Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 28 April 2022

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Kirsty Irvine	IGARD Chair
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Chair
Jenny Westaway	Lay Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Maria Clark	Lay Member
Prof. Nicola Fear	Specialist Academic Member
Dr. Robert French	Specialist Academic / Statistician Member
Dr. Maurice Smith	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Michael Ball	Data Access Request Service (DARS) (Items 3.5, 3.6, 7.1)
Vicky Byrne-Watts	Data Access Request Service (DARS) (Observer: item 2.1)
Dave Cronin	Data Access Request Service (DARS) (SAT Observer: items 3.2 - 3.3)
Catherine Day	Data Access Request Service (DARS) (Item 3.4)
Louise Dunn	Data Access Request Service (DARS) (**SAT Observer**: item 3.4) (Item 2.1)
Duncan Easton	Data Access Request Service (DARS) (**SAT Observer**: items 3.5 - 3.6)
Dan Goodwin	Data Access Request Service (DARS) (Item 7.1)
Dickie Langley	Privacy, Transparency & Ethics (PTE) (Item 7.2)
Abigail Lucas	Data Access Request Service (DARS) (Items 3.1 - 3.2)
Karen Myers	IGARD Secretariat

Amy Ogborne	Privacy, Transparency & Ethics (PTE) (Item 2.1)
Dr. Jonathan Osborn	Deputy Caldicott Guardian (Observer: items 3.1 - 3.3)
Denise Pine	Data Access Request Services (DARS) (Items 3.1 - 3.2)
Jamie Sanderson	Privacy, Transparency & Ethics (PTE) (Observer: item 2.1)
Kimberley Watson	Data Access Request Service (DARS) (**SAT Observer**: item 3.1)
Anna Weaver	Data Access Request Service (DARS) (Item 3.3)
Emma Whale	Data Access Request Service (DARS) (Item 3.1 - 3.2)
Vicki Williams	IGARD Secretariat
***SAT** – Senior Approval Team (DARS)	

1	**Declaration of interests:** There were no declarations of interest. **Review of previous minutes and actions:** The minutes of the 7th April 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**
2.1	Relying on consultees as a basis for participating in research where an individual lacks capacity to consent – Briefing Paper (Presenter: Louise Dunn / Amy Ogborne) When researchers are attempting to carry out research but there are participants who lack the capacity to provide consent, the use of a consultee may be an appropriate gateway to include those participants. Under sections 30 to 33 of the Mental Capacity Act 2005 ("MCA"), the use of a consultee provides a basis for inclusion of a participant who lacks the ability to provide consent to take part in some forms of research. This does not include clinical trials. It must be noted however, that this consultee does not provide consent on behalf of the participant but rather advice. It is a statutory authority, on the condition that the requirements of sections 30 to 33 of the MCA are met. The most appropriate lawful basis for NHS Digital to rely upon concerning the dissemination of data is section 261(5)(d) of the Health and Social Care Act 2012. This section would be used on the basis that if researchers can satisfy the requirements of Article 6(1)(e) UK GDPR, then this could be relied upon in regard to section 261(5)(d). To support the DARS team, the PTE team created a 'Decision making workflow for DARS applications wishing to rely on the MCA Consultee Process' table. This was produced to

	provide a checklist for DARS, setting out when the MCA Consultee Process applies and the statutory requirements that must be satisfied for this to be relied upon. IGARD noted that high-level comments had previously been provided on this briefing paper at the IGARD business as usual meeting on the 9th December 2021, in addition to the IGARD BAU meetings on the 13th May 2021 and 20th May 2021. IGARD noted that the briefing paper had also previously been seen at the IGARD – NHS Digital COVID-19 Response meeting on the 25th May 2021. NHS Digital advised IGARD that discussions were still ongoing internally, in respect to any perceived or actual barriers to the dissemination of data, where legitimate interests was relied on as a UK General Data Protection Regulation (UK GDPR) legal basis. IGARD and NHS Digital had a further discussion on this point within the meeting, where different options were discussed in respect of the UK GDPR legal basis. IGARD noted NHS Digital's verbal update in respect of the ongoing discussions and looked forward to an update in due course. IGARD noted that they had previously suggested to NHS Digital that a large proportion of the flowchart chart provided could be substituted with appropriate Health Research Authority Research Ethics Committee (HRA REC) support; and noted that prior to the meeting, NHS Digital had confirmed that they had discussed with HRA, the level of information which was currently supplied within the HRA REC support letters. NHS Digital advised that currently the information on consideration of consultee usage was varied, and that HRA were looking at standardising the approach and, in addition, were sending NHS Digital written confirmation, which sets out the HRA ethics approach to considering consultee recruitment to support how this is evidenced. IGARD noted the verbal update from NHS Digital and looked forward to an update in due course. **Outcome:** IGARD welcomed the briefing paper and looked forward to receiving a further update in due course.
3	**Data Applications**
3.1	<u>The Nuffield Trust For Research And Policy Studies In Health Services: Nuffield Trust Primary DSA - Amendment / Renewal- For 1/7/22 to 30/6/25 (Presenter: Denise Pine) NIC-226261-M2T0Q-v4.6</u> **Application:** This was a renewal and extension application to permit the holding and processing of pseudonymised Community Services Data Set (CSDS), Emergency Care Data Set (ECDS), Hospital Episode Statistics Admitted Patient Care (HES APC) and HES Outpatients data. The purpose of the application is to support The Nuffield Trust's strategic priorities for 2020 to 2025; which include: workforce; technology and digital; primary care; small hospitals; quality and equity; and politics, legislation, and governance. The quality and equity area includes care for specific population groups, for example children and young people, as well as care for underserved populations, for example prisoners, and inequalities in health and care service delivery. The work of The Nuffield Trust is organised into a number of programmes which address these priorities. This application was formally NIC-384572-J7P6Y; and is linked to NIC-194629-S4F9X (item 3.2). NHS Digital noted that prior to the meeting, an IGARD member had submitted a query in respect of The Nuffield Trust's privacy notice, which had not been updated to include all the

	NHS Digital datasets held, for example, the CSDS dataset. NHS Digital confirmed that the applicant had updated the privacy notice to reflect the correct information. NHS Digital also noted that IGARD had previously suggested that The Nuffield Trust may wish to update their published Data Protection Impact Assessment (DPIA) to include all the NHS Digital datasets held; and confirmed that this had been completed and was now available on their public facing website. NHS Digital noted that prior to the meeting, an IGARD member had submitted a query in respect of a statement within section 5(a) (Objective for Processing) that stated *"At the current time, the Trust are receiving funding for projects which use HES data from the National Institute for Health Research (NIHR), the NHS Race and Health Observatory (RHO) and the Health Foundation"*; and whether there were any other bodies involved; and, if so, if they were joint Data Controllers. NHS Digital advised that the Nuffield Trust had confirmed that no other bodies were involved and that any projects that would involve working with partners who would be considered joint Data Controllers would need a separate Data Sharing Agreement (DSA). **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 23rd May 2019 and 29th July 2021. IGARD noted and thanked NHS Digital for the verbal update, in respect of the updated privacy notice and the DPIA. IGARD asked that for transparency a working weblink for the DPIA was added in section 5(a). IGARD noted and thanked NHS Digital for the verbal update but suggested that the Nuffield Trust should keep a close eye on whether commissioned projects were designed and / or executed such that the commissioner has a joint data controllership role alongside the Nuffield Trust. IGARD queried the reference in section 5(a) to the Nuffield Trust being the "*primary"* Data Controller, and asked that the reference to *"primary"* was removed, noting that the Nuffield Trust were the **sole** Data Controller, and to avoid any potential misunderstanding that there were other parties involved in the data controllership. IGARD noted that the application stated that the data requested was **not** for commercial purposes, however suggested that the Nuffield Trust should continue to review the revised NHS Digital DARS Standard for Commercial Purpose, to assess whether any future work required disclosures under that Standard. IGARD noted the points provided in section 5(a) under point 5aiii, that provided clarification on the areas of responsibility of the Nuffield Trust Project Planning Group (PPG) ; however, advised that not all the areas of responsibility outlined for the PPG within the application were reflected in the PPG Terms of Reference (ToR) provided as a supporting document. IGARD asked that, for consistency, the applicant should update the ToR to also include the responsibilities outlined in the application, specifically in relation to information governance requirements and stakeholder engagement. In addition, IGARD noted the helpful information within section 5(a) under point 5aiii, in relation to The Nuffield Trust's Project Planning Committee (PPC) and Project Planning Group (PPG) and asked that the applicant also update the ToR to add an additional assurance requirement for both PPC and PPG that the projects using NHS Digital data would benefit health and / or social care in England and Wales. IGARD noted that the frequency of the data flowing was currently monthly, however, noted that publicly available information did not appear to have been updated as regularly as the

	monthly drops of data. IGARD asked that the justification for the monthly dissemination of the data was reviewed in section 5(c) (Specific Outputs Expected), and confirmation was provided that the frequency was still required. In addition, noting that some of the outputs in section 5(c) referred to reports etc that had been produced following the monthly dissemination of data, IGARD asked that a weblink was provided in section 5(c) to the relevant reports. IGARD noted that if the monthly dissemination of the data was no longer relevant, that the application was updated throughout to reflect the correct frequency of the data. IGARD noted and commended the applicant on the yielded benefits outlined in section 5(d) (Benefits) (iii) (Yielded Benefits), for example the evaluation of the COVID-19 virtual wards and COVID-19 oximetry at home. However, IGARD asked that these were reviewed, and for transparency and ease of reference, broken down into discrete projects, for example, what the project was, how the data was used, and the yielded benefit(s) accrued to health and social care, in line with NHS Digital DARS Standard for Expected Measurable Benefits. IGARD noted that section 5(d) (ii) (Expected Measurable Benefits to Health and / or Social Care) contained information on the benefits that had been achieved, and asked that in line with NHS Digital DARS Standard for Expected Measurable Benefits, these were correctly moved to the yielded benefits in section 5(d) (iii), for example, COVID-19 virtual wards and use of COVID-19 Oximetry at home. IGARD noted that section 5(d) (iii) contained information in relation to ongoing projects, and asked that in line with NHS Digital DARS Standard for Expected Measurable Benefits, these were correctly moved to the expected benefits in section 5(d) (ii). IGARD queried the content of the last sentence in section 5(d) (iii) in respect of '*service delivery*', and asked that this was reviewed and amended to be more specific on the yielded benefits accrued, 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 or extension, or amendment not covered by NHS Digital's Precedent route, due to the large quantum of data held by the applicant and programmatic access. **Outcome:** recommendation to approve The following amendments were requested: 1. To update the ToR to add the two additional areas of responsibilities as outlined in section 5(b) (under point 5aiii), which address: a) Information Governance requirements; and, b) Stakeholder engagement. 2. To update the ToR to add an additional assurance requirement for both PPC and PPG, that the projects will benefit the health and / or social care in England and Wales. 3. To provide a working weblink in section 5(a) to the DPIA. 4. To remove the reference in section 5(a) to The Nuffield Trust being the *"primary"* Data Controller. 5. In respect of the monthly dissemination of data: a) To review the justification in section 5(c) for monthly dissemination of the data and confirm that the frequency is still required; and, b) To provide a link in section 5(c) to the relevant reports that have been produced following the monthly dissemination of data; or, c) If the dissemination of the data is no longer relevant, to update the application throughout to reflect the correct frequency of the data.

	6. In respect of the benefits in section 5(d) and in line with NHS Digital DARS Standard for Expected Measurable Benefits: a) To remove the benefits that have been achieved from section 5(d) (ii) and move to section 5(d) (iii), for example, virtual wards and use of Oximetry at home. b) To move ongoing projects from section 5(d) (iii) and add to section 5(d) (ii). c) To review and amend the last sentence in section 5(d) (iii) to be specific on the yielded benefit accrued. d) To review the yielded benefits in section 5(d) (iii) and break down into discreet projects, for example, what the project was, how the data was used, and the yielded benefit(s) accrued to health and social care. The following advice was given: 1. IGARD suggested that The Nuffield Trust should keep a close eye on whether commissioned projects are designed and/or executed such that the commissioner has a joint data controllership role alongside The Nuffield Trust. 2. IGARD suggested that The Nuffield Trust should continue to review the revised NHS Digital DARS Standard for Commercial Purpose, to assess whether any future work requires disclosures under that Standard. 3. IGARD advised that they **would wish to review** this application when it comes up for renewal or extension (or amendment not covered by NHS Digital's Precedent route) because of the large quantum of data held by the applicant and programmatic access.
3.2	The Nuffield Trust For Research And Policy Studies In Health Services: Nuffield RSET DSA Amendment / Renewal (Presenter: Denise Pine) NIC-194629-S4F9X-v4.2 **Application:** This was a renewal and extension application to permit the holding and processing of pseudonymised Emergency Care Data Set (ECDS), Hospital Episode Statistics Admitted Patient Care (HES APC) and HES Outpatients data. The application was also an amendment to add the Community Services Data Set (CSDS) to the list of datasets accessed under this Data Sharing Agreement (DSA) from the data disseminated under NIC-226261. The purpose of the application is for a number of projects (outlined in now NIC-226261-M2T0Q (item 3.1) – formally NIC-384572-J7P6Y), to investigate the impact of COVID-19 on the use of health services which are dependent on, or would benefit from, access to more timely data. These include, for example, an analysis of outpatient attendances with a view to identify variations in activity by Trust and specialty over the early pandemic period as part of evaluation work. The Nuffield Trust are starting a project to understand the profile of patients discharged before and during the pandemic, and their subsequent use of services in the community. As part of the Nuffield Trust's Quality Watch programme the Nuffield Trust are also planning more wide-ranging analysis of hospital activity and performance over the pandemic period and especially in the run up to, and over, the winter period for which, again, more timely data would be of benefit. NHS Digital advised that CSDS data was incorrectly noted within section 3(a) (Data Access Already Given), and noted that this would need removing, since it has not previously been requested or disseminated. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 22nd November 2018, 14th February 2019 and 19th August 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 18th February 2021. IGARD noted and thanked NHS Digital for the verbal update, in respect of the incorrect reference to CSDS data in section 3(a) being removed. IGARD queried how the data in this DSA and NIC-226261-M2T0Q would be kept distinct and separate, noting the different data controllership arrangements, including, but not limited to, the Quality Watch programme, which was referenced in both applications. IGARD asked that clarity was provided in section 5(c) (Specific Outputs Expected) of how data was used and how the different data controllership arrangements were maintained. IGARD noted the helpful information with the protocol that was provided as a supporting document, in respect of the distinction between the patient and public involvement (PPI) group and the Rapid Service Evaluation Team (RSET) Advisory Board; and asked that for transparency, information about the PPI activities contained in the protocol was also added to section 5(a) (Objective for Processing). IGARD queried the reference in section 5(d) (Benefits) (iii) (Yielded Benefits) to *"linkage"* with NHS England's Outpatient Transformation Programme; and noting that it was unclear what was meant by *"linkage"*, asked that further clarity was provided, in line with NHS Digital DARS Standard for Expected Measurable Benefits. IGARD noted the content of the first paragraph in section 5(d) (iii) *"The analysis of the Care Quality Commission's special measures for quality regime carried out by the RSET team has led to the project team presenting findings to senior staff at the Department for Health and Social care and NHSEI's Joint strategic oversight group"*; and asked that either the statement that findings will be *"presented to senior staff at DHSC and NHSE/I's Joint Strategic Oversight Group"* was removed; or a further explanation was provided of the specific benefit of this to the health and social care system, in line with NHS Digital DARS Standard for Expected Measurable Benefits. IGARD noted that at the IGARD BAU meeting on the 19th August 2021, IGARD had asked that DARS clarify with the NHS Digital Security Advisor, what (if any) special conditions should be included within DSAs to address remote working arrangements, particularly during the COVID-19 pandemic. IGARD noted the update within section 1 (Abstract) that this issue was still ongoing and reiterated the point previously made. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 5(a) with the helpful information in the protocol relating to the distinction between the PPI Group and the RSET Advisory Board. 2. To provide clarity in section 5(c) how the data in this DSA and NIC-226261-M2T0Q are kept distinct, noting the different data controllership arrangements, including (but not limited to), the Quality Watch programme, which is referenced in both applications, how the data is used and how the different data controllership arrangements are maintained. 3. In respect of the yielded benefits in section 5(d) and in line with NHS Digital DARS Standard for Expected Measurable Benefits: a) To provide clarity in section 5(d) (iii) on the reference to *"linkage"* with NHS England's Outpatient Transformation Programme.

	b) To review the first paragraph in section 5(d) (iii) and either remove the statement that findings will be *"presented to senior staff at DHSC and NHSE/I's Joint Strategic Oversight Group"*; or provide a further explanation of the specific benefit of this to the health and social care system. The following amendment was requested: 1. IGARD reiterated their request (from the 19th August 2021): that DARS clarify with the NHS Digital Security Advisor, what (if any) special conditions should be included within DSAs as standard to address any remote working arrangements and particularly during the COVID-19 pandemic.
3.3	Imperial College London (ICL): COSMOS: Cohort Study of mobile phone use and health (MR1367) (Presenter: Anna Weaver) NIC-370843-R6V8T-v4.2 **Application:** This was an extension application to permit the holding and processing of identifiable Cancer Registration Data, Civil Registration (Deaths), Demographics data, Emergency Care Data Set (ECDS), Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC), HES Critical Care, HES Outpatients, Medical Research Information Service (MRIS) - Cause of Death Report, MRIS - Cohort Event Notification Report, MRIS - Flagging Current Status Report and MRIS - List Cleaning Report. The application was also an amendment to **1)** add a sub-licensing model for onward sharing to consortium members; and **2)** to change the territory of use from 'England & Wales' to 'UK & EEA'. The purpose of the application is for a major international research programme (COSMOS Study) into the possible health effects of long-term use of mobile phones and wireless technologies, and other environmental exposures, in particular addressing limitations of previous studies and gaps in the scientific evidence in order to provide clarity in respect of health effects of long-term use of mobile phones. The cohort consists of approximately 105,000 adult participants in the UK, who were invited to participate in the COSMOS study from mobile phone subscriber lists, data marketing lists and electoral register lists, and who consented to participate in the COSMOS study between 2009 and 2012. The application was previously considered on the 5th March 2020 where IGARD had deferred making a recommendation. NHS Digital noted that prior to the meeting, an IGARD member had submitted a request for a copy of the written advice from Privacy, Transparency and Ethics (PTE), in relation the sub-licensing; noting that this was usually provided as a supporting document. NHS Digital advised that the initial discussion with PTE was at a meeting between Data Access Request Service (DARS) and PTE, and that written confirmation of the PTE advice discussed at the meeting had been requested, however this had not yet been received. NHS Digital advised IGARD that there had been issues with the formatting of the draft sub licencing agreements documentation, and this had therefore meant that they had not been visible / available to IGARD members prior to the meeting as per usual process. NHS Digital confirmed that this issue had not been spotted until after the papers had been disseminated and that steps would be taken going forward to ensure this did not become a recurring issue, and apologised to members for any inconvenience. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the Data Access Advisory Group (DAAG) (IGARD's

	predecessor) / IGARD business as usual (BAU) meeting on the 13th August 2015, 5th March 2020 and the 20th May 2021. It was also discussed under 'AOB' at the IGARD BAU meeting on the 1st July 2021. IGARD noted that aspects of this application had been previously seen at the IGARD – NHS Digital COVID-19 Response meeting on the 15th June 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 11th November 2021. IGARD noted and thanked NHS Digital for the verbal update in respect of the outstanding written PTE advice with regards to sub-licensing; and asked that once the written advice was received from PTE, that this was uploaded to NHS Digital's customer relationships management (CRM) system for future reference and provided at any future IGARD meeting as a supporting document. IGARD noted and thanked NHS Digital for the verbal update in respect of the issues with the formatting of the draft sub licencing agreements documentation, which had meant members were unable to review prior to the meeting as per process. IGARD asked that for clarification and future reviews / reference, section 1 (Abstract) was updated, to clearly state that the draft sub-licensing arrangements had been reviewed by, and an analysis undertaken by, NHS Digital and had met NHS Digital DARS standard for sub-licencing and onward sharing in **all** respects. IGARD noted the conflicting information in section 5(a) (Objective for Processing) that stated *"Sublicensing agreements will be limited to consortium members and the number of sub-licensees will not exceed 4 at any one time."*, and section 10 (Sub-licensing) that listed more than four sub-licensees. IGARD asked that the application was reviewed to ensure it accurately reflected the correct number of sub-licensees and that the description of the numbers reflected the facts now and in the future. IGARD noted the data flow diagram that had been provided as a supporting document, however queried some of the content, including, but not limited to *"Imperial College will request the Data Processors to delete record ID number from the dataset and therefore the data will become fully anonymised"*. IGARD asked that the data flow diagram was reviewed to ensure the description of the flows and nature of the data accurately described what was happening with the data in the hands of the sub-licensees and at what point it would stop being NHS Digital data and stop being covered by contract accordingly. IGARD asked that NHS Digital considered whether they were satisfied with the effectiveness of automatic termination (sub licence terminating immediately upon termination of Data Sharing Framework Contract (DSFC) or Data Sharing Agreement (DSA)) and with the governing law provisions in the sub-licensing documentation. IGARD noted that the applicant had previously provided protocol addendums, which had been reviewed by members; and that in previous versions of the application, for example, version 2.5 that was discussed at the IGARD – NHS Digital COVID-19 Response meeting on the 15th June 2021, contained a special condition that ICL would produce and provide NHS Digital with an updated study protocol, reflecting the changes made to the original version via the respective addendums in 2007, 2013, 2017 and 2021. Noting that the special condition was not included in this version of the application, and that the updated protocol was still outstanding, IGARD asked that the special condition was again added to the special conditions in Section 6, with an agreed timeframe for providing the updated protocol.

	Outcome: recommendation to approve The following amendments were requested: 1. In respect of sub-licensing: a) To update section 1 to clearly state that the draft sub-licensing arrangements have been reviewed and have met NHS Digital DARS standard for sub-licencing and onward sharing in all respects. b) To ensure the application accurately reflects the correct number of sub-licensees and that the description of the numbers reflects the facts now and in the future. c) To review the data flow diagram to ensure the description of the flows and nature of the data accurately describes what is happening with the data in the hands of the sub-licensees and at what point it will stop being NHS Digital data and covered by contract accordingly. 2. To insert a special condition in section 6 that ICL will produce and provide NHS Digital with an updated study protocol, reflecting the changes made to the original version via the respective addendums in 2007, 2013, 2017 and 2021 (as noted in version 2.5 of the DSA) with an agreed timeframe for providing this. The following advice was given: 1. That NHS Digital consider whether they are satisfied with the effectiveness of the automatic termination (sub licence terminating immediately upon termination of DSFC or DSA) and governing law provisions in the sub-licensing documentation.
3.4	Medicines and Healthcare Products Regulatory Agency (MHRA) / Clinical Practice Research Datalink (CPRD): R23 - Clinical Practice Research Datalink (CPRD) Routine Linkages Application (Presenter: Catherine Day) NIC-15625-T8K6L-v11.2 **Application:** This was an amendment application to request NHS Digital to link the GP System data provided by CPRD to the following datasets provided to NHS Digital from University Hospitals Birmingham (UHB): **1)** Secondary Care data (including demographics, diagnoses, prescriptions, procedures and clinical investigations) from the Birmingham and Solihull Sustainability and Transformation Partnership (STP); **2)** Screening data from the Birmingham Solihull and Black Country Diabetic Eye Screening Service (BSBCDESS). The purpose of the amendment was for NHS Digital to act as a Trusted Third Party to link GP System data (as supplied by CPRD) to the above datasets; which comprise data from a number of different clinical systems held within UHB, including prescribing systems (PICS), laboratory systems (Telepath), health record noting (PICS / Clinical Portal / Medisoft) and patient administrative system, Imaging modalities (e.g. XRay: MRI: CT: OCT: Retinal photography) and clinically relevant parameters (ECG and EEG). NHS Digital advised IGARD that, following the IGARD business as usual (BAU) meeting on the 27th January 2022 where a briefing paper had been presented providing IGARD with an update on some of the previous issues raised in respect of this application, work was ongoing with CPRD to resolve the outstanding issues. NHS Digital also advised IGARD that an audit of this organisation / data sharing agreement (DSA) was due to take place imminently, and that findings from the audit were expected to be made available to the public later this year. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the Data Access Advisory Group (DAAG) (IGARD's predecessor) / IGARD BAU meetings on the on 24th January 2017, 22nd June 2017, 20th

	September 2018, 17th October 2019, 6th February 2020, 27th February 2020, 19th March 2020 and 16th July 2020. A briefing paper was provided to IGARD on this application and discussed at the IGARD BAU meeting on the 27th January 2022. The application had also been discussed under 'AOB' at the IGARD BAU meetings on the 8th November 2018 and 27th August 2020. IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 12th May 2020, 19th May 2020, 26th May 2020, 6th October 2020 and 13th October 2020. IGARD noted that they would be reviewing this application in respect of the two amendments **only** and would not be undertaking a full review of the application. IGARD queried what the specific benefit of processing the UHB data would add and whether or not it would replicate the data UHB send to NHS Digital as a matter of course, and subsequently be available from NHS Digital. IGARD asked that for transparency, a clear explanation was added to section 5(a) (Objective for Processing). IGARD noted that prior to the meeting, an IGARD member had queried with NHS Digital if there was any evidence that the UHB datasets were on the list covered by the current Health Research Authority Confidentiality Advisory Group (HRA CAG) support. NHS Digital advised CPRD were in discussions with HRA CAG to have an appropriate master data setlist published on the CPRD website. IGARD noted the update from NHS Digital and advised that they would expect an update on this on renewal. IGARD noted that there should be transparency available to those individuals residing in Birmingham or captured in the UHB datasets, and that the CPRD transparency materials should not be solely relied upon in terms of compliance with the UK General Data Protection Regulation (UK GDPR). IGARD noted the yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits) and advised that IGARD would provide comments / suggestions out of committee, to support the review / updates to this section; and advised that all updates and amendments should be done in line with the NHS Digital DARS Standard for expected measurable benefits. IGARD noted the importance of up to date yielded benefits in section 5(d) (iii) (Yielded Benefits) and noted they were not currently in a form ready to be reviewed by IGARD, and would expect this section to have been updated on renewal and in line with NHS Digital DARS Standard for Expected Measurable Benefits. IGARD noted that there were several special conditions in Section 6 relating to where the COVID-19 Hospitalization in England Surveillance System (CHESS) and COVID-19 Second Generation Surveillance System (SGSS) datasets can be held and for how long they can be retained. There are also restrictions on the CHESS and SGSS datasets within Section 10 (sub-licensing). IGARD suggested DARS review the restrictions in Section 6 and section 10 to ensure they are aligned with current policy, for example, it is currently stated CHESS and SGSS data must be destroyed within 30 days of the COPI notice expiring if HRA CAG approval had not been requested. IGARD suggested a careful review was carried out of all CPRD activities in line with the NHS Digital DARS Standard for Commercial Purpose, and that the public facing section 5 (Purpose / Methods / Outputs) should be updated to ensure that all commercial aspects were explained in a transparent manner, and would expect an update on renewal.

	IGARD noted a number of open issues for resolution and as discussed at previous IGARD meetings, and would expect these to be addressed on renewal. IGARD advised that they **would wish to review** this application when it comes up for renewal, extension or amendment, to review the yielded benefits accrued to date and progress on open issues. IGARD suggested that this application **would not** be suitable for NHS Digital's Precedent route, including the SIRO Precedent. **Outcome:** recommendation to approve in respect of the two amendments only The following amendments were requested: 1. To update section 5(a) with a clear explanation as to the specific benefit processing the UHB data will add, in light of the fact that it would appear to replicate the data UHB would send to NHS Digital as a matter of course (and subsequently be available from NHS Digital). 2. To update the yielded benefits in line with the NHS Digital DARS Standard for expected measurable benefits as per the verbal update from NHS Digital. 3. To update section 6 and section 10, to reflect current restrictions on the use of the CHESS / SGSS data. The following advice was given: 1. IGARD noted that publication of CPRD's master data setlist was being discussed with HRA CAG, and would expect an update on renewal. 2. IGARD noted that there should be transparency available to those individuals residing in Birmingham or captured in the UHB datasets and that the CPRD transparency materials should not be relied upon in terms of compliance with the UK GDPR. 3. IGARD noted the importance of up to date yielded benefits and noted they were not in a form ready to be reviewed by IGARD, and would expect an update on renewal and in line with NHS Digital DARS Standard for Expected Measurable Benefits. 4. IGARD suggested a careful review was carried out of all CPRD activities in line with the NHS Digital DARS Standard for Commercial Purpose, and that section 5 should be updated to ensure that all commercial aspects are explained in a transparent manner, and would expect an update on renewal. 5. IGARD noted a number of open issues for resolution and would expect these to be addressed on renewal. 6. IGARD advised that they **would wish to review** this application when it comes up for renewal, extension or amendment, to review the yielded benefits accrued to date and progress on open issues. 7. IGARD suggested that this application **would not** be suitable for NHS Digital's Precedent route, including the SIRO Precedent.
3.5	Alcohol Dependence Class Action Application for CCGs (Presenter: Michael Ball) NIC-433201-T9F0N **Application:** This was a new class action application for **all** Clinical Commissioning Groups (CCGs) in England (please see Appendix B) with Delegated Commissioning responsibilities to receive Alcohol Dependence data. The NHS Long Term Plan (LTP) sets out a number of commitments in relation to prevention including optimisation of hospital services that support alcohol dependent inpatients, specifically in the form of Alcohol Care Teams (ACTs); which are liaison services that support

	patients who are in hospital who have alcohol use disorders, mainly those who are alcohol dependent. ACTs provide specialist treatment interventions such as facilitating medically assisted withdrawal to ensure that they can be safely treated for their primary admission. ACTs also provide psychosocial intervention and liaise with in and out of hospital services to contribute to a pathway of care that improves the likelihood that individuals can remain alcohol free. Patient level data is required specifically to monitor activity and impact of ACTs in hospitals in receipt of targeted funding, especially in terms of clinical outcomes and the impact on closing health inequalities. **Discussion:** IGARD queried if the Alcohol Dependence dataset would automatically be available to each CCG via their individual Data Sharing Agreement (DSA) and were advised by NHS Digital that each individual CCG would need to expressly request the dataset from the Data Services for Commissioners Regional Office (DSCRO), and this dataset was not automatically disseminated to each CCG. IGARD noted and thanked NHS Digital for the verbal update, and asked that for transparency, section 5(b) (Processing Activities) was updated to reflect this. In addition, IGARD suggested across all CCG / Integrated Care Board (ICB) documentation, where there was a permissive mechanism within the DSA for access to datasets, that it was clear that each CCG / ICB would have to proactively ask the DSCRO for each dataset. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 5(b) to make clear that each individual CCG will need to expressly request the dataset from the DSCRO and this is not automatically disseminated to them. The following advice was given: 1. IGARD suggested across all CCG / ICB documentation where there is a permissive mechanism within the DSA for access to datasets, that it is clear that each CCG / ICB will have to proactively ask the DSCRO for each dataset.
3.6	<u>Tobacco Dependence Class Action Application for CCGs (Presenter: Michael Ball) NIC-448436-M5H5P</u> **Application:** This was a new class action application for **all** Clinical Commissioning Groups (CCGs) in England (please see Appendix B) with Delegated Commissioning responsibilities to receive Tobacco Dependence data. The NHS Long Term Plan (LTP) set out a number of commitments towards the prevention of ill health, including the implementation of the Prevention Programme – NHS funded tobacco dependence treatment services. To deliver these commitments, NHS England / Improvement is investing £150m by 2023/24 through the LTP, specifically to roll out the NHS-funded tobacco dependence treatment services across inpatient, maternity and specialist mental health outpatient/community settings. This work builds on the previous Preventing Ill Health Commissioning for Quality and Innovation (CQUIN) which incentivised the data collection and reporting on smoking status and the provision of very brief advice at a point when people are more likely to make changes and adopt healthier behaviours. This CQUIN (which was extended into 2019/20) has acted as an enabler to now stand up a distinct data collection for identifying smokers so that this

	information can be used to underpin the identification of smokers and onward development / delivery of local services. **Discussion:** IGARD queried if the Tobacco Dependence dataset would automatically be available to each CCG via their individual Data Sharing Agreement (DSA) and were advised by NHS Digital that each individual CCG would need to expressly request the dataset from the Data Services for Commissioners Regional Office (DSCRO), and this dataset was not automatically disseminated to each CCG. IGARD noted and thanked NHS Digital for the verbal update, and asked that for transparency, section 5(b) (Processing Activities) was updated to reflect this. In addition, IGARD suggested across all CCG / Integrated Care Board (ICB) documentation where there was a permissive mechanism within the DSA for access to datasets, that it was clear that each CCG / ICB would have to proactively ask the DSCRO for each dataset. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 5(b) to make clear that each individual CCG will need to expressly request the dataset from the DSCRO and this is not automatically disseminated to them. The following advice was given: 1. IGARD suggested across all CCG / ICB documentation where there is a permissive mechanism within the DSA for access to datasets, that it is clear that each CCG / ICB will have to proactively ask the DSCRO for each dataset.
4	<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).
4.1	<u>NIC-274291-Q5T1S-v2.3 NHS Nottingham and Nottinghamshire CCG (No Presenter)</u> The purpose of this application is to ensure that analysis of health care provision can be completed to support the needs of the health profile of the population within each CCG area based on the full analysis of multiple pseudonymised datasets. IGARD noted that this application was last reviewed at the IGARD business as usual meeting on the 3rd March 2022. IGARD noted that on the 5th April 2022, NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had agreed to authorise a three month renewal to the data sharing agreement (DSA) to allow additional time for the outstanding conditions / amendments to be addressed. IGARD noted and thanked NHS Digital for the written update and asked that the next iteration of the DSA should be brought to a future IGARD BAU meeting.
4.2	<u>NIC-12784-R8W7V-v9.6 Genomics England (No Presenter)</u> The purpose of this application, is to support the national Genomic Medicine Service (GMS), building on the 100,000 Genomes Project. This includes a national Whole Genomic Sequencing provision and supporting informatics infrastructure developed in partnership with

	Genomics England. Genomics England will therefore undertake genomic sequencing and clinical data collection for the new GMS. IGARD noted that this application was last reviewed at the IGARD business as usual meeting on the 13th August 2020. IGARD noted that on the 13th April 2022, NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had agreed to authorise a three month renewal to the data sharing agreement (DSA). IGARD noted and thanked NHS Digital for the written update and asked that the next iteration of the DSA should be brought to a future IGARD BAU meeting, **Separate to this application**: NHS Digital to provide its position on remote access in relation to the listed territory of use in the DSA.
5	Oversight & Assurance IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. Due to the volume and complexity of applications at today's meeting, IGARD were unable to review any Data Access Request Service (DARS) applications as part of their oversight and assurance role. IGARD 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 January 2022. IGARD Members noted that the last IG COVID-19 release register that they had reviewed and provided comments on was January 2022. IGARD noted that the NHS Digital webpage excel spreadsheet had now been updated for the period March 2020 to February 2022: NHS Digital Data Uses Register - NHS Digital.
6	COVID-19 update *No items discussed*
7 **7.1**	AOB: NIC-580886-S2M3Z-v0.3 - NHS Oldham CCG (Presenters: Dan Goodwin / Michael Ball) IGARD noted that at the IGARD BAU meeting on the 3rd February 2022, the following action was raised on the above application: > NHS Digital to provide IGARD with a copy of the analysis of how the CLDoC is satisfied in respect of the receipt of GP data and Adult Social Care data; and that moving forward, a brief explanation should be included in section 1 of relevant applications as standard practice (see amendment points 1(a), 1(b) and 4). NHS Digital attended the meeting to discuss an initial response provided and advice from the NHS Digital legal team. It was agreed that DARS should discuss further with the Caldicott Guardian, senior managers in DARS and the Legal Team and noted that it was up to the applicant to establish how the common law duty of confidentiality was being met when transferring data that is subsequently linked with NHS Digital data. IGARD noted there was a

	reputational risk to NHS Digital but that the duty of confidentiality needed to be met by the CCG and the body supplying identifiable data to the CCG.
7.2	<u>Information Governance</u> A member of NHS Digital's Privacy, Transparency and Ethics, attended the meeting to provide a brief update / overview of ongoing information governance (IG) work. IGARD raised a number of outstanding IG related points, namely the request for an update on issues raised on previously disseminated IG COVID-19 release register (March 2020 to January 2022), a request for an update on their feedback of IG-00517, and a request for a further release register entry to provide an in-depth review (see section 5). 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 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 22/04/22

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)
NIC-460711-S8W6S-v0.13	Liverpool Heart and Chest Hospital NHS FT	10/03/2022	1. To confirm that the data flow diagram provided as a supporting document is the same data flow diagram provided to and approved by HRA CAG. 2. In respect of Heartflow Inc. (based in Redwood City, USA): a) To list Heartflow Inc. as a funding source in section 8(b) (as indicated in the protocol provided as a supporting document), and b) To update the application throughout to make clear that Heartflow Inc. were the organisation who originally developed the tool (and funded the FORECAST trial which used NHS Digital data under NIC-292087-M7V9Q), and c) NHS Digital to satisfy itself that Heartflow Inc are not carrying out any Data Controller activities, and in line with the NHS Digital DARS Standard for Data Controllers, and to specifically address the facts for	IGARD members	Quorum of IGARD members	**Request from IGARD:** 5b needs amending, currently it states *"All analysis will be performed on the linked data by LHCH CTU. HeartFlow Inc, will have no access to any NHS Digital data and are not processing the data.* ***There will be no subsequent flows of data****."* Taken at face value this would prevent Heartflow receiving even anonymous data. 5a, 5c and 5e imply they are likely to receive aggregated data with small numbers suppressed. This is appropriate but needs to be transparent and explained consistently throughout the application, since the response to the condition and narrative in 5e

			example the references to Heartflow Inc. appointing a UK lead for engagement and advocacy and Heartflow Inc. UK Lead working closely and NHS England and the link to the accelerated access collaboration, and d) To make clear in section 5 that Heartflow Inc are a funder. e) To update section 5b outlining the nature of the data received by Heartflow Inc as set out in section 5e.			suggests they may get the aggregated supressed data. The text in 5b is contradictory suggesting they are not allowed to have any date. This needs updating to acknowledge Heartflow may get aggregated suppressed data.
NIC-605115-L0W3V-v1.3	University of Oxford	17/03/2022	1. In respect of the SCR (repeating the advice from IGARD's previous review): a) That the transparency wording for patients on NHS Digital's website be updated to expressly refer to the SCR being used for research and specifically name the Panoramic Trial, noting it is a specific exception to the SCR policy (which states that the SCR will not be used for research). b) NHS Digital to update CRM to reflect the current / correct status of this action and note that the previous action taken updated the transparency pages for clinicians only and omitted updating the pages aimed at the general public. 2. In respect of the legal basis: a) To provide written confirmation from NHS Digital's Caldicott Guardian that they are content that only COPI is	IGARD members	Quorum of IGARD members	**Request from IGARD:** **Condition 2(a):** The request that was sent to the Caldicott Guardian stated *"Upon Expiry of COPI, Legal Basis would revert to Consent"* implying it would only be accessed under COPI before then. However, it is not clear that *"access to SCR was agreed by IGARD under COPI"*. This may be a reference to a COVID-19 Response Meeting discussion. We think it is problematic to *"revert to Consent"* – it suggests consent is being taken but then overridden by COPI (but if consent is in place there is no need to override it).

			being relied on for both pillar 2 data and access to the SCR; and, b) To update the application throughout to reflect the NHS Digital's Caldicott Guardian's contentment. c) To upload the written conformation to NHS Digital's CRM system for future reference.			**Condition 2(c):** we would advise that the Caldicott Guardian is updated pointing out that the SCR patient webpage refers to use within the trials with the permission of the participants not via the Health Service (Control of Patient Information) Regulations 2002.

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

Appendix B

Alcohol Dependence Class Action Application (item 3.5) and Tobacco Dependence Class Action Application (item 3.6) - CCGs

NHS BARNSLEY CCG
NHS BASILDON AND BRENTWOOD CCG
NHS BASSETLAW CCG
NHS BATH AND NORTH EAST SOMERSET, SWINDON AND WILTSHIRE CCG
NHS Bedfordshire, Luton and Milton Keynes CCG
NHS BERKSHIRE WEST CCG
NHS BIRMINGHAM AND SOLIHULL CCG
NHS Black Country and West Birmingham CCG
NHS BLACKBURN WITH DARWEN CCG
NHS BLACKPOOL CCG
NHS BOLTON CCG
NHS BRADFORD DISTRICT AND CRAVEN CCG
NHS BRIGHTON AND HOVE CCG
NHS BRISTOL, NORTH SOMERSET AND SOUTH GLOUCESTERSHIRE CCG
NHS BUCKINGHAMSHIRE CCG
NHS BURY CCG
NHS CALDERDALE CCG
NHS CAMBRIDGESHIRE AND PETERBOROUGH CCG
NHS CANNOCK CHASE CCG
NHS CASTLE POINT AND ROCHFORD CCG
NHS CHESHIRE CCG
NHS CHORLEY AND SOUTH RIBBLE CCG
NHS COUNTY DURHAM CCG
NHS Coventry and Warwickshire CCG
NHS DERBY AND DERBYSHIRE CCG
NHS DEVON CCG
NHS DONCASTER CCG
NHS DORSET CCG
NHS EAST AND NORTH HERTFORDSHIRE CCG
NHS EAST LANCASHIRE CCG
NHS EAST LEICESTERSHIRE AND RUTLAND CCG
NHS EAST RIDING OF YORKSHIRE CCG
NHS EAST STAFFORDSHIRE CCG
NHS EAST SUSSEX CCG
NHS Frimley CCG
NHS FYLDE AND WYRE CCG
NHS GLOUCESTERSHIRE CCG
NHS GREATER PRESTON CCG

NHS HALTON CCG
NHS Hampshire, Southampton and Isle of Wight CCG
NHS HEREFORDSHIRE AND WORCESTERSHIRE CCG
NHS HERTS VALLEYS CCG
NHS HEYWOOD, MIDDLETON AND ROCHDALE CCG
NHS HULL CCG
NHS IPSWICH AND EAST SUFFOLK CCG
NHS KENT AND MEDWAY CCG
NHS KERNOW CCG
NHS Kirklees CCG
NHS KNOWSLEY CCG
NHS LEEDS CCG
NHS LEICESTER CITY CCG
NHS LINCOLNSHIRE CCG
NHS LIVERPOOL CCG
NHS MANCHESTER CCG
NHS MID ESSEX CCG
NHS MORECAMBE BAY CCG
NHS NEWCASTLE GATESHEAD CCG
NHS NORFOLK AND WAVENEY CCG
NHS NORTH CENTRAL LONDON CCG
NHS NORTH CUMBRIA CCG
NHS NORTH EAST ESSEX CCG
NHS NORTH EAST LINCOLNSHIRE CCG
NHS North East London CCG
NHS NORTH LINCOLNSHIRE CCG
NHS NORTH STAFFORDSHIRE CCG
NHS NORTH TYNESIDE CCG
NHS North West London CCG
NHS NORTH YORKSHIRE CCG
NHS NORTHAMPTONSHIRE CCG
NHS NORTHUMBERLAND CCG
NHS NOTTINGHAM AND NOTTINGHAMSHIRE CCG
NHS OLDHAM CCG
NHS OXFORDSHIRE CCG
NHS PORTSMOUTH CCG
NHS ROTHERHAM CCG
NHS SALFORD CCG
NHS SHEFFIELD CCG
NHS Shropshire, Telford and Wrekin CCG
NHS SOMERSET CCG
NHS SOUTH EAST LONDON CCG
NHS SOUTH EAST STAFFORDSHIRE AND SEISDON PENINSULA CCG

NHS SOUTH SEFTON CCG
NHS SOUTH TYNESIDE CCG
NHS SOUTH WEST LONDON CCG
NHS SOUTHEND CCG
NHS SOUTHPORT AND FORMBY CCG
NHS ST HELENS CCG
NHS STAFFORD AND SURROUNDS CCG
NHS STOCKPORT CCG
NHS STOKE ON TRENT CCG
NHS SUNDERLAND CCG
NHS SURREY HEARTLANDS CCG
NHS TAMESIDE AND GLOSSOP CCG
NHS TEES VALLEY CCG
NHS THURROCK CCG
NHS TRAFFORD CCG
NHS VALE OF YORK CCG
NHS WAKEFIELD CCG
NHS WARRINGTON CCG
NHS WEST ESSEX CCG
NHS WEST LANCASHIRE CCG
NHS WEST LEICESTERSHIRE CCG
NHS WEST SUFFOLK CCG
NHS WEST SUSSEX CCG
NHS WIGAN BOROUGH CCG
NHS WIRRAL CCG