Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 23 June 2022

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member (Acting Chair)
Maria Clark	Lay Member
Prof. Nicola Fear	Specialist Academic Member
Dr. Robert French	Specialist Academic / Statistician Member
Dr. Maurice Smith	Specialist GP Member (Acting Vice Chair: item 5.3 only)
Jenny Westaway	Lay Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Kirsty Irvine	IGARD Chair
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Chair
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Helen Buckels	Data Access Request Services (DARS) (**Observer:** Item 3.3)
Garry Coleman	Associate Director / Senior Information Risk Owner (SIRO) (**Observer**: item 2.1) (Items 7.2-7.3)
Cath Day (CD)	Data Access Request Services (DARS) (Item 2.1)
Louise Dunn	Data Access Request Service (DARS) (**SAT Observer**: item 3.3)
Duncan Easton (DE)	Data Access Request Services (DARS) (Item 7.3)
Mujiba Ejaz	Data Access Request Services (DARS) (item 3.3)
Dickie Langley	Privacy, Transparency and Ethics (PTE) (Item 7.2-7.4)
Dr. Jonathan Osborn	Deputy Caldicott Guardian (Item 1 & 7.1)
Charlotte Skinner	Data Access Request Services (DARS) (Item 3.1)
Kimberley Watson	Data Access Request Services (DARS) (**SAT Observer**: item 2.1)
James Watts	Data Access Request Service (DARS) (Observer: items 2.1 – 3.2)

Emma Whale	Data Access Request Service (DARS) (**Observer**: item 3.2)
Vicki Williams	IGARD Secretariat
Clare Wright	Data Access Request Service (DARS) (Item 3.2)
***SAT** – Senior Approval Team (DARS)	

1	**Declaration of interests:** Paul Affleck noted a personal connection to one of the cohort studies; and membership of the UK Longitudinal Linkage Collaboration Involvement Network [NIC-470203-Y2L7J]. It was agreed this did not preclude Paul from taking part in the discussions about this application, however it was agreed that Dr Maurice Smith would chair this particular item. Maria Clark noted a professional link to the British Medical Association (BMA) who are a customer of PHIN (NIC-13906-G0F3F-v12.2). However, she noted no specific connections to NIC-13906-G0F3F-v12.2 or the staff involved, and it was agreed that this was not a conflict of interest. Prof Nicola Fear noted a professional link to the staff involved with NIC-420168-K4N1F-v2.4 (University of Bristol), but noted no specific connection with this application and it was agreed this was not a conflict of interest. Dr Robert French noted a professional link to the staff involved with NIC-420168-K4N1F-v2.4 (University of Bristol), but noted no specific connection with this application and it was agreed this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 16th June 2022 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record. **Out of committee recommendations:** An out of committee report was received (see Appendix A).
2	**Briefing Notes**
2.1	<u>Public Health England (PHE) Data Sharing Agreement (DSA) Transition to UK Health Security Agency (UKHSA) and Office for Health Improvement and Disparities – Briefing Paper (Presenter: Cath Day)</u> This briefing paper was to inform IGARD of the changes made to the PHE DSA following PHE's closure at the end of September 2021, and the transfer of its public health functions to four receiver organisations. The DSA was extended to the 30th September 2022 to ensure the continuity of business-critical data transfers to the receiver organisations. This briefing also set out the intention to align the DSA of the former Joint Biosecurity Centre, which joined with PHE and NHS Test and Trace on 1 October 2021. UKHSA is responsible for preventing, detecting, analysing, responding to, and leading partnerships to protect the UK, from communicable diseases and other threats to public health. It is a direct provider of health protection services.

	Outcome: IGARD welcomed the briefing paper and made the following high-level comments: 1. IGARD supported NHS Digital's action in ensuring that appropriate legal advice had been sought in relation to Data Controllership. 2. IGARD noted the memoranda of understanding and other agreements in place to manage access to the UKHSA-owned IT network by former PHE staff who have transferred to the other receiver organisations, and suggested that NHS Digital be assured that these agreements provide satisfactory controls. 3. IGARD noted that the data register had not been published since September 2021 and suggested that for transparency that UKHSA look to publishing the data registers and before any application was submitted to IGARD. 4. To amend the briefing note to ensure acronyms are defined upon first use, for example "*EDGE*". 5. In respect of the application: a. IGARD noted that the application should clearly articulate the UKHSA internal processes for approvals. b. IGARD asked that a narrative be included in Section 5 with regard to NHS Test and Trace, such as providing a link to the relevant UKHSA webpage. c. That a clear rationale be provided in section 5 for the onward sharing of data, particularly if not using the sub licencing process outlined in the NHS Digital DARS Standard for sub-licencing and onward sharing of data. d. That a clear narrative is included in the application with regard to accessing the 'data lake' and the governance processes in place. IGARD welcomed the draft briefing paper and looked forward to receiving the finalised briefing paper, either out of committee (OOC) or tabled at a future meeting (before, or contemporaneously with, any first of type applications received by IGARD).
3	**Data Applications**
3.1	Private Healthcare Information Network (PHIN): PHIN Private Healthcare Market Investigation CMA Order 2014 (Presenter: Charlotte Skinner) NIC-13906-G0F3F-v12.2 **Application:** This was a renewal application to permit the holding and processing of pseudonymised Hospital Episode Statistics Admitted Patient Care (HES APC) data on a quarterly basis. In April 2015, the Competition and Markets Authority (CMA) designated PHIN as the official information organisation and requested all hospitals providing private healthcare in the UK to submit information relating to each episode of care relating to private patients. PHIN also needs to compare and benchmark private activity with NHS data. PHIN's overarching mission is to enable patients to be able to make better informed choices about their healthcare providers and through the provision of comparative information to help private providers to continuously improve their care and clinical outcomes. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the Data Access Advisory Group (DAAG) (IGARD's predecessor) on the 9th February 2016 and IGARD business as usual (BAU) meeting on the 2nd July 2020. IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 8th December 2020.

	IGARD noted reference in section 1 (Abstract) to "…*insufficient time for IGARD to review the application before expiry of the application*" and asked that this reference was removed, since the statement was misleading, since the application had not been put forward for IGARD review at the time of expiry. IGARD suggested that technical terms in section 3(b) (Additional Data Access Requested) were explained, for example, "*ADMIMETH = 11, 12 and 13: EPITYPE = 1*" or replaced with a suitable description. IGARD also noted the inclusion of a number of technical phrases and words within section 5(b) (Processing Activities), such as "*Site ODS Code*", and asked that this public facing section, which forms NHS Digital's data uses register, was amended throughout, to ensure technical terms were explained in a manner suitable for a lay audience. IGARD noted reference in section 5(a) (Objective for Processing) to "*Telstra Health UK*" and suggested that it be explained why Telstra were referenced, for example as an exemplar, or to remove the reference. IGARD queried the funding arrangements for PHIN, since it was not clear in the application or supporting documents provided; and asked that section 8(b) (Funding Sources) was updated to outline who the funder(s) of PHIN were. In addition, IGARD asked that a brief summary of the funding arrangements was outlined in section 5(c) (Specific Outputs Expected), since this forms NHS Digital's data uses register. IGARD also asked that any pertinent funding documentation was uploaded to NHS Digital's customer relationship management (CRM) system for future reference. IGARD noted the commercial aspect of the application in section 5(e) (Is the Purpose of this Application in Anyway Commercial), however, noting that this was not public facing, asked that for transparency, and in line with NHS Digital DARS Standard for commercial purpose, a brief summary was also provided in section 5(a). IGARD noted that in line with the NHS Digital's DARS Standard for Expected Measurable Benefits, that section 5(d)(iii) (Yielded Benefits) was amended to be clear what the primary yielded benefits were to patients, since the current text focuses on the benefits accrued to consultants. IGARD queried the content within section 5(d)(iii), and noted that some of the information provided were outputs and asked that these were moved to correctly sit in section 5(c); in line with NHS Digital DARS Standard for Expected Outcomes. 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 also suggested that reference in section 5(d) that "*the data will **only** be used to fulfil the CMA requirement to provide information for the general public*…" should be updated to be clear that the data was used for a variety of reasons, including, for example, quality assurance. IGARD noted that the application was silent on any public and patient involvement and engagement (PPIE) and suggested that the applicant involve relevant public and patient representatives / groups for the lifecycle of the project, and that the applicant should endeavour to include a brief update in section 5 (Purpose / Methods / Outputs) since this forms NHS Digital's data uses register, on renewal, amendment or extension. IGARD advised that NHS Digital draw the applicant's attention to the contractual obligation in section 4 (Privacy Notice), in respect of maintaining a UK General Data Protection Regulation (GDPR) compliant, publicly accessible transparency notice throughout the life of this

	agreement, in order to maintain public trust in using health data from national datasets; and in line with NHS Digital's DARS Standard for Transparency (fair processing); and that the privacy notice was updated to outline all of the data being processed. IGARD suggested that this application would be suitable for NHS Digital's Precedent route, including the SIRO Precedent. Separate to this application, IGARD asked that NHS Digital advised on the s261 legal basis for NHS Digital's dissemination, for example, which section of s261 is relevant, since NHS Digital appeared to be only citing the overarching s261. **Outcome:** recommendation to approve The following amendments were requested 1. To updated section 1 to remove reference to "*insufficient time for IGARD to review the application before expiry of the application*" since that statement was misleading. 2. To remove any technical detail from section 3(a), for example "*ADMIMETH = 11, 12 and 13: EPITYPE = 1*" and replace with a suitable description. 3. In respect of section 5(a) a) To provide further detail in section 5(a) that Telstra Health UK are being referenced as an exemplar, or remove. b) IGARD noted a number of technical terms in section 5(b), and asked that this public facing section, that forms NHS Digital's data uses register, was amended throughout, to ensure technical terms are explained in a manner suitable for a lay audience, for example, "*Site ODS Code*". 4. To remove or amend the reference in section 5(d) that "*the data will **only** be used to fulfil the CMA requirement to provide information for the general public*…" to be clear that the data is used for a variety of reasons, including for example, quality assurance. 5. In line with the NHS Digital DARS Standard for commercial purpose, to provide a brief summary in section 5(a) of the commercial aspect of this application, as outlined in section 5(e). 6. In respect of funding: a) To update section 5(c) and 8(b) outlining who the funders of PHIN are, and b) To upload any pertinent funding documentation to NHS Digital's CRM system for future reference. 7. In respect of the benefits in section 5(d) in line with the NHS Digital's DARS Standard for Expected Measurable Benefits: a) To amend section 5(d)(iii) to be clear what the primary yielded benefits are to patients, and b) To remove any specific outputs from section 5(d) (iii) and move to section 5(c), and c) To update section 5(d) to use a form of wording such as "*it is hoped* …", rather than "*it will…*". The following advice was given: 1. IGARD suggested that the applicant involve relevant public and patient representatives / groups for the lifecycle of the project. 2. In respect of the privacy notice, and in line with NHS Digital's DARS Standard for Transparency (fair processing), IGARD wished to draw to the applicant's attention to the statement in section 4, that a UK GDPR compliant, publicly accessible transparency notice is maintained throughout the life of the agreement; and that the privacy notice is updated to outline all of the data being processed.

	3. IGARD suggested that this application would be suitable for NHS Digital's Precedent route, including the SIRO Precedent. **ACTION:** Separate to this application, NHS Digital to advise on the s261 legal basis for NHS Digital's dissemination.
3.2	University of Oxford: Active Monitoring for AtriaL Fibrillation (AMALFI) trial (Presenter: Clare Wright) NIC-470203-Y2L7J-v0.8 **Application:** This was a new application for identifiable Civil Registration (Deaths) data, Emergency Care Data Set (ECDS), HES Admitted Patient Care (APC), HES Critical Care, HES Outpatients and Medicines dispensed in Primary Care (NHSBSA data). The purpose of the application is for a study of a randomised clinical trial of screening for subclinical (undiagnosed) Atrial fibrillation (AF) in elderly patients with no previous AF, who are at increased risk of both AF and a subsequent stroke. The study is comparing a two-week remote continuous cardiac monitoring period with a ZioPatch to usual care alone; consenting participants will be assigned to one of the two groups AF is the most common sustained cardiac arrhythmia worldwide, and is estimated to affect over 1 million people in the UK. In AF, the atria (upper chambers of the heart) beat in an uncoordinated way, which disturbs the normal blood flow and can lead to the formation of blood clots inside the heart, which can travel through the bloodstream and create a blockage in the arteries supplying the brain, causing a stroke. Patients with AF are at a five-fold increased risk of stroke, but this risk can be effectively reduced by up to two thirds with anticoagulation (blood-thinners). However, AF can occur only in short and infrequent episodes that make it hard to capture and start treatment, and it may also not cause any symptoms; as a result, some patients might have undetected AF until the time when they have a stroke. The size of the cohort is approximately 5,040 patients; and the study is relying on consent for the flow of data out of NHS Digital. NHS Digital noted that it was not clear in section 1 that the historical data requested will not be provided until September 2023 and that this would be clarified. **Discussion:** IGARD noted the update from NHS Digital and agreed that section 1 (Abstract) should be updated to be clear what data was being supplied on which date in relation to the historical data, including the historical data drop which is scheduled for September 2023. IGARD had raised in advance of the meeting a query as to whether the "*trial methodology research*" provided intelligence about the safety and effectiveness of medicines and fitted under the relevant Direction for the collection of NHSBSA data. NHS Digital confirmed that the NHS Digital Information Asset Owner (IAO) for NHSBSA data had confirmed that the stated purpose and use of the data was in line with the Direction. IGARD noted the response, and asked that section 5(b) (Processing Activities) was updated and in line with the NHS Digital DARS Standard for Processing Activities when referencing processing of NHSBSA data, to ensure a clear narrative was provided linking the purposes and processing to the relevant Direction. IGARD had a lengthy discussion about the consent materials provided as supporting documents and whether the participant consent covered NHSBSA data, or only HES and Mortality data. NHS Digital were of the view that NHSBSA data, as well as the HES and Mortality data set, was included in the participant consent. However, IGARD pointed out that only "*SD3.3 Amalfi PIL* V3.0 01-May-2021*" contained the specific wording: "*…and other sources of health information held by NHS Digital (such as medications and primary care*

	records) for each person taking part". IGARD therefore suggested that the applicant confirm that study participants (more than 3 but less than 7), who received the earlier consent forms and information sheets, had been consulted and that they agreed their consent encompassed NHS Digital supplying medication data. IGARD suggested that a suitable number to consult would be three to seven such participants. **Patient Information Leaflet* IGARD also suggested that the applicant may wish to take the opportunity of any future newsletters or other communications with participants to inform them how the study was obtaining and using their healthcare data, and reminding participants of their ability to withdraw from the study if they no longer wished to take part. In addition, IGARD also asked that section 1 and section 5(a) (Objective for Processing) provide an indicative size of the cohort recruited under each version of the consent materials provided for transparency. IGARD had raised in advance of the meeting a query whether the study would still be able to achieve its aims without NHS Digital supplying GP data. NHS Digital had confirmed that having spoken to the applicant that the study was not dependent on the supply of GP data by NHS Digital since they were already collecting primary data from each GP practice taking part in the study, however once available the NHS Digital GP data would streamline and automate the data collection for the applicant. IGARD noted the update and thanked the applicant for providing a clear narrative, and suggested that a statement should be included in section 5 (Purpose / Methods /Outputs) that clearly articulated how a national collection of primary care data would be a valuable resource for this study to draw upon. IGARD noted that section 5(a) and 5(b) referred to "*gender*", however an IGARD clinician noted that there was a clear risk difference for AF between the male and female sex, and suggested section 5 was updated to refer to "*sex*", since in this case "*sex*" was the key factor. IGARD reiterated previous commentary that "*sex*" and "*gender*" were not interchangeable data fields. Noting that no study can prevent death, but it may prevent premature death, IGARD suggested that section 5(a) be amended to be clear that the programme "*could prevent stroke, disability, and **premature** death*". IGARD noted the commercial aspect of the application in section 5(e) (Is the Purpose of this Application in Anyway Commercial), however, noting that this was not public facing, asked that for transparency, and in line with NHS Digital DARS Standard for commercial purpose, a brief summary was also provided in section 5(a). IGARD noted the reference to patient and public involvement and engagement (PPIE) in the application, however suggested that the applicant may wish to consider involving the relevant public and patient groups throughout the lifecycle of the project in line with HRA guidance on Public Involvement. IGARD suggested that this application would be suitable for NHS Digital's Precedent route, including the SIRO Precedent. **Outcome**: recommendation to approve subject to the following condition: 1. The applicant to confirm that study participants (more than 3 but less than 7), who received the earlier consent forms and information sheets, have been consulted and that they agree their consent encompasses NHS Digital supplying medication data.

	The following amendments were requested: 1. To update section 5(b) when referencing processing of NHSBSA dataset to ensure a clear narrative is provided linking the purposes to the scope of the Direction. 2. To amend section 5(a) to be clear that the programme "*could prevent stroke, disability, and* ***premature*** *death*". 3. To update sections 5(a) and 5(b) to refer to *"sex"* rather than "*gender*" since in this case "*sex*" was the key factor, noting they are not interchangeable data fields. 4. In line with the NHS Digital DARS Standard for commercial purpose, to provide a brief summary in section 5(a) of the commercial aspect of this application, as outlined in section 5(e). 5. To update section 1 and section 5(a) with an indicative size of the cohort recruited under each version of the consent. 6. To amend section 1 to be clear what data is being supplied on which date in relation to the historical data. The following advice was given: 1. IGARD suggested the applicant take the opportunity of any future newsletters or other communications with participants to inform them of how the study is obtaining and using their healthcare data, and reminding them of their ability to withdraw from the study if they no longer wished to take part. 2. IGARD suggested that a statement should be included in section 5 that clearly articulated how a national collection of primary care data would be a valuable resource for this study to draw upon. 3. IGARD suggested that, if not already happening, the applicant involve relevant public and patient groups for the lifecycle of the project in line with HRA guidance on Public Involvement. 4. IGARD suggested that this application would be suitable for NHS Digital's Precedent route, including the SIRO Precedent. It was agreed the condition would be approved out of committee (OOC) by IGARD members.
3.3	University of Bristol: University of Bristol - Longitudinal Linkage Collaboration (Presenter: Mujiba Ejaz) NIC-420168-K4N1F-v2.4 **Application:** This was an amendment application to **1)** include additional cohort members that were initially recruited under various research studies; and **2)** change the legal basis from The Health Service Control of Patient Information (COPI) Regulations 2002 to consent. The UK Chief Scientific Advisor has established a programme of National Core Studies (NCS) for COVID-19 research as a coordinated, long-term, national research initiative. This will consider COVID-19 in terms of a viral pandemic and in terms of the health and social impacts of behavioural restrictions designed to mitigate the harms of the pandemic. This NCS sub-programme is linking data from long running cohort studies with NHS Digital data within the UK LLC Trusted Research Environment (TRE) for COVID-19 research studies. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 21st January 2021, 4th February 2021 and 4th March 2021. IGARD noted that this application had previously been discussed as part of the 'returning applications' section of the IGARD business as usual (BAU) meeting on the 5th May 2022.

	IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 8th December 2020, 15th December 2020, 12th January 2021, 26th January 2021, 2nd February 2021, 16th March 2021, 30th March 2021, 27th April 2021 and 5th October 2021. IGARD had raised in advance of the meeting a number of queries with regard to the consent materials for the studies and thanked the applicant for providing additional supporting documents ahead of the meeting to aid the discussion. IGARD noted they had undertaken a very high-level review of the consent materials provided and were concerned that some of the consent materials were **not** compatible with the application, for example, but not limited to, consent documents restricting access to researchers from a specified institution or not encompassing the research purposes. IGARD noted that the NHS Digital assessment of the consent materials had judged that the consent gathered in the past was sufficient to cover the novel approach of pooling cohort studies. IGARD noted that it appeared not all consent materials had been provided as supporting documents, and that there appeared to be gaps, and asked that all relevant versions of all consent materials across all studies were uploaded to NHS Digital's customer relationship management (CRM) system as future supporting documentation. IGARD suggested that NHS Digital provide a satisfactory written assessment across **all** the consent materials which demonstrated NHS Digital's view that the processing was compatible with the consent participants provided. IGARD noted that providing a participant with an opt out, or providing a website link, or updating the privacy notice, or stating participants were recruited prior to current legislation, was not equivalent to the participant providing informed consent to be part of this study. NHS Digital noted that the applicant was still to submit a new application to REC. IGARD noted the verbal update and noted that an aged HRA REC letter had been provided as a supporting document, however it was unclear what activities the HRA REC letter covered and what activities were covered under the individual cohort studies, so were unable to assess the ethical support. IGARD noted that UCL was currently not considered a joint Data Controller, however queried a statement in section 5(a) (Objective for Processing) that "…*The Longitudinal Health & Wellbeing National Core Study is* ***led from the University College London*** *(UCL) and the UK LLC reports into UCL on delivery of UK LLC objectives*…" and asked that an analysis was provided in section 1 (Abstract) as to why UCL were not considered a joint Data Controller in line with NHS Digital's DARS Standard for Data Controllers, as borne out of the facts; or, if the facts lead to the UCL being considered joint Data Controller, to update the application throughout. IGARD noted reference throughout section 5 (Purpose / Methods / Outputs) of the application to "*opting out*" and that patient objections had **not** been applied. However, IGARD noted that this may not be accurate dependent on whether consent was the appropriate legal basis and how different contributing studies may be applying opt outs prior to sending the data to NHS Digital. IGARD suggested, depending on the legal basis for each study, that for transparency the type of opt out being applied on what flow of data was included in section 5. IGARD queried the current funding arrangements for the study, since it was not clear in the application or supporting documents provided, noting that NHS Digital had confirmed that the applicant was self-funding. IGARD asked that section 8(b) (Funding Sources) was updated to outline who the funder(s) of the study were. In addition, IGARD asked that a brief summary of

	the funding arrangements was outlined in section 5(c) (Specific Outputs Expected), since this forms NHS Digital's data uses register. IGARD also asked that any pertinent funding documentation was uploaded to NHS Digital's CRM system for future reference. 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, for example, *"GDPPR", "UKSeRP" "GPES"*. IGARD also queried in section 5(b) what was meant by the term "*household register*" and suggested that the term was further explained for a lay audience. IGARD were unclear what was meant by "*NHS Digital definition*" in section 5a which read "*UOB fully adopt the standard **NHS Digital definition** of the COVID-19 relevant dataset"* and therefore suggested that this was clearly explained. IGARD noted in section 5(a) reference to "*cannot meaningfully inform the science…"* and asked that this was clarified or updated to use a better form of words. IGARD were unclear what was meant by *"technological and socio-governance controls applied at the UK LLC*…" in section 5(a) and asked that it be explained for a lay audience or amended to simply state *"governance controls",* if that was what was meant. IGARD noted reference in section 5(a) to *"a reasonable expectation will have been set through fair processing for the use of NHS record*…" and asked that this be amended or removed, given the issues raised regarding adequacy of consent. IGARD noted that the yielded benefits in section 5(d) (iii) (Yielded Benefits) contained benefits not accrued via the LLC using NHS Digital data and asked that these be removed; and that the section retain the details provided on the specific yielded benefits accrued to date using NHS Digital data, and asked that it was clear as to the benefits to both the patients and the health and social care system more generally and in line with NHS Digital's DARS Standard for Expected Measurable Benefits. IGARD noted that the study protocol provided as a supporting document was dated November 2020, and suggested this should be updated to encompass the current processing being undertaken across the study. IGARD supported NHS Digital's suggestion to put in place a short-term extension, providing there was a legal basis to do so, noting that IGARD were supportive of the study, whilst NHS Digital continued to work with the applicant. 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, to enable IGARD to review progress on open issues. **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. 1. In respect of the consent materials: a. IGARD noted that they had undertaken a high-level review of the consent materials provided and were concerned that some of the consent materials were not compatible with the application. For example, but not limited to, consent documents restricting access to researchers from a specified institution or not encompassing the research purposes. b. NHS Digital to provide satisfactory written assessment across all the consent materials which demonstrates NHS Digital's view that the processing is

compatible with the consent participants provided, noting that providing a participant with an opt out, providing a website link, updating the privacy notice or stating participants were recruited prior to current legislation is not equivalent to informed consent.

c. To upload the final version of **all** consent materials to NHS Digital's CRM system.

2. IGARD noted the HRA REC letter provided as a supporting document but it was unclear what activities it covered and what activities are covered under the individual cohort studies.
3. In respect of UCL:
    a. To provide an analysis in section 1 as to why UCL are not considered a joint Data Controller in line with NHS Digital's DARS Standard for Data Controllers, and as borne out of the facts; or,
    b. If the facts lead to the UCL being considered a joint Data Controller, to update the application throughout.
4. IGARD noted that patient objections had not been applied, however this may not be accurate depending on whether consent is the appropriate legal basis and how different contributing studies may be applying opt outs prior to sending the data to NHS Digital.
5. As section 5 forms NHS Digital's data uses register, to amend section 5 and in line with the NHS Digital DARS Standards:
    a. to ensure acronyms be defined upon first use, for example *"GDPPR", "UKSeRP" "GPES"*; and
    b. To update section 5(a) to clarify what is meant by the term "*household register*".
    c. To clarify what is meant in section 5(a) by "*UOB fully adopt the standard NHS Digital definition of the COVID-19 relevant dataset*".
    d. To clarify what is meant in section 5(a) to "*cannot meaningfully inform the science…".*
    e. To explain in section 5(a) what is meant by the *"technological and socio-governance controls applied at the UK LLC*…" or amend the wording to simply state *"governance controls".*
    f. Reference in section 5(a) to *"a reasonable expectation will have been set through fair processing for the use of NHS record*…" should be amended or removed, given the issues raised regarding adequacy of consent.
6. In respect of funding:
    a. To update section 5(c) and 8(b) outlining the current funding.
    b. To upload any pertinent funding documentation to NHS Digital's CRM system for future reference.
7. In respect of the Yielded Benefits in section 5(d)(iii):
    a. To update the yielded benefits in line with the NHS Digital DARS Standard for Expected Measurable Benefits, and
    b. To provide any specific yielded benefits accrued to date using NHS Digital data for this study, and ensure these are clear as to the benefits to either patients or the health and care system more generally, and
    c. To remove any benefits not accrued by LLC using NHS Digital to date.

The following advice was given:

1. IGARD noted that the protocol was dated November 2020 and should be updated to encompass the current processing being undertaken across the study.

	2. IGARD supported NHS Digital's suggestion to put in place a short-term extension, providing there is a legal basis to do so, noting that IGARD were supportive of the study. 3. IGARD advised that they **would wish to review** this application when it comes up for renewal, extension or amendment, to review progress on open issues. 4. IGARD suggested that this application **would not** be suitable for NHS Digital's Precedent route, including the SIRO Precedent, to review progress on open issues.
3.4	London School of Hygiene & Tropical Medicine (LSHTM): Evaluation of community-based health and social care multi-disciplinary teams (MDTs) - data linkage and comparison patients (Presenter: No Presenter) NIC-332870-B6Z4R-v0.10 **Application:** This was a new application for pseudonymised Civil Registration (Deaths) - Secondary Care Cut, Hospital Episode Statistics Admitted Patient Care (HES APC) and HES Critical Care. The purpose of the application is for a long-term programme of research on the Integrated Care and Support Pioneers in order to identify factors that enable or inhibit progress towards the integration of health and social care services and to assess whether such integrated services lead to better outcomes for patients in a more patient-centered and cost-effective way. The current research programme, which is due to be completed in Autumn 2022, follows on from an earlier evaluation of the Pioneers which was undertaken by the same research team (2014-15), and involves three work packages: **Work package 1**: Implementation and progress – Pioneer level process evaluation and (limited) impact evaluation in all 25 Pioneers via interviews, web based panel surveys and analysis of performance indicators relevant to integrated health and social care; **Work package 2**: Impacts, costs and patient outcomes – impact and economic evaluations of selected Pioneer initiatives using mixed methods, and designed to follow patients, carers and staff over the longer-term; **Work package 3**: Lessons learned – Working with Pioneers, national policy makers and partners, patient/user organisations and experts to derive and spread learning on improving integrated care. The cohort comprises of 441 consented patients and a comparison group. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD BAU meeting on the 3rd March 2022; where the application had been recommended for approval with conditions and amendments. IGARD noted that, as outlined in the Out of Committee (OOC) Standard Operating Procedure, any applications returned to the IGARD Secretariat for review OOC by the IGARD Chair or quorum of IGARD Members which were over three months old, would be automatically placed on the next available BAU meeting agenda for review by IGARD Members as per the current standard processes. Members would only review if the conditions have been met or not, and would not re-review the application, unless significant legislative or policy changes had occurred since last reviewed by a full meeting of IGARD or the application had been significantly updated, in which case the conditions may be updated to reflect such changes which will be noted for transparency in the published minutes and a full review of the application undertaken. The condition from the 3rd March 2022 BAU meeting was as follows: 1. In respect of data minimisation: a) To update the application throughout in line with NHS Digital DARS standard for data minimisation; and

	b) To outline the steps taken to ensure the minimum amount of data possible is used to create the comparison group, c) To ensure that any data not required is destroyed and that the applicant has provided a data destruction certificate. A quorum of IGARD members were content that the multi-limbed condition had been met.
4 **4.1**	<u>Applications progressed via NHS Digital's Precedent route, including the SIRO Precedent</u> 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). <u>NIC-365354-R3M0Q-v7.3 University of Oxford (No Presenter)</u> The purpose of this application was for 'The Randomised Evaluation of COVid-19 thERapY' (RECOVERY) trial, which aims to compare different treatments that may be useful for patients with COVID-19. The trial allows reliable assessment of the effects of multiple different treatments (including re-purposed and novel drugs) on major outcomes in COVID-19. IGARD noted that this application was last reviewed at the IGARD business as usual meeting on the 14th October 2021. IGARD noted that on the 20th June 2022, NHS Digital had advised in writing (via the IGARD Secretariat) that there was an error within the current data sharing agreement (DSA) in respect of a single period missing from the Hospital Episode Statistics (HES) product, resulting in the trial not being able to receive their quarterly HES Admitted Patient Care (HES APC) data for June 2022. NHS Digital confirmed that this would be proceeding down the 'Approval for simple amendments to DSA' Precedent route. NHS Digital confirmed that where appropriate, further iterations of this DSA would be brought to a future IGARD BAU meeting, as per process. IGARD noted and thanked NHS Digital for the written update and supported the next iteration of the DSA being brought to a future IGARD BAU meeting.
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. IGARD Members noted that they had not yet been updated on the issues raised at the 27th May 2021 IGARD business as usual (BAU) meeting with regard to previous comments made on the IG COVID-19 release registers March 2020 to May 2021. IGARD noted that in addition, they had not been updated on the issues raised on the IG COVID-19 release registers June 2021 to April 2022. 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.
6	<u>COVID-19 update</u> *No items discussed*

7	AOB:
7.1	PAG standard special conditions in DARS applications (Presenter: Jonathan Osborn) The Deputy Caldicott Guardian / Deputy Chair of the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG), attended the meeting to discuss the conditions that have been added to section 6 (Special Conditions) of data sharing agreements (DSA) in response to PAG feedback. As noted in previous minutes, including but not limited to the 16th June 2022, IGARD has raised concerns about the "PAG conditions" including, but not limited to, the blanket ban on performance management. IGARD further noted that aspects of the "PAG conditions" may be impossible to comply with, for example, no identification of practices, due to the nature of the data being disseminated and processed; and that the applicant may inadvertently breach the terms of their DSA with the inclusion of these conditions. The Deputy PAG Chair noted that PAG provided feedback, as outlined in their published Terms of Reference and that their feedback should **not** directly populate section 6 (Special Conditions) of a DSA without the requisite rationale being provided as part of that feedback. PAG feedback on individual applications should be added as an appendix to the appropriate IGARD minutes to show that IGARD had taken account of feedback from BMA and RCGP when making their recommendations. This is consistent with the PAG Terms of Reference. IGARD suggested that any PAG commentary should be prefaced with "*PAG advise*…" or "*PAG suggest*…" or similar, so it is clear to NHS Digital that this is advice, not an instruction. The Deputy PAG Chair noted that they would undertake an internal review of PAG processes. IGARD thanked the Deputy PAG Chair for attending IGARD and looked forward to an update on any internal process review at a future meeting of IGARD.
7.2	Office for National Statistics (ONS) (Presenter Garry Coleman) The SIRO attended IGARD to give a brief update on a mandatory request from ONS under the Statistics & Service Registration Act (SRSA) 2017, section 45(c). IGARD thanked the SIRO for attending to give a brief verbal overview of the mandatory request and looked forward to reviewing the ONS application in due course, following a short term extension to their existing DSA under the NHS Digital SIRO Precedent.
7.3	NIC-384608-C9B4L-v3.2 - NHS England (Quarry House) (Presenter: Garry Coleman / Duncan Easton) IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meetings on the 23rd September 2021, 23rd July 2020, 6th August 2020 and the 27th May 2021. IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 21st July 2020, 4th August 2020 and 23rd March 2021. IGARD noted that this application had been reviewed at the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 22nd July 2020, the 5th August 2020; the 31st March 2021, 5th May 2021, 26th May 2021 and 9th February 2022. NHS Digital attended to give an urgent verbal briefing to IGARD on a work request from NHS England which included a request for a number of additional datasets. Noting that conditions

7.4	remained outstanding from when last reviewed at IGARD on the 23rd September 2021, IGARD highlighted the need for public transparency and due diligence on any proposed changes, and thanked NHS Digital for their attendance. <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 raised a number of outstanding IG related points, including the request for an update on issues raised regarding the IG COVID-19 release register (March 2020 to April 2022). IGARD noted and thanked NHS Digital for the verbal update and looked forward to receiving further updates at a future IGARD meeting. There was no further business raised, the Acting Chair of the meeting thanked the Secretariat, 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 17/06/22

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			a)			

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