

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 17 September 2020

IGARD MEMBERS IN ATTENDANCE:	
Name:	Position:
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Kirsty Irvine (Chair)	IGARD Lay Chair
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	Position:
Prof. Nicola Fear	Specialist Academic Member
Dr. Maurice Smith	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	Team:
Dave Cronin	Data Access Request Service (DARS)
Louise Dunn	Data Access Request Service (DARS)
Richard Hatton	Clinical Informatics (Observer: 2.2 – 2.4)
Sara Lubbock	Data Access Request Service (DARS) (Observer: 2.1 – 2.4)
Abigail Lucas	Data Access Request Service (DARS) (Observer: 2.1 – 2.4)
Karen Myers	IGARD Secretariat
Amy Ogborne	Information Governance (Observer: Item 5)
Heather Pinches	Data Access Request Service (DARS)
Denise Pine	Data Access Request Service (DARS) (Observer: 2.5)
Aisha Powell	Data Access Request Service (DARS) (Observer: 2.1)
Beth Simpson	Data Access Request Service (DARS) (Observer: 2.1)
Tom Wright	Data Access Request Service (DARS)

1	Declaration of interests: There were no declarations of interest.
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	<p>Review of previous minutes and actions:</p> <p>The minutes of the 3rd September 2020 IGARD meeting were reviewed out of committee by IGARD, and subject to a number of minor changes were agreed as an accurate record of the meeting.</p> <p>Out of committee recommendations:</p> <p>An out of committee report was received (see Appendix A).</p>
2	Data Applications
2.1	<p><u>National Institute for Health Research (St George's University Hospitals NHS FT): Novavax (Presenters: Louise Dunn / Heather Pinches) NIC-401171-F9Z8T</u></p> <p>Application: This was a new application from St George's University Hospitals NHS Foundation Trust to utilise the COVID-19 Permission to Contact (CV19 PtC) dataset, as part of the NHS COVID-19 vaccine research registry launched with the intention of helping large numbers of people to be recruited into trials over the coming months. St George's will use this service to recruit participants to a vaccine trial for those aged 18-84 for new vaccine SARS-CoV 2 Recombinant(r) Spike(S) Protein Nanoparticle Vaccine (SARS CoV 2rS) with Matrix-M Adjuvant, the trial will also give valuable information on safety aspects of the vaccine.</p> <p>Following the review of certain aspects of this application at the IGARD – NHS Digital COVID-19 Response meeting on the 15th September 2020, NHS Digital advised that a number of updates and amendments had been made to the application.</p> <p>In addition, NHS Digital also advised that the ethics approval was still outstanding and that the application would be updated once they received this from the applicant.</p> <p>Discussion: IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 15th September 2020.</p> <p>IGARD also noted the update from NHS Digital in respect of the updates and amendments made to the application, and in particular noted the current status of the ethics approval. IGARD asked that, as per usual process, written evidence was provided confirming that the applicant had successfully secured ethics approval.</p> <p>IGARD queried the rationale for only communicating with potential participants via e-mail when individuals may prefer letters or telephone calls. They were advised by NHS Digital that the channels for communication were under review.</p> <p>IGARD also queried if, following the IGARD – NHS Digital COVID-19 Response meeting, there was any further update on the status of the CV19 PtC privacy notice; and were advised by NHS Digital that the next version was currently with NHS Digital's Information Governance for final sign-off. IGARD noted the update from NHS Digital and advised that IGARD would be happy to review the draft privacy notice and provide feedback before this was published.</p> <p>IGARD noted the information provided in section 5(e) (Is the Purpose of this Application in any way Commercial), and asked, that noting section 5(e) would not be in the public domain, that a brief summary of the commercial benefit, as outlined in section 5(e) was also added elsewhere to the publicly available information in section 5 (Purpose / Methods / Outputs).</p> <p>IGARD noted the statement in section 5(e) “...the benefit to the UK government is proportionate to the commercial interests...” and suggested that this wording was revised to state the benefit to the “UK public”.</p> <p>IGARD queried why the ‘postcode’ identifiable element was not included in the data access table in section 3(b) (Additional Data Access Requested), noting that this would be required to</p>

	<p>help identify possible trial site participants, and asked that section 3(b) was amended to include this element.</p> <p>IGARD noted the reference in section 5(a) (Objective for Processing) to the University of Oxford as Data Controller and asked that this was removed as it was incorrect. IGARD also noted a reference to St George's University Hospitals NHS Foundation being the Data Controller for the Permission to Contact service, which is also incorrect.</p> <p>IGARD queried the reference in supporting document 1, the NIHR study review outcome dated the 28th August 2020, that referred to "<i>exclusion criteria</i>", and asked that, to avoid any confusion, section 5(b) (Processing Activities) was updated to provide a brief explanation confirming that exclusion criteria was based on the information provided by cohort members on the permission to contact dataset, and is not collected from other NHS data sources. NHS Digital advised that an additional screening may take place, for example at the individual trial sites. IGARD asked that this was also reflected in section 5(b).</p> <p>IGARD also noted the concern outlined in supporting document 1, in respect of "<i>inclusive language</i>" and noted the efforts to ensure communications were inclusive and open to the wider public, and suggested the applicant may wish to consider the involvement of lay members in reviewing any communications, alongside ethical review.</p> <p>Outcome: recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> 1. To provide written evidence that the applicant has successfully secured ethics approval. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To amend section 3(b) to include 'postcode' to the identifiable elements. 2. To update section 5(a) to remove the reference to St George's University Hospitals NHS FT being a Data Controller for the permission to contact dataset. 3. To update section 5(b): <ol style="list-style-type: none"> a) To provide a brief explanation that exclusion criteria is based on the information provided by cohort members on the permission to contact dataset, and is not collected from other NHS data sources. b) To make clear that additional exclusion screening will take place. 4. To revise the reference in section 5(e) from "<i>UK Government</i>" to "<i>UK public</i>". 5. To update section 5 to include a brief summary of the commercial benefit as outlined in section 5(e). <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD suggested that NHS Digital continues with discussions in relation to the permission to contact database and the communication channels with volunteers (presently only via email), and the equality of access to the dataset for participants to sign-up. 2. IGARD noted the efforts to ensure communications are inclusive and open to the wider public, and suggested the applicant may wish to consider the involvement of lay members in reviewing any communications, alongside ethical review. <p>It was agreed the condition would be approved Out of Committee (OOC) by the IGARD Chair</p>
2.2	<p><u>NHS England: Flu – Vaccination Programme – Ethnic Category information for secondary uses (Presenter: Louise Dunn / Dave Roberts) NIC-402116-G1T7V NHS England</u></p> <p>Application: This was a new application for identifiable Hospital Episode Statistics (HES) and GPES Data for Pandemic Planning and Research (GDPPR), for the purpose of supporting NHS England's national call / recall for the flu vaccination programme and to provide ethnicity</p>

data for circa 60 million people. The first application is secondary uses for flu and will be followed up for COVID-19 secondary uses.

NHS Digital advised IGARD that following the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) review of the application on the 16th September 2020, the application had been updated to reflect the comments and queries made.

NHS Digital also advised they had received confirmation from NHS Digital’s Information Governance that The Health Service Control of Patient Information (COPI) Regulations 2002 was the correct legal basis for the release of data under this application, and that this confirmation had been added to NHS Digital’s Customer Relationship Management (CRM) system.

Discussion: IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 15th September 2020.

IGARD also noted that this application had also been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) (see Appendix B) on the 16th September 2020.

IGARD endorsed the comments made by PAG, in particularly the advice that the applicant should, as a minimum, complete an equality impact assessment. In addition to this, IGARD noted the special condition in section 6 (Special Conditions) that the applicant “must complete an equality impact assessment”, and suggested that this was updated to state that this should be completed “as soon as reasonably practicable”.

IGARD noted the update from NHS Digital in relation to COPI being used as the legal basis for the work outlined in the application, and that this had been uploaded to NHS Digital’s CRM system. IGARD asked that in light of this, section 5(a) (Objective for Processing) was updated to provide additional details as to how the processing outlined would support the COVID-19 response and COPI legal basis.

In addition, IGARD also advised NHS Digital that as per previous advice, a special condition should be inserted in section 6 that placed an obligation on the Data Controller to ensure that they had appropriate contractual arrangements in place with the Data Processor(s) which satisfied section 7 of COPI.

IGARD noted that both System C Healthcare Ltd and Graphnet Health Ltd were Data Processors in section 1(c) (Data Processor(s)), and asked for further details of what roles they will undertake, and how they differ.

In addition, IGARD also advised that the applicant’s privacy notice should reflect the relevant information in relation to the two Data Processors outlined.

IGARD queried the information provided in section 3(b) (Additional Data Access Requested) that stated some of the data flows would be provided by NHS Digital on a fortnightly basis, and asked that section 5 (Purpose / Methods / Outputs) was updated to provide a further explanation as to why some of the data flows would be provided on a fortnightly basis.

IGARD noted references throughout the application to “Ethnicity” and asked that this was updated where relevant to reflect the correct wording “*Certain ethnic groups...*”.

Outcome: recommendation to approve

The following amendments were requested:

1. To update section 1 and section 5(b) to confirm the roles of System C Healthcare Ltd and Graphnet Health Ltd, and if they are both carrying out processing, how each processor carries out a different role.

	<ol style="list-style-type: none"> 2. To update section 5 to provide an explanation as to why some of the data flows are provided fortnightly. 3. To update section 5(a) to provide additional details as to how the processing outlined will support the COVID-19 response and COPI legal basis. 4. In relation to section 6: <ol style="list-style-type: none"> a) To update the existing special condition that NHS England should complete an Equality Impact Assessment “as soon as reasonably practicable”. b) To insert a special condition placing an obligation on the Data Controller to ensure that they have appropriate contractual arrangements in place with the Data Processor(s) which satisfies section 7 of COPI. c) To update the application where relevant to replace “<i>Ethnicity...</i>” with “<i>Certain ethnic groups...</i>”.
2.3	<p><u>Great Ormond Street Hospital for Children NHS Foundation Trust: Gender Mortality Differences in Children Admitted to UK Critical Care Units (Presenter: Louise Dunn) NIC-188901-P9M0S</u></p> <p>Application: This was a new application for identifiable Hospital Episode Statistics (HES), Civil Registrations and the Maternity Services Data Set (MSDS), for the purpose of a research project.</p> <p>Every year, more than 20,000 children are admitted to Paediatric Intensive Care Units (PICUs) in the UK. Previous small studies have showed that baby girls may have higher mortality rates than baby boys in PICU. In 2017, an analysis was completed of all babies (0-12 months old) who were admitted to PICUs over an 11-year period. Anonymous records from PICANet of 86,000 babies were obtained and the rates of death for girls and boys after their admission to PICU were compared. It was shown that girls had higher death rates than boys. This is different to what is seen in the general population where boys have higher death rates than girls for children of all ages. Careful examination was carried out of whether this difference could be due to age, disease severity, infections, and a number of other factors. None of the factors could explain why girls died more than boys in PICU. The purpose of this research project now is to examine these findings in greater detail as this could have implications for the care of critically ill children generally.</p> <p>NHS Digital advised IGARD that the Health Research Authority Confidentiality Advisory Group (HRA CAG) approval was in place. However, this application involves some data that has already being disseminated under a different Data Sharing Agreement (DSA). Therefore the description in the HRA CAG approval differs from the application.</p> <p>Discussion: IGARD welcomed the application and noted the importance of the study.</p> <p>IGARD noted and endorsed NHS Digital’s review that the applicant did not meet NHS Digital’s Standard for privacy notices.</p> <p>IGARD noted the update from NHS Digital in relation to the HRA CAG approval not aligning exactly with the processing outlined in the application, and suggested that the applicant notify HRA CAG that they had modified their research methodology and set out how NHS Digital would be processing the data.</p> <p>In addition, IGARD also suggested that NHS Digital facilitate an amendment to the overarching DSA containing the NHS Digital datasets already held, and that the amendment covered the processing under this DSA; and that IGARD would be supportive of the amendment to the permitted purposes for processing progressing down the SIRO precedent route in this instance.</p>

IGARD noted PICANet's involvement in this research project, and that they were based at the University of Leeds, and queried whether or not they should also be considered a joint Data Controller, given that one of the supervisors is based there. In addition, IGARD also asked that the Data Controllers were assessed against NHS Digital's Controllers Standard 1b.

IGARD also noted that the Data Controller named in section 1(b) (Data Controller(s)) was also named as a Data Processor in section 1(c) (Data Processor(s)), and asked that this was reviewed, noting it had been previously agreed with NHS Digital that they would only be listed in section 1(b).

IGARD queried the information provided in section 3(b) (Additional Data Access Requested), in particular in relation to the MSDS dataset, which appeared to indicate that this covered all mothers who had given birth within the timeframe specified, and asked that the data minimisation column was updated to make it clear that the MSDS dataset was minimised to only those mothers who had an infant in the Paediatric Intensive Care Units (PICUs) in the relevant date range.

IGARD also noted the references throughout the application to infants in PICU and suggested clarifying in section 5 (Purpose / Methods / Outputs) if the project also included infants in Newborn Intensive Care Units (NICU) and / or transitional care. IGARD queried whether PICANet captured all the necessary fields and infants required for the study. For completeness, IGARD suggested considering if any other datasets were required to give full coverage to achieve the research goals.

IGARD noted the references in section 3(b) to the data being "identifiable" and asked that this updated to correctly reference the data as being "pseudonymised"; in addition, IGARD also asked that an explanation was provided as to identifiers were flagged and to set out why s251 was being relied on. IGARD also asked for table 3(b) to set out the legal basis relied on by NHS Digital for flowing the data.

IGARD noted the references in section 1 (Abstract) and section 5(a) (Objective for Processing) to the "*UK and Ireland*", and queried if this should be UK alone.

IGARD queried the inconsistencies within the application and asked that this was revised to ensure that where appropriate the term '*gender*' was replaced with the term '*sex*', if '*sex*' was the data field held by NHS Digital.

IGARD noted the statement in section 5(a) "*All outputs from the safe haven are authorised by the chief investigator and data controller and are subject to disclosure controls*", and queried what precisely this meant, and asked that either further detail was provided or that the statement was removed.

IGARD queried the reference in section 5(d) (Benefits) ii (Expected Measurable Benefits) to "morbidity", and noted that this was not consistent with the rest of the application that made reference to "mortality", and asked that further clarification was provided, and if appropriate that this reference was amended.

IGARD noted the reference in section 5(d) to a "data flow diagram" and asked that this was removed, as the data flow diagram would not in the public domain, or that a summary of the data flow diagram was provided in the narrative.

IGARD noted and applauded the use of the Project Advisory Group, which included two members of the public, and the PICANet Annual Report that was published on an annual basis.

Outcome: recommendation to approve

The following amendments were requested:

	<ol style="list-style-type: none"> 1. To amend section 1 and section 5(a) to refer to “<i>the UK</i>”. 2. To ensure that where appropriate the term “<i>gender</i>” is replaced with the term “<i>sex</i>”. 3. In relation to the Data Controllers: <ol style="list-style-type: none"> a) To assess the Data Controllers against NHS Digital’s Controllers Standard 1b. b) To ensure that the Data Controllers and Data Processor listed reflect the factual situation. c) To ensure that any Data Controllers listed in section 1(b) that are also Data Processors, are not also listed in section 1(c). 4. In respect of section 3(b): <ol style="list-style-type: none"> a) To update the data minimisation column to be clear that the MSDS dataset is minimised to only those mothers who have had an infant in PICU in the relevant date range. b) To change the reference to ‘identifiable’ to ‘pseudonymised’ and provide an explanation as to why identifiers are flagged and why s251 is being relied on. c) To clarify NHS Digital’s legal basis being relied on. 5. To either provide further clarification on the statement in section 5(a) that starts “<i>All outputs from the safe haven are authorised...</i>”, or remove. 6. To clarify the reference to “<i>morbidity</i>” in section 5(d) (ii) and amend if appropriate. 7. To either remove the reference to the “<i>data flow diagram</i>” in section 5(d) or provide a summary in the narrative. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD suggested that the applicant notify HRA CAG that they have modified their methodology and set out how NHS Digital will be processing the data. 2. IGARD noted the references within the application to infants in PICU and suggested clarifying in section 5 if this project also includes infants in NICU and / or transitional care; and that the PICANet captures all the necessary fields and infant subjects and consider if any other datasets are required to give full coverage to achieve the research goals. 3. IGARD suggested that NHS Digital facilitate an amendment to the overarching DSA containing the NHS Digital datasets already held, and that the amendment covers the processing under this DSA; and that IGARD would be supportive of the amendment to the permitted purposes for processing progressing down the SIRO precedent route in this instance.
2.4	<p><u>The University of Manchester: TIGERTEETH Study - University of Manchester (Presenter: Louise Dunn) NIC-381624-F0K4Y</u></p> <p>Application: This was a new application which had come for advice on the consent materials and patient information leaflet, and whether there is 1) a sufficient legal basis for NHS Digital to provide Hospital Episode Statistics (HES) data for the participants in the study; and 2) whether or not collecting this data from NHS digital falls within the scope of what was said on the Patient Information Sheets and consent forms given to the participants.</p> <p>The purpose of the study, is to reduce the incidence of child Dental General Anaesthetic (DGA) operation referrals for childhood extractions in high risk families (defined as where one or more children have previously undergone a DGA) by testing a distributed toothpaste & tooth-brushing programme.</p> <p>Discussion: IGARD welcomed the unique application and noted the importance and value of the study.</p>

	<p>IGARD discussed the consent materials and concluded that they did not cover NHS Digital providing HES data. For example, IGARD queried the statement within the Patient information sheet “Only your regular dental team have access to your child/children’s dental records...”</p> <p>IGARD also queried references to being able to withdraw from the study within 24 months and what happened at 24 months that would prevent withdrawal. Often such limits are because at that point the data is rendered anonymous and withdrawal is no longer possible (which would also limit follow up).</p> <p>IGARD discussed the Common Law Duty of Confidentiality and whether reconsent was a possibility. There is a risk of further widening of inequalities in access to dental care if only some participants could be reconsented and IGARD suggested two possible alternatives.</p> <ol style="list-style-type: none"> 1) The researchers could contact the Health Research Authority Confidentiality Advisory Group (HRA CAG) with a view to potentially seeking s251 support. 2) The researchers could use a cryptographic ‘salt’ to enable data linkage without sending personal identifiers to NHS Digital. There are precedents for this approach, although the researchers may need to delete personal identifiers to prevent the possibility of re-identification. <p>Outcome: Thank you for presenting this application to IGARD on Thursday 17th September 2020. IGARD welcomed the application which came for advice on the consent materials and patient information leaflets, and without prejudice to any additional issues that may arise when the application is fully reviewed.</p>
2.5	<p><u>The University of Manchester: BILAG Biologics Prospective Cohort: The Use of Novel Biological Therapies in the Treatment of Systemic Lupus Erythematosus (SLE) (Presenter: Dave Cronin) NIC-148247-CH0Z6</u></p> <p>Application: This was a renewal and extension application for identifiable Medical Research Information Service (MRIS), Civil Registration, Cancer Registration Data, and Demographics data. The purpose is for long-term observational study to monitor the safety of new biologic and targeted therapies prescribed for Systemic Lupus Erythematosus (SLE) during routine healthcare, specifically to understand if these new drugs increase the risks of developing cancer or premature death above the expected risks in a population with similar disease characteristics not receiving these therapies.</p> <p>The primary objective of the study is to compare the risk of key safety outcomes (including cancer and death) between UK patients with Systemic Lupus Erythematosus (SLE) starting any new biologic, biosimilar or other new targeted therapy with an appropriate comparator cohort already established in the BILAG BR. The data requested will allow the study team to link the hospital and treatment data already captured under the study consent with national cancer and death data on study participants to ensure the register has no missing data on these two major outcomes. This will then allow the study to understand whether there is any increased risk of cancer and death in patients receiving these drugs.</p> <p>NHS Digital advised IGARD that this was a long-running study and it was their view that the consent materials need updating to reflect current expectations.</p> <p>Discussion: IGARD noted the update from NHS Digital in respect of the applicant’s consent materials, and also noted the thoughtful and thorough review of the applicant’s consent materials by NHS Digital, and the proposed plans for future improvements, and advised that IGARD endorsed NHS Digital’s review and agreed with the actions outlined.</p> <p>IGARD queried the statement in section 5(d) (Benefits) that one of the conditions for receiving the drug was that patients must be registered with the BILAG Biologics Register (BR), and</p>

	<p>asked that section 5(d) was update to remove any suggestion that this registration was a strict requirement to receive the drug.</p> <p>IGARD noted the information provided in section 5(e) (Is the Purpose of this Application in any way Commercial), and asked, that noting section 5(e) would not be in the public domain, that a brief summary of the commercial benefit, as outlined in section 5(e) was also added elsewhere to the publicly available information in section 5 (Purpose / Methods / Outputs).</p> <p>IGARD noted in section 5(b) (Processing Activities) that all data processing was carried out by substantive employees of the University of Manchester, however information provided in section 5(c) (Specific Outputs Expected) appeared to indicate that access would be much broader than this: "In terms of exploitation of the results/outputs, people can apply to access study data for research purposes, any application is reviewed by the steering committee before approval." IGARD asked that either further clarity was provided or that the statement in 5c was removed.</p> <p>IGARD noted the references in section 5(e) to other sources of data being used by the applicant for this study, and suggested that NHS Digital may wish to advise the applicant that the source of this additional data is referenced within section 5(e) where applicable.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update section 5(d) to remove any suggestion that it is a strict requirement for a patient to be on the register with the BILAG BR to receive the drug. 2. To update section 5(a) to include a summary of the commercial benefit as outlined in section 5(e). 3. To provide further clarity on who will access the data and if access is restricted to substantive employees of the University of Manchester, to remove the reference in 5c to applying to access study data for research purposes.
2.6	<p><u>Office for National Statistics (ONS): Investigating COVID-19 - request for acquisition of GPPR & ECDS data (Presenter: Dave Cronin) NIC-400304-S1P1B</u></p> <p>Application: This was a new application for identifiable Hospital Episode Statistics (HES), Emergency Care Data Set (ECDS), and GPES Data for Pandemic Planning and Research data, and to link this with HES data already supplied under a different Data Sharing Agreement (DSA) (NIC-175120-W5G2X).</p> <p>ONS already has access to the datasets being requested in this application within NHS Digital's data environment (NIC-388794-Z9P3J), ONS is now requesting access to the data in the form of extracts to be transferred to ONS rather than accessing the data within NHS Digital's environment and ONS is requesting access to less data than can currently be accessed in NHS Digital's environment, and the reason for this request is to enable ONS to link the NHS Digital data with Census data. The overall purpose is to produce statistics on the risk factors, including comorbidities, associated with COVID-19.</p> <p>NHS Digital advised they had received confirmation from NHS Digital's Information Governance confirming that The Health Service Control of Patient Information (COPI) Regulations 2002 was the correct legal basis for the release of data under this application and that Data Opt-Outs would not be applied.</p> <p>NHS Digital also advised that the applicant has confirmed that they will update and publish a General Data Protection Regulation (GDPR) compliant privacy notice before any NHS Digital flows.</p>

<p>Discussion: IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 8th September and 15th September 2020.</p> <p>IGARD also noted that this application had also been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) (see Appendix B) on the 9th September 2020. IGARD welcomed the update by NHS Digital in section 1 (Abstract) of outlining how the comments made by PAG had been addressed.</p> <p>IGARD noted the update from NHS Digital in relation to COPI being the correct legal basis for the work outlined in the application, and asked that this was uploaded to NHS Digital's Customer Relationship Management (CRM) system. In addition, IGARD also asked that the application was updated throughout, to reflect that COPI would be the legal basis relied on, including (but not limited to) the National Data Opt-Out not being applied.</p> <p>In addition, IGARD asked that a special condition was inserted in section 6 (Special Conditions), setting out the agreed sunset clause wording relating to actions to be taken upon expiry of the COPI Notice, which is relied upon to collect GDPR data.</p> <p>IGARD advised NHS Digital that the applicant should be aware that relying on COPI as a legal basis will have long-term implications in respect of how long the data can be held.</p> <p>IGARD noted within section 3(b) (Additional Data Access Requested) that the applicant was requesting sensitive Ordnance Survey grid Reference data, and advised NHS Digital that they were supportive of this in light of the clear legal basis that had been established.</p> <p>IGARD queried if there had been an update on whether ethical oversight was required, following the review of the application at the IGARD – NHS Digital COVID-19 Response meeting on the 15th September 2020, and were advised by NHS Digital that they had not received any further information. In light of this, IGARD asked that confirmation was provided that the Data Ethics Advisory Committee have reviewed the additional data processing outlined in this application; and that relevant evidence was uploaded to NHS Digital's CRM system.</p> <p>In addition, IGARD also asked that section 7 (Approval Considerations) was updated to clarify that ethics approval was not required because that applicant has its own Data Ethics Advisory Committee.</p> <p>IGARD noted and endorsed NHS Digital's review that the applicant did not meet NHS Digital's Standard for privacy notices, and noted and endorsed the update from NHS Digital that the applicant will publish a GDPR compliant privacy notice before any NHS Digital data flows.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update the application throughout, to reflect that COPI will be the legal basis relied on, including (but not limited to) National Data Opt-Out not being applied. 2. To ensure that the IG advice is circulated to IGARD for information, and to upload to NHS Digital's CRM system. 3. In respect of the Ethics Approval: <ol style="list-style-type: none"> a) To provide confirmation that the Data Ethics Advisory Committee have reviewed the additional data processing outlined in this application. b) To upload confirmation of this to NHS Digital's CRM system. c) To update section 7 to clarify that ethics approval is not required because ONS has its own Data Ethics Advisory Committee.

	<p>4. To insert a special condition in section 6 setting out the agreed sunset clause wording relating to actions to be taken upon expiry of the COPI Notice (which is relied upon to collect GDPR data).</p>
3	<p><u>Returning Applications</u></p> <p>Due to the volume and complexity of applications at today's meeting, IGARD were unable to review any applications as part of their oversight and assurance role.</p>
4	<p><u>Clinical Registry Annexe Template (Presenter: Tom Wright / Amy Ogbourne)</u></p> <p>NHS Digital have previously presented the Clinical Registries for Commissioners Briefing Paper to IGARD, the paper was accepted with suggested amendments and used to support the NHS England application to flow the Clinical Registries into NCDR.</p> <p>A workshop was held on the 13th August to discuss and resolve any outstanding issues with the paper, and an updated template was presented to IGARD to reflect these previous discussions.</p> <p>NHS Digital also advised IGARD that they had one further annex to submit to IGARD for review, the Sentinel Stroke National Audit Programme (SSNAP).</p> <p>IGARD confirmed that they were content with the revised template and thanked NHS Digital for the efforts made to update this.</p> <p>In addition, IGARD also advised NHS Digital that IGARD would be happy to provide an initial review of the SSNAP annex at the IGARD – NHS Digital COVID-19 Response Meeting on the 22nd September 2020, and if required, the IGARD meeting on the 24th September 2020.</p>
5	<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 8th September and 15th September 2020 can be found attached to these minutes as Appendix B.</p>
6	<p><u>AOB:</u></p> <p><u>NIC-396113-N9L4L - Imperial College London</u></p> <p>IGARD noted that following the 20th August 2020 meeting, when IGARD recommended for approval subject to conditions.</p> <ol style="list-style-type: none"> 1. In respect of this application being for service evaluation: <ol style="list-style-type: none"> a. To provide written confirmation of NHS Digital's CMO's analysis undertaken to evidence that this was service evaluation not research, or to seek and provide written confirmation from HRA re the same; b. To upload a copy of the relevant written assurance to CRM; c. To update any questions to be answered in section 5 which were more supportive of a research study than a service evaluation. 2. In respect of data minimisation:

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| | <ul style="list-style-type: none">a. To update the table in 3b to make clear that the GDPR data has been minimised to the virtual ward cohort;b. To clarify the specific code clusters. |
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NHS Digital had taken the decision to disseminate the data. The IGARD Chair had been informed of this out of committee.

IGARD discussed this application and notwithstanding the NHS Digital Chief Medical Officer's analysis, IGARD members were still of the view that as the purpose of the project was to produce outputs that could be generalised the project should most likely be classified as research.

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 11/09/20

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-377644-X9J4P	University of Sheffield	27/09/2020	1. In respect of the HRA CAG conditional support (which falls away in October 2020): a. To provide a written update setting out progress made to address the specific conditions of support, b. To upload a copy of the documentation to CRM.	IGARD Members	Quorum of IGARD Members	<i>"The supporting document should be updated, with the SD number added, NIC number noted etc"</i> <i>"NHS Digital to confirm what plan is in place to check that the HRA CAG update is submitted within the time frame and that evidence of the continuing support is provided to NHS Digital. IGARD's recommendation is only for so long as there is HRA CAG support in place."</i>
NIC-385550-Y8T2M	Worcestershire County Council	27/08/2020	1. In respect of the reference to the shielded patient list (SPL) and updating section 5(a): a. Noting the applicant has not requested SPL data from NHS Digital, to clarify where they have obtained the SPL data from, b. To clarify how they are intending to use the SPL data,	IGARD Members	Quorum of IGARD Members	N/A

			C. To confirm that any activity with the SPL is within the permitted parameters of the SPL Direction.			
NIC-349273-T3L4K	Royal College of Physicians of London	13/08/2020	<ol style="list-style-type: none"> 1. To insert a special condition in section 6 stating that within 1-month a GDPR-compliant Privacy Notice, as assessed by NHS Digital, will be published for HQIP. 2. To provide a satisfactory update to the yielded benefits in section 5(d) (iii) to ensure they comply with NHS Digital's Expected Measurable Benefits Standard 5d. 	IGARD Members	Quorum of IGARD members	
NIC-147997-R8B9S	University of Leeds	09/07/2020	<ol style="list-style-type: none"> 1. To provide confirmation that that the cohort for whom NHS Digital is supplying HES data to the University of Leeds is restricted to the cohort of patients in the ResearchOne database. 2. To provide a suitable explanation in section 5 of the role of the University of Oxford in this project (noting that while they are stated not to be a Data Controller or Data Processor, there is information about this study on their website). 	IGARD Members	Quorum of IGARD members	N/A
NIC-380714-D3R8F	CCG Group Application	30/07/2020	<ol style="list-style-type: none"> 1. To provide further explanation of the statement in section 5 "...to identify specific patients..." and if this does involve re-identifying individuals, to set out the appropriate security measures and legal basis that is being relied on to do so. 	IGARD Chair	IGARD Chair	<p><i>"The IGARD Chair has requested the following further amendment for consistency with recent CCG applications that have come through, "For the avoidance of doubt, no individuals will be identified under this agreement."</i></p> <p><i>"I note that provision of the IG advice is still in</i></p>

						<i>progress. Has this now been resolved?"</i>
NIC-59669-F6Y3W	The Royal College of Surgeons of England	21/05/2020	<ol style="list-style-type: none"> The applicant to provide a detailed communication plan to IGARD, which confirms: <ol style="list-style-type: none"> how they are contacting patients, particularly those who have received emergency surgery and whose data is being processed under s251 support. the plan for updating the consented cohort on how their data is being processed, for example, via website and Privacy Notice updates. how participants are able to withdraw from the study. To update the application to reflect the COVID-19 research questions in the s251 amendment, and to clarify whether or not the consented cohort will also be studied in this way and to provide further detail in the communication plan about how that cohort will be updated on the wider study goals. 	IGARD members	IGARD Chair via Chairs Action	<i>"On balance I am content to take chair's action for this application to move to the next phase. I would ask that a note is added to s1 (abstract) and / or CRM that this is not suitable for the precedent route in future."</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):

- NIC-41549-G2V6J NHS Flyde & Wyre CCG
- NIC-90680-M5B5W NHS North Lincolnshire

Appendix B

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 16th September 2020

Application: NHS England – Influenza-NIC-402116 -G1T7V Organisation name: NHS Digital Profession Advisory Group Agenda item: 3
<p>NHS Digital thanked PAG for the consideration of the application noting this was submitted out of agreed process.</p> <ul style="list-style-type: none">• PAG advised that the purpose for the utilisation of ethnicity data needed to be clarified for the use in flu. Confirmation that the utilisation will be for reporting for example to identify categories on ethnicity that are not accessing the flu vaccine.• PAG would seek assurance that the application will only be utilised for overall system management and planning. The data must not be used for performance management.• PAG requested clarification of the requests for these data sets and clarity as to the other sources of data required and discounted.• The applicant should consider all protected characteristics• We recognise that optimal vaccine uptake across the population is necessary. Ensuring that the vaccination is reaching all eligible groups is important. Ethnicity is only one of all the factors that influence vaccine uptake – there are many hard to reach patient groups.• To prevent inequality of vaccination provision consideration must be given to other protected characteristics (and any other relevant factors such as language barriers) and we request that an equality impact assessment is completed as a minimum by the applicant. <p>If the application is uplifted with the above, PAG are happy to support the application.</p>

Attendees	Role	Organisation
Arjun Dhillon	Chair, Caldicott Guardian	NHS Digital
Anu Rao	GPC IT Policy Lead	BMA
Amir Mehrkar	GP, Clinical Researcher	RCGP
Helen Buckels	Secretariat	NHS Digital
Liz Gaffney	Head of Data Access	NHS Digital
Dave Roberts	Head of Business and Operational Delivery	NHS Digital
Peter Short	Directorate Lead	NHS Digital

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 9th September 2020

Application: DARS-NIC-400304-S1P1B-v0
Organisation name: Office for National Statistics (ONS)
Profession Advisory Group Agenda item: 4

PAG noted the number of data extracts being requested across applications, and were supportive of NHS Digital (and the wider system) increasing the use of Trusted Research Environments rather than providing individual extracts. For this and future applications, PAG asked that NHS Digital included greater explanation around why a TRE was not used.

PAG wanted to ensure maximum benefit from data sharing, and would ask that ONS liaise with other national bodies to ensure that the research was complementary and not duplicative.

PAG suggested that the data could be pseudonymised prior to the data flowing.

PAG recommended that NHS Digital clarify that no pseudonymised data could be downloaded to a laptop that was not encrypted at rest (and specifically that any local device was not included within the definition of the environment).

PAG stated that any outputs created from the GP dataset should be shared with the BMA / RCGP at the same time as others.

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
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, 8th September 2020

In attendance (IGARD Members):	Paul Affleck (Specialist Ethics Member) Kirsty Irvine (IGARD Lay Chair)
In attendance (NHS Digital):	Dave Cronin (DARS – items 3.4 to 3.5) Louise Dunn (DARS – items 3.1 to 3.3) Liz Gaffney (DARS – item 2 and 3.1) Collette Healy (DARS – item 3.1) Karen Myers (IGARD Secretariat – Observer) Heather Pinches (DARS – Item 3.1) Vicki Williams (IGARD Secretariat)
In attendance (external):	Emily Cross (IBM – item 2 only) Stephen Pettitt (IBM – item 2 only)

2	<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 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 Data Access Request Service (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.</p> <p>Declaration of interests:</p> <p>There were no declarations of interest.</p>
2	<p><u>IBM update</u></p> <p>IGARD members were given a brief update to the IBM work underway in NHS Digital including improvements to the customer experience and current projects. It was agreed that this would be a weekly update to the COVID-19 response meeting.</p> <p>IGARD members thanked IBM and NHS Digital for the update and reiterated their previous suggestion that IGARD should be included early in any process or drafting changes including, but not limited to, application pro forma wording, checklists, standards and precedents.</p>
3.1 (a)	<p><u>Permission to Contact (no NIC number available): IQVIA</u></p> <p>Background: This was a verbal update to the verbal presentation at the COVID-19 response meeting on the 1st September and an application to be submitted by IQVIA Ltd and</p>

<p>3.1 (b)</p>	<p>AstraZeneca to access the Permission to Contact (PtC) dataset for potential vaccine trial recruitment.</p> <p>The following observations were made on the basis of the verbal briefing only.</p> <p>IGARD Observations:</p> <p>IGARD members noted the verbal update from NHS Digital and looked forward to further updates in due course.</p> <p>IGARD members suggested that, noting the trial was being run from the USA with IQVIA running the UK arm of the trial, that NHS Digital ensure that relevant transparency materials for the PtC dataset (and subsequent consent documentation) clearly articulated if data was being sent outside of England and Wales and the involvement of any commercial companies.</p> <p><u>Permission to contact: NIC-396423-H4Z6Z University of Oxford</u></p> <p>Background: This was a verbal update to documentation presented at the COVID-19 response meeting on the 18th August 2020 utilising the PtC dataset.</p> <p>NHS Digital noted the ongoing work being undertaken with the University with regard to the development of a feedback loop for when contacting participants and adding new recruitment sites to the application by way of an amendment.</p> <p>The following observations were made on the basis of the verbal briefing only.</p> <p>IGARD Observations:</p> <p>IGARD members noted the verbal update from NHS Digital and the approach taken by the University to ensure a robust feedback loop was in place for PtC volunteers.</p> <p>IGARD members also noted potential amendment to the application to include additional recruitment sites in order to target areas of recruitment that may be underrepresented, such as participants over a certain age or in a certain geographical area.</p> <p>IGARD suggested that any such approach to updating the application, for transparency, be included on a future IGARD business as usual (BAU) Thursday meeting agenda under any other business (AOB).</p>
<p>3.2</p>	<p><u>NIC-08472-V9S6K UK BioBank</u></p> <p>Background: This was an update to an application that had been previously considered at the COVID-19 response meeting on the 1st September 2020. The application had also been previously considered at the IGARD business as usual meeting on Thursday, 16th January 2020.</p> <p>This was an amendment application to include GPES Data for Pandemic Planning & Research (GDPPR). GDPPR data was being requested to enable a fuller case ascertainment of the disease, given that the majority of people experience mild to moderate symptoms and do not require hospitalisation.</p> <p>The following observations were made on the basis of the verbal briefing only, as the application had not been updated since last week's COVID-19 response meeting.</p> <p>IGARD Observations:</p> <p>NHS Digital noted that they were still waiting for written confirmation from the Information Governance (IG) directorate with regard to any restrictions that are in place for the use of</p>

	<p>GDPPR pseudonymised data, particularly in terms of use outside England and Wales and any restriction on the purpose of its use by international researchers (in light of the legal gateway under which GDPPR data was collected).</p> <p>NHS Digital updated IGARD with regard to a previous point raised with regard to the applicant requesting the GDPPR data for the entire c. 500,000 cohort, and that the GDPPR data would replace the GP data the applicant currently held from TPP and EMIS. However, IGARD noted that since GDPPR had been collected under emergency legislation for COVID-19 purposes only, that the applicant may wish to consider ring fencing the GDPPR data until that data falls away, to enable any long term research using GP data to continue using TPP and EMIS data. This ringfencing approach would also allow the continuation of any non-COVID-19 purpose research, using data from TPP and EMIS.</p> <p>IGARD members noted that UK Biobank are well placed to underpin COVID-19 research by linking diverse sources of data.</p> <p>NHS Digital updated IGARD with regard to a previous point raised at the 16 January 2019 business as usual (BAU) IGARD meeting with regard to the applicant updating their suite of documentation for sharing data with researchers. IGARD noted the significant project underway by the applicant in reviewing this suite of contractual documentation.</p> <p>Notwithstanding this review, IGARD suggested that in the interests of expediency the applicant consider a short term mechanism by which any applications for the GDPPR data are processed with the researcher applicant acknowledging and agreeing that the GDPPR data flow is conditional on accepting the special restrictions placed on the use of that data.</p> <p>IGARD members noted the new amendments proposed to address the benefits and purposes in section 5 (Purpose / Method / Outputs) and suggested the language with regard to the use of GDPPR data be refined, given the nature of the dataset.</p> <p>IGARD members noted the update with regard to the number of withdrawals from the programme, but suggested the language be refined and written more neutrally, and in addition to the number of withdrawals for those where their data was not to be used, that the number of withdrawals for those where they did not want to be contacted but the data still be used be inserted in section 5, for transparency.</p> <p>IGARD members also noted the interplay between the University of Oxford and UK Biobank and since the consent was clearly for one party to handle the identifiers and data, to ensure that the correct parties were aligned across all documentation.</p> <p>IGARD members also noted the aged special condition in section 6 (Special Conditions) and suggested that NHS Digital may wish to review this section and amend as appropriate.</p>
3.3	<p><u>NIC-156334-711SX University of Cambridge</u></p> <p>Background: This was an update to an application that had previously been considered at the COVID-19 response meetings on the 21st April and 28th April 2020. IGARD noted that the previous datasets released as part of this application had been approved by NHS Digital (SIRO precedent) and IGARD was not providing a view on those datasets and was therefore only considering the amendment request.</p> <p>The amendment application was to increase the data frequency from bi-annual to monthly, to permit the linkage of NHS Digital data to additional datasets to support COVID-19 research</p>

	<p>and to permit visiting academics who are not employed by the University of Cambridge to access the data.</p> <p>NHS Digital noted that this application would be considered by the Profession Advisory Group (PAG) on Wednesday 9th September and would be presented to the IGARD business as usual (BAU) meeting on Thursday, 17th September 2020, after relevant updates to the application.</p> <p>IGARD Observations:</p> <p>NHS Digital noted that they had assessed the consent materials and felt that it satisfied the Common Law Duty of Confidentiality.</p> <p>IGARD members noted that the applicant would be receiving a large volume of data across a variety of datasets and, noting the NHS Digital DARS Standard for Data Minimisation, suggested that section 5 (Purpose / Methods / Outputs) be updated to justify the data requested, and in addition that section 5(d) (Benefits) be updated to show how the data they were currently processing had produced relevant benefits to the health and social care system, as detailed in NHS Digital DARS Standard for Benefits.</p> <p>IGARD members noted that section 3(b) (Additional Data Requested) should be updated to clearly outline the data being disseminated under this application, including the GPES Data for Pandemic Planning & Research (GDPPR) data.</p> <p>IGARD members noted that the applicant had consulting with members of the public via the Health Data Research UK (HDR UK) Cambridge Advisory Group but suggested that the applicant may wish to consult members of the current cohort of participants.</p> <p>In addition, IGARD members noted that the applicant was in regular contact with participants of the study, but noted that in the next round of communication that the applicant may wish to focus on the current use of the data and COVID-19.</p> <p>IGARD members noted the Data Access Committee and queried if their Terms of Reference (TOR) had been finalised and if it aligned with TORs submitted by other applicants to NHS Digital using similar data.</p> <p>IGARD members noted the outline in section 1 (Abstract) with regard to relevant University of Cambridge employees having access to the data with permissions for visiting academics to access the data. IGARD members noted this was sensible to maximise the benefits flowing from the use of the requested data and suggested that NHS Digital ensure that relevant protections and permissions were in place.</p>
3.4	<p><u>NIC-400304-S1P1B Office for National Statistics (ONS)</u></p> <p>Background: This was a new application from ONS for extracts of GPES Data for Pandemic Planning & Research (GDPPR) data and Emergency Care Dataset (ECDS) to link with the Hospital Episode Statistics (HES) data already supplied to ONS via a separate Data Sharing Agreement (DSA) (NIC-388794-Z9P3J).</p> <p>The request is to enable ONS to link the NHS Digital data with Census data. The data is required for an analysis of national public health which has been requested by the Scientific Advisory Group for Emergencies (SAGE) and the results will inform SAGE, Members of Parliament and government officials of the differing COVID-19 profiles experienced by UK citizens, which will enable the Government to refine its policy response to the pandemic using the best evidence available.</p>

	<p>NHS Digital noted that this application would be considered by the Profession Advisory Group (PAG) on Wednesday 9th September and would be presented to the IGARD business as usual (BAU) meeting on Thursday, 17th September 2020.</p> <p>IGARD Observations:</p> <p>IGARD members welcomed the application and noted the benefits to public health were clearly articulated in the documentation provided.</p> <p>IGARD members suggested that section 1 (Abstract) be updated to remove alternative legal bases for this application and that they be included as background in an additional supporting document, and that section 1 clearly articulate the legal basis for this application.</p> <p>For completeness, IGARD members noted that the application included a request for ordnance survey grid reference data which, as per the HES Data Dictionary, requires express IGARD approval at a BAU meeting.</p> <p>IGARD members suggested that the original ONS paper presented outlining ONS's legal basis be consulted to ensure the application was fully informed and suggested if not clear that information governance (IG) should be consulted, with written confirmation provided as supporting documents for both the Profession Advisory Group (PAG) and the IGARD BAU meeting.</p> <p>Noting that this was presented as a service evaluation application, IGARD members suggested that the Health Research Authority (HRA) be consulted as to whether ethics approval was required for this application.</p> <p>IGARD members suggested that a verbal update be provided at next week's COVID-19 response meeting.</p>
3.5	<p><u>NHS England (no NIC number available)</u></p> <p>Background: this was a verbal update for NHS England and Public Health England (PHE) to access the NHS Digital Cancer Trusted Research Environment (TRE). The Cancer Alliance Data, Evidence & Analysis Service (CADEAS) is a partnership between NHS England and PHE and request reliable ethnicity data to link at patient level with National Cancer Waiting Times (CWT) data in order to investigate whether this is any ethnicity related inequality in patient urgent referrals or treatment volumes during the current COVID-19 pandemic.</p> <p>The following observations are made on the basis of the verbal briefing only.</p> <p>IGARD Observations:</p> <p>IGARD members welcomed the verbal update from NHS Digital with regard to the NHS Digital Cancer TRE.</p> <p>Noting that they had received a briefing paper with regard to the cardiovascular TRE and that other TREs are currently being set up, NHS Digital suggested that prior to any inclusion on an IGARD business as usual (BAU) meeting that a briefing paper or verbal update be provided for IGARD members with regard to the Cancer TRE by the relevant programme lead within NHS Digital. IGARD members welcomed this approach.</p> <p>IGARD members queried whether the urgent application from NHS England should be separated from the setting up of the Cancer TRE and that consideration be given by NHS Digital to a two-track approach. IGARD members noted that this would then ensure that the</p>

	application was not unduly delayed and that governance arrangements across different TREs were aligned. This would also ensure that all new TREs were set up consistently and separately to any applications in-train.
4.	<u>AOB</u> 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, 15th September 2020

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

In attendance (NHS Digital): Louise Dunn (DARS – items 3.1 to 3.3)
Liz Gaffney (DARS – item 2 and 3.1)
Karen Myers (IGARD Secretariat – Observer)
Vicki Williams (IGARD Secretariat)

In attendance (external): Emily Cross (IBM – item 2 only)

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 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 Data Access Request Service (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.</p> <p>Declaration of interests:</p> <p>There were no declarations of interest.</p>
2	<p><u>IBM update</u></p> <p>IGARD members were given a brief update to the IBM work underway in NHS Digital including improvements to the customer experience and current projects. It was agreed that this would be a weekly update to the COVID-19 response meeting.</p> <p>IGARD members thanked IBM and NHS Digital for the update and reiterated their previous suggestion that IGARD should be included early in any process or drafting changes including, but not limited to, application pro forma wording, checklists, standards and precedents.</p>
3.1	<p><u>NIC-401171-F9Z8T National Institute for Health Research / St George's University Hospitals NHS Foundation Trust</u></p> <p>Background: This was a new application from St George's University Hospitals NHS Foundation Trust to utilise the COVID-19 Permission to Contact (CV19 PtC) dataset as part of the NHS COVID-19 vaccine research registry launched with the intention of helping large numbers of people to be recruited into trials over the coming months. St George's will use this service to recruit participants to a vaccine trial for those aged 18-84 for new vaccine SARS-</p>

	<p>CoV 2 Recombinant(r) Spike(S) Protein Nanoparticle Vaccine (SARS CoV 2rS) with Matrix-M Adjuvant, the trial will also give valuable information on safety aspects of the vaccine.</p> <p>IGARD Observations:</p> <p>IGARD members noted that the application was to be presented to the IGARD BAU Meeting on Thursday, 17th September 2020.</p> <p>IGARD Members noted that the discussion today was not to pre-empt discussions that would take place at the BAU meeting on Thursday and thanked NHS Digital for their verbal update.</p>
3.2	<p><u>NIC-402116-G1T7V NHS England</u></p> <p>Background: this was a verbal presentation of a new GPES Data for Pandemic Planning & Research request linked to Hospital Episode Statistics (HES) to provide ethnicity data for circa 60 million people. The first application is secondary uses for flu and will be followed up for COVID-19 secondary uses.</p> <p>NHS Digital noted that this was an urgent application that would be considered by the Profession Advisory Group (PAG) on Wednesday 16th September and would be presented to the IGARD business as usual (BAU) meeting on Thursday, 17th September 2020.</p> <p>IGARD Observations:</p> <p>IGARD members noted that the application was to be presented to the IGARD BAU Meeting on Thursday, 17th September 2020, following a review by the Profession Advisory Group (PAG) on Wednesday, 16th September, with an extract of the PAG minutes appended to IGARD's published minutes.</p> <p>IGARD members noted that the discussion today was not to pre-empt discussions that would take place at the BAU meeting on Thursday and thanked NHS Digital for their verbal update, however a number of observations were made which NHS Digital may wish to consider before the application is presented to both PAG and IGARD, and these observations by IGARD members are based on the verbal briefing only, including, but not limited to,:</p> <ul style="list-style-type: none"> • Justification as to why the applicant is requesting GDPPR data, when Personal Demographics Service data may provide sufficient detail. • To clearly establish why this ethnicity data is relevant to the flu vaccine programme and how this will feed into the future COVID-19 vaccine programme. • To be explicitly clear that the GDPPR data collected under emergency legislation has a limited time span and purpose. • To provide NHS Digital information governance advice on the legal basis to collect / disseminate the data.
3.3	<p><u>NIC-400304-S1P1B Office for National Statistics</u></p> <p>Background: This was a new application from ONS for data extracts from GPES Data for Pandemic Planning & Research (GDPPR) and the Emergency Care Dataset (ECDS) to link with the Hospital Episode Statistics (HES) data already supplied to ONS via a separate Data Sharing Agreement (DSA) (NIC-388794-Z9P3J).</p> <p>The request is to enable ONS to link the NHS Digital data with Census data. The data is required for an analysis of national public health which has been requested by the Scientific Advisory Group for Emergencies (SAGE) and the results will inform SAGE, Members of</p>

	<p>Parliament and government officials of the differing COVID-19 profiles experienced by UK citizens, which will enable the Government to refine its policy response to the pandemic using the best evidence available.</p> <p>NHS Digital noted that this application had been considered by the Profession Advisory Group (PAG) on Wednesday 9th September and would be presented to the IGARD business as usual (BAU) meeting on Thursday, 17th September 2020.</p> <p>IGARD Observations:</p> <p>IGARD members noted that the application was to be presented to the IGARD BAU Meeting on Thursday, 17th September 2020, and that it was to be presented following a review by the Profession Advisory Group (PAG) on Wednesday, 9th September, with an extract of the PAG minutes appended to IGARD's published minutes.</p> <p>IGARD Members noted that the discussion today was not to pre-empt discussions that would take place at the BAU meeting on Thursday and thanked NHS Digital for their verbal update, however noted that a key action from today was to discuss the application with the NHS Digital Caldicott Guardian in respect of National Data Opt-Outs.</p>
4.	<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>