Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 27 May 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Prof. Nicola Fear	Specialist Academic Member
Kirsty Irvine (Chair)	IGARD Chair / Lay Representative
Dr. Geoffrey Schrecker	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 / IGARD Alternate Deputy Lay Chair
Dr. Imran Khan	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Arjun Dhillon	Caldicott Guardian (Item 5.2 only)
Duncan Easton	Data Access Request Service (DARS)
James Gray	Data Access Request Service (DARS)
Dickie Langley	Privacy, Transparency and Ethics (PTE) (Item 5.2 only)
Shaista Majid	Data Access Request Service (DARS) (Observer: item 2.6)
Karen Myers	IGARD Secretariat
Denise Pine	Data Access Request Service (DARS)
Vicki Williams	IGARD Secretariat

1	**Declaration of interests:** Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising the Scientific Advisory Group for Emergencies (SAGE) on COVID-19. Dr. Maurice Smith noted that a professional link with NIC-193456-W3M0H-v3.1 (CCG Group Application) as part of his role at Liverpool CCG, and it was agreed this **did** preclude Dr. Smith

	from taking part in the discussions and would not participate in making a recommendation about the application. It was agreed that as part of Dr. Smith's role in supporting NHS Digital in providing Subject Matter Expert advice in respect of DARS Fast Track Process, that he would remain in the meeting as an observer **only**. **Review of previous minutes and actions:** The minutes of the 20th May 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	Care Quality Commission (CQC): CQC agreement for HES, MHSDS, MSDS, CSDS and ECDS and associated datasets (Presenter: Denise Pine) NIC-359603-D2Q6M-v8.4 **Application:** This was an extension and renewal application for identifiable Hospital Episode Statistics (HES) Accident and Emergency (A&E), HES Admitted Patient Care (APC), HES Critical Care, HES Outpatients, Civil Registrations (CR), Emergency Care Data Set (ECDS), Mental Health Services Data Set (MHSDS), Mental Health Learning Disability Data Set (MHLDDS) and Community Services Data Set (CSDS). It was also an amendment to remove Atos as a Data Processor, following the completion of the transfer from Atos to Microsoft Azure, as approved under the previous version of the Data Sharing Agreement (DSA). In addition, the application has also been amended to remove Atos from the processing and storage locations. CQC's remit is to make sure health and social care services provide people with safe, effective, compassionate, high-quality care and CQC encourages them to improve. It does that through effective monitoring and inspection activity underpinned by an Intelligence insight programme that draws together risk and bench marking metrics at core service level. The data directly influence the risk and benchmarking models and help determine both when inspections take place and where they should focus. They also help with CQC's statutory responsibility to monitor the use of the Mental Health Act. **Discussion:** IGARD noted that supporting document 2.2, the Data Protection Impact Assessment (DPIA) (May 2018), stated that the data was held on a "*server within a secure area of the CQC virtual data centre in Azure (UK South)";* however IGARD noted that section 1(c) (Data Processor(s)) of the application stated that the Data Processor was *"Microsoft Ireland Operations Limited"*, with an address located in Dublin, Ireland but that section 1 (Abstract) stated that the Data Processor was located in *"Northern Ireland"*, which was incorrect. NHS Digital confirmed that the data was only held in locations in England and Wales but that the Microsoft Azure parent company was located in Dublin, Ireland, which is in the European Union. IGARD noted the verbal update from NHS Digital, and asked that section 1 was updated, to set out the appropriate security assurances by NHS Digital's Security Team, and any relevant assurances from NHS Digital's commercial contracts team, that the necessary checks had been undertaken on the contractual arrangements, noting the Data Processor is an Irish company with its registered office is in Ireland, outside the permitted territory of use and not subject to the UK General Data Protection Regulation (UK GDPR). IGARD also asked that the existing special conditions were amended, or a new special condition was inserted in section 6 (Special Conditions), that the NHS Digital Security may

	think advisable and in light of jurisdiction of the Microsoft Azure parent company noted as the Data Processor and based in Dublin, Ireland. IGARD noted that Maternity Services Data Set (MSDS) was referenced within the application as a dataset required by the applicant, but noted that this had not been requested in section 3(b) (Additional Data Access Requested). IGARD confirmed that if the MSDS dataset was required by the applicant, they would be supportive of this being included as an amendment to this application, and that section 3(b) should be updated accordingly. IGARD queried the information provided in the *"sensitive fields"* section, of the table in section 3 (Datasets Held / Requested), specifically, how what these fields were, and how the information contained was provided, and asked that NHS Digital provide further clarification. IGARD noted that section 5 (Purpose / Methods / Outputs) was silent on CQC's powers of enforcement; and asked that, as section 5 formed NHS Digital's public data release register, that this was updated to include this information for transparency. IGARD queried the references in section 5 to *"Dr Foster Intelligence Ltd"*, and queried if this raised data minimisation concerns with regards to Dr Foster Intelligence Ltd receiving the same data for the same purpose under a different agreement. IGARD asked that section 5(c) (Specific Outputs Expected) was updated, with clarity of how the CQC processing of data in this application was different to that undertaken by Dr Foster Intelligence Ltd, and in line with the NHS Digital DARS Standard for Data Minimisation. IGARD queried the reference in section 5(d) (Benefits) that outlier analyses were undertaken on a *"monthly or bi-monthly basis"*; and asked that section 5(d) was updated to stipulate whether this was fortnightly or every two months. IGARD noted the yielded benefits outlined in section 5(d) (iii) (Yielded Benefits), however, noting that section 5 formed NHS Digital's public data release register, asked that section 5(d) was updated with further examples of the yielded benefits accrued from the CQC work, for example, how many improvement notices had been issued, and what benefits had flowed from the quality agenda. IGARD noted their previous raised points with regard to the CQC privacy notice, and notwithstanding the representation in section 4 (Privacy Notice) that stated *"The data controller(s) listed within this agreement…confirm that they will ensure that a GDPR compliant, publicly accessible transparency notice is maintained throughout the life of this agreement"*; noted that due to the large volume of national data flowing and the national importance that the CQC should have a **compliant** UK GDPR privacy notice. In addition, IGARD noted the potentially misleading wording in the current published privacy notice that referenced a citizen's ability not to have their records reviewed as part of an inspection by the CQC. Notwithstanding this flag, any such nomination by a citizen, including exercising a type 1 objection or National Data Opt-out (NDO), would have no effect on the flow of data from NHS Digital to CQC, due to the CQC's extensive statutory powers. IGARD suggested that this was further clarified in the privacy notice because, as currently worded, it was potentially misleading and that steps should be taken to rectify at the earliest opportunity. IGARD noted that CQC's DPIA specifically referenced the IGARD review as a risk mitigating measure; and therefore 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. **Outcome:** recommendation to approve

	The following amendments were requested: 1. To update section 1 to set out the appropriate security assurances by NHS Digital's Security Team, and any relevant assurances from NHS Digital's commercial contracts team, that the necessary checks have been undertaken on the contractual arrangements, noting the Data Processor is an Irish company with its registered office is in Ireland, outside the permitted territory of use. 2. To amend or add any special condition to section 6 that the NHS Digital Security Advisor may think advisable, in light of jurisdiction of the Microsoft Azure parent company noted as the Data Processor. 3. To update section 3(b) to add the MSDS (if desired). 4. To update section 5 to draw out the CQC's powers of enforcement. 5. To update section 5(c) to clarify how the CQC processing of data in this application is different to that done by Dr Foster, in line with NHS Digital DARS Standard for Data Minimisation. 6. To update section 5(d) to provide clarity on what is meant by "Bi-monthly" (i.e. fortnightly or every two months). 7. As section 5 forms NHS Digital's public data release register, to provide further details in section 5(d) of the yielded benefits accrued from the CQC work, for example, how many improvement notices have been issued, and what benefits have flowed from the quality agenda. The following advice was given: 1. IGARD asked that NHS Digital provide further clarification as to what the "sensitive fields" are and how the fields are generated in section 3. 2. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment due to the CQC DPIA specifically referencing IGARD review as a risk mitigating measure. 3. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent due to the CQC DPIA specifically referencing IGARD review as a risk mitigating measure. 4. With regards to CQC's privacy notice: a) IGARD noted their previous raised points with regard to the CQC privacy notice, and notwithstanding the representation in section 4, IGARD noted that due to the significant volume of national data flowing and national importance, that the CQC should have a compliant UK GDPR privacy notice. b) IGARD noted the potentially misleading wording in the current privacy notice that referenced a citizen's ability, not to have their records reviewed as part of an inspection by the CQC. Notwithstanding this flag, any such nomination by a citizen, including exercising a type 1 objection or NDO, would have no effect on the flow of data from NHS Digital to CQC, due to the CQC's extensive statutory powers. IGARD suggested that this was further clarified in the privacy notice as, as currently worded, it is potentially misleading and should be rectified at the earliest opportunity.
2.2	University of Dundee: Renewal request for 'Allopurinol and cardiovascular outcomes in patients with ischaemic heart disease ALL-HEART' study (Presenter: Denise Pine) NIC-369348-H6H8B-v4.3

	Application: This was an extension and renewal application for identifiable Civil Registration (Deaths) data, Hospital Episode Statistics (HES) Admitted Patient Care (APC), Demographics data, Cancer Registration data and Medical Research Information Service (MRIS) data. The purpose is for a study aiming to improve the treatment of patients with Ischaemic Heart Disease (IHD), by investigating whether adding allopurinol up to 600mg daily to these patients' usual medications, will reduce their risk of having a stroke, heart attack or of dying due to cardiovascular disease. The study cohort, consists of 3,460 patients from England and Wales, aged 60 years and over with IHD, and who have consented to share their information; recruitment started in June 2014 and ended in September 2017. NHS Digital advised IGARD that the role of NHS Tayside was not referred to in section 5(a) (Objective for Processing) and that the application would be updated to ensure this was accurately reflected. **Discussion:** IGARD noted the verbal update and supported the update to section 5(a) to accurately reflect the role of NHS Tayside. IGARD noted that SD 3.3, version 6 of the patient information sheet, informed participants that NHS Tayside was a study sponsor, and that part of their role was to check that the research was properly conducted and the interests of those taking part were adequately protected. IGARD noted the Health Research Authority guidance that stated that *"It is the sponsor who determines what data is collected for the research study through the protocol, case report form and/or structured data fields in a database. The sponsor therefore acts as the controller in relation to the research data."* and, noting NHS Digital's policy position that a sponsor was a controller as a starting position, asked if further analysis had been undertaken to rebut this. NHS Digital advised IGARD that following discussions with the applicant, they had confirmed that NHS Tayside were not considered a joint Data Controller, and they did not determine the purpose and means of the processing of the data. IGARD noted the verbal update from NHS Digital, and asked that as per NHS Digital policy that an analysis be inserted into section 1 (Abstract) and relevant standard wording be inserted in section 5(a) to reflect that, notwithstanding their role as a co-sponsor, they were **not** considered joint a Data Controller based on an analysis of the facts. IGARD confirmed that they were of the view that the **most recent** consent materials were compatible with the processing outlined in the application. IGARD noted that the first cohort members were recruited using supporting document (SD) 3.0, version 3 of the participant information sheet dated 12th September 2013, where it referenced that the benefits included improved symptoms and a reduced risk of conditions such as heart attack and stroke, but lacked the reference to *"other health problems"* introduced in subsequent versions, and that cohort members may be surprised that cancer data had flowed, alongside cardiovascular related data. IGARD were of the view that consent was not incompatible with the processing outlined in this application, but for those recruited on SD3.0, communications could be improved to explain the breadth of data collected and held about them. IGARD suggested that the applicant may wish to test with a small group of cohort members (more than 3 but less than 7), with regards to the nature of the data the cohort members think is flowing, and then take a view whether further communication with that section of the cohort should be carried out; explaining, in particular, that cancer data had flowed and was held, and reminding them of their ability to withdraw from the study, if they no longer wished to take part. IGARD confirmed that they were of the view that versions 5 and 6

	of the participant information sheets of the consent materials provided the appropriate legal gateway and were broadly compatible with the processing outlined in the application. IGARD queried some of the statements within section 5 (Purpose / Methods / Outputs), for example *"…huge cost savings for the NHS in terms of admissions…"*,and asked that this was amended to ensure the focus of the study was on the impact and benefit to the public and patients and not the potential cost savings. IGARD noted the reference in section 5 to *"Article 89(1)"*, and asked that this was updated to clarify that this referred to the UK General Data Protection Regulation (UK GDPR). IGARD noted a number of acronyms in section 5 and asked that this public facing section be updated to ensure that all acronyms upon first use were expanded and clearly defined with a supportive explanation in a language suitable for a lay reader, for example, *"e-CRF design"*. IGARD suggested that section 5 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 noted that in response to the standard question posed in section 1(a) (Application Summary) *"Review requested by IGARD"*, the answer stated was *"no"*; and suggested that NHS Digital review their internal processes and IT systems, for example, to ensure this doesn't incorrectly default to state *"no"*. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of NHS Tayside: a. To update section 1 and section 5(a) to reflect that, notwithstanding their role as a co-sponsor, they are not considered joint Data Controller based on an analysis of the facts. b. To amend section 5 to ensure the focus of the study is on the impact and benefit to the public and patients and not the potential cost savings. 2. To update section 5 to clarify that the reference to "Article 89(1)" is in the UK GDPR. 3. As section 5 forms NHS Digital's public data release register, to amend section 5 to ensure acronyms be defined upon first use, and technical terms are explained. 4. To update 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. Noting the very first cohort members were recruited on SD3.0, where it lacked the reference to "*other health problems*", they may be surprised that cancer data had flowed, alongside cardiovascular related data. IGARD were of the view that consent was not incompatible with the processing but for those recruited on SD3.0, communications could be improved to explain the breadth of data collected and held about them. The applicant may wish to test with a small group of cohort members (more than 3 but less than 7), with regards to the nature of the data the cohort members think is flowing, and then take a view whether further communication with that section of the cohort should be carried out (explaining, in particular, that cancer data had flowed and was held and reminding them of their ability to withdraw from the study, if they no longer wished to take part). 2. IGARD noted that section 1 stated that a review by IGARD was not required; and suggested that NHS Digital review their internal processes and IT systems, for example, to ensure this doesn't incorrectly default to state *"no"*.

2.3	University of Oxford: MR1483 - HPS-4/TIMI 65/ORION-4: A double-blind randomized placebocontrolled trial assessing the effects of inclisiran on clinical outcomes among people with atherosclerotic cardiovascular disease. Application for data for invitation (Presenter: James Gray) NIC-172240-R4R0L-v3.2 **Application:** This was a renewal application for identifiable Hospital Episode Statistics (HES) Admitted Patient Care (APC), Demographics data, and Medical Research Information Service (MRIS) data. It was also an amendment to 1) include a second invitation letter to individuals who have not responded to the first invitation; 2) to update the processing location and contact details for Paragon Customer Communications (now Paragon Customer Communications (London) Limited); 3) to change the objective for processing in light of the acquisition of The Medicines Company by Novartis, who are now co-sponsor of the trial; 4) to update sections 1 (Abstract), 3 (Datasets Held / Requested) and 5 (Purpose / Methods / Outputs) of the Data Sharing Agreement, to reflect the amendments outlined. The purpose is for the ORION-4 study, looking at the safety and effectiveness of a new cholesterol lowering medication called Inclisiran. Inclisiran is given as an injection 2-3 times a year and reduces bad (LDL) cholesterol. The study will seek to find out whether inclisiran safely reduces heart attacks, strokes and cardiovascular deaths in people who already have cardiovascular disease. If it is shown to be effective, this treatment could substantially reduce premature death and disability from these conditions. A secondary objective is to develop streamlined trial methods that would benefit future research. The study is relying on s251 of the NHS Act 2006, for the flow of data from NHS Digital. **Discussion:** IGARD confirmed that they were of the view that the relevant s251 support provided the appropriate legal gateway and was broadly compatible with the processing outlined in the application. IGARD noted that the written communication to citizens was not clear on a number of important factors, including, but not limited to: providing a clear explanation as to how citizens data had been acquired under the s251 support from the Health Research Authority Confidentiality Advisory Group (HRA CAG); how citizens could request that they were not contacted again in the future, via operation of the National Data Opt-out (NDO), and asked that written confirmation was provided that going forward, the applicant would ensure that both the invite letter and follow-up letter disseminated to citizens would include this information. IGARD also noted that the original letter had been through Ethics and HRA CAG, but were nonetheless concerned that that the invite letter did not explain how the potential participants contact details had been acquired or how the NDO could be exercised, and IGARD members felt that this lack of transparency could reflect poorly on NHS Digital, and that this needed to be addressed. IGARD also noted that this level of transparency may help improve the response rate. IGARD noted that the original letter contained an appointment (date and time) and that the onus was on the recipient to cancel the appointment; IGARD were surprised at such an approach since It could be perceived as coercive. IGARD noted that NHS Digital's Service User Manual suggests keeping communication gender neutral, and not asking users for their title such as Mr, Miss, Mrs or Ms. Given the data field supplied is *"sex"* not *"gender",* it may present a misrepresentation and cause greater offence by mis-gendering recipients, since it is assuming the title of a person from their

	biological sex. IGARD therefore suggested that the communications do **not** include a title, such as Mr or Ms. IGARD queried the requirement of a follow-up letter since no clear justification had been provided, and asked that section 5(a) (Objective for Processing) was updated to clarify this, for example, by stating the percentage of the original uptake of the invite letter. IGARD noted within supporting documents Novartis was presented as a co-sponsor and queried if this had any data controllership implications, noting that the Health Research Authority guidance state that *"It is the sponsor who determines what data is collected for the research study through the protocol, case report form and/or structured data fields in a database. The sponsor therefore acts as the controller in relation to the research data "* and, noting NHS Digital's policy position that a sponsor was a controller as a starting position, if further analysis had been undertaken to rebut this. IGARD asked that as per NHS Digital policy that an analysis be inserted into section 1 and relevant standard wording be inserted in section 5(a) to reflect that, notwithstanding their role as a co-sponsor, Novartis were **not** considered a joint Data Controller based on an analysis of the facts. In addition, IGARD asked that section 5 (Purpose / Methods / Outputs) was updated to expressly state that Novartis would **not** attempt to influence the design of the study, nor supress any aspect of publication of the findings. IGARD noted that section 5(e) (Is the Purpose of this Application in Anyway Commercial) stated there was **no** commercial purpose, however queried if Novartis had any commercial interest in this study, which it was funding and co-sponsoring. IGARD asked that both section 5(a) **and** section 5(e) be updated, in line with the published NHS Digital DARS Standard for Commercial Purpose, to provide details of the potential benefit accruing to the pharmaceutical company, for example, that they were the manufacturer of a relevant drug. IGARD queried the information in section 5(a) that stated *"Paragon Customer Communications (London) Ltd will also process personal data (name, address, sex) in order to produce, print and mail the invitation letter."*, however noted that supporting document 3.7, the HRA CAG letter dated the 25th March 2019, confirmed that approval was only provided for 'name', 'address' and 'title' to be shared with Paragon. IGARD asked that section 5 was updated to remove reference to Paragon receiving the *"sex"* data field. IGARD noted a number of acronyms in section 5 and asked that this public facing section be updated to ensure that all acronyms upon first use were expanded and clearly defined with a supportive explanation in a language suitable for a lay reader, for example, in relation to the various types of trials referenced. IGARD suggested that section 5 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 due to the unusual method of recruitment, 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. **Outcome:** recommendation to approve subject to the following condition: 1. To provide written confirmation that going forward the applicant will ensure that the invite letter and follow-up letter disseminated to citizens, will include (but is not limited to) explaining how their data has been acquired under s251 support, and how to request that they are not contacted again in the future via operation of the NDO. The following amendments were requested:

	1. In respect of Novartis: a) To update section 1 and section 5(a) to reflect that, notwithstanding their role as a co-sponsor, Novartis are not considered joint Data Controllers based on an analysis of the facts. b) To expressly note in section 5 that Novartis will not attempt to influence the design of the study, nor supress any aspect of publication of the findings. c) To update section 5(a) in line with the published NHS Digital DARS Standard for Commercial Purpose, to provide details of the potential benefit accruing to the pharmaceutical company, for example, that they are the manufacturer of a relevant drug. d) To update section 5(e) NHS Digital DARS Standard for Commercial Purpose re the same. 2. With reference to "Paragon" receiving the data field "sex", to remove from section 5 as they are not receiving that data field. 3. To amend section 5 to ensure that all acronyms upon first use be defined and further explained if the meaning is not self-evident. 4. To update section 5(d) to use a form of wording such as "*it is expected"* or *"it is hoped …"*, rather than "*it will…*". 5. To update section 5(a) to clarify the requirement of a follow-up letter, for example stating the percentage of the original uptake of the invite letter. The following advice was given: 1. NHS Digital's Service User Manual, suggests keeping communication gender neutral. Given the data field supplied is "sex" not "gender", and may present a misrepresentation and cause greater offence by mis-gendering recipients, since it is assuming the title of a person from their biological sex, IGARD suggested that the communications did **not** include a title such as Mr or Ms. 2. Noting the original letter had been through Ethics and HRA CAG, IGARD were nonetheless concerned that the invite letter did not explain how the potential participants contact details had been acquired or how the NDO could be exercised, and IGARD members felt that this lack of transparency could reflect poorly on NHS Digital, and that this needed to be addressed. IGARD suggested that this level of transparency may help improve the response rate. 3. IGARD noted that the original letter contains an appointment (date and time), and that the onus was on the recipient to cancel the appointment; IGARD were surprised at such an approach since it could be perceived as coercive. 4. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the unusual method of recruitment. 5. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the unusual method of recruitment. It was agreed the condition would be approved out of committee (OOC) by the IGARD Chair
2.4	Surrey and Sussex Cancer Alliance: Cancer Alliance access to National Cancer Waiting Times Monitoring Data Set (NCWTMDS) from the Cancer Wait Times (CWT) System (Presenter: Duncan Easton NIC-225927-H5J7J-v0.4 **Application:** This was an application for pseudonymised National Cancer Waiting Times Monitoring DataSet (CWT).

	The independent Cancer Taskforce set out an ambitious vision for improving services, care and outcomes for everyone with Cancer: fewer people getting Cancer, more people surviving Cancer, more people having a good experience of their treatment and care, whoever they are and wherever they live, and more people being supported to live as well as possible after treatment has finished. Cancer Alliances, set up across England, are key to driving the change needed across the country to achieve the Taskforce's vision. Bringing together local clinical and managerial leaders from providers and commissioners who represent the whole Cancer pathway, Cancer Alliances provide the opportunity for a different way of working to improve and transform Cancer services. The CWT system collects and validates the National Cancer Waiting Times Monitoring Data Set, allowing performance to be measured against operational Cancer standards. Data is validated and records merged to the same pathway to cover the period from referral to first definitive treatment for Cancer and any additional subsequent treatments. The application was previously considered on the 29th October 2020, when IGARD had been unable to make a recommendation, because the substantive points raised previously when reviewed by IGARD on the 8th August 2019 had not been addressed. IGARD reiterated the outstanding points namely: to provide a brief explanation of why the other members of the Cancer Alliance are not also considered joint Data Controllers. To clarify why the applicant has requested CWT on behalf of the Cancer Alliance, since individual CCGs forming part of the same Cancer Alliance had previously requested this dataset (for example to provide a brief explanation of how the Cancer Alliance handling of the data may be different from the CCG use of the data). **Discussion:** IGARD noted that the application had been updated to reflect most of the comments previously made. IGARD noted that as part of the meeting pack of papers to support this application, supporting document 1.0, the 2019 written advice from NHS Digital's Information Governance (now Privacy, Transparency and Ethics) in respect of data controllership, had been provided. IGARD advised that they had previously noted that the historical advice provided was incorrect, in that Data Controllers could not be *"nominated"*; and politely requested that to avoid any confusion going forward, this was removed from NHS Digital's Customer Relationship Management (CRM) system. IGARD noted in section 5(a) (Objective for Processing) the volume of organisations requiring access to the data, and suggested to NHS Digital that the most efficient way of undertaking this, would be via an honorary contract, noting that the Data Sharing Agreement (DSA) would be in place with the Data Controller, and they were determining the purpose and means. IGARD asked that a special condition was inserted in section 6 (Special Conditions), to state that only those with substantive or honorary contracts with the Data Controller should carry out any of the activities of a Data Controller, and as per the checklist as outlined by the Information Commissioner's Office (ICO). In addition, IGARD suggested that NHS Digital may wish to draw to the attention of the applicant, the special condition in section 6 that stated, that only those with substantive or honorary contracts with the Data Controller may carry out Data Controller activities. IGARD noted that section 1(c) (Data Processor(s)) stated that "*Royal Surrey County Hospital NHS Foundation Trust"* were the Data Processor, however noting that the name of this Trust

	had now changed, asked that this was updated to correctly state *"Royal Surrey NHS Foundation Trust"*. IGARD noted the references in section 5 (Purpose / Methods / Outputs) to *"free text"* and queried this in light of the pseudonymised data flows requested, since free text could be identifying dependent on the text included. IGARD asked that section 5 was updated with written confirmation of how the flow of free text would not compromise the pseudonymised classification of the data flows and application. If this could not be confirmed, IGARD asked that the free text field was removed from the DSA, or that a legal gateway for potentially confidential information to flow was provided and updated within the application. IGARD noted that the yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits) did not contain any information, however, noting that section 5 formed NHS Digital's public data release register, asked that section 5(d) was updated with further examples of the yielded benefits accrued to date, on the past use of this type of data, and to ensure that they were clear as to the benefits to both patients and the health care system more generally. IGARD noted the statement in section 5(b) (Processing Activities) that *"…outputs may be shared with national/ regional bodies including Open Exeter…"*, and asked that this was removed and updated to correctly reference Open Exeter as a system. IGARD noted a number of acronyms in section 5 and asked that this public facing section be updated to ensure that all acronyms upon first use were expanded and clearly defined with a supportive explanation in a language suitable for a lay reader. **Outcome:** recommendation to approve subject to the following condition: 1. To update section 5 with written confirmation how the flow of free text will not compromise the pseudonymised classification of the data flows and application; and if this cannot be confirmed , to remove the free text field or provide a legal gateway for potentially confidential information to flow. The following amendments were requested: 1. To insert a special condition in section 6, to state that only those with substantive or honorary contracts with the Data Controller shall carry out any of the activities of a data controller (as per the checklist as outlined by the ICO). 2. To update section 1(c) to ensure the correct name of the Data Controller is referenced. 3. As section 5 forms NHS Digital's public data release register, to provide further details in section 5(d) of the yielded benefits accrued to date on the past use of this type of data, and ensure these are clear as to the benefits to both patients and the health care system more generally. 4. To remove the reference in section 5(b) to *"open Exeter"* being a national / regional body and correctly reference it as a system. 5. As section 5 forms NHS Digital's public data release register, to amend section 5 to ensure acronyms be defined upon first use and explained where necessary. The following advice was given: 1. NHS Digital to draw to the attention of the applicant the special condition in section 6 stating that only those with substantive or honorary contracts with the Data Controller may carry out data controller activities . It was agreed the condition would be approved out of committee (OOC) by IGARD members

2.5	NHS England (Quarry House): COVID-19 – NHS England Application (Presenter: Duncan Easton) NIC-384608-C9B4L-v2.2 **Application:** This was an amendment application, to 1) Data under this DSA is linkable to National Commissioning Data Repository (NCDR) via separate pseudonym; 2) the addition of SUS for Commissioners data, NHS 111 Dataset, Shielded Patient List, Civil Registrations (deaths) data, Medicines Dispensed in Primary Care, COVID-19 Second Generation Surveillance System (SGSS) Dataset; 3) the addition Palantir Technologies UK Limited, Egton Medical Information Services (EMIS), The Phoenix Partnership Ltd - TPP UK, Amazon Web Services as Data Processors; 4) to update section 5(a) (Objective for Processing) to describe the additional processing by the applicant. COVID-19 has led to a change in demand on general practices (GPs), including an increasing number of requests to provide patient data to inform planning and support vital insights on the cause, effects, treatments and outcomes for patients of the virus. To support the response to the COVID-19 outbreak, NHS Digital has been legally directed to collect and analyse healthcare information about patients, including from their GP record, for the duration of the COVID-19 emergency period, under the COVID-19 Public Health Directions 2020 (COVID-19 Direction). All GP practices in England are legally required to share data with NHS Digital for this purpose under the Health and Social Care Act 2012. This collection will reduce burden on general practices, allowing them to focus on patient care and support the COVID-19 response. **Discussion:** IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 23rd March, 21st July and 4th August 2020. IGARD noted that this application had been reviewed at the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 22nd July 2020, (notes from that meeting had been attached to the IGARD minutes from the 23rd July 2020); the 5th August 2020 (notes from that meeting had been attached to the IGARD minutes from the 6th August 2020); the 31st March, 5th May, and 26th May 2021 (Please see Appendix B). IGARD noted and supported the comments made by PAG from the 31st March, 5th May, and 26th May 2021. IGARD noted that points previously raised at the IGARD business as usual (BAU) meeting on the **6th August 2020** (Please see Appendix C), had not been addressed. IGARD noted that since the points remained relevant and outstanding, that section 1 (Abstract) was updated with confirmation of how **all** the points raised had been sufficiently addressed and that the application was updated throughout, and where relevant, to ensure **all** the points raised by IGARD at the 6th August 2020 meeting had been addressed in the relevant sections. IGARD noted that points previously raised at the IGARD – NHS Digital COVID-19 Response meeting on the **23rd March 2021** (Please see Appendix C), had not been addressed. IGARD noted that since the points remained relevant and outstanding, that section 1 was updated with confirmation of how **all** the points raised had been sufficiently addressed and that the application was updated throughout, and where relevant, to ensure **all** the points raised by IGARD at the 23rd March 2021 meeting had been addressed in the relevant sections. IGARD noted that section 1 did not capture all the previous IGARD BAU minutes and the IGARD – NHS Digital COVID-19 Response meeting action notes; and asked that for audit and transparency, these were either included in section 1 as per process, or contained within a supporting document and uploaded to NHS Digital's customer relationship management (CRM) system as a future supporting document.

	In addition, IGARD noted that section 1 did not capture all the previous PAG notes, and asked that for audit and transparency, these were either included in section 1 as per process, or contained within a supporting document and uploaded to CRM as a future supporting document. IGARD noted that the application covered separate flows of data to the COVID-19 data store and OpenSAFELY, and queried what the rationale for this approach was. NHS Digital advised IGARD that the request for the data to flow to OpenSAFELY would be removed from the application, as there was not a clear justification for this. IGARD noted the verbal update from NHS Digital, in respect of removing OpenSAFELY, and asked the application was reviewed and amended throughout, to remove all references to *"OpenSAFELY"*; and that any linked references, for example, The Phoenix Partnership (TPP), Egton Medical Information Services (EMIS) and Amazon Web Services (AWS), were also removed, as they were no longer relevant. IGARD queried the legal basis for the dissemination of the data outlined in section 3 (Datasets Held / Requested), 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 9 of the UK General Data Protection Regulation (UK GDPR). IGARD queried the information provided in the *"sensitive fields"* section, of the table in section 3, specifically, how what these fields were, and how the information contained was provided, and asked that NHS Digital provided further clarification. IGARD noted that the Health Service (Control of Patient Information) Regulations 2002 (COPI) were being relied upon as a legal basis, even though the data under this Data Sharing Agreement (DSA) was pseudonymised; and asked that written confirmation was provided in section 1 and section 5 (Purpose / Methods / Outputs), as to why the pseudonymised data was being disseminated under COPI, as this was not clear, and that the confirmation was uploaded to CRM as a future supporting document. IGARD noted that section 3(c) (Patient Objections) was not clear that Opt-outs were **not** applied, due to the data being pseudonymised; and asked that section 3(c) was updated to reflect this. IGARD noted in section 5(d) (Benefits) the statement that a benefit of the study would be to *"Support primary care to increase capacity and to meet heightened demand as a result of a shift from face to face contacts to 111 calls"*; and asked that the yielded benefits in section 5(d) (iii) was updated, with clarification of how the NHS 111 calls would increase primary care capacity; or that this was removed if not achieved. IGARD noted that at the meeting on the 6th August 2020, IGARD had requested that section 5 was updated, to clearly explain **what** the NHS England approval process was, and that this had not been addressed within the updated application. IGARD therefore reiterated the request for section 5 to be updated with this information. IGARD noted that point 2 in section 5(a), referred to research about chloroquine and ACE2 Receptors, and asked that, as both these questions had been answered by the Recovery Trial and QResearch respectively, that this information was removed from the application. IGARD noted the request for the NHS Business Services Authority (BSA) data, and asked that a special condition was inserted in section 6 (Special Conditions), that any use of the NHS BSA data must be within the parameters of the relevant Direction authorising that collection.

	IGARD reiterated their previous request that reference to the *"ICO Anonymisation Code of Practice"* in section 5(a),be removed as it was no longer relevant. IGARD noted a number of acronyms in section 5 and asked that this public facing section be updated to ensure that all acronyms upon first use were expanded and clearly defined with a supportive explanation in a language suitable for a lay reader, for example *"TRA"*. IGARD noted a reference in section 5(a) to a supporting document, and asked that this public facing section be updated to provide a web link, or to remove the reference. IGARD noted that in response to the standard question posed in section 1(a) (Application Summary) *"Review requested by IGARD"*, the answer stated was *"no"*; and suggested that NHS Digital review their internal processes and IT systems, for example, to ensure this doesn't incorrectly default to state *"no"*. 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; in light of the national datasets requested and the national importance of the study. **Outcome:** recommendation to approve subject to the following conditions: 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 all linked references, for example, *"TPP"*, *"EMIS"* and *"AWS"*. The following amendments were requested: 1. To update section 5 to clearly explained **what** the NHS England approval process was. *(as previously requested by IGARD on the 8th August 2020)* 2. To update the yielded benefits in section 5(d) (iii) to clarify how the NHS 111 calls will increase primary care capacity; or remove if not achieved. 3. In respect of the legal basis for dissemination: a) To update section 3, to ensure the processing outlined aligns with the legal basis for dissemination. b) To provide written confirmation in section 1 and section 5 as to why the pseudonymised data is being disseminated under COPI. 4. To amend section 3(c) to reflect that Opt-outs are **not** applied due to the data being pseudonymised. 5. In respect of section 5(a): a) To remove the reference to the *"ICO Anonymisation Code of Practice"*.

	b) As section 5 forms NHS Digital's public data release register, to amend section 5(a) to ensure the correct acronyms are referenced **and** are defined upon first use, such as *"TRA".* c) To update the references to supporting documents in section 5(a), to either remove or add a relevant web link. d) To update section 5(a) (point 2), to remove reference to research about chloroquine and ACE2 Receptors, since both these questions have been answered by the Recovery Trial and QResearch respectively. 6. To insert a special condition in section 6, that any use of the NHS BSA data must be within the parameters of the relevant Direction authorising that collection. 7. To update section 1 to ensure that all IGARD minutes BAU minutes, and COVID-19 Action Notes are included, for audit and transparency; or to provide as a supporting document. 8. To update section 1 to ensure that all PAG notes are included, for audit and transparency; or to provide as a supporting document. The following advice was given: 1. IGARD noted that section 1 stated that a review by IGARD was not required; and suggested that NHS Digital review their internal processes and IT systems, for example, to ensure this doesn't incorrectly default to state *"no"*. 2. IGARD asked that NHS Digital provided further clarification as to what the "sensitive fields" are, and how the fields are generated in section 3. 3. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment; in light of the national datasets requested and the national importance of the study. 4. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent; in light of the national datasets requested and the national importance of the study. It was agreed the condition would be approved out of committee (OOC) by IGARD members (or at an IGARD BAU meeting under AOB).
2.6	<u>Group Application – [1]28 CCGs: DSfC - STP 28 CCGs Comm (Presenter: Duncan Easton) NIC-193456-W3M0H-v3.1</u> **Application:** This was a renewal application for pseudonymised Acute-Local Provider Flows, SUS for Commissioners data, and Civil Registration (Deaths) data. It was also an amendment to 1) add Greater Manchester Health and Social Care Partnership (Hosted by NHS Manchester CCG and NHS England) as a Data Processor; 2) to update the processing and storage locations; 3) to add Computing UK Limited as a Data Processor; 4) to add Microsoft Limited as a Data Processor; 5) to add Google UK Limited as a Data Processor who provide cloud services to Snowflake Computing UK Limited. The NHS and local councils have come together in 44 areas covering all of England to develop proposals to improve health and care. They have formed new partnerships, known as

[1] NHS Bolton CCG, NHS Bury CCG, NHS Cheshire CCG, NHS Heywood, Middleton and Rochdale CCG, NHS Manchester CCG, NHS Oldham CCG, NHS Salford CCG, NHS Stockport CCG, NHS Tameside & Glossop, CCG NHS Trafford CCG, NHS Wigan CCG, NHS Halton CCG, NHS Knowsley CCG, NHS Liverpool CCG, NHS South Sefton CCG, NHS Southport & Formby CCG, NHS St Helens CCG, NHS Warrington CCG, NHS Wirral CCG, NHS Blackburn & Darwin CCG, NHS Blackpool CCG, NHS Chorley & South Ribble CCG, NHS East Lancashire CCG, NHS Fylde & Wyre CCG, NHS Greater Preston CCG, NHS Morecambe Bay CCG, NHS West Lancashire CCG, NHS North Cumbria CCG.

	Sustainability and Transformation Partnerships (STPs), to plan jointly for the next few years. STPs build on collaborative work that began under the NHS Shared Planning Guidance for 2016/17 - 2020/21, to support implementation of the Five Year Forward View. The CCGs will work proactively and collaboratively with the other CCGs in the STP to redesign services across boundaries to integrate services; collaborative sharing is necessary for CCGs to understand these requirements. The CCGs will use the data to provide intelligence to support the commissioning of health services. The data (containing both clinical and financial information) is analysed so that health care provision can be planned to support the needs of the population within the STP area. **Discussion:** IGARD noted the amendment to add Google UK Limited as a Data Processor who provide cloud services to Snowflake Computing UK Limited, and noting that this was the first time this specific company had been referenced in an application; asked that for clarity, NHS Digital provided confirmation that Snowflake Computing UK Limited was on NHS Digital's approved list of Data Processors, or would otherwise fulfil the criteria to be on the list of approved Data Processors. In addition, IGARD asked that section 1 (Abstract) was updated, to set out the appropriate security assurances by NHS Digital's Security Team and any other assurances, as to the suitability and bona fides of the new Data Processor. Noting the large volume of Data Processors outlined in section 1(c) (Data Processors), IGARD queried if each of the Data Processors has a distinct set task and that there is no duplication of effort or work, for example, in relation to data minimisation, and asked that for transparency, section 5 (Purpose / Methods / Outputs) was updated with confirmation; and in line with NHS Digital's DARS standard for Data Minimisation. IGARD noted that the previous version of the application referenced 31 CCGs, but that this version of the application referenced 28 CCGs; and asked that section 1 and section 5 were updated, to provide further clarity on the discrepancy with the number of CCGs referenced, for example had some CCGs merged. Noting the large volume of storage and processing locations referenced in section 2(a) (Processing Location(s)) and section 2(b) (Storage Location(s)); IGARD asked that section 1 was updated, with confirmation that NHS Digital were content that there were no risks in relation to the volume of storage and processing locations, for example, in terms of audit and management. IGARD queried the objectives outlined in section 5, in respect of redesign principles; and asked that this was updated to ensure this was accurate and consistent, as to where there are a number of redesign principles, and how have they been applied and interact, for example 'value' versus 'quality'; and that this was achievable and realistic. IGARD noted the reference in section 5(b) (Processing Activities) to onward sharing for *"direct care"*, and asked that this was either updated, with a clear legal basis and case for the onward sharing being for the purpose of direct care; or, that the reference was removed if deemed not relevant. IGARD noted that the yielded benefits in section 5(d) (iii) (Yielded Benefits) contained minimal information, however, noting that section 5 formed NHS Digital's public data release register, asked that section 5(d) was updated with further examples of the yielded benefits accrued to date, and to ensure that they were clear as to the benefits to both patients and the health care system more generally; and in line with NHS Digital's DARS Standard for Expected Measurable Benefits.

	IGARD queried the inconsistent use of the *"CCG's / CCGs'"* referenced throughout section 5, and asked that this was reviewed and updated, to ensure the correct use of the possessive apostrophe, noting that this would change the meaning of the sentence. IGARD noted the references in section 5(a) and 5(b) to *"patients that…"*, and noting that section 5 forms NHS Digital's public data release register, asked that these were updated to *"patients who…"*. **Outcome:** recommendation to approve subject to the following condition: 1. NHS Digital to confirm that Snowflake Computing UK Limited is on NHS Digital's approved list of Data Processors, or would otherwise fulfil the criteria to be on the list of approved Data Processors. The following amendments were requested: 1. To update section 1, to set out the appropriate security assurances by NHS Digital's Security Team and any other assurances as to the suitability and bona fides of the new Data Processor. 2. To update section 5 to confirm that each of the Data Processors has a distinct set task, and there is no duplication of effort. 3. To update section 1 and section 5 to provide further clarify on the discrepancy with the number of CCGs referenced. 4. To update section 1 to provide confirmation that NHS Digital are content that there are no risks in relation to the volume of storage and processing locations, for example, in terms of audit and management. 5. To review and update the language in section 5, to ensure this is accurate and consistent in respect of the objectives, where there are a number of redesign principles, and how have they been applied and interact, for example 'value' versus 'quality'; and that this is achievable and realistic. 6. In respect of the reference in section 5(b) to onward sharing for *"direct care"*: a) To update this reference with a clear legal basis and case for the onward sharing being for the purpose for direct care; or, b) To remove the reference if deemed not relevant. 7. To provide further details in section 5(d) of the yielded benefits accrued to date and ensure these are clear as to the benefits to both patients and the health care system more generally; and in line with NHS Digital's DARS Standard for Expected Measurable Benefits. 8. To update section 5 to ensure the correct use of the possessive apostrophe in relation to CCGs. 9. As section 5 forms NHS Digital's public data release register, to amend the references in section 5(a) and section 5(b) from *"patients that…"* to *"patients who…"*. It was agreed the condition would be approved out of committee (OOC) by the IGARD Chair.
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>Information Governance (IG) Release Register</u> Dr. Arjun Dhillon and Mr Langley attended IGARD to discuss the IG Release Register March 2020 to March 2021, and the queries that had been fed back from IGARD to NHS Digital. IGARD thanked Dr. Dhillon and Mr Langley for attending the meeting and looked forward to welcoming NHS Digital back to a future IGARD business as usual meeting with relevant feedback on the highlighted key points raised in-meeting, and before any further IG release registers are forwarded to IGARD for their comments.
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 25th May 2021** can be found attached to these minutes as Appendix D.
6 **6.1**	<u>AOB:</u> <u>NIC-218380-R8L2R - Imperial College London</u> IGARD noted that this application was reviewed on the 4th March 2021, where IGARD had been unable to make a recommendation, the outcome from the discussion is as follows: *"IGARD were unable to recommend for approval, on the grounds of the potential reputational risk to NHS Digital of being associated with this research as currently summarised in section 5, which forms the basis of NHS Digital's Data Release Register. Notwithstanding this, NHS Digital may choose to flow the data, (noting that IGARD did not identify any problems with the legal basis or any other data protection problems), and if NHS Digital did choose to do so, IGARD would suggest replacing the current section 5(a) with sections 1, 2 and 3 of the protocol provided as a supporting document."* NHS Digital advised the IGARD Secretariat via e-mail on 25th May 2021, that following discussions with senior NHS Digital colleagues, it had been agreed that the data for this agreement would flow. IGARD noted and thanked NHS Digital for providing an update on the status of this application.
6.2	<u>IGARD Webpage Refresh for IGARD members and the Caldicott Guardian</u> The IGARD Secretariat provided a brief verbal update to members and the Caldicott Guardian, in respect of the ongoing programme of work, to update the IGARD webpage; in collaboration with NHS Digital's Web Team. The IGARD Secretariat advised that subject to approval, this was expected to be published towards the end of June 2021; and that they would continue to work closely with members and the Caldicott Guardian as this progressed.

	IGARD members and the Caldicott Guardian thanked the IGARD Secretariat for the update and looked forward to further updates in due course, to support the anticipated date of publishing. There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 21/05/21

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-346859-C9J6J	University of York	14/01/2021	1. In respect of HRA CAG: a) To provide evidence of unconditional HRA CAG support, including all relevant application documentation. b) That the unconditional HRA CAG support aligns with the proposed processing set out in this application. c) That the NDO questions have been addressed to IGARD's satisfaction, and amendments made as appropriate to the application.	IGARD members	OOC by Chair's Authority	The IGARD Chair made the following comments: *Given the conditional CAG support I would request:* *a special condition to be inserted in section 6 stating that the CAG conditions of support must be satisfied by 17 December 2021* *this application is not suitable for precedent route, including SIRO, past December 2021, because of the conditional CAG support* *IGARD would wish to see it upon extension, renewal or amendment past December 2021, because of the conditional CAG support*

NIC-435753-D4J0Y	Imperial College London	18/05/2021	1. In respect of the requisite ethical support and in line with the NHS Digital DARS Standard for Ethical Approval: a) To provide written confirmation that HRA ethical support is in place. b) To upload the written confirmation to NHS Digital's CRM system.	IGARD Chair	OOC by the IGARD Chair	N/A
NIC-432598-Q6S0C	University of Oxford	29/04/2021	1. In respect of the data minimisation: a) To provide a written justification in section 5 as to how the NHS Digital DARS Standard for Data Minimisation has been satisfied, particularly in respect of the minimisation of the code sets in respect of cohort members; and, b) To either minimise further, for example to minimise the code sets further; or c) If the code sets are not to be minimised further, to explain the relevance of why code sets, such as appendectomy are relevant to shoulder replacement surgery.	IGARD members	OOC by a quorum of IGARD members	N/A
NIC-419453-G3G1G-	University College London	22/04/2021	1. In respect of any potential commercial element present now or that may be derived directly or indirectly from the data in the future (noting the wide scope of NHS Digital DARS Standard for Commercial Purpose): a) To update section 5(a) to clarify any anticipated commercial nature or intention to monetise / generate income, for example, by charging for workshops; or b) If there is no commercial element, to clearly state this; and c) To update section 5(e) to reflect any commercial aspects and in line with the	IGARD members	OOC by a quorum of IGARD members	*Condition 1a and 1c are no longer applicable*

			NHS Digital DARS Standard for Commercial Purpose.			

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

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

Liaison Financial Service and Cloud storage:

- None

Optum Health Solutions UK Limited Class Actions:

- None

Graphnet Class Actions:

- None

Appendix B

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 31st March 2021

Application & application version number: DARS NIC 384608 NHS England Amendment and DARS NIC 310321 Comparison **Organisation name: NHS England** **Profession Advisory Group Agenda item: 3**
PAG noted AM is a researcher with Open Safely and agreed there was no material conflict for this discussion. PAG note and support the aim of this application in responding to the COVID19 pandemic. PAG are not currently able to approve this application without further clarity addressing the issues below and look forward to reviewing it once uplifted. PAG requested all acronyms to be expanded, and to take care to note the relationship where appropriate between processors e.g., Palantir and Foundry. PAG request clarity of which data processor has access to which dataset for complete transparency. PAG request clarity on where the linkage of GPDPR occurs and clarity that this does not involve Palantir. PAG request a supporting technical & data architecture with associated data flows in order to assure where GP data is exactly being processed. PAG note the privacy information has not been updated since last year and recommend this is updated before processing commences. Noting the special condition that GP Data is not to be used for Performance Management, more clarity is required on the granularity of aggregation of consultation mode as articulated in the application. PAG would not support practice level views of data and recommend CCG level would appropriate. PAG would highlight that "GP Appointment data" is a separate workstream and Appointment activity as described in this application should not undermine the professional negotiations that has taken place. PAG request that this data is explicitly not used for this purpose. Please can the applicant confirm that OpenSAFELY only outputs aggregate small number suppressed data? i.e. No patient level data will leave OpenSAFELY into the COVID19 Datastore. The Purpose overlap between OpenSAFELY and the COVID19 Datastore needs to be more clearly explained with justifications on p26. There needs to be greater clarification / justification for why the NHS Digital TRE cannot support the analysis needs of the applicant (the explanations of "linkage keys" appears to be an insufficient justification). The intended benefits and audience for outputs could be much clearer. The profession would wish to have a view of the same data including JGPITC, PCNs, & GPs. PAG highlight its previous advice that appropriate Audit arrangements are in place due to the novel, contentious and repercussive nature of the covid data store. PAG would like to have sight of the DARS "Clarified Feedback and Response" document.

PAG request that the application is transparent as by sharing the code lists, and study design on outputs.

Attendees	Role	Organisation
Arjun Dhillon	Chair and Caldicott Guardian	NHS Digital
Peter Short	Clinical Lead	NHS Digital
Amir Mehrkar	GP, Clinical Researcher	RCGP
Mark Coley	Deputy IT Policy Lead	BMA
Janine Robayo	Secretariat	NHS Digital
Duncan Easton	Senior Business and Operational Delivery Manager	NHS Digital

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 5th May 2021

Application & application version number: **DARS-NIC-384608-C9B4L-v2.2** **Organisation name: NHS England** **Profession Advisory Group Agenda item: 2**
PAG support this application subject to the subsequent minor amendments: 1. Consistency regarding the use of Foundry and Palantir terms. 2. Explanation of the acronym NCDR. 3. Confirmation that GPES GP data is not linked with the Covid-19 Data Store (as the diagram and explanation was inconsistent and confusing). 4. Amendment of the diagrams to show where data actually flows Vs which organisation have a view of the data. 5. PAG require that any results not published in the public domain must be shared with the RCGP/BMA via DARS at the same time that they are circulated internally. 6. PAG recommend the applicant adopts an open science approach: to publish their study protocols/analytic code, statistical codes, and code lists in the open. 7. PAG require clarification that the OpenSAFELY patient level data does not flow into the Arden & Gem data store (except for the transfer of the pseudonym for linkage). 8. PAG require that each use case has an allocated National Clinician from NHS England Improvement.

Attendees	Role	Organisation
Peter Short	Chair, 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
Duncan Easton	Data Approvals Officer	NHS Digital
Pam Soorma	Secretariat	NHS Digital

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 26th May 2021

Application & application version number: DARS-NIC-384608-C9B4L-v2.2 **Organisation name: NHS England** **Profession Advisory Group Agenda item: AOB**
PAG has noted responses and are content with the responses. It needs to proceed through the usual DARS IGARD process.

Attendees	Role	Organisation
Arjun Dhillon	Chair and Caldicott Guardian	NHS Digital
Peter Short	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

Appendix C

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 6 August 2020

Extract from published minutes

NHS England (SKH): GDPPR COVID-19 – NHS England - Pseudo (Presenter: Garry Coleman / Duncan Easton) NIC-384608-C9B4L

Background: This was a new application for GPES Data for Pandemic Planning and Research (GDPPR) data. COVID-19 has led to a change in demand on general practices (GPs), including an increasing number of requests to provide patient data to inform planning and support vital insights on the cause, effects, treatments and outcomes for patients of the virus. To support the response to the COVID-19 outbreak, NHS Digital has been legally directed to collect and analyse healthcare information about patients, including from their GP record, for the duration of the COVID-19 emergency period, under the COVID-19 Public Health Directions 2020 (COVID-19 Direction). All GP practices in England are legally required to share data with NHS Digital for this purpose under the Health and Social Care Act 2012. This collection will reduce burden on general practices, allowing them to focus on patient care and support the COVID-19 response.

The application had been previously considered on the 23rd July 2020 when IGARD had deferred making a recommendation pending: IGARD endorsed the comments made by PAG and in reference to the two specific requests from PAG, suggested that a) NHS Digital may wish to consider auditing this organisation in relation to this application / data sharing agreement, b) NHS Digital to provide confirmation whether or not the applicant could access the NHS Digital data in an NHS Digital TRE; and if not, why not; To update section 3 to address the Common Law Duty of Confidentiality, with the application of National Data Opt Out in regards to the use of a statutory exemption versus the nature of the data as pseudonymised data and to make this consistent; IGARD suggested that NHS England update their privacy notice to reflect this new dataset and to ensure compliance with the NHS Digital Standard; To update section 5(a) and section 5(b) to provide justification for the data requested, and any onward dissemination of the data; To amend section 5(a) to state *"…cases of the data include **and** are limited to the COPI Regulations";* To provide further clarification in section 5(a) of how the provision of the GDPPR data will meet the objectives; To clarify within the application as to whether the GDPPR data will be linked, explain the purpose for this and provide details of the process of linkage; To provide clarification in section 5(a), clearly distinguishing between Risk Stratification for the purpose of modelling and planning, and the purpose of identification of individuals for individual intervention; IGARD suggested that the applicant provide further information in section 5(c) and section 5(d) of the target dates for this urgent dissemination of data; To insert a special condition in section 6 that any further dissemination of the GDPPR data under this DSA should be subject to oversight from a group represented by the GP profession and patients/Lay members; To provide further clarity on the use of COPI Regulations for the use of pseudonymised data and to consider whether REC approval should be sought; To provide justification as to whether sub-licensing is the appropriate route for this application or whether other options, including (but not limited to) adding as joint Data Controller(s) and / or Data Processor(s); or other organisations applying directly to NHS Digital; To confirm if any

commercial organisations are involved in sub-licensing and if so, confirmation that the application will come through NHS Digital for an amendment; To confirm that if a sub-licensing model is used, NHS Digital will maintain a public and transparent register of all such sub-licenses together with details of data disseminated; IGARD suggested If there are any substantial amendments to this application, this should go via PAG prior to being reviewed by IGARD; Accepting the large number of processing and storage locations listed, any additional locations, would constitute an amendment, and as such would not be suitable for NHS Digital's Precedent route or Director / IAO approval; IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment; IGARD suggested that this application would not be suitable for NHS Digital's Precedent route.

Discussion: IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 21st July and 4th August 2020.

IGARD noted that this application had been reviewed at the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 22nd July 2020, (notes from that meeting had been attached to the IGARD minutes from the 23rd July 2020), and on the 5th August 2020 (see Appendix B).

IGARD noted that the application had been extensively re-written since the last review.

IGARD noted and supported the comments made by PAG from the 5th August 2020, and with reference to point 1 "*In order to satisfy ourselves that all alternative avenues (to large data transfers) have been fully explored, PAG respectfully request that NHS Digital to provide documentary evidence of the discussion with each of the available Trusted Research Environments (including NHS Digital's TRE and the TRE already established by NHS England OpenSAFELY) establishing that these TREs would be unable to satisfy the needs of NHS England in regard its responsibilities around research and planning as applicable to the COVID-19 pandemic…*" and requested that relevant written documentary evidence be provided and uploaded to NHS Digital's Customer Relationship Management (CRM) system with regard to the full exploration of TREs.

IGARD noted and supported the comments made by PAG from the 5th August 2020, and with reference to point 5 "*PAG requested that the statement within section 3c be amended to make clear that Type 1 opt-outs would be upheld in relation to GP data*" and requested that a statement be inserted into section 3(c) (Patient Objections) to clarify that the type 1 opt-outs would be upheld in relation to GP data.

IGARD noted and supported the comments made by PAG from the 5th August 2020, and with reference to point 6 "*PAG also requested that on page 21 it was made explicit that PHE will not have access to the GP data. Also that it is explicitly that the approval route for GP linkage was through NHS England's approval team to ensure that COPI was appropriately applied and related to data provided by NHS Digital*" and suggested that section 5 (Purpose / Methods / Outputs) be updated to be clear that Public Health England (PHE) would not have access to the data, that it be explicitly clear that the approval route for GP linkage was through NHS England's approval team and in addition to clearly explain **what** the NHS England approval process was, for transparency.

IGARD noted and supported the comments made by PAG from the 5th August 2020, and with reference to point 8 "*PAG advised that the scale and nature of this new processing activity warrants open publication of any updated Data Protection Impact Assessment*".

IGARD agreed that an appropriate DPIA should be produced and noted the special condition which had been inserted in section 6 (Special Conditions) "*The DPIA for NHS COVID-19 datastore and datastore (sic) must be updated to mention this dataset within 6 weeks of receiving the dat*a".

IGARD noted the comment made by PAG from the 5th August 2020, and with reference to point 3 "*The PAG expects that whichever route is taken, there will continue to be full and proper engagement with the profession via JGPITC and GP data controllers, proper safeguards on access to data, whether that be in NHSE or a TRE, and that all IG and legal issues are satisfactorily addressed, as was the case with the GPES process and the GP Data for Research and Planning programme",* IGARD additionally suggested that any engagement with the GP Data Controllers in the future, should be done through the appropriate avenues.

IGARD noted the comment made by PAG from the 5th August 2020, and with reference to point 7 "*PAG wished to advise IGARD that we feel that as a general position, any and all derived intellectual property (such as machine learning models, AI, and algorithms, etc) from the GP data must remain the property of the NHS (and ideally open-sourced or otherwise published for maximum public and professional benefit). This clause should cascade down through any processing arrangements*." IGARD suggested that this point be explored further by NHS Digital with the appropriate stakeholders.

IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices and suggested that an additional special condition be inserted in section 6 that that the applicant should update and publish a General Data Protection Regulation (GDPR) compliant Privacy Notice, as assessed by NHS Digital and within 6 weeks of receiving the data, aligning that timing with the publication of the DPIA special condition.

IGARD suggested rewording the special condition in section 6 as follows to make it clear that both GDPR applies and also that even though the data is pseudonymised it is being handled as confidential patient information under COPI: *"The Disseminated data, provided by NHS Digital to the Data Controllers, is pseudonymised patient information and is treated as confidential patient information under COPI. The Disseminated data must be protected by the Data Controller and its Data Processors in accordance with the GDPR and COPI. In particular, the Data Controller must ensure that it and its Data Processors comply with the Data Controller's legal responsibilities under COPI when processing the Disseminated data, including the restrictions laid down in Regulation 7 of COPI."*

IGARD suggested that section 5(c) (Specific Outputs Expected, including Target Date) be updated to remove the text "…*as well as diagnoses recorded*" since it was not felt relevant to this application.

IGARD noted a number of acronyms were noted in section 1 (Abstract) and section 5 and asked that this public facing section be updated to ensure that all acronyms upon first use were expanded and clearly defined with a supportive explanation in a language suitable for a lay reader, for example "ExCo", "TDA", "nosocomial".

Noting the sentence in section 5(b) (Processing Activities) "*The COVID Data Store consists of different areas of processing, one of those is the Palantir Foundry Platform. The GDPR data will not be processed by Palantir or ingested into the Foundry Platform*", suggested it be

explicitly clear that the Palantir Foundry Platform were not involved with the dataset, storage or other form of processing under this application or Data Sharing Agreement (DSA).

IGARD noted a number of benefits had been outlined in section 5(d) (Benefits) but suggested that these be refined and updated to ensure they were both realistic and achievable within the timeframe of the DSA and data disseminated under this application.

Noting that everyone has an ethnicity, suggested that where the term "*ethnic*" was used, it was prefaced with "*minority*".

IGARD noted in section 5(a) (Objective for Processing) reference to "*Use Case 04 – mortality increased risk in patients with obesity*" and asked if this also included those considered to be 'overweight' and if so, to update the text in section 5 appropriately.

IGARD noted in section 5(a) reference to "*Use Case 05 – vaccinations and immunisations*" however it was unclear as whether this workstream would also include school vaccinations and suggested section 5 be updated to clarify.

IGARD suggested that they would wish to review this application again when it comes up for renewal, extension or amendment; and that this application would not be suitable for NHS Digital's precedent route.

Outcome: recommendation to approve.

The following amendments were requested:

1. IGARD noted the comments made by PAG:
    a. With reference to point 1, to provide relevant documentary evidence and upload to CRM.
    b. With reference to point 5, to amend the statement in 3(c) to clarify that type 1 opt-outs would be upheld in relation to GP data.
    c. With reference to point 6, that section 5 be updated as suggested, but in addition requested that it be clearly explained **what** the NHS England approval process was.
    d. With reference to point 8, agreed that an appropriate DPIA should be produced (noting the special condition in Section 6).
2. To amend the special condition in section 6 stating that within 6 weeks a GDPR-compliant Privacy Notice, as assessed by NHS Digital, will be published
3. To update the special condition in section 6 with regard to GDPR and CPI.
4. To update section 5(c) to remove reference to '*diagnoses recorded'*.
5. To amend section 5 to ensure that all acronyms upon first use within the document and within the published sections be defined and further explained, as may be necessary for a lay reader.
6. To make it explicitly clear in section 5 that Palantir Foundry Platform are **not** involved with the dataset, storage or other form of processing under this application.
7. To revise the language in section 5(d) and ensure that the benefits are realistic and achievable.
8. Preface 'ethnic' with '**minority**'.
9. When referencing 'obesity' to advise whether Use Case 4 also includes those considered to be 'overweight'.
10. To update section 5 to clarify if the vaccine stream of work will also include school vaccinations.

The following advice was given:

1. IGARD noted the comments made by PAG:
    a. With reference to point 3, IGARD noted the comments made, but would also suggest further, that any engagement with GP Data Controllers is done through appropriate avenues.
    b. With reference to point 7, IGARD suggested that this is explored further by NHS Digital and appropriate stakeholders.
2. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment.

IGARD suggested that this application would not be suitable for NHS Digital's Precedent route.

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

Extract from published action notes

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.

Appendix D

Independent Group Advising on the Release of Data (IGARD)

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

held via videoconference, Tuesday, 25th May 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):	Catherine Day (DARS – observer item: 2.1)
	Louise Dunn (DARS)
	James Gray (DARS – observer item: 2.1)
	Karen Myers (IGARD Secretariat)
	Vicki Williams (IGARD Secretariat)

2	**Welcome** The IGARD Chair noted that this was a weekly meeting convened to support NHS Digital's response to the COVID-19 situation and was separate from the IGARD business as usual (BAU) meetings. IGARD members present would only be making comments and observations on 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	<u>Use of consultee lawful basis – briefing paper (No NIC Number)</u> **Background:** this was an IGARD business as usual (BAU) meeting briefing paper that had been previously verbally discussed at the BAU meeting on Thursday, 13th May. The briefing paper v0.3 had been scheduled to be discussed at the 18th May meeting, however the presenter had not been available. DARS / Digi-trials have recently received a number of applications whereby some or all of the cohort members of a study had been recruited using consultees. Given the pandemic and the need for trials and research studies increasing where participants may be lacking in capacity to consent, DARS / Digi-Trials have seen an increase where consultees are used. Consent is valid if the person lacks capacity but individuals who lack capacity should not be denied evidence-based care or be excluded from the benefits of research. The inclusion of adults unable to consent for themselves is governed by the provisions of the Clinical Trials Regulations, where an adult is a person aged 16 and over and the provisions of the Mental

	Capacity Acts do not apply to the conduct of Clinical Trials of Investigational Medicinal Products. The Mental Capacity Act 2005 includes provision relating to research involving adults aged 16 or over who are unable to consent for themselves in England and Wales. The following observations were made on the basis of v0.3 of the briefing note only. **IGARD Observations:** IGARD Members noted the advice from Privacy, Ethics & Transparency (PTE) Directorate that confidential patient information can be disclosed either a) with a patient's explicit consent or b) where there is a statutory basis or legal duty to disclose or c) where disclosure is in the overriding public interest. Sections 30 to 33 of the Mental Capacity Act 2005 (England and Wales) relates to being able to carry out an approved research project in relation to a person who lacks capacity, however it does not [expressly] set out a legal obligation to allow NHS Digital to disseminate the personal data it holds to the research study. The PTE advice is aligned with the advice previously given verbally by IGARD, as well at that provided to DARS by the Caldicott Guardian. NHS Digital noted that HRA CAG advice had been sought and they had stated that it was not appropriate to rely on s251 support as a legal basis for those patients who cannot consent due to lacking capacity and noted that the research provisions of the Mental Capacity Act (England and Wales) 2005 should be used. IGARD explored the explanatory notes of the Mental Capacity Act 2005 and noted that while there was no *express* gateway for NHS Digital to flow identifying data, the explanatory notes did support the HRA CAG interpretation. IGARD suggested that the briefing note should be updated in line with the verbal discussion, ensuring that all legal references were cited in the briefing note where applicable, and that an updated version of the briefing note be circulated to the relevant parties. In addition, NHS Digital noted that they would seek forward formal advice from HRA CAG as provided for in schedule 7 of the Care Act 2014 (and on the HRA website) with regard to issues relating to how NHS Digital disseminates identifiable information, or information that may become identifiable and as part of the process, noting that NHS Digital must have regard to any advice given to it by CAG. IGARD agreed that HRA CAG was the appropriate body to determine this issue and it would be helpful for a formal statement on this aspect of the operation of the Mental Capacity Act 2005 to be issued.
2.2	NIC-459114-J3C1F v0.1 AstraZeneca UK Limited **Background:** this was a new urgent public health priority application to assess the real-world effectiveness and safety of the Oxford / AstraZeneca COVID-19 vaccine in England (ORCHID linkage). Civil Registration (Deaths) data, COVID-19 Second Generation Surveillance System (SGSS), COVID-19 UK Non-Hospital Antibody Testing Results (pillar 3), COVID-19 UK Non-Hospitalisation Antigen Testing Results (pillar 2), COVID-19 Vaccination Status, Hospital Episode Statistics (HES) Admitted Patient Care (APC), and HES Critical Care datasets have been requested to be used to build algorithms for analysis in a smaller cohort to which they will be linked, prior to these algorithms being deployed in the national level data within the NHS Digital Trusted Research Environment (TRE) under the Data Sharing Agreement (DSA) NIC-445543-W0D4N (see item 2.3 below)

	The following observations were made on the basis of v0.1 application summary and version 1.0 *Real-world effectiveness of the Oxford/AstraZeneca COVID-19 vaccine in England Observational Study Protocol 22-Mar-21 – CSP 26Apr21_clean* NHS Digital noted that they had not undertaken a review of the documentation including the DPA, security etc. **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, noting that not all the supporting documents available had been provided for consideration. 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 AstraZeneca had cited Article 6(1)(e) (public task) of the UK General Data Protection Regulations (UK GDPR) and that this should be reviewed, since legitimate interests Article 6(1)(f) may be a more appropriate legal basis. It was agreed that a UK GDPR legal basis was not required for the date of death but NHS Digital should provide confirmation in section 1 (Abstract) that the flow of date of death data is in line with NHS Digital's policy assessment and would not increase the likelihood of re-identification of data subjects. IGARD suggested NHS Digital should receive confirmation that AstraZeneca has carried out a Data Protection Impact Assessment (DPIA) which addresses the significant volume of data, the flow of data and the processing outlined in the application. 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 regarding DPIAs (see, for example, a recent BMJ article (BMJ 2021;372:n587 http://dx.doi.org/10.1136/bmj.n587 Published: 01 March 2021)). IGARD members noted previous lengthy discussions with regard to the different legal entities of AstraZeneca and noting that section 1(b) (Data Controllers) was currently blank suggested that the correct legal entity be cited. IGARD members suggested that in alignment with the definition of Controller in Article 4(7) UK GDPR, the Data Protection Officer (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 DARS Standard for Data Controllers; and that the written confirmation was uploaded to NHS Digital's customer relationships management (CRM) system for future reference. However, noting the facts available in the application summary and protocol provided, IGARD members suggest that the University of Oxford appeared to be a joint Data Controller, alongside AstraZeneca UK Limited, and suggested that the parties involved should be assessed in line with NHS Digital's DARS standard for Data Controllers and in line with the factual scenario. IGARD members noted that the 'Oxford Royal College of General Practitioners Clinical Informatics Hub' (ORCHID) platform outlined in section 5 had been cited in other applications presented to IGARD, where the University of Oxford had been assessed as being a joint Data Controller, asked that further clarification was provided in section 5 (purpose / method /

	outputs) of the platform and its use, noting that the ORCHID transparency page on their webpage was still "*under construction*" IGARD members noted that the requested datasets would be used to build algorithms for analysis in a smaller cohort before the algorithms were deployed at national level data (under NIC-445543) and suggested that further narrative should be included in section 5 as to how these algorithms and their outputs are likely to be used, since section 5 forms part of NHS Digital's data release register. In addition, IGARD members noted that as per NHS Digital's published 'register of processing activities' that some datasets have specific territories of use and cannot, for example, be transferred outside of England and Wales. In addition, noting that this application was concerned with England, section 5 should remove any reference to 'Wales', since it was not relevant. IGARD members suggested that an indicative cohort size or number of records flowing under this DSA should be included in section 5, for transparency. In addition, and noting the useful narrative included in the protocol provided as a supporting document, IGARD members suggested that some of this narrative be included in section, since section 5 forms part of NHS Digital's published data release register, and that it should be clearly articulated within section 5 why NHS Digital's Trusted Research Environment (TRE) could not be used for the research being undertaken in this application. IGARD members noted that the specific outputs noted in section 5(c) (specific outputs expected, including target dates) appeared to be internal facing, and since the application was looking at the real world effectiveness for the COVID-19 vaccine in England, suggested that further detail be included in section 5(c) setting out how the benefits translated into benefits for patients and the public, by way of for example a communications plan, public engagement and appropriate communications with relevant national and international bodies such as the Joint Committee on Vaccinations & Immunisation (JCVI), and in line with NHS Digital's DARS standard for Expected Outputs. In addition, section 5 should clearly state that any "unfavourable" results would not be supressed and given equal prominence and widespread dissemination, given the other vaccines being studied under this DSA, since NHS Digital was legally obliged to ensure that the data was not used solely for the commercial benefit of Astra Zeneca. Finally, IGARD members suggested that the application be checked to ensure that it meets all current NHS Digital published DARS Standards. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the high profile and impactful nature of the application. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent (with the exception of this application which would progress under SIRO due to the urgency of the request). NHS Digital noted that due to the urgency of the application that it would be progressed under NHS Digital's SIRO Precedent, on this occasion only, IGARD were supportive of this approach.
2.3	NIC-445543-W0D4N v0.3 AstraZeneca UK Limited

	Background: this was a new urgent public health priority application to assess the real-world effectiveness and safety of the Oxford / AstraZeneca COVID-19 vaccine in England – Trusted Research Environment (TRE) analysis. Civil Registration (Deaths) data, Hospital Episode Statistics (HES) Admitted Patient Care (APC), and HES Critical Care datasets will be accessed via NHS Digital's TRE. The purpose of the processing the requested data is to run a retrospective, non-interventional study to assess the effectiveness of the COVID-19 vaccination to reduce severe COVID-19 infection and mortality in the population of England and the study will define a cohort of patients who have received a COVID-19 vaccination and define matched controls from non-vaccinated populations. No data will be extracted out of NHS Digital under this Data Sharing Agreement (DSA) and all processing will be conducted within the NHS Digital TRE. The following observations were made on the basis of v0.3 application summary and version 1.0 *Real-world effectiveness of the Oxford/AstraZeneca COVID-19 vaccine in England Observational Study Protocol 22-Mar-21 – CSP 26Apr21_clean* NHS Digital noted that they had not undertaken a review of the documentation including the DPA, security etc. **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, noting that not all the supporting documents available had been provided for consideration. 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 this application was linked to NIC-459114-J3C1F v0.1 AstraZeneca UK Limited (item 2.2 above). IGARD members noted that AstraZeneca had cited Article 6(1)(e) (public task) of the UK General Data Protection Regulations (GDPR) and that this should be reviewed, since legitimate interests Article 6(1)(f) may be a more appropriate legal basis. It was agreed that a UK GDPR legal basis was not required for the date of death but NHS Digital should provide confirmation in section 1 (Abstract) that the flow of date of death data is in line with NHS Digital's policy assessment and would not increase the likelihood of re-identification of data subjects. In addition, IGARD members noted that the datasets outlined in section 5 (purpose / methods / outputs) were not reflected in the additional data requested tables in section 3b (additional data access requested), and that this section should be updated with the relevant datasets requested under this DSA. IGARD suggested NHS Digital should receive confirmation that AstraZeneca has carried out a Data Protection Impact Assessment (DPIA) which addresses the significant volume of data, the flow of data and the processing outlined in the application. 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 regarding DPIAs (see, for example, a recent BMJ article (BMJ 2021;372:n587 http://dx.doi.org/10.1136/bmj.n587 Published: 01 March 2021)).

	IGARD members noted previous lengthy discussions with regard to the different legal entities of AstraZeneca and noting that section 1(b) (Data Controllers) was currently blank suggested that the correct legal entity be cited IGARD members suggested that in alignment with the definition of Controller in Article 4(7) UK GDPR, the Data Protection Officer (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 DARS Standard for Data Controllers; and that the written confirmation was uploaded to NHS Digital's customer relationships management (CRM) system for future reference. However, noting the facts available in the application summary and protocol provided, IGARD members suggest that the University of Oxford appeared to be a joint Data Controller, alongside AstraZeneca UK Limited, and suggested that the parties involved should be assessed in line with NHS Digital's DARS standard for Data Controllers and in line with the factual scenario. IGARD members noted that further narrative with regard to the datasets requested under NIC-459114-J3C1F to build algorithms for analysis in a smaller cohort before deployed at national level data should be included in section 5 as to how these algorithms and their outputs are likely to be used, since section 5 forms part of NHS Digital's data release register. In addition, IGARD members noted that as per NHS Digital's published 'register of processing activities' that some datasets have specific territories of use and cannot, for example, be transferred outside of England and Wales. IGARD members suggested that an indicative cohort size or number of records flowing under this DSA should be included in section 5, for transparency. IGARD members noted that the specific outputs noted in section 5(c) (specific outputs expected, including target dates) appeared to be internal facing, and since the application was looking at the real world effectiveness for the COVID-19 vaccine in England, suggested that further detail be included in section 5(c) setting out how the benefits translated into benefits for patients and the public, by way of for example a communications plan, public engagement and appropriate communications with relevant national and international bodies such as the Joint Committee on Vaccinations & Immunisation (JCVI), and in line with NHS Digital's DARS standard for Expected Outputs. In addition, section 5 should clearly state that any "unfavourable" results would not be supressed and given equal prominence and widespread dissemination, given the other vaccines being studied under this DSA, since NHS Digital was legally obliged to ensure that the data was not used solely for the commercial benefit of Astra Zeneca. Finally, IGARD members suggested that the application be checked to ensure that it meets all current NHS Digital published DARS Standards. NHS Digital noted that due to the inclusion of GP Data for Pandemic Planning and Research (GDPPR), that the application would be presented to a Profession Advisory Group (PAG) meeting and before it was presented to an IGARD business as usual meeting (BAU), as per due process for applications for GDPPR data. IGARD further advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the high profile and impactful nature of the application.

	IGARD suggested that this application would **not** be suitable for NHS Digital's Precedent route, including the SIRO Precedent, since this application was relying on the outputs from NIC-459114-J3C1F v0.1 (which would not be subject to independent review) and contained GDPPR data (which as per process, required PAG and IGARD approval).
3	<u>AOB</u> There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.