

**Independent Group Advising on the Release of Data (IGARD)**

**Minutes of meeting held via videoconference 27 January 2022**

<b>IGARD MEMBERS IN ATTENDANCE:</b>	
<b>Name:</b>	<b>Position:</b>
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member
Prof. Nicola Fear	Specialist Academic Member
Dr. Robert French	Specialist Academic / Statistician Member (Observer)
Kirsty Irvine	IGARD Chair
Dr. Imran Khan	Specialist GP Member
Jenny Westaway	Lay Member (Observer)
<b>IGARD MEMBERS NOT IN ATTENDANCE:</b>	
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Chair
Dr. Maurice Smith	Specialist GP Member
<b>NHS DIGITAL STAFF IN ATTENDANCE:</b>	
<b>Name:</b>	<b>Team:</b>
Garry Coleman	Associate Director / Senior Information Risk Owner (SIRO) (Observer: item 2.1)
Michael Ball	Data Access Request Service (DARS) (Item 3.2)
Vicky Byrne-Watts	Data Access Request Service (DARS) (SAT Observer: item 3.3)
Dave Cronin	Data Access Request Service (DARS) (Item 3.4)
Catherine Day	Data Access Request Service (DARS) (Observer: 2.1) (Item 3.1)
Faris Dean	Data Access Request Service (DARS) (SAT Observer: item 3.5)
Louise Dunn	Data Access Request Service (DARS) (Item 2.1) (SAT Observer: item 3.1)
Duncan Easton	Data Access Request Service (DARS) (SAT Observer: items 3.2, 3.6)
Dan Goodwin	Data Access Request Service (DARS) (Item 3.3, 3.5, 3.6)
Dickie Langley	Privacy, Transparency & Ethics (PTE) (Item 7.1)

Karen Myers	IGARD Secretariat
Caroline Olatunji	Data Access Request Service (DARS) (Observer: items, 2.1, 3.1 – 3.3)
Dr. Jonathan Osborn	Deputy Caldicott Guardian (Observer: 2.1, 3.1 - 3.4)
Vicki Williams	IGARD Secretariat
<b>SAT – Senior Approval Team (DARS)</b>	

<b>1</b>	<p><b>Welcome and Introductions:</b></p> <p>IGARD welcomed Jenny Westaway to the meeting as an observer, as part of her new role on IGARD as a Lay Member.</p> <p><b>Declaration of interests:</b></p> <p>Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising the Scientific Advisory Group for Emergencies (SAGE) on COVID-19.</p> <p>Nicola Fear noted that as part of her role at King's College London, she had a professional interest in the Clinical Practice Research Datalink (CPRD) briefing paper (item 2.1). It was agreed this did not preclude Nicola from taking part in the discussions about this briefing paper.</p> <p>Robert French noted a previous working relationship with the University of Bristol [NIC-17875-X7K1V], but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest.</p> <p>Jenny Westaway noted that as part of her role at the Department of Health and Social Care, she had professional links to the Medicines and Healthcare products Regulatory Agency (MHRA) [NIC-424723-D5Q9W]; but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest.</p> <p><b>Review of previous minutes and actions:</b></p> <p>The minutes of the 20<sup>th</sup> January 2022 IGARD meeting were reviewed out of committee by IGARD following conclusion of the meeting, and subject to a number of minor changes, were agreed as an accurate record.</p> <p><b>Out of committee recommendations:</b></p> <p>An out of committee report was received (see Appendix A).</p>
<b>2</b>	<b>Briefing Notes</b>
<b>2.1</b>	<p><u>Clinical Practice Research Datalink (CPRD) Briefing Paper (Presenter: Louise Dunn)</u></p> <p>Clinical Practice Research Datalink (CPRD) is a real-world research service supporting retrospective and prospective public health and clinical studies. CPRD is jointly sponsored by the Medicines and Healthcare products Regulatory Agency (MHRA) and the National Institute for Health Research (NIHR), as part of the Department of Health and Social Care. CPRD collects anonymised patient data from a network of GP practices across the UK. Primary care</p>

	<p>data are linked to a range of other health related data to provide a longitudinal, representative UK population health dataset. The data encompass 60 million patients, including 16 million currently registered patients.</p> <p>The briefing paper was to provide IGARD with an update on some of the previous issues raised in respect of NIC-15625-T8K6L.</p> <p>IGARD noted that the application and relevant supporting documents for NIC-15625-T8K6L had previously been presented at the Data Access Advisory Group (IGARD's predecessor) / IGARD business as usual (BAU) meetings on the 24<sup>th</sup> January, 22<sup>nd</sup> June 2017, 20<sup>th</sup> September 2018, 17<sup>th</sup> October 2019, 6<sup>th</sup> February, 19<sup>th</sup> March and the 16<sup>th</sup> July 2020.</p> <p>IGARD noted that this application had previously been discussed at the IGARD – NHS Digital COVID-19 Response meetings on the 12<sup>th</sup> May, 19<sup>th</sup> May, 26<sup>th</sup> May, 6<sup>th</sup> October and 13<sup>th</sup> October 2020.</p> <p>The application was also discussed under “AOB” at the IGARD BAU meetings on the 27<sup>th</sup> August 2018 and the 27<sup>th</sup> August 2020.</p> <p><b>Outcome:</b> IGARD welcomed the briefing paper and made the following high-level comments:</p> <ol style="list-style-type: none"> <li>1. IGARD noted the verbal update from NHS Digital that PTE were working through the relevant actions, as raised previously, and noted that PTE may wish to utilise IGARD's previous work, for example, reviews of transparency materials.</li> <li>2. IGARD noted the verbal update from NHS Digital that work was still ongoing with regards to outstanding actions and looked forward to receiving further updates in due course.</li> <li>3. IGARD noted that the applicant was to be audited with a particular view to ascertaining the identifiability of the data onwardly disseminated and welcomed this approach by NHS Digital.</li> </ol> <p>IGARD welcomed the briefing paper and looked forward to receiving an updated version in due course; and asked that this was provided as a supporting document alongside NIC-15625-T8K6L when it next comes for review, as per usual practice.</p>
<b>3</b>	<b>Data Applications</b>
<b>3.1</b>	<p><u>Clinical Practice Research Datalink: SUS-COVID vaccination datasets for MHRA surveillance through CPRD (CPRD) (Presenter: Catherine Day) NIC-424723-D5Q9W-v1.3</u></p> <p><b>Application:</b> This was a renewal and extension application to permit the holding and processing of Minimal SUS Dataset for COVID-19 Surveillance data for a further 12-months. It was also an amendment to remove reference to Crown Hosting Data Centres Ltd from the application.</p> <p>The Clinical Practice Research Datalink (CPRD) is a government not for profit research organisation, jointly supported by the Medicines and Healthcare products Regulatory Agency (MHRA) and the National Institute of Health Research (NIHR), supplying anonymised health data for studies to safeguard and improve patient and public health.</p> <p>The purpose of this application is for the continuation of a daily flow of data from NHS Digital to enable MHRA to carry out essential regulation of the COVID-19 vaccination roll out.</p> <p>NHS Digital advised that the 'Minimal SUS Dataset for COVID-19 Surveillance' data, is a product that had been created specifically for this data sharing agreement (DSA); and that there was no identifiable data flows out of NHS Digital under this DSA.</p>

NHS Digital noted that this 12-month DSA would be in place until such time that the GP system providers are able to integrate this information into their own systems and subsequently feed in to CPRD; and, once this was in place, this DSA would cease.

**Discussion:** IGARD noted the verbal update from NHS Digital in respect of the bespoke dataset; and the plan for GP system providers to eventually feed this data in to CPRD, and that the DSA would cease at that point. IGARD asked that, for transparency, section 5 (Purpose / Methods / Outputs) was updated to reflect this.

IGARD queried if Type 1 Opt-outs were applied, and noting that this was not clear within the application, asked that confirmation was provided from the applicant; and that section 5 was updated as appropriate to confirm whether Type 1 Opt-outs are or are not applied.

IGARD noted that the information on the applicant's website referred to the National Data Opt-out (NDO), and suggested that the applicant's privacy notice was updated to reflect the application of Type 1 Opt-out if applicable, and the relationship with the application of the NDO; and in line with the [NHS Digital DARS Standard for Transparency](#).

In addition, and in respect of the privacy notice, and in line with [NHS Digital DARS Standard for Transparency](#); IGARD wished to draw the applicant's attention to the statement in section 4 (Privacy Notice), that a UK General Data Protection Regulation (UK GDPR) compliant, publicly accessible transparency notice is maintained throughout the life of the agreement, in order to maintain public trust in using health data from national datasets, and IGARD noted the ongoing discussion between NHS Digital and CPRD on this topic.

IGARD queried the reference in section 5(b) (Processing Activities) to "GP\_ID", and asked that, for transparency, this was updated with a brief explanation of what this is; and provide an explanation as to how GP\_ID was used in processing and to spell out the acronym on first use, since section 5 formed [NHS Digital's data uses register](#).

NHS Digital noted that section 3(a) (Data Access Already Given) and section 3(b) (Additional Data Access Requested) currently stated "923180006", and would need updating to provide the correct information in respect of the frequency of the dataflows. IGARD noted the verbal update from NHS Digital and supported the updated to section 3(a) and section 3(b) to include the correct frequency of the data flows.

IGARD queried the reference in section 3 (Datasets Held / Requested) to 'The Health Service (Control of Patient Information) Regulations 2002 (COPI)', noting that this would infer a flow of confidential data flowing. IGARD asked that this was amended to correctly reflect that **no** confidential data was flowing.

In addition, IGARD noted the special condition in section 6 (Special Conditions) that referred to the "COPI Notice"; and asked that this was edited as appropriate to remove the reference.

IGARD noted the reference in section 6 to "Crown Hosting Data Centres Ltd", and noting the amendment to remove them from the application, asked that this was edited as appropriate to remove the reference.

IGARD suggested that this application would be suitable for NHS Digital's Precedent route including the SIRO Precedent.

**Outcome:** recommendation to approve.

The following amendments were requested:

1. To update section 5 to reflect that the DSA will cease once the GP system providers are able to integrate this information into their own systems.

	<ol style="list-style-type: none"> <li>2. In respect of GP_ID: <ol style="list-style-type: none"> <li>a) To update section 5(b) with a brief explanation of what GP_ID is.</li> <li>b) To update section 5(b) to explain how GP_ID is used in processing.</li> </ol> </li> <li>3. To amend section 3 to reflect that there will be no confidential data flowing.</li> <li>4. To update section 3(a) and section 3(b) to include the frequency of the data flows.</li> <li>5. In respect of the special conditions in section 6: <ol style="list-style-type: none"> <li>a) To remove the special condition in section 6 relating to the COPI Notice.</li> <li>b) To remove reference to “<i>Crown Hosting Data Centres Ltd</i>” from the special condition in section 6.</li> </ol> </li> <li>6. In respect of Type 1 Opt-outs: <ol style="list-style-type: none"> <li>a) To provide confirmation from the applicant that Type 1 Opt-outs are applied.</li> <li>b) To update section 5 to confirm that Type 1 Opt-outs are or are not applied.</li> </ol> </li> </ol> <p>The following advice was given:</p> <ol style="list-style-type: none"> <li>1. IGARD suggested that the applicant’s privacy notice was updated to reflect the application of Type 1 Opt-out and its relationship with the application of the NDO.</li> <li>2. In respect of the privacy notice, and in line with <a href="#">NHS Digital’s DARS Standard for Transparency (fair processing)</a>; IGARD wished to draw the applicant’s attention to the statement in section 4, that a UK GDPR compliant, publicly accessible transparency notice is maintained throughout the life of the agreement, in order to maintain public trust in using health data from national datasets, and IGARD noted the ongoing discussion between NHS Digital and CPRD on this topic.</li> <li>3. IGARD supported NHS Digital’s verbal update in respect of the audit of this organisation in relation to this application / Data Sharing Agreement.</li> <li>4. IGARD suggested that this application would be suitable for NHS Digital’s Precedent route including the SIRO Precedent.</li> </ol>
3.2	<p><u>NHS England (Quarry House): NHS England – DSfC – NHS England &amp; Improvement Data Platform (Presenter: Michael Ball) NIC-139035-X4B7K-v8.1</u></p> <p><b>Application:</b> This was an amendment application to <b>1)</b> clarify that National Diabetes Audit (NDA) data, by default includes the modules that sit under the current NDA programme which are National Diabetes Core Audit (NDA Core), National Pregnancy in Diabetes Audit (NPID), National Diabetes Footcare Audit (NDFA), National Inpatient Diabetes Audit, including National Diabetes I-Patient Audit – Harms (NaDIA-Harms), Diabetes Prevention Programme (DPP); <b>2)</b> to make it clear within the application that intervention alone won’t reduce the impact of diabetes and that patients need to be given the skills to self-manage.</p> <p>The purpose of the application is to ensure that NHS England / Improvement can meet its 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.</p> <p>NHS Digital noted IGARD’s previous advice that this overarching application should be reviewed, and advised that NHS Digital were in the process of reviewing the application, in line with NHS Digital merging into NHS England, as announced on the <a href="#">22<sup>nd</sup> November 2021</a>. NHS Digital advised that section 1 (Abstract) had been updated to acknowledge / address this.</p> <p><b>Discussion:</b> IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meetings on the 25<sup>th</sup> April, 15<sup>th</sup> August, 17<sup>th</sup> October, 12<sup>th</sup> December 2019, 13<sup>th</sup> February, 19<sup>th</sup> July, 17<sup>th</sup> November, 17<sup>th</sup> December 2020, 28<sup>th</sup> January and the 19<sup>th</sup> August 2021.</p>

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

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

IGARD noted the verbal update from NHS Digital, in respect of the ongoing work to review this overarching application, however 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 noted that the reference to “*self-management*” in section 1 and section 5(a) (Objective for Processing), came from the NICE guidelines 2011, as amended; and suggested that consideration be given, with regard to the impact of self-management, which can be beyond the control of the participant / patient. In addition, IGARD noted the reference in section 5 (Purpose / Methods / Outputs) to “*self-management of diabetes*”, and asked that this was updated to also acknowledge the socioeconomic factors that would impact on the success or otherwise of self-management.

IGARD suggested that NHS Digital updated their transparency materials around the NDA programme, for example, to explain where the Local Providers Flows are coming from; noting that the current transparency materials were silent on this.

In addition, IGARD suggested that the applicant gave consideration to the transparency for participants about how their data is obtained and used, and in line with the processing outlined in this application and Article 26(2) of the UK General Data Protection Regulation (GDPR).

IGARD noted the reference in section 5(d) (Benefits) (ii) (Expected Measurable Benefits to Health and/or Social Care) to “*Using value as the redesign principle*” when referring to the e-Referral Service (eRS) and asked that this was removed.

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 Senior Information Risk Owner (SIRO) Precedent.

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

1. To remove the reference to “*Using value as the redesign principle*” in section 5(d) (ii).
2. To update the reference in section 5 to “*self-management of diabetes*”, to also acknowledge the socioeconomic factors that will impact on the success or otherwise of self-management.

The following advice was given:

1. 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.

	<ol style="list-style-type: none"> <li>2. 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.</li> <li>3. IGARD noted that the reference to “<i>self-management</i>” came from the NICE guidelines 2011, as amended; and suggested that consideration be given, with regard to the impact of self-management, which can be beyond control of the participant / patient.</li> <li>4. IGARD suggested that NHS Digital updated their transparency materials around the NDA programme, for example, to explain where the Local Provider Flows are coming from.</li> <li>5. IGARD suggested that the applicant gave consideration to the transparency for participants about how their data is obtained and used, and in line with the processing outlined in this application.</li> <li>6. 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.</li> <li>7. 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.</li> </ol>
3.3	<p><u>University of Bristol: Using geographic variation in hospital care to identify opportunities to improve the effectiveness and efficiency of patient care (Presenter: Dan Goodwin) NIC-17875-X7K1V-v4.2</u></p> <p><b>Application:</b> This was a renewal and extension application to permit the holding and processing of pseudonymised Hospital Episode Statistics Admitted Patient Care (HES APC) and HES Outpatients data for a further three-years.</p> <p>It was also an amendment to <b>1)</b> add a one-off dissemination of M11 HES APC and HES Outpatients data; and <b>2)</b> to add an annual dissemination of Diagnostic Imaging Dataset (DIDs), Civil Registration (Deaths), Bridge file: HES to DIDs and HES: Civil Registration (Deaths) bridge.</p> <p>The purpose of the application is for a programme of work based around identifying the magnitude and causes of variations in admitted patient and outpatient care, which can help highlight opportunities to reduce use of particular procedures (disinvest) and optimise use of limited NHS resources.</p> <p><b>Discussion:</b> IGARD noted that the application and relevant supporting documents had previously been presented at the Data Access Advisory Group (IGARD’s predecessor) meeting on the 1<sup>st</sup> March 2016.</p> <p>IGARD noted and commended the applicant and NHS Digital on the quality of the information provided within the application, for example, the specific references to the public interest, geographical variations and the benefits, which supported the review of the application by Members.</p> <p>IGARD noted that a special condition in section 6 (Special Conditions), relating to the destruction of NHS Digital data had been amended, in light of the COVID-19 public inquiry, which prevented NHS Digital from requesting data destruction at the current time. Noting the discussion at the IGARD business as usual (BAU) meeting on the 2<sup>nd</sup> December 2021, IGARD had received a verbal update from NHS Digital to confirm that the retention of data <b>only</b> applied where the application was related to COVID-19, and that the blanket cessation had been removed. IGARD therefore asked that section 6 was updated, to remove the special condition as this was no longer relevant to this specific application.</p> <p>IGARD noted that following the verbal update from NHS Digital on the 2<sup>nd</sup> December 2021, the published minutes stated “<i>IGARD noted they had been previously advised via narrative in</i></p>

application abstracts and the verbal updates from NHS Digital in respect of the current guidance from NHS Digital in respect of pausing the destruction of data, in light of the forthcoming COVID-19 inquiry. IGARD, at the time, had suggested that the blanket cessation of destruction of data may not be the best course of action in all cases, for example, should the study not be connected in any way to COVID-19, noting UK GDPR principles still applied. IGARD received a verbal update from NHS Digital to confirm that this only applied where the application was related to COVID-19 and that the blanket cessation had been removed. IGARD noted the verbal update and **suggested that NHS Digital urgently review all applications that had proceeded either via IGARD or down the precedent route during the period of the blanket cessation to update applicant's appropriately and ensure that no applicant was holding data that should have been destroyed.**". IGARD suggested that NHS Digital have regard to the latest guidance, in relation to special conditions within applications which were no longer needed, regarding pausing data destruction where the data and processing had no connection to the COVID-19 inquiry.

In addition, IGARD expressed concern that non-COVID-19 applications still had clauses preventing the destruction of data, due to the COVID-19 inquiry, which had not been retrospectively updated (in terms of removing narrative in section 1 (Abstract) and special conditions in section 6, as recorded in the IGARD BAU minutes from the 2<sup>nd</sup> December 2021.

IGARD suggested that, for audit purposes, where applicants were retaining data for the COVID-19 inquiry, further information was recorded, including, but not limited to, what the data was used for and the time periods.

IGARD noted that section 7 (Ethics Approval) stated that ethics approval was **not** required, however advised that this did not align with the information published on the University of Bristol website, where it stated that "**All research within the University involving human participants, tissue and/or data must have a research ethics review**". IGARD suggested that the applicant checked with the University ethics committee as to whether or not ethics support was required, even though it is pseudonymised data; and if University ethics support was required, IGARD asked the relevant documentation was updated to NHS Digital's customer relationships management (CRM) system for future reference.

IGARD noted the honorary research fellow at the University of Bristol, that was referenced within the application; however asked that confirmation was provided, if the honorary research fellow at the University of Bristol had a substantive employment contract with another body; and if so; that written confirmation was provided that the honorary research fellow contract had been counter-signed by the employing body.

IGARD noted point 5 within section 1 (Abstract) of the application, in relation to the Conditions of Access document, and supported the request by NHS Digital for this document to be updated.

**Outcome:** recommendation to approve

The following amendments were requested:

1. To update section 6 to remove the special condition relating to the destruction of data, as this is no longer relevant.
2. In respect of the honorary research fellow at the University of Bristol:
  - a) To provide confirmation if the honorary research fellow at the University of Bristol has a substantive employment contract with another body; and if so;
  - b) To provide written confirmation that the honorary research fellow contract has been counter-signed by the employing body.



	<p>The following advice was given:</p> <ol style="list-style-type: none"> <li>1. IGARD suggested that NHS Digital have regard to comments previously made on 2nd December 2021 in relation to special conditions within applications which are no longer needed regarding pausing data destruction where the data and processing has no connection to the COVID-19 inquiry.</li> <li>2. IGARD suggested that where applicants are retaining data for the COVID-19 inquiry, further information was recorded, including (but not limited to) what the data was used for and the time periods.</li> <li>3. IGARD suggested that the applicant check with the University ethics committee as to whether or not ethics support is required, even though it is pseudonymised data; and if University ethics support is provided, IGARD asked the relevant documentation is updated to NHS Digital's CRM system for future reference.</li> <li>4. IGARD noted point 5 within section 1 of the application, in relation to the Conditions of Access document, and supported the request by NHS Digital for this document to be updated.</li> </ol> <p><b>Significant risk area:</b> IGARD are concerned that non-COVID-19 applications still have clauses preventing the destruction of data, due to the COVID-19 inquiry which have not been retrospectively updated (in terms of removing narrative in section 1 and special conditions in section 6), as recorded in the IGARD BAU minutes from the 2<sup>nd</sup> December 2021:</p> <p><i>"IGARD noted they had been previously advised via narrative in application abstracts and the verbal updates from NHS Digital in respect of the current guidance from NHS Digital in respect of pausing the destruction of data, in light of the forthcoming COVID-19 inquiry. IGARD, at the time, had suggested that the blanket cessation of destruction of data may not be the best course of action in all cases, for example, should the study not be connected in any way to COVID-19, noting UK GDPR principles still applied. IGARD received a verbal update from NHS Digital to confirm that this only applied where the application was related to COVID-19 and that the blanket cessation had been removed. IGARD noted the verbal update and suggested that NHS Digital urgently review all applications that had proceeded either via IGARD or down the precedent route during the period of the blanket cessation to update applications appropriately and ensure that no applicant was holding data that should have been destroyed."</i></p>
3.4	<p>Office for National Statistics (ONS): Investigating COVID-19 (Presenter: Dave Cronin) <a href="#">NIC-400304-S1P1B-v4.1</a></p> <p><b>Application:</b> This was an amendment application to <b>1)</b> update the specified purposes for use of the data; <b>2)</b> update the permitted data linkages; <b>3)</b> to reuse Improving Access to Psychological Therapy (IAPT) data, Birth Notifications and Personal Demographics Service (PDS) data ; <b>4)</b> to process COVID-19 Vaccination Status data.</p> <p>ONS requires data for three purposes all relating to the COVID-19 pandemic: <b>1) Emerging questions relating to COVID-19</b> – providing rapid responses to the COVID-19 pandemic on emerging research questions which are arising as the pandemic continues and as understanding of COVID-19 and its impact increases. This work is to support the ongoing government response and has been requested by central government leaders and advisors such as SAGE and the government, via the National Statistician. <b>2) QCOVID analysis</b> – to urgently quality assure a QCOVID algorithm developed by the University of Oxford to identify clinical vulnerability to COVID-19. This algorithm will be used operationally by Public Health England as a replacement for the previously used shielding list. <b>3) Investigating quality of</b></p>

**ethnicity data** – reporting by ethnicity has become increasingly apparent as a key requirement to help understand inequalities during the COVID-19 pandemic.

NHS Digital advised IGARD that ONS were working with NHS Digital in respect of the ongoing issues with transparency, as highlighted in previous IGARD meetings.

NHS Digital noted that as per IGARD's previous advice, they were in the process of arranging an information sharing session with ONS and IGARD.

**Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 17<sup>th</sup> September 2020, 19<sup>th</sup> November 2020, and the 18<sup>th</sup> February 2021.

IGARD noted that aspects of this application had been previously seen at the IGARD – NHS Digital COVID-19 Response meeting on the 8<sup>th</sup> September 2020 and 15<sup>th</sup> September 2020.

IGARD also noted that this application had been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 9<sup>th</sup> September 2020 and that notes from this meeting had been attached to the IGARD minutes from the 17<sup>th</sup> September 2020; the 18<sup>th</sup> November 2020, and that notes from this meeting had been attached to the IGARD minutes from the 19<sup>th</sup> November 2020; and the 26<sup>th</sup> January 2022.

IGARD noted that PAG did **not** support the application in its current form; and that the notes from the PAG meeting on the 26<sup>th</sup> January 2022 were in the process of being updated and ratified by PAG members, to ensure the reason for this was clear and transparent. IGARD confirmed that although out of process, the revised PAG notes would be included in the IGARD BAU minutes on the 10<sup>th</sup> February 2022 for transparency.

In respect of the comments raised by PAG: IGARD noted the yielded benefits outlined in section 5(d) (Benefits), however asked that in due course, and in line with [NHS Digital DARS Standard for Expected Measurable Benefits](#), the yielded benefits should be further developed to give examples of how the ONS outputs with the expanded purposes and linkages have impacted on health and social care.

IGARD noted and thanked the National Statistician for the letter dated the 25<sup>th</sup> January 2022, provided to IGARD (via NHS Digital) in advance of application being presented to IGARD for review. IGARD queried the reference within the letter to the National Statistician's "*delegates*", and asked that for clarity, further information was provided in the context of this application as to their roles and how many "*delegates*" there were.

IGARD noted the verbal update from NHS Digital, that ONS were working with NHS Digital in respect of their transparency, and suggested, that given the breadth of citizen data held by ONS, that transparency may need to go beyond updating their website, and extend to more active public engagement, so that the public understand the breadth of data held and extent of processing carried out.

IGARD reiterated advice on other ONS applications, NIC-413717 and NIC-388794, in respect of the privacy notice and in line with [NHS Digital's DARS Standard for Transparency \(fair processing\)](#), IGARD wished to draw to the applicant's attention the statement in section 4 (Privacy Notice), that a UK General Data Protection Regulation (UK GDPR) compliant, publicly accessible transparency notice was maintained throughout the life of the agreement. IGARD suggested that ONS refresh the advice previously received from the Information Commissioners' Office (ICO) in respect of transparency to the public.

IGARD queried ONS' internal review and approval process for new projects, for example, the impact of vaccination on fertility as outlined in the National Statistician's letter; and noting that

the application was not clear on this point, asked that a satisfactory procedure was provided, for the **prospective** review and approval of new projects under this DSA. In addition, IGARD asked that if the National Statistician's Data Ethics Advisory Committee (NSDEC) was **not** utilised, that the procedure included the outline membership of the review committee, and to set out its terms of reference, which accord with similar oversight committee terms of reference for controllers holding large stores of NHS Digital data for programmatic access. IGARD asked that a copy of the plan was uploaded for the prospective internal oversight to NHS Digital's customer relationships management (CRM) system for future reference.

IGARD also asked that a special condition was inserted in section 6 (Special Conditions), that any use of the data for projects that come under the amended specified purposes and data linkages, must be prospectively reviewed and approved by the relevant internal oversight committee (for example, NSDEC).

IGARD queried when investigating the quality of ethnicity data had been re-added as a purpose in the DSA, noting that they were of the understanding that this had previously been removed. NHS Digital advised that the dataset required by ONS to undertake this objective, had only just been onboarded to NHS Digital, and had been approved by the Senior Information Risk Owner (SIRO) week ending the 21st January 2022, with the understanding that the full application would be reviewed by IGARD at this meeting. IGARD noted the verbal update from NHS Digital, and asked that for future reference, section 1 (Abstract) was updated with the current purpose and processing activities relating to the ethnicity data.

IGARD noted that a Data Protection Impact Assessment (DPIA) had been completed, but suggested that this was updated with the proposed development and processing, including, but not limited to, the processing of ethnicity data; and in advance of the processing of data under this data sharing agreement (DSA), and in accordance with UK General Data Protection Regulation (UK GDPR).

IGARD queried the reference to "*personal characteristics*" in section 5(a) (Objective for Processing), and that "*ethnicity*" had been provided as an example; and asked that further examples were provided.

IGARD noted and thanked NHS Digital for the verbal update, in respect of the information sharing session that was in the process of being arranged and looked forward to meeting with ONS in due course.

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 quantum of data flowing.

**Outcome:** recommendation to approve the reuse of IAPT, Birth Notifications and PDS data and permission to process COVID-19 vaccination status.

**Outcome:** recommendation to approve the changes to the specified purposes for use of the data and changes to permitted data linkages by a quorum of 4 members, with one member dissenting, subject to the following condition:

1. To provide a satisfactory procedure for the **prospective** review and approval of new projects under this agreement. To include the outline membership of the review committee (unless NSDEC is utilised), and to set out its terms of reference (which accord with similar oversight committee terms of reference for controllers holding large stores of NHS Digital data for programmatic access).
2. To upload a copy of the procedure for the prospective oversight to NHS Digital's CRM system for future reference.

	<p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To insert a special condition in section 6, that any use of the data for projects that come under the additional specified purposes and data linkages, must be prospectively reviewed and approved by the relevant oversight committee (for example, NSDEC).</li> <li>2. To update section 1 with the current purpose and processing activities relating to the ethnicity data.</li> <li>3. To provide further examples in section 5(a) of “<i>personal characteristics</i>”, in addition to “<i>ethnicity</i>”.</li> <li>4. To provide further information in section 5(a) of who the National Statistician’s “<i>delegates</i>” are.</li> <li>5. In due course, and in line with <a href="#">NHS Digital DARS Standard for Expected Measurable Benefits</a>, the yielded benefits in section 5(d) should be further developed to give examples of how the ONS outputs with the expanded purposes and linkages have impacted on health and social care.</li> </ol> <p>The following advice was given:</p> <ol style="list-style-type: none"> <li>1. IGARD noted that a DPIA had been completed, but suggested that this was updated with the proposed development and processing, including (but not limited to) the processing of ethnicity data; and in advance of the processing of data under this DSA, and in accordance with UK GDPR.</li> <li>2. In respect of transparency: <ol style="list-style-type: none"> <li>a) IGARD reiterated their advice (NIC-413717 and NIC-388794), in respect of the privacy notice and in line with <a href="#">NHS Digital’s DARS Standard for Transparency (fair processing)</a>, IGARD wished to draw to the applicant’s attention the statement in section 4, that a UK GDPR compliant, publicly accessible transparency notice is maintained throughout the life of the agreement. IGARD suggested that ONS refresh the advice previously received from the ICO in respect of transparency to the public.</li> <li>b) IGARD noted that ONS were working with NHS Digital in respect of their transparency, and suggested, that given the breadth of citizen data held by ONS, that transparency may need to go beyond updating their website, and extend to more active public engagement, so that the public understand the breadth of data held and extent of processing carried out.</li> </ol> </li> <li>3. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the large quantum of data flowing.</li> <li>4. IGARD suggested that this application would not be suitable for NHS Digital’s Precedent route, including the SIRO Precedent, due to the large quantum of data flowing.</li> </ol> <p>It was agreed the conditions would be approved out of committee (OOC) by IGARD members.</p>
<p><b>3.5</b></p>	<p><u>Worcestershire County Council: Social Care demand profiling using health and social care data (Presenter: Dan Goodwin) NIC-457686-H6K6R-v0.3</u></p> <p><b>Application:</b> This was a new application for pseudonymised Community Services Data Set (CSDS), Maternity Services Data Set (MSDS), Mental Health Services Data Set (MHSDS) and Secondary Uses Service (SUS) for Commissioners data.</p> <p>The purpose of the application is to maximise the combination of health and social care data, to help inform how the Council plans strategically for a demand profile, that looks very different to what existed before COVID-19, in terms of geographical demand, individual needs and</p>

	<p>resource requirements. It will specifically help the council to; <b>1)</b> design the Council's response activity to social care demand more efficiently and effectively; <b>2)</b> identify the high cost percentile for health and care services; <b>3)</b> follow the pathway of cohorts with specific criteria in terms of their health and social care needs over time; <b>4)</b> understand the difference between different GP practices / Care Homes / Geographical area on demand for services and develop strategies to support this through use of the Local Authority Social Care dataset.</p> <p>The data flowing from NHS Digital will be linked to Adult Social Care data, which the Commissioning Support Unit (CSU) will obtain from the Council directly.</p> <p>Worcestershire County Council currently hold a separate Data Sharing Agreement (DSA) (NIC-385550-Y8T2M) which covers the use of the same datasets requested under this DSA, for the purpose of Social Care demand profiling in response to the COVID-19 pandemic in line with the expiry of The Health Service (Control of Patient Information) Regulations 2002 (COPI).</p> <p><b>Discussion:</b> IGARD noted and commended the applicant for completing an Equality Impact Assessment (EQIA), as outlined in section 7 (Ethics Approval) of the application.</p> <p>IGARD noted the large number of storage and processing locations in section 2 (Locations), and noting this may cause difficulty for NHS Digital in respect of auditing, suggested that NHS Digital work with the applicant to review and consider if the locations could be consolidated; and noting the discussion at the workshop at the business as usual (BAU) meeting on the <a href="#">18<sup>th</sup> November 2021</a>.</p> <p>IGARD queried the reference in section 5(a) (Objective for Processing) "<i>None Patient-Level: Acorn segmentation socio-economic data</i>", and asked that for transparency, this was either edited or updated with a further explanation as to what this meant.</p> <p><b>Outcome:</b> recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. IGARD noted the large number of storage and processing locations, and, noting this may cause difficulty for NHS Digital in respect of auditing, suggested that NHS Digital worked with the applicant to review and consider if the locations could be consolidated.</li> <li>2. To edit or explain reference in section 5(a) to "<i>None Patient-Level: Acorn segmentation socio - economic data</i>".</li> </ol>
3.6	<p><u>NHS Lincolnshire CCG: DSfC - Lincolnshire CCG and Lincolnshire County Council - Comm (Presenter: Dan Goodwin) NIC-454217-D9J5X-v1.2</u></p> <p><b>Application:</b> This was a renewal application to permit the holding and processing of pseudonymised Secondary Uses Service (SUS+) data, Local Provider Flows, Mental Health Minimum Data Set (MHMDS), Mental Health Learning Disability Data Set (MHLDDS), Mental Health Services Data Set (MHSDS), Maternity Services Data Set (MSDS), Improving Access to Psychological Therapy (IAPT), Child and Young People Health Service (CYPHS), Community Services Data Set (CSDS), Diagnostic Imaging Data Set (DIDS), National Cancer Waiting Times Monitoring Data Set (CWT), Civil Registration Data (Births), Civil Registration Data (Deaths), National Diabetes Audit (NDA), Patient Reported Outcome Measures (PROMs), e-Referral Service (eRS), Personal Demographics Service (PDS), Summary Hospital-level Mortality Indicator (SHMI), Medicines Dispensed in Primary Care (NHSBSA Data).</p>

It was also an amendment application to add Adult Social Care data for Commissioning purposes.

The purpose 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 CCG area.

The CCG also works collaboratively with Lincolnshire County Council in order to deliver the joint aims to support primary care networks and deliver population health management. Lincolnshire County Council needs to have visibility of the data without suppression applied in order to collaboratively redesign services to improve population outcomes.

NHS Digital noted that the application did not currently set out a justification for requesting a minimum of ten-years of NHS Digital data; and advised that this would be updated to ensure that a clear justification was outlined.

**Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 24<sup>th</sup> June 2021.

It was also discussed under “AOB” at the IGARD BAU meetings on the 15<sup>th</sup> July and 12<sup>th</sup> August 2021.

IGARD noted the verbal update from NHS Digital in respect of the application being updated to provide a justification of the years of data requested; and advised they were supportive of the appropriate updates to the application.

IGARD queried why section 3(a) (Data Access Already Given) had not been populated, noting that data had already flowed to the applicant previously; and were advised by NHS Digital, that this was a logistical issue, in order to reduce the length of the data sharing agreement (DSA). IGARD noted the verbal update from NHS Digital, however asked that for future reference, section 1 (Abstract) was updated with a brief explanation as to why section 3(a) had not been populated.

IGARD noted that at the workshop at the business as usual (BAU) meeting on the [18<sup>th</sup> November 2021](#), the issues around using data for direct care were discussed, and *“It was agreed that “direct care” should be called that in applications for transparency for the public, and so applications from CCGs should be for “commissioning / risk stratification / invoice validation / direct care”, noting that section 5 of all applications submitted through the DARS process formed the [NHS Digital data uses register](#)”*. IGARD noted that although “direct care” had been referred to in the application, further updates were required throughout section 5 (Purpose / Methods / Outputs), to ensure that the description of direct care activities was transparent, accurate and consistent with the latest agreed NHS Digital wording.

IGARD noted the “annual report” referred to in section 5(d) (Benefits) (iii) (Yielded Benefits), and asked that for transparency, this was updated to include the ‘year’ of the annual report, and in line with [NHS Digital DARS Standard for Expected Measurable Benefits](#).

IGARD queried the statement in section 5(d) (iii) *“Work has been underway to implement a Rapid Diagnostic Concept pathway that will commence in June...”*; and asked that if this was referring to June ‘2022’, this was correctly moved to section 5(d) (ii) (Expected Measurable Benefits to Health and/or Social Care); or if it was referring to June ‘2021’, this was updated with further information on the specific yielded benefit(s) accrued to date, in line with [NHS Digital DARS Standard for Expected Measurable Benefits](#).



	<p>IGARD noted the reference in section 5(b) (Processing Activities) to “<i>frequent flyers</i>” when referring to benchmarking and comparative analysis, and asked that this was reworded with a less pejorative form of words such as “<i>high utilisation of services</i>”.</p> <p><b>Outcome:</b> recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To provide a brief explanation in section 1 as to why section 3(a) has not been populated.</li> <li>2. To update the application to provide a justification for the years of data (as per the verbal update from NHS Digital).</li> <li>3. To reword the reference to “<i>frequent flyers</i>” in section 5(b) with a less pejorative form of words such as “<i>citizens with high utilisation of services</i>”.</li> <li>4. To update section 5 throughout to ensure that the description of direct care activities is transparent, accurate and consistent with the latest agreed NHS Digital wording.</li> <li>5. In respect of the yielded benefits in section 5(d) and in line with <a href="#">NHS Digital DARS Standard for Expected Measurable Benefits</a>: <ol style="list-style-type: none"> <li>a) To update section 5(d) (iii) to include a ‘year’ of the annual report referred to.</li> <li>b) To move the information in section 5(d) (iii) relating to “<i>Rapid Diagnostic Concept pathway</i>” to section 5(d) (ii) (if it refers to June 2022); or update the reference with further information on the specific yielded benefit(s) accrued to date if the reference is to June 2021.</li> </ol> </li> </ol>
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-365354-R3M0Q-v7.3 University of Oxford (No Presenter)</u></p> <p>The purpose of this application was for ‘The Randomised Evaluation of COVid-19 thERapY’ (RECOVERY) trial, which aims to compare different treatments that may be useful for patients with COVID-19. The trial allows reliable assessment of the effects of multiple different treatments (including re-purposed and novel drugs) on major outcomes in COVID-19.</p> <p>IGARD noted that this application was last reviewed at the IGARD business as usual meeting on the 14<sup>th</sup> October 2021.</p> <p>IGARD noted that on the 21<sup>st</sup> January 2022, NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had agreed to authorise the Data Sharing Agreement (DSA), with the exception of any onwards sharing of NHS Digital data.</p> <p>IGARD noted and thanked NHS Digital for the written update, and asked that NHS Digital ensure that the relevant senior colleagues / SIRO are sighted on all previous IGARD minutes to support the SIRO authorisation. IGARD suggested that the next iteration(s) should be brought to a future IGARD BAU meeting.</p>
5	<p><u>Oversight &amp; 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</p>

	<p>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 27<sup>th</sup> May 2021 IGARD business as usual (BAU) meeting with regard to previous comments made on the IG COVID-19 release registers.</p> <p>IGARD Members noted that the last IG COVID-19 release register that they had reviewed and provided comments on was July 2021.</p>
<b>6</b>	<p><u>COVID-19 update</u></p> <p>IGARD noted that colleagues from DigiTrials had requested use of this slot prior to the meeting for an urgent discussion item, however attended the meeting to confirm that the issue had been resolved and the slot was therefore not required. IGARD noted and thanked DigiTrials for the verbal update.</p>
<b>7</b>  <b>7.1</b>	<p><u>AOB:</u></p> <p><u>Information Governance</u></p> <p>A member of NHS Digital's Privacy, Transparency and Ethics, attended the meeting to provide a brief update / overview of ongoing information governance work.</p> <p>IGARD noted and thanked NHS Digital for the verbal update and looked forward to receiving further updates at a future IGARD 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 21/01/22

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-147885-0TV66-v9.3	University of Oxford	04/11/2021	1. To provide written confirmation in section 5(a) that there will be <b>no</b> data sharing with the international parties referenced in the application.	IGARD Chair	OOC by the IGARD Chair	None

In addition, a number of applications were processed by NHS Digital following the Precedents approval route. IGARD carries out oversight of such approvals and further details of this process can be found in the Oversight and Assurance Report.

In addition, a number of applications were approved under class action addition of:

#### Liaison Financial Service and Cloud storage:

- None

#### Optum Health Solutions UK Limited Class Actions:

- None

#### Graphnet Class Actions:

- None

