Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 17 November 2020

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Kirsty Irvine (Chair)	IGARD Lay Chair
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Prof. Nicola Fear	Specialist Academic Member
Dr. Imran Khan	Specialist GP Member
Dr. Maurice Smith	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Louise Dunn	Data Access Request Service (DARS)
Karen Myers	IGARD Secretariat
Vicki Williams	IGARD Secretariat
Tom Wright	Data Access Request Service (DARS)

1	**Declaration of interests:** There were no declarations of interest.
2	**Data Applications**
2.1	Regional Drug & Therapeutic Centre: access to HES and GDPPR (COVID-19) (Presenter: Louise Dunn) NIC-135277-R8M3G **Application:** The was an amendment application to access the GPES Data for Pandemic Planning & Research (GDPPR) data via the NHS Digital Portal – Data Access Environment (DAE) and for continued access to Hospital Episode Statistics (HES). The amendment is to broadly continue the provision of accurate prescribing information which is needed to support the NHS at a primary care / integrated care system (ICS) level to fulfil their statutory duties.

	There is significant increased pressures caused by the lack of knowledge of the impact of COVID-19 on both the short term and long term prescribing costs, the specific costs presented for prescribing are also used by the CCG to inform their budget decisions, planning and finance arrangements. **Discussion:** IGARD noted that this application had been reviewed at the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 7th October 2020 (see Appendix B), and had also been reviewed by PAG on the 28th October 2020. IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 1st September 2020. It was not clear to IGARD if PAG had reviewed an updated version of the application when presented at the 28th October PAG meeting, and IGARD were therefore unclear if the comments made at the 7th October PAG meeting had been adequately addressed from PAG's perspective. IGARD asked that written confirmation be provided that PAG had reviewed an updated application at their meeting on the 28th October and were satisfied with the responses to their initial queries; and if they had not reviewed an updated application, that the updated application addressing PAG's comments be provided to PAG, and their written contentment be provided back to NHS Digital. In addition a copy of PAG's notes should be uploaded to NHS Digital's Customer Relationship Management (CRM) system for future reference. IGARD noted and understood the concerns pertaining to PAG's comment re "…*performance management*…" but thought that there was still scope for identifying development needs that, if addressed, would ultimately benefit the patient population. IGARD queried the request for GDPPR data via the Data Access Environment (DAE) and linking to HES in order to gather the relevant prescribing data queries, as a newly onboarded dataset, NHS Business Services Authority (NHSBSA) data, would give information on the prescribed medicines and what had been paid for/claimed. IGARD asked that confirmation be provided the clinical data contained in the GDPPR dataset was being utilised in order to ensure the appropriate weighting was applied to refine the prescribing data. In addition, the NHSBSA dataset is not timebound in the way that the GDPPR dataset currently is. NHS Digital noted that NHSBSA data was available in the DAE and IGARD noted their support of the applicant applying for NHSBSA data, and suggested that the NHSBSA data may be more appropriate to use for their projects outlined in the application, and that should the applicant choose to apply for this data, instead of GDPPR data, that the application be updated throughout to reflect any changes in the data requested. In addition, and if the applicant still wished to apply for the GDPPR data, the applicant may wish to consider requesting NHSBSA data to use in parallel with GDPPR data, since this may give additional information, such as those medicines prescribed but not dispensed or groups of patients who were not receiving prescriptions issued. IGARD noted that the references to "…*NHS Digital portal*…" and "…*Data Access Environment*…" in section 5 (Purpose / Methods / Outputs) and suggested that this was updated to ensure consistency of terminology, and to also give a brief overview of the DAE within section 5(a) (Objective for Processing). In addition, section 5(b) (Processing Activities) should be updated where referencing "….*national data is required in order that the Trust will filter this to only include the exact CCGs they require*…" to include reference to the data access being undertaken via the DAE.

	IGARD noted that the data flow diagram supporting document referenced Amazon Web Services (AWS), and asked that confirmation be provided in section 1 (Abstract) that AWS would only remove data from the DAE which was aggregated with small numbers suppressed. IGARD suggested that the wording in section 3(c) (Patient Objections) referring to "…*the common law duty of confidentiality is addressed by: does not include the flow of confidential data*…" be updated to correctly reference the agreed text as outlined in section 1, namely that "…*the data requested under this agreement is not deemed confidential…and therefore not owed a duty of confidence*…" IGARD noted throughout section 5 reference to "…*better performing CCGs*…" and suggested that this phrasing was updated to include a brief overview as to what was meant, for example higher admissions with higher prescription costs may be a factor in requiring additional support in an area, or identifying an area of development for a CCG to meet best practice, since it was about promoting best practice with any cost savings reinvested back into the care of the patients. IGARD noted that the applicant's Data Security and Protection Toolkit (DSPT) for 2019/20 Standards had **not** been fully met and that a special condition had been inserted in section 6 (Special Conditions), however the special condition stated that the applicant would "…*maintain their DSPT…during the period of the DSA*…" and suggested this was updated with an indicative timeframe for completion. IGARD noted and endorsed NHS Digital's review that the applicant did not meet NHS Digital's Standard for privacy notices. **Outcomes:** recommendation to approve subject to the following condition: 1. In respect of the PAG comments: a. To confirm that PAG at their meeting on 28th October received the updated application which addressed the points raised at the 7th October PAG meeting; b. or if not the case, the revised application be presented to PAG and they confirm, in writing, that they are content with responses received The following amendments were requested: 1. In respect of the data: a. To provide confirmation that the applicant is using the clinical data contained in the GDPPR dataset to ensure that appropriate weighting is applied to refine the prescription data, or if not, b. To consider whether NHSBSA data is a more appropriate dataset to use for their projects outlined and the application be updated accordingly. 2. To confirm in section 1 that AWS would only remove data from the DAE which was aggregated with small numbers suppressed. 3. To update section 3(c) with the agreed standard wording as outlined in section 1 with regard to the duty of confidentiality. 4. To revise the use of "…*better performing CCG's*…" throughout section 5 to give a brief explanation as to what was meant by this phrasing. 5. In respect of the DAE in section 5: a. To ensure consistency in terminology in respect of the NHS Digital Portal and / or DAE, b. To give a brief explanation at the start of section 5(a) with regard to what a DAE is,

	c. To further clarify in section 5(b) when referencing the "…*national data*…" that this is via the DAE. 6. To update the DSPT special condition section 6 with an indicative timeframe for completion. The following advice was given: 1. IGARD suggested that the applicant may wish to consider if NHSBSA data may be a more appropriate dataset to apply for - to use solely, or in parallel with GDPPR data request. It was agreed the condition would be approved out of committee (OOC) by the IGARD Chair
2.2	<u>Imperial College London: SAHSU annual renewal and amendment – HES – adding provisional APC, Critical Care, Emergency Care for COVID-19 related studies (Presenter: Louise Dunn) NIC-204903-P1J7Q</u> **Application:** This was a renewal to extend the current Data Sharing Agreement end date to September 2021, and amendment application to 1) to increase the data dissemination frequency from annual to roughly bi-annual (ad hoc) to enable the Small Area Health Statistics Unit (SAHSU) to undertake COVID-19 related work, 2) to add Emergency Care Dataset (ECDS) as Hospital Episode Statistics (HES) Accident & Emergency (A&E) is no longer being produced, 3) to add the new data storage location (Virtus) and removing the previous storage location (St Mary's Campus) due to a planned server move. SAHSU's aim is to inform the UK public health and NHS response to the COVID-19 emergency by determining the spatio-temporal patterns in excess mortality and morbidity during the pandemic. **Discussion:** IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 28th May 2020. IGARD welcomed the application and were supportive of the important and valuable work being undertaken. IGARD noted that there was a very strong public interest in seeing this work continue, however given the use of identifiable data without consent, and the volume and scope of the data involved, noted that transparency was vital. Noting that a condition of research ethics committee approval was to maintain a publicly accessible register of research projects, asked that a special condition be inserted in section 6 (Special Conditions), that within 6 months of signing the Data Sharing Agreement (DSA), an appropriate publicly accessible summary of projects would be available on the website, and that on renewal all projects should be published on their website. Noting the internal process and the Public Health England-Small Area Health Statistics Unit (PHE-SAHSU) Liaison Committee providing confirmation it was within the funding remit, and noting the formal minuted approval from the PHE Programme Board, IGARD asked that the Liaison Committee provide a copy of its Terms of Reference (ToR) or operating procedures. In addition, that a copy be uploaded to NHS Digital's Customer Relationship Management (CRM) system. If no such ToR or operating procedures existed, IGARD suggested that on renewal that the applicant provide a copy of such documentation and that this documentation be published on its website, for transparency. IGARD also suggested that on renewal, that the applicant published full minutes of the Liaison Committee meetings on their website, or if deemed sensitive, to publish suitably redacted minutes of the meeting. Consideration should also be given to public and patient involvement

	(PPI) on the committee, since the membership was unknown and not publicly available, and that the applicant considered PHE's wider patient groups, which may offer suitable lay representation. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices, and noted that since IGARD was specifically referenced on the applicant's privacy notice, that this underscored the need for both transparency and governance processes being made publicly available. IGARD reiterated their previous comment and the query raised by the Health Research Authority Confidentiality Advisory Group (HRA CAG) in respect of project specific opt-outs. Noting the applicant's response in section 1 (Abstract) that started "*Opt-outs can introduce bias because they are not randomly distributed in space and time or by age, sex, ethnicity, and socio-economic status…*" IGARD suggested that on renewal that the applicant have corresponded with HRA CAG advising them on the project specific opt-outs, and that HRA CAG's written acknowledgement was uploaded to CRM, since a project specific opt-out would give people the opportunity to opt out of a specific project but still remain in the other projects, meaning less scope for introducing bias. IGARD reiterated their previous comments with regard to the reference in section 3 (Datasets Held / Requested) to the "*ordnance survey (OS) grid reference*", and noted that since this grid reference was 4 digits eastings and 5 digits northings and considerably smaller than postcode area, that any disseminated OS grid reference be no more identifying that a postcode, or that further detail be included about the small size of the field. IGARD noted the new storage location (Virtus SDC Limited) and asked that confirmation be provided as to whether Virtus SDC Limited were an additional Data Processor, by considering the facts of their involvement and as laid out in NHS Digital's DARS standard for Data Controllers / Data Processors. It was not clear in section 5(a) (Objective for Processing) as to why the frequency to the data dissemination had increased from annually to bi-annually, and IGARD suggested that supporting text from section 5(d) (Benefits) be inserted in section 5(a) outlining why the data was required more frequently in order to address the response to the COVID-19 pandemic. IGARD noted reference in section 5(b) (Processing Activities) to "…*authorised data linkage*…" outlined in the application, and asked that section 5(b) be updated to explicitly state that the only data linkage was that permitted within this application. IGARD noted a number of yielded benefits outlined in section 5(c) (Specific Outputs Expected) and suggested that these were correctly moved to section 5(d)(iii) (Yielded 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. **Outcomes:** recommendation to approve. The following amendments were requested: 1. To insert a special condition in section 6 that within 6 months of signing the DSA, an appropriate publicly-accessible summary of projects would be available on the website. 2. In respect of any ToR / operating procedures: a. To provide a copy of the PHE SAHSU-Liaison committee ToR or operating procedures, if available, b. To upload a copy to CRM.

	3. To update section 3 or the narrative in section 5 to clarify the use of and necessity for OS grid references. 4. To confirm that Virtus SDC Ltd are not considered a Data Processor (NHS Digital's DARS standard for Data Controllers / Data Processors). 5. To update section 5(a) with the benefits outlined in section 5(d) and further clarify why the data was needed more frequently. 6. To explicitly state within section 5(b) that the only data linkage would be that as outlined in the application. 7. To update section 5(d)(iii) with some of the yielded benefits achieved, as outlined in section 5(c). The following advice was given: 1. IGARD noted that if a ToR or operating procedure did not exist for the Liaison Committee, that on renewal a copy of the ToR or operating procedure is provided as part of the supporting documentation, and that any such documents are published on their website, for transparency. 2. IGARD noted that on renewal, consideration should have been undertaken by the applicant with regard to the committee membership and appropriate PPI. 3. IGARD noted that on renewal that all registries should be published on their website, for transparency. 4. IGARD suggested that, on renewal, that the applicant have published full minutes, or redacted minutes on their website, for transparency and if not, to advise why this was not possible. 5. IGARD noted that on renewal, that a copy of the HRA CAG communication was provided as a supporting document advising them on the project specific opt outs and that HRA CAG's acknowledgement was uploaded to CRM. 6. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent. 7. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment.
2.3	<u>Patient Level Medicines Data Class Application (Presenter: Tom Wright) NIC-403394</u> **Application:** This was a class application for all 135 CCGs in England to receive patient-level medicines data. Data Controllership will be based on existing Data Sharing Agreements (DSAs). Patient-level medicines data is taken from electronic and paper prescriptions that are submitted to the NHS Business Services Authority (NHSBSA) for reimbursement each month. The data comprises prescriptions for medicines that are dispensed or supplied by community pharmacists, appliance contractors and dispensing doctors and prescriptions submitted by prescribing doctors in England for medicines personally administered in England. Data includes prescriptions issued by prescribers in general practice, community clinics, hospital clinics, dentists, community nursing services. NHS Digital has the legal obligation to establish and operate informatics systems for the collection or analysis of information, and to exercise systems delivery functions in respect of medicines dispensed or supplied under Direction. **Discussion:** IGARD welcomed the class action application for 135 CCGs which had come for advice and without prejudice to any additional issues that may arise when the individual CCG application(s) are fully reviewed (which may be review of a selection of applications before proceeding down a templated route). NHS Digital noted that 135 amendment applications

	would need to be approved using the basis of this class action template for amendments to live CCG Data Sharing Agreements (DSAs). IGARD noted that the briefing paper had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 7th July 2020 and also the business as usual (BAU) meeting on the 30th July 2020. Noting the very strong public interest in using the data for secondary uses, for example to inform and support prescribing behaviour, decision making, commissioning and research, the NHS Business Services Authority (NHSBSA) Medicines Data Directions 2019 Direction states: "…*The purpose is to deliver comprehensive data about medicines dispensed or supplied, as currently held by the NHSBSA, and drive the linkage of medicines data with other data sets* ***to provide intelligence about the safety and effectiveness of medicines***…". NHS Digital noted that they had sought advice from the Privacy, Transparency and Ethics (PTE) Directorate (formally the Information Governance (IG) Directorate) and Information Asset Owner who were confident that the CCG processing outlined in section 5 (Purpose / Methods / Outputs) of the application covered the purposes as defined in the Direction. However, before any class action CCG application could be presented to IGARD, IGARD requested sight of the question asked of the PET Directorate in relation to the scope of the Direction and the response given. In addition, the documentation should be uploaded to NHS Digital's Customer Relationship Management (CRM) system and appended as a supporting document to each class action CCG application. IGARD noted that the purpose of the processing outlined in the class action application cited roles undertaken by the CCG that were not within their usual commissioning remit, such as CCGs commissioning GP services (that is usually undertaken by NHS England, with a few exceptions) and that CCGs currently undertook the work within the application without access to this data. Another example was the reference to pharmacovigilance which is usually carried out by the MHRA. IGARD suggested that any application would need to ensure that the objectives were clearly within the remit of the CCG and how the new and improved commissioning would be carried out using this new flow of data, for example informing their pathways. In addition, such new commissioning using this data flow would at all times need to be within the scope of the Direction, namely to "provide intelligence about the safety and effectiveness of medicines". IGARD queried if any prescriptions prescribed and not dispensed or where patients were not getting the prescriptions would be missing from the data. NHS Digital acknowledged that data for those prescriptions not filled was not part of the data. IGARD noted this was an important area of research and the short term fix with regard to collecting pseudonymised data at source (from the GP surgery), but that in due course the GPES data for planning and research would onboard to DARS and may be a useful data source. IGARD reiterated their comments from the 7th July COVID-19 response meeting that the updated privacy notices had been included on both the NHS Digital and NHS Business Services Authority (BSA) website, however, noted that patients may not necessarily check those websites in the first instance and suggested that thought be given as to transparency material being available in both the GP practice and prescribing pharmacy. IGARD members suggested that more thought be given to how to ensure the patient was made aware of and kept up to date with transparency measures including the Out of Hours Service, using the current text messaging service used by GP practices and pharmacies, or looking at utilising the NHS app.

	IGARD reiterated their comments from the 7th July COVID-19 response meeting noting that NHS Digital had developed a policy proposal for the handling of medicines associated with legally restricted and sensitive conditions, treatments and procedures, which had been clinically led internally by clinicians in NHS Digital, with external legal advice sought and had subsequently been signed off by NHS X. IGARD requested a copy of the policy proposal and any other internal documentation that may be shared with regard to how the sensitive categories of data were determined. IGARD noted that when previously presented to the 7th July COVID-19 response meeting, that NHS Digital had noted that national data opt-outs did not apply to NHSBSA dissemination of the data to NHS Digital, however any dissemination of medicines data from NHS Digital will be in accordance with the national data opt-outs. IGARD reiterated their point and queried reference to type 1 objections and if this related to dispensing practices (the presentation stated "…*neither NHSBSA nor NHS Digital collect medicines data from dispensing GP practices*…" and suggested that further clarity be sought as to whether the dispensing element of a dispensing practice was a separate entity. IGARD noted that before the class action CCG applications could proceed via the NHS Digital Precedent route, that a representative selection of CCG applications should be presented to IGARD, as per usual practice. **Outcomes:** IGARD welcomed the class action application for 135 CCGs which came for advice and without prejudice to any additional issues that may arise when the application is fully reviewed. 1. That before any CCG class action application is presented to IGARD for consideration, that a copy of the PET (formally IG) documentation be provided with regard to the scope of the processing mapped against the scope of the Direction. 2. In respect of the class action application: a. to ensure that the objectives outlined in the application are within CCGs' remit for commissioning. b. To clarify within the application how the new and improving commissioning would be carried out using this new flow of data. 3. NHS Digital to provide a copy of the policy proposal and any other internal documents that may be shared with regard to the determination of sensitive categories of data. 4. To clarify as to whether the dispensing element of a dispensing practice was a separate entity. 5. To provide an update as to the transparency material being made available in both the GP practice and prescribing pharmacy.
2.4 **2.4(a)**	<u>Clinical Registry Annex x 7 (NICOR) (Presenter: Tom Wright) NIC-139035</u> **Application 1 National Audit of Percutaneous Coronary Interventions (NAPCI):** The National Audit of Percutaneous Coronary Interventions (NAPCI) is used to collect data for interventions when obstructions in the heart arteries occurs. Obstructions within the arteries of the heart lead to exertion-induced chest pain (angina) that cannot be controlled by medical treatment, then patients may be helped by methods to improve blood flow. One technique is to use percutaneous coronary intervention (PCI) (often referred to as 'angioplasty'). The purpose of the audit is to stimulate quality improvement through the provision of comparative information on the structure and activity of PCI services; the access to, appropriateness and quality of care against national standards; outcome for patients such as complications, adverse cardiac events and death/survival. Data collected for the audit is from all centres in the UK, where PCI has been undertaken. The NAPCI assesses the process of PCI care and

	speed of the PCI delivery as well as the patient outcomes for example complication rates, or mortality. The audit is managed by the National Institute for Cardiovascular Outcomes Research (NICOR), with clinical leadership by the British Cardiovascular Intervention Society (BCIS).
2.4(b)	**Application 2 Myocardial Ischaemia National Audit Project (MINAP)**: The Myocardial Ischaemia National Audit Project (MINAP) was established in 1999 in response to the national service framework (NSF) for coronary heart disease, to examine the quality of management of heart attacks (myocardial infarction) in hospitals in England and Wales. Part of the National Cardiac Audit Programme (NCAP), the audit aims to improve the quality of care and outcomes of patients who have heart attacks. It aims to improve the whole pathway from the call to the emergency services, to the prescription of preventive medications on discharge from hospital. The audit is managed by the National Institute for Cardiovascular Outcomes Research (NICOR), with clinical leadership with the British Cardiovascular Society (BCS).
2.4(c)	**Application 3 National Adult Cardiac Surgery Audit (NACSA):** The National Adult Cardiac Surgery Audit (NACSA) collects data on all major heart operations carried out on NHS patients in the UK. The audit is managed by the National Institute for Cardiovascular Outcomes Research (NICOR), with clinical direction and strategy provided by the Society for Cardiothoracic Surgeons (SCTS) and the Project Board. Data collected for NACSA is primarily for consecutive operation data from all NHS hospitals in the UK that carry out adult heart surgery. NICOR is hosted by Barts Health NHS Trust, for the operational delivery of a number of clinical databases and registries associated with specialist cardiac services commissioned by NHS England as prescribed specialised services.
2.4(d)	**Application 4 National Cardiac Heart Rhythm Management Audit (CRM):** The National Cardiac Heart Rhythm Management Audit (CRM) collects information about all implanted cardiac devices and all patients receiving interventional procedures for management of cardiac rhythm disorders in the UK. The audit is managed by the National Institute for Cardiovascular Outcomes Research (NICOR), with clinical leadership is provided by the British Heart Rhythm Society (BHRS).
2.5(e)	**Application 5 National Congenital Heart Disease Audit (NCHDA):** The National Congenital Heart Disease Audit (NCHDA) collects information about Congenital heart disease, which refers to any defect of the heart present from birth. It includes structural defects, congenital arrhythmias, and cardiomyopathies. The audit is managed by the National Institute for Cardiovascular Outcomes Research (NICOR), with clinical leadership led by the British Congenital Cardiac Association and The Society for Cardiothoracic Surgery in Great Britain and Ireland. Data collected for the audit is from all centres across the UK undertaking paediatric and congenital cardiac surgery and interventional procedures, including electrophysiology. Children with congenital heart disease are treated in a small number of specialised (tertiary) centres, all of whom send their outcome data to National Congenital Heart Disease Audit. Some adults with congenital heart disease are also treated at these specialised centres. However, many adults are also treated at other cardiac centres who do not currently send their data to National Congenital Heart Disease Audit. This means that data collected on the survival of patients over the age of 16 is not complete. NHS England continue to encourage these centres to participate in the national audit.
2.4(f)	**Application 6 National Heart Failure Audit:** The National Heart Failure Audit collects data on patients with an unscheduled admission to hospital in the UK and who are discharged with a primary diagnosis of heart failure. The audit aims to drive up the quality of the diagnosis, treatment and management of heart failure by collecting, analysing and disseminating data, and eventually to improve mortality and morbidity outcomes for heart failure patients. The audit

	is managed by NICOR, with clinical direction and strategy provided by the British Society of Heart Failure (BSH).
2.4(g)	**Application 7 Transcatheter Aortic Valve Implantation (TAVI) Audit:** The main purpose of the TAVI data collection is to provide a detailed and accurate description of this non-surgical alternative to open heart surgery to replace the aortic valve. It is mainly for patients where their condition (severe aortic stenosis and significant comorbidity) raises them to high operative risk status. The registry is managed by National Institute for Cardiovascular Outcomes Research (NICOR) with clinical direction and strategy provided by the British Cardiovascular Interventional Society (BCIS), the Society for Cardiothoracic Surgeons (SCTS). Data collected for the audit is from all units in the UK, implanting transcatheter aortic valves will complete this dataset for each procedure. A web-based user interface allows the data to be directly entered into TAVI dataset held by NICOR. **Discussion:** IGARD noted that the purpose of the presentation was to add an additional seven registries to the Clinical Registries Database and that no additional application had been presented. IGARD also noted that each of the annexes presented included a section with regard to "*data dissemination to NHS England*" and since this was not part of this submission, that this section be removed from all seven of the annexes presented. In addition, IGARD noted that an amendment application from NHS England to receive the clinical registries datasets for NICOR was to be presented to a future IGARD meeting, detailing the new NICOR data flows and setting out the purpose and processing of the NICOR data. IGARD suggested that each annex presented should be a standalone document and asked that each one was updated to reflect the correct Data Controller and Data Processor associated with that particular clinical registry or audit, including the correct legal entity (for example clarifying if NICOR itself was a legal entity). In addition, to clarify the involvement of the University College London (UCL) and Barts Health NHS Trust and whether they could be considered an additional Data Controller, an additional Data Processor or interested party (by considering the facts of their involvement and as laid out in NHS Digital's DARS standard for Data Controllers / Data Processors). IGARD asked that each annex be updated to clarify the legal basis for NICOR, since within the annexes it was not clear which legal basis cited referred to which area of processing. In respect of the National Heart Failure audit annex document, IGARD noted that the Data Security and Protection Toolkit (DSPT) did not appear to be published and that this should be clarified. In respect of the Transcatheter Aortic Valve Implantation (TAVI) Audit annex document, IGARD queried if the name was correct, since the website described it as the *"UK TAVI registry"* and asked that this be updated. IGARD noted that the privacy notices mentioned NHS Digital but only with regard to the data flowing to NICOR, and they appeared to be silent on the data flowing to NHS Digital and then onto other bodies, and suggested that the relevant privacy notices were updated accordingly. IGARD noted that the Health Research Authority Confidentiality Advisory Committee (HRA CAG) predecessor the National Information Governance Board for Health and Social Care (NIGB), in 2012, had asked for a number of actions to move towards pseudonymisation of data, however there was no record of these actions moving to HRA CAG, and noting that these were questions for HRA CAG to answer, suggested that in respect of the underlying HRA CAG predecessor support, that NICOR put HRA CAG on notice as to the current

	handling of and status of the NICOR data. In addition, any written acknowledgement from HRA CAG should be provided to NHS Digital and uploaded to their Customer Relationship Management (CRM) system as a future supporting document for each registry. IGARD noted that when the overarching briefing note by NHS England was presented to future meetings, that the full suite of embedded documentation was provided as a suite of documents for review, since a number of links within the overarching briefing note were broken. In particular, IGARD would appreciate the up to date document containing all registries now sitting within the Clinical Registry Dataset. IGARD noted that in general for the clinical registries, that NHS Digital should confirm the position now as well as the plan going forward in respect of the application of the national data opt-out, in so far as it applies to the underlying registry data populating the Clinical Registry Database (noting that this did not apply to those registries that were relying on consent as the legal basis). IGARD also requested in general for the clinical registries, that NHS Digital confirm whether or not any of the registries would continue with their own front door access to their own data, alongside access via NHS Digital, since it was not clear in the overarching briefing note. **Outcomes:** IGARD welcomed the seven NICOR annexes which came for advice and without prejudice to any additional issues that may arise when the annexes are fully reviewed 1. In respect of each of the NICOR annexes (x 7) a. To remove section 10 which refers to the flow of data to NHS England, since it is not relevant to the annex document. b. To ensure that each annex is updated to be a standalone document. c. To remove reference to any potential use by any other Data Controller or Data Processor not associated with the particular annex. d. To clarify the legal basis for NICOR in relation to each of processing. e. To clarify the involvement of UCL and Barts Health NHS Trust with a view to whether each party could be considered at Data Controller, Data Processor or interested party. 2. To update the relevant privacy notices to accurately reflect that data was flowing both ways, and onwardly being shared. 3. In respect of original underlying CAG predecessor support: a. that NICOR put CAG on notice as to current handling and status of the NICOR data b. that a copy of the HRA CAG communication was provided as a supporting document c. HRA CAG's acknowledgement is uploaded to CRM 4. To clarify if the National Heart Failure DSPT has been published 5. To update the TAVI audit name, to correctly reference it as being *"UK TAVI registry".* 6. To table an amendment DSA for NHS England at a future IGARD to receive the clinical registry datasets for the NICOR data flow. 7. To provide a copy of the overarching briefing note with the amendment application from NHS England and NICOR annexes with the full suite of embedded documentation. 8. Clinical Registry dataset general points: a. NHS Digital to confirm the position now and plan going forward in respect of the application of the NDO in so far as application to the underlying registry data populating the clinical registry database.

	b. NHS Digital to confirm whether or not any of the registries will continue with their own front door access to their data.
3	<u>AOB</u> There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.

Appendix A

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 7th October 2020

Application: DARS-NIC-135277-R8M3G Newcastle Upon Tyne Hospital NHS Health FT **Organisation name: NHS Digital** **Profession Advisory Group Agenda item: 3**
PAG recognise the benefit of this application and supported subject to the comments below. PAG discussed the statement that the data was not owed a duty of confidence. It was understood that the data was anonymised in context, but PAG suggested that (1) the statement could be made clearer as to why it is not owed and (2) a paper be shared on how the data is anonymised within the TRE/DAE. PAG recommended that the applicant details within the application as to why the medicines dispensed data could not be used instead of the GDPPR data. https://digital.nhs.uk/data-and-information/data-tools-and-services/data-services/medicines-dispensed-in-primary-care-nhsbsa-data PAG also asked the applicant to demonstrate that they are engaging collaboratively with GPs within practices and PCNs not simply the prescribing leads within the CCG. PAG recommended that the applicant should strengthen the benefits and use cases within the application, with particular focus on safety and quality and prescribing and patient care, and not performance management.

Attendees	Role	Organisation
Arjun Dhillon	Chair, Caldicott Guardian	NHS Digital
Garry Coleman	Associate Director of Data Access	NHS Digital
Anu Rao	GPC IT Policy Lead	BMA
Amir Mehrkar	GP, Clinical Researcher	RCGP
Julian Costello	Senior Clinical Advisor	RCGP
Peter Short	Directorate Lead	NHS Digital
Dave Roberts	Head of Business and Operational Delivery	NHS Digital
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