Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 5 November 2020

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Kirsty Irvine (Chair)	IGARD Lay Chair
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Prof. Nicola Fear	Specialist Academic Member
Dr. Maurice Smith	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Vicky Byrne-Watts	Data Access Request Service (DARS)
Dave Cronin	Data Access Request Service (DARS)
Louise Dunn	Data Access Request Service (DARS) (Observer: Item 2.3)
Duncan Easton	Data Access Request Service (DARS)
Dan Goodwin	Data Access Request Service (DARS)
Richard Hatton	Clinical Informatics and Deputy Caldicott Guardian (Observer: items 2.1 – 2.4)
Karen Myers	IGARD Secretariat
Vicki Williams	IGARD Secretariat

1	**Declaration of interests:** Paul Affleck noted a personal link to the University of Cambridge application [NIC-156334-711SX]. It was agreed this did not preclude Paul from taking part in the discussions about this application. **Review of previous minutes and actions:**

	The minutes of the 29th October 2020 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	<u>NHS Bedford CCG: DSfC - NHS Bedfordshire CCG - IV & Comm (Presenter: Duncan Easton) NIC-49738-Q2B0D</u> **Application:** This was a renewal application for pseudonymised Secondary Uses Service (SUS+), Local Provider Flows, Mental Health Minimum Data Set (MHMDS), Mental Health Learning Disability Data Set (MHLDDS), Mental Health Services Data Set (MHSDS), Maternity Services Data Set (MSDS), Improving Access to Psychological Therapy (IAPT), Child and Young People Health Service (CYPHS), Community Services Data Set (CSDS), Diagnostic Imaging Data Set (DIDS), National Cancer Waiting Times Monitoring Data Set (CWT), Civil Registries Data, National Diabetes Audit (NDA), Patient Reported Outcome Measures (PROMs) and NHS e-Referral Service (e-RS). It was also an amendment to 1) add AH Analysis Ltd as a Data Processor for commissioning purposes, 2) add ANS Group Ltd as a Data Processor who will assist in the setup and management of SCW CSU cloud, 3) add Microsoft Azure for South, Central and West Commissioning Support Unit, 4) add NHS e-Referral Service (e-RS) data, 5) add National Diabetes Audit and Patient Reported Outcome Measures (PROMS). The overall purpose is for Invoice Validation (IV) which is part of a process by which providers of care or services are paid for the work they do; and to provide intelligence to support the commissioning of health services. NHS Digital advised IGARD that section 1 (Abstract) included a statement confirming that NHS Digital's Security Advisor was satisfied with the use of Cloud storage, and that this would need moving to section 1(b) (Data Processor(s)) as per usual process. NHS Digital also advised IGARD that section 1 stated that Data Processor 1, South Central and West Commissioning Support Unit had *"no involvement in Invoice Validation"*, and that this was an error and would need updating to align with the correct information outlined in section 5(b) (Processing Activities). **Discussion:** IGARD noted the updates from NHS Digital and supported the amendments, to remove the statement from section 1 that stated that NHS Digital's Security Advisor was satisfied with the use of Cloud storage, and insert into section 1(b) as per the agreed process; and to update section 1 to align the Data Processor 1 information with section 5(b). IGARD noted that within section 2(b) (Storage Location(s)) Capability House was listed as a storage location twice, however the addresses had different postcodes, and asked that these were checked and where relevant amended to ensure the correct postcode was referenced and if necessary the duplicate entry removed. IGARD queried the references in section 5(a) (Objective for Processing) and section 5(c) (Specific Outputs Expected) to risk / patient *"stratification"*, and noting that the application was for Invoice Validation and Commissioning, asked that these references were reviewed and removed if necessary.

	IGARD noted the statement in section 5(b) *"Patient level data will not be shared outside of the CCG unless it is for the purpose of Direct Care…"*, and asked that this was reviewed and removed if necessary, since it was not relevant. IGARD noted a number of acronyms in section 5(a) and asked that this public facing section be updated to ensure that all acronyms upon first use were expanded and clearly defined with a supportive explanation in a language suitable for a lay reader, for example *"SLAM"*. IGARD queried the yielded benefits outlined in section 5(d) (Benefits) (iii) (Yielded Benefits), noting that there was minimal information provided, and asked that a satisfactory update was provided of the yielded benefits to date, and to ensure they complied with the NHS Digital DARS Standard for Benefits. Separate to this application, IGARD discussed how the yielded benefits for CCG applications could be reviewed, please refer to AOB for further details. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. **Outcome:** recommendation to approve. The following amendments were requested: 1. To insert the reference to the cloud storage security assurances, in section 1(b). 2. To update section 1 to align the Data Processor 1 information with section 5(b). 3. To amend section 2(b) in reference to different postcodes for Capability House. 4. To amend section 5(a) and section 5(c) to review any reference to *"stratification"* and remove if necessary. 5. To amend section 5(b) to review the reference to *"direct care"* and remove if necessary. 6. To amend section 5 to ensure that all acronyms upon first use be defined and further explained if the meaning is not self-evident. 7. To review section 5(d)(iii) in line with NHS Digital's DARS Standard for Benefits.
2.2	<u>NHS Wolverhampton CCG: NHS Social Care Digital Programme - Black Country & West Birmingham STP (Presenter: Dan Goodwin) NIC-218988-L5K0G</u> **Application:** This was a renewal application for pseudonymised Secondary Uses Service (SUS+) data; and an amendment to add four Data Controllers, NHS Dudley CCG, Dudley Metropolitan Borough Council, NHS Sandwell and West Birmingham CCG and NHS Walsall CCG. The overall purpose is to provide intelligence to support the commissioning of health services. NHS Digital advised IGARD that following the submission of the application for IGARD to review, there had been some further changes made, including updating the DPA expiry dates. In addition, NHS Digital advised that the applicant had sent through additional information in relation to the yielded benefits, that advised that these had been added to the application following submission to IGARD. **Discussion:** IGARD noted and supported the updates from NHS Digital that had been made to the application following submission, which included updating the DPA expiry dates. IGARD also noted the additional yielded benefits added to the application following submission to IGARD, however suggested that in addition, NHS Digital should work with the applicant to provide further details of the benefits flowing to the local community. Separate to this application IGARD discussed how the yielded benefits for CCG applications could be reviewed, please refer to AOB for further details.

	IGARD queried what the DSCRO regional processing restrictions were, that mean NHS Midlands and Lancashire CCG had to be used as a *"landing point"*; and were advised by NHS Digital this had been discussed with DSCRO contact for Central Midlands who worked for NHS Midlands and Lancashire CCG, who had confirmed that this was due to a resource issue. IGARD noted the update from NHS Digital, however advised that this would create additional risk due to the additional step with the processing of data. IGARD noted that NHS Sandwell and West Birmingham CCG and NHS Wolverhampton CCG had not met Data Security and Protection Toolkit (DSPT) training requirements, and queried if it was a requirement for at least 95% of staff to have completed their annual security training, and were advised by NHS Digital that 95% of staff successfully completing their annual security training remains a DSPT standard. IGARD asked that a statement be included in section 1 (Abstract) that the NHS Digital DSPT team were assured that appropriate protections were in place for NHS Digital data. IGARD noted the statement in section 5(b) (Processing Activities) that *"The pseudonymisation key cannot be used to re-identify data as the tool does not allow for this to happen, it only allows for one way pseudonymisation."*, and queried if PI Ltd flowed the outputs using new pseudonyms, or was this issue covered by the agreement stating there will be no re-identification of individuals. NHS Digital advised that a different pseudo ID applied to the record level outputs the Local Authorities would receive; and suggested that additional text was added to section 5(b) that 'Pi Ltd send pseudonymised outputs to the local authorities, these outputs have a different pseudonymisation key applied to what is held by the Local Authority.' IGARD noted the update and supported the amendments to the existing text in section 5(b) that addressed the pseudonymisation key. IGARD noted and endorsed NHS Digital's review that some of the Data Controllers did **not** meet NHS Digital's Standard for privacy notices. **Outcome:** recommendation to approve The following amendments were requested: 1. To include in section 1 a statement from the NHS Digital DSPT team that they are assured that the appropriate protections are in place for NHS Digital data. 2. To update section 1 in line with NHS Digital's comments, including (but not limited to) updating the DPA expiry date. 3. To amend section 5(b) to highlight the new text addressing the pseudonymisation key. The following advice was given: 1. IGARD suggested that NHS Digital work with the applicant to provide further details of the benefits flowing to the local community.
2.3	<u>University of Cambridge: INTERVAL and COMPARE trial cohorts: Long-term follow up of health outcomes and associations with genetic, biological and lifestyle traits (Presenter: Vicky Byrne-Watts) NIC-156334-711SX</u> **Application:** This was an amendment application to request an additional dataset, the GPES Data for Pandemic Planning and Research (GDPPR) for participants in the INTERVAL and COMPARE studies. The INTERVAL and COMPARE studies are large, richly characterised cohorts with approximately 75,000 participants in total. The aim of this research is to determine risk factors

	for infection of the SARSCoV-2 virus and investigate why some people who carry the virus are symptomatic while others are asymptomatic. The University of Cambridge are requesting the GDPPR dataset to understand the risk factors associated with COVID-19 status and prognosis in order to inform targeted preventative measures (e.g. prioritisation of vaccinations when available), establish molecular factors associated with susceptibility to COVID-19 and clinical trajectory of the disease, and understand resilience to, and recovery from, severe clinical consequences of SARS-CoV-2 infection. **Discussion:** IGARD noted that this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 21st April, 28th April and the 8th September 2020. IGARD also noted that this application had been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) (see Appendix B) on the 28th October 2020. IGARD supported and endorsed all the comments made by PAG, and specifically discussed the point made by PAG in relation to other organisations and / or third parties accessing the data under this Data Sharing Agreement (DSA). IGARD advised NHS Digital that in light of the GDPPR data requested, that should the application return to IGARD in the future, that this would require PAG, or its successor's, approval before returning. The IGARD Chair noted that they would write to the PAG Chair with regard to the point raised by PAG in respect to future onward sharing being removed from the application. IGARD noted that during the last review of this application on the 21st June 2018, NHS Digital were advised that this application was not suitable for Director delegated authority, however observed that numerous versions of the application had been produced since the independent review and approved under SIRO precedent. IGARD advised that on renewal of the application, in April 2021, IGARD would expect that the flow of data and identifiers between the researcher and NHS Digital would be clearly explained; or that further consideration was given as to whether the transfer of identifiers could be reduced further, and that this was in line with NHS Digital's DARS Standard for Data Minimisation. In addition, 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 Senior Information Risk Owner (SIRO) Precedent. IGARD noted the draft patient newsletters dated Autumn 2020, and advised that they were unclear if these had been sent out as yet to the cohort. However, advised that working on the assumption that the newsletters were still in draft, suggested that updates be made prior to circulation, which included, but not limited to; the addition of a short statement to remind the cohort they could withdraw from the study; a link to the privacy notice published on the website; and to retain the helpful highlighting of the reference to GP data. IGARD queried the legal basis referenced in section 3 (Datasets Held / Requested) for NHS Digital to disseminate the GDPPR data and asked that this was reviewed to ensure the correct legal basis was stated. IGARD noted the repeated statement in section 5 (Purpose / Methods / Outputs) that *"University of Cambridge intend to track participants' health over many years"*, and asked that, with regard to GDPPR data, it was made clear that the data would rely on a suitable continuing

	legal basis for this dataset and, in the absence of such continuing legal basis, the long term follow up would **not** apply to GDPPR data. In addition, IGARD asked that a special condition was inserted in section 6 (Special Conditions), setting out the agreed sunset clause wording relating to actions to be taken upon expiry of the COPI Notice, which is relied upon to collect GDPPR data. IGARD noted the references within the application to the Data Access Committee and the Blood Donors Studies Steering Committee, and asked that further information was provided, including, but not limited to, updating section 5 to clearly differentiate between the two committees; to provide further details on the current status of the committees; and to provide a brief overview of the governance of the committees. IGARD noted the statement in section 5(c) (Specific Outputs Expected) that **only researchers from the** University of Cambridge would access the data requested in this application, and queried if this was correct, and were advised by NHS Digital that it was researchers and those on honorary contracts. IGARD noted the update from NHS Digital and asked that the application was updated throughout to ensure that the wording was wide enough for visiting academics; and that any documentation in relation to honorary contracts was uploaded NHS Digital's Customer Relationship Management (CRM) system. IGARD advised that they would be supportive of the applicant requesting and receiving the Business Services Authority (BSA) dataset, which would provide a rich and comprehensive source of medicine data. IGARD suggested that section 5(a) (Objective for Processing) be updated to ensure that where appropriate the term *"gender"* was replaced with the term *"sex"* to reflect the available field in the data set requested. IGARD noted and commended the applicant for providing a table outlining the SNOMED clusters requested and the justification for each one, and recognised the thought that had gone into data minimisation etc. **Subsequent to the meeting:** The Associate Director of Data Access confirmed via email to the IGARD Chair that PAG's comment was that they wanted the application to only describe the current situation and that PAG were not expressing a view on any future application. **Outcome:** recommendation to approve The following amendments were requested: 1. Assuming that the newsletter is still in draft format: a) To include a short statement to remind the cohort they can withdraw from the study. b) To provide a link to the privacy notice published on the website. c) To retain the helpful highlighting of the reference to GP data. 2. To review the legal basis in section 3 for NHS Digital to disseminate the GDPPR data. 3. In relation to the Data Access Committee and the Blood Donors Studies Steering Committee: a) To update section 5 to clearly differentiate between the two committees. b) To provide detail on the current status of the committees. c) To provide a brief overview of the governance of the committees. 4. To ensure that where appropriate the term *"gender"* is replaced with the term *"sex"* to reflect the available field in the data set requested. 5. In respect of the honorary contracts:

	a) To update the application throughout to ensure the wording is wide enough for visiting academics. b) To upload the appropriate documentation to NHS Digital's CRM system. 6. Where reference to tracking participants over many years in section 5, with regard to GDPPR data, to make clear that the data will rely on a suitable continuing legal basis for this dataset and, in the absence of such continuing legal basis, the long term follow up will **not** apply to GDPPR data. 7. To insert a special condition in section 6 setting out the agreed sunset clause wording relating to actions to be taken upon expiry of the COPI Notice (which is relied upon to collect GDPPR data). The following advice was given: 1. IGARD would support the applicant requesting and receiving the BSA dataset, which would provide a rich and comprehensive source of medicine data. 2. On renewal in April 2021, IGARD would expect that the flow of data and identifiers between the researcher and NHS Digital would be clearly explained; or further consideration was given as to whether the transfer of identifiers could be reduced further (in line with NHS Digital's DARS Standard for Data Minimisation). 3. IGARD advised NHS Digital that the application would need PAG or its successor's approval before returning to IGARD. 4. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment. 5. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route.
2.4	<u>Cardiff University: Exploring the mechanisms through which specialist home visiting produces health and well-being benefits for families. (Presenter: Vicky Byrne-Watts) NIC-374907-Q5W5W</u> **Application:** This was a new application for the University College London to access data already supplied by NHS Digital under agreement NIC-333498-D1K7G. Under NIC-333498-D1K7G The Department of Health commissioned the 'Building Blocks' randomised controlled trial (RCT) from Cardiff University to provide independent evidence on the effectiveness of the Family Nurse Partnership (FNP) programme in improving short term outcomes for young parents and their babies. This new request reflects the receipt of additional funding to analyse the existing pseudonymised study data already held, and will explore the mechanisms by which specialist home visiting may have its effect for recipient families. **Discussion:** IGARD queried why this was considered a 'new' application, instead of an amendment to the original Data Sharing Agreement (DSA), NIC-333498-D1K7G. NHS Digital advised that the project outlined for this specific work stream, had an additional Data Controller of the University College London (UCL) who were not listed in the original agreement, and that this application had separate funding arrangements. IGARD also noted that the original application stated *"The research database will not be made available to other researchers (this will be a project specific resource)"*, and suggested that NHS Digital amend NIC-333498-D1K7G to expressly refer to UCL accessing the data under this DSA, in order to prevent a breach of that particular DSA; and confirmed that they would be supportive of that DSA amendment proceeding via the relevant precedent route.

	IGARD noted that section 7 (Ethics Approval) stated that ethics approval was not required because there was no flow of confidential data; which IGARD confirmed that they agreed with this. IGARD queried if the Research Ethics Committee (REC) that approved the original study had been notified and asked whether this application was a study amendment; and were advised by NHS Digital that the applicant had confirmed that the REC had not been consulted. IGARD's view was that the REC should be consulted, and asked that either written evidence was provided that a positive REC opinion had been obtained in respect of the amendments outlined, or; written confirmation was provided that the REC were satisfied that a study amendment was not required. IGARD also asked that a copy of the ethics approval, or a suitable response from REC confirming that updated ethics approval was not required, was uploaded to NHS Digital's Customer Relationship Management (CRM) system. IGARD queried if NHS Digital had assessed whether the proposed use of the data within this application was compatible with the original consent materials for NIC-333498-D1K7G; and asked that written confirmation was provided that the original consent materials were **no**t incompatible with, or in any way precluded UCL from analysing the data. IGARD queried if the published privacy notice and the application aligned with the justification for the continued possession of the identifiers, and asked that these were reviewed accordingly. IGARD noted that section 3(c) (Patient Objections) stated that patient objections had not been applied, however advised that they had been applied to the underlying dataset in the original DSA; and asked that section 3 (Datasets Held / Requested) was updated where relevant to note this. IGARD queried if any members of the cohort had been involved in the funding applications, deciding the proposed use of the data held within SAIL, or any other aspect of this application; and were advised by NHS Digital that lay input to the study had involved a lay group of mothers, who had previously advised the Research Team on earlier phases of work. IGARD noted the update from NHS Digital and asked that section 5 (Purpose / Methods / Outputs) was updated to reflect lay involvement in the design of the study. In addition, IGARD suggested that the lay members involved in the study design were also asked how transparency with cohort members might be improved, beyond updating the website privacy notices. IGARD noted that section 5(e) (Is the Purpose of this Application in Anyway Commercial) stated that there was no commercial purpose, however queried if this was correct in light of the statement in section 5(a) (Objective for Processing) that *"The Family Nurse Partnership (FNP) was developed and licensed by the University of Colorado…"*; and asked that, if relevant, section 5 was updated to outline any potential commercial benefits flowing. IGARD noted that the yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits) contained no information, and asked that this was updated with some brief highlights from the underlying application. **Outcome:** recommendation to approve subject to the following conditions: 1. In respect of the ethical approval, to either: a) Provide written evidence that a positive REC opinion has been sought in respect of the amendments outlined, or; b) Provide written confirmation that REC is satisfied that an updated REC opinion is not required for the study amendment.

	c) To upload a copy of the ethics approval; or a suitable response from REC confirming that updated ethics approval is not required, to NHS Digital's CRM system. 2. To provide written confirmation that the original consent materials are not incompatible with, or in any way preclude UCL from analysing the data. The following amendments were requested: 1. To ensure the privacy notice and application align with regard to the justification for the continued possession of the identifiers. 2. To update section 3 to note that patient objections have been applied to the underlying dataset. 3. To update section 5 to reflect the involvement of the lay members in the design of the study. 4. To update section 5 to outline any potential commercial benefits flowing. 5. To update section 5(d)(iii) with brief highlights from the underlying application. The following advice was given: 1. IGARD suggested that NHS Digital amend NIC-333498 to expressly refer to UCL accessing the data under this DSA, and would be supportive of that DSA amendment proceeding via the precedent route. 2. IGARD suggested that the lay involved in the study design are also asked how transparency with cohort members might be improved, beyond updating the website privacy notices. It was agreed the condition would be approved out of committee (OOC) by IGARD Members
2.5	<u>University of Manchester: GP Data for Diabetes My Way - NHS Test Bed Programme, University of Manchester (Reference GDPPRDR045) (Presenter: Vicky Byrne-Watts) NIC-400600-D8Z2W</u> **Application:** This was a new application for GPES Data for Pandemic Planning and Research (GDPPR) for the Diabetes My Way - NHS Test Bed Programme. The main objective is to assess whether digital interventions, provided and coordinated through the DiabetesMyWay app (called MyDiabetesMyWay across NHS Scotland), provide effective self-management support for people with type 2 diabetes across Greater Manchester during the Covid-19 pandemic. The University of Manchester will be focusing on whether use of these digital interventions is associated with better glucose levels, blood pressure levels and cholesterol levels (i.e. better management of diabetes) during the COVID-19 pandemic, and whether patients using these interventions use GP health services less frequently compared to those who are not using the digital interventions. **Discussion:** IGARD welcomed the application and noted the importance of the study. IGARD noted that this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 22nd September 2020. IGARD noted that this application had also been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) (see Appendix B) on the 14th October 2020. IGARD noted the comments made by PAG. In relation to the specific conditions of support, IGARD also noted that PAG advised that the GP practice code should not be provided unless

	the justification was accepted by the NHSD Caldicott Guardian; and asked that the GP practice code justification be sent to the Caldicott Guardian, and that acceptance of this was confirmed in writing. In addition, IGARD noted that PAG had confirmed support of the data being accessed within an NHS Digital TRE, and NHS Digital's confirmation within the application that this was not a viable solution for this study; and asked that NHS Digital informed PAG of this outcome, and subsequently that PAG would need to consider and advise if they still supported the use of GDPPR data. NHS Digital acknowledged that PAG had requested, that given the involvement of the commercial company, the protocol should be published in the public domain before the study started, and that the results of the study must be published regardless of the outcomes, and that the RCGP BMA received a prior notice of publication; and NHS Digital confirmed that this would take place. IGARD noted the advice received from NHS Digital's Information Governance (IG) in respect of the legal basis, in particular that *"…confidential patient information must be processed solely for a COVID-19 purpose.";* and the applicant's response to this *"I can confirm the data will be processed for covid reasons…".* IGARD asked that NHS Digital seek further advice from IG in relation to this, in light of the information provided within the application that suggests that the data would be used for reasons other than solely for a COVID-19 purpose. In addition, the IGARD Chair noted that they would write to the PAG Chair with regard to this specific point and if PAG had considered the "…*solely for a COVID-19 purpose*…" since it did not sit squarely with the wider involvement of the various parties and the fact the study predated the COVID-19 pandemic. IGARD further queried why the applicant had not sought to update the consent for the cohort, which could extend to activities wider than "solely for a COVID-19 purpose". IGARD noted the statement in section 3(c) (Patient Objections) that *"Patient Objections do not apply to data that is disseminated under the Control of Patient Information (COPI) Notice"*; and asked that notwithstanding the COPI legal basis, the National Data Opt-out was applied to the control group. In addition, IGARD asked that in light of the statement from the applicant that data would only be processed for COVID-19 reasons, asked that the application and relevant supporting documents were revised, to reflect that the application related specifically to the impact of COVID-19 on citizens with Type 2 Diabetes; for example, updating section 5(a) (Objective for Processing) to be clear that this relates only to Type 2 diabetes; to update section 5 (Purpose / Methods / Outputs) to be clear that this study concerns the complications of COVID-19 and not Type 2 diabetics' susceptibility to COVID-19; and to ensure that only the SNOMED codes that related to Type 2 diabetes were included. In addition, IGARD asked that section 5(d) (Benefits) was updated to ensure it referenced benefits that mapped to the processing being for solely COVID-19 purposes. IGARD queried if the Research Ethics Committee (REC) had been notified of the change of processing and datasets requested for the study, and asked that as a minimum, the applicant should seek advice from the REC. IGARD queried the data controllership arrangements, in particularly noting the role of other organisations referenced in the application and supporting documents; and asked that a written explanation was provided why the other parties involved were **not** considered joint Data Controllers, including, but not limited to, MyDiabetesMyWay. IGARD also asked that if

	other parties were considered joint Data Controllers, that the application was updated throughout to reflect this. IGARD noted that section 5(e) (Is the Purpose of this Application in Anyway Commercial) stated that there was no commercial purpose to the application, however asked that section 5 was updated to clearly reflect that commercial partners were testing commercial products. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. In addition, IGARD also noted the statement within the draft privacy notice that *"As the University of Manchester cannot identify individual in the data we hold, please contact NHS Digital if you would like to exercise any of these rights"*, and asked that this reference was removed. **Outcome:** Recommendation to defer, pending: 1. In respect of the PAG conditions of support: a) The GP practice code justification to be sent to the Caldicott Guardian, who needs to accept the justification in writing. b) Noting the TRE is not possible at this time, NHS Digital to inform PAG, who need to consider and advise if they still support the use of GDPPR data. 2. NHS Digital to seek further IG advice with regards to the applicant's response to the legal basis requirement that they are processing data *"solely for COVID-19 purposes"*. 3. Given that the app users are a consented cohort, to provide a justification as to why their consent is not being sought for the proposed data processing. 4. To ensure the application and supporting documents reflect *"solely COVID-19 purposes"* and to update section 5(d) to ensure it references benefits that map to the processing being for solely CV-19 purposes. 5. To revise the application and supporting documents, to reflect that the application relates specifically to the impact of CV-19 on citizens with Type 2 Diabetes, for example: a) To update section 5(a) to be clear that this relates only to Type 2 diabetes. b) To update section 5 to be clear that this study concerns the complications of COVID-19 and not Type 2 diabetics' susceptibility to COVID-19. c) To ensure that only the SNOMED codes that relate to Type 2 diabetes are included. 6. To seek advice from REC in relation to the change in processing and datasets requested. 7. In respect of the data controllership: a) To provide a written explanation why the other parties involved were **not** considered joint Data Controllers, including (but not limited to) MyDiabetesMyWay. b) If other parties are considered joint Data Controller's, to update the application throughout to reflect this. 8. Notwithstanding the COPI legal basis, the National Data Opt-out is applied to the control group. 9. To update the privacy notice to remove reference to study participants exercising their rights by contacting NHS Digital. 10. To update section 5 to clearly explain that commercial partners are testing commercial products.
2.6	University of Bristol: Routine Data Extraction for CAP (Cluster randomised trial of PSA testing for Prostate cancer) MR783A (Presenter: Dave Cronin) NIC-119910-K6W9Q

	Application: This was a renewal and extension application for identifiable Medical Research Information Service (MRIS) data, Demographics data, Cancer Registration data and Civil Registration data, and pseudonymised Hospital Episode Statistics (HES) and Diagnostic Imaging Data Set (DIDS); and an amendment 1) to the purpose which has been significantly amended to meet the current data sharing standards, and 2) the study has completed the 10-year follow-up of its data subjects and commenced a 15-year follow-up. The purpose is for a Cluster randomised trial of Prostate Specific Antigen (PSA) testing for Prostate cancer (CAP), which is a pragmatic, cluster Randomised Clinical Trial (RCT) that compares an invitation to attend for population-based PSA- testing for prostate cancer (intervention group) with standard NHS care (control group). This trial aims to assess the effectiveness of PSA testing in reducing prostate cancer mortality, and its cost effectiveness (i.e. comparing the health-related costs in the two groups in combination with the effectiveness of PSA testing, in order to assist policy makers in their decisions about how to achieve the best use of resources). This Data Sharing Agreement covers the individuals whose data is accessed with informed consent. **Discussion:** IGARD welcomed the application and noted the importance of the study. IGARD noted and supported NHS Digital's review of the study's consent materials, that they were broadly compatible. IGARD noted that the applicant was in contact with the cohort, and suggested that for transparency, the annual review takes the opportunity to set out the continuing long-term follow up, and the timeframes involved. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices and suggested that the privacy notice was updated to clarify the nature of the follow-up and the timings. IGARD suggested that, given the long-running nature of the study, the applicant considered wider patient and public involvement (PPI) engagement, for example, working with the screening population in addition to men who have been diagnosed with prostate cancer. **Outcome:** recommendation to approve. The following advice was given: 1. IGARD suggested that, given the applicant is in contact with the cohort, that the annual review takes the opportunity to set out the continuing long-term follow up, and the timeframes involved. 2. IGARD suggested the privacy notice is also updated to clarify the nature of the follow-up and the timings. 3. IGARD suggested that, given the long-running nature of the study, the applicant considers wider PPI engagement, for example, working with the screening population.
2.7	<u>University of Bristol: Routine Data Extraction for CAP (Cluster randomised trial of PSA testing for Prostate cancer) MR783 (Presenter: Dave Cronin) NIC-319171-G7H8K</u> **Application:** This was a renewal and extension application for identifiable Medical Research Information Service (MRIS) data, Demographics data, Cancer Registration data and Civil Registration data, and pseudonymised Hospital Episode Statistics (HES) and Diagnostic Imaging Data Set (DIDS); and an amendment 1) to the purpose which has been significantly

	amended to meet the current data sharing standards, and 2) the study has completed the 10-year follow-up of its data subjects and commenced a 15-year follow-up. The purpose is for a cluster randomised trial of Prostate Specific Antigen (PSA) testing for Prostate cancer (CAP), which is a pragmatic, cluster Randomised Clinical Trial (RCT) that compares an invitation to attend for population-based PSA- testing for prostate cancer (intervention group) with standard NHS care (control group). This trial aims to assess the effectiveness of PSA testing in reducing prostate cancer mortality, and its cost effectiveness (i.e. comparing the health-related costs in the two groups in combination with the effectiveness of PSA testing, in order to assist policy makers in their decisions about how to achieve the best use of resources). This Data Sharing Agreement covers the individuals whose data was accessed without consent but with support under section 251. **Discussion:** IGARD welcomed the application and noted the importance of the study. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices and suggested that the privacy notice was updated to clarify the nature of the follow-up and the timings, for example using GP Practice Newsletters. IGARD suggested that, given the long-running nature of the study, the applicant considered wider patient and public involvement (PPI) engagement, for example, working with the screening population in addition to men who have been diagnosed with prostate cancer. **Outcome:** recommendation to approve The following advice was given: 1. IGARD suggested the privacy notice is also updated to clarify the nature of the follow-up and the timings, in addition to other communication such as GP Practice Newsletters and posters referring to the study by name. 2. IGARD suggested that, given the long-running nature of the study, the applicant considers wider PPI engagement, for example, working with the screening population.
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. • NIC-16016-Y9H1D Wilmington Healthcare 1. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment. 2. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route. • NIC-10328-S0H5J Cumbria, Northumberland, Tyne & Wear NHS Foundation Trust • NIC-208561-Z1M7V Imperial College London (ICL) • NIC-150780-W6W3Z University of Sheffield IGARD welcomed the four applications as part of their oversight and assurance role and noted a number of comments to NHS Digital and suggested that further information and comments be provided in an IGARD Oversight and Assurance Report. Moving forward, IGARD agreed that COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 applications may also be included as part of the

	oversight and assurance review, not just those that were approved via NHS Digital's precedent route.
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. The ratified action notes from Tuesday 3rd November 2020 can be found attached to these minutes as Appendix C.
5 **5.1**	<u>AOB:</u> <u>CCG Applications – Yielded Benefits</u> IGARD discussed the quantum of data that CCGs were getting under their various DSAs and how the yielded benefits for CCG applications were being updated and subsequently reviewed by DARS, noting that this section was not always updated within the renewals submitted to IGARD. It was agreed that going forward, where a CCG application was recommended for approval **without** having provided transparent yielded benefits or that proceeded via NHS Digital's DARS precedent route that IGARD would review these applications as part of the Oversight and Assurance work. 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 30/10/20

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-178836-V1G3V	Royal Devon and Exeter NHS Foundation Trust	15/10/2020	1. In respect of the patients not consented: a) To provide confirmation what percentage of patients did not consent and are not included within the dataset. b) To provide confirmation if there are any service evaluation implications in respect of the patients not included within the dataset. c) If there is a significant number of patients missing from the dataset, to confirm if the applicant can carry out the service evaluation, using **only** NHS Digital data. 2. To provide justification why NHS Digital are not applying National Data Opt-out's.	IGARD members	Quorum of IGARD members	*IGARD note that 1.5% of people refused consent to participate in the NJR. National Data Opt-outs are to be applied and the opt-out rate is 2.67%. This does not suggest that it is "very few patients". Many of those who refused NJR participation may also have an NDO, but it could be that one in 33 or higher are missing from the dataset. IGARD therefore suggested it may be a factor for the applicant to consider carefully.*

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, Cloud storage, Optum as a Data Processor):

- None

Appendix B

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 28th October 2020

Application & application version: DARS-NIC-156334-711SX-v6.4 **Organisation name: University of Cambridge** **Profession Advisory Group Agenda item: 2**
PAG were content with the adequacy of the consent process having looked at the forms. PAG noted the explanation given by NHS Digital in relation to the location of data use (i.e.: that it is stored at a specific location), however more detail on where the data will be processed such as personal devices would be helpful. PAG noted the visiting academic comment within the application but requested confirmation that such visiting academics would have an honorary contract in place. PAG recommend NHS Digital change the following wording on page 18: “Approval for access by third parties (bona fide researchers) may be considered, by the study, as a future amendment to the data sharing agreement. Under this agreement no further access is permitted”. Change to: "Under this agreement, no further access (such as other organisations or third parties) is permitted." PAG support this application subject to the above comment.

Attendees	**Role**	**Organisation**
Peter Short	Deputy Chair	NHS Digital
Garry Coleman	Associate Director of Data Access	NHS Digital
Mark Coley	Deputy IT Policy Lead	BMA
Amir Mehrkar	GP	RCGP
Julian Costello	GP	RCGP
Pam Soorma	Secretariat	NHS Digital

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 14th October 2020

Application: DARS-NIC-400600 GP Data for Diabetes My Way - NHS Test Bed Programme, University of Manchester
Organisation name: NHS Digital
Profession Advisory Group Agenda item: 3

- PAG recommended that given the involvement of the commercial company, then the protocol should be published in the public domain before the study starts, the results of the study must be published regardless of the outcomes and RCGP BMA receive a prior notice of publication.
- PAG asked that the application make explicit that the commercial company must not influence the study methodology nor have access to results prior to publication.
- PAG also noted the three other organisations mentioned within the application and asked for it to be clarified whether data resulting from them is included within the dataset flowing, or if not then reference to them could be removed.
- PAG suggested that the data could be minimised directly to select only Type 2 individuals through the coding of GP data.
- PAG noted they do not have access to protocol and requested that NHS Digital ensure that it aligns to the methodology outlined in the application.
- PAG requested that NHSD confirmed that the statement in the application that it is not a clinical trial was consistent with the ethics approval. Clarity required on whether this is a service evaluation.
- GP practice code should not be provided unless justification accepted by NHSD Caldicott Guardian.
- PAG request the technology company confirm if they have a clinical safety case according to the DCB 0129 specification and available to share.

PAG supported the application if the points above were addressed, but only if the data were accessed within the NHS Digital TRE.

Attendees	Role	Organisation
Arjun Dhillon	Chair, Caldicott Guardian	NHS Digital
Garry Coleman	Associate Director of Data Access	NHS Digital
Anu Rao	GPC IT Policy Lead	BMA
Amir Mehrkar	GP, Clinical Researcher	RCGP
Julian Costello	Senior Clinical Advisor	RCGP
Peter Short	Directorate Lead	NHS Digital
Jonathan Hope	Principal Data Manager – Data Science	NHS Digital
Janine Robayo	Secretariat	NHS Digital

Appendix C

Independent Group Advising on the Release of Data (IGARD)

Action Notes from the IGARD – NHS Digital COVID-19 Response Meeting

held via videoconference, Tuesday, 3rd November 2020

In attendance (IGARD Members):	Prof Nicola Fear (Specialist Academic Member)
	Kirsty Irvine (IGARD Lay Chair)
	Dr Geoffrey Schrecker (Specialist GP Member / Deputy Specialist Chair)
In attendance (NHS Digital):	Louise Dunn (DARS)
	Karen Myers (IGARD Secretariat)
	Andy Rees (DARS)
	Vicki Williams (IGARD Secretariat)

2	**Welcome** The IGARD Chair noted that this was a weekly meeting convened to support NHS Digital's response to the COVID-19 situation and was separate from the IGARD business as usual (BAU) meetings. IGARD members present would only be making comments and observations on any items that were presented, and were not making formal recommendations to NHS Digital. Should an application require a full review and recommendation, then it should go through the usual Data Access Request Service (DARS) process and be presented at a Thursday IGARD meeting. The action notes from the Tuesday meeting would be received at the next Thursday meeting of IGARD and published as part of those minutes as an appendix. **Declaration of interests:** Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising on COVID-19.
2.1	IQVIA NIC-409290-L1F3L: Permission to Contact **Background:** This was a verbal update to the verbal presentation at the COVID-19 response meetings on the 1st and 8th September and business as usual (BAU) meeting on the 22nd October 2020. This was a new application to utilise the COVID-19 Permission to Contact (CV19 PtC) dataset for the purpose of recruiting participants in the PROVENT vaccine trial The following observations were made on the basis of the verbal briefing only. **IGARD Observations:** NHS Digital noted that a copy of the letter to be sent out to participants and the ethics approval were still outstanding but that these documents were imminent. IGARD members noted that to support the applicant and NHS Digital on this occasion that they could consider any documentation out of committee this week, noting the pressure to get invitations sent out to participants by the end of this week. IGARD members noted the verbal update from NHS Digital and looked forward to further updates in due course.

	Subsequent to the meeting: IGARD received a copy of the PROVENT Study Cover Letter and PROVENT Communication Template for review out of committee. Although the information regarding the study did not fully align with the information given to people who had signed up for the PtC service, in view of the importance of the study it was appropriate to proceed. IGARD Members advised that, in future, anyone seeking to use the PtC service where the agent is not specifically a vaccine makes this clear in all materials for patients which are submitted for ethical approval.
2.2	NIC-356980 MAC Clinical Services Finance Ltd ("MAC") **Background:** This was a draft business as usual (BAU) application for Hospital Episode Statistics (HES) Admitted Patient Care (APC) to look at enhancing clinical research on consented patients who want to enter clinical trials. The following observations were made on the basis of the verbal briefing and draft application only. **IGARD Observations:** IGARD members welcomed sight of this early application from MAC. IGARD members made a number of observations to support progressing any future application. IGARD members were supportive overall of the applicant trying to create cohorts in an efficient and cost-effective way.
2.3	NIC-205466-T2F7N University of York **Background:** This was a verbal update to a business as usual (BAU) application presented to the IGARD BAU meeting on the 30th April 2020 when IGARD had been unable to make a recommendation for approval. NHS Digital noted that they had spoken to the applicant alongside the Associate Director Data Access and Caldicott Guardian, and that additional information was now available for IGARD to consider. The following observations were made on the basis of the verbal briefing. **IGARD Observations:** IGARD members noted the update from NHS Digital and looked forward to further updates in due course.
3.	AOB There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.