Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 7 October 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member
Kirsty Irvine (Chair)	IGARD Chair / Lay Representative (Chair: item 3.1)
Dr. Imran Khan	Specialist GP Member
Dr. Maurice Smith (Chair)	Specialist GP Member (Chair: items 1, 2.1, 3.2 – 3.7)
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Prof. Nicola Fear	Specialist Academic Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Dan Goodwin	Data Access Request Service (DARS)
Frances Hancox	Data Access Request Service (DARS)
Karen Myers	IGARD Secretariat
Jonathan Osborn	Deputy Caldicott Guardian (Observer: items 1- 3.3)
Tania Palmariellodiviney	Data Access Request Service (DARS)
Denise Pine	Data Access Request Service (DARS)
Vicki Williams	IGARD Secretariat
Tom Wright	Data Services for Commissioners

1	**Declaration of interests:** Maurice Smith noted a professional link with NHS Liverpool CCG (NIC-47191-D9X6J) and would not be part of the discussion. It was agreed that Maurice would not remain in the meeting for the discussion of that application. **Review of previous minutes and actions:**

	The minutes of the 30th September 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	<u>One London Collaborative – Briefing Paper (Presenter: Tom Wright)</u> Following the Integrated Care System (ICS) sublicensing paper that was discussed at the IGARD business as usual (BAU) meeting on the 30th September 2021 and the CCGs sharing commissioning data with members of their ICS paper that was discussed at the IGARD BAU meeting on the 26th August 2021; this briefing paper was to inform IGARD about an application from NHS North West London CCG (NWL), NHS North East London CCG (NEL) and NHS South West London CCG (SWL), to sub license identifiable Secondary Uses Service (SUS) for commissioners to the member organisations of their respective Integrated Care System (ICS) to enable both commissioning and direct care uses of the data. In May 2018, ONE London was one of the first three Local Health and Care Record Exemplars (LHCRE) to be announced by NHS England. Each LHCRE was expected to develop a Data Service that had 23 capabilities[i] which included Data Integration & Data landing, Data processing, Data Rules Management, Data Transfer and Dissemination, and De-identification/Re-Identification. At that time NEL, NWL and SWL decided to jointly develop the Discovery Data Service (DDS) as their integrated data store. From that time, they have been working to develop the data service to bring data together to support, Individual (direct) care, Population Health Management (including individual care), Public Health and Commissioning. To date the principal data feed into the DDS is from primary care with personal coded data being accessed in close to real time from all the 840 GP practices in the collaborative's ICSs. The ICS Digital Teams are all expected to acquire information from all major contributors to the ICSs – Primary Care, Secondary Care, Mental Health, Social Care and Community Care. Work is currently underway on secondary care data sources. A standard is being developed for admission, discharge and transfer (ADT) and Test result (ORU) HL7 feeds for the collaborative. In order to obtain a totally standardised extract and to acquire secondary care data from wherever their patients experienced it the collaborative will be making an application to NHS Digital via the Data Access Request Service (DARS). **Outcome:** IGARD welcomed the briefing paper and made the following high-level comments: 1. IGARD confirmed that they were supportive of the overall concept outlined in the briefing paper. 2. To update the briefing paper, in line with all previous comments within published minutes, on this topic, for example, the IGARD business as usual (BAU) minutes from the 30th September 2021. 3. To provide an analysis of how the SUS data aligns with the scope of the Direction, and permitted use of the data. 4. To provide an analysis of how the SUS data aligns with the NHS Digital UK GDPR Register. 5. In respect of the ICS Data Access Committees:

	a) To clarify how panel members are recruited. b) To clarify if panel members are renumerated. c) To clarify if the Lay members represent the community in which the ICS resides. d) To clarify if the ICS Data Access Committees have any clinical input. e) To provide a copy of the ICS Data Access Committees ToR. f) To clarify if the ICS Data Access Committee have any set processes or criteria for access to the data. 6. IGARD noted that the case studies provided, should be reviewed or removed as necessary. 7. To review the briefing paper throughout, to correct any typos. IGARD welcomed the draft briefing paper and looked forward to receiving the updated briefing paper at a future meeting, and before any first of type applications were received by IGARD.
3	**Data Applications**
3.1	<u>NHS Liverpool CCG: (Presenter: Dan Goodwin) DSfC - Liverpool Joint Commissioning NIC-47191-D9X6J-v6.4</u> **Application:** This was a renewal and extension application for pseudonymised Secondary Uses Service (SUS+) data, 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) and Medicines Dispensed in Primary Care (NHSBSA Data). It was also an amendment to **1)** add Liverpool City Council as a Data Controller, **2)** to remove NHS Liverpool CCG's processing of SUS data for the purposes of Risk Stratification and Invoice Validation, and **3)** to add Adult Social Care Data. The purpose of the data request is to provide intelligence to support the commissioning of health services. NHS Digital noted that prior to the meeting, an IGARD member had queried how the points from the IGARD business as usual (BAU) meeting on the 9th July 2020 had been addressed; and NHS Digital verbally confirmed that following this query, a further supporting document had been shared with the IGARD, outlining the updates on the relevant points made at this meeting. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the Data Access Advisory Group (DAAG) (IGARD's predecessor) on the 28th July 2016; and the IGARD business as usual (BAU) meetings on the 28th March 2019 and the 9th July 2020. IGARD noted the verbal update from NHS Digital, in respect of the query, requesting an update on the points raised at the IGARD BAU meeting on the 9th July 2020; and noted that an additional supporting document had been shared with members outlining how the points had been addressed. IGARD did however query the update on amendment point 6 *"To insert a special condition in section 6, that the applicant's privacy notice should be updated within 6-months…"*, and noted that NHS Digital had removed this. NHS Digital advised that the special

	condition had been removed as it was deemed no longer relevant. IGARD noted the verbal update from NHS Digital, however advised that due to the substantive issues raised on the applicant's privacy notice previously, the special condition should only be removed once the special condition had been adequately addressed. IGARD queried the statement in section 1 (Abstract) that one of the purposes of the application, was to seek clarification whether *"…IGARD members are content for applications where a Local Authority is being added as a data controller for commissioning purposes to be approved via *IAO and Director under the Class Action Governance Path Category."* (*IAO = Information Asset Owner). IGARD noted that NHS Digital had presented a briefing paper at the IGARD BAU meeting on the 6th May 2021, in respect of local authorities being regarded as commissioners along with CCGs, however advised that they had not had sight of the updated briefing paper, that reflected the updates made following the comments made by members. IGARD therefore advised that they would be unable to support the class action request, until they had received a copy of the updated briefing paper, as per process. IGARD queried the references in section 5(b) (Processing Activities) to *"direct care"*, noting that there was no reference to this elsewhere in the application; and queried, how direct care aligned with the purpose of the application which was for *"commissioning"*. IGARD asked that for transparency and to ensure consistency and accuracy throughout the DSA, section 5(a) (Objective for Processing) was also updated to reflect that the data requested would be for the purpose of direct care, as outlined in section 5(b). IGARD also reiterated their previous advice that the reidentification of patients for direct care should only be undertaken in exceptional circumstances, and not as a routine function of *"commissioning"* applications. In addition, NHS Digital advised that there were ongoing discussions internally, in respect of how direct care was addressed in these applications and IGARD suggested that a workshop be put in place to discuss how the direct care element is addressed in commissioning applications and to look at agreeing a consistent approach for this type of application moving forward. It was agreed that the IGARD Secretariat would arrange a workshop with Data Access Request Service (DARS), Data Services for Commissioners Regional Offices (DSCROs) and IAOs, to discuss direct care, how this is addressed in commissioning and other applications, and agree a consistent approach going forward. IGARD noted information published on NHS Digital's public facing website, for example, in respect of the SUS for commissioning data, that stated *"This information is also useful to commissioners and providers of NHS-funded care for 'secondary' purposes - purposes other than direct or 'primary' clinical care…"*; and noted that there was a significant risk to NHS Digital, in respect of data being used for direct care where that may not be within the scope for the collection of the data, and suggested that an analysis of the relevant Direction should be undertaken. 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. IGARD noted that a query had been raised on this particular point with the Privacy, Transparency and Ethics (PTE) Directorate and welcomed an update from DARS in due course.

	IGARD noted the inconsistent references to *"The University of Liverpool"* and "*Liverpool University*" within the application, and asked that the application was reviewed throughout, to ensure it correctly referred to *"The University of Liverpool".* IGARD noted the addition of Liverpool City Council as a Data Controller, however queried the UK General Data Protection Regulation (UK GDPR) legal basis for processing, noting that this was not clear within the application; and asked that section 1 was updated, Liverpool City Council's UK GDPR legal basis for processing and, if relevant, how it meets Data Protection Act (DPA) 2018 requirements for processing of special category personal data. IGARD noted and thanked the applicant for the updated yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits), however asked that further details were provided of the specific yielded benefits accrued to date, and asked that it was clear as to the benefits to both the patients and the health and social care system more generally, for example, the benefits to the CCG and local community; and in line with NHS Digital's DARS Standard for Expected Measurable Benefits. **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 approach is supported by advice on this point from PTE. 2. To update section 5(a) to reflect that the data requested, will be used for the purpose of direct care, as outlined in section 5(b). 3. To update the application throughout to correctly refer to *"The University of Liverpool"* (as opposed to Liverpool University). 4. To provide further details in section 5(d) of the yielded benefits accrued to date and ensure these are clear as to the benefits to both patients and the health care system more generally, for example, the benefits to the CCG and local community; and in line with NHS Digital's DARS Standard for Expected Measurable Benefits. 5. To set out in section 1 Liverpool City Council's UK GDPR legal basis for processing and, if relevant, how it meets DPA 2018 requirements for processing of special category personal data. The following advice was given: 1. IGARD reiterated their previous advice that the reidentification of patients for direct care should only be done in exceptional circumstances, and not as a routine function of *"commissioning"* applications. **ACTION:** IGARD Secretariat to arrange a workshop with DARS, DSCROs and IAOs, to discuss the need for data for direct care, how this is addressed in commissioning and other applications, and agree a consistent approach going forward. **Significant risk area:** using data for direct care where that may not be envisaged as part of the scope for the collection of the data, for example, SUS for commissioning.
3.2	University of Oxford: Study of Heart and Renal Protection (SHARP) Post-trial (Presenter: Frances Hancox) NIC-147782-0D7TX-v4.2 **Application:** This was an extension application, to permit the holding and processing of identifiable Hospital Episode Statistics Admitted Patient Care (HES APC), Medical Research

	Information Service (MRIS) - Cause of Death Report, MRIS - Cohort Event Notification Report, MRIS - Flagging Current Status Report, and MRIS - Members and Postings Report. The SHARP trial which started in 2003 and finished in 2010, assessed the effect of lowering low-density lipoprotein (LDL) cholesterol with a combination of simvastatin 20mg plus ezetimibe 10mg versus a matching placebo on major vascular disease (e.g. heart attacks, strokes) and renal disease (e.g. starting dialysis) events. The purpose of this application is for the SHARP post-trial follow-up (PTFU) project, which is to assess the longer-term effects among surviving SHARP patients on the time to first major atherosclerotic events (MAEs) and major vascular events (MVEs), defined as non-fatal myocardial infarction or cardiac death, non-fatal or fatal stroke, or any arterial revascularisation procedure (excluding vascular access surgery for dialysis). This will be done by analysing data routinely reported into UK clinical databases from when the SHARP trial ended in 2010. The secondary aims are to assess the longer-term effects among surviving SHARP patients on: a) progression to end stage renal disease, b) any hazardous effects (such as site-specific cancers, other than non-melanoma skin cancer) and mortality by cause. The follow-up trial has been limited to a cohort of 1,759 participants from England and Wales; and is relying on s251 of the NHS Act 2006, for the flow of data from NHS Digital. NHS Digital advised IGARD that there were references to *"Cancer Registration data"* in section 5 (Purpose / Methods / Outputs), and noted that this was historical information from a previous version of the application, and confirmed that Cancer Registration data was not requested under this Data Sharing Agreement (DSA), and all references would be removed from the application. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 1st November 2018. IGARD noted the verbal update from NHS Digital, in respect of the references to *"Cancer Registration data"* incorrectly stated within the application; and supported the update to remove these references. IGARD confirmed that they were of the view that the relevant s251 support provided the appropriate legal gateway and was broadly compatible with the processing outlined in the application. IGARD noted the purpose of the application was to extend the current DSA, however queried what this covered, noting the reference in section 1 (Abstract) to the *"current DSA"* resending data, and queried what this related to, for example, has the data already reflowed, and if so, has the previous supply of data been destroyed. IGARD therefore asked that confirmation was provided, that any necessary data destruction had taken place and that a copy of the data destruction certificate was uploaded to NHS Digital's CRM system for future reference. 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, and technical terms are explained in a manner suitable for a lay audience, for example *"logrank analyses"*. IGARD queried the conflicting information in the application that the Medical Research Council (MRC) were funding the study, and the University of Oxford Clinical Trial Service Unit (CTSU) SHARP website that stated Merck, Sharp and Dohme (MSD) were funding the study. The CTSU website does not explicitly state that MSD do not fund the PTFU project IGARD asked that this was aligned, and that confirmation was provided in section 8(b) (Funding Sources)

	that MSD were no longer funding the study, and that the MRC were funding the study going forward; and that any funding documentation was uploaded to NHS Digital's CRM system for future reference. **Outcome:** recommendation to approve subject to the following condition: 1. In respect of the funding: a) To confirm in section 8(b) that Merck, Sharp and Dohme (named as funder on the CTSU SHARP website) are no longer funding the study. b) To confirm in section 8(b) that the Medical Research Council (MRC) are funding the study going forward. c) To upload any funding documentation to NHS Digital's CRM system for future reference. 2. In respect of the resupply of data and data destruction: a) To provide confirmation that any necessary data destruction had taken place. b) To upload a copy of the data destruction certificate, to NHS Digital's CRM system for future reference. The following amendments were requested: 1. As section 5 forms NHS Digital's public data release register, to amend section 5 throughout, to ensure acronyms be defined upon first use, and technical terms are explained in a manner suitable for a lay audience, for example, *"logrank analyses"*. The following advice was given: 1. Noting that the application was due to expire on the 20th October 2021, IGARD suggested that NHS Digital put in place a short-term extension until the conditions and amendments above had been addressed. It was agreed the conditions would be approved out of committee (OOC) by IGARD members.
3.3	<u>Ignite Data Limited: Investigation of TRELEGY Effectiveness: Usual Practice Design (INTREPID) Exploratory data set (Presenter: Denise Pine) NIC-297783-V4P6H-v1.3</u> **Application:** This was an extension application to permit the holding and processing of pseudonymised Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC), HES Critical Care and HES Outpatients; and an amendment to add the David Jack Centre for Research and Development as an additional storage and processing location. Healthcare resource utilisations (HCRU) is the quantifiable measure of a person's use of services for the purpose of both preventing and curing health problems, the promotion of maintenance of health and wellbeing. Through systematic review the disease burden experienced by both the patient and their healthcare providers can be assessed. The purpose is for a study, to **1)** assess the feasibility of using routine healthcare data to collect secondary care healthcare resource utilisation data (all cause and Chronic Obstructive Pulmonary Disease (COPD) related) in clinical trials using NHS Digital data for patients consented into the INTREPID study. The study will describe the recording and completeness of different components of secondary care HCRU and the ability to apply Healthcare Resource Group (HRG) tariffs to these where possible; and **2)** to use the NHS Digital data to summarise HCRU and costs using Healthcare Resource Group (HRG) tariffs for COPD patients on inhaled triple therapy for patients consented into the INTREPID study. The trial consists of 629 consented individuals from England only.

	NHS Digital advised IGARD that (NHS Digital) auditors were currently in the process of undertaking an audit on this Data Sharing Agreement, and that the applicant had notified colleagues within Data Access Request Service (DARS), to advise that although the audit had not concluded, the auditors had identified a technical breach, in respect of the territory of use. **Discussion:** IGARD thanked NHS Digital for the verbal update, in respect of the ongoing NHS Digital audit on the DSA, and the technical breach that had been identified in respect of the territory of use. IGARD noted that as the audit was still ongoing, they would have to await the outcome of this report, to support a full review of the application at a future IGARD business as usual (BAU) meeting, as per process. IGARD noted the action plan set out in section 1 (Abstract) on some of the areas that need addressing, for example, the update to section 5 (Purpose / Methods / Outputs), and confirmed that they were supportive of the points raised. IGARD confirmed that they were of the view that the most recent consent materials provided the appropriate gateway and were broadly compatible with the processing outlined in the application. NHS Digital advised IGARD, that following submission of the application and supporting documents for IGARD to review, the applicant had submitted a supplementary privacy notice, that was specific to the study, and would be available within GP Practices and published on the GP Practice websites. IGARD noted the verbal update from NHS Digital, however, were unable to make specific comments on the content of the study specific privacy notice, noting they had not had sight of this. IGARD, however, asked that the applicant ensured that a UK General Data Protection Regulation (UK GDPR) compliant privacy notice was accessible and available, for example, via a study specific website. In addition, IGARD noted that the applicant should not rely on GP Practices to make the privacy notice available, since it was the applicant's responsibility to make the privacy notice accessible and available. IGARD noted the statement in section 5(a) (Objective for Processing) *"…the disease burden experienced by both the patient and their healthcare providers can be assessed…",* and asked that this was amended, as healthcare providers do not experience *"disease burden"* and was therefore incorrect. IGARD noted the link provided in section 5(a) to the NHS.uk weblink explaining Healthcare Resource Group (HRG) tariffs, however advised that the link was incorrect, and asked that this was updated with the correct weblink. IGARD suggested that section 5(d) (Benefits) be updated to remove reference to "*it will*…" and instead use a form of words such as "*it is hoped*…". IGARD queried the benefits outlined in section 5(d), and noted that some of the information provided were outputs, and asked that section 5(d) was updated to remove any outputs and edit to only leave examples that reflect the benefits to the Health and Social Care System; and in line with NHS Digital's DARS Standard for Expected Measurable Benefits. IGARD noted the statement in section 5(d) (iii) (Yielded Benefits) *"Due to delays, quality checks of the data prior to analysis are only just being completed as detailed in the Statistical Analysis Plan"*, and asked that additional information was provided on the statistical analysis plan; or, the statement was removed and replaced with a brief explanation as to why there were no yielded benefits accrued to date, and in line with NHS Digital's DARS Standard for Expected Measurable Benefits:

	Noting that the current DSA was due to expire on the 19th October 2021, IGARD suggested that NHS Digital put in place a short-term extension, pending the formal audit report being received and before it is fully reviewed at a future IGARD BAU meeting. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the technical data breach. **Outcome:** IGARD welcomed the application which came for advice and without prejudice to any additional issues that may arise when the application is fully reviewed. 1. IGARD suggested that NHS Digital put in place a short-term extension, pending the formal audit report being received. 2. IGARD noted NHS Digital's action plan and were supportive on all the points raised. *3.* To amend the statement in section 5(a) *"…the disease burden experienced by both the patient and their healthcare providers can be assessed…"* as healthcare providers do not experience *"disease burden".* 4. To add the correct NHS.uk weblink explaining HRG in section 5(a). 5. In respect of the benefits and in line with NHS Digital's DARS Standard for Expected Measurable Benefits: a) To update section 5(d) to use a form of wording such as "*it is hoped* …", rather than "*it will*…". b) To remove any specific outputs from section 5(d) and move to section 5(c), or edit as appropriate. c) To update the reference to *"Statistical Analysis Plan"* in section 5(d) (iii), with additional information; or, d) To remove the information in respect of the *"Statistical Analysis Plan"* in section 5(d) (iii), and replace with a brief explanation as to why there are no yielded benefits accrued to date. 6. In respect of the study specific privacy notice (which IGARD had not seen): a) The applicant to ensure that a UK GDPR compliant privacy notice was accessible and available, for example, via a study specific website. b) IGARD noted that the applicant should not rely on GP Practices, since it was the applicant's responsibility to make the privacy notice, accessible and available. 7. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the technical data breach. 8. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the technical data breach.
3.4	University College London (UCL): Educational outcomes in children born after assisted reproductive technology; a population-based linkage study (Presenter: Tania Palmariellodiviney) NIC-258079-G7W1Y-v0.10 **Application:** This was a new application for pseudonymised Birth Notification Data and Civil Registration (Births); and identifiable Demographics data. The purpose is for a population-based cohort study, to, **1)** compare educational outcomes among children born following assisted reproductive technology (ART) with children born following natural conception (siblings); **2)** to compare the frequency of special educational needs (SEN) and school exclusion among children born following ART with children born following natural conception; **3)** To compare outcomes for specific types of ART and specific causes of infertility.

	The cohort of ART conceived children and their naturally conceived siblings will be linked with the National Pupil Database (NPD), in order to explore their educational outcomes. The NPD contains detailed information about the educational attainment of all pupils in state sector schools and sixth-form colleges in England; and is now being made available for research purposes through the Office for National Statistics Secure Research Service (ONS-SRS). The NPD will also be used to identify a second control group of unrelated (non-sibling) school-matched controls for the ART Cohort. The Department for Education (DfE) will flow the identifiers of the unrelated school-matched controls to the ONS, for the ONS to retrieve their key confounding variables for deposition in the ONS-SRS. The study is relying on s251 of the NHS Act 2006, for the flow of data from NHS Digital. **Discussion:** IGARD advised NHS Digital that they were aware that DfE was subject to an audit by the Information Commissioner's Office (ICO) in 2020, which raised a number of concerning issues regarding data handling. IGARD asked that written confirmation, such as an e-mail, was provided that NHS Digital's Security Advisor had expressed satisfaction that the appropriate security was in place; and that the confirmation was uploaded to NHS Digital's customer relationships management (CRM) system for future reference. IGARD confirmed that they were of the view that the relevant s251 support provided the appropriate legal gateway and was broadly compatible with the processing outlined in the application. IGARD noted the cohort of children was all pupils in state sector schools and sixth-form colleges in England, and advised that this will exclude non-state funded independent schools, and those special schools which were privately funded, which may limit the research being undertaken. IGARD noted the sensitives outlined within the application, in respect of the cohort of children and the subject matter being studied, and potential risks involved; and suggested that the applicant carried out a Data Protection Impact Assessment (DPIA), to address the possible contentious nature of the processing, and the sensitivities around the data. IGARD noted that the applicant was requesting flows of data for individuals born between 1992-2009, and asked that further clarification was provided in section 5(a) (Objective for Processing) of the rationale, and why data was not being requested from 2010 onward since this was an evolving area of science in respect of ART. IGARD noted the identifiable **and** pseudonymised data requested, and queried what data would be flowing to DfE, noting that this may impact on the identifiability of the data subjects. IGARD asked that clarification was provided in section 3(b) (Additional Data Access Requested) if only the identifiable Demographics data would be flowing to DfE; or, to clarify in section 3(b) if the pseudonymised datasets would be flowing to DfE at the same time, thus rendering all the data as identifiable. IGARD asked that this was also clarified within the public facing section 5 (Purpose / Methods / Outputs), for transparency. IGARD suggested that section 5(d) (Benefits) be updated to remove reference to "*it will*…" and instead use a form of words such as "*it is hoped*…". IGARD noted the incorrect reference to there being *"joint"* Data Controllers in section 1(b) (Data Controller(s)), and asked that this was removed, noting that University College London were the sole Data Controller.

	IGARD queried the statement in section 1(c) (Data Processor(s)) for DfE *"NHS Digital DSPT team confirmed 'Standards Met' on 26/06/2020"*, and asked that the date was reviewed and updated as appropriate. IGARD noted the inclusion of a number of technical phrases and words within section 5(a) such as *"conditional analyses"* and suggested that this was updated to be written in a language suitable for a lay reader and technical terms were either removed, or used only where necessary, and further explained upon first use, and in line with NHS Digital's DARS Standard for Objective for Processing. IGARD noted the summary of the patient and public involvement and engagement (PPIE) undertaken to date within the application, and strongly suggested that the applicant undertakes further PPIE, in some form and throughout the lifetime of the DSA, given the significant amount of data flowing, the public interest and the wide scope of the application, and in line with the HRA guidance on Public Involvement. **Outcome:** recommendation to approve subject to the following condition: 1. In respect of the security arrangements: a. To provide written confirmation (such as an e-mail) that NHS Digital's Security Advisor has expressed satisfaction that the appropriate security is in place. b. To upload the written confirmation from NHS Digital's Security Advisor to NHS Digital's CRM system for future reference. The following amendments were requested: 1. To clarify in section 5(a) the rationale for the years of data flowing. 2. To update section 5(d) to use a form of wording such as "*it is hoped* …", rather than "*it will…*". 3. To update section 1(b) to remove the incorrect reference to *"joint"* Data Controllers. 4. In respect of the data requested: a) To clarify in section 3(b) if DfE will only be getting identifiable Demographics data; or, b) To clarify in section 3(b) if DfE will also be getting the pseudonymised datasets at the same time, thus rendering all the data as identifiable. c) To clarify the above points in section 5 for transparency. 5. To amend section 5(a) to ensure statistical terms of art and technical terms are either removed or explained in a manner suitable for a lay audience, for example, *"conditional analyses"*. 6. To review and update the standards met date in section 1(c) for DfE. The following advice was given: 1. IGARD noted the summary of the PPIE undertaken to date within the application, and strongly suggested that the applicant undertakes PPIE, in some form and throughout the lifetime of the DSA, given the significant amount of data flowing, public interests and wide scope of the application, and in line with the HRA guidance on Public Involvement. 2. IGARD noted the cohort of children is limited, by the exclusion of non-state funded independent schools, and those special schools which are privately funded, which may limit the research being undertaken. 3. IGARD suggested the applicant carried out a DPIA, due to the possible contentious nature of the processing, and the sensitivities around the data.

	It was agreed the condition would be approved out of committee (OOC) by IGARD members.
3.5	The University of Manchester: Evaluating prescribing safety indicators embedded in computerised clinical decision support software (Presenter: Vicky Byrne-Watts) NIC-253220-Q1X8H-v0.5 **Application:** This was a new application presented at the IGARD business as usual (BAU) meeting on the 11th March 2021, for Hospital Episodes Statistics Admitted Patient Care (HES APC) and Critical Care data, and Civil Registrations (deaths) data; for the purpose of evaluating two large-scale interventions in English general practices that employ prescribing safety indicators to reduce hazardous prescribing and avoidable harm to patients, 1) the clinical decision support software OptimiseRx, and 2) a pharmacist-led IT based intervention (PINCER). **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD BAU) meeting on the 11th March 2021; where the application had been recommended for approval with a condition, amendments and advice. IGARD noted that as outlined in the Out of Committee (OOC) Standard Operating Procedure, any applications returned to the IGARD Secretariat for review OOC by the IGARD Chair or quorum of IGARD Members which were over three months old, would be automatically placed on the next available BAU meeting agenda for review by IGARD Members as per the current standard processes. Members would only review if the conditions have been met or not, and would not re-review the application, unless significant legislative or policy changes had occurred since last reviewed by a full meeting of IGARD or the application had been significantly updated, in which case the conditions may be updated to reflect such changes which will be noted for transparency in the published minutes and a full review of the application undertaken. The condition from the 11th March 2021 BAU meeting were as follows: 1. To update section 1 and throughout section 5 to clarify that this study relates to the economic evaluation of point of prescription decision support and not just one commercial product. A quorum of IGARD members were content that the condition had been met subject to the following amendments: 1. In respect of amendment point 1: To update section 5(e), in line with NHS Digital DARS Standard for Commercial Purpose, to reflect any commercial aspects, for example the intellectual property (IP) rights.
4	Applications progressed via NHS Digital's Precedent route, including the SIRO Precedent 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.*
5	Oversight & Assurance 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 requested, but had not as yet been provided with, an IG CV19 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.
6	<u>COVID-19 update</u> To support NHS Digital's response to COVID-19, from Tuesday 21st April 2020, IGARD will hold a separate weekly meeting, to discuss COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 urgent applications that have been submitted to NHS Digital. Although this is separate to the Thursday IGARD meetings, to ensure transparency of process, a meeting summary of the Tuesday meeting will be captured as part of IGARD's minutes each Thursday and published via the NHS Digital website as per usual process. The ratified action notes from **Tuesday 5th October 2021** can be found attached to these minutes as Appendix B.
7	<u>AOB:</u> There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 01/10/21

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-386376-Z1H5J	Renal Registry	03/06/2021	1. In respect of data controllership, and in line with NHS Digital's DARS Standard for Data Controllers: a) To provide written confirmation that King's College London as the legal entity for KiTEC is **not** a joint Data Controller, given KiTEC's activities outlined in the application. r. b) To provide written confirmation that NHS England is **not** a joint Data Controller, given NHS England's activities outlined in the application. c) To provide written confirmation that NICE is **not** a joint Data Controller, given NICE's activities outlined in the application. To update the application throughout, as may be required, to reflect the factual scenario. 2. To provide evidence that the OMB and Lead Clinician, have approved the sharing of data with KiTEC in accordance with the information provided to patients in the PIS as stated in Section 5.	OOC by IGARD members	A quorum of IGARD members at the IGARD BAU meeting on the 23/09/2021, due to the period of over 3-months that had passed since the conditions were agreed – and as outlined in the Out of Committee (OOC) Standard Operating Procedure,	• Condition 1(a) – please amend section 1c to remove King's Technology Evaluation Centre (not a legal entity) as a Data Processor and to include King's College London (as the legal entity and in line with the DARS Standard for Data Processors) • Condition 1(c) – NICE are still referred to in section 5 as "commissioning" (first paragraph 5a) – please remove this reference (and in line with the DARS Standard for Data Controllers)

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

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

Liaison Financial Service and Cloud storage:

- None

Optum Health Solutions UK Limited Class Actions:

- None

Graphnet Class Actions:

- None

Appendix B

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

held via videoconference, Tuesday, 5th October 2021

In attendance (IGARD Members):	Kirsty Irvine (IGARD Chair / Lay representative)
	Dr Imran Khan (IGARD Specialist GP Member)
	Dr. Geoff Schrecker (IGARD Specialist GP Member)
In attendance (NHS Digital):	Louise Dunn (DARS)
	Mujiba Ejaz (DARS)
	James Gray (Digi-Trials)
	Dickie Langley (Privacy, Transparency & Ethics - Observer)
	Karen Myers (IGARD Secretariat)
	Andy Rees (Digi-Trials)
	Vicki Williams (IGARD Secretariat)

3	**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:** There were no declarations of interest.
2.1	NIC-365354-R3M0Q-v7.3 University of Oxford **Background:** this was an update with regard to the Randomised Evaluation of COVID-19 Therapy (RECOVERY) Trial having been previously discussed at the COVID-19 response meetings on the 28th September 2021, 26th January 2021, 1st December 2020, 22nd September 2020, 21st July 2020, 7th July 2020, 19th May 2020, 12th May 2020, 5th May 2020, 28th April 2020 and 21st April 2020. The application and relevant supporting documentation had also been discussed at the IGARD business as usual (BAU) meetings on the 26th August 2021 (unable to make a recommendation as not all the necessary information was available in order for IGARD to make a full assessment), 12th November 2020 (recommendation to approve subject to amendments and advice), 30th July 2020 (recommendation to approve subject to conditions,

	amendments and advice) and 11th June 2020 (recommendation to approve subject to amendments and advice). NHS Digital had requested a meeting with IGARD to discuss the outcomes of the previous BAU Meeting discussion and next steps. The following observations were made on the basis of the verbal update from NHS Digital only. **IGARD Observations:** IGARD members noted that although version 7.3 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 only. IGARD members noted that due to the nature of the meeting and the fact that they had received no documentation, that should a full review of the application and documentation be required, the full suite of documentation should be presented to a IGARD business as usual (BAU) meeting for a recommendation IGARD noted that all their comments made at the 26th August 2021 BAU meeting (when they had been unable to make a recommendation as not all the necessary information was available in order for IGARD to make a full assessment) **remained live**, in addition to any previous comments made at BAU or COVID-19 response meetings (where applicable) for example, their comments in March 2020 with regard to the consent materials. IGARD members noted the verbal update from NHS Digital and that the application was to be presented at the IGARD BAU meeting on the 14th October 2021. IGARD Members noted that the discussion today was not to pre-empt discussions that would take place at the BAU meeting, thanked NHS Digital for the update and looked forward to receiving the full suite of documentation at the BAU meeting.
2.2	<u>NIC-420168-K4N1F University of Bristol</u> **Background:** this was an update with regard to the longitudinal linkage collaboration (LLC) which had previously been discussed at the COVID-19 response meeting on the 27th April 2021, 30th March 2021, 16th March 2021, 2nd February 2021, 26th January 2021, 21st January 2021 (CV19 slot on the BAU agenda) 12th January 2021, 15th December 2020 and 8th December (education session presentation by the University to the meeting). The application and relevant supporting documentation had also been discussed at the IGARD business as usual (BAU) meetings on the 4th March 2021 (recommendation to approve subject to conditions, amendments & advice) and 4th February 2021 (for advice on consent and description of the data). NHS Digital was seeking IGARD's advice on the proposed updated fair processing documentation due to be shared with the study cohort members by the Longitude Linkage Collaboration (LLC). NHS Digital noted that they had already flagged some initial areas of concern and wanted to talk these through with members together with seeking IGARD's view on the materials and proposals. The following observations were made on the basis of the verbal update from NHS Digital, '*Annex I UKLLC Study Evidence*', '*Annex II UK LLC Participation Notification Sheet*', '*Annex III UKLLC Privacy Notice*', '*Annex IV UKLLC FAQs*', '*Annex V UKLLC fair processing key points*',

	'*Annex VIUKLLC overview infographic*', '*Briefing UKLLC fair processing 30.09.2021*' and '*UKLLC Consenting update October 2021*'. **IGARD Observations:** IGARD members noted that although version 0.11 of the application and supporting documentation was available on NHS Digital's customer relationship management (CRM) system, they had not been provided for review at this meeting and their observations were based on the verbal update from NHS Digital only plus the eight documents highlighted above. IGARD members noted that due to the nature of the meeting and the fact that they had received no further documentation, that should a full review of the application and documentation be required, the full suite of documentation should be presented to a IGARD business as usual (BAU) meeting for a recommendation IGARD members commended the Senior Case Officer involved in reviewing the materials presented at today's meeting and suggested that this analysis was shared internally as an exemplar of good practice and thanked NHS Digital for such a detailed document. IGARD suggested that the document should be authored, dated and version controlled in line with usual record management good practice. IGARD members agreed with the key point raised in the NHS Digital analysis in that without seeing the consent materials for the studies, it was impossible to deduce if they might contain express statements that limited the scope of processing the data, or future use. IGARD agreed with NHS Digital that a full review of the consent materials alongside the updated documentation be undertaken across each of the studies in the LLC with consent as the legal basis and by NHS Digital. IGARD members were in agreement with NHS Digital that the statement in the '*Annex V UKLLC fair processing key points*' document that "*everyone is bound by oaths of confidentiality and legal contracts*" was not accurate and should be updated to more accurately reflect that "*everyone is bound by the duty of confidentiality and appropriate legal contracts*" In addition, the Health Research Authority Confidentiality Advisory Group (HRA CAG) section 251 support should also be reviewed alongside the updated documentation across each of the studies with s251 support to ensure that HRA CAG did not have for example any specific conditions of support, and restrictions on the data flowing or time periods involved, any restriction on the purpose etc. IGARD noted that restrictive statements in the consent materials or s251 support were unlikely to be able to be "cured" by updating the fair processing notice. IGARD members also noted that sufficient time was built into the programme of work by NHS Digital and the applicant to ensure that the consent and s251 materials could be reviewed and any necessary conversations with HRA CAG could be taken timely and before the end of the Health Service (Control of Patient Information) Regulations 2002 (COPI) Notice (currently 31st March 2022). IGARD Members noted that there were many free open pseudonymiser tools available and that the applicant may wish to consider for using them to pseudonymise data before it is sent to the LLC. IGARD Members noted that '*Annex II UKLLC Participation Notification Sheet*' referred to how study participants could opt out of the studies which were part of the LLC, however IGARD

	members were unsure how this would work since the LLC would not be receiving identifiers to enable them to perform the opt out. IGARD members suggested that a clear process should be put in place, for example, how does the local study advise the LLC that a study participant wishes to be withdrawn and the process in place to remove them from the LLC. IGARD members noted that '*Annex III UK LLC Privacy notice*' discussed the rights of individuals such as the right to rectify, to erase, to restrict and to port their personal information, however the LLC does not have identifiers for studies in the LLC (with the exception for the AVON longitudinal Study for which they are the data controller) and so Articles 15 to 20 of UK General Data Protection Regulation (UK GDPR) would only apply to those cohort members that could be identified. IGARD members suggested that the applicant may wish to have two privacy notices: one for their own AVON study and one for the LLC or to clearly set out in the privacy notice which rights applied to which cohorts. IGARD members also noted that if the applicant was citing the legal basis under UK GDPR, that they should list the relevant Articles: Article 6(1)(e) and Article 9(2)(j). IGARD members also noted in '*Annex II UKLLC Participation Notification Shee*t' to "*high quality research*" and in '*Annex III UK LLC Privacy notice*' to "*high quality public benefit research*" and suggested that this was expanded to be clear this is high quality research for health and social care, and is in the interest of the patients and public for which the data is held, which aligned with the purpose for which the LLC was set up. IGARD members suggested that the documentation could link back to the study's Terms of Reference (TOR) and that the TOR had the appropriate provision that the research must align with the purpose of the LLC and the research must be to the benefit of health and social care, noting NHS Digital data was being used in the LLC.
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.