Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held in-person (Leeds) and via videoconference 24th November 2022

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member / Co-Deputy IGARD Chair
Maria Clark	Lay Member
Dr. Robert French	Specialist Academic / Statistician Member
Kirsty Irvine	IGARD Chair
Dr. Imran Khan	Specialist GP Member / Co-Deputy IGARD Chair (Items 3.2 – 7.1)
Dr. Geoffrey Schrecker	Specialist GP Member
Dr. Maurice Smith	Specialist GP Member
Jenny Westaway	Lay Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Prof. Nicola Fear	Specialist Academic Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Michael Ball	Data Access Request Services (DARS) (**Presenter**: item 4.1)
Michael Chapman	Director of Research and Clinical Trials (**Observer:** Item 7.1)
Garry Coleman	Associate Director, Deputy SIRO & Audit Services (**Observer**: items 3.1 and 7.1)
Dave Cronin	Data Access Request Services (DARS) (**SAT Observer**: item 4.2)
Catherine Day	Data Access Request Services (DARS SAT) (**Presenter**: item 4.3)
Louise Dunn	Data Access Request Services (DARS SAT) (**SAT Observer**: item 4.1 and 4.5)
Duncan Easton	Data Access Request Services (DARS SAT) (**SAT Observer**: item 4.1)
Liz Gaffney	Head of Data Access, Data Access Request Service (DARS) (**Observer**: Item 7.1)
Jackie Gray	Solicitor and Executive Director, Privacy, Transparency, Ethics & Legal (PTEL) (**Presenter**: item 7.1)

Dickie Langley	Head of Information Governance, Privacy, Transparency, Ethics, and Legal (PTEL) (**Observer**: Item 7.1) (**Presenter**: item 7.2)
Abigail Lucas	Data Access Request Services (DARS) (**Observer**: item 4.4)
Karen Myers	IGARD Secretariat Team
Frances Perry	Digi-Trials (**Presenter:** item 4.5)
Aisha Powell	Data Access Request Services (DARS) (**Presenter**: item 4.2) (**Observer**: item 4.3)
Charlotte Skinner	Data Access Request Services (DARS) (**Presenter:** item 4.4)
Kimberley Watson	Data Access Request Services (DARS SAT) (**SAT Observer**: item 4.3 to 4.4)
Vicki Williams	IGARD Secretariat Team
***SAT** – Senior Approval Team (DARS)	

1	**Declaration of interests:** Dr. Imran Khan noted a potential conflict with NHS Buckinghamshire, Oxfordshire, and Berkshire West ICB (NIC-616007-R3H0G), as part of his role as Clinical Digital Place Lead for Buckinghamshire, Oxfordshire and Berkshire West Integrated Care Board. It was agreed that Dr.Khan would not remain in the room for the discussion of that application. Dr. Imran Khan noted a potential conflict with any applications reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) (NIC-381078-Y9C5K), as part of his roles as Deputy Chair of the Health Informatics Group at the RCGP and Co-deputy Chair of the Joint GP IT Committee. It was agreed this did not preclude Dr. Khan from taking part in the discussions about this application, however it was agreed that he would not participate in making a recommendation about the application. Maria Clark noted professional links to the University of Sheffield (NIC-381078-Y9C5K) but no specific connection with the application or staff involved and it was agreed this was not a conflict of interest. Dr. Maurice Smith noted professional links to the University of Liverpool (NIC-381078-Y9C5K) but 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 17th November 2022 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	<u>NHS Buckinghamshire, Oxfordshire, and Berkshire West ICB: DSfC - NHS Buckinghamshire, Oxfordshire And Berkshire West Integrated Care Board- IV, RS & Comm (Presenter: Michael Ball) NIC-616007-R3H0G-v0.2</u> **Application:** This was a new application for pseudonymised Commissioning Datasets; and identifiable Invoice Validation Datasets and Risk Stratification Datasets. This application is for the newly formed Integrated Care Board (ICB) and Oxfordshire County Council to access NHS Digital data. The purpose of the application is for **1)** Invoice Validation, which is part of a process by which providers of care or services get paid for the work they do **2)** Risk Stratification, which is a tool for identifying and predicting which patients are at high risk (of health deterioration and using multiple services) or are likely to be at high risk and prioritising the management of their care in order to prevent worse outcomes; and **3)** Commissioning, to provide intelligence to support the commissioning of health services. The data (containing both clinical and financial information) is analysed so that health care provision can be planned to support the needs of the population within the ICB area. This application also includes linkage to 'Better Housing Better Health Plus' data for commissioning purposes. The existing 'Better Housing Better Health' service is a longstanding telephone support service (delivered by the National Energy Foundation) working to reduce and prevent the number of people in fuel poverty, and so improve health and wellbeing. The Council has put a pilot in place extending this service as the 'Better Housing Better Health Plus' service, which is for vulnerable residents in the area. A **consented** home visit takes place, which offers an integrated holistic assessment to better identify the range of the service users' needs and enable them to access relevant support services such as signposting to social prescribing. The Council and ICB now wishes to evaluate the service to understand the impact of the service on the health and wellbeing of the participants. **Discussion:** IGARD requested that the Associate Director, Deputy SIRO and Audit Services, observed part of the discussion for this application. Prior to the meeting an IGARD member queried how the common law duty of confidentiality (CLDoC) was being met for the use and linkage of 'Better Housing Better Health Plus' data. In addition, IGARD also noted concerns in respect of some of the 'script' wording used when obtaining consent from individuals during the home visits, in particular, the fact that it was not clear that individuals were also providing consent for linkage / evaluation of the 'Better Housing Better Health Plus' data; for example, it implied that allowing data to be used for the evaluation was necessary to receive an appropriate service in the following statement *"…to ensure I receive the services that benefit me..."*. NHS Digital advised that the applicant considered that as the linkage of the datasets would be with pseudonymised datasets, there was no breach of confidentiality and therefore there was no requirement to meet the CLDoC. In addition, the applicant considered that when the identifiable data was passed to the Commissioning Support Unit (CSU) to pseudonymise the data, they operated as a Data Processor on behalf of the Council and therefore a legal basis to meet the CLDoC was not required, as the data was still under the control of the Council. IGARD noted and thanked NHS Digital for the verbal responses provided, however, expressed concern with the statement in the 'script': *"I understand that you need to use my and my*

	household's personal information… to ensure I receive the services that benefit me"; and advised that the consent provided by patients may not have been freely given, and was required to receive a service. In addition, IGARD expressed concern that some members of the cohort who provided consent may be vulnerable individuals, and again, may **only** have provided consent due to the provision of a specific service. IGARD noted that earlier versions of the consent materials had not been provided, and expressed concern that it was their understanding that earlier versions of the consent materials were **not** clear on the subsequent processing of a participant's data. IGARD noted the statement within the published privacy notice and the process for withdrawing consent *"You have the option to opt out within **7 days** of the visit to your home. We cannot guarantee to action your decision to opt out beyond this time. We will make reasonable and proportionate efforts to remove your data after this time, should you request it"*; and expressed concern on the restrictions of the rights of an individual to withdraw consent. IGARD suggested that any future consent materials were more explicit on the future processing and that it was made clear that consent for data to be used in evaluation was separate from the provision of the services offered. IGARD felt a legal basis, in terms of the CLDoC, for the proposed disclosure for linkage. IGARD suggested that the applicant looked into whether Chapter 5 of the Digital Economy Act 2017 provided a potential route for the Council to process and then share the data. IGARD suggested that NHS Digital's Data Access Request Services (DARS) discussed the proposed processing with NHS Digital's Caldicott Guardian; and were advised by NHS Digital that this was already in progress. IGARD noted and thanked NHS Digital for the verbal update and asked that the response from the Caldicott Guardian was shared with IGARD once received. In addition, IGARD also suggested that DARS discussed the proposed linkage with NHS Digital's Associate Director, Deputy SIRO and Audit Services; noting that he had been in attendance for part of the discussion. IGARD noted the references within section 5 to *"Data Controller"*, and asked that, for transparency, these references were updated to be clear which Data Controller(s) was being referred to and in line with the NHS Digital's DARS Standard for Data Controllers. IGARD noted the objectives for processing that were outlined in section 5(a) (Objective for Processing); however, asked that, for transparency, these were updated further to be clear whether the Council will or will not have access to the data under each purpose heading. IGARD asked that section 5(a) was updated to add a brief objective for processing for the 'Better Housing Better Health', in line with NHS Digital DARS Standard for Objective for Processing, since it was not currently clear with the application. IGARD noted that section 5(c) (Specific Outputs Expected) did not set out the expected outcomes for the 'Better Housing Better Health' linkage and contained only templated wording; and asked that section 5(c) was updated, to add the expected outcomes for the 'Better Housing Better Health' processing, in line with NHS Digital DARS Standard for Expected Outcomes IGARD noted that section 5(d) (Benefits) (ii) (Expected Measurable Benefits to Health and / or Social Care) did not set out the expected benefits for the 'Better Housing Better Health' linkage and contained only templated wording; and asked that section 5(d) was update to add the

	expected benefits for the 'Better Housing Better Health' processing, in line with NHS Digital DARS Standard for Expected Measurable Benefits. **Outcome:** recommendation to approve for the templated aspects of the application only **Outcome:** unable to recommend for approval for the 'Better Housing Better Health' linkage 1. To update section 5 to clarify which Data Controller is being referred to. 2. To update section 5 to clarify whether the Council will or will not have access to the data under each purpose heading. 3. To update section 5(a) to add a brief objective for processing for the 'Better Housing Better Health', in line with NHS Digital DARS Standard for Objective for Processing. 4. To update section 5(c) to add the expected outcomes for the 'Better Housing Better Health' processing, in line with NHS Digital DARS Standard for Expected Outcomes 5. To update section 5(d) (ii) to add the expected benefits for the 'Better Housing Better Health' processing, in line with NHS Digital DARS Standard for Expected Measurable Benefits. The following advice was given: 1. IGARD noted a number of concerns in respect of the consent in line with NHS Digital DARS Standard for Duty of Confidentiality: a) The consent may not have been freely given, for example, consent being required to receive a service; and, b) Some members of the cohort who provided consent, may be vulnerable individuals, for example, consent may have only been provided due to the provision of a service; and, c) The earlier consent materials were **not** clear on the subsequent processing of their data; and, d) IGARD noted concern on the process / timeline for participants withdrawing consent, i.e. the 7-day window. e) IGARD suggested that future consent materials were more explicit on the future processing and that it is made clear that consent for data to be used in evaluation is separate from the provision of the services offered. 2. Concern there is not a sufficient legal basis in terms of the CLDoC for the proposed disclosure for linkage. 3. IGARD suggested that the applicant looked into whether Chapter 5 of the Digital Economy Act 2017 provided a potential route for the Council to process and then share the data. 4. IGARD suggested discussing with NHS Digital's Caldicott Guardian the proposed processing; and noting that this was already in progress, asked that a response was shared. 5. IGARD suggested that NHS Digital's DARS discussed the proposed linkage with the Associate Director, Deputy SIRO and Audit Services.
3.2	IQVIA Ltd: IQVIA Ltd. - Analytical Services (Presenter: Aisha Powell) NIC-373563-N8Z9J-v11.5 **Application:** This was a renewal application to permit the holding and processing of pseudonymised Civil Registration (Deaths) - Secondary Care Cut, Emergency Care Data Set (ECDS), Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC), HES Outpatients, Summary Hospital-level Mortality Indicator, HES:Civil

	Registration (Deaths) bridge, HES-ID to MPS-ID HES Admitted Patient Care and HES-ID to MPS-ID HES Outpatients. The purpose of the application is to enable IQVIA Ltd. and IQVIA Technology Services Ltd. to provide services and solutions to its customers which include analysis, interpretation and reports. Those analyses, interpretations and reports assist such customers in supporting the understanding of care pathways, delivering clarity to hospitals on their use of medicines, enabling the development of diagnostic algorithms, enabling patients to be recruited to trials, and supporting healthcare commissioners and providers in achieving exceptional data quality. These services will enable the development of health economic models that evaluate care delivery in relation to outcomes achieved for the patient and in so doing, help advance and benefit healthcare in a variety of different ways. NHS Digital advised IGARD that section 5(a) (Objective for Processing) incorrectly made reference to *"Hospital Treatment Insights Service (HTI)"*; and advised that this would be removed. NHS Digital advised IGARD that section 6 (Special Conditions) contained two duplicate special conditions relating to the NHS Digital data citation; and advised that this would be updated to remove one of the special conditions. NHS Digital also advised IGARD that section 6 contained a special condition relating to *"ISEAC"*; and advised that this was no longer relevant and would be removed from the application. **Discussion:** IGARD noted and commended NHS Digital, on the efforts taken to update the application, which supported the review of the application by members. IGARD noted that the application and relevant supporting documents had previously been presented at the Data Access Advisory Group (DAAG) *(IGARD's predecessor)* meeting on the 13th September 2016, 27th September 2016; and at the IGARD meetings on the 7th February 2019, 6th February 2019 and the 28th January 2021. IGARD noted the verbal update from NHS Digital in respect of the reference to *"HTI"* being removed from section 5(a); the duplicate NHS Digital data citation special condition being removed from section 6; and the special condition relating to *"*ISEAC"* being removed from section 6; and confirmed that they were supportive of all the relevant updates being made to the application as advised. * Independent Scientific Ethical Advisory Committee (ISEAC) IGARD noted in section 1 (Abstract), that in respect of 'service 2' – the Advanced Statistical Analysis, which was bespoke analysis for external organisations on a project-by-project basis - ISEAC had been previously given the authority, by NHS Digital, to review / approve the projects within the scope of Service 2. IGARD noted that it was stated in the ISEAC Terms of Reference (ToR) that *"Minutes will be available on request and a summary of decisions will be available in ISEAC's annual report"*; which was also reflected in this / other IQVIA data sharing agreements (DSA). IGARD noted that following a request from NHS Digital, IQVIA were unable to provide the minutes from the last twelve months; or subsequently the annual report; and as a result, the authority to approve projects within the scope of service 2 had now been rescinded by NHS Digital. IGARD asked that section 1 was updated to reflect that there would be **no** new 'service 2' projects. IGARD also asked that for transparency to the public, section 5(a) that forms NHS Digital's data uses register was updated, to reflect the more restricted permitted data use.

	IGARD reiterated their previous advice point from the IGARD meeting on the 28th January 2021: that for, transparency, IQVIA ISEAC considered making a summary of approved projects publicly available. IGARD noted that a link to bibliography of papers had been provided, but that this was not the same as transparency about what projects had been approved. IGARD reiterated their previous advice point from the IGARD meeting on the 28th January 2021: In respect of future project updates to NHS Digital, and any public disclosures, to ensure it was transparent, when pharmaceutical company clients supplied the drug that was being studied; or an illness or disease that was being researched for, which they produced relevant treatment or medical devices. IGARD noted and thanked NHS Digital for providing a copy of the audit report from August 2022 prior to the meeting; and asked that section 1 was updated to include the further information of the audit, for example a weblink once published, and for future review. IGARD noted the information in section 5(e) (Is the Purpose of this Application in Anyway Commercial) that outlines the commercial aspect of the application; however, asked that this was updated further, in line with NHS Digital DARS Standard for Commercial Purpose to clarify that the applicant was a commercial organisation, as well as an organisation which provides a service to commercial organisations. IGARD also asked that the public facing section 5(a) that forms NHS Digital's data uses register was updated, to provide a brief summary of the commercial aspects of the application as outlined in section 5(e), in line with NHS Digital DARS Standard for Commercial Purpose and NHS Digital DARS Standard for Objective for Processing. IGARD also asked that as per the update to section 5(e), section 5(a) was also updated, to clarify that the applicant was a commercial organisation, as well as an organisation who provides a service to commercial organisations. IGARD noted that the application would need updating to cite the relevant part of s261 of the Health and Social Care Act 2012 in line with the latest guidance from NHS Digital's Privacy, Transparency, Ethics and Legal. **Separate to this application**: IGARD noted that at previous IGARD meetings, for example, on the 15th September (NIC-355818-H7T3C), 16th June (NIC-448252-L2R6Q) and 7th July (NIC-148369-8PPWK), the s261 legal basis had been discussed. IGARD had requested that NHS Digital advised on the s261 legal basis for NHS Digital's dissemination, for example which section of s261 of the Health and Social Care Act 2012 was relevant since NHS Digital appeared to be only citing the overarching s261. While NHS Digital verbally advised the selected legal basis for dissemination, IGARD reiterated the request that NHS Digital **urgently** advise IGARD, in writing, on the s261 legal basis for NHS Digital's dissemination. IGARD noted a number of incorrect statements within the published privacy notice and suggested that this was updated to amend any incorrect information, including, but not limited to, information relating to opt-outs, and to reflect that the provision of data to NHS Digital is mandatory. IGARD queried the references in section 5 (Purpose / Methods / Outputs) to the *"hospital feedback service"*, and noting that there was no supporting narrative, asked that the public facing section 5, that forms NHS Digital's data uses register, was updated with clarification as to what access to the data the hospital feedback service would have; and, if there were any *quid pro quo* arrangements between Trusts and IQVIA; and to clarify at what stage the data was being paid for.

	IGARD queried the information in section 5(b) (Processing Activities) relating to the technical specifications / programmes; and asked that this was amended to reduce the narrative, and to use less restrictive wording, in line with NHS Digital DARS Standard for processing activities. IGARD noted the statement in section 5(a) *"IQVIA will determine the **maximum amount of Data necessary** for each project"*; and asked that, in line with UK General Data Protection Regulation (UK GDPR); this was updated to state *"…minimum amount of data…"*. IGARD noted the references to *"Sustainability and Transformation Plans"* (STPs) in section 5(a), and asked that these were removed, and updated with the correct references, noting that STPs no longer exist. IGARD queried the statement in section 5(a) *"…to provide services such as"*; and noting that a list of organisations followed, and not a list of services; asked that this was amended as appropriate. IGARD asked that once the relevant updates had been made to section 5(a), including, but not limited to, the new restricted permitted data use; that section 5(c) (Specific Outputs Expected) was updated to reflect the expected outcomes, in line with NHS Digital DARS Standard for Expected Outcomes; and the expected benefits in section 5(d) (Benefits) (ii) (Expected Measurable Benefits to Health and / or Social Care) were updated in line with NHS Digital DARS Standard for Expected Measurable Benefits. IGARD queried the statement in section 5(c) *"Our initial work has demonstrated that it is not possible to replicate the published SHMI numbers…"*; and asked that further clarity was provided on this, in line with NHS Digital DARS Standard for Expected Outcomes noting it was unclear whether this work was ongoing. IGARD noted the statement in section 5(c) *"Approximately 24 distinct projects using such Data were completed in 2021/22…"*; and asked how these projects mapped to the project log, provided as a supporting document, noting the minimal information provided within this document; and asked that section 5(c) was provided with further information. IGARD noted that a number of the expected benefits in section 5(d) (Benefits) (ii) (Expected Measurable Benefits to Health and / or Social Care) were yielded benefits; and asked that these were correctly moved from section 5(d) (ii) to section 5(d) (iii), in line with NHS Digital DARS Standard for Expected Measurable Benefits. IGARD queried the benefits outlined in section 5(d) (Benefits), and noted that some of the information provided were outputs, and asked that section 5(d) was updated to move any outputs to section 5(c), and edited to only leave examples that reflect the benefits to the Health and Social Care System, in line with the NHS Digital's DARS Standard for Expected Measurable Benefits. IGARD queried the statement in section 5(c) *"In September 2021…"*; and noting this date had passed, asked that either further clarity was provided on this specific expected benefit; or that the statement was removed if no longer relevant. IGARD queried the statement in 5(d) (ii) *"IQVIA expects to have a basic version of the EBI in September …"* and asked that the applicant clarify if this referred to the Evidence Based Interventions (EBI) module mentioned in section 5(c). Noting that no year was given IGARD also asked that the applicant clarify when they expected a basic version of the EBI to be ready.

	IGARD asked that section 5 was amended throughout, to ensure that all acronyms upon first use be defined and further explained if the meaning was not self-evident. IGARD suggested that section 5 be updated to remove reference to "*it will*…", and instead use a form of words such as "*it is hoped*…". 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 issues raised in the recent audit. **Outcome:** unable to recommend for approval since failure to follow required procedures for 'service 2', and then failure to make improvements in a timely fashion, raise concerns as to the ability to appropriately provide 'service 1'. 1. To update section 5(a) to remove references to *"HTI"* (as per the verbal update from NHS Digital). 2. To amend section 6 to remove the NHS Digital citation duplication (as per the verbal update from NHS Digital). 3. To amend section 6 to remove the "ISEAC" special condition (as per the verbal update from NHS Digital). 4. To update section 3 with the s261 legal basis for NHS Digital to disseminate data. 5. In respect of the hospital feedback service: a) To clarify in section 5 what access to the data the hospital feedback service will have; and, b) To clarify in section 5 if there are any *quid pro quo* arrangements with Trusts; and, c) To clarify in section 5 at what stage the data is being paid for. 6. To amend section 5(b) to reduce the narrative relating to the technical specifications / programmes. 7. In respect of the commercial aspect of the application in line with NHS Digital DARS Standard for Commercial Purpose: a) To update section 5(e) to clarify that the applicant is a commercial organisation, as well as an organisation who provides a service to commercial organisations. b) To provide a brief summary in section 5(a) of the commercial aspect of the application; and, c) To update section 5(a) to clarify that the applicant is a commercial organisation, as well as an organisation who provides a service to commercial organisations. 8. In respect of section 5(c) and in line with NHS Digital DARS Standard for Expected Outcomes: a) To provide further clarity in section 5(c) on the statement *"Our initial work has demonstrated that it is not possible to replicate the published SHMI numbers…"*. b) To update section 5(c) to align the expected outcomes with section 5(a) (once updated). c) To update section 5(c) to clarify how the 24 projects map to the log. d) To provide further clarity on the specific expected benefit dated as September 2021 or that the statement was removed if no longer relevant. 9. In respect of section 5(d) and in line with NHS Digital DARS Standard for Expected Measurable Benefits: a) To update section 5(d) (ii) to align the expected benefits with section 5(a) (once updated). b) To remove the yielded benefits from section 5(d) (ii) to section 5(d) (iii). c) To update section 5(d) (ii) to provide further clarity on the reference to *"September"*; and *"the EBI"*.

	d) To remove any specific outputs from section 5(d) and move to section 5(c). 10. In respect of section 5(a) and in line with NHS Digital DARS Standard for Objective for Processing: a) To amend section 5(a) to remove the reference to *"maximum amount of Data"* and replace with *"minimum amount of data"*, in line with UK GDPR principles. b) To update section 5(a) to reflect the new restricted permitted data use. c) To amend the references in section 5(a) to *"Sustainability and Transformation Partnerships (STPs)"*. d) To amend the reference in section 5(a) "…to provide services such as", to reflect the organisations listed. 11. As section 5 forms NHS Digital's data uses register, to amend section 5 throughout: a. To ensure acronyms be defined upon first use; and, b. To update section 5 to use a form of wording such as "*it is hoped* …", rather than "*it will*…". 12. In respect of section 1: a) To update section 1 to add reference to the audit process. b) To update section 1 to reflect there will be no new 'service two' projects. The following advice was given: 1. IGARD reiterated their previous advice point: that the IQVIA ISEAC oversight committee consider making a summary of approved projects publicly available. 2. IGARD reiterated their previous advice point: In respect of future project updates to NHS Digital (and any public disclosures), to ensure it is transparent when pharmaceutical company clients supply the drug that is being studied or an illness or disease is being researched for which they produce relevant treatment or medical devices. 3. IGARD suggested that the applicant update their published privacy notice, to amend any incorrect information relating to opt-outs and to reflect that the provision of data to NHS Digital is mandatory. 4. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the issues raised in the recent audit. 5. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the issues raised in the recent audit. **Separate to this application**: IGARD noted that at previous IGARD meetings, for example, on the 15th September (NIC-355818-H7T3C), 16th June (NIC-448252-L2R6Q) and 7th July (NIC-148369-8PPWK), the s261 legal basis had been discussed. IGARD had requested that NHS Digital advised on the s261 legal basis for NHS Digital's dissemination, for example which section of s261 of the Health and Social Care Act 2012 was relevant since NHS Digital appeared to be only citing the overarching s261. While NHS Digital verbally advised the selected legal basis for dissemination, IGARD reiterated the request that NHS Digital **urgently** advise IGARD, in writing, on the s261 legal basis for NHS Digital's dissemination.
3.3	Health Data Research UK: R14.2 - COVID-IMPACT-UK. Cardiovascular disease and COVID-19: using UK-wide linked routine healthcare data to address the impact of cardiovascular disease on COVID-19 and the impact of COVID-19 on cardiovascular diseases. (Presenter: Catherine Day) NIC-381078-Y9C5K-v8.2 **Application:** This was an amendment application **to 1)** add University of Liverpool as a joint Data Controller; **2)** to add University of Southampton as a joint Data Controller; **3)** to add

	University of Sheffield as a joint Data Controller; **4)** to include the addition of the Uncurated Low Latency Hospital Emergency Care data set. The British Heart Foundation (BHF) Data Science Centre, which is embedded within Health Data Research UK (HDR UK), is working in partnership with NHS Digital to establish a Trusted Research Environment (TRE) [service] for England, to enable analyses of linked, nationally collated healthcare datasets. This project is now entitled 'COVID-IMPACT-UK' and will enable timely research on the effects/impacts of pre-existing health on COVID-19, and the direct and indirect impacts of COVID-19 on health; coordinate similar approaches across the four nations of the UK; and demonstrate how accessing data within a TRE could support future research initiatives. The programme commenced in July 2020. NHS Digital advised IGARD, that this version of the data sharing agreement (DSA) would **not** exceed the current end date of the 14th October 2023; and that, going forward, each of the themes would be split into separate applications. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD meetings on the 25th June 2020, 23rd July 2020, 15th October 2020, 3rd December 2020, 25th February 2021 and the 29th July 2021. It was also discussed under 'AOB' on the 20th August 2020; and as part of the 'applications progressed via NHS Digital's SIRO Precedent route' on the 22nd October 2020. IGARD also noted that this application had previously been discussed as part of the 'returning applications' section of the IGARD meeting on the 25th May 2022. IGARD noted that aspects of this application had been seen by the IGARD – NHS Digital COVID-19 Response meetings on the 26th May 2020, 2nd June 2020, 9th June 2020, 16th June 2020, 23rd June 2020, 24th November 2020, 19th January 2021 and the 29th June 2021. IGARD also noted that this application had also been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 24th June 2020 *(the notes from this meeting had been attached to the IGARD minutes from the 23rd July 2020)*; and the 28th July 2021 *(the notes from this meeting had been attached to the IGARD minutes from the 29th July 2021)*. IGARD noted and thanked NHS Digital for the verbal update in respect of this application not proceeding beyond the end date of the 14th October 2023; and being split into separate DSAs; and advised that they were supportive of this approach. IGARD noted and welcomed the efforts by the applicant, in ensuring that detailed protocols and statistical analysis plans for each approved project were made available in the public domain through the British Heart Foundations (BHF) Data Science Centre's GitHub repositories. IGARD noted that, prior to the meeting, an IGARD member had queried if all the joint Data Controllers had signed a Joint Data Controller Agreement as per the previous special condition. NHS Digital had noted that individual researchers sign up to the Principles for Participation Ways of Working Document and that all data controllers must sign the DSA and have a valid Data Sharing Framework Contract (DSFC). IGARD noted that the information within the public domain, for example, the website and the published privacy notice, was not clear on who was responsible for what, in terms of data controllership; and therefore noted a significant risk area to NHS Digital, in that the joint data controllership arrangements were not fully transparent to the data subjects, in terms of Article 26 of the UK General Data Protection

	Regulation (UK GDPR), which states "*The essence of the arrangement shall be made available to the data subject*". IGARD noted that, prior to the meeting, an IGARD member queried the special condition in section 6 (Special Conditions) that stated the data flows must stop "*at the end of the *COPI regulations*". NHS Digital advised that the previous wording of the special conditions was incorrect and would be updated to reflect that the data can be requested **only** for the purposes set out in the COVID-19 Public Health Directions 2020, which were currently limited to COVID-19 purposes. IGARD noted and thanked NHS Digital for the verbal update and supported the relevant updates to the special conditions in section 6. *The Health Service Control of Patient Information (COPI) Regulations 2002 IGARD noted that prior to the meeting, an IGARD member had raised a query in respect of the last review of the application on the 25th May 2022; where IGARD had asked that a special condition was inserted in section 6, that any use of the Medicines Dispensed in Primary Care NHSBSA data must be within the parameters of the relevant Direction authorising that collection. IGARD noted that the incorrect special condition had been added to section 6. NHS Digital advised IGARD that the correct special condition relating to the restriction of the NHSBSA data had now been added to section 6. IGARD noted and thanked NHS Digital for the verbal update and the amendment to section 6. IGARD queried the statement in section 5(b) (Processing Activities) *"All possible ways of data minimisation have been considered and undertaken where possible…"*; and asked that this was amended to reflect that actual data minimisation had not been possible, and therefore the safeguarding of the data was achieved via contractual controls. IGARD noted a number of yielded benefits within section 5(c) (Specific Outputs Expected) of the application; and asked that in line with the NHS Digital DARS Standard for Expected Measurable Benefits, these were correctly moved to section 5(d) (Benefits) (iii) (Yielded Benefits). IGARD noted that there were a number of good, yielded benefits outlined on the project website, that were not stated in section 5(d) (iii); and asked that for transparency, a weblink was added to section 5(d) (iii) to further support this section of the application and NHS Digital's data uses register. IGARD noted the references in section 5 (Purpose / Methods / Outputs) to the 'Scientific Advisory Group for Emergencies' (SAGE); and asked that for future reference, section 5(a) was updated with a brief narrative of what SAGE was. IGARD noted that the citation special condition had been added in section 6, however asked that this was updated, to state that, where practicable, outputs cite the source of the data as *"This work uses data provided by patients and collected by the NHS as part of their care and support".* **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of the yielded benefits in section 5(d) (iii) and in line with the NHS Digital DARS Standard for Expected Measurable Benefits: a) To remove any yielded benefits from section 5(c) and move to section 5(d) (iii). b) To update section 5(d) (iii) with a link to the project website. 2. To update section 5(a) with a brief narrative of *"SAGE"*.

	3. To amend section 5(b) to reflect that data minimisation is not possible, and that safeguarding of the data was achieved via contractual controls. 4. In respect of the special conditions and in line with NHS Digital DARS Standard for Special Conditions: a) To delete the reference to the 'COPI' special condition(s) and replace with the correct NHS BSA special condition (as per the verbal update from NHS Digital). b) To amend the special condition in section 6, to state that, where practicable, outputs cite the source of the data as *"This work uses data provided by patients and collected by the NHS as part of their care and support".* **Risk Area:** The joint data controllership arrangements are not fully transparent to the data subjects, in terms of Article 26 UK GDPR.
3.4	University of Bristol: Mortality and Cancer in Christ's Hospital School Cohort (Presenter: Charlotte Skinner) NIC-147837-RJMRN-v6.3 **Application:** This was an 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 and MRIS - Members and Postings Report. The purpose of the application is for a retrospective cohort study, that comprises former male students of Christ's Hospital School (CHS) born between 1927 and 1956. During this period, students had regular measures of height and weight conducted by the School Medical Officer. Growth record cards with height and weight measures were found in the School archive and was the basis of testing the developmental origins hypothesis that growth patterns around puberty and young adulthood may have a long-term effect on chronic diseases such as cancer and heart disease. With the help of the School alumni office, former pupils for whom there was contact information were asked to complete a postal questionnaire to obtain data on lifestyles and chronic diseases and, if willing, attend their local general practice to measure weight, blood pressure and have a blood sample taken. The data collected enabled the study to look at whether growth and development during childhood and adolescence may be associated with risk factors for chronic diseases such as heart disease and diabetes. The University of Bristol have previously demonstrated that participants who had an earlier pubertal growth spurt, as determined by the age of peak height velocity, had higher levels of a hormone called insulin-like growth factor I (IGF-I); this is a risk factor for certain types of cancer. The University of Bristol plans to use the data in the future for biomedical research. Data sharing agreements (DSA) linked to this application are NIC-148336-V4SL1 and NIC-147814-86GS4. The study is relying on s251 of the NHS Act 2006, for the flow of data out of NHS Digital. **Discussion:** NHS Digital noted that the application had not previously been presented at a Data Access Advisory Group (DAAG) meeting (IGARD's predecessor) or IGARD meeting. IGARD noted that the application and relevant supporting documents for NIC-148336-V4SL1 had previously been presented at the IGARD meeting on the 4th April 2019; and NIC-147814-86GS4 had previously been presented at the IGARD meeting on the on the 26th March 2020. IGARD confirmed that they were of the view that the relevant s251 support was broadly compatible with the processing outlined in the application.

	IGARD noted the information within section 3(c) (Patient Objections) that stated patient objections **would** be applied, and queried if this was correct, noting that the historical data was disseminated prior to the National Data Opt-out being introduced on the 25th May 2018, and that there was no new data flowing under this version of the application. NHS Digital advised IGARD that section 3(c) was incorrect and that patient objections would only be applied for any future flows of data. IGARD noted the verbal update from NHS Digital and asked that section 3(c) was updated to reflect that patient objections had **not** been upheld; and to also note that any future flows of data **would** have patient objections upheld. IGARD noted the information within the applicant's published privacy noted; and suggested that the applicant review and amend this, to ensure that the legal basis cited for processing the NHS Digital data within the privacy notice was correct and aligned with the information within the data sharing agreement (DSA). IGARD noted the statement in section 5(a) (Objective for Processing) *"By linking the existing detailed **anthropometry** with these health outcomes…"*; and noting that section 5 forms NHS Digital's data uses register, asked that this was updated, to ensure that technical terms were used only where necessary and explained in a manner suitable for a lay audience, in line with NHS Digital DARS Standard for Objective for Processing. IGARD asked that a special condition was inserted in section 6 (Special Conditions), that, where practicable, outputs cite the source of the data as *"This work uses data provided by patients and collected by the NHS as part of their care and support"* (use MY data - our data citation project), in line with NHS Digital DARS Standard for Special Conditions. IGARD noted the statement in section 5(b) (Processing Activities) *"the data stored on the Safe Haven is not backed-up by design"*; and suggested that a backup was implemented. IGARD advised that they would be supportive of a backup due to the importance of the historical data; and asked that the application was updated as required to reflect any changes in respect of a backup. IGARD queried the statement in section 5(a) *"Researchers at the University of Bristol are currently exploring the possibility of using stored DNA to undertake genome wide analysis…"*. IGARD suggested that NHS Digital refer the applicant to the Information Commissioner's Office (ICO) funded 'The GDPR and genomic data project'; which was undertaken by the Public Health Genomics (PHG) Foundation (formally the PHG Unit), (a non-profit think tank, and a linked exempt charity of the University of Cambridge), and has specifically looked into the use of DNA. IGARD queried the statement in section 1 (Abstract) *"This application has been discussed with **NHS Digital's Senior Management** and Senior Approvals Team…"*; and asked that for future reference / audit, further clarity was provided on who the NHS Digital's Senior Management was referring to. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of patient objections: a) To update section 3(c) to reflect that patient objections have **not** been upheld; and, b) To update section 3(c) to note that any future flows of data **will** have patient objections upheld. 2. To update section 5(a) to ensure technical terms are used only where necessary and explained in a manner suitable for a lay audience, for example *"anthropometry"*.

	3. To insert a special condition in section 6, that, where practicable, outputs cite the source of the data as *"this work uses data provided by patients and collected by the NHS as part of their care and support"*, in line with the NHS Digital DARS Standard for Special Conditions. 4. To update section 1 with further clarity on the reference to *"…NHS Digital's Senior Management…"*. The following advice was given: 1. IGARD suggested that the applicant review and amend their published privacy notice, to ensure that legal basis cited for processing NHS Digital data is correct and aligns with the information within the DSA. 2. IGARD suggested that NHS Digital refer the applicant to the Information Commissioner's Office (ICO) funded 'The GDPR and genomic data project'; which has specifically looked into the use of DNA. 3. IGARD noted that *"the data stored on the Safe Haven is not backed-up by design"*; and suggested that a backup was implemented. IGARD advised that they would be supportive of a backup and asked that the application was updated as required to reflect any changes.
3.5	University of Oxford: A Study of Cardiovascular Events iN Diabetes – PLUS (ASCEND PLUS) - Recruitment agreement (Presenter: Frances Perry) NIC-655024-S2H5Q-v0.5 **Application:** This was a new application for aggregated with Small Numbers Suppressed Customer - Data Quality Report - Aggregate (Comms), Customer - Data Quality Report - Aggregate (Recruitment); identifiable Demographics data and Mailing - Cohort - Non-aggregate (Comms & Recruitment). The purpose of the application is specifically to support the recruitment of a cohort by writing out to individuals who meet the required eligibility criteria; and is relying on s251 of the NHS Act 2006, for the flow of data out of NHS Digital. The purpose of the application is for the first element of the recruitment process, for the identifiable data from NHS Digital to flow to Paragon Customer Communications Ltd for the purpose of University of Oxford inviting them to join the ASCEND PLUS trial; and is relying on s251 of the NHS Act 2006. For the second element of the recruitment process, the University of Oxford are relying on consent. Interested potential participants will return a reply form to University of Oxford which will include consent to obtain information. The overall purpose of the application is for the ASCEND PLUS trial, which aims to provide evidence about both the efficacy and safety of prolonged treatment with oral semaglutide. The hypothesis of the ASCEND PLUS trial is that treatment with oral semaglutide reduces cardiovascular events and other complications of diabetes in individuals aged at least 55 years, with type 2 diabetes mellitus (T2DM), without a history of a heart attack or stroke, and without any upper or lower Haemoglobin A1c (HbA1c) threshold. **Discussion:** IGARD confirmed that they were of the view that the relevant s251 support was broadly compatible with the processing outlined in the application. IGARD noted that prior to the meeting, an IGARD member had raised a query in respect of the NHS Business Services Authority (NHSBSA) Medicines Data Directions 2019, that limits the use of the data to providing intelligence about the safety and effectiveness of medicines; noting that for this application, it was being used to identify candidates for a clinical trial;

	IGARD queried whether the proposed use of the data was compatible with the Direction. IGARD noted that prior to the meeting, a written response had been provided by NHS Digital, that confirmed how the Direction provided for the use of the data for identification services in Clinical Trials. IGARD noted the content of the written update from NHS Digital but stressed the crucial wording was the text in the direction not the supporting materials. IGARD could see that recruitment of a trial aimed at improving the effectiveness of medication could plausibly fall within the Direction. **ACTION**: IGARD to discuss NHSBSA data use with the Information Asset Owner (IAO) to clarify what is covered by the Direction. IGARD noted the information in section 5(e) (Is the Purpose of this Application in Anyway Commercial) that outlined the commercial aspect of the application; however, asked that this was updated further, in line with NHS Digital DARS Standard for Commercial Purpose to provide further information. IGARD also asked that the public facing section 5(a) (Objective for Processing) that forms NHS Digital's data uses register was updated, to provide additional narrative in respect of the commercial aspects of the application as outlined in section 5(e), in line with NHS Digital DARS Standard for Commercial Purpose and NHS Digital DARS Standard for Objective for Processing. IGARD queried the statement in section 5(a) *"…then this could also increase revenue for the manufacturer Novo Nordisk.* ***However, this is not the main objective of the research****"*; and asked that this was removed as it was not relevant. IGARD noted that prior to the meeting, an IGARD member had raised a query in respect of the involvement of Novo Nordisk and the funding; noting that this study was looking at one drug in the GLP-1 RA class and that there were four other licenced drugs listed in this class and in the British National Formulary. IGARD queried why the applicant was only looking at one and how had this been decided. NHS Digital advised that the applicant had confirmed that semaglutide was the only medication in this class in a form available to take by mouth. The other drugs are given by injection so would not be suitable for this type of trial design and may be more difficult for patients to take; and this is why they approached Novo Nordisk rather than the other manufacturers. IGARD noted the written update from NHS Digital, and asked that section 5(a) was updated to clarify why the specific drug was being studied. IGARD also asked that further clarification was provided in section 5(a) and section 5(e) of the funding arrangements. IGARD suggested that DigiTrials considered the advantage for 'first movers' given the limited pool of research subjects, limiting recruitment possibilities for other pharmaceutical companies or researchers. IGARD noted that section 5(a) referred to trying to 'nudge' people to participate, which could be seen as interfering with a person's autonomy. NHS Digital advised IGARD that they had liaised with the applicant about this wording, and it had been agreed that this would be removed from the application. IGARD noted the update from NHS Digital, and supported the update to the application, to remove references to *"nudge"*. IGARD suggested that the full ethical implications of using behavioural techniques (nudges) are considered. IGARD suggested patient and public involvement and engagement (PPIE) was undertaken to check the views of participants, including, but not limited to, the behavioural techniques outlined.

	IGARD noted the figures / calculations stated within the application, in respect of the number of patients to be contacted in order to recruit the cohort; and asked that NHS Digital discussed this with the applicant, to determine if these may / will change in the future; and, the implications and process for any future amendments to the DSA; and, to update the application as necessary to make any subsequent amendments to the current figure stated. Alternatively, if the applicant confirmed that the calculation for the number of patients who would be contacted was correct and no future amendments were expected, to update section 5 (Purpose / Methods / Outputs) to reflect this. In addition, IGARD asked that for future reference and transparency, section 5 was updated, to outline the process for making any future amendments to the DSA, in respect of the number of patients contacted. IGARD queried, what happened to the information that the Ascend Team at the University of Oxford receive, from NHS Digital about those individuals who respond to the initial invitation, but who do not go on through the screening assessment to join the study, for example, either because they don't take the next step or were not eligible at screening. NHS Digital advised that this had been queried with the applicant, who had confirmed that personal data for patients who had returned the reply form, but then either don't complete the screening assessment or were not eligible at screening and so don't provide full informed consent for the trial, would be held until the end of recruitment and then destroyed. IGARD noted and thanked NHS Digital for the update and asked that section 5(b) (Processing Activities) was updated, to reflect that the data for those individuals who were contacted and responded but did not proceed to the trial, would be held for a period and then deleted. IGARD noted that the citation special condition had been added in section 6 (Special Conditions), however asked that this was updated, to state that, where practicable, outputs cite the source of the data as *"This work uses data provided by patients and collected by the NHS as part of their care and support".* IGARD noted that both the National Data Opt-out (NDO) and a study-specific opt-out were available to participants who did not wish to be contacted / take part in this research; however, and separate to this application, IGARD suggested that further consideration was given to a Digi-Trials specific opt-out, given that an NDO would also remove their data from a range of other uses. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of the commercial aspect of the application in line with NHS Digital DARS Standard for Commercial Purpose: a) To update section 5(e) further to clarify the commercial aspect of the application. b) To provide a brief summary in section 5(a) of the commercial aspect of the application; and, c) To update section 5(a) **and** section 5(e) with further clarification of the funding arrangements. 2. In respect of the specific drug being studied: a) To update section 5(a) to clarify why the specific drug is being studied; and, 3. To update section 5(a) to remove references to *"nudge people"*. 4. In respect of the calculations in respect of the patients contacted: a) NHS Digital to discuss with the applicant the current figures stated within the application, to determine if these may / will change in the future; and, the implications / process for any future amendments to the DSA; and,

	b) To update the application as necessary to make any subsequent amendments to the current figure stated; or, c) To update section 5 to clarify that the applicant has confirmed that the calculation for the number of patients who will be contacted is correct and no future amendments are expected; and, d) To update section 5 to outline the process for making any future amendments to the DSA, in respect of the number of patients contacted. 5. To update section 5(b) to reflect that the data for those individuals who were contacted and responded but did not proceed to the trial, will be held for a period and then deleted. 6. To amend section 5(a) to remove the statement *"However, this is not the main objective of the research"*. *7.* To amend the special condition in section 6, to state that, where practicable, outputs cite the source of the data as *"This work uses data provided by patients and collected by the NHS as part of their care and support".* The following advice was given: 1. IGARD suggested that the full ethical implications of the behavioural techniques (nudges) approach were considered. 2. IGARD suggested PPIE was undertaken to check the views of participants, including, but not limited to, the behavioural techniques outlined. 3. IGARD suggested that DigiTrials considered the advantage for 'first movers' given the limited pool of research subjects, limiting recruitment possibilities for other pharmaceutical companies or researchers. **Separate to this application**: consideration be given to a Digi-Trial specific opt-out. **ACTION**: IGARD to discuss NHSBSA data use with the IAO to clarify what is covered by the Direction.
4	<u>Applications progressed / to be progressed via NHS Digital's SIRO Precedent route</u> Applications that have been progressed or will / may be progressed via NHS Digital's Precedent route, including the SIRO Precedent, and NHS Digital have notified IGARD in writing (via the Secretariat). *No items discussed*
5	<u>Oversight & Assurance</u> IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. 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. The NHS Digital SIRO was currently reviewing the feedback provided on the IG release registers by IGARD for the period March 2020 to May 2022, alongside the process of review, and as discussed on the 11th August 2022, would come back to IGARD in due course with any feedback or response. IGARD noted that the NHS Digital webpage Excel spreadsheet had now been updated for the period March 2020 to April 2022: NHS Digital Data Uses Register - NHS Digital. IGARD noted

	that May 2022 appeared to be outstanding, following them returning their comments on the May 2022 release register on 1st July 2022.
6	<u>COVID-19 update</u> *No items discussed*
7 **7.1**	<u>AOB:</u> <u>NHS Digital / NHS England merger (Presenter: Jackie Gray / Michael Chapman / Garry Coleman)</u> NHS Digital's Executive Director, Privacy, Transparency, Ethics & Legal (PTEL), Director of Research and Clinical Trials and Associate Director, Deputy SIRO & Audit Services attended the meeting to provide an update with the latest developments on NHS Digital's merger with NHS England and the possible future of IGARD, or its successor, up to and beyond the merger. NHS Digital advised that they would continue the engagement with IGARD and provide further updates as this area of work develops, to ensure that IGARD were kept up to date with developments, especially with regard to the future role of IGARD or its successor. IGARD thanked NHS Digital colleagues for attending the meeting, and for the information provided; and advised that would welcome further engagement at future IGARD meeting, or via separate meetings with groups of IGARD members.
7.2	<u>Information Governance</u> A member of NHS Digital's Privacy, Transparency and Ethics, attended the meeting to provide a brief update / overview of ongoing information governance (IG) work. IGARD noted and thanked NHS Digital for the verbal update and looked forward to further relevant updates at a future IGARD meeting. 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 18/11/22

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

NIC Reference	Applicant	IGARD meeting date	Recommendation conditions as set at IGARD meeting	IGARD minutes stated that conditions should be agreed by:	Conditions agreed as being met in the updated application by:	Notes of out of committee review (inc. any changes)
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