

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 21 January 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	Position:
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair (Chair: items 2, 3.5 – 3.7, 5.1, 6)
Prof. Nicola Fear	Specialist Academic Member
Kirsty Irvine (Chair)	IGARD Lay Chair (Chair: items 3.1- 3.4, 5.2)
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	Position:
Dr. Imran Khan	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	Team:
Dave Cronin	Data Access Request Service (DARS)
Louise Dunn	Data Access Request Service (DARS)
Mujiba Ejaz	Data Access Request Service (DARS) (Observer: item 5.2)
Richard Hatton	Clinical Informatics and Deputy Caldicott Guardian (Observer: items 1 - 3.4)
Karen Myers	IGARD Secretariat
Denise Pine	Data Access Request Service (DARS)
Kimberley Watson	Data Access Request Service (DARS)
Vicki Williams	IGARD Secretariat

1	Declaration of interests: Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising on COVID-19.
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	<p>Nicola Fear noted a professional link with Kings College London [NIC-324170-J4P1J] but noted no specific connection with the application or staff involved and it was agreed that this was not a conflict of interest.</p> <p>Nicola Fear noted a professional link to staff at the University of Southampton [NIC-148284-T2GPT] but noted no specific connection with the application or staff involved and it was agreed that this was not a conflict of interest.</p> <p>Nicola Fear noted a professional link to staff at South London and Maudsley NHS Foundation Trust [NIC-292279-Z2S5T] but noted no specific connection with the application or staff involved and it was agreed that this was not a conflict of interest.</p> <p>Paul Affleck noted professional links to the University of Leeds [NIC-402417-N9Z5W] but noted no specific connections with the application or staff involved and it was agreed that this was not a conflict of interest.</p> <p>Review of previous minutes and actions:</p> <p>The minutes of the 14th January 2021 IGARD meeting were reviewed, and subject to a number of minor amendments were agreed as an accurate record of the meeting.</p> <p>Out of committee recommendations:</p> <p>An out of committee report was received (see Appendix A).</p>
2	<p><u>Cancer Data Sets from PHE to be made available in the TRE – Briefing Presentation</u> (Presenter: Dave Cronin)</p> <p>This briefing paper was to inform IGARD of the five cancer data sets which are collected by Public Health England (PHE), that will be transferred to NHS Digital for use in the Cancer Trusted Research Environment (TRE).</p> <p>NHS Digital advised that the dataset collections were as follows: 1) National Cancer Registration Data Set - collected and managed by National Cancer Registration and Analysis Service (NCRAS) at PHE; 2) Radiotherapy Data Set (RTDS) - collected and managed by the National Disease Registration Service (NDRS) at PHE; 3) Systemic Anti-Cancer Therapy (SACT) Data Set - collected and managed by National Cancer Registration and Analysis Service (NCRAS) at PHE; 4) Rapid Cancer Registrations Data Set – collected and managed by the National Disease Registration Service (NDRS) at PHE; and 5) Rapid Diagnostic Centre (RDC) Data Set – collected and managed by the National Cancer Registration and Analysis Service (NCRAS) at PHE.</p> <p>Access to the datasets is permitted to DARS customers for the purposes of COVID-19-related research only, such as the effects of COVID-19 on cancer referrals, services, diagnosis, pathways, treatments, and outcomes.</p> <p>IGARD noted that to help progress this area of work, this briefing presentation had been circulated out of committee in advance of the meeting, and that comments had been collated and shared with NHS Digital prior to the meeting.</p> <p>IGARD welcomed the pre-briefing presentation and looked forward to receiving a briefing note (on the relevant template). Key points to be addressed in the briefing paper had already been circulated out of committee to NHS Digital, and included, but were not limited to:</p> <ol style="list-style-type: none"> 1. Being clear that the “<i>Cancer Data Sets</i>”, are not in fact limited to cancer data and will capture data of citizens who do not have malignancies.

	<p>2. To provide relevant feedback to PHE, with regards to their transparency information and opting out (particularly the separate operation of the National Data Opt-Out and the National Cancer Registration and Analysis Service cancer registration opt-out).</p> <p>3. To ensure a consistent and accurate use of language when referring to clinical terminology.</p>
3	Data Applications
3.1	<p><u>University of Bristol: The High-volume Haemodiafiltration vs High-flux Haemodialysis Registry Trial (H4RT) (Presenter: Kimberley Watson) NIC-166879-K4Z0S</u></p> <p>Application: This was a new application for pseudonymised Hospital Episode Statistics (HES) and Civil Registration data, for the purpose of following up participants of the H4RT trial.</p> <p>The primary outcome of the trial will be the determination of any difference between high-volume HDF and high-flux haemodialysis HD in terms of non-cancer mortality, and hospital admission due to a cardiovascular event or infection. The secondary outcome will be the understanding of the impact of high-volume HDF on: cause specific and all causes of mortality; quality of life; indirect effects such as inflammation, anaemia and bone mineral disorder management; and NHS costs/ cost-effectiveness.</p> <p>Discussion: IGARD noted that supporting document 1.2, the 20th November 2019 letter from the University of Bristol confirming the collaborators for the agreement, stated North Bristol NHS Trust did not consider itself to be a Data Controller or Data Processor <i>for the “sub-set of data provided by NHS Digital”</i>; IGARD queried if this was correct, in light of the contradictory information within the application. NHS Digital confirmed that subsequent to the papers being provided to IGARD for review, relevant discussions had taken place with the applicant, where it been agreed that the University of Bristol were a joint Data Controller with North Bristol NHS Trust. IGARD noted the update from NHS Digital and asked that supporting document 1.2 was removed from NHS Digital’s customer relationships management (CRM) system since it was no longer relevant.</p> <p>IGARD noted and commended the quality and transparency of the consent materials, and advised that they supported NHS Digital’s assessment of the consent materials.</p> <p>IGARD noted that section 2(b) (Storage Location(s)) listed Slough Data Centre as a storage location, and that information provide in supporting document 4, the System Level Information Security Policy, dated the 18th September 2020, stated that this would be managed by Virtus, a specialist data centre provider. IGARD asked that confirmation was provided that Virtus would not have access to the NHS Digital data, and were not considered a Data Processor, citing NHS Digital’s DARS Standard for Data Controllers / Data Processors.</p> <p>IGARD queried information within supporting document 1.1, the data flow diagram, that stated the patient questionnaire data flowing to the university of Bristol was pseudonymised, and queried if this was correct. IGARD suggested that clarification was sought from the applicant, and that the data flow diagram was amended as may be necessary.</p> <p>IGARD queried when the data start date was for the data flowing, and noted that section 5(a) (Objective for Processing) stated that <i>“NHS Digital data will be required for each patient from their individual trial start date”</i>; IGARD queried if this was correct since it would appear to be onerous to provide data for the start date of each individual cohort member, and asked that section 5(a) and section 5(b) (Processing Activities) were updated where relevant, to correctly reflect the start date from when the data would flow.</p>

	<p>IGARD noted the data minimisation information provided in section 3(b) (Additional Data Access Requested) stated “<i>Applicant has only requested data items relevant to cohort of 1550 patients aged 18 years and over with kidney disease, and that there is a planned use for.</i>”, and asked that this was updated further, with an example of how the data would be minimised, for example, by the relevant code sets.</p> <p>IGARD noted the statement in section 5(a) that “<i>...the study team do not anticipate any moral or ethical risks from the processing of their data</i>”, but noted that there could be potentially some moral and ethical risks. IGARD asked that this was amended to expressly state that the moral and ethical risks had been considered and appropriately addressed, and that there are no further issues anticipated.</p> <p>IGARD noted that there was duplicate information in section 5(a) in respect of the cost effectiveness to the NHS, and asked that this was consolidated where relevant.</p> <p>IGARD noted and applauded the thought and effort that had gone into the patient and public involvement (PPI) outlined in section 5(c) (Specific Outputs Expected), specifically the inclusion of the various groups of patients.</p> <p>In addition, IGARD noted and applauded the honest appraisal in section 5(d) (Benefits) when referring to the uncertainty with the type of research outlined, and that some of the benefit were still unknown.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To amend the data flow diagram, as may be necessary, to accurately reflect the status of the returned questionnaire data. 2. To provide confirmation in section 5 that Virtus (Slough Data Centre) will not have access to the NHS Digital data, and are not considered a Data Processor. 3. To update section 3(b) with an example of how the data will be minimised, for example, by the relevant code sets. 4. To update section 5(a) and section 5(b) , where relevant, to reflect the date from when the data will flow. 5. To amend the reference to “<i>moral and ethical</i>” risks, to expressly state that they had been considered and appropriately addressed, and that there are no further issues anticipated. 6. To consolidate the duplicate information in section 5(a) in respect of cost effectiveness.
<p>3.2</p>	<p><u>King’s College London Hospital NHS Foundation Trust: PREgnancy-associated progression of chronic kidney Disease: development of a Clinical predictive Tool (PREDICT):The National Registry of Rare Kidney Diseases (RaDaR), UK Renal Registry (UKRR), Hospital Episode Statistics(HES), and Maternity Services Data Set (MSDS) Linkage (Presenter: Kimberley Watson) NIC-324170-J4P1J</u></p> <p>Application: This was a new application for pseudonymised Hospital Episode Statistics (HES) and Maternity Services Data Set (MSDS), for the purpose of developing a 'calculator' which can predict how much kidney function women are likely to lose in pregnancy.</p> <p>The study team have established unique research collaborations to develop a prediction tool for pregnancy-associated progression of Chronic Kidney Disease (CKD) using data from approximately 60,000 women. The prediction calculator will allow women, their families and partners and health care professionals to input relevant data (e.g. severity of kidney disease,</p>

presence of high blood pressure) and the tool will estimate the chance of kidney function loss as result of pregnancy. Of the 60,000 women provided in the cohort to NHS Digital, it is estimated that between approximately 750 and 6,000 cohort members will be identified as pregnant.

Discussion: IGARD welcomed the application and noted the importance of the study.

IGARD queried the role of King's College London (the University) in the study, noting the information in supporting document 10.1, the PREDICT privacy notice, that specifically referred to King's College London, as a 'Data Controller' and asked that confirmation was provided of the University's role in this application.

IGARD noted that one of the Health Research Authority Confidentiality Advisory Group (HRA CAG) conditions of support, was *"All staff with access to confidential patient information have received appropriate ongoing training to ensure they are aware of their responsibilities and are acting in compliance with the application detail."*; and asked that this was also replicated as a special condition within section 6 (Special Conditions) of the application.

IGARD noted the data minimisation information provided in section 3(b) (Additional Data Access Requested) stated that for the HES data, 23 fields had been requested out of 298; IGARD asked that for transparency, similar information was included for the MSDS data, for example, 51 fields had been requested out of "x" number of fields.

IGARD queried the information in section 5(a) (Objective for Processing) that stated *"Of the 60,000 women provided in the cohort to NHS Digital, it is estimated that between approximately 750 and 6,000 cohort members will be identified as pregnant."*, and asked that further confirmation was provided that clarified if the researcher was only capturing women who are currently pregnant, or those women who had a pregnancy; and to make any amendments as necessary to the application.

In addition, IGARD also queried if the HES and MSDS data that had been requested, was reliable in capturing current or prior pregnancy data, depending on what was necessary to carry out the desired processing; and asked that clarification of this was provided.

IGARD discussed whether the MSDS would capture neonatal deaths that don't take place in a hospital setting, and that although this would account for a very small number of neonatal deaths, it was important that this was captured. IGARD advised that they would be supportive of the applicant requesting additional datasets and for additional datasets flowing to support the study outcomes, and in line with NHS Digital's process and procedures.

IGARD noted the information provided in section 5 (Purpose / Methods / Outputs), in relation to CKD, and advised that the information provided, and language used may cause undue anxiety to CKD patients. IGARD asked that this was updated to provide a more accurate description of the cohort, provide further information of the disease being studied, and the impact on pregnancy outcomes. In addition, IGARD asked that the update within the application mapped to both the study protocol and the data available. IGARD advised NHS Digital that to further support this, they would provide some additional written clinical support wording out of committee.

IGARD queried if there were any anticipated future commercial aspects to the study, for example, the calculator that was being developed to predict how much kidney function women are likely to lose in pregnancy, and whether this would be a licensed product or free to use; and asked that section 5 was updated accordingly.

IGARD noted the reference in section 5(a) to “...*Fertility rates*...” when referring to women with CKD, and asked that this was updated to further define what was meant by this.

IGARD queried the technical information provided in section 5(b) (Processing Activities) in respect of the encryption standards, and asked that this was updated to provide a plain English explanation.

IGARD also queried the information in section 5(b) that “*The Caldicott Guardian will remain responsible for the security of the key file...*”, and asked for confirmation that this was correct since it was not usual for the Caldicott Guardian to provide this function, and if not, that section 5(b) was updated accordingly.

IGARD noted that section 5(b) referred to a “*supporting document*”, and asked that this was removed from this public facing section of the application, as the supporting documents would not be available to view by the public, and was therefore not relevant.

IGARD suggested that the applicant may wish to consider replacing the reference to “*delivery*” with “*birth*” in section 5(c) (Specific Outputs Expected).

Outcome: recommendation to approve subject to the following condition:

1. To provide confirmation of the role of King’s College London (the University) in this application, noting that they have been referenced as a Data Controller in the PREDICT transparency materials.

The following amendments were requested:

1. To update section 6 to replicate the HRA CAG special condition, in respect of staff training.
2. To update section 3(b) to note that the 51 fields in MSDS are out of “x” number of fields.
3. To update section 5 to clarify if the researcher is only capturing women who are currently pregnant, or those women who had a pregnancy; and make any amendments as necessary to the application.
4. To provide clarification if the HES and MSDS data requested is reliable to capture current pregnancy or prior pregnancy (depending on what is necessary to carry out the desired processing).
5. To update section 5 with any anticipated future commercial element, with regard to the calculator/tool.
6. To update section 5(a) to further define the reference to “*fertility rates*”.
7. To update section 5(b), to provide a plain English explanation of the encryption standard applied.
8. To confirm in section 5(b) that the Caldicott Guardian will be responsible for the encryption key and amend if this is not the case.
9. To update section 5(b) to remove the reference to a “*supporting document*”.
10. To update section 5 with regards to CKD to more accurately describe the cohort, disease being studied and impact on pregnancy outcomes, to ensure that it;
 - a. doesn’t cause undue anxiety to CKD patients, and
 - b. maps to both the protocol and data available (suggested wording provided by IGARD).

The following advice was given:

1. IGARD suggested that the applicant may wish to consider replacing the reference to “*delivery*” with “*birth*” in section 5(c).

	It was agreed the condition would be approved OOC by IGARD Members.
3.3	<p><u>University of Birmingham Application Summary: MR785 - PD MED Trial- A randomised assessment of the cost effectiveness of different classes of drugs for Parkinson's Disease (Presenter: Denise Pine) NIC-147927-8K193</u></p> <p>Application: This was an extension and renewal application for identifiable Hospital Episode Statistics (HES) and Medical Research Information Service (MRIS) data; and an amendment to 1) request a one-off dissemination of identifiable Demographic, Civil Registration, and Cancer Registration Data for the period October 2018 and March 2020; and 2) an update to section 5 (Purpose / Methods / Outputs) to ensure this meets NHS Digital DARS Standards.</p> <p>PD MED (Parkinson's Disease Medicines) is a randomised, pragmatic, open label trial that is one of the largest (1,896 UK patients) and longest running trials (20 years) around the world. Its purpose is to compare the long-term cost-effectiveness of four different classes of PD medicines, which are currently prescribed to improve Early (newly or less than 6 months diagnosis) and Later (has PD diagnosis plus motor complications unresponsive to LD dosing changes or timings) patients' Parkinsonian symptoms. The medications being assessed are levodopa (LD), dopamine agonists (DA), monoamine oxidase type B inhibitors (MAOBI) and catechol-O-methyltransferase inhibitors (COMTI). The purpose of the application is to allow researchers to complete their time to event analyses as part of the PD MED clinical trial.</p> <p>NHS Digital advised IGARD that following submission of the application for review, an error had been noted in the Health Research Authority Confidentiality Advisory Group (HRA CAG) letter of support, which incorrectly stated that the data flowing from NHS Digital would be pseudonymised; and noted that HRA CAG would need to be notified of this error.</p> <p>Discussion: IGARD welcomed the application and noted the importance of the research; and commended the applicant and NHS Digital on the quality of the application provided.</p> <p>IGARD noted the update from NHS Digital in respect of the error within the HRA CAG support that stated the data flowing from NHS Digital was pseudonymised. / IGARD asked that the applicant send an express notice to HRA CAG correctly confirming that <u>identifiable</u> data would be flowing. IGARD also asked that a copy of any relevant documentation, confirming HRA CAG's contentment in relation to this issue, were provided to them, and that a copy was also uploaded on to NHS Digital's customer relationships management (CRM) system for future reference.</p> <p>In addition, IGARD asked that a special condition was inserted in section 6 (Special conditions), that that applicant must provide NHS Digital with written evidence that HRA CAG had accepted the notification that the data flowing from NHS Digital was identifiable and not pseudonymised.</p> <p>IGARD noted that the UK General Data Protection Regulation (GDPR) Article 9 legal basis, cited in section 3(b) (Additional Data Access Requested), differed from what was stated elsewhere in the application; and asked that this was updated to correctly align with the rest of the application.</p> <p>IGARD queried the information in section 5(b) (Processing Activities) that the University of Glasgow would retain the data "<i>for at least 25 years</i>", and noted that this did not align with information stated in the supporting documents and privacy notice. IGARD asked that the reference in section 5(b) was removed, as it was necessary to include reference to 25 years, and suggested that the applicant should also update their privacy notice as appropriate, to address the information in relation to the data being held "<i>for at least 25 years</i>".</p>

	<p>IGARD noted the special condition in section 6 relating to the University of Glasgow's security arrangement, that stated <i>"Upon its expiry (27/02/2023), this should be renewed."</i>, and asked that this was updated to more clearly state it "must" be renewed upon expiry.</p> <p>In addition, IGARD also noted that supporting document 6, the data flow diagram, did not include any details about the University of Glasgow's security arrangements, and asked that this was updated as appropriate.</p> <p>IGARD noted the statement in section 1 (Abstract) to <i>"...individuals that have a diagnosis..."</i>, and asked that this was amended to sensitively refer to <i>"individuals who have a diagnosis..."</i>.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. In respect of the HRA CAG support: <ol style="list-style-type: none"> a) The applicant to send express notice to HRA CAG that identifiable data will be flowing from NHS Digital (and not only pseudonymised data). b) To provide a copy of any relevant documentation, confirming HRA CAG's contentment and upload onto NHS Digital's CRM system. c) To insert a special condition in section 6, that that applicant must provide NHS Digital with written evidence that HRA CAG have accepted the notification that the data flowing from NHS Digital is identifiable and not pseudonymised. 2. To ensure the Article 9 UK GDPR legal basis in section 3(b) is aligned with the rest of the application. 3. To remove the reference in section 5(b) to the University of Glasgow holding the data <i>"for at least 25 years"</i>. 4. In respect of the University of Glasgow's security arrangements: <ol style="list-style-type: none"> a) To update the special condition in section 6 to state that the University of Glasgow's security arrangements "must" be renewed upon expiry. b) To update the data flow diagram to reflect the University of Glasgow's security arrangements. 5. To amend section 1 to state <i>"individuals who have a diagnosis..."</i>. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD suggested that the applicant should update their privacy notice, to address the information in respect of the University of Glasgow holding the data <i>"for at least 25 years"</i>.
<p>3.4</p>	<p><u>University of Southampton: MR278 - Study of Birth Cohort from Hertfordshire (Presenter: Denise Pine) NIC-148284-T2GPT</u></p> <p>Application: This was an extension and renewal application for identifiable Hospital Episode Statistics (HES), Civil Registration, Medical Research Information Service (MRIS) and Demographic data; and an amendment, to 1) add additional identifiable HES data, 2) to change the frequency of the Civil Registration data from quarterly to annual releases, 3) an update to section 5 (Purpose / Methods / Outputs) to explain the General Data Protection Regulation (GDPR) legal basis being used and to provide a justification for the HES and Civil Registration data, 4) an update to the outputs (section 5(c) (Specific Outputs Expected)) and benefits section 5(d) (Benefits) have been updated to outline what will be achieved with the additional HES data, and 5) the yielded benefits have been updated (section 5(d)(iii) (Yielded Benefits)).</p>

	<p>The purpose is for The Hertfordshire Cohort Study (HCS), was established in late 1980's, during which time it has contributed to the understanding of life course influences on health in later life. The wider cohort was established by the Medical Research Council (MRC) Environmental Epidemiology to test the hypothesis that chronic, noncommunicable diseases of ageing had their roots in foetal and infant life. 37,000 men and women born in Hertfordshire between 1911 and 1939, whose early health had been documented by health visitors, were flagged for continuous notification of death. Given the accrual of deaths over time and the increasing age of the cohort, a re-examination of early life influences on mortality is due.</p> <p>Discussion: IGARD welcomed the application and noted the importance of the study.</p> <p>IGARD noted that the applicant had made a good effort to include some benefits of the study in section 5(d) (Benefits) (iii) (Yielded Benefits), however asked that these were expanded further to ensure it was clear as to the <i>benefits</i> that accrued to both patients and / or the health care system more generally.</p> <p>IGARD suggested that for transparency, the applicant provide further details about the study to the consented cohort in the next newsletter update, but no later than 12 months from the date of this agreement. Details should include what has happened with consented cohort's data in the past, the role of NHS Digital, and further developments with the study.</p> <p>IGARD noted and commended the approach taken to involve the study participants in the research review.</p> <p>Outcome: recommendation to approve</p> <p>The following amendment was requested:</p> <ol style="list-style-type: none"> 1. To provide further details in section 5(d)(iii) to ensure these are expanded to be clear as to the benefits accruing to patients and/or the health care system more generally. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD suggested that the applicant provide further details about the study to the consented cohort in the next newsletter update (but no later than 12 months from the date of this agreement). Such details should include what has happened with their data in the past, the role of NHS Digital, and further developments with the study.
3.5	<p><u>South London and Maudsley (SLaM) NHS Foundation Trust: MR808 - SLaM IG Clinical Dataset Linking Service (Presenter: Dave Cronin) NIC-292279-Z2S5T</u></p> <p>Application: This was an amendment application, to 1) permit the use of Cloud Storage, and 2) permitting additional data linkages with Lambeth DataNet (LDN) data.</p> <p>SLaM provides a wide range of NHS mental health services; it also includes the National Institute for Health Research (NIHR) Maudsley Biomedical Research Centre (BRC) which works in partnership with the Institute of Psychiatry, Psychology and Neuroscience at King's College London. Together they aim to develop more individualised treatments and support advances in the prevention, diagnosis, treatment and care of mental ill health and dementia. To do this, they bring together researchers, clinicians, allied health professionals and service users from across the University/Trust partnership to work together better in order to meet the challenges of finding better treatments and improved care for patients.</p> <p>The purpose of the application, is to create a research resource to be used for research projects aiming to investigate physical health outcomes (including mortality) and receipt of health care in people with mental disorders attending secondary mental health care services provided by SLaM.</p>

The application was been previously considered on the 29th November 2018, when IGARD had deferred pending: to update section 5 to clarify why Kings College London are not considered as joint Data Controllers; to send a letter of clarification to REC setting out, contrary to the earlier document provided to REC, that the applicant is dealing with pseudonymised data with direct identifiers removed and, in some cases, individuals may be re-identified on request; to update the honorary contract to explicitly reference that substantive employers will be accountable for breaches of data protection laws and confidentiality; to explicitly state in section 5 the identifiers sent to NHS Digital, to align with the s251 support; to update the abstract sections on Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD, including (but not limited to) the justification of public task for Foundation Trusts.

NHS Digital advised IGARD that section 3(b) (Additional Data Access Requested) stated both a UK General Data Protection Regulation (GDPR) Article 9 legal basis, for the Civil Registration deaths data set requested **and** the statement “*GDPR does not apply to data solely relating to deceased individuals*”; and that as the statement was correct in this instance, the Article 9 legal basis would need removing.

Discussion: IGARD noted that the application had been updated to reflect all of the comments previously made. In addition, IGARD noted and commended the applicant and NHS Digital in respect of the updates made to the application, and since IGARD’s last review.

IGARD also noted and supported the update by NHS Digital in respect of the amendment to section 3(b), to remove the erroneous reference to the Article 9 legal basis for the Civil Registration deaths dataset.

IGARD noted that where the UK GDPR Article 6 legal basis was referred to in section 5(a) (Objective for Processing), that a helpful summary of this was provided; however, where the UK GDPR Article 9 legal basis was referred to, a summary had **not** been included; and asked that for consistency and transparency, this was updated as appropriate to further expand this.

IGARD suggested that the applicant reviewed the outdated language in section 5 (Purpose / Methods / Outputs), with their patient group(s) for example, when referring to “*mental disorder*”, and before submitting for any future amendment, extension or renewal.

IGARD also suggested that the Data Controller, liaised with their legal team and Data Protection Officer (DPO), to ensure they were content that this was not personal data; and they are therefore not at risk of a UK GDPR breach, due to misleading statements, such as “*anonymous*”, and in addition, to ensure that all public facing materials were fully transparent about the nature of the data held.

Outcome: recommendation to approve

The following amendments were requested:

1. To update section 5(a) to expand the commentary with regard to Article 9.
2. To update section 3(b) to amend the erroneous reference to Article 9(2)(j) in the Civil Registration – Deaths dataset

The following advice was given:

1. IGARD suggested that the applicant review the outdated language in section 5, with their patient group(s) for example “*mental disorder*”, and before submitting for any future amendment, extension or renewal.
2. IGARD suggested that the Data Controller, liaise with their legal team and DPO to ensure they are content that this is not personal data; and they are therefore not at risk

	<p>of a UK GDPR breach, due to misleading statements, such as “<i>anonymous</i>”, and ensure all public facing materials are fully transparent about the nature of the data held.</p>
3.6	<p><u>University of Leeds: Enumerating the impact of COVID-19 on cancer pathways: a robust evaluation of the NHS Digital Trusted Research Environment (Presenter: Dave Cronin) NIC-402417-N9Z5W</u></p> <p>Application: This was a new application for the University of Leeds and Leeds Teaching Hospitals NHS Foundation Trust (LTHT), to request access to the Cancer Trusted Research Environment (TRE) service for England, to undertake a programme of work on behalf of DATA-CAN, the Health Data Research UK Hub for cancer.</p> <p>The purpose is to enable analyses of linked, nationally collated healthcare datasets to enumerate the impact of COVID-19 on cancer pathways. The research questions will delineate the precise impact of the COVID-19 pandemic on cancer systems and cancer patients.</p> <p>NHS Digital advised IGARD, that following submission of the application for review, further information had been received from the applicant, in respect of the patient and public involvement (PPI); and proceeded to provide a verbal update to IGARD.</p> <p>NHS Digital also advised that additional information had been received, in respect of the governance considerations outlined in section 5 (Purpose / Methods / Outputs); and again, provided a verbal update, outlining the proposed new text.</p> <p>Discussion: IGARD noted that this was a first of type application and had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 6th October, 13th October, 10th November, 1st December, 8th December and 15th December 2020, and the 19th January 2021.</p> <p>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 19th January 2021.</p> <p>IGARD noted and supported the comments made by PAG, and with reference to the point raised in respect of the study outputs, asked that section 5(c) (Specific Outputs Expected) was updated with confirmation that the general practice level outputs would not be identified as part of this application.</p> <p>IGARD also endorsed PAG’s support for the study outputs being shared openly. And that, on renewal, IGARD would expect to see those outputs recorded in section 5(c), and on the Health Data Research UK website and GitHub Repository.</p> <p>IGARD noted the verbal update from NHS Digital in respect of the additional PPI information received following submission of the application for review, and asked that section 5 was updated accordingly to include the additional information received by NHS Digital in the form of an email from the applicant.</p> <p>In addition, IGARD noted the verbal update from NHS Digital in respect of proposed additional wording in relation to the governance considerations, and asked that this was also included within section 5, with the exception of the reference to the word “<i>autonomy</i>” and this be updated to more accurately confirm that the University of Leeds and Leeds Teaching Hospitals NHS Trust were making the decisions, in line with their responsibilities as joint Data Controllers. IGARD also asked that it was made explicitly clear that all decisions were being made by the two Leeds organisations.</p>

<p>IGARD noted the list of the historical collaborators in section 1 (Abstract), and asked that this information was also added to section 5(a) (Objective for Processing) for transparency; however, asked that it was made explicitly clear that the organisations listed had no involvement with this agreement.</p> <p>IGARD noted the processing taking place for the NHSBSA data, and asked that a special condition was added to section 6 (Special conditions) of all other relevant applications, that the processing must be strictly within the scope of use set out in the NHS Business Services Authority (NHSBSA) Medicines Data Directions 2019, relating to this data collection and dissemination.</p> <p>IGARD also asked that a special condition was inserted in section 6, setting out the agreed sunset clause wording relating to actions to be taken upon expiry of the Health Service (Control of Patient Information) Regulations 2002 (COPI) Notice, which is relied upon to collect the General Practice Extraction Service (GPES) Data for Pandemic Planning and Research (GDPPR) GDPPR data.</p> <p>IGARD noted the Data Security and Protection Toolkit (DSPT) code within section 1 referred to the University's Clinical Trials Research Unit, and asked if this was the correct reference.</p> <p>IGARD noted that a copy of the applicant's Data Protection Impact Assessment (DPIA) had not been provided as per usual process, and were advised by NHS Digital that this had been requested, however a copy had not yet been received. IGARD noted and endorsed NHS Digital's request for a copy of the DPIA; and asked that once received, a copy was uploaded to NHS Digital's customer relationships management (CRM) system for future reference.</p> <p>IGARD noted that section 1 made references to "<i>sole</i>" Data Controller, and asked that this was removed as it could be misleading in light of the joint Data Controllership arrangements in place.</p> <p>IGARD queried the reference to "<i>NHS England</i>" in section 5(a), and asked that this was removed as it was not relevant to this application.</p> <p>In addition, IGARD also noted that section 1 contained a slight typo when referring to the DPIA, and asked that this was updated to ensure the "<i>DPIA</i>" acronym when spelt out in full was correct.</p> <p>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.</p> <p>Separate to this application, IGARD suggested that NHS Digital may wish to consider auditing one of the TRE Data Sharing Agreements.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update section 5(a) with the list of collaborators as outlined in section 1, and to explicitly state that they have no involvement with this agreement. 2. Noting the proposed new wording for section 5, to update the application with this wording, but to remove the reference to "<i>autonomy</i>" and be clear that it is the two Leeds organisations making the decisions. 3. To update section 5 with further detail of the PPI, as verbally updated in-meeting. 4. To insert a special condition in section 6 that the processing for NHSBSA data, must be strictly within the scope of use set out in the Direction, relating to the data collection and dissemination.
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	<ol style="list-style-type: none"> 5. 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 GDPR data). 6. To remove reference to “NHS England” from section 5 as this is not relevant. 7. To insert in section 1, the correct DSPT details, for the relevant organisations. 8. With reference to DPIA: <ol style="list-style-type: none"> a) IGARD endorsed NHS Digital’s request for a copy of the DPIA. b) To ensure the “DPIA” acronym when spelt out in full is correct. c) NHS Digital to upload a copy of the DPIA on to their CRM system. 9. In respect of the PAG comments: to clarify in section 5(c) that the general practice level outputs will not be identified as part of this application. 10. To update section 1 to remove references to “sole” Data Controller. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. In respect of the PAG comments: <ol style="list-style-type: none"> a) IGARD endorsed PAG’s support for the study outputs being shared openly via the HDR UK website and GitHub Repository. b) IGARD would expect, on renewal, to see these outputs recorded in section 5(c), and on the HDR UK website/GitHub Repository as appropriate. 2. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment. 3. IGARD suggested that this application would not be suitable for NHS Digital’s Precedent route, including the SIRO Precedent. <p>Separate to this application, NHS Digital may wish to consider auditing one of the TRE Data Sharing Agreements.</p>
3.7	<p><u>NHS England (Quarry House): Rapid Diagnostic Centre - Cancer TRE (Presenter: Dave Cronin) NIC-411785-Z6X7M</u></p> <p>Application: This was a new application to request access to the Cancer Trusted Research Environment (TRE) service for England, to undertake a programme of work evaluating the impact of the national roll out of Rapid Diagnostic Centres (RDCs).</p> <p>RDCs are being rolled out nationally as an important part of a broader strategy to deliver faster and earlier diagnosis and improved patient experience. In time, it is the vision for RDCs to offer: 1) a single point of access to a diagnostic pathway for all patients with symptoms that could indicate cancer; 2) a personalised, accurate and rapid diagnosis of patients’ symptoms by integrating existing diagnostic provision and utilising networked clinical expertise and information locally.</p> <p>NHS Digital advised IGARD that, following the review of the application by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) (see Appendix B) on the 19th January 2021, further discussions had taken place with the applicant, and it had been agreed that the request for the GDPR data would be removed from this application.</p> <p>NHS Digital noted that section 5(c) stated that a dashboard would be developed that “...<i>will enable Cancer Alliances to integrate their own data...</i>”; and that this was a typo and would be updated to correctly state “<i>interrogate</i>”.</p> <p>Discussion: IGARD noted that this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 8th December 2020 and the 19th January 2021.</p>

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 19th January 2021.

IGARD noted the update from NHS Digital in respect of the GDPPR data being removed from the application, and fully endorsed PAG's comment, that should the applicant request GP data in the future, that the application clearly articulated what GP data they are requesting, the purpose for which they were requesting it, and how it would address that purpose.

In addition, IGARD also asked that the application was amended throughout, to remove all references to the applicant requiring GDPPR data.

IGARD also noted that PAG had queried the membership of the Oversight Committee, referred to in the application, and asked that a copy of the Committee's Terms of reference (ToR) were provided and as per usual practice. IGARD asked NHS Digital to assess the ToR to ensure it aligned with the processing undertaken within this application; and that a copy was uploaded to NHS Digital's customer relationships management (CRM) system for future reference.

IGARD fully endorsed the other comments made by PAG, and in particular suggested that the outputs of this work were made publicly available as soon as they were shared outside of NHS England.

IGARD queried the Data Controllershship arrangements, in particular in relation to Monitor and the NHS Trust Development authority who are the legal entities that form NHS Improvement. IGARD asked that clarity was provided as to which legal entities should be considered Data Controllers, as borne out of the facts presented; and also to the sub-contracting arrangements that were in place and in line with the NHS Digital's DARS Standard for Data Controllers.

IGARD also asked that the application and supporting documents were updated with a clear justification of the Data Controllershship arrangements, and in line with the NHS Digital's DARS Standard for Data Controllers.

IGARD noted the information in section 1 that stated "*...no individual employed by NHS England will require access to the Cancer TRE...*", and queried what the relationship was between NHS England and the Strategy Unit hosted by Midlands and Lancashire Commissioning Support Unit (CSU); and asked that confirmation was provided if Midlands and Lancashire CSU were part of NHS England **or** if they are a legal entity in their own right. IGARD asked that if the CSU were part of NHS England, that the reference to no one from NHS England would be processing data was removed from section 5 and in the transparency materials since it would be a contradictory statement of fact.

IGARD noted that there was reference within the application, and the supporting documents, to various commercial organisations and asked that section 5 was updated to clearly articulate and explain the involvement of the commercial organisations.

IGARD noted the information in section 1(c) that the ISO 27001 certification for Ipsos MORI had been extended for 6-months, and queried if this was correct since IGARD were not aware a certification could be extended. IGARD asked that confirmation was provided if the certification had been extended **or** renewed; and that the relevant evidence was provided and uploaded to NHS Digital's CRM system. In addition, IGARD also asked that confirmation was provided that NHS Digital's Security Advisor was content with the 6-month "extension" (if that was the case), and that section 1(c) was updated to reflect their statement.

IGARD noted the benefits outlined in section 5(d), and asked that these were updated to ensure they were written in a way which did not pre-empt the outcome, for example '*to assess whether the RDC's deliver the benefits...*'.

IGARD advised that, upon renewal, section 5(d) should be expanded to also include the benefits accrued directly to patients, and how the outputs may be disseminated directly to them.

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.

Outcome: recommendation to approve subject to the following conditions:

1. In respect of the data controllership:
 - a) To clarify which legal entities should be considered a Data Controller, as borne out of the facts presented with particular reference to Monitor and NHS TDA, and also to the sub-contracting arrangements, in line with the NHS Digital's DARS Standard for Data Controllers.
 - b) To update the application and any relevant supporting documents with a clear justification, and in line with the NHS Digital's DARS Standard for Data Controllers.
2. In respect of the ToR:
 - a) To provide a copy of the Oversight Committee's ToR.
 - b) To ensure the ToR aligns with the processing undertaken within this application.
 - c) To upload a copy of the ToR to the NHS Digital CRM system.
3. To update section 5 to clearly articulate and explain the involvement of the commercial organisations outlined in the application and supporting documents.

The following amendments were requested:

1. To amend the application throughout, to remove all references to the applicant requiring GDPR data.
2. To update section 5(c) to amend the reference **from "integrate" to "interrogate"**.
3. In respect of Midlands and Lancashire CSU:
 - a) To confirm if Midlands and Lancashire CSU are part of NHS England **or** if they are a legal entity in their own right.
 - b) If they are part of NHS England, to remove reference that no one from NHS England will be processing data, from section 5 and in the transparency materials.
4. In respect of Ipsos MORI ISO 27001 certification:
 - a) To confirm in section 1(c) if the ISO 27001 certification has been extended or renewed.
 - b) To provide relevant evidence and upload to NHS Digital's CRM system.
 - c) To confirm that NHS Digital's Security Advisor is content with the 6-month extension, if that is the case to provide an update in section 1(c).
5. To update the benefits in section 5(d) to ensure they are written in a way which does not pre-empt the outcome for example '*to assess whether the RDC's deliver the benefits...*'

The following advice was given:

1. IGARD advised that upon renewal, section 5(d) should be expanded on the benefits accruing directly to patients, and how the outputs may be disseminated directly to the participants.

	<ol style="list-style-type: none"> 2. Noting that GDPR data is to be removed from this agreement, IGARD fully endorsed PAG's comment, that should the applicant request GP data, that the application clearly articulates what GP data they are requesting, the purpose for which they are requesting it, and how it will address that purpose. 3. IGARD fully endorsed the PAG comments and suggested that the outputs of this work, are made publicly available as soon as they are shared outside of NHS England. 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, including the SIRO Precedent. <p>It was agreed the conditions would be approved OOC by IGARD Members.</p>
4	<p><u>Returning Applications</u></p> <p>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.</p> <p>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.</p>
5.1	<p><u>COVID-19 update</u></p> <p>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.</p> <p>The ratified action notes from Tuesday 18th January 2021 can be found attached to these minutes as Appendix C.</p>
5.2	<p><u>NIC-420168-K4N1F University of Bristol (Presenter: Louise Dunn)</u></p> <p>Background: The draft application and supporting documents had previously been seen by the IGARD – NHS Digital COVID-19 Response meeting on the 8th December, 15th December and 12th January 2021.</p> <p>IGARD noted that NHS Digital had specifically requested that the 'Longitudinal Linkage Collaboration: Anonymisation in Context' Briefing Note was considered, which forms part of the supporting documentation for this application.</p> <p>Observations: IGARD noted that they were supportive of the work outlined in the application.</p> <p>IGARD noted that that the paper referred to case law and legislation that has now been superseded, for example "DPA 1998" and "ICO Code on Anonymisation", and suggested that this be updated accordingly.</p> <p>IGARD noted that the applicant considered the data as "anonymous" and queried whether the data was in fact 'personal'. IGARD suggested that the applicant refer to the Information Commissioner's Office (ICO) guidance 'Can we identify an individual indirectly from the information we have (together with other available information)?' when considering this query.</p>

	<p>IGARD queried why the applicant was opting to operate this model to take data outside of the UK General Data Protection Regulation (GDPR), noting that the paper did not provide any justification for this; and highlighted the risks involved if the applicant was processing personal data without complying with the UK GDPR.</p> <p>IGARD suggested that the applicant work with NHS Digital to consider other TREs and the way they hold and class data.</p>
6	<p><u>AOB:</u></p> <p>There was no further business raised, the IGARD Alternate Deputy Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.</p>

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 11/12/20

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-365602-V5H3Z	King's College London	19/11/2020	1. In respect of the date of death (noting NHS Digital policy): a) To provide a rationale as to why the date of death is considered not to be owed a duty of confidence given the other data sets involved and the context within which this data sits. b) To provide a statement in section 1 asserting that, in light of an assessment of the fact, the data is not owed a duty of confidence.	IGARD members	Quorum of IGARD members	None
NIC-327960-M2P9M	Swansea University	26/11/2020	2. In respect of the references to "presumed consent", to update section 5 throughout: a) To remove all references to " <i>presumed consent</i> ". b) To replace with a clear explanation of how the cohort members are selected and identified. c) To also include the legal basis for following and processing the cohort's health information (for example by reference to the s251 support).	IGARD members	Quorum of IGARD members	In respect of amendment 5, IGARD noted: There is one more reference to aggregate data in Section 5: " <i>Study outputs will present aggregate data only; small groups will be merged where possible and meaningful.</i> " IGARD suggested adding a further query about the study output small numbers being suppressed " <i>where possible</i> "

						and would check this aligns with permissions and policy.
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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

Appendix B

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 20th January 2021

Application & application version number: DARS-NIC-402417-N9Z5W-v0.1 Organisation name: University of Leeds Profession Advisory Group Agenda item: 2
<p>PAG clarified the TRE is inside NHS Digital and support the use of TRE.</p> <p>PAG are supportive of the purpose and that the study outputs are being shared openly via the HDRUK GIT hub repository. It was clarified that practice level outputs will not be identified as part of this application.</p> <p>PAG are supportive of this application.</p>

Attendees	Role	Organisation
Arjun Dhillon	Chair, Caldicott Guardian	NHS Digital
Liz Gaffney	Head of Data Access	NHS Digital
Amir Mehrkar	GP, Clinical Researcher	RCGP
Mark Coley	Deputy IT Policy Lead	BMA
Pam Soorma	Secretariat	NHS Digital
Kirsty Irvine	IGARD Lay Member (Observer at meeting)	NHS Digital
Karen Myers	IGARD Secretariat (Observer at meeting)	

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 20th January 2021

Application & application version number: DARS-NIC-411785-Z6X7M-v0.1 Organisation name: NHS England Profession Advisory Group Agenda item: 3
<p>PAG support the use of TRE and support the overarching purpose of the work.</p> <p>PAG request clarification of the membership in relation to the Oversight Group mentioned in the abstract of the application. PAG support the use of an Independent Oversight Group for this purpose.</p> <p>PAG members do not currently support this application as it is unclear what GP data the applicant is requesting. The purpose is unclear and is difficult to match to the data available. For example, within section 15 the applicant should confirm what GP data will be utilised. Normally we would expect variables such as co-mobilities, ethnicity factors to be analysed.</p> <p>PAG request NHS Digital to remind the applicant that patients with type 1 objections are not present in the dataset.</p> <p>PAG requests that the outputs of this work are publicly available as soon as they are shared outside of NHS England.</p>

Attendees	Role	Organisation
Arjun Dhillon	Chair, Caldicott Guardian	NHS Digital
Liz Gaffney	Head of Data Access	NHS Digital
Amir Mehrkar	GP, Clinical Researcher	RCGP
Mark Coley	Deputy IT Policy Lead	BMA
Pam Soorma	Secretariat	NHS Digital
Kirsty Irvine	IGARD Lay Member (Observer at meeting)	NHS Digital
Karen Myers	IGARD Secretariat (Observer at meeting)	

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, 19th January 2021

In attendance (IGARD Members):	Prof Nicola Fear (IGARD Specialist Research Member) Kirsty Irvine (IGARD Lay Chair) Dr. Geoff Schrecker (IGARD Specialist GP Member)
In attendance (NHS Digital):	Dave Cronin (DARS) Louise Dunn (DARS) Dan Goodwin (DARS) Liz Gaffney (DARS) James Gray (DARS) Karen Myers (IGARD Secretariat) Vicki Williams (IGARD Secretariat)

2	<p>Welcome</p> <p>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.</p> <p>Declaration of interests:</p> <p>Geoff Schrecker noted a previous working relationship with some staff involved with NIC-382794-T3L3M University of Oxford application when he was a member of the QResearch Advisory Board. It was agreed this did not represent a substantive conflict of interest.</p> <p>Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising on COVID-19.</p>
2.1	<p><u>NIC-186885-Q1T3D NHS Bristol, North Somerset & South Gloucestershire CCG</u></p> <p>Background: This was an amendment application to add Personal Demographics Services (PDS) data and Summary Hospital-level Mortality Indicator (SHMI) data for commissioning purposes and to add linkage to COVID-19 testing data that the CCG receives from Public Health England (PHE).</p> <p>The application had previously been discussed at the IGARD business as usual (BAU) meeting on 8th October 2020.</p> <p>IGARD Observations:</p>

	<p>IGARD members reiterated comments made in relation to NIC-139035-X4B7K NHS England (Quarry House) business as usual (BAU) application considered at the COVID-19 response meeting on 7th January 2021, that section 5(a) should be updated to provide further justification for the inclusion of the PDS and SHMI data and how this relates to commissioning, since this data is usually used to help to assess healthcare outcomes and patient safety, and identify poor performance with consequent opportunity for quality improvement.</p> <p>Separate to this application, IGARD members suggested that NHS Digital / DARS internal processes should be strengthened to ensure that updates to overarching applications were consequently fed into linked applications.</p> <p>IGARD members noted reference to the University of Bath in the data flow diagram provided as a supporting document and noting they were not party in the application suggested that the data flow diagram be updated to reference the correct University, or if the University of Bath were party to the application to update the application throughout.</p> <p>Noting the limitation of the legal gateway (Direction) that it be clearly articulated in section 5 that the University can only process data as set out in the application, for example updating the application with the previously provided advice from NHS Digital's Privacy, Transparency & Ethics (PTE) Directorate (formerly Information Governance Directorate) with regard to the scope of the processing mapped against the Direction.</p> <p>Separate to this application, IGARD noted that a scoring mechanism had been used to assess internally whether the application should be presented to IGARD and suggested that DARS provide further background information and table a discussion at a BAU meeting.</p> <p>Significant risk areas: none identified.</p>
2.2	<p><u>NIC-386685-K2B6G Royal Free London NHS Foundation Trust</u></p> <p>Background: This was a draft application for the request for Covid-19 UK Non-hospital Antigen Testing Results (pillar 2) data for the FLARE Trial. The draft application and supporting documentation had been previously discussed at the COVID-19 response meeting on the 12th January 2020</p> <p>The following observations were made on the basis of the updated application and supporting documentation only.</p> <p>IGARD Observations:</p> <p>IGARD members noted the update from the applicant with regard to the queries previously made and wanted to clarify a point made with regard to the Telephone Preference Service (TPS).</p> <p>Noting that TPS is usually used for marketing purposes, IGARD members had raised the point previously that under these circumstance it could be seen as a useful proxy for researchers to ascertain those within the proposed cohort who were deemed vulnerable or anxious and did not want to be contacted by phone, or where their family had registered them for TPS to ensure they were not contacted by phone.</p> <p>Separate to this application, IGARD members suggested that NHS Digital look to whether there could be the functionality to create data-set or research specific opt-outs, in addition to citizens being able to apply for the NDO.</p>

	<p>Significant risk areas: none identified.</p>
2.3	<p><u>NIC-424723-D5Q9W Clinical Practice Research Datalink (CPRD)</u></p> <p>Background: This was a new urgent application seeking the minimal SUS dataset for COVID-19 surveillance which is a tailored extract from SUS with a daily data-feed linked to CPRD latest cohort for the duration of the agreement or until the GP system providers were able to integrate this information into their own systems and feed into CPRD in order to effectively monitor the new COVID-19 vaccines.</p> <p>NHS Digital noted that section 5(a) required more information with regard to the objective for processing.</p> <p>IGARD Observations:</p> <p>IGARD members noted that this was valuable and important work and were supportive of the application.</p> <p>In line with the NHS Digital DARS Standard for Objective for Processing, IGARD members agreed with NHS Digital's assessment that section 5(a) needed further information to outline the processing activities being undertaken, including but not limited to, any statutory functions of the applicants.</p> <p>In addition, a special condition should be inserted in section 6 that the data could only be used for the specific purpose outlined in the application and in accordance with the applicant's statutory function.</p> <p>IGARD members supported NHS Digital's assessment that the application would be approved under the NHS Digital DARS SIRO Precedent</p> <p>Significant risk areas: none identified.</p>
2.4	<p><u>NIC-381078-Y9C5K British Heart Foundation / HDRUK (CVD TRE)</u></p> <p>Background: further to the application being recommended for approval at the IGARD business as usual (BAU) meeting on 3rd December 2020, the applicant has requested that the University of Oxford be added as a joint Data Controller and section 5 updated accordingly.</p> <p>This application and various supporting documents had been previously discussed at the COVID-19 response meetings on 26th May, 2nd June, 9th June, 16th June, 23rd June and 24th November 2020, and in addition had been discussed at the IGARD business as usual (BAU) meetings on 25th June, 23rd July, 15th October and 1st December 2020.</p> <p>The following observations were made on the basis of the updated application only.</p> <p>IGARD Observation:</p> <p>Noting Article 26 of the UK General Data Protection Regulation (GDPR) IGARD reiterated comments previously made and asked if the joint Data Controllership Agreement was in place, and if not, if it would be in place within 2 months of signing the data sharing agreement (DSA). NHS Digital noted this was still a live issue.</p> <p>IGARD members reiterated comments made previously with regard to data minimisation and in line with NHS Digital's DARS Standard for Data Minimisation. NHS Digital noted that this was still a live issue and that talks were continuing.</p>

	<p>Noting that the first oversight committee meeting took place on the 30th October 2020 and that NHS Digital were members of that committee, queried if the committee had met since October, since the committee played an important governance role in the context of the operation of the TRE and DSA. NHS Digital noted this was still a live issue.</p> <p>IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent</p> <p>Significant risk areas: Data controllership agreement, data minimisation and oversight committee.</p>
2.5	<p><u>NIC-382794-T3L3M University of Oxford</u></p> <p>Background: This was an amendment application (v2) to add in Covid-19 UK Non-hospital Antigen Testing Results (pillar 2) data, COVID-19 Hospitalisations in England Surveillance System (CHESS) Data, Second Generation Surveillance System (SGSS) data, receive more Civil Registration (Deaths) data, receive one more drop of Secondary Uses Service (SUS) data, and add additional data processors as they were co-applicants on the NIHR New and Emerging Respiratory Virus Threats Advisory Group (NERVTAG) grant.</p> <p>The application and supporting documentation had been previously discussed at the COVID-19 response meeting on the 12th January 2020.</p> <p>NHS Digital noted that since submitting the application for review, the SLSP had been reviewed by the NHS Digital security advisor who had provided recommendations to Dancing House Consulting (Data Processor) and that this would be uploaded to NHS Digital's customer relationship management (CRM) system as a future supporting document.</p> <p>NHS Digital also noted that they were still awaiting a more detailed response with regard to the justification for the amount of data requested.</p> <p>The following observations were made on the basis of the updated application and supporting documentation only.</p> <p>IGARD Observations:</p> <p>IGARD members were supportive of the application and importance that the data under this application should continue to flow to the applicant in order to inform the appropriate construction and revalidation of the algorithm.</p> <p>IGARD members noted that overarching amendment application, <i>NIC-240279 University of Oxford: D27 QResearch-Oxford Data Linkage Project</i>, and supporting documentation had been previously considered at the COVID-19 response meeting on the 21st April 2020 and that this application had proceeded via NHS Digital's DARS SIRO Precedent.</p> <p>IGARD members had noted that the application and by inference any "spin off" application were not suitable for NHS Digital's precedent route and that they wished to review this application again when it comes up for renewal, amendment or extension.</p> <p>IGARD members noted the update provided by NHS Digital and thanked them and the applicant for the work undertaken, including but not limited to the SLSP update with regard to Dancing House Consulting and the overview for the data requested.</p>

	<p>IGARD members reiterated their previous comment in support of NHS Digital's request that noting the NHS Digital DARS Standard for Data Minimisation and the significant volume of data being requested, that a justification be set out of the value and necessity to receive all the requested data (and confirmation that all the data requested will be used solely for the COVID-19 specific processing outlined in this application).</p> <p>Noting the policy change in NHS Digital with regard to reviewing applicant privacy notices but noting that NHS Digital had flagged the non-compliant UK General Data Protection Regulation (GDPR) privacy notice in April 2020, reiterated their comment that since no update was available, and given the high-profile nature of this processing, IGARD suggested that the privacy notice be reviewed to ensure that it was UK GDPR compliant including, but not limited to, an explanation as to how this data is being used for the COVID-19 risk stratification including machine learning and production of algorithms. In addition, that a special condition be inserted in section 6 that the applicant will publish a GDPR compliant privacy notice within 1 month of the receipt of the data under this application.</p> <p>IGARD members queried if the applicant had applied for Office for National Statistics (ONS) survey testing data and were supportive of including this data within the application in order to help further inform the processing activities.</p> <p>IGARD members noted that section 2(c) had been updated to reflect the territory of use as the "EEA" (due to staff being based in Spain and Italy) but suggested that the special condition in section 6 be updated and in line with other similar types of applications for SGSS and CHES data, for consistency, to be clear that the special condition of UK access only to SGSS and CHES data applies in all circumstances.</p> <p>IGARD members notes that the ethics approval documentation provided was dated March 2020 and suggested that if later versions of materials were available that they be provided to NHS Digital and copies held on NHS Digital customer relationship management (CRM) system as supporting documentation.</p> <p>Noting the rotating membership of IGARD, members present suggested that a brief overview of the linked applications be provided in section 1 for background and transparency.</p> <p>IGARD members advised they would wish to review this application again when it comes up for renewal, amendment or extension; and suggested that after this amendment had progressed via the SIRO route that this application would not be suitable for NHS Digital's precedent route (including SIRO).</p> <p>Significant risk areas: Public transparency of processing, data minimisation.</p>
2.6	<p><u>NIC-426830-M1C1K London School of Hygiene & Tropical Medicine (LSHTM)</u></p> <p>Background: NHS Digital were seeking advice on the consent material summary provided for review. NHS Digital noted that no application or other supporting documentation was available.</p> <p>A pilot study is being undertaken to confirm whether medical detection dogs are able to distinguish between positive and negative samples using traditional sniffer dog training methods which will then inform a main study to determine accuracy of the dog's ability to detect the virus by way of detection of volatile odour characteristics of COVID-19 infection.</p> <p>The following observations were made on the basis of the "Summary Protocol v3.0 27 Aug 2020" and a NHS Digital-prepared summary review of the Participant Information Sheet and</p>

	<p><i>"Consent Form v4.0 12 Oct 2020"</i>. IGARD did not receive a copy of the underlying consent materials.</p> <p>IGARD Observations:</p> <p>IGARD noted that this was interesting concept involving a cohort of over 800 participants in a proof of concept study involving medical detection dogs.</p> <p>IGARD members were supportive of the proposition and noting that an application was yet to be submitted by the applicant, suggested if the proof of concept was to move forward to a wider research study, that the applicant work with NHS Digital on the participant consent materials to address the points raised below.</p> <p>For the current proof of concept cohort, IGARD members were in agreement with NHS Digital's assessment that the consent materials were not sufficiently detailed about the processing of data to satisfy the Common Law Duty of Confidentiality; specifically, the assurance to cohort members that their data would not be shared beyond the study team, which was inconsistent with the proposed processing which would involve confidential data being sent to NHS Digital. IGARD suggested that the contradictory statements in the consent materials were addressed by way of clear communications with the cohort, such as an email, that expressly stated the change in study approach since the original consent had been sought and explaining that participants' test data would be sought/corroborated from NHS Digital-held datasets. Such communication to the cohort should advise cohort members that should they no longer wish to participate in the study how they could withdraw their consent (with at least two ways of exercising this ability were provided such as a direct phone number or "click here" link to a relevant email address).</p> <p>IGARD suggested that this update to cohort members be set in train now and before the wider study application was submitted for NHS Digital data to verify the status of whether an individual had COVID-19 at the relevant point in the study.</p> <p>Significant risk areas: incompatibility of consent materials with proposed processing.</p>
2.7	<p><u>Cancer Data Sets from Public Health England (PHE) to be made available in the Trusted Research Environment (TRE) Briefing paper</u></p> <p>Background: the briefing paper was in preparation of the onboarding of five data sets to DARS which permitted DARS customers to access the data for COVID-19 related research only via the cancer TRE:</p> <ul style="list-style-type: none"> • National Cancer Registration Data Set collected and managed by the National Cancer Registration & Analysis Service (NCRAS) at PHE; • Radiotherapy Data Set (RTDS) collected and managed by the National Disease Registration Service (NDRS) at PHE; • Systematic Anti-Cancer Therapy (SACT) Data Set collected and managed by NCRAS at PHE; • Rapid Cancer Registrations Data Set collected and managed by NDRS at PHE; and • Rapid Diagnostic Centre (RDC) Data Set collected and managed by NCRAS at PHE.

	<p>The briefing note had been disseminated out of committee to IGARD members for review, and in addition it was to be considered at the IGARD business as usual (BAU) meeting on the 21st January 2021</p> <p>IGARD Observations:</p> <p>IGARD noted that the presentation was not on the usual IGARD briefing note template but were informed by NHS Digital that this was a pre-briefing and that a briefing note would be prepared and submitted to IGARD in due course and as per usual process.</p> <p>IGARD members noted that this discussion was not to pre-empt discussions that would take place at the BAU meeting on Thursday (21st January 2021) and made the following overarching comments:</p> <ul style="list-style-type: none"> • Noting the COVID-19 Direction had a restricted purpose and time span, and that this was a rich source of data, that this be clearly articulated in the briefing note with a note for how this would be monitored by and communicated to applicants. • That use of language throughout the briefing paper and subsequent applications be used carefully when referencing “cancer” and of particular importance that this be sensitively mapped to all transparency materials. • Related to the above point, not all of the datasets were in fact “Cancer Data Sets” (for example the Radiotherapy Dataset which will capture many patients who do not have, and will not develop, malignancies). • Noting that National Data Opt Outs (NDOs) would not apply to the cancer registry and that a special opt out applied to the registry, that there would be a number of people included in the registry who had exercised their NDO but that would not be effective for these datasets, and that this may have a public perception impact for NHS Digital. <p>Significant risk areas: transparency in particular regarding application of NDOs; specifically, those citizens who had applied for a NDO but may be unaware that their data was being captured for this data collection and that a separate cancer registry opt out was required to give effect to their wishes.</p>
2.8	<p><u>NIC-402417 UCL Partners / University of Leeds (DATA-Can)</u></p> <p>Background: This was a verbal update to the updates that had been previously provided at the COVID-19 response meetings on 6th October, 13th October, 10th November, 1st December, 8th December and 15th December 2020 and was to be considered at the IGARD business as usual (BAU) meeting on 21st January 2021 with regard to the NHS Digital Cancer Trusted Research Environment (TRE) and an application from UCL Partners and the University of Leeds to access the Cancer TRE.</p> <p>IGARD Observations:</p> <p>IGARD members noted this was valuable and useful work.</p> <p>IGARD members noted the update from NHS Digital and that the application was to be presented to the IGARD business as usual (BAU) Meeting on Thursday, 21st January 2021.</p> <p>IGARD members noted that the discussion today was not to pre-empt discussions that would take place at the BAU meeting on Thursday and thanked NHS Digital for their verbal update.</p>

2.9	<p><u>NIC-411785 NHS England (DATA-Can)</u></p> <p>Background: This was a verbal update to a draft application that had been previously provided at the COVID-19 response meeting on 8th December 2020 and was to be considered at the IGARD business as usual (BAU) meeting on 21st January 2021 with regard to Rapid Diagnostic Centres (RDC) which are being rolled out nationally as an important part of a broader strategy to deliver faster and earlier diagnosis and improved patient experience.</p> <p>IGARD Observations:</p> <p>IGARD members noted this was valuable and useful work.</p> <p>IGARD members noted the update from NHS Digital and that the application was to be presented to the IGARD business as usual (BAU) Meeting on Thursday, 21st January 2021.</p> <p>IGARD members noted that the discussion today was not to pre-empt discussions that would take place at the BAU meeting on Thursday and thanked NHS Digital for their verbal update.</p>
3	<p><u>AOB</u></p> <p>There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.</p>