Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 25 March 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Kirsty Irvine (Chair)	IGARD Chair / Lay Representative
Dr. Imran Khan	Specialist GP Member
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Prof. Nicola Fear	Specialist Academic Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist Chair
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Vicky Byrne-Watts	Data Access Request Service (DARS)
Louise Dunn	Data Access Request Service (DARS)
Dan Goodwin	Data Access Request Service (DARS)
Richard Hatton	Clinical Informatics and Deputy Caldicott Guardian (Observer: item 1 - 2.3)
Karen Myers	IGARD Secretariat
Heather Pinches	Data Access Request Service (DARS)
Andy Rees	Data Access Request Service (DARS)
Vicki Williams	IGARD Secretariat
Tom Wright	Data Access Request Service (DARS)

1	**Declaration of interests:** Dr. Maurice Smith noted that as part of his role at Liverpool CCG, he had direct involvement with the COVID-19 Oximetry @Home (CO@H) trial within this geographical area (NIC-421528-J6S3N and NIC-421524-R0Y3P), but noted no specific connections with the applications or staff involved and it was agreed that this was not a conflict of interest.

	Review of previous minutes and actions: The minutes of the 18th March 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	<u>General Practice Workforce Data Set - Briefing Paper</u> The briefing paper was to inform IGARD about the General Practice (GP) Workforce data set, which contains data on individual staff members providing services at a General Practice in England. The Department for Health and Social Care (DHSC) and other Arms-Length Bodies (ALBs) use the data for policy formulation and workforce planning. The General Practice (GP) Workforce Data Set is currently being onboarded into NHS Digital's Data Access Request Service (DARS) at the request of stakeholders. This data has been collected by NHS Digital via the National Workforce Reporting System (NWRS), formally known as the Primary Care Web Tool, since Sept 2015. Prior to that, an annual GP workforce census used information provided by National Health Applications and Infrastructure Services (NHAIS). This briefing paper was previously presented to IGARD on the 7th November 2019, 13th February 2020, 26th March 2020 and 28th January 2021, where IGARD made a number of comments. IGARD noted that this briefing paper had been reviewed by members out of committee, and comments had been shared (via the IGARD Secretariat) with the presenters on the 19th March 2021. IGARD welcomed the briefing paper and made no further comments. IGARD looked forward to receiving the finalised briefing paper as a supporting document, alongside a first of type application.
3	**Data Applications**
3.1	<u>The Health Foundation: COVID Oximetry At Home - (CO@H): Improvement Analytics Unit (Presenter: Vicky Byrne-Watts) NIC-421528-J6S3N-v0.4</u> **Application:** This was a new application for pseudonymised Civil Registration (Deaths) data, COVID-19 Oximetry @ Home (CO@H), COVID-19 Second Generation Surveillance System (SGSS), COVID-19 UK Non-hospital Antigen Testing Results (pillar 2), Emergency Care Data Set (ECDS), GPES Data for Pandemic Planning and Research (GDPPR), Hospital Episode Statistics (HES) Admitted Patient Care (APC), Critical Care, Personal Demographic Service (PDS) and Shielded Patient List. The purpose is for a study, evaluating the national roll out of the NHS England and NHS Improvement COVID-19 Oximetry @Home (CO@H) programme, which involves the remote monitoring of patients with COVID-19 symptoms, by using a pulse oximeter, a small monitor clipped to their finger, to measure their oxygen saturation levels three times a day. The aim of this study is to quantitatively assess the cost effectiveness and clinical effectiveness of the CO@H intervention as well as variation in access and outcomes. The cohort of patients for the study will be aged 65 or over; or, aged 18 and over and considered clinically vulnerable; or aged 18 and over and diagnosed with a learning disability.

	Discussion: IGARD noted that this was one of a number of linked applications that was being submitted to IGARD for review (item 3.2 also links), and that the overarching application (NIC-396113-N9L4L) that had been seen by the IGARD – NHS Digital COVID-19 Response meeting on the 15th December 2020. IGARD also noted that this application had been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 10th and 17th March 2021 (please see Appendix B). IGARD noted and supported the comments made by PAG (on the 10th and 17th March 2021), and acknowledged the confirmation from PAG, that they were supportive of the work outlined and were content that all the points raised had been addressed by NHS Digital. IGARD noted that section 1(b) (Data Controller(s)) stated that NHS England were the sole Data Controller, however queried if this was correct, in light of conflicting information elsewhere in the application, for example, section 5(a) (Objective for Processing), that stated the work outlined had been commissioned by NHS England and NHS Improvement. In addition, IGARD noted that the linked application (item 3.2 - NIC-421524-R0Y3P) stated that the work had been commissioned by NHS England, NHS Improvement and the National Institute for Health Research (NIHR). Similarly, IGARD noted that the Data Processor intends to produce a policy briefing and queried whether all of its activities would be directed by NHS England. NHS Digital advised IGARD that a data controllership assessment had been undertaken in conjunction with various colleagues within NHS Digital, for example Privacy, Transparency and Ethics (PTE) (formerly Information Governance), and it had been agreed that based on the facts presented, NHS England were the sole Data Controller. IGARD noted the verbal update from NHS Digital, and asked that section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) were updated to ensure that the narrative was consistent with there being a **sole** Data Controller, in line with the NHS Digital Data Access Request Service (DARS) Standard for Data Controllers. IGARD queried how the Health Services Control of Patient Information (COPI) Regulation 2002 could be relied upon as a legal basis if the data flowing was pseudonymised, noting that this emergency legislation was for the flow of confidential patient data. NHS Digital advised IGARD that due to the volume of data flowing, it was NHS Digital PTE's view that there was a risk that some of the data flowing may become identifiable, and for this reason, the legal basis relied on should be COPI. IGARD noted the verbal update from NHS Digital, and asked that the application was reviewed, to ensure there was a consistent narrative throughout, to support the identifiability status of the data. In addition, IGARD asked that written justification was provided from NHS Digital's PTE, as to why the pseudonymised data was being disseminated under COPI; and that reference to the written justification was also inserted in section 1; and that the written justification from NHS Digital's PTE was also uploaded to NHS Digital's customer relationships management (CRM) system for future reference. IGARD noted that Civil Registration (death) data had been requested, and highlighted that where this specific data was flowing, that NHS Digital would review on a case-by-case basis, to determine if there was an increased risk of identification. IGARD agreed that, in this particular case, there was less risk due to NHS Digital undertaking the linkage. IGARD asked that if COPI was **not** relied on as a legal basis, that section 1 (Abstract) was updated confirming that the flow of date of death data was in line with NHS Digital's policy assessment and would not increase the likelihood of re-identification of data subjects.

	IGARD noted that in light of the discussion and ongoing queries around the legal basis with NHS Digital's PTE, that once this had been confirmed, that section 3 (Datasets Held / Requested) was updated to ensure it aligned with the correct legal basis. IGARD queried the description of the work outlined, and also noted the reference to *"clinical effectiveness"*, and advised that a service evaluation could not be undertaken, if something was not already clinically effective. IGARD asked that on the assumption that the application was in respect of service evaluation, that section 5 was updated to ensure a consistent narrative throughout; and that further clarification was provided in respect of the numerous references to *"clinical effectiveness"*. IGARD queried if the need for a service evaluation was apparent when the scheme was being rolled out, and if participants had been informed of this; and suggested that the applicant considered further transparency measures, such as improving ongoing communications throughout the rollout. IGARD advised that they had presumed that the service evaluation would take in to account the significant number of members in the control group, who may already have a pulse oximeter for their own personal use, given the reference in mainstream media to their potential utility and the overt promotion of pulse oximeters by high profile public figures on social media. IGARD noted and commended the applicant for providing a paper-based option at all sites, for patients who were uncomfortable with or unable to use a digital solution to record their readings. IGARD noted that section 3(b) (Additional Data Access Requested) did not contain any information within the data minimisation section, in respects of how the cohort was going to be minimised, and asked that this was updated, to ensure the appropriate minimisation to the control cohort of circa 3.7 million, and / or patients who had been offered the service, as may be the case and in line with the NHS Digital Standard for Data Minimisation. IGARD also asked that section 5(a) was updated to reference the correct approximate cohort numbers, noting that this section was currently silent on any cohort numbers. IGARD noted the references to *"clinically vulnerable"* and *"clinically extremely vulnerable"* patients in section 5, and asked that this was updated throughout, to ensure the references were mapped, to align with those patients who were offered the service according to the CO@H standard operating procedure (SoP), as this was not currently clear. IGARD noted the language used within section 5(b) (Processing Activities) of the application, for example, referring to people as *"cases"*, and asked that this was reviewed and amended accordingly. IGARD queried the reference in section 5(d) to "…*formally the shielding list…"*, and noting the shielded patient list was still in use and valid, asked that this reference was removed, as it was not relevant. IGARD noted the benefits outlined in section 5(d), however asked that this was updated further, to reflect that a key benefit, may be, that the continued roll out of this programme could potentially reduce morbidity and mortality from COVID-19. IGARD highlighted a potential reputational risk to NHS Digital, in that ethical support had not been sought and it might be subsequently determined that this application had research aspects. IGARD also discussed some of the health inequality ethical issues regarding use of pulse oximetry devices and Black, Asian and minority ethnic (BAME) patients, particularly in

	light of recent British Medical Association (BMA) and Food and Drug Administration (FDA) publications. A member of IGARD observed that the programme design had elements of enforcing systemic bias/structural racism. **Outcome:** recommendation to approve subject to the following conditions: 1. To update section 1 and section 5 to ensure that that the narrative is consistent with there being a **sole** Data Controller. 2. In respect of the legal basis: a) To provide written justification from NHS Digital's PTE as to why the pseudonymised data is being disseminated under COPI and include reference to this in the application abstract. b) To ensure a consistent narrative throughout the application to support the identifiability status of the data. c) To upload the written justification from NHS Digital's PTE to NHS Digital's CRM system for future reference. The following amendments were requested: 1. *If* COPI is not relied on, NHS Digital to confirm in section 1 that the flow of date of death data is in line with NHS Digital's policy assessment and will not increase the likelihood of re-identification of data subjects. 2. To ensure a consistent narrative throughout section 5, that this is a *"service evaluation"*, for example, removing reference to *"study"* and providing clarification of the numerous references to *"clinical effectiveness"*. 3. To update section 3 to ensure aligns with the correct legal basis. 4. To update section 3(b) to ensure appropriate minimisation to the control cohort of c.3.7m and/or patients who have been offered the service, as may be the case. 5. To ensure section 5(a) references the correct approximate cohort number. 6. To update section 5 throughout to map the references to clinically vulnerable and clinically extremely vulnerable to align with who is offered the service according to the CO@H SoP. 7. In respect of section 5(b), to consider the language used, for example, referring to people as "cases" and amend accordingly. 8. In respect of section 5(d): a) To remove reference to *"formally the shielding patient list"*. b) To update section 5(d) to reflect that a key benefit may be the continued roll out of this programme potentially reducing morbidity and mortality from COVID-19. The following advice was given: 1. IGARD have presumed that the service evaluation will take into account the significant number of members in the control group who may already have a pulse oximeter for their own use given the reference in mainstream media to their potential utility and the overt promotion of pulse oximeters by high profile public figures on social media. 2. IGARD suggested that the applicant consider further transparency measures, such as improving ongoing communications throughout the rollout. **Significant risk areas:** 1. Area of potential reputational risk to NHS Digital: if it is subsequently determined that this application has research aspects for which ethical support was not sought. 2. Area of concern for the Oximetry@home programme: evidence suggests people from Black, Asian and minority ethnic backgrounds are more likely to stay at home longer

	(COVID Oximetry @home - digital and data services - NHS Digital) and yet they are not included within the programme unless they meet one of the qualifying criteria or clinical discretion is exercised. This could exacerbate existing health inequalities. IGARD strongly recommends NHS Digital raises this issue with the applicants. It was agreed the conditions would be approved out of committee (OOC) by IGARD members.
3.2	Imperial College London: COVID Oximetry At Home - (CO@H): Imperial (Presenter: Vicky Byrne-Watts) NIC-421524-R0Y3P-v0.4 **Application:** This was a new application for pseudonymised Civil Registration (Deaths) data, COVID-19 Oximetry @ Home (CO@H), COVID-19 Second Generation Surveillance System (SGSS), COVID-19 UK Non-hospital Antigen Testing Results (pillar 2), Emergency Care Data Set (ECDS), GPES Data for Pandemic Planning and Research (GDPPR), Hospital Episode Statistics (HES) Admitted Patient Care (APC), Critical Care, Personal Demographic Service (PDS) and Shielded Patient List. The purpose is for a study, evaluating the national roll out of the NHS England and NHS Improvement COVID-19 Oximetry @Home (CO@H) programme, which involves the remote monitoring of patients with COVID-19 symptoms, by using a pulse oximeter, a small monitor clipped to their finger, to measure their oxygen saturation levels three times a day. The aim of this study is to quantitatively assess the cost effectiveness and clinical effectiveness of the CO@H intervention as well as variation in access and outcomes The cohort of patients for the study will be aged 65 or over; or, aged 18 and over and considered clinically vulnerable; or aged 18 and over and diagnosed with a learning disability. **Discussion:** IGARD noted that this was one of a number of linked applications that was being submitted to IGARD for review (item 3.1 also links), and that the overarching application (NIC-396113-N9L4L) had been seen by the IGARD – NHS Digital COVID-19 Response meeting on the 15th December 2020. IGARD also noted that this application had been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 10th March, and as part of the discussion on the 17th March 2021 for NIC-421528-J6S3N (please see Appendix B). IGARD noted and supported the comments made by PAG (on the 10th and 17th March 2021), and acknowledged the confirmation from PAG, that they were supportive of the work outlined and were content that all the points raised had been addressed by NHS Digital. IGARD noted that section 1(b) (Data Controller(s)) stated that NHS England were the sole Data Controller, however queried if this was correct, in light of conflicting information elsewhere in the application, for example, section 5(b) (Processing Activities), that stated the work outlined had been commissioned by NHS England/Improvement and the National Institute for Health Research. NHS Digital advised IGARD that a data controllership assessment had been undertaken in conjunction with various colleagues within NHS Digital, for example Privacy, Transparency and Ethics (PTE) (formerly Information Governance), and it had been agreed that based on the facts presented, NHS England were the sole Data Controller. IGARD noted the verbal update from NHS Digital, and asked that section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) were updated to ensure that the narrative was consistent with there being a **sole** Data Controller, in line with the NHS Digital Data Access Request Service (DARS) Standard for Data Controllers.

	IGARD queried how the Health Services Control of Patient Information (COPI) Regulation 2002 could be relied upon as a legal basis if the data flowing was pseudonymised, noting that this emergency legislation was for the flow of confidential patient data. NHS Digital advised IGARD that due to the volume of data flowing, it was NHS Digital PTE's view that there was a risk that some of the data flowing may become identifiable, and for this reason, the legal basis relied on should be COPI. IGARD noted the verbal update from NHS Digital, and asked that the application was reviewed, to ensure there was a consistent narrative throughout, to support the identifiability status of the data. In addition, IGARD asked that written justification was provided from NHS Digital's PTE, as to why the pseudonymised data was being disseminated under COPI; and that reference to the written justification was also inserted in section 1; and that the written justification from NHS Digital's PTE was also uploaded to NHS Digital's customer relationships management (CRM) system for future reference. IGARD noted that Civil Registration (death) data had been requested, and highlighted that where this specific data was flowing, that NHS Digital would review on a case-by-case basis, to determine if there was an increased risk of identification. IGARD agreed that, in this particular case, there was less risk due to NHS Digital undertaking the linkage. IGARD asked that if COPI was not relied on as a legal basis, that section 1 (Abstract) was updated confirming that the flow of date of death data was in line with NHS Digital's policy assessment and would not increase the likelihood of re-identification of data subjects. IGARD noted that in light of the discussion and ongoing queries around the legal basis with NHS Digital's PTE, that once this had been confirmed, that section 3 (Datasets Held / Requested) was updated to ensure it aligned with the correct legal basis. IGARD queried the description of the work outlined. IGARD asked that on the assumption that the application was in respect of service evaluation, that section 5 was updated to ensure a consistent narrative throughout; and that further clarification was provided in respect of the numerous references to *"clinical effectiveness"*. IGARD queried if the need for a service evaluation was apparent when the scheme was being rolled out, and if participants had been informed of this; and suggested that the applicant considered further transparency measures, such as improving ongoing communications throughout the rollout. IGARD also noted the reference in section 5(b) (Processing Activities) to the applicant undertaking an internal assessment process that concluded that the work outlined was a service evaluation, and asked that the evidence of the assessment was uploaded to NHS Digital's CRM system for future reference. IGARD noted the benefits outlined in section 5(d), however asked that this was updated to reflect that the programme *may* be rolled out more widely, depending on the service evaluation findings. IGARD noted and commended the applicant for providing a paper-based option at all sites, for patients who were uncomfortable with, or unable to use, a digital solution to record their readings. IGARD noted that section 3(b) (Additional Data Access Requested) did not contain any information within the data minimisation section, in respects of how the cohort was going to be minimised, and asked that this was updated, to ensure the appropriate minimisation to the control cohort of circa 3.7 million, and / or patients who had been offered the service, as may be the case and in line with the NHS Digital Standard for Data Minimisation.

	IGARD also asked that section 5(a) was updated to reference the correct approximate cohort numbers, noting that this section was currently silent on any cohort numbers. IGARD suggested that the statement in section 5(b) (Processing Activities) that stated *"…there are no moral or ethical issues…"* was removed. IGARD discussed some of the health inequality ethical issues regarding use of pulse oximetry devices and BAME patients, particularly in light of recent British Medical Association (BMA) and Food and Drug Administration (FDA) publications. A member of IGARD observed that the programme design had elements of enforcing systemic bias/structural racism. IGARD noted the reference to shared learning in section 5(b), and asked that this was also reflected as an output in section 5(c) (Specific Outputs Expected); and that addition informational was provided as to how the shared learning, as directed by the Data Controller, was to be publicised to the public, as this was not clear. IGARD highlighted a potential reputational risk to NHS Digital, in that ethical support had not been sought and it might be subsequently determined that this application had research aspects. **Outcome:** recommendation to approve subject to the following conditions: 1. To update section 1 and section 5 to ensure that that the narrative is consistent with there being a **sole** Data Controller. 2. In respect of the legal basis: 3. To provide written justification from NHS Digital's PTE as to why the pseudonymised data is being disseminated under COPI and include reference to this in the application abstract. 4. To ensure a consistent narrative throughout the application regarding the identifiability status of the data. 5. To upload the written justification from NHS Digital's PTE to NHS Digital's CRM system for future reference. The following amendments were requested: 1. *If* COPI is not relied on, NHS Digital to confirm in section 1 that the flow of date of death data is in line with NHS Digital's policy assessment and will not increase the likelihood of re-identification of data subjects. 2. To ensure a consistent narrative throughout section 5, that this is a "service evaluation, for example, removing reference to *"study"* and providing clarification of the numerous references to *"clinical effectiveness"*. 3. To update section 3 to ensure it aligns with the correct legal basis. 4. To update section 3(b) to ensure appropriate minimisation to the control cohort of c.3.7m and/or patients who have been offered the service, as may be the case. 5. To ensure section 5(a) references the correct approximate cohort number. 6. In respect of section 5(b): 7. To remove reference to '*there are no moral or ethical issues*". 8. To reference the assessment process undertaken internally which concluded that this was a service evaluation, and to upload any evidence to NHS Digital's CRM system for future reference. 9. Referencing the shared learning in section 5(b), to reflect in section 5(c), how the shared learning, as directed by the Data controller, is to be publicised to the public. 10. To update section 5(d) to make clear that the programme *may* be rolled out more widely, depending on the service evaluation findings.

	The following advice was given: 1. IGARD have presumed that the service evaluation will take into account the significant number of members in the control group who may already have a pulse oximeter for their own use given the reference in mainstream media to their potential utility and the overt promotion of pulse oximeters by high profile public figures on social media. 2. IGARD suggested that the applicant consider further transparency measures, such as improving ongoing communications throughout the rollout. **Significant risk area:** 1. Area of potential reputational risk to NHS Digital: if it is subsequently determined that this application has research aspects for which ethical support was not sought. 2. IGARD noted that an emerging issue regarding pulse oximetry at home is that readings in people with dark colour skin may underestimate low oxygen levels (hypoxaemia) as discussed in the BMJ article *"Pulse oximetry may underestimate hypoxaemia in black patients, study finds"* https://www.bmj.com/content/371/bmj.m4926/rr-0 and reported by the US regulator FDA in a recent communication https://www.fda.gov/medical-devices/safety-communications/pulse-oximeter-accuracy-and-limitations-fda-safety-communication . IGARD strongly recommends NHS Digital raises this issue with the applicants as a potential area of reputational risk to the bodies responsible for the programme. It was agreed the conditions would be approved out of committee (OOC) by IGARD members.
3.3	Southend-on-Sea Borough Council: GDPPR COVID-19 – LA - Pseudo (Presenter: Dan Goodwin) NIC-432008-F0J0M-v0.2 **Application:** This was a new application for pseudonymised GPES Data for Pandemic Planning and Research (GDPPR) data; for the purpose of supporting and improving the local responsiveness to COVID-19 and enhance the capability of the local public health intelligence team to undertake analyses of patterns and variation in the incidence and prevalence of COVID-19, demand for and access to treatment and variations in health outcomes between groups in the population. It will also be used to support the statutory duties of the Local Authority, including the duty to improve public health and the duty to provide public health advice to NHS commissioners. As they move to the COVID-19 recovery phase. **Discussion:** IGARD noted that this application had been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 24th March 2021 (please see Appendix B). IGARD noted the comments made by PAG (on the 24h March 2021), and acknowledged the confirmation from PAG, that they were supportive of the work outlined. In respect of the PAG point raised in relation to NHS Digital providing clarity on the minimisation by area (address or GP registration), IGARD asked that section 5(c) (Specific Outputs Expected) was updated with further clarity of this in line with NHS Digital's Data Access Request Service (DARS) standard for Data Minimisation. IGARD also asked that a satisfactory rationale was provided, for GP practices providing consent for identification and, if satisfactory, that an appropriate special condition was inserted in section 6 (Special Conditions) to address this.

	PAG requested that GP practices consent to being identified in any resulting publications. Without knowing the rationale for this approach IGARD were unable to offer an opinion on this point. IGARD queried how the Health Services Control of Patient Information (COPI) Regulation 2002 could be relied upon as a legal basis if the data flowing was pseudonymised, noting that this emergency legislation was for the flow of confidential patient data. NHS Digital advised IGARD that due to the volume of data flowing, it was NHS Digital PTE's view that there was a risk that some of the data flowing may become identifiable, and for this reason, the legal basis relied on should be COPI. IGARD noted the verbal update from NHS Digital, and asked that the application was reviewed, to ensure there was a consistent narrative throughout, to support the identifiability status of the data. In addition, IGARD asked that written justification was provided from NHS Digital's PTE, as to why the pseudonymised data was being disseminated under COPI; and that reference to the written justification was also inserted in section 1; and that the written justification from NHS Digital's PTE was also uploaded to NHS Digital's customer relationships management (CRM) system for future reference. IGARD noted the special condition in section 6 that stated "*The disseminated data is confidential patient information*…", and asked that this was updated to accurately reflect that the data flowing was pseudonymised. IGARD noted that the Article 6 UK General Data Protection Regulation (UK GDPR) legal basis cited was Article 6(1)(c) (legal obligation), however in relation this application and as a wider issue, a query had been raised with NHS Digital's PTE as to whether this was correct, or whether Article 6(1)(e) public task was a more suitable legal basis, given the data subject rights, which were no longer available to the data subject when legal obligation was relied upon. NHS Digital confirmed that they were aware of the query that had been raised with NHS Digital's PTE, and following further discussions with the applicant, advised that the application would be updated where appropriate, to reflect that Article 6 legal basis relied on was public task and not legal obligation. IGARD noted the verbal update from NHS Digital, and supported the update to the application to reflect the correct Article 6 legal basis. IGARD noted that in respect of data minimisation, the narrative description in respect of the data fields requested in section 5(a) (Objective for Processing), and asked that this was moved to sit in section 5(b) (Processing Activities) as it was more relevant to the processing activities. IGARD queried how the area would be minimised, for example, was it the address of the patient or the address of the GP practice; and asked that section 3(b) (Additional Data Access Requested) and section 5(b) were updated with further clarity, in line with NHS Digital's DARS Standard for Data Minimisation. IGARD noted that this was a significant new flow of data not previously received, and asked that further details were provided in section 5(d) (Benefits) of the specific potential ***benefits*** accruing to health and/or social care, for example, how does the Joint Strategic Needs Assessment (JSNA) outputs in section 5(c) create a benefit which could be explained in section 5(d). IGARD advised NHS Digital that they would want to see another templated application before being considered for NHS Digital's Precedent route. **Outcome:** recommendation to approve subject to the following conditions: 1. In respect of the legal basis:

	a) To provide written justification from NHS Digital's PTE as to why the pseudonymised data is being disseminated under COPI and include reference to this in the application abstract. b) To ensure a consistent narrative throughout the application to support the identifiability status of the data. a) To upload the written justification from NHS Digital's PTE to NHS Digital's CRM system for future reference. 2. In respect of the PAG points raised: a) To clarify in section 5(c) the minimisation by area. b) To provide a satisfactory rationale for GP practices providing consent for identification and, if satisfactory, insertion of an appropriate special condition in section 6 to address this. The following amendments were requested: 1. To update the special conditions in section 6 to reflect that it is pseudonymised data flowing. 2. To amend the application where appropriate to ensure the Article 6 legal basis relied on is public task and not legal obligation. 3. In respect of data minimisation: a) To move some of the narrative description from section 5(a) to 5(b) in respect of data fields. b) To clarify in section 3(b) and 5(b) how the area is minimised, for example, is it the address of the patient or the GP practice. 4. Noting that this is a significant new flow of data not previously received, to provide further details in section 5(d)of the specific potential ***benefits*** accruing to health and/or social care, for example, how does the JSNA outputs in section 5(c) create a benefit which could be explained in section 5(d). The following advice was given: 1. IGARD advised that they would want to see another template application before being considered for NHs Digital's Precedent route. It was agreed the conditions would be approved out of committee (OOC) by IGARD members.
3.4	<u>Imperial College London: Imperial College London - REACT Data and Connectivity National Core Studies (Presenter: Louise Dunn) NIC-431352-G7F1M-v0.4</u> **Application:** This was a new application for identifiable Civil Registration (Deaths) data, pseudonymised COVID-19 Hospitalization in England Surveillance System (CHSS), COVID-19 Second Generation Surveillance System (SGSS), Covid-19 UK Non-hospital Antibody Testing Results (Pillar 3), Covid-19 UK Non-hospital Antigen Testing Results (Pillar 2), COVID-19 Vaccination Adverse Reactions, COVID-19 Vaccination Status, GPES Data for Pandemic Planning and Research (COVID-19) and Hospital Episode Statistics (HES) Admitted Patient Care (APC) and HES Outpatients data. The Real-Time Assessment of COVID Transmission (REACT) Study was established in May 2020, and provides monthly estimates of the prevalence of SARS-CoV-2 virus and bi-monthly estimates of the prevalence of antibodies to SARS-CoV-2 virus in the general population of England. The purpose is to enhance the existing REACT research cohorts, by linking the study data from adult participants, who have provided consent, to their health records held by the NHS. This enhanced dataset will then be used to advance understanding of the risks of infection and

	reinfection with COVID-19 and future health following a COVID infection. The outputs from this study will be delivered by June 2021 and directly feed into the UK government's pandemic response through the partnership between Imperial College London and the Department of Health and Social Care. This application is limited to requesting linkage on the adult participants who have consented from the REACT I (NIC-393650-B7J6F-v2.3) and REACT II (NIC-389914-N9R8R-v3.2) study cohorts, and the estimated size of the cohort for data linkage is 1 million people. **Discussion:** IGARD noted that this application had been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 24th March 2021 (please see Appendix B). IGARD noted and supported the comments made by PAG (on the 24h March 2021), and acknowledged the confirmation from PAG, that they were supportive of the work outlined. IGARD confirmed that they were of the view that the **most recent** consent materials provided the appropriate legal gateway and was broadly compatible with the processing outlined in the application. In addition, NHS Digital advised IGARD that the applicant had engaged with members of the consented cohort to discuss the proposed processing as outlined in the application. IGARD noted and thanked NHS Digital for the additional information in respect of the communication with cohort members, however, suggested that further work was undertaken on the public facing transparency materials, for example, the patient facing website, and any other direct communications with the cohort; and suggested that this could include additional information, such as the processing outlined in the application and in particular the retrospective look at medical records. IGARD queried why children and young people were not included in this follow up study, and noting the potential downside of this, suggested that the applicant may wish to consider their inclusion. IGARD noted the language used in section 5 (Purpose / Methods / Outputs), for example *"dark fibre"*, and asked that this public facing section be updated, to ensure that it was in a language suitable for a lay reader, noting that section 5 served as NHS Digital's public facing data release register. IGARD noted the benefits outlined in section 5(d) (Benefits), however asked that this was updated to also reflect that one of the key benefits may ultimately be the reduction of morbidity and mortality from COVID-19. IGARD noted that supporting document 1.0, the study protocol, referred to data linkage from March 2015, and suggested that at the earliest opportunity, this was updated to reflect the updated date as outlined in the application, which was January 2019. IGARD commended the applicant on the clear information provided in section 5(a) (Objective for Processing) of the datasets requested and how they would be used, and suggested to NHS Digital that this was used as an exemplar to future applicants of NHS Digital data, and that this would be excellent in terms of NHS Digital's public facing data release register. **Outcome:** recommendation to approve The following amendments were requested:

	1. Noting that section 5 serves as NHS Digital's public facing data release register, to ensure this is in a language suitable for a lay reader, for example, providing further clarity on the reference to *"dark fibre"*. 2. To update section 5(d) to reflect that a key benefit may ultimately be the reduction of morbidity and mortality from COVID-19. The following advice was given: 1. IGARD suggested that further work was undertaken on the public facing transparency materials, for example, the patient facing website, and any other direct communications with the cohort. 2. IGARD queried why children and young people were not included in this follow up and suggested that their inclusion be considered.
3.5	<u>King's College London: CovPall-Connect. Evaluation of the COVID-19 pandemic response in palliative and end of life care: Connecting to boost impact and data assets. (Presenter: Louise Dunn) NIC-432271-H5R8D-v0.8</u> **Application:** This was a new application for pseudonymised Civil Registration (Deaths) data, COVID-19 Second Generation Surveillance System (SGSS), Covid-19 UK Non-hospital Antigen Testing Results (pillar 2), GPES Data for Pandemic Planning and Research (COVID-19) (GDPPR), Hospital Episode Statistics (HES) Accident and Emergency (A&E) / Admitted Patient Care (APC) / Critical Care / Outpatients data, Medicines dispensed in Primary Care (NHS Business Services Authority (NHS BSA) data) and Patient Reported Outcome Measures (PROMs) data; the datasets will be stored within the NHS Digital's Trusted Research Environment (TRE). The study is a rapid multinational observational study of palliative care during COVID-19, involving a cross-sectional on-line survey of hospice and specialist palliative services in the UK between April and July 2020. The survey used open and closed questions to ask about their practices and how these have changes, and their challenges and innovations. **Discussion:** IGARD noted that this application had been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 24th March 2021 (please see Appendix B). IGARD noted and supported the comments made by PAG (on the 24h March 2021), and acknowledged the confirmation from PAG, that they were supportive of the work outlined and the use of NHS Digital's TRE. IGARD queried if the consent the Palliative Care and Hospice Clinical Leads provided when completing the original questionnaire was compatible with transferring their responses into the TRE. NHS Digital advised IGARD that the applicant has assessed that participants would not be surprised. IGARD noted the verbal update, however, asked that NHS Digital satisfied itself that the consent was compatible with the data ingested into NHS Digital's TRE, in particular with regard to any arrangements for withdrawing questionnaire responses. IGARD noted that Civil Registration (death) data had been requested, and highlighted that where this specific data was flowing, that NHS Digital would review on a case-by-case basis, to determine if there was an increased risk of identification. IGARD agreed that, in this particular case, there was less risk due to NHS Digital undertaking the linkage. IGARD asked that section 1 (Abstract) was updated confirming that the flow of date of death data was in line with NHS Digital's policy assessment and would not increase the likelihood of re-identification of data subjects.

	IGARD queried the reference in section 5(a) that the Office for National Statistics (ONS) provided the Civil Registration (deaths) data; and noting that this was historical information, asked that this was either amended to reflect the current process, or removed. IGARD noted the data fields requested for the Civil Registration (deaths) data set in section 3(b) (Additional Data Access Requested), specifically the *"occupation of the Mother of the deceased juvenile"*, and queried why this data was required; and asked that this was reviewed and established if this data was demonstrably necessary for processing; noting that this was not clearly outlined in the application. In addition, IGARD also asked that when establishing if the occupation of the mother of the deceased juvenile was necessary, that the applicant clarified in section 5(a) (Objective for Processing) that the processing for the NHS BSA data was strictly within the scope of use set out in the Direction relating to this data set's use. IGARD noted that *"social factors"* were referenced in section 5(d) (Benefits) of the application, however asked that in light of the query in relation to the occupation of the of the mother of the deceased juvenile; that if social factors were in fact a significant aspect of the study, that section 5(a) was updated to also include this, noting that it was currently silent on this point. In addition, IGARD also asked that clarification was provided, that all of the other data fields listed for the Civil Registration (deaths) data set, as outlined in section 3(b) (Additional Data Access Requested) were necessary. IGARD queried whether the information in section 3(b) that stated the Civil Registration (deaths) data was *"identifiable"* was correct, and were advised by NHS Digital that this was incorrect, and that the data was in fact pseudonymised; IGARD noted the verbal update from NHS Digital, and asked that the application was reviewed and updated where necessary to correctly reference the Civil Registration (deaths) data as being pseudonymised. IGARD noted the breadth of the datasets requested, and the quantum of data in the TRE, and asked that for transparency, a brief description was provided in section 5(a), of what each dataset would be used for vis-à-vis achieving the stated outputs. IGARD noted that within some of the supporting documents provided, for example, supporting document 1.0, the study protocol, it stated that King's College Hospital NHS Foundation Trust was the study sponsor; and asked that an analysis was provided in section 1, as to why they were not considered a joint Data Controller. If the facts supported King's College Hospital NHS Foundation Trust being named a joint Data Controller, IGARD asked that the requisite amendments were made in the application, as outlined in the NHS Digital Data Access Request Service (DARS) Standard for Data Controllers. IGARD noted the storage location referenced in section 2(b) (Storage Location(s)) for NHS Digital's TRE, and asked that this was reviewed and amended if appropriate, to reflect the correct address. IGARD noted the length of section 5(a) and suggested that this was amended, to remove the significant amount of duplicated text, and removing excessive detail, to reduce the description of processing, which was potentially too lengthy for NHS Digital's data release register; for example, by removing reference to the data being requested from Wales, Scotland and Northern Ireland, as this information was not necessary for the data sharing agreement (DSA). IGARD noted the helpful lay summary within the study protocol, and asked that for transparency and ease of reference to the public, this was replicated in section 5(a). IGARD noted the benefits outlined in section 5(d), and advised NHS Digital that there was the potential for a real benefit to health and social care; however asked that these were re-ordered

	to ensure that the primary focus to primary care and patient experience was noted above any financial cost-saving benefit. IGARD noted a number of acronyms and technical phrases in section 5 (Purpose / Methods / Outputs), for example *"statistical data controls" and "VPN"*, and asked that this public facing section be updated to ensure that all acronyms and technical phrases upon first use were expanded and clearly defined with a supportive explanation in a language suitable for a lay reader; for example, statistical data controls could be replaced with standard wording in respect of the HES Analysis Guide. IGARD queried the references within section 5 to *"researchers"*, and asked that this was updated to ensure that the first reference to "researchers" was clear that **only** King's College London researchers would have access to the data. **Outcome:** recommendation to approve The following amendments were requested: 1. NHS Digital to confirm in section 1 that the flow of date of death data is in line with NHS Digital's policy assessment and will not increase the likelihood of re-identification of data subjects. 2. To provide an analysis in section 1 of why the King's College Hospital NHS Foundation Trust are not considered a joint Data Controller, despite them being named as a study sponsor. If the facts support KHCFT being named a joint Data Controller, to make requisite amendments in the application. 3. NHS Digital to satisfy itself that the consent is compatible with the data ingested into NHS Digital's TRE. 4. To review the NHS Digital TRE storage location in section 2(b) and amend if appropriate. 5. In respect of the data sets requested: a) In respect of the death data, to establish if the *"occupation of the Mother of the deceased juvenile"* field is demonstrably necessary for processing. b) To provide clarification that all the data fields in the death data requested are necessary. c) To amend the references to the death data being *"identifiable"* to correctly reference that the data is pseudonymised. 6. In respect of section 5(a): a) Given the breadth of the datasets requested, and the quantum of data in the TRE to provide a brief description of what each dataset will be used for vis-à-vis achieving the stated outputs. b) When carrying out 6a above, to ensure that the processing for the NHS BSA data is strictly within the scope of use set out in the Direction relating to this data set's use. c) To remove the significant amount of duplicated text. d) To edit section 5(a) to remove excessive detail to reduce the description of processing, which is potentially too lengthy for NHS Digital's data release register, for example, removing reference to the data being requested from Wales, Scotland and Northern Ireland, as it is not necessary for this DSA. e) To amend or remove the reference to ONS providing the Civil Registration (deaths) data in section 5(a). f) To update section 5(a) to include the helpful lay summary from the protocol. g) If social factors are a significant aspect of the study, to include this within section 5(a).

	7. To amend section 5(d) to ensure the primary focus to primary care and patient experience is noted above any financial cost-saving benefit. 8. To amend section 5 to ensure that all acronyms upon first use be defined and further explained if the meaning is not self-evident, for example, *"statistical data controls*" (which may be replaced with the usual wording re HES Analysis Guide) and *"VPN"*. 9. To update section 5 to ensure that at the first reference to *"researchers"* is clear that only KCL researchers will have access to data.
3.6	AstraZeneca UK Limited: DAPA MI (Presenter: Heather Pinches / Andy Rees) NIC-433176-J8Q2S-v0.2 **Application:** This was a new application for pseudonymised Civil Registration (Deaths) data and National Institute for Cardiovascular Outcomes Research (NICOR) Myocardial Ischaemia National Audit Project (MINAP) data. The purpose is for a registry based randomised double-blinded placebo-controlled cardiovascular outcomes trial to evaluate the effect of Dapagliflozin on the incidence of heart failure or cardiovascular death in patients without diabetes with acute myocardial infarction at increased risk for subsequent development of heart failure. Dapagliflozin is a drug that was originally developed for the treatment of type 2 diabetes. This application is limited to patients who have consented into the trial and enrolled according to the strict inclusion and exclusion criteria of the trial protocol. It is anticipated that the first patient will be enrolled in the UK in April 2021 and enrolment is planned for 18 months or until 3,200 cohort members have been recruited. **Discussion:** IGARD noted that aspects of this application had last been seen by the IGARD – NHS Digital COVID-19 Response meeting on the 16th March 2021. IGARD confirmed that they were of the view that the **most recent** consent materials provided the appropriate legal gateway and was broadly compatible with the processing outlined in the application. IGARD and NHS Digital had a lengthy discussion in respect of data controllership, and in particular around the role of AstraZeneca AB based in Sweden, in light of the information provided in the application and the supporting documents. NHS Digital advised IGARD that AstraZeneca AB, were an affiliate of the AstraZeneca global organisation, and that it was AstraZeneca UK Ltd that were registered with the Information Commissioners Office (ICO). For purposes of compliance with the UK General Data Protection Regulation (UK GDPR), AstraZeneca AB were the lead entity, and the Swedish Data Supervisory authority was the lead authority for AstraZeneca's Binding Corporate Rules (BCR)s. NHS Digital also advised that the AstraZeneca group have one EU Data Protection Officer, who was currently employed by AstraZeneca UK Ltd, and that as such, any communications to AstraZeneca's Data Protection Officer (DPO) in the UK would also be a communication to the DPO for AstraZeneca AB, who would facilitate any correspondence with the ICO. IGARD noted the verbal update and asked that in alignment with the definition of Controller in Article 4(7) UK GDPR, the DPO of AstraZeneca UK Limited provided written confirmation, that AstraZeneca UK Limited was the **sole** legal person determining the purposes and means of processing of the NHS Digital data, such processing as outlined in the application in line with NHS Digital's Data Access Request Service (DARS) Standard for Data Controllers; and that the written confirmation was uploaded to NHS Digital's customer relationships management (CRM) system for future reference.

	IGARD noted that Article 6(1)(c) (legal obligation) of the UK GDPR was referenced within the application, and queried if this legal basis covered all the purposes outlined. NHS Digital advised IGARD that following submission of the application for review, further discussions had taken place with the applicant, and that it had been confirmed that Article 6(1)(c) and Article 6(1)(f) (Legitimate Interest) were appropriate for different aspects of the trial, and that the necessary updates would need to be made to the application to reflect this. In addition, NHS Digital also advised IGARD that following the review of the Article 6 UK GDPR legal basis, and the subsequent amendments that would need making to the application; they advised that the applicant's privacy notice and a completed Legitimate Interest Assessment (LIA) would need completing and submitting to NHS Digital within four weeks of the DSA being signed. IGARD noted the updates from NHS Digital in respect of the Article 6 UK GDPR legal basis and asked that the application was updated throughout, to clarify which aspects of the processing outlined, was being undertaken under each Article 6 UK GDPR legal basis cited. In addition, IGARD asked that, in in respect of Article 6(1)(c), and in line with the ICO guidance, that the application clearly set out, which regulation or law in force in England and Wales obliges the Data Controller to process the data, and note which aspect of processing was required by such obligation, for example, a suite of safety outcomes relating to morbidity, mortality and adverse events. In respect of Article 6(1)(f), which would be relied on for the other aspects of processing, IGARD asked that relevant amendments were made throughout the application, to note which aspects of processing would be carried out under this gateway and that a brief reference was included in section 5(a) (Objective for Processing) confirming what the legitimate interests are. IGARD noted and supported the suggestion by NHS Digital, that an LIA would need completing / submitting; and asked that a special condition was inserted in section 6 (Special Conditions), that the applicant would furnish NHS Digital with an LIA within four weeks of signing the DSA and that as per process a brief outlined of the LIA be included at the start of section 5(a). IGARD noted that section 5 (Purpose / Methods / Outputs) referred to *"AstraZeneca"*, and asked that this was updated, to be clear on first use which AstraZeneca body was being referred to; and that if it was referring to more than one, to be clear which AstraZeneca entity was carrying out what activity. IGARD noted the territory of use in section 2(c) (Territory of Use) was stated as being the European Economic Area *"EEA"*, however asked that this was updated, to accurately reflect that the territory of use was England and Wales **and** the EEA. IGARD queried the output stated in section 5(c) (Specific Outputs Expected) that *"An internal report will be produced for the study. Submissions will be prepared for peer-reviewed publications, as well as for presentations at cardiovascular conferences."*, and asked that confirmation was provided, as to whether there would be further reporting of results in the more immediate term and before submission to peer review journals, and if so, how this reporting would be made available. In addition, IGARD also asked that section 5(c) was updated to expressly state that any outputs that would be produced, would comply with and satisfy the relevant legal obligation. IGARD noted a number of acronyms and scientific terms in section 5(a), for example *"event driven"*, and asked that this public facing section be updated to ensure that all acronyms and

	scientific terms, upon first use were expanded and clearly defined with a supportive explanation in a language suitable for a lay reader. IGARD noted the benefits outlined in section 5(d) Benefits), however asked that this was updated to also reflect that one of the positive results would be a *"significant clinical benefit"*. IGARD queried the funding source in section 8(b) (Funding Sources), which was stated as being *"private"*, and asked that this was updated to accurately state that the funding was provided by AstraZeneca. **Outcome:** recommendation to approve 1. In respect of data controllership: a) In alignment with the definition of Controller in Article 4(7) UK GDPR, the DPO of AstraZeneca UK Limited to provide written confirmation that AstraZeneca UK Limited is the sole legal person determining the purposes and means of processing of the NHS Digital data (such processing as outlined in the application). b) To upload the written confirmation to NHS Digital's CRM system. 2. In respect of the legal basis: a) To update the application throughout to clarify which aspect of processing is being undertaken under each Article 6 UK GDPR legal basis cited. b) With regard to Article 6(1)(c) (legal obligation), noting the ICO guidance, to clearly set out which regulation or law in force in England and Wales obliges the controller to process the data and note which aspect of processing is required by such obligation (for example: a suite of safety outcomes relating to morbidity, mortality and adverse events). c) With regard to Article 6(1)(f) (Legitimate Interest) which will be relied on for the other aspects of processing, to make relevant amendments throughout to note which aspects of processing will be carried out under this gateway and include brief reference in 5(a) to what the legitimate interests are. d) to insert a special condition in section 6 that the applicant will furnish NHS Digital with an LIA within 4 weeks of signing the DSA. 3. To update section 2(c) to reflect that the territory of use is England and Wales **and** the EEA. 4. To update section 5(a) to either expand acronyms and scientific terms, or provide a supportive explanation upon first use, for example, *"event driven"*. 5. To update section 5 to be clear on first use which AstraZeneca body is being referred to and if referring to more than one, be clear which AstraZeneca entity is carrying out what activity. 6. In respect of section 5(c): a) To confirm if there will be further reporting of results in the more immediate term and before submission to peer review journals and how this reporting will be made available. b) To expressly state any outputs that will be produced to comply with and satisfy the relevant legal obligation. 7. To update section 5(d) to reflect that one of the positive results will be a *"significant clinical benefit"*. 8. To update section 8(b) to state that funding is provided by AstraZeneca rather than *"private"*.
3.7	<u>COVID-19 Vaccine Data for CCGs and Local Authorities (Presenters: Tom Wright / Bethan Thomas) NIC-448129-H1V1G</u>

	Application: This was a new templated application for CCGs and Local Authorities, to receive Vaccinations data in support of the management of the COVID-19 emergency. NHS England have been commissioned by the Secretary of State for Health and Social Care to operate the COVID-19 vaccination programme and for that data to be made available to a number of organisations for COVID-19 purposes such as Local Authorities and CCGs. The Vaccine data is identifiable patient data and contains patient demographics, source organisation (where the vaccination data originated), vaccination appointment and outcome details, and vaccine batch details. **Discussion:** IGARD queried how the Health Services Control of Patient Information (COPI) Regulation 2002 could be relied upon as a legal basis, if the data flowing was pseudonymised, noting that this emergency legislation was for the flow of confidential patient data. NHS Digital advised IGARD that due to the volume of data flowing, it was PTE's view, that there was a risk, that some of the data flowing may become identifiable, and for this reason, the legal basis relied on, should be COPI. IGARD noted the verbal update from NHS Digital, and asked that the application was reviewed, to ensure there was a consistent narrative throughout, to support the identifiability status of the data. In addition, IGARD asked that written justification was provided from NHS Digital's Privacy, Transparency and Ethics (PTE) (formerly Information Governance), as to why the pseudonymised data was being disseminated under COPI; and that, reference to the written justification was also referenced in section 1 (Abstract); and that the written justification from NHS Digitals PTE was also uploaded to NHS Digital's customer relationships management (CRM) system for future reference. IGARD also noted that where applicable, requisite changes would need making to the special condition wording in section 6 (Section 6), to reflect any changes to the legal basis. IGARD noted the Local Authority (LA) templated wording "*ensuring vulnerable individuals and groups are identified and supported through the vaccination process to ensure the maximum possible vaccination uptake*", and asked that this was removed, since this identification is usually a role undertaken by the CCG in providing direct care. IGARD advised, that should a LA wish to identify vulnerable individuals or groups, that a written justification must be provided for each LA request in section 5 of the LA templated application, and this could be assessed on a case-by-case basis. **Outcome:** IGARD agreed there were appropriate use cases and recommended the flow of CV-19 vaccine data for the CCG and LA templated applications (whether by way of amendment letter or DSA amendment, whichever is more expedient), subject to the following conditions: 1. In respect of the legal basis: a) To provide written justification from NHS Digital's PTE as to why the pseudonymised data is being disseminated under COPI. b) To ensure a consistent narrative throughout the application to support the identifiability status of the data. c) To upload the written justification from NHS Digital's PTE to NHS Digital's CRM system for future reference. d) to make requisite changes to the special condition wording in section 6, to reflect any changes to the legal basis. 2. To remove from the LA templated wording "*ensuring vulnerable individuals and groups are identified and supported through the vaccination process to ensure the maximum*

	possible vaccination uptake" since this identification is usually a role undertaken by the CCG in providing direct care. The following advice was given: 1. Should a LA wish to identify vulnerable individuals or groups, that a written justification must be provided for each LA request in section 5 of the LA templated application, and this could be assessed on a case-by-case basis. It was agreed the condition would be approved out of committee (OOC) by the IGARD Chair.
4	<u>Returning Applications</u> IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. 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.
5	<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 23rd March 2021** can be found attached to these minutes as Appendix C.
6	<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 19/03/21

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)
None						

In addition, a number of applications were processed by NHS Digital following the Precedents approval route. IGARD carries out oversight of such approvals and further details of this process can be found in the Oversight and Assurance Report.

In addition, a number of applications were approved under class action addition of:

Liaison Financial Service and Cloud storage:

- None

Optum Health Solutions UK Limited Class Actions:

- NIC-55710-W8F8C-v7.2 - NHS West Essex

Graphnet Class Actions:

- None

Appendix B

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 10th March 2021

Application & application version number: DARS-NIC-421528-J6S3N-v0.3 **Organisation name: NHS England (The Health Foundation)** **Profession Advisory Group Agenda item: 6**
PAG support the clinical purpose behind the application. PAG have raised the following points which they would like to be addressed before recommending approval. Firstly, PAG request NHS Digital to confirm if this application could be supported within the NHS Digital TRE. If confirmed to seek justification from the applicant as to why they have requested the extract. PAG understand that NHS England already have/receive the GP dataset and relevant others that are being requested in this application and would like clarification about why this cannot be fulfilled in their current TRE environments. PAG note that the cohort number is circa 40,000. However, the control cohort is the rest of the England population which is circa 55 million and would like justification as to why this is necessary and proportionate.

Attendees	Role	Organisation
Arjun Dhillon	Chair, Caldicott Guardian	NHS Digital
Peter Short	GP, Clinical Lead	NHS Digital
Amir Mehrkar	GP, Clinical Researcher	RCGP
Mark Coley	Deputy IT Policy Lead	BMA
Liz Gaffney	Head of Data Access	NHS Digital
Pam Soorma	Secretariat	NHS Digital
Vicky Byrne-Watts	Senior Case Officer	NHS Digital

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 17th March 2021

Application & application version number: **DARS-NIC-421528-J6S3N-v0.3** **Organisation name: NHS England (The Health Foundation)** **Profession Advisory Group Agenda item: 4**
PAG support this request based on the 3.7 million and any resultant delta that are reasonably required. NHS Digital confirmed that in this case they are unable to support the analysis in their TRE.

Attendees	Role	Organisation
Arjun Dhillon	Chair and Caldicott Guardian	NHS Digital
Amir Mehrkar	GP, Clinical Researcher	RCGP
Mark Coley	Deputy IT Policy Lead	BMA
Liz Gaffney	Head of Data Access	NHS Digital
Pam Soorma	Secretariat	NHS Digital
Louise Dunn	Data Approvals Officer	NHS Digital

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 10th March 2021

Application & application version number: **DARS-NIC-421528-J6S3N-v0.3** **Organisation name: NHS England (The Health Foundation)** **Profession Advisory Group Agenda item: 6**
PAG support the clinical purpose behind the application. PAG have raised the following points which they would like to be addressed before recommending approval. Firstly, PAG request NHS Digital to confirm if this application could be supported within the NHS Digital TRE. If confirmed to seek justification from the applicant as to why they have requested the extract. PAG understand that NHS England already have/receive the GP dataset and relevant others that are being requested in this application and would like clarification about why this cannot be fulfilled in their current TRE environments. PAG note that the cohort number is circa 40,000. However, the control cohort is the rest of the England population which is circa 55 million and would like justification as to why this is necessary and proportionate.

Attendees	**Role**	**Organisation**
Arjun Dhillon	Chair, Caldicott Guardian	NHS Digital
Peter Short	GP, Clinical Lead	NHS Digital
Amir Mehrkar	GP, Clinical Researcher	RCGP
Mark Coley	Deputy IT Policy Lead	BMA
Liz Gaffney	Head of Data Access	NHS Digital
Pam Soorma	Secretariat	NHS Digital
Vicky Byrne-Watts	Senior Case Officer	NHS Digital

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 24th March 2021

Application & application version number: **DARS-NIC-432008-F0J0M-v0.2** **Organisation name: Southend-on-Sea Local Authority** **Profession Advisory Group Agenda item: 2**
PAG support this application with the following caveats: PAG recognise the needs for a JSNA. PAG note that GP data can enrich the JSNA. PAG would like to highlight the limitations of the data held within this extract which could lead to the incorrect conclusion being used within any analysis. **https://digital.nhs.uk/coronavirus/gpes-data-for-pandemic-planning-and-research/guide-for-analysts-and-users-of-the-data** PAG note that the applicant will only be using the aggregate data by using suppressed numbers. GP data for planning and research should not be used for performance management of practices. Recognising that practice level identifiers are requested and would be beneficial to a JSNA, as this is a new dataset and a new method of informing the JSNA, PAG request that this time practices consent to being identified in any resulting publications. PAG would like NHS Digital to clarify in the application the minimisation by area (address or GP registration) and this should be consistent through all local authority applications.

Attendees	Role	Organisation
Arjun Dhillon	Chair and Caldicott Guardian	NHS Digital
Amir Mehrkar	GP, Clinical Researcher	RCGP
Mark Coley	Deputy IT Policy Lead	BMA
Helen Buckels	Business & Operational Delivery Manager	NHS Digital
Pam Soorma	Secretariat	NHS Digital
Dan Goodwin	Case Officer	NHS Digital

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 24th March 2021

Application & application version number: **DARS-NIC-431352-G7F1M-v0.4** **Organisation name: Imperial College London** **Profession Advisory Group Agenda item: 4**
PAG are supportive of the work and its aim. PAG are mindful of the need to minimise the dissemination of sensitive GP data. PAG request that NHS Digital assess whether the study can be conducted with NHS Digital's TRE or that of the ONS. If the aims of the study cannot be reasonably supported by another mechanism PAG support the dissemination to the applicant.

Attendees	**Role**	**Organisation**
Arjun Dhillon	Chair and Caldicott Guardian	NHS Digital
Amir Mehrkar	GP, Clinical Researcher	RCGP
Mark Coley	Deputy IT Policy Lead	BMA
Helen Buckels	Business & Operational Delivery Manager	NHS Digital
Pam Soorma	Secretariat	NHS Digital
Louise Dunn	Data Approvals Officer	NHS Digital

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 24th March 2021

Application & application version number: **DARS-NIC-432271-H5R8D-v0.8** **Organisation name: Kings College London** **Profession Advisory Group Agenda item: 5**
PAG support the aims of this work for this group of patients and the use of NHS Digital's TRE. PAG support this application.

Attendees	**Role**	**Organisation**
Arjun Dhillon	Chair and Caldicott Guardian	NHS Digital
Amir Mehrkar	GP, Clinical Researcher	RCGP
Mark Coley	Deputy IT Policy Lead	BMA
Helen Buckels	Business & Operational Delivery Manager	NHS Digital
Pam Soorma	Secretariat	NHS Digital
Louise Dunn	Data Approvals Officer	NHS Digital

Appendix C

Independent Group Advising on the Release of Data (IGARD)

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

held via videoconference, Tuesday, 23rd March 2021

In attendance (IGARD Members):	Prof. Nicola Fear (IGARD Specialist Academic Member)
	Kirsty Irvine (IGARD Chair, Lay representative)
	Dr. Imran Khan (IGARD Specialist GP Member)
In attendance (NHS Digital):	Louise Dunn (DARS)
	Duncan Easton (DAR)
	Andy Rees (DARS)
	Karen Myers (IGARD Secretariat)
	Vicki Williams (IGARD Secretariat)

1	**Welcome** The IGARD Chair noted that this was a weekly meeting convened to support NHS Digital's response to the COVID-19 situation and was separate from the IGARD business as usual (BAU) meetings. IGARD members present would only be making comments and observations on items that were presented, and were not making formal recommendations to NHS Digital. Should an application require a full review and recommendation, then it should go through the usual Data Access Request Service (DARS) process and be presented at a Thursday IGARD meeting. The action notes from the Tuesday meeting would be received at the next Thursday meeting of IGARD and published as part of those minutes as an appendix. **Declaration of interests:** Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising on COVID-19. Nicola Fear noted a professional link to application NIC-431881-N8B0N University of Oxford. It was agreed that this was not a substantive conflict of interest.
2.1	NIC-384608-C9B4L-v1.5 NHS England **Background:** this was an amendment application from NHS England and NHS Improvement (under the legal entities of Monitor and NHS Trust Development Agency (TDA)) that would usually be presented to an IGARD business as usual (BAU) meeting for a recommendation, however due to the Easter holiday period, the application had not been prioritised as an application to review on Thursday, 25th March and would therefore be progressed via NHS Digital's SIRO precedent. The amendments were 1) to link the data under this Data Sharing Agreement (DSA) to NCDR via a separate pseudonym 2) addition of the following datasets: SUS for commissioners, NHS 111 dataset, Shielded Patient list, Civil Registration (death) data and Medicines Dispensed in

	Primary Care, 3) to add the following data processors: Palantir Technologies UK Ltd, Egton Medical Information Services (EMIS), The Phoenix Partnerships Ltd (TPP UK), 4) to update section 5 (purpose / methods / outputs) to describe additional processing by the applicant. Version 0.7 of the application had previously been discussed at the COVID-19 response meeting on the 4th August 2020 and at the IGARD business as usual (BAU) meeting on the 6th August 2020. The following observations were made on the basis of v1.5 of the application and relevant supporting documentation only. **IGARD Observations** IGARD members noted that due to the nature of the meeting and when papers were disseminated, they had not conducted a full review of the application and supporting documents provided. 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 the PAG comments previously raised should be set out in section 1 (Abstract) or as a supporting document and clearly note how they had been addressed, and as per usual process. Noting the recent legal challenge against NHS England with regard to its decision to award a two-year contract in December to the United States data mining firm Palantir Technologies UK Ltd, IGARD noted a potential reputational risk to NHS Digital of facilitating continued data transfer to this processor. By way of mitigation, IGARD suggested NHS Digital should receive a copy of NHS England's updated Data Protection Impact Assessment (DPIA) which addresses this flow of data and the processing outlined in the application, or, in the alternative, confirmation from NHS England that they have updated their DPIA accordingly. IGARD members noted that the DPIA is not a public-facing document and does **not** need to published but that NHS Digital should have the appropriate assurances, noting widespread media coverage and a recent BMJ article (BMJ 2021;372:n587 http://dx.doi.org/10.1136/bmj.n587 Published: 01 March 2021). IGARD members noted that section 5 (Purpose / Method / Outputs), which forms NHS Digital's published data release register, did not include the usual description and justification for all the new datasets requested under this amendment and as set out in NHS Digital's published DARS standards and that in the case of the medicines data, which did have a helpful narrative that this should also be linked back to the purpose of the relevant Direction (namely the safety and effectiveness of medicines) under which the data was collected and would be disseminated for the specific purposes outlined in the application. https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/directions-and-data-provision-notices/secretary-of-state-directions/nhs-business-services-authority-nhsbsa-medicines-data-directions-2019 IGARD members also noted that if NHS England had received similar data under similar Data Controllership arrangements under the OpenSAFELY programme of work under a separate DSA, that the this could be highlighted in section 5 in order to provide reassurance that there was no excessive processing of data being undertaken, and as set out in NHS Digital's DARS standard for Data Minimisation.

	IGARD members suggested a number of minor amendments including, but not limited to updating the end date for COPI from March 2021 to 30th September 2021; to include reference to PCMD data, since it is not showing in section 3(b) (Additional Data Access Requested) and to remove reference to the ICO Code of Anonymisation from section 5. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment at a IGARD BAU meeting. **Significant risk areas:** clear evidence that PAG comments/queries have been addressed, potential reputational risk to NHS Digital vis-a-vis Palantir (mitigated by NHS England's updated DPIA). Subsequent to the meeting: IGARD members noted that NIC-397618-T8L8Z NHS England was also undertaking OpenSAFELY programme of work and had been presented to the COVID-19 response meeting on the 18th August 2020 and IGARD business as usual meeting on the 20th August 2020.
2.2	<u>NIC-385550-Y8T2M-v1.2 Worcestershire Council</u> **Background:** this was an amendment application that would usually be presented to an IGARD business as usual (BAU) meeting for a recommendation, however due to the Easter holiday period, this application had not been prioritised as an application to review on Thursday, 25th March and would therefore be progressed via NHS Digital's SIRO precedent. The renewal and amendments were to 1) add external linkage to COVID-19 testing data (COVID-19 situational awareness explorer – positive and negative tests and cases) and 2) to add further clarity around the linkage to the shielded patient list in section 5(b) (processing activities). Version 0.2 of the application had previously been discussed at the COVID-19 response meeting on the 11th August 2020 and version 0.4 at the IGARD BAU meeting on the 27th August 2020 The following observations were made on the basis of v1.2 of the application and relevant supporting documentation only. **IGARD Observations:** NHS Digital noted that the application would be presented at the PAG meeting on Wednesday, 24th March 2021. IGARD members noted the update and stressed the importance to NHS Digital of receiving unequivocal support for the data flowing under this data sharing agreement (DSA) and to bring to PAG's attention that this application would not be presented to an IGARD BAU meeting for a recommendation. Notwithstanding the contractual assurances set out in section 5 (Purpose / Methods / Outputs) of the application that the activities are within the permitted parameters, IGARD suggested that NHS Digital review the processing outlined against the restrictions set out in the IG letter of release for the Shielded Patient List. IGARD members also stated that for clarity that when referring in section 5 to the "*IG letter*" that this wording was expanded to state "*separate data flow from NHS Digital authorised by*

	way of an IG letter", or similar wording, since section 5 formed NHS Digital's published data release register IGARD members suggested that the applicant may wish to consider applying for the vaccine related datasets held by NHS Digital and under this DSA, as it would appear that the additional datasets may advance the processing goals outlined in section 5. IGARD would be supportive of the applicant receiving the relevant data with the appropriate data minimisation (as set out in NHS Digital's DARS standard for Data Minimisation) such as by geographical area and relevant justification inserted into section 5. **Significant risk areas:** receipt of unequivocal PAG support, ensuring the processing of the SPL data outlined in the application is within the bounds of the IG letter of release.
2.3 (a)	Permission to Contact (PtC) (No NIC number provided): Medicago **Background:** NHS Digital updated on three items under the umbrella of "permission to contact". Medicago are undertaking an international phase 3 trial (including in the UK), utilising the PtC database, to recruit approximately 3,000 healthy adults and those adults with co-morbidities aged under 40 years of age. Medicago had confirmed that noting there was a successful national rollout of a vaccine in the UK that participants had the right to be unblinded from the study in order for them to receive the national vaccine if they had received the placebo. It was noted that the applicant was clear that anyone receiving the trial vaccine that it would be explained to the participant that they could not then get the national approved vaccine. NHS Digital noted that confirmation of ethical support was outstanding and that a copy of the relevant documentation when received would be uploaded to the NHS Digital customer relationship management (CRM) system. NHS Digital also noted that all relevant security assurances were in place. The following observations were made on the basis of the verbal update only **IGARD Observations:** IGARD members welcomed the verbal update and noted that due to the urgency of the Medicago application that it would progressed under NHS Digital's SIRO Precedent and were supportive of this approach, assuming full ethical support had been received.
2.3 (b)	Permission to Contact (PtC) (No NIC number provided): Valneva **Background:** NHS Digital updated on three items under the umbrella of "permission to contact". Valneva are currently moving to a phase 3 trial (noting NHS Digital supported the phase 1 and 2 trials) and looking to recruit a cohort of approximately 4,000 healthy adults aged 18 to 40 to test their vaccine against a comparator vaccine. NHS Digital noted that the study had been funded by the Vaccine Task Force. NHS Digital also noted that all relevant security assurances were in place.

2.3 (c)	The following observations were made on the basis of the verbal update only **IGARD Observations:** IGARD members welcomed the verbal update and noted that due to the urgency of the Valneva application, that it would progressed under NHS Digital's SIRO Precedent and were supportive of this approach. <u>Permission to Contact (No NIC number provided): Com-CoV2</u> **Background:** NHS Digital updated on three items under the umbrella of "permission to contact". Com-CoV2 is a non-commercial application (noting NHS Digital supported the Com-CoV application) and is looking to recruit approximately 4,000 participants to look at a different booster vaccine to the first vaccine given. NHS Digital noted that there were four different vaccine options available but were awaiting further detail. NHS Digital also noted that all relevant security assurances were in place. The following observations were made on the basis of the verbal update only **IGARD Observations:** IGARD members noted that for Com-CoV2 application that due consideration be given to reviewing the Data Controllership bearing in mind the funding arrangements and who is named as a sponsor on the ethics application and study protocol. Notwithstanding these comments and noting the urgency of the Com-CoV2 application, IGARD members were supportive of it progressing under the NHS Digital SIRO Precedent.
2.4	<u>NIC-431881-N8B0N-v0.6 University of Oxford</u> **Background:** This was a new application v0.6 from the University of Oxford requesting new data for the National Core Studies (NCS) "*can phenotypes developed from enhanced remove primary care assessments of COVID-19 be used to identify a cohort of community cases, and enable comparison of recovered and long-COVID?*" study. The application would usually be presented to an IGARD business as usual (BAU) meeting for a recommendation, however due to the Easter holiday period the application had not been prioritised as an application to review on Thursday, 25th March and would therefore be progressed via NHS Digital's SIRO precedent. The study is being funded by the Health Data Research UK (HDR UK). NHS Digital explained that no data was proposed to be flowed under this data sharing agreement (DSA) and that the data that would be accessed to support this study would be via NIC-381683-R6R6K and NIC-431355-B1L8W. The data under the above two DSAs will be linked to the cohort of patients registered within the Royal College of General Practitioners (RCGP) Research and Surveillance Centre (RSC) network. Version 0.1 of the application had previously been discussed at the COVID-19 response meeting on the 16th March 2021.

	The following observations were made on the basis of the draft v0.6 application summary and relevant draft supporting documents. **IGARD Observations:** IGARD members noted that due to the nature of the meeting and when papers were disseminated, they had not conducted a full review of the application and supporting documents provided. 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 they were supportive of the National Core Studies and thanked NHS Digital for the update as to how previously raised queries had been addressed and thanked the applicant for their thoughtful and detailed responses. Notwithstanding the above points and noting the national importance and prioritisation of this application, IGARD members supported NHS Digital's assessment that the application would be approved under the NHS Digital SIRO Precedent. **Significant risk areas:** none
2.5	<u>NIC-431355-B1L8W-v0.6 University of Oxford</u> **Background:** This was a new application v0.6 from the University of Oxford and University of Edinburgh requesting new data (Civil Registration (death) data, COVID-19 Second generation Surveillance System (SGSS) data, COVID-19 UK Non-hospital Antigen Testing Results (Pillar 2) data, COVID-19 Vaccination Adverse Reaction data, COVID-19 Vaccination Status data, Maternity Services dataset (MSDS)) for the National Core Studies (NCS) "*data and connectivity: COVID-19 vaccines pharmacovigilance (DaC-VaP)*" study. The application would usually be presented to an IGARD business as usual (BAU) meeting for a recommendation, however due to the Easter holiday period, the application had not been prioritised as an application to review on Thursday, 25th March and would therefore be progressed via NHS Digital's SIRO precedent. The study is being funded by the Health Data Research UK (HDR UK). NHS Digital explained that data being disseminated under NIC-381683-R6R6 will be accessed for this study to prevent duplicate data flows but that additional data flows had also been requested that would flow under this data sharing agreement (DSA) and also be reused under NIC-431881-N8B0N The data will be linked to the cohort of patients registered within the Royal College of General Practitioners (RCGP) Research and Surveillance Centre (RSC) network. Version 0.3 of the application had previously been discussed at the COVID-19 response meeting on the 16th March 2021 and had been updated following feedback received. The following observations were made on the basis of the draft v0.6 application summary and relevant draft supporting documents. **IGARD Observations** IGARD members noted that due to the nature of the meeting and when papers were disseminated, they had not conducted a full review of the application and supporting documents provided. 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 they were supportive of the National Core Studies and thanked NHS Digital for the update as to how previously raised queries had been addressed by the applicant. IGARD members suggested that further clarity be included in section 3 (Data Sets Held / Requested) and section 5 (Purpose / Methods / Outputs) with regard to the re-use of data, as outlined verbally at last week's COVID-19 response meeting. IGARD members noted a number of organisations listed in the protocol submitted as a supporting document and suggested that an explicit statement be included in section 1 (Abstract) and section 5 that only those named parties to the data sharing agreement (DSA) could access the data. IGARD members reiterated their previous comments with regard to transparency and cited NHS Digital's DARS standard for Transparency (fair processing) that privacy notices should not include incorrect information, for example, an incorrect legal basis. Notwithstanding the above points and noting the national importance and prioritisation of this application, IGARD members supported NHS Digital's assessment that the application would be approved under the NHS Digital SIRO Precedent. **Significant risk area:** transparency
3	AOB There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.