Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 16 September 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark (Chair)	Lay Member
Prof. Nicola Fear	Specialist Academic Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Kirsty Irvine	IGARD Chair / Lay Representative
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
Dr. Maurice Smith	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Catherine Day	Data Access Request Service (DARS)
Mujiba Ejaz	Data Access Request Service (DARS)
Karen Myers	IGARD Secretariat
Jonathan Osborn	Deputy Caldicott Guardian (Observer: items 1- 2.2)
Kimberley Watson	Data Access Request Service (DARS)
Vicki Williams	IGARD Secretariat

Additional Meeting Information

IGARD noted that as per the written confirmation to NHS Digital on the 12th August 2021 (from the IGARD Secretariat), today's meeting would be a half-day meeting, due to IGARD member availability and in addition that there were no GP members available to attend the meeting, and would therefore be unable to provide a recommendation on any requests for GPES Data for Pandemic Planning and Research (COVID-19) (GDPPR) data.

IGARD advised NHS Digital in advance of the meeting, that per the agreement that has been in place since the start of the COVID-19 pandemic, the meeting quoracy would temporarily be reduced to three members (from the usual quoracy of four members), that would include a Chair and two specialist

members. The latest information in respect of the reduced meeting quoracy can be found under AOB in the IGARD business as usual meeting minutes from the 9th September 2021.	
1	**Declaration of interests:** Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising the Scientific Advisory Group for Emergencies (SAGE) on COVID-19. **Review of previous minutes and actions:** The minutes of the 9th September 2021 IGARD meeting were reviewed, and subject to a number of minor amendments were agreed as an accurate record of the meeting. **Out of committee recommendations:** An out of committee report was received (see Appendix A).
2	**Data Applications**
2.1	Queen Mary University of London: COVIDENCE/CORONAVIT - 1141 - 12/05/2021 16:46 (Presenter: Mujiba Ejaz / Kimberley Watson) NIC-449801-W5J4M-v0.9 **Application:** This was a new application for pseudonymised Civil Registration (Deaths) data, COVID-19 Hospitalization in England Surveillance System, COVID-19 Second Generation Surveillance System (SGSS), COVID-19 Vaccination Status, Electronic Prescribing and Medicines Administration (EPMA) data in Secondary Care for COVID-19, Hospital Episode Statistics Admitted Patient Care (HES APC), HES:Civil Registration (Deaths) bridge, Medicines dispensed in Primary Care (NHSBSA data) and GPES Data for Pandemic Planning and Research (COVID-19) (GDPPR). The purpose is for a study, investigating how lifestyle factors might influence the risk of catching COVID-19, the severity of symptoms, speed of recovery and any longer-term effects on health. People aged 16 and over from all parts of the UK and from all walks of life are being asked to provide their informed consent and some baseline information about their lifestyle and health using an online questionnaire. They are then contacted once a month to check if they have developed symptoms of coronavirus infection or if they have attended a hospital for treatment. **Discussion:** IGARD welcomed the application and noted the importance of the study. IGARD noted that as per the written confirmation to NHS Digital on the 12th August 2021 (from the IGARD Secretariat), there were no GP members present at the meeting, and IGARD would therefore be unable to provide a recommendation on the GDPPR data requested in this application. IGARD confirmed that as agreed with NHS Digital prior to submission of the application for review, they would provide a recommendation on all other datasets requested as per usual process and in line with IGARD's Terms of Reference; and would provide advice / feedback on the GDPPR data request. IGARD noted that this application had been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 15th September 2021 (see Appendix B). IGARD noted that PAG supported the application, and noted the comments made on the application; in particular the advice made by PAG in respect of the Type 1 Opt-outs, and confirmed that they were supportive of the request made by PAG, in respect of providing appropriate communication to the consented cohort.

	IGARD queried the conflicting information within the application, the transparency and consent materials provided, in that they did not align in respect of the data controllership and data processing arrangements for the study, for example, the role of Swansea University. IGARD expressed concern that the participant materials may not cover the location of the processing at Swansea University; and asked that the applicant disseminated a newsletter, to the cohort outlining the data controllership and data processing arrangements, including, but not limited to, the role of Swansea University. In addition, IGARD asked that the applicant, sought clarity from the Research Ethics Committee (REC), in respect of consent and data handling, given the discrepancies in the protocol, patient information sheet (PIS), the consent form and website; and that all relevant documentation was uploaded to NHS Digital's customer relationships management (CRM) system for future reference. In light of the issues raised, IGARD noted that the consent may **not** be compatible with the proposed processing outlined in the application. For example, the participant information sheet states data will be stored on servers at Queen Mary University of London and King's College London and that NHS data will flow to those institutions not the University of Swansea. IGARD queried the information in section 5(c) (Specific Outputs Expected) that referred to other collaborators, including but not limited to King's College London, and asked that for transparency, section 5(a) (Objective for Processing) was updated with clarity on the role of the collaborators; and confirmation that they would not have access to any of the NHS Digital data, with relevant standard wording inserted in section 5 (Purpose / Methods / Outputs). IGARD noted the constraints placed in the Direction for the collection of NHS BSA Medicines dispensed in Primary Care data, and asked that a special condition was inserted in section 6 (Special Conditions), that any use of the NHS BSA data must be within the parameters of the relevant Direction authorising that collection. IGARD noted in section 3(b) that a number of fields had been excluded, for example, pregnant women; and asked that a justification be provided in section 3(b) for the exclusion of pregnant women, since the study was not invasive. IGARD noted one of the benefits in section 5(d) (Benefits) would be *"an understanding of the impact of coronavirus disease on the physical, **mental** and economic wellbeing of the UK population"*, however queried how this could be achieved noting the applicant had not requested the Mental Health Services Dataset (MHSDS). IGARD advised that they would be supportive of the applicant receiving the MHSDS data as an amendment in the future, without coming back for an IGARD recommendation. IGARD noted the benefits outlined in section 5(d), for example, one of the benefits was to *"alleviate pressure on the NHS…"*, however asked that they were expanded, to ensure they complied with NHS Digital's DARS Standard for Expected Measurable Benefits, and are clear as to the benefits to patients, the public **and** the health care system. IGARD noted the references within the application to the CORONAVIT consented trial, however noting the information provided online outlined the involvement of pharmaceutical companies in the trial, asked that section 5(b) (Processing Activities) was updated with a brief explanation of the trial, and to ensure any wording is in line with NHS Digital DARS Standard for Commercial Purpose. IGARD queried the reference in supporting document 4, the Integrated Research Application System (IRAS), to a PhD student; and noting that the application was silent on this point,

	asked that section 5(b) was updated, to provide clarity on the role of the PhD student, and to confirm whether PhD students would have access to NHS Digital data. IGARD noted that supporting document 1, the protocol, contained a helpful narrative outlining the patient and public involvement and engagement (PPIE) that had been undertaken to date; and asked that this was replicated in the public facing section 5(a) of the application, for transparency. In addition, IGARD suggested that the applicant may wish to consider ongoing PPIE, for example, an ongoing PPIE group, throughout the duration of the study. IGARD queried the reference in section 5 to "*lifestyle"*, and asked that this was removed, and consideration was given to another form of wording, since this may not be within the control or agency of the patient, for example, *"life circumstances"*. **Outcome:** IGARD were unable to provide a recommendation for the GDPPR data requested, however provided a positive statement of support. **Outcome:** recommendation to approve subject to the following condition: 1. In respect of consent and transparency: a) The applicant to disseminate a newsletter, to the cohort outlining the data controllership and data processing arrangements, including (but not limited to) the role of Swansea University and reminding them of their ability to withdraw consent if they object to those arrangements. a) To consult the REC, in respect of consent and data handling (given the discrepancies in the protocol, PIS, consent form and website) and undertake any actions the REC consider necessary. b) To upload all relevant documentation to NHS Digital's CRM system. The following amendments were requested: 1. To insert a special condition in section 6, that any use of the Medicines Dispensed in Primary Care NHS BSA data must be within the parameters of the relevant Direction authorising that collection. 2. To update section 5(a) with the helpful PPIE narrative in SD1. 3. To justify in section 3(b) why certain fields have been excluded, for example, maternity. 4. To remove reference in section 5 to *"lifestyle"* and consider another form of wording, since this may not be within the control or agency of the patient, for example, *"life circumstances"*. 5. To update section 5(a) to provide clarity on the role of the collaborators, and to confirm that they will not have access to any of the NHS Digital data. 6. To provide a brief explanation in section 5(b) with regard to the CORONAVit consented trial (noting the pharmaceutical companies involved in that trial, to ensure any wording is in line with NHS Digital DARS Standard for Commercial Purpose). 7. To update section 5(b) to provide clarity on the role of the PhD student, referred to in the IRAS application and confirm whether PhD students will have access to NHS Digital data. 8. To expand the stated benefits in section 5(d) to ensure they comply with NHS Digital's DARS Standard for Expected Measurable Benefits, and are clear as to the benefits to patients, the public and the health care system. The following advice was given: 1. IGARD noted the PAG advice in respect of the Type 1 Opt-outs, and were supportive. 2. IGARD advised that they would be supportive of the applicant receiving MHSDS data, as an amendment in the future, without coming back for IGARD approval.

	3. IGARD suggested that the applicant may wish to consider ongoing PPIE. **Significant risk area:** the consent may not cover processing at the University of Swansea. It was agreed the condition would be approved out of committee (OOC) by IGARD members
2.2	<u>Department of Health and Social Care (DHSC): Department of Health and Social Care (DHSC) TRE access - Enabling Policy Analysis (Presenter: Kimberley Watson / Catherine Day) NIC-484452-H8S1L-v0.3</u> **Application:** This was a new application for access to the following pseudonymised datasets via NHS Digital's Trusted Research Environment (TRE): Community Services Data Set (CSDS), COVID-19 Hospitalization in England Surveillance System, Covid-19 UK Non-hospital Antibody Testing Results (Pillar 3), Covid-19 UK Non-hospital Antigen Testing Results (pillar 2), COVID-19 Vaccination Adverse Reactions, Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC), HES Critical Care, HES Outpatients and GPES Data for Pandemic Planning and Research (COVID-19) (GDPPR). DHSC currently holds an active Data Sharing Agreement (DSA) under NIC-365132-V5S8H-v1.2, which includes access to NHS Digital's Data Access Environment (DAE) for the same purpose. This purpose of this DSA is to replace the existing DAE agreement as the datasets currently held under NIC-365132-V5S8H-v1.2 that are still required, become available within the TRE. DHSC will use the data within NHS Digital's TRE for the analysis of data, in support of the Secretary of State for Health in delivery of their duties set out within the National Health Service Act 2006. NHS Digital advised IGARD that this application had been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 15th September 2021, and that PAG had confirmed that they were currently unable to support the request for GDPPR data; and that the application would need to be updated accordingly. NHS Digital noted that DHSC complies with Her Majesty's Government (HMG) Security Policy Framework (SPF), as opposed to the NHS Information Governance Toolkit; and therefore all security and reports are submitted to the Cabinet Office on an annual basis. **Discussion:** IGARD noted that as per the written confirmation to NHS Digital on the 12th August 2021 (from the IGARD Secretariat), there were no GP members present at the meeting, and IGARD would therefore be unable to provide a recommendation on the GDPPR data requested in this application. IGARD confirmed that as agreed with NHS Digital prior to submission of the application for review, they would provide a recommendation on all other datasets requested as per usual process and in line with IGARD's Terms of Reference; and would provide advice / feedback on the GDPPR data request. IGARD noted the verbal update from NHS Digital in respect of the PAG review, and that they were currently unable to support the request for the addition of the GDPPR data. IGARD asked that the application was updated throughout, to remove **all** references to GDPPR data. IGARD also noted the comments made by PAG on the application. In addition, IGARD noted the special condition in section 6 (Special Conditions) that excluded GDPPR data from benchmarking. Notwithstanding the fact that GDPPR data would be removed from the application, IGARD noted that without a clear rationale it may be questioned by the public as to why the GDPPR data is not suitable for benchmarking, that could benefit patients and the health and care system.

	IGARD also noted the verbal update from NHS Digital in respect of DHSC complying with HMG SPF, and not the NHS Information Governance Toolkit; and asked that written confirmation was provided, for example, an e-mail, that NHS Digital's Security Advisor had expressed satisfaction that the appropriate security was in place. IGARD noted the purpose of the application, in respect of accessing the data in a TRE instead of a DAE, however queried what the benefit of this would be. Noting that this was not clearly outlined within the application, IGARD asked that, for transparency, section 5(a) (Objective for Processing) was updated with a brief explanation. IGARD also queried what the timing was for the transition from the DAE to the TRE; and asked that further detail was provided in section 5(a). IGARD also queried whether there would be a duplication of data in both the DAE and TRE, and if so, asked that a rationale was provided for this in section 5(a), for example, in respect of data minimisation and in line with the NHS Digital DARS Standard for Data Minimisation. In addition, IGARD queried when access to the DAE would cease, and asked that an indicative timeframe was provided in section 5. IGARD noted that the already large scope of the Data Sharing Agreement (DSA) had increased from what was originally outlined in NIC-365132-V5S8H-v1.2, and suggested that NHS Digital may wish to keep this application under review to avoid any excess processing and in line with relevant NHS Digital DARS Standards. IGARD queried the last statement in section 5(b) (Processing Activities) that stated *"The Data Controller has assessed the possibility of implementing further Data Minimisation, however due to the range of analysis DHSC request access to all available pseudonymised record-level data for datasets currently available via the TRE."*, and asked that this was removed, noting there was no data minimisation being undertaken. IGARD noted the yielded benefits outlined in section 5(d) (Benefits) (iii) (Yielded Benefits). However, IGARD asked that a satisfactory update was provided, to ensure they were clear as to the benefits to both patients and the health and social care system more generally and that they complied with NHS Digital's DARS Standard for Expected Measurable Benefits. IGARD noted within section 5(a), that this DSA would not allow access to the Mental Health Services Data Set (MHSDS) and the Maternity Services Data Set (MSDS), and asked that section 5(a) was updated, with further clarification as to why these datasets would not be accessed in the TRE, as this was not clear. In addition, in light of the MHSDS and MSDS datasets not included within this DSA, IGARD asked that the outputs in section 5(c) (Specific Outputs Expected) and the Benefits in section 5(d) were reviewed and amended as necessary, for example, in respect of the references to mental health outcomes. Although the application can be framed as policy analysis, IGARD noted the numerous references to *"research"* and strongly suggested the applicant undertakes patient and public involvement and engagement (PPIE) in some form and throughout the lifetime of the agreement. This is not academic research but PPIE would seem justified by: the volume of data flowing; the interests of the public, and the wide scope of the application. IGARD noted that some of the information in section 5 (Purpose / Methods / Outputs) was unclear and suggested that it was updated to ensure that it was written in a language suitable for a lay reader and that further consideration was given to the public audience, for example when referring to *"data wranglers".* IGARD queried the two DHSC storage locations in section 2(c), in light of the data being accessed via the TRE, and asked these were reviewed and amended if appropriate.

	IGARD queried the reference in section 5(b) to *"Health-led Trials"*, and advised that upon further research, these were consented trials possibly involving the Department for Work and Pensions (DWP) as a sponsor and Data Controller; and therefore asked that the reference was removed, noting this would need a separate DSA. 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 large volume of data flowing, the wide scope of the project, and the duplication of activities in the short-term (DAE and TRE). **Outcome:** IGARD were unable to provide a recommendation for the GDPPR data requested. **Outcome:** recommendation to approve subject to the following conditions: 1. To provide written confirmation (such as an e-mail) that NHS Digital's Security Advisor has expressed satisfaction that the appropriate security is in place. 2. To provide a satisfactory update to the yielded benefits in section 5(d) (iii) to ensure they are clear as to the benefits to both the patients and the health and social care system more generally and comply with NHS Digital's DARS Standard for Expected Measurable Benefits. The following amendments were requested: 1. To update the application throughout to remove all references to GDPPR data (as per the verbal update from NHS Digital). 2. In respect of the DAE and TRE: a) To update section 5(a) with a brief explanation as to the benefits of processing the data within the TRE and not the DAE. b) To update section 5(a) with clarity as to the timing of the transition of all the data from the DAE to the TRE. c) To clarify in section 5(a) whether there will be a duplication of data in both the DAE and TRE, and what the rationale for this is; or, d) If it is possible to remove access to the DAE once TRE access is in place, and to confirm when this will be undertaken. e) To provide an indicative timeframe of when access to the DAE will cease. 3. In respect of the MHSDS and MSDS datasets: a) To update section 5(a) with clarification as to why the MHSDS and MSDS datasets will not be accessed in the TRE. b) To review the outputs and benefits in section 5(c) and section 5(d) and amend as necessary in light of the MHSDS and MSDS datasets not included within this DSA. 4. To update the application throughout to ensure it is written in language suitable for a lay reader and that consideration is given to the patient audience, for example when referring to *"data wranglers".* 5. To review the storage locations in section 2(b) and amend if appropriate. 6. To remove the reference in section 5(b) to *"Health-led Trials"*, noting this may have different data controllership arrangements and would be subject to a separate DSA. 7. To remove the last paragraph from section 5(b) relating to data minimisation. The following advice was given: 1. IGARD noted that the already large scope of the DSA had increased, from what was originally outlined in NIC-365132-V5S8H-v1.2, and suggested that NHS Digital may wish to keep this under review to avoid any excess processing.

	2. IGARD noted the numerous references to “research” within the application, and strongly suggested that the applicant undertakes PPIE, in some form and throughout the lifetime of the agreement, given the significant amount of data flowing, public interests and wide scope of the application. 3. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the large volume of data flowing, the wide scope of the project, and the duplication of activities in the short-term (DAE and TRE). 4. IGARD suggested that this application would not be suitable for NHS Digital’s Precedent route, including the SIRO Precedent, due to the large volume of data flowing, the wide scope of the project, and the duplication of activities in the short-term (DAE and TRE). **Significant risk areas:** 1. Noting the special condition to exclude GDPPR data from benchmarking, without a clear rationale, it may be questioned by the public as to why this data is not suitable for benchmarking that could benefit patients and the health and care system. 2. Appropriate security assurances not being in place. It was agreed the conditions would be approved out of committee (OOC) by IGARD members
3	<u>Returning Applications</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. Due to the volume and complexity of applications at today’s meeting, IGARD were unable to review any applications as part of their oversight and assurance role.
4	<u>COVID-19 update</u> To support NHS Digital’s response to COVID-19, from Tuesday 21st April 2020, IGARD will hold a separate weekly meeting, to discuss COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 urgent applications that have been submitted to NHS Digital. Although this is separate to the Thursday IGARD meetings, to ensure transparency of process, a meeting summary of the Tuesday meeting will be captured as part of IGARD’s minutes each Thursday and published via the NHS Digital website as per usual process. IGARD noted that due to member availability, and as notified to NHS Digital on the 26th July (by the IGARD Secretariat), the COVID-19 response meeting on Tuesday 14th September 2021 was cancelled.
5	<u>AOB:</u> There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 10/09/21

These applications were previously recommended for approval with conditions by IGARD, and since the previous Out of Committee Report the conditions have been agreed as met out of committee.

NIC Reference	Applicant	IGARD meeting date	Recommendation conditions as set at IGARD meeting	IGARD minutes stated that conditions should be agreed by:	Conditions agreed as being met in the updated application by:	Notes of out of committee review (inc. any changes)
NIC-419335-H5P8T	University of Oxford	15/07/2021	1. In line with NHS Digital's DARS Data Minimisation Standard: a) to provide a justification in section 5 as to why the pseudonymised dataset will be held by both the University of Oxford and ICNARC. b) To clarify in section 5, why the data cannot be held in one location, and bring the researchers to it, especially since remote access is envisaged.	IGARD members	Quorum of IGARD members	*None*
NIC-526363-C3M1K-V0.2	Sanofi Pasteur	26/08/2021	1. In respect of the Data Controllership and in line with NHS Digital's DARS standard for data controllers: a) If Aventis Pharma Ltd (subsidiary company of Sanofi Pasteur) also make decisions about the work being undertaken, to update section 1(b) to reflect the factual scenario and include them as a joint Data Controller; **and** b) To update section 1(b) to remove the DPA registration details and DSPT details for Aventis Pharma Ltd from Sanofi Pasteur listing;	IGARD Chair	OOC by the IGARD Chair	As this OOC was reviewed prior to the minutes being ratified, NHS Digital updated the IGARD Chair verbally and by writing, as to how the condition would be addressed. The IGARD Chair provided the following confirmation in response to the written confirmation received from NHS Digital: *"I confirm that this is an accurate summary of the conversation with NHS Digital. I confirm that I am*

			c) If both Sanofi Pasteur and Aventis Pharma Ltd are joint data controllers, to ensure the appropriate DSFC is in place for both organisations.			*content to take Chair's action to recommend that this application proceed on this basis with the relevant amendments made.*
NIC-435152-C0H4N	Royal Devon and Exeter NHS Foundation Trust	26/08/2021	1. In respect of the data controllership and in line with NHS Digital's DARS standard for Data Controllers: a. To clarify that none of the other named funders or parties named on the applicant's website or protocol should be considered a joint data controller; b. If the facts lead to the Imperial College London, the University of Hull and Hull University Teaching Hospital NHS FT (or others) being considered joint data controllers, to update the application throughout; *OR* c. To make the requisite updates to section 5(a) if Imperial College London are not considered a joint data controller, and to also outline why the University of Hull and Hull University Teaching Hospital NHS FT are also not considered joint data controllers given the significant role those parties appear to play (and noting that access to data is **not** determinative of controllership). 2. In respect of the commercial element, noting that benefits may be indirect, delayed or non-financial, and in line with NHS Digital's DARS standard for Commercial purpose: a. To update section 5(a) to outline the potential commercial benefits flowing	IGARD members	Quorum of IGARD members	IGARD are content that the condition 1 has been met **if** the following wording can be removed from section 5a *"Imperial College London will have no access to NHS Digital data"* ***and*** *the statement about the other parties uses the GDPR language or concepts around "determining the purpose and means"*. The current wording just covers off not having input into the means of processing, but is not explicit that Hull University have no input into the **purpose** of processing the data. (If that statement cannot be made then they may well have controllership responsibilities.)

			to each of the funders described in this section; b. To update section 5(e) in line with the Commercial Standard.			

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

Professional Advisory Group Outcomes
Record of feedback Wednesday, 15 September 2021

Application & version	DARS-NIC-449801-W5J4M
Applicant Organisation	QMUL and Swansea
Data Controller Organisation	QMUL and Swansea
Professional Advisory Group Agenda Item	3

The profession supported the application with the addition

The profession would request that the applicant commit to provide appropriate communication to the consented cohort to advise them that should they have a type 1 opt out applied directly with their GP for data to be included within this study they should discuss with the GP the removal of the Opt out.

Appropriate material should be supplied so that the consented cohort would be able to have an appropriate discussion with their GP. The profession would like to see this communication to the cohort providing this update.

Attendees	Role	Organisation
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
Kimberley Watson	SDAO NHS Digital	NHS Digital

Professional Advisory Group Outcomes
Record of feedback Wednesday, 15 September 2021

Application & version	DARS-NIC-484452-H8S1L
Applicant Organisation	DHSC
Data Controller Organisation	DHSC
Professional Advisory Group Agenda Item	5

The profession cannot yet support the application.
The profession has a set of standards that are applied to all applicants; these are applied consistently, and the profession understands that the applicant seeks exception (in particular the email response in relation to standards 5B, C & D) to these standards. Should this be confirmed to be the case the applicant will need to have a discussion with the representative's senior executives of the BMA/RCGP. Given the apparent lack of commitment to the PAG standards the scope of analyses outlined appears to be far in excess (and unconstrained) to that of other applicants; we recommend in the first instance that the applicant outlines a much smaller and clearly defined set of outcomes to progress the application.

5B. All efforts **MUST** be made to ensure **no** GP practice or Primary Care Network (PCN) can be identified, unless there is written evidence that their CCG or LMC have obtained such permission from practices; or similar agreement from the BMA/RCGP. Note that this clause does not preclude practice-level research, only the **publication** of practice-level data.

5C. Results **MUST NOT** be used for performance management of GP practices or PCNs, unless it has been **explicitly agreed, and in writing,** through normal negotiating routes with the BMA.

5D. Any results that are not published in the public domain, for example for closed circulation to SAGE or used to inform policy papers, **MUST** be shared with the BMA/RCGP (via DARS) at the same time as they are circulated; this includes all related content, such as, executive summaries, recommendation on changes in policy, appendices, etc.

The profession would also like to request that condition 6 is also committed to within the application.

To encourage best practices around open science, all applicants MUST agree to work towards making public their finalised protocols, analysis code, and codelists, both for review but also re-use under an Open Source Initiative approved licence; copyright must be equivalent to CC-BY or CC0 GitHub is a commonly used tool to share such content, but organisational websites are also acceptable; https://www.opencodelists.org/ can be used to create and host codelists. Links to such content MUST be referenced in published works.

Attendees	Role	Organisation
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
Kimberley Watson	SDAO NHS Digital	NHS Digital
Cath Day	SCO NHS Digital	NHS Digital