Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 13 October 2022

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member / Co-Deputy IGARD Chair
Maria Clark	Lay Member
Dr. Robert French	Specialist Academic / Statistician Member
Kirsty Irvine	IGARD Chair
Dr. Imran Khan	Specialist GP Member / Co-Deputy IGARD Chair
IGARD MEMBERS NOT IN ATTENDANCE:	
Prof. Nicola Fear	Specialist Academic Member
Dr. Geoffrey Schrecker	Specialist GP Member
Dr. Maurice Smith	Specialist GP Member
Jenny Westaway	Lay Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Viraj Alawa	Data Access Request Services (DARS) (**Observer:** items 3.1 to 3.3)
Dave Cronin	Data Access Request Services (DARS) (Item 3.1)
Louise Dunn	Data Access Request Services (DARS) (**Observer**: item 3.1) (**SAT Observer**: items 3.2 to 3.4)
Mujiba Ejaz	Data Access Request Services (DARS) (Item 3.4)
Mary Kisanga	Data Access Request Services (DARS) (**SAT Observer**: items 3.2 to 3.3)
Karen Myers	IGARD Secretariat
Frances Perry	DigiTrials (Item 3.2)
Denise Pine	Data Access Request Services (DARS) (Item 3.3)
Terry Service	Data Access Request Services (DARS) (Item 7)
Charlotte Skinner	Data Access Request Services (DARS) (Item 3.5)
Joanna Warwick	Data Access Request Services (DARS) (Item 7)

Kimberley Watson	Data Access Request Services (DARS) (**SAT Observer**: item 3.5)
Vicki Williams	IGARD Secretariat
***SAT** – Senior Approval Team (DARS)	

1	**Declaration of interests:** Dr. Imran Khan noted a potential conflict with any applications reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) [NIC-403158-D1L7V], 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 this application, however it was agreed that he would not participate in making a recommendation about the application. Kirsty Irvine noted professional links to the Royal College of Obstetricians and Gynaecologists (NIC-596409-F0T3M), but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest. Maria Clark noted professional links to the Royal College of Obstetricians and Gynaecologists (NIC-596409-F0T3M), but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 6th 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**
	There were no briefing papers submitted for review.
3	**Data Applications**
3.1	University of Leicester: United Kingdom Research Study into Ethnicity And COVID-19 outcomes in Healthcare Workers (UK-REACH) (Presenter: Dave Cronin) NIC-403158-D1L7V-v0.17 **Application:** This was a new application for pseudonymised Civil Registration (Deaths), COVID-19 Hospitalization in England Surveillance System (CHESS) (now called *"SARI Watch")*, COVID-19 Second Generation Surveillance System (SGSS), Emergency Care Data Set (ECDS), GPES Data for Pandemic Planning and Research (COVID-19) (GDPPR), Hospital Episode Statistics Admitted Patient Care (HES APC), HES Critical Care; and identifiable Covid-19 UK Non-hospital Antigen Testing Results (pillar 2) data. The purpose of the application, is for an urgent research project to tackle COVID-19; that will use existing data held by national healthcare organisations to understand if and why ethnic minority healthcare workers are more susceptible to COVID-19 and poorer outcomes. Specifically, the study for this work package aims to link pseudonymised human resource, health regulator, and NHS outcomes datasets to assess the relationship between ethnicity and

	COVID-19 diagnosis, hospitalisation, and death in people working in health care settings, adjusting for known predictors. The cohort will include all adults (aged 16 years and over) registered with at least one professional regulator on the 1st February 2020. The cohort, when complete, is expected to encompass approximately 1.6 million healthcare workers in the UK though only data for workers residing in England will be shared with NHS Digital. The study is relying on s251 of the NHS Act 2006, for the processing of confidential patient data within NHS Digital. **Discussion:** IGARD noted that aspects of this application had been previously seen at the IGARD – NHS Digital COVID-19 Response meeting on the 18th May 2021. IGARD also noted that this application had been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 21st April 221 *(notes from that meeting had been attached to the IGARD minutes from the 20th May 2021)*, 8th September 2021, 3rd November 2021, 18th May 2022 and 5th October 2022 (please see appendix B). IGARD noted that following the PAG meeting on the 5th October 2022, a response from NHS Digital to the points raised at that meeting had been noted in section 1 (Abstract). Noting that this information had **not** been shared with PAG, IGARD asked that this feedback was shared with PAG members via the appropriate PAG process. IGARD noted that on the 23rd June 2022, The Deputy Caldicott Guardian / Deputy Chair of the GPES Data for 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 PAG Chair 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 confirmed that they were of the view that the relevant s251 support was broadly compatible with the processing outlined in the application. IGARD queried the information within the letter from Health Research Authority Confidentiality Advisory Group (HRA CAG) dated the 12th January 2022, that referred to support for the retention and linkage of *"professional registration confidential data"*; noting that professional registration information was not related to their health, and was therefore not confidential **patient** information. NHS Digital confirmed that prior to the meeting, they had discussed this point with the applicant, who had advised that it was the view of the Regulators that the professional registration data was **not** deemed confidential as certain fields, for example, name, address and data of birth were already in the public domain. IGARD noted the verbal update from NHS Digital, however advised that they were **not** of the view that the Regulators could rely on the fact that certain fields would be in the public domain, and suggested that it was handled as confidential information. In addition, IGARD asked that written confirmation was provided that the Regulators have an appropriate legal basis to flow the confidential information, for example, by relevant statutory powers and that this written documentation was uploaded to NHS Digital's customer relationship management (CRM) for future reference. IGARD noted the risk to NHS Digital of there being no articulation of legal basis, for example, statutory power, for the flow of confidential patient information from the Regulators. IGARD noted the information within the privacy notice, provided as a supporting document, that states members of the cohort can register a National Data Opt-out (NDO) if they do not

	wish for their data to be used in the study. IGARD noted a number of concerns, including, but not limited to, the fact that the NDO was not intended for the removal of individuals for 'specific' studies; the practical implications of applying the NDO; the language used within the privacy notice in respect of the timing of the NDO which was misleading, i.e. that the NDO could be applied at any time; and the lack of information relating to the rights of members of the cohort in line with the UK General Data Protection Regulation (UK GDPR). IGARD suggested that the applicant gave further consideration to the information within the privacy notice relating to the application of the NDO. IGARD noted and supported NHS Digital's view outlined in section 1, that it was the responsibility of the Data Controllers for the respective datasets, i.e. the Regulators, to ensure their datasets were processed in a transparent manner. IGARD therefore asked that the applicant ensured that the Regulators had appropriate transparency about the processing of the data, noting that the cohort members were more likely to find this information via their Regulator, than via the University of Leicester. IGARD noted the information in respect of the cohort involvement (under the heading *"Patient and Public Involvement"*); and asked that the public facing section 5 (Purpose / Methods / Outputs), that forms NHS Digital's data uses register, was updated to reflect the cohort involvement in line with the protocol. IGARD suggested that the applicant further developed the cohort involvement and engagement, to ensure that cohort members across **all** of the Regulatory bodies were actively engaged and involved in the study. IGARD noted and supported the approach taken to publish the protocol in the British Medical Journal (BMJ), that was published in June 2021. 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 areas of concerns discussed, and the application not having unanimous IGARD support. **Outcome:** IGARD were unable to make a formal recommendation as there was not a quorum of members available (potential conflict on the part of the GP Specialist member present). Two members were supportive of the application (with two members dissenting): 1. To provide written confirmation that the Regulators have an appropriate legal basis to flow the confidential information, for example, by relevant statutory powers. 2. The applicant to ensure the Regulators have appropriate transparency about the processing. 3. To remove the PAG 'standard conditions' from section 6, since no justification for their inclusion has been provided. 4. To update section 5 to reflect the cohort involvement in line with the information within the protocol. The following advice was given: 1. IGARD suggested that the applicant further developed the cohort involvement and engagement, to ensure that cohort members across all of the Regulatory bodies are actively engaged and involved in the study. 2. IGARD suggested that the applicant gave further consideration to the information within the privacy notice relating to the application of the NDO. 3. Noting the latest PAG comments from the 5th October 2022, IGARD asked that NHS Digital provided PAG with a response to the PAG comments.

	4. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the areas of concerns discussed, and the application not having unanimous IGARD support. 5. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the areas of concerns discussed, and the application not having unanimous IGARD support. **Risk Factor:** PAG 'standard conditions' are still being added to applications without a supporting rationale. **Risk Factor:** No articulation of legal basis, for example, statutory power, for the flow of confidential patient information from the Regulators.
3.2	University College London (UCL): Assessing the utility of healthcare systems data for trials: data utility comparisons in the STAMPEDE trial (DUCkS) (previously: ODR1718_094) (Presenter: Frances Parry) NIC-656801-R9F6Z-v1.3 **Application:** This was a renewal application to permit the holding and processing of pseudonymised National Disease Registration Service (NDRS) Cancer Registry, NDRS Linked Hospital Episode Statistics Accident & Emergency (A&E), NDRS Linked HES Admitted Patient Care (APC), NDRS Linked HES Outpatient, NDRS National Radiotherapy Dataset (RTDS) and NDRS Systemic Anti-Cancer Therapy Dataset (SACT). It was also an amendment to add the following datasets: **1)** HES Outpatients; **2)** HES Admitted Patient Care (APC); **3)** HES A&E; **4)** Emergency Care Dataset (ECDS). The HES data provided by NHS Digital provides additional fields to those previously received from PHE therefore this will enrich the data previously held. The purpose of the application is for a clinical study aiming to identify new treatments for prostate cancer. University College London aim to assess the concordance agreement between traditional trial-specific data collection and healthcare systems data *("routinely-collected healthcare data"*) in approximately 10,500 '**S**ystemic **T**herapy in **A**dvancing or **M**etastatic **P**rostate Cancer: **E**valuation of **D**rug **E**fficacy' (STAMPEDE) participants. The analyses will involve assessment of five objectives: **1)** assessment of survival; **2)** chemotherapy treatments; **3)** radiotherapy treatment; **4)** second-line treatment; and **5)** toxicities. Consent to data linkage has been sought for approximately 8,900 participants. Approximately 1,600 participants were recruited, however consent for data linkage was not recorded, therefore, the study is relying on s251 of the NHS Act 2006, for the flow of data out of NHS Digital for these participants. NHS Digital advised IGARD that prior to the meeting, the applicant had confirmed that the identifiers being provided by UCL in the cohort had been incorrectly stated in the application, and that NHS Number, First Name, Last Name and Postcode would be flowing; and not NHS Number, Date of Birth and Postcode. NHS Digital confirmed that section 5(a) (Objective for Processing) would be updated to reflect the correct information. NHS Digital advised IGARD that prior to the meeting, the applicant had provided a redacted copy of the signed Chief Investigators agreement. NHS Digital noted that they had reviewed the terms, and that there was a clearly stated provision that the substantive employer will invoke disciplinary action should there be a data breach carried out by the employee; and that NHS Digital were therefore content with the liability terms stated in the agreement. NHS Digital confirmed that section 1 (Abstract) would be updated as appropriate to reflect that that the

	agreement had been received and reviewed by NHS Digital; and that the documentation would be uploaded to NHS Digital's customer relationships management (CRM) system for future reference. NHS Digital also advised that the special condition in section 6 (Special Conditions), relating to the Chief Investigators agreement would be removed, as it was no longer relevant. NHS Digital advised, that whilst the Chief Investigators agreement was being reviewed, it had been noticed that six pharmaceutical companies were named as funding the STAMPEDE trial. NHS Digital confirmed that this had been queried further with the applicant, who had confirmed that no record level NHS Digital or ODR data had been shared with the pharmaceutical companies; the pharmaceutical companies have had no influence over the way the STAMPEDE Trial was conducted, how results were / are reported, nor any influence over how the DUCkS Evaluation would be undertaken; the pharmaceutical companies had individuals involved with the STAMPEDE collaboration groups, with appropriate contracts in place, and they saw the final study report with access to study data (not ODR/ NHS Digital data), and that they have no involvement with the DUcKS analysis study; and the pharmaceutical companies provided various medications used during the STAMPEDE Trial. NHS Digital noted that for transparency, a statement would be added to Section 5(a) and section 5(e) (Is the Purpose of this Application in Anyway Commercial) confirming this information. **Discussion:** IGARD noted the NDRS datasets had previously flowed from Public Health England (PHE) (under agreement ODR1718_094) prior to its closure at the end of September 2021; and therefore had not had a previous IGARD review. IGARD noted and commended NHS Digital and the applicant, on the quality of the information within the application, which supported the review of the application by members. 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 confirmed that they were of the view that the relevant s251 support was broadly compatible with the processing outlined in the application. IGARD noted that the Health Research Authority Confidentiality Advisory Group (HRA CAG) annual review date was the 28th September 2022; noting that the application was silent on whether the HRA CAG annual review had been submitted, IGARD asked that written confirmation that the HRA CAG annual review had been submitted; that for future reference, section 1 was updated with confirmation that the annual review had been submitted and that a copy of the written confirmation be uploaded to NHS Digital's customer relationship management (CRM) system for future reference. IGARD noted the verbal update in respect of the identifiers being provided by UCL; and supported the update to section 5(a) to accurately reflect that NHS Number, First Name, Last Name and Postcode would be flowing. IGARD noted the verbal update from NHS Digital, in respect of the redacted copy of the signed Chief Investigators agreement being provided by the applicant; and that NHS Digital were therefore content with the liability terms stated in the contract. IGARD supported the updates outlined to update section 1 as appropriate to reflect that that the document had been received and reviewed by NHS Digital; the documentation being uploaded to NHS Digital's CRM system for future reference; and the removal of the special condition in section 6 relating to the Chief Investigator's agreement.

	IGARD noted the verbal update from NHS Digital, in respect of the commercial aspect of the trial; and supported the updates to the public facing section 5(a) that forms NHS Digital's data uses register to reflect the verbal update provided, and section 5(e), in line with NHS Digital DARS Standard for Commercial Purpose. IGARD asked that a special condition was inserted 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"* (use MY data - our data citation project). IGARD suggested that the applicant may wish to consider involving the relevant public and patient groups for the lifecycle of the project The HRA guidance on Public Involvement is a useful guide. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of the HRA CAG Annual Review: a) To provide written confirmation that the HRA CAG Annual review has been submitted; and, b) To update section 1 with confirmation that the HRA CAG Annual Review has been submitted; and, c) To upload the written confirmation from HRA CAG to NHS Digital's CRM system. 2. To update section 5(a) with clarity of the update to the data fields (as per the verbal update from NHS Digital). 3. In respect of the Chief Investigator (as per verbal update from NHS Digital) a) To upload a redacted copy of the signed Chief Investigators' agreement to NHS Digital's CRM system for future reference; and, b) To provide clarification in section 1 that the redacted copy of the signed Chief Investigators agreement has been received, and NHS Digital are content with the liability terms stated in the contract; and, c) To remove the special condition in section 6 relating to the Chief Investigators, as this is no longer relevant. 4. In respect of the commercial aspect of the application, and in line with NHS Digital DARS Standard for commercial purpose (as per the verbal update from NHS Digital): a) To provide a brief summary in section 5(a) of the commercial aspect of this application. b) To provide a brief summary in section 5(e) of the commercial aspect of this application. 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 suggested that the applicant may wish to consider involving the relevant public and patient groups for the lifecycle of the project. The HRA guidance on Public Involvement is a useful guide.
3.3	University of Oxford: MR261 - ISIS 2:Streptokinase Aspirin after Myocardial Infarct (Presenter: Denise Pine) NIC-148130-46N08-v6.3 **Application:** This was a renewal application to permit the holding of identifiable Medical Research Information Service (MRIS) - Cause of Death Report, MRIS - Cohort Event

	Notification Report, MRIS - Flagging Current Status Report and MRIS - Members and Postings Report. Further processing and analysis is **not** permitted under this data sharing agreement (DSA). It was also an amendment application to **1)** change the legal basis to s251 of the NHS Act 2006 for the retention of data until 4th July 2023; **2)** the applicant wishes only to retain the data that has been previously provided and therefore needs to extend the period of their previous data sharing agreement (DSA). ISIS-2 (second international study of infarct survival) was a landmark randomised trial that recruited 17,187 acute myocardial patients from 16 countries (including 6,231 patients from the UK) between March 1985 and December 1987. It demonstrated clear benefits of aspirin and streptokinase and changed clinical practice sharply. Similar treatments remain a part of routine care in acute heart attack today. The aim of the ISIS-2 trial was to study the effect on cardiovascular outcomes and death of intravenous streptokinase and oral aspirin in patients suffering an acute myocardial infarction. Eligible patients were randomized within 24 hours of the onset of chest pain. In a hospital setting they received either IV Streptokinase or placebo, plus aspirin or placebo for a month. Although, no further analyses are currently planned, analyses in public health interest could be requested, for example as part of a meta-analysis or long-term follow-up. **Discussion:** NHS Digital noted that the application had not previously been presented at an IGARD business as usual (BAU) or at a Data Access Advisory Group (DAAG) meeting (IGARD's predecessor). IGARD welcomed the application and noted the historical importance of the study. IGARD confirmed that they were of the view that the relevant s251 support was broadly compatible with the processing outlined in the application. IGARD noted that Health Research Authority Confidentiality Advisory Group (HRA CAG) had provided support for the applicant to retain identifiable data until the 4th July 2023, after which, the datasets would need to be anonymised and all items of confidential patient information deleted. Noting that there were ongoing discussions with the applicant and HRA CAG to secure s251 support for the longer-term retention of identifiable data for future research beyond the 4th July 2023; IGARD suggested that, although out of process, NHS Digital engage directly with HRA CAG in respect of this application. In addition, IGARD suggested that, if not already done so, and noting the historical significance of the data; that the applicant formulate a research proposal demonstrating why the identifiable data would need to be retained. IGARD noted that section 3(c) (Patient Objections) stated that patients objections would be applied; however, noting that the s251 support was for the retention of the data, and that no processing was being undertaken; asked that this was updated to correctly reflect that patient objections would not be applied. IGARD noted the references in section 5(a) (Objective for Processing) to *"Myocardial Infarct"*; and asked that this public facing section that forms NHS Digital's data uses register was amended to simplify the language in a manner suitable for a lay reader. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 3(c) to reflect that patient objections will **not** be applied.

	2. To amend section 5(a) to provide a simplified explanation of *"Myocardial Infarct"* in language suitable for a lay reader. The following advice was given: 1. In respect of the retention of the identifiable data: a) Noting that there were ongoing discussions with the applicant and HRA CAG, to secure s251 support for the longer-term retention of identifiable data for future research beyond July 2023. IGARD suggested that, although out of process, NHS Digital engage directly with HRA CAG in respect of this application. b) IGARD suggested that, noting that historical significance of the data, the applicant formulate a research proposal demonstrating why the identifiable data would need to be retained.
3.4	<u>King's College London: Sentinel Stroke National Audit Programme (SSNAP) (Presenter: Mujiba Ejaz) NIC-387635-C9Y0W-v8.4</u> **Application:** This was a renewal and extension application to permit the holding and processing of pseudonymised Civil Registration (Deaths), Demographics data, Hospital Episode Statistics Admitted Patient Care (APC); identifiable Medical Research Information Service (MRIS) - Cause of Death Report, MRIS - Cohort Event Notification Report and MRIS - Flagging Current Status Report. It was also an amendment application to **1)** clarify the roles of the organisations involved in this data sharing agreement (DSA); **2)** to update the purpose section 5 to meet the NHS Digital DARS Standards that were not previously met; **3)** to change the HES APC data release from annually to quarterly. The purpose of the application is to support SSNAP, which measures the quality and organisation of stroke care in the NHS and is the single source of stroke data in England, Wales, and Northern Ireland. The overall aim of SSNAP is to provide timely information to clinicians, commissioners, patients, and the public on how well stroke care is being delivered so it can be used as a tool to improve the quality of care that is provided to patients. SSNAP has been voted the most effective national clinical audit in the UK for seven consecutive years by healthcare professionals involved in audit. The cohort size in approximately 500,000 patients. The programme is relying on s251 of the NHS Act 2006, for the flow of data out of NHS Digital for patients in the first six months following a stoke. Consent is then sought for patients from six months onwards. The application was previously considered on the 21st February 2019 where IGARD were unable to make a recommendation. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the Data Access Advisory Group (DAAG) *(IGARD's predecessor)* meeting on the 16th February 2016; and the IGARD meeting on the 21st February 2019. IGARD noted that the application had been updated to reflect all of the previous points raised. NHS Digital provided a verbal update to members, outlining how the legal basis for the data flowing would change from s251 in the first six-months, to consent from six-months onwards. IGARD thanked NHS Digital for the verbal update; however asked that section 5 (Purpose /

	Methods / Outputs) of the application was updated, to ensure that the flows of data described in the application align with the terms of s251 support, which is specifically for six-months **from the date** of admission; and was not flowing, for example on quarterly basis, which may result in more than six-months of data flowing for some cohort members. IGARD queried if at six-months a patient did not have capacity to consent, that for future recruitment, suggested the applicant may wish to consider an assent model, which would enable participation from those patients who have had a stroke, but have not yet gained capacity to consent at six-months. IGARD noted that the NHS Digital data relates **only** to stroke patients who have been admitted to hospital and for example, does not include those who attended accident and emergency; and asked that for transparency, the beginning of section 5(a) (Objective for Processing) was updated to reflect this, in line with NHS Digital DARS Standard for Objective for Processing. Noting the feedback from the patient engagement group on the National Diabetes Audit (NDA), IGARD suggested that the applicant considered whether or not there were any innovations being explored in terms of improving transparency to those cohort members about the audit, for example, during the initial six-months before providing consent. IGARD queried the special condition in section 6 (Special Conditions) relating to the data not being processed or onwardly shared for any other purpose not described within the data sharing agreement; and asked that this was removed as it was not relevant. IGARD asked that a special condition was inserted 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"* (use MY data - our data citation project), in line with NHS Digital DARS Standard for Special Conditions. IGARD noted the potential valuable outputs that may be identified in respect of stroke patients and the impact of COVID-19, and suggested the applicant may wish to review the datasets requested, for example in respect of any potential COVID-19 objectives. IGARD advised that they would be supportive of the applicant receiving additional flows of data if required, for example, COVID-19 datasets, to ensure they were working with as full set of relevant data as possible; and that an appropriate justification for this additional data should be added in section 5 in line with NHS Digital DARS Standards. IGARD queried the references in section 5 to *"managing patients"* and asked that these were updated to more sensitively refer to *"managing **the care of** patients".* **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 5 to ensure the flows of data described in the application align with the terms of s251 support. 2. To update the beginning of section 5(a) to reflect that the NHS Digital data relates **only** to stroke patients who have been admitted to hospital. 3. In respect of the special conditions in section 6, and in line with NHS Digital DARS Standard for Special Conditions: a) To remove the special condition in Section 6 relating to the sharing of data. b) 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"*.

	4. To amend references in section 5 from *"managing patients"* to *"managing **the care of** patients".* The following advice was given: 1. IGARD suggest that for future recruitment, the applicant should consider an assent model, which would enable participation from those patients who have had a stroke, but have not yet gained capacity to consent at six-months. 2. IGARD noted the potential valuable outputs that may be identified in respect of stroke patients and the impact of COVID-19, and suggested the applicant may wish to review the datasets requested, for example in respect of any potential COVID-19 objectives. IGARD advised that they would be supportive of the applicant receiving additional flows of data if required, for example, COVID-19 datasets, to ensure they were working with as full set of relevant data as possible; and that an appropriate justification for this additional data should be added in section 5 in line with NHS Digital DARS Standards. 3. Noting the feedback from the patient engagement on the NDA, IGARD suggested that the applicant considered whether or not there was any innovations being explored in terms of improving transparency to those cohort members about the audit, for example, during the initial six-months before providing consent.
3.5	Royal College of Obstetricians and Gynaecologists (RCOG): DHSC - Safe Staffing in Maternity Project (Presenter: Charlotte Skinner) NIC-596409-F0T3M-v0.9 **Application:** This was a new application for pseudonymised Hospital Episode Statistics Admitted Patient Care (HES APC) data. The purpose of the application is for a project that will undertake a rapid research and workforce planning exercise to determine the number of obstetricians and anaesthetists required in maternity units across England. This will produce estimates of the number of staff required which can be used for local and national planning. A key aspect of this is the calculation of 'complexity adjusted births', a birth rate for each maternity unit that reflects the case-mix used by that hospital. This project aims to answer three questions using routinely collected maternity data: **1)** what is the current need for obstetricians and anaesthetists in England, at all levels, both at unit level and nationally, on an annual basis; **2)** how does this relate to the number and complexity of births in each maternity unit; and **3)** how does staffing relate to maternity safety outcomes. Data will be restricted to a cohort for births from 1st January 2018 to 31st December 2021 that is derived from hospital admissions records that contain valid information about either mode of birth or outcome of delivery. The study team estimate that this will be approximately 3 million women and their babies. All historic admissions episodes from 2000-2017 should be provided for all individuals with a record in this cohort. **Discussion:** IGARD noted that prior to the meeting, they had raised a query in relation to data controllership with NHS Digital; specifically, that section 1 (Abstract) stated that the Department of Health and Social Care (DHSC) were commissioning the project, and were the project sponsor; and section 3(b) (Additional Data Access Requested) that cited Article 6(1)(e) (Public Task) as the legal basis for processing; which seemed to align with DHSC being a Data Controller. IGARD therefore queried why, notwithstanding the NHS Health Research Authority guidance, which states *"It is the sponsor who determines what data is collected for the research study through the protocol, case report form and/or structured data fields in a database. The sponsor therefore acts as the controller in relation to the research data."*; the application and supporting documents provided, including, but not limited to, the grant funding

	agreement, did not reference DHSC as a Data Controller. NHS Digital advised that the applicant had confirmed that DHSC have no input or control over the processing of the personal data involved; and that as mentioned in the application, DHSC was the project sponsor and do not process any personal data or determine the purposes and means of the processing of personal data. In addition, the applicant had confirmed that DHSC had agreed with this assessment and confirmed that RCOG were the sole Data Controller. Noting that NHS Digital and subsequently IGARD had queried the data controllership, and had been provided with a response from the applicant, would proceed on the basis that RCOG were the sole Data Controller. In respect of the UK General Data Protection Regulation (UK GDPR) Article 6 legal basis, IGARD noted that they had also raised a query on this prior to the meeting; noting that Article 6(1)(e) was cited in the application, however the grant funding agreement provided as a supporting document cited 6(1)(f) (Legitimate Interests) and a Legitimate Interest Assessment had been provided as a supporting document. NHS Digital advised IGARD that Article 6(1)(f) was the correct UK GDPR legal basis; and that the application would be updated to correctly reflect this. NHS Digital noted the verbal update from NHS Digital, and supported the update to the application to reflect the correct Article 6 legal basis. IGARD noted that the application would need updating to cite the relevant part of s261 in line with the latest guidance from NHS Digital's Privacy, Transparency, Ethics and Legal. **Separate to this application**: IGARD noted that at previous IGARD meetings, for example, on the 15th September (NIC-355818-H7T3C), 16th June (NIC-448252-L2R6Q) and 7th July (NIC-148369-8PPWK), the s261 legal basis had been discussed. IGARD had requested that NHS Digital advised on the s261 legal basis for NHS Digital's dissemination, for example which section of s261 of the Health and Social Care Act 2012 was relevant since NHS Digital appeared to be only citing the overarching s261. IGARD reiterated the request that NHS Digital **urgently** advise IGARD on the s261 legal basis for NHS Digital's dissemination. IGARD suggested that due to the significant volume of data flowing, the type of data being processed, i.e. 3 million women and babies, and the sensitive nature of the data being processed; that the applicant carried out a Data Protection Impact Assessment (DPIA) **before** processing commenced. IGARD noted that they had been supplied as part of the agenda pack with two supporting documents purporting to be DPIAs, but they were not, and suggested that the supporting documents saved on NHS Digital's customer relationships management (CRM) system and incorrectly labelled as a *"DPIA"*, were amended as appropriate to accurately reflect the nature of the documents. IGARD noted and commended the applicant on the use of some of the language used within the application, for example, *"caesarean birth"*. However asked that that in line with RCOG Women's Network language guidance, a number of other language points would need updating to the public facing section 5 (Purpose / Methods / Outputs) that forms NHS Digital's data uses register, including, but not limited to: section 5(a) (Objective for Processing) being amended to provide a brief explanation of *"maternal parity"* in language suitable for a lay reader; references to *"patients"* being removed from section 5 and replaced with *"women"*; and section 5 being updated to replace the references to *"delivery"* with *"birth"*. 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. IGARD advised that they would be supportive of the flow of version 1 of the Maternity Services Dataset (MSDS) which provided data up to 2019 and / or version 2 when available; to augment the HES data requested; subject to the relevant updates being made to the application in line with NHS Digital's DARS Standards, and the application would not need to return to IGARD for a review for this amendment. IGARD noted that discussions had taken place between NHS Digital and the applicant in respect of the patient and public involvement and engagement (PPIE); and suggest that the applicant involve RCOG Women's Network, that currently consists of 14 core lay members and 4 clinicians from across the UK; or other patient groups in the Steering Group, referenced within the application for this audit. 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 size, complexity and sensitivity of the datasets / processing and to review the DPIA. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of the legal basis for processing the data: a. To update the application throughout to reflect the correct UK GDPR legal basis for processing the data (as per the verbal update from NHS Digital); and, b. To update section 3 with the s261 legal basis for NHS Digital to disseminate data. 2. In respect of the language in section 5: a) To amend section 5(a) to provide a brief explanation of *"maternal parity"* in language suitable for a lay reader. b) To remove references to *"patients"* and replace with *"women"*. c) To replace the reference to *"delivery"* in section 5 with *"birth"*. 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. IGARD suggest that the applicant involve RCOG Women's Network or other patient groups in the Steering Group, referenced within the application, for this audit. 2. In respect of the DPIA: a) IGARD suggested that due to the significant volume of data flowing, the type of data being processed, i.e. 3 million women and babies, and the sensitive nature of the data being processed; that the applicant carries out a DPIA **before** processing commences. b) IGARD suggested that the supporting documents saved on NHS Digital's CRM system and incorrectly labelled as a *"DPIA"*, were amended as appropriate to accurately reflect the nature of the documents. 3. IGARD advised that they would be supportive of the flow of the Maternity Services Dataset (MSDS) (version 1 and / or version 2) to augment the HES data requested, subject to the relevant updates being made to the application in line with NHS Digital's

	DARS Standards, and the application would not need to return to IGARD for a review for this amendment. 4. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the size, complexity and sensitivity of the datasets / processing. 5. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the size, complexity and sensitivity of the datasets / processing. **Separate to this application**: IGARD noted that at previous IGARD meetings, for example, on the 15th September (NIC-355818-H7T3C), 16th June (NIC-448252-L2R6Q) and 7th July (NIC-148369-8PPWK), the s261 legal basis had been discussed. IGARD had requested that NHS Digital advised on the s261 legal basis for NHS Digital's dissemination, for example which section of s261 of the Health and Social Care Act 2012. IGARD reiterated the request that NHS Digital **urgently** advise IGARD on the s261 legal basis for NHS Digital's dissemination.
3.6	Imperial College London: MR1108: CT colonography, colonoscopy, or barium enema for diagnosis of colorectal cancer in older symptomatic patients: SIGGAR1 (Special Interest Group in Gastrointestinal and Abdominal radiology). Plus SOCCER (Symptoms of Colorectal Cancer Evaluation Research). (No Presenter) NIC-291981-Y7J2F-v6.11 **Application:** This was an extension application to permit the holding and processing of identifiable Medical Research Information Service (MRIS) Cause of Death Report, MRIS - Cohort Event Notification Report and MRIS - Flagging Current Status Report. The purpose is for the SOCCER study, which follows on from an earlier study on bowel cancer symptoms (the Special Interest Group Gastrointestinal and Abdominal Radiology (SIGGAR) study), with the aim of providing evidence that is needed to show whether flexible sigmoidoscopy (a technique which examines only the last [distal] part of the colon) is an effective and safe alternative to whole colon examinations for many people; which may change how doctors diagnose bowel cancer in their patients based on their symptoms. The size of the cohort is 7,472 patients; and the study is relying on consent and s251 of the NHS Act 2006, for the flow of data into NHS Digital. The application was previously considered on the 9th September 2021 where IGARD were unable to make a recommendation as not all the necessary information about the SIGGAR database was available to enable IGARD to make a full assessment of the Health Research Authority Confidentiality Advisory Group (HRA CAG) correspondence. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD BAU meeting on the 16th June 2022; where the application had been recommended for approval by a quorum of 4 members, with one specialist member dissenting, subject to a condition. 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 16th June 2022 meeting was as follows: 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) To upload the written confirmation from HRA CAG to NHS Digital's CRM system. A quorum of IGARD members were content that the multi-limbed condition had been met.
4 **4.1**	<u>Applications progressed via NHS Digital's Precedent route, including the SIRO Precedent</u> 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). <u>NIC-384608-C9B4L-v6.2 NHS England (Quarry House) (No Presenter)</u> The purpose of the application was to support the response to the COVID-19 outbreak, NHS Digital has been legally directed to collect and analyse healthcare information about patients, including from their GP record, for the duration of the COVID-19 emergency period, under the COVID-19 Public Health Directions 2020 (COVID-19 Direction). IGARD noted that this application was last reviewed at the IGARD meeting on the 25th August 2022 where IGARD were unable to make a recommendation as not all the necessary information was available in order for IGARD to make a full assessment. However, noting this application would proceed down the NHS Digital SIRO Precedent, IGARD made a number of high-level comments for the SIRO. IGARD noted that on the 4th October 2022 NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had agreed to authorise a renewal of the Data Sharing Agreement (DSA). In addition, IGARD noted that the SIRO had approved the addition of the following four datasets once onboarded into NHS Digital: **1)** Children and Young People – National Child Mortality Database (NCMD); **2)** Vaccinations and Immunisations; **3)** Covid Therapeutics/Blueteq; **4)** Covid Patient Notification System (CPNS). IGARD noted and thanked NHS Digital for the written update and asked that the next iteration of the DSA should be brought to a future IGARD meeting, in line with the new process, as per the discussion at the IGARD meeting on the 8th September 2022 and agreed by NHS Digital via email, whereby NHS England applications would be brought to IGARD for **advice only** and would then proceed under NHS Digital's SIRO precedent if appropriate. The new process, implemented from the 1st September 2022, was made in line with IGARD's published Terms of Reference and to support NHS Digital / NHS England ahead of the transition of NHS Digital into NHS England on 1st April 2023, where both organisations will become one entity.
5	<u>Oversight & Assurance</u> 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. • **NIC-112633-G0C0H-V1.6 - University of Ulster (Precedent: extension & renewal / APMS)**

IGARD noted that in line with the APMS precedent, either limb "1a" or "1b" should be cited of the precedent to ensure that the precedent is being followed correctly and that the abstract should clearly articulate how the precedent has been met, including the which limb has been used.

IGARD noted that the history of the application was not clear and queried how the first iteration of the DSA had been signed off?

IGARD noted that the current precedent had a number of typos and should be updated accordingly by NHS Digital.

IGARD noted that two precedents had been put forward.

- **NIC-309751-G8D4H-v1.4 - Kings College London (Precedent: extension & renewal / APMS)**

  IGARD noted that in line with the APMS precedent, either limb "1a" or "1b" should be cited of the precedent to ensure that the precedent is being followed correctly and that the abstract should clearly articulate how the precedent has been met, including the which limb has been used.

  IGARD noted that the history of the application was not clear and queried how the first iteration of the DSA had been signed off?

  IGARD noted that the current precedent had a number of typos and should be updated accordingly by NHS Digital.

  IGARD noted that two precedents had been put forward, however for the extension and renewal extension precedent to be met, standard 10a transparency should be met.

  IGARD also noted that the privacy notice stated that "*the study is being conducted as part of a doctoral studentship which began in June 2019 and will be ending in May 2022*".

  IGARD also noted that the privacy notice cited out of data DPA 1998 and erroneously cites GDPR as 2018.

- **NIC-226261-M2T0Q-v5.3 - The Nuffield Trust (Precedent: simple amendment)**

  IGARD noted that no special condition had been inserted into section 6 with regard to the provision of an annual confirmation report. IGARD queried how this would be handled. NHS Digital were unable to provide an update in-meeting.

  IGARD noted that when the application had been presented to IGARD the applicant had requested 2015/16 to 2021/22 Q01, however in this iteration it had changed to 2019/20 Q03 to 2020/21 March. IGARD were unclear why there was this discrepancy since there was no narrative in the abstract (section 1).

  IGARD reiterated pervious advice given on the 28th April 2022 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 lack of special condition with regard to the annual confirmation report, large quantum of data held by the applicant and programmatic access.

- **NIC-656844-M6K7Y-V0.2 (PHE migrated) - The Royal Marsden FT (Precedent: N/A)**

  IGARD noted that issues raised would be discussed with NHS Digital at the 27th October 2022 IGARD meeting.

- **NIC-656884-R1N3C-v0.2 (PHE migrated) - University of Hull (Precedent: N/A)**

  IGARD noted that issues raised would be discussed with NHS Digital at the 27th October 2022 IGARD meeting.

- **NIC-656886-D8H1H-v0.2 (PHE migrated) - Adelphi Group Ltd (Precedent: N/A)**

  IGARD noted that issues raised would be discussed with NHS Digital at the 27th October 2022 IGARD meeting.

- **NIC-656887-Q7M1C-v0.2 (PHE migrated) - Adelphi Group Ltd (Precedent: N/A)**

	IGARD noted that issues raised would be discussed with NHS Digital at the 27th October 2022 IGARD meeting. 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	<u>COVID-19 update</u> *No items discussed*
7	<u>AOB:</u> <u>IGARD Terms of Reference (ToR)</u> IGARD had a brief discussion about the IGARD ToR and suggested a log be set up by the IGARD Secretariat, to capture amendments required, including typos, suggested additional text around GP data, process changes etc. IGARD noted that the timing of any update to the IGARD ToR would need to take account of the transition of NHS Digital into NHS England on 1st April 2023, where both organisations will become one entity; and suggested that NHS England may wish to consider that any future IGARD ToR be subject to a consultation with the public, as previously done. 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 07/10/22

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)
None						

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-403158-D1L7V-v0.17

Organisation name: University of Leicester UK Reach

Profession Advisory Group Agenda item: 3

For, WP1, where "the primary aim is to determine whether COVID-19 diagnosis, hospitalisation and mortality rates differ between ethnic and occupational groups in HCWs", PAG see that all regulators have voted for option 2: they believe their registrants are aware of the use of their data for linkage, that they would see this as acceptable, and there is no need to inform registrant via email or letter, offer an opt out route, or make it explicit on their websites exactly what they are doing with their registrants data in this specific study.

We have also learnt from the CAG response that individuals will have their NDOO upheld and thus not be included in the study.

Issues for NHS D to consider:

1. Several responses appear to be templated from a source standard response; this poses a risk of groupthink that if one organisation appears to think the action is ok, then the others will follow suit.
2. Pag continues to be unclear if the UK-REACH study is voluntary or if all Health and social care staff of regulators will have their data used and linked (minus individuals with a NDOO):
    a. We are confused by the GMC website that continues to suggest that the UK-REACH study is "[Participation in the study is] *of course voluntary, but I would encourage as many doctors as possible to take part the UK-REACH study.*" (https://www.gmc-uk.org/news/news-archive/statement-about-gmc-participation-in-uk-reach-study-into-covid-19-and-bame-healthcare-workers).
    b. In addition, the UK-REACH website continues to say: "*including recruiting 15,000 healthcare workers*", (https://uk-reach.org/main/).
    c. Why does the CAG application mention on p.3, "*This equates to 1.5 million people*" when this number does not appear on the uk-reach website front page?
    d. On the UK-reach website it states: "e*xploration of the sensitivities of using and linking staff data to healthcare data will complement the outcomes ensuring public acceptability*"; is this the 1.5 million referred to in the CAG document?

3. We would like to share a contradiction that seems to exist in this application:
    a. The GMC states, “Doctors are aware, through information available on our website and through our regular communications with them, of the GMC’s use of registrant data for research purposes.”
    b. Then why did UK-REACH conduct a WP3 to assess the ethics of this study, stating it was “novel”, when the GMC and all regulators already believed such a study would be how their members would expect their data to be used; i.e. **not** novel.
4. We would like to point out that CAG also seemed to have advised the applicant to conduct a similar process to PAG’s Option 1 suggestion (namely to write to individuals and offer an opt-out):
    a. “*Within one month, the applicant is asked to devise a specific notification mechanism which involves GMC and NMC newsletters and which allows the applicant to opt-out*.”
    b. PAG is aware that CAG was content that the regulators believed Option 2 was sufficient.
5. Given that the NDOO is being upheld, we suggest that regulators make it clear on their websites that participants who do not wish for their data to be used in this study, can register a NDOO. We suggest regulators add a link to NHS Digital’s NDOO page to allow registrants to exercise this choice.

Attendees	**Role**	**Organisation**
Jonathan Osborn	Deputy Chair, Caldicott Guardian	NHS Digital
Amir Mehrkar	GP, Clinical Researcher	RCGP
Mark Coley	Deputy IT Policy Lead	BMA
Duncan Easton	Senior Approvals Team	NHS Digital
Dave Cronin	Senior Approvals Team	NHS Digital
Florence Geut	Secretariat	NHS Digital

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 3rd November 2021

Application & application version number: DARS-NIC-403158-D1L7V-v0.9 **Organisation name: University of Leicester** **Profession Advisory Group Agenda item: 3**
PAG note the detailed reply from the applicant. PAG advise that there are two options available in this case: Option 1. To support openness and transparency amongst the registrants of the GMC (and by extension all regulators), the GMC (and by extension all regulators) undertake to write to (and/or email) their registrants and inform them of the data that they will share and with whom, given this novel approach to linkage. Additionally, they undertake to explain whether they will allow their registrants a mechanism for opting out of this data sharing, and if not, that they will inform their registrants of this and also that they can, through the invocation of a Type 1 Opt Out via each registrant's General Practitioner, prevent their GP data being used in this study. Sufficient time should be allowed for registrants to register an opt out before data extraction occurs. Option 2. That the GMC (and by extension all regulators) write to NHS Digital stating that they believe option 1 is not necessary.

Attendees	Role	Organisation
Jonathan Osborn	Deputy Chair, Caldicott Guardian	NHS Digital
Kimberley Watson	Senior Data Approvals Officer	NHS Digital
Amir Mehrkar	GP, Clinical Researcher	RCGP
Mark Coley	Deputy IT Policy Lead	BMA
Pam Soorma	Secretariat	NHS Digital
Frances Perry	Senior Case Officer	NHS Digital

Professional Advisory Group Outcomes

Record of feedback Wednesday, 08 September 2021

Application & version	DARS-NIC-403158-D1L7V-v0.9
Applicant Organisation	University of Leicester
Data Controller Organisation	University of Leicester
Professional Advisory Group Agenda Item	2

PAG do not support this application in its current form.

- Concerns about class identification of medical professions
- What is the role of GMC
    - Is this what clinicians expected with the use of their data by the GMC?
    - Has the GMC been fully informed and is fully aware and thought through the implications of this data sharing (beyond lawful basis)?
    - Has the GMC considered, in writing, about any unintended consequences with respect to their members becoming aware of this study and the ultimate release of data regarding medical professional.
- Why can the UK-REACH not do a consent based cohort?

Currently PAG is not in a position to support this application.

Attendees	Role	Organisation
Jonathan Osborn	Chair and Deputy Caldicott Guardian	NHS Digital
Peter Short	NHS Digital Clinical Lead	NHS Digital
Mark Coley	Profession Representative	BMA
Amir Mehrkar	Profession Representative	RCGP
Liz Gaffney	Head of Data Access	NHS Digital
Frances Perry	DARS & DigiTrials Senior Case Officer	NHS Digital
Richard Langley	Principal Information Assurance Specialist Information Assurance	NHS Digital