Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 9th April 2020

In attendance (IGARD Members): Paul Affleck, Maria Clark, Kirsty Irvine (Chair), Geoffrey Schrecker, Maurice Smith.

In attendance (NHS Digital): Stuart Blake, Louise Dunn, Karen Myers, Kimberley Watson, Vicki Williams.

Not in attendance (IGARD Members): Nicola Fear, Imran Khan.

1	**Declaration of interests:** Maria Clark noted professional links to the University of Sheffield (NIC-296034-T4Y4K IQVIA Solutions UK Limited), but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 2nd April 2020 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record of the meeting. **Out of committee recommendations:** An out of committee report was received (see Appendix B).
2	**Data Applications**
2.1	Ernst and Young LLP: Renewal - Bespoke Extract (Louise Dunn) NIC-369596-F6Q9V **Application:** This was an extension and renewal application for pseudonymised Secondary Uses Service (SUS) Payment by Results (PbR) data; and an amendment to add Microsoft Azure Cloud Storage as a data processor, as well as a data processing and storage location. The purpose of requesting the data, is to calculate relevant local and national Key Performance Indicators (KPIs) to share with clients and to bring about change, so that the applicant can quickly, and with insight, be responsive to tenders from the whole health and social care community and economy. NHS Digital noted that the application incorrectly stated in section 8a (Data Retention) that the indicative data retention period was until 31/08/2022 and confirmed this would be updated to state "31/08/2020" in line with the Data Sharing Agreement (DSA) **Discussion:** IGARD noted the amendment to the data retention date to align with the DSA end date of 31 August 2020. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices and that this point had also been raised by its predecessor the Data Access Advisory Group (DAAG). IGARD noted reference to the 'Health Data Panel' both within the application and supporting document (SD) 2 (Health Data Panel Terms of Reference) having been established in 2016, however the document provided seemed to be still in draft and asked that further evidence be provided that the Panel had been functioning as described by way of a summary report, which should be in the form of sample minutes and sample advice given by the Panel. In addition, IGARD also suggested that the applicant may wish to consider effective patient and public involvement (PPI) on the Health Data Panel, since the Panel appeared to consist mainly of experts.

	IGARD noted that its predecessor DAAG had discussed the applicant's international clients and asked if this work was still ongoing. NHS Digital confirmed that no work was being undertaken for international clients, however IGARD noted since the application clearly stated in section 2(c) (Territory of Use) the location area as "England and Wales", that a definitive statement should be made in section 5(a) (Objective for Processing) that there were no international clients or projects, and that no international healthcare organisations would receive any products derived from the data under this application. IGARD also suggested moving reference to the Legitimate Interest Assessment (LIA) from section 5(d) (Benefits) to section 5(a) and removing reference to the international healthcare organisations from the LIA, since it was not relevant to this application. In addition, and noting that under the current pandemic legislation from the UK Government and previous discussions at IGARD where it was imperative that the remote users was based in the 'territory of use', that a special condition should be inserted in Section 6 (Special Conditions) with regard to the Virtual Desktop Interface (VDI) protocol to ensure that any users accessing the data (apart from those accessing aggregated data with small numbers suppressed) are physically located in England and Wales when logging on remotely. IGARD suggested using existing wording as advised by the NHS Digital Security Advisor in relation to other commercial organisations with similar arrangements. There was a lengthy discussion with regard to section 5(e) (Is the Purpose of the Application in Anyway Commercial?) and suggested that this section was revised to ensure compliance with NHS Digital's Commercial Purpose Standard (5e) including, but not limited to, providing clarity on all aspects of the commercial elements of the arrangements; to specifically address whether the data would be used to respond to tenders and to clarify if other tenderers would have access to the same information. IGARD noted that the applicant was using the data for the benefits of the health and social care system, however, if the applicant was using the information for submitting tenders, then that should be clearly outlined within section 5 (Methods / Purpose / Outputs). It was noted that section 5(d) (Benefits) was particularly technical and suggested that benefits outlined were explained in a way that was suitable for a lay audience. IGARD also suggested that section 5(d) be reviewed to ensure that when referring to the project savings that the applicant consider using terms such as 'transactional costs' and 'reflected in alternative provision'. IGARD noted that the applicant had requested a rolling three years of data but noted that for a short period of time the applicant would hold an additional year and asked that Section 1 (Abstract) be updated to make reference to this and that relevant data destruction certificates were uploaded to NHS Digital's Customer Relationship Management (CRM) as additional evidence. IGARD noted reference to the ICO Code of Practice in section 3(b) (Additional Data Access Requested) and asked that it was removed or amended in line with the form of words agreed with NHS Digital's Information Governance (IG). IGARD suggested that NHS Digital might wish to consider a short-term extension to permit the applicant to hold, but not in any other way process, the data while work was undertaken to address the queries raised by IGARD. **Outcome Summary:** recommendation to defer, pending: 1. To revise section 5(e) to ensure compliance with NHS Digital's Commercial Purpose Standard 5(e) including (but not limited to); a) clarity on all aspects of the commercial elements of the arrangements, b) to specifically address whether the data will be used to respond to tenders; and

	c) to clarify if other tenderers will have access to the same information. 2. To insert a special condition in section 6 in respect of the VDI protocol, to ensure that any users who are accessing data (apart from aggregated data with small numbers supressed) are physically located in England and Wales when logging on remotely and suggest using similar wording as advised by the NHS Digital Security Advisor for other commercial organisations with similar arrangements. 3. To provide further information on the 'Health Data Panel' outlined within the application and supporting documentation and provide evidence that they have been functioning as described in the supporting document and a summary report, for example in the form of sample minutes and sample advice given by the Panel. 4. To make a definitive statement in section 5(a) that there are no international clients or projects and that no international healthcare organisations will receive any products derived from this data. 5. To remove reference to the LIA from section 5(d) and to move this into section 5(a); and to remove reference to the international healthcare organisation(s). 6. To provide a copy of the data destruction certificates, to include a reference to this in section 1 and to upload the documents to NHS Digitals CRM system. 7. To update section 5(d) to ensure the benefits outlined are explained in a way that is suitable for a lay audience. 8. To review section 5(d) to ensure that when referring to the projected savings, consideration is given to instead using terms such "transactional costs" and "reflected in alternative provision". 9. To remove reference to the ICO Code of Practice from section 3(b) and / or amend in line with a form of wording agreed with NHS Digital IG. 10. To amend section 8 to align the data retention date with the Data Sharing Agreement end date. The following advice was given: 1. IGARD suggested that NHS Digital might wish to consider a short-term extension to permit the applicant to hold, but not in any other way process, the data while work was undertaken to address the queries raised by IGARD. 2. IGARD suggested that the applicant may wish to consider PPI involvement on the Health Data Panel.
2.2	<u>3M United Kingdom PLC: Data extract to support the continued accuracy of 3M developed quality and performance indicators for commissioners and providers. (Presenter: Louise Dunn) NIC-91972-S9W9T</u> **Application:** This was a renewal application for pseudonymised Hospital Episode Statistics (HES) data which will be used to anglicise the 3M APR-DRG and 3M CRG (grouper) solutions, specifically by supporting the development of crosswalk tables and algorithms between UK coding classifications (and other NHS Data Dictionary items) and their international equivalents. The quality and performance indicators derived from these 3M solution suites will help the NHS better perform its duties by highlighting actionable areas for clinical and process improvement. **Discussion:** IGARD noted that project benefits should be realistic and had been expressed as speculative, but that the Tool had only gone live on the 13 February 2020. NHS Digital noted that because evidence of outputs and benefits was not provided in section 5 (Purpose / Methods / Outputs) that they would ask the applicant to provide quarterly updates to NHS Digital. IGARD endorsed the provision of a quarterly report and suggested that a special condition be inserted in Section 6 (Special Conditions) detailing that the applicant would

	provide a quarterly report to NHS Digital confirming progress towards achieved projected benefits. There was a lengthy discussion with regard to section 5(e) (Is the Purpose of the Application in Anyway Commercial?) and IGARD suggested that this section was revised to ensure compliance with NHS Digital's Commercial Purpose Standard (5e) including, but not limited to, an explanation of how the benefits to the public, in terms of providing benefits to the health and social care system is proportionately balanced with the commercial benefit; and to ensure that all the commercial aspects were addressed and the commercial transactions clearly explained. IGARD noted that since the Tool cannot be a commercial Tool until validated it must still be in trial or pilot phase since the data within this application was being provided to validate the Tool, however this was not clear within the application or supporting documents provided and so asked that confirmation was sought that the applicant had not launched the commercial Tool. In addition, section 5(d) (iii) (Yielded Benefits) should be updated to remove reference to the Tool having been commercially launched. IGARD noted reference to 'NHS' throughout the application and how they could benefit from the Tool, but since the NHS is made up of a variety of entities including Trusts, Commissioners etc, that the application should be updated to ensure that any generic reference to 'NHS' was amended to provide a more specific NHS category such as 'commissioners'. IGARD noted that in section 5(a) (Objective for Processing) under the title 'Balancing Test' that there was reference to 3M collaborating with the US Children's Hospital Association to ensure these algorithms address the needs of paediatric populations and asked that a justification was provided for using children's data and confirming why this data had not been minimised to exclude the children. Section 5 should also be updated to ensure that it was written in a language suitable for a lay reader and that use of technical phrases was used only when necessary and if it was necessary to use, to provide further supportive explanation. In addition, IGARD noted that some of the acronyms within section 5 of the application were not always defined upon first use and asked that this was updated as necessary and to ensure they were spelt out upon first use to make this clear. Any repetitive text across section 5 should also be removed. In addition, to address the conflicting information with regard to processing activities in section 5 (Purpose / Methods / Outputs) and section 6 (Special Conditions) and to ensure that the application is clear throughout that for a short period of time the applicant will hold 6 years and not 5 years' worth of data during the dissemination process of the new data being flowed from NHS Digital to the applicant. IGARD made a positive statement with regard to the applicant's Privacy Notice, noting that it met NHS Digital's Standard for privacy notices. IGARD suggested that they would wish to review this application again when it comes up for renewal and that this application would not be suitable for NHS Digital's Precedent route. **Outcome Summary:** recommendation to approve subject to the following condition: 1. 3M United Kingdom PLC to provide confirmation that they have not launched the commercial Tool. The following amendments were requested: 1. To amend the reference in section 5(d) (iii) Tool having been commercially launched. 2. To insert a special condition in section 6 that the applicant is to provide a quarterly report to NHS Digital confirming progress towards achieving the projected benefits.

	3. To update section 5 to ensure: a) this is written in language suitable for a lay reader; b) the use of technical phrases is used only where necessary and where it is necessary to also provide a further supportive explanation; c) that all acronyms upon first use in the application be defined and further explained; and d) to ensure repetitive text is removed. 4. To revise section 5(e) to reflect NHS Digital's Commercial Purpose Standard 5(e) including (but not limited to): a) an explanation of how the benefit to the public, in terms of providing benefit to the health and social care system, is proportionately balanced with the commercial benefit; and b) to ensure that all commercial aspects are addressed and that commercial transactions are explained. 5. To update the application throughout to ensure that all generic references to the 'NHS' are amended to provide a more specific NHS category, for example commissioners. 6. Regarding the reference in section 5(a) to *"paediatric populations"* and the *"US Children's Hospital Association"*: to link this to the justification for using children's data and confirming why the data has not been minimised to exclude children. 7. To address the conflicting information in section 5 and the special condition in section 6 in relation to the processing activities; and to ensure that the application is clear that there will be a short period where the applicant will hold 6-years and not 5-years' worth of data. 8. To ensure the stated projected benefits are realistic and expressed as being speculative. The following advice was given: 1. IGARD advised that they would wish to review this application again when it comes up for renewal. 2. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route. It was agreed the condition would be approved Out of Committee (OOC) by the IGARD Chair.
2.3	<u>IQVIA Solutions UK Limited: Pulmonary Hypertension (PH) population characterisation and epidemiological analysis (Presenter: Louise Dunn) NIC-296034-T4Y4K</u> **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) data for the purpose of a study that will focus on describing and comparing Pulmonary Arterial Hypertension (PAH), Chronic Thromboembolic Pulmonary Hypertension (CTEPH) and Sarcoidosis-Associated Pulmonary Hypertension (SAPH) populations (and define sub-populations) in terms of characteristics of patients, clinical pathways pre-diagnosis and diagnostic procedures, treatment patterns post diagnosis, clinical outcomes and Healthcare Resource Utilisation (HCRU). NHS Digital noted the application incorrectly referred to IQVIA Limited and that the application would be updated to reference the correct legal entities. **Discussion:** IGARD welcomed the application and supported the amendment to update the application throughout to correctly reference the two IQVIA legal entities: IQVIA Solutions UK Limited and IQVIA Technology Services Limited. There was a lengthy discussion with regard to the Data Controllers and noting that NHS Digital had met with relevant parties, IGARD queried why the University of Sheffield (referenced within

	the minutes as 'the University') was not listed as a Data Controller or Data Processor. The University had been referenced in supporting document (SD) 3.1, SD4 and SD5 provided for review and IGARD asked that either the documentation and application be updated to provide an explanation as to why the University was not listed as a Data Controller or Data Processor, or to add the University as a Data Controller or Data Processor, whichever case reflected the facts of the situation. In addition section 5 (Purpose / Methods / Outputs) noted that trained researchers from IQVIA and specific members from the University were under honorary contracts or held Research Passports at Sheffield Teaching Hospital NHS Foundation Trust (STHFT) and asked that evidence was provided of effective honorary contracts as referred to. In addition IGARD noted that in the case of those personnel from IQVIA entities, that any reference to inter-company personnel move were recorded as 'secondment agreements' rather than 'honorary contracts'. It was noted that Janssen-Cilag Limited were only listed as a Data Controller however section 5(a) (Objective for Processing) noted that they "…*are processing the data in line with their goals as part of their legitimate interests*…" and suggested this paragraph be updated to clarify that Janssen-Cilag Limited were not processing any patient level data. In addition, Section 5(a) and Section 5(d) (Benefits) should be updated to ensure that their involvement was clearly articulated to include, but not limited to, that they are a pharmaceutical company that may be the body to develop novel drug treatment on the basis of the research being carried out under this application. IGARD noted there were four joint Data Controllers: IQVIA Solutions UK Limited, IQVIA Technology Services Limited, STHFT and Janssen-Cilag Limited for the research study and suggested that there was a distinct and bespoke Privacy Notice for each Data Controller. In addition, each Privacy Notice should be accessible on each Data Controllers website, suggesting that other Data Controller Privacy Notices were referenced via a weblink from each website. IGARD noted that SD8 (IQVIA Hospital Episode Statistics (HES) Data Confidentiality Agreement v1.0) referenced incorrect legislation and suggested this was updated to correctly reference, for example, the Data Protection Act (DPA) 2018. IGARD noted additional disseminations and published results would be shared with the Pulmonary Hypertension Association (PHA UK) patient advisory group who had also provided input into the development of the trial, and suggested that both section 5(a) and 5(d) be updated to reference the helpful support of PHA UK and that consideration be given by the applicant to their involvement in the oversight of the project. IGARD noted that section 5(e) (Is the Purpose of this Application in Anyway Commercial?) noted the primary goal of providing the data was for scientific research and the commercial element was secondary, however suggested that section 5(e) be updated to reflect NHS Digital's Commercial Purpose Standard (5e) including, but not limited to, setting out how the benefit to the public is proportionately balanced with the benefit accruing to all the Data Controllers (including the pharmaceutical company). IGARD noted that section 5 should be updated to be clear that the projected outputs and benefits are realistic and expressed on a speculative basis. **Outcome Summary:** recommendation to approve subject the following conditions: 1. To provide evidence of effective honorary contracts as referred to in the agreement (and in the case of those personnel from IQVIA entities, IGARD suggested that any reference to inter-company personnel moves are recorded as secondment agreements rather than "honorary contracts").

	2. To update section 5(a) and section 5(e) to ensure that Janssen-Cilag Limited's involvement and motivation is clearly articulated including (but not limited to) that they are a pharmaceutical company that may be the body to develop novel drug treatment on the basis of the research being carried out. The following amendments were requested: 1. To update the application throughout to ensure the correct name is used of the two IQVIA entities. 2. To ensure there is a distinct and bespoke Privacy Notice for each Data Controller and that these are easily accessible on each Data Controller's website (other Data Controllers Privacy Notice may be referenced via a link from each website). 3. To update any supporting documents or to provide an explanation to reflect the fact that the University of Sheffield is not listed as a Data Controller or a Data Processor, or to add the University of Sheffield as a Data Controller or a Data Processor, whichever case may accurately reflect the facts of the situation. 4. To review the HES data agreement to refer to updated legislation (for example updating references to the DPA 2018). 5. To update section 5(a) and section 5(d) to reference the helpful support of PHA UK and that consideration was given to their involvement in the oversight of the project. 6. To revise section 5(e) to reflect NHS Digital's Commercial Purpose Standard 5(e) including (but not limited to), setting out how the benefit to the public is proportionately balanced with the benefit accruing to all the Data Controllers (including the pharmaceutical company). 7. To ensure that section 5 reflects that the prospective outputs and benefits are expressed on a speculative basis. 8. To provide clarification in the application that Janssen-Cilag Limited are not processing any patient level data. It was agreed the conditions would be approved Out of Committee (OOC) by IGARD members.
2.4	<u>University of Leicester: In silico trials of surgical interventions - using routinely collected data to model trial feasibility and design efficiency in vivo randomised controlled trials (Presenter: Stuart Blake) NIC-262908-X5F4Q</u> **Application:** This was a new application for pseudonymised Emergency Care Data Set (ECDS), Diagnostic Imaging Dataset (DIDs), Hospital Episode Statistics (HES) and Civil Registrations data for the purpose of a project to establish a database of patients with cardiovascular diagnosis in England. This database will be used to model trials of surgical interventions in silico and devise a set of pragmatic trial proposals to address the priority research questions in cardiac surgery. NHS Digital noted that the Data Protection Act (DPA) registration date had been updated since it had been submitted for review by IGARD. **Discussion:** IGARD were unsure if this application should be considered a programme level agreement since the supporting documents (SD) provided, including the Protocols (SD2 and SD2.1) suggested that this was a programme with a number of projects, and asked that clarity be provided, and if NHS Digital were in agreement, that this application should be uplifted to map to other similar programme level agreements. IGARD noted that the cohort size was roughly 1.5 million admissions a year for adult patients (aged 18 and above) with cardiovascular diseases (primary or secondary diagnosis) and although recognised by the applicant as a large cohort, IGARD asked that a clear justification

	was provided for the quantum of data requested in line with NHS Digital's Data Minimisation Standard (3). In addition, since the potential outputs and benefits were commensurate with the quantity of national data requested, the applicant should ensure there is a national dissemination of the outputs and benefits to reflect the fact that national data was being received. The British Heart Foundation were noted as a funder and IGARD suggested, if the applicant had not done so already, further public and patient involvement (PPI) via the British Heart Foundation and James Lind Alliance and that evidence be provided in section 5 (Methods / Purpose / Outputs). IGARD noted the collaboration between the University of Leicester and the James Lind Alliance (a National Institute for Health Research initiative) however it was not clear in section 5 what the James Lind Alliance involvement was and asked for evidence of the collaboration agreement that would have been provided in order to obtain the relevant funding. IGARD noted that reference to the applicant "purchasing" of data should be updated to accurately reflect that NHS Digital does not sell data. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. In addition, IGARD supported the amendment to update the DPA registration date for the University of Leicester from 18 March 2020 to 18 March 2021. **Outcome Summary:** recommendation to approve subject to the following conditions: 1. To provide justification for the quantum of data requested, in line with NHS Digital's Data Minimisation Standard 3. 2. To provide clarity if this is considered a programme level agreement and, if so, to clearly articulate this within the application and to uplift the application to map to similar programme level agreements. The following amendments were requested: 1. To ensure that both the potential benefits and outputs are commensurate with the quantity of data requested, including (but not limited to) ensuring there is national dissemination of the outputs to reflect the fact that national data is being received. 2. To update section 8(b) to amend the reference to data being "purchased". 3. To provide clarity in section 5 of the involvement of James Lind Alliance, for example, providing evidence of the collaboration agreement that would have been provided in order to obtain funding. The following advice was given: 1. IGARD suggested that the applicant may wish to consider (if they haven't already) further level of PPI via the British Heart Foundation and James Lind Alliance, and if there is evidence of this, to ensure this is reflected within the application. It was agreed the conditions would be approved Out of Committee (OOC) by IGARD members.
2.5	<u>University Hospitals Birmingham NHS Foundation Trust: Epidemiology of Cancer after solid Organ Transplantation – EPCOT study (Presenter: Stuart Blake) NIC-77142-Q4D1D</u> **Application:** This was a new application for Hospital Episodes Statistics (HES) and Civil Registrations data. Data regarding transplantation, cancer, hospital episodes and death is currently routinely collected as part of mandatory data collection for different registries but these records are not linked to each other which means it is impossible to get an integrated

insight into cancer epidemiology after solid organ transplantation and therefore know why post-transplant cancer risk is different for different recipients, what morbidity is associated with post-transplant cancer, and how outcomes differ for post-transplant cancer versus the general population among many other unanswered questions.

This study's main objective is to link data sets which already exist in isolation to create an integrated data set that can explore post-transplant cancer epidemiology and help answer some of these questions.

Discussion: IGARD noted that the application and supporting documents stated that University Hospitals Birmingham NHS Foundation Trust (UHBFT) would receive data which didn't relate to the cohort of transplant patients and to IGARD this suggested excessive flow of data to UHBFT if NHS Digital returned the identifiers for patients in UK Transplant registry cohort, since the National Cancer Registration and Analysis Service (NCRAS) can provide this data and this data only to UHBFT removing the requirement for UHBFT to receive and destroy identifiable data not relating to the cohort. IGARD asked for confirmation that the cohort supplied by NCRAS was matched to the cohort supplied by the UK Transplant registry by NHS Digital and that only those patients from the NCRAS cohort who were also in the UK Transplant Registry cohort had their data transferred to UHBFT.

IGARD noted that supporting document SD9 (Proposed Privacy Notice EPCOT v1) referenced the University of Birmingham (known in the minutes as 'the University') as a Data Controller, however the application only listed them as a Data Processor and asked that an explanation be provided within section 5 (Purpose / Methods / Outputs) why the University was not considered a Data Controller or to add them as a Data Controller, whichever case reflected the facts of the situation.

IGARD noted that SD1.1 (NHSBT legal basis letter 2020 NIC 77142) noted that NHS Blood and Transplant (NHSBT) would be providing data on the understanding that NHS Digital would check for and exclude any individuals who had centrally opted out of sharing their data, however section 3(c) (Patient Objections) stated that patient objections would not be applied. IGARD suggested that section 3(c) be updated to reflect the obligations on NHS Digital in respect of patient objections.

IGARD noted reference to the National Cancer Intelligence Network (NCIN) which ceased to exist in 2016 and suggested this was removed and the application updated throughout to replace with the new organisation NCRAS.

IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices.

Outcome Summary: recommendation to approve subject to the following conditions:

1. To confirm that the cohort supplied by NCRAS is matched to the cohort supplied by UK Transplant registry by NHS Digital and that only those patients from the NCRAS cohort who are also in the UK Transplant Registry cohort have their data transferred to University Hospital Birmingham NHS FT.
2. To update section 3(c) to reflect the obligations of NHS Digital in respect of patient objections as set out in SD1.1.

The following amendments were requested:

1. To update the application throughout to remove the reference(s) from 'National Cancer Intelligence Network' (or "NCIN") and replace with 'National Cancer Registration and Analysis Service (or NCRAS)'.
2. To provide an explanation of the reference in SD9 to the University of Birmingham being a Data Controller, or to add the University of Birmingham as a Data Controller.

	It was agreed the conditions would be approved Out of Committee (OOC) by IGARD members.
3	Covid-19 update IGARD noted that there were no Covd-19 related items to discuss at this week's meeting, however the IGARD Chair noted that support may be required by NHS Digital over the Easter weekend. In addition, NHS Digital had asked that a separate meeting to IGARD's Thursday meetings be set up to discuss Covid-19 and COPI regulation urgent applications to NHS Digital. Discussions were ongoing including how to ensure transparency of process and how these discussions would be captured as part of IGARD's minutes each Thursday, published via the NHS Digital website. It was agreed that the IGARD Chair, IGARD Secretariat Manager and NHS Digital would meet to discuss additional meeting for this work, and in agreement with the Senior Responsible Officer for IGARD, the Caldicott Guardian (Dr Arjun Dhillon).
4	Standard 10a – Transparency There was a lengthy discussion with regard to NHS Digital's Transparency Standard (10a) with the conclusion of the discussion being that IGARD would work with NHS Digital to come up with approaches for how to review compliance with the Standard and a range of responses that might be available to IGARD and NHS Digital in terms of monitoring compliance with the Standard.
5	Returning Applications IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. • NIC-91374-Z5V6Y University College London • NIC-268750-B3T4W University of Bristol • NIC-389823-P1P6B NHS England IGARD welcomed the three applications as part of their oversight and assurance role and noted a number of comments to NHS Digital and suggested that further information and comments be provided in an IGARD Oversight and Assurance Report which would be published separately to the minutes of the meetings, for transparency of process, and on a quarterly basis. Moving forward, IGARD agreed that Covid-19 and COPI regulation applications may also be included as part of the oversight and assurance review, not just those that were approved via NHS Digital's precedent route.
6 **6.1**	AOB: **IGARD Meeting: 23rd April** NHS Digital requested the reinstatement of the cancelled IGARD meeting on the 23rd April due to a backlog of applications awaiting independent review. IGARD members agreed to the reinstatement.

6.2	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.

Independent Group Advising on Releases of Data (IGARD): Out of committee report 03/04/20

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-303379-H4C8H	Liverpool Heart and Chest Hospital NHS Foundation Trust	13/02/2020	1. To further expand on the data minimisation information provided in section 5(a), which includes a justification for the nature of the DIDs data requested along with further justification to the request for the HES fields requested. 2. NHS Digital to satisfy itself and provide written confirmation to IGARD that both Data Controllers have published revised Privacy Notices, ensuring that they are compliant with the notice requirements under the GDPR and meets NHS Digital's published 10a Transparency Standard.	IGARD Members	OOC BY quorum of IGARD members	N/A
NIC-243359-X4T5M	Cambridge Centre for Health Services Research	12/03/2020	1. To update the application throughout to ensure the correct legal entity 'RAND Europe Community Interest Company' is correctly referenced in full where deemed relevant (and remove the shortened version of RAND Europe).	IGARD Chair	OOC by IGARD Chair	*I am content that this condition has been met if the following could be tidied up:* *- Section 1b Data Controller / Data Processor: in each section use full name "Rand Europe Community Interest Company" not "Rand Europe"*

						- there is a quite a bit of repeated text at bottom pg 16 and top p17 *- the special condition "Any reference to RAND in this application refers solely to RAND Europe Community Interest Company (CIC)." does not work with this statement at the bottom of page 16: "RAND Europe, a research unit of the RAND Corporation, is comprised of two legal entities, RAND Europe Community Interest Company and..." . Either the special condition needs to be amended or the statement on p16 removed or amended.*
NIC-157873-F6F8K	Imperial College London	10/10/2019	1. To update the application throughout to ensure the correct legal entity 'RAND Europe Community Interest Company' is correctly referenced in full where deemed relevant (and remove the shortened version of RAND Europe).	IGARD Members	OOC BY quorum of IGARD members	*"I am, on balance, content if the following could be changed from this:* *Your GP Surgery has agreed to share data from its patients to support the TOGETHER Study. The data which will be shared* ***will not be identifiable*** *so it will not contain your name, Date of Birth or address details.* *to this:*

						*Your GP Surgery has agreed to share data from its patients to support the TOGETHER Study. The data which will be shared **will not directly identify you** so it will not contain your name, Date of Birth or address details."*
NIC-277499-D3D0X	Optum Health Solutions UK Ltd	12/03/2020	1. To update the application throughout to ensure the full company name 'Optum Health Solutions UK Limited' is correctly referred to.	IGARD Chair	OOC by IGARD Chair	N/A
NIC-369348-H6H8B	University of Dundee	12/03/2020	1. To clarify why the University of Dundee is considered the sole Data Controller and the other study partners (the University of Glasgow and the University of Nottingham) are not also considered as joint Data Controllers, in light of the information provided in the study protocol and consent materials.	IGARD Members	OOC BY quorum of IGARD members	N/A
NIC-15625-T8K6L	MHRA (CPRD)	26/03/2020	**Outcome Summary:** If the data **is anonymous** and therefore outside the scope of GDPR, IGARD recommend for approval subject to the following conditions: 1) To insert a special condition in section 6 expressly stating that in the interests of transparency the applicant should keep a log of how they have assured themselves that **in each instance** a sub-licencee is receiving data that has been sufficiently anonymised to render it truly "anonymous" and outside GDPR.	IGARD Members	OOC BY quorum of IGARD members	*"I am content that the revised outcomes/special conditions have been accurately captured in section 6 of the application and therefore the conditions have been satisfied, if the points in the note below could be addressed:* *For audit purposes, please could NHS Digital note in the abstract that they have determined that the data disseminated by CPRD is anonymous and outside the*

			This log may be audited by NHS Digital. 2) To insert a special condition in section 6 expressly stating that the applicant must produce a process flow diagram and checklist, that provides evidence of how the intended benefits (and accrued benefits at time of a sub-licencee's application to CPRD for extension or renewal) to the Health or Social Care in England and Wales will be established and recorded for each sub-licence agreement, specifically: a) Draft process with NHS Digital within 1 month of agreement signature b) Process agreed with NHS Digital within 3 months of agreement signature 3) To insert a special condition is section 6 stating that Details of the record of intended benefits (and accrued benefits at time of a sub-licensee's application to CPRD) for extension or renewal) will be included in the flow of sub-licensing information provided by the applicant to NHS Digital on a regular basis, specifically: a) Intended benefits to continue to be captured as presently. b) Noting that a system change may be required, CPRD to confirm by time of agreement renewal (Oct			*scope of GDPR and therefore have applied the IGARD outcomes relating to "anonymous" data. (As of course we provided two sets of outcomes depending on the nature of the data; accordingly, it needs to be clear which path NHS Digital is following).*

			2020) the implementation timetable for the system change to enact that flow of data. c) To demonstrate when requested (with suitable notice) to a senior NHS Digital DARS member of staff how the benefits are being captured and assessed through the end to end CPRD process. **Outcome Summary:** If the data **is not anonymous** and therefore within the scope of GDPR, IGARD recommend for approval subject to the following conditions: 1) To revise the application throughout to reflect that it is personal information under GDPR and that numerous amendments would need to be made to the application and any supporting documentation, particularly in respect of sub-licencees outside the UK. 2) To insert a special condition in section 6 expressly stating that the applicant must produce a process flow diagram and checklist, that provides evidence of how the intended benefits (and accrued benefits at time of a sub-licencee's application to CPRD for extension or renewal) to the Health or Social Care in England and Wales will be established and recorded for each sub-licence agreement, specifically:			

			a) Draft process with NHS Digital within 1 month of agreement signature b) Process agreed with NHS Digital within 3 months of agreement signature 3) To insert a special condition is section 6 stating that details of the record of intended benefits (and accrued benefits at time of a sub-licensee's application to CPRD) for extension or renewal) will be included in the flow of sub-licensing information provided by the applicant to NHS Digital on a regular basis, specifically: a) Intended benefits to continue to be captured as presently. b) Noting that a system change may be required, CPRD to confirm by time of agreement renewal (Oct 2020) the implementation timetable for the system change to enact that flow of data. c) To demonstrate when requested (with suitable notice) to a senior NHS Digital DARS member of staff how the benefits are being captured and assessed through the end to end CPRD process.			
NIC-72180-R2L5Y	University of Glasgow	12/03/2020	1. In relation to data controllership to: a) To provide clarity of who is in the 'Study Team'.	IGARD Members	OOC BY quorum of IGARD members	N/A

			b) If the Study Team comprises only the University of Dundee to clearly articulate the case for the University of Dundee being the sole Data Controller; and to revise the current language within the application to reflect this, for example by removing reference to the 'Study Team'. c) To include an express statement in the application that the University of Glasgow acts on the instruction of the University of Dundee; and with no discretion to how the data is analysed; and does not form part of the Study Team. d) To update section 5 to add an express statement that no other Universities form part of the Study Team or are involved in the study in any other way. 2 In respect of Menarini Pharma SAS to: a) To revise section 5(e) to reflect NHS Digital's Commercial Purpose Standard 5(e) including (but not limited to) making reference to Menarini's royalty free licence as referenced elsewhere in the application. b) To clearly outline any connection Menarini may have with any of the drugs being studied. c) To amend section 5(a) to ensure this accurately captures Menarini's interest with the study, particularly with			

			reference to contractual obligations (as outlined in section 5(b)).			

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 notified to IGARD