Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 29 July 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker (Chair)	Specialist GP Member / IGARD Deputy Specialist GP Chair
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Maria Clark	Lay Member
Prof. Nicola Fear	Specialist Academic Member
Kirsty Irvine	IGARD Chair / Lay Representative
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Catherine Day	Data Access Request Service (DARS)
Mujiba Ejaz	Data Access Request Service (DARS)
James Gray	Data Access Request Service (DARS)
Frances Hancox	Data Access Request Service (DARS)
Karen Myers	IGARD Secretariat
Jonathan Osborn	Deputy Caldicott Guardian (Observer: item 2.1)
Emma Russell	Data Access Request Service (DARS)
Claire Welsh	Data Access Request Service (DARS) (Observer: items 2.1 – 2.3)
Vicki Williams	IGARD Secretariat

1	**Declaration of interests:** Dr Maurice Smith declared an interest with regard to application NIC-388794-Z9P3J-v5.3 Office for National Statistics, in that he is a GP Partner in a NHS GP Practice but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest.

	Review of previous minutes and actions: The minutes of the 22nd July 2021 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	Health Data Research UK (HDR UK): R14.2 - COVID-IMPACT-UK. Cardiovascular disease and COVID-19: using UK-wide linked routine healthcare data to address the impact of cardiovascular disease on COVID-19 and the impact of COVID-19 on cardiovascular diseases. (Presenter: Catherine Day) NIC-381078-Y9C5K-v6.2 **Application:** This was an amendment application **1)** to add the University of Glasgow as a Data Controller; **2)** to add the following pseudonymised datasets to the Trusted Research environment (TRE): Improving Access to Psychological Therapies Data Set (IAPT), Mental Health of Children and Young People (MHCYP) dataset, Maternity Services Dataset (MSDS), Patient Reported Outcome Measures (PROMs), COVID-19 Genomics UK (COG UK), Uncurated Low Latency datasets for Hospital Episode Statistics Admitted Patient Care (HES APC), HES Outpatients, HES Critical Care; **3)** to amend the purpose of the application from the 'CVD-COVID-UK' to 'COVID-IMPACT-UK'; **4)** to remove the University of Liverpool and The National Institute for Health and Care Excellence (NICE) as Data Controllers. The British Heart Foundation (BHF) Data Science Centre, which is embedded within Health Data Research UK (HDR UK), is working in partnership with NHS Digital to establish a Trusted Research Environment (TRE) [service] for England, to enable analyses of linked, nationally collated healthcare datasets. This project is now entitled 'COVID-IMPACT-UK', and will enable timely research on the effects/impacts of pre-existing health on COVID-19, and the direct and indirect impacts of COVID-19 on health; coordinate similar approaches across the four nations of the UK; and demonstrate how accessing data within a TRE could support future research initiatives. NHS Digital advised IGARD, that following the submission of the application for review, the applicant had requested an additional update to the application which was to add Imperial College London (ICL) as a joint Data Controller. **Discussion:** IGARD noted that aspects of this application had last been seen by the IGARD – NHS Digital COVID-19 Response meeting on the 29th June 2021. IGARD also noted that this application had also been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 24th June 2020, and that notes from this meeting had been attached to the IGARD minutes from the 23rd July 2020; and the 28th July 2021 (see Appendix B). IGARD noted that PAG supported the application, and noted the comments made on the application. IGARD queried the statement in section 5 (Purpose / Methods / Outputs) *"Should any research project be proposed that would require the identification of individual practices, researchers would seek guidance from NHS Digital and their *GP advisory group…"* *(PAG), and asked that NHS Digital confirmed if this was a possible pathway to PAG and part of PAG's Terms of Reference (ToR). IGARD noted the verbal update from NHS Digital in relation to the additional request from the applicant to add ICL as a joint Data Controller. IGARD confirmed they were supportive of this addition. NHS Digital confirmed that there was a Data Sharing Framework Contract (DSFC) in

	place for ICL, and IGARD noted that since ICL had been included on other Data Sharing Agreements (DSA) as both a Data Controller and Data Processor, asked that the application was updated throughout to include ICL as a joint Data Controller, and in line with NHS Digital's DARS Standard for Data Controllers. IGARD noted that this inclusion could be by way of the NHS Digital DARS simple amendment precedent for ICL or any other organisation named as a potential Data Controller within the application but that this did not set a general precedent for any other organisation. IGARD queried the rationale for removing the University of Liverpool and NICE as Data Controllers, and were advised by NHS Digital that there were currently no approved projects for the two organisations, hence their removal. IGARD noted and thanked NHS Digital for the verbal update but queried why they had been included originally if no projects had been in place. IGARD noted the special condition in section 6 (Special Conditions) that a Joint Data Controller Agreement would be put in place and signed by all relevant data controllers within 2 months of signing the DSA and queried if this condition had been met. NHS Digital advised IGARD that the special condition had not been met. IGARD noted the verbal update from NHS Digital and advised that this was a potential reputational risk for NHS Digital. IGARD suggested that NHS Digital discuss with the applicant and reiterated their comments from when the application was last reviewed by IGARD on the 25th February 2021, namely: to ensure that a finalised data controllership agreement was uploaded to NHS Digital's customer relationship management (CRM) system, to ensure the essence of the agreement is communicated in the public facing transparency materials, and that the privacy notice be updated to reflect the current joint data controllers and different responsibilities from the wider consortium members. IGARD noted that the CVD-COVID-UK Approvals & Oversight Board (known as the 'Oversight Board' in these minutes) had provided a number of meeting minutes as supporting documents and thanked the applicant for providing these. However, IGARD noted the minutes did not reference the consideration of data minimisation as outlined in the Oversight Board's ToR. In addition, IGARD advised that, as data in the TRE was not minimised and minimisation needed to be considered on a project-by-project basis, this was a significant area of risk. IGARD queried why the applicant was requesting Uncurated Low Latency Hospital Data Sets, noting that these datasets were usually only requested where there was an urgency for the data, and the data contained within the Uncurated Low Latency datasets would also be available within the other data requested, albeit with a small time lag. IGARD therefore asked that section 5 (Purpose / Methods / Outputs) was updated with a justification for the requirement of the Uncurated Low Latency HES APC, HES Outpatients, HES Critical Care Data Sets. IGARD queried the amendment outlined in the application, that requested COVID-19 Genomics UK (COG UK) data, noting that they were unfamiliar with this dataset and had not received a briefing, as per due process. NHS Digital advised that the COG UK dataset was not yet onboarded to NHS Digital, and that this had been added to the application for the future. IGARD thanked NHS Digital for the verbal update, however noting that they had not yet received a briefing note from NHS Digital, as per due process, they were unable to make a recommendation on the addition of this dataset, as not all the necessary information was available in order for IGARD to make a full assessment, such as the legal basis for collection and dissemination, the purpose of the data etc. IGARD noted the constraints placed in the Direction for the collection of NHSBSA Medicines dispensed in Primary Care data, by NHS Digital, specifically *"Providing intelligence about the safety and effectiveness of medicines…"*; and asked that In line with NHS Digital's DARS

	Standard for Objective for Processing, when referencing processing of Medicines Dispense in Primary Care NHSBSA data to ensure a clear narrative is provided linking the purposes and processing to the relevant Direction. In addition, IGARD remained concerned that there may be widespread use of the NHSBSA dataset despite the narrow scope of the relevant Direction. IGARD asked that a special condition was inserted in section 6, that any use of the NHSBSA data must be within the parameters of the relevant Direction authorising that collection. IGARD queried the reference in section 3(b) (Additional Data Access Requested), to the flow of COVID-19 Second Generation Surveillance System (SGSS) being "*identifiable*", and asked that this was updated to remove this reference, and to correctly reflect that the SGSS data was *"pseudonymised"*. IGARD noted in section 3(c) (Patient Objections) that the National Data Opt-out (NDO) would not be applied, however queried if this was correct, noting that there was data flowing for datasets which, at some point in their formation, were collected under s251. IGARD asked that NHS Digital confirm whether the NDO should be applied, pending the full rollout of the NHS Digital's NDO policy, and in line with NHS Digital's current practice. IGARD noted the objective for processing outlined in section 5(a) (Objective for Processing), however asked that this was updated further, in line with NHS Digital's DARS Standard for Objective for Processing, to insert a clear summary of the aims of the research, written in a language suitable for a lay reader and for inclusion in NHS Digital's data release register. IGARD queried the references in section 5(a) to *"future proofing"*, for example, in respect of post-COVID-19, and asked that, noting that some of the data collections relied upon The Health Service Control of Patient Information (COPI) Regulations 2002, that this was either updated to remove the references, or that further details were provided. IGARD queried the information within section 5(b) (Processing Activities) that referred to "…*not all medications prescribed are actually taken by patients or by the patients for whom they are prescribed*", and asked that this was updated, to accurately reflect that not all *"prescriptions are collected by patients"* as this is what the dataset will show. IGARD noted the references in section 5 to *"CVD use only"* and, noting that the TRE had significantly expanded since its creation, asked that this was updated to remove the "*CVD use only*" references, to reflect the expansion of the use of the TRE. IGARD noted that some of the information in section 5 was not clear and suggested that it was updated to ensure that it was written in a language suitable for a lay reader and that further consideration was given to the patient audience, for example when referring to *"COG UK".* IGARD suggested that section 5(c) (Specific Outputs Expected) and section 5(d) (Benefits) be updated to remove reference to "*it will*…" and instead use a form of words such as "*it is expected…"* or *"it is hoped …".* IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the novel nature of the TRE and how the data controllership agreement is progressing; with the exception of adding ICL as a joint Data Controller, which can be done under the simple amendment Precedent. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the novel nature of the TRE and how the data controllership agreement is progressing; with the exception of adding ICL as a joint Data Controller or any other organisation named as a potential data controller within the application , which can be done under the NHS Digital DARS Simple Amendment Precedent.

	Outcome: unable to make a recommendation as not all the necessary information was available in order for IGARD to make a full assessment, with regard to the COG UK data. **Outcome:** recommendation to approve subject to the following condition (this excludes the COG UK data): 1. To provide a justification in section 5, for the requirement of the Uncurated Low Latency Hospital Data Sets. The following amendments were requested: 1. To update the application throughout to include ICL as a Data Controller, and as per the verbal update from NHS Digital, and in line with NHS Digital's DARS Standard for Data Controllers. 2. To update section 3(b) to remove reference to *"identifiable"* for the SGSS data and replace with *"pseudonymised"*. 3. In respect section 5(a) and in line with NHS Digital's DARS Standard for Objective for Processing: a. To insert a clear summary of the aims of the research written in a language suitable for a lay reader and for inclusion in NHS Digital's data release register. b. When referencing processing of Medicines Dispense in Primary Care NHS BSA data to ensure a clear narrative is provided linking the purposes to the relevant Direction. 4. To update section 5(a) to either remove or provide further details about the reference to *"future proofing"*. 5. To insert a special condition in section 6, that any use of the Medicines Dispensed in Primary Care NHS BSA data must be within the parameters of the relevant Direction authorising that collection. 6. To update section 5(b) to reflect that not all *"prescriptions are collected by patients"* as this is what the datasets will show. 7. To update section 5 to remove reference to *"CVD use only"* to reflect the expansion of the use of the TRE. 8. To update section 5(c) and section 5(d) to use a form of wording such as "*it is expected…"* or *"it is hoped …"*, rather than "*it will…*". 9. To update section 5 to ensure it is written in language suitable for a lay reader and that consideration is given to the patient audience, for example when referring to *"COG UK".* The following advice was given: 1. IGARD confirmed they were supportive of the addition of ICL as a joint Data Controller, because there is a DSFC in place, and they have been included on other DSAs as both a Data Controller and Data Processor; and the inclusion via a simple amendment, does not set a precedent for any other organisation. 2. IGARD reiterated their previous comments, and suggested that the minutes of the Oversight Board, expressly reference the consideration of data minimisation as outlined in their ToR. 3. NHS Digital should confirm whether the NDO should be applied, for the data flowing for those datasets which are at some point in their formation collected under s251, pending the full rollout of the NDO policy, and in line with NHS Digital's current practice. 4. IGARD noted reference within section 5 of the application with regard to researchers seeking guidance from PAG, and NHS Digital should consider if this is a possible pathway and part of PAG's ToR.

	5. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the novel nature of the TRE and how the data controllership agreement is progressing; with the exception of adding ICL as a joint Data Controller, which can be done under the simple amendment Precedent. 6. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the novel nature of the TRE and how the data controllership agreement is progressing; with the exception of adding ICL as a joint Data Controller or any other organisation named as a potential Data Controller within the application, which can be done under the simple amendment Precedent. **Significant Risk Areas:** 1. The data controllership agreement as outlined in the special conditions and IGARD's recommendation, has not been provided, and this is a potential reputational risk for NHS Digital. 2. The minutes of the Oversight Board, do not appear to make reference to the consideration of the data minimisation, as outlined in their ToR. 3. IGARD remained concerned that there may be widespread use of the NHS BSA dataset that goes beyond the narrow scope of the relevant Direction.
2.2	<u>Roehampton University: Understanding diversity in childbirth and London's ethnic gap in maternal morbidity Understanding diversity in childbirth and London's ethnic gap in maternal morbidity (Presenter: Catherine Day) NIC-350331-P9L1M-v0.4</u> **Application:** This was a new application for pseudonymised Civil Registration (Deaths) data, Hospital Episode Statistics Admitted Patient Care (HES APC) and Maternity Services Data Set (MSDS). The purpose is for a pilot study to explore the extent to which the parameter of childbirth and the rate of birth interventions, differ among women of different ethnic groups in London. There are substantial ethnic gaps in maternal morbidity, for example,black women in Britain are five times more likely to die in childbirth than white women. The study will explore, **1)** any ethnic gap in maternal mortality and morbidity within the same geographic areas and care providers; **2)** whether key parameters of childbirth, such as the length of the two main stages of labour, duration of pregnancy, birth weight, baby's presentation at birth etc, differences in white, Asian, East Asian and black women in London; **3)** whether specific childbirth interventions, such as hormonal induction, forceps application, C-sections, are used more frequently in some ethnic groups; **4)** whether any identified ethnic difference in the rate of interventions correlates with differences in the process of labour; **5)** whether any identified ethnic difference in the rate of certain interventions could contribute to the ethnic morbidity and mortality gaps. The cohort size is anticipated to be approximately 200,000 women. **Discussion:** IGARD queried if there had been any public and patient involvement (PPI) on the project to date, noting that this was not clear in the application or any of the supporting documentation provided; and asked that section 5 (Purpose / Methods / Outputs) was updated with confirmation of any PPI activity the applicant had undertaken or was to undertake. In addition and noting the involvement of the Advocacy Group, suggested that there may be benefit to involving patients earlier in the study, as per the HRA guidance on Public Involvement. IGARD queried information in section 5, in respect of derived data, for example, the reference relating to the duration of second stage of labour, and the statement that *"it may be possible to*

	reverse it for the calculation…"; and asked that section 5 was updated to clarify the process with regard to derived data, to ensure that the data does not become identifiable. IGARD also asked that section 5 was updated, to ensure this section reflected the processing that would be undertaken as part of this study and removed reference to the "first person" narrative, since this formed NHS Digital's Data Release Register. IGARD queried if the ethnicity information contained within the MSDS dataset was adequate for the study, and asked that section 5 was updated with confirmation or that clarity was provided that the data processed would determine this aspect. Although not part of their remit, IGARD noted that the funding appeared to only just cover the cost of the provision of data, and suggested that NHS Digital may wish to assure itself that there were sufficient resources in place to complete this work. IGARD noted the information provided in section 1 (Abstract) with regard to the use of a single computer to store the data, and agreed with NHS Digital's analysis in terms of it being good practice to have a back-up. IGARD noted that the applicant was yet to respond on this point but supported NHS Digital's request that the application may be updated further if the applicant takes on board NHS Digital's solution. IGARD suggested that section 5(c) (Specific Outputs Expected) and section 5(d) (Benefits) be updated to remove reference to "*it will*…" and instead use a form of words such as "*it is expected…"* or *"it is hoped …".* **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 5 with confirmation of any PPI activity in the project to date, as per the HRA guidance on Public Involvement. 2. In respect of the derived data: a) To update section 5, to clarify the process with regard to derived data, to ensure that it does not become identifiable. b) To update section 5 to ensure this reflects the processing that will be undertaken, since this forms NHS Digital's Data Release Register. 3. To update section 5, to confirm that the MSDS dataset, has adequate ethnicity information; or clarify that the data processed will determine this aspect. 4. To update section 5(c) and section 5(d) to use a form of wording such as "*it is expected…"* or *"it is hoped …"*, rather than "*it will…*". The following advice was given: 1. IGARD noted the involvement of the Advocacy Group, and suggested that there may be benefit to involving patients earlier in the study, as per the HRA guidance on Public Involvement. 2. IGARD noted that the funding appeared to only just cover the cost of the provision of data, and suggested that NHS Digital may wish to assure itself that there are sufficient resources in place to complete this work. 3. IGARD agreed with NHS Digital's analysis with regard to the use of a single computer to store the data.
2.3	Imperial College London: Examining the healthcare inequalities in breast cancer screening during COVID-19 (Presenter: Catherine Day) NIC-422971-B8P2V-v0.6

	Application: This was a new application for pseudonymised GPES Data for Pandemic Planning and Research (COVID-19) (GDPPR) data. COVID-19 has had an unprecedented impact upon breast cancer screening services, in addition, studies have shown that women from non-white backgrounds are up to 63% less likely to attend screening mammograms compared to their white British counterparts. In addition, women from more deprived areas and those with more medical co-morbidities status are less likely to attend breast screening invitations. These studies have all been conducted with closed, as opposed to the novel open, invitation structure. There are, however, concerns that this open model may exacerbate these existing inequalities by introducing further logistical barriers, for example, practical barriers to booking appointments. Currently, screening services in London are utilising both open and closed invitations, and therefore, the true effect of the new invitations on individual patients is unclear. Furthermore, the effect upon ethnic minorities, those with clinical comorbidities or those who were identified as clinically extremely vulnerable is not known, as this is not collected by screening hubs. The purpose of this application is for a study to understand the impact on these groups, to allow services to: **1)** target resources on potentially low attendance groups, **2)** amend invitations to meet the needs of the local populations, **3)** maintain pre-COVID breast cancer screening uptake, and **4)** aim to maintain screening levels sufficient for the screening programme as a whole to be of benefit. NHS Digital advised IGARD that a cohort of 1.2 million patients had been approved by NHS Digital's Privacy, Transparency and Ethics (PTE). NHS Digital also advised IGARD that Imperial College London (ICL) were the Data Processor for the study, however this had not been reflected in the application, and that this would be updated as appropriate to reflect this information. **Discussion:** IGARD noted that aspects of this application had been previously seen at the IGARD – NHS Digital COVID-19 Response meetings on the 2nd February 2021. IGARD also noted that this application had also been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 20th January 2021 (see Appendix B). IGARD noted that PAG did **not** support the application and highlighted this as a significant risk to NHS Digital. In addition, IGARD also noted the comments made by PAG on the application. IGARD noted the verbal update from NHS Digital, in respect of the cohort of 1.2 million patients, having been approved by PTE. However, IGARD queried if this was correct, noting the statement in section 5(a) (Objective for Processing) that "*Imperial College London estimate approximately 200,000 patients will be invited to screen…*"; and asked that section 5(a) (Objective for Processing) was updated to clarify the correct size of the cohort. In addition, IGARD asked that once the correct cohort size was established, the application was amended throughout to remove any incorrect references to the cohort size. IGARD also noted the verbal update from NHS Digital in respect of ICL being added as a Data Processor, noting that section 1(c) (Data Processors) was currently blank on the application. IGARD confirmed they were supportive of this addition. NHS Digital confirmed that there was a Data Sharing Framework Contract (DSFC) in place for ICL and IGARD noted that since ICL had been included on other Data Sharing Agreements (DSA) as both a Data Controller and Data Processor asked that the application was updated throughout, to reflect the addition of ICL as a Data Processor and in line with NHS Digital's DARS Standard for Data Processors. IGARD queried which entities were Data Controllers, noting that supporting document 5.0, the e-mail correspondence between NHS Digital and NHS England, which appeared to advise that

	it was NHS England, NHS Improvement, and ICL who were joint Data Controllers, not just NHS England as listed currently in the application, stating "*NHSEI are to be joint Data Controllers with Imperial College London on this study…*". IGARD suggested however, that if ICL were being commissioned to carry out a service evaluation, that they may in fact be a Data Processor as opposed to a Data Controller, and in line with the information presented and NHS Digital's DARS Standard for Data Processors. IGARD also asked, that in respect of the data controllership, clarification was provided as to which legal entities should be considered a joint Data Controller, as borne out of the facts presented with particular reference to NHS Improvement (the legal bodies being: Monitor and NHS Trust Development Authority (TDA)), noting the information provided within supporting document 5.0, and in line with the NHS Digital's DARS Standard for Data Controllers. IGARD also asked that the application was updated, and any relevant supporting documents with a clear justification of the joint data controllership arrangement were uploaded to NHS Digital's customer relationship management (CRM) system as future supporting documents and in line with the NHS Digital's DARS Standard for Data Controllers. IGARD noted that section 3(c) (Patient Objections) stated that the National Data Opt-outs (NDO) would not be applied, however asked that this was amended to accurately reflect that the NDO was not applied due to The Health Service Control of Patient Information (COPI) Regulations 2002 being the legal basis for the flow of data into NHS Digital. IGARD noted the reference in section 5(b) (Processing Activities) to the GDPPR data being "*confidential patient data "*, and asked that this was removed, noting that it conflicted with information elsewhere in the application. IGARD queried why the application was regarded a *"service evaluation"* and not research, and asked that for transparency, the beginning of section 5(a) was updated, with the clarity provided within supporting document 3.0, the protocol, which helpfully outlined the aims and outcome measures, noting the ascertainment of whether the introduction of open invitations has affected screening uptake is entirely laudable, particularly given the concerns that it may further reduce uptake in known low attendance groups. IGARD noted a number of acronyms in section 5(b) and asked that this public facing section be updated to ensure that all acronyms upon first use were expanded, and technical terms were clearly defined with a supportive explanation in a language suitable for a lay audience, or removed, for example, the information relating to *"encryption"*. IGARD also asked that the language used in section 5(c) (Specific Outputs Expected) was reviewed, and update as appropriate, for example, reference to *"Q3"*. **Outcome:** recommendation to approve subject to the following condition: 1. In respect of the data controllership and in line with NHS Digital's DARS Standard for Data Controllers: a) To clarify which legal entities should be considered a Data Controller, as borne out of the facts presented with particular reference to NHS Improvement (Monitor and NHS TDA), noting that the Head of Screening confirmed in an email that "NHSEI" are to be joint data controllers. b) To update the application and any relevant supporting documents with a clear justification. The following amendments were requested: 1. To update the application throughout to reflect the addition of ICL as a Data Processor, as per the verbal update from NHS Digital and in line with NHS Digital's DARS Standard for Data Processors.

	2. To amend section 3(c) to reflect that NDO is not applied due to COPI being the legal basis for the flow of data into NHS Digital. 3. In respect of the cohort size: a) To update section 5(a) to clarity the correct size of the cohort (1.2m versus 200,000). b) To amend the application throughout to remove any incorrect references to the cohort size. 4. To update the beginning of section 5(a) with clarity as to why the application is a *"service evaluation"* and not research, as helpfully outlined in the protocol aims and outcome measures. 5. As section 5 forms NHS Digital's public data release register: a) To amend section 5(b) to ensure acronyms be defined upon first use, and technical terms are explained in a manner suitable for a lay audience, or removed, for example, the information relating to *"encryption"*. b) To review the language used in section 5(c) and update as appropriate, for example, reference to *"Q3"*. 6. To remove the reference in section 5(b) to the GDPPR data being "*confidential patient data " as* this conflicts with information elsewhere in the application. **Significant Risk Area:** 1. PAG has indicated that it does not support this application.
2.4	<u>Office for National Statistics (ONS): Request for remote access to data in NHS Digital's environment for COVID-19 purposes (Presenter: Frances Hancox / Emma Russell) NIC-388794-Z9P3J-v5.3</u> **Application:** This was a renewal and extension application for identifiable Civil Registration (Deaths) data, COVID-19 UK Non-hospital Antigen Testing Results (pillar 2), GPES Data for Pandemic Planning and Research (COVID-19) (GDPPR), Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC), HES Critical Care and HES Outpatients. It was also an amendment to seek renewal until the 30th June 2022 for a broader scope of responsive research. The purpose is for research into the production of official statistics in respect of COVID-19. The results of the analysis will be used to inform members of the Scientific Emergency Group for emergencies (SAGE), Members of Parliament (MPs) and other government officials of the differing COVID-19 risk profiles experienced by UK citizens. This will enable the government to refine its policy response to the pandemic using the best evidence available. The analysis may also improve the public's understanding of the risk faced by individuals, leading to more informed personal decision making, and add to the growing body of literature being produced and evaluated by the global academic community. In addition, it is hoped that the work, will improve understanding of and support the development of statistics on what the data can be used to learn about, the short, medium and long-term impacts of having had COVID-19; and the impact COVID-19 and its associated social, economic and environmental impacts has had on health and well-being. NHS Digital advised IGARD that the expiry date for this application was the 2nd August 2021. NHS Digital also highlighted to IGARD that the legal basis for dissemination of the data from NHS Digital was The Health Service Control of Patient Information (COPI) Regulations 2002; and therefore the application had been updated, 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 GDPPR data.

	Discussion: IGARD noted that aspects of this application had last been seen by the IGARD – NHS Digital COVID-19 Response meeting on the 8th December 2020. IGARD noted that this application had been reviewed at PAG on the 9th December, and that notes from this meeting had been attached to the IGARD minutes from the 17th December 2020; the 8th July 2020, and that notes from this meeting had been attached to the IGARD minutes from the 9th July 2020; and the 28th July 2021 (see Appendix B). IGARD noted that PAG supported the application, and noted the comments made on the application; in particular, IGARD supported PAG's recommendation that new clinical research questions should have ethics review, and suggested that ONS consult with the Health Research Authority (HRA) as to whether the research under this agreement falls within the HRA's remit. In addition, noting within the application that ethics approval was not required because ONS has a National Statistics Data Ethics Advisory Committee (NSDEC), IGARD asked that written confirmation was provided that NSDEC had received a briefing on the application at their regular meetings and did not raise any substantial points. If ONS have already briefed NSDEC on this application, IGARD asked that they provided to NHS Digital a copy of this written support. If the application or briefing was scheduled on the next NSDEC agenda, IGARD asked that confirmation of this was provided. IGARD asked that in all cases, a copy of the written confirmation, which raised no substantial points from NSDEC, was upload to NHS Digital's CRM system for future reference. IGARD noted the verbal update from NHS Digital in respect of the expiry date for the DSA, and in light of this, suggested that NHS Digital might wish to consider a short-term extension with ONS, in order for them to retain access to the Data Access Environment (DAE), while work was undertaken to update the application. IGARD noted the verbal update in respect of COPI being legal basis for the dissemination of the data, and the sunset clause wording relating to actions to be taken upon expiry of the COPI Notice. IGARD noted that section 3(c) (Patient Objections) stated that the National Data Opt-out (NDO) would not be applied, however asked that this was amended to accurately reflect that the NDO was not applied due to The Health Service Control of Patient Information (COPI) Regulations 2002 being the legal basis for the flow of data into NHS Digital. IGARD also asked that section 3(c) was updated, to accurately reflect that the National Data Opt-out (NDO) was not applied, due to COPI being the legal basis for the flow of data into NHS Digital. IGARD queried why ONS required both the disseminated data extract and access to the Data Access Environment (DAE) to continue until 2022. NHS Digital noted that access to both had initially been a short term proposal. Noting the verbal update from NHS Digital, IGARD asked that section 5(a) (Objective for Processing) was updated with an explanation, in order to satisfy the UK General Data Protection Regulation (UK GDPR) requirements in avoiding excessive processing. IGARD noted that section 2 (Locations) did not contain any details about the processing and storage locations, for example, for the DAE; and asked that in line with the information provided for access to the Trusted Research Environment (TRE), that section 2 was updated to include the processing and storage locations for the DAE. Separate to this application, IGARD advised that NHS Digital should include all processing and storage locations for DAE applications, and in line with the TRE applications, to ensure consistency across DAE and TRE applications.

	IGARD noted section 2(c) (Territory of Use) stated that the territory of use was *"England and Wales"*, however asked that NHS Digital's DAE Team, confirmed in section 1 (Abstract) , that the territory of use stated, aligned with the location of the Data Processors and the geographical restrictions on the datasets, as noted in NHS Digital's UK GDPR transparency pages. IGARD strongly suggested that ONS consider expressly addressing the proposed processing within its Data Protection Impact Assessment (DPIA), which is designed to assess the risk to the rights and freedoms of natural persons, with particular reference to the rights of individuals including, but not limited to, the right to erasure, the right to restricted processing and the right to object. In respect of the privacy notice and in line with NHS Digital's DARS Standard for transparency (fair processing), IGARD wished to draw the applicant's attention to the statement in section 4 (Privacy Notice) of the application, that a UK GDPR compliant, publicly accessible transparency notice was maintained throughout the life of the agreement. In addition, IGARD suggested that ONS may wish to refresh the advice previously received from the Information Commissioner's Office (ICO) in respect of transparency to the public. IGARD noted the importance of transparency and asked that the proposed processing was reflected in the privacy notice. IGARD suggested that section 5(d) (Benefits) be updated to remove reference to "*it will*…" and instead use a form of words such as "*it is expected…"* or *"it is hoped …".* IGARD queried the benefit outlined in the last paragraph in section 5(d) (ii) (Expected Measurable Benefits), and asked that this was revised, to clarify how the understanding obtained by the analysis supports the use of this data, as this was not clear, and in line with and in line with NHS Digital's DARS Standard for Expected Measurable Benefits. IGARD queried the benefits outlined in section 5(d), and noted that some of the information provided were outputs, and asked that section 5(d) was updated to remove any outputs and edited to only leave examples that reflect the benefits to the Health and Social Care System. IGARD asked that for transparency, section 5 (Purpose / Methods / Outputs) was updated, to indicate how the reduction in COVID-19 related mortality and morbidity, would be accelerated outside of the natural history of a pandemic reducing these over time. IGARD noted the inclusion of a number of technical phrases and words within section 5, for example, *"SNOMED Codes"*, and suggested that these were replaced with a term, such as *"diagnostic codes"* ; and that this section was updated to be written in a language suitable for a lay reader and technical terms used only where necessary, or further explained upon first use. **Outcome:** recommendation to approve subject to the following condition: 1. In respect of the ethical approval and in line with NHS Digital's DARS Standard for Ethical Approval: a) To provide written confirmation that NSDEC have received a briefing on the application, at their regular meetings, and did not raise any substantial points; or, b) If ONS have already briefed NSDEC on this application, that they provide to NHS Digital a copy of this written support; or, c) To confirm that the application or briefing is scheduled on the next NSDEC agenda. d) In all cases, to upload a copy of the written confirmation from NSDEC to NHS Digital's CRM system. The following amendments were requested:

1. To amend section 3(c) to reflect that NDO is not applied due to COPI being the legal basis for the flow of data into NHS Digital.
2. To provide an explanation in section 5(a) as to why both the disseminated data and access to the DAE needs to continue to 2022, in order to satisfy the UK GDPR requirements in avoiding excessive processing.
3. To update section 5 to indicate how the reduction in COVID-19 related mortality and morbidity, will be accelerated outside of the natural history of a pandemic reducing these over time.
4. In respect of section 5(d) and in line with and in line with NHS Digital's DARS Standard for Expected Measurable Benefits:
    a) To update section 5(d) to use a form of wording such as "*it is expected…"* or *"it is hoped …"*, rather than "*it will…*".
    b) To revise the final paragraph of section 5(d) (ii) to clarify how the understanding obtained by the analysis supports the use of this data.
    c) To remove any specific outputs from section 5(d) and move to section 5(c).
5. In respect of the processing and storage locations:
    a) To update section 2, to include the processing and storage locations for the DAE in line with that happens with TRE applications.
    b) The NHS Digital DAE Team to confirm that the territory of use in section 2(c) aligns with the location of the Data Processors, and the geographical restrictions on the datasets; and to confirm in section 1.
6. As section 5 forms NHS Digital's public data release register:
    a) IGARD noted the inclusion of a number of technical phrases and words within section 5 such *"SNOMED Codes"* and suggested replacing with *"diagnostic codes"*
    b) Section 5 should be updated to be written in a language suitable for a lay reader and technical terms used only where necessary, or further explained upon first use.

The following advice was given:

1. IGARD noted PAG's comments, and suggested that ONS consult with the HRA on whether the research under this agreement falls within the HRA's remit.
2. IGARD strongly suggested that ONS consider expressly addressing the proposed processing within its DPIA (which is designed to assess the risk to the rights and freedoms of natural persons) with particular reference to the rights of individuals including (but not limited to) the right to erasure, right to restrict processing and the right to object.
3. In respect of the privacy notice and in line with NHS Digital's DARS Standard for Transparency (fair processing), IGARD wished to draw to the applicant's attention to the statement in section 4, that a UK GDPR compliant, publicly accessible transparency notice is maintained throughout the life of the agreement. IGARD suggested that ONS may wish to refresh the advice previously received from the ICO in respect of transparency to the public.
4. IGARD noted that the applicant's Data Sharing Agreement with NHS Digital was due to expire; in light of this, it was suggested that NHS Digital might wish to consider a short-term extension with ONS, in order for them to retain access to the DAE, while work was undertaken to update the application.
5. Separate to this application, NHS Digital should include all processing and storage locations for DAE applications, and in line with the TRE applications, to ensure consistency.
6. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the volume of data and transparency

	7. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the volume of data and transparency. **Significant Risk Area:** 1. IGARD noted the importance of transparency and the proposed processing be reflected in the privacy notice. It was agreed the condition would be approved out of committee (OOC) by the IGARD Deputy Chair.
2.5	<u>The Nuffield Trust For Research And Policy Studies In Health Services: Nuffield Trust Primary DSA - April 2021 Amendment - Upgrade Dissemination frequency from quarterly to monthly between 1/7/21 30/6/22. (Presenter: Mujiba Ejaz) NIC-226261-M2T0Q-v3.6</u> **Application:** This was an amendment application to update and continue frequency of data distribution of monthly drops of Hospital Episode Statistics Admitted Patient Care (HES APC), HES Outpatients and Emergency Care Data Set (ECDS) from the 1st July 2021 to the 30th June 2022. The purpose of the amendments is to gain access to more timely data, for example, to support COVID-19 research. There are six priority areas between 2020 and 2025, which include: workforce; technology and digital; primary care; small hospitals; quality and equity; and politics, legislation, and governance. The quality and equity area includes care for specific population groups, for example children and young people, as well as care for underserved populations, for example prisoners, and inequalities in health and care service delivery. The work of the Trust is organised into a number of programmes which address these priorities. **Discussion:** IGARD members noted that section 1 (Abstract) was particularly well put together, detailing a complicated history. IGARD observed, given the volume of data and wide ranging purposes, that there would seem a strong case for patient and public involvement (PPI). IGARD noted the verbal update from NHS Digital that the applicant had confirmed that the public and patients were involved via several routes including the Board of Trustees having a varied range of experience, and engagement with a wide range of stakeholders including patient organisations and health charities. However, IGARD suggested that the Nuffield Trust Project Planning Committee may benefit from the inclusion of appropriate patient or public representation, since there appeared to be none included. IGARD suggested that there may be benefit to involving patients early in studies, as per the HRA guidance on Public Involvement. IGARD noted reference in section 5(c) (specific outputs expected) to "*10 corporate events*" and in section 5(e) (is the purpose of the application in any way commercial) "*No*", and in line with the NHS Digital DARS Standard for Commercial Purpose, suggested that both sections be updated to clarify the arrangements of the corporate events, providing detail of what the events entails, and if there was a commercial element. IGARD noted reference, in section 5(a) (Objective for Processing) to the "*DH Policy Innovation Research Unit based at the London School of Hygiene and Tropical Medicine*" (LSHTM) who would be working with the Nuffield Trust on the Integrated Care Pioneers evaluation. In line with the NHS Digital DARS Standard for Data Controllers, IGARD asked for clarification as to which other organisations were involved in the projects who should be considered a Data Controller(s), and as borne out of the facts presented in both the application and relevant supporting documentation. Section 5 (Purpose / Methods / Outputs) of the application and relevant supporting documentation should be updated with a clear justification of the Data

	Controller(s) involved and the analysis undertaken by NHS Digital be included in section 1 (Abstract). IGARD noted in section 5(a) that "…*the data may, if required, be linked with national datasets in the public domain (e.g. indices of social deprivation) subject to a risk assessment that the linkage will not increase the risk of reidentification of individuals within the dataset*…" and queried who would be undertaking the "*risk assessment*", and that this be clearly articulated in section 5(a). IGARD also noted that since section 5 formed NHS Digital's public data release register and in line with NHS Digital's DARS Standard for Objective for Processing, that it was potentially too lengthy, and that, where possible, it should be edited to remove excessive detail of the descriptions which were not relevant. IGARD suggested that projects that have already been undertaken should be removed for example, and restrict section 5(a) to the processing being undertaken under this data sharing agreement (DSA). In addition, reference to "*no moral or ethical issues*" should be removed and the DSA should specifically address that the project is looking for indicators for severe harm in a hospital setting and how the Nuffield Trust will address the ethical issues raised should they identify individuals who were subject to harm in a hospital setting. NHS Digital noted that reference to "*quarterly*" should be updated and replaced with "*monthly*" in line with the new frequency of data dissemination, IGARD were in agreement with this update. IGARD also noted that in line with the NHS Digital DARS Standard for Data Minimisation that the description in section 3 (Datasets Held / Requested) should be revised with regard to the period of data requested, to distinguish if from the period of time for which the data is held, in order to satisfy the UK General Data Protection Regulation (UK GDPR) requirements in avoiding excessive processing. In addition, relevant data minimisation narrative should be included in section 5(b), in line with the NHS Digital DARS Standard for Data Minimisation. IGARD noted reference to "…*National data is required which involves analysis* ***outside of discrete research projects*** *to support NHS and health care policy…*" and suggested removing this reference to "*outside of discrete research projects*" specifically from section 3. IGARD also suggested section 3(b) (Additional Data Access Requested) be updated to remove reference to ECDS being "*identifiable*" and replaced with "*pseudonymised*". IGARD queried the reference in section 3, to "*GDPR does not apply to data solely relating to deceased individuals*", in respect of the Civil Registration data; noting that the data would also provide information on the entire cohort, including those who were still alive. IGARD asked that section 3 was updated to include a UK GDPR legal basis for those datasets that relate to cohort members still alive. IGARD queried the benefits outlined in section 5(d) (Benefits), and noted that some of the information provided were outputs, and asked that section 5(d) was updated to remove any outputs and edit to only leave examples that reflect the benefits of the research. IGARD noted the yielded benefits in section 5(d) (iii) (Yielded Benefits) and, noting these were more aligned with *"outputs"*, asked that further details were provided of the specific yielded benefits accrued to date, and asked that it was clear as to the benefits to both the patients and the health and social care system more generally, and in line with NHS Digital's DARS Standard for Expected Measurable Benefits. IGARD suggested that section 5(d) be updated to remove reference to "*it will*…" and instead use a form of words such as "*it is expected…*" or "*it is hoped* …".

	In respect of the privacy notice, IGARD wished to draw the applicant's attention to the statement in section 4 (Privacy Notice) of the application and in line with NHS Digital's DARS Standard for Transparency (fair processing), that a UK GDPR compliant, publicly accessible transparency notice was maintained throughout the life of the agreement, noting that the current transparency materials do not include all the dataset outlined in the DSA, and that the applicant may wish to produce a separate privacy notice for the data they receive from NHS Digital, which may be helpful for the applicant, since the current published privacy notice covers other types of data. IGARD commended the Nuffield Trust for making their Data Processing Impact Assessment (DPIA) publicly available, which has been provided as a supporting document, and suggested that the applicant may wish to revisit this document to expand, for example, on the datasets held. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the yielded benefits and volume of data. **Outcome:** recommendation to approve subject to the following conditions: 1. To provide clarification with regards to the arrangements of the corporate events outlined in section 5(c), and if there is a commercial element, to outline this in section 5(a) and section 5(e); in line with NHS Digital DARS Standard for Commercial Purpose. 2. In respect of the data controllership and in line with NHS Digital's DARS Standard for Data Controllers: a) To clarify which other organisations involved in the projects should be considered a joint Data Controller, as borne out of the facts presented with particular reference to *"DH Policy Innovation Research Unit"*. b) To update the application and any relevant supporting documents with a clear justification. 3. To clarify in section 5, who is undertaking the *"risk assessment"* in relation to the linkage with the national datasets and how, to ensure this does not lead to the additional risk of reidentification of individuals. The following amendments were requested: 1. In respect of data minimisation and in line with NHS Digital's DARS Data Minimisation Standard: a) To review the description of data minimisation in respect of the period of data requested, and to distinguish it from period of time for which the data is held, in order to avoid excessive processing. b) To include the relevant data minimisation wording in section 5(b). 2. To clarify the reference to *"analysis outside of discrete research projects"* in sections 3(a) and 3(b), or to remove the reference. 3. To update section 3(b) to remove reference to *"identifiable"* for the ECDS data and replace with *"pseudonymised"*. 4. To update section 3(b) to include a UK GDPR legal basis for dissemination and receipt of data in respect of HES Civil Registration (Deaths) bridge. 5. In respect of section 5: a) To update section 5 to amend any references to the frequency of the data from *"quarterly"* and replace with *"monthly"*. b) To edit section 5 to remove excessive detail to reduce the description, which is potentially too lengthy for NHS Digital's data release register.

	6. In respect of section 5(a) in line with the NHS Digital DARS Standard for Objective for Processing: a) To revise section 5(a) to remove reference to projects that have already been completed, and restrict to the processing being undertaken for this agreement. b) To remove from section 5(a) reference to there being *"no moral or ethical issues*"; and to specifically address that the project is looking for indicators for severe harm in a hospital setting and how the Nuffield Trust address the ethical issues raised should they identify individuals subject to harm. 7. In respect of section 5(d) and in line with NHS Digital's DARS Standard for Expected Measurable Benefits a) To remove any specific outputs from section 5(d) and move to section 5(c). b) To update section 5(d) to use a form of wording such as "*it is expected…"* or *"it is hoped …"*, rather than "*it will…*". c) To provide further details in section 5(d) of the benefits accrued to date and ensure these are clear as to the benefits to both patients and the health care system more generally. The following advice was given: 1. In respect of the privacy notice and in line with NHS Digital's DARS Standard for Transparency (fair processing), IGARD wished to draw to the applicant's attention, the statement in section 4, that a UK GDPR compliant, publicly accessible transparency notice is maintained throughout the life of the agreement, noting that current transparency materials, do not include all the datasets, outlined in this DSA; and that the applicant may wish to produce a separate privacy notice for the data they received from NHS Digital, as this may be helpful to the public. 2. IGARD noted that the Nuffield Trust Project Planning Committee, doesn't appear to have any patient or public input, and there may be an appropriate addition to the team; and suggested that there may be benefit to involving patients early in all projects, as per the HRA guidance on Public Involvement. 3. IGARD commended the Nuffield Trust, for making their DPIA publicly available, but suggested they may wish to revisit this document, to expand the datasets held. 4. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the yielded benefits and the volume of data. 5. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the yielded benefits and the volume of data. It was agreed the condition would be approved out of committee (OOC) by the IGARD Deputy Chair.
2.6	Keele University: "BioImpedance (BI) Spectroscopy To maintain Renal Output" (BISTRO) Trial application for NHS Digital data for data linkage (Presenter: James Gray) NIC-90126-D4Z2W-v0.5 **Application:** This was a new application for pseudonymised Civil Registration (deaths) data, Hospital Episode Statistics Admitted Patient Care (HES APC), HES Critical Care and HES Outpatients; for the purpose of a randomised controlled trial funded by the National Institute for Health Research (NIHR). Most patients who develop kidney failure choose unit-based haemodialysis treatment. Dialysis removes waste products and excess fluid from the blood when the kidneys stop working properly. Haemodialysis involves diverting blood to a machine to be cleaned.

	One of the main functions of dialysis is to control the amount of fluid in the body, too much fluid can lead to raised blood pressure that damages the heart, increases the risk of stroke, and may cause fluid to collect in the lungs leading to breathing difficulties. Too little fluid causes dehydration, cramps, low blood pressure and more rapid or complete loss of any remaining kidney function. Bioimpedance (BI) is a simple, bedside measurement giving information about body composition, specifically how much excess fluid is present. Clinicians can use this to guide how much fluid should be removed from the body with the normal clinical assessment of the amount of fluid in the body, but it is not known if this results in better decisions and outcomes for patients. This trial aims to test whether taking regular measurements with a bioimpedance device, which gives information about body composition, improves outcomes for people who have newly started haemodialysis treatment for kidney failure. In particular, the trial aims to see if this helps patients maintain their remaining kidney function, as this is associated with improved survival, fewer symptoms of kidney failure, fewer side effects of dialysis treatment and a better quality of life including confidence in managing their health, and cost benefit analysis. The trial consists of 381 consented individuals from England only. **Discussion:** IGARD noted that the participants had given consent for Keele University to use their data to see if the amount of fluids in the bodies of patients having haemodialysis could be better controlled. However, IGARD noted that the Patient Information Sheet (PIS) did not state that their data would be passed to the University of Warwick for the health economic analysis, which would seem to be a separate purpose. SD5.0, the BISTRO trial consent form, does refer to the possible use of information in other research "*anonymously*", and SD9.0, the BISTRO data privacy notice, mentions the University of Warwick as a study collaborator. IGARD therefore suggested that the applicant consult study participants (more than 3 but less than 7) as to whether they felt their consent encompassed the transfer of data to and from NHS Digital and their data flowing to the University of Warwick for health economic analysis. IGARD also noted that the SD2.0, the BISTRO protocol v3.2, noted that they planned to recruit to "*516*" participants but that the application noted the trial had recruited only "*438*" participants, and noting there was no justification provided in section 5(a) (Objective for Processing) as to why this number was substantially lower than the figure outlined in the study protocol as required to deliver the necessary statistical power, noting their protocol noted a "90% power" and a "5% loss to follow up", asked what was the justification for breaking with their own protocol. IGARD were of the view that SharePoint was secure when appropriately managed, but that they had not seen it used as a data transfer method previously, and asked that section 1 (Abstract) be updated to confirm that NHS Digital's Security Advisor had approved the use of SharePoint as an appropriate method of data transfer. In addition the written email confirmation should be uploaded to NHS Digital's customer relationship management (CRM) system as a future supporting document. IGARD queried the reference in section 3 (Datasets Held / Requested), to "*GDPR does not apply to data solely relating to deceased individuals*", in respect of the Civil Registration data; noting that the data would also provide information on the entire cohort, including those who were still alive. IGARD asked that section 3 was updated to include a UK GDPR legal basis for those datasets that relate to cohort members still alive. IGARD noted the benefits in section 5(d) (Benefits) did not appear to align with the processing outlined in the application and asked that it was clear as to the benefits to both the patients and the health and social care system more generally, and in line with NHS Digital's DARS

	Standard for Expected Measurable Benefits. In addition, section 5(d) should be updated to remove the generic paragraph that relates to dialysis, as it is not relevant. IGARD suggested that section 3(c) (Patient Objections) should be updated with the relevant standard wording to clarify that the identifiably data is under the legal basis of "consent". In respect of the privacy notice, IGARD wished to draw the applicant's attention to the statement in section 4 (Privacy Notice) of the application and in line with NHS Digital's DARS Standard for Transparency (fair processing), that a UK GDPR compliant, publicly accessible transparency notice was maintained throughout the life of the agreement and noting the information within the privacy notice that referred to the sharing of anonymised clinical data to researchers in other countries, to updated section 5(b) (Specific Outputs Expected) to confirm what this data might be and how it might be anonymised. **Outcome:** recommendation to approve subject to the following conditions: 1. To provide a justification, with regard to the numbers recruited being substantially lower than the figure outlined in the study protocol as required to deliver the necessary statistical power. 2. The applicant to confirm that study participants (more than 3 but less than 7) have been consulted as to whether they feel the consent encompasses data flowing to the University of Warwick for health economics analysis, and the transfer of data to NHS Digital. The following amendments were requested: 1. With regard to SharePoint as a data transfer method: a. To update section 1 to confirm that NHS Digital's Security Advisor, has approved the use of SharePoint as an appropriate transfer method. b. To upload e-mail confirmation from NHS Digital's Security Advisor to NHS Digital's CRM system. 2. Noting information within the privacy notice that refers to the sharing of anonymised clinical data to researchers in other countries, to update section 5(b) to confirm what this data might be and how it might be anonymised. 3. To update section 3(b) to include a UK GDPR legal basis for dissemination and receipt of data in respect of Civil Registration (Deaths) - Secondary Care Cut and HES Civil Registration (Deaths) bridge. 4. To update section 3(c) with the relevant standard wording, to clarify that the identifiable data is under the legal basis of consent and not s251. 5. In respect of section 5(d) and in line with NHS Digital's DARS Standard for Expected Measurable Benefits: a. To update section 5(d) to remove the generic paragraph that relates to dialysis, as it is not relevant. b. To update section 5(d) to ensure the benefits are accruing directly to patients or the health and care system, and are in line with the processing outlined. It was agreed the condition would be approved out of committee (OOC) by IGARD members.
3	Returning Applications IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. Due to the volume and complexity of applications at today's meeting, IGARD were unable to review any applications as part of their oversight and assurance role.

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 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. The ratified action notes from **Tuesday 27th July 2021** can be found attached to these minutes as Appendix C.
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 23/07/21

These applications were previously recommended for approval with conditions by IGARD, and since the previous Out of Committee Report the conditions have been agreed as met out of committee.

NIC Reference	Applicant	IGARD meeting date	Recommendation conditions as set at IGARD meeting	IGARD minutes stated that conditions should be agreed by:	Conditions agreed as being met in the updated application by:	Notes of out of committee review (inc. any changes)
NIC-384608-C9B4L-v2.2	NHS England (Quarry House)	27/05/2021	1. In respect of the points previously raised by IGARD at the IGARD BAU meeting on the 6th August 2020: a) To update section 1 with confirmation of how **all** the points raised have been sufficiently addressed. b) To update the application throughout, and where relevant to ensure **all** the points raised by IGARD have been addressed in the relevant sections. 2) In respect of the points previously raised by IGARD at the IGARD – NHS Digital COVID-19 Response meeting on the 23rd March 2021: a) To update section 1 with confirmation of how **all** the points raise have been sufficiently addressed. b) To update the application throughout, and where relevant to ensure **all** the points raised by IGARD have been addressed in the relevant sections. 3) To update the application throughout to remove all references to *"OpenSAFELY"* and	IGARD members	OOC by quorum of IGARD members	IGARD noted the position is still that although the GDPPR data is pseudonymised, it is being "*treated as confidential patient data due to this being a restricted data set that is collected only for the purpose of COVID-19 management*". IGARD believe this treatment of pseudonymised data as confidential is problematic and raises questions with regard to how NHS Digital should regard other flows of pseudonymised data. IGARD has flagged this as a risk to NHS Digital. IGARD advised that they did not understand the statement, "*Sensitive fields relate to special category data, personal data but does not indicate identifiability*."

			all linked references, for example, *"TPP"*, *"EMIS"* and *"AWS"*.			However, IGARD believe the definition of "sensitive fields" is part of a wider discussion with NHS Digital.

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-525778-F2K8G-v0.2 DSfC - NHS Liverpool CCG; RS & IV

Optum Health Solutions UK Limited Class Actions:

- None

Graphnet Class Actions:

- None

Appendix B

2021-22 BMA/RCGP GP Data access standard

Introduction

This document is the first iteration of a set of standards with which the BMA and RCGP would support access to GP GPES Data for Pandemic Planning and Research (Covid-19) (GDPPR). These standards will also be applied for the general purpose GP Data for Planning and Research (GPDPR)**.**

Described below are a minimum set of requirements that **MUST** be met by all applicants seeking to process GP Data; once met, the standard defines in what location the applicant can access the GP Data.

The BMA/RCGP have agreed that NHS Digital's DARS process checks for compliance against the standard's requirements. The BMA/RCGP Professional Advisory Group (PAG) must be engaged where applications fall outside of the standards described below.

Checklist for DARS to complete for PAG

Date of PAG review: 28/07/2021

Applicant Organisation Name: University of Glasgow - DARS-NIC-381078-Y9C5K-v6.2

Does the applicant request sublicensing rights? NO

Note: For applicants who apply for sublicensing rights, all sublicencees **MUST** comply with the following obligations.

#	**Requirement to be met**	**DARS review**	**Notes (date stamped; pre-fixed DARS or PAG)**
1	The applicant **MUST** represent organisations with an established track record for conducting research or analysis on health care datasets (such as, but not limited to, a university or public body); in circumstances when this is the applicant's initial foray into generating insights from healthcare data (perhaps from combining it with data they are more familiar with), they **MUST** have a track record of data science research (specifically publications in peer-reviewed journals) in other domains.	Met	
2	For research questions, the applicant **MUST** have obtained ethical approval from the HRA; it is recognised that many organisations, such as NHS bodies and Universities also have local ethics committees but these do not replace the requirement for HRA ethical approval. Note: Where research questions are directly commissioned by SAGE, a related sub-committee, or evidenced from the Chief Medical Officer or the Chief Scientific Advisor, ethical approval **MUST** still be obtained *before* the data is processed. It is recognised that there may be exceptional circumstances, such as a pandemic, where rapid ethical review is required, but it is expected that the Department of Health and the HRA will provide guidance when expedition is warranted.	Met	28-07-2021: HRA Application ref: 283869

3	For service evaluation or audit (which do not usually require ethical approval), the applicant **MUST** provide the name of their National or Regional **Senior Clinical** NHS England and Improvement sponsor.	NA Name of NHSEI Sponsor:	
4	For all commissioner/ICS/Local authority led applications, the applicant **MUST** provide evidence that the relevant clinical director or clinical lead for the commissioner/ICS endorses the application, that the GP practices and relevant LMCs have been informed of (and have voiced no concerns with) the application, and provide copies of the patient / transparency communications relating to the application.	NA If met = DARS have email evidence from applicant, such as confirmation from LMC.	
5	Pertaining to the creation, publication or circulation of results, applicants **MUST** agree in writing to the following expectations A. All efforts **MUST** be made to ensure **no** individual (including an individual healthcare professional) can be identified (i.e. any published/shared results are statistically non-disclosive). B. All efforts **MUST** be made to ensure **no** GP practice or Primary Care Network (PCN) can be identified, unless there is written evidence that their CCG or LMC have obtained such permission from practices; or similar agreement from the BMA/RCGP. Note that this clause does not preclude practice-level research, only the **publication** of practice-level data.	Met Has the applicant have written evidence from CCG/LMC or BMA/RCGP to release practice identifiers? NA Has the applicant	28-07-2021: DARS to ask applicant for links to all published outputs; current work in progress for NHS Digital to hold a copy of all outputs.

	C. Results **MUST NOT** be used for performance management of GP practices or PCNs, unless it has been **explicitly agreed, and in writing,** through normal negotiating routes with the BMA. D. Any results that are not published in the public domain, for example for closed circulation to SAGE or used to inform policy papers, **MUST** be shared with the BMA/RCGP (via DARS) at the same time as they are circulated; this includes all related content, such as, executive summaries, recommendation on changes in policy, appendices, etc. Nevertheless NHS Digital should continue to encourage all applicants to publish their findings; this not only supports the benefits realisation strand around the use of GP Data but also transparency with the public. E. A copy of any result or report (whether published or not) **MUST** be shared with NHS Digital.	agreed to share any results not published in the public domain with the BMA/RCGP (via DARS) at the same time as they are made available for closed circulated? Yes	
6	To encourage best practices around open science, all applicants **MUST** agree to make public their finalised protocols, analysis code, and codelists, both for review but also re-use under an Open Source Initiative approved licence; copyright must be equivalent to CC-BY or CC0 GitHub is a commonly used tool to share such content, but organisational websites are also acceptable; https://www.opencodelists.org/ can be used to create and host codelists. Links to such content **MUST** be referenced in published works.	Under Review	28-07-2021: DARS to speak to customer about compliance with this requirement

7	Does the applicant (following both DARS/IGARD review) adhere to appropriate privacy notices, consent information, security and privacy standards, and can support the necessary retention periods used to evidence and audit data outputs for any publications. A. If consent is used as the legal basis to meet the common law duty of confidence (or possibly as the lawful basis for processing under GDPR), the applicant **MUST** ensure that the patient and the GP practice have easy to understand and accurate supporting material that fully explains (but not limited to) the following: a Type 1 Opt-out prevents all information from leaving the GP practice for secondary uses (including research); that a patient who consents to a study **and** has a Type 1 Opt-out **will not** be able to have their data used for the study; and that if the patient or the GP practice revokes the Type 1 Opt-out, then the patient's GP data will be available for **any analysis** and not solely the specific one for which they have consented to (i.e. revocation of the Type 1 Opt-out is not application specific). The patient and the GP practice must be fully aware of the implications of revoking a Type 1 Opt-out (i.e. that on revoking a Type 1 Opt-out the patient's data will not be solely restricted for use in the specific application). B. All applicants **MUST** agree to provide the public with audience-appropriate web-based accessible content that explains	Under Review Where consent is used as a legal gateway, are patients and GP practices provided with clear written information about the function of Type 1 Out-outs and the implications of revoking them? NA Has the applicant agreed to share any results using web-based accessible content?	28-07-2021: IGARD review 29-07-2021 28-07-2021: DARS to discuss with applicant website content sharing within 3 months of publication.

	a. the purpose no later than 1 month from the application approval b. the conclusions and recommendations resulting from the work no later than 3 months from peer review journal publication (and ideally within 1 month)	**Yes**	
7	All applicants **MUST** agree to declare any commercial interests (including intermediaries' sub-licensees) or relationships with individuals, organisations or vendors that ***could*** call into question the public's trust in the GP profession sharing confidential and sensitive healthcare data for research and planning. All applicants (and NHS Digital should it become aware of) **MUST** agree to declare at the onset of the application *or* should it occur at any time whilst processing the GP data **if there are any current or pending investigations* or** legal cases they are subject to, including, but not limited to, the CQC, MHRA, GMC, ICO or other legal body, with regards to how the applicant or their associated data processors use patient or public data (and not limited solely to healthcare data). This includes concerns held in other nation states.	Met	
	PROCESSING LOCATIONS: COVID-19 related requests		
8	One of the following **Trusted Research Environments (TRE)** of NHS Digital, Office of National Statistics,	**Yes** **TRE location:**	

	OpenSAFELY-EMIS/-TPP operating under COPI powers, or Genomics England.	**NHS Digital**	
~~9~~	~~When an extract is requested: all applicants must meet the Data Security and Protection Toolkit / ISO 270001 or equivalent. For commissioning **extracts, only** the relevant practices' subset of GP data **can** be shared.~~ ~~For any extract, NHS Digital confirms they are unable to service the applicant's requirements by running the relevant cohort and statistical code on data held by NHS Digital on behalf of the applicant.~~	~~Yes / No / Under Review~~ ~~Organisation extract sent to:~~	
~~10~~	~~**Extract supported by patient consent**~~ ~~NHS Digital confirms they have discussed with the applicant the feasibility of conducting the study within one of the aforementioned TREs. If after such discussion an extract is still to proceed, NHS Digital must provide an explanation as to why the study could not be conducted in the TREs.~~ ~~**NOTE:** should an unconsented cohort also be required (for example, as a control), PAG and CAG (except when COPI applies) **MUST** be consulted before any extract is sent.~~	~~Yes / No / Under Review~~ ~~Organisation extract sent to:~~ ~~Is there an unconsented cohort: Yes / No~~	

*pending legal feedback

PAG Conclusion

1. PAG support the application
2. With regard to point 6 PAG would like further details about how the study content (protocols; code; codelists) will be openly shared.

Delegated assessment by NHS Digital DARS

It is envisaged that as this standard is road-tested and matures, PAG will enable the NHS Digital DARS team to assess applications against the standard and in circumstances when all the requirements are met, NHS Digital will approve the application with a note informing PAG as to the assessment. This will become a PAG precedent route.

When an applicant does not fit the above examples, PAG **MUST** be consulted before any application is approved.

To assure PAG that the assessment process is working as intended, PAG will audit an appropriate percentage (and no less than 10%) of applications every 4 months.

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 20th January 2021

Application & application version number: DARS-NIC-422971-B8P2V v0.5 **Organisation name: Imperial College London** **Profession Advisory Group Agenda item: 4**
PAG support the overlying principle of the work, however PAG would like the applicant to justify why it could not carry this out using existing datasets/infrastructure; 1: NHS Digital's Cancer TRE or 2: NHS England's OpenSAFELY. As representatives of the profession PAG have a duty to promote best practice in privacy enhancing techniques and, minimise the flow of personal and sensitive data while maximising utility. PAG noted wording on page 8 which reads 'we recommend use of controls', and request this to be changed to 'we require use of controls'. Depending on the nature of the research it may be worth ensuring that the ethnicity data available in GP data is sufficient to fulfil their needs. In its current form PAG do not support this application.

Attendees	Role	Organisation
Arjun Dhillon	Chair, Caldicott Guardian	NHS Digital
Liz Gaffney	Head of Data Access	NHS Digital
Amir Mehrkar	GP, Clinical Researcher	RCGP
Mark Coley	Deputy IT Policy Lead	BMA
Pam Soorma	Secretariat	NHS Digital
Kirsty Irvine	IGARD Lay Member (Observer at meeting)	NHS Digital
Karen Myers	IGARD Secretariat (Observer at meeting)	

2021-22 BMA/RCGP GP Data access standard

Introduction

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Described below are a minimum set of requirements that **MUST** be met by all applicants seeking to process GP Data; once met, the standard defines in what location the applicant can access the GP Data.

The BMA/RCGP have agreed that NHS Digital's DARS process checks for compliance against the standard's requirements. The BMA/RCGP Professional Advisory Group (PAG) must be engaged where applications fall outside of the standards described below.

Checklist for DARS to complete for PAG

Date of PAG review: 28/07/2021

Applicant Organisation Name: ONS DARS-NIC-388794-Z9P3J-v5.3

Does the applicant request sublicensing rights? NO

Note: For applicants who apply for sublicensing rights, all sublicencees **MUST** comply with the following obligations.

#	Requirement to be met	DARS review	Notes (date stamped; pre-fixed DARS or PAG)
1	The applicant **MUST** represent organisations with an established track record for conducting research or analysis on health care datasets (such as, but not limited to, a university or public body); in circumstances when this is the applicant's initial foray into generating insights from healthcare data (perhaps from combining it with data they are more familiar with), they **MUST** have a track record of data science research (specifically publications in peer-reviewed journals) in other domains.	**Met**	
2	For research questions, the applicant **MUST** have obtained ethical approval from the HRA; it is recognised that many organisations, such as NHS bodies and Universities also have local ethics committees but these do not replace the requirement for HRA ethical approval. Note: Where research questions are directly commissioned by SAGE, a related sub-committee, or evidenced from the Chief Medical Officer or the Chief Scientific Advisor, ethical approval **MUST** still be obtained *before* the data is processed. It is recognised that there may be exceptional circumstances, such as a pandemic, where rapid ethical review is required, but it is expected that the Department of Health and the HRA will provide guidance when expedition is warranted.	**Under Review**	28-07-2021: PAG recommend existing research that has ONS internal ethics approval to continue; new clinical research questions to meet this requirement.
3	For service evaluation or audit (which do not usually require ethical approval), the applicant **MUST** provide the name of	**Under Review**	28-07-2021: PAG recommend existing service evaluation or audit that has ONS internal ethics

	their National or Regional **Senior Clinical** NHS England and Improvement sponsor.	Name of NHSEI Sponsor: will be potentially several	approval to continue; new questions to meet this requirement.
4	For all commissioner/ICS/Local authority led applications, the applicant **MUST** provide evidence that the relevant clinical director or clinical lead for the commissioner/ICS endorses the application, that the GP practices and relevant LMCs have been informed of (and have voiced no concerns with) the application, and provide copies of the patient / transparency communications relating to the application.	**NA** If met = DARS have email evidence from applicant, such as confirmation from LMC.	
5	Pertaining to the creation, publication or circulation of results, applicants **MUST** agree in writing to the following expectations A. All efforts **MUST** be made to ensure **no** individual (including an individual healthcare professional) can be identified (i.e. any published/shared results are statistically non-disclosive). B. All efforts **MUST** be made to ensure **no** GP practice or Primary Care Network (PCN) can be identified, unless there is written evidence that their CCG or LMC have obtained such permission from practices; or similar agreement from the BMA/RCGP. Note that this clause does not preclude practice-level research, only the **publication** of practice-level data. C. Results **MUST NOT** be used for performance management of GP practices or PCNs, unless it has	**Under Review** Has the applicant have written evidence from CCG/LMC or BMA/RCGP to release practice identifiers? Yes / No / Under-discussion / NA Has the applicant agreed to share any results not	28-07-2021: DARS will put a special condition to ensure items A, B and C met. 28-07-2021: D already met in agreement. 28-07-2021: DARS to ask ONS for a link to all their published outputs; current work in progress for NHS Digital to hold a copy of all outputs.

	been **explicitly agreed, and in writing,** through normal negotiating routes with the BMA. D. Any results that are not published in the public domain, for example for closed circulation to SAGE or used to inform policy papers, **MUST** be shared with the BMA/RCGP (via DARS) at the same time as they are circulated; this includes all related content, such as, executive summaries, recommendation on changes in policy, appendices, etc. Nevertheless NHS Digital should continue to encourage all applicants to publish their findings; this not only supports the benefits realisation strand around the use of GP Data but also transparency with the public. E. A copy of any result or report (whether published or not) **MUST** be shared with NHS Digital.	published in the public domain with the BMA/RCGP (via DARS) at the same time as they are made available for closed circulated? Yes / No / Under-discussion / NA	
6	To encourage best practices around open science, all applicants **MUST** agree to make public their finalised protocols, analysis code, and codelists, both for review but also re-use under an Open Source Initiative approved licence; copyright must be equivalent to CC-BY or CC0 GitHub is a commonly used tool to share such content, but organisational websites are also acceptable; https://www.opencodelists.org/ can be used to create and host codelists. Links to such content **MUST** be referenced in published works.	Under Review	28-07-2021: DARS to speak to customer about compliance with this requirement
7	Does the applicant (following both DARS/IGARD review) adhere to appropriate privacy notices, consent information,	**Under Review**	28-07-2021: IGARD review 29-07-2021 28-07-2021: DARS to discuss with applicant

	security and privacy standards, and can support the necessary retention periods used to evidence and audit data outputs for any publications. A. If consent is used as the legal basis to meet the common law duty of confidence (or possibly as the lawful basis for processing under GDPR), the applicant **MUST** ensure that the patient and the GP practice have easy to understand and accurate supporting material that fully explains (but not limited to) the following: a Type 1 Opt-out prevents all information from leaving the GP practice for secondary uses (including research); that a patient who consents to a study **and** has a Type 1 Opt-out **will not** be able to have their data used for the study; and that if the patient or the GP practice revokes the Type 1 Opt-out, then the patient's GP data will be available for **any analysis** and not solely the specific one for which they have consented to (i.e. revocation of the Type 1 Opt-out is not application specific). The patient and the GP practice must be fully aware of the implications of revoking a Type 1 Opt-out (i.e. that on revoking a Type 1 Opt-out the patient's data will not be solely restricted for use in the specific application). B. All applicants **MUST** agree to provide the public with audience-appropriate web-based accessible content that explains a. the purpose no later than 1 month from the application approval	Where consent is used as a legal gateway, are patients and GP practices provided with clear written information about the function of Type 1 Out-outs and the implications of revoking them? Yes / No / Under-revew / NA Has the applicant agreed to share any results using web-based accessible content? **Under-revew**	website content sharing

	b. the conclusions and recommendations resulting from the work no later than 3 months from peer review journal publication (and ideally within 1 month)		
7	All applicants **MUST** agree to declare any commercial interests (including intermediaries' sub-licensees) or relationships with individuals, organisations or vendors that ***could*** call into question the public's trust in the GP profession sharing confidential and sensitive healthcare data for research and planning. All applicants (and NHS Digital should it become aware of) **MUST** agree to declare at the onset of the application *or* should it occur at any time whilst processing the GP data **if there are any current or pending investigations* or** legal cases they are subject to, including, but not limited to, the CQC, MHRA, GMC, ICO or other legal body, with regards to how the applicant or their associated data processors use patient or public data (and not limited solely to healthcare data). This includes concerns held in other nation states.	Met	28-07-2021: DARS - non declared
	PROCESSING LOCATIONS: COVID-19 related requests		
8	One of the following **Trusted Research Environments (TRE)** of NHS Digital, Office of National Statistics, OpenSAFELY-EMIS/-TPP operating under COPI powers, or Genomics England.	**Yes** TRE location: **NHS Digital**	

9	When an extract is requested: all applicants must meet the Data Security and Protection Toolkit / ISO 270001 or equivalent. For commissioning **extracts, only** the relevant practices' subset of GP data **can** be shared. For any extract, NHS Digital confirms they are unable to service the applicant's requirements by running the relevant cohort and statistical code on data held by NHS Digital on behalf of the applicant.	Yes / No / Under Review Organisation extract sent to:	
10	**Extract supported by patient consent** NHS Digital confirms they have discussed with the applicant the feasibility of conducting the study within one of the aforementioned TREs. If after such discussion an extract is still to proceed, NHS Digital must provide an explanation as to why the study could not be conducted in the TREs. **NOTE:** should an unconsented cohort also be required (for example, as a control), PAG and CAG (except when COPI applies) **MUST** be consulted before any extract is sent.	Yes / No / Under Review Organisation extract sent to: Is there an unconsented cohort: Yes / No	

*pending legal feedback

PAG Conclusion

1. **We support the existing work in flight for the application**
2. For new research / service evaluation / audit questions to provide PAG support we require a response for items 2, 3, 5 and 6.
3. Item 7 - DARS to relay any concerns identified by IGARD
4. Currently, it is noted that this application must terminate when the COPI legal basis expires.

Delegated assessment by NHS Digital DARS

It is envisaged that as this standard is road-tested and matures, PAG will enable the NHS Digital DARS team to assess applications against the standard and in circumstances when all the requirements are met, NHS Digital will approve the application with a note informing PAG as to the assessment. This will become a PAG precedent route.

When an applicant does not fit the above examples, PAG **MUST** be consulted before any application is approved.

To assure PAG that the assessment process is working as intended, PAG will audit an appropriate percentage (and no less than 10%) of applications every 4 months.

Appendix C

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

held via videoconference, Tuesday, 27th July 2021

In attendance (IGARD Members):	Paul Affleck (IGARD Specialist Ethics Member)
	Prof Nicola Fear (IGARD Specialist Academic Member)
	Dr. Geoff Schrecker (IGARD Specialist GP Member)
In attendance (NHS Digital):	James Gray (Digi-Trials)
	Karen Myers (IGARD Secretariat)
	Kimberley Watson (DARS)
	Vicki Williams (IGARD Secretariat)

2	**Welcome** The IGARD Deputy Chair noted that this was a weekly meeting convened to support NHS Digital's response to the COVID-19 situation and was separate from the IGARD business as usual (BAU) meetings. IGARD members present would only be making comments and observations on items that were presented, and were not making formal recommendations to NHS Digital. Should an application require a full review and recommendation, then it should go through the usual Data Access Request Service (DARS) process and be presented at a Thursday IGARD meeting. The action notes from the Tuesday meeting will be received out of committee and then published alongside the minutes of the next Thursday BAU meeting as an appendix. **Declaration of interests:** Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising the Scientific Advisory Group for Emergencies (SAGE) on COVID-19.
2.1	NIC-343380-H5Q9K Public Health England (PHE) **Background:** this was a verbal update outlining an amendment to the PHE application to enable NHS Digital to link the identifiers of approximately 190,000 records from the National Congenital Anomaly & Rare Disease Register with the Shielded Patient List (SPL) for the purpose of research into public health for future pandemics. PHE wish to compare the outcomes from those on the SPL to those not on the SPL, looking at the impact of shielding from COVID-19 and impact of shielding for catching COVID-19, hospitalisation from COVID-19 and mortality from COVID-19. NHS Digital noted that due to time constraints and the urgency of the request, NHS Digital would be progressing under the NHS Digital SIRO precedent. The following observations were made on the basis of the verbal update from NHS Digital only. **IGARD Observations:**

	IGARD members noted that all comments previously raised at the business as usual (BAU) meeting on the 3rd June 2021 remained live and were appended to these notes as 'appendix a' and welcomed the verbal update from NHS Digital. IGARD members noted that although version 10.2 of the application and supporting documentation was available on NHS Digital's customer relationship management (CRM) system, they had not been provided for review at this meeting and their observations were based on the verbal update from NHS Digital only. IGARD members noted that due to the nature of the meeting and the fact that they had received no supporting documentation, that should a full review of the application and documentation be required, the full suite of documentation should be presented to a IGARD business as usual (BAU) meeting for a recommendation. IGARD members queried if NHS Digital had undertaken a review of the processing outlined in the application against the restrictions set out in the Information Governance (IG) letter of release for the Shielded Patient List, dated 27th April 2020. NHS Digital noted that the guidance with regard to SPL had changed and that the SPL could now be used for research purposes and this was supported by the Privacy, Transparency and Ethics Directorate. IGARD members noted the verbal update that SPL could be used for research, and cited the SPL transparency notice published on the NHS Digital website which stated that "…*We will also use and share information from the shielded patient list for planning, commissioning and research purposes, including clinical trials, relating to coronavirus* …" and queried if the new purpose of "*future pandemics*" was within its remit. In addition, IGARD members noted that since those on the SPL had received a number of communications over the last year, that it was important to ensure they were informed of the changes to the purposes, for which their data is used, and had the ability to opt out of their data being used for research, if that was possible, or, if not, informed of this fact. IGARD members also noted that since the current pandemic had not ended and the purpose of the research was for "*future pandemics*" queried the urgency of the request and why this application would progress under the NHS Digital SIRO precedent and were **not** supportive of this approach. IGARD members noted the imminent transfer of PHE operations to the new UK Health Security Agency (UKHSA), which will mean current DSAs will need to be revisited and aligned with the new organisational structure before the end of September 2021 (as advised by NHS Digital at the BAU meeting on the 3rd June 2021); and ensuring the processing of SPL data is within the bounds the IG letter of release and published transparency materials. **Significant risk area:** ensuring the processing of the SPL data outlined in the application (not reviewed by IGARD) is within the bounds of the IG letter of release.
2.2	NIC-460641-M8X4D Department for Health & Social Care (DHSC) – Cough in a Box **Background**: this was a verbal update outlining a new application from DHSC for data to support the 'cough in a box' (CIAB) project. The study follows a UK Government Number 10 commission to assess the potential to screen for COVID-19 vocal biomarkers. NHS Digital noted that there were three different sources of participants: the first group are all those who have had a positive or negative COVID-19 test in England who will be contacted by Agile Lighthouse teams who contact patients as part of NHS Test and Trace. When the patient receives their test result they will be asked if they wish to take part in further research and for those who say 'yes' will be contact by the CIAB project, directed to the privacy notice and

website for further information, where potential participants who agree to participate, submit their voice records via the webform. The data is then linked to the patient test results in the Pillar 2 testing data previously provided by NHS Digital under NIC-406871-Q9G2Q DHSC* . The second group are participants in the REACT-1 study and have agreed to be contacted for further research and will receive an email from Ipsos MORI about the CIAB projects and directed to the privacy notice and website for further information, where the potential participant if they agree to participate, submit their voice records via the webform. This data is then linked to the patient test results in the REACT-1 study, not to NHS Digital data. The third group are participants in the Human Challenge study who, if they agree to be contacted for further research, will be directed to the privacy notice and website for further information, where the potential participant, if they agree to participate, submit their voice records via the webform. This data is then inked to the patient test results in the Human Challenge study, not to NHS digital data.

NHS Digital noted that the webforms had been developed by Fujitsu Services Limited and confirmed that they do not access or process the NHS Digital data.

The CIAB project is about developing and assessing the algorithm for the purpose of screening for COVID-19 and once a strong enough algorithm is found an 'app' will be developed, however the development of an 'app' is not within the scope of this application.

NHS Digital noted that this application would be brought to a future IGARD business as usual (BAU) meeting for a recommendation.

*see COVID-19 action notes dated 26th January 2021 appended to the business as usual (BAU) minutes dated 28th January 2021, and COVID-19 action notes dated 13th October 2020 appended to the BAU minutes dated 15th October 2020.

IGARD Observations:

IGARD members noted that the application was to be presented to a IGARD BAU Meeting in the next couple of weeks. IGARD members noted that although version 0.5 of the application and supporting documentation was available on NHS Digital's customer relationship management (CRM) system, they had not been provided for review at this meeting, and their observations were based on the verbal update from NHS Digital only.

IGARD members noted that the discussion today was not to pre-empt discussions that would take place at the BAU meeting on the Thursday and thanked NHS Digital for their verbal update.

To support NHS Digital and the applicant, IGARD made a number of high level comments:

- IGARD members were in agreement with NHS Digital's verbal analysis that consent was given at the point of agreeing to be part of the study on the website when submitting a voice recording via the webform, however reserved the right to comment further since they had not had sight of the consent materials or patient information leaflets that potential participants would read.
- IGARD members also suggested that the researchers may wish to consider if they require further additional datasets, such as HES for all potential participants in the study (including those not linking to NHS Digital data), for example to identify whether pre-existing conditions like COPD or Heart Failure might impact on the algorithm. It might also be valuable in terms of long term follow up due to the nature of the disease

	and scientific interest in long term effects. It would be sensible to bear this in mind when drafting consent materials. • IGARD members noted that positive ethics approval should be in place before coming to IGARD and all relevant documentation should be provided as supporting documents. • IGARD members noted the involvement of researchers from the Alan Turing Institute who would be supporting the analysis, and could not offer an opinion to NHS Digital as to whether an honorary contract would suffice for those Alan Turing Institute researchers, and suggested that NHS Digital seek appropriate advice to ensure the appropriate contractual arrangements were in place. • IGARD members suggested that thought be given to the transparency materials, especially in relation to the profiling and automated decision making which may take place as a result of the outputs of this study. **Subsequent to the meeting** IGARD members noted that NIC-406871-Q9G2Q DHSC had been a verbal update to the COVID-19 response meeting on the 26th January 2021 and that IGARD had noted a **significant area of risk**, namely "*transparency and public perception (there had been no independent review of the application or supporting documentation*).
2.3	<u>NIC-526384-M3T5R St George's University Hospitals NHS Foundation Trust (PTC)</u> **Background:** this was a new application for a phase II randomised, single-blind, platform trial to assess the safety, reactogenicity and immunogenicity of the COVID-19 vaccines in pregnant women in the UK (Preg-CoV). The study is looking to recruit up to 900 cohort participants aged 18 to 47 years and between 13 and 34 weeks gestation on the day of the planned vaccination. St George's will be the sole Data Controller, with NHS Digital as the sole Data Processor. NHS Digital will contact the potential participants directly as per the previous permission to contact applications and St George's will have no access to any data provided by NHS Digital. The following observations were made on the basis of the verbal update from NHS Digital plus a copy of the draft "*Preg-Cov NHS Digital email v2.0 23.07.2021 EG*". **IGARD Observations:** IGARD members noted that due to the nature of the meeting and the fact that they had received no draft documentation, that should a full review of the application and documentation be required, the full suite of documentation should be presented to a IGARD business as usual (BAU) meeting for a recommendation. IGARD members noted that v0.1 of the application was available on NHS Digital's customer relationship management (CRM) system but had not been provided for review at this meeting and their observations were based on the verbal update by NHS Digital only, alongside draft document "*Preg-Cov NHS Digital email v2.0 23.07.2021 EG*". IGARD members noted this was incredibly important research into vaccination and pregnancy. IGARD members noted that the applicant had provided draft "*Preg-Cov NHS Digital email v2.0 23.07.2021 EG*" which had been updated following the discussion at the COVID-19 response meeting on the 20th July 2021. NHS Digital confirmed verbally that the applicant will attempt to recruit via leaflets and posters located in appropriate antenatal settings, institutional websites, both hospital and university, social media, press release, information provided directly to

	women when attending for an antenatal appointment, mailout and via the National Institute for Health Research (NIHR) vaccine registry. IGARD members reiterated their comments from last week's meeting, that this was a novel and potentially sensitive use of the database, since some of those women who had signed up to the database may have suffered a miscarriage, still birth or neonatal death. IGARD suggested that in addition to sign off of any communications going out from NHS Digital to a large number of women (and noting the contact letter had been updated to signpost the recipients to relevant national charities who would be able to offer support if they were distressed by a communication asking if they were pregnant such as the Miscarriage Association and SANDS), the applicant seek advice from those organisations with regard to the actual content of the letter. In particular, that the sentence "…*if you have been affected in any way by this invitation due to a recent loss you can contact these national charities that can offer support…*" clearly articulates what is meant by "*recent loss*" since the Miscarriage Association, by way of example, uses terminology such as "*pregnancy loss*". In addition, and noting recruitment was yet to start, suggested that there may also be benefit to involving potential participants earlier in the study as per the HRA guidance on Public Involvement. IGARD members agreed with NHS Digital's analysis that the sentence "…*We have sent this email to all those on the registry because it may be of interest to you or someone you know*…" may imply that everyone on the registry had received a copy of the message, when in fact it was only those women aged 18 to 47 years, and should be updated appropriately. IGARD members also noted that this may be considered a 'proxy' and to ensure this was within the parameters of the consent which had been sought when members signed up to the registry. IGARD members noted that "…*during the course of this trial we have put in place a process to make sure people on this trial are not disadvantaged*…" and suggested this may raise additional queries and that the sentence be amended as appropriate. IGARD members noted reference to "…*the total length of trial participation is up to 12 months after* ***delivery****…*" and suggested this was updated to replace "*delivery*" with "…*birth of your baby(ies)*" Finally, IGARD members noted that although they had made a number of observations on the communication letter, it was not for IGARD to determine what language is most appropriate given it is a highly sensitive and emotive topic, and impressed upon the applicant the need to engage with the relevant charities / bodies to seek the opinions of those who may be affected, and to ensure that the letter was written in language suitable for a lay reader and that consideration was given to the potential participant audience. IGARD members queried if NHS Digital had had sight of the ethics and consent materials and NHS Digital confirmed they had not. IGARD members noted the importance of ensuring a careful review of the ethics and consent materials to ensure they aligned with the processing outlined in the application and protocol, and that the materials did not preclude the applicant from, for example, receiving further additional datasets, linking to other datasets, and carrying out long term follow up due to the nature of the disease and scientific interest in long-term effects. IGARD reiterated comments made previously: Noting the language used in this and other applications using the NHS Digital COVID-19 permission to contact register (CV19 PtC)

	(internal process name), consideration should be given to the external name of the registry: "NHS Digital COVID-19 vaccine research registry". Since the vaccine registry was a standalone registry that cannot be linked to any other registry, consideration should be given to its external name, since it could imply that the registry contained all those that had had a vaccine, rather than what the database is; a database of those who have consented to be part of a registry of people who are happy to be contacted about vaccine research. IGARD suggested that in due course the language within this and other permission to contact applications should be updated to ensure that section 5, which forms part of NHS Digital's data release register, contained an accurate description of the registry and what it was. IGARD members welcomed the verbal update and noted that NHS Digital had indicated that due to the urgency of the application that it would be progressed under NHS Digital's SIRO Precedent, however IGARD were **not** supportive of this approach given the potential sensitivity and outstanding ethical support and asked that the application and relevant supporting documents (if available) be brought back to a future IGARD meeting, alongside the full unconditional ethical support, noting that no documentation other than the draft communication letter, had been seen by IGARD. **Significant risk area:** failure to consult the relevant charities and / or seek patient and public involvement to minimise and mitigate the risk of causing distress through the current v2.0 letter of communication which will be disseminated by NHS Digital on behalf of the applicant (reputational risk to NHS Digital).
3	<u>AOB</u> There was no further business raised, the IGARD Deputy Chair thanked members and NHS Digital colleagues for their time and closed the meeting.

Appendix A

Published IGARD BAU Minutes Extract: 3rd June 2021

Public Health England (PHE): D1.1 - PHE Single Data Sharing Agreement (Presenter: Kimberley Watson) NIC-343380-H5Q9K-v10.2

Application: This was an amended active application, for pseudonymised Civil Registration (Deaths) data, Community Services Data Set (CSDS), Diagnostic Imaging Dataset (DIDs), Emergency Care Data Set (ECDS), Health Survey for England, Hospital Episode Statistics (HES) Accident and Emergency (A&E), HES Admitted Patient Care (APC), HES Critical Care, HES Outpatients, Improving Access to Psychological Therapies (IAPT) Data Set, Mental Health and Learning Disabilities Data Set (MHLDDS), Mental Health Services Data Set (MHSDS), Maternity Services Data Set (MSDS), National Diabetes Audit (NDA), Primary Care Mortality Data; and identifiable NHS 111 Online Dataset, ECDS, Secondary Uses Service (SUS+) data.

PHE is a direct provider of health protection and health improvement services to patients and the public in England. The successful fulfilment of its remit depends on its ability to process data on the health status of patients and the public, and on the social, economic and environmental factors that determine health. Some of the data it uses it collects directly, but PHE also depends on appropriate and timely access to other sources of health and care data, such as the health status and healthcare provider activity data collected at a national level by NHS Digital.

NHS Digital advised IGARD that this Data Sharing Agreement (DSA), is the main DSA for PHE, and superseded the Memorandum of Understanding between NHS Digital and PHE. The imminent transfer of PHE operations to the new UK Health Security Agency (UKHSA), will mean this current DSA will need to be revisited and aligned with the new organisational structure before the end of September 2021.

Discussion: IGARD welcomed the application which came for advice and without prejudice to any additional issues that may arise when the application is fully reviewed.

IGARD noted the verbal update from NHS Digital outlining the purpose of the IGARD review. IGARD noted that previous versions of this application had previously been approved by the Senior Information Risk Owner (SIRO) without IGARD review.

IGARD noted the volume of information contained within the overarching DSA, and the substantial number of datasets requested, as outlined in section 3 (Datasets Held / Requested); and discussed whether it was possible for this DSA to be separated into smaller and more manageable DSAs, for example, by purpose, noting that there was wide range of purposes listed within section 5 (Purpose / Methods / Outputs).

IGARD queried the legal basis for the dissemination of the data outlined in section 3, and asked that this was reviewed to ensure that the processing outlined, aligned with the legal basis for dissemination, for example, in respect of the Article 6 and Article 9 of the UK General Data Protection Regulation (UK GDPR).

IGARD suggested that NHS Digital may wish to consider breaking this application into separate and more manageable DSAs, in light of the volume of information, the wide range of purposes and the forthcoming organisational changes.

IGARD asked that the application was reviewed and updated throughout, to reflect the flows of data and the legal bases.

In addition, IGARD also asked, that noting the volume of datasets requested, that it would be helpful at a future IGARD review if a data flow diagram was provided that clearly outlined the flow(s) of data.

IGARD noted the volume of data fields listed in section 5(a) (Objective for Processing) and suggested that these were removed, as they were not necessary to include.

IGARD noted the useful information within section 1 (Abstract) that outlined the version history, however asked that for the purpose of a clear audit trail, this was updated to also include the relevant dates.

IGARD noted that section 2(a) (Processing Location(s)) and section 2(b) (Storage Location(s)) only listed one processing and storage location, and, noting that PHE are a large organisation with multiple sites, asked that this was reviewed and updated as necessary to reflect all the processing and storage locations.

IGARD discussed the merits of NHS Digital carrying out an audit to identify if there were any other significant active DSAs that have not previously been reviewed by IGARD.

Outcome: IGARD welcomed the application which came for advice and without prejudice to any additional issues that may arise when the application is fully reviewed.

1. IGARD advised that the application should be reviewed and updated throughout, to reflect the flows of data and their legal bases.
2. IGARD suggested that NHS Digital may wish to consider breaking this application into separate and more manageable DSAs, in light of the volume of information, the wide range of purposes and the forthcoming organisational changes.
3. IGARD advised that NHS Digital consider carrying out an audit to identify if there are any other significant historic DSAs that have not previously been reviewed by IGARD.