

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

**Minutes of meeting held via videoconference 21 July 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. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Chair
Dr. Maurice Smith	Specialist GP Member
Jenny Westaway	Lay Member
<b>IGARD MEMBERS NOT IN ATTENDANCE:</b>	
Dr. Robert French	Specialist Academic / Statistician Member
Kirsty Irvine	IGARD Chair
Dr. Imran Khan	Specialist GP Member
<b>NHS DIGITAL STAFF IN ATTENDANCE:</b>	
<b>Name:</b>	<b>Team:</b>
Michael Ball	Data Access Request Services (DARS) (Items 2.1, 3.1)
Garry Coleman	Associate Director / Senior Information Risk Owner (SIRO) (Item 7.1)
Louise Dunn	Data Access Request Service (DARS) (Item 7.1)
Duncan Easton	Data Access Request Services (DARS) ( <b>SAT Observer:</b> items 2.1, 3.1 - 3.2)
Shaista Majid	Data Access Request Services (DARS) (Item 3.2)
David Morris	Data Access Request Services (DARS) (Observer: items 2.1, 3.1)
Karen Myers	IGARD Secretariat
<b>*SAT – Senior Approval Team (DARS)</b>	

<b>1</b>	<b>Declaration of interests:</b> There were no declarations of interest.  <b>Review of previous minutes and actions:</b>
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	<p>The minutes of the 14<sup>th</sup> July 2022 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record the meeting</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>Integrated Care Boards (ICB) sharing commissioning data with members of their Integrated Care System – Briefing Paper (No Presenter)</u></p> <p>This was an updated NHS Digital executive management team (EMT) paper outlining the requirement and proposed implementation for the ICBs to share commissioning data with members of their Integrated Care System (ICS).</p> <p>ICSs are partnerships that bring together providers and commissioners of NHS services across a geographical area with local authorities and other local partners to collectively plan health and care services to meet the needs of their population. The central aim of ICSs is to integrate care across different organisations and settings, joining up hospital and community-based services, physical and mental health, and health and social care. All parts of England are now covered by one of 42 ICSs.</p> <p>The commissioning landscape across England has experienced significant legal change with the introduction of the Health and Social Care Act 2022. This has abolished CCGs and introduced Integrated Care Boards.</p> <p>IGARD noted that the briefing paper had previously been presented at the IGARD business as usual (BAU) meeting on the 26<sup>th</sup> August 2021 and 30<sup>th</sup> September 2021.</p> <p>IGARD welcomed the updated EMT paper and provided a number of high-level comments including, but not limited to:</p> <ol style="list-style-type: none"> <li>1. Noting the significant change in the way in which patient data is being accessed and processed for commissioning, IGARD noted that further work should be done on transparency to the public, including (but not limited to): <ol style="list-style-type: none"> <li>a) Ensuring that the ICBs are made aware of the importance of transparency to the public for instance by placing further emphasis on this within the DSAs between ICBs and NHS Digital and within the sub-licensing guidance that NHS Digital will provide to ICBs; and</li> <li>b) The ICBs ensure that there is further transparency to the public, for example, by NHS Digital requiring ICBs to publish Data Uses Registers which make visible all sub-licensing agreements, the purposes, the legal basis for processing and the sub-licensees.</li> </ol> </li> <li>2. In respect of sub-licences and in line with <a href="#">NHS Digital DARS standard for sub-licencing and onward sharing</a>: <ol style="list-style-type: none"> <li>a) IGARD were supportive of the sub-licencing option. However, with the sub-licencing option there are risks that sub-licensors will lack the requisite expertise and experience to manage the volume of sublicenses appropriately.</li> <li>b) To provide further clarity within the paper of the extent <b>and</b> nature of the sub-licensees, noting that public perception may be unfavourable towards sub-licensing the data to some organisations.</li> <li>c) To clarify within the paper and within the sub-licensing guidance and/or ICB DSAs that the sublicensing purposes must fit within the purposes for which NHS Digital are required to share data, i.e. for the benefit of health and social care.</li> </ol> </li> </ol>

	<p>d) IGARD noted concerns that sub-licensees may use requiring the data as a matter of “urgency”, as a means to accelerate the process to obtain the data, and therefore reduce scrutiny of the application.</p> <p>e) To confirm that all organisations who would legitimately be applying for sub-licenses, would also be appropriate for DSPT, and would not require alternative security assurances, akin to an assessment of a System Level Security Policy by NHS Digital’s Security Team.</p> <p>3. In respect of re-identification:</p> <p>a) To clarify 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; and,</p> <p>b) Further consideration will need to be given as to how this is made transparent to the public.</p> <p>c) To provide confirmation that any re-identification under a sub-license must be undertaken by NHS Digital.</p> <p>4. More thought should be given to whether some organisations, who may be reasonably involved in public health activities that could impact on commissioning, which are not themselves healthcare providers, might be able to access data held by ICBs.</p> <p>5. To provide clarification that the individual GP access to the data beyond their own GP practice, is fully controlled via role-based access control.</p> <p>6. To review the reference to “<i>Ambulatory Care Sensitive Conditions</i>”, noting that, whilst an appropriate care plan can reduce hospital attendance for some patients, it is by no means the case that all hospital admissions for patients with ACSC are inappropriate and avoidable.</p> <p>7. To amend the reference “<i>IGARD approval</i>” to accurately reflect that IGARD make recommendations.</p> <p>8. IGARD welcomed and supported the verbal information from NHS Digital in respect of auditing an ICB early, for example, in respect of sub-licensing and sharing the knowledge with other ICBs.</p> <p>IGARD would expect the briefing note to be a living document and to be updated and returned to IGARD as appropriate.</p>
<b>3</b>	<b>Data Applications</b>
<b>3.1</b>	<p><u>NHS Norfolk and Waveney Integrated Care Board (ICB): Comm, RS and IV (Presenter: Michael Ball) NIC-616046-J1Q0N-v0.2</u></p> <p><b>Application:</b> This was a new, second 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 an 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> <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.</p>

The processing outlined within the application is relying on s251 of the NHS Act 2006, 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 26<sup>th</sup> August 2021, 30<sup>th</sup> September 2021, and at today’s meeting (item 2.1).

IGARD noted that the first of type application (NIC-615960-G7W1L) was presented at the IGARD BAU meeting on the 30<sup>th</sup> June 2022.

IGARD noted that the previous CCG DSA had been novated to the ICB, and that the ICB was therefore holding the novated CCG DSA. 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 that section 5 (Purpose / Methods / Outputs) was not clear that the ICB was holding and processing patient data under the novated CCG DSA, and asked that, for transparency, this public facing section was updated accordingly.

IGARD also noted that it was not clear in section 5 which CCG(s) previously occupied the geographical footprint of the ICB, and asked that for transparency section 5 was updated with further clarity.

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

IGARD noted that they had previously asked NHS Digital to advise on the s261 legal basis for NHS Digital’s dissemination, for example which subsection of s261 of the Health and Social Care Act 2012 was relevant since NHS Digital appeared to be only citing the overarching s261. IGARD asked that section 3 (Datasets Held / Requested) be updated with the most appropriate s261 subsection, in line with the latest advice from NHS Digital’s Privacy, Transparency & Ethics (PTE).

IGARD noted that, prior to the meeting, they 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; and asked that in line [with the NHS Digital DARS Standard for Data Controllers](#), a written analysis of the ICP Terms of Reference (ToR) membership and functions, in respect of data controllership was provided.

IGARD also asked that the application was updated throughout to accurately reflect the data controllership arrangements, as borne of the facts, and in line with [NHS Digital DARS Standard for Data Controllers](#); or, that written confirmation was provided, clarifying why the ICP members were **not** considered to be undertaking data controllership activities.

IGARD noted that the ‘Integrated Care Board’s (ICB) sharing commissioning data with members of their Integrated Care System – Briefing Paper’ (item 2.1) stated “...*there will be times when the organisations using pseudonymised data may discover a small cohort of patients that require direct care intervention*”; and that this did not align with the content of the application. IGARD asked that for clarity, section 5(a) (Objective for Processing) was updated, to state 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. In addition, IGARD asked that section 5(a) was updated to clarify that re-identification may be undertaken for the purpose of risk stratification by the risk stratification providers.

IGARD asked that clarity was provided in section 5(a), that any re-identification under a sub-license, must be undertaken by NHS Digital, and **not** by any other Data Processors being used by the ICB / sub-licensee.

IGARD noted that although the ICB does not provide direct care, it may assist service providers to provide the most appropriate care, and asked that this was clearly articulated in section 5.

IGARD noted in section 5(a) that direct care would be an *“inevitable secondary result”*; however asked that this was updated further, to also clarify that in other instances, work would be undertaken for the primary purpose of delivering direct care.

IGARD noted that following the discussion on NIC-615960-G7W1L on the 30<sup>th</sup> June 2022, it had been agreed with NHS Digital’s Senior Information Risk Owner (SIRO), that processing and storage locations, usually noted in section 2 (Locations) of the application, would not be recorded in 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; 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](#).

IGARD queried the statement in section 1(b) (Data Controller(s)) *“The ICB has submitted the 21/22 \*DSPT in the former CCG name”*; and noting that this was incorrect, asked that the statement was updated to accurately reflect that the ICB was *“relying”* on the DSPT submitted by the CCG. In addition, IGARD noted the special condition in section 6 (Special Conditions) relating to the DSPT, and asked that this was updated, to ensure that the DSPT covered the relevant bodies.

\* DSPT - Data Security & Protection Toolkit

As section 5 forms [NHS Digital’s data uses register](#), IGARD asked that, for transparency, section 5 was updated to be clear that the DSPT for the year 2021/2022 was submitted by the CCG, and that the ICB would submit a DSPT for the year 2022/23 onwards.

Separate to this application, IGARD suggested that where **multiple** CCGs were previously in the footprint of the new ICB, NHS Digital should consider if relying on multiple previous CCG DSPT submissions was appropriate in respect of adequate security arrangements and whether NHS Digital’s Security Team should review the process.

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, for example, by assessment of a System Level Security Policy (SLSP).

IGARD noted the special condition in section 6 relating to transparency, and asked that this was also replicated in section 4 (Privacy Notice).

IGARD noted the special conditions in section 6 relating to Data Processors, and asked that and in line with [NHS Digital DARS Standard for processing activities](#), these were also replicated in section 5(b).

IGARD noted that section 5(b) (Processing Activities) was silent on the onward sharing of data under sub-licensing arrangements, and asked that section 5(b) was updated with further clarity, in line with [NHS Digital DARS Standard for processing activities](#).

IGARD noted the statement in section 5(d) (Benefits) relating to reducing “*emergency readmissions*”, and asked that this was re-ordered, for example, how this will be achieved followed by the outcome, in line with [NHS Digital DARS Standard for Expected Measurable Benefits](#).

IGARD queried whether the ICB would wish to obtain data for those patients historically registered within the ICB geographical footprint but who had moved away. IGARD noted this would need to be an amendment application, via the usual NHS Digital process.

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, the novel processing and the recent creation of ICBs.

**Outcome:** recommendation to approve subject to the following condition:

1. In respect of the data controllership and [in line with the NHS Digital DARS Standard for Data Controllers](#):
  - a) To provide a written analysis of the ICP ToR membership and functions in respect of data controllership; and
  - b) To update the application throughout to accurately reflect the data controllership arrangements, as borne of the facts, and in line with [NHS Digital DARS Standard for Data Controllers](#); or
  - c) To provide written confirmation as to why the ICP members are not considered to be undertaking Data Controllership activities.

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-license, 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:
  - a) 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.

The following advice was given:

- 1. IGARD noted that the previous CCG DSA have novated to the ICB, and that the ICB is therefore holding the novated CCG DSA. 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 30<sup>th</sup> 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.

**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.

**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](#).

**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 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.

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

	<p><b>Subsequent to the meeting:</b> Following ratification of these minutes (21st July 2022) at the IGARD BAU meeting on the 28<sup>th</sup> July 2022, a discussion was held on NIC-615958-F7Q7Z NHS Bristol, North Somerset and South Gloucestershire Integrated Care Board. It was agreed by IGARD that some of the outcomes from NIC-615958-F7Q7Z were also relevant to this application, NIC-616046-J1Q0N. Please refer to the IGARD BAU minutes on the 28th July 2022, for updated / ratified outcomes for this application, NIC-616046-J1Q0N.</p>
3.2	<p><u>London School of Hygiene and Tropical Medicine: Modelling norovirus transmission dynamics and evaluating vaccination strategies: implications for acute kidney injury epidemiology (Presenter: Shaista Majid) NIC-486044-S3T0J-v0.16</u></p> <p><b>Application:</b> This was a new application for pseudonymised Hospital Episode Statistics Admitted Patient Care (HES APC) data for the period between 2005/06 and 2018/19.</p> <p>The purpose of the application is for a study, investigating the contribution of norovirus transmission dynamics to acute kidney injury hospitalisations. Norovirus is one of the most common gastrointestinal viruses, with more than 3 million reported cases in the UK annually.</p> <p>One of the most serious consequences of diarrhoeal illnesses is acute kidney injury (AKI) where kidney function declines rapidly. AKI is associated with increased risk of mortality, hospitalisation, and longer duration of stay which increases the cost and impact on the health system. However, AKI is a complex illness and how much gastrointestinal viruses contribute to AKI burden is not known.</p> <p>Recent studies have demonstrated a seasonal winter pattern to AKI hospital admissions in the UK, suggesting potential associations with winter epidemics, such as norovirus. There is mounting evidence for the importance of diarrhoeal illness in AKI, especially for people who already have established chronic kidney disease. The prevalence of CKD is increasing in the UK, so there is an urgent need to identify risk factors for illness and strategies to decrease it.</p> <p>The estimated cohort size is a minimum of 2.29 million cases of AKI.</p> <p>NHS Digital noted that prior to the meeting, an IGARD member had raised a query in respect of the contradictory statement in section 7 (Ethics Approval), that ethics approval was not required because there was no flow of confidential data; and the study protocol that referred to the London School of Hygiene and Tropical Medicine Research Ethics Committee (REC). NHS Digital advised that the applicant had confirmed that the REC had reviewed and provided ethical support for the study.</p> <p><b>Discussion:</b> IGARD noted the verbal update from NHS Digital in respect of the ethical support provided by the London School of Hygiene and Tropical Medicine REC; and asked that the appropriate documentation was uploaded to NHS Digital's customer relationships management (CRM) system for future reference.</p> <p>IGARD noted the reference in section 1 (Abstract) to the funding being provided by the National Institute for Health Research (NIHR), however, noting that there had been no funding documentation provided with the application for review, asked that NHS Digital ensure that this information and relevant documentation was uploaded to NHS Digital's CRM system for future reference.</p> <p>IGARD queried how the Study Team would determine who had had norovirus, and noting that this was not clear within the application, asked that section 5(a) (Objective for Processing) was updated with written confirmation.</p>



IGARD noted that it was unclear within the application if any of the patient level data, would be linked to the UK Health Security Agency (UKHSA) data; and asked that written confirmation was provided in section 5(a).

Alternatively, IGARD queried if the study was in fact an ecological study (an observational study at the population or group level not at an individual patient level), and if so, why aggregated data would **not** be sufficient and why patient level data was required; and asked that written confirmation was provided in either case, in section 5(a).

IGARD noted the statement in section 5(a) *"It is a statutory requirement that evidence of the health economic benefits of new vaccination programmes have to be considered by policy/decision makers in the UK before making decisions on whether introducing a publicly funded norovirus vaccination programme would be beneficial to the population"*. IGARD asked that an express statement was added to section 5(a), that this study had **not** been commissioned by the Joint Committee on Vaccinations and Immunisations (JCVI) or other organisation, for the purpose of evaluating vaccine recommendations.

IGARD queried the estimated proportion of norovirus patients affected by AKI, noting that the application was not clear on this; and asked that section 5(a) was updated with further clarity.

IGARD noted the statement in section 5(a) *"AKI is associated with increased risk of mortality, hospitalisation, and longer duration of stay which increases the cost and burden on the health system"*; and asked that prior to the information relating to the economic burden, the statement was amended to reflect that AKI was detrimental to patients.

IGARD asked that as section 5 (Purpose / Methods / Outputs) forms [NHS Digital's data uses register](#), section 5(a) was amended throughout, so technical terms were used only where necessary and explained in a manner suitable for a lay audience, for example *"Bayesian methods"*.

IGARD noted a number of statements in section 5(d) (Benefits) relating to specific savings, for example *"If the AKI burden could be reduced by just 1%, the equivalent of £10 million could thus be freed up for the NHS"* and asked that these were reviewed and updated in terms of productivity gain or similar, in line with [NHS Digital DARS Standard for Expected Measurable Benefits](#).

IGARD noted the information in section 5(a) in relation to the organisations involved in the study, however asked that in line with [NHS Digital DARS Standard for commercial purpose](#), section 5(a) was updated to clarify that there were **no** commercial benefits to either the applicant or the funders from any vaccine production.

IGARD noted in section 5(a), that patient and public involvement meetings were planned in 2022, and suggested that, if not already happening, the applicant involve relevant public and patient groups for the lifecycle of the project in line with [HRA guidance on Public Involvement](#).

**Outcome:** recommendation to approve subject to the following condition:

1. In respect of the data requested:
  - a) To provide written confirmation in section 5(a) as to how the Study Team are determining who has had Norovirus; and
  - b) To provide written confirmation in section 5(a) of any data linkage to the UKHSA data; or
  - c) To provide written confirmation in section 5(a) if it is an ecological study; and
  - d) If it is an ecological study, to provide confirmation in section 5(a) as to why aggregated data would **not** be sufficient and why patient level data is required.

	<p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To update the statement in section 5(a) “AKI is associated with increased risk of mortality...” to reflect that this is detrimental to patients; and before the information relating to the economic burden.</li> <li>2. As section 5 forms <a href="#">NHS Digital’s data uses register</a>, to amend section 5(a) throughout, so technical terms are used only where necessary and explained in a manner suitable for a lay audience, for example “Bayesian methods”.</li> <li>3. To make an express statement in section 5(a) that this study has <b>not</b> been commissioned by the JCVI or other organisation, for the purpose of evaluating vaccine recommendations.</li> <li>4. To update section 5(a) to include further information on the numbers or a rough proportion of norovirus patients who are affected by AKI.</li> <li>5. To review the statements in section 5(d) relating to any specific savings, and update in terms of productivity gain or similar.</li> <li>6. In line with <a href="#">NHS Digital DARS Standard for commercial purpose</a>, to clarify in section 5(a) that there are no commercial benefits to either the applicant or the funders from any vaccine production.</li> </ol> <p>The following advice was given:</p> <ol style="list-style-type: none"> <li>1. IGARD noted that the ethics approval <b>and</b> the funding documentation had not been provided as supporting documents as per usual process; and asked that NHS Digital ensure that this information was uploaded to NHS Digital’s customer relationships management (CRM) system for future reference.</li> <li>2. IGARD noted that Patient and public involvement meetings are planned in 2022, and suggested that, if not already happening, the applicant involve relevant public and patient groups for the lifecycle of the project in line with <a href="#">HRA guidance on Public Involvement</a>.</li> </ol> <p>It was agreed the condition would be approved out of committee (OOC) by IGARD members.</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> <p><i>No items discussed.</i></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 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 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: <a href="#">NHS Digital Data Uses Register - NHS Digital</a>.</p>

6	<p><u>COVID-19 update</u></p> <p><i>No items discussed</i></p>
<p>7</p> <p>7.1</p>	<p><u>AOB:</u></p> <p><u>National Disease Registration Service (NDRS) (Presenters (Garry Coleman / Louise Dunn)</u></p> <p>NHS Digital's Associate Director / Senior Information Risk Owner (SIRO) and a member of the Data Access Request Services (DARS) Senior Approvals Team (SAT) attended the meeting, to provide a verbal update on NDRS applications.</p> <p>NHS Digital advised that the UK Health Security Agency (UKHSA) had been providing interim support to NHS Digital from the 1<sup>st</sup> October 2021, however confirmed that this support had now ended, and all applications, queries etc, in relation to NDRS, had moved to NHS Digital.</p> <p>NHS Digital advised that there was an ongoing programme of work, to ensure that all the applications, queries etc were prioritised and processed as appropriate.</p> <p>NHS Digital noted that there were a small number of applications, that had been through the relevant processes within the UKHSA Office for Data Release (ODR) prior to transferring over to NHS Digital, including a positive review by the ODR Moderation panel; but had not had a contract issued. NHS Digital advised that noting that the applications had already progressed via governance processes within UKHSA, and to prevent any further delays, it was NHS Digital's intention to flow data to the applicants for a period of 12-months via the SIRO Precedent route. This was to support the important work of the applicants and to enable NHS Digital to work with the applicant to ensure any future versions of the application are fully compliant with <a href="#">NHS Digital DARS Standards</a>. In addition, NHS Digital advised that any future versions of the applications would be submitted to IGARD for review as per process.</p> <p>NHS Digital confirmed that the applications that proceed via the SIRO Precedent route would be transparent within <a href="#">NHS Digital's data uses register</a>. In addition, IGARD noted that NHS Digital would undertake a routine audit on some of the applications proceeding via the SIRO Precedent in line with standard processes.</p> <p>IGARD noted and thanked NHS Digital for the update and confirmed that they were broadly supportive of NHS Digital's proposal in respect of progressing these applications, noting the governance process already undertaken and the public benefit in supporting the applicants to continue and / or proceed with important work.</p> <p>IGARD and NHS Digital agreed that a further discussion would be held at a future IGARD meeting, to determine how IGARD would be kept up to date with the specific applications proceeding via the SIRO Precedent, noting that this should also be transparent within published IGARD minutes, in-line with other applications submitted via NHS Digital's DARS process.</p> <p>There was no further business raised, the Deputy 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 15/07/22

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)
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