the process of assuring and onboarding of the additional datasets.

IGARD advised that this application was updated to reference where the use of the data under this data sharing agreement (DSA) was linked to data in other DSAs, including, but not limited to NIC-397618-T8L8Z NHS England (item 3.2).

IGARD noted that section 1 (Abstract) stated that the application “...*was last recommended for approval by IGARD on Thursday 27th January 2022...*”, however asked that for a clear audit trail, this was amended to more accurately state that IGARD recommended for approval “*for the two amendments and the specific highlighted new text only*”, as reflected in the published minutes.

IGARD noted in section 1 that the application had proceeded down the NHS Digital Data Access Request Services (DARS) Senior Information Risk Owner (SIRO) Precedent approval route, following the presentation of the Alcohol Dependence dataset and Tobacco Dependence dataset briefing papers at the IGARD BAU meetings on the 24th February 2022 and 10th March 2022. IGARD asked that for audit purposes and future reference, section 1 was updated with a clear justification of why the progression of the application was via the SIRO precedent, i.e. why it could not wait an additional one to two weeks to go on the IGARD agenda, noting that IGARD had previously advised NHS Digital that the application would **not** be suitable for NHS Digital's Precedent route, including the SIRO Precedent.

Separate to this application, IGARD noted that they would follow-up with the SIRO, to ensure that the use of the SIRO precedent had a clear justification and that this was provided in section 1 of the application for information and as per the agreed process.

IGARD noted that following the presentation of the Alcohol Dependence dataset and Tobacco Dependence dataset briefing papers at the IGARD BAU meetings on the 24th February 2022 and 10th March 2022, they had suggested that NHS Digital should review information on their website about this collection, which erroneously stated that patients had to consent to a privacy notice. IGARD queried the update in section 1 relating to this point, noting that it was

unclear if this point had been addressed, and also noting that the weblink provided was not working. IGARD asked that section 1 was updated to confirm that this action had been undertaken and to update with the correct weblinks to NHS Digital's webpages.

IGARD noted the helpful information provided within the Data Protection Impact Assessment (DPIA) provided as a supporting document, that explained the relationship and flow of data between WAHSN and HInM; and asked that for transparency, section 5 (Purpose / Methods / Outputs) was also updated with this information, noting that this served as NHS Digital's public facing [data uses register](#).

Notwithstanding that NHS England have asserted that this application was for service evaluation, IGARD suggested that the University of Manchester [reviewed](#) their own activities to ascertain if they were carrying out research and if they were required to obtain local ethics support or approvals. If local ethics was required or not required, to confirm in either case to NHS Digital in writing.

IGARD advised that they would wish to review this overarching application and any spin-off applications when it comes up for renewal, extension or amendment; and that it would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent.

Outcome: recommendation to approve for the two amendments and the specific highlighted new text only.

The following amendments were requested:

1. To update section 1 to reflect that the previous IGARD recommendation on the 27th January 2022, was for the two amendments and the specific highlighted new text only.
2. To update section 1 with a clear justification of why the progression of the application was via the SIRO precedent (i.e. why it could not wait for an additional 1-2 weeks to go on the IGARD agenda).
3. To update section 1 to confirm that the previous action with regards to information on the NHS Digital website had been undertaken and update with the correct weblinks.
4. To update section 5 with the helpful information provided within the DPIA, to explain the relationship and flow of data between WAHSN and HInM.

The following advice was given:

1. IGARD advised that this application was updated to reference where the use of the data under this DSA is linked to data is other DSAs, including (but not limited to) NIC-397618-T8L8Z.
2. Notwithstanding that NHS England have asserted that this application is for service evaluation, IGARD suggested that the University of Manchester review their own activities to ascertain if they are required to obtain local ethics support or approvals. If local ethics is required or not, to confirm in either case to NHS Digital.
3. IGARD reiterated their previous action point that NHS Digital convene a working group, to review the process of assuring and onboarding of the additional datasets.
4. IGARD reiterated their previous advice, that this overarching application should be broken up into relevant bespoke project applications. IGARD noted that they would want to be involved in early-stage work on the rationalisation of the applications, as appropriate, in order to support both NHS Digital and the applicant.
5. IGARD advised that they would wish to review this overarching application and any spin-off applications when it comes up for renewal, extension or amendment.
6. IGARD suggested that this overarching application and any spin-off applications, would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent.

	<p>Separate to this application: IGARD to follow-up with the SIRO to ensure that the use of the SIRO precedent has a clear justification and that this is provided in section 1 of the application.</p>
3.2	<p>NHS England (Quarry House): OpenSAFELY and High Cost Drugs Linkage (Presenter: Michael Ball) NIC-397618-T8L8Z-v3.2</p> <p>Application: This was an amendment application to 1) change the frequency of the data from "one off" to "ad hoc"; 2) add the North of England (NoE) Commissioning Support Unit (CSU) as a Data Processor as they land the data before this is flowed to The Phoenix Partnership Ltd (TPP) and Egton Medical Information Systems Limited (EMIS); 3) to add Microsoft Limited as a Data Processor who provide cloud services to NoE CSU; 4) the addition of NoE CSU processing and storage locations; 5) to amend the purpose to make it clear that OpenSafely also uses data NHS England receives via other data sharing agreements with NHS Digital.</p> <p>OpenSAFELY is a suite of analytics software that is deployed inside an existing Electronic Health Records (HER) system to carry out studies (using the underlying data), created to deliver urgent results during the global COVID-19 emergency. It is now successfully delivering analyses across more than 24 million patients' full pseudonymised primary care NHS records (TPP patient GP data).</p> <p>The purposes of the application, is to identify medical conditions and medications that affect the risk or impact of COVID-19 infection on individuals; this will assist with identifying risk factors associated with poor patient outcomes as well as information to monitor and predict demand on health services.</p> <p>NHS Digital noted that prior to the meeting, an IGARD member had submitted a query in respect of any data flowing to the NoE CSU, noting the statement in section 5(b) (Processing Activities) that <i>"*DSCROs will share pseudonymised high cost drugs data directly with the electronic health record (EHR) vendors, TPP, NHS North of England Commissioning Support Unit and EMIS respectively, who are acting as data processor for NHS England."</i> NHS Digital clarified that the DSCROs would flow data to the NoE CSU, which would onwardly flow the data to TPP and EMIS. Apart from forwarding the data the NoE CSU would not be undertaking any data processing activities.</p> <p>*DSCROs - Data Services for Commissioners Regional Offices (DSCROs)</p> <p>Discussion: IGARD welcomed the application and noted the importance of the research undertaken; and commended the applicant on the benefits achieved to date.</p> <p>IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 20th August 2020.</p> <p>IGARD noted that this application had been previously seen at the IGARD – NHS Digital COVID-19 Response meeting on the 18th August 2020.</p> <p>IGARD noted and thanked NHS Digital for the verbal update, in respect of the data flowing to the NoE CSU, and asked that, for transparency, section 5(a) (Objective for Processing) was updated, to make clear why the CSU was being utilised, in line with NHS Digital DARS Standard for Objective for Processing. In addition, IGARD asked that in line with NHS Digital DARS Standard for processing activities, the statement in section 5(b) <i>"DSCROs will share pseudonymised high cost drugs data..."</i> was updated, to make clear that the data would be shared via the NoE CSU and to reflect the complexities and bodies involved.</p> <p>IGARD noted that flows of data from other data sharing agreements (DSA) would be utilised by this DSA; and asked that for transparency and audit purposes, section 1 (Abstract) and section 5(a) were updated, to make reference to the specific DSAs that provided the other</p>

flows of data for this DSA, which were then utilised by this DSA, noting that section 5 of the DSA served as NHS Digital's public facing [data uses register](#).

IGARD also advised that this application was updated to specifically reference NIC-139035-X4B7K (NHS England) and the use of the data under that DSA in this application; and that IGARD would be supportive of this simple amendment without a further review.

IGARD suggested that NHS England reviewed their privacy notice, for example, to ensure it was transparent on OpenSAFELY and it accurately reflects **all** sources of data and in line with the [NHS Digital DARS Standard for transparency \(fair processing\)](#).

IGARD noted that there was a reputational risk to NHS Digital that the current transparency about OpenSAFELY, including the OpenSAFELY website, did not reflect the number of bodies involved and multiplicity of storage locations, and what data was where at any one time.

IGARD queried the statement in section 7 (Ethics Approval) *"Ethics approval is not required because the request is for service improvement and evaluation - not research"*, in light of the references within the application to "research", for example, the statement in section 5(c) *"Work is ongoing to onboard other researcher organisations to use the OpenSAFELY analytics software"*; and the supporting documents, for example, within the data flow table that stated *"the design is purposeful to support rapid research studies whilst keeping the data as minimally disclosive as possible"*. In addition, IGARD noted that ethics approval had been obtained for OpenSAFELY, from a Health Research Authority Research Ethics Committee (HRA REC) and London School of Hygiene and Tropical Medicine, which suggested that they may view the work outlined as *"research"*. IGARD therefore asked that section 7 was updated to correctly reflect that ethical support had been obtained.

IGARD noted the special condition in section 6 (Special Conditions) that stated *"...processing of the data must stop and data destruction must occur upon cessation of the current **COPI notice..."*. Noting that the expiry of the COPI Notice was the 30th June 2022, IGARD advised that a new legal basis may be required following the expiry of the COPI Notice, noting that the application currently reflected wide-ranging research activities. IGARD noted that activities permitted under [Regulation 3](#) of COPI are strictly prescribed.

****The Health Service Control of Patient Information (COPI) Regulations 2002**

IGARD noted and supported the statement in this application *"As both ***TPP and ****EMIS would have the technical ability to re-identify the data through the use of mapping tables, the data is considered as confidential and requires COPI to address the common law duty of confidentiality"*, but noted that this was contradictory to advice from NHS Digital's Privacy, Transparency and Ethics (PTE) in respect of other applications, that contractual controls were sufficient to address the common law duty of confidentiality. IGARD suggested that the Deputy Caldicott Guardian investigated further and that IGARD be provided with an update in due course.

*****TPP - The Phoenix Partnership**

******EMIS - Egton Medical Information Systems**

IGARD noted the outdated language within the application in relation to the COVID-19 pandemic, for example *"...if there is a future wave..."* and *"...in the event of a second wave..."*, and asked that the application was reviewed and updated throughout, to ensure it accurately reflected the current status of the COVID-19 pandemic.

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

	<p>Precedent route, including the Senior Information Risk Owner (SIRO) Precedent; with the exception of the simple amendment as outlined above (i.e. the update to reference NIC-139035-X4B7K).</p> <p>Outcome: recommendation to approve up until the expiry of the COPI Notice (currently 30th June 2022), by a quorum of 4 members, with one GP 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"> 1. To update section 5(a) to make clear why the CSU is being utilised. 2. To update the statement in section 5(b) <i>“DSCROs will share pseudonymised high cost drugs data directly...”</i>, to make clear the data will be shared via the CSU. 3. To update section 1 and section 5(a) to make reference to the specific DSAs that provide the other flows of data for this DSA, which are then utilised by this DSA. 4. To review and update the application throughout, to ensure it accurately reflects the current status of the COVID-19 pandemic, for example, the references to <i>“if there is a future wave”</i>. 5. To amend section 7 to reflect ethical support has been obtained. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD advised that a new legal basis may be required following the expiry of the COPI Notice, which is currently the 30th June 2022; noting that the application currently reflects wide-ranging research activities, and activities permitted under Regulation 3 of COPI are strictly prescribed. 2. IGARD suggested that NHS England reviewed their privacy notice, for example, to ensure it is transparent on OpenSAFELY and it accurately reflects all sources of data. 3. IGARD advised that this application was updated to reference NIC-139035-X4B7K and the use of the data under that DSA in this application. IGARD would be supportive of this simple amendment without a further review. 4. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the change of legal basis (with the exception of the simple amendment outlined in point 3 above). 5. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the change of legal basis (with the exception of the simple amendment outlined in point 3 above). <p>Advice to NHS Digital's Deputy Caldicott Guardian: IGARD noted and supported the statement in this application <i>“As both TPP and EMIS would have the technical ability to re-identify the data through the use of mapping tables, the data is considered as confidential and requires COPI to address the common law duty of confidentiality”</i>, but noted that this was contradictory to advice from NHS Digital's PTE in respect of other applications (that contractual controls were sufficient to address the common law duty of confidentiality), and suggested that the Deputy Caldicott Guardian investigated further. IGARD asked that they be provided with an update in due course.</p> <p>Risk Factors: There is a reputational risk to NHS Digital that the current transparency about OpenSAFELY does not reflect the number of bodies involved and multiplicity of storage locations.</p>
3.3	<p>University of Oxford: EMPA-KIDNEY (The Study of Heart and Kidney Protection With Empagliflozin) (Presenter: Denise Pine) NIC-449860-L0D6W-v0.11</p> <p>Application: This was a new application for identifiable Demographics data.</p>

The purpose of the application, is for a study investigating the effect of empagliflozin (a drug belonging to the class of medication called SGLT-2 (sodium glucose co-transport 2) inhibitors which reduce blood sugar levels in people with diabetes) on kidney disease progression or cardiovascular death versus placebo on top of standard of care in patients with pre-existing chronic kidney disease.

The data subjects will all be UK participants of The Study of Heart and Kidney Protection with Empagliflozin (EMPA-KIDNEY) randomized controlled trial, which is approximately 1,133 (minus Scottish participants) who have consented to have their data linked via electronic health records.

NHS Digital advised IGARD that the benefits in section 5(d) (Benefits) would need further updates to reflect the benefits outlined in section 5(a) (Objective for Processing) that reflected the purpose and subsequent benefits of the processing of the date of death field.

Discussion: IGARD welcomed the application and noted the importance of the study.

IGARD noted and thanked NHS Digital for the verbal update, in respect of the additional update to section 5(d) to reflect the benefits of the processing of the date of death field as outlined in section 5(a).

IGARD advised that they would be supportive of the cause of death data flowing under this DSA so long as there were appropriate contractual mechanisms in place to cover the recipients of such data, such as being named Data Processors. IGARD would not need to re-review, however, asked that the application was updated throughout to reflect this.

IGARD advised that they were of the view that the consent materials provided the legal gateway for the flow of NHS Digital data to the study and not just the named Data Controller.

IGARD queried the statement in section 5(a) that *“Such consent was mandatory to enter the trial”* and asked that this was removed as it was not necessary.

IGARD had a lengthy discussion on the data controllership and the role of Boehringer Ingelheim International GmbH (BI); noting that the University of Oxford were listed as the sole Data Controller in the application, however the patient information sheet version 1.3 stated that BI was also a joint Data Controller, in addition to being a study sponsor. IGARD noted that BI did appear to have a role in determining the purpose(s) of processing the NHS Digital data, for example by providing members of the Steering Committee that has oversight of the EMPA-KIDNEY trial that was *“...responsible for the review and approval of proposals for subsequent analyses and publications”*; and that the Steering Committee was not just advisory, and members were able to vote. IGARD therefore asked, that in line with the [NHS Digital DARS Standard for Data Controllers](#), the application was updated throughout to add BI as a joint Data Controller, as borne out of the facts; **or**, to make an express statement in section 5(a) that BI would **not** vote on the Steering Committee decisions in respect of NHS Digital data, in order to support the assertion that they do not carry out data controllership activities.

IGARD noted that it may be a reasonable interpretation that participants had consented to NHS Digital data being shared with the EMPA-KIDNEY study and that EMPA-KIDNEY includes the site that the participant was recruited at, and, taken in the round with the Patient Information Sheet (PIS) and consent forms provided as supporting documents, advised that they would be supportive of the addition of the Study Centres as joint Data Processors. IGARD would not need to re-review, however, noted that the application would need to be updated throughout to reflect this, in line with [NHS Digital's DARS Standard for Data Processors](#).

IGARD noted the reference to the patient and public involvement and engagement (PPIE) in the application taken place **prior** to the study, and noting the study Protocol provided as a

	<p>supporting document did not include any further PPIE information, suggested that the applicant may wish to consider involving the relevant public and patient groups for the lifecycle of the project and in line with HRA guidance on Public Involvement. In addition, IGARD noted that the applicant may wish to consider adding PPIE representatives to the Steering Committee and the Data Monitoring Committee.</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(d) with the expected benefits as outlined in section 5(a) (as per the verbal update from NHS Digital). 2. In respect of the data controllership and in line with the NHS Digital DARS Standard for Data Controllers: <ol style="list-style-type: none"> a) To update the application throughout to add Boehringer Ingelheim International GmbH (BI) as a joint Data Controller, as borne out of the facts; or, b) To make an express statement in section 5(a) that BI will not vote on the Steering Committee decisions in respect of NHS Digital data, in order to support the assertion that they do not carry out data controllership activities. 3. To remove the reference in section 5(a) to consent being “<i>mandatory</i>”. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD advised that they were of the view that the consent materials provided the legal gateway for the flow of NHS Digital data to the study and not just the named Data Controller. 2. In respect of the PPIE: <ol style="list-style-type: none"> a) IGARD noted the reference to PPIE in the application taken place prior to the study, however suggested that the applicant may wish to consider involving the relevant public and patient groups for the lifecycle of the project in line with HRA guidance on Public Involvement. b) IGARD noted that the applicant may wish to consider PPIE involvement on the Steering Committee and the Data Monitoring Committee. 3. IGARD advised that they would be supportive of the addition of the Study Centres as Data Processors. IGARD would not need to re-review, however asked that the application would need to be updated throughout to reflect this, in line with NHS Digital’s DARS Standard for Data Processors. 4. IGARD advised that they would be supportive of the cause of death data flowing under this DSA so long as there were appropriate contractual mechanisms in place to cover the recipients of such data (such as being named Data Processors). IGARD would not need to re-review, however asked that the application was updated throughout to reflect this. <p>Subsequent to the meeting: IGARD noted that when the IGARD minutes from the 12th May 2022 were ratified at the IGARD BAU meeting on the 19th May 2022; a discussion point had been raised by an IGARD member not in attendance. IGARD agreed that this would be added to the meeting agenda for the IGARD BAU meeting on the 26th May 2022, and if appropriate, any additional points would be shared with the presenter out of committee, and noted within the meeting minutes as per process.</p>
3.4	<p><u>Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust (FT): (Presenter: Charlotte Skinner) NIC-10328-S0H5J-v11.3</u></p>

Application: This was a renewal application to permit the holding and processing of pseudonymised Emergency Care Data Set (ECDS), Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC), HES Critical Care and HES Outpatients.

It was also an amendment application to **1)** update the application in line with NHS Digital DARS Standards; **2)** update section 5(a) (Objective for Processing) to **a)** clarify the North East Quality Observatory Service (NEQOS) hosting arrangements, explaining why only one of the two foundation trusts which host NEQOS are the Data Controller who process data, **b)** to provide further clarity as to the nature of the relationship between NEQOS and the Academic Health Science Network (AHSN) in the North East and North Cumbria (NENC) **c)** provide further clarity as when HES data would not be used, **d)** to expand upon the approvals process for project recipients who request HES analysis by NEQOS; **3)** to update section 5(d) (Benefits) to reflect the likely benefits in 2022/23.

The purpose of the application is for NEQOS to use the NHS Digital online portal to support the measurement of quality of care, including care delivered in hospital. NEQOS provides quality measurement for NHS organisations (both providers and commissioners) and leads on the measurement programmes for the Academic Health Science Network (AHSN) in North East and North Cumbria. NEQOS services are delivered by clinical epidemiological expertise combined with high level analytical skills. NEQOS has Service Level Agreements (SLA) with subscribers, which provide core projects and services as well as tailored bespoke projects. NEQOS is also commissioned to deliver specific quality measurement projects.

Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the Data Access Advisory Group (DAAG) (IGARD's predecessor) business as usual (BAU) meeting on the 5th July 2016.

IGARD noted that this application had previously been discussed as part of the 'returning applications' section of the IGARD business as usual (BAU) meeting on the 5th November 2020. IGARD noted that comments made on the 5th November 2020 had not been captured in section 1 and suggested that NHS Digital review its internal processes to ensure that IGARD comments were captured and actioned, where appropriate.

IGARD queried the statement in section 5(b) (Processing Activities) that only summary, aggregate results data were exported from the online portal by Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust subject to the "*approval of NHS Digital's trained output checkers*"; and asked that this was amended to clarify that NHS Digital do **not** check every output.

IGARD noted the yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits), however asked that they were updated further, to ensure they were clear as to the benefits to both the patients and the health and social care system more generally and comply with [NHS Digital's DARS Standard for Expected Measurable Benefits](#), specifically in relation to the "*Falls reduction initiative*" and whether the number of admissions and attendances due to falls increased, decreased or stayed the same; and, the "*NICE Guidance*" and if this guidance was updated or re-affirmed because of the outputs generated.

IGARD noted the content of Cumbria, Northumberland, Tyne and Wear NHS FT's privacy notice, however suggested that as a matter of urgency, and for transparency to the public, this was updated to provide clarity regarding that they operate the North East Quality Observatory Service and the data analytics service they provide for other organisations; the data subjects

	<p>and service users; and the activities carried out to date, noting this comment had been provided to NHS Digital when reviewed on the 5th November 2020.</p> <p>IGARD noted the reference in section 5(e) (Is the Purpose of this Application in Anyway Commercial) to work being “<i>commissioned by other NHS or third sector organisations</i>”, and suggested that the applicant provided further transparency within the application, on the commissioners of the work, including, but not limited to, the number of applicants, names of the applicants and types of commissioners.</p> <p>IGARD advised that this application would be suitable for NHS Digital’s Precedent route if all qualifying Data Access Request Services (DARS) Standards were met.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To amend the reference in section 5(b) “...<i>approval of NHS Digital’s trained output checkers</i>” to clarify that NHS Digital do not check every output. 2. To update the yielded benefits in section 5(d) (iii) to ensure they are clear as to the benefits to both the patients and the health and social care system more generally and comply with NHS Digital’s DARS Standard for Expected Measurable Benefits, specifically in relation to: <ol style="list-style-type: none"> a) The “<i>Falls reduction initiative</i>” and whether the number of admissions and attendances due to falls increased, decreased or stayed the same; and, b) The “<i>NICE Guidance</i>” and if this guidance was updated or re-affirmed because of the outputs generated. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD suggested that as a matter of urgency, Cumbria, Northumberland, Tyne and Wear NHS FT updated their privacy note to provide clarity on: <ol style="list-style-type: none"> a) That they operate the North East Quality Observatory Service and the data analytics service they provide for other organisations. b) To provide further clarification on the data subjects and service users. c) To reflect the activities carried out to date. 2. IGARD suggested that the applicant provided further transparency on the commissioners of the work, including (but not limited to) the number of applicants, names of the applicants and types of commissioners. 3. IGARD advised that this application would be suitable for NHS Digital’s Precedent route if all qualifying DARS Standards are met.
4	<p><u>Applications progressed via NHS Digital’s Precedent route, including the SIRO Precedent</u></p> <p>Applications that have been progressed via NHS Digital’s Precedent route, including the SIRO Precedent, and NHS Digital have notified IGARD in writing (via the Secretariat).</p>
4.1	<p><u>NIC-194340-D6F3B-v2.6 Office for National Statistics (ONS) (No Presenter)</u></p> <p>The purpose of this application was for the ONS Longitudinal Study, with the specific purpose of 1) maintenance of the LS Research Database; 2) providing access to the LS Research database; 3) adding 2021 Census data to the LS.</p>

	<p>IGARD noted that this application was last reviewed at the IGARD business as usual meeting on the 24th March 2022 where IGARD had provided advice on 1) ethics; 2) the right to be informed / transparency and 3) the legal basis for processing special category data.</p> <p>IGARD noted that on the 5th May 2022, NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had agreed to authorise a one-year extension to the Data Sharing Agreement.</p> <p>IGARD noted and thanked NHS Digital for the written update, and noted the four points in section 1 (Abstract) that ONS must address by the 31st July 2022. IGARD advised that they would follow-up with NHS Digital on the 1st August 2022.</p> <p>IGARD asked that the next iteration should be brought to a future IGARD BAU meeting.</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.</p> <ul style="list-style-type: none"> <p>NIC-209200-S9H5R-v2.3 Royal College of Psychiatrists (extension & renewal precedent)</p> <p>NHS Digital noted that section 1 (Abstract) did not contain the usual history to explain how previous actions or special conditions had been evidenced.</p> <p>IGARD members noted that section 5(d)(iii) (Yielded Benefits) was a good example of explaining why no yielded benefits had been accrued to date and suggested this application be used as an exemplar or as part of learning and development of DARS Staff.</p> <p>NIC-274251-H0G6M-v1.4 King's College London (extensions & renewals precedent)</p> <p>NHS Digital noted that the statement in section 1 (Abstract) "<i>IGARD review confirmed as not required</i>" was not correct since IGARD's previous review on the 4th April 2019 was prior to the precedents process commencing on the 1st May 2019 plus IGARD had been unable to recommend for approval at that time due to HQIP's legal basis (now resolved).</p> <p>IGARD noted that section 5(d)(iii) (Yielded Benefits) had not been updated in line with the published NHS Digital DARS Standard for expected measurable benefits, for example was the reference to the strategy in the expected benefits achieved and if so why had this not been included in the yielded benefits section?</p> <p>NIC-10343-Z3M1B Royal College of Physicians of London (extension & renewal precedent / DARS simple amendment precedent)</p> <p>IGARD noted that section 1 (Abstract) did not contain the usual history to explain how previous actions had been evidenced, including dates, for example when was version 6.2 approved? IGARD reiterated previous comments that section 1 should provide the history of the application to date in order to support oversight & assurance but also the Director / IAO signing off under precedent.</p> <p>NHS Digital noted outdated terminology in section 1 such as "<i>IAO and Director Approval</i>" and that this would be updated.</p> <p>IGARD noted that the application should not have proceeded down this precedent route due to the addition of a new Data Processor, a query to the Data Controllorship, a query with regard to whether the COVID-19 purpose was new, and additional flow of identifying data which had not been explained in section 1.</p>

	<p>IGARD noted that the NHS Digital DARS standard for expected measurable benefits had not been met because no yielded benefits had been achieved, or an explanation as to why they had not been accrued to date. IGARD noted this would be a good example for learning and development of DARS staff.</p> <ul style="list-style-type: none"> • NIC-259538-Q4V0W University College London (Population Health Survey: data access approvals precedent) IGARD noted in section 1 (Abstract) reference to “...does not require IGARD approval...” and reminded NHS Digital that IGARD provide “recommendations”. IGARD noted the update from NHS Digital that the APMS information pack would be further updated to ensure that all relevant materials for DARS staff were current and up to date. • NIC-604129-X4D1K University of Bristol (Population Health Survey: data access approvals precedent) <p>IGARD Members noted that they had not yet been updated on the issues raised at the 27th May 2021 IGARD business as usual (BAU) meeting with regard to previous comments made on the IG COVID-19 release registers March 2020 to May 2021. IGARD noted that in addition, they had not been updated on the issues raised on the IG COVID-19 release registers June 2021 to January 2022.</p> <p>IGARD noted that the NHS Digital webpage excel spreadsheet had now been updated for the period March 2020 to February 2022: NHS Digital Data Uses Register - NHS Digital</p> <p>IGARD noted that the IG COVID-19 Release Register February 2022 to April 2022 had been circulated and reviewed out of committee by members, discussed in-meeting and agreed the comments that would be shared with the Privacy, Transparency and Ethics Directorate.</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>NIC-09519-D5G0R-v17 Methods Analytics (Presenter: Dave Cronin)</u></p> <p>NHS Digital attended the meeting to provide a verbal update on the above application, that had previously been presented at the IGARD business as usual (BAU) meeting on the 20th January 2022.</p> <p>IGARD noted the verbal update provided and thanked NHS Digital for attending the meeting.</p>
7.2	<p><u>Permission to Contact Service Precedent (No Presenter)</u></p> <p>IGARD noted that following comments / feedback provided by IGARD members out of committee in April 2022, that an updated draft of the Precedent had been provided to members.</p> <p>IGARD noted and thanked NHS Digital for providing an updated version of the Precedent, and thanked them for their hard work in updating this, and asked that once this had been through the appropriate internal channels and had been signed off, that a final version was provided to the IGARD Secretariat and Data Access Request Services (DARS); and if appropriate, that a copy was uploaded to NHS Digital’s website.</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.
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Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 06/05/22

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

NIC Reference	Applicant	IGARD meeting date	Recommendation conditions as set at IGARD meeting	IGARD minutes stated that conditions should be agreed by:	Conditions agreed as being met in the updated application by:	Notes of out of committee review (inc. any changes)
NIC-148204-7B1XT-v8.4	University of Oxford	10/02/2022	1. In respect of the HRA CAG support: <ol style="list-style-type: none"> To provide written confirmation from HRA CAG that the existing s251 support provides a gateway for NHS Digital to flow identifiable data to the CTSU-ctfs; or, To provide written confirmation from HRA CAG that the s251 support has been extended to cover this flow of data. To upload the written confirmation from HRA CAG to NHS Digital's CRM system for future reference. To update section 5(b) to ensure this section accurately aligns with the HRA CAG support. 	IGARD members	Quorum of IGARD members	None
NIC-01207-V9G9P-v8.4	Compufile Systems Limited	17/02/2022	1. In respect of the Yielded Benefits in section 5(d)(iii): <ol style="list-style-type: none"> To update the yielded benefits in line with the NHS Digital DARS Standard for Expected Measurable Benefits, and Given the significant volume of data, to provide 2 or 3 specific yielded benefits accrued to date and ensure these are clear as to the benefits to both patients 	IGARD members	Quorum of IGARD members	N/A

			and the health care system more generally.			
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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