Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 19 May 2022

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member (Item 7.2 only)
Maria Clark	Lay Member
Prof. Nicola Fear	Specialist Academic Member
Dr. Robert French	Specialist Academic / Statistician Member
Kirsty Irvine	IGARD Chair
Dr. Imran Khan	Specialist GP Member (Item 7.2 only)
Dr. Maurice Smith	Specialist GP Member
Jenny Westaway	Lay Member (Item 7.2 only)
IGARD MEMBERS NOT IN ATTENDANCE:	
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Chair
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Laura Bellingham	Head of Data Services for Commissioners (DSfC) (Item 7.2)
Rhys Bowen	Data Access Request Services (DARS) (**Observer**: item 3.6)
Vicky Byrne-Watts	Data Access Request Services (DARS) (Items 3.1 - 3.2) (**Observer:** item 7.1)
Louise Dunn	Data Access Request Services (DARS) (**SAT Observer**: items 3.3, 3.4, 3.6) (**Observer:** item 7.2)
Duncan Easton	Data Access Request Services (DARS) (Item 3.5, 7.1) (**Observer:** item 7.2)
Mujiba Ejaz	Data Access Request Service (DARS) (Item 3.6)
Liz Gaffney	Head of Data Access, Data Access Request Service (DARS) (Item 7.1)
Mary Kisanga	Data Access Request Service (DARS) (Observer: Item 7.2)
Aldo Maugeri	Privacy, Transparency and Ethics (PTE) (**Observer:** items 3.1 - 3.3)
Karen Myers	IGARD Secretariat

Frances Perry	Digi-Trials (Item 3.4)
Aisha Powell	Data Access Request Services (DARS) (Item 3.3)
Tania Palmariellodiviney	Data Access Request Services (DARS) (**Observer**: item 7.2)
Vicki Williams	IGARD Secretariat
Tom Wright	Data Services for Commissioners (DSfC) (Item 7.2)
***SAT** – Senior Approval Team (DARS)	

1	**Declaration of interests:** Dr. Maurice Smith noted professional links to AIMES Management Service [NIC-625841-T2V6N] but no specific connection with the application or staff involved and it was agreed that there was no conflict of interest. Dr. Maurice Smith noted that as a practising GP partner at the Mather Avenue Surgery, which is a member of a local Primary Care Network (PCN), that he would be unable to participate in the discussion relating to the performance management of GP practices [NIC-388185-C4D6J]. it was agreed that this was a conflict of interest, and he would not participate in making a recommendation about the application. Maria Clark noted a professional link with the British Medical Association (BMA), which applies to any applications reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG), as part of her role as officer of the BMA as Vice Chair of its Patient Liaison Group. However, she noted no specific connections with NIC-388185-C4D6J or the staff involved and it was agreed that this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 12th May 2022 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record the meeting. **Out of committee recommendations:** An out of committee report was received (see Appendix A).
2	**Briefing Notes**
	There were no briefing papers submitted for review.
3	**Data Applications**
3.1	Queen Mary University of London: Consortium of Parkinson's Disease Cohort Studies. (Presenter: Vicky Byrne-Watts) NIC-460424-Q7T2P-v0.4 **Application:** This was a new application that came for advice on the feasibility of the proposal put forward. The aim of the application is to achieve linkage of longitudinal Parkinson's disease (PD) cohort study data, to routinely collected health records data to increase the value and impact of PD cohort data, where explicit participant consent to health records linkage has been

	obtained. The scale and breadth that UK-based PD cohorts cover is unique on the world stage, and represents a huge opportunity to better understand the full disease course, in turn benefitting patients. The aim of the application is to begin with three UK cohorts **1)** 'PREDICT-PD' - a web-based, longitudinal cohort study, aiming to identify groups at increased risk of PD using an algorithm comprising risk factors and early features; the study is recruiting 10,000 participants; **2)** 'Discovery' - a large and well-characterised, population-based cohort of patients with PD recruited within 3.5 years of diagnosis from 2010-2014. At baseline, approximately 1000 patients with PD were recruited, along with 280 patients with sleep study-diagnosed REM sleep behaviour disorder and 300 healthy controls; and **3)** 'Tracking' - a large and well-characterised cohort of patients with PD, also recruited soon after diagnosis and followed-up over time. Approximately 2000 patients with PD were recruited, plus 260 patients with early onset PD. This is to demonstrate proof of concept and develop a 'template' to 'on board' other UK PD cohorts in a streamlined manner. **Discussion:** IGARD noted that the application was coming for advice on the feasibility of the proposal put forward, and without prejudice to any additional issues that may arise when the application is fully reviewed. IGARD had carried out a brief overview of the consent materials for three studies but noted that a full consent review needed to be undertaken. IGARD noted that the proposal under this Data Sharing Agreement (DSA), as outlined in the draft proposal document provided as a supporting document was to pool studies together, and queried if this was for efficiency or scientific innovation, or both. IGARD suggested that this be clearly defined within section 5 (Purpose / Methods / Outputs) of the DSA. An IGARD specialist GP member gave a brief clinical overview of Parkinson's, and in particular around the onset of Parkinson related memory and dementia symptoms and that the impact that may have on the cohort in terms of any attempt to reconsent, should that be required. IGARD advised NHS Digital that in respect of obtaining consent from cohort members, that those with Parkinson-related dementia may not be able to reconsent or have capacity to meaningfully engage with additional transparency communications and that the study may lose an important part of the cohort, since it was important to the study that everyone consented remained part of the study. IGARD noted that given the progression of Parkinson's, and following an initial review of the consent materials provided as supporting documents, the applicant may wish to explore seeking s251 support from the Health Research Authority Confidentiality Advisory Group (HRA CAG) for some cohorts of some of the studies. Which, if any, aspects of the studies required s251 support would only become clear after a detailed consent review. IGARD also suggested that the applicant may wish to seek advice from HRA CAG on upholding patient objections, for example where a participant's decision to give their consent may override their decision under the National Data Opt-out , since HRA CAG had the ability to set aside objections if a compelling case was put forward. IGARD queried the most appropriate legal basis for including the control groups of individuals who did not have Parkinson's in the pooled dataset, noting the legal basis may be different from cohort member legal basis. IGARD suggested that this was given further consideration by the applicant and further detail was included in section 5. IGARD queried the data controllership arrangements, noting that this had been one of the most complex issues to resolve on similar applications reviewed. IGARD asked that this was made clear within the DSA, as borne of the facts; and that further consideration may wish to

	be given in respect of other arrangements that covered complex data controllership arrangements such as the British Heart Foundation Trusted Research Environment (BHF TRE) multi-controller structure. IGARD suggested that the applicant should consider involving the relevant public and patient groups for the lifecycle of the project in line with HRA guidance on Public Involvement, and suggested that **now** was a good opportunity to involve the public at the creation stage and also as part of the consent review. IGARD noted that commercial sub-licensing may be a particular issue for the applicant, noting the detail provided in the supporting documents, that may require re-consenting unless the data was sufficiently derived and no longer NHS Digital data, in which case a sub licencing agreement by NHS Digital would not be required. IGARD supported the applicant seeking Research Ethics Committee (REC) approval and suggested the REC was fully appraised of possible future plans including the data, any potential sharing of data, such as commercial sublicensing. IGARD noted that NHS Digital may wish to provide further guidance to the applicant to support the progression of this application, and that IGARD would welcome this application coming to future IGARD BAU meetings for further advice. **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. IGARD provided the following high-level comments: 1. IGARD would welcome this application coming to a future IGARD BAU meeting for further advice. 2. To clarify whether the plan to pool studies is for efficiency or scientific innovation, or both. 3. To be aware that those with Parkinson-related dementia may not be able to reconsent or have capacity to meaningfully engage with additional transparency communications. 4. Following a detailed consent review, the applicant may wish to explore HRA CAG s251 support, noting the particular progression of the illness. 5. The applicant may wish to seek advice from HRA CAG on patient objections. 6. To consider the most appropriate legal basis for including the various different control groups in the pooled dataset, noting it may be different from cohort members. 7. To be clear about data controllership as borne of the facts; to consider other arrangements such as the BHF TRE multi-controller structure. 8. IGARD suggested that the applicant should consider involving the relevant public and patient groups for the lifecycle of the project in line with HRA guidance on Public Involvement, now was a good opportunity to involve the public at the creation stage and also as part of the consent review. 9. IGARD noted that sub-licensing may be a particular issue, that may require re-consenting, unless the data is sufficiently derived. 10. IGARD supported the applicant seeking REC approval and suggested the REC was fully appraised of possible future plans, such as sublicensing. 11. NHS Digital may wish to provide further guidance to support the applicant.
3.2	Cancer Research UK (and the University of Leeds): COVID RT - Assessing the impact of COVID-19 on radiotherapy in the UK. (Presenter: Vicky Byrne-Watts) NIC-625841-T2V6N-v0.4

	Application: This was a new amendment application for a one-off flow of pseudonymised NDRS Clinical and Translational Radiotherapy (CTRad) data. The purpose of the application is for the COVID radiotherapy (RT) study, which is aiming to understand why changes in radiotherapy treatment schedules were implemented during the COVID-19 pandemic; and to then explore the impact of these changes on patient outcomes and the UK radiotherapy services. This application is purely to understand the changes in patients' radiotherapy treatment due to the COVID-19 pandemic. The study will give a national picture of the decision making by patients and clinical staff and the impact on patient's treatment. It also provides knowledge of how radiotherapy was used as a bridge to surgery when surgical services weren't viable due to the pandemic and therefore what are the further requirements for cohorts of patients. The data subjects will be all individuals aged 18 years or over who received radiotherapy in participating UK Cancer centres between March 2020 and August 2021. **Discussion:** IGARD noted that the briefing presentation for this dataset was presented at the IGARD business as usual (BAU) meeting on the 12th May 2022, and that this was a first of type application. IGARD reiterated their observation that this bespoke Data Provision Notice with the intention of flowing data to a single recipient does set a precedent, and there was a reputational risk to NHS Digital that there was not equality of access to data. Such a risk could be mitigated by NHS Digital publicising this data asset to make other researchers aware, and to provide researchers with a mechanism to apply for access. IGARD suggested that NHS Digital's Onboarding Team proactively promoted this to other researchers, for example, via the NHS Digital Research Bulletin. IGARD noted that the protocol provided as a supporting document, referenced the analysts based at the Big Data Institute at the University of Oxford, and queried what their role was in the study, noting that the application was silent on this. IGARD asked that in line with NHS Digital DARS Standard for Data Processors, written confirmation was provided as to why the University of Oxford were not considered a joint Data Processor; noting the activities outlined in the protocol of the Big Data Institute at the University of Oxford; or, that the application was updated throughout to reflect the University of Oxford as a joint Data Processor, and as borne out of the facts; or, that section 5(a) (Objective for Processing) was updated to confirm that the University of Oxford did **not** undertake any data processing activities. In addition, IGARD asked that written confirmation was provided in section 5 (Purpose / Methods / Outputs) as to why the University of Oxford were **not** considered a joint Data Controller, in line with NHS Digital's DARS Standard for Data Controllers, and as borne out of the facts. IGARD noted the statement in section 1 (Abstract) that the data would only be processed by *"…substantive employees of the listed data processors (CRUK)…"*; and asked that for transparency, section 5 which served as NHS Digital's public facing data uses register was also updated to state that only *"substantive employees"* of Cancer Research UK would have access to the data, and to confirm that this will **only** be for the purposes set out in this data sharing agreement (DSA). IGARD queried the statement in section 5(a) *"The proposed work has been classed as audit/service evaluation…"*; and asked that this was amended to correctly reflect that the work within the DSA was for audit, service evaluation **and** research, in line with NHS Digital DARS Standard for Objective for Processing.

	IGARD noted within the protocol and application, that the data subjects were aged 18 years and over; and asked that section 5(a) was updated with further clarity as to why it **only** related to those over the age of 18 years, noting the impact of COVID-19 on children and young people's services. IGARD queried what, if any, patient and public involvement and engagement (PPIE) there had been, or planned; and asked that section 5 was updated to provide further details of any PPIE carried out to date; or to provide an indicative plan of future PPIE activity, in line with HRA guidance on Public Involvement. IGARD noted the references in section 5(a) to the sharing of data that was *"anonymous"* and *"anonymised"* in section 5(b) (Processing Activities); and asked that they were updated to instead with consistent terms to state that the results of this work would be shared. IGARD noted the statement in section 5(b*) "Data will be analysed using R software and/or Excel…"*, and asked that this information was removed as it was not necessary. IGARD noted the restrictive statement in section 5(b) that the data would be *"accessed from secure CRUK laptops"*, and asked that this was removed as it was not necessary. IGARD queried the statement in section 5(c) (Specific Outputs Expected) *"grey literature"* reports would be published, and noting that section 5 served as NHS Digital's public facing data uses register, asked that this was updated with a further explanation of what this meant. IGARD noted the statement in section 5(c) to there being *"no funding"*, and asked that this was removed as it was not necessary. IGARD noted within the application reference to outputs being shared in line with the Cancer Research UK's Statistical Disclosure Policy, and suggested that NHS Digital ensure this aligned with NHS Digital's policy. IGARD noted that the study was looking at excess deaths with regard to delays and restricted access during the COVID-19 pandemic, and suggested that the researchers may wish to consider whether there would be other confounding factors impacting the research outputs, for example, could COVID-19 exacerbate cancer development; see for example this pre-print. **Outcome:** recommendation to approve subject to the following conditions: 1. In respect of the Data Processor and in line with NHS Digital DARS Standard for Data Processors: a) To provide written confirmation why the University of Oxford, are not considered a joint Data Processor; noting the activities outlined in the protocol of the Big Data Institute at the University of Oxford; or, b) To update the application throughout to reflect the University of Oxford as a joint Data Processor, and as borne out of the facts; or, c) To update section 5(a) to confirm that the University of Oxford do **not** undertake any data processing activities. 2. To provide written confirmation in section 5 as to why the University of Oxford are not considered a joint Data Controller, in line with NHS Digital's DARS Standard for Data Controllers, and as borne out of the facts. The following amendments were requested: 1. To update section 5 to state that only *"substantive employees"* of Cancer Research UK will have access to the data, and to confirm that this will only be for the purposes set out in this DSA.

	2. To update section 5(a) to clarify why the protocol and DSA **only** relate to those over the age of 18, noting the impact of COVID-19 on children and young people's services. 3. To amend section 5(a) to reflect that work within the DSA is for audit, service evaluation **and** research. 4. In respect of PPIE: a) To update section 5 to provide details of any PPIE carried out to date; or b) To provide an indicative plan of future PPIE activity, in line with HRA guidance on Public Involvement. 5. To remove the references to sharing data that is *"anonymous"* in section 5(a) and *"anonymised"* in section 5(b) and instead state that the results will be shared. 6. To remove the reference(s) to specific software packages in section 5(b), as this is not necessary. 7. To remove the restrictive statement in section 5(b) that the data will be *"accessed from secure CRUK laptops"*. 8. To provide a further explanation of the term *"grey literature"* reports in section 5(c). 9. To remove the reference in section 5(c) to there being *"no funding"*, as this is not necessary. The following advice was given: 1. IGARD reiterated their observation that this bespoke Data Provision Notice with the intention of flowing data to a single recipient does set a precedent and there is a reputational risk to NHS Digital that there was not equality of access to data. Such a risk could be mitigated by NHS Digital publicising this data asset to make other researchers aware, and to provide researchers with a mechanism to apply for access. 2. IGARD suggested that NHS Digital's Onboarding Team proactively promoted this to other researchers, for example, via the NHS Digital Research Bulletin. 3. IGARD suggested that NHS Digital ensure that Cancer Research UK's Statistical Disclosure Policy aligns with NHS Digital policy. 4. IGARD suggested that the researchers may wish to consider whether there would be other confounding factors impacting the research outputs, for example, could COVID-19 exacerbate cancer development; see for example this pre-print. It was agreed the conditions would be approved out of committee (OOC) by the IGARD Chair.
3.3	Cegedim Rx Ltd: Cegedim Rx Ltd 2020 (Presenter: Aisha Powell) NIC-355818-H7T3C-v1.6 **Application:** This was a renewal application to permit the holding and processing of pseudonymised Civil Registration (Deaths) - Secondary Care Cut, Emergency Care Data Set (ECDS), Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC), HES Critical Care, HES Outpatients and HES:Civil Registration (Deaths) bridge. The purpose of the application is to create a licensed secondary healthcare large scale data resource, that will enable research providing insight in important disease areas, with national coverage over patient population, that is fundamental for the understanding of the patient healthcare clinical experience. This type of research will underpin decision-making in the continual improvement of clinical management of patients and service delivery at national and local levels. The geographical coverage of the data set will also provide the actionable evidence required to drive equity in the provision of care and optimise the utilisation of resources. This resource will offer new opportunities to ascertain the strength of previous evidence, providing a test bed

	for validation of public health, epidemiological and clinical research. It will also aim to measure and improve the quality of the research data stock in the United Kingdom. This processing will be used to perform public health, epidemiological, clinical and health economics research, supporting improvements in healthcare service delivery, treatment, technology appraisals and patient safety monitoring, using statistical, epidemiological and computational methods. NHS Digital noted that section 1 (Abstract) incorrectly stated that the end date for the data sharing agreement (DSA) was the 20th March 2022; and advised that this had been updated to correctly state that the DSA had expired on the 24th January 2022. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 12th November 2020. IGARD noted and thanked NHS Digital for the verbal update in respect of the DSA expiry date. Noting that no yielded benefits had been provided since the application was last reviewed on the 12th November 2020, IGARD reiterated their previous statement that a detailed analysis of the yielded benefits achieved should be provided in line with NHS Digital DARS Standard for Expected Measurable Benefits. If the yielded benefits had not been fully achieved, then a detailed update and plan for steps towards completion should be provided in section 5(d) (Benefits). IGARD noted that on the 12th November 2020, IGARD had endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices and reiterated their previous statement around lack of transparency. In respect of the privacy notice, noting the applicant was relying on legitimate interest as the legal basis, and in line with NHS Digital's DARS Standard for Transparency (fair processing), IGARD wished to draw to the applicant's attention to the statement in section 4 (Privacy Notice), that a UK General Data Protection Regulation (GDPR) compliant, publicly accessible transparency notice was maintained throughout the life of the agreement. IGARD queried the information within the section 5(d) (Benefits) in relation to The Health Improvement Network (THIN); and asked that section 5 (Purpose / Methods / Outputs) was reviewed, to ensure that any information relating to THIN was specifically relevant to **this** application; and, that section 5 was reviewed to remove any unnecessary information relating to THIN. Noting that the public facing section 5 forms NHS Digital's data uses register, IGARD noted the following in respect of the language throughout section 5, and asked that the relevant text highlight below was updated in line with NHS Digital DARS Standard for Objective for Processing: IGARD queried the objective for processing outlined in section 5(a) (Objective for Processing), particularly the references to the applicant being a *"leading supplier"* and driving *"cutting edge improvements"*; and asked that this was updated to reflect realistic and achievable goals from the use of the data and to remove generic marketing text. IGARD noted the references in section 5(a) to *"Strategic Health Authority"* (SHA), and noting that SHAs were now defunct, asked that this was either amended or removed. Noting the forthcoming Clinical Commissioning Group (CCG) / Integrated Care System (ICS) transition that was due to be completed later this year, prior to the end date of the agreement and the data retention period, IGARD asked that section 5(a) was updated to include a

	reference to this for information, and to future-proof the application in relation to the system changes across healthcare. IGARD queried the statement in section 5(a) to there being a reduction in *"health inequalities"*, and asked that this was removed unless there was a specific example to support this. IGARD noted the references to the data underpinning / performing *"essential public health" research* , and asked that unless the work outlined within the application was being specifically commissioned by UK Health Security Agency (UKSHA) or similar, that these were removed. IGARD noted a number of specific illnesses referenced in section 5(a), for example *"Psychosis and Schizophrenia in adults (2015)"* and *"Metastatic Breast cancer (2016)"*; and asked that further information was provided as to what the dates related to and when / if this guidance was changed. In addition, IGARD asked that in line with NHS Digital DARS Standard for Expected Outcomes and NHS Digital DARS Standard for Expected Measurable Benefits, the outputs in section 5(c) (Specific Outputs Expected) and the benefits in section 5(d) reflected the research into the illnesses / dates referred to in section 5(a); or, that the references to the illnesses / dates referred to in section 5(a) were removed. IGARD queried the statement in section 5(b) (Processing Activities) *"There are no upload and download restrictions…"*; and asked that this was updated, to make clear that access to data would be in line with appropriate role-based access specifications. IGARD noted the reference in section 5(b) to the *"AD Group"*, and noting there was no explanation within the application as to what this was, asked that for transparency, section 5(b) was updated with further clarity. IGARD queried the reference in section 5(c) to *"small number suppression"*, and asked that this reference / information was removed noting that it had been addressed elsewhere in the application. IGARD suggested that section 5(a) and section 5(d) be updated to remove reference to "*it will*…", and instead use a form of words such as "*it is hoped*…". Noting that the application had expired on the 24th January 2022, IGARD suggested that NHS Digital put in place a short-term three-month extension until the points outlined had been addressed. 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 outstanding actions on yielded benefits and transparency. **Outcome:** unable to recommend for approval 1. IGARD reiterated their previous statement that on return a detailed analysis of the yielded benefits achieved should be provided. If the yielded benefits have not been fully achieved, then a detailed update and plan for steps towards completion should be provided. 2. IGARD reiterated their previous statement around lack of transparency. In respect of the privacy notice and in line with NHS Digital's DARS Standard for Transparency (fair processing), 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. In respect of The Health Improvement Network (THIN):

	a) To review section 5, to ensure that any information relating to THIN is specifically relevant to **this** application; and, b) To update section 5 to remove any unnecessary information relating to THIN. 4. In respect of section 5(a) and in line with NHS Digital DARS Standard for Objective for Processing: a) To update section 5(a) to reflect realistic and achievable goals from the use of the data and remove generic marketing text. b) To amend or remove the references in section 5(a) to defunct bodies, for example *"SHA's"*. c) To update section 5(a) with a reference to the forthcoming CCG / ICS transition, to future- proof in relation to the system changes across healthcare. d) To remove the reference in section 5(a) to there being a reduction in *"health inequalities"*, unless there is a specific example to support this. e) To remove reference to *"essential public health"* unless is being specifically commissioned by UKSHA or similar. 5. In respect of the specific illnesses referred to in section 5(a), for example *"Psychosis and Schizophrenia in adults (2015)":* a) To provide further information on what the dates relate to and when / if this guidance was changed; and, b) To ensure the expected outputs in section 5(c) and benefits in section 5(d), reflect the research into the illnesses / dates referred to in section 5(a); or. c) To remove the references to the illnesses / dates referred to in section 5(a). 6. To update the reference in section 5(b) to *"download restrictions"*, to make clear this will be in the role-based access specification. 7. To provide clarity in section 5(b) as to what the *"AD Group"* is. 8. To remove the reference in section 5(c) to *"small number suppression"*. 9. To update section 5(a) and section 5(d) to use a form of wording such as "*it is hoped* …", rather than "*it will…*". The following advice was given: 1. Noting that the application had expired on the 24th January 2022, IGARD suggested that NHS Digital put in place a short-term 3-month extension until the conditions and amendments above had been addressed. 2. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the outstanding actions on yielded benefits and transparency. 3. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the outstanding actions on yielded benefits and transparency.
3.4	University of Aberdeen: UK-REBOA study (Presenter: Frances Perry) NIC-196211-N2W0D-v0.21

	Application: This was a new application for pseudonymised Civil Registration (Deaths) - Secondary Care Cut, Emergency Care Data Set (ECDS), Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC), HES Critical Care, HES Outpatients and HES:Civil Registration (Deaths) bridge. Trauma is the leading cause of death in the first four decades of life, accounting for more than 1.3 million deaths per year globally. Each year around 5,400 people in England and Wales die after being severely injured, for example, in a road traffic collision, or as a result of a major fall. The leading cause of preventable death following injury is uncontrolled bleeding (haemorrhage), which usually requires immediate surgery; if bleeding can be controlled quickly, patients often recover, however, some patients die before they can reach an operating theatre. Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) is a new and novel technique, which involves passing a small inflatable balloon into the aorta (the main artery) to stop the bleeding until a patient can be taken to an operating theatre. REBOA has shown some early promise, but it is not yet known if it is better than standard care given to trauma patients. The UK-REBOA study aims to compare a control arm of the study against REBOA intervention. The control arm comprises standard treatment of patients with life-threatening torso haemorrhage, in the setting of a major trauma centre, which includes a rapid, consultant-led assessment. Life-saving interventions such as intubation of the airway, respiratory support, blood product transfusion, and imaging, are directed by protocols and guidelines, and aimed at minimising the time to control of haemorrhage, by surgical or endovascular means. The control arm of this study is designed to mirror standard care for this cohort of patients. The intervention arm of the RCT is REBOA in addition to control / standard care. The UK-REBOA study aims to compare standard major trauma centre care with REBOA versus standard major trauma care alone, in a fair and balanced way. Recruitment commenced on 21st January 2018 and concluded in April 2022, which will generate a cohort of approximately 90 patients randomised to the UK-REBOA study, from across 11 major trauma centres in England. NHS Digital noted that when this application was previously reviewed by IGARD on the 20th May 2021, IGARD were unable to recommend for approval for those cohort members who did not recover capacity after the procedure, and were unable to provide informed consent, and where consultee advice was sought. NHS Digital confirmed that following discussions between NHS Digital's Legal Team, the Data Access Request Service (DARS) Senior Management Team and IGARD, this application was being brought back to seek a recommendation for the cohort of the study who have been recruited under consultee advice. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 20th May 2021. IGARD noted and thanked NHS Digital for the verbal update in respect of the application being brought back to seek a recommendation for the cohort of the study who have been recruited under consultee advice. IGARD queried the reference in section 5(a) (Objective for Processing) to the data being linked *"anonymously"*; and noting that this was incorrect, asked that the referenced was reviewed and amended as appropriate.

	IGARD noted that when this application was previously presented to IGARD on the 20th May 2021, the cohort numbers were stated as being 130, and that this differed from the figures stated within this version of the application. IGARD asked that for future reference / audit purposes, section 1 (Abstract) was updated, with a brief explanation of the history of the cohort numbers, for example 120 vs 90. **Outcome:** recommendation to approve The following amendments were requested: 1. To amend the reference in section 5(a) to data being linked *"anonymously"*. 2. To update section 1 with a brief explanation of the history of the cohort numbers, for example 120 vs 90.
3.5	<u>NHS Norfolk and Waveney CCG: GDPPR/Ethnicity/Vaccine COVID-19 – CCG - Pseudo (Presenter: Duncan Easton) NIC-388185-C4D6J-v4.2</u> **Application:** This was a renewal application to permit the holding and processing of pseudonymised COVID-19 Ethnic Category dataset / Management Information Ethnic Category (MIECC) Dataset, COVID-19 Vaccination Status and GPES Data for Pandemic Planning and Research (COVID-19) (GDPPR) data. It was also an amendment to remove The Health Service Control of Patient Information (COPI) Regulations 2002 as the legal basis for dissemination as the data is pseudonymised and not considered confidential. NHS Digital has been provided with the necessary powers to support the Secretary of State for Health and Social Care's response to COVID-19 under the COVID-19 Public Health Directions 2020 (COVID-19 Directions) and support various COVID-19 purposes, the data shared under this data sharing agreement (DSA) can be used for these specified purposes except where they would require the reidentification of individuals. The purpose of the application is to provide intelligence to support the local response to the COVID-19 emergency; the data is analysed, so that health care provision can be planned to support the needs of the population within the CCG area for COVID-19 purposes. NHS Digital noted that section 1 (Abstract) did not provide a clear history of approvals and that this would be updated to include the most recent approval under NHS Digital's SIRO precedent. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 17th March 2022. IGARD noted that this application had been reviewed by the GPES Data for Pandemic Planning and Research (GDPPR) – Profession Advisory Group (PAG) on the 9th March 2022, and that notes from this meeting had been attached to the IGARD minutes from the 17th March 2022. IGARD noted the update from NHS Digital in relation to ensuring that section 1 (Abstract) contained the full approval history. IGARD queried the special condition that had been inserted in section 6 (Special Conditions), restricting performance management using the GDPPR data, and why the CCG was being prevented from fulfilling this statutory responsibility (if required). IGARD noted that NHS Digital had previously advised on the 17th March 2022, that this had been inserted at the request of PAG, who stipulated that the GDPPR data did not contain the full population and could

	therefore give misleading results. IGARD again questioned whether such a blanket restriction was justified. IGARD asked that NHS Digital provide a more detailed justification or modified the special condition. IGARD reiterated the request from the 17th March 2022, to speak to the PAG Chair about the standard PAG conditions. IGARD reiterated concerns about the blanket ban on performance management. IGARD further noted the special condition may be impossible to comply with, for example, identification of practices, due to the nature of the data being disseminated and processed. IGARD noted a number of risk factors for NHS Digital, including, applicants may be inadvertently breaching the terms of their DSA with the inclusion of the PAG standard conditions; and by including PAG standard conditions, consideration did not appear to be being given to a Commissioning Board's duty to monitor GP performance. IGARD noted the request in section 5(a) (Objective for Processing) and section 5(b) (Processing Activities) for COVID-19 *"vaccine data"* under The Health Service Control of Patient Information (COPI) Regulations 2002; however, asked that this was updated to refer to a possible alternate legal basis, for example, Regulation 3(1)(d)(iii). IGARD noted the yielded benefits outlined in section 5(d) (Benefits) (iii) (Yielded Benefits), however asked that this was updated further in line with the NHS Digital DARS Standard for Expected Measurable Benefits, to give some specific examples of how the vaccine dataset has been helpful, for example, mobile vaccine clinics or targeted community initiatives. In addition, IGARD also asked that the yielded benefit in relation to the GDPPR data, was updated, to provide more detail about the specific limitations identified, in line with the NHS Digital DARS Standard for Expected Measurable Benefits. IGARD queried the reference in section 5(a) to there being *"...limited cases…"* where CCGs may utilise the pseudonymised data under this DSA to identify sets of records. IGARD asked that this was updated with the text outlined in the supporting document provided, to state *"…limited cases, involving small numbers of individuals…"*. As section 5 (Purpose / Methods / Outputs) forms NHS Digital's data uses register, IGARD asked that 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 replacing the reference to *"SNOMED Codes"* and replacing with *"diagnostic codes"*, in line with NHS Digital DARS Standard for Objective for Processing. IGARD noted the reference in section 5(a) to *"highlight patients"* in respect of risk stratification and predictive modelling; and asked that this was amended to state *"highlight a cohort of…"* or similar. **Outcome:** recommendation to approve The following amendments were requested: 1. To update the application with the text as outlined in the supporting document, to state *"…limited cases, involving small numbers of individuals…"*. 2. As section 5 forms NHS Digital's data uses register, to amend section 5(a) throughout, so technical terms are used only where necessary and explained in a manner suitable for a lay audience, for example replacing the reference to *"SNOMED Codes"* and replacing with *"diagnostic codes"*.

	3. To amend the reference in section 5(a) from *"highlight patients"* to *"highlight a cohort of…"* or similar. 4. To update the references to *"vaccine data"* in section 5(a) and section 5(b), to refer to a possible alternate legal basis, for example, COPI Regulation 3(1)(d)(iii). 5. In respect of the Yielded Benefits in section 5(d)(iii) and in line with the NHS Digital DARS Standard for Expected Measurable Benefits: a) To update the yielded benefits, to give some specific examples of how the vaccine dataset has been helpful, for example, mobile vaccine clinics or targeted community initiatives. b) To update the yielded benefit in relation to the GDPPR data in section 5(d) (iii) to be provide more detail about the specific limitations identified. The following advice was given: 1. NHS Digital to propose how the CCG requirement to carry out appropriate performance management of GP practices where required and necessary, will be handled and justify the exclusion of this data from that process (as per the special conditions inserted at the request of PAG). **Risk Factors:** Applicants may be inadvertently breaching the terms of their DSA with the inclusion of the PAG standard conditions. **Risk Factors:** By including PAG standard conditions, consideration is not being given to the Commissioning Board duty to monitor GP performance. **ACTION:** IGARD reiterated the request to speak to the PAG Chair about the standard PAG conditions. IGARD reiterated concerns about the blanket ban on performance management. IGARD further noted the special condition many be impossible to comply with, for example, identification of practices, due to the nature of the data being disseminated and processed.
3.6	University of York: 'Your Tube': the role of different diets in children who are gastrostomy fed (Presenter: Mujiba Ejaz) NIC-334459-R9H4C **Application:** This was a new application for pseudonymised Emergency Care Data Set (ECDS), Hospital Episode Statistics Admitted Patient Care (HES APC) and HES Outpatients. There are increasing numbers of children with complex health care needs that require having all, or part, of their nutritional intake via gastrostomy feeds. The recommended feed for children via gastrostomy is commercially produced formula, however, there is a growing body of parents who are interested in feeding their children home-blended meals. These parents often report benefits such as improved gastro-oesphageal reflux symptoms, less constipation, and less distress in their child. The 'Your Tube' study is a consented cohort study, aiming to recruit 300 children aged between 6 months - 18 years, who are fed via a gastrostomy tube and follow them up for an 18-month period. The main research question for the study is: What are the risks, benefits, and resource implications for using home-blended food for children with gastrostomy tubes compared to currently recommended formula feeds. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD BAU meeting on the 21st October 2021; where the application had been recommended for approval with conditions and amendments.

	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 21st October 2021 BAU meeting was as follows: 1. In respect of the consultee form: a) To provide written confirmation from NHS Digital's PTE, on the appropriate legal basis for the 15 participants, who are part of the cohort, where the consultee form was used instead of consent / assent. b) To upload the written confirmation from PTE to NHS Digital's CRM system for future reference. NHS Digital advised that section 3(c) (Patient Objections) incorrectly stated that patient objections would **not** be applied, and confirmed that this would be amended to reflect that patient objections would be applied. A quorum of IGARD members were content that the multi-limbed condition had been met.
4 **4.1**	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). GRAIL Bio UK Ltd - NIC-604847-S4B5L-v1.2 (No Presenter) The purpose of this application is to carry out follow-up analysis based on a cohort of patients who are being recruited to a clinical trial called 'NHS-Galleri'. IGARD noted that this application was last reviewed at the IGARD business as usual meeting on the 13th January 2022 where IGARD had recommended for approval for one year; and were unable to recommend for approval for a three-year DSA, until such time the NHS Digital DARS Standard(s) has been updated. IGARD noted that on the 10th May 2022, NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had agreed to authorise an extension to the Data Sharing Agreement (DSA) of eight years, which reflected the length of DSA's for other similar applications SYMPLIFY and NHS Galleri (NIC-604847-S4B5L). IGARD noted and thanked NHS Digital for the written update, however IGARD remained concerned that there was a reputational risk to NHS Digital, in respect of the transparency on the length of the DSA of eight years. In addition, IGARD noted that the form of the annual review had not yet been agreed and this also remained a risk, especially in light of the eight year DSA, and that they had requested an update from NHS Digital, but this was yet to be discussed at an IGARD BAU meeting.
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 Members noted that they had not yet been updated on the issues raised at the 27th May 2021 IGARD business as usual (BAU) meeting with regard to previous comments made on the IG COVID-19 release registers March 2020 to May 2021. IGARD noted that in addition, they had not been updated on the issues raised on the IG COVID-19 release registers June 2021 to January 2022. 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
6	COVID-19 update *No items discussed*
7 **7.1**	AOB: NIC-139035-X4B7K-v10.2 NHS England (Quarry House) (Presenters: Liz Gaffney / Duncan Easton) NHS Digital attended IGARD to provide a verbal update on the above application, which had last been reviewed at an IGARD BAU meeting on the 12th May 2022. NHS Digital advised that Ambulance Dataset would be added to this DSA and progressed via the SIRO Precedent route as a matter of urgency, noting that IGARD would be provided with further information on the onboarding of this dataset at the IGARD BAU meeting on the 26th May 2022. In addition, NHS Digital noted that this application would be submitted for a further review in the near future for an additional amendment, and IGARD would be asked for comments on the flow of Ambulance Dataset at this point, again, noting that this was out of process. IGARD noted and thanked NHS Digital for the verbal update, however reiterated their previous advice that this overarching application and any spin-off applications, would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent. IGARD did not raise any significant concern on the flow of the Ambulance Dataset, however supported NHS Digital's advice that this application would be brought to a future IGARD BAU meeting for review, as per process.
7.2	Workshop for IGARD briefing re Integrated Care Boards (ICB) / Integrated Care System (ICS) transition from Clinical Commissioning Groups (CCGs) (Presenters: Laura Bellingham / Tom Wright) NHS Digital attended the meeting to provide a verbal overview of the ICB / ICS transition from CCGs, including but not limited to: • How the landscape was changing. • What is an ICS: partnerships that bring together providers and commissioners of NHS Services across a geographical area with Local Authorities and other local partners to collectively plan health and care services to meet the needs of their population. • National versus local data flows.

	• How data is shared with an ICB. • How an ICB shares the data with the wider ICS. • Information processing standards. IGARD thanked NHS Digital for attending the meeting, and for the helpful and informative information provided. IGARD noted that the presentation used at the workshop would be shared with members following the meeting. 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 13/05/22

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-484452-H8S1L-v1.5	Department of Health and Social Care	07/04/2022	1. To provide a justification in section 5, for the requirement of the Uncurated Low Latency Hospital Data Sets.	IGARD members	Quorum of IGARD members	IGARD Comments: Given the justification for the data, when this application returns, IGARD would expect there to be a clear narrative of outputs from use of this data set such as "*changes in activity levels closer to real-time*" and how this information was utilised to benefit health and social care.

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