

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 30 September 2021

| IGARD MEMBERS IN ATTENDANCE: | |
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| Name: | Position: |
| Paul Affleck | Specialist Ethics Member |
| Kirsty Irvine (Chair) | IGARD Chair / Lay Representative |
| Dr. Imran Khan | Specialist GP Member |
| Dr. Geoffrey Schrecker | Specialist GP Member / IGARD Deputy Specialist GP Chair |
| IGARD MEMBERS NOT IN ATTENDANCE: | |
| Name: | Position: |
| Maria Clark | Lay Member |
| Prof. Nicola Fear | Specialist Academic Member |
| Dr. Maurice Smith | Specialist GP Member |
| NHS DIGITAL STAFF IN ATTENDANCE: | |
| Name: | Team: |
| Michael Ball | Data Access Request Service (DARS) |
| Louise Dunn | Data Access Request Service (DARS) |
| Duncan Easton | Data Access Request Service (DARS) |
| Karen Myers | IGARD Secretariat |
| Jonathan Osborn | Deputy Caldicott Guardian (Observer: items 1 - 3.2) |
| Tania Palmariellodiviney | Data Access Request Service (DARS) |
| Fran Perry | Data Access Request Service (DARS) |
| Vicki Williams | IGARD Secretariat |

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| 1 | <p>Declaration of interests:</p> <p>There were no declarations of interest.</p> <p>Review of previous minutes and actions:</p> <p>The minutes of the 23rd September 2021 IGARD meeting were reviewed, and subject to a number of minor amendments were agreed as an accurate record of the meeting.</p> |
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| | <p>Out of committee recommendations:</p> <p>An out of committee report was received (see Appendix A).</p> |
| <p>2</p> | <p>Briefing Notes</p> |
| <p>2.1</p> | <p><u>CCGs sharing commissioning data with members of their Integrated Care System – Briefing Paper (Presenters: Michael Ball / Duncan Easton)</u></p> <p>This was an NHS Digital executive management team (EMT) paper outlining the need for a smooth transition to the new commissioning landscape to allow Clinical Commissioning Groups (CCGs) to share data with providers and local authorities in the interim period before April 2022. Currently CCGs are prevented from giving access to other organisations within their ICS due to the anonymised small number suppression rule for onward sharing. Noting that ICSs are not legal entities until 1st April 2022, the briefing paper is seeking approval for CCGs, who are already working with the other constituent organisations of the ICS to fulfil their commissioning responsibilities and work collaboratively, to enable them to be able to share NHS Digital data within their ICS group prior to ICSs becoming legal entities.</p> <p>NHS Digital outlined a number of options: 1) joint data controllership and amend all CCG applications accordingly via a class action and a requirement to update the customer relationship management (CRM) system to allow for many multiples of data controllers to be included on data sharing agreements (DSA); 2) to allow data controllers to onwardly share data and amend all CCG applications accordingly via a class action; 3) sub-licencing agreement to allow the CCG to onwardly share the data with other organisations but under specific rules set by NHS Digital as part of the CCG’s DSA.</p> <p>IGARD noted that the briefing paper had previously been presented at the IGARD business as usual (BAU) meeting on the 26th August 2020.</p> <p>IGARD welcomed the draft EMT paper and provided a number of high-level comments including, but not limited to:</p> <ol style="list-style-type: none"> 1. Given the options put forward in the EMT briefing paper, 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 apply the sublicenses appropriately. For the immediate interim step to flow data to the CCG who would sub-licence to the sub-licencees, NHS Digital would need to ensure additional safeguards were in place, beyond simply only allowing sublicensing within the ICS boundary. 2. The minimum safeguard requirements could include, but not limited to: <ol style="list-style-type: none"> a. a sublicensing oversight board with public involvement from members of the relevant local community (this could be constituted from existing bodies within the CCG or other body). b. developing a pro forma oversight board TOR (to be tabled alongside the updated EMT briefing paper, alongside any other relevant documents), c. ensure robust record keeping processes so that it was known who had received what data for what purposes and where it was held, d. the need for a Caldicott Guardian who is on the Caldicott Guardian Register, ideally a board level Chief Clinical Information Officer (who could also be the Caldicott Guardian), and e. the need for NHS Digital to keep a watching brief of when the statutory duties and responsibilities were legislated for and to make appropriate changes to arrangements. |

3. More thought should be given to the data used for “direct care”, given the risks for potential misuse of data under a sub-licencing agreement. IGARD noted that the [NHS Digital DARS standard for sub-licencing and onward sharing](#) provided that the purpose could be narrower for the sub-licencee than the purpose for the sub-licensor and this could possibly be a useful mechanism to use to ensure only those recipients with a legitimate basis to use data for direct care could do so.
4. Additionally, more thought should be given whether the direct care data flow could be covered by separate arrangements rather than under the one agreement, which would still be in line with [NHS Digital’s DARS standard for data minimisation as they are two distinct purposes with differing data requirements](#).
5. IGARD suggested that NHS Digital speak to their Commercial Legal Team with regard to sub-licencing to ensure that all relevant contractual arrangements had been discussed and were in place before commencing with this option (noting that although discussions with PTE were helpful, the Commercial Team should also be briefed).
6. IGARD noted that the draft EMT briefing was to be circulated internally within NHS Digital and would welcome an updated EMT briefing paper in due course.

IGARD made the following comments on the worked examples provided:

1. Careful thought needs to be given to the SNOMED terms to be used as opt outs for the data flows, where specific terms are not available these should be requested through the [SNOMED request submission portal](#), on NHS Digital’s website.
2. To update the GEMIMA document, including (but not limited to) the points made in meeting, with regards to implied consent, social prescribing and Common Law Duty of Confidentiality.

The following advice was given:

1. IGARD noted that the briefing note model outlined was theoretically viable, but suggested that NHS Digital audit as a high priority case.
2. Noting the concerns raised on the supporting documents tabled, IGARD suggested NHS Digital discuss with the applicant, and underscore the issues raised, in order to maintain public trust and confidence in a new system.

IGARD would expect the briefing note to be a living document and to be updated and returned to IGARD once the legislation from Government had been approved under the [Health & Care Bill 2021](#).

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| 3 | Data Applications |
| 3.1 | <p><u>AstraZeneca UK Limited: Real-world effectiveness of the Oxford/AstraZeneca covid-19 vaccine and investigation of the epidemiology of thrombotic thrombocytopenia and other adverse events of interest following COVID-19 vaccination in England - TRE Analysis (Presenter: Louise Dunn) NIC-445543-W0D4N-v2.2</u></p> <p>Application: This was an amendment application to 1) add a second purpose to the use of the data; 2) add additional non sensitive pseudonymised fields to the Hospital Episode Statistics data, COVID-19 Vaccination data and Uncurated Low Latency Hospital Data Sets; 3) to add three additional data products: HES: Deaths Bridging file, COVID-19 Vaccination Adverse Reactions and Uncurated Low Latency Hospital Data Sets (Outpatient). Access to the data requested in this Data Sharing Agreement (DSA) will be via the NHS Digital Trusted Research Environment (TRE) and no record level data will leave NHS Digital.</p> |

Purpose 1 of the study is to assess the real-world effectiveness of the Oxford/AstraZeneca COVID-19 vaccine, among people who receive one dose of the vaccine, overall and by age group and time period after 1 dose. In addition, the study aims to: **a)** assess the vaccine effectiveness in people who have received the two doses; the timing after the 1st and 2nd dose, interval between the two doses and comorbidity status **b)** replicate the above analyses in people receiving the Pfizer COVID-19 vaccine.

Purpose 2 of the study (as per the amendments) is to estimate occurrence and describe the demographic characteristics and medical history of patients with thrombotic thrombocytopenia, thromboembolism, and thrombocytopenia the following COVID-19 vaccination.

The cohort will consist of every citizen registered with a GP practice in England who has not registered a Type 1 Objection.

Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 1st July 2021.

IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 25th May, 15th June and 22nd June 2021.

IGARD also noted that this application had also been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 26th May 2021 and the 16th June 2021, and that notes from these meetings had been attached to the IGARD minutes from the 1st July 2021; and the 15th September 2021 (see Appendix B). IGARD noted that PAG supported the application subject to a specific condition, however IGARD advised that they would be against making such mandatory conditions, since it would be for NHS Digital to enforce the PAG condition in a contractual agreement between the applicant and NHS Digital.

IGARD noted that at the meeting on the 1st July 2021, they had expressed concern that the revised privacy notice (not provided at the meeting), may contain an inaccurate description of the processing, and suggested that NHS Digital undertake a review, and raise any risks with the applicant. In addition, IGARD noted that a specialist member had supported the applicant / NHS Digital, by way of an out of committee review of the privacy notice, following the previous meeting. NHS Digital confirmed that the comments provided by the specialist member were fed back to the applicant, and subsequent updates and amendments were made to the privacy notice. IGARD noted the verbal update from NHS Digital, however advised that the privacy notice still contained reference to “*consent*”, which was incorrect and would need removing, and that a further update would be required, to ensure the privacy notice was transparent, that the processing would take place within NHS Digital’s TRE, noting that this was currently not clear.

IGARD noted the information outlined within section 5(a) (Objective for Processing) for purpose 2 of the study, and queried the objective “*Conduct exploratory assessment of case definitions and disease aetiology using artificial intelligence (AI)-based approaches*”; and noting that no additional information was provided, asked that further explanatory information was provided in section 5(a) of the application. In addition, IGARD asked that confirmation was provided, as to whether or not any additional UK General Data Protection Regulation (UK GDPR) considerations needed to be addressed, including, but not limited to, carrying out or updating the Data Protection Impact Assessment (DPIA).

IGARD noted the additional purpose (2) that had been added to the Data Sharing Agreement (DSA), and queried why the comparative analysis was on people receiving the Pfizer COVID-

19 vaccine and no other vaccine had been cited, noting that this was also outlined in supporting document 1.1, the study protocol. IGARD asked that for transparency, a further justification was provided in section 5(a), clarifying why the comparative analysis was on people receiving the Pfizer COVID-19 vaccine only, for example, it may be that the statistical power is not high enough to compare to another vaccine used in the UK.

IGARD queried if the comparative analysis would be expanded to other COVID-19 vaccines used in the UK, and asked that the applicant consider expanding section 5(a), to reflect that as more data becomes available, further comparisons may be undertaken on other COVID-19 vaccines, if this reflects the factual scenario. IGARD also asked that any potentially restrictive information outlined, which restricted the permitted purposes for processing was removed, for example, only referring to the *“Pfizer-BioNTech COVID 19 vaccination”*.

In addition, IGARD noted the technical language in section 5(a), when describing purpose 2, for example, *“Estimate occurrence of thrombotic thrombocytopenia, thromboembolism, and thrombocytopenia (definitions including sub-setting for specific diagnostic units described in the Case definitions section)...”*, and asked that this was simplified, to reflect that the study would be looking at the vaccine *“side effects”*.

IGARD queried the statement in section 3(b) (Additional Data Access Requested) that *“GDPR does not apply to data solely relating to deceased individuals”*, however, noting that the status of those patients that are still alive would be revealed, asked that this was updated to include a UK General Data Protection Regulation (UK GDPR) legal basis for dissemination and receipt of data. IGARD noted that a query had been raised on this particular point with the Privacy, Transparency and Ethics (PTE) Directorate and welcomed an update from Data Access Request Service (DARS) in due course.

IGARD noted that there were no yielded benefits within section 5(d) (Benefits) (iii) (Yielded Benefits); and were advised by NHS Digital that the applicant had only had access to the TRE since mid-August (2021), hence why there were no yielded benefits outlined. IGARD noted the verbal update from NHS Digital, however asked that for transparency, a brief explanation was added to section 5(d) (iii), as to why there were no yielded benefits accrued to date.

IGARD advised that they would wish to review this application when it comes up for renewal, to review the yielded benefits accrued to date.

Outcome: recommendation to approve subject to the following condition:

1. In respect of the *“artificial intelligence (AI)-based approaches”*:
 - a) To provide a further explanation in section 5(a) of the reference to *“artificial intelligence (AI)-based approaches”*.
 - b) To confirm in section 5(a) whether or not any additional UK GDPR considerations need to be addressed including (but not limited to) carrying out or updating the DPIA.

The following amendments were requested:

1. In respect of the new purpose:
 - a) To provide a justification in section 5(a) why the comparative analysis is on people receiving the Pfizer COVID-19 vaccine only (as described in the protocol).
 - b) To simplify the language in section 5(a) to reflect that the study will be looking at the vaccine *“side effects”*, and edit or supplement technical language as necessary.
 - c) To consider expanding the section 5(a) to reflect that as more data becomes available, further comparisons may be undertaken on other COVID-19 vaccines, (if

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| | <p>this reflects the factual scenario); and remove any potentially restrictive information outlined which restricts the permitted purposes for processing.</p> <ol style="list-style-type: none"> 2. To update section 3 to include a UK GDPR legal basis for those datasets that give information about cohort members who are still living, if this approach is supported by advice on this point from PTE. 3. To update section 5(d) (iii) with a brief explanation as to why there are no yielded benefits accrued to date. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD advised that they would wish to review this application when it comes up for renewal, to review the yielded benefits accrued to date. <p>It was agreed the condition would be approved out of committee (OOC) by IGARD members.</p> |
| <p>3.2</p> | <p><u>Department of Health and Social Care / Ipsos MORI: IPSOS MORI/Imperial REACT I Antigen study (Presenters: Fran Perry / Louise Dunn) NIC-393650-B7J6F-v7.2</u></p> <p>Application: This was an amendment application from the Department of Health and Social Care (DHSC) and Imperial College London, to request further identifiable Demographics data for Waves 16 - 20 of the study, between October 2021 and February 2022, at a sample size of approximately 835,000 individuals.</p> <p>The purpose is to support Antigen testing study, round 2, (REACT-1-Round 2), one element of the REal-time Assessment of Community Transmission 1 (REACT 1): a study that will provide the basis for estimation of the R value in the community at regional and local authority levels.</p> <p>This study is one component of a larger programme and sits alongside the REal-time Assessment of Community Transmission 2 (REACT 2): Usability and feasibility study of widespread home self-testing for SARS-CoV-2 antibodies.</p> <p>The data requested will be used in order to select a nationally representative sample of the population aged 5+ to take part in the testing. The study needs to provide reliable estimates of infection point prevalence at the level of local authority, as this is the administrative level responsible for local government and will feed into the local public health response. It is also powered to explore differences by key sociodemographic variables.</p> <p>Waves 16 to 20 hope to assist the government understanding of the pandemic and its impact over the autumn and winter 2021, as well as establish the prevalence of infection among groups with different (booster) vaccination coverage.</p> <p>Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 12th August 2021.</p> <p>IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 4th August and 8th December 2020, and the 20th April, 24th August and 21st September 2021.</p> <p>IGARD noted that Data Processors were based in Germany and Scotland, and queried if The Health Service Control of Patient Information (COPI) Regulations 2002 could be relied on to process the data, noting that COPI only applied to England and Wales. IGARD asked that written confirmation was provided that Data Processors not based in England and Wales could rely on COPI to process the data outlined in this application; and that a copy of the written confirmation was uploaded to NHS Digital’s customer relationships management (CRM) system for future reference.</p> |

IGARD noted that some yielded benefits had been cited in section 5(d) (Benefits) (iii) (Yielded Benefits), however, asked that further details were provided of the specific yielded benefits accrued to date, and asked that it was clear as to the benefits to both the patients and the health and social care system more generally, for example, reducing transmission and more detailed information for the public, and in line with [NHS Digital's DARS Standard for Expected Measurable Benefits](#).

IGARD also queried how the REACT study had been used in recent months, for example, noting the reduction in public health measures across the four devolved nations of the UK in presence of rising prevalence as shown by the REACT study, and noting the large volume of data flowing, asked that further detail was provided in section 5(d) (iii).

IGARD reiterated points they had previously raised, in respect of possibly recontacting individuals who had already objected, and how this was managed. In the absence of any other method, IGARD suggested that NHS Digital may wish to consider delaying the request for the applicant to destroy data, in certain circumstances, to ensure that these individuals were not recontacted.

IGARD suggested that noting this may be a long running study, NHS Digital may wish to explore other options of managing individuals who have opted out of being contacted, for example, by the way of proxies, utilising the Telephone Preference Service (TPS) and the Mail Preference Service (MPS), for those who did not want to be contacted and / or those who were considered vulnerable.

IGARD queried the incorrect information in section 1 (Abstract), that stated a review of the application was not requested by IGARD; and asked that this was reviewed and updated to correctly reflect that a review was required.

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.

Outcome: recommendation to approve subject to the following condition:

1. In respect of COPI:
 - a) To provide written confirmation that Data Processors not based in England and Wales can rely on COPI to process the data.
 - b) To upload a copy of the written confirmation to NHS Digital's CRM system, for future reference.

The following amendments were requested:

1. In respect of the yielded benefits and in line with [NHS Digital's DARS Standard for Expected Measurable Benefits](#):
 - a) To provide further specificity in section 5(d) (iii) of the yielded benefits accrued to date and ensure these are clear as to the benefits to patients, the NHS and the health and care system more generally, for example, reducing transmission and more detailed information for the public.
 - b) To provide further details in section 5(d) (iii) as to how the REACT study has been used in recent months, noting the change (reduction) in public health measures and the large volume of data flowing.
2. To review the information in section 1 that stated a review by IGARD was not requested.

The following advice was given:

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| | <ol style="list-style-type: none"> 1. In respect of recontacting individuals who have opted out of such contact: <ol style="list-style-type: none"> a) IGARD reiterated points previously raised, in respect of recontacting individuals who have already objected, and how this is managed. In the absence of any other method, IGARD suggested that NHS Digital may wish to consider delaying data destruction, in certain circumstances, to ensure that these individuals are not recontacted. b) IGARD suggested that noting this may be a long running study, NHS Digital may wish to explore other options of managing individuals who have opted out of being contacted, for example, by the way of proxies, utilising the TPS and MPS, for those who do not want to be contacted and / or those who are considered vulnerable. 2. 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. 3. 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. <p>It was agreed the condition would be approved out of committee (OOC) by IGARD members.</p> |
| <p>3.3</p> | <p><u>University College London (UCL: Childhood outcomes after perinatal brain injury (Data flowing to ONS) (Presenter: Tania Palmariellodiviney) NIC-342322-Q1N7M-v0.15</u></p> <p>Application: This was a new application for pseudonymised Birth Notification Data, Civil Registration (Births) and Civil Registration (Deaths), Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC), HES Outpatients and Mental Health Services Data Set (MHSDS).</p> <p>For this study, NHS Digital data will be disseminated for three cohorts of children under this Data Sharing Agreement (DSA) to create an overarching cohort by NHS Digital. Additional identifiable demographics data is also requested for three cohorts under NIC-475526-F3Z5H (item 3.4), to allow linkage to the National Pupil Database (NPD) at the Department for Education, allowing University College London (UCL) to explore long term health and educational outcomes.</p> <p>The purpose of this application is for a study comparing health and educational outcomes in children with perinatal brain injury; and will consist of two matched control groups, 1) a preterm control group (before 34 weeks gestation) and 2) a term control group (after 34 weeks gestation); providing the most complete picture of how children's lives are affected by perinatal brain injury.</p> <p>Reducing the number of infants with perinatal brain injury is a current governmental priority. Over 3000 infants suffer a perinatal brain injury in England every year and in 2015 the Department of Health and Social Care (DHSC) declared a national ambition to halve the rates of perinatal brain injury by 2030.</p> <p>The proposed matched cohort includes approximately 130,384 infants. The maximum proposed follow up would be twelve years, and the minimum follow up of one year; and would include a total of 833,183 person follow-up years. The study is relying on s251 of the NHS Act 2006, for the flow of data into NHS Digital.</p> <p>Discussion: IGARD confirmed that they were of the view that the relevant s251 support provided the appropriate legal gateway and was broadly compatible with the processing outlined in the application.</p> <p>IGARD noted the Health Research Authority Confidentiality Advisory Group (HRA CAG) conditions of support, outlined in supporting document 3.2, the HRA CAG letter dated the 28th</p> |

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| | <p>January 2021; and asked that a special condition was inserted in section 6 (Special Conditions), that the applicant must ensure the HRA CAG specific conditions of support were met during the life of the DSA. In addition, IGARD asked that the applicant provided written evidence to NHS Digital, that the HRA CAG conditions of support had been met, and that the written evidence was uploaded to NHS Digital’s customer relationships management (CRM) system for future reference.</p> <p>NHS Digital advised IGARD that the HRA CAG condition of support, in respect of the patient information leaflet had now been completed and approved by HRA CAG. IGARD noted the verbal update and thanked NHS Digital.</p> <p>IGARD noted and commended the applicant, for the significant level of engagement with charities, parents and ex-neonatal unit patients; and highlighted the importance of patient and public involvement and engagement throughout the duration of the study, noting the large volume of data requested, and the public interest.</p> <p>IGARD noted the reference to “<i>perinatal</i>” brain injuries within section 5(a) (Objective for Processing), and noting there was no additional supporting information, asked that a brief definition was added to the beginning of section 5(a) as to what was meant by this term.</p> <p>IGARD noted and thanked the applicant / NHS Digital for the brief explanation in section 5(d) (Benefits) (iii) (Yielded Benefits), confirming why there were no yielded benefits to date.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To provide a brief definition of “<i>perinatal</i>” at the beginning of section 5(a). 2. In respect of the HRA conditions of support: <ol style="list-style-type: none"> a) To insert a special condition in section 6 that the applicant must ensure the HRA CAG specific conditions of support are met during the life of the DSA. b) The applicant to provide written evidence to NHS Digital, that that HRA CAG conditions of support have been met. c) To upload the written evidence from the applicant to NHS Digital’s customer relationships management (CRM) system for future reference. |
| <p>3.4</p> | <p><u>University College London (UCL: Childhood Outcomes after Perinatal Brain Injury (Data flowing to DfE) (Presenter: Tania Palmariellodiviney) NIC-475526-F3Z5H-v0.4</u></p> <p>Application: This was a new application for identifiable Demographics data.</p> <p>For this study, demographics data will be disseminated for three cohorts of children created under NIC-342322-Q1N7M (item 3.3) to flow to the Department for Education (DfE). The DfE use the demographic data provided by NHS Digital to extract the cohorts’ pseudonymised education data for the flow into the Office for National Statistics (ONS) Secure Research Service (SRS). NIC-342322-Q1N7M covers the provision of the cohorts into the creation of a cohort by NHS Digital. Demographics data is requested for the three cohorts of children under this Data Sharing Agreement (DSA), to allow linkage to the National Pupil Database (NPD) at the DfE, allowing University College London (UCL) to explore long term health and educational outcomes.</p> <p>The purpose is for a study, comparing health and educational outcomes in children with perinatal brain injury; and will consist of two matched control groups, 1) a preterm control group (before 34 weeks gestation) and 2) a term control group (after 34 weeks gestation);</p> |

providing the most complete picture of how children's lives are affected by perinatal brain injury.

Reducing the number of infants with perinatal brain injury is a current governmental priority. Over 3000 infants suffer a perinatal brain injury in England every year and in 2015 the Department of Health and Social Care (DHSC) declared a national ambition to halve the rates of perinatal brain injury by 2030.

The proposed matched cohort includes approximately 130,384 infants. The maximum proposed follow up would be twelve years, and the minimum follow up of one year; and would include a total of: 833,183 person follow-up years. The study is relying on s251 of the NHS Act 2006, for the flow of data from NHS Digital.

Discussion: IGARD noted and commended the applicant and NHS Digital on the quality of the information provided in the application.

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

IGARD advised NHS Digital that they were aware that DfE was subject to an audit by the Information Commissioner's Office (ICO) in 2020, which raised a number of concerning issues regarding data handling. IGARD asked that written confirmation, such as an e-mail, was provided that NHS Digital's Security Advisor had expressed satisfaction that the appropriate security was in place; and that the confirmation was uploaded to NHS Digital's customer relationships management (CRM) system for future reference.

IGARD noted the Health Research Authority Confidentiality Advisory Group (HRA CAG) conditions of support, outlined in supporting document 3.2, the HRA CAG letter dated the 28th January 2021; and asked that a special condition was inserted in section 6 (Special Conditions), that the applicant must ensure the HRA CAG specific conditions of support were met during the life of the DSA, and, in particular, the specific condition of support that must be met at every annual review. In addition, IGARD asked that the applicant provided written evidence to NHS Digital, that that HRA CAG conditions of support had been met, at the appropriate time, and that the written evidence was uploaded to NHS Digital's customer relationships management (CRM) system for future reference.

IGARD noted the reference to "*perinatal*" brain injuries within section 5(a) (Objective for Processing), and noting there was no additional supporting information, asked that a brief definition was added to the beginning of section 5(a).

IGARD queried the three processing locations in section 2(a) (Processing Location(s)) and storage locations in section 2(b) (Storage Location(s)), noting that Microsoft Azure were providing cloud storage, and asked that they were reviewed and updated as necessary, to ensure they are all in use and relevant.

IGARD noted the outputs in section 5(c) (Specific Outputs Expected) and the benefits in section 5(d) (Benefits), however, asked that they were reviewed, to reflect how the pathway to impact for the educational sector would be achieved, to ensure that the outputs reached the appropriate educational sector audience, so as to enable the education-related benefits to be realised.

Outcome: recommendation to approve subject to the following condition:

1. In respect of the security arrangements:

- a. To provide written confirmation (such as an e-mail) that NHS Digital's Security Advisor has expressed satisfaction that the appropriate security is in place.
- b. To upload the written confirmation from NHS Digital's Security Advisor to NHS Digital's customer relationships management (CRM) system for future reference.

The following amendments were requested:

- 1. To provide a brief definition of "*perinatal*" at the beginning of section 5(a).
- 2. In respect of the HRA conditions of support:
 - a) To insert a special condition in section 6 that the applicant must ensure the HRA CAG specific conditions of support are met during the life of the DSA and, in particular, the specific condition of support that must be met at every annual review.
 - b) The applicant to provide written evidence that that HRA CAG conditions of support have been met, at the appropriate time.
 - c) In due course, to upload the written evidence from the applicant to NHS Digital's customer relationships management (CRM) system for future reference.
- 3. To review the processing locations in section 2(a) and storage locations in section 2(b) to ensure they are all in use and relevant, particularly in light of the utilisation of cloud storage.
- 4. To review the outputs in section 5(c) and the benefits in section 5(d) to reflect how the pathway to impact for the educational sector will be achieved, to ensure that the outputs reach the appropriate educational sector audience so as to enable the education-related benefits to be realised.

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

3.5 University College London (UCL): Virus Watch: Understanding community incidence, symptom profiles, and transmission of COVID-19 in relation to population movement and behaviour (Presenter: Louise Dunn) NIC-372269-N8D7Z-v1.6

Application: This was an amendment application to **1)** include COVID-19 Vaccination Status data and COVID-19 Vaccination Adverse Reaction data to the Data Sharing Agreement (DSA); and, **2)** to add the Test Result field to the Covid-19 UK Non-hospital Antigen Testing Results (pillar 2) dataset which had been previously omitted.

The purpose of the study is to help inform NHS planning and the national public health response to COVID-19.

There is currently a lack of understanding of COVID-19 community incidence, symptom profile, severity, infectious period, risk factors, strength and duration of immunity, genetic differences in immune response, asymptomatic infection and viral shedding, household and community transmission risk and population behaviours during periods of wellness and illness (including social contact and movement and respiratory hygiene). This information can only be gathered accurately through large scale community-based studies.

Virus Watch is a household community cohort study. Approximately 42,500 participants will be recruited and will consent, via a postal invitation, and asked to fill out a baseline questionnaire, followed by weekly and monthly update questionnaires, all online.

NHS Digital noted that the special condition in section 6 (Special Conditions), in relation to the Data Security and Protection Toolkit (DSPT) was out of date, and advised that this would either be removed, or would be updated as appropriate to reflect the most recent dates.

Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 30th July 2020.

IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 26th May and 30th June 2020, and the 20th July 2021.

IGARD noted the verbal update from NHS Digital, in respect of the special condition in section 6 that was now out of date, and supported the removal or update, as deemed appropriate.

IGARD confirmed that they were of the view that the most recent consent materials provided the appropriate gateway and were broadly compatible with the processing outlined in the application; however, reiterated comments made previously, in respect of the review of the children's assent / consent materials.

IGARD reiterated the suggestion made at the IGARD BAU meeting on the 30th July 2020, that the children's assent materials were updated, to be clear as to the follow-up period, and that this was aligned with the other transparency materials, for example, ten years as opposed to five years. IGARD suggested that the revised assent materials are uploaded to NHS Digital's Customer Relationship Management (CRM) system for future reference.

IGARD noted that they had previously advised on the 30th July 2021, that the applicant secure Research Ethics Committee (REC) approval for a number of amendments outlined, and that this had been taken forward. IGARD however, suggested that the applicant may wish to consider informing REC about the conflicting information between the reviewed assent materials and the other transparency materials.

IGARD suggested that in the next iteration of the newsletter, the applicant should consider updating participants on the correct data retention period, and not just relying on an embedded link within the newsletter, as was currently the case and which may not be accessible to some members of the cohort.

IGARD noted that the applicant had produced information sheets and consent forms in six different languages, however, the weekly and monthly surveys would be in English only. IGARD advised that this may cause potential ethical and practical implications of recruiting participants in their first language, and then completing the surveys in English; and suggested that the applicant may wish to consider the potential bias and stratification and gaps that this may create in the study outputs, and to consider how these gaps or bias may be mitigated, for example, by translating the surveys into the other six languages, or acknowledging the potential bias or gaps in the outputs within the application for transparency.

IGARD queried the information in section 3(b) (Additional Data Access Requested) that referred to some of the datasets being "*pseudonymised*", and queried if this was correct, noting that the cohort had been consented; and were advised by NHS Digital that this was an error, and that the data should be corrected to state it was "*identifiable*". IGARD noted the verbal update from NHS Digital, and asked that section 3(b) was amended to correctly reflect that the data requested was "*identifiable*" and not pseudonymised.

IGARD noted the references in section 5(a) (Objective for Processing) and section 5(b) (Processing Activities) to "*Polish*" groups being recruited, and asked that this was amended, in light of the study changing and the targeted participant groups being expanded, as outlined elsewhere in section 5(a).

IGARD noted the information within the application in respect of the patient and public involvement (PPI) programme, and suggested that the applicant gave further consideration to

actively involving participants as part of the oversight limb, alongside the subject matter experts; and in line with the [HRA guidance on Public Involvement](#). IGARD noted the information within the application in respect of the patient and public involvement (PPI) programme, and suggested that the applicant gave further consideration to actively involving participants as part of the oversight limb, alongside the subject matter experts; and in line with the [HRA guidance on Public Involvement](#).

IGARD noted in section 5(d) (Benefits) (iii) (Yielded Benefits) that there were no yielded benefits to date, however queried the information relating to publications that had been produced; and asked that these were removed as they were not a yielded benefit.

IGARD noted that on return they would expect to be provided with a detailed analysis of the yielded benefits achieved to date, with the data received under this application, and in line with [NHS Digital's DARS Standard for Expected Measurable Benefits](#).

IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the outstanding point previously raised in respect of the assent materials, PPI and yielded benefits.

Outcome: recommendation to approve

The following amendments were requested:

1. To amend section 3(b) to reflect that the data requested is "*identifiable*" and not pseudonymised.
2. To update section 5(a) and section 5(b) to remove references to "*Polish*" groups being recruited (in light of the study changing and targeted participant groups being expanded).
3. To update section 5(d) (iii) to remove the reference to the publications that have been produced.

The following advice was given:

1. In respect of comments previously made on the review of assent / consent materials:
 - a) IGARD reiterated their suggestion that the assent materials were updated, to be clear as to the follow-up period and to align with the other transparency materials (ten years).
 - b) IGARD suggested that the applicant may wish to consider informing REC about the conflicting information between the reviewed assent materials and other transparency materials.
 - c) IGARD suggested that in the next iteration of the newsletter, the applicant should consider updating participants on the correct data retention period, and not just relying on an embedded link within the newsletter.
 - d) IGARD suggested that the revised assent materials are uploaded to NHS Digital's CRM system for future reference.
2. IGARD noted the information within the application in respect of the PPI programme, and suggested that the applicant gave further consideration to actively involving participants as part of the oversight limb, alongside the subject matter experts; and in line with the [HRA guidance on Public Involvement](#).
3. IGARD noted that the applicant had produced information sheets and consent forms in six different languages, however the weekly and monthly surveys would be in English only. IGARD advised that this may cause potential ethical and practical implications of recruiting participants in their first language, and then completing the surveys in

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| | <p>English; and suggested that the applicant may wish to consider the potential bias and stratification and gaps that this may create in the study outputs, and to consider how these gaps or bias may be mitigated, for example, by translating the surveys into the other six languages, or acknowledging the potential bias or gaps in the outputs within the application for transparency.</p> <ol style="list-style-type: none"> 4. IGARD noted that on return, a detailed analysis of the yielded benefits to date, should be provided, and in line with NHS Digital's DARS Standard for Expected Measurable Benefits. 5. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the outstanding point previously raised in respect of the assent / consent materials, PPI and yielded benefits. 6. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the outstanding point previously raised in respect of the assent materials, PPI and yielded benefits. |
| 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 where NHS Digital have notified IGARD in writing (via the Secretariat).</p> <p><i>No items discussed.</i></p> |
| 5 | <p><u>Oversight & Assurance</u></p> <p>IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. Due to the volume and complexity of applications at today's meeting, IGARD were unable to review any Data Access Request Service (DARS) applications as part of their oversight and assurance role.</p> <p>IGARD noted that they had requested, but had not as yet been provided with, an IG CV19 release register suite of documents on a particular data release for review by IGARD as part of their oversight and assurance. This was agreed in June 2020 with the Executive Director Privacy, Transparency and Ethics (PTE) when it had been agreed that IGARD review an agreed number per month, by way of a review of all documentation revised by PTE, and as part of continuous improvement and quality.</p> |
| 6 | <p><u>COVID-19 update</u></p> <p>To support NHS Digital's response to COVID-19, from Tuesday 21st April 2020, IGARD will hold a separate weekly meeting, to discuss COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 urgent applications that have been submitted to NHS Digital. Although this is separate to the Thursday IGARD meetings, to ensure transparency of process, a meeting summary of the Tuesday meeting will be captured as part of IGARD's minutes each Thursday and published via the NHS Digital website as per usual process.</p> <p>The ratified action notes from Tuesday 28th September 2021 can be found attached to these minutes as Appendix C.</p> |

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| 7 | <p><u>AOB:</u></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> |
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Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 24/09/21

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-318632-TON3M-v0.9 - | University of Leeds | 09/09/2021 | 1. In respect of HQIP: <ol style="list-style-type: none"> a) To remove the reference in section 5(a) to Leeds University being “<i>commissioned</i>” by HQIP to undertake the service evaluation; or b) If HQIP have commissioned the service evaluation, to update the application throughout to address the potential data controllership implication of the commissioning, in line with NHS Digital's DARS Standard for Data Controllers. | IGARD Chair | OOC by the IGARD Chair | <i>None</i> |

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

Appendix B

Professional Advisory Group Outcomes Record of feedback Wednesday, 15 September 2021

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| Application & version | DARS-NIC-445543-W0D4N |
| Applicant Organisation | Oxford and AstraZeneca |
| Data Controller Organisation | Oxford and AstraZeneca |
| Professional Advisory Group Agenda Item | 4 |
| <p>The profession supported the application but request clarification with regards the below requirement, should this be accepted by the applicant the profession supports;</p> <p>To encourage best practices around open science, all applicants MUST agree to make public their finalised protocols, analysis code, and codelists, both for review but also re-use under an Open Source Initiative approved licence; copyright must be equivalent to CC-BY or CC0 GitHub is a commonly used tool to share such content, but organisational websites are also acceptable; https://www.opencodelists.org/ can be used to create and host codelists. Links to such content MUST be referenced in published works.</p> | |

| Attendees | Role | Organisation |
|------------------|---------------------------|--------------|
| Peter Short | NHS Digital Clinical Lead | NHS Digital |
| Mark Coley | Profession Representative | BMA |
| Amir Mehrkar | Profession Representative | RCGP |
| Liz Gaffney | Head of Data Access | NHS Digital |
| Kimberley Watson | SDAO NHS Digital | NHS Digital |
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Appendix C

Action Notes from the IGARD – NHS Digital COVID-19 Response Meeting held via videoconference, Tuesday, 28th September 2021

In attendance (IGARD Members): Paul Affleck (IGARD Specialist Ethics Member)
Kirsty Irvine (IGARD Chair / Lay representative)
Dr. Geoff Schrecker (IGARD Specialist GP Member)

In attendance (NHS Digital): James Gray (Digi-Trials)
Suzanne Hartley (SH) (Item: 2.1)
Karen Myers (IGARD Secretariat)
Andy Rees (Digi-Trials)
Vicki Williams (IGARD Secretariat)

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| 3 | <p>Welcome</p> <p>The IGARD Chair noted that this was a weekly meeting convened to support NHS Digital's response to the COVID-19 situation and was separate from the IGARD business as usual (BAU) meetings. IGARD members present would only be making comments and observations on items that were presented, and were not making formal recommendations to NHS Digital. Should an application require a full review and recommendation, then it should go through the usual Data Access Request Service (DARS) process and be presented at a Thursday IGARD meeting.</p> <p>The action notes from the Tuesday meeting will be received out of committee and then published alongside the minutes of the next Thursday BAU meeting as an appendix.</p> <p>Declaration of interests:</p> <p>There were no declarations of interest.</p> |
| 2.1 | <p><u>NIC-365354-R3M0Q-v7.3 University of Oxford</u></p> <p>Background: this was an update with regard to the Randomised Evaluation of COVID-19 Therapy (RECOVERY) Trial having been previously discussed at the COVID-19 response meetings on the 26th January 2021, 1st December 2020, 22nd September 2020, 21st July 2020, 7th July 2020, 19th May 2020, 12th May 2020, 5th May 2020, 28th April 2020 and 21st April 2020.</p> <p>The application and relevant supporting documentation had also been discussed at the IGARD business as usual (BAU) meetings on the 26th August 2021 (unable to make a recommendation as not all the necessary information was available in order for IGARD to make a full assessment), 12th November 2020 (recommendation to approve subject to amendments and advice), 30th July 2020 (recommendation to approve subject to conditions, amendments and advice) and 11th June 2020 (recommendation to approve subject to amendments and advice).</p> <p>NHS Digital had requested a meeting with IGARD to discuss the outcomes of the previous BAU Meeting discussion and next steps.</p> |

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| | <p>The following observations were made on the basis of the verbal update from NHS Digital, alongside v7.3 of the application summary and a limited number of supporting documents (SDs) 1.1, 11.1, 14, 15, 16 and 17 only.</p> <p>IGARD Observations:</p> <p>IGARD members noted that although 181 supporting documents had been provided as part of the suite of meeting papers, and were also available on NHS Digital’s Customer Relationship Management system (CRM), they had only been asked to review v7.3 of the application summary alongside a limited number of SD’s.</p> <p>IGARD members noted that due to the nature of the meeting should a full review of the application and documentation be required, the full suite of documentation should be presented to a IGARD business as usual (BAU) meeting for a recommendation.</p> <p>IGARD noted that all their comments made at the 26th August 2021 BAU meeting (when they had been unable to make a recommendation as not all the necessary information was available in order for IGARD to make a full assessment) remained live, in addition to any previous comments made at BAU or COVID-19 response meetings (where applicable) for example, their comments in March 2020 with regard to the consent materials. In addition to all points previously made, IGARD made a new observation that it might be useful to ask the applicant if the Trial Steering Committee had reviewed the onward sharing models (with both manufacturers and other researchers) and suggested that any minutes or documentation of such consideration be uploaded to NHS Digital’s CRM.</p> <p>IGARD members noted that the discussion today was not to pre-empt discussions that would take place at a future BAU meeting (and no later than 31st March 2022) and thanked NHS Digital for the update and looked forward to receiving the full suite of documentation at the BAU meeting in due course.</p> <p>Risk area: NHS Digital appear not to have followed internal due processes, ensuring relevant analyses are undertaken prior to utilising the precedent route and correctly documented and uploaded to NHS Digital’s CRM.</p> <p>Subsequent to the meeting: the IGARD Chair requested, via email, that the Caldicott Guardian (or their deputy) and the Director Clinical Trials (or their deputy) attend the BAU session of IGARD when this application is presented, and that adequate time be set aside on the BAU agenda to discuss this ground-breaking and important study.</p> |
| <p>2.2</p> | <p><u>NIC-411161-G4K7X-v4.4 University of Oxford</u></p> <p>Background: This was an update with regard to the PRINCIPLE trial which is the only national Urgent Public Health priority clinical trial evaluating potential therapeutics for COVID-19 in the primary care setting, endorsed by the four Chief Medical Officers, aiming to find out whether early treatment in the community speeds recovery and reduces the need for hospital admission for those with COVID-like-illness, having been previously discussed at the COVID-19 response meetings on the 9th February 2021, 10th November 2020 and 27th October 2020.</p> <p>The application and relevant supporting documentation had also been discussed at the IGARD business as usual (BAU) meeting on the 25th February 2021 (recommendation to approve subject to amendments and advice).</p> |

This was an extension, renewal and amendment because the agreement was due to expire on 30th September 2021 and NHS Digital were seeking support from IGARD to progress the application via the SIRO precedent, noting the amendment to this version of the application was to add the Medicines dispensed in Primary Care (NHSBSA data) to the existing output provided to University of Oxford, and the renewal and extension to the expiry of the COPI Notice on the 31st March 2022.

The following observations were made on the basis of the verbal update from NHS Digital, alongside v4.4 of the application summary only.

IGARD Observations:

NHS Digital verbally noted in-meeting that their request today was in relation to the extension and renewal **only**, and that the amendment would come to a full BAU meeting in due course, and not as stated in section 1 (Abstract).

IGARD members noted that although v4.4 of the application summary and 23 supporting documents had been provided as part of the suite of meeting papers, and were also available on NHS Digital's Customer Relationships Management (CRM) system, they had only been provided with v4.4 of the application as background only.

IGARD members noted that due to the nature of the meeting should a full review of the application and documentation be required, the full suite of documentation should be presented to a IGARD business as usual (BAU) meeting for a recommendation.

IGARD noted that their points made at the 25th February 2021 BAU meeting **remained live**. In addition, IGARD noted the following additional comments:

1. IGARD noted the constraints placed in the Direction for the collection of NHSBSA Medicines dispensed in Primary Care data, by NHS Digital, specifically "*Providing intelligence about the safety and effectiveness of medicines...*"; and asked that the application was updated throughout, to align with the scope of the Direction to ensure that the objectives, processing and outputs are permitted use of the data.
2. IGARD also asked, that a special condition was inserted in section 6 (Special Conditions), that any use of the NHSBSA data must be within the parameters of the relevant Direction authorising that collection.
3. IGARD reiterated their comment from the 25th February 2021 BAU meeting: "*IGARD queried whether the applicant would find the NHS Business Services Authority (NHS BSA) data more timely and complete to achieve their research goals outlined, **instead of the GPPR data requested, or as well as the GPPR data requested.** IGARD confirmed that they would be supportive of this flow of data should the applicant wish to apply for it via NHS Digital. In addition, and should the applicant apply for this data, that **an appropriate justification for this dataset should be included in section 5 (Purpose / Methods / Outputs), as appropriate.**" IGARD noted that if both data sets were requested (as appeared to be the plan) then a robust justification for the overlap between the data sets should be provided (in light of data protection data minimisation requirements).*
4. IGARD reiterated their comment from the 25th February 2021 BAU meeting (which had not been actioned by NHS Digital) namely: "*IGARD noted the Caldicott Guardian's assessment of the legal basis for access to SCR in supporting*

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| | <p><i>document 6, and suggested that the NHS Digital Data Access Request Service (DARS) Team, shared the Caldicott Guardian’s opinion with NHS Digital’s Privacy, Transparency and Ethics (PTE) (formerly Information Governance). IGARD asked that written confirmation be sought that PTE were content with the Caldicott Guardian’s assessment; and that the written confirmation was uploaded to NHS Digital’s customer relationship management (CRM) system for future reference.”</i></p> <p>IGARD members noted the verbal update from NHS Digital on this particular application and supported NHS Digital’s assessment that the application would be approved under the DARS SIRO precedent for a short term extension and renewal only. IGARD members noted that the discussion today was not to pre-empt discussions that would take place at a future BAU meeting (and no later than 31st March 2022) with regard to the amendment (to add NHSBSA data to the DSA) and thanked NHS Digital for the verbal update and looked forward to receiving the full suite of documentation at the BAU meeting in due course.</p> <p>IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, to ensure that the benefits have been appropriately detailed and PTE endorsement of the SCR approach. IGARD suggested that this application would not be suitable for NHS Digital’s Precedent route, including the SIRO Precedent, with the exception of this short term extension and renewal.</p> |
| <p>2.3</p> | <p><u>NIC-381634-X8H0H Public Health England (PHE)</u></p> <p>Background: The purpose of this application is to support the PHE surveillance system on household transmission of COVID-19 to enhance the national public health surveillance of COVID-19 infections in the population of England. COVID-19 laboratory and case data from PHE will be linked to NHS Digital controlled data sets using a one-way encrypted versions of NHS number and unique property reference number to identify the household contacts of COVID-19 patients. This linked dataset is called “HOSTED” and is used to establish the COVID-19 status and associated outcomes of these household contacts.</p> <p>Aspects of this application had last been last been discussed at the COVID-19 Response meeting on the 6th June 2020 under NIC-372789-B6Q2B PHE.</p> <p>The application and relevant supporting documentation had also been discussed at the IGARD business as usual (BAU) meeting on the 18th March 2021 (recommendation to approve subject to conditions, amendments and advice).</p> <p>NHS Digital noted that this was an extension and renewal because the agreement was due to expire on the 30th September 2021 and NHS Digital were seeking support from IGARD to progress the application via a DARS precedent.</p> <p>The following observations were made on the basis of the verbal update from NHS Digital, alongside v3.2 of the application summary only.</p> <p>IGARD Observations:</p> <p>IGARD members noted that although v3.2 of the application summary and 7 supporting documents had been provided as part of the suite of meeting papers, and were also available on NHS Digital’s Customer Relationships Management (CRM) system, they had only been asked to review v3.2 of the application.</p> |

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| | <p>IGARD members noted that due to the nature of the meeting should a full review of the application and documentation be required, the full suite of documentation should be presented to a IGARD business as usual (BAU) meeting for a recommendation.</p> <p>IGARD members noted the imminent transfer (on the 1st October 2021) of many PHE operations to the new UK Health Security Agency (UKHSA), and the update by NHS Digital at the BAU meeting on the 3rd June 2021 that all current DSAs would need to be revisited and aligned with the new organisational structure before the end of September 2021.</p> <p>IGARD noted that some of their points made at the 18th March 2021 IGARD BAU meeting remained live. In addition, IGARD noted the following additional comments:</p> <ol style="list-style-type: none"> 1. Noting that PHE’s Research Ethics & Governance Group (REGG) would presumably cease operating on the 30th September 2021, <ol style="list-style-type: none"> a. to provide documentary evidence, as a supporting document, that REGG approved the amendments outlined in the application presented to IGARD on the 18th March 2021, and b. to confirm where the PHE’s REGG governance is transferring to within the relevant successor organisation, and that the successor governance committee is kept apprised of the application, any amendments, and necessary permissions had been, or would be, granted. 2. IGARD reiterated their comment from the 18th March 2021 BAU meeting to provide a satisfactory update to the yielded benefits in section 5(d) (iii) to populate NHS Digital’s data release register and in line with NHS Digital’s DARS Standard for Expected Measurable Benefits. 3. IGARD were unclear if the DPIA had been updated to include reference to the ethnicity data and noting this is a significant special category dataset, and that confirmation be provided that the DPIA had been updated to specifically address the processing of ethnicity data. <p>IGARD members noted the update from NHS Digital on this particular application and supported NHS Digital’s assessment that the application would be approved under the DARS SIRO precedent for a short term extension and renewal only. IGARD members noted that the discussion today was not to pre-empt discussions that would take place at a future BAU meeting (and no later than 31st March 2022) with regard to the amendment (to add the Booster Vaccine Data) and thanked NHS Digital for the verbal update and looked forward to receiving the full suite of documentation at the BAU meeting in due course.</p> <p>IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the high profile and impactful nature of the application. IGARD suggested that this application would not be suitable for NHS Digital’s Precedent route, including the SIRO Precedent, with the exception of this short term extension and renewal.</p> |
| 3 | <p><u>AOB</u></p> <p>There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.</p> |

