Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 11th June 2020

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Prof. Nicola Fear	Specialist Academic Member
Kirsty Irvine (Chair)	IGARD Lay Chair
Dr. Imran Khan	Specialist GP Member
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Victoria Byrne-Watts	Data Access Request Service (DARS)
Louise Dunn	Data Access Request Service (DARS)
Duncan Easton	Data Access Request Service (DARS) **(Observer 2.1 - 2.4)**
Karen Myers	IGARD Secretariat
Heather Pinches	Data Access Request Service (DARS)
Kimberley Watson	Data Access Request Service (DARS)
Vicki Williams	IGARD Secretariat

1	**Declaration of interests:** Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising on COVID-19. Nicola Fear noted a professional link to applicants at the University of Oxford (NIC-359651-H3R1P), but noted no specific connection with the application and it was agreed this was not a conflict of interest. Maurice Smith noted professional links to AIMES Management Service (NIC-226185-B6C2J University of Hull) but no specific connection with the application or staff involved and it was agreed that there was no conflict of interest.

	Paul Affleck noted professional links to AIMES Management Service (NIC-226185-B6C2J University of Hull) but no specific connection with the application or staff involved and it was agreed that there was no conflict of interest. **Review of previous minutes and actions:** The minutes of the 28th May 2020 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record of the meeting. **Out of committee recommendations:** An out of committee report was received (see Appendix A).
2	**Data Applications**
2.1	<u>Ernst and Young LLP: Renewal - Bespoke Extract (Louise Dunn) NIC-369596-F6Q9V</u> **Application:** This was an extension and renewal application for pseudonymised Secondary Uses Service (SUS) Payment by Results (PbR) data; and an amendment to add Microsoft Azure Cloud Storage as a data processor, as well as a data processing and storage location. The purpose of requesting the data is to calculate relevant local and national Key Performance Indicators (KPIs) to share with clients and so that the applicant can quickly, and with insight, be responsive to tenders from the health and social care community. The application was been previously considered on the 9th April 2020 when IGARD had deferred pending: to revise section 5(e) to ensure compliance with NHS Digital's Commercial Purpose Standard 5(e) including (but not limited to); a) clarity on all aspects of the commercial elements of the arrangements, b) to specifically address whether the data will be used to respond to tenders; and c) to clarify if other tenderers will have access to the same information. To insert a special condition in section 6 in respect of the VDI protocol, to ensure that any users who are accessing data (apart from aggregated data with small numbers supressed) are physically located in England and Wales when logging on remotely and suggest using similar wording as advised by the NHS Digital Security Advisor for other commercial organisations with similar arrangements. To provide further information on the 'Health Data Panel' outlined within the application and supporting documentation and provide evidence that they have been functioning as described in the supporting document and a summary report, for example in the form of sample minutes and sample advice given by the Panel. To make a definitive statement in section 5(a) that there are no international clients or projects and that no international healthcare organisations will receive any products derived from this data. To remove reference to the LIA from section 5(d) and to move this into section 5(a); and to remove reference to the international healthcare organisation(s). To provide a copy of the data destruction certificates, to include a reference to this in section 1 and to upload the documents to NHS Digitals CRM system. To update section 5(d) to ensure the benefits outlined are explained in a way that is suitable for a lay audience. To review section 5(d) to ensure that when referring to the projected savings, consideration is given to instead using terms such "transactional costs" and "reflected in alternative provision". To remove reference to the ICO Code of Practice from section 3(b) and / or amend in line with a form of wording agreed with NHS Digital IG. To amend section 8 to align the data retention date with the Data Sharing Agreement end date. IGARD suggested that NHS Digital might wish to consider a short-term extension to permit the applicant to hold, but not in any other way process, the data while work was undertaken to address the queries raised by IGARD. IGARD suggested that the applicant may wish to consider PPI involvement on the Health Data Panel.

	Discussion: IGARD noted that the application had been updated to reflect most of the comments previously made. IGARD noted that during the previous review of the application on the 9th April 2020, a request had been made of sample minutes from the 'Health Data Panel' that was established in 2016; and noted that supporting document 5.1, the Health Data Panel minutes from the 14th March 2018 had been provided. IGARD requested that that the applicant provide the most recent example of the Health Data Panel minutes since those provided were aged. In addition, IGARD also reiterated the point previously suggested that the applicant may wish to consider effective patient and public involvement (PPI) on the Health Data Panel, since the Panel appeared to consist mainly of experts. IGARD again noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices, and advised that this had also been raised by its predecessor, the Data Access Advisory Group (DAAG), and IGARD at the last review. IGARD therefore asked that a special condition was inserted in section 6 (Special Conditions) stating that no data would flow until such time as a General Data Protection Regulation (GDPR) compliant Privacy Notice, as assessed by NHS Digital, had been published; which related to the specific processing as set out in this Data Sharing Agreement (DSA) and supported the stated Legitimate Interest Assessment (LIA). IGARD queried the statement in section 5(b) (Processing Activities) that stated *"Data will not leave the EEA (European Economic Area) unless aggregated…",* and in light of the information in section 2(c) (Territory of Use) that stated the territory of use would be England Wales asked that section 5 (Purpose / Methods / Outputs) was updated to make clear throughout that record level data would not leave England and Wales, including, but not limited to, removing any reference to the European Economic Area (EEA). In addition, IGARD also asked that section 5 was updated to clearly state that the only data that would be shared would be aggregated numbers with small numbers supressed. IGARD noted that section 5(a) (Objective for Processing) referred to the applicant's projects falling into *"five categories"*, noting that background information was only provided on four categories, and asked that this was updated to ensure the correct number of datasets was accurately reflected or to include background information on the fifth category. IGARD queried the statement in section 5(d) (Benefits) to the applicant's activities being *"…essential to the future of the NHS"*, and asked that this hyperbolic statement was removed. IGARD noted that the Data Sharing Agreement was only until November 2020 and suggested that NHS Digital may wish to consider an agreement timeframe that expired at the end of this calendar year to ensure that the applicant had sufficient time to process the data and update the benefits and yielded benefits with more up to date, realistic and achievable projects and plans. IGARD suggested that they would wish to review this application again when it comes up for renewal, extension or amendment; and that this application would not be suitable for NHS Digital's Precedent route. **Outcome Summary:** recommendation to approve subject to the following conditions: 1. To provide the most recent example of the 'Health Data Panel' meeting minutes. 2. To insert a special condition in section 6 stating that no data will flow until such time as a GDPR-compliant Privacy Notice, as assessed by NHS Digital, has been published; which relates to the specific processing as set out in this DSA and supports the stated LIA.

	The following amendments were requested: 1. To update section 5 to make clear throughout that record level data will not leave England and Wales, including (but not limited to) removing any reference to the EEA. 2. To update section 5 to clearly state that the only data that will be shared will be aggregated numbers with small numbers supressed. 3. To update section 5 to ensure the correct number of datasets is accurately reflected. 4. To update section 5(d) to remove the reference to the activities being *"essential to the NHS"*. The following advice was given: 1. IGARD suggested that NHS Digital may wish to consider an agreement timeframe that expires at the end of the calendar year, to ensure the applicant has sufficient time to process the data and update the benefits and yielded benefits with more up to date, realistic and achievable projects and plans. 2. IGARD suggested that the applicant may wish to consider PPI involvement on the Health Data Panel. 3. IGARD advised that they would wish to review this application again when it comes up for renewal, extension or amendment. 4. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route. It was agreed the conditions would be approved Out of Committee (OOC) by IGARD members.
2.2	Northgate Public Services (UK) Limited: National Joint Registry Annual Extract 2020 (Presenter: Louise Dunn) NIC-07289-G8J6C **Application:** This was a renewal application for identifiable Hospital Episode Statistics (HES) data, Patient Reported Outcome Measures (PROMs) and Civil Registrations data; and an amendment to 1) add NHS England as a joint Data Controller, 2) remove Sunguard as a Storage Location, 3) to add Gyron Internet Ltd as Data Processor and a Processing / Storage Location, 4) to remove Iron Mountain as Data Processor and Processing Location. The National Clinical Audit and Outcomes Programme (NCAPOP) is a large programme of circa 35 projects consisting of National Clinical Audits. The application was been previously considered on the 7th May 2020 when IGARD had deferred pending: In relation to patient safety: To confirm if this is referring to 'general' patient safety for all patients **or** patient safety specific to individuals. To provide clarification of how this issue was dealt with by HRA CAG and which of the supporting documents covers the legal basis for this. To provide a copy of the HRA CAG letter dated the 5th February 2019, which confirms the initial condition of approval referencing the linkage of data is not now taking place or, if this letter is not available, to provide a copy of the annual review or confirmation of its submission to HRA CAG by way of an email. To provide confirmation within the application that there are no sub-licenses permitted under this DSA, in light of the information provided in the supporting documents and clarify this within section 5(a) of application. To provide a copy of the February 2020 consent materials as published on the study website and provide confirmation that the applicant has addressed the opt out issue raised by PIAG, and if addressed how they have complied. To provide confirmation that the University of Bristol has destroyed all historical data and provided data destruction certificates. To explain why, given the updated consent the applicant is continuing to rely on s251 for the linkage of data to NHS Digital and why the updated consent did not address the linkage for those patients consenting to participate in the NJR with reliance on s251 only for those individuals where they have not

	been able to obtain consent. To provide the analyses of the cohorts and tasks, and the legal basis for the individual streams and to update the Data Flow Diagram to reflect this information. IGARD suggested whether the applicant may wish to consider whether a rolling data set would be more appropriate rather than chunks of data, via numerous applications. **Discussion:** IGARD noted that the application had been updated to reflect some of the comments previously made. IGARD noted that during the previous review of the application on the 7th May 2020, they had requested the Health Research Authority Confidentiality Advisory Group (HRA CAG) letter dated the 5th February 2019, as referred to in supporting document 23, the s251 annual review form, which specifically referred to an initial condition of approval referencing the linkage of data, and that this was now not taking place be provided. IGARD advised that this had still not been provided and reiterated the request for this document. IGARD also requested again, that confirmation was provided that the applicant had addressed the opt out issues raised by the Patient Information Advisory Group (PIAG) in supporting document 15, and if this has been addressed, how they have complied. IGARD noted they had previously asked for confirmation that the University of Bristol had destroyed all historical data and had provided data destruction certificates; and discussed the update from NHS Digital that the historical data had not been destroyed and that they must not process this data further until this agreement is approved. IGARD asked that the application was updated throughout to accurately reflect the data currently held by the University of Bristol and the data that would be held by them in the future. IGARD discussed the previous points raised on the cohorts and legal bases for these, and asked that further information was provided clearly setting out the different types of processing of the data, for each cohort; and in respect of each cohort, outline the legal bases and processing permitted by the s251 support and draw the distinction between the research and safety aspects, as the permitted processing is different between these cohort. IGARD queried if consideration had been given to further routes of communication for both the cohort and the interested general public with regard to current and future treatment(s), beyond the publication of the annual report, and asked that section 5(c) (Specific Outputs Expected) was updated with further information. IGARD suggested that NHS Digital may wish to consider auditing this organisation in relation to this application / Data Sharing Agreement. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. IGARD suggested that they would wish to review this application again when it comes up for renewal, extension or amendment; and that this application would not be suitable for NHS Digital's Precedent route. **Outcome Summary:** Recommendation to defer, pending: 1. To provide a copy of the HRA CAG letter dated the 5th February 2019, which confirms the initial condition of approval referencing the linkage of data is not now taking place (the letter as referred to in paragraph 9, page 4, SD23). 2. To provide confirmation that the applicant has addressed the opt out issue raised by PIAG, and if addressed, how they have complied. 3. To update the application throughout to accurately reflect the data currently held by the University of Bristol and the data that will be held by them in the future. 4. To clearly set out the different types of processing of the data, divided into cohort groups; and in respect of each cohort group, outline the legal bases and processing

	permitted by the s251 support and draw the distinction between the research and safety aspects (as the permitted processing is different between these cohort groups). 5. To update section 5(c) to outline if consideration has been given to further routes of communication for both the cohort and the interested general public, beyond the publication of the annual report. 6. IGARD suggested that NHS Digital may wish to consider auditing this organisation in relation to this application / Data Sharing Agreement. 7. IGARD advised that they would wish to review this application again when it comes up for renewal, extension or amendment. 8. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route.
2.3	<u>NorthWest EHealth Limited: Retrospective data analysis of HES and DID data from patients with Refractory Chronic Cough (RCC) who have given consent for their electronic healthcare records to be used in the analysis of healthcare resource utilisation. (Presenter: Louise Dunn) NIC-290527-P5C0Y</u> **Application:** This was a new application for identifiable Hospital Episode Statistics (HES) and Diagnostic Imaging Dataset (DIDs) data for a feasibility study aiming to increase the understanding of the profile and characteristics of patients with unexplained Refractory Chronic Cough (RCC) by understanding the healthcare resource utilisation (HRU) and treatment patterns of these patients. The primary objective of the initial work is: To determine the outpatient and primary care healthcare costs in the 5-years prior to a diagnosis of RCC, compared to a control cohort, matched by demographics and smoking status. The application had previously been presented to IGARD on the 6th February 2020 and IGARD had recommended for approval subject to conditions: 1) NHS Digital Security to approve and sign-off the data security arrangements for Merck Sharp & Dohme Limited (MSD), and before data can flow; 2) The applicant to update and publish their Privacy Notice ensuring the points raised as part of NHS Digital's fair processing criteria for privacy notices are addressed; 3) To insert a special condition in section 6 stating that MSD will not have general access to the data for this application, and if access is required for audit purposes, that this will take place within Manchester University NHS Foundation Trust premises; and that no data will flow outside of England and Wales. NHS Digital advised that the conditions had **not** been met within the 3 months following the meeting on the 6th February 2020 and reviewed as per usual process. **Discussion:** IGARD queried if an assessment had been undertaken in respect of the Data Controller(s) and Data Processor(s) for this application, and were advised by NHS Digital that an extensive assessment had been undertaken to determine the correct Data Controller(s) and Data Processor(s). IGARD noted the update from NHS Digital and confirmed that they were satisfied the relevant enquires had been completed and the correct Data Controller(s) and Data Processor(s) had been identified. IGARD also asked that the application was reviewed throughout to ensure that the language was consistent with the role of the Data Controllers and Data Processors when referring to the parties involved, for example when using the term "partnership". IGARD queried the role of Merck Sharp & Dohme Limited (MSD), in light of the inconsistent information provided in the application and supporting document 8, the data flow diagram, and asked that an explanation was provided as to what data MSD were accessing, where they were accessing the data from and for what reason; and that the application be updated

	accordingly; or if the application was correct, to update the privacy notice to accurately reflect what is happening. In addition, IGARD also noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. IGARD suggested that they would wish to review this application again when it comes up for renewal, extension or amendment; and that this application would not be suitable for NHS Digital's Precedent route. IGARD also advised when this application returns to IGARD, they would expect to see further information provided in section 5 (Purpose / Methods / Outputs), for example with regard to the *"urgency"* reference and the statement *"This study is an initial analysis to see if it is even worth MSD focusing their research on RCC"*. **Outcome Summary:** recommendation to approve subject to the following conditions: 1. To provide an explanation as to what data MSD are accessing, where they are accessing the data from and for what reason; and that the application be updated accordingly; or if the application is correct, to update the privacy notice to accurately reflect what is happening. The following amendments were requested: 1. To review the application throughout to ensure that the language is consistent with the role of the Data Controllers and Data Processors when referring to the parties involved. 2. To update section 5 to ensure consistency of language throughout. The following advice was given: 1. IGARD advised that they would wish to review this application again when it comes up for renewal, extension or amendment. 2. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route. It was agreed the conditions would be approved Out of Committee (OOC) by IGARD members
2.4	<u>University of Oxford: R1 (D09) - Data support to COVID-19 RCT (Presenter: Vicky Byrne-Watts / Heather Pinches) NIC-365354-R3M0Q</u> **Application:** This was an amendment application to include GPES Data for Pandemic Planning and Research (COVID-19), the applicant is requesting to use the NHS Digital Clinical Trials Service for access to data for a study entitled Randomised Evaluation of COVid-19 thERapY (RECOVERY). There are currently no approved treatments for COVID-19, this study aims to compare several different treatments that may be useful for patients with COVID-19, that have been recommended by an expert panel that advises the Chief Medical Officer in England. This trial allows reliable assessment of the effects of multiple different treatments (including re-purposed and novel drugs) on major outcomes in COVID-19. NHS Digital advised IGARD, that following submission of the application for review, there had been some changes to the trial and that the application would need amending to reflect the latest information. **Discussion:** IGARD noted that this application had been previously reviewed by the IGARD – NHS Digital COVID-19 Response meetings on the 28th April, 5th May and 12th May 2020; and in addition, that this application had also been reviewed at the GPES Data for Pandemic Planning and Research – Profession Advisory Group (see Appendix B) on the 4th June 2020. IGARD noted the update from NHS Digital in relation to the changes to the trial and asked that section 5 (Purpose / Methods / Outputs) was updated to ensure the latest COVID-19

	information was reflected, including, but not limited to, the scale and description of the pandemic. IGARD noted that the data retention period for the study, stated within the applicant's privacy notice was 25 years, however the date stated within the application was to retain the data until 2030 and asked the correct data retention period was aligned across the application and supporting documents. IGARD noted the good work being undertaken by the trial and because this was a potentially long running study with potentially long term health impacts that an outline was provided of the work already being undertaken with NHS DigiTrials and the University of Oxford's overarching Patient and Public Involvement (PPI) engagement, and that further consideration was given to a study-specific patient group. IGARD queried information provided in section 5(b) (Processing Activities) in relation to the data access and data transfer, for example the statement *"NHS Digital will send the extracts of data (baseline and deltas) to a 'Message Exchange for Social Care and Health' MESH mailbox"* and asked that section 5 was updated to reflect that data was being accessed via a 'Secure File Transfer Protocol' (SFTP) or MESH account. IGARD queried the information provided in section 5(d) (Benefits), specifically in relation to the statement that it would *"improving the health of the whole population"*; and were advised by NHS Digital that this could signal a new platform approach to conducting trials and the wider benefits that can flow from this innovation. IGARD noted the update from NHS Digital and asked that section 5(d) was updated to reflect this. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. IGARD suggested that they would wish to review this application again when it comes up for renewal, extension or amendment; and that this application would not be suitable for NHS Digital's Precedent route. **Outcome Summary:** recommendation to approve The following amendments were requested: 1. To align the data retention period across the application and supporting documents. 2. To provide an outline of the work already undertaken with NHS DigiTrials and the University of Oxford's overarching PPI engagement, and to give consideration to a study-specific patient group since this is a long running study. 3. To update section 5 to ensure the latest COVID-19 information is reflected, including (but not limited to) the scale and description of the pandemic. 4. To update section 5 with regard to data access and data transfer, to reflect that the data is being accessed via a secure SFTP or MESH account. 5. To update section 5(d) to reflect *how* the benefits can accrue to the whole population, for example, how this could signal a new platform approach to conducting trials and the wider benefits that can flow from this innovation. The following advice was given: 1. IGARD advised that they would wish to review this application again when it comes up for renewal, extension or amendment. 2. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route.

2.5	Health IQ Ltd: Health iQ - Benchmarking and reporting (Presenter: Kimberley Watson) NIC-15293-R6V2H **Application:** This was a renewal and extension application for pseudonymised Hospital Episodes Statistics (HES) and Emergency Care Data Set (ECDS); and an extension to extend the years of data permitted to be retained on the Vantage online tool; and an amendment to extend the years of data permitted to be retained in the Vantage online tool from 3 years plus the current provisional year to 5 years plus the current provisional year so a maximum of 6 years of data will be held at any one time; and to utilise the use of a Cloud (Amazon Web Services). The purpose of the application is to support the Vantage online tool that produces dashboards and reports to support the delivery of healthcare and the delivery of key healthcare strategic priorities; which include the NHS Five-Year Forward View, Quality, Innovation, Productivity and Prevention (QIPP) targets and Joint Strategic Needs Assessment (JSNA) targets. Potential users of the reports are NHS (Provider Trusts, GPs etc), Commissioning Support Units (CSUs), Governmental organisations, Social Care, Charities and Life Science organisations. The application was been previously considered on the 30th January 2020 when IGARD had been unable to recommend point 4 (additional years) for approval pending: the application being uplifted to meet NHS Digital's Standards including Sub-Licencing and Onward Sharing of Data and the Commercial Purpose Standards. A robust Legitimate Interest Assessment being articulated, in particular, linking it to the specific processing outlined within the application. **Discussion:** IGARD had a lengthy discussion on the territory of use, in light of the information within the application that referred to "worldwide outputs" and asked that it was made explicitly clear that the territory of use related to the applicant's controllership of processing data to feed into the Vantage tool in England and Wales, and that further detail be provided with regard to how this related to the reference to the *"worldwide outputs"* within the application. IGARD also noted the statement in section 5(a) (Objective for Processing) that stated "*Processing of the data is restricted to within England, but outputs are anonymous, aggregate and small-number suppressed and therefore could be used worldwide"* and asked that this was replicated in section 6 (Special Conditions) as a special condition. There was a lengthy discussion on the Vantage tool, in particular the involvement of pharmaceutical organisations, and IGARD asked that confirmation was provided of the level of the pharmaceutical organisation(s) uptake of the tool and likely involvement, for example, by providing a clear worked example of how they might use the Vantage tool and how they would use the outputs, since it was not clear if they were just producing reports from the tool or using it as a means for the promotion of any drug(s). In addition, IGARD also asked that it was explicitly clear within the application that a Vantage tool user could only see aggregated data with small numbers suppressed and do not at any stage have a view of the underlying data, since it was not clear if the user could see any underlying pseudonymised data. IGARD noted the achieved outputs that were outlined in section 5(c) (Specific Outputs Expected) and asked that section 5(d) (Benefits) iii (Yielded Benefits) was updated to reflect these specific outputs. IGARD noted the information provided in section 5(c) relating to the *"Outputs relating to Objective 2"* and asked that this was reviewed to ensure that all acronyms upon first use be defined and further explained, as may be necessary for a lay reader, for example *"VOC"*. In

addition, IGARD also asked that further information was provided on *"Meningococcal disease"* as referenced.

IGARD queried statements made within the application, for example when referring to list of potential users of the reports, and asked that the application was reviewed throughout to specifically review any hyperbolic statements made.

IGARD noted the addition of Amazon Web Services as a Data Processor and asked for a further explanation of the division of tasks between Amazon Web Services and UK Fast, since it was not clear within the application.

IGARD noted that supporting document 1.2, the terms and conditions for the Vantage tool was dated 2017, and asked if a more up to date document was available, noting that the version provided referred to outdated legislation, for example, the Data Protection Act 1998.

IGARD suggested the applicant may wish to consider oversight or governance of the granting of licences to use the tool, and whether this could be incorporated into the patient and public involvement (PPI).

Outcome Summary: recommendation to approve subject to the following conditions:

1. In respect of Territory of use:
    a) To be explicitly clear that the territory of use relates to the applicant's controllership of processing data to feed into the Vantage tool in England and Wales, and how this relates to the reference to the *"worldwide outputs"* within the application.
    b) To replicate the statement in section 5(a) that states *"Processing of the data is restricted to within England, but outputs are anonymous, aggregate and small-number suppressed and therefore could be used worldwide"* as a special condition in section 6.
2. In respect of the Vantage tool:
    a) To provide confirmation of the level of pharmaceutical organisation(s) uptake of the tool and likely involvement, for example, by providing a clear worked example of how they might use the Vantage tool and the outputs.
    b) To make it explicitly clear within the application that a Vantage tool user can only see aggregated data with small numbers suppressed and do not at any stage have a view of the underlying record level data.

The following amendments were requested:

1. To update the yielded benefits in section 5(d) (iii) with the achieved outputs outlined in section 5(c).
2. In respect of the "Outputs relating to Objective 2" within section 5(c):
    a) to ensure that all acronyms upon first use be defined and further explained, as may be necessary for a lay reader, for example *"VOC"*.
    b) to provide further information on *"Meningococcal disease"* as referenced.
3. To review the document throughout to review any hyperbolic statements made, for example, the list of potential users of the reports.
4. To explain the division of tasks between Amazon Web Services and UK Fast.
5. To provide a more up to date terms and conditions document for the Vantage tool, noting the current version refers to outdated legislation.

The following advice was given:

1. IGARD suggested the applicant may wish to consider oversight or governance of the granting of licences to use the tool, and whether this could be incorporated into the PPI group.

	It was agreed the conditions would be approved Out of Committee (OOC) by IGARD members.
2.6	University of Bristol: Learning Disabilities Mortality Review Programme - ONS mortality data link (Presenter: Kimberley Watson) NIC-121996-T2R7B **Application:** This was a renewal and extension application for pseudonymised Civil Registration data; and an amendment to remove Healthcare Quality Improvement Partnership (HQIP) as the Data Controller and to add NHS England. The overall purpose is to link data about people with learning disabilities who have died, with mortality data, to identify the exact cause of death of people with learning disabilities in England. Analysis of Medical Certificates of Cause of Death (MCCD) is important for monitoring the health of the population, designing and evaluating public health interventions, recognising priorities for medical research and health services, planning health services, and assessing the effectiveness of those services. However, at present, people with learning disabilities can't be identified from analyses of MCCD or population level vital statistics, so there is little information about causes of death at population level in relation to people with learning disabilities, nor of ways in which services should be prioritised in relation to avoiding premature mortality in this population group. NHS Digital advised IGARD that following submission of the application to IGARD for review, that they had received a verbal update from the Health Research Authority Confidentiality Advisory Group (HRA CAG) confirming that the s251 conditions had been met and that the support was now unconditional, and that written confirmation of this was to be issued imminently. **Discussion:** IGARD welcomed and supported the application and noted the importance of the study. IGARD noted the update from NHS Digital in relation to the HRA CAG letter confirming that that the s251 conditions had been met and that the support was now unconditional however since this was a verbal communication between the applicant and NHS Digital asked that the applicant provide written evidence, for example an e-mail of the verbal confirmation from HRA CAG that a supporting letter was forthcoming. In addition, IGARD also asked that once the letter from HRA CAG had been received, that a copy of this was uploaded to NHS Digital's Customer Relationship Management (CRM) system. IGARD queried information provided in section 5 (Purpose / Methods / Outputs) in relation to the aims and processing, and asked that this was revised to ensure that the aims outlined in section 5(a) (Objective for Processing) were correctly aligned with the processing outlined in section 5(b) (Processing Activities). In addition, IGARD also asked that confirmation was provided as to whether the mortality data flows were linked to the data on the University of Bristol server since this information was not clear within section 5. IGARD queried the role of the NHS South Central and West Commissioning Support Unit (CSU), noting that there was a reference to them in a supporting e-mail provided and asked that NHS Digital consider why they were not a joint Data Processor; and to consider if they and any other additional Data Processors could be added to the Data Sharing Agreement (DSA) now, contingent on suitable approvals being obtained in the future, for example HRA CAG and others. IGARD suggested that although a privacy notice was not required under the General Data Protection Regulation (GDPR) due to the study relating to deceased individuals, this could still be updated as a useful source of transparency information for next of kin of the deceased and should offer useful information with regard to the study and contact details of the researcher.

	Outcome Summary: recommendation to approve subject to the following conditions: 1. The applicant to provide written evidence (for example an email filenote) of the verbal confirmation from HRA CAG that the support was unconditional and that a supporting letter was forthcoming. 2. To revise section 5 throughout to ensure that: a) the aims outlined in section 5(a) are aligned with the processing outlined in section 5(b). b) confirmation is provided as to whether the mortality data flows are linked to the data on the University of Bristol server. The following amendments were requested: 1. To upload the letter confirming unconditional support from HRA CAG to NHS Digital's CRM system upon receipt. 2. NHS Digital to consider why NHS South Central and West CSU are not considered joint Data Processors; and to consider if they and any additional Data Processors can be added to the DSA now, contingent on suitable approvals being obtained in the future (e.g. HRA CAG and others). The following advice was given: 1. IGARD suggested that although a privacy notice was not required under GDPR due to the study relating to deceased individuals, this could still be updated as a useful source of transparency information for next of kin of the deceased and should offer useful information with regard to the study and contact details of the researcher. It was agreed the conditions would be approved Out of Committee (OOC) by IGARD members.
3	<u>Returning Applications</u> 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. • NIC-14340-R7G1F Meditrends • NIC-226185-B6C2J University of Hull • NIC-359651-H3R1P University of Oxford IGARD welcomed the three applications as part of their oversight and assurance role and noted a number of comments to NHS Digital and suggested that further information and comments be provided in an IGARD Oversight and Assurance Report. Moving forward, IGARD agreed that COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 applications may also be included as part of the oversight and assurance review, not just those that were approved via NHS Digital's precedent route.
4	<u>COVID-19 update</u> 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 COPI regulation 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.

	The ratified action notes from Tuesday 2nd June and Tuesday 9th June 2020 can be found attached to these minutes as Appendix B. IGARD noted that there were no additional COVID-19 related items to discuss at this week's meeting.
5	<u>AOB:</u> 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.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 05/06/20

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-316443-V5Z4Y	University of Oxford	23/04/2020	1. To provide written justification for the quantum of data requested, in line with NHS Digital's Data Minimisation Standard 3, confirming how each of the points in the Standard have been considered and addressed. 2. To provide confirmation that the condition of the NJR approval in SD8 does not prohibit NHS Digital from flowing mortality data.	IGARD members	Quorum of IGARD members	*"In respect of condition 1, IGARD would be content this had been met if there was an express statement in the application along the lines of..."each element of the NHS Digital Data Minimisation Standard has been considered and NHS Digital is satisfied that they have been addressed"*
NIC-322051-S8N9N	University of Aberdeen	30/04/2020	1. To provide written confirmation of the exact involvement of the commercial organisation(s) and their activity in respect of this study, and to provide details of any funding or any other material benefits provided by or to these commercial organisations. 2. To confirm if there is a version 9 of the study Protocol and if so, to provide a copy to IGARD. 3. If relevant, to update section 5 and section 8 with further details of the involvement of the commercial organisations and funding. 4. To produce a suitable communication plan with specific timeframes for communication with the participants of the cohort.	IGARD members	Quorum of IGARD members	*"Even though the existence of condition 4 has been disputed, it is IGARD'S view the applicant has in fact satisfied the* **spirit** *of condition 4 with the additional level of detail that they have provided, as highlighted below, and further reinforced with the special condition."*

NIC-296034-T4Y4K	IQVIA Solutions UK Limited	09/04/2020	1. To provide evidence of effective honorary contracts as referred to in the agreement (and in the case of those personnel from IQVIA entities, IGARD suggested that any reference to inter-company personnel moves are recorded as secondment agreements rather than “honorary contracts”). 2. To update section 5(a) and section 5(e) to ensure that Janssen-Cilag Limited’s involvement and motivation is clearly articulated including (but not limited to) that they are a pharmaceutical company that may be the body to develop novel drug treatment on the basis of the research being carried out.	IGARD members	Quorum of IGARD members	
NIC-249035-R2Z5Y	Northumbria Healthcare NHS Foundation Trust	02/04/2020	1. The applicant to update the study website to ensure: a) That it is compliant with the GDPR notice requirements. b) There is a clear and accurate description of the data flow process. c) It is clear that no “anonymised” data will be flowing to NHS Digital. d) There is a full and transparent description of all aspects of the study, including (but not limited to) the involvement of the commercial funders.	IGARD members	Quorum of IGARD members	“To make the privacy notice itself more accessible by referring to it as such. I.e. ”Data processing statement/Privacy Notice” rather than simply “Data processing statement” as it is currently listed on the applicants website.” “To ensure the Privacy Notice is in PDF format rather than a Word document since it is for information not editing.”

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 notified to IGARD

Appendix B

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Thursday, 4th June 2020

Application: DARS-NIC-365354-R3M0Q **Organisation name: NHS Digital** **Profession Advisory Group Agenda item: 1**
The Group supported this application. The Group would recommend that the transparency material is updated to be in line with the detail within the application, including the fact that Primary Care data would not be shared outside the University. The Group notes NHS Digital's Trusted Research Environment, and asks that it could be considered to support such work in the future, rather than requiring extracts of data.

Attendees	Role	Organisation
Arjun Dhillon	Chair, Caldicott Guardian	NHS Digital
Garry Coleman	Associate Director of Data Access	NHS Digital
Anu Rao	GPC IT Policy Lead	BMA
Amir Mehrkar	GP, Clinical Researcher	RCGP
Julian Costello	GP	RCGP
Peter Short	Clinical Lead GP	NHS Digital
Pam Soorma	Secretariat	NHS Digital
Helen Buckels	Secretariat	NHS Digital

Appendix C

Independent Group Advising on the Release of Data (IGARD)

Action Notes from the IGARD – NHS Digital COVID-19 Response Meeting

held via videoconference, Tuesday, 2 June 2020

In attendance (IGARD Members):	Prof. Nicola Fear (Specialist Academic Member)
	Kirsty Irvine (Lay Chair)
	Dr. Geoffrey Schrecker (Specialist GP Member)
In attendance (NHS Digital):	Vicky Byrnes-Watts
	Catherine Day
	Louise Dunn
	Dickie Langley
	Kimberley Watson
	Vicki Williams
In attendance (external):	Natasha Dunkley (item 2.1)

1	**Welcome** 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 any 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 DARS process and be presented at a Thursday IGARD meeting. The action notes from the Tuesday meeting would be received at the next Thursday meeting of IGARD and published as part of those minutes as an appendix. **Declaration of interests:** Nicola Fear noted a professional link with University College London [item 2.3] and that she knew members of the study team, however she had no specific connection with the application and it was agreed that this was not a conflict of interest. Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising on COVID-19.
2.1	Health Research Authority Confidentiality Advisory Group (HRA CAG) Natasha Dunkley, Head of the Confidentiality Advice Service, noted that currently HRA CAG was providing informal advice, not under its usual statutory powers, for research only applicants obtaining local data with regards to COVID-19. The route for non-research applications seeking national data was via the NHS X front door process which also engages with HRA who may seek informal advice from the CAG. HRA CAG had raised queries with regard to the situation once the COPI* Notice expires noting that it was likely to be extended beyond the 30 September 2020. CAG was currently

	advising applicants relying upon the COPI notice to ensure that they had the relevant legal bases in place post-COPI Notice expiry. NHD Digital noted that they had a system in place and for those applications relying on s251 that had extended their purpose for COVID-19 related datasets. In addition it was noted that the vast majority of data releases from NHS Digital were to national bodies such as NHS England with regard to managing the pandemic and that they were aware of the requirements when the COPI Direction ceases. IGARD members raised a query with regard to the data destruction once COPI ceased and should the applicant not have adequate legal bases in place and that a pragmatic solution between IGARD, DARS and HRA CAG should be sought such as a special condition in the section of the NHS Digital application that the applicant may hold but not process data on expiry of the COPI Notice and until relevant legal bases were in place. IGARD members noted the national data opt outs did not apply to data under the COPI Notice but that they would apply under Regulation 5 COPI applications and that NHS Digital should flag to the applicant whether consideration be given to applying national data opt outs under the current COPI Regulations. NHS Digital and IGARD thanked Natasha Dunkley for attending and suggested that she, on behalf of HRA CAG, may wish to attend a future COVID-19 response meeting in early August 2020. *Health Service Control of Patients information (COPI) Regulations 2002
2.2	<u>NIC-372789-B6Q2B Public Health England (PHE) HOSTED Project</u> **Background:** This was an update to the application presented for advice on the 5th May and the verbal update to the COVID-19 Response meeting on the 12th May 2020. The application is to assess the overall transmissions of COVID-19 against the transmission for people currently at a stated address. Presently there is no consistent data indicating household contact status within COVID-19 surveillance and monitoring datasets held by PHE in order to model scenarios. Existing NHS Digital datasets can be used to identify individuals with the same address and this linkable asset would enable PHE to undertake a range of analysis to support the pandemic response. NHS Digital noted that a sunset clause had been linked to the Health Service Control of Patient Information (COPI) Regulations 2002 and that NHS Digital's Information Governance (IG) directorate had asked that a data sharing agreement (DSA) be put in place via Data Access Request Service (DARS) to formalise the sharing of the data. There were several other points for consideration raised in supporting documents provided to IGARD. **IGARD Observations:** IGARD members noted these points and thanked NHS Digital for providing an update to the meeting. Members asked for clarification of the number of records shared thus far. IGARD members noted that following the discussion with Health Research Authority Confidentiality Advisory Committee (HRA CAG) earlier in the meeting, it was clear that if the purpose was COVID-19-related and fitted under the COPI Regulations, then at this current point in time HRA CAG did **not** wish the applicant to submit an application for s251 support. However, since it was a potentially long-running and important study, PHE should have a plan

	in place to ensure it could transition from COPI to s251, and to have this paperwork lined up in good time before the expiry of the COPI Direction. IGARD members noted that the Data Privacy Impact Assessment (DPIA) was evolving in line with the application. IGARD members noted the request for the identifying unique property reference number (UPRN). In line with how ordnance survey (OS) grid reference data is outlined in NHS Digital's Hospital Episode Statistics (HES) dictionary of terms, IGARD suggested that the UPRN should have the same oversight and assurance as given to OS grid reference requests (ie express IGARD oversight) and as a condition of further data use. IGARD noted that they would welcome sight of the updated privacy notice published on the PHE website.
2.3	University College London (no NIC reference available) **Background:** This was verbal update along with a draft protocol that outlined the study which aims to use longitudinal linked data from education, social care and hospitalisation records to assess the impact of the COVID-19 pandemic on vulnerable children and young people (CYP) and derive these vulnerability indicators from a linked longitudinal dataset comprising social care, education and Hospital Episode Statistics records (HES) for all CYP in England. **IGARD Observations:** IGARD noted a previous application presented to IGARD on the 18 January 2018: NIC-27404-D5Z3F University College London which was about the relationship between education and health outcomes for children and young people across England: the value of using linked administrative data. IGARD noted the case made for the legal basis for identifying data flowing from the Department for Education to NHS Digital for NIC-27404-D5Z3F but since this is such a significant amendment to a previously approved application the legal bases would need to be carefully considered to check they still applied in this instance. IGARD suggested updating the data flow diagram in the protocol with the legal basis for data flows at each stage. IGARD members noted that the previous application had requested data for 2 million CYP, however it now appeared that the applicant wished to increase the number of CYP linked by an additional 16 million to a total of 18 million. In order to satisfy the General Data Protection Regulation's (GDPR) data minimisation requirements, IGARD asked for justification for this substantial increase to the cohort size. Noting that the previous application had a narrow purpose and the new purpose of the research being undertaken as outlined in the protocol provided was wider, IGARD members suggested that the applicant may wish to consider how the current questions could be expanded to match the significantly expanded cohort (for example to consider the impact on all children, not just vulnerable children) or to justify why the narrow questions were still relevant even though they are accessing a much larger dataset. IGARD members supported DARS' advice that the applicant should seek new ethics approval via Research Ethics Committee (REC) (alternatively, a substantial amendment application could be submitted but that would not be ideal, given the significant change in size and scope of the project).

	IGARD members queried if national data opt outs would be applied to data flowing to NHS Digital under the legal basis of the Education Act and that NHS Digital may wish to consider applying national data opt outs before the data is disseminated.
2.4	National Institute for Health Research Inflammatory Bowel Disease (NIHR IBD) BioResearch (no NIC reference available) **Background:** NHS Digital had provided IGARD members with a number of links to various websites with a specific question: was the Research Passport able to be used as an honorary contract for accessing the data? **IGARD Observations:** IGARD members noted that although supportive of the Research Passport system, the information provided explained the arrangements for checking the bona fides of researchers but did not furnish a copy of the actual honorary contract that flowed from the Research Passport. IGARD members requested a copy of the honorary contract in order to review its content (to check for usual safeguards such as counter signature of someone in authority over the researcher who could enforce any action required if, for instance, there was a data breach). NHS Digital advised that they would be bringing the consent materials to a future meeting.
2.5	NIC-381633-K9Y2T University of Oxford **Background:** This was a new application, phase 2/3 of a participant-blinded randomized controlled trial in adults and healthy children in the UK administering a single dose of two-doses of a vaccine to determine the efficacy, safety and immunogenicity of the candidate COVID-19 vaccine ChAdOx1 nCoV-19 (COVI002). This is the first evaluation of the vaccine in healthy adults aged 18-55 in the UK was planned to start in April 2020 with over 1000 participants. The trial is now being expanded to include children (aged 5-12 years) and those aged 56+ years and is awaiting ethical approval for inclusion of those groups. The materials provided to IGARD also contained assent materials for children aged 5-12 years old. **IGARD Observations:** IGARD members noted the importance of the research and close involvement and contact with the cohort, therefore, steps should be taken to improve both transparency for the consented cohort and the consent materials for use in the future. While Reg 3 of the Health Service Control of Patient Information (COPI) Regulations 2002 may be available as an interim measure while transparency was improved and the consent materials clarified, at the expiry of the COPI Direction, it was unlikely that Health Research Authority Confidentiality Advisory Committee (HRA CAG) would grant s251 support to remedy any deficiencies, given the fact the applicant was in regular contact with the cohort and fully informed consent was possible. IGARD noted that with regard to the consent materials provided and reviewed by Data Access Request Service (DARS), that consideration should be given to include reference identifying data flowing to NHS Digital, to reference data linkage now and in the future, to remove statements such as “confidential information will not leave the hospital” and to provide the ability for the participant to withdraw their consent. The applicant could also consider likely long-term follow up and whether it would be prudent to refer to longer-term linkage with cohort members’ health data that may be obtained from NHS Digital in the future. IGARD members

	noted that since the applicant was in contact with the cohort on a regular basis, that these clarificatory issues could be remedied with the consented cohort via an updated flyer, letter or newsletter to the cohort. IGARD did **not** suggest that re-consenting was necessary. IGARD members noted that the applicant should consider splitting the assent/consent materials for those aged 5 to 12 years, into two distinct groups: 5 to 9 years and 10 to 12 years, since the content and discussion with regard to pregnancy testing should be differentiated for younger children. IGARD members, noting this may outside their Terms of Reference, queried if there were any ethical issues for six blood draws for younger children since this was an intrusive and potentially distressing procedure and would have no direct therapeutic benefit to the children. IGARD members were also unclear as to how many were in the cohort as a whole and within each age range and asked for further clarity on this. With regard to the data requested, IGARD members asked for a clear rationale for the data sets requested and what it was providing over and above the data they would already be collecting themselves as part of the study. Would the data disseminated by NHS Digital be sufficiently rigorous to fulfill the research purposes? In terms of the long term follow up, consent should anticipate any additional follow up, design of the study and the datasets reflected in the application as appropriate. Bearing in mind the nature of the research, IGARD queried if the applicant was working with any commercial companies in the development and testing the efficacy of a vaccine and, if so, this should be noted within the application along with details of any funding or other non-monetary support.
2.6	<u>NIC-381078-Y9C5K Cardiovascular Disease Trusted Research Environment for British Heart Foundation (CVD TRE for BHF)</u> **Background:** This was a new application to access data for COVID-19 purposes under a TRE following the presentation of the COVID-19 Data Request Front Door document on the 26th May 2020. Patients with pre-existing cardiovascular disease have a disproportionately elevated risk of symptomatic infection and mortality and understanding which patients with cardiovascular diseases are affected and why, will be a major step towards developing strategies to reduce their risk. The British Health Foundation Data Science Centre (embedded within the Health Data Research UK (HDRUK)) working in partnership with NHS Digital will establish a CVD TRE for England to enable the analysis of linked, nationally collated healthcare datasets. The outputs of each piece of work will be reported to the SAGE and other equivalent bodies to drive evidence based policy decisions for health service providers and clinical professional groups. NHS Digital were seeking advice on section 5 of the application summary. **IGARD Observations:** IGARD members suggested the Data Access Request Service (DARS) and Information Governance should discuss the TRE with the customer to ensure their expectation are met and that an update be provided at next week's meeting, since it was not clear in section 5 if

	the applicant was seeking access to the overarching TRE or the CVD TRE, and whether the CVD TRE would be separate from or a subset of the full TRE.
2.7	Trusted Research Environment (TRE) NHS Digital noted that discussions were still ongoing with regard to TRE's with the open issues including: accessing multiple datasets, the environment, the controls in place and data minimisation.
3	AOB There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.

Independent Group Advising on the Release of Data (IGARD)

Action Notes from the IGARD – NHS Digital COVID-19 Response Meeting

held via videoconference, Tuesday, 9 June 2020

In attendance (IGARD Members):	Prof. Nicola Fear (Specialist Academic Member)
	Kirsty Irvine (Lay Chair)
	Dr. Geoffrey Schrecker (Specialist GP Member)
In attendance (NHS Digital):	Vicky Byrnes-Watts
	Garry Coleman (items 2.6, 2.7 and 2.8)
	Catherine Day
	Louise Dunn
	Liz Gaffney (items 2.5, 2.6, 2.7 and 2.8)
	Karen Myers (Observing)
	Kimberley Watson
	Vicki Williams

2	**Welcome** 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 any 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 DARS process and be presented at a Thursday IGARD meeting. The action notes from the Tuesday meeting would be received at the next Thursday meeting of IGARD and published as part of those minutes as an appendix. **Declaration of interests:** Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising on COVID-19.
2.1	<u>National Institute for Health Research Inflammatory Bowel Disease (NIHR IBD) BioResearch (no NIC reference available)</u> **Background:** This item had been previously discussed at the COVID-19 response meeting on the 2 June 2020. NHS Digital noted that the previous observations made by IGARD had been discussed with the applicant and subsequent to that feedback the cohort numbers consented to each version of the consent materials has been provided. NHS Digital were seeking advice on the BioResource consent materials provided. **IGARD Observations:** IGARD members noted and endorsed NHS Digital's review of the consent materials.

	IGARD members observed that although the existing consent materials were broadly compatible with the proposed processing, in order to give long term support to this important study suggested (without prejudice to any further comment from NHS Digital and IGARD upon a future detailed review) that the applicant should endeavour to ensure they are updated for future participants/augmented with further communication for existing participants, as appropriate, and as per the specific points below. IGARD members asked for confirmation as to what was meant by 'future study' within the patient information sheet (PIS) v6 supporting document provide for review, which referenced that in the future, a number of studies would be carried out and that **the cohort would be contacted to take part** on the basis of genetic / biochemical results obtained from the cohort sample. The PIS stated that the cohort would be provided with full information regarding each of these studies and then free to decide whether or not to participate. Although it was noted within the PIS that some research may not require any further input from the cohort, it was unclear if this related to the COVID-19 specific purpose. IGARD members asked that, dependent on the answer as to whether it's a new study using the biochemical samples, then new communication materials to the cohort may be suitable step to ensuring the validity of the current consent in place, but if this is a completely new study relating to COVID-19 that the researchers would need to consider how to obtain consent for this study and each 'future study' undertaken with the cohort, in terms of their existing PIS. In either case, it would be helpful for future PIS to be clearer, and give examples, of what studies based on genetic/biochemical results might entail. IGARD members agreed with the NHS Digital Information Governance observation that the applicant may wish to look at the COPI notice in order to get sufficient coverage in the short term **if** this research was a "new study" in terms of the PIS and reconsenting was being undertaken. **Subsequent to the meeting** IGARD asked that the applicant's response to providing a copy of the honorary contract under the research passport was provided at the next COVID-19 response meeting.
2.2	<u>NIC-381683-R6R6K Public Health England (PHE)</u> **Background:** This item had been previously discussed at the COVID-19 response meeting on the 26 May 2020 with regard to five University of Oxford studies: three of which were observational and two of which were clinical trials. This application related to the three observational studies. NHS Digital noted that these studies have received Health Data Research UK (HDRUK) prioritisation. PHE had commissioned the Royal College of General Practitioners (RCGP) Research Surveillance Centre (RSC) to incorporate the monitoring of COVID-19 into its virology surveillance scheme and a vital part of this work has been to monitor the number of suspected COVID-19 cases in the community in a timely way. The aim of the application was for RCGP RSC to conduct observational epidemiological studies to inform the national public health response to COVID-19 with three distinct workstreams of: COVID-19 surveillance; defining the characteristics of individuals with suspected novel COVID-19 and risk factors of developing the disease; and monitoring attendance, investigation, referral, and outcomes in Primary Care and recovering from COVID-19 lockdown.

	NHS Digital noted that the previous observations made by IGARD had been discussed with the applicant **IGARD Observations:** IGARD members noted and supported the concerns of NHS Digital analysis with regard to the volume and frequency of data requested and other data minimisation concerns, plus what data is currently held and for what purpose. For example, IGARD members were unsure why the applicant was requesting certain data sources from 2009 (for example, SUS). Each of these factors may be justifiable but the reasoning needed to be documented transparently in the application. IGARD members were also supportive of NHS Digital's analysis with regard to the legal basis and suggested that the applicant, in order to future-proof the long running study, could consider revising the existing Reg 3 Direction that has been used in the past for this surveillance, rather than relying on the current emergency COPI Notice. In addition IGARD members suggested that the applicant should consider current transparency measures in place and that NHS Digital / applicant may wish to review the transparency materials for a sample of participating GP Practices to ensure that the appropriate communications for patients were visible both in surgeries and on the GP practice website, to ensure from a patient perspective that they were fully informed as to what was happening with their data, where their data was going and that every patient had the ability to opt out. IGARD members noted reference to opt outs for the data collection by Apollo from practices, but it wasn't clear if this referred to national opt outs, type 1 objections or more specific study opt outs and that this should be clearly updated within relevant materials provided to the cohort and explained within the application. In addition, IGARD members noted that it wasn't clear with regard to the role of the University of Oxford within the application summary provided and although NHS Digital noted that the work being undertaken by the University of Surrey would be transferring to the University of Oxford in summer 2020 that they would make explicitly clear within the application that if any data was to be processed at University of Oxford and staff would need access, that this would be reflected in the application.
2.3	<u>NIC-381633-K9Y2T University of Oxford</u> **Background:** This application had previously been discussed at the COVID-19 response meeting on the 2 June 2020. This application was phase 2/3 of a participant-blinded randomized controlled trial in adults and healthy children in the UK administering a vaccine to determine the efficacy, safety and immunogenicity of the candidate COVID-19 vaccine ChAdOx1 nCoV-19 (COVI002). This is the first evaluation of the vaccine in healthy adults aged 18-55 in the UK was planned to start in April 2020 with over 1000 participants. The trial is now being expanded to include children (aged 5-12 years) and those aged 56+ years and is awaiting ethical approval for inclusion of those groups. The materials provided to IGARD also contained assent materials for children aged 5-12 years old. NHS Digital noted that this study is on the National Institute for Health Research (NIHR) priority list.

	NHS Digital noted that the previous observations made by IGARD had been discussed with the applicant including the involvement of children in the study and that the applicant had confirmed that no data would be requested for those aged 17 years or under. NHS Digital also noted that NHS Digital's information governance (IG) directorate had confirmed contentment with release of data under the COPI notice but that due to this being a long-running study, the applicant may wish to update their current consent materials and provide additional patient communications to those already consented to ensure participants were fully informed about the use of their data. **IGARD Observations:** IGARD members noted and endorsed IG's analysis of the documentation and legal bases. IGARD members noted that ethics approval was still not in place. IGARD member reiterated that comments from last week's meeting that bearing in mind the nature of the research, queried if the applicant was working with any commercial companies in the development and testing the efficacy of a vaccine and, if so, this should be noted within the application along with details of any funding or other non-monetary support. NHS Digital asked for support in discussing this with the applicant and IGARD agreed to provide additional comments out of committee. **ACTION:** IGARD to provide additional comments with regard to the commercial aspect, including a copy of the current NHS Digital commercial standard. IGARD members suggested that NHS Digital provide a compilation of the advice given by NHS Digital to the applicant with regard to consent so that IGARD members could support NHS Digital (and provide any further points), this document could then form part of the supporting documentation pack to support the applicant in improving their consent in anticipation of the COPI Notice expiry (especially as recruit is expected to last for at least 6 months). **ACTION:** NHS Digital to forward suite of consent advice provided to the applicant to IGARD for comment out of committee. It was noted weekly testing using home test kits would be undertaken in partnership with the Department of Health & Social Care national community testing programme. IGARD members discussed whether it was just home testing results or also data acquired via other testing results and that this be explicitly stated. With regard to the data requested, although the applicant had provided additional commentary for the data sets requested, IGARD members queried if there were any potential duplications of data flows and if the applicant was getting results from elsewhere, and if so, to provide a justification within the application including data minimisation efforts undertaken, where applicable.
2.4	<u>NIC-383356-N8J6Z Cambridge University</u> **Background:** The prophylaxis for vulnerable patients at risk of COVID-19 infection trial (PROTECT) is a trial of prophylactic interventions in multiple at-risk patient groups. Those patients who require renal replacement therapy and emerging data from the UK Renal Registry show that dialysis patients are at risk of contracting COVID-19, and that for those who contract COVID-19 there is a fatality rate considerably higher than in the general population.

	The study is looking at a number of proposed agents to be tested, with the first being hydroxychloroquine (HCQ), a well-tolerated and widely used licenced medication which makes it an ideal candidate to re-purpose and trial as an anti-viral agent. Small studies have shown that HCQ may be an effective prophylactic treatment. NHS Digital were seeking advice on the patient information sheet and protocol in order to support a long-term data sharing agreement, since the applicant does not want to rely on current emergency legislation. The request will be for mortality and Hospital Episode Statistics (HES) data. **IGARD Observations:** IGARD members noted and supported the applicant in their view that relying on COPI Notice for this long running study would not be advantageous and that although the existing consent materials were broadly compatible with the proposed processing, in order to give long term support to this important study suggested (without prejudice to any further comment from NHS Digital and IGARD upon a future detailed review): • The patient information sheet (PIS) / consent materials, if they are intended for UK-wide use, should be clear that each nation uses differing technical terms, for example, Scotland refer to 'central healthcare records', whilst England refers to 'healthcare data'. • That it be clearly stated how this study fits in with wider international studies and the other parties involved. • That in light of the drug being studied and the number of funders involved, to ensure that any funders / funding sources do not come with any 'strings attached' or the ability to suppress outputs / findings. • If recruitment has not started, that the PIS be updated to include further information on HCQ, however if recruitment is due to start imminently or has started that the applicant ensure appropriate verbal communication with the study participants with regard to HCQ and to provide, at their earliest opportunity, a newsletter that clearly and factually updates the participants with regard to HCQ. In particular, IGARD suggested that the applicant acknowledge that participants may have seen publicity about HCQ and explain in a layperson-friendly manner the difference between treatment and prophylaxis and how this study is different from other high-profile research into HCQ. In addition, IGARD members noted that Medical and Healthcare products Regulator Agenda (MHRA) approval should be in place before the study can start and that a copy be obtained by NHS Digital and held on the customer relationship management (CRM) system. IGARD noted that this application would need to come back to a full meeting of IGARD for review and recommendation.
2.5	<u>IGARD and GPES Data for Pandemic Planning Research (GPDPPR)</u> IGARD members noted that the Professional Advisory Group (PAG) was meeting every Wednesday afternoon to review documentation. IGARD members suggested that for any application for GPES Data for Pandemic Planning Research (GPDPPR) that a prominent statement be made in section 1 (abstract) if a PAG review had been undertaken, in which case to reference the supporting document number and

	provide as part of the meeting papers. If a review was yet to take place, to clearly highlight that next step and timing. NHS Digital noted that on some occasions it may be that an application for GPDPPR may come to IGARD with a PAG review that had raised concerns, and it was agreed that on those occasions the GP data would not be discussed and removed from the application until the concern had been addressed. IGARD members noted that should members not have time to properly review the PAG commentary (for example if it arrived the night before / morning of an IGARD meeting) and / or if queries raised by PAG raised significant issues for IGARD members, that IGARD may not be able to form a recommendation at that meeting. NHS Digital noted that applications may be added to a Thursday agenda following review the previous day by PAG. IGARD noted that should members not have time to properly review the application and PAG commentary and / or if queries were raised that IGARD may not be able to form a recommendation at that meeting, due to the short notice of such a request. IGARD members also noted that there was a COVID-19 slot on the Thursday IGARD meeting but that documentation, as per process, should be circulated by midday on the Wednesday. IGARD members asked that the Terms of Reference for PAG and any other standard operating procedures be provided so that they could understand the remit and boundaries of PAG, its review of applications, any additional queries raised by the documentation and if a loop back from IGARD to PAG should be included. IGARD members also suggested that the NHS Digital website be updated to clearly state that PAG had a limited review of GPDPPR applications. IGARD members noted that following review at a full IGARD meeting, comments had been disseminated out of committee to NHS Digital with regard to the CCG and Local Authority templated applications for GPDPPR and that these comments should be provided to PAG as part of their review of the templated documentation. IGARD members noted that it may be advantageous for IGARD / PAG / NHS Digital along with a select number of representatives from CCGs and Local Authorities workshop the templated applications in order to move these types of applications to the precedent process more expediently.
2.6	<u>NIC-381078-Y9C5K Cardiovascular Disease Trusted Research Environment for British Heart Foundation (CVD TRE for BHF)</u> **Background:** This application to access data for COVID-19 purposes under a TRE had previously been discussed at the COVID-19 response meetings on 26 May 2020 and 2 June 2020. NHS Digital noted that the application required further work to ensure the relevant Data Controllers were listed and that each party's role was explicitly clear. **IGARD Observations:** IGARD members noted that the application had been provided but that they had not been asked to provide comments and endorsed NHS Digital's view that the application should clearly list all the Data Controllers accessing the data, to check if any potential Data Controllers should instead be considered a Data Processor and to be explicitly clear with regard to the role of each party involved. It was essential that every entity wishing to access

	data in the TRE be party to the DSA and NHS Digital agreed that they would discuss this in detail with the applicant.
2.7	Trusted Research Environment (TRE) The Associate Director Data Access noted that a Data Access Environment (DAE) was the infrastructure used for accessing data and that all datasets would be available via a DAE. The Director noted that TRE's were areas within a DAE for a specific purpose and that each would include a 'service wrapper', that each would contain a specific view on a dataset, and that datasets would only be available within a specific TRE. The Director noted that there will be three different models of TRE. The Director also updated IGARD members on the proposed governance model and next steps. IGARD members noted the update from NHS Digital and suggested that a terminology document be created as a reference article to describe and define the different models. Further, IGARD members suggested that additional thought be given with regard to data minimisation, at user level, within each TRE. The Director noted that as new TRE's emerged in the coming months that these would be brought back to IGARD **and before** they were presented within an application.
2.8	Primary Care Data (PCD) The Associate Director Data Access updated IGARD members with regard to the GPES Data for Pandemic Planning Research (GPDPPR), noting that a first of type application was to be reviewed by IGARD on Thursday, 11 June. IGARD members noted the update from NHS Digital and suggested that acronyms, especially for the different types of GP data, be clearly spelt out on first use and used correctly, since a number of acronyms were closely aligned but had significantly differing meanings.
3	AOB There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time, including the Associate Director Data Access, and closed the meeting.