

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held in-person (Leeds) and via videoconference 17 March 2022

IGARD MEMBERS IN ATTENDANCE:	
Name:	Position:
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member
Prof. Nicola Fear	Specialist Academic Member
Dr. Robert French	Specialist Academic / Statistician Member (Observer)
Kirsty Irvine	IGARD Chair
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Chair
Dr. Maurice Smith	Specialist GP Member
Jenny Westaway	Lay Member (Observer)
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	Team:
Michael Ball	Data Access Request Services (DARS) (item 3.5)
Duncan Easton	Data Access Request Services (DARS) (SAT* Observer: item 3.5)
Dan Goodwin	Data Access Request Services (DARS) (Item 3.4)
David Morris	Data Access Request Services (DARS) (Item 3.3)
Karen Myers	IGARD Secretariat
Tania Palmariellodiviney	Data Access Request Services (DARS) (SAT* Observer: items 3.1 - 3.2)
Frances Perry	DigiTrials (Items 3.1 - 3.2)
Kimberley Watson	Data Access Request Services (DARS) (SAT* Observer: item 3.3 - 3.4)
Vicki Williams	IGARD Secretariat
*SAT – Senior Approval Team (DARS)	

1	<p>Declaration of interests:</p> <p>Dr. Imran Khan noted a potential conflict with any applications reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) [NIC-388185-C4D6J], as part of his roles as Deputy Chair of the Health Informatics Group at the RCGP and Co-deputy Chair of the Joint GP IT Committee. It was agreed this did not preclude Dr. Khan from taking part in the discussions about this application, however it was agreed that he would not participate in making a recommendation about the application.</p> <p>Dr. Maurice Smith noted that as a practising GP partner at the Mather Avenue Surgery, which is a member of a local Primary Care Network (PCN), that he would be unable to participate in the discussion relating to the performance management of GP practices [NIC-388185-C4D6J]. it was agreed that this was a conflict of interest, and he would not participate in making a recommendation about the application.</p> <p>Maria Clark noted a professional link with the British Medical Association (BMA), which applies to any applications reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG), as part of her role as officer of the BMA as Vice Chair of its Patient Liaison Group. However, she noted no specific connections with NIC-388185-C4D6J or the 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 10th March 2022 IGARD meeting were reviewed out of committee by IGARD following conclusion of the meeting, and subject to a number of minor changes 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>Briefing Notes</p>
	<p><i>There were no briefing papers submitted for review.</i></p>
3	<p>Data Applications</p>
3.1	<p><u>University of Oxford: PANORAMIC: Platform Adaptive trial of NOvel antiVIrals for eArly treatMent of covid-19 In the Community (Presenter: Frances Perry) NIC-605115-L0W3V-v1</u></p> <p>Application: This was a renewal application to permit the holding and processing of pseudonymised Civil Registration (Deaths), Hospital Episode Statistics Admitted Patient Care (HES APC), HES Critical Care (CC), Medicines dispensed in Primary Care (NHSBSA data) and identifiable Access to Summary Care Records and Covid-19 UK Non-hospital Antigen Testing Results (pillar 2) data.</p> <p>It was also an amendment to 1) extend the current data sharing agreement (DSA) end date to the 30th June 2022 in line with The Health Service Control of Patient Information (COPI) Regulations 2002; 2) to add Low Latency HES APC and Low Latency HES CC Datasets; 3) to add extra fields for HES APC; 4) to add extra fields for HES CC; 5) to add HES Outpatients; 6) to add Emergency Care Data Set (ECDS).</p> <p>The purpose is for the PANORAMIC trial, which is the only national priority clinical trial evaluating potential novel antivirals for COVID-19 in the primary care setting, endorsed by the Chief Medical Officers (CMOs) of all four devolved nations. The primary aim is to determine</p>

	<p>the effectiveness of selected antiviral agents in preventing hospitalisation and / or death in higher-risk patients with a confirmed positive SARS-CoV-2 PCR test result.</p> <p>This is a sister application to the 'Platform Randomised Trial of Treatments in the Community for Epidemic and Pandemic Illnesses' (PRINCIPLE) trial (NIC-411161-G4K7X).</p> <p>This DSA covers both the recruitment of participants to the trial, and the request for follow-up data after recruitment and consent.</p> <p>Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 2nd December 2021.</p> <p>IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 23rd November 2021.</p> <p>IGARD noted that at the IGARD BAU meeting on the 2nd December 2021, they had advised that the restrictive transparency wording for patients on NHS Digital's website would need updating, to expressly refer to the SCR being used for research and specifically name the PANORAMIC Trial, as a specific exception to the SCR policy, which stated that the SCR would not be used for research. IGARD had advised NHS Digital previously of the significant risk to NHS Digital if the website and transparency notice for SCR were not updated prior to the trial commencing. IGARD noted that whilst important in supporting GPs to fulfil their obligations, only the transparency pages for health and care staff had been updated and NHS Digital had omitted updating the pages aimed at the general public. IGARD therefore reiterated their previous request that NHS Digital update their website aimed at the general public and in line with the NHS Digital DARS Standard for Transparency (Fair Processing). In addition, IGARD requested that the customer relationships management (CRM) system was also updated, to reflect the current / correct status of this action.</p> <p>IGARD noted that COPI Regulations were being relied upon to enable recruitment, however queried whether this was also the legal basis for NHS Digital to disseminate further information once a person had consented, noting that if a participant had consented, then there would not be a requirement to set aside the common law duty of confidentiality (CLDoC); and that consent and the COPI Regulation could not apply simultaneously to the same dissemination. NHS Digital advised that COPI Regulation was being relied upon for the dissemination of the COVID-19 UK Non-hospital Antigen Testing Results (Pillar 2) data and SCR, and that for all other flows of data consent was being relied upon. IGARD noted the verbal update from NHS Digital and asked that written confirmation was provided from NHS Digital's Caldicott Guardian that they were content that the COPI Regulation was being relied on for access to the SCR and that this was uploaded to NHS Digital's CRM system for future reference. In addition, IGARD asked that for transparency, the application was updated throughout to reflect the NHS Digital's Caldicott Guardian's contentment on this particular topic.</p> <p>In addition, NHS Digital advised verbally that following the expiry of the COPI Notice, currently the 30th June 2022, consent would be relied on for the SCR data, and s251 for the Pillar 2 data. IGARD noted the verbal update from NHS Digital.</p> <p>IGARD asked that section 3 (Datasets Held / Requested) was reviewed and updated as appropriate, to ensure that that the legal basis for each data flow was accurately recorded.</p> <p>IGARD noted that section 3 stated that CLDoC was addressed by "<i>Statutory exemption to flow confidential data without consent</i>", however, noting that both COPI Regulations and consent were being relied upon to flow the data, IGARD asked that this was updated to correctly reflect</p>
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that the CLDoC was “mixed”, and in line with the published [NHS Digital DARS Standard for Duty of Confidentiality](#).

IGARD queried the identifiability status for the datasets noted in section 3, and asked that this was reviewed and updated as appropriate to ensure the identifiability for the data was accurately recorded where relevant as identifying and not pseudonymised; for example, where COPI Regulation was relied on as the legal basis, noting that this was for identifying data only.

Noting that NHS Digital had upheld National Data Opt-outs (NDO) in respect of the case ascertainment step (use of Pillar 2 data), IGARD queried whether NHS Digital had checked with NHS England that this deviation from [NDO operational policy guidance](#) (that the NDO **does not apply** when data is flowing under Regulation 3 of the COPI Regulation) was acceptable. Furthermore, the operating policy guidance should be updated to reflect an assessment step to consider the application of the NDO where the legal basis for setting aside the duty of confidentiality is Regulation 3 and that differing approaches had been taken during the COVID-19 pandemic.

IGARD noted that following submission of the initial application there had been significant changes, for example in respect of COVID-19 testing and access to polymerase chain reaction (PCR) tests; and asked that a clear statement was provided at the start of section 5(a) (Objective for Processing), acknowledging how the researchers will review the running of the study in light of the Government’s recent policy changes to PCR testing in the community and whether this would impact on the data requested, the processing and the expected outcomes.

IGARD noted that the information within supporting document 1.0, the protocol, stated that SCRs would be used after consent but prior to randomisation, and noting that this did not align with the information within the application, asked that section 5 (Purpose / Methods / Outputs) was updated with a brief explanation reflecting the information in the protocol that the SCR will be used after consent but prior to randomisation.

IGARD also queried the statement in section 5(d) (Benefits) (iii) (Yielded Benefits) “*The Summary Care Record (SCR) data should help to assess eligibility of participants...*”; and asked that this was updated to explain how the eligibility would be assessed, for example, after consent but prior to randomisation.

IGARD noted that when the application had previously been reviewed, they had suggested including an explanation within the application, as to why clinically extremely vulnerable children were being excluded, given the impact the COVID-19 has had, and will continue to have, on this section of society; and that had been addressed in section 5(a) of the application which stated “*The first treatment included in the PANORAMIC trial has conditional licensing for adults and therefore the study team are unable to include under children at this stage. Depending on the advice from the Antiviral Taskforce regarding future treatment arms, and their licensing conditions, the inclusion criteria may be amended in future to include under 18’s.*”. IGARD queried if there had been any developments in this area since the text had last been updated.

IGARD queried the statement in section 5(a) that the Data Safety Monitoring Committee (DSMC) and Trial Steering Committee (TSC) “*...will not have access to any NHS Digital record level data...*”; and asked that this was updated to correctly state that any data accessed by DSMC and TSC would be aggregated with small numbers suppressed.

IGARD noted the statement in section 5(a) “*The trial team will apply the Telephone Preference Service (TPS)...*”, and asked that this was updated to correctly refer to the “TPS flag” or similar.

IGARD queried the references in section 5(a) to “*futility*”, and asked that this was amended in a language suitable for a lay reader, for example “*treatment failure*” or similar.

IGARD noted the participant numbers had increased, and asked that the application was reviewed and updated throughout, to ensure the participant numbers referenced were consistent.

IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital’s Precedent route, including the SIRO Precedent, due to the novel use of SCRs.

Outcome: recommendation to approve subject the following conditions:

1. In respect of the SCR (repeating the advice from IGARD’s previous review):
 - a) That the transparency wording for patients on NHS Digital’s website be updated to expressly refer to the SCR being used for research and specifically name the Panoramic Trial, noting it is a specific exception to the SCR policy (which states that the SCR will not be used for research).
 - b) NHS Digital to update CRM to reflect the current / correct status of this action and note that the previous action taken updated the transparency pages for clinicians only and omitted updating the pages aimed at the general public.
2. In respect of the legal basis:
 - a) To provide written confirmation from NHS Digital’s Caldicott Guardian that they are content that only COPI is being relied on for both pillar 2 data and access to the SCR; and,
 - b) To update the application throughout to reflect the NHS Digital’s Caldicott Guardian’s contentment.
 - c) To upload the written conformation to NHS Digital’s CRM system for future reference.

The following amendments were requested:

1. In respect of section 3:
 - a) To update section 3 to reflect that CLDoC is “*mixed*”.
 - b) To update section 3 to ensure the identifiability for the data is accurately recorded, where relevant, as identifying and not pseudonymised.
 - c) To update section 3 to ensure the legal basis for each data flow is accurately recorded.
2. To update section 5 with a brief explanation reflecting the information in the protocol that the SCR will be used after consent but prior to randomisation.
3. To update section 5(d) (iii) to explain how the eligibility will be assessed, for example, after consent but prior to randomisation.
4. To update section 5(a) that any data accessed by DSMC and TSC will be aggregated with small numbers suppressed.
5. To amend section 5(a) to refer to “*TPS flag*” or similar.
6. To amend the reference in section 5(a) from “*futility*” to “*treatment failure*” or similar.
7. To provide a clear statement at the beginning of section 5(a) acknowledging how the researchers will be reviewing:
 - a) How the study will be run in light of the Government’s recent policy changes to PCR testing in the community; and,
 - b) Whether this will impact on the data requested, the processing and the expected outcomes.
8. To update the application to ensure the participant numbers referenced are consistent.

	<p>The following advice was given:</p> <ol style="list-style-type: none"> 1. Noting the applicant's response to previous questions regarding licencing and the consequent exclusion of children/young people, IGARD queried whether there had been any developments in this area. 2. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the novel use of SCRs. 3. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the novel use of SCRs. <p>Separate to this application:</p> <p>Noting that NHS Digital had upheld National Data Opt-outs (NDOs) in respect of the case ascertainment step (use of Pillar 2 data) , IGARD asked whether NHS Digital had checked with NHS England that this deviation from NDO operational policy guidance (that the NDO does not apply when data is flowing under Regulation 3 of The Health Service (Control of Patient Information) Regulations 2002) was acceptable. Furthermore, should the operating policy guidance be updated to reflect an assessment step to consider the application of the NDO where the legal basis for setting aside the duty of confidentiality is COPI Regulation 3 and that differing approaches had been taken during the COVID-19 pandemic.</p> <p>It was agreed the conditions would be approved out of committee (OOC) by IGARD members.</p>
3.2	<p><u>Department of Health & Social Care (UK Health Security Agency (UKHSA): D24 - Request to share data for Covid-19 purposes – HOSTED Project (Presenter: Frances Perry) NIC-381634-X8H0H-v4</u></p> <p>Application: This was a renewal application to permit the holding and processing of pseudonymised COVID-19 Hospitalization in England Surveillance System, COVID-19 Second Generation Surveillance System, COVID-19 Vaccination Status, Hospital Episode Statistics Accident and Emergency (HES A&E), Personal Demographic Service and Secondary Uses Service Payment By Results Episodes (SUS PBR).</p> <p>It was also an amendment to 1) remove the following datasets: HES Admitted Patient Care (APC), HES Outpatients, Emergency Care Dataset (ECDS) ; 2) to add COVID-19 Ethnic Category dataset / Management Information Ethnic Category (MIECC) Dataset; 3) to add COVID-19 UK Non-hospital Antigen Testing Results (Pillar 2 data); 4) to add additional wording in section 5(b) (Processing Activities) to allow for receipt of all COVID-19 vaccines and boosters within 'Covid Vaccination Status' product (previously just first and second vaccine); 5) to add UKHSA as a joint Data Controller.</p> <p>The purpose of this application is to support the UK Health Security Agency (UKHSA) (previously PHE) surveillance system on household transmission of COVID-19 to enhance the national public health surveillance of COVID-19 infections in the population of England. COVID-19 laboratory and case data from UKHSA will be linked to NHS Digital controlled data sets using a one-way encrypted versions of NHS number and unique property reference number to identify the household contacts of COVID-19 patients. This linked dataset is called "HOSTED" and is used to establish the COVID-19 status and associated outcomes of these household contacts.</p> <p>The HOSTED data sets will be used to identify: a) the testing status of household contacts b) secondary cases of COVID-19 infection among household contacts c) hospital admissions for COVID-19 among household contacts d) risk factors for Covid-19 among household contacts e) deaths from COVID-19 among household contacts.</p>

Discussion: IGARD noted and commended NHS Digital on the quality of the information provided within section 1 (Abstract) of the application, which supported the review of the application by Members.

IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 18th March 2021.

IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 28th September 2021.

IGARD noted that section 1(b) (Data Controller(s)) stated that the Data Security and Protection Toolkit (DSPT) Standards for 2020/21 were not met and *“Published as Baseline 09/03/2022. Review Requested”*, and the DSPT website register stated *“Not Published”*. IGARD asked that written confirmation was provided, for example, an e-mail, that NHS Digital’s Security Advisor has expressed satisfaction that appropriate security assurances were in place for the purpose of this Data Sharing Agreement (DSA) and in line with the [NHS Digital DARS Standard for Security Assurance](#); and that the written confirmation from NHS Digital’s Security Advisor was uploaded to NHS Digital’s customer relationships management (CRM) system for future reference.

IGARD noted the amendment to the application, to add UKHSA as a joint Data Controller, however, noting the information within the [framework document](#) between DHSC and UKHSA published on the 27th January 2022, asked that confirmation was provided that the Data Controller(s) were appropriately described in the application reflecting as may be required, the publicly available framework document; noting that data controllership cannot be assigned and in line with the [NHS Digital DARS Standard for Data Controllers](#).

IGARD noted that the COVID-19 Ethnic Category dataset / MEICC dataset had been requested under this DSA, and queried if this had been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG), noting the process outlined to IGARD via a briefing paper presented at the IGARD BAU meeting on the 6th May 2021 and finalised at the IGARD BAU meeting on the 20th May 2021; that stated *“All applications for COVID-19 Ethnic Category Data Set will be assessed as part of the DARS Applications and Approvals process which will include review by the PAG assurance group and IGARD”*. IGARD asked that written confirmation was provided that PAG had reviewed the proposal and were content, as per the review process notified to IGARD; or, that the policy pathway has changed, and to provide written confirmation to IGARD of what that policy was now; and to upload a copy of the written confirmation to NHS Digital’s customer relationships management (CRM) system for future reference.

IGARD queried if the applicant had undertaken any patient and public involvement and engagement (PPIE), noting that the application was silent on this, and asked that an explanation was provided as to why it was not deemed appropriate to seek the views of the data subjects or their representatives prior to processing. IGARD asked that a narrative be included in the Data Protection Impact Assessment (DPIA) as per the UK General Data Protection Regulation (UK GDPR) Article 35(9) which states *“Where appropriate, the controller shall seek the views of data subjects or their representatives on the intended processing, without prejudice to the protection of commercial or public interests or the security of processing operations.”*. IGARD noted that the ICO offers advice on consulting with data subjects as part of a DPIA process and advises that the DPIA should record if it has been decided that it is not appropriate to undertake this consultation. IGARD also asked that an indicative plan of future PPIE activity was provided, and it was suggested the [HRA guidance on Public Involvement](#) would be a useful reference.

IGARD advised that, as part of the review of the application and supporting documents, it had been noted that an employee of University College London (UCL) had published academic papers using data under this DSA; and asked that confirmation was provided in section 5 (Purpose / Methods / Outputs) that access to the data was by way of their substantive employment with UKHSA (or predecessor organisation); or, to otherwise provide confirmation in section 5 of how the access to the data took place.

IGARD queried the statement in section 5(a) (Objective for Processing) that stated “...*results of specific focussed analyses are shared with technical experts as relevant...*”; and asked that an explanation was provided in section 5 as to who the technical experts are; the level of data that had been shared; and, if necessary to provide the legal gateway in section 5 for sharing of the data.

IGARD noted the inclusion of a number of technical phrases and words within section 5 (Purpose / Methods / Outputs), such as “*discordant vaccination status*” and “*target failures*”, asked that this public facing section, which forms [NHS Digital’s data uses register](#), was amended throughout, to ensure technical terms are explained in a manner suitable for a lay audience.

As section 5 forms [NHS Digital’s data uses register](#), IGARD asked that section 5 were amended, to ensure that all acronyms upon first use be defined and further explained if the meaning is not self-evident, for example “*IMD*”.

IGARD noted the references in section 5 to “*patients that...*”, and asked that these were updated to “*patients who...*”.

Noting that the flow of data excludes s-flags, IGARD suggested that the applicant consider if this raises additional risks of inadvertent reidentification, and whether they needed to put in place any additional steps to mitigate this, noting the contractual obligation in the DSA not to attempt re-identification.

Subsequent to the meeting: IGARD would like the applicant to consider if the identification of the household more generally raises additional risks of inadvertent recognition, for example the identification of a high-profile couple with two children aged 11 and 13, both with type 1 diabetes.

IGARD noted that separate to this application, the SAT team observer had agreed to ask NHS Digital’s Data Production Team whether there was a process in place for assessing multiple data flows or particular combinations of data flows and the risk of identifiability.

IGARD noted that section 1 erroneously stated that a review by IGARD was not required and asked that NHS Digital review their internal processes to ensure that this is always checked and corrected where required.

IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital’s Precedent route, including the SIRO Precedent, due to the nature of the data flows.

Outcome: recommendation to approve subject the following conditions:

1. In respect of the security assurance:
 - a) To provide written confirmation (such as an e-mail) that NHS Digital’s Security Advisor has expressed satisfaction that the activities in this DSA have appropriate security in place.
 - b) To upload a copy of the written confirmation to NHS Digital’s CRM system for future reference.

2. To confirm that the Data controller(s) are appropriately described in the application reflecting, as may be required, the publicly available [framework document](#) between DHSC and UKHSA.
3. In respect of the COVID-19 Ethnic Category dataset / MIECC:
 - a. To provide written confirmation that PAG have reviewed the data and are content, as per the review process notified to IGARD; or,
 - b. That the policy pathway has changed, and to provide written confirmation to IGARD of what that policy is now; and
 - c. To upload a copy of the written confirmation to NHS Digital's CRM system for future reference.
4. In respect of PPIE
 - a) To explain why it was not deemed appropriate to seek the views of the data subjects or their representatives prior to processing and include that narrative in the DPIA as per UK GDPR Article 35(9):
 - b) To provide an indicative plan of future PPIE activity, in line with [HRA guidance on Public Involvement](#).

The following amendments were requested:

1. In respect of the UCL employee who has published academic papers using data under this DSA:
 - a) To confirm in section 5 that access to the data was by way of their substantive employment with UKHSA (or predecessor organisation); or,
 - b) To otherwise provide confirmation in section 5 of how the access to the data took place.
2. In respect of the "*technical experts*" referred to receiving data:
 - a) To provide an explanation in section 5 as to who the technical experts are;
 - b) To explain in section 5 the level of data that has been shared; and,
 - c) If necessary to provide the legal gateway in section 5 for sharing of the data.
3. IGARD noted that section 1 erroneously stated that a review by IGARD was not required and asked that NHS Digital review their internal processes to ensure that this is always checked and corrected where required.
4. As section 5 forms [NHS Digital's data uses register](#), to amend section 5 throughout:
 - a. To ensure acronyms be defined upon first use, for example "*IMD*"; and
 - b. To ensure that technical terms are used only where necessary and explained in a manner suitable for a lay audience, for example "*discordant vaccination status*" and "*target failures*".
5. As section 5 forms NHS Digital's public data release register, to amend the references in section 5(a) and section 5(b) from "*patients that...*" to "*patients who...*".

The following advice was given:

1. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the nature of the data flows.
2. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the nature of the data flows.
3. Noting that the flow of data, which excludes s-flags, IGARD suggested that the applicant consider if this raises additional risks of inadvertent reidentification, and whether they needed to put in place any additional steps to mitigate this (noting the contractual obligation in the DSA not to attempt re-identification).

Separate to this application:

	<p>SAT team observer to ask NHS Digital's Data Production Team whether there was a process in place for assessing multiple data flows or particular combinations of data flows and the risk of identifiability.</p> <p>It was agreed the conditions would be approved out of committee (OOC) by IGARD members</p>
3.3	<p><u>Monitor (NHS Improvement (Monitor / NHS Trust Development Authority): 12-month Renewal (Presenter: David Morris) NIC-15814-C6W9R-v22</u></p> <p>Application: This was a renewal application to permit the holding and processing of pseudonymised Civil Registration (Deaths) - Secondary Care Cut, Community Services Data Set (CSDS), Diagnostic Imaging Dataset (DIDs), Emergency Care Data Set (ECDS), HES:Civil Registration (Deaths) bridge, Hospital Episode Statistics Admitted Patient Care (HES APC), HES Critical Care, HES Outpatients, Improving Access to Psychological Therapies Data Set (IAPT), Linked-Patient Level Costing Integrated Data Set (Linked-PLCINTDS)_NHSI, Mental Health Services Data Set (MHSDS), National Cancer Waiting Times Monitoring DataSet (NCWTMDS), Patient Level Costing Acute Data Set HES-APC (NHSI), Patient Reported Outcome Measures (PROMs) (Linkable to HES), Secondary Uses Service Payment By Results (SUS PbR), SUS PbR Accident & Emergency, SUS PbR Outpatients and SUS PbR Results Spells.</p> <p>The application seeks to request data for both the NHS Trust Development Agency, NHS England / NHS Improvement, and Monitor as join Data Controllers and will be used to support the delivery of the applicant's statutory function and support direct improvement and / or oversight of Trusts.</p> <p>Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 26th March 2020 and 2nd July 2020.</p> <p>The application was also discussed under the '<i>Applications progressed via NHS Digital's Precedent route, including the SIRO Precedent</i>' at the IGARD BAU meeting on the 13th January 2022.</p> <p>IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 21st July 2020, 4th August 2020, 2nd February 2021 and 23rd March 2021.</p> <p>IGARD noted the special condition in section 6 (Special Condition) "<i>NHS I/E are to keep a register of where and when NHS Digital data has been shared with small numbers unsuppressed and this will be shared with NHS Digital on a quarterly basis</i>", and queried if this condition had been met, noting that the application was silent on this. IGARD asked that copies of the quarterly registers were provided, of where and when NHS Digital data has been shared with small numbers unsuppressed; or that NHS Digital advise what steps had been taken in respect of the Data Sharing Agreement (DSA) breach noting that special conditions are important contractual terms specific to this application and in line with the NHS Digital DARS Standard for Special Conditions; and that the relevant documentation was uploaded to NHS Digital's customer relationships management (CRM) system for future reference.</p> <p>IGARD queried the statement in section 5(a) (Objective for Processing) that "...*RNOH wishes to analyse a wide range of data about NHS providers..." (*RNOH - Royal National Orthopaedic Hospital NHS Trust); and asked that an analysis was provided in section 1 (Abstract) as to why RNOH were not considered a joint Data Controller in line with NHS Digital's DARS Standard</p>

[for Data Controllers](#), and as borne out of the facts; or, if the facts lead to the RNOH being considered joint data controllers, to update the application throughout.

IGARD queried the reference in section 5 (Purpose / Methods / Outputs) to *“formal sub licencing arrangements”* and asked that a further explanation was provided, noting that section 10 (Sub-licensing) stated that sub-licensing was not permitted, and in line with [NHS Digital DARS Standard for Sub-licensing and Onward Sharing of Data](#).

IGARD noted that Section 5(d) (Benefits) (iii) (Yielded Benefits) did not appear to be in line with the [NHS Digital DARS Standard for Expected Measurable Benefits](#) and asked that this section was updated accordingly. In addition, IGARD asked that applicant provided two or three specific yielded benefits accrued to date in section 5(d) (iii) and to ensure these are clear about the benefits to both patients and the health care system more generally.

IGARD suggested that section 5(d) be updated to remove reference to *“it will...”*, and instead use a form of words such as *“it is hoped...”*.

IGARD queried the conflicting information within section 5(a) in relation to the NCIP Theatre dataset that stated *“The data will be collected in a form which identifies individual patients and associated information about their health care”*, and section 3(b) (Additional Data Access Requested) that stated the dataset was *“pseudonymised”*; and asked that section 5(a) was updated to accurately reflect that the flow of the NCIP Theatre dataset out of NHS Digital will be pseudonymised in accordance with the Data Provision Notice (DPN) and table 3(b).

In addition, IGARD asked that all data flows in the [NHS Digital data uses register](#) were accurately described as pseudonymised, since it appeared that some were not.

IGARD noted the inclusion of a number of technical phrases and words within section 5 (Purpose / Methods / Outputs), such as *“Add PROCEDURE field”*, asked that this public facing section, which forms [NHS Digital’s data uses register](#), was amended throughout, to ensure technical terms are explained in a manner suitable for a lay audience.

As section 5 forms [NHS Digital’s data uses register](#), IGARD also asked that all acronyms upon first use be defined and further explained if the meaning is not self-evident, for example *“LHE”*.

IGARD queried the content of the third paragraph in section 5(a) that started *“The last amendment to this agreement...”*, and asked that this was removed as it was not relevant.

Noting the forthcoming CCG / Integrated Care System (ICS) transition that was due to be completed later this year, prior to the end date of the agreement and the data retention period, IGARD asked that section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) were updated to also include a reference to this for information.

IGARD noted that section 1 erroneously stated that a review by IGARD was not required and asked that NHS Digital review their internal processes to ensure that this is always checked and corrected where required.

IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital’s Precedent route, including the SIRO Precedent, due to the complexity of the application.

IGARD advised NHS Digital that two IGARD specialist members dissented from making a recommendation, due to the impenetrable length of the application and the numerous previous requests by IGARD to simplify, split and re-write the application.

Outcome recommendation to approve by a quorum of 5 members, with two members dissenting, subject to the following conditions:

	<ol style="list-style-type: none"> 1. In respect of the quarterly register special condition in section 6: <ol style="list-style-type: none"> a) To provide copies of the quarterly registers of where and when NHS Digital data has been shared with small numbers unsuppressed; b) NHS Digital to advise what steps have been taken in respect of the DSA breach. c) To upload the relevant documentation to NHS Digital's CRM system for future reference. 2. In respect of the RNOH and their "<i>wish to analyse</i>": <ol style="list-style-type: none"> a) To provide an analysis in section 1 as to why RNOH are not considered a joint Data Controller in line with NHS Digital's DARS Standard for Data Controllers, and as borne out of the facts; or, b) If the facts lead to the RNOH being considered joint Data Controllers, to update the application throughout. 3. Noting that sub-licensing is not permitted under section 10, to provide an explanation as to what "<i>formal sub-licensing</i>" refers to in section 5. 4. In respect of the Yielded Benefits in section 5(d)(iii): <ol style="list-style-type: none"> a. To update the yielded benefits in line with the NHS Digital DARS Standard for Expected Measurable Benefits, and b. Given the significant volume of data, to provide 2 or 3 specific yielded benefits accrued to date and ensure these are clear as to the benefits to either patients or the health and care system more generally. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. IGARD noted that section 1 erroneously stated that a review by IGARD was not required and asked that NHS Digital review their internal processes to ensure that this is always checked and corrected where required. 2. As section 5 forms NHS Digital's data uses register, to amend section 5 throughout, <ol style="list-style-type: none"> a. To ensure acronyms be defined upon first use, for example "<i>LHE</i>"; and b. Technical terms are used only where necessary and explained in a manner suitable for a lay audience, for example "<i>Add PROCODE field</i>". c. To remove the third paragraph in section 5(a) as it is not relevant. 3. To update section 1 and section 5 with a reference to the forthcoming CCG / ICS transition. 4. To update section 5(d) to use a form of wording such as "<i>it is hoped ...</i>", rather than "<i>it will ...</i>". 5. To update section 5(a) to reflect that the flow of the NCIP Theatre dataset out of NHS Digital will be pseudonymised in accordance with the DPN and table 3(b). 6. To ensure that all data flows in the NHS Digital data uses register are accurately described as pseudonymised. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the complexity of the application. 2. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the complexity of the application. <p>It was agreed the conditions would be approved out of committee (OOC) by IGARD members.</p>
3.4	<p><u>St George's University of London (SGUL): MR515 - Randomised Prevention Trial of H. Pylori Screening (Presenter: Dan Goodwin) NIC-147843-8NKTW-v5</u></p>

Application: This was a renewal application to permit the holding and processing of identifiable Cancer Registration Data, Civil Registration (Deaths) and Demographics data; and an amendment to add an additional back up storage location at SGUL.

The purpose of this application is for the follow up of participants in the Randomised Trial of Helicobacter Pylori Screening (HPSS).

Helicobacter pylori (H pylori) is an infection of the stomach that accounts for most cases of stomach cancer worldwide. The risk of stomach cancer is about five times greater in infected than in uninfected persons. While the association is accepted as causal, it is not known whether screening and treatment of the infection in middle age can reverse this excess risk.

The study is hoping to determine if treatment of H pylori can decrease risk of cancer in later life. If this trial demonstrates screening is worthwhile and the national screening committee adopt it, it may prevent deaths from stomach cancer in the future.

The trial started recruiting on the 8th July 1997 and finished recruiting on the 31st January 2006, during which 62,454 participants were recruited.

The study is relying on s251 of the NHS Act 2006, for the flow of contact details out of NHS Digital.

NHS Digital noted that prior to the meeting, an IGARD specialist member had submitted a query in relation to the references to 'St George's University Hospital of London' and 'St George's Hospital Medical School' within the application and supporting documents provided. NHS Digital confirmed that the correct legal entity was 'St George's Hospital Medical School', and that the application would be updated to reflect this.

Discussion: NHS Digital noted that the application had not previously been presented at an IGARD business as usual (BAU) or at a Data Access Advisory Group (DAAG) meeting (IGARD's predecessor).

IGARD noted the verbal update in respect of the correct legal entity for St George's Hospital Medical School, and supported the update to the application to reflect this.

IGARD confirmed that they were of the view that the relevant s251 was broadly compatible with the processing outlined in the application; however queried if the applicant had continued to meet the Health Research Authority Confidentiality Advisory Group (HRA CAG) conditions of support regarding transparency to the cohort. IGARD asked that written confirmation was provided and what steps had been taken; and that the written confirmation was uploaded to NHS Digital's customer relationship management (CRM) system for future reference.

In addition, IGARD asked that the applicant update their website, which inaccurately summarised study members' ability to object to the processing of their data under s251 and accordingly impacted on their compliance with the HRA CAG conditions of support.

IGARD queried the statement in section 5(a) (Objective for Processing) "*Eligibility for recruitment was restricted to individuals...and was based on men aged 35 to 69 years and women aged 45 to 69 years.*"; and noting that no additional information had been provided, asked that a brief explanation was added to section 5(a) of the 10-year divergence between the collection of men's and women's data.

IGARD queried the statement in section 5(c) (Specific Outputs Expected) "*...regular reports on the numbers of stomach cancers, oesophageal cancers, deaths from Ischemic heart disease (in the likelihood of stress obtained from having cancer) and deaths from all causes will be reported to the researchers working on the HPylori study.*"; and asked that the reference to

	<p><i>“stress obtained from having cancer”</i> was removed, unless there was an evidential basis to support the statement.</p> <p>IGARD queried the patient and public involvement and engagement (PPIE), noting that the application was silent on this; and asked that section 5 (Purpose / Methods / Outputs) was updated with any PPIE past endeavours and planned efforts, in line with HRA guidance on Public Involvement.</p> <p>IGARD noted the reference to the study website in section 5(c), and asked that this was updated with a live and easily accessible link for ease of reference and transparency.</p> <p>IGARD noted the references to <i>“will”</i> in section 5(d) (Benefits), for example <i>“It is expected that this trial will provide evidence concerning whether screening and treatment for H pylori infection is worthwhile”</i> and asked that these were removed and replaced with <i>“would”</i>.</p> <p>Outcome: recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> 1. In respect of the HRA CAG support: <ol style="list-style-type: none"> a) To provide written confirmation that the applicant has continued to meet the HRA CAG conditions of support re transparency to the cohort and the steps taken to meet the condition on an ongoing basis. b) To upload a copy of the written confirmation to NHS Digital’s CRM system. <p>The following amendments were requested.</p> <ol style="list-style-type: none"> 1. The applicant to update their website, which inaccurately summarises study members ability to object to the processing of their data under s251 and accordingly impacts on their compliance with HRA CAG conditions of support. 2. To provide a brief explanation in section 5(a) of the 10-year divergence between the collection of men’s and women’s data. 3. To update section 5(c) to remove the reference to <i>“stress obtained from having cancer”</i>, unless there is an evidential basis to support the statement. 4. In respect of the PPIE: <ol style="list-style-type: none"> a) To update section 5 with any PPIE past endeavours and planned efforts. b) To include a live and easily accessible link in section 5(c) to the study website referred to. 5. To remove the reference to <i>“will”</i> in section 5(d) and replace with <i>“would”</i>. 6. To update the application throughout to reflect the correct legal entity for ‘St George’s Hospital Medical School; (as per the verbal update). <p>It was agreed the conditions would be approved out of committee (OOC) by IGARD members.</p>
3.5	<p><u>NHS Norfolk & Waveney CCG: GDPR/Ethnicity/Vaccine COVID-19 – CCG - Pseudo (Presenter: Michael Ball) NIC-388185-C4D6J-v3</u></p> <p>Application: This was a renewal application to permit the holding and processing of pseudonymised COVID-19 Ethnic Category dataset / Management Information Ethnic Category (MIECC) Dataset, COVID-19 Vaccination Status and GPES Data for Pandemic Planning and Research (COVID-19) (GDPR) data.</p> <p>It was also an amendment to remove The Health Service Control of Patient Information (COPI) Regulations 2002 as the legal basis for dissemination as the data is pseudonymised and not considered confidential.</p> <p>NHS Digital has been provided with the necessary powers to support the Secretary of State for Health and Social Care’s response to COVID-19 under the COVID-19 Public Health Directions</p>

2020 (COVID-19 Directions) and support various COVID-19 purposes, the data shared under this data sharing agreement (DSA) can be used for these specified purposes except where they would require the reidentification of individuals.

The purpose of the application, is to provide intelligence to support the local response to the COVID-19 emergency; the data is analysed so that health care provision can be planned to support the needs of the population within the CCG area for COVID-19 purposes.

Discussion: NHS Digital noted that the application had not previously been presented at an IGARD business as usual (BAU) or at a Data Access Advisory Group (DAAG) meeting (IGARD's predecessor).

IGARD noted that this application had been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 9th March 2022 (see Appendix B).

IGARD noted that at the PAG review on the 9th March 2022, PAG had requested further clarity in section 3 (Datasets Held / Requested) of the application under the common law of duty of confidentiality (CLDoC) and asked what due diligence had been applied to pseudonymised data in relation to duty of confidence, and that this must be signed off by NHS Digital's Caldicott Guardian. NHS Digital confirmed that the Privacy, Transparency and Ethics (PTE) directorate had responded to this query, and that the response was currently with the Caldicott Guardian for sign-off, as per the requested process. IGARD noted the verbal update from NHS Digital but noted this was not as per PAG's request and asked that written confirmation from the Caldicott Guardian was provided, that they were content with the "*due diligence*" carried out by PTE and that this meets the requirements to provide PAG support.

In addition to the written confirmation from PTE, IGARD asked that NHS Digital provided written confirmation that the Caldicott Guardian, in light of case law such as *R. v. Department of Health ex parte Source Informatics Ltd.* Court of Appeal: Simon Brown, Aldous and Schiemann L.J.J.; [2000] 1 All E.R. 786), was content that the CLDoC was not an issue that needed to be addressed in this application, and in line with [NHS Digital's DARS Standard for Duty of Confidentiality](#).

IGARD queried the special condition that had been inserted in section 6 (Special Conditions), restricting performance management using the GDPPR data, and why the CCG was being prevented from fulfilling this statutory responsibility (if required). NHS Digital advised that this had been inserted at the request of PAG, who stipulated that the GDPPR data did not contain the full population and could therefore give misleading results. IGARD noted the verbal update from NHS Digital, but questioned whether such a blanket restriction was justified. IGARD asked that NHS Digital provide a more detailed justification or modified the special condition.

IGARD noted that the [COVID-19 Public Health Directions 2020](#) had been extended indefinitely via a letter from the Secretary of State for Health & Social Care [to the NHS Digital Chief Executive on the 17th February 2022](#), and that the Directions would be reviewed annually, with the first review due in December 2022. IGARD noted that the continuation of the DSA was linked to the continued existence of the Direction underpinning the GP data collection and asked that a special condition was inserted in section 6 clarifying this.

Separate to this application: IGARD noted that they would correspond directly with PAG with regard to the indefinite extension of the GDPPR data collection under the COVID-19 Public Health Directions 2020 and the letter received by NHS Digital.

IGARD noted a risk area to NHS Digital, in respect of the lack of transparency around the continued and indefinite collection of GDPPR data. NHS Digital's transparency pages for the

public that still referred to the COVID-19 emergency period; and suggested that this should be updated as a matter of urgency, to reflect the continued collection and in line with the [NHS Digital DARS Standard for Transparency \(Fair Processing\)](#).

IGARD queried the statement in section 5(b) (Processing Activities) *“The Recipients will take all required security measures to protect the disseminated data and they will not generate copies of their cuts of the disseminated data unless this is strictly necessary”*; and asked that section 1 (Abstract) and section 5(b) were updated, to remove the reference to *“...generate copies of their cuts of the disseminated data...”*; or to provide a justification **and** details of recipients if this dissemination was happening.

IGARD noted the amendment to the legal basis for flowing the data, and stated that although they felt the new basis was appropriate, queried whether consideration had been given to the UK General Data Protection Regulation (UK GDPR) implications of changing the Article 6 legal basis once processing was underway, noting the [ICO guidance](#) on this specific point, for example *“...retrospectively switching lawful basis is likely to be inherently unfair to the individual and lead to breaches of accountability and transparency requirements”*. IGARD asked that written confirmation was provided confirming that this had been considered, and that copy of the written confirmation was uploaded to NHS Digital’s customer relationships management (CRM) system for future reference.

In addition, IGARD asked that written confirmation was provided of the paper trail of the classification of the dissemination of the data collected under COPI.

IGARD queried whether the classification of the data was consistent with the ability in the DSA to re-identify for direct care, noting the unclear information within section 5 (Purpose / Methods / Outputs) that stated *“...data shared under this agreement can be used for these specified purposes except where they would require the reidentification of individuals”*, *“...data shared under this agreement will not be reidentified”* and *“Re-identification of individuals under the vaccination dataset is permitted”*; and asked that section 5 was updated to ensure the classification of the data was consistent with the ability in the DSA to re-identify for direct care.

IGARD noted the large number of storage and processing locations in section 2 (Locations), and noting this may cause difficulty for NHS Digital in respect of auditing, suggested that NHS Digital worked with the applicant to review and consider if the locations could be consolidated and in line with the [NHS Digital DARS Standard for Processing and Storage Locations](#).

Noting the forthcoming CCG / Integrated Care System (ICS) transition that was due to be completed later this year, prior to the end date of the agreement and the data retention period, IGARD asked that section 1 and section 5 were updated to also include a reference to this for information.

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.

Outcome: IGARD were unable to make a recommendation as not all the necessary information was available in order for IGARD to make a full assessment. This statement was made with a quoracy of five members (two members noting a declaration of / potential conflict of interests).

1. To update section 5(b) to remove the reference to *“...generate copies of their cuts of the disseminated data...”*; or to provide a justification **and** details of recipients if this dissemination is happening.

	<ol style="list-style-type: none"> 2. In respect of the legal basis: <ol style="list-style-type: none"> a) NHS Digital to provide written confirmation that they have considered the UK GDPR implication of changing the Article 6 legal basis once processing is underway (noting the ICO guidance on this specific point). b) To upload a copy of the written confirmation to NHS Digital's CRM system. 3. To insert a special condition in section 6 linking the continuation of the DSA to the continued existence of the Direction underpinning the GP data collection. 4. To provide written confirmation of the paper trail of the classification of the dissemination of the data collected under COPI. 5. IGARD noted the large number of storage and processing locations, and, noting this may cause difficulty for NHS Digital in respect of auditing, suggested that NHS Digital worked with the applicant to review and consider if the locations could be consolidated. 6. In respect of the PAG review: <ol style="list-style-type: none"> a) To provide written confirmation from the PAG Chair that they are content with the "due diligence" carried out by PTE and that this meets their requirements to provide PAG support. b) NHS Digital to provide written confirmation that the Caldicott Guardian, in light of case law such as <i>R. v. Department of Health ex parte Source Informatics Ltd.</i> Court of Appeal: Simon Brown, Aldous and Schiemann L.J.J.; [2000] 1 All E.R. 786), is content that the CLDoC is not an issue that needs to be addressed in this application. 7. To update section 5 to ensure the classification of the data is consistent with the ability in the DSA to re-identify for direct care. 8. NHS Digital to propose how the CCG requirement to carry out appropriate performance management of GP practices where required and necessary, will be handled and justify the exclusion of this data from that process (as per the special conditions inserted at the request of PAG). 9. To update section 1 and section 5 with a reference to the forthcoming CCG / ICS transition. 10. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent. <p>Risk Area: NHS Digital's lack of transparency around the continued and indefinite collection of GDPPR data. NHS Digital's transparency pages for the public still refer to the COVID-19 emergency period; this should be updated as a matter of urgency, to reflect the continued collection.</p> <p>Separate to this application: IGARD noted that they would correspond directly with PAG with regard to the indefinite extension of the GDPPR data collection under the COVID-19 Public Health Directions 2020.</p>
4	<p><u>Applications progressed via NHS Digital's Precedent route, including the SIRO Precedent</u></p> <p>Applications that have been progressed via NHS Digital's Precedent route, including the SIRO Precedent, and NHS Digital have notified IGARD in writing (via the Secretariat).</p>

4.1	<p><u>NIC-20951-D2K6S-v8 Office for National Statistics (ONS) (No Presenter)</u></p> <p>The purpose of this application was for the data, to be used in conjunction with other administrative data for estimating internal and international migration, the local authority distribution of international migrants component of change for the mid-year estimates and small area population estimates within England and Wales and estimating migration between England and Wales, Scotland and Northern Ireland.</p> <p>IGARD noted that this application was last reviewed at the IGARD business as usual meeting on the 22nd July 2021, where IGARD had been unable to make a recommendation as not all the necessary information was available in order for IGARD to make a full assessment.</p> <p>IGARD noted that on the 11th March 2022, NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had agreed to authorise a further 3-month extension to the Data Sharing Agreement (DSA), to the 16th June 2022; in addition to the 3-month extension authorised on the 25th November 2021 (as noted in the IGARD BAU minutes on the 9th December 2021).</p> <p>IGARD noted that an amended application would be submitted to IGARD for review in the coming weeks, which would address points previously made.</p> <p>IGARD noted and thanked NHS Digital for the written update and confirmed that they supported NHS Digital's assessment that the next iteration should be brought to a future IGARD BAU meeting.</p>
5	<p><u>Oversight & Assurance</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. Due to the volume and complexity of applications at today's meeting, IGARD were unable to review any Data Access Request Service (DARS) applications as part of their oversight and assurance role.</p> <p>IGARD Members noted that they had not yet been updated on the issues raised at the 27th May 2021 IGARD business as usual (BAU) meeting with regard to previous comments made on the IG COVID-19 release registers March 2020 to May 2021. IGARD noted that in addition, they had not been updated on the issues raised on the IG COVID-19 release registers June 2021 to January 2022.</p> <p>IGARD Members noted that the last IG COVID-19 release register that they had reviewed and provided comments on was January 2022.</p> <p>IGARD also noted that the NHS Digital webpage Excel spreadsheet was for the period March 2020 to May 2021 and that they had queried for some considerable time with PTE why the COVID-19 (non-DARS) data release register was not being updated in a timely fashion: NHS Digital Data Uses Register - NHS Digital</p>
6	<p><u>COVID-19 update</u></p> <p><i>No items discussed</i></p>
7 7.1	<p><u>AOB:</u></p> <p>COVID-19 Public Health Directions 2020</p> <p>IGARD noted that the COVID-19 Public Health Directions 2020 had been extended indefinitely via a letter from the Secretary of State for Health & Social Care to the NHS Digital Chief</p>

	<p>Executive on the 17th February 2022, and that the Directions would be reviewed annually, with the first review due in December 2022.</p>
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	<p>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.</p>
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Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 10/03/22

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

NIC Reference	Applicant	IGARD meeting date	Recommendation conditions as set at IGARD meeting	IGARD minutes stated that conditions should be agreed by:	Conditions agreed as being met in the updated application by:	Notes of out of committee review (inc. any changes)
NIC-619023-C7K5V-v0.6	NHS Blood and Transplant (NHSBT)	03/02/22	<ol style="list-style-type: none"> In respect of the data handled in Germany: <ol style="list-style-type: none"> To clarify if the PDS data will be processed in Germany; or To clarify if only the data supplied by the cohort will be processed in Germany; and To amend section 5 with relevant narrative explaining the above; To make any necessary amendments to the listed data processors and storage locations; To ensure the territory of use aligns with the processing of the PDS data. NHS Digital to confirm that the Spine service (no 2) 2014 Direction which underpins PDS, allows the use of PDS in this research context. 	IGARD Members	Quorum of IGARD Members	<p>Even though PTE have acknowledged that there are no specific exclusions in the Spine Directions and in particular the Annex, research as an appropriate use of data set is not mentioned in the fair processing information in any context. IGARD would strongly recommend the webpage is reviewed to ensure it encompasses provision of data to enable research recruitment and that this is brought to the IAO's attention asap, plus DARS are updated to ensure narrative is included as appropriate in applications.</p> <p>IGARD note that the application has not been updated to reflect the</p>

						updated PTE opinion, and request that a summary of the opinion is included in the abstract and the full email trail is included on CRM should this application come up for extension, renewal or amendment.
NIC-400304-S1P1B-v4	Office for National Statistics (ONS)	27/01/22	<ol style="list-style-type: none"> 1. To provide a satisfactory procedure for the prospective review and approval of new projects under this agreement. To include the outline membership of the review committee (unless NSDEC is utilised), and to set out its terms of reference (which accord with similar oversight committee terms of reference for controllers holding large stores of NHS Digital data for programmatic access). 2. To upload a copy of the procedure for the prospective oversight to NHS Digital's CRM system for future reference. 	IGARD Members	Quorum of IGARD Members	<p>Regarding the special condition, IGARD should be mentioned as receiving a copy of the briefing and then NHS Digital can make its decision based on advice from PAG and IGARD. If "reviewed" is the negotiated position with PAG (IGARD don't know, IGARD weren't there and there are no detailed notes) then NHS Digital could keep in "reviewed" by PAG and state "provided to" IGARD. For the avoidance of doubt, and as stated this afternoon, IGARD don't agree with NHS Digital not providing a copy to IGARD. Please amend the special condition as noted below:</p> <p><i>"If the new specific uses include either the GPES Data</i></p>

						<p>for Pandemic Planning and Research (GDPPR) dataset or the COVID-19 Ethnic Category Data Set, the briefing will be provided to reviewed by NHS Digital's Profession Advisory Group (PAG) and Independent Group Advising (NHS Digital) on Release of Data (IGARD) and NHS Digital approval will be subject to taking advice from IGARD and the PAG</p>
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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

Graphnet Class Actions:

- None

Appendix B

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 9th March 2022

Application & application version number: DARS-NIC-388185-C4D6J-v3.4
Organisation name: Norfolk and Waveney CCG
Profession Advisory Group Agenda item: 2
PAG support the CCG template application changes subject to the following: PAG would like more clarity in section 3 of the application under the common law of duty which clearly notes what due diligence has been applied to pseudonymised data in relation to duty of confidence. This must be signed off by NHS Digital's Caldicott Guardian.

Attendees	Role	Organisation
Arjun Dhillon	Chair, Caldicott Guardian	NHS Digital
Amir Mehrkar	GP, Clinical Researcher	RCGP
Mark Coley	Deputy IT Policy Lead	BMA
Louise Dunn	Data Approvals Officer	NHS Digital
Duncan Easton	Data Approvals Officer	NHS Digital
Pam Soorma	Secretariat	NHS Digital