Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 8 September 2022

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member / Co-Deputy IGARD Chair
Prof. Nicola Fear	Specialist Academic Member (3.1 – 3.5)
Kirsty Irvine	IGARD Chair
Dr. Geoffrey Schrecker	Specialist GP Member
Jenny Westaway	Lay Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Maria Clark	Lay Member
Dr. Robert French	Specialist Academic / Statistician Member
Dr. Imran Khan	Specialist GP Member / Co-Deputy IGARD Chair
Dr. Maurice Smith	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Dave Cronin	Data Access Request Services (DARS) (**SAT Observer**: item 3.5) (Item 7.1)
Cath Day	Data Access Request Services (DARS) (**SAT Observer**: items 3.2)
Louise Dunn	Data Access Request Services (DARS) (**SAT Observer**: items 3.3, 3.4)
Liz Gaffney	Head of Data Access, Data Access Request Service (DARS) (Item 7.1)
Dickie Langley	Privacy, Transparency, Ethics and Legal (PTEL) (Observer: item 7.1)
Susan Main	Data Access Request Services (DARS) (Item 7.1)
Mark McDaid	Data Access Request Services (DARS) (Item 7.1)
David Morris	Data Access Request Services (DARS) (Item 3.3)
Karen Myers	IGARD Secretariat
Tania Palmariellodiviney	Data Access Request Services (DARS) (**SAT Observer**: item 3.1)

Aisha Powell	Data Access Request Services (DARS) (Item 3.4)
Charlotte Skinner	Data Access Request Services (DARS) (Item 3.5)
Emma Whale	Data Access Request Services (DARS) (Observer: items 3.1, 3.2)
Clare Wright	Data Access Request Services (DARS) (Items 3.1, 3.2)
***SAT** – Senior Approval Team (DARS)	

1	**Declaration of interests:** Prof. Nicola Fear noted that in her role at King's College London she was a recipient of UK Biobank data, but she had no specific connection with the application or staff involved and it was agreed that this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 25th August 2022 IGARD meeting were reviewed out of committee by IGARD following conclusion of the meeting, and subject to a number of minor changes were agreed as an accurate record of the meeting. **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	UK Biobank: R3 & R5 - MR1109 - UK Biobank (Presenter: Clare Wright) NIC-08472-V9S6K-v15.3 **Application:** This was an amendment application to **1)** remove Emergency Care Data Set (ECDS) data; **2)** to change the frequency of data as follows: **a)** COVID-19 Vaccination data will change from a monthly flow to a quarterly flow, **b)** Demographics data will change from a monthly flow to an annual flow, **c)** Civil Registration (Deaths) data will change from a monthly flow to a quarterly flow, and **d)** Cancer Registration data will change from a monthly flow to an annual flow; **3)** to update the Sub Licensing Material Transfer Agreement (MTA) to reflect the changes in application processes and procedures that UK Biobank has put in place to facilitate use of the data by researchers; **4)** to update section 10 to include special conditions for sub licensing. UK Biobank is a national and international health resource, and a registered charity, with the aim of improving the prevention, diagnosis and treatment of a wide range of serious and life-threatening illnesses, including cancer, heart diseases, stroke, diabetes, arthritis, osteoporosis, eye conditions, depression and forms of dementia. UK Biobank recruited 500,000 people aged between 40-69 years in 2006 - 2010 from across the UK to take part, of these, 466,818 consented participants remain. The participants have answered detailed questionnaires, undergone a range of physical measures, provided blood,

	urine and saliva samples for future analysis, and agreed to have their health followed-up over time through linkage to their health and health-related records. The purpose of the application is to enable worldwide research. Researchers can apply to UK Biobank for de-identified data within the resource to undertake health-related research that is in the public interest. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD meetings on the 15th November 2018, 29th November 2018, 5th December 2019, 16th January 2020, 24th September 2020 and 3rd June 2021. It was also discussed as part of the 'applications progressed via NHS Digital's SIRO Precedent route' on the 13th December 2018. IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 1st September 2020 and the 8th September 2020. IGARD noted that this application had been reviewed at the GPES Data for Pandemic Planning and Research (GDPPR) – Profession Advisory Group (PAG) on the 16th September 2020 *(notes from that meeting had been attached to the IGARD minutes from the 24th September 2020)*. IGARD confirmed that they were of the view that the **most recent** consent materials provided the appropriate legal gateway and were broadly compatible with the processing outlined in the application. IGARD noted the references to COVID-19 Hospitalization in England Surveillance System (CHESS) data in the application, and asked that the application was reviewed / updated throughout to remove references to CHESS data and correctly replace with *"Severe Acute Respiratory Infection-Watch (SARI) Watch"* data; noting that SARI Watch replaced CHESS in summer 2020, and collects the same data items as CHESS but includes infections other than COVID-19. IGARD noted that the COVID-19 datasets in the data sharing agreement (DSA), for example the COVID-19 Hospitalization in England Surveillance System (CHESS) (now called *"SARI Watch"*) and COVID-19 Vaccination Status datasets, were restricted to COVID-19 related research; and asked that a special condition outlining any restrictions was inserted in section 6 (Special Conditions), i.e. processing must be for the purpose of COVID-19 related research **only**. In addition, and for transparency, IGARD asked that section 5(a) (Objective for Processing) was updated, with a brief reference to the restrictions on the COVID-19 datasets as per the special condition. IGARD queried how UK Biobank had, to date, restricted access to the COVID-19 datasets, to ensure that these were only used for the purpose of COVID-19 research. IGARD noted that this was currently unclear in the application, and asked that confirmation was provided in section 5(a). IGARD suggested that if UK Biobank did **not** have rigorous controls in place to ensure that access to the COVID-19 datasets was restricted for the purpose of COVID-19 related research, they should review and update their internal application process and MTA, as may be necessary. IGARD noted the Sub Licensing MTA review undertaken by NHS Digital and provided as a supporting document, in particular noting point 10 *"In the event of termination or expiry of the Data Sharing Framework Contract between NHSD and the applicant, all sub licences shall automatically terminate"*, and supported NHS Digital's view that the MTA should be updated to

	include an automated termination clause for any sub-licensing agreement should the DSA between NHS Digital and UK Biobank cease. In addition, IGARD asked that the MTA was updated as appropriate, to ensure that all COVID-19 datasets were processed appropriately, in addition to the restrictions outlined on the processing for the GDPPR dataset, which is restricted to COVID-19 planning and research. IGARD noted that Improving Access to Psychological Therapies Data Set (IAPT) was only requested up to March 2022, and queried whether UK Biobank would wish to receive IAPT data on an ongoing basis. NHS Digital advised IGARD that this would need confirming with the applicant. IGARD noted the verbal update from NHS Digital, and advised that they would be supportive of the ongoing flow of the IAPT dataset, subject to the relevant updates being made to the application in line with NHS Digital's DARS Standards, and would not need to return to IGARD for a review for this amendment. IGARD noted that prior to the meeting a query had been raised by an IGARD member, in relation to the sharing of UK Biobank's data with researchers in China. IGARD noted that there was a statement in the participant information leaflet provided as a supporting document, dated the 21st April 2010, that *"Information and samples from UK Biobank participants will be available only to researchers who have relevant scientific and ethics approval for their planned research. This could include researchers who are working **in other countries**…"*; and queried if UK Biobank had explored the sharing of data with participants, for example, in relation to a shift in geopolitical relations and sublicensing. NHS Digital related that the applicant had advised that UK Biobank's senior counsel had directed their communications team to put together and send to NHS Digital relevant material that had been sent to participants about data sharing with China. NHS Digital shared this material with IGARD in-meeting for information. IGARD suggested that, in respect of the worldwide use of the data, UK Biobank **proactively** explored this with participants, as opposed to providing information and responding to individual enquiries as they are raised, for example, by utilising the regular participant newsletters or fora. In addition, IGARD suggested that UK Biobank were more proactive in engaging with the participants more generally, for example, by setting up a patient and public involvement and engagement (PPIE) forum, where issues could be discussed / explored further. IGARD noted that the public facing section 5(a) was not clear that the data may be shared with other researchers in other countries (as outlined in the participant information leaflet), and asked that for transparency, section 5(a) was updated to ensure that the worldwide use of the data was clarified. In addition, IGARD also asked that the applicant updated their Data Protection Impact Assessment (DPIA), to ensure that the worldwide use of the data was addressed, along with the associated risks. **Separate to this application:** IGARD flagged that in section 1 (Abstract) of the application, the geographical restrictions which were noted on historic privacy notices on the NHS Digital website had now been updated to state *"NHS Digital may transfer the data within Europe. It may also be transferred outside of the UK if this is approved by NHS Digital through the DARS process for any **particular dissemination**"*. IGARD asked that this updated text was amended by NHS Digital, to ensure that it did not give the impression that NHS Digital / IGARD are reviewing every single international dissemination of data, noting that in this case (and other similar applications), this would be the responsibility of the applicant. IGARD noted on the applicant's website the large volume of ongoing projects, and queried what the oversight mechanism was for these, and asked that confirmation was provided in

	section 5 (Purpose / Methods / Outputs). In addition, IGARD queried if the large volume of ongoing projects were producing / submitting annual reports and asked that confirmation was provided in section 5. IGARD queried how such a large volume of applications were managed by the UK Biobank's Access Sub-Committee, noting they only meet four times per year; and noting that there was no supporting information within the application or supporting documents addressing this point, asked that for transparency, section 5 was updated with further clarity. IGARD also suggested that, as part of UK Biobank's PPIE, they involve participants in the internal approval of applications process, i.e. via UK Biobank's Access Sub-Committee. IGARD queried the information in section 5(e) (Is the Purpose of this Application in Anyway Commercial) that stated there were no commercial aspect to the application; and asked that in line with the NHS Digital DARS Standard for commercial purpose, section 5(e) was updated to provide a brief summary of the commercial aspect of the application, for example, the cost recovery basis and the access to the data by commercial companies. IGARD noted that the storage locations referenced in section 2(b) (Storage Location(s)) did not align with the information provided in section 5(b) (Processing Activities), and asked that the storage locations were reviewed and aligned in line with NHS Digital's DARS Standard for processing and storage locations as appropriate to reflect the factual scenario. IGARD noted that the references to the cohort size differed throughout the application, and asked that this was reviewed and updated to ensure the cohort size is accurate and consistent throughout the application. IGARD noted that, on return, section 5(d) (Benefits) (iii) (Yielded Benefits) should be updated, to **only** provide 2 or 3 specific yielded benefits accrued to date, to ensure the processing activities as outlined in section 5(a) were reflected in the excellent and wide-ranging yielded benefits achieved to the health and social care system; in line with NHS Digital DARS Standard for Expected Measurable Benefits. 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 size and complexity of the datasets. **Outcome:** recommendation to approve subject to the following conditions: 1. In respect of the COVID-19 datasets: a) To insert a special condition in section 6 outlining the restrictions on the COVID-19 datasets, i.e. processing must be for the purpose of COVID-19 related research **only**; and, b) To update section 5(a) with a brief reference to the restrictions on the COVID-19 datasets as per the special condition. c) To update section 5(a) with confirmation as to how Biobank UK has, to date, restricted access to the COVID-19 datasets for COVID-19 related research only. The following amendments were requested: 1. In respect of transparency: a) To update section 5(a) to ensure that the worldwide use of the data is clarified; and, b) To update the DPIA to ensure that the worldwide use of the data is addressed, along with the associated risks. 2. In respect of the MTA:

a) To update the MTA to include an automated termination clause for any sub-licensing agreement (as per the verbal update by NHS Digital), and
b) To update the MTA as appropriate, to ensure that all COVID-19 datasets are processed appropriately (in addition to the GDPPR datasets).

3. In line with the NHS Digital DARS Standard for commercial purpose, to provide a brief summary in section 5(e) of the commercial aspect of the application, for example, the cost recovery basis and the access to the data by commercial companies.
4. In respect of the large volume of ongoing projects:
   a) To confirm in section 5 if the large volume of ongoing projects are producing / submitting annual reports; and,
   b) To confirm in section 5 what the oversight mechanism is for the large volume of ongoing projects.
   c) To update section 5 to clarify how such a large volume of applications are managed by the UK Biobank's Access Sub-Committee, noting they only meet four times per year.
5. To align the storage locations in section 2(b) and section 5(a).
6. To ensure the cohort size is accurate and consistent throughout the application.
7. To amend any reference to *"CHESS"* data, to reflect the current name of *"SARI Watch"*.

The following advice was given:

1. IGARD suggested that, if rigorous controls were not already in place, UK Biobank review and update their internal application process and MTA as may be necessary, in order to restrict access to the COVID-19 datasets for the purpose of COVID-19 related research only.
2. IGARD suggested that, in respect of the worldwide use of the data, UK Biobank **proactively** explored this with participants, in addition to responding to individual enquiries as they are raised, for example, by utilising the regular participant newsletters or fora to engage with participants.
3. IGARD suggested that UK Biobank engage with the participants more generally, for example via a PPIE forum, where issues can be discussed / explored further.
4. IGARD suggested that UK Biobank involve participants in the applications process, i.e. via UK Biobank's Access Sub-Committee.
5. Noting that IAPT data was only requested up to March 2022, IGARD queried whether UK Biobank would wish to receive IAPT data on an ongoing basis. IGARD advised that they would be supportive of the ongoing flow of data, subject to the relevant updates being made to the application in line with NHS Digital's DARS Standards, and the application would not need to return to IGARD for a review for this amendment.
6. IGARD noted that, on return, section 5(d) (iii) should be updated to only provide 2 or 3 specific yielded benefits accrued to date, to ensure the processing activities as outlined in section 5(a) are reflected in the excellent and wide-ranging yielded benefits achieved to the health and social care system; in line with NHS Digital DARS Standard for Expected Measurable Benefits.
7. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the size and complexity of the datasets.
8. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the size and complexity of the datasets.

Separate to this application: IGARD flagged that the geographical restrictions which were noted on historic privacy notices on the NHS Digital website had now been updated to state

	"NHS Digital may transfer the data within Europe. It may also be transferred outside of the UK if this is approved by NHS Digital through the DARS process for any ***particular dissemination****"*. IGARD asked that this updated text was amended by NHS Digital, to ensure that it does not give the impression that NHS Digital / IGARD are reviewing every single international dissemination of data, noting that in this case (and other similar applications), this would be the responsibility of the applicant. It was agreed the conditions would be approved out of committee (OOC) by IGARD members.
3.2	Coventry University: Predictors of patient outcomes following referral to improving access to psychological therapies services in Coventry and Warwickshire (Presenter: Clare Wright) NIC-440554-T7X8W-v0.15 **Application:** This was a new application for pseudonymised Improving Access to Psychological Therapies Data Set (IAPT) from 2018 - 2021. The purpose of the application, is for a proposed analysis, to identify any demographic variables that relate to IAPT service outcomes, which will inform IAPT service provision locally in Coventry and Warwickshire. Coventry University is contracted by Warwickshire County Council to support the service evaluation of Public Health Warwickshire, which goes beyond population needs analysis and seeks to test local hypotheses and answer questions which may be generalisable. The data requested will enable Coventry University to perform the analysis to inform service provision changes. The service evaluation will be undertaken as part of a Mental Health Joint Strategic Needs Assessment (JSNA), which aims to provide an understanding of adult mental health and wellbeing needs across Coventry and Warwickshire. The assessment incorporates national and local evidence to support local priority setting and action. **Discussion:** IGARD noted that prior to the meeting, a query had been raised by an IGARD member in respect of whether the applicant had consulted their relevant University Research Ethics Committee (REC) to see if a review was required; noting that although the purpose of the application was for a service evaluation commissioned by a council, the intention to publish in a research journal suggested that it had a research element. NHS Digital advised that the applicant had acquired university ethical approval in June 2021 and provided IGARD with written evidence prior to the meeting. IGARD noted and thanked NHS Digital for the update, and asked that in line with NHS Digital DARS Standard for Objective for Processing, section 5(a) (Objective for Processing) **and** in line with NHS Digital DARS Standard for Ethical Approval section 7 (Ethics Approval), was updated to clarify that ethical issues had been considered and University REC approval had been sought and obtained. IGARD noted the reference to *"NHS Clinical Commissioning Group (CCG)"* in section 5(a) and asked that this was updated to correctly reference *"Integrated Care Board (ICB)"*, noting that ICBs replaced CCGs on the 1st July 2022. IGARD also asked that section 5(a) was updated with clarification that the ICB had no involvement in determining the purpose and means of processing and was **not** carrying out any data controllership activities. IGARD queried what, if any patient and public involvement and engagement (PPIE) had been carried out to date, noting that the application was silent on this; and asked that section 5 (Purpose / Methods / Outputs) was updated with further details, for example, was there any PPIE undertaken as part of the JSNA from the Health and Wellbeing Board.

	IGARD suggested that, if not already happening, the applicant involve relevant patient or public groups, applicable to the stage of the project. The HRA guidance on Public Involvement is a useful guide. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of ethical approval: a) To update section 5(a) to clarify that ethical issues have been considered and University REC approval has been obtained. b) To updated section 7 to clarify that University REC support has been obtained. 2. In respect of the reference to CCG / IBB a) To update section 5(a) to remove reference to "*CCG*" and replace with "*ICB*". b) To clarify in section 5(a) that the ICB has no involvement in determining the purpose and means of processing and is **not** carrying out any data controllership activities. 3. To update section 5 to provide details of any PPIE carried out to date, for example, as part of the JSNA from the Health and Wellbeing Board. The following advice was given: 1. IGARD suggested that, if not already happening, the applicant involve relevant patient or public groups, applicable to the stage of the project. The HRA guidance on Public Involvement is a useful guide.
3.3	Department of Health and Social Care (DHSC): DHSC TRE access - Enabling Policy Analysis (Presenter: David Morris) NIC-484452-H8S1L-v3.6 **Application:** This was an extension application to permit the holding and processing of pseudonymised Civil Registration (Deaths), Community Services Data Set (CSDS), COVID-19 Hospitalization in England Surveillance System, Covid-19 UK Non-hospital Antigen Testing Results (pillar 2), Covid-19 UK Non-hospital Antibody Testing Results (Pillar 3), COVID-19 Vaccination Adverse Reactions, COVID-19 Vaccination Status, Emergency Care Data Set (ECDS), Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC), HES Critical Care, HES Outpatients, Improving Access to Psychological Therapies (IAPT) v2, Medicines dispensed in Primary Care (NHSBSA data), Maternity Services Data Set (MSDS) v1.5, Uncreated Low Latency Hospital Data Sets – APC, Uncurated Low Latency Hospital Data Sets - Critical Care and Uncurated Low Latency Hospital Data Sets – Outpatient. It was also an amendment application to **1)** add Mental Health Services Dataset (MHSDS) v4 and v5, to be processed via the Trusted Research Environment (TRE) once available. Section 5 of the application has been updated to outline the purpose of requesting these datasets and examples of processing; **2)** to add Maternity Services Dataset (MSDS) v2.0 to be processed via the TRE once available (in addition to MSDS v1.5 already requested); **3)** to extend the Data Sharing Agreement (DSA) to the 7th September 2025; **4)** to update section 5(a) to reference the currently active DSA - NIC-365132-V5S8H. DHSC currently holds an active Data Sharing Agreement (DSA) under NIC-365132-V5S8H, which includes access to NHS Digital's Data Access Environment (DAE) for the same purpose. This purpose of this DSA is to replace the existing DAE agreement as the datasets currently held under NIC-365132-V5S8H-v1.2 that are still required, become available within the TRE.

	DHSC will use the data within NHS Digital's TRE for analysis in support of the Secretary of State for Health and Social Care in delivery of their duties set out within the National Health Service Act 2006. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD meeting on the 16th September 2021 and 7th April 2022. IGARD noted that this application had been reviewed by the GPES Data for Pandemic Planning and Research (GDPPR) – Profession Advisory Group (PAG) on the 25th August 2021 and 15th September 2021 *(notes from this meeting had been attached to the IGARD minutes from the 16th September 2021)*. IGARD also noted that further PAG reviews had taken place on the 3rd November 2021 and 24th November 2021, however, as the applicant was not currently requesting GDPPR data under this version of the DSA, these notes had not been reviewed nor provided to IGARD. IGARD advised that if GDPPR data was requested in the future, the notes (and any subsequent PAG meeting notes) would be reviewed as supporting documentation and attached to the published IGARD meeting minutes as per process. IGARD noted that updated versions of the MHSDS and MSDS datasets would be incorporated into the DSA when they become available; and advised that they would be supportive of this, subject to the relevant updates being made to the application in line with NHS Digital's DARS Standards, and would not need to return to IGARD for a review for this amendment. IGARD asked that for transparency, the public facing section 5 (Purpose / Methods / Outputs) was updated to clarify that the updated versions of the MHSDS and MSDS datasets will be incorporated into the DSA when they become available. IGARD noted that NHS Digital's Data Security Centre had reviewed DHSC data security assurance and had provided data security assurance in support of DARS Annual Review up until the 30th June 2022; and that a further review was being conducted on the latest version of the Her Majesty's Government (HMG) Security Policy Framework (SPF) to provide further data security assurance, and that this was expected to be approved soon. IGARD asked that a copy of the security assurance was provided, and that this was uploaded to NHS Digital's customer relationships management (CRM) system for future reference. IGARD noted that at the meeting on the 7th April 2022, in response to IGARD's previous suggestion (on the 16th September 2021) that the applicant undertook patient and public involvement and engagement (PPIE), in some form and throughout the lifetime of the agreement; NHS Digital had confirmed that there was ongoing work with individual teams using the data within DHSC, for example, the maternity team, as to how PPIE could be undertaken. Noting that the application had not been updated to reflect any progress on PPIE, IGARD reiterated their request that section 5(a) (Objective for Processing) was updated with further information. In addition, NHS Digital advised that the applicant was in the process of producing a PPIE plan. IGARD noted the verbal update from NHS Digital, and asked that the applicant provided a copy of the PPIE plan to NHS Digital, and that this was uploaded to NHS Digital's customer relationships management (CRM) system for future reference once received. IGARD noted the references in the application to the NHS Digital data being *"released"*, and noting that the data was being processed within the DAE / TRE, asked that this was updated to more accurately state that the data was being *"accessed"*. IGARD noted that there were statements within section 5(a) that referred to staff in the Joint Work and Health Unit using the data. Noting that this unit is joint between DHSC and the

	Department for Work and Pensions (DWP) , IGARD asked section 5(a) was updated to make clear that **only** DHSC staff in this unit would be accessing the data. IGARD noted the references in section 5(a) to the dual-running of the DAE and the TRE, and asked that for transparency, this public facing section was updated to include a timeframe for the continuation / end of the dual-running; and to also update section 5(a) to make clear that that the DSA relating to the access of data via the DAE will cease once all the data is contained within the TRE. IGARD noted that it was not clear within section 5(a) whether all the purposes and projects listed would need pseudonymised data, and asked that this was updated, to clarify the process in place to ensure the use of the pseudonymised data was necessary for the all processing being undertaken, in line with NHS Digital DARS Standard for Objective for Processing. IGARD queried the information within section 3(b) (Additional Data Access Requested) in relation to the MHSDS and asked that this was updated to reflect the version number of the MHSDS dataset was in line with the other datasets (and version numbers) listed. IGARD noted the yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits), however suggested that the applicant updated these, to **only** provide 2 or 3 specific yielded benefits accrued to date, to ensure the processing activities as outlined in section 5(a) are reflected in the wide-ranging yielded benefits achieved to the health and social care system; in line with NHS Digital DARS Standard for Expected Measurable Benefits. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of the security assurance: a) To provide a copy of the security assurance (as per the verbal update from NHS Digital); and, b) To upload a copy of the security assurance to NHS Digital's CRM system for future reference. 2. To clarity in section 5 that the updated new versions of the MHSDS and MSDS datasets will be incorporated into the DSA when they become available. 3. In respect of PPIE: a) To update section 5(a) with further information of the PPIE (as requested at the last IGARD review). b) The applicant to provide a copy of the PPIE plan to NHS Digital; and, c) To upload the copy of the PPIE plan to NHS Digital's CRM system for future reference, once received. 4. To update the application throughout to remove references to data being *"released"* and replace with *"accessed"*. 5. In respect of the DAE / TRE: a) To update section 5(a) to ensure that where reference is made to the dual-running of the DAE and TRE, that the timeframe for this is updated; and, b) To update section 5(a) that the DSA relating to the access of data via the DAE will cease. 6. To update section 5(a) to clarify the process in place to ensure the use of the pseudonymised data is necessary for the processing being undertaken, in line with NHS Digital DARS Standard for Objective for Processing. 7. To update section 3(b) to ensure the correct version of the MHSDS dataset is reflected.

	8. To update section 5(a) to make clear that only DHSC staff in the Joint Work and Health Unit will be accessing the data. The following advice was given: 1. IGARD noted the yielded benefits in section 5(d) (iii), however suggested that the applicant updated these, to **only** provide 2 or 3 specific yielded benefits accrued to date, to ensure the processing activities as outlined in section 5(a) are reflected in the excellent and wide-ranging yielded benefits achieved to the health and social care system; in line with NHS Digital DARS Standard for Expected Measurable Benefits. 2. IGARD noted that updated versions of the MHSDS and MSDS datasets would be incorporated into the DSA when they become available; and advised that they would be supportive of this, subject to the relevant updates being made to the application in line with NHS Digital's DARS Standards, and would not need to return to IGARD for a review for this amendment.
3.4	The University of Manchester: Understanding the role of adult community health services in avoiding hospital admissions (Presenter: Aisha Powell) NIC-482271-S6S1V-v0.4 **Application:** This was a new application for pseudonymised Civil Registration (Deaths) - Secondary Care Cut, Community Services Data Set (CSDS), Hospital Episode Statistics Accident and Emergency, Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC) and HES Outpatients data. The purpose of the application is for a research project aiming to examine how rising demand and limited investment in adult community health services has influenced their provision and affected hospital admissions, how this varies by ethnicity, deprivation, and rurality, and how to develop the economic case for investment. The data will be processed for use in three of the five work packages (WPs) in the overall research project. These are: **WP2** Workforce and supply – the aim is to examine how supply of adult community health services has responded to rising demand (uses CDSD only); **WP4** Impact on hospital use – the aim is to examine the impact of adult community health services on hospital utilisation (uses linked HES and CSDS); **WP5** Economic case for investment – the aim is to examine the costs and benefits of adult community health services (uses linked HES and CSDS). **Discussion:** IGARD welcomed the application and noted the importance of the research. Prior to the meeting a query had been raised by an IGARD member in respect of whether the applicant had consulted their University Research Ethics Committee (REC) to see if a review was required; noting that section 1 (Abstract) stated *"ethics approval is not required because only non-identifiable data will be received"*. NHS Digital advised that the applicant had confirmed prior to the meeting that they had discussed this with University REC and the outcome of those discussion was that University REC approval was **not** required. IGARD noted and thanked NHS Digital for providing confirmation and asked that any relevant emails on this topic were uploaded to the customer relationship management (CRM) system for future reference. IGARD noted the statement in section 1 *"The University of Manchester requires pseudonymised extracts of Hospital Episode Statistics (HES) and the Community Services Data Set (CSDS) linked to date of death for the purpose of undertaking the research project"*; and asked that section 1 was updated with an analysis that the inclusion of date of death data did **not** render the flow of data identifiable.

	IGARD noted, and wished to draw to the applicants attention, the concern that the outcomes of the research project may have been pre-judged, in that it is assumed there has been under investment in adult community services and that investment in such services will reduce hospital admissions. For example, the statement in section 5(a) (Objective for Processing) *"The aim of this research project is to examine how rising demand and limited investment in adult community health services has influenced their provision and affected hospital admissions, how this varies by ethnicity, deprivation, and rurality, and how to develop the economic case for investment"*. The research should be open to the possibility that the economic case does not support investment. However, IGARD acknowledged that the research would have undergone considerable peer review as part of its Institute for Health Research (NIHR) funding application. IGARD noted the references in section 5 (Purpose / Methods / Outputs), in relation to specific systems used, for example, *"iCSF friendly network file system (NFS) data store";* and asked that section 5 was reviewed throughout and amended as appropriate to ensure that this was not too restrictive. IGARD noted and commended the applicant on the statement in section 5(a) (Objective for Processing) *"The University of Manchester project team engaged with members of the public and people with lived experience of community health services (themselves or as carers) when preparing the research project application and protocol, to ensure that the evidence produced will be of value to the public"*. As section 5 forms NHS Digital's data uses register, IGARD asked that section 5 was amended, to ensure that all acronyms upon first use be defined and further explained if the meaning was not self-evident. IGARD also noted the inclusion of a number of technical phrases and words within section 5 (Purpose / Methods / Outputs), and asked that this public facing section, was amended throughout, to ensure technical terms were explained in a manner suitable for a lay audience. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 1 include to make clear that the inclusion of date of death data does **not** render the flow of data identifiable. 2. To review the text throughout in section 5 to ensure that this is not too restrictive, for example, in relation to the specific systems referred to, and amend as appropriate. 3. 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 ensure that technical terms are used only where necessary and explained in a manner suitable for a lay audience. The following advice was given: 1. IGARD noted, and wished to draw to the applicant's attention, the concern that the outcomes of the research project may have been pre-judged. IGARD asked that the researchers be open to the possibility that the economic case may not support investment.
3.5	University of Oxford: WAX: Weight Bearing in Ankle Fractures. A randomised clinical trial of weight-bearing following operatively treated ankle fracture (Presenter: Charlotte Skinner) NIC-504846-J6X8M-v0.12

	Application: This was a new application for pseudonymised Emergency Care Data Set (ECDS), Hospital Episode Statistics Admitted Patient Care (HES APC), HES Critical Care and HES Outpatients. The purpose of the application is for a study, aiming to determine whether functional outcomes after early weight-bearing in patients with operatively treated unstable ankle fractures are not worse than adopting a delayed weight-bearing regime which is usual care. The data will be analysed the dataset to **1)** investigate the difference in risk of adverse events between the trial treatment groups in the first 12 months post-surgery; **2)** to investigate the resource use, costs and comparative cost utility between the trial treatment groups in the first 12-months post-surgery. This study is a randomised clinical trial, which is the best method to compare treatments to guide the care of patients. Randomisation will be used to produce two groups of patients: those given advice to walk on their operated ankle 2-weeks after surgery, and those who wait until 6-weeks. Patient follow-up will extend to 12-months. There were 560 patients recruited / consented between 13th January 2020 and 29th October 2021, from more than 20 hospitals. **Discussion:** IGARD welcomed the application and noted the importance of the study and the potentially excellent benefits that could flow. In addition, IGARD noted and commended the applicant on the excellent patient and public involvement and engagement (PPIE), particularly in respect of the early involvement of the patients during the development stage of the study; this is an exemplar for future research. IGARD confirmed that they were of the view that the consent materials provided the appropriate gateway and were broadly compatible with the processing outlined in the application. IGARD noted as part of NHS Digital's consent review, a number of recommendations had been put to the applicant, in respect of suggested updates to the study website, including, but not limited to, providing further information on the specific data being accessed and the process for withdrawing consent. IGARD confirmed that they were supportive of the suggested updates made by NHS Digital; and in addition, suggested that, for transparency, the applicant updated the study website to clarify what level of data would be retained after the 1-year period, noting that this was currently unclear. In addition, IGARD also suggested that the applicant update the study website, to ensure clear guidance was published for participants, clarifying how they could withdraw consent from the study if they no longer wished to take part, including, but not limited to, two methods of communication, for example, a telephone number and e-mail address. IGARD noted that participants had given consent for onward sharing of their data to other researchers. IGARD suggested that NHS Digital draw this to the attention of the applicant; and advised that if they did wish to share the data with other researchers, this would be subject to an amendment of the DSA via the usual NHS Digital DARS process, and potentially other internal information governance process, depending on the level of data they wanted to share. Alternatively, if the applicant did not wish to share the data with other researchers, IGARD suggested that this was made clear on the study website for transparency. IGARD queried the statement in section 5(a) (Objective for Processing) *"The data subjects will be the trial participant cohort who fulfil all eligibility criteria as defined in the project Protocol"*; and asked that for transparency to the public, section 5(a) was updated with a weblink to the study protocol or further information of the inclusion / exclusion criteria of participants, in line with NHS Digital DARS Standard for Objective for Processing.

	IGARD noted the reference to the study requiring 'historic preceding life course of data' in section 5(a), and asked that this was updated to clarify that **only** four years of HES data was required by the applicant, and not a participant's entire medical history. IGARD also noted the inclusion of a number of technical phrases and words within section 5 (Purpose / Methods / Outputs), and asked that this public facing section, that forms NHS Digital's data uses register, was amended throughout, to ensure technical terms were explained in a manner suitable for a lay audience. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 5(a) with a weblink to the study protocol **or** further information of the inclusion / exclusion criteria of participants. 2. IGARD noted a number of technical terms in section 5, and asked that this public facing section, which forms NHS Digital's data uses register, was amended throughout, to ensure technical terms are explained in a manner suitable for a lay audience. 3. To clarify in section 5(a) that **only** four years of HES data is required by the applicant, and not a participant's entire medical history. The following advice was given: 1. In respect of the website: a) IGARD suggested that for transparency, the applicant updated the study website to clarify what level of data will be retained after the 1-year period. b) IGARD suggested that the applicant update the study website, to ensure clear guidance was published for participants, clarifying how they can withdraw consent from the study if they no longer wished to take part, including (but not limited to) two methods of communication, for example, telephone and e-mail. 4. In respect of sharing the data with other researchers: a) IGARD noted that participants had given consent for onward sharing of their data to other researchers. IGARD suggested that NHS Digital draw this to the attention of the applicant; and advised that if they do wish to share the data with other researchers, this would be subject to an amendment of the DSA via the usual NHS Digital DARS process, and potentially other internal information governance process, depending on the level of data they want to share. b) Alternatively, if the applicant does not wish to share the data with other researchers, IGARD suggested that this is made clear on the study website for transparency.
4	Applications progressed via NHS Digital's Precedent route, including the SIRO Precedent Applications that have been progressed via NHS Digital's Precedent route, including the SIRO Precedent, and NHS Digital have notified IGARD in writing (via the Secretariat). *No items discussed*
5	Oversight & Assurance IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. Due to the volume and complexity of applications at today's meeting, IGARD were unable to review any Data Access Request Service (DARS) applications as part of their oversight and assurance role.

	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	COVID-19 update *No items discussed*
7 **7.1**	AOB: Improving Data Access Programme Following the last updated at the IGARD meeting on the 7th July 2022, this was a further update by NHS Digital with regard to the improving data access programme workstream; and other relevant areas of work linked to the programme. NHS Digital provided an update on three key areas: Improving Data Access Programme, Proposed updates to Standard 5(a) and Standard 5(b), and Review of Precedent criteria. a) Improving Data Access Programme (verbal update) (Presenter: Susan Main) NHS Digital provided a verbal update via a presentation shared with IGARD in-meeting, that outlined progress to date and the expected outcomes and benefits of the Programme. IGARD noted a number of queries to NHS Digital (which would also be sent via e-mail following the meeting), which included a request for the latest draft of the Annual Report; further clarification as to who was on the Data Access Oversight Board; and whether the comments previously provided by IGARD on DARS' Due Diligence had been considered, and whether it would be helpful for IGARD to have input into this work stream. In addition, IGARD advised that they would be happy to provide comments on the Annual Report prior to circulation to external parties if required. b) Proposed updates to Standards 5(a) (Objective for Processing) and 5(b) (Processing Activities) (verbal update) (Presenter: Dave Cronin) NHS Digital provided a verbal update on the ongoing work with DARS to review and update NHS Digital DARS Standards 5(a) and 5(b). NHS Digital advised that these would be circulated to a number of stakeholders (including IGARD) as soon as possible for comments / feedback, as per process. NHS Digital advised that following the update to Standards 5(a) and 5(b), a review / update of other NHS Digital DARS Standards would be undertaken in due course. IGARD noted and thanked NHS Digital for the verbal update, and looked forward to receiving the updated NHS Digital Standards 5(a) and 5(b) for review in due course. c) Review of Precedent Exclusion Criteria (Presenter: Liz Gaffney) IGARD noted that a draft paper had been circulated to members in advance of the meeting for discussion, that provided further information on the exclusion criteria. IGARD provided verbal feedback on the document in-meeting to NHS Digital.

	IGARD thanked NHS Digital for providing the paper in advance of the meeting, and advised that they would welcome a further discussion once the relevant updates had been made to the paper following the meeting, and in line with comment provided by IGARD.
7.2	IGARD review of NHS England applications (No Presenter) IGARD noted that on the 22nd August 2022, an e-mail had been circulated to key senior NHS Digital colleagues (by the IGARD Secretariat on behalf of IGARD), with a proposal for how IGARD would manage / review NHS England applications from the 1st September 2022. This proposal was made in line with IGARD's published Terms of Reference and to support NHS Digital / NHS England ahead of the transition of NHS Digital into NHS England on 1st April 2023, where both organisations would become one entity. IGARD suggested that, as per current process, they would welcome NHS England applications to IGARD for advice, and would provide a positive statement of support, or statement that they are unable to support; as opposed to providing a recommendation for approval. The outcomes would focus on key elements, for example, transparency in the public domain, possible risks, areas for improvements, issues to focus on for future assurance, and whether future assurance was essential / advisable / not necessary, and a time frame. The applications would then proceed under NHS Digital's SIRO precedent. IGARD noted that the Head of Data Access, Data Access Request Service (DARS), had responded on behalf of NHS Digital to the e-mail on the 6th September, confirming support for the proposal. It was agreed that NHS England applications progressed via this route would be tracked and reviewed on the 1st December 2022, with a report produced for discussion at the IGARD meeting on the 15th December 2022. This would then feed into a wider discussion around process and how this area of work would proceed from January 2023 onwards.
7.3	IGARD Deputy Chair It was discussed and agreed by IGARD members that Paul Affleck and Dr. Imran Khan would jointly take over the role of co-Deputy IGARD Chair, for one year, as per agreed procedures; replacing Dr. Geoff Schrecker who had fulfilled this role since June 2019. NHS Digital, IGARD members and the IGARD Secretariat thanked Dr Schrecker for the valuable support he had provided to IGARD meetings, IGARD Chair, IGARD Secretariat and NHS Digital in his role as Deputy Chair over the three years. 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 12/08/22

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