

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 28 July 2022

| IGARD MEMBERS IN ATTENDANCE: | |
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| Name: | Position: |
| Paul Affleck | Specialist Ethics Member |
| Prof. Nicola Fear | Specialist Academic Member |
| Kirsty Irvine | IGARD Chair |
| Dr. Geoffrey Schrecker | Specialist GP Member / IGARD Deputy Chair |
| Dr. Maurice Smith | Specialist GP Member |
| IGARD MEMBERS NOT IN ATTENDANCE: | |
| Maria Clark | Lay Member |
| Dr. Robert French | Specialist Academic / Statistician Member |
| Dr. Imran Khan | Specialist GP Member |
| Jenny Westaway | Lay Member |
| NHS DIGITAL STAFF IN ATTENDANCE: | |
| Name: | Team: |
| Michael Ball | Data Access Request Services (DARS) (Item 3.1, 3.2, 7.2) |
| Michael Chapman | Director of Research and Clinical Trials (Item 7.1) |
| Garry Coleman | Associate Director / Senior Information Risk Owner (SIRO) (Item 7.1) |
| Louise Dunn | Data Access Request Service (DARS) (SAT Observer: item 3.2) |
| Duncan Easton (DE) | Data Access Request Service (DARS) (SAT Observer: items 3.1 - 3.2) |
| Mujiba Ejaz | Data Access Request Services (DARS) (Item 3.3) |
| Laura Evans | DigiTrials (Observer: Item 3.4) |
| Liz Gaffney | Head of Data Access, Data Access Request Service (DARS) (Observer: items 3.1, 7.1) |
| David Morris | Data Access Request Services (DARS) (Observer: item 3.1) |
| Karen Myers | IGARD Secretariat |
| Frances Perry | DigiTrials (Item 3.4) |

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| Kimberley Watson | Data Access Request Service (DARS) (SAT Observer: item 3.4) |
| Vicki Williams | IGARD Secretariat |
| *SAT – Senior Approval Team (DARS) | |

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| 1 | <p>Declaration of interests:</p> <p>Paul Affleck noted professional links to AIMES Management Service [NIC-59669-F6Y3W] but no specific connection with the application or staff involved and it was agreed this was not a conflict of interest.</p> <p>Dr. Maurice Smith noted professional links to AIMES Management Service [NIC-59669-F6Y3W] but no specific connection with the application or staff involved and it was agreed this was not a conflict of interest.</p> <p>Review of previous minutes and actions:</p> <p>The minutes of the 21st July 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>Improving Access to Psychological Therapies (IAPT) Version 2.1 - Letter of Note (No Presenter)</u></p> <p>This was a letter of note to inform IGARD of Improving Access to Psychological Therapies (IAPT) version 2.1, which is an additional IAPT dataset, that will provide customers with the most current IAPT data i.e. from April 2022 onwards. See: https://www.england.nhs.uk/mental-health/adults/iapt/</p> <p>IAPT version 2.0, covers the periods of 1st September 2020 until 31st March 2022, IAPT version 2.1 does not cover any period prior to April 2022.</p> <p>IGARD thanked NHS Digital for providing a comprehensive update by way of a “letter of note”.</p> <p>Outcome: IGARD welcomed the letter of note and made no further comments.</p> |
| 3 | Data Applications |
| 3.1 | <p><u>NHS Bristol, North Somerset and South Gloucestershire Integrated Care Board: Comm, RS and IV (Presenter: Michael Ball) NIC-615958-F7Q7Zv0.2</u></p> <p>Application: This was a new, third of type application for the newly formed Integrated Care Board (ICB) for the purpose of commissioning, risk stratification and invoice validation and is a request for: pseudonymised commissioning datasets, identifiable risk stratification datasets and identifiable invoice validation datasets.</p> <p>The application is based on a draft ICB template, which in turn is based on the standard Clinical Commissioning Group (CCG) template, with all changes agreed by NHS Digital’s Senior Information Risk Owner (SIRO).</p> |

Sub-licencing to members of the ICB is part of the application. Pseudonymised record-level commissioning data can only be shared by the Data Controller with substantive organisations who are part of the ICB's Integrated Care System (ICS), which includes Trusts, GPs, Local Authorities and other health care providers who will contribute to commissioning decisions.

The processing outlined within the application is relying on s251 of the NHS Act 2006 and s261(7) of the Health and Social Care Act 2012 , for the flow of data out of NHS Digital.

Discussion: IGARD noted that the 'ICB's sharing commissioning data with members of their Integrated Care System Briefing Paper', had previously been presented at the IGARD business as usual (BAU) meeting on the 26th August 2021, 30th September 2021, and the 21st July 2022.

IGARD noted that the first of type application (NIC-615960-G7W1L) was presented at the IGARD BAU meeting on the 30th June 2022 and the second of type application (NIC-616046-J1Q0N) was presented at the IGARD BAU meeting on the 21st July 2022.

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

Separate to this application: IGARD noted the recent presentation at the IGARD BAU meeting on the 14th July 2022, in respect of the Common Law duty of Confidentiality (CLDoC), and how this was satisfied in terms of providers of confidential data, linking with NHS Digital data. IGARD noted that this may also be an issue with the ICB applications and agreed that this would be discussed further at a future IGARD BAU meeting.

IGARD noted that following the discussion on NIC-615960-G7W1L on the 30th June 2022 and NIC-616046-J1Q0N on the 21st July 2022, it had been agreed with NHS Digital's Senior Information Risk Owner (SIRO), that processing and storage locations in section 2 (Locations) of the application, would not be recorded in the ICB applications. IGARD reiterated previous advice that [NHS Digital DARS Standard for Processing and Storage Locations](#) should be updated as a matter of urgency to reflect this new process; and that there was a risk to NHS Digital in respect of the policy / process of how the ICB applications were recording the processing and storage locations; and that the process was changing before the [NHS Digital DARS Standard for Processing and Storage Locations](#). NHS Digital's Head of Data Access, Data Access Request Service (DARS) confirmed that the Standard was in the process of being updated and would be shared with IGARD as soon as possible. IGARD noted and thanked NHS Digital for the verbal update.

IGARD noted that a CCG DSA for the ICB's geographical area had been novated to the ICB. IGARD highlighted that, as ICBs were different statutory bodies from CCGs, there was a risk to NHS Digital that the CCG DSA may **not** be accurate in respect of the ICB; or would not permit the ICB to undertake processing in the manner that they require. IGARD highlighted that this was a risk to NHS Digital.

IGARD noted the references within the application to "*supersede*", for example, "this Agreement supersedes the CCG's DSA"; and asked that the application was updated throughout to remove the references to "*supersede*" and correctly replaced with "*the CCG DSA has been novated to the ICB*" or similar.

IGARD noted that at the meeting on the 21st July 2022, whilst discussing NIC-616046-J1Q0N, IGARD had raised a query in respect of the role of the Integrated Care Partnerships (ICP); and that NHS Digital had advised that an ICP was a statutory committee, jointly formed between the ICB and all upper-tier Local Authorities that fall within the Integrated Care Systems (ICS) area, but that staff do not work directly for the ICP. IGARD queried if organisations in the ICS

were required to be involved in the decision making for commissioning, and whether or not the organisations that formed the ICP were considered Data Controllers. IGARD asked that in line with the [NHS Digital DARS Standard for Data Controllers](#), written confirmation was provided that the ICP and the ICPs constituent members (save for the ICB) **do not** carry out data controllership activities.

In addition, IGARD asked that section 5(a) (Objective for Processing) was updated with confirmation that the ICP / ICP Constituent members (save for the ICB) will **not** make any decisions on sub-licensing; and that a special condition was added in section 6 (Special Conditions) that the ICP and / or the ICPs constituent members (save for the ICB) **do not** carry out data controllership activities, that they will not make any decisions on sub-licensing.

IGARD noted that the University of Bristol and the University of the West of England were listed as Data Processors within the application; however, noting that there was no supporting information, IGARD queried what their role was and whether they carried out any data controllership activities. IGARD asked that [in line with the NHS Digital DARS Standard for Data Controllers](#), written confirmation was provided in section 5(a), the Universities **do not** carry out data controllership activities; and that a special condition was added in in section 6 that the Universities **do not** carry out data controllership activities.

IGARD noted the special condition in section 6 *“The ICB commits to update it’s [sic] transparency notice to inform the public of it’s [sic] data sharing”*; and asked that in line with [NHS Digital’s DARS Standard for Transparency \(fair processing\)](#), this was updated to state that the ICB must have a UK General Data Protection Regulation (UK GDPR) compliant, publicly accessible transparency notice that is maintained throughout the life of the agreement. Noting that section 6 does not form part of [NHS Digital’s data uses register](#), IGARD asked that for transparency, the special condition was replicated in section 5(b) (Processing Activities).

IGARD also noted the lack of transparency within the application in respect of the sub-licensing arrangements, and asked that the application was updated throughout, in line with [NHS Digital DARS standard for sub-licencing and onward sharing](#).

In addition, IGARD asked that a special condition was added to section 6, that a sub-licence register would be published in the public domain on a quarterly basis; and that, for transparency to the public, section 5(a) was updated to confirm that a sub-licence register would be published on a quarterly basis.

IGARD noted the example provided in section 5(a) in respect of re-identification for the purpose of polypharmacy and asked that this was removed as it was not relevant to include at the current time.

IGARD noted that section 1(b) (Data Controller(s)) and section 1(c) (Data Processor(s)) was silent on the Data Protection Act (DPA) Registration details and asked that this was updated accordingly.

IGARD noted that section 2(c) (Territory of Use) incorrectly stated that the territory of use was *“England and Wales”* and asked that this was updated to correctly state *“UK”*.

Separate to this application: IGARD suggested that where a ICB covers the footprint of **multiple** former CCGs, NHS Digital should consider if relying on multiple previous CCG Data Security & Protection Toolkit (DSPT) submissions was appropriate in respect of adequate security arrangements and suggested NHS Digital’s Security Team should review proposed arrangements.

Separate to this application: IGARD suggested that NHS Digital confirm that the organisations who apply for sub-licenses will all be appropriate for DSPT, and will not require alternate security assurances.

IGARD noted and welcomed the verbal update previously provided on the 21st July 2022 by NHS Digital in respect of the plan to audit an ICB early, especially, in respect of sub-licensing, and suggested that this was applicable to this application to support other ICB applications and the wider system.

IGARD noted that on amendment or renewal, they would expect to see further information within the yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits), in respect of how the NHS Digital data enables clinical intervention to prevent adverse outcomes, such as A&E attendance and examples of any work undertaken as a result of reidentification allowed by this DSA.

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 large quantity of data flowing and the novel processing and recent creation of ICBs.

Separate to this application: IGARD noted that following the review of this application, amendments would be required to the outcomes for NIC-616046-J1Q0N presented at the IGARD BAU meeting on the 21st July 2022. (Please see below for further information).

Outcome: recommendation to approve subject to the following conditions:

1. In respect of the ICP / ICP Constituent data controllership and [in line with the NHS Digital DARS Standard for Data Controllers:](#)
 - a) To provide written confirmation in section 5(a) that the ICP (save for the ICB) **do not** carry out data controllership activities; and
 - b) To provide written confirmation in section 5(a) that the ICPs constituent members (save for the ICB) **do not** carry out data controllership activities; and
 - c) To update section 5(a) with confirmation that the ICP / ICP Constituent members (save for the ICB) will **not** make any decisions on sub-licensing; and
 - d) To add a special condition in section 6 that the ICP and / or the ICPs constituent members (save for the ICB) **do not** carry out data controllership activities, that they will not make any decisions on sub-licensing.
 - e) Should the ICP or any constituent of the ICS wish to undertake data controllership activities then they will need to apply for an amendment as per DARS processes.
2. In respect of the University data controllership and [in line with the NHS Digital DARS Standard for Data Controllers:](#)
 - a) To provide written confirmation in section 5(a) that the Universities **do not** carry out data controllership activities; and
 - b) To add a special condition in section 6 that if the Universities **do not** carry out data controllership activities.
3. In respect of transparency:
 - a) To update the application in line with [NHS Digital's DARS Standard for Transparency \(fair processing\)](#); and,
 - b) To update the special condition in section 6, to state that they must have a UK GDPR compliant, publicly accessible transparency notice that is maintained throughout the life of the agreement; and,

- c) To update section 5(b) to state that they will have a UK GDPR compliant, publicly accessible transparency notice that is maintained throughout the life of the agreement.
- d) To update the application in line with [NHS Digital DARS standard for sub-licencing and onward sharing](#); and
- e) To add a special condition in section 6 that a sub-licence register will be published in the public domain on a quarterly basis; and
- f) To update section 5(a) to confirm that a sub-licence register will be published on a quarterly basis.

The following amendments were requested:

- 1. To explain the data processing roles of the University of Bristol and the University of the West of England in section 5(a).respect of re-identification:
- 2. To update the application throughout to remove the references to “*supersede*” and replace with “*the CCG DSA has been novated to the ICB*” or similar.
- 3. To amend section 5(a) to remove reference to the example provided in respect of polypharmacy re-identification.
- 4. To update section 1(b) and section 1(c) with the ICB DPA Registration details.
- 5. To amend the territory of use in section 2(c) from “*England and Wales*” to “*UK*”.

The following advice was given:

- 1. IGARD noted and welcomed the verbal update previously provided by NHS Digital in respect of an early ICB audit, for example, in respect of sub-licensing and the exercise of actions of data controllership, and suggested that this was applicable to this application to support ICBs and the wider system.
- 2. IGARD noted that on amendment or renewal, they would expect to see further information within the yielded benefits, in respect of how the NHS Digital data enables clinical intervention to prevent adverse outcomes, such as A&E attendance and examples of any work undertaken as a result of reidentification allowed by this agreement.
- 3. IGARD noted the novation of a CCG agreement. IGARD highlighted that, as ICBs are different statutory bodies from CCGs, there is a risk to NHS Digital that the CCG DSA may not be accurate in respect of the ICB, or not permit the ICB to undertake processing in the manner that they require.
- 4. IGARD noted the change of process in respect of how the processing and storage locations were listed within the application, following discussions at the IGARD BAU meetings on the 30th June 2022 in respect of the ICB applications. IGARD advised that [NHS Digital DARS Standard for Processing and Storage Locations](#) should be updated as a matter of urgency to reflect this new process.
- 5. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the large quantity of data flowing and the novel processing and recent creation of ICBs.
- 6. IGARD suggested that this application would not be suitable for NHS Digital’s Precedent route, including the SIRO Precedent, due to the large quantity of data flowing and the novel processing and recent creation of ICBs.

RISK AREA: There is a risk to NHS Digital in respect of the novated DSA to the ICB; and the processing that ICB may not be permitted to undertake.

Separate to this application: IGARD noted the recent presentation at the IGARD BAU meeting on the 14th July 2022, in respect of CLDoC, and how this was satisfied in terms of

providers of confidential data, linking with NHS Digital data. IGARD noted that this may also be an issue with the ICB applications and agreed that this would be discussed further at a future IGARD BAU meeting.

Separate to this application: IGARD noted that following the review of this application, amendments would be required to the outcomes for NIC-616046-J1Q0N presented at the IGARD BAU meeting on the 21st July 2022.

Separate to this application: IGARD suggested that where **multiple** CCGs were previously in the footprint of the new ICB, NHS Digital should consider if DSPT is appropriate in respect of adequate security arrangements and whether the security team should review the process.

Separate to this application: IGARD suggested that NHS Digital confirm that all organisations who would be applying for sub-licenses would also be appropriate for DSPT, and would not require alternate security assurances.

It was agreed the conditions would be approved out of committee (OOC) by IGARD members.

IGARD noted that following the review of NIC-615958-F7Q7Z, that further amendments would be required to the outcomes for NIC-616046-J1Q0N presented at the IGARD BAU meeting on the 21st July 2022:

NHS Norfolk and Waveney Integrated Care Board (ICB): Comm, RS and IV - NIC-616046-J1Q0N-v0.2

Outcome: recommendation to approve subject to the following condition:

1. In respect of the ICP / ICP Constituent data controllership and [in line with the NHS Digital DARS Standard for Data Controllers:](#)
 - a) To provide written confirmation in section 5(a) that the ICP (save for the ICB) **do not** carry out data controllership activities; and
 - b) To provide written confirmation in section 5(a) that the ICPs constituent members (save for the ICB) **do not** carry out data controllership activities; and
 - c) To update section 5(a) with confirmation that the ICP / ICP Constituent members (save for the ICB) will **not** make any decisions on sub-licensing; and
 - d) To add a special condition in section 6 that the ICP and / or the ICPs constituent members (save for the ICB) **do not** carry out data controllership activities, that they will not make any decisions on sub-licensing.
 - e) Should the ICP or any constituent of the ICS wish to undertake data controllership activities then they will need to apply for an amendment as per DARS processes.
2. In respect of transparency:
 - a) To update the application in line with [NHS Digital's DARS Standard for Transparency \(fair processing\)](#); and,
 - b) To update the special condition in section 6, to state that they must have a UK GDPR compliant, publicly accessible transparency notice that is maintained throughout the life of the agreement; and,
 - c) To update section 5(b) to state that they will have a UK GDPR compliant, publicly accessible transparency notice that is maintained throughout the life of the agreement.
 - d) To update the application in line with [NHS Digital DARS standard for sub-licensing and onward sharing](#); and,

- e) To add a special condition in section 6 that a sub-licence register will be published in the public domain on a quarterly basis; and,
- f) To update section 5(a) to confirm that a sub-licence register will be published on a quarterly basis.

The following amendments were requested:

1. To update section 3(b) with the s261 legal basis for NHS Digital to disseminate data.
2. In respect of re-identification:
 - a) To clarify in section 5(a) that although some re-identification will be as a result of coincidental findings, there will be other activities, where the purpose of the activity is to define groups that will need to be re-identified.
 - b) To clarify in section 5(a) that any re-identification under a sub-licence, must be undertaken by NHS Digital, and not by any other Data Processors being used by the ICB / sub-licensee.
 - c) To clearly articulate the ICB can identify cohorts of patients for service providers to provide the most appropriate care, but the ICB cannot provide direct care.
3. In respect of Direct Care, to update section 5(a) to clarify that in other instances work will be undertaken for the primary purpose of delivering direct care.
4. To clarify in section 5 which CCG(s) previously occupied the geographical footprint of the ICB.
5. To update section 4 with the special conditions outlined in section 6, relating to transparency.
6. In respect of section 5(b) and in line with [NHS Digital DARS Standard for processing activities:](#)
 - a) To update section 5(b) with the special conditions outlined in section 6, relating to Data Processors.
 - b) To update section 5(b) with further clarity of the onward sharing of data under sub-licensing arrangements, in line with [NHS Digital DARS standard for sub-licencing and onward sharing](#).
7. In respect of the DSPT:
 - a. To amend section 1(b) to accurately reflect that the ICB is “relying” on the DSPT submitted by the CCG.
 - b. To update section 5 to be clear that the DSPT for the year 2021/2022 was submitted by the CCG, and that the ICB will submit a DSPT for the year 2022/23 onwards, and
 - c. To update section 6 to ensure that the DSPT covers the relevant bodies and is in line with point (a) above.
8. To re-order the statement in section 5(d) relating to reducing “emergency readmissions” in line with [NHS Digital DARS Standard for Expected Measurable Benefits](#)
9. To clarify in section 5 that the ICB is holding and processing patient data under the novated CCG DSA.
10. To update the application throughout to remove the references to “supersede” and replace with “CCG DSA have novated to the ICB, and that the ICB is therefore holding the novated CCG DSA” or similar.
11. In respect of re-identification to clarify in section 1 and section 5 that re-identification will **not** be undertaken by NHS Digital.

The following advice was given:

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| | <ol style="list-style-type: none"> 1. IGARD noted that the previous CCG DSA has novated to the ICB. IGARD highlighted that, as ICBs are different statutory bodies from CCGs, there is a risk to NHS Digital that the CCG DSA may not be accurate in respect of the ICB, or not permit the ICB to undertake processing in the manner that they require. 2. IGARD noted the change of process in respect of how the processing and storage locations were listed within the application, following discussions at the IGARD BAU meetings on the 30th June 2022 in respect of the ICB applications. IGARD advised that NHS Digital DARS Standard for Processing and Storage Locations should be updated as a matter of urgency to reflect this new process. 3. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the large quantity of data flowing and the novel processing and recent creation of ICBs. 4. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the large quantity of data flowing and the novel processing and recent creation of ICBs. <p>RISK AREA: There is a risk to NHS Digital in respect of the novated DSA to the ICB; and the processing that ICB may not be permitted to undertake.</p> <p>RISK AREA: There is a risk to NHS Digital that, in respect of the policy / process of how the ICB applications are recording the processing and storage locations; and that the process is changing before the NHS Digital DARS Standard for Processing and Storage Locations.</p> <p>Separate to this application: IGARD suggested that where multiple CCGs were previously in the footprint of the new ICB, NHS Digital should consider if DSPT is appropriate in respect of adequate security arrangements and whether the security team should review the process.</p> <p>Separate to this application: IGARD suggested that NHS Digital confirmed that all organisations who would legitimately be applying for sub-licenses, would also be appropriate for DSPT, and would not require alternate security assurances.</p> <p>It was agreed the condition would be approved out of committee (OOC) by IGARD members.</p> <p>IGARD noted that following comments in respect of the ICB template due to be discussed at a future IGARD BAU meeting:</p> <ol style="list-style-type: none"> 1. IGARD noted that all the outcomes raised on NIC-615958-F7Q7Z would be relevant to the template, with the exception of amendment point 1. 2. IGARD noted that once all the conditions and amendments on NIC-615958-F7Q7Z, NIC-615960-G7W1L (presented at the IGARD BAU meeting on the 30th June 2022) and NIC-616046-J1Q0N (presented at the IGARD BAU meeting on the 21st July 2022) had been addressed as per process; that IGARD would be in a position to provide a further review on the ICB template. 3. IGARD noted that in some ICB applications, re-identification was performed by MedeAnalytics; and asked that for transparency, section 1 and section 5 (Purpose / Methods / Outputs) were updated to clarify that re-identification was performed by MedeAnalytics who follow their own internal processes, and that re-identification will not be undertaken by NHS Digital where this is applicable to the application |
| 3.2 | <u>Bradford Teaching Hospitals NHS Foundation Trust: DSfC - Bradford Teaching Hospitals NHS Foundation Trust - Comm (Presenter: Michael Ball) NIC-627124-V8Z6Z-v0.2</u> |

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| <p>Application: This was a new application for pseudonymised Civil Registration (Deaths) data. The purpose of the application is to provide intelligence to support the commissioning of health services. The data is analysed so that health care provision can be planned to support the needs of the population within the Trust's Integrated Care System (ICS) area.</p> <p>Connected Yorkshire is one of the identified Connected Health Cities data linkage programmes across health and social care to improve patient pathways that is hosted by Bradford Teaching Hospitals NHS Foundation Trust (BTHFT).</p> <p>The aim of the programme is to develop safe and secure anonymised datasets that will be critical to the NHS's goal to improving quality, safety and efficiency of the health care provided to patients. The dataset is used for all pathways of care projects and evaluation identified by the programme, which includes child health, diabetes, epilepsy, emergency care, medically unexplained symptoms, and frailty patient care pathways.</p> <p>Discussion: IGARD noted that this was a "first of type" application, in that the Trust was requesting data for the purpose of commissioning as part of an Integrated Care System (ICS) and was requesting a separate flow of data for the same purpose as the ICB, who were receiving the data same data flow under a separate NHS Digital Data Sharing Agreement (DSA).</p> <p>IGARD queried why NHS Digital had not sought advice earlier in the end-to-end process for this novel application, rather than bringing the application for a recommendation. IGARD raised the concern that having members of ICSs apply for their own commissioning data flows runs contrary to ICBs receiving data and using sub-licensing to manage analysis to inform commissioning.</p> <p>IGARD had a lengthy discussion on the purpose of processing, which was currently stated as "commissioning", and why the applicant would want to restrict their purpose to commissioning. IGARD asked that written confirmation was provided as to why the purpose of the application was not for the purpose of "<i>research</i>", noting potentially greater utility for the Connected Yorkshire initiative and positive impact on the wider health and care system.</p> <p>If this was a commissioning application, IGARD asked that to further support the purpose for processing, that written support was provided from the ICB, and that the analysis was necessary to support the commissioning carried out by the ICB.</p> <p>Alternatively, if it was deemed that the purpose for processing was in fact research, that the application was revised throughout to amend the purpose of the application from "<i>commissioning</i>" to "<i>research</i>" and to make all other necessary changes to reflect that change of purpose.</p> <p>IGARD noted the restrictions for the applicant if processing was for the purpose of "<i>commissioning</i>", and suggested that NHS Digital discussed this with the applicant, to clarify that this would not impact on the expected outcomes and benefits.</p> <p>IGARD suggested that NHS Digital may wish for a future IGARD business as usual (BAU) session to discuss the outcomes of the conversation with the applicant and senior NHS Digital colleagues.</p> <p>Outcome: IGARD were unable to make a recommendation as not all the necessary information was available in order for IGARD to make a full assessment.</p> <ol style="list-style-type: none"> 1. In respect of the purpose for processing: <ol style="list-style-type: none"> a) To provide confirmation as to why the purpose of the application is not for the purpose of "<i>research</i>" as opposed to "<i>commissioning</i>", noting the potential greater |
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| | <p>utility for the Connected Yorkshire initiative and positive impact on the wider health and care system if this was carried out as research; and,</p> <ul style="list-style-type: none"> b) To provide written confirmation from the ICB, that the application is necessary to support the commissioning carried out by the ICB.; or c) To revise the application throughout to amend the purpose of the application from “<i>commissioning</i>” to “<i>research</i>” and make all other necessary changes to reflect that change of purpose. <p>2. IGARD noted the restrictions for the applicant if processing is for the purpose of “<i>commissioning</i>”, and suggested that NHS Digital discussed this with the applicant, to clarify that this will not impact on the expected outcomes and benefits.</p> <p>3. IGARD suggested that NHS Digital may wish for a future BAU session to discuss the outcomes of the conversation with the applicant and senior NHS Digital colleagues.</p> |
| 3.3 | <p><u>The Royal College of Surgeons of England: National Vascular Registry - patient level HES and Civil Registration Mortality data request (Presenter: Mujiba Ejaz) NIC-59669-F6Y3W-v2.2</u></p> <p>Application: This was an amendment application to amend the way the Common Law Duty of Confidentiality (CLDoC) will be addressed, by ensuring that the National Data Opt-Outs (NDOs), historically applied to the data disseminated under this agreement, are not applied to this cohort.</p> <p>The aim of the National Vascular Registry (NVR) is to improve the quality of care of patients having vascular surgery by providing high quality comparative information on clinical practice and outcomes and support quality improvement by NHS hospitals.</p> <p>The Royal College of Surgeons (RCS) of England is commissioned by the Healthcare Quality Improvement Partnership (HQIP) on behalf of NHS England as part of the Clinical Audit and Patient Outcomes Programme (NCAPOP).</p> <p>The audit programme is relying on consent and s251 of the NHS Act 2006, for the flow of identifiable data into NHS Digital.</p> <p>NHS Digital advised that following submission of the application for IGARD to review, the applicant had provided further details on the yielded benefits accrued to date, that were currently not reflected in the application. IGARD asked that the incorrect statement in section 5(d) (Benefits) (iii) (Yielded Benefits) “...<i>there have not been any achievable benefits to date</i>” was removed; and that in line with the NHS Digital DARS Standard for Expected Measurable Benefits, section 5(d) (iii) was updated, reflecting the additional information provided by the applicant, as per the verbal update.</p> <p>Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 21st May 2020, 28th October 2021 and the 11th November 2021.</p> <p>IGARD noted the verbal update from NHS Digital in respect of the additional information provided by the applicant on the yielded benefits.</p> <p>IGARD confirmed that they were of the view that the consent materials provided the appropriate gateway and were broadly compatible with the processing outlined in the application.</p> <p>IGARD noted that there was Health Research Authority Confidentiality Advisory Group (HRA CAG) support for NVR to send confidential information to NHS Digital in respect of “<i>patients undergoing emergency procedures, from whom consent could not be sought</i>”; and that HRA CAG had now agreed that the National Data Opt-out (NDO) should not be applied to patients</p> |

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| | <p>included in the activities specified in the HRA CAG support. In addition, IGARD noted that section 3(a) (Data Access Already Given) stated <i>“For patients who have declined consent their data will flow to NHS Digital under Section 251, but their data will not be linked and will be destroyed after analysis”</i>; however, s251 only applied to <i>“patients undergoing emergency procedures, from whom consent could not be sought”</i>. IGARD queried what the NVR’s basis was, for sending confidential information regarding individuals that refused participation. NHS Digital advised that where consent had been refused then no data would flow for those individuals, and they would therefore not form part of any cohort under the DSA. IGARD noted the verbal update from NHS Digital and asked that section 5 (Purpose / Methods / Outputs) was updated clarifying this point.</p> <p>Noting that although the flow of data from NHS Digital was classified as pseudonymised, in the hands of the recipient, it was potentially identifiable patient data as they have the technical means to reidentify; and the s251 support is only for the original flow of data to NHS Digital. IGARD suggested that NHS Digital confirmed with HRA CAG, that there were no confidentiality issues for the receipt of data by the party who have the means to re-identify. IGARD requested an update by the end of August 2022.</p> <p>IGARD noted the statement in section 5(c) (Specific Outputs Expected) <i>“The main benefit of this data for patients is that this will allow The RCS to provide longer term outcomes for the patients...”</i>; and asked that this was amended to state <i>“...provide longer term outcomes to help inform decisions about treatment and care”</i>.</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 to clarify that where consent has been refused, then no data will flow for those individuals, and they will therefore not form part of any cohort under this DSA. 2. To amend the reference in section 5(c) from <i>“longer term outcomes”</i> to <i>“...provide longer term outcomes to help inform decisions about treatment and care.”</i> 3. In respect of the Yielded Benefits in section 5(d)(iii): <ol style="list-style-type: none"> a. To remove the incorrect statement from section 5(d) (iii) <i>“...there have not been any achievable benefits to date”</i>. b. To update section 5(d) (iii) with the yielded benefits in line with the NHS Digital DARS Standard for Expected Measurable Benefits (as per the verbal update from NHS Digital). <p>ACTION: Noting that although the flow of data from NHS Digital is classified as pseudonymised, in the hands of the recipient it is potentially identifiable patient data as they have the technical means to reidentify; and the s251 support is only for the original flow of data to NHS Digital. IGARD suggested that NHS Digital confirmed with HRA CAG that there are no confidentiality issues for the receipt of data by the party who have the means to re-identify. IGARD requested an update by the end of August 2022.</p> |
| 3.4 | <p><u>GRAIL Bio UK Ltd: NHS Galleri Clinical Trial Communications via NHS DigiTrials request (Presenter: Frances Perry) NIC-651660-J5T6C-v0.3</u></p> <p>Application: This was a new application for identifiable Demographics data.</p> <p>The purpose of the application is to request vital status information for a consented cohort of participants who have been recruited to a clinical trial called ‘NHS-Galleri’. The NHS Galleri Trial Team are looking to send an invitation letter to participants to book their follow up appointments and therefore need to know if any have changed their address; in addition, this</p> |

service will help to identify any participants known to have died so that the trial team can avoid sending an invitation letter to these participants. In order to ensure that the NHS-Galleri trial contains the most accurate and up to date participant details, study participants have consented for NHS Digital to provide the study with updated contact details, using the NHS DigiTrials Communication Service.

The trial has two sister applications NIC-456778-J0G3H and NIC-604847-S4B5L.

This trial aims to find out whether it is better at discovering cancer early, compared to other tests that the NHS currently uses. The purpose of NHS-Galleri is to demonstrate the clinical utility of the MCEd blood test for individuals in a general screening population in a real-world NHS setting. The rationale behind this trial is that MCEd is a novel screening paradigm, and assessment of the use and impact of test results is necessary to enable integration into clinical practice.

Discussion: IGARD noted that NIC-456778-J0G3H and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 24th June 2021.

IGARD noted that NIC-604847-S4B5L and relevant supporting documents had previously been discussed / presented at the IGARD BAU meeting on the 25th November 2021, 16th December 2021, 13th January 2022 and the 19th May 2022.

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

IGARD advised that the applicant may wish to consider whether or not future iterations of the consent materials could be revised to remove restrictive language in respect of the timeframes of the follow-up, including, but not limited to “*up to 10 years*”; and replaced with more open-ended language.

IGARD queried why the applicant was requesting a fortnightly flow of data, noting that this was unclear within the application; and asked that for transparency, section 5(b) (Processing Activities) was updated with a further explanation.

IGARD noted the reference in section 1 to data sharing agreements having previously received “IGARD approval”; and asked that this was amended to correctly state “*IGARD recommendation for approval*”, noting that IGARD do not approve DSAs.

Separate to the application: IGARD noted that they would provide comments on the annual confirmation report and special condition wording, to senior NHS Digital Managers.

Outcome: recommendation to approve

The following amendments were requested:

1. To update section 5(b) to provide a further explanation for the fortnightly flow of data.
2. To amend the statement in section 1 from “*IGARD approval*” to “*IGARD recommendation for approval*”.

The following advice was given:

1. IGARD advised that the applicant may wish to consider whether or not future iterations of the consent materials could be revised to remove restrictive language in respect of the timeframes of the follow-up, including (but not limited to) “*up to 10 years*”; and replaced with more open-ended language.

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| | <p>Separate to the application: IGARD noted that they would provide comments on the annual confirmation report and special condition wording, to senior NHS Digital Managers.</p> |
| 3.5 | <p><u>St George's University of London (SGUL): MR515 - Randomised Prevention Trial of H. Pylori Screening (No Presenter) NIC-147843-8NKTW-v5</u></p> <p>Application: This was a renewal application to permit the holding and processing of identifiable Cancer Registration Data, Civil Registration (Deaths) and Demographics data; and an amendment to add an additional back up storage location at SGUL.</p> <p>The purpose of this application is for the follow up of participants in the Randomised Trial of Helicobacter Pylori Screening (HPSS).</p> <p>Helicobacter pylori (H pylori) is an infection of the stomach that accounts for most cases of stomach cancer worldwide. The risk of stomach cancer is about five times greater in infected than in uninfected persons. While the association is accepted as causal, it is not known whether screening and treatment of the infection in middle age can reverse this excess risk.</p> <p>The study is hoping to determine if treatment of H pylori can decrease risk of cancer in later life. If this trial demonstrates screening is worthwhile and the national screening committee adopt it, it may prevent deaths from stomach cancer in the future.</p> <p>The trial started recruiting on the 8th July 1997 and finished recruiting on the 31st January 2006, during which time 62,454 participants were recruited.</p> <p>The study is relying on s251 of the NHS Act 2006, for the flow of contact details out of NHS Digital.</p> <p>Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD BAU meeting on the 17th March 2022; where the application had been recommended for approval with conditions and amendments.</p> <p>IGARD noted that, as outlined in the Out of Committee (OOC) Standard Operating Procedure, any applications returned to the IGARD Secretariat for review OOC by the IGARD Chair or quorum of IGARD Members which were over three months old, would be automatically placed on the next available BAU meeting agenda for review by IGARD Members as per the current standard processes. Members would only review if the conditions have been met or not, and would not re-review the application, unless significant legislative or policy changes had occurred since last reviewed by a full meeting of IGARD or the application had been significantly updated, in which case the conditions may be updated to reflect such changes which will be noted for transparency in the published minutes and a full review of the application undertaken.</p> <p>The condition from the 17th March 2022 BAU meeting was as follows:</p> <ol style="list-style-type: none"> 1. In respect of the HRA CAG support: <ol style="list-style-type: none"> a) To provide written confirmation that the applicant has continued to meet the HRA CAG conditions of support re transparency to the cohort and the steps taken to meet the condition on an ongoing basis. b) To upload a copy of the written confirmation to NHS Digital's CRM system. <p>A quorum of IGARD members were content that the multi-limbed condition had been met.</p> |
| 4 | <p><u>Applications progressed via NHS Digital's Precedent route, including the SIRO Precedent</u></p> <p>Applications that have been progressed via NHS Digital's Precedent route, including the SIRO Precedent, and NHS Digital have notified IGARD in writing (via the Secretariat).</p> |

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| | <i>No items discussed.</i> |
| 5 | <p><u>Oversight & Assurance</u></p> <p>IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. Due to the volume and complexity of applications at today's meeting, IGARD were unable to review any Data Access Request Service (DARS) applications as part of their oversight and assurance role.</p> <p>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 May 2022.</p> <p>IGARD noted that the NHS Digital webpage excel spreadsheet had now been updated for the period March 2020 to April 2022: NHS Digital Data Uses Register - NHS Digital.</p> |
| 6 | <p><u>COVID-19 update</u></p> <p><i>No items discussed</i></p> |
| 7 | <p><u>AOB:</u></p> |
| 7.1 | <p><u>NHS Digital Transition (Presenters: Michael Chapman / Garry Coleman / Liz Gaffney)</u></p> <p>NHS Digital's Director of Research and Clinical Trials, Associate Director / Senior Information Risk Owner (SIRO) and Head of Data Access, Data Access Request Service (DARS), attended the meeting, to provide a verbal update on the ongoing work within NHS Digital in respect of preparation for the transition of NHS Digital into NHS England.</p> <p>NHS Digital had been seeking IGARD's views on the current DARS service including the current applications in the system and predicted applications coming into the DARS service, without increasing the risk to NHS Digital around data disseminations.</p> <p>NHS Digital suggested a further discussion at the IGARD BAU meeting on the 4th August 2022, and would provide further information ahead of the meeting.</p> <p>IGARD noted the verbal update provided, and noted that additional information would be provided on or before the 4th August 2022.</p> |
| 7.2 | <p><u>NHS Continuing Health Care (CHC) - updated Class Action template (Presenter: Michael Ball)</u></p> <p>IGARD noted the updated CHC class action template that had been provide for information / comments.</p> <p>IGARD discussed a number of outstanding points that were resolved in-meeting and confirmed that they had no further comments to make.</p> <p>IGARD thanked NHS Digital for providing the template for review and for attending the meeting.</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 22/07/22

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) |
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| NIC-605115-LOW3V | University of Oxford | 16/06/2022 | 1. In respect of HRA CAG: <ol style="list-style-type: none"> To provide evidence of unconditional HRA CAG support, including all relevant documentation. That the unconditional HRA CAG support aligns with the proposed processing set out in this application. To upload the written confirmation from HRA CAG to NHS Digital's CRM system. | IGARD Chair | IGARD Deputy Chair | Deputy Chair Comments: I would wish to draw the attention of NHS Digital to the special conditions 1 and 2 in the HRA CAG final outcome letter: <ul style="list-style-type: none"> To confirm with the customer that they have a process in place to provide the notification strategy to CAG by 28 September to satisfy the first special condition. To confirm that the customer has developed a local and national opt out method in addition to the National Data Opt-Out. |

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