Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 20 October 2022

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member / Co-Deputy IGARD Chair
Dr. Robert French	Specialist Academic / Statistician Member
Dr. Imran Khan	Specialist GP Member / Co-Deputy IGARD Chair
Dr. Maurice Smith	Specialist GP Member
Jenny Westaway	Lay Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Maria Clark	Lay Member
Prof. Nicola Fear	Specialist Academic Member
Kirsty Irvine	IGARD Chair
Dr. Geoffrey Schrecker	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Deepu Austine	Data Access Request Services (DARS) (**Observer:** items 2.1 to 3.2)
Jenny Broughan	National Disease Registration Service (**Observer**: Item 2.1)
Dave Cronin	Data Access Request Services (DARS) (**SAT Observer**: Item 3.1)
Louise Dunn	Data Access Request Services (DARS) (**SAT Observer**: items 3.2 to 3.4)
Mujiba Ejaz	Data Access Request Services (DARS) (Item 3.3)
Gavin Harrison	Data Access Request Services (DARS) (Item 2.1)
Karen Myers	IGARD Secretariat
Denise Pine	Data Access Request Services (DARS) (Item 3.4)
Charlotte Skinner	Data Access Request Services (DARS) (Item 3.2)
Sarah Stevens	Director of the National Disease Registration Service (Item 2.1)
Kimberley Watson	Data Access Request Services (DARS) (**SAT Observer**: item 7.1)

Vicki Williams	IGARD Secretariat
Clare Wright	Data Access Request Services (DARS) (Item 2.1)
***SAT** – Senior Approval Team (DARS)	

1	**Declaration of interests:** Dr. Maurice Smith noted a professional link with the Royal College of General Practitioners (RCGP) as a practising GP partner at the Mather Avenue Surgery in relation to comments made by PAG on the National Institute for Health and Care Excellence (NICE) [NIC-610798-N0G8Z-v0.4] but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest. Dr. Imran Khan noted a potential conflict with any applications reviewed by the General Practice Extraction Service (GPES) Data for Pandemic Planning and Research – Profession Advisory Group (PAG) [NIC-561357-X0F3N and NIC-610798-N0G8Z], as part of his roles as Deputy Chair of the Health Informatics Group at the RCGP and Co-deputy Chair of the Joint GP IT Committee. It was agreed this did not preclude Dr. Khan from taking part in the discussions about these applications, however it was agreed that he would not participate in making any recommendations. It was agreed that Paul Affleck would chair these two items. **Review of previous minutes and actions:** The minutes of the 13th October 2022 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>National Disease Registration Service (NDRS) Congenital Anomalies Data Sets – Briefing Paper (Presenter: Gavin Harrison / Sarah Stevens)</u> The purpose of this briefing paper was to inform IGARD of the onboarding of the National Disease Registration Service (NDRS) Congenital Anomaly data products. The NDRS is split into two disease registers: **1)** National Cancer Registration and Analysis Service (NCRAS); and **2)** National Congenital Anomaly and Rare Disease Registration Service (NCARDRS). NDRS were formerly managed by Public Health England (PHE) prior to its closure and have now been brought into NHS Digital. The NDRS data sets within scope of this briefing paper are the two NCARDRS Congenital Anomalies data sets: **1)** Congenital Anomalies Data Set (national data from 2018 onward); and **2)** Regional Congenital Anomalies Data Set (2015-2017, with data collection led by NCARDRS but only some regions reporting data). NCARDRS collects data on individuals with confirmed, suspected or at high genetic or other risk of congenital anomalies or rare diseases, and relevant family members in England. This includes data pertaining to affected foetuses. Congenital anomalies are structural or functional anomalies present at delivery, originating before birth, and include structural, biochemical,

	chromosomal and genetic anomalies. In cases of congenital anomalies, details of the mother are also registered. Data about congenital anomalies is collected in order to help the NHS in England, researchers, charities, people with congenital anomalies and the public understand what is happening with congenital anomalies in this country and to support the wider understanding of these conditions. **Outcome:** IGARD welcomed the briefing paper and supporting document and made the following high-level comments: 1. In respect of opt outs: a. IGARD were unclear which opt outs would be applied, when and in what circumstances, and asked that the briefing paper was updated to provide further clarity. b. IGARD suggested that the briefing paper was updated to clarify how the national data opt-out (NDO) is applied, in line with other datasets. c. IGARD suggested that NHS Digital discuss with stakeholders whether the NDO / NDRS specific opt-out should be harmonised and, if so, what a fair and transparent process for doing so might be. 2. IGARD suggested that the briefing paper was updated to clarify the cohort, for example, who is in the cohort, the cohort size etc. 3. IGARD suggested that the briefing paper clarify the lifetime collection within the database. 4. IGARD support the ongoing discussion with NDRS Team / IGARD member with regard to transparency. IGARD welcomed the draft and looked forward to receiving the finalised briefing paper, either out of committee (OOC) or tabled at a future meeting (before, or contemporaneously with, any first of type applications received by IGARD).
3	**Data Applications**
3.1	University of Birmingham: BASIL-3 Clinical Trial: BAlloon vs. Stenting in severe Ischaemia of the Leg-3 (Presenter: Clare Wright) NIC-341768-K2T6V-v0.11 **Application:** This was a new application for pseudonymised Civil Registration (Deaths) - Secondary Care Cut, Hospital Episode Statistics Admitted Patient Care (HES APC) and HES:Civil Registration (Deaths) bridge. The purpose of the application is for a research project hoping to evaluate the clinical efficacy and cost-effectiveness of the interventions for people with severe limb ischaemia; which is where blood vessels between the hip and knee are blocked. The data requested will allow the research team to double-check the main outcomes against routine data sources, and extend the follow-up of patients in the trial and collect the long-term outcome and health resource usage data without needing further contact with the study participants. This will link a trial of treatments that may become a clinical standard of care to long-term outcomes that are routinely collected in clinical data but will not be collected during the follow-up period of the trial. The study cohort consist of 481 consented patients.

	Discussion: IGARD confirmed that they were of the view that the **most recent** consent materials provided the appropriate legal gateway and were broadly compatible with the processing outlined in the application. IGARD noted that the applicant had been clear in section 5 (Purpose / Methods / Outputs) that there would be no requirement or attempt to re-identify individuals and that all analysis would use pseudonymised data, however, IGARD suggested that the applicant may wish to reconsider their rationale, since in a clinical trial the applicant may need to re-identify a cohort member. IGARD noted, that since this was part of an NHS Digital Pilot (see item 7.1 below), section 1 (Abstract) should still include key details from the DARS assessment including, but not limited to, the consented cohort and the consent assessment, the website update commitment by the applicant, and transparency. IGARD asked that, as section 5 forms NHS Digital's data uses register, section 5(a) (Objective for Processing) was amended throughout, so technical terms were used only where necessary and explained in a manner suitable for a lay audience, for example "*bail-out*". IGARD asked that a special condition was inserted in section 6 (Special Conditions), that, where practicable, outputs cite the source of the data as *"this work uses data provided by patients and collected by the NHS as part of their care and support"* (use MY data - our data citation project), in line with NHS Digital DARS Standard for Special Conditions. In line with the NHS Digital DARS Standard for Expected Measurable Benefits, 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 reference to patient and public involvement and engagement (PPIE) in section 5(d) and noting this was the first reference to PPIE in the application, suggested that this was not a benefit of the use of the data and that the narrative be moved to section 5(a). IGARD noted the enquiries undertaken by the DARS Team to determine if there was any commercial aspects to the application, which there were not, and thanked NHS Digital for the narrative provided in advance, which supported the review of the application. **Outcome:** recommendation to approve The following amendments were requested: 1. As section 5 forms NHS Digital's data uses register, to amend section 5(a) to ensure that technical terms are used only where necessary and explained in a manner suitable for a lay audience, for example "*bail-out*". 2. In respect of the benefits in section 5(d) and in line with the NHS Digital DARS Standard for Expected Measurable Benefits: a. To update section 5(d) to use a form of wording such as "*it is hoped* …", rather than "*it will*…", and b. To remove the PPIE information from section 5(d) and move into section 5(a). 3. To insert a special condition in section 6, that, where practicable, outputs cite the source of the data as *"this work uses data provided by patients and collected by the NHS as part of their care and support"*, in line with the NHS Digital DARS Standard for Special Conditions. 4. To include in section 1 key elements of the DARS assessment form, for example consent assessment, website update detail, transparency, cohort details. The following advice was given:

	1. IGARD suggested that the applicant may wish to reconsider their rationale in relation to pseudonymised data only, since in a clinical trial the applicant may need to re-identify a cohort member.
3.2	London School of Hygiene and Tropical Medicine (LSHTM): Small-area analysis of morbidity risks associated to environmental stressors (Presenter: Charlotte Skinner) NIC-329869-Q9Z2Z-v0.6 **Application:** This was a new application for pseudonymised Hospital Episode Statistics Admitted Patient Care (HES APC) data. Several environmental exposures, such as air pollutants, heat and cold temperature, and pollens are established risk factors for human health; however, several questions about their association with health conditions still exist: **1)** epidemiological studies on environmental stressors have mainly focused on mortality risks, while milder health outcomes such as hospital admissions have received less attention; **2)** analyses have used data aggregated over large areas and within limited study periods, preventing the analysis of the substantial geographical and temporal variation in risks; and **3)** little is known about vulnerability factors responsible for differential risks within and between populations. The purpose of this application is for a project aiming to address these limitations by characterising the morbidity risk associated with environmental stressors at small-area geographical scale across England. It will offer a detailed picture of current and future morbidity risks associated to environmental stressors in England, extending the knowledge of underlying causal mechanisms and providing critical information for the definition and implementation of integrated public health and climate change policies. This project follows up similar analysis performed by this research team at LSHTM on mortality risks in the UK using data from the Office of National Statistics (ONS), that has provided accurate maps of risks from temperature. **Discussion:** IGARD noted that section 1 (Abstract) outlined that the Research Ethics Committee (REC) had been informed of the changes to the protocol and that they had confirmed that the changes were non-substantive. IGARD asked that, as per due process, a copy of the REC confirmation, such as an email from REC, be uploaded to NHS Digital's customer relationship management (CRM) system for future reference. Noting the data minimisation and description of the data fields in section 3(b) (Additional Data Access Requested), IGARD suggested that further narrative be included in section 5 (Purpose / Methods / Outputs) with regard to the data fields disseminated under this data sharing agreement (DSA), as section 5 forms NHS Digital's data uses register, in order to better understand the volume of data being requested. In addition, and noting there are approximately 32,800 lower layer super output areas (LSOAs) in England with an average size of 1500 residents or 650 households (Lower Layer Super Output Areas (LSOAs) - data.gov.uk), IGARD asked that section 5(b) (Processing Activities) be updated to explain how the analysis includes work using individual level data, even though the outputs are at LSOA level. IGARD noted that they would also be more reassured about the volume of data and years of data being disseminated if there was evidence of patient and public involvement and engagement (PPIE) and suggested that the applicant may wish to engage with PPIE groups to discuss, for example (but not limited to) the volume of data requested. In addition, and noting there appeared to be no detail with regard to the dissemination of the benefits to public and

	given the public interest in the subject of the research, suggested that PPIE groups also be engaged to discuss the dissemination of the outputs. IGARD also suggested that details of any PPIE engagement carried out to date should be included in section 5 and that the applicant give consideration to the ongoing study specific PPIE. The HRA guidance on Public Involvement is a useful guide. IGARD asked that a special condition was inserted in section 6 (Special Conditions), that, where practicable, outputs cite the source of the data as *"this work uses data provided by patients and collected by the NHS as part of their care and support"* (use MY data - our data citation project), in line with NHS Digital DARS Standard for Special Conditions. In line with the NHS Digital DARS Standard for Expected Measurable Benefits, 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 asked that as section 5 forms NHS Digital's data uses register, section 5(a) (Objective for Processing) was amended throughout, so technical terms were used only where necessary and explained in a manner suitable for a lay audience, for example "*…aggregated spatial level…*". In addition, to remove or update the paragraph in section 5(a) with regard *"the only potential harm to the public by dissemination lies in the potential re-identification of subjects in the case of rare health outcomes*". **Outcome:** recommendation to approve The following amendments were requested: 1. To upload a copy of the most recent REC approval documentation to NHS Digital's CRM for future reference. 2. As section 5 forms NHS Digital's data uses register, a. To include further narrative in section 5 with regard to the data fields disseminated under this DSA in order to better understand the volume of data being requested, and b. to explain in section 5(b) how the analysis includes work at the individual level even though the outputs are at LSOA level, and c. to amend section 5(a) to ensure that technical terms are used only where necessary and explained in a manner suitable for a lay audience, for example "…*aggregated spatial level*…", and d. To remove or update the paragraph in section 5(a) with regard to "…*re-identify the individuals…*", and e. To update section 5(a) to use a form of wording such as "*it is hoped* …", rather than "*it will…*". 3. To insert a special condition in section 6, that, where practicable, outputs cite the source of the data as *"this work uses data provided by patients and collected by the NHS as part of their care and support"*, in line with the NHS Digital DARS Standard for Special Conditions. The following advice was given: 1. In respect of PPIE a. IGARD advised that the applicant may wish to engage with PPIE groups, including (but not limited to) the volume of data requested and the dissemination of outputs. b. IGARD suggested that the applicant may wish to provide details of any PPIE carried out to date in section 5.

	c. IGARD suggested that the applicant give consideration to ongoing study specific PPIE. The HRA guidance on Public Involvement is a useful guide.
3.3	Evidera Ltd: Health Burden of COVID-19 and Healthcare Resource Utilisation in England (Presenter: Mujiba Ejaz) NIC-561357-X0F3N-v0.21 **Application:** This was a new application for pseudonymised Civil Registration (Deaths) data, COVID-19 Hospitalization in England Surveillance System (CHESS) *(now called "SARI Watch")*, COVID-19 Second Generation Surveillance System (SGSS), COVID-19 Vaccination Status, Diagnostic Imaging Dataset (DIDs), Emergency Care Data Set (ECDS), General Practice Extraction service (GPES) Data for Pandemic Planning and Research (COVID-19) (GDPPR), Hospital Episode Statistics (HES) Accident and Emergency (A&E), HES Admitted Patient Care (APC), HES Critical Care, HES Outpatients and Medicines dispensed in Primary Care (NHSBSA data). The purpose of the application is for a study to generate the evidence necessary to understand unmet need in the prevention and treatment of COVID-19 following the deployment of vaccination campaigns. This may also help inform the assessment and usage guidance of EVUSHELD, a long-acting antibody combination for prevention against, and treatment of, COVID-19 in the most vulnerable people. The core study objectives are to: **1)** estimate the size of populations (pre-defined) in England that potentially are ineligible for vaccines or are at risk of inadequate response to COVID-19 vaccines; **2)** estimate incidence of COVID-19 by age group, disease severity, and selected comorbidities; **3)** estimate incidence of long-COVID-19 by age, disease severity, and selected comorbidities; **4)** describe patterns of healthcare resource utilisation and costs associated with an episode of COVID-19, stratified by age, selected comorbidities, disease severity, and the occurrence (vs. absence) of long-COVID-19. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD meeting on the 16th June 2022. IGARD noted that this application had been reviewed by the General Practice Extraction Service (GPES) Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 5th October 2022 *(please see appendix B).* IGARD reiterated their previous point raised on the 16th June 2022: IGARD noted the commercial aspect of the application in section 5(e) (Is the Purpose of this Application in Anyway Commercial), however, noting that this was not public facing, asked that for transparency, and in line with NHS Digital DARS Standard for commercial purpose, a brief summary was also provided in section 5(a) (Objective for Processing). IGARD reiterated their advice from the 16th June 2022: IGARD suggested that if the applicant had carried out a Data Protection Impact Assessment (DPIA), due to the scale, nature and scope of the processing, for example, in light of the machine learning and the volume of data, that a copy be uploaded to NHS Digital's customer relationship management (CRM) system for future reference. IGARD reiterated their advice from the 16th June 2022: IGARD suggested that the applicant involve relevant public and patient groups for the lifecycle of the project in line with HRA guidance on Public Involvement. IGARD reiterated their advice from the 16th June 2022: IGARD wished to draw to the applicant's attention the statement in section 4 (Privacy Notice), that a UK General Data Protection Regulation (UK GDPR) compliant, publicly accessible transparency notice is

	maintained throughout the life of the agreement. IGARD members agreed that it would be important for the applicant to make information publicly available so that patients and the public could find out that applicant was receiving personal data derived from NHS records and the purposes it was being used for. In addition, and in line with NHS Digital's DARS Standard for Transparency (fair processing), IGARD asked that special conditions be inserted in section 6 (Special Conditions) that draws the applicant's attention to the contractual statement in section 4 of the data sharing agreement (DSA) and Article 12 of the UK GDPR, whereby individuals have the right to be informed about the collection and use of their personal data. IGARD noted reference in section 5(a) (Objective for Processing) to "*EVUSHIELD is the first antibody that has been authorised for COVID-19 prevention in the US, UK and many other countries*" and suggested this sentence was updated to "*EVUSHIELD is the first antibody* ***product*** *that has been*…". IGARD asked that a declarative statement be inserted in section 5(b) (Processing Activities) that the EVUSHIELD prescriptions are **not** in the NHSBSA dataset, or, if they are in the dataset, to provide a rationale for their inclusion in section 5(b). IGARD asked that as section 5 forms NHS Digital's data uses register, section 5(a) was amended throughout, so technical terms were used only where necessary and explained in a manner suitable for a lay audience, for example "*tree-based supervised learning methods*". As section 5 forms NHS Digital's data uses register, IGARD asked that section 5 (Purpose / Methods / Outputs) was amended, to ensure that all acronyms upon first use be defined and further explained if the meaning was not self-evident, for example "*LAAB*", "*PrEP".* IGARD asked that section 5(d) (Benefits) be updated with a weblink to the "*Phase III trial PROVENT*" or that further narrative be included as background information to the trial. IGARD noted that any references to books or journals should be correctly cited (Harvard referencing) in section 5, or a web link provided, so that the books or journals can be easily found, noting that section 5 forms NHS Digital's data uses register. IGARD asked that a special condition was inserted in section 6 (Special Conditions), that, where practicable, outputs cite the source of the data as *"this work uses data provided by patients and collected by the NHS as part of their care and support"* (use MY data - our data citation project), in line with NHS Digital DARS Standard for Special Conditions. **Separate to this application:** IGARD noted and supported PAG's request for NHS Digital to convene a meeting with the Health Research Authority (HRA) and other appropriate bodies to explore the criteria for when Research Ethics Committee (REC) consideration is required, in particular with regard to the use of pseudonymised data. In addition, IGARD suggested that NHS Digital review the NHS Digital DARS Standard for Ethical Approval. IGARD noted reference throughout the application to "*SDE*"* and "*TRE*"* and suggested the terminology be updated to ensure a consistent use of language. *Secure Data Environment / Trusted Research Environment **Action:** IGARD noted that separate to this application the terminology TRE / online portal / SDE / DAE* did not seem to be used in a consistent fashion within and across applications and asked NHS Digital to consider standardising usage of these terms. *Data Access Environment

	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 transparency issues and commercial aspect of the application **Outcome:** recommendation to approve by a quorum of 4 members, with one GP Specialist member present not participating in making a recommendation on the application due to a potential conflict of interest. The following amendments were requested: 1. IGARD reiterated their previous advice point: In line with NHS Digital DARS Standard for commercial purpose, to provide a brief summary in section 5(a) of the commercial aspect of this application, as outlined in section 5(e) including addressing the specific potential commercial gain if EVUSHELD is shown to be safe and effective in routine clinical practice. 2. IGARD reiterated their previous advice point: IGARD suggested that if the applicant had carried out a Data Protection Impact Assessment (DPIA), due to the scale, nature and scope of the processing, that a copy be uploaded to NHS Digital's CRM for future reference. 3. In respect of the privacy notice and in line with NHS Digital's DARS Standard for Transparency (fair processing) to insert a special condition in section 6: a. drawing the applicant's attention to the contractual statement in section 4 of the DSA, and b. drawing the applicant's attention to Article 12 of the UK GDPR. 4. In respect of the EVUSHIELD prescriptions: a. To provide a declarative statement in section 5(b) that the EVUSHIELD prescriptions are **not** in the dataset, or b. If they are in the dataset, to provide a rationale for their inclusion. 5. As section 5 forms NHS Digital's data uses register, to amend section 5 throughout: a. To ensure acronyms be defined upon first use, for example "*LAAB*", "*PrEP*", and b. To ensure that technical terms are used only where necessary and explained in a manner suitable for a lay audience, for example, "*tree-based supervised learning methods*", and c. To update section 5(d) with a weblink to the PROVENT trial or further provide further information, and d. IGARD noted that any reference to books or journals should be correctly cited (Harvard referencing) in section 5 or a web link provided, and e. Amend the reference "*first antibody*" in section 5(a) to "*first antibody* ***product***", and f. To ensure consistent use of language with regard to the "*SDE*" or "*TRE*". 6. To insert a special condition in section 6, that, where practicable, outputs cite the source of the data as *"this work uses data provided by patients and collected by the NHS as part of their care and support"*, in line with the NHS Digital DARS Standard for Special Conditions. The following advice was given: **1.** IGARD reiterated their previous advice point: IGARD suggested that the applicant involve relevant public and patient groups for the lifecycle of the project in line with HRA guidance on Public Involvement.

	2. IGARD reiterated their previous advice point: IGARD wished to draw to the applicant's attention to the statement in section 4, that a UK GDPR compliant, publicly accessible transparency notice is maintained throughout the life of the agreement. 3. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the transparency issues and commercial aspect of the application. 4. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the transparency issues and commercial aspect of the application. **Separate to this application:** IGARD noted and supported PAG's request for NHS Digital to convene a meeting with the HRA and other appropriate bodies to explore the criteria for REC review. In addition, IGARD suggested that NHS Digital review the NHS Digital DARS Standard for Ethical Approval.
3.4	National Institute for Health and Care Excellence (NICE): TRE - NICE (Presenter: Denise Pine) NIC-610798-N0G8Z-v1.4 **Application:** This was an amendment application to access Maternity Services Data Set (MSDS) v2.0 data via NHS Digital's Trusted Research Environment (TRE). Work using data from the TRE will be continuous, and the exact data that is required will be dependent on referrals to NICE. The data will be used: during the scoping, development and review of guidance, standards and indicators; to resolve issues of uncertainty and improve access to new innovations for patients; to assess the impact of NICE's products; and to develop guidance tools. The data accessed under this data sharing agreement (DSA) will be used for purposes relating to the provision of healthcare or the promotion of health in line with the requirements of the Health and Social Care Act 2012 as amended by the Care Act 2014. In addition, COVID-19 datasets and Hospital Episode Statistics (HES), Civil Registration (Deaths), Medicines dispensed in Primary Care (NHSBSA data) datasets will also be accessed for specific COVID-19 purposes, such as the development of COVID-19 guidelines. NIC-610798-N0G8Z was put in place as a TRE DSA to supersede NICE's other DSA NIC-11302-Q1L1F, which was for DAE access for the same purpose described in NIC-610798-N0G8Z. NIC-11302-Q1L1F is now a closed DSA, and the yielded benefits have been noted within NIC-610798-N0G8Z. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD meeting on the 24th February 2022. IGARD noted that this application had been reviewed by the General Practice Extraction Service (GPES) Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 16th February 2022 *(notes from that meeting had been attached to the IGARD minutes from the 24th February 2022)*. IGARD noted the work of NICE and that it was well respected around the world. Noting that GPES Data for Pandemic Planning and Research (GDPPR) data would only be used for COVID-19 specific purposes and that the application stated in reference to GDPPR data "…*to provide information on medical history, patient characteristics and prescribing information for people who have and have not gone on to develop COVID-19*…." IGARD asked that further narrative be included in section 5(b) (Processing Activities) as to how the GDPPR data was still supporting the COVID-19 diagnosis activity, noting that a large

	proportion of the population may have had COVID-19 by now and that it may not have been coded into General Practitioner (GP) records. IGARD noted that on the 23rd June 2022, The Deputy Caldicott Guardian / Deputy Chair of PAG, had attended the meeting, to discuss the conditions that have been added to section 6 (Special Conditions) of data sharing agreements (DSA) in response to PAG feedback. The Deputy Chair of PAG noted that PAG provided feedback, as outlined in their published Terms of Reference and that their feedback should **not** directly populate section 6 (Special Conditions) of a DSA without the requisite rationale being provided as part of that feedback. IGARD therefore requested that the PAG 'standard conditions' were removed from section 6, since no justification for their inclusion had been provided. IGARD asked that a special condition was inserted in section 6 (Special Conditions), that, where practicable, outputs cite the source of the data as *"this work uses data provided by patients and collected by the NHS as part of their care and support"* (use MY data - our data citation project), in line with NHS Digital DARS Standard for Special Conditions. Noting that section 5(c) (Expected Measurable Outcomes) seemed to include narrative from the applicant's strategy document, IGARD suggested this was updated to be more specific about the outputs that would be achieved using NHS Digital data under this data sharing agreement (DSA) and in line with the NHS Digital DARS Standard for Expected Outcomes. IGARD asked that section 5(d)(iii) (Yielded Benefits) was updated in line with NHS Digital DARS Standard for Expected Measurable Benefits with specific yielded benefits accrued to date using NHS Digital data, for example, the 8 projects outlined in section 5(c) which are supporting NICE's strategic priorities and which had produced benefits to both the patients and health and social are system more generally. Noting this was 1-year agreement, on renewal or extension IGARD would expect to see further information within section 5(d)(ii) (expected measurable benefits) and section 5(d)(iii), and in line with NHS Digital DARS Standard for Expected Measurable Benefits. 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 public interest, large volume of data requested and yielded benefits. **Separate to the application:** IGARD asked that NHS Digital provide an update of the ongoing programme of work around the TRE / SDE / DAE*, following the programme update on the 25th August 2022. *Trusted Research Environment / Secure Data Environment / Data Access Environment **Outcome:** recommendation to approve by a quorum of 4 members, with one GP Specialist member present not participating in making a recommendation on the application due to a potential conflict of interest. 1. To provide further narrative in section 5(b) as to how the GDPPR data is still supporting the COVID-19 diagnosis objective. 2. To update section 5(c) to be more specific about the outputs, in line with the NHS Digital DARS Standard for Expected Outcomes. 3. To update section 5(d)(iii) with further information on the 8 projects that have produced yielded benefits, in line with NHS Digital DARS Standard for Expected Measurable Benefits. 4. To remove the PAG 'standard conditions' from section 6 since no justification for their inclusion has been provided.

	5. To insert a special condition in section 6, that, where practicable, outputs cite the source of the data as *"this work uses data provided by patients and collected by the NHS as part of their care and support"*, in line with the NHS Digital DARS Standard for Special Conditions. The following advice was given: 1. IGARD noted that this was 1-year agreement, and that on renewal or extension they would expect to see further information within section 5(d)(ii) and 5(d)(iii), in line with NHS Digital DARS Standard for Expected Measurable Benefits. 2. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the public interest, large volume of data requested and yielded benefits. 3. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the public interest, large volume of data requested and yielded benefits. **Risk Factor:** IGARD noted a general risk (not specific to this application) to NHS Digital in that PAG 'standard conditions' are still being added to applications without a supporting rationale. **ACTION:** IGARD asked that NHS Digital provide an update of the ongoing programme of work around the TRE / SDE / DAE, following the programme update on the 25th August 2022.
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. The NHS Digital SIRO was currently reviewing the feedback provided on the IG release registers by IGARD for the period March 2020 to May 2022, alongside the process of review, and as discussed on the 11th August 2022, would come back to IGARD in due course with any feedback or response. IGARD noted that the NHS Digital webpage Excel spreadsheet had now been updated for the period March 2020 to April 2022: NHS Digital Data Uses Register - NHS Digital. IGARD noted that May 2022 appeared to be outstanding, following them returning their comments on the May 2022 release register on 1st July 2022.
6	COVID-19 update *No items discussed*
7 **7.1**	AOB: DARS process change (Presenter: Dave Cronin)

	NHS Digital noted that a pilot was underway with regard to new ways of working within the Data Access Request Service (DARS) team, including new approaches to working with applicants to meet the NHS Digital DARS Standards. NHS Digital noted that the main focus of the pilot was section 5 of the application summary and that they had devised questions based on the current DARS Standards which in turn led to multiple choice model answers with the ability to include free text. The aim of the pilot is to get a consistent structure in section 5 across all applications. IGARD welcomed the new pilot approach which included a supporting document provided as part of the agenda pack, detailing the assessment work DARS had undertaken with the applicant, questions asked by DARS of the applicant, how conclusions were reached by DARS etc. However, IGARD noted that the supporting document inclusion in the agenda pack, should not be at the detriment of including key detail in section 1 (Abstract). IGARD queried if all applicants would be assessed via this new pilot and NHS Digital confirmed that it was a controlled pilot, with recognition that some applicants would not use this new approach due to the complexity of their applications, at this time. NHS Digital thanked IGARD for feedback as part of the discussion for item 3.1, which would feed back into the pilot.
7.2	ECHILD (Presenter: Kimberley Watson) NHS Digital attended IGARD to seek advice with regard to the University College London (UCL) (NIC-381972-Q5F0V) application and a new Department for Education (DfE) (NIC-TBC) application which had been submitted to access ECHILD. NHS Digital's verbal update at IGARD was to seek IGARD's view with regard to the data controllership relationships. IGARD noted the UCL application had last been discussed at IGARD on the 31st May 2022. IGARD thanked NHS Digital for bringing this verbal discussion item to IGARD in advance of an application coming to IGARD for a recommendation, either the updated UCL application or new DfE application, and hoped that the differing views offered had proved helpful to NHS Digital in order to formulate their next steps.
7.3	Removal of DARS Standard 2 (Processing and Storage Locations) and DARS Precedent 4 (linked to Standard 2) (No Presenter) IGARD noted that on the 17th October 2022, they had been notified by e-mail (via the IGARD Secretariat) that DARS Standard 2 (Processing and Storage Locations) and DARS Precedent 4 (linked to Standard 2); had been retired / removed from the NHS Digital website. IGARD noted that, in line with good practice, the retired documents version control table should be updated to capture the date retired, rationale for retirement and body approving DARS Standards and Precedents, and that a copy should be kept on file by NHS Digital and a copy forwarded to IGARD for information. There was no further business raised, the Co-Deputy 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 14/10/22

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-291981-Y7J2F	Imperial College London	16/06/2022	1. In respect of the HRA CAG support: a) To provide written confirmation from HRA CAG that there is an appropriate legal gateway for all members of the cohort. b) b) To upload the written confirmation from HRA CAG to NHS Digital's CRM system.	Quorum of IGARD members	Quorum of IGARD members in the IGARD meeting on the 13/10/2022.	*None*
NIC-283774-B9Z6K-v0.19	Imperial College London	18/08/2022	1. In respect of the published HRA CAG Register and HRA CAG support: a) The applicant to confirm with HRA CAG that they are content that even though the applicant has the ability to re-identify the cohort, sufficient controls are in place to satisfy the requirements of the data flowing back being "pseudonymised", as per the entry on the HRA CAG register; and b) To upload any relevant / supporting documentation to NHS Digital's CRM system for future reference.	Quorum of IGARD members	Quorum of IGARD members	Our suggestion is that this condition is now set aside, but that DARS refer expressly to the verbal advice received from CAG to support that view, or take PTEL advice for the contention that the data is outside of CLDOC

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

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

Liaison Financial Service and Cloud storage:

- None

Optum Health Solutions UK Limited Class Actions:

- None

Graphnet Class Actions:

- None

Appendix B

GPES Data for Pandemic Planning and Research – Profession Advisory Group Record of feedback: Wednesday 5 October 2022

Application & application version number: DARS-NIC-561357-X0F3N-v0.21 **Organisation name: Evidera Ltd** **Profession Advisory Group Agenda item: 2**
PAG have only one concern with this application to advise NHS Digital on: PAG feel there is an emergent gap in the NHS REC review process. REC reviews appear to be tied directly to the risk of identifiability of individuals in data. This would thus suggest that anonymised (or pseudonymised) NHS patient data could be analysed for any research question without oversight by a REC. As the vastness of datasets being linked increases, the types of questions that could be asked become ever more novel. Research work carried out in a TRE will continue to raise the bar to protect people from being identified, but it does not seem to protect against questions that could have significant unintended consequences; questions that could put at risk patient and public trust; questions that could seriously deter patients from sharing intimate details. For example, it could be conceivable that studies could be carried out to look for a "gay-gene"; https://www.newsclick.in/quest-gay-gene-bound-face-scientific-and-ethical-questions; https://larc.cardozo.yu.edu/cgi/viewcontent.cgi?article=1400&=&context=faculty-articles&=&sei-redir=1&referer=https%253A%252F%252Fscholar.google.co.uk%252Fscholar%253Fq%253Dgay%252Bgene%252Bstudy%252Bethical%252Bconcerns%2526hl%253Den%2526as_sdt%253D0%2526as_vis%253D1%2526oi%253Dscholart#search=%22gay%20gene%20study%20ethical%20concerns%22; https://www.nature.com/articles/d41586-019-02585-6 . Who would be providing professional and public oversight if there is no REC review? This application may not present serious concerns in the way it is presented, but in this case, there is involvement of a commercial company, who will have access to results earlier than potentially regulators, JCVI and other professional bodies. What if results show concerns? How do we know that commercial organisations will act quickly to share these? The absence of a REC review suggests there is no forum to be curious to these types of issues and no professional organisation which takes accountability for how NHS data is being used. PAG does not have the expertise, resource or time to provide this ethical review; but PAG believes that NHS Digital needs to assure itself that the sharing of such vast quantities of linked data will not result in more harm than good. PAG request that NHS Digital also convene a meeting with the HRA and other appropriate bodies to explore this issue. For the avoidance of any doubt PAG understands that NHS Digital will be progressing this application.

Attendees	Role	Organisation
Jonathan Osborn	Deputy Chair, Caldicott Guardian	NHS Digital
Amir Mehrkar	GP, Clinical Researcher	RCGP
Mark Coley	Deputy IT Policy Lead	BMA
Liz Gaffney	Head of Secure Data Access	NHS Digital
Florence Geut	Secretariat	NHS Digital
Mujiba Ejaz	Senior Case Manager	NHS Digital
Duncan Easton	Senior Approvals Team	NHS Digital
Dave Cronin	Senior Approvals Team	NHS Digital