Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 9 July 2020

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Kirsty Irvine (Chair)	IGARD Lay Chair
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Prof. Nicola Fear	Specialist Academic Member
Dr. Maurice Smith	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Dave Cronin	Data Access Request Service (DARS)
Catherine Day	Data Access Request Service (DARS)
Arjun Dhillon	Caldicott Guardian (Observer: item 2.8)
Louise Dunn	Data Access Request Service (DARS)
Duncan Easton	Data Access Request Service (DARS)
Frances Hancox	Data Access Request Service (DARS)
Richard Hatton	Clinical Informatics (Observer: items 2.1 to 2.4)
Karen Myers	IGARD Secretariat

1	**Declaration of interests:** Paul Affleck noted professional links to the University of Leeds (NIC-147997-R8B9S) but noted no specific connections with the application or staff involved and it was agreed that this was not a conflict of interest. Paul Affleck noted professional links to PICANet (NIC-192305-X3T0Y NHS England (Quarry House)) but noted no specific connections with the application or staff involved and it was agreed that this was not a conflict of interest. **Review of previous minutes and actions:**

	The minutes of the 2nd July 2020 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	<u>NHS Liverpool CCG: DSfC - NHS Liverpool CCG; RS, IV, Comm (Presenter: Duncan Easton) NIC-47191-D9X6J</u> Application: This was a renewal 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 (DID), National Cancer Waiting Times Monitoring Data Set (CWT), Civil Registries Data (CRD), National Diabetes Audit (NDA) and Patient Reported Outcome Measures (PROMs). It was also an amendment application to, 1) to add Liaison Financial Services Ltd for Invoice Validation purposes; 2) to add Microsoft Limited as they provide Cloud services for Liaison Financial Services Ltd, 3) To remove Blackpool Teaching Hospitals NHS Foundation Trust, 4) to remove Nottingham University Hospitals NHS Trust as a data processor (for commissioning), 5) to add Cloud 2 Limited. The overall purpose is for Invoice Validation (IV) which is part of a process by which providers of care or services are paid for the work they do, Risk Stratification (RS) which is a tool for identifying and predicting which patients are at high risk or likely to be at high risk and prioritising the management of their care; and to provide intelligence to support the commissioning of health services. **Discussion:** IGARD noted the reference within the application to two Power Business Intelligence (BI) processors, Cloud 2 Limited and NHS Arden and Greater East Midlands (GEM) Commissioning Support Unit. IGARD asked for further clarity of the difference between the two Power BI processors and queried what different tasks the two Power BI processors were undertaking, and why one Power BI processor was not sufficient, and that further clarity / confirmation be included in Section 5 (Purpose / Methods / Outputs). IGARD noted that section 5(d) (Benefits) (iii) (Yielded Benefits) only outlined the yielded benefits for commissioning, and asked that this was updated further to reflect the benefits for **all** of the purposes outlined. IGARD queried the reference in section 5(d) (ii) (Expected Measurable Benefits to Health and/or Social Care) to Liverpool CCG's future plans of hosting *"its own business intelligence tool"*; and asked that this was removed as it could be misleading. IGARD noted that some of the NHS Digital data requested dated back to 2013, and asked for confirmation of why this historical data was required. In addition, IGARD asked to clarify if this data could be destroyed on a rolling basis. IGARD discussed supporting document 1, the data flow diagram, and in particular the reference to *"type 2 Objections"* and asked that this was removed and updated with the correct reference to the *"National Data Opt Out"*. IGARD also noted that the diagram referred to identifiable data flowing, and asked that this was updated to accurately reflect that the NHS Digital data flowing was pseudonymised.

	IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. IGARD asked that a special condition was inserted in section 6 (Special Conditions) that the applicant's privacy notice should be updated within 6-months, including, but not limited to, ensuring that it was General Data Protection Regulation (GDPR) compliant; that further details on the profiling and any other automated decision making in relation to the Risk Stratification processing activities, particularly in relation to low risk patients who appear to be subject to automated decision making was provided; That specific reference was made to the identifiers going back to the GPs for specific use; and that there was reference to the National Data Opt Out. It was noted that section 1 (Abstract) would need amending to use the full agreed wording from the NHS Digital Security Adviser regarding Cloud Storage. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of the two Power BI processors, to update section 5: a) To provide clarity of the difference between the two BI processors. b) To confirm what different tasks the two BI processors are undertaking. c) To clarify why one BI processor is not sufficient. 2. To update section 5(d) (iii) to reflect the yielded benefits for **all** purposes outlined and not just commissioning. 3. To confirm why 8 years plus of historical NHS Digital data is required; and if this data could be destroyed on a rolling basis. 4. In respect of the data flow diagram: a) To remove the reference to *"type 2 Objections"* and replace with *"National Data Opt Out"*. b) To update to accurately reflect that the NHS Digital data flowing is pseudonymised and not identifiable. 5. To update section 5(d) (ii) to remove the reference to Liverpool CCG's future plans of hosting *"its own business intelligence tool"*. 6. To insert a special condition in section 6, that the applicant's privacy notice should be updated within 6-months, including (but not limited to): a) Ensuring it is GDPR compliant. b) Providing further details on the profiling and any other automated decision making in relation to the Risk Stratification processing activities, particularly in relation to low risk patients who appear to be subject to automated decision making. c) To make specific reference to the identifiers going back to the GP's for specific use. d) To reference the National Data Opt Out. 7. To amend section 1 to include NHS Digital's Security Advisor's advice on Cloud storage and to use the full agreed wording.
2.2	<u>DSfC CCG GDPPR Template: GDPPR COVID-19 – CCG – Pseudo (Presenter: Duncan Easton) NIC-390200-K2X4F</u> **Application:** This was a new template application for CCG's to receive pseudonymised GDPPR for Commissioning, for the purpose of provide intelligence to support CCGs in their local response to the COVID-19 emergency. The data is analysed so that health care provision can be planned to support the needs of the population within the CCG area. Such uses of the data include but are not limited to, analysis of missed appointments, patient stratification and predictive modelling, and resource allocation. NHS Digital advised IGARD that the template had been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 8th July 2020,

	where it was advised that PAG were supportive of the Template application, however asked that any reference(s) to the onward sharing of data should be removed from the Template. **Discussion:** IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 21st April and 30th June 2020. IGARD noted that this application had also been reviewed at the GPES Data for Pandemic Planning and Research – Profession Advisory Group (see Appendix B) on the 8th July 2020. IGARD noted the update from NHS Digital in relation to PAG's support of the Template, and confirmed that they also supported the Template and acknowledged the work that NHS Digital had undertaken to produce this document. IGARD also supported PAG's comments in relation to removing the reference(s) to the onward sharing of NHS Digital data; and in addition asked that section 5(a) (Objective for Processing) of the Template was updated to remove the information under *"onward sharing"* and that this was replaced with a statement confirming that onward sharing was **not** permitted. IGARD discussed the list of outputs noted in section 5(c) (Specific Outputs Expected), in particular the reference to *"**Diagnosing** …the effects of COVID-19"*, and advised that as COVID-19 cannot be diagnosed that this statement was misleading, and asked that this was either removed or amended. IGARD also queried the reference in section 5(c) to one of the outputs being patient stratification, such as, *"Patients at highest risk of admission"* and asked that further clarity was provided on this, for example were these patients at high risk with a view to appropriate resource planning? In addition, IGARD also noted the reference in section 5(c) to *"Patients that are currently in hospital"* and asked that further clarity of this was provided, including confirmation of what the outputs would be. In relation to the 'Engagement on GPES Data for Pandemic Planning and Research (COVID-19)' Briefing Paper, IGARD suggested that this was updated further, to provide clarity of the number and nature of the NHS Digital data flows; to clarify the flow of data from NHS Digital to the Data Services for Commissioners Regional Offices (DSCRO) was 'identifiable'; and to confirm what data flows out of the DSCRO and the nature of the flow depending on which template is being relied upon. **Outcome:** IGARD were supportive of the revised Template if the following amendments could be made: 1. To amend section 5(a) to remove the information under *"onward sharing"* and replace with a statement confirming that onward sharing is not permitted. 2. To either remove or amend the reference in section 5(c) to the outputs *"**Diagnosing** …the effects of COVID-19"*. 3. To provide further clarity to the reference in section 5(c) to *"Patients at highest risk of admission"*, for example, are these patients at high risk with a view to appropriate resource planning? 4. To clarify the reference in section 5(c) to *"Patients that are currently in hospital"* and confirm what the outputs would be. Amendments to the Briefing Paper: 1. To update the briefing paper to clarify the number and nature of the data flows. 2. To clarify that the flow of data from NHS Digital to the DSCRO is 'identifiable'. 3. To confirm what data flows out of the DSCRO and the nature of the flow depending on which template is being relied upon.

2.3	NHS England (Quarry House): NHS England - DSfC - NCDR amendment (Presenter: Duncan Easton) NIC-139035-X4B7K **Application:** This was an amendment application to the existing Data Sharing Agreement (DSA), to 1) extend data flows of the clinical registries data until the 16th April 2023 in line with the DSA end date, 2) to add the new e-Referral Service data set, 3) to add Civil Registries – Births. In addition, the processing and storage locations have also been updated for the Commissioning Support Units and their IT providers. NHS England requires access to data collected within Clinical Registries, Databases and Audits. Part of NHS England's responsibility is to oversee the budget, planning, delivery and day-to-day operation of the commissioning side of the NHS in England as set out in the Health and Social Care Act 2012. The application was been previously considered on the 13th February 2020 when IGARD had been unable to make any recommendation as there was not enough information to address the previously-raised questions in order for IGARD to form a view and advised NHS Digital that they may wish to consider a short-term extension until resolved. NHS Digital advised IGARD that following their review of the Clinical Registries, Databases and Audits Briefing Paper on the 13th February 2020, there were some outstanding queries that NHS Digital were currently progressing in respect of NHS Digital's assessment of Data Controllership / Processorship for each Registry, however confirmed that these outstanding queries did not impact on the review of this application in respect of the amendments outlined; and that the outstanding queries would be addressed in due course. **Discussion:** IGARD noted the update from NHS Digital in respect of the outstanding queries on the Clinical Registries, Databases and Audits Briefing Paper from the 13th February 2020, and that these would be addressed in due course; in addition, IGARD discussed the breadth and scope of this complex application and advised NHS Digital that they would be focussing only on the amendments highlighted. IGARD discussed the process of assuring and onboarding of the additional datasets and advised that to support this, suggested that a working group should be convened, consisting of colleagues from IGARD and NHS Digital (Data Access Request Service (DARS), Information Governance and the Office of the Data Protection Officer (DPO)). IGARD noted the reference in section 5(a) (Objective for Processing) that the NHS Digital data would support the applicant's *"understanding of the …quality of Births"*, and asked that this was reviewed and amended as this was misleading. IGARD queried the potential outputs of the e-RS data described in section 5(a) and section 5(c) (Specific Outputs Expected), and asked that the language used was revised to ensure that these outputs were realistic and achievable. IGARD noted the reference in section 5(a) and section 5(c) to NHS England identifying *"community based alternatives"* and asked that this was either removed, since this statement was inaccurate; or that this was updated to accurately describe what NHS England could achieve within its powers. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. IGARD discussed the yielded benefits outlined in section 5(d) (Benefits) (iii) (Yielded Benefits) and advised that upon renewal, these should be updated in accordance with NHS Digital's published Expected Measurable Benefits Standard 5d.

	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. **ACTION:** NHS Digital to convene a working group to review the process of assuring and onboarding of the additional datasets. **Outcome:** recommendation to approve The following amendments were requested: 1. To review and amend the statement in section 5(a) to *"understanding of the …**quality of Births"***. 2. To revise the language in section 5(a) and section 5(c) when describing the potential outputs of the e-RS data and ensure that these are realistic and achievable. 3. To amend section 5(a) and section 5(c) to either remove the reference to NHS England identifying *"community based alternatives"*, or to update to accurately describe what NHS England can achieve within its powers. The following advice was given: 1. IGARD advised that upon renewal, the yielded benefits should be updated in accordance with NHS Digital's published Standard 5d. 2. IGARD advised that they would wish to review this application again when it comes up for renewal, extension or amendment. 3. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route.
2.4	<u>NHS England (Quarry House): National Cancer Waiting Times Monitoring Data Set (NCWTMDS) (Presenter: Frances Hancox) NIC-192305-X3T0Y</u> **Application:** This was a renewal application for pseudonymised National Cancer Waiting Times Monitoring DataSet (CWT); and amendment to 1) permit NHS England to share aggregate reports containing small numbers with Cancer Alliances, only where the Cancer Alliance has their own data sharing agreement in place to cover this flow of data, and 2) to include an additional purpose relating to the use of a sub-set of the data to conduct trend analyses on those missing a scheduled routine breast screening invitation. In addition, the applicant also wishes to share aggregate reports containing small numbers with Cancer Alliances who do not currently have their own active data sharing agreement in place for a limited time-period up to the 30th November 2020. The purpose is to monitor the time taken to diagnose and treat patients with cancer and ensure these are in-line with the expectations and rights of patients set out in the NHS Constitution. The application has been previously considered on the 21st November 2019 when IGARD had deferred pending: to provide a diagram outlining the actors involved including description of the contracting structures, roles and organisations (NHS England, NHS Digital, Cancer Alliances), flows of data; and to clarify who has responsibility for enforcing the contractual arrangements; to clearly articulate the need for the Cancer Alliances to receive the aggregated reports containing small numbers unsuppressed and confirmation that the individual Cancer Alliances have requested this data; to provide confirmation what the aggregated reports can offer the individual Cancer Alliances in addition to what is already available to them on the Cancer Waiting Times system; to update section 1 and section 5 for the cohort of patients who were identified as having missed a scheduled routine breast screening invitation, to make it clear that these individuals are not being *"tracked"* or followed-up, rather that trend analyses is being undertaken; to provide further

	clarity on the statement in section 5(d) (ii) *"28-day referral to diagnosis – TBC"*; to update section 5 to ensure acronyms are spelt out on first use (for example: *"IAO" and "SIRO"*); to amend section 1 to ensure the correct legal basis under GDPR is referenced (i.e. not research); to update section 1 under the heading *"The Data"* to remove the reference to *"anonymised"* data and replace with *"pseudonymised"* data; and to ensure this is reflected, where necessary, throughout the application. NHS Digital advised IGARD that there was a slight error within the application that stated the sub-licence template agreement end date, which currently read as the 31st November 2020, had been amended to accurately reflect the 30th November 2020. **Discussion:** IGARD noted and supported the amendment to the sub-licence template agreement to ensure this reflected the correct end date of the 30th November 2020. In addition, IGARD also welcomed the application and noted the importance of the flow of the National Cancer Waiting Times Monitoring DataSet (CWT) and the expertise of the Cancer Alliances in light of the impact to cancer services during the COVID-19 pandemic. IGARD noted that the application had been updated to reflect all of the comments previously made. IGARD queried if NHS England had carried out an appropriate Data Protection Impact Assessment (DPIA), which addressed, for example, the sharing of aggregated data with small numbers unsuppressed and the risk of re-identification; and asked that written confirmation was provided that this had been carried out. IGARD noted supporting document 4, the sub-licence template Data Sharing Agreement that had been provided and queried the period of the agreement stated, in particular the end date of December 2020, and asked that this was updated to state the correct end date of the 30th November 2020. In addition, IGARD also asked that the reference to *"**ownership** of the shared data remains with NHS England"* was amended to correctly state data *"**controllership** of the..."*. IGARD queried the information in supporting document 3, the data flow diagram, and noted that the terminology within this document did not align with the information in the application, for example the reference to *"anonymised"* data; and asked that the diagram was updated to ensure that the terminology accurately reflected the flows of data as described in the application. IGARD noted the information in point A, in section 5(a) (Objective for Processing) that stated that record level patient data was pseudonymised, and asked that this was amended to accurately reflect that this data was de-identified. **Outcome:** recommendation to approve subject to the following condition: 1. To provide written confirmation that NHS England have carried out a DPIA, that addresses (amongst other things) the sharing of aggregated data with small numbers unsuppressed and the risk of re-identification. The following amendments were requested: 1. In respect of supporting document 4, the sub-licence template agreement: a) To update to reflect the correct DSA period end date of the 30th November 2020. b) To amend the reference from data *"ownership"* to data *"controllership".* 2. To update the data flow diagram to ensure the terminology accurately reflects the flows of data as described in the application. 3. To amend point A in section 5(a) to reflect that that record level patient data is de-identified.

	It was agreed the condition would be approved OOC by IGARD Chair.
2.5	University College London: Understanding excess child and adolescent mortality in the UK (Presenter: Catherine Day) NIC-141410-W6H4Y **Application:** This was an extension application to continue to hold and process pseudonymised Hospital Episode Statistics (HES) and Civil Registration data, for a further three years; and an amendment to update the purpose of this DSA to clarify additional use of aggregate data with small numbers suppressed. The purpose is for a project exploring why the rate at which children and young people (CYP) die in the United Kingdom is higher than in many other developed countries; and to describe the overall burden and trends of healthcare utilization in England amongst CYP, which will contribute to Paediatrics 2040, a project led by the Royal College of Paediatrics and Child Health (RCPCH). Paediatrics 2040 seeks to establish a credible vision for the future of paediatric services in the UK. A key strand of this work is to understand how patterns and trends in health service utilisation may be contributing to the UK's poor international performance for multiple health outcomes, (including CYP mortality). **Discussion:** IGARD welcomed the application and noted the importance of the research. IGARD noted that ethics approval had been provided for the project outlined, however queried if, in light of the of the revised purpose, this support was continuing, for example, that the appropriate Ethics Annual Reviews had been submitted and were up to date, and that any required steps to update the Ethics Review Panel of the amendments to the study had been taken; and asked that written confirmation was provided. IGARD noted that some of the information in section 5 (Purpose / Methods / Outputs) was not clear and suggested that it was updated to ensure that it was written in a language suitable for a lay reader including reference to '*burden*' and that further sensitive consideration was given to the patient audience and how this type of language could be perceived. IGARD noted the statement in section 5(a) (Objective for Processing) to *"This will include analysing aggregated data…",* and asked that this was amended to correctly reflect that this was *"row level data"*. IGARD queried the age groups referenced in section 5(b) (Processing Activities), 1-4, 5-9, 10-14, 15-19, 20-24, and noted that these groups did not reflect the information in supporting document 1, the protocol, and asked that this information was updated to also include the 0-1 age bracket. IGARD noted the reference *"Variability in the contribution of health service factors to predominant mortality causes for CYP in England by NHS provider Trust…."* within the application, and asked that appropriate consideration was given to this, specifically in section 5(a). IGARD suggested that a plan was articulated for a mechanism for alerting the appropriate body, for example NHS England, of any significant variability by Trust. In addition, IGARD also asked that the end of section 5(c) (Specific Outputs Expected) was updated to address any variability by Trust outputs and where this could be fed into and appropriately dealt with. IGARD queried the references in section 1 (Abstract) and section 5 to *"age matched"* controls, and asked that further clarification was provided of where the age matched controls were coming from. IGARD discussed the applicant's privacy notice, and noted the statement *"If parents or adolescents over the age of 13 do not wish their health data to be made available for any non-clinical uses (such as this project), they are able to request this…"*; and asked that the privacy

	notice was updated to accurately reflect that National Data Opt Out was **not** applied in respect of the data being used in this study, and to consider that given the date range of data flowing, that not all data subjects would still be children. IGARD suggested that NHS Digital should consider connecting the applicant for this application to the applicant under NIC-331142, to ensure that any synergy from professional collaboration could be enabled. **Outcome**: recommendation to approve subject to the following condition: 1. To provide written confirmation that the Ethics support is continuing, for example, that the appropriate Ethics Annual Reviews have been submitted and are up to date, and that any required steps to update the Ethics Review Panel of the amendments to the study have been taken. The following amendments were requested: 1. To update section 5 to ensure it is written in language suitable for a lay reader and that consideration is given to the patient audience (for example when referring to *"burden"*). 2. To amend the reference in section 5(a) from *"This will include analysing aggregated data…"*, to correctly reflect that this is *"row level data"*. 3. To update section 5(b) to also include the 0-1 age bracket. 4. In respect of the reference to variation by NHS Provider Trust: a) To update section 5(a) to ensure appropriate consideration is given to the reference to the NHS Provider Trust, and that a plan is articulated for a mechanism for alerting the appropriate body, for example NHS England, of any significant variability by Trust. b) To update the end of section 5(c) to address any variability by Trust outputs and where this could be fed into and appropriately dealt with. 5. To provide further clarification in section 1 and section 5 to the where the *"age matched"* controls are coming from. 6. To update the privacy notice to accurately reflect that National Data Opt Out is **not** applied in respect of the data being used in this study, and to consider that given the date range of data flowing, that not all data subjects will still be children. The following advice was given: 1. IGARD suggested that NHS Digital consider connecting the applicants for this application to the applicants under NIC-331142, to ensure that any synergy from professional collaboration can be effected. It was agreed the condition would be approved OOC by IGARD members.
2.6	<u>Northgate Public Services (UK) Limited: National Joint Registry Annual Extract 2020 (Presenter: Louise Dunn) NIC-07289-G8J6C</u> **Application:** This was a renewal application for identifiable Hospital Episode Statistics (HES) data, Patient Reported Outcome Measures (PROMs) and Civil Registrations data; and an amendment to 1) add NHS England as a joint Data Controller, 2) remove Sunguard as a Storage Location, 3) to add Gyron Internet Ltd as Data Processor and a Processing / Storage Location, 4) to remove Iron Mountain as Data Processor and Processing Location. The National Clinical Audit and Outcomes Programme (NCAPOP) is a large programme of circa 35 projects consisting of National Clinical Audits. The application was been previously considered on the 11th June 2020 when IGARD had deferred pending: to provide a copy of the HRA CAG letter dated the 5th February 2019, which confirms the initial condition of approval referencing the linkage of data is not now taking place

	(the letter as referred to in paragraph 9, page 4, SD23); to provide confirmation that the applicant has addressed the opt out issue raised by PIAG, and if addressed, how they have complied; to update the application throughout to accurately reflect the data currently held by the University of Bristol and the data that will be held by them in the future; to clearly set out the different types of processing of the data, divided into cohort groups; and in respect of each cohort group, outline the legal bases and processing permitted by the s251 support and draw the distinction between the research and safety aspects (as the permitted processing is different between these cohort groups); to update section 5(c) to outline if consideration has been given to further routes of communication for both the cohort and the interested general public, beyond the publication of the annual report. **Discussion:** IGARD noted that the application had been updated to reflect most of the comments previously made. In particular, IGARD acknowledged the positive steps taken to address deferral point 5, in relation to the consideration given to the further routes of communication for both the cohort and the interested general public, beyond the publication of the annual report. In respect of deferral point 3, *"To update the application throughout to accurately reflect the data currently held by the University of Bristol and the data that will be held by them in the future"*, IGARD queried why the University of Bristol was currently holding approximately 20 years of NHS Digital data, and that a clear justification of this was provided. If a justification could not be provided by the applicant, that a suitable data deletion programme for the older years of historical data was outlined in section 1 and section 5(b). In respect of deferral point 2, *"to provide confirmation that the applicant has addressed the opt out issue raised by PIAG, and if addressed, how they have complied"*, IGARD asked that a special condition was inserted in section 6 (Special Conditions), that the patient information materials would be updated and in use within 3 months of the signing of the Data Sharing Agreement (DSA). IGARD also noted that the applicant had suggested adding the proposed information to the Patient Information Leaflet, and confirmed that they supported these changes being made. In addition to the points raised under deferral point 2, IGARD also queried if Health Research Authority Confidentiality Advisory Group (HRA CAG) had been notified that there was a cohort of patients who had not given consent to be added to the Registry and were not aware that their data was being held for other purposes. IGARD asked that subsequent guidance from HRA CAG was followed in respect of this cohort and that written confirmation was provided of the outcome of the discussions. IGARD also suggested that the applicant's privacy notice was updated to make clear that the National Data Opt Out was being applied, even if a patient had consented to taking part in the Registry. In respect of deferral point 4, *"To clearly set out the different types of processing of the data, divided into cohort groups; and in respect of each cohort group, outline the legal bases and processing permitted by the s251 support and draw the distinction between the research and safety aspects (as the permitted processing is different between these cohort groups)",* IGARD asked that *a*n explicit statement was included in section 5 (Purpose / Methods / Outputs) that research into the 'unknown' cohort came under purpose 2 of the s251 support; and that there was sufficient oversight within the NJR internal assurance procedures to ensure that any research using the 'unknown' cohort's data was within the parameters of purpose 2 of the s251 support.

	IGARD noted that section 3 (Common Law Duty of Confidentiality) stated that the common law duty of confidentiality was addressed by s251, and asked that this was updated to correctly state that it was addressed by s251 **and** consent. IGARD noted and applauded the yielded benefits in section 5(d) (Benefits) (iii) (Yielded benefits), which showed the impact of the research and the processing activities, and advised that these should be used as an exemplar of good practice going forward. IGARD also acknowledged the excellent outputs of the programme and the patient and public involvement. **Outcome:** recommendation to approve subject to the following condition(s) 1. To provide written confirmation that HRA CAG have been notified that there is a cohort of patients who did not give consent to be added to the Registry but are not aware that their data is being held for other purposes; and that any subsequent guidance from HRA CAG is followed in respect of this cohort. 2. In respect of the previous deferral point 3: to provide clear justification in section 1 and section 5(b) as to why the University of Bristol is currently holding approximately 20 years of NHS Digital data; and if a justification cannot be provided to outline a suitable data deletion programme for the older years of historical data. The following amendments were requested: 1. In respect of the previous deferral point 2: to insert a special condition in section 6 that the patient information materials will be updated and in use within 3 months of the signing of the DSA. 2. In respect of the previous deferral point 2: to make the suggested changes to the patient information materials. 3. In respect of the previous deferral point 4: to include an explicit statement in section 5 that research into the 'unknown' cohort comes under purpose 2 of the s251 support; and that there is sufficient oversight within the NJR internal assurance procedures to ensure that any research using the 'unknown' cohort's data is within the parameters of purpose 2 of the s251 support. 4. To update section 3 to state that the duty of confidentiality is addressed by s251 **and** consent. The following advice was given: 1. IGARD suggested that the applicant's privacy notice is updated to make clear that the National Data Opt Out is being applied, even if a patient consented to taking part in the Registry. It was agreed the conditions would be approved OOC by IGARD members.
2.7	University of Leeds: Towards UK post Arthroplasty Follow-up rEcommendations (UK-SAFE) - Work Package 2a (RO-HES) (Presenter: Louise Dunn) NIC-147997-R8B9S **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) data, for the purpose of a project which will examine the requirements for arthroplasty follow-up and produce evidence and consensus-based recommendations as to how, when and on whom follow-up should be conducted. There are 3 work packages, these will be discrete research projects, conducted independently. Knowledge and information from each will feed into and inform the other work streams with some tasks being conducted in parallel. This research seeks to demonstrate that good after-care is not necessarily expensive, in terms of time and money on the part of both patient and hospital staff, and that individual patient-

	centred follow-up can better identify potential problems in a timely fashion, to the benefit of all concerned. **Discussion**: IGARD queried if the cohort for whom NHS Digital was supplying HES data to the University of Leeds was restricted to the cohort of patients in the ResearchOne database, and asked that confirmation of this was provided since it was not clear within the application or supporting documents provided. IGARD noted the reference to the University of Oxford in section 5(a) (Objective for Processing), and in the absence of any explanation within the application or supporting documents provided asked that a suitable explanation was provided in section 5 (Purpose / Methods / Outputs) of their role in this project; noting that whilst the application does state that they were not a Data Controller or Data Processor, there was information about this study on the University of Oxford's website. IGARD noted that some of the supporting documents provided referenced Health Research Authority Confidentiality Advisory Group (HRA CAG) support, and that section 1 (Abstract) stated that the applicant had initially sought HRA CAG approval, however this application had been withdrawn. IGARD asked that a further update of the HRA CAG history was provided in section 1, which included the initial approach to HRA CAG and the subsequent withdrawal of the application. IGARD queried the presumptive statement in section 1 and section 5(a) that *"This research seeks to demonstrate that good after-care is not necessarily expensive, in terms of time and money…"*, and asked that this statement was revised in a manner which does not anticipate the outcomes of the research. IGARD noted the summary of the data flows listed in the seven points within section 5(b) (Processing Activities), and asked that these were also aligned with the bullet points also in section 5(b) that outlined the data extracts from ResearchOne. In addition, IGARD also asked that the description of the processing was clearly aligned with the information outlined in supporting document 4, the study protocol, to avoid any discrepancies. IGARD queried the references within section 5(c) (Specific Outputs Expected) to The Project / Study *"will" a*nd asked that the application was amended throughout to more accurately reflect that *The Project / Study "**may"***. IGARD noted and commended the role of the Lay members as outlined in section 1 and section 5(c), and asked that further details were provided of who the Lay members were, for example, patients with lived experience of the study matter. IGARD noted the list of organisations who supported the study in section 5(c) and asked that further information was provided of the role, if any, of those organisations. IGARD queried the reference in section 5(c) to *"the University of Leeds having strong ties with Arthritis Care…"*, noting that this organisation no longer existed, and asked that this reference was removed, or updated with its current incarnation; and to ensure that reference to any other organisations were current and reflected the situation now. IGARD noted that section 1 referred to another application using the same methodology, that had been previously recommended for approval by IGARD, however noted that the IGARD review date of the similar application was incorrect, and asked that for future ease of reference, this was updated to reflect the correct review date of the 26th April 2019. IGARD queried the information in section 3(b) (Additional Data Access Requested) that stated the data requested was *"Pseudo/Anonymised"*, and asked that this was updated to accurately reflect that the data requested was *"pseudonymised"*.

	IGARD noted the standard wording in the second paragraph of section 4 (Privacy Notice), stating that *"All Data Controllers are expected to provide a privacy notice that is compliant…"*, and asked that this was removed as the applicant had a privacy notice that met NHS Digital's Standard for privacy notices. In addition, IGARD suggested that the applicant ask ResearchOne to publish a privacy notice that would appropriately cover the dissemination of data outlined in the application. **Outcome:** recommendation to approve subject to the following conditions: 1. To provide confirmation that that the cohort for whom NHS Digital is supplying HES data to the University of Leeds is restricted to the cohort of patients in the ResearchOne database. 2. To provide a suitable explanation in section 5 of the role of the University of Oxford in this project (noting that while they are stated not to be a Data Controller or Data Processor, there is information about this study on their website). The following amendments were requested: 1. To update section 1 to provide a further update of the history of the initial approach to HRA CAG and the subsequent withdrawal of the HRA CAG application. 2. To revise the statement in section 1 and section 5(a) that *"This research seeks to demonstrate…"*. 3. To align the data flows listed in section 5(b) (points 1-7) with the bullet points (also in section 5(b)); and to ensure the description of processing is clearly aligned with the information outlined in the protocol. 4. To update section 5(c) to amend the references from *The Project / Study "will"…"* to *"may"*. 5. To provide further details in section 1 and section 5(c) of who the Lay members are, for example, patients with lived experience. 6. To update section 5(c) to provide further information of the role (if any) of the 'supportive organisations' listed. 7. To remove reference to *"Arthritis Care"* in section 5(c) as this no longer exists, or to update with its current incarnation; and to ensure reference to any other organisations are current and reflect the situation now. 8. To update section 1 to reflect the review date of the other application using the same methodology was the 26th April **2019**. 9. To update section 3(b) to accurately reflect that the data requested is *"pseudonymised"*. 10. To amend section 4 to remove the second paragraph of the privacy notice statement. The following advice was given: 1. IGARD suggested that the applicant ask ResearchOne to publish a privacy notice that would appropriately cover the dissemination of data outlined in the application. It was agreed the condition would be approved OOC by IGARD members.
2.8	<u>Office for National Statistics (ONS): Request for remote access to GPES data (Presenter: Dave Cronin) NIC-388794-Z9P3J</u> **Application:** This was a new application for identifiable GPES Data for Pandemic Planning and Research, Hospital Episode Statistics (HES) and Civil Registration data, for the purpose of research into the production of official statistics in respect of COVID-19. The results of the analysis will be used to inform members of the Scientific Emergency Group for emergencies (SAGE), Members of Parliament (MPs) and other government officials of the differing COVID-19 risk profiles experienced by UK citizens. This will enable the government to refine its policy

	response to the pandemic using the best evidence available. The analysis may also improve the public's understanding of the risk faced by individuals, leading to more informed personal decision making, and add to the growing body of literature being produced and evaluated by the global academic community. NHS Digital advised IGARD that this application had been reviewed by NHS Digital's Information Governance (IG) in respect of the proposed Health Service (Control of Patient Information) Regulations 2002 (COPI) legal basis; and NHS Digital IG had confirmed that COPI was compatible and they supported access to the data under this. **Discussion:** IGARD welcomed the application which came for advice and, without prejudice to any additional issues that may arise when the application is fully reviewed, and were supportive of this application. IGARD noted that this application had been reviewed at the GPES Data for Pandemic Planning and Research – Profession Advisory Group (see Appendix B) on the 8th July 2020. IGARD noted the update from NHS Digital in respect of the legal basis advice sought from NHS Digital's IG. IGARD asked that a written copy of this advice was uploaded NHS Digital's Customer Relationship Management (CRM) system as a future supporting document. IGARD queried the purpose of the application and asked that the introductory paragraphs in section 5(a) (Objective for Processing) were updated, to make it explicitly clear that the evaluation work was related to official statistical use, for example removing the reference *to "better understanding GPES data"*; or asked that this information was moved elsewhere within section 5(a). IGARD had a lengthy discussion with regard to the data minimisation, and noting the potential volume of data the applicant would have access to within NHS Digital's Trusted Research Environment, and asked that in line with NHS Digital's Data Sharing Standard 3, the application was updated to provide an analysis of what possible data minimisation could be undertaken. In addition, IGARD asked that if no further data minimisation was possible, an explanation was provided as to why this was not possible, in order to address both reliance on COPI as a legal basis and the General Data Protection Regulation (GDPR) data minimisation requirements. IGARD also discussed why the data could not be restricted, for example via code cluster and asked that sufficient consideration was given to this in terms of data minimisation. IGARD queried what analyses had been undertaken during the pre-assessment phase and asked that a brief summary or confirmation of analyses was provided of this analysis. IGARD noted NHS Digital's role as outlined in the application and asked that due consideration was given as to whether they should / could also be recorded as a Data Processor and a Data Storage Location. IGARD noted the data retention end data of the 12th October 2020, and suggested that consideration was given to aligning the data retention period with the current COPI Notice end date of the 30th September 2020, or to provide a further explanation of the 12th October 2020 expiry date stated. In addition, IGARD also asked that the agreed that a special condition was inserted in section 6 (Special Conditions), in relation to the transition at the end of the COPI Notice period. IGARD queried the reference in section 5(c) (Specific Outputs Expected) to the outputs being published in a *"peer reviewed journal"*; and asked that this was revised, noting that this may potentially undermine the stated purpose and legal basis relied on.

	IGARD noted the benefits outlined in section 5(d) (Benefits), and asked that these were reviewed to ensure they were not overstated, and that the potential limitations on outputs were acknowledged, for example with regard being made to affected patient groups including those in vulnerable or shielding categories. **Outcome:** IGARD welcomed the application which came for advice and, without prejudice to any additional issues that may arise when the application is fully reviewed, and were supportive of this application. IGARD suggested the following points are addressed: 1. To provide a copy of NHS Digital's IG advice regarding the legal basis and upload to NHS Digital's CRM system. 2. To update the introductory paragraphs in section 5(a) to make it explicitly clear that the evaluation work is related to official statistical use, for example removing the reference to *"better understanding GPES data"*; or to move this information elsewhere within section 5(a). 3. In respect of data minimisation (NHS Digital Data Sharing Standard 3): a) To provide an analysis of what possible data minimisation could be undertaken. b) If no further data minimisation is possible, to explain why this is not possible, in order to address both reliance on COPI as a legal basis and GDPR data minimisation requirements. c) To consider the possibility of restricting the data via code cluster. 4. To provide a brief summary or confirmation of analyses that have been undertaken during the pre-assessment phase. 5. To consider whether in section 1 and section 2 NHS Digital should / could be recorded as a Data Processor and a Data Storage Location. 6. To consider aligning the data retention period with the current COPI Notice, or to provide a further explanation of the 12th October 2020 expiry date. 7. To revise the reference in section 5(c) to outputs being published in a *"peer reviewed journal"*, as this may potentially undermine the stated purpose and legal basis relied on. 8. To ensure that the benefits in section 5(d) are not overstated and that the potential limitations on outputs are acknowledged, for example with regard being made to affected patient groups including those in vulnerable or shielding categories. 9. To insert the agreed special condition in section 6, in relation to the transition at the end of the COPI Notice period.
3	<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 COPI regulation 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 7th July can be found attached to these minutes as Appendix C. IGARD noted that there were no additional COVID-19 related items to discuss at this week's meeting.
4	<u>Returning Applications</u> Due to the volume and complexity of applications at today's meeting, IGARD were unable to review any applications as part of their oversight and assurance role.

5	AOB: 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 03/07/20

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

NIC Reference	Applicant	IGARD meeting date	Recommendation conditions as set at IGARD meeting	IGARD minutes stated that conditions should be agreed by:	Conditions agreed as being met in the updated application by:	Notes of out of committee review (inc. any changes)
NIC-331733-T2K1Z	Sandwell and West Birmingham Hospitals NHS Trust	18/06/2020	1. The applicant to complete and provide a copy of the EU Funding Form via the NHS Digital website.	IGARD members	Quorum of IGARD members	None
NIC-238282-X0B6H	Group Application x 3 CCG's *(NHS Coventry & Rugby CCG NHS South Warwickshire CCG NHS Warwickshire North CCG)*	28/06/2020	1. To provide a clear in justification section 5 for the addition of the two new Data Processors to the DSA and clarification of the benefits they will bring. 2. In respect of the pseudonymised data conversion process, in section 5(a): a) to provide a clear outline of the process and how easily this can be reversed; b) to confirm how data opt outs apply; c) to update the data flow diagram to include all relevant data flows.	IGARD members	Quorum of IGARD members	Condition 2a – "*It should be updated to reflect the NDO is not applied at any point (if this is indeed the case).*" Condition 2b – "To *state the data flow is as described in section 5b*"

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) in the period 1st February to 30th June 2020

- NIC-116548-M7Z5F NHS North East Hampshire and Farnham CCG
- NIC-116582-F2F2J NHS Oxfordshire CCG

- NIC-134552-B5T6B NHS North Cumbria CCG
- NIC-362236-D7W4M NHS Surrey Heartlands CCG
- NIC-362273-D4H7T NHS North Yorkshire CCG
- NIC-41104-C0Y4K NHS Dudley CCG
- NIC-47118-L9M1G NHS Milton Keynes CCG
- NIC-54738-M4C8H NHS South Eastern Hampshire CCG
- NIC-54781-M2F2K NHS North Hampshire CCG
- NIC-82404-V2S5B NHS South Warwickshire CCG
- NIC-89613-L9D8C NHS Sheffield CCG
- NIC-90658-F0W4R NHS East Riding of Yorkshire CCG
- NIC-90713-T3K1V NHS Wakefield CCG
- NIC-54756-R4Y4V NHS Isle of Wight CCG
- NIC-140037-T3W0M NHS Knowsley CCG

Appendix B

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 8th July 2020

Application: CCG templated content **Organisation name: NHS Digital** **Profession Advisory Group Agenda item: 4**
PAG noted that there was reference to Onward Sharing and reidentification and use for Direct Care (page 6). This should be removed since the GDPPR data was collected for secondary use (planning and research) only, as agreed by NHS Digital and RCGP/BMA. Instead it should make clear that onward sharing is not permitted. PAG supported the use of the template.

Attendees	Role	Organisation
Arjun Dhillon	Chair, Caldicott Guardian	NHS Digital
Garry Coleman	Associate Director of Data Access	NHS Digital
Anu Rao	GPC IT Policy Lead	BMA
Amir Mehrkar	GP, Clinical Researcher	RCGP
Julian Costello	GP	RCGP
Peter Short	Clinical Lead GP	NHS Digital
Pam Soorma	Secretariat	NHS Digital

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 8th July 2020

Application: DARS-NIC-388794-Z9P3J-v0.1 ONS **Organisation name: ONS** **Profession Advisory Group Agenda item: 2**
PAG supported the application. PAG noted the wide role of ONS, and felt that the application could be written to make clearer that their evaluation work is related to official statistical use rather than general data quality. PAG queried the use of identifiable rather than pseudonymised data. Whilst it was understood that there were technical constraints, and on balance it was felt that the use of identifiable was justified. PAG recommends the application explains these constraints more clearly that justify the use of identifiable data. PAG noted that the Privacy Notice needed to be updated, and it would be helpful to make clear that the common law duty is being addressed through COPI. PAG also expressed a principle that if outputs were being used to inform policy such as MPs or SAGE, then the outputs must be shared publicly. PAG also wanted to ensure that ONS were aware that Type 1 outputs were being upheld; this represents potential limitations and bias from inferences they make of their studies. PAG welcome that this application has come through the NHS Digital IGARD process rather than mandatory legal powers, this has allowed engagement with BMA and RCGP.

Attendees	Role	Organisation
Arjun Dhillon	Chair, Caldicott Guardian	NHS Digital
Garry Coleman	Associate Director of Data Access	NHS Digital
Anu Rao	GPC IT Policy Lead	BMA
Amir Mehrkar	GP, Clinical Researcher	RCGP
Julian Costello	GP	RCGP
Peter Short	Clinical Lead GP	NHS Digital
Pam Soorma	Secretariat	NHS Digital

Appendix C

Independent Group Advising on the Release of Data (IGARD)

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

held via videoconference, Tuesday, 7 July 2020

In attendance (IGARD Members):	Kirsty Irvine (Lay Chair)
	Dr. Imran Khan (Specialist GP Member)
	Dr. Geoffrey Schrecker (Specialist GP Member)
In attendance (NHS Digital):	Paul Brown (NHSD)
	Dave Cronin (DARS)
	Louise Dunn (DARS)
	Fintan Grant (NHSD)
	Fran Hancox (DARS)
	Steve Marks (NHSD)
	Karen Myers (IGARD Secretariat – Observer)
	Frances Perry (DARS)
	Heather Pinches (DARS)
	Pritpal Rayat (NHSD)
	Andy Rees (DARS – Observer)
	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 any items that were presented, and were not making formal recommendations to NHS Digital. Should an application require a full review and recommendation, then it should go through the usual Data Access Request Service (DARS) process and be presented at a Thursday IGARD meeting. The action notes from the Tuesday meeting would be received at the next Thursday meeting of IGARD and published as part of those minutes as an appendix. **Declaration of interests:** There were no declarations of interest.
2.1	<u>Patient-level Medicines data from the NHS Business Services Authority (NHSBSA)</u> **Background:** The data comprises prescriptions for medicines that are dispensed or supplied by community pharmacists, appliance contractors and dispensing doctors and prescriptions submitted by prescribing doctors in England for medicines personally administered in England. Since the outbreak of COVID-19 there has been a huge amount of interest in using this data to support the response to the pandemic including clinical trials via NHS Digital's Trusted

	Research Environments (TRE), excluding legally restricted and sensitive medicines data. National data opt-outs do not apply to NHSBSA dissemination of the data to NHS Digital however any dissemination of medicines data from NHS Digital will be in accordance with the national data opt-outs. **IGARD Observations:** IGARD members welcomed the presentation with regard to the onboarding of this dataset to the Data Access Request Service (DARS). IGARD members noted that updated privacy notices had been included on both the NHS Digital and NHSBSA website however noted that patients may not necessarily check those websites in the first instance and suggested that thought be given as to transparency material being available in both the GP practice and prescribing pharmacy. NHS Digital noted that the 'FP10' prescription had been updated in January 2020, and notwithstanding legacy stock still being used by some GP practices, that the back of this form had been updated to include further information and links to updated privacy notices. Noting that most patients would not look at the back of a paper prescription notice and that there was a move to electronic prescriptions going straight form the GP practice to the prescribing pharmacy, IGARD members suggested that more thought be given to how to ensure the patient was made aware of and kept up to date with transparency measures including with the Out of Hours Service, using the current text messaging service used by GP practices and pharmacies, or looking at utilising the NHS app. Noting NHS Digital's Data Minimisation Standard 3: Data Minimisation and the NHS Digital overview that the data minimisation function was limited on this data presently, IGARD members suggested that due to the demand for this data, that more thought be given around what data fields could be minimised by the Production Team now, and what could / could not be made available via a TRE. IGARD members queried reference to type 1 objections and if this related to dispensing practices (the presentation stated "*neither NHSBSA nor NHS Digital collect medicines data from GP practices*") and suggested that further clarity be sought as to whether the dispensing element of a dispensing practice is a separate entity. IGARD members queried if there was an intention to use this data set as part of the clinical trials to identify previously uncontacted cohorts of people and reach out to them to see if they were on 'X' medicine and if they wish to be part of future research and if this was a future intention to ensure there was a clear step plan including, but not limited to, legal bases. NHS Digital noted there were no immediate plans for using this data in that way for clinical trials. IGARD members noted that NHS Digital had developed a policy proposal for the handling of medicines associated with legally restricted and sensitive conditions, treatments and procedures, which had been clinically led internally by clinicians in NHS Digital, with external legal advice sought. NHS Digital advised that the sensitive category data was formulated entirely by reference to published legal categorisation and there was no subjective element to that grouping. It was noted that the National Data Guardian had been briefed and the proposal was with NHS X for approval. Moving forward, NHS Digital may wish to look at patient involvement in respect of this long-term project and including around the possibility of assessing the "sensitive" category data.

	Noting that the Personal Demographics Service (PDS) Team had presented to IGARD on Thursday, 3 July 2020, and IGARD members had raised with them whether '*gender*' accurately reflected the data sitting within PDS, suggested that NHS Digital ensure that where appropriate the term '*gender*' was replaced with the term '*sex*', if '*sex*' was the data set held by NHS Digital, or it was clear that both '*gender*' and '*sex*' were required, since for some medicines it may be unsafe for a particular '*biological sex*', so both '*gender*' and '*sex*' may be required. Moving forward, IGARD members suggested working with the DARS team with regard to templated applications and precedents to ensure there was no hold up in the process and suggested that the team come back to a future Thursday business as usual IGARD meeting in a couple of months to update IGARD on progress to date (especially around data minimisation) and before any applications for the new onboarded data to DARS were presented to IGARD for a recommendation. **Subsequent to the Meeting:** IGARD members noted that the privacy notice the presenters had referred to regarding the medicines data was not easily accessible, located on NHS Digital's website under '*NHSBSA Medicines Data: GDPR*'.
2.2	<u>COVID-19 Vaccine Trials (no NIC number available)</u> **Background:** This was an update to a verbal presentation to the COVID-19 response meeting on the 23 June 2020 which was about the proposed 'permission to contact' service for UK citizens and other current clinical trials which were ongoing as noted in both the UK Government's press briefings and associated news items on the BBC news website (or other news outlet website). **IGARD Observations:** IGARD members noted that NHS Digital wished to move to a precedent route, however suggested that should the number of applications be sufficient low i.e. no more than dozen or so, that the applications should be presented to a business as usual (BAU) Thursday IGARD meeting for recommendation. If after the presentation of a small number of applications to IGARD, it may be that at that time that NHS Digital consider the use of templated wording and / or a precedent in consultation with IGARD, with any such precedent having a clear list of the exclusion criteria that must be met. IGARD members suggested that in the first instance these application(s) would not be suitable for NHS Digital's Precedent route, given the potentially repercussive and high-profile nature of the work being undertaken with the data. IGARD members said that they would be looking to assess who the applicants were working with and the nature of the underlying contract between those parties to ascertain where and how the NHS Digital dataset would be used and to confirm that such use of data would be of benefit to the public in the United Kingdom. IGARD members noted that the applicants were limited to academic research institutions but cautioned that this did not necessarily protect against – in extremis - another country buying the entire world stock of a vaccine created on the basis of UK trial results. IGARD members would consider joint commercial data controllers if that reflected the true nature of the arrangement and if appropriate protections were in place for the onward use of the data. The National Institute for Health Research (NIHR), who are performing due diligence on the approved vaccine trialists should also provide NHS Digital

	with any outputs from those investigations to support applications to the Data Access Request Service (DARS). IGARD members noted the commercial section of the templated application and that further thought should be given to this section, working with the Vaccine Taskforce, to ensure that it accurately reflected the nature of pharmaceutical company funding or support and other commercial aspects of the work. This section needs to meet the current NHS Digital DARS standard 5(e) for commercial purpose. IGARD asked that a copy of the privacy notice be provided to them for comment since they had not been provided with a copy to review and it would assist in aligning the draft application with the privacy notice. IGARD suggested that moving forward NHS Digital should proactively work with the vaccine trial organisations to review draft consent documentation and before they request data from NHS Digital to ensure that the downstream work progresses smoothly.
2.3	<u>RECOVERY Trials</u> **Background:** This was a verbal update to the presentation of a number of applications and briefings to the COVID-19 response meeting on the 21 April, 28 April, 5 May, 12 May and 19 May 2020. NHS Digital noted that another English University would be added to the relevant application as a Data Processor in order to validate the study outputs / outcomes and that this would be done via NHS Digital's amendment precedent route. Moving forward worldwide verification of the outputs / outcomes would be needed and more work was being undertaken. **IGARD Observations:** IGARD members welcomed the verbal update and proposed next steps to verify the outputs / outcomes of the RECOVERY trial since independent verification was a crucial step.
2.4	<u>NIC-385834-W3T1V University of Warwick</u> **Background:** The Warwick Clinical Trials Unit (CTU) in the Warwick Medical School at the University of Warwick run a non-CTIMPS* trial called "Big Baby" to compare two widely used modes of giving birth; inducement at 38 weeks versus standard care. Recruitment had been ongoing since June 2018 via a written consent form and Patient Information Sheet. Recruitment to the Randomised Control Trial (RCT) is anticipated to continue until December 2021 with approximately 4,000 RCT participants. There is no recruitment target for the Cohort group. They currently have 1673 participants in the RCT group and 959 participants in the Cohort group. The onset of COVID-19 has not stopped the study from continuing, but has hampered the ability to recruit further participants simply due to not being able to speak to potential participants face-to-face. NHS Digital wishes to understand if the verbal collection of consent would be acceptable to allow the release of patient data at a later date. In addition, NHS Digital have requested an update to the current NHS Digital Data Access Request Service (DARS) standard 7b: Duty of Confidentiality. **IGARD Observations:** IGARD members noted that the Medicines and Health products Regulatory Agency (MHRA) and Health Research Authority (HRA) had issued a joint statement on seeking and

	documenting consent by electronic (non face-to-face) methods and agreed that this excerpt from the joint statement was particularly relevant: "*For research which is **not** a CTIMP*, it is **not** a legal requirement to provide written information or document consent in writing. Nevertheless, for the majority of research it is considered best practice and investigators should document consent unless not doing so can be justified (and approved by a Research Ethics Committee (REC))*." In the circumstances outlined in this instance, IGARD thought that the proposed means of taking consent from participants *could* be justified. Accordingly, IGARD members supported the updating of NHS Digital's DARS Standard 7b Duty of Confidence to insert an additional paragraph with regard to written consent being best practice i.e. consent being collected via face to face consent, but that consent by other means may be justified and especially due to the current ongoing COVID-19 pandemic. In reference to the proposed e-consent materials, IGARD queried the need for a second member of staff to 'witness' the telephone conversation and initialling of the consent form by staff, since witnessing was not a legal requirement and, assuming that there was appropriate procedures to follow, did not particularly add to achieving appropriate informed consent. NHS Digital also noted that there were three copies of the new e-consent form, one for the research, one for the file and one for the participant, and IGARD welcomed the fact the applicant would either post out a copy of the new e-consent form in hard copy or provide at the participants next hospital visit. IGARD members also suggested that NHS Digital work with the applicant to ensure that the consent material was appropriately worded to ensure that the applicant would be able to receive all the relevant NHS Digital data - on both the mother and baby – that they required for the study. NHS Digital noted within the '*Big Baby tracked protocol v8.0 8 June 2020*' the following newly inserted paragraph: "*Women who require a translator to understand the Participant Information Sheet and the consent form may not be recruited into the trial through a process of remote consent, as it will be difficult for the research staff to assess if the woman has understood the information provided*." and asked if this would affect the results of the study. IGARD members noted that it was quite commonplace to use the NHS telephone interpreting service and that this paragraph should be removed or re-worded and the applicant encouraged to ensure equality of access to potential participants. (**Clinical Trial of an Investigational Medicinal Product*)
2.5	<u>NIC-390154-Z4M0F Public Health England (PHE)</u> **Background:** This was a new application for GPES Data for Pandemic Planning & Research (GDPPR) and is a priority request with a legal basis of the National Health Service (Control of Patient Information Regulations) 2002 (COPI). The broad aim is understanding COVID-19 and risks to public health, trends in COVID-19 and such risks, and controlling and preventing the spread of COVID-19 and such risks, for research and planning purposes. NHS Digital noted that this was a verbal update of an application which would be presented to both the Profession Advisory Group (PAG) before submission to a business as usual (BAU) Thursday IGARD meeting for a recommendation.

	IGARD Observations: Noting that the applicant is aware of the restrictions of receiving data under the COPI notice, IGARD suggested that the legal basis relied upon in section 1 (Abstract) should be updated to correctly reference 'research' and to align the research aims with the relevant COPI notice. IGARD members suggested that since the GDPPR dataset was such a rich source of data and that not all the data may be relevant to their study, that applicant should provide detail of how it meets NHS Digital's DARS standard 3: Data Minimisation. The application was clearly about the risk factors of COVID-19 only, not predictive or modelling for COVID-19, so suggested that the applicant may also wish to consider minimising the data to those that tested positive for COVID-19, for example (and an appropriately sized control group, if also strictly necessary). IGARD members suggested that a verbal update be given at next week's COVID-19 response meeting following NHS Digital's further discussions with the applicant with regard to data minimisation.
2.6	<u>NIC-331142-P5K6M University of Bristol</u> **Background:** This was an early application discussion with associated supporting documentation with regard to child mortality review data gathered by the National Child Mortality Database (NCMD) which holds data on all children in England who were liveborn and died before their 18th birthday. This is a statutory process and provision is made within the Children Act 2004 for the collection and processing of this data without consent and the legal basis for the NCMD to receive, hold and analyse the data collected is rooted in the statutory authority set out in the Children Act Section Under s16m(3). The University of Bristol have been commissioned by NHS England via Healthcare Quality Improvement Partnership (HQIP) to undertake a real time survey of COVID-19 related mortality data. **IGARD observations:** IGARD members noted the verbal update from NHS Digital and limited information available for review, but observed that this was an important study to ensure that all child deaths were investigated appropriately. IGARD members noted the legal opinion document provided and suggested that the applicant may wish to rely on provision under the Children Act 2004 as a legal basis, rather than emergency National Health Service (Control of Patient Information Regulations) 2002 (COPI) powers which will fall away at some point in the future. However, IGARD members noted reference to statutory guidance being updated to establish a clear legal gateway and suggested that NHS Digital check if it had indeed been updated and that it was the best fit for the proposed processing. NHS Digital noted that they were working with the applicant to bring an application and relevant supporting documents to a business as usual Thursday IGARD Meeting, however IGARD members suggested that NHS Digital may wish to discuss at a COVID-19 response meeting prior to this. In terms of aspects to focus on, the applicant may wish to consider how they will maximise the impact of their research outputs, particularly considering that the UK has very high/rising child mortality rates compared to comparable nations.

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