Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 2 December 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member
Prof. Nicola Fear	Specialist Academic Member
Kirsty Irvine	IGARD Chair
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Chair
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Michael Ball	Data Access Request Services (DARS) (Item 3.6)
Dave Cronin	Data Access Request Service (DARS) (Observer: items 3.2 – 3.6) (Item 4)
Dan Goodwin	Data Access Request Service (DARS) (Item 3.5)
Frances Hancox	Data Access Request Service (DARS) (Items 3.3 – 3.4)
Dickie Langley	Privacy, Transparency and Ethics (PTE) (Observer: item 3.1)
Karen Myers	IGARD Secretariat
Dr. Jonathan Osborn	Deputy Caldicott Guardian (Observer: 3.1)
Fran Perry	DigiTrials (Item 3.1)
Andy Rees	DigiTrials (Item 3.1)
Charlotte Skinner	Data Access Request Services (DARS) (Item 3.2)
Vicki Williams	IGARD Secretariat

1	**Declaration of interests:**

	Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising the Scientific Advisory Group for Emergencies (SAGE) on COVID-19. Nicola Fear noted a professional link with King's College London [NIC-147955-M8D2Q] but noted no specific connection with the application or staff involved and it was agreed that this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 25th November 2021 IGARD meeting were reviewed, and subject to a number of minor amendments were agreed as an accurate record of the meeting. **Out of committee recommendations:** An out of committee report was received (see Appendix A).
2	**Briefing Notes**
	There were no briefing papers submitted for review.
3	**Data Applications**
3.1	University of Oxford: PANORAMIC: 'Platform Adaptive trial of NOvel antiviRals for eArly treatMent of covid-19 In the Community' (Presenter: Frances Perry / Andy Rees) NIC-605115-L0W3V-v0.4 **Application:** This was a new application for pseudonymised Civil Registration Data (Deaths), Hospital Episode Statistics Admitted Patient Care (HES APC), HES Critical Care, Medicines dispensed in Primary Care (NHSBSA data); and identifiable COVID-19 Access to Summary Care Records, Covid-19 UK Non-hospital Antigen Testing Results (pillar 2). 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 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. 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) which is from the same trial team at the University of Oxford and run along similar lines and datasets to PANORAMIC. This Data Sharing Agreement covers both the recruitment of participants to the trial, and the request for follow-up data after recruitment and consent. **Discussion:** IGARD noted that this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 23rd November 2021. IGARD had a lengthy discussion on the consent materials, in particular the potentially restrictive statement "*I understand that relevant sections of my GP and hospital medical notes and data collected during the study may be looked at by members of the research team and individuals from University of Oxford, both during and for up to 10 years after the scheduled follow-up period*". IGARD suggested that the applicant future proof the 10-year reference, to use a form of words, such as *"at least 10 years".*

	IGARD suggested that, to address any ambiguity with regards to the use of 10-year follow-up data across the different documents, this could be clarified via the newsletter. IGARD noted that at the IGARD – NHS Digital COVID-19 Response meeting on the 23rd November 2021, they had reiterated their comment from the 25th February 2021 BAU and 28th September COVID-19 response meetings in relation to NIC-411161-G4K7X, which also applied in this application, namely: "*IGARD noted the Caldicott Guardian's assessment of the legal basis for access to *SCR in supporting document 6, and suggested that the NHS Digital Data Access Request Service (DARS) Team, shared the Caldicott Guardian's opinion with NHS Digital's Privacy, Transparency and Ethics (PTE) (formerly Information Governance). IGARD asked that written confirmation be sought that PTE were content with the Caldicott Guardian's assessment; and that the written confirmation was uploaded to NHS Digital's customer relationship management (CRM) system for future reference*." (*Summary Care Record (SCR)). NHS Digital advised that extensive discussions had taken place with the Caldicott Guardian and PTE, who had confirmed that they were supportive of the use of SCR for the purpose outlined in the application, however noted that the Data Protection Impact Assessment (DPIA) would need updating for transparency. IGARD noted the verbal update from NHS Digital, and supported NHS Digital's undertaking to update the DPIA. In addition, IGARD noted that the restrictive transparency wording on NHS Digital's website would need updating to specifically name the Panoramic Trial, as a specific exception to the SCR policy which stated that the SCR would not be used for research; and advised 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 the legal representative consent wording in supporting document (SD) 4.1, version 1 of the consent form, appeared more akin to seeking advice from a consultee, and suggested the applicant speak to the Research Ethics Committee (REC) on this point, to ensure the wording was correct. IGARD noted the list of organisations referenced within the study protocol, for example, Cardiff University and University of Liverpool, and noting that the organisations were not referenced within the application; asked that an analysis was provided in section 5 (Purpose / Methods / Outputs), as to why the numerous parties outlined in the protocol were **not** considered joint Data Controllers or Data Processors; and in line with NHS Digital's DARS Standard for Data Controllers and NHS Digital's DARS Standard for Data Processors, and as borne out of the facts. IGARD noted a number of potential health inequality exclusions within the study, for example, in respect of those children previously identified as clinically extremely vulnerable being excluded, and suggested that an explanation was provided as to why they were excluded, given the impact COVID-19 has had, and will continue to have, on this section of society. IGARD also noted the statement in section 5(b) (Processing Activities) that filters would be applied for *"…special categories of people for whom the data should not be disseminated, such as prisoners."*; and suggested that section 5 was updated with a specific list of **all** the special category exclusions; and why they have been excluded from this research and whether there was any scope to include frequently excluded groups. IGARD noted in section 5(c) (Specific Outputs Expected) that the outcomes of the study would only be published via the website, and noted the digital exclusion to some vulnerable members of society that this would result in.

	IGARD suggested that the applicant may wish to consider the potential bias and stratification and gaps that the exclusions may create in the study outputs, and to consider how these gaps or bias may be mitigated. IGARD noted a further ethical issue. Members of the public, who were given the opportunity to opt-in to research off the back of their positive PCR result and did not take that opportunity, would nonetheless be contacted to see if they would like to take part in research. IGARD highlighted to NHS Digital that this may undermine public trust and confidence in the use of their health data. IGARD suggested that when weighing up how many times to contact potential cohort members, the applicant should take into account all the other bodies with access to this data who may also be making contact with citizens, for example, for pulse oximetry at home. IGARD noted the information in section 3(c) (Patient Objections) in respect of the National Data Opt-outs (NDO), and advised that although the application of the NDO was sensible, the explanations as to why the NDO has, and has not, been applied needed updating as this was incorrect. IGARD noted the reference in section 5(b) to the 'telephone preference service' (TPS), and noting that it was unclear whether this would be applied, asked that section 5 was updated with further clarity. IGARD queried the references in section 3(b) (Additional Data Access Requested) and section 5 to some of the datasets being *"pseudonymised"* , however, noting the data fields flowing, asked that this was updated to be clear that the data was identifying in the hands of the researcher and **not** pseudonymised. IGARD queried the statement in section 3(b) that *"GDPR does not apply to data solely relating to deceased individuals"*, however, noting that the status of those patients that are still alive would be revealed, asked that, this was updated to include a UK General Data Protection Regulation (UK GDPR) legal basis for dissemination and receipt of data; if this is in accordance with the latest advice from the Privacy, Transparency and Ethics (PTE) Directorate. IGARD suggested that NHS Digital may wish to ask the applicant whether any pharmaceutical company has any involvement with the study whatsoever, not just funding, for example, were they providing drug samples or other expert support throughout the trial; and to record the outcome of this conversation in section 1 (Abstract) for future reference and in Section 5(e) if warranted, and in line with NHS Digital's DARS Standard for Commercial Purpose. IGARD noted the statement in section 5(b) in respect of the HES analysis guide *"cell values from 1 to 7 (inclusive) are suppressed at a **local** level to prevent possible identification of individuals…"*; and asked the reference to "local" was replaced with *"sub-national"*. IGARD queried the references in section 5(c) and section 5(d) (Benefits) to reducing the *"NHS burden"*, and asked that this was expanded to be clear that the burden is not just on the NHS. IGARD noted a number of technical terms in section 5, and asked that this public facing section, which forms NHS Digital's data uses register, was amended throughout, to ensure they were defined upon first use, if the meaning is not self-evident, for example *"futility and superiority criteria"*. 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

The following amendments were requested:

1. To update section 3 to include a UK GDPR legal basis for those datasets that give information about cohort members who are still living, if this accords with the latest advice from PTE.
2. To provide an analysis in section 5 as to why the numerous parties outlined in the protocol are not considered a joint Data Controller or Data Processor; and in line with NHS Digital's DARS Standard for Data Controllers and NHS Digital's DARS Standard for Data Processors, and as borne out of the facts.
3. To update section 3(b) and section 5 to be clear that the data is identifying in the hands of the researcher and **not** pseudonymised.
4. Noting that the application of NDO is sensible in section 3, to update the incorrect explanations as to why the NDO has, and has not, been applied.
5. To provide further clarification in section 5 of when TPS may be applied.
6. To update section 5 to ensure technical terms are explained in a manner suitable for a lay audience, for example *"futility and superiority criteria"*.
7. With reference to the HES analysis guide in section 5(b), to replace *"local"* with *"sub-national"*.
8. To update section 5(c) and section 5(d) to expand the text to be clear it is not just a *"burden on the NHS"*.

The following advice was given:

1. In respect of the 10-year follow-up:
   a) IGARD suggested that the applicant future proof the 10-year reference, to use a form of words, such as *"at least 10 years"*.
   b) IGARD suggested that any ambiguity with regards to the use of 10-year follow-up across different documents, could be augmented via the newsletter.
2. In respect of the SCR:
   a) IGARD noted and supported NHS Digital's undertaking to update the DPIA.
   b) That the transparency wording on NHS Digital's website be updated to specifically name the Panoramic Trial, as a specific exception to the SCR policy which states that the SCR will not be used for research.
3. IGARD noted there was potentially an issue impacting on public trust and confidence in NHS Digital, as members of the public, who were given the opportunity to opt-in to further research off the back of their positive PCR result – and did not take that opportunity – were nonetheless contacted to see if they would like to take part in further research.
4. IGARD suggested that when weighing up how many times to contact potential cohort members, the applicant take into account all the other bodies with access to this data who may also be making contact with citizens (for example for pulse oximetry at home).
5. In respect of health inequality exclusions:
   a) IGARD suggested including an explanation 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.
   b) IGARD suggested that section 5 specifically lists all the special category exclusions, for example, prisoners; and why they have been excluded from this research.

	c) IGARD noted that the outcomes of the study would only be published via the website, and noted the digital exclusion to some vulnerable members of society that this would result in. d) IGARD suggested that the applicant may wish to consider the potential bias and stratification and gaps that the above exclusions may create in the study outputs, and to consider how these gaps or bias may be mitigated. 6. IGARD suggested that NHS Digital may wish to ask the applicant whether any pharmaceutical company has any involvement whatsoever (not just funding) for example, are they providing drug samples or other expert support throughout the trial; and to record the outcome of this conversation in section 1 and, if warranted, in Section 5e. 7. IGARD queried the legal representative wording in SD4.1, and suggested the applicant speak to the REC to ensure it is correct. 8. 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. 9. 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. **Significant Risk Area:** If the NHS Digital website and transparency notice for SCRs are not updated prior to the trial commencing. **Risk Area:** That the practice of contacting members of the public to take part in research when they have already been given the opportunity to take part (and did not take up this offer) may undermine public trust and confidence in the use of their health data.
3.2	London School of Economics and Political Science (LSE): MR-1461 - Improving the experience of dementia and enhancing active life: living well with dementia - the IDEAL study (Data linkage extension) (Presenter: Charlotte Skinner) NIC-29822-N0N7W-v0.34 **Application:** This was a new application for Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC), HES Outpatients, Mental Health Minimum Data Set (MHMDS) and Mental Health Services Data Set (MHSDS). The purpose is for the IDEAL study, which aimed to characterise the social and psychological factors that support or constrain the ability of people with dementia and carers to live well, with any type of dementia; and examine the impact of assets and resources on the ability to live well with dementia. Interviewing of the IDEAL cohort began in March 2014 and ended in July 2018. Participants with dementia (for some, the carers responded on behalf of participants) were asked to provide informed consent, to complete the study questionnaires at the baseline interview and subsequently asked to provide consent to complete the study questionnaires at the second and third time points. The application was previously considered on the 21st June 2018 where IGARD had deferred making a recommendation. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at IGARD business as usual (BAU) meeting on the 21st June 2018. IGARD noted that the application had been updated to reflect all the previous deferral points. IGARD noted that following circulation of the meeting papers for review, NHS Digital had shared a draft version of the Privacy Notice. IGARD thanked NHS Digital for sharing this document, however advised that members had not undertaken a review of this prior to the

	meeting. IGARD also reiterated their advice, first provided in 2018, and suggested that the updated Privacy Notice be disseminated to participants with the next iteration of the newsletter; or to include key elements of the updated privacy notice in the next newsletter. IGARD queried the reference in section 1 (Abstract) to *"joint controllers of the data"*; and noting that only LSE were named Data Controllers within the application, asked that the application was updated throughout to reflect that there was a *"sole"* Data Controller. IGARD noted that the University of Exeter would be responsible for transferring the list of study participant identifiers to NHS Digital for linkage purposes, and queried what contractual arrangements were in place between NHS Digital and the University of Exeter for the flow of this data. Noting that this was not addressed within the application, IGARD asked that section 1 and section 5 (Purpose / Methods / Outputs) were updated to provide confirmation that appropriate contractual arrangements were in place between the University of Exeter and NHS Digital. IGARD noted the significant area of risk to NHS Digital in respect of there not appearing to be appropriate contractual arrangements in place between the University of Exeter and NHS Digital. IGARD noted a mismatch in respect of the data flow diagram provided, and the application, in terms of description of the data flowing; and asked that section 3 (Datasets Held / Requested) was updated to accurately describe whether the data flowing was pseudonymised **or** identifiable. In addition, IGARD suggested that if the data flow diagram was incorrect, that this was either updated or removed from NHS Digital's customer relationships management (CRM) system. In addition, IGARD queried the legal basis for the processing of the HES APC data; and asked that section 3 was updated accordingly to include this information. IGARD queried the statement in the data minimisation column in section 3 *"The objective is to carry out a longitudinal analysis of use of health care services and mortality in the cohort…"*; and asked that the reference to "*mortality"* was amended, noting that if a member of the cohort was deceased, they would not be in the baseline assessment. IGARD queried the reference in section 5(b) (Processing Activities) to *"consultee consent"*; and asked that the incorrect references in the application to *"consultee consent"* were updated to correctly refer to *"consultee advice"*. IGARD noted in section 5(b) that the Alzheimer's Society were funding the research from 2018 - 2022, however asked that if this was correct, section 8(b) (Funding Sources) was updated to reflect this, noting it was currently not populated; and, that there will not be an attempt to influence the design of the study, nor supress any aspect of publication of the findings, as borne out of the facts presented. IGARD noted references in section 5(a) (Objective for Processing) to academic papers, for example *"Hamel et al., 2015; Li et al., 2017"*; and asked that this public facing section, which forms NHS Digital's data uses register, was reviewed and either updated to include a relevant weblink, or a brief lay summary, and in line with NHS Digital's DARS Standard for Objective for Processing. IGARD noted that the study protocol contained additional helpful supporting information in relation to the references to *"T1, T2 and T3"* within the application; and asked that for transparency, this was replicated in section 5(b) (Processing Activities). IGARD suggested that section 5(c) (Specific Outputs Expected) be updated to remove reference to "*it will*…" or "it can…", and instead use a form of words such as "*it is hoped*…"

	IGARD noted the statement in section 5(d) (Benefits) *"The data may reflect the involvement of participants with dementia without a participating carer on hand, a **hard-to-reach** group whose needs and characteristics are under-researched"*; and asked that the reference to *"hard-to-reach"* was updated to *"seldom heard from"*. IGARD noted a number of technical terms in section 5, and asked that this public facing section, that forms NHS Digital's data uses register, was amended throughout, to ensure they were defined upon first use, if the meaning is not self-evident, for example *"descriptive analysis"* and *"inferential analysis"*. IGARD noted a number of acronyms in section 5 and asked that this public facing section, that forms NHS Digital's data uses register, be updated to ensure that all acronyms upon first use were expanded and clearly defined with a supportive explanation in a language suitable for a lay reader, for example *"ADRP"*. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 1 and section 5 to provide confirmation that appropriate contractual arrangements are in place between the University of Exeter and NHS Digital. 2. To update the words *"consultee consent"* to *"consultee advice"* within the application. 3. To update the application throughout to reflect there is a *"sole"* Data Controller. 4. As section 5 forms NHS Digital's data uses register, to amend section 5 to ensure that all acronyms upon first use are defined and further explained if the meaning is not self-evident, for example *"ADRP"*. 5. Noting the mis-match between the data flow diagram and the application, to ensure the application accurately describes the flow of data, and if the data flow diagram is no longer accurate, to either update or remove from CRM. 6. In respect to section 3(b): a) To update section 3 to describe whether the data is pseudonymised or identifiable. b) To update section 3 with the legal basis for the inclusion of the HES APC data. c) To amend the reference to *"mortality"* in section 3(b). 7. To update section 5(c) to use a form of wording such as "*it is hoped* …", rather than "*it will…*" or *"it can"*. 8. To review the reference in section 5(a) to academic papers and either add a relevant weblink, or amend to add a brief lay summary. 9. To update section 5 to ensure technical terms are explained in a manner suitable for a lay audience, for example *"descriptive analysis"* and *"inferential analysis"*. 10. To update section 8(b) with the source of funding, and that there will not be an attempt to influence the design of the study, nor supress any aspect of publication of the findings. 11. To copy the helpful wording from the protocol in section 5(b), that provides clarity on the references to *"T1, T2 and T3"*. 12. To amend the reference in 5(d) from *"hard-to-reach"* to *"seldom heard from"*. The following advice was given: 1. IGARD reiterated their advice, first provided in 2018, and suggested that the updated Privacy Notice be disseminated to participants with the next iteration of the newsletter; or to include key elements of the updated privacy notice in the next newsletter. **Significant Risk Area:** There does not appear to be appropriate contractual arrangements in place between the University of Exeter and NHS Digital.

3.3	University of Leicester: The 'United Kingdom Aneurysm Growth Study' (UKAGS) (Presenter: Frances Hancox) NIC-148437-C9YSC-v5.7 **Application:** This was a renewal and extension application to permit the holding and processing of identifiable Civil Registration (Deaths), Demographics and Hospital Episode Statistics Admitted Patient Care (HES APC). It was also an amendment to **1)** add HES APC data from 2010/11 - 2020/21 and annual releases thereafter; **2)** to amend the processing location from Leicester Royal Infirmary to Glenfield General Hospital (both locations are part of the same organisation). The purpose is for a prospective cohort study of men, attending the NHS aneurysm screening programmes in the UK. Between 2010 and 2019 men were recruited into the study after they had been screened for abdominal aortic aneurysm (AAA). The cohort have been followed up for up to 5 years by annual postal questionnaires. The overall aims of the study are to: **1)** Identify clinical and biological factors associated with the progression of AAA. This information will be used to design clinical interventions to slow the progression of AAA, reduce the risks of fatal AAA rupture and prevent the need for surgery in men with AAA; **2)** determine if AAA screening programmes are an opportunity to improve the overall health of men, irrespective of the diagnosis or management of AAA. The consented cohort is approximately 11,342 participants. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at IGARD BAU meetings on the 25th January 2018, 6th September 2018, 17th January 2019 and 25th April 2019. It was also discussed as part of oversight and assurance at the IGARD BAU meeting on the 4th March 2021. IGARD confirmed that they were of the view that the most recent consent materials provided the appropriate gateway and were broadly compatible with the processing outlined in the application. IGARD noted that there was no reference within the application to any patient and public involvement and engagement (PPIE); and strongly suggested that the applicant formed a PPIE group comprising of cohort members who could support the study outputs and narrative, and any future queries; and in line with the HRA guidance on Public Involvement. IGARD noted the statements in section 5(a) (Objective for Processing) *"The data obtained from NHS Digital will be used to define clinical events such as AAA repair* ***or death from AAA rupture****"*; and asked that this was amended to state *"…even death…"*, and that *"any adverse clinical events such as death from AAA rupture or surgical repair"* be amended to "*including* death from AAA rupture or surgical repair". IGARD queried why men were the focus of the study, for example, men were more likely to suffer from AAA; and asked that for transparency, section 5(a) was updated with a statement outlining the reason why men were the focus of the study. IGARD suggested that section 5(d) (Benefits) be updated to remove reference to "*it will*…", and instead use a form of words such as "*it is hoped*…" IGARD noted that section 1 (Abstract) stated that a review by IGARD was not required; and again requested that NHS Digital review their internal processes and IT systems to ensure this doesn't incorrectly default to state *"no"*.

	Outcome: recommendation to approve The following amendments were requested: 1. To amend the paragraph in section 5(a) that refers to *"..or death from AAA rupture.."*, to state *"…even death…"*, and " …any adverse clinical events such as death from AAA rupture" to state "…*including* death from AAA rupture" 2. To update section 5(a) with a statement outlining why men are the focus of the study. 3. To update section 5(d) to use a form of wording such as "*it is hoped* …", rather than "*it will…*". 4. IGARD noted that section 1 stated that a review by IGARD was not required; and again requested that NHS Digital review their internal processes and IT systems to ensure this doesn't incorrectly default to state *"no"*. The following advice was given: 1. IGARD strongly suggested that the applicant formed a PPIE group comprising of cohort members who can support the study outputs and narrative, and any future queries; and in line with the HRA guidance on Public Involvement.
3.4	King's College London: TwinsUK: Phenotypic enrichment of the TwinsUK cohort through linkage to electronic health records and other databases. (Presenter: Frances Hancox) NIC-147955-M8D2Q-v2.14 **Application:** This was a renewal and extension application to permit the holding and processing of identifiable Medical Research Information Service (MRIS) Cause of Death Report, MRIS Cohort Event Notification Report, MRIS – Flagging Current Status Report, MRIS Members and Postings Report. It was also an amendment to add identifiable Cancer Registration Data, Civil Registration (Deaths), Emergency Care Data Set (ECDS), Hospital Episode Statistics Accident & Emergency (HES A&E), HES Admitted Patient Care (APC), HES Critical Care, HES Outpatients and Mental Health Minimum Data Set (MHMDS). TwinsUK is a data registry within King's College London, and is an important source of information on life course on health and social development; it is a productive resource providing insight into many health questions. The primary objective of TwinsUK is to investigate how environmental factors and genetics interact to impact health and disease over the life course. TwinsUK offers a multidimensional approach to the study of human health and individuality, availing health researchers with a portfolio of methods to observe the effects of both genes and environment on development, health and ageing. This is because the unique natural pairing of twins allows key factors to be held stable while the impact of others is investigated. The principal objective of this purpose is to consolidate and enhance TwinsUK as a research resource conducting a programme of epidemiological research. The study is relying on s251 of the NHS Act 2006, for the flow of data out of NHS Digital for the current 13,244 participants that signed up to TwinsUK before 2020, who have not attended a clinic visit during or after 2020. In addition, consent has currently been provided by approximately 561 participants. NHS Digital advised IGARD that although s251 support was in place, it was the long-term aim of the study team, to obtain consent from the participants.

	Discussion: IGARD noted that the application had not previously been presented at an IGARD business as usual (BAU) meeting. IGARD welcomed the application and noted the importance of the study. IGARD noted the verbal update from NHS Digital, in respect of cohort members moving from the s251 legal basis, to consent. IGARD confirmed that they were of the view that the most recent consent materials provided the appropriate gateway and were broadly compatible with the processing outlined in the application. IGARD noted that they had a number of queries that may impact on the s251 support from the Health Research Authority Confidentiality Advisory Group (HRA CAG); and advised that NHS Digital may wish to have further discussions with HRA CAG to seek clarification / guidance on the following points: IGARD queried if the participants who were alive but inactive received the Data Linkage Information Sheet and the Data Linkage Decision Form; and were advised by NHS Digital that NHS Digital were in the process of chasing this query up with the applicant. IGARD noted the verbal update from NHS Digital, however asked that in order to inform the discussion with HRA CAG, NHS Digital sought confirmation as to what the cohort members were told when they elected to be inactive on the database. IGARD suggested that, once this information had been obtained from the applicant, NHS Digital discussed this issue HRA CAG, to ensure that they were aware that the cohort members who were alive, but inactive may not have received the data linkage forms. IGARD noted that the 251 support, covered class 2,4,5 and 6, but did not cover class 3; and asked that written confirmation was provided that HRA CAG were content that the s251 support was used for contacting the cohort, even though class 3 was not ticked. IGARD queried the best way to log the data flows under the two legal bases in section 3 (Datasets Held / Requested), noting that similar applications had logged the data flows separately, one for consent and one for s251; and asked that NHS Digital confirmed with the Data Production Team how the two flows of data could be logged in section 3. IGARD noted within the data minimisation that there were no specific cohort numbers for those covered under 251 and consent; and asked that this was updated with an estimate, noting that recruitment was ongoing, and the numbers stated would change. IGARD also noted that the references to cohort numbers were inconsistent, for example, noting the reference in section 5 (Purpose / Methods / Outputs) to *"14,400"* individuals, and that this did not align with figures stated elsewhere. IGARD noted the historical fields in section 5(a) for the MRIS data, and in respect of data minimisation, asked that this was reviewed and updated as necessary, in line with NHS Digital DARS standard for data minimisation. IGARD queried the information within supporting document 5.4, the patient information sheet, including, but not limited to, the incorrect reference to *"General Data Protection Regulation 2018"* and incorrect information in respect of the National Data-opt Out; and suggested that NHS Digital discussed the content of this document with the applicant. IGARD queried the statement in section 3(b) (Additional Data Access Requested) that *"GDPR does not apply to data solely relating to deceased individuals"*, however, noting that the status of those patients that are still alive would be revealed, asked that this was updated to include a UK General Data Protection Regulation (UK GDPR) legal basis for dissemination and receipt

	of data; if this is in accordance with the latest advice from the Privacy, Transparency and Ethics (PTE) Directorate. IGARD suggested that NHS Digital confirm with the applicant that the contractual terms restricting access to substantive employees in section 5 (Purpose / Methods / Outputs), means just that, and there will be no wider access to King's College London research passport holders etc. IGARD noted there were other mechanisms available for small numbers of PhD students, to access the data, rather than them being substantive employees. IGARD noted and applauded the cohort participant on the Data Access Committee, however suggested that the applicant may wish to consider additional cohort members, to give greater participant involvement. IGARD queried the reference in section 5(a) (Objective for Processing) to the *"fair processing campaign"*, and asked that for transparency, further details were provided on this. In addition, IGARD noted the statement *"The healthcare records requested are minimised to TwinsUK participants and those that stay within the campaign…"*; and asked that this was updated to confirm that participants will remain in the 'study' following the fair processing campaign. IGARD queried the statement in section 5(b) (Processing Activities) *"TwinsUK will then use "General Practice Registration Details to seek GP assent to access the primary care records of the participants";* and asked that further narrative was provided in section 5 as to how the applicant was obtaining the GP data for the cohort members. IGARD queried the statement in section 5(c) (Specific Outputs Expected) that referred to journals wanting *"individual level data"*, and asked that this was removed. IGARD queried the statement in section 5(b) *"There will be no requirement or attempts to re-identify individuals at this stage…"*; and noting that they would be re-identifying individuals, asked that this incorrect information was removed. IGARD noted the references throughout section 5(a) to *"mental health disorder"*, and noting that section 5 formed NHS Digital's data uses register, asked that this was updated, with an alternative, more sensitive term, such as *"mental health condition"* or *"mental ill health"*. IGARD noted the reference in section 5(a) to *"high-risk lifestyle"*, and as section 5 forms NHS Digital's data uses register, to update the reference, to another form of wording, for example, social or economic determinants of health. IGARD suggested that section 5(a) and section 5(d) (Benefits) be updated to remove reference to "*it will*…" or "it can…", and instead use a form of words such as "*it is hoped*…". IGARD noted that some of the information in section 5(d) (iii) (Yielded Benefits) was a 'future benefit' and not a yielded benefit, and asked that this section was reviewed, and any future benefits were moved to section 5(d) (ii) (Expected Measurable Benefits to Health and/or Social Care), in line with NHS Digital DARS Standard for Expected Measurable Benefits. IGARD queried the information in section 5(d) (iii) relating to the PhD students, and asked that this was correctly moved to section 5(b), in line with NHS Digital DARS Standard for Expected Measurable Benefits. IGARD noted the inclusion of a number of technical phrases and words within section 5 (Purpose / Methods / Outputs) such as *"Once quality controlled, cleaned and shaped for consumption"*, and suggested that this was updated to be written in a language suitable for a lay reader and technical terms used only where necessary, or further explained upon first use.

	IGARD noted a number of acronyms in section 5 and asked that this public facing section, that forms NHS Digital's data uses register, be updated to ensure that all acronyms upon first use were expanded and clearly defined with a supportive explanation in a language suitable for a lay reader, for example *"ARC"*. IGARD advised that they would wish to review this application when it comes up for renewal, as the legal basis is in a state of transition as cohort members move from s251 to consent. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 3 to include a UK GDPR legal basis for those datasets that give information about cohort members who are still living, if this accords with the latest advice from PTE. 2. In respect of the HRA CAG support: a) In order to inform the discussion with HRA CAG, to confirm what the cohort members were told when they elected to be inactive on the database. b) To discuss with HRA CAG to ensure they are aware that the cohort members who are alive, but inactive may not have received the data linkage forms (if this is the case). c) To provide written confirmation that HRA CAG are content that the s251 support is used for contacting the cohort, even though class 3 was not ticked. 3. NHS Digital to confirm with the Data Production Team how the two flows of data can be logged in section 3. 4. To update the data minimisation column in section 3(b) with an estimate of the cohort numbers. 5. In respect of section 5(a): a) To update section 5(a), to amend the references from *"mental health disorder"* to an alternative such as *"mental health condition"* or "*ill health"*. b) As section 5 forms NHS Digital's public data release register, to update reference in section 5 to *"high-risk lifestyle"* to another form of wording, for example, social or economic determinants of health. c) To update section 5(a) with further details of the MRIS data fields. 6. To update section 5(a) and section 5(d) to use a form of wording such as "*it is hoped …*", rather than "*it will…*". 7. In respect of the fair processing campaign: a) To provide further detail in section 5(a) in respect of the fair processing campaign. b) To confirm in section 5(a) that participants will remain in the study following the fair processing campaign. 8 To update section 5(b) to remove any standard wording that *"no attempts will be made to re-identify"* since they will be re-identifying. 9 As section 5 forms NHS Digital's data uses register, to amend section 5 to ensure that all acronyms upon first use are defined and further explained if the meaning is not self-evident, for example *"ARC"*. 10 To update section 5 to ensure the cohort numbers are consistent throughout, for example, the reference to *"14,400"*. 11 To amend section 5 to ensure the use of technical jargon is used only where necessary such as *"Once quality controlled, cleaned and shaped for consumption"*. 12 To provide further narrative in section 5 as to how the applicant is obtaining the GP data for the cohort members.

	13 To update section 5(c) to remove the reference to journals wanting *"individual level data"*. 14 In respect of the yielded benefits: a) To move any future benefits to section 5(d) (ii). b) To move the reference to PhD students to section 5(b). The following advice was given: 1. IGARD suggested that NHS Digital confirm with the applicant that the contractual terms restricting access to substantive employees in section 5, mean just that, and there will be no wider access to KCL research passport holders etc. IGARD noted there were other mechanisms available for small numbers of PhD students, to access the data, rather than them being substantive employees. 2. IGARD noted and applauded the cohort participant on the Data Access Committee, however suggested that the applicant may wish to consider additional cohort members, given the size of the cohort and the nature of the long running study. 3. IGARD suggested that NHS Digital discuss with the applicant the comments made with regards to SD5.4. 4. IGARD advised that they would wish to review this application when it comes up for renewal, as the legal basis is in a state of transition as cohort members move from s251 to consent.
3.5	NHS Oxfordshire CCG: DSfC - NHS Oxfordshire CCG and Oxfordshire County Council; Comm. (Presenter: Dan Goodwin) NIC-116582-F2F2J-v11.2 **Application:** This was an amendment application to **1)** remove North and East London CSU as a Data Processor; **2)** add the University of Oxford as a Data Processor for the purpose of commissioning; **3)** add the National Cancer Registration and Analysis Service (NCRAS) data linkage; **4)** the addition Adult Social Care for the purpose of commissioning. The purpose is for NHS Oxfordshire CCG and Oxfordshire County Council to receive data to provide intelligence to support the commissioning of health services. The data is analysed so that health care provision can be planned to support the needs of the population within the CCG area. NCRAS is a service available from the National Disease Registration Service (NDRS) who, prior to the 30th September 2021, were under the controllership of Public Health England (PHE), however from the 1st October 2021 transferred into NHS Digital. NHS Oxfordshire CCG want to evaluate the outcomes of patients referred to the Oxfordshire's Suspected CANcer (SCAN) pathway evaluation, for investigation of a pre-specified set of symptoms compared to the outcomes of patients with the same symptoms investigated through existing routes to cancer diagnosis in Oxfordshire before and while the SCAN pathway was available. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at IGARD business as usual (BAU) meetings on the 13th July 2017, 21st December 2017 and 8th July 2021. **In respect of the NCRAS data, IGARD made the following comments / queries:** IGARD noted that NCRAS had transferred in to NHS Digital from the 1st October 2021, however advised NHS Digital that as per the usual process, a briefing paper would need to be submitted to IGARD with further details of this specific data. IGARD noted that this briefing paper had not yet been received, and they would therefore be unable provide a

	recommendation for the NCRAS data as not all the necessary information was available in order for IGARD to make a full assessment. IGARD therefore asked that the relevant documentation were provided, such as the Direction, Executive Management Team (EMT) Briefing Paper or IGARD Briefing Paper, with regards to the NCRAS data. IGARD noted reference within section 5(a) (Objective for Processing) to a 'pilot project', however asked that the outputs in section 5(c) (Specific Outputs Expected) and the benefits in section 5(d) (Benefits) aligned with the fact that this was a 'pilot', in line with NHS Digital's DARS Standard for Expected Outcomes and NHS Digital's DARS Standard for Expected Measurable Benefits. IGARD noted that the NCRAS Direction specifically states that NCRAS data can only be used for medical research, and asked that the application was aligned throughout, including, but not limited to, section 7 (Ethics Approval), that stated *"Ethics approval is not required because the release is not for the purpose of research"*. Noting the national impact and wider rollout, IGARD suggested that NHS Digital follow the former PHE Office for Data Release (ODR) model of requiring either Health Research Authority Research Ethics Committee (HRA REC) or local University REC support. **In respect of all other aspects of the application (with the exception of the NCRAS data), IGARD made the following comments / queries:** IGARD queried if the use of Adult Social Care data would align with the restrictions on the use of Adult Social Care data for Risk Stratification in terms of the s251 support; and noting that this was not clear in the application, asked that an express statement was made in section 5 (Purpose / Methods / Outputs) for transparency. IGARD noted that there was an issue with the application, in terms of a clear case not being made for re-identification for the purpose of direct care as part of a commissioning application; and that the application referred to re-identification in exceptional cases with aggregated numbers with small numbers supressed. IGARD noted that, based on the discussion at the workshop at the IGARD BAU on the 18th November 2021, the reference to *"small numbers"* under the heading *"re-identification process for direct care"* in section 5(b) (Processing Activities) was incorrect, and asked that this was removed. IGARD asked that section 5(b) was instead updated to make clear that there were two main limbs to the re-identification process for direct care, i) clinical / commissioning led, and ii) data led; and it was clear that this would be on a programmatic basis or, rarely, individual / small group cohort, for example, less than ten. IGARD noted the examples provided in section 5(b) of A&E usage and polypharmacy, however asked that prior to this information and for transparency, it was made clear these were generic examples and not necessarily linked to the applicant CCG, and as discussed at the workshop at the IGARD BAU meeting on the 18th November 2021. In addition, IGARD asked that section 5(b) was updated with an example of programmatic re-identification that could be substituted for the generic examples; or, if they have taken part in A&E / polypharmacy, section 5(b) was updated with further clarification. IGARD queried the following statement in section 5(b) *"The DSCRO (either through an automated system or manual checking in line with the request) assesses as to whether the request passes the specified re-identification process checks"*; and asked that for further transparency in respect of the role of the Data Services for Commissioners Regional Office (DSCRO), section 5(b) was updated with further information as to how the DSCRO manually reviewed the approval for the re-identification, in addition to the *"automated system"* reference.

	IGARD noted a number of acronyms in section 5 and asked that this public facing section, that forms NHS Digital's data uses register, be updated to ensure that all acronyms upon first use were expanded and clearly defined with a supportive explanation in a language suitable for a lay reader, for example *"wave 2"*. IGARD noted the various references in section 5 to *"point 1 above"*, and asked that the numbering is updated to ensure clarity as to what specific point was being referred to on each occasion. IGARD noted the forthcoming system changes across healthcare, in respect of the Integrated Care Systems (ICSs); which are new partnerships between the organisations that meet health and care needs across an area, to coordinate services and to plan in a way that improves population health and reduces inequalities between different groups; and therefore asked that section 1 (Abstract) and section 5 were updated with a reference to the forthcoming CCG / ICS transition. IGARD queried if all the benefits outlined were produced as a result of the use of the NHS Digital data, for example, were local data flows used; and asked that this was updated in line with NHS Digital's DARS Standard for Expected Measurable Benefits, with clarification that the yielded benefits were produced as a result of the use of NHS Digital data. **Outcome:** IGARD were unable to make a recommendation for the NCRAS data as not all the necessary information was available in order for IGARD to make a full assessment. 1. To provide the relevant documentation such as the Direction, EMT Briefing Paper or IGARD Briefing Paper, with regards to the NCRAS data. 2. To align the pilot outputs and benefits, with the pilot project. 3. Noting the NCRAS Direction specifically states that NCRAS data can only be used for medical research, to align the application throughout, including (but not limited to) section 7, that states ethics approval is not required because no research is being undertaken. 4. Noting the national impact and wider rollout, IGARD suggested that NHS Digital follow the former PHE ODR model of requiring either HRA REC or local University REC support. **Outcome:** recommendation to approve (with the exception of the NCRAS dataset). The following amendments were requested: 1. To make an express statement in section 5 that the use of Adult Social Care data will align with the restrictions on the use of Adult Social Care data for Risk Stratification in terms of the s251 support. 2. In respect of the *"re-identification process for direct care"* in section 5(b): a) To remove the reference to *"small numbers"*. b) To make clear that there are two main limbs i) clinician / commissioning led, and ii) data led. c) To make clear this will be on a programmatic basis or, rarely, individual / small group cohort. 3. In respect of A&E / polypharmacy in section 5(b): a) To update section 5(b) prior to the information on A&E / polypharmacy, to make it clear these are generic examples and not necessarily linked to the applicant CCG. b) To update section 5(b) with an example of programmatic re-identification that could be substituted for the generic examples; or,

	c) If they have taken part in A&E / polypharmacy, to update section 5(b) with further clarification. 4. To update section 5(b) to provide further transparency as to how the DSCRO manually reviews the approval for the re-identification, in addition to the *"automated system"* reference. 5. IGARD noted a number of technical terms in section 5, and asked that this public facing section, that forms NHS Digital's data uses register, was amended throughout, to ensure acronyms be defined upon first use, and technical terms are explained in a manner suitable for a lay audience, for example *"wave 2"*. 6. To update section 5 with regard to references to *"point 1 above"* by amending the numbering to ensure clarity. 7. To update section 1 and section 5 with a reference to the forthcoming CCG / ICS transition. 8. To update section 5(d) (iii) with clarification that the yielded benefits were produced as a result of the use of NHS Digital data.
3.6	NHS Bristol, North Somerset and South Gloucestershire CCG: DSfC - IV, RS & Comm (Presenter: Michael Ball) NIC-186885-Q1T3D-v6.2 **Application:** This was an amendment application to **1)** add Medicines Dispensed in Primary Care (NHSBSA Data) and Adult Social Care data for commissioning purposes; **2)** to add COVID-19 Mapping and Mitigation in Schools (CoMMins) project which is led by University of Bristol. This will involve linkage to an external dataset; **3)** to add details for the BNSSG CCG project that evaluates the key deliverables from 5 sub-projects, around hip and knee osteoarthritis patients within the BNSSG CCG's area. This will involve linkage to an external dataset; **4)** to add details for a second independent part of the Evaluation project, conducted by University of Bristol on behalf of the CCG. The overall purpose for this application is for: Invoice Validation (IV) which is part of a process by which providers of care or services are paid for the work they do; Risk Stratification (RS) which is a tool for identifying and predicting which patients are at high risk or likely to be at high risk and prioritising the management of their care; and to provide intelligence to support the commissioning of health services. NHS Digital advised that this application was being brought to IGARD for advice only, on data controllership, and whether NHS Bristol, North Somerset and South Gloucestershire CCG continued to be the sole Data Controller. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at IGARD business as usual (BAU) meetings on the 21st November 2019 and the 8th October 2020. IGARD noted that aspects of this application had been previously seen at the IGARD – NHS Digital COVID-19 Response meeting on the 19th January 2021. IGARD welcomed the application which came for advice on data controllership (along with NIC-568791-M1W8V), and without prejudice to any additional issues that may arise when the application is fully reviewed. IGARD noted the addition of the University of Bath and University of Exeter to the Data Sharing Agreement (DSA) as joint Data Processors to undertake health research, which is outside the scope of the current purpose. IGARD queried why the Universities were not considered sole Data Controllers, in light of their roles outlined within the application, and in line with the UK General Data Protection Regulation (UK GDPR) and the NHS Digital DARS

	Standard for Data Controllers. It was not clear how the research projects could be delivered if the data was restricted to commissioning purposes. Applications, for data concerning respective research participants, directly to NHS Digital would seem more appropriate. IGARD suggested that prior to this application being submitted for a full review at a future IGARD BAU meeting, the application was refined and aligned with the purpose of commissioning and the geographical need. IGARD also advised that when this application returns for a full review at a future IGARD BAU meeting, they would be content for a colleague from a Data Services for Commissioners Regional Office (DSCRO) to also attend to support the discussion. **Outcome:** IGARD welcomed the application which came for advice and without prejudice to any additional issues that may arise when the application is fully reviewed, and suggested that NHS Digital may wish to review its policy position, on commissioning applications which are being used for research purposes, which is outside the scope of the current purpose.
3.7	NHS Hull CCG: DSfC - Sentinel Quality Improvement Programme (Presenter: Michael Ball) NIC-568791-M1W8V-v0.4 **Application:** This was a new application for pseudonymised Secondary Uses Service (SUS) for Commissioners data. The purpose is for NHS Hull CCG and NHS East Riding CCG to receive data to provide intelligence to support the commissioning of health services. The data is analysed so that health care provision can be planned to support the needs of the population within the CCG area. NHS Digital advised that NHS Hull CCG and NHS East Riding CCG has been approached by the University of Hull who are conducting the SENTINEL Quality Improvement Programme (QIP) to receive data to support the treatment of Adult Asthma in Hull and East Riding. NHS East Riding CCG and NHS Hull CCG have a key interest in this as part of their commissioning work and have instructed the University of Hull under a 'letter of instruction' to undertake this work. In addition, NHS Digital confirmed that AstraZeneca UK Ltd would be the funder for the processing outlined. **Discussion:** IGARD welcomed the application which came for advice on the data controllership (along with NIC-186885-Q1T3D), and without prejudice to any additional issues that may arise when the application is fully reviewed. IGARD noted the role of the University of Hull within the Data Sharing Agreement (DSA) as joint Data Processors to undertake health research, which is outside the scope of the current purpose. IGARD queried why they the University was not considered a joint Data Controller, or sole Data Controller, in light of their role outlined within the application, and in line with the UK General Data Protection Regulation (UK GDPR) and NHS Digital DARS Standard for Data Controllers. IGARD suggested that prior to this application being submitted for a full review at a future IGARD BAU meeting, the application was refined and aligned with the purpose of commissioning and the geographical need. IGARD also advised that when this application returns for a full review at a future IGARD BAU meeting, they would be content for a colleague from a Data Services for Commissioners Regional Office (DSCRO) to also attend to support the discussion.

	Outcome: IGARD welcomed the application which came for advice and without prejudice to any additional issues that may arise when the application is fully reviewed, and suggested that NHS Digital may wish to review its policy position, on commissioning applications which are being used for research purposes, which is outside the scope of the current purpose.
4	Applications progressed via NHS Digital's Precedent route, including the SIRO Precedent 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).
4.1	NIC-10328-S0H5J-v10 Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust The purpose of this application was for access to NHS Digital's On-line Portal system, which enables organisations to access Hospital Episode Statistics (HES) data for a wide range of data analytical purposes. The system is an online analytical processing tool through which the users of this organisation data has access to a wide range of analytical, graphical, statistical and reporting functions. The North East Quality Observatory Service (NEQOS) uses the system to support the measurement of quality of care, including care delivered in hospital. NEQOS provides quality measurement for NHS organisations (both providers and commissioners) and leads on the measurement programmes for the Academic Health Science Network in North East and North Cumbria. IGARD noted that this application was last reviewed by the Data Access Advisory Group (DAAG) (IGARD's predecessor) on the 29th July 2016. IGARD noted that on the 23rd November 2021, NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had agreed to authorise a fixed term renewal for six months, with a special condition requiring the applicant to provide additional information about some commercial aspects of their work. In addition, NHS Digital have confirmed that the next iteration of the application would be presented at a future IGARD BAU meeting. 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.
5	Oversight & Assurance 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. IGARD noted that they had reviewed an IG COVID-19 release register suite of documents on a particular data release for review by IGARD as part of their oversight and assurance, and as agreed in June 2020 with the Executive Director Privacy, Transparency and Ethics (PTE) when it had been agreed that IGARD review an agreed number per month, by way of a review of all documentation revised by PTE, and as part of continuous improvement and quality. A summary of the points raised will be included under this section in the coming weeks.

	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. IGARD Members noted that the last IG COVID-19 release register that they had reviewed and provided comments on was July 2021.
6	COVID-19 update To support NHS Digital's response to COVID-19, from Tuesday 21st April 2020, IGARD will hold a separate weekly meeting, to discuss COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 urgent applications that have been submitted to NHS Digital. Although this is separate to the Thursday IGARD meetings, to ensure transparency of process, a meeting summary of the Tuesday meeting will be captured as part of IGARD's minutes each Thursday and published via the NHS Digital website as per usual process. IGARD noted that at the request of NHS Digital, the COVID-19 response meeting on Tuesday, 30th November 2021 was cancelled.
7 **7.1**	AOB: NIC-13925-Q7R2D-v9 - IQVIA Ltd (Presenter: Dave Cronin) NHS Digital attended IGARD to discuss concerns over the use of NHS Digital data within the above Data Sharing Agreement (DSA). IGARD discussed with NHS Digital how this could be addressed and confirmed they were supportive of the approach outlined by NHS Digital.
7.2	Destruction of Data IGARD noted they had been previously advised via narrative in application abstracts and the verbal updates from NHS Digital in respect of the current guidance from NHS Digital in respect of pausing the destruction of data, in light of the forthcoming COVID-19 inquiry. IGARD, at the time, had suggested that the blanket cessation of destruction of data may not be the best course of action in all cases, for example, should the study not be connected in any way to COVID-19, noting UK GDPR principles still applied. IGARD received a verbal update from NHS Digital to confirm that this only applied where the application was related to COVID-19 and that the blanket cessation had been removed. IGARD noted the verbal update and suggested that NHS Digital urgently review all applications that had proceeded either via IGARD or down the precedent route during the period of the blanket cessation to update applicant's appropriately and ensure that no applicant was holding data that should have been destroyed.
7.3	Statutory Public Inquiry into the COVID 19 pandemic IGARD noted that NHS Digital were in the process of preparing for the statutory COVID-19 public inquiry, and following their request to NHS Digital at the 4th November 2021 BAU meeting that they were kept up to date with any processes that they needed to be aware of / take responsibility for in terms of retaining information (noting IGARD members accessed information relating to IGARD via their individual NHS accounts), NHS Digital noted that a

	formal update would be provided to IGARD members. IGARD thanked NHS Digital for the verbal update and looked forward to receiving a written update in due course. There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 26/11/21

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

NIC Reference	Applicant	IGARD meeting date	Recommendation conditions as set at IGARD meeting	IGARD minutes stated that conditions should be agreed by:	Conditions agreed as being met in the updated application by:	Notes of out of committee review (inc. any changes)
None						

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