Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 25 November 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member
Kirsty Irvine	IGARD Chair
Dr. Imran Khan	Specialist GP Member
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Prof. Nicola Fear	Specialist Academic Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Chair
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Safiyyah Akudi	Data Access Request Services (DARS) (Observer: 3.1 – 3.4)
Garry Coleman	SIRO (Item 8.3)
Catherine Day	Data Access Request Service (DARS) (Item 3.5)
Faris Dean	Data Access Request Service (DARS) (Observer: 3.1 – 3.5)
Louise Dunn	Data Access Request Services (DARS) (Item 2.1, 4)
Dan Goodwin	Data Access Request Service (DARS) (items 3.1 – 3.2)
James Gray	DigiTrials (Item 4)
Dickie Langley	Privacy, Transparency and Ethics (PTE) (Item 8.2)
Karen Myers	IGARD Secretariat
Andy Rees	DigiTrials (Item 4)
Charlotte Skinner	Data Access Request Services (DARS) (Items 3.3 – 3.4)
Vicki Williams	IGARD Secretariat
Kevin Willis	Privacy, Transparency & Ethics (Item 8.1)
Tom Wright	Data Services for Commissioners (Item 2.1)

1	**Declaration of interests:** There were no declarations of interest. **Review of previous minutes and actions:** The minutes of the 18th November 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	**Briefing Notes**
2.1	Flu Vaccination Data - Briefing Paper (Presenter: Tom Wright) The seasonal flu programme is a long-established vaccination programme that is proven to save lives and deliver a cost-effective prevention programme, along with reducing pressures on NHS services during the winter. Seasonal influenza and COVID-19 viruses have the potential to add substantially to the winter pressures usually faced by the NHS, particularly if infection waves from both viruses coincide. The Joint Committee on Vaccination and Immunisation (JCVI) considers that a synergistic approach to the delivery of COVID-19 and influenza vaccination may support delivery and maximise uptake of both vaccines in the population. The priority for deployment teams should be the delivery of influenza and COVID-19 booster vaccines to individuals identified in stage 1 at the earliest possible time, progressing to COVID-19 booster revaccination of individuals identified in stage 2 without causing undue delay and without displacement of the timely delivery of annual influenza vaccinations. Within each of the stages, where practicable, those with the longest interval since the second dose of their primary course of vaccination should be called first. The briefing paper was to inform IGARD that NHS Digital have been asked by the Secretary of State and NHS England to provide flu vaccination data to NHS South, Central and West Commissioning Support Unit, the organisation that is providing the national call and recall service on behalf of NHS England. IGARD welcomed the discussion on the draft briefing paper and looked forward to receiving an updated briefing paper at a future meeting, if appropriate, noting that if NHS Digital were not the Data Controller (as they had been in previous years) then it would not usually be within IGARD's remit to provide a recommendation and suggested that NHS Digital follow its own policies, as borne out of the facts, and to seek guidance from the Privacy, Transparency & Ethics Directorate.
3	**Data Applications**
3.1	NHS Stockport CCG*:* DSfC - Stockport CCG / Council Application – Comm (Presenter: Dan Goodwin) NIC-580883-G7N1K-v0.2 **Application:** This was a new application for pseudonymised Secondary Uses Service (SUS+), Local Provider Flows, Mental Health Minimum Data Set (MHMDS), Mental Health Learning Disability Data Set (MHLDDS), Mental Health Services Data Set (MHSDS), Maternity Services Data Set (MSDS), Improving Access to Psychological Therapy (IAPT), Child and Young People Health Service (CYPHS), Community Services Data Set (CSDS), Diagnostic Imaging Data Set (DIDS), National Cancer Waiting Times Monitoring Data Set (CWT), Civil Registration Data (Births), Civil Registration Data (Deaths), National Diabetes Audit (NDA), Patient Reported

	Outcome Measures (PROMs), e-Referral Service (eRS), Personal Demographics Service (PDS), Summary Hospital-level Mortality Indicator (SHMI), Medicines Dispensed in Primary Care (NHSBSA Data) and Adult Social Care Data. The purpose is for NHS Stockport CCG and Stockport Metropolitan Borough Council to receive data to provide intelligence to support the commissioning of health services. The data is analysed so that health care provision can be planned to support the needs of the population within the CCG area. NHS Digital noted that the Invoice Validation and Risk Stratification aspect of this application, were covered under NIC-110660-G9W6M, and that Commissioning would be removed from that Data Sharing Agreement (DSA), noting this was now covered under this DSA. **Discussion:** NHS Digital noted that the application had not previously been presented at an IGARD business as usual (BAU) or at a Data Access Advisory Group (DAAG) meeting (IGARD's predecessor). IGARD noted the verbal update from NHS Digital in respect of the Risk Stratification and Invoice Validation being covered under a separate DSA; however, to avoid confusion, asked that a special condition was inserted in section 6 (Special Conditions), that no commissioning processing could take place under this DSA, until such time that NIC-110660-G9W6M had been updated to remove commissioning. IGARD queried the statement in section 3(b) (Additional Data Access Requested) that *"GDPR does not apply to data solely relating to deceased individuals"*, however, noting that the status of those patients that are still alive would be revealed, asked that this was updated to include a UK General Data Protection Regulation (UK GDPR) legal basis for dissemination and receipt of data; if this was in accordance with the latest advice from the Privacy, Transparency and Ethics (PTE) Directorate. IGARD noted the large number of storage and processing locations in section 2 (Locations), and noting this may cause difficulty for NHS Digital in respect of auditing, suggested that NHS Digital worked with the applicant to review and consider if the locations could be consolidated, noting the discussion at the workshop at the business as usual (BAU) meeting on the 18th November 2021. IGARD noted that there was an issue with the application, in terms of a clear case not being made for re-identification for the purpose of direct care as part of a commissioning application; and that the application referred to re-identification in exceptional cases with aggregated numbers with small numbers supressed. IGARD noted that, based on the discussion at the workshop at the IGARD BAU on the 18th November 2021, the reference to *"small numbers"* under the heading *"re-identification process for direct care"* in section 5(b) (Processing Activities) was incorrect, and asked that this was removed. IGARD asked that section 5(b) was instead updated to make clear that there were two main limbs to the re-identification process for direct care, i) clinical / commissioning led, and ii) data led; and it was clear that this would be on a programmatic basis or, rarely, individual / small group cohort, for example, less than ten. IGARD noted the examples provided in section 5(b) of A&E usage and polypharmacy, however asked that prior to this information and for transparency, it was made clear these were generic examples and not necessarily linked to the applicant CCG, and as discussed at the workshop at the IGARD BAU meeting on the 18th November 2021. In addition, IGARD asked that section 5(b) was updated with an example of programmatic re-identification that could be substituted for the generic examples; or, if they have taken part in A&E / polypharmacy, section 5(b) was updated with further clarification.

	IGARD queried the following statement in section 5(b) *"The DSCRO (either through an automated system or manual checking in line with the request) assesses as to whether the request passes the specified re-identification process checks"*; and asked that for further transparency in respect of the role of the Data Services for Commissioners Regional Office (DSCRO), section 5(b) was updated with further information as to how the DSCRO manually reviewed the approval for the re-identification, in addition to the *"automated system"* reference. IGARD queried the statement in section 5(a) (Objective for Processing) that the data would be used to understand *"…cohorts of residents who are at risk of becoming users of some of the more expensive services…"*; and asked that the reference to *"risk"* was amended to *"understanding the demands"*. IGARD noted that there were ongoing discussions with NHS Digital, in respect of the yielded benefits for CCGs, and that those discussions may impact on the yielded benefits section of the application moving forward; however asked that in line with NHS Digital's DARS Standard for Expected Measurable Benefits, section 5(d) (Benefits) (iii) (Yielded Benefits) was updated with programmatic re-identification benefits. In addition, IGARD queried if all the benefits outlined were produced as a result of the use of the NHS Digital data, for example, were local data flows used; and asked that this was updated in line with NHS Digital's DARS Standard for Expected Measurable Benefits, with clarification that the yielded benefits were produced as a result of the use of NHS Digital data. IGARD also noted that that the yielded benefits do not necessarily need to consist of 'good news stories', for example, a discovery of reduction in the quality of care could lead to action being taken to improve services. IGARD noted the forthcoming system changes across healthcare, in respect of the Integrated Care Systems (ICSs); which are new partnerships between the organisations that meet health and care needs across an area, to coordinate services and to plan in a way that improves population health and reduces inequalities between different groups; and therefore asked that section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) were updated with a reference to the forthcoming CCG / ICS transition. **Outcome:** recommendation to approve The following amendments were requested: 1. To insert a special condition in section 6 that no commissioning processing can take place under this DSA, until such time that NIC-110660-G9W6M has been updated to remove commissioning. 2. To update section 3 to include a UK GDPR legal basis for those datasets that give information about cohort members who are still living, if this accords with the latest advice from PTE. 3. To amend the generic wording in section 5(a) from the "*risk*" of using more expensive services to *"understanding the demands"*. 4. In respect of the *"re-identification process for direct care"* in section 5(b): a) To remove the reference to *"small numbers"*. b) To make clear that there are two main limbs i) clinician / commissioning led, and ii) data led. c) To make clear this will be on a programmatic basis or, rarely, individual / small group cohort. 5. in respect of A&E / polypharmacy in section 5(b):

	a) To update section 5(b) prior to the information on A&E / polypharmacy, to make it clear these are generic examples and not necessarily linked to the applicant CCG. b) To update section 5(b) with an example of programmatic re-identification that could be substituted for the generic examples; or, c) If they have taken part in A&E / polypharmacy, to update section 5(b) with further clarification. 6. To update section 5(b) to provide further transparency as to how the DSCRO manually reviews the approval for the re-identification, in addition to the *"automated system"* reference. 7. In respect of the yielded benefits and in line with NHS Digital DARS Standard for Expected Measurable Benefits (noting the ongoing discussions on this topic): a) To update section 5(d) (iii) with any programmatic re-identification planned. b) To update section 5(d) (iii) with clarification that the yielded benefits were produced as a result of the use of NHS Digital data. 8. IGARD noted the large number of storage and processing locations, and, noting this may cause difficulty for NHS Digital in respect of auditing, suggested that NHS Digital worked with the applicant to review and consider if the locations could be consolidated. 9. To update section 1 and section 5 with a reference to the forthcoming CCG / ICS transition. The following advice was given: 1. IGARD noted that that the yielded benefits do not necessarily need to consist of 'good news stories', for example, a discovery of reduction in the quality of care could lead to action being taken to improve services.
3.2	NHS Newcastle Gateshead CCG: DSfC - Newcastle Joint LA / CCG - Comm (Presenter: Dan Goodwin) NIC-580880-D9Q9P-v0.2 **Application:** This was a new application for pseudonymised Secondary Uses Service (SUS+), Local Provider Flows, Mental Health Minimum Data Set (MHMDS), Mental Health Learning Disability Data Set (MHLDDS), Mental Health Services Data Set (MHSDS), Maternity Services Data Set (MSDS), Improving Access to Psychological Therapy (IAPT), Child and Young People Health Service (CYPHS), Community Services Data Set (CSDS), Diagnostic Imaging Data Set (DIDS), National Cancer Waiting Times Monitoring Data Set (CWT), Civil Registration Data (Births), Civil Registration Data (Deaths), National Diabetes Audit (NDA), Patient Reported Outcome Measures (PROMs), e-Referral Service (eRS), Personal Demographics Service (PDS), Summary Hospital-level Mortality Indicator (SHMI), Medicines Dispensed in Primary Care (NHSBSA Data) and Adult Social Care Data. The purpose is for NHS Newcastle Gateshead CCG and Gateshead Metropolitan Borough Council to receive data to provide intelligence to support the commissioning of health services. The data is analysed so that health care provision can be planned to support the needs of the population within the CCG area. NHS Digital noted that the Invoice Validation and Risk Stratification aspect of this application, was covered under NIC-134638-Z3C2N, and that Commissioning would be removed from that Data Sharing Agreement (DSA), noting this was now covered under this DSA. **Discussion:** NHS Digital noted that the application had not previously been presented at an IGARD business as usual (BAU) or at a Data Access Advisory Group (DAAG) meeting (IGARD's predecessor).

	IGARD noted the verbal update from NHS Digital in respect of the Risk Stratification and Invoice Validation being covered under a separate DSA; however, to avoid confusion, asked that a special condition was inserted in section 6 (Special Conditions), that no commissioning processing can take place under this DSA, until such time that NIC-134638-Z3C2N had been updated to remove commissioning. IGARD queried the statement in section 3(b) (Additional Data Access Requested) that *"GDPR does not apply to data solely relating to deceased individuals"*, however, noting that the status of those patients that are still alive would be revealed, asked that, this was updated to include a UK General Data Protection Regulation (UK GDPR) legal basis for dissemination and receipt of data; if this is in accordance with the latest advice from the Privacy, Transparency and Ethics (PTE) Directorate. IGARD noted the large number of storage and processing locations in section 2 (Locations), and noting this may cause difficulty for NHS Digital in respect of auditing, suggested that NHS Digital worked with the applicant to review and consider if the locations could be consolidated; noting that fewer storage locations were needed, due to the fact the processing involved linkage in a shared cloud, and noting the discussion at the workshop at the business as usual (BAU) meeting on the 18th November 2021. IGARD noted that there was an issue with the application, in terms of a clear case not being made for re-identification for the purpose of direct care, as part of a commissioning application; and that the application referred to re-identification in exceptional cases with aggregated numbers with small numbers supressed. IGARD noted that based on the discussion at the workshop at the IGARD BAU meeting on the 18th November 2021, the reference to *"small numbers"* under the heading *"re-identification process for direct care"* in section 5(b) (Processing Activities) was incorrect, and asked that this was removed. IGARD asked that section 5(b) was instead updated to make clear that there were two main limbs to the re-identification process for direct care, i) clinical / commissioning led, and ii) data led; and it was clear that this would be on a programmatic basis or, rarely, individual / small group cohort, for example, less than ten. IGARD noted the examples provided in section 5(b) of A&E usage and polypharmacy, however asked that prior to this information and for transparency, it was made clear these were generic examples and not necessarily linked to the applicant CCG, and as discussed at the workshop at the IGARD BAU meeting on the 18th November 2021. In addition, IGARD asked that section 5(b) was updated with an example of programmatic re-identification that could be substituted for the generic examples; or, if they have taken part in A&E / polypharmacy, section 5(b) was updated with further clarification. IGARD queried the following statement in section 5(b) *"The DSCRO (either through an automated system or manual checking in line with the request) assesses as to whether the request passes the specified re-identification process checks"*; and asked that for further transparency in respect of the role of the Data Services for Commissioners Regional Offices (DSCRO), section 5(b) was updated with further information as to how the DSCRO manually reviewed the approval for the re-identification, in addition to the *"automated system"* reference. IGARD queried the statement in section 5(a) (Objective for Processing) that the data would be used to understand *"…cohorts of residents who are at risk of becoming users of some of the more expensive services…"*; and asked that the reference to *"risk"* was amended to *"understanding the demands"*. IGARD noted that there were ongoing discussions with NHS Digital, in respect of the yielded benefits for CCGs, and that those discussions may impact on the yielded benefits section of the application moving forward; however asked that in line with NHS Digital's DARS Standard for

	Expected Measurable Benefits, section 5(d) (Benefits) (iii) (Yielded Benefits) was updated with programmatic re-identification planned. In addition, IGARD noted the yielded benefits outlined within section 5(d) (iii), however queried if all the benefits outlined were produced as a result of the use of the NHS Digital data, for example, were local data flows used; and asked that this was updated in line with NHS Digital's DARS Standard for Expected Measurable Benefits, with clarification that the yielded benefits were produced as a result of the use of NHS Digital data. IGARD also noted that that the yielded benefits do not necessarily need to consist of 'good news stories', for example, a discovery of reduction in the quality of care could lead to action being taken to improve services. IGARD noted the forthcoming system changes across healthcare, in respect of the Integrated Care Systems (ICSs); which are new partnerships between the organisations that meet health and care needs across an area, to coordinate services and to plan in a way that improves population health and reduces inequalities between different groups; and therefore asked that section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) were updated with a reference to the forthcoming CCG / ICS transition. **Outcome:** recommendation to approve The following amendments were requested: 1. To insert a special condition in section 6 that no commissioning processing can take place under this DSA, until such time that NIC-134638-Z3C2N has been updated to remove commissioning. 2. To update section 3 to include a UK GDPR legal basis for those datasets that give information about cohort members who are still living, if this accords with the latest advice from PTE. 3. To amend the generic wording in section 5(a) from the "*risk*" of using more expensive services to *"understanding the demands"*. 4. In respect of the *"re-identification process for direct care"* in section 5(b): a) To remove the reference to *"small numbers"*. b) To make clear that there are two main limbs: i) clinician / commissioning led, and ii) data led. c) To make clear this will be on a programmatic basis or, rarely, individual / small group cohort. 5. in respect of A&E / polypharmacy in section 5(b): a) To update section 5(b) prior to the information on A&E / polypharmacy, to make it clear these are generic examples and not necessarily linked to the applicant CCG. b) To update section 5(b) with an example of programmatic re-identification that could be substituted for the generic examples; or, c) If they have taken part in A&E / polypharmacy, to update section 5(b) with further clarification. 6. To update section 5(b) to provide further transparency as to how the DSCRO manually reviews the approval for the re-identification, in addition to the *"automated system"* reference. 7. In respect of the yielded benefits and in line with NHS Digital DARS Standard for Expected Measurable Benefits (noting the ongoing discussions on this topic): a) To update section 5(d) (iii) with any programmatic re-identification planned. b) To update section 5(d) (iii) with clarification that the yielded benefits were produced as a result of the use of NHS Digital data.

	8. IGARD noted the large number of storage and processing locations, and, noting this may cause difficulty for NHS Digital in respect of auditing, suggested that NHS Digital worked with the applicant to review and consider if the locations could be consolidated, noting fewer storage locations are needed, due to the fact the processing involves linkage in a shared cloud. 9. To update section 1 and section 5 with a reference to the forthcoming CCG / ICS transition. The following advice was given: 1. IGARD noted that that the yielded benefits do not necessarily need to consist of 'good news stories', for example, a discovery of reduction in the quality of care could lead to action being taken to improve services.
3.3	<u>University of York: Economic Analyses of Health and Social Care -Evaluation of differences in the performance of health care providers in terms of the amount and cost of provision and in patient outcomes including mortality and self-reported morbidity (Presenter: Charlotte Skinner) NIC-84254-J2G1Q-v4.4</u> **Application:** This was an amendment application, to **1)** to add an additional purpose under 'Project 4' – Evidence to support efficient and effective reduction of health inequality; **2)** the addition of Amazon Web Services as a cloud processor, relating to the University of York's Data Safe Haven (DSH); **3)** to reflect the use of Associate Status for some individuals working on the listed projects; **4)** to provide contract documentation covering student use of NHS Digital data; **5)** to update the anticipated outputs and yielded benefits; and, **6)** to request additional quarters (Q) / annual refreshes (AR) of data required under each of the specified projects (Q3/Q4 21/22, 21/22 A/R). The data is required for a number of projects which all involve economic analyses of health and social care, the aim being to study the way in which services are provided and the outcomes of those services in order to improve health and healthcare services in the NHS. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at IGARD business as usual (BAU) meetings on the 14th June 2018, 7th February 2019 and the 19th November 2020. IGARD noted that they had previously requested that the applicant's privacy notice was updated, for example in respect of updating / removing misleading statements, and ensuring the correct information was published with regards to the National Data Opt-out; and thanked the applicant for making the subsequent updates. IGARD queried the statement in section 3(b) (Additional Data Access Requested) that *"GDPR does not apply to data solely relating to deceased individuals"*, however, noting that the status of those patients that are still alive would be revealed, asked that, this was updated to include a UK General Data Protection Regulation (UK GDPR) legal basis for dissemination and receipt of data; if this was in accordance with the latest advice from the Privacy, Transparency and Ethics (PTE) Directorate. IGARD noted that section 1 (Abstract) did not contain the usual statement / confirmation in respect of NHS Digital's Security Advisor's advice on Cloud storage; and asked that section 1 was updated to use the full agreed wording. IGARD queried the statement in section 5(a) (Objective for Processing) that referred to a collaboration with the London School of Economics and Political Science (LSE), and queried the role of LSE, for example, in terms of data controllership, noting that LSE were not named as a

	joint Data Controller. NHS Digital advised that the applicant had confirmed that the University of York are the sole Data Controller. IGARD noted the verbal update from NHS Digital, and asked that an analysis was provided in section 1 as to why LSE were not considered a joint Data Controller; and in line with NHS Digital's DARS Standard for Data Controllers, and as borne out of the facts. In addition, and for the purpose of transparency, IGARD asked that section 5(a) was updated with a brief explanation of LSE's collaboration role. IGARD queried how many students would be accessing the data, noting that this was unclear in the application; and asked that NHS Digital ensured that the appropriate controls were in place for the number of University of York students who may access the data, via the letter, for example, by narrowing to students studying in a specific department or working under the supervision of certain researchers. IGARD suggested that section 5(d) (Benefits) be updated to remove reference to "*it will*…" or "it can…", and instead use a form of words such as "*it is hoped*…" IGARD queried the statement in section 5(d) *"survival is the primary measure of health outcomes"*, and noting that in some cases this may not necessarily be correct, asked that in line with NHS Digital DARS Standard for Expected Measurable Benefits, the statement was removed. IGARD noted the statement in section 5(d) (ii) (Expected Measurable Benefits to Health and/or Social Care) *"Inpatient mortality (based on discharge information) is an imperfect measure of quality of care because it is censored at discharge"*; and asked that in line with NHS Digital DARS Standard for Expected Measurable Benefits, further clarification was provided as to what was meant by *"censored",* as this was not clear. IGARD queried the statement in section 5(d) (iii) *"Other strands of the research have established that incentive payments made to GPs to increase the numbers of individuals diagnosed with dementia have been effective, but that there may have been* ***unintended consequences*** *on patient experience and access"*; and asked that for transparency, and in line with NHS Digital DARS Standard for Expected Measurable Benefits, this was updated with further clarity on the reference to *"unintended consequences"*. IGARD noted that section 5 (Purpose / Methods / Outputs) contained references to *"Clinical Commissioning Groups (CCGs)"*, and asked that this was updated to ensure the references were replaced with *"commissioning bodies"*. IGARD noted a number of acronyms and technical terms in section 5, and asked that this public facing section, that forms NHS Digital's data uses register, was amended throughout, to ensure acronyms be defined upon first use, if the meaning is not self-evident, for example *"CCG"* (if at any point the reference(s) to *"CCG"* remain in the application). IGARD queried the reference in section 5(a) to the *"online web tool"* that had been developed, and advised that this had been difficult to locate online, and therefore asked that this was updated with an accessible weblink or further description. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 3 to include a UK GDPR legal basis for those datasets that give information about cohort members who are still living, if this accords with the latest advice from PTE. 2. To amend section 1 to include NHS Digital's Security Advisor's advice on Cloud storage and to use the full agreed wording.

	3. To update section 5(a) to provide further clarity as to how the data is deemed *"sensitive"*, for example, a statutory definition, NHS Digital's sensitive fields, or a more subjective review undertaken by the researchers. 4. As section 5 forms NHS Digital's data uses register, to amend section 5 to ensure that all acronyms upon first use are defined and further explained if the meaning is not self-evident, for example *"CCG"*. 5. To replace the references in section 5 from *"CCGs"* to *"commissioning bodies"*. 6. In respect of the role of LSE: a) To provide an analysis in section 1 as to why LSE are not considered a joint Data Controller; and in line with NHS Digital's DARS Standard for Data Controllers, and as borne out of the facts (as per the verbal update from NHS Digital). b) To provide a brief explanation in section 5(a) of LSE's collaboration role. 7. NHS Digital to ensure that the appropriate controls in place for the number of University of York students who may access the data, via the letter, for example, by narrowing to students studying in a specific department or working under the supervision of certain researchers. 8. In respect of the benefits and in line with NHS Digital DARS Standard for Expected Measurable Benefits: a) To update section 5(d) to use a form of wording such as "*it is hoped* …", rather than "*it will…*" or *"it can"*. b) To update section 5(d) to remove the reference to *"survival is the primary measure of health outcomes"*. c) To provide further clarification in section 5(d) (ii) as to what is meant by "censored". d) To update section 5(d) (iii) with further clarity on the reference to *"unintended consequences"*. 9. To update the reference to *"online web tool"* in section 5(a) with an accessible weblink or further description.
3.4	London School of Economics and Political Science (LSE): Evaluating the Heterogeneous Impacts of the Improving Access to Psychological Therapies (IAPT) Programme (Presenter: Charlotte Skinner) NIC-403870-H8L5B-v0.7 **Application:** This was a new application for a one-off flow of pseudonymised Improving Access to Psychological Therapies Data Set (IAPT); for the purpose of a project, to support policy-makers understand the sources of heterogeneity (dissimilarities and diversity) in the effectiveness of IAPT treatments for different patients and in the performance of different service providers. In the UK, mental health problems are the largest single cause of disability, with one in four adults experiencing at least one diagnosable mental health problem in any given year. In 2008, the National Health Service (NHS) began with the nationwide implementation of IAPT, with one of the ambitions to achieve at least a 50% recovery rate. While this goal was achieved in 2017, treatment outcomes differ substantially between patients of different socio-economic and ethnic groups as well as different geographical locations. The findings about the treatment effect of the programme, and its heterogeneities will provide better understand the sources of inequality in treatment outcomes of the IAPT patients. They will reveal which patient groups are more responsive to particular treatments in particular services, allowing us to identify the best diagnosis-treatment match. It will also provide information as to whether different patient groups are systematically influenced by different service and local area characteristics and in which ways. The sources of heterogeneity identified in this analysis and

	their relevant importance will help to understand what drives heterogeneity in the share of recovered patients among different service providers. **Discussion:** IGARD queried if there had been any public involvement and engagement (PPIE), since it was not clear within the application or supporting documentation if any PPIE had been undertaken; and were advised by NHS Digital, that the applicant had confirmed that no PPIE had taken place. IGARD noted the verbal update from NHS Digital, however given the quantum of data flowing and the sensitive nature of the data, asked that a satisfactory indicative plan was provided, for the development and implementation of PPIE initiatives, in line with the HRA guidance on Public Involvement. IGARD noted that section 7 (Ethics Approval) stated that ethical review was not required due to the data requested not including the flow of confidential data; and queried if a University ethics committee had undertaken a review, and were advised by NHS Digital that LSE had followed due process in respect of the University ethical review, and it had been confirmed there were minimal ethical risks. IGARD noted the verbal update from NHS Digital, however noted concern that in addition to there being no ethical support, there was also no PPIE, and queried what information had been shared with the University. IGARD asked that written confirmation was provided, that the relevant University body **were** aware of the quantum of data flowing and the sensitive nature of the data, including, but not limited to, disability, ethnicity and religion fields; or, if the body were **not** aware, asked that the applicant resubmitted an application for review, with the additional information. In addition, IGARD asked that either written confirmation was provided that the re-submitted application had been reviewed by the relevant body, who have provided ethical support; or, that written confirmation was provided that they supported their original decision, that ethics support was not required. In all cases, IGARD asked that the written confirmation was uploaded to NHS Digital's customer relationships management (CRM) system for future reference. Noting that the application outputs could have significant impact on service provision and currently had no ethical support, IGARD suggested that alongside PPIE, a number of other steps could be taken, such as an Equality and Health Inequalities Impact Assessment and a Data Protection Impact Assessment (DPIA). IGARD noted the reference in section 5(a) (Objective for Processing) to *"mental health disorder"*, and noting that section 5 (Purpose / Methods / Outputs) formed NHS Digital's public data release register, asked that this was updated, with an alternative, more sensitive term, such as *"mental health condition"* or "*ill health",* in line with NHS Digital's DARS Standard for Objective for Processing. IGARD noted the inconsistent references to *"gender"* and *"sex"* in section 5(c) (Specific Outputs Expected), for example, *"Gender differences – no studies have specifically investigated age and sex differences in patients…"*; and asked that this was updated to ensure consistency, since they are not interchangeable data fields. IGARD queried the statement in section 5(d) (Benefits) (ii) (Expected Measurable Benefits to Health and/or Social Care) *"Although it is difficult to conclusively say how many patients in England are likely to benefit from our work, we can make a* ***back-of-the-envelope calculation****."*; and asked that this was amended to refer to *"estimate"* or similar. IGARD noted the language used within section 5(d) (ii) to patients *"suffering"* from depression or anxiety, and suggested that this reference was amended to refer to patients *"living with the condition"* or similar.

IGARD queried the reference in section 8(b) (Funding Sources) that the funding was 8(b) was *"private"*, and were advised by NHS Digital that funding was provided internally within LSE. IGARD noted the verbal update from NHS Digital, and asked that section 8(b) was updated, to make it clear that the funding was being sourced internally within LSE as opposed to *"private"*.

Outcome: recommendation to approve subject to the following conditions:

1. To provide a satisfactory indicative plan for the development and implementation of PPIE initiatives, in line with the HRA guidance on Public Involvement.
2. In respect of the Ethics:
   a) To provide written confirmation that the University ethics committee were aware of the quantum of data flowing and the sensitive nature of the data, including (but not limited to) disability, ethnicity and religion fields; or,
   b) If the University ethics committee were not aware (as above), the applicant to resubmit an application for review, with the additional information; and,
   c) To provide written confirmation that the re-submitted application has been reviewed by the University ethics committee, who have provided ethical support; or,
   d) To provide written confirmation that the re-submitted application has been reviewed by the University ethics committee, who support their original decision, that ethics support is not required.
   e) In all cases, to upload the written confirmation to NHS Digital's CRM system for future reference.

The following amendments were requested:

1. In respect of the language within the application:
   a) To update section 5(a), to amend the references from *"mental health disorder"* to an alternative such as *"mental health condition"* or "*ill health"*.
   b) To amend the reference in section 5(d) (ii) from *"back-of-the-envelope calculation"* to *"estimate"* or similar.
   c) To update section 5(c) to be consistent when using the terms *"gender"* or *"sex"*, since they are not interchangeable data fields.
   d) To update the reference in section 5(d) (ii) from *"suffering"* to *"living with the condition"* or similar.
2. To update section 8(b) to make clear that the funding is being sourced internally within LSE as opposed to *"private"*.

The following advice was given:

1. Noting that the application outputs could have significant impact on service provision and currently has no ethical support, IGARD suggested that alongside PPIE, a number of other steps could be taken, such as an Equality and Health Inequalities Impact Assessment and a DPIA.

It was agreed the conditions would be approved out of committee (OOC) by IGARD members.

Subsequent to the meeting:

In respect of the points raised on an ethics review, IGARD noted the statement on the University website *"An ethics review is required for any study involving: human participants (e.g. for interviews, online surveys, observations, social media); use of datasets containing identifiable information (e.g. names, emails, social media profile names - anything that might identify an individual) - even if you plan to anonymise the data;* ***or for research that might have negative repercussions for any individuals or groups."***

3.5	University College London (UCL): Assessing the impact of the COVID-19 pandemic on vulnerable children: the ECHILD-COVID study (Presenter: Catherine Day) NIC-381972-Q5F0V-v1.3 **Application:** This was an amendment application to **1)** transfer to the Office for National Statistics Secure Research Service (ONS SRS) a pseudonymised 'mum-baby' linkage flag, attached to the relevant pseudonymised Hospital Episode Statistic (HES) record; **2)** to enable inclusion of maternal characteristics (such as age), and to follow up the health of young people to the age of 34; **3)** to extend the age range to all 'young' people in England born on or after 1st September 1984, from the current age limit of 1st September 1995; **4)** the extension of the data retention period for the identifier file of all individuals linked in NPD-MPS/PDS and MPS/PDS-HES and all the postcodes used in linkage and postcode dates from 12 months to 24 months; **5)** clarification of the funding sources; **6)** updates related to the use of MPS for new data linkage. This agreement will allow the data to be linked to data held under NIC-393510- D6H1D, which is already held at UCL. The purpose is for a study looking at the impact of COVID-19 and lockdown on Children and young people (CYP) and whether there are any differences in the health and social effects of household confinement on vulnerable children and young people when compared to other CYP. CYP who are vulnerable due to social welfare or chronic health needs are expected to experience more adverse health and social effects of the COVID-19 lockdown than other CYP. Key concerns for services are the effects of household confinement during the COVID-19 lockdown, combined with the limited access to support from health, social care and education services. The researchers need to understand what impacts COVID-19 infection and related public health responses (such as lockdown) have had on CYP aged 25 years and under, to inform strategies for the current wave of infection, and any future waves. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at IGARD business as usual (BAU) meetings on the 25th June 2020. IGARD noted that when the application was reviewed on the 25th June 2020, IGARD had requested that clarity was provided as to what 'vulnerable' definitions were being relied on for the purpose of this application, which at the time of the review, was for children and young people. IGARD advised that following review of the latest iteration of the application, and updated ethics approval and protocol, there had now been a significant change in the cohort for the study, for example in terms of the age range now being studied. IGARD therefore asked that confirmation was provided, as to what definition of *"vulnerable"* applied to the 25 - 37-year-old cohort, for whom the Children's Act definition of 'vulnerable' does not cover, noting that this was only relevant up to the age of 24. IGARD also noted the statement in section 5 (Purpose / Methods / Outputs) *"…**vulnerabilities in parents**, related to child maltreatment, poverty, or poor mental or physical health, and school factors such as special needs, influence the outcomes of children into adulthood"*; and noting that it was unclear, asked that an explanation was provided, as to how the applicant had identified the cohort of vulnerable parents and what the criteria was for inclusion in the cohort. In addition, IGARD also noted the statement in section 5(a) (Objective for Processing) *"Researchers will examine vulnerability characteristics in a child's mother (such as…**previous birth**)"*; and queried how the *"previous birth"* contributed to the vulnerable characteristics of the cohort of vulnerable mothers; and asked that an explanation was provided. IGARD noted the benefit outlined in section 5(d) (Benefits) (ii) (Expected Measurable Benefits to Health and/or Social Care) *"The research will also add evidence on the impact of COVID-19 on*

	health inequalities - including for black and minority ethnic groups…"; and asked that it was updated to note, if at any point ethnicity data would be used as a determinant of vulnerability, as this was not clear. IGARD queried the reference in section 5(a) to children who were *"otherwise vulnerable"* would be part of the cohort; and asked that section 5 was updated, with a clear definition as to what was meant by this, including, but not limited to, what factors would lead a child to be defined as *"otherwise vulnerable"*. IGARD noted the 'Request Title' in section 1 (Abstract) *"Assessing the impact of the COVID-19 pandemic on **vulnerable children**: the ECHILD-COVID study"* and suggested this was misleading given the study now extends up to the age of 37. Since this populates NHS Digital's data uses register, IGARD suggested the title was updated to reflect the factual scenario of the age group being studied. IGARD noted the references in the application to *"mum-baby"*, and asked the application was updated throughout, to more accurately refer to *"Mother and baby / babies"*. IGARD asked that for transparency, section 5 was updated to be clear that the Maternity Services Data Set (MSDS) data has already been *"pre-linked"* by NHS Digital. IGARD had a lengthy discussion on the National Data Opt-out (NDO) and whether this applied to the data flowing under this Data Sharing Agreement (DSA); and agreed that, on face value, the NDO would not be applied, due to the data flowing being pseudonymised. IGARD did however query a misleading statement within the privacy notice that referred to patients opting out; and asked that this was updated to be clear that the NDO does **not** apply to the data used in this study. IGARD also suggested that, as advised on other similar applications, the applicant should consider linking the privacy notices together, so they were more accessible, which is a key requirement under the UK General Data Protection Regulation (UK GDPR). IGARD noted and applauded the efforts made in respect of the patient and public involvement and engagement (PPIE) endeavours, however, noting that the cohort had significantly changed (in size and age range), suggested that the PPIE was reviewed and expanded with this expanded cohort in mind. IGARD suggested that section 5(d) be updated to remove reference to "*it will*…", and instead use a form of words such as "*it is hoped*…" IGARD noted the yielded benefits in section 5(d) (iii) (Yielded Benefits), however asked that a further definitive statement was provided, as to how the NHS Digital data has been used; for example has this research helped refine targeted funding for catch up schools, and asked that further links were provided to show the impact of the research, in line with NHS Digital DARS Standard for Expected Measurable Benefits. IGARD queried the statements in section 1 and section 5(b) (Processing Activities) "*…new research estimates that 25% of all children are ever designated a child in need and that 44% are ever referred to children's social care before the age of 16 years."*; and asked that this was amended to make clear what the *"44%"* figure stated is referring to (i.e. 44% of the 25% figure stated). IGARD noted that section 1 stated that a review by IGARD was not required; and again requested that NHS Digital review their internal processes and IT systems to ensure this does not incorrectly default to state *"no"*.

IGARD suggested the applicant carried out a Data Protection Impact Assessment (DPIA), due to the significant volume of data flowing, and the processing of special category data on a large scale. If a DPIA has already been produced, IGARD suggested that this was updated to reflect the additional data flows.

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, to ensure the yielded benefits align with the quantum of data flowing.

Outcome: recommendation to approve subject to the following condition:

1. In respect of the *"vulnerable"* cohort(s):
    a) To provide confirmation as to what definition of *"vulnerable"* applies to the 25 - 37-year-old cohort, for whom the Children's Act definition of 'vulnerable' does not cover (it is only relevant up to age 24).
    b) To provide an explanation as to how the applicant has identified the cohort of vulnerable parents and what is the criteria for inclusion in that cohort.
    c) To provide an explanation of how *"previous birth"* contributes to the vulnerable characteristics of the cohort of vulnerable mothers.
    d) To note if at any point ethnicity data will be used as a determinant of vulnerability.
    e) To update section 5 with a clear definition of what is meant by children who were *"otherwise vulnerable"* as part of the cohort, including (but not limited to) what factors would lead a child to be defined as *"otherwise vulnerable"*.

The following amendments were requested:

1. In respect of section 1:
    a) IGARD noted that section 1 stated that a review by IGARD was not required; and again requested that NHS Digital review their internal processes and IT systems to ensure this doesn't incorrectly default to state *"no"*.
    b) To update the 'Request Title' in section 1, which populates NHS Digital's Data Uses Register, noting the current reference to vulnerable *"children"* is misleading, given the cohort study can extend up to the age of 37.
    c) To amend section 1 and section 5(b) to make clear what the *"44%"* figure stated is referring to (i.e. 44% of the 25% figure stated).
2. To update the privacy notice to be clear that the NDO does not apply to the data used in this study.
3. To update the application throughout to amend the reference from *"mum-baby"* to *"Mother and baby / babies"*.
4. To update section 5 to be clear that the MSDS data has already been *"pre-linked"* by NHS Digital.
5. In respect of the benefits and in line with NHS Digital DARS Standard for Expected Measurable Benefits:
    a) To update section 5(d) to use a form of wording such as "*it is hoped* …", rather than "*it will*…".
    b) To provide a definitive statement in section 5(d) (iii) as to how the NHS Digital data has been used; for example has this research helped refine targeted funding for catch up schools, and provide further links to show the impact of the research.

The following advice was given:

1. IGARD suggested the applicant carried out a DPIA, due to the significant volume of data flowing, and the processing of special category data on a large scale. If a DPIA has

	already been produced, IGARD suggested that this was updated to reflect the additional data flows. 2. IGARD suggested that as advised on other similar applications, the privacy notices were linked together, so they are more accessible, which is a key requirement under the UK GDPR. 3. IGARD noted and applauded the efforts made in respect of the PPIE endeavours, however noting that the cohort had significantly changed (in size and age range), suggested that the PPIE was reviewed and expanded with this expanded cohort in mind. 4. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, to ensure the yielded benefits align with the quantum of data flowing. 5. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route including the SIRO Precedent, to ensure the yielded benefits align with the significant quantum of data flowing. It was agreed the conditions would be approved out of committee (OOC) by members.
4	<u>NHS-Galleri Trial and Simplify Trial (Presenters: Louise Dunn / James Gray / Andy Rees)</u> At the IGARD business as usual meeting on the 24th June 2021, NHS Digital presented NIC-456778-J0G3H (GRAIL Bio UK Ltd) which was for the 'NHS-Galleri' trial. The NHS-Galleri Trial, is a new Multi-Cancer Early Detection (MCED) test (Galleri) that has been developed, that can detect many types of cancer from a single blood sample. The trial aims to determine whether it is better at discovering cancer early, compared to other tests that the NHS currently uses; and to demonstrate the clinical utility of the MCED blood test for individuals in a general screening population in a real-world NHS setting. NHS Digital attended the meeting to provide a verbal update on a related trial, entitled the 'Simplify Trial', and advised that due to the urgency of the data required by the applicant, and the high-profile nature of the trial, further information would be shared with IGARD imminently. IGARD noted the verbal update from NHS Digital, and advised that they would be content to receive a briefing paper (amended accordingly) also shared with NHS Digital's Executive Management Team (EMT), to provide the necessary background information. In addition, IGARD advised that as per process, the consent materials would be a critical element of any IGARD review. IGARD thanked NHS Digital for providing an overview of this urgent / impending work, and looked forward to receiving the relevant background papers / application as per process.
5	<u>Applications progressed via NHS Digital's Precedent route, including the SIRO Precedent</u> Applications that have been progressed via NHS Digital's Precedent route, including the SIRO Precedent, and NHS Digital have notified IGARD in writing (via the Secretariat). *No items discussed.*
6	<u>Oversight & Assurance</u> IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. Due to the volume and complexity of applications at today's meeting, IGARD were unable to review any Data Access Request Service (DARS) applications as part of their oversight and assurance role.

	IGARD noted that they had reviewed an IG COVID-19 release register suite of documents on a particular data release for review by IGARD as part of their oversight and assurance, and as agreed in June 2020 with the Executive Director Privacy, Transparency and Ethics (PTE) when it had been agreed that IGARD review an agreed number per month, by way of a review of all documentation revised by PTE, and as part of continuous improvement and quality. A summary of the points raised will be included under this section in the coming weeks. IGARD Members noted that they had not yet been updated on the issues raised at the 27th May 2021 IGARD business as usual (BAU) meeting with regard to previous comments made on the IG COVID-19 release registers. IGARD Members noted that the last IG COVID-19 release register that they had reviewed and provided comments on was July 2021.
7	COVID-19 update To support NHS Digital's response to COVID-19, from Tuesday 21st April 2020, IGARD will hold a separate weekly meeting, to discuss COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 urgent applications that have been submitted to NHS Digital. Although this is separate to the Thursday IGARD meetings, to ensure transparency of process, a meeting summary of the Tuesday meeting will be captured as part of IGARD's minutes each Thursday and published via the NHS Digital website as per usual process. The ratified action notes from **Tuesday 23rd November 2021** can be found attached to these minutes as Appendix B.
8 **8.1** **8.2** **8.3**	AOB ICO Consultation - Anonymisation, pseudonymisation and privacy enhancing technologies guidance Noting that the above consultation was due to close on the 28th October 2021, and following the discussion at the IGARD business as usual meeting on the 18th November 2021, where IGARD shared their initial collective feedback with senior NHS Digital colleagues; NHS Digital attended the meeting to discuss this item further. The IGARD Chair thanked NHS Digital for attending the meeting, and it was agreed that IGARD would review the revised document and feedback any further advice to NHS Digital and where NHS Digital had not accepted IGARD's advice, they may wish to draw this out in their response under a separate header. Information Governance A member of NHS Digital's Privacy, Transparency and Ethics, attended the meeting to provide a brief update / overview of ongoing information governance work. IGARD noted and thanked NHS Digital for the verbal update and looked forward to receiving further updates at a future IGARD meeting. NHS Digital Organisational Changes The SIRO attended IGARD to give members a brief update following the announcement that NHS Digital would be merging into NHS England, as announced on the 22nd November 2021.

	There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 19/11/21

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-147941-XX4JP-v4.5	The University of Manchester	14/10/2021	1. To clearly outline in section 1 and section 5 what steps have been undertaken to reconsent those participants that have turned 16 years of age. 2. To confirm in section 1 and section 5, where referring to the sharing of data with pharmaceutical companies outside of the EEA, that this does not include any NHS Digital data.	IGARD members	Quorum of IGARD members	N/A
NIC-445543-W0D4N	AstraZeneca UK Limited	30/09/2021	1. In respect of the *"artificial intelligence (AI)-based approaches"*: a) To provide a further explanation in section 5(a) of the reference to *"artificial intelligence (AI)-based approaches".* b) To confirm in section 5(a) whether or not any additional UK GDPR considerations need to be addressed including (but not limited to) carrying out or updating the DPIA.	IGARD members	Quorum of IGARD members	None

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

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

Liaison Financial Service and Cloud storage:

- None

Optum Health Solutions UK Limited Class Actions:

- NIC-43362-G7T9X-v6.2 - DSfC - NHS Somerset CCG IV, RS, Comm & Van

Graphnet Class Actions:

- None

Appendix B

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

held via videoconference, Tuesday, 23rd November 2021

In attendance (IGARD Members):	Prof. Nicola Fear (IGARD Specialist Academic Member)
	Kirsty Irvine (IGARD Chair)
	Dr. Geoff Schrecker (IGARD Specialist GP Member / IGARD Deputy Chair)
In attendance (NHS Digital):	Laura Evans (Digi-Trials)
	James Gray (Digi-Trials)
	Karen Myers (IGARD Secretariat)
	Frances Perry (Digi-Trials)
	Vicki Williams (IGARD Secretariat)

1	**Welcome** The IGARD Chair noted that this was a weekly meeting convened to support NHS Digital's response to the COVID-19 situation and was separate from the IGARD business as usual (BAU) meetings. IGARD members present would only be making comments and observations on items that were presented, and were not making formal recommendations to NHS Digital. Should an application require a full review and recommendation, then it should go through the usual Data Access Request Service (DARS) process and be presented at a Thursday IGARD meeting. The action notes from the Tuesday meeting will be received out of committee and then published alongside the minutes of the next Thursday BAU meeting as an appendix. **Declaration of interests:** Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising the Scientific Advisory Group for Emergencies (SAGE) on COVID-19
2.1	NIC-605115-L0W3V University of Oxford **Background:** This was a new application for record level data for the Platform Adaptive trial of NOvel antiviRals for eArly treatment of covid-19 In the Community (PANORAMIC), a "sister" application to NIC-411161-G4K7X Platform Randomised trial of INterventions against COVID-19 In older peoPLE (PRINCPLE) which had been presented to the IGARD business as usual meeting on the 25th February 2021, and the COVID-19 meetings on the 28th September 2021, 9th February 2021, 10th November 2020 and 27th October 2020. The following observations were made on the basis of the verbal update from NHS Digital only and three supporting documents: '*DARS consent review DARS-NIC-605115-L0W3V-v0-final*', '*PANORAMIC consent form v1.0 08Nov2021 clea*n' and '*PANORAMIC PIS v1.0 08Nov2021 clean*'.

IGARD Observations:

IGARD members noted that although version 0.3 of the application and supporting documentation was available on NHS Digital's customer relationship management (CRM) system, they had **not** been provided for review at this meeting and their observations were based on the verbal update from NHS Digital and the three documents provided only.

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 documentation. Should a full review of the application and any supporting 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 the verbal update from NHS Digital and that the application was to be presented at an IGARD BAU meeting on the 2nd or 9th December 2021. IGARD members noted that the discussion today was not to pre-empt discussions that would take place at the BAU meeting and thanked NHS Digital for the verbal update and looked forward to receiving the full suite of documentation at the BAU meeting in due course, and made the following high level comments:

Consent and Patient Information Sheet (PIS)

- Section 5 of the consent form appeared to have restrictive language which may preclude confidential patient information being sent to and handled by NHS Digital. Care should be taken to align the consent form and patient information sheet. While mentioning NHS Digital, there was still an express statement in the PIS that only a limited number of people would look at the data (and did not mention NHS Digital in that context), section 5: "*I understand that relevant sections of my GP and hospital medical notes and data collected during the study may be looked at by members of the research team and individuals from University of Oxford, both during and for up to 10 years after the scheduled follow-up period. It may also be reviewed by relevant people from regulatory authorities and from the NHS Trust(s). I give permission for these individuals to have access to my records*"
- As previously discussed with DARS and Digi-Trials IGARD noted that the term "*regulatory authorities*" would **not** encompass NHS Digital, since NHS Digital was **not** a regulatory authority, as outlined in the updated Health Research Authority Confidentiality Advisory Group (HRA CAG) consent documentation
- A careful review should be undertaken of the consent and PIS materials to ensure that it covered the data requested eg the materials suggested that it may only be data from the study that would be used but the researcher may request eg Hospital Episode Statistics (HES) data, and data from prior to the date of consent.
- The PIS mentioned the value of the study and sharing data overseas, however the consent materials were silent on this point.
- The PIS cited the current Health Service (Control of Patient Information) Regulations 2002 (COPI) legal basis, noting that the applicant was looking to move to s251 support before the end of the March 2022.
- The design of a single use consent form which also covered those who lacked capacity and was usually covered by way of a separate "*assent form*", was open to risk of someone without appropriate legal basis to sign on behalf of the participant.

	• The signatory of the consent form noted "*relationship*" and that further narrative should be included, for example was that a Lasting Power of Attorney (LPA) for Health and Welfare? • As previously discussed with DARS and Digi-Trials, IGARD suggested that in relation to telephone calls, short message service (SMS) and email communications with regard to recruitment, that consideration be given to the Privacy and Electronic Communications Regulations (PECR) that sit alongside the Data Protection Act 2018 and UK General Data Protection Regulation (UK GDPR) and which gives specific privacy rights in relation to electronic communications. • Those that had "*opted out*" of being contacted for participation in the trials, appeared to being contacted via the test and trace website and NHS Digital should ensure it has a clear policy decision and has ascertained from the applicant the number of complaints that have been received in relation to a participant being contacted by the trial teams when they have specifically ticked the "*do not contact*" box on the test and trace website. • The PIS may wish to state that the trial would like to keep in contact with the participants throughout the trial to update participants on the progress of the study. • (As advice, beyond the scope of NHS Digital / IGARD review: transparency should be provided for those whose data was being collected as part of the "*trial partner*" option and the privacy notice should clearly state how the "trial partner" data is being handled, noting that they are not part of the cohort for the trial). **COPI Regulations and COPI Notice** • As previously discussed with DARS and Digi-Trials, the COPI Regulations 2002 do not fall away, however the COPI Notice is due to end on the 31st March 2022 and IGARD noted that the applicant was seeking s251 support from HRA CAG. **Summary Care Record (SCR) data request:** • IGARD reiterated their comment from the 25th February 2021 BAU and 28th September COVID-19 response meetings in relation to NIC-411161-G4K7X, which also applied in this application, (which had not been actioned by NHS Digital) namely: "*IGARD noted the Caldicott Guardian's assessment of the legal basis for access to SCR in supporting document 6, and suggested that the NHS Digital Data Access Request Service (DARS) Team, shared the Caldicott Guardian's opinion with NHS Digital's Privacy, Transparency and Ethics (PTE) (formerly Information Governance). IGARD asked that written confirmation be sought that PTE were content with the Caldicott Guardian's assessment; and that the written confirmation was uploaded to NHS Digital's customer relationship management (CRM) system for future reference*." **IGARD strongly suggested that this action was completed before any application including SCR was brought to IGARD BAU.** • IGARD noted that this trial was **not** looking at the common use drugs already in use and which had known allergies, as was happening in the PRINCIPLE trial, but was looking at a new drug where allergies would not be known, and it should be clearly articulated what the trial were looking for in terms of allergies, for example chicken egg allergy. **Application / Data Sharing Agreement (DSA)** • Section 1 should clearly articulate that DARS / Digi-trials have conducted a consent review and their conclusion following that review.

	• Relevant patient and public involvement and engagement (PPIE) plans should be included in section 5 IGARD noted that although there may be a legal basis addressing the common law duty of confidentiality, based on the limited information they had received, there were significant ethical issues relating to the points raised above. IGARD also asked that NHS Digital ensure that the Caldicott Guardian or Deputy Caldicott Guardian be present at the IGARD BAU meeting where this application was to the discussed. With regard to NIC-411161-G4K7X, IGARD noted that they had **not** been asked to review consent materials **prior** to their use.
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.