Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 27 October 2022

Version 2 of minutes published 18/11/2022 replacing version 1 published 04/11/2022

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Prof. Nicola Fear	Specialist Academic Member (items 1 to 3.4)
Dr. Robert French	Specialist Academic / Statistician Member
Kirsty Irvine (Chair)	IGARD Chair
Dr. Imran Khan	Specialist GP Member / Co-Deputy IGARD Chair
Dr. Maurice Smith	Specialist GP Member
Jenny Westaway	Lay Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Paul Affleck	Specialist Ethics Member / Co-Deputy IGARD Chair
Maria Clark	Lay Member
Dr. Geoffrey Schrecker	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Garry Coleman	Associate Director, Deputy SIRO & Audit Services (**Observer:** Item 5.1)
Catherine Day	Data Access Request Services (DARS SAT) (**SAT Observer**: item 4)
Louise Dunn	Data Access Request Services (DARS SAT) (**SAT Observer**: items 3.2 to 3.4, and 5.1) (Item 4 and item 7.2)
Duncan Easton	Data Access Request Services (DARS SAT) (Item 6)
Suzanne Hartley	Data Access Request Services (DARS) (Item 5.1)
Mary Kisanga	Data Access Request Services (DARS SAT) (**SAT Observer**: item 3.3)
Susan Main	Data Access Request Services (DARS) (Item 7)
Frances Perry	Digi-Trials (Item 3.4)
Denise Pine	Data Access Request Services (DARS) (Item 3.2)

Aisha Powell	Data Access Request Services (DARS) (Item 3.3)
Emma Russell	Digi-Trials (**Observer**: Item 3.4)
Charlotte Skinner	Data Access Request Services (DARS) (Item 3.1)
Jodie Taylor-Brown	Data Access Request Services (DARS) (**Observer**: items 3.2 to 3.3)
Kimberley Watson	Data Access Request Services (DARS SAT) (**SAT Observer:** 3.1) (item 7.2)
Vicki Williams	IGARD Secretariat Team
***SAT** – Senior Approval Team (DARS)	

1	**Declaration of interests:** Prof Nicola Fear noted a professional link to one of the co-investigators involved with NIC-666525-M8L1F-v0.3 [University of Leeds] but noted no specific connection with this application and it was agreed this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 20th October 2022 IGARD meeting were reviewed and, subject to a number of minor amendments, were agreed as an accurate record of the meeting. **Out of committee recommendations:** An out of committee report was received (see Appendix A).
2	**Briefing Notes**
2.1	*No items discussed*
3	**Data Applications**
3.1	University of Leeds: Frequent Users of the Emergency Department (FUsED): improving and standardising services – a mixed methods study (Presenter: Charlotte Skinner) NIC-666525-M8L1F-v0.3 **Application:** This was a new application for pseudonymised Civil Registration (Deaths) secondary care cut data, Emergency Care Data Set (ECDS), Hospital Episode Statistics (HES) Accident & Emergency (A&E) data, HES Admitted Patient Care (APC), HES Critical Care, HES Outpatients, Medicines dispensed in Primary Care (NHSBSA data) and Mental Health Services data set (MHSDS). The purpose of the application is for research to understand patterns of frequent use, health costs and impact of current services on frequent users of emergency departments in England. There is no agreed definition of 'frequent users' of emergency departments and for the purpose of this study, the research team begin with the definition of frequent attendance as 5 or more attendances in a 12-month period. This application is one of four workstreams of mixed method projects of frequent users of emergency departments and the services provided for this group of patients. The objectives of

	workstream 2, this data sharing agreement (DSA), are to characterise patterns of frequent use and their association with patient characteristics; examine use of the whole urgency and emergency care network by frequent users; describe the costs associated with frequent users; conduct interrupted time series analysis of frequent user use to understand the impact of initiations of services for those users and the COVID-19 pandemic. Prior to the meeting, NHS Digital notified IGARD that the request for NHSBSA data had been removed from the application, however this was later retracted because the Information Asset Administrator (IAA) had later confirmed that the scope of processing was within the parameters of the Direction. **Discussion:** IGARD welcomed the application and noted the importance of study, in addition they noted it was a well written and constructed application, which supported the review of the application by members. IGARD had raised queries in advance with NHS Digital with regard to the request by the applicant for national data and asked if there had been any discussion on the justification for this. NHS Digital was of the view that a justification for the breadth of national data had been provided in the protocol, provided as a supporting document. Noting that the applicant's protocol was not published on the NHS Digital data uses register, IGARD asked that section 5 (Purpose / Methods / Outputs) was updated with a narrative around the consideration of data minimisation in line with the NHS Digital DARS Standard for Data Minimisation and that a further justification for the request for national data be included. In addition and in line with NHS Digital DARS standard for data minimisation, IGARD asked that the data minimisation column in section 3(b) (Additional Data Access Requested), be updated to provide an explanation of the data minimisation efforts undertaken specific to each dataset requested. IGARD noted that, in the main, the language used was sensitive and sympathetic to the needs of frequent users, but that there was a couple of lapses in this, for example references to those individuals being a *"problem for healthcare services"* or 'a "..***burde**n on EDs*…"* and asked that further sensitive consideration was given to the patient audience, how this type of language could be perceived and removed where necessary. **Emergency Departments* IGARD noted that section 7 (Ethics Approval) stated *"Ethics approval is not required because no flow of confidential data is included"*; however, queried this, noting that the application and protocol had confirmed that local institutional ethics had been obtained for the study. IGARD asked that section 7 was updated to reflect that there was local institutional ethics approval for the study and that a copy be uploaded to NHS Digital's customer relationship management (CRM) system for future reference (see AOB item 7.2), particularly because section 5(a) (Objective for Processing) of the application stated "…*the FUsED project has received ethical approval on the 26th July 2022 (MREC 21-061)*…" IGARD noted reference to patient and public involvement and engagement (PPIE) in section 5(d) (Benefits) and noting this was the first reference to PPIE in the application, suggested that while this was welcome, this was not a benefit of the use of the data, and that the narrative be moved to section 5(a). IGARD noted that prior to the meeting, NHS Digital had noted that the applicant had wished to remove the NHSBSA data from their request, but that the NHS Digital Information Asset Administrator (IAA) had confirmed in writing that the applicant's request was within the scope of the Direction for the collection of NHSBSA data, specifically, *"Providing intelligence about*

	the safety and effectiveness of medicines…". IGARD thanked NHS Digital and the IAA and asked that the email, confirming this position, from the IAA be uploaded to NHS Digital's customer relationship management (CRM) system for future reference. IGARD confirmed that they would be supportive of the inclusion of the NHSBSA data, and asked that section 3(b) was updated as appropriate to reflect the addition of this dataset (if NHS Digital had already removed the dataset from the updated DSA) and the application would not need to return to IGARD for a review for this amendment. In addition, IGARD asked that a special condition was inserted in section 6 (Special Conditions), that any use of the NHSBSA data must be within the parameters of the relevant Direction authorising that collection, if the applicant chose to include the NHSBSA data. **Separate to this application**: IGARD reiterated their suggestion from the 7th April 2022, that the Data Access Request Service (DARS) update their relevant onboarding documentation to ensure DARS staff are aware of the constraints placed in the Direction for the collection of NHSBSA data and the relevant updates required within the DSA. IGARD suggested that if the applicant had carried out a Data Protection Impact Assessment (DPIA), due to the scale and sensitive nature of the data flowing, that a copy be uploaded to NHS Digital's customer relationship management (CRM) system for future reference. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of data minimisation and in line with NHS Digital DARS standard for data minimisation: a. To update the data minimisation column in section 3, to provide an explanation specific to each dataset, b. To update section 5 with a further narrative around the data minimisation, and c. To update section 5 with further justification for the request for national data. 2. To update section 5 to ensure it is written in language suitable for a lay reader and that sensitive consideration is given to the patient audience, for example removing reference to *"burden".* 3. In respect of the NHSBSA data: a. To insert a special condition in section 6, that any use of the NHSBSA dataset must be within the parameters of the relevant Direction authorising that collection, if that data is included in the DSA. b. To re-add the NHSBSA data to section 3(b), if it had been removed by NHS Digital c. To upload a copy of the IAA email to CRM as a future supporting document. 4. In respect of the benefits in section 5(d) and in line with the NHS Digital DARS Standard for Expected Measurable Benefits to remove the PPIE information from section 5(d) and move into section 5(a). 5. In respect of local / institutional ethics: a. To update section 7 to reflect that there is local institutional ethics approval for the study. b. To upload a copy of the most recent local ethics documentation to NHS Digital's CRM for future reference. The following advice was given:

	1. IGARD suggested that if the applicant had carried out a DPIA, due to the scale and sensitive nature of the data flowing, that a copy be uploaded to NHS Digital's CRM for future reference. 2. Noting that NHS Digital would need to discuss with the applicant the NHSBSA data re-inclusion in the DSA (if it had already been removed by NHS Digital), IGARD advised that they would be supportive of the flow of this 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. **Separate to this application:** IGARD reiterated their suggestion from the 7th April 2022, that DARS update their relevant onboarding documentation to ensure DARS were aware of the constraints placed in the Direction for the collection of NHSBSA data and the relevant updates required within the DSA. **NHS Digital DARS internal process pilot** Separate to the application and in relation to the pilot, IGARD suggested: 1. Additional narrative be provided on the assessment form including: a. Data minimisation discussions, b. Data controllership questions asked and answered. 2. Ensure relevant key information is included in section 1 of the application.
3.2	3M United Kingdom Plc: Data extract to support the continued accuracy of 3M developed quality and performance indicators for commissioners and providers (Presenter: Denise Pine) NIC-91972-S9W9T-v7.4 **Application**: This was an extension application to permit the continued retention and processing of pseudonymised Hospital Episode Statistics (HES) Admitted Patient Care (APC) and HES Outpatients data. 3M wish to process five years of pseudonymised HES data, received under previous iterations of this data sharing agreement (DSA), in order to validate and refine complex clinical algorithms and ensure they remain tuned as accurately as possible to the NHS experience. The data will be used to anglicise the 3M APR-DRG and 3M CRG (grouper) solutions, specifically by supporting the development of crosswalk tables and algorithms between UK coding classifications (and other NHS Data Dictionary items) and their international equivalents. The quality and performance indicators derived from these 3M solution suites will help the NHS better perform its duties by highlighting actionable areas for clinical and process improvement. NHS Digital noted that the current DSA had expired on the 2nd August 2022. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on 1st February and 1st November 2018, 17th January and 14th March 2019, 9th April 2020, 17th June 2021 and 3rd February 2022. It was also discussed under "AOB" at the IGARD BAU meeting on 30th April 2020. IGARD noted that when this application was reviewed on the 17th June 2021, they had advised NHS Digital that if, in 12-months, the applicant was not demonstrating effective use of the data, and could not produce / evidence satisfactory yielded benefits, then IGARD may recommend that the data was destroyed. IGARD noted that this iteration of the application appeared to have been updated in line with IGARD's requirements to demonstrate that the

	applicant had progressed with NHS clients. However, IGARD's request at the IGARD meeting on the 3rd February 2022, that a subject matter expert within NHS Digital undertake an assessment had not been met and IGARD members did not feel they could adequately evaluate necessity of ongoing use of the data for algorithmic validation outlined by the applicant in the application. IGARD noted a reputational risk factor to NHS Digital, that it was unclear if there was a robust use of health data, noting that IGARD advised NHS Digital to utilise their own internal expertise to assess this, and, following senior internal consideration, NHS Digital declined to act on that advice. Noting that IGARD remained unclear as to when any validation would be completed by, supporting NHS Digital's position that the DSA could not continue to be extended indefinitely, IGARD asked that section 5(c) (Specific Outputs Expected) was updated with specific narrative around the validation timeline. In addition, IGARD noted that, on return, they would expect to see 2 or 3 specific yielded benefits accrued to date relating to the validation of the tool. Noting that the world had significantly changed since this application was first submitted by the applicant, IGARD asked that section 5 (Purpose / Methods / Outputs) was updated to explain how the aged data was still informing the algorithm, for example (but not limited to) should the applicant be requesting 5 years of more recent data? In addition, further narrative should be included in section 5 providing a justification for the ongoing data retention. IGARD noted and thanked the applicant for the easily accessible transparency materials available via their website. IGARD noted in the applicant's quarterly report which had been submitted to NHS Digital that the applicant had "…*Submitted joint bid with IQVIA to support Population Health Management programme at London Procurement Partnership*…" and noting that there was no narrative in section 5 which forms NHS Digital's data uses register with regard to working with IQVIA, asked that for transparency, further detail of work with IQVIA be included in section 5. IGARD noted the useful information in section 5(e) (Is the purpose of this application in any way commercial) in relation to the commercial aspect of the application; and asked that the pertinent aspects of this were replicated in section 5(a) (Objective for Processing) of this application for transparency, and in line with NHS Digital DARS Standard for commercial purpose In respect of section 5(d) (Benefits) (iii) (Yielded Benefits) and in line with NHS Digital DARS Standard for Expected Measurable Benefits, to repopulate the yielded benefits as per the NHS Digital verbal update, which had noted that section 5(d) (iii) had been deleted in error. IGARD noted the reference to *"NHS Clinical Commissioning Groups (CCGs)"* in section 5 and asked that this was updated to correctly reference *"Integrated Care Boards (ICBs)"*, noting that ICBs replaced CCGs on the 1st July 2022. IGARD suggested that if the applicant had carried out a Data Protection Impact Assessment (DPIA), due to the processing of special-category data on a large scale, that a copy be uploaded to NHS Digital's customer relationship management (CRM) system for future reference. 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 need to consider whether continued use of large volumes of NHS data for ongoing validation of the 3M tool was justifiable.

	Outcome: recommendation to approve for 12 months **only**. The following amendment were requested: 1. To update section 5(c) with specific narrative around the validation timeline. 2. To provide a justification in section 5 for the ongoing data retention. 3. To update section 5 to explain how the aged data is still informing the algorithm. 4. To provide further detail in section 5 of the work with IQVIA. 5. To provide a brief summary in section 5(a) of the commercial aspect of this application, as outlined in section 5(e). 6. In respect of section 5(d) (iii) and in line with NHS Digital DARS Standard for Expected Measurable Benefits, to repopulate yielded benefits as per verbal update. 7. To update section 5 to remove reference to "*CCG*" and replace with "*ICB*". The following advice was given: 1. IGARD suggested that if the applicant had carried out a DPIA, due to the processing of special-category data on a large scale, that a copy be uploaded to NHS Digital's CRM for future reference. 2. IGARD noted that, on return they would expect to see specific yielded benefits accrued to date, relating to the validation of the tool. 3. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the ongoing validation of the tool 4. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to ongoing validation of the 3M tool using large volumes of NHS data. **Reputational Risk Factor:** it was unclear if there was a robust use of health data, noting that IGARD advised NHS Digital to utilise their own internal expertise to assess this, and, after consideration, NHS Digital declined to act on that advice. **Subsequent to the meeting**: IGARD noted that following publication of the IGARD minutes from the 27th October 2022, further background had been provided by NHS Digital regarding the issues considered internally regarding the 'reputational risk factor'. The NHS Digital Deputy SIRO advised that NHS Digital takes care to avoid creating the perception that, in considering data access requests, they might be seen to be endorsing a particular product and this was why they had not expressly assessed the potential utility of the algorithm. The Deputy SIRO suggested that to demonstrate benefit to health that a supporting statement from the named client of the applicant, confirming the forward work package, and a review in an appropriate timeframe, be required via a special condition to the agreement.
3.3	UK Haemophilia Centre Doctors' Organisation (UKHCDO): National Haemophilia Database (NHD) (Presenter: Aisha Powell) NIC-148030-Q5N4D-v4.2 **Application:** This was a renewal application for identifiable Civil Registration (Deaths) data, Medical Research Information Service (MRIS) Cause of Death Report, MRIS Cohort Event Notification Report, MRIS Flagging Current Status Report, MRIS Members & Postings Report, for the purpose of the National Haemophilia Database (NHD) which is a registry of more than 30,000 patients with bleeding disorders and changes in life expectancy registered since 1968, and has monitored treatment trends, morbidity and mortality associated with bleeding disorders, and changes in life expectancy. The UKHCDO requires data for the purpose of maintaining the NHD and using the database for both research and non-research purposes.

	The cohort of patients for the study is limited to 31,387, plus new additions, and is relying on s251 of the NHS Act 2006, for the flow of data from NHS Digital. NHS Digital noted that the current data sharing agreement (DSA) had expired on the 30th August 2022. NHS Digital noted that section 6 should be updated to include a special condition that the outputs cite the source of the data. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on 14th May 2021. It was also discussed as part of the 'applications progress via NHS Digital's SIRO Precedent' on the 26th August 2021 IGARD confirmed that they were of the view that the relevant s251 support was broadly compatible with the processing outlined in the application and asked that section 5 clearly stated that this data sharing agreement (DSA) was for those covered under s251 support **only**. IGARD noted that in 2019 the UKHCDO had spoken with the Health Research Authority Confidentiality Advisory Group (HRA CAG) and was advised to implement a process of obtaining written informed consent for those data subjects whose data was recorded in the Research Registry. The UKHCDO obtained consent for around 2,000 individuals before deciding not to continue and instead to seek s251 support to process data without informed consent. However, the HRA CAG s251 letter, provided as a supporting document, stated that the 2,000 individuals previously consented would be outside the scope of this support. IGARD was unclear whether HRA CAG considered that the consent given by those 2000 patients was compatible with the proposed flow of data or not. IGARD noted that NHS Digital had assessed the historical consent materials and did not consider the consent to be sufficient to provide a legal basis, as outlined in IGARD's published minutes of the 7th April 2021. IGARD therefore asked that section 5 (Purpose / Methods / Outputs) make clear that this DSA does **not** cover those 2,000 individuals who were previously consented, notwithstanding the HRA CAG letter as discussed above. Noting that it was unclear in the application, IGARD also suggested that the applicant and NHS Digital should ensure that appropriate technical controls were in place for those who had declined to consent, to ensure there was **no** accidental flow of their data under this DSA. In addition, IGARD suggested that the applicant should follow up with HRA CAG around the 2,000 consented individuals, to clarify if they were part of the s251 support or not. IGARD also suggested that the applicant may wish to also seek clarity from HRA CAG as to whether HRA CAG had expectations that the applicant would be using a consent model for all new recruits moving forward, since it was not clear in the application or documentation provided if s251 was to be extended for new additions to the database. IGARD noted that they had previously queried in terms of UK General Data Protection Regulations (UK GDPR) and in line with NHS Digital's DARS Standard for Data Controllers Data Controllers data controllership, and noting that NHS Digital had spoken to the UKHCDO's Data Protection Officer, NHS Digital were of the view that the UKHCDO were the sole Data Controller responsible for determining the purpose for processing the data. IGARD thanked NHS Digital for seeking clarity on this point. Notwithstanding the diligence undertaken by NHS Digital with regard to Data Controllership, IGARD noted reference in section 5(d) (Benefits) (ii) (Expected Measurable Benefits) to "…*the*

	UK Health Security Agency (UKHSA) request UKHCDO to provide a report to them every six months on any cases of Jacob Kreutzfield Disease or variant Jacob Kreutzfield disease…" and asked that section 5 was updated to clarify whether the provision of the reports was discretionary or mandatory reporting. IGARD noted that **if** the applicant was producing mandatory reports for the UKHSA, then further questions should be asked around Data Controllership, in line with NHS Digital's DARS Standard for Data Controllers IGARD noted reference in section 5(d) to the Data Analysis Group (DAG), however noting this was their first reference in section 5, which forms NHS Digital's data uses register, suggested more detail was included in 5(a), for example using narrative from section 1 (Abstract) which noted that DAG had delegated powers from the Data Management Working Party and that DAG consisted of clinicians, commissioners, patient representatives, analysts who met monthly to review data requests. In addition, IGARD suggested that the applicant may wish to add more detail to their website with regard to DAG's work for transparency to the public. In line with NHS Digital's DARS Standard for Expected Measurable Benefits, IGARD asked that section 5(d) (iii) (Yielded Benefits) be updated to include more granular detail with regard to the impact on patients, accrued using NHS Digital data. IGARD asked that a special condition was inserted in section 6 (Special Conditions), that, where practicable, outputs cite the source of the data as *"this work uses data provided by patients and collected by the NHS as part of their care and support"* (use MY data - our data citation project), in line with NHS Digital DARS Standard for Special Conditions. IGARD 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 unresolved issues around the extent of CAG s251 support and uncertainty as to the future model to address the Duty of Confidentiality for new recruits to the registry. **Outcome:** recommendation to approve for those cohort members covered by s251 support **only**. The following amendments were requested: 1. To update section 5(a) to include more detail about the Data Analysis Group. 2. To clarify in section 5 reference to UKHSA and whether it was a) discretionary or b) mandatory reporting. 3. In respect of consent: a. To make clear in section 5(a) that **no** data is flowing for those who declined to give consent. b. To update section 5 to be clear that the consented cohort are **not** part of this application. 4. To make clear in section 5 that this application is for those covered under s251 support **only**. 5. To provide more granular detail with regard to the impact on patients in section 5(d)(iii). 6. To insert a special condition in section 6, that, where practicable, outputs cite the source of the data as *"this work uses data provided by patients and collected by the NHS as part of their care and support"*, in line with the NHS Digital DARS Standard for Special Conditions. The following advice was given: 1. IGARD suggested that the applicant may wish to add more detail to their website with regard to Data Analysis Group, for transparency to the public.

	2. IGARD suggested that if the applicant was producing a mandatory report to the UKHSA, further questions should be asked around Data Controllership and in line with NHS Digital's DARS Standard for Data Controllers. 3. The applicant / NHS Digital should ensure appropriate technical controls are in place for those declining to consent, to ensure no accidental flow of data. 4. In respect of HRA CAG: a. To follow up with HRA CAG re the 2000 consented and ask: are they part of s251 support or not? Was consent considered adequate or not by HRA CAG? b. To follow up with HRA CAG with regard to their expectations around consent model for new recruits. 5. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to unresolved issues around the extent of CAG s251 support and uncertainty as to the future model to address the Duty of Confidentiality for new recruits to the registry. 6. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the uncertainty as to the future model to address the Duty of Confidentiality for new recruits to the registry
3.4	University of Oxford: SIMPLIFY Trial communications via NHS DigiTrials request (Presenter: Frances Perry) NIC-661736-Y2Q9R-v0.5 **Application:** This was a new application to use the NHS Digi-Trials Communications service for the SYMPLIFY Study. No data will be returned to Grail Bio UK Ltd. SIMPLIFY is an observational study to assess a multi-cancer early detection (MCED) test in individuals referred with signs and symptoms of cancer. SIMPLIFY are requesting a mailout sent to a consented cohort of participants who have been recruited to SYMPLIFY, a study designed to assess Grail's Galleri (trademarked) MCED test. This application is related to NIC-604851-W0M3S, NIC-456778-J0G3H and NIC-651660-J5T6C. NHS Digital noted that section 6 should be updated to include a special condition that the outputs cite the source of the data. NHS Digital noted that there was reference to "*KCL**" in the application and that this should be "*University of Oxford*". *King's College London. **Discussion:** IGARD noted that linked application NIC-604851-W0M3S and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on 13th January 2022 and 3rd February 2022. It was also discussed as part of the 'applications progress via NHS Digital's SIRO Precedent' on the 5th May 2022. IGARD noted that linked application NIC-456778-J0G3H and relevant supporting documents had previously been presented at the IGARD BAU meeting on the 26th June 2021. IGARD noted that linked application NIC-651660-J5T6C and relevant supporting documents had previously been presented at the IGARD BAU meeting on the 28th July 2022. 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 verbal update from NHS Digital with regard to the removal of "*KCL*" and insertion of "*University of Oxford*" in section 5(a). IGARD noted two references in section 5(a) to "…*and **lead** for this agreement*…" and "…*as joint Data Controller (and **lead**)…"* and suggested reference to "***Lead***" be removed from the data sharing agreement (DSA) since it was not relevant, and there was no concept of a "*Lead Data Controller*" in UK General Data Protection Regulation (UK GDPR); or to update language to more accurately reflect that "*party X are leading this activity*" or similar. If, however the term "*lead*" was being used as shorthand to being the first point of contact, then NHS Digital should consider how best to reflect this term. IGARD noted the NHS Digital verbal update and asked that a special condition was inserted in section 6 (Special Conditions), that, where practicable, outputs cite the source of the data as *"this work uses data provided by patients and collected by the NHS as part of their care and support"* (use MY data - our data citation project), in line with NHS Digital DARS Standard for Special Conditions. Noting that the draft participant letter, supporting document 3.0, had been provided by the applicant and had already been reviewed by NHS Digital and comments submitted back, IGARD suggested that the draft letter may benefit from a review by the patient and public involvement and engagement (PPIE) group, for example (but not limited to) the first paragraph which indicates the letter is about, thanks and updates, but does not draw the participants' attention to the future-focused nature of the content below (i.e. the key fact that the applicant is re-contacting the participants to remind them that their data will be transferred to the USA) and in language suitable for a lay reader. IGARD also noted that a hyperlink for participants who did not wish their data to be sent to Grail, IGARD suggested that the full website link be included, particularly if the letter was to be sent physically, as a footer to the letter for example, and that a postal address and / or telephone number be provided for those that were not able to access the hyperlink. IGARD advised that they would wish to review all sister applications to this DSA when they come up for renewal, extension or amendment and that all sister applications to this DSA would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent; due to the quantum of data involved and the international aspect of the project. IGARD advised that this application **only** would be suitable for NHS Digital's Precedent route if all qualifying NHS Digital DARS Standards are met. **Outcome:** recommendation to approve The following amendments were requested: 1. To amend section 5(a) to remove reference to "*KCL*" and replace with "*University of Oxford*". 2. To remove all references to "***lead***" from "***lead** controller*" from section 5(a) of the application or update to "*the party leading this activity*", or similar. 3. To insert a special condition in section 6, that, where practicable, outputs cite the source of the data as *"this work uses data provided by patients and collected by the NHS as part of their care and support"*, in line with the NHS Digital DARS Standard for Special Conditions. The following advice was given: 1. IGARD suggested that the draft letter to participants would benefit from review by the applicant's PPIE group.

	2. IGARD advised that this application **only** would be suitable for NHS Digital's Precedent route if all qualifying DARS Standards are met 3. IGARD advised that they would wish to review all sister applications when they come up for renewal, extension or amendment, due to the quantum of data involved and the international aspect of the project. 4. IGARD suggested that all sister applications would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the quantum of data involved and the international aspect of the project.
3.5	Clinical Practice Research Datalink (CPRD): NHS Digital Data Sharing Remote Audit (Presenter) NIC-15625-T8K6L The purpose of the NHS Digital Data Sharing Remote Audit was to update IGARD on the key findings of the audit of CPRD between April and July 2022 against Data Sharing Framework Contract (DSFC) CON-325063-H0M5Y-V2.01 and Data Sharing Agreement (DSA) NIC-15625-T8K6L-v11.2. IGARD thanked NHS Digital for the verbal update and looked forward to receiving the updated DSA in due course, duly updated in line with previous advice given. **Outcome:** IGARD supported NHS Digital's suggestion to put in place a short-term extension, noting that the DSA is due to expire at the end of October 2022, to support NHS Digital's ongoing discussions with the applicant ahead of the application coming back to IGARD in due course.
4 **4.1**	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). University of Glasgow (University of Dundee): MS1462- data linkage request for the Febuxostat verse Allopurinol Streamlined Trial (FAST) (Presenter: Suzanne Hartley) NIC-72180-R2L5Y-v5.4 The purpose of this application is for a study designed to find out whether febuxostat is safer, less safe or just as safe as allopurinol for long term use in practice. IGARD noted that application was last discussed at an IGARD meeting on the 31st March 2022 where NHS Digital had submitted a briefing paper relating to a breach of the DSA. Prior to this, the application was last reviewed at the IGARD meeting on the 12th March 2020, where IGARD had recommended for approval subject to conditions, amendments and advice. IGARD noted that on the 21st October 2022, NHS Digital had advised in writing (via the IGARD Secretariat) that this application had progressed via the NHS Digital SIRO Precedent, for a 6-month extension to allow time for University of Dundee to make a decision with regard to Data Controllership (i.e. whether Menarini Ltd are a joint Data Controller) and whether there will be any future requirement for Menarini to retain data they have received in breach of the agreement or any future requirement to onward share with Menarini Ltd. NHS Digital attended the meeting, in addition to the written update, to provide IGARD with a verbal update. IGARD noted that since there appeared to be a breach of the data sharing agreement (DSA) and / or data sharing framework contract (DSFC) enquired whether NHS Digital would be enforcing the audit fees of £15,000 as outlined in Section 11 (Charges).

	IGARD noted and thanked NHS Digital for the written update and repeated their previous advice that they would wish to review this application again when it comes up for renewal.
4.2	University of Oxford: HPS3 / TIMI 55 – Randomised EValuation of the Effects of Anacetrapib through Lipid-modification (REVEAL) (No Presenter) NIC-147757-8SVGP-v2.3 The purpose of this application is for the REVEAL legacy study, which is a randomised, double-blinded, placebo-controlled trial of Cholesterol ester transfer protein (CETL) inhibitor anacetrapib. 30,449 men and women older than 50 years of age were recruited between August 2011 and October 2013 in Europe (UK, Germany, Italy, Demark, Finland, Norway and Sweden), North America (USA and Canada) and China. IGARD noted that the application was last reviewed by the Data Access Advisory Group (DAAG) (IGARD's predecessor) on the 19th April 2011 and had had no independent review since that date. IGARD noted that on the 19th October 2022, NHS Digital had advised in writing (via the IGARD Secretariat) that this application had progressed via the NHS Digital SIRO Precedent, to permit a further extension until the 27th March 2023. IGARD noted and thanked NHS Digital for the written update.
4.3	University of Cambridge: INTERVAL and COMPARE Trial cohorts – long term follow up of health outcomes and associations with genetic biological and lifestyle traits (No Presenter) NIC-156334-711SX-v8.8 The purpose of the application is to create a multi-purpose resource, by linking detailed lifestyle and biological information collected on INTERVAL and COMPARE study participants with health-related records. This will enable detailed study of the health of blood donors and, more generally, allow studies of cardiovascular disease and other health-related outcomes. IGARD noted that the application was last reviewed at the IGARD meeting on the 29th April 2021, where IGARD had recommended for approval subject to conditions, amendments and advice. IGARD noted that on the 19th October 2022, NHS Digital had advised in writing (via the IGARD Secretariat) that the NHS Digital SIRO had agreed to authorise a short term 3-month extension which permits the release of existing overdue data and other data also due to be issued over the period to the end of the agreement. IGARD noted and thanked NHS Digital for the written update and repeated their previous advice: 1. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment due to the use of the GDPPR data. 2. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent due to the use of the GDPPR data
4.4	University College London: MR623 National Mother & Child Cohort (No Presenter) NIC-148128-815J1-v3.6 The purpose of the application is to collect data on pregnancies in women living with HIV and their infants.

	IGARD noted that the application was last reviewed at the IGARD meeting on the 4th August 2022, where IGARD had recommended for approval subject to conditions, amendments and advice. IGARD noted that on the 21st October 2022, NHS Digital had advised in writing (via the IGARD Secretariat) that the NHS Digital SIRO had agreed to authorise a short-term extension until the 31st January 2023 to give NHS Digital and the applicant sufficient time to work through the outstanding points previously raised by IGARD on the 4th August 2022. IGARD noted and thanked NHS Digital for the written update and supported the short-term extension, and repeated their previous advice: 1. IGARD advised that they would wish to review this application, or any subsidiary or related applications, when it comes up for renewal, extension or amendment, due to the novel use of data, sensitive data flowing, complicated history of the application and the extensive extensions and lack of participant involvement. 2. IGARD suggested that this application, or any subsidiary or related applications, would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the novel use of data, sensitive data flowing, complicated history of the application and the extensive extensions and lack of data subject involvement. **Subsequent to the meeting:** IGARD Secretariat, on behalf of IGARD, emailed the NHS Digital Deputy SIRO and Caldicott Guardian to flag that the reason the DSA end date of January had been suggested was to allow further time for discussions ahead of the merger between NHS Digital and NHS England, however since the merger had been brought forward to January 2023, IGARD raised a query. The NHS Digital Deputy SIRO responded to confirm that there was work ongoing as part of the merger to flag all existing DSA's which have NHS England as a data controller, of which this is one of those applications. IGARD thanked NHS Digital for the update.
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	AOB:
7.1	Office for National Statistics (ONS) (Presenter: Duncan Easton) NIC-400304-S1P1B NHS Digital attended IGARD to discuss the special condition included in the data sharing agreement (DSA) which allows ONS to carry out newly described specific uses of the data under the approved DSA without submitting an amendment DSA, but only if they meet certain requirements, including submitting a paper to NHS Digital with the requested detail. NHS Digital noted that if the new activity uses the General Practice Extraction Service (GPES) Data for Pandemic Planning and Research (GDPPR) i.e. GP data then the paper needs to be submitted to PAG and IGARD for advice and before ONS start doing the new work. IGARD noted that the paper had been presented to PAG on the 19th October (see appendix B) IGARD thanked NHS Digital for the update and made the following high-level comments: 1. Data Controllership: IGARD raised a question around whether the Department of Health & Social Care (DHSC) are determining the purpose and means as outlined in the documentation provided (noting it is **not** PAG's remit to raise controllership). 2. Noting NHS Digital data uses register will not be updated, to ensure transparency via the ONS website. 3. Notwithstanding PAG support, this application raises potential challenges of inconsistency re the interpretation of "COVID-related purpose" by NHS Digital, and may set a precedent for future requests for GDPPR data. 4. IGARD noted that NSDEC support is required before ONS start new analysis and data is disseminated by NHS Digital.
7.2	Local / institutional ethics documentation Following discussion of NIC-666525-M8L1F-v0.3 University of Leeds (see item 3.1), IGARD discussed local / institutional ethics with two members of the NHS Digital DARS Senior Approvals Team (SAT). IGARD reiterated previous requests that all local / institutional ethics documentation should be provided as a supporting document within the agenda pack to support IGARD's review of the application, particularly important when the local ethics is referenced in both the application and supporting documentation, has happened in item 3.1. NHS Digital DARS SAT agreed that local ethics documentation should be provided and would ensure that the teams were updated accordingly. In addition, IGARD reiterated their suggestion from the 11th August 2022, that section 7 is not always clear that local institutional ethics support has been received, and suggested that NHS Digital review their internal processes to determine if this can be accurately reflected within section 7 of the application. NHS Digital updated IGARD in-meeting that work was ongoing with regard to updates to the online customer relationship management (CRM) system for a drop down menu to allow the applicant to pick "local ethics". IGARD thanked NHS Digital for the verbal update.
7.3	Improving Data Access Programme (Presenter: Sue Main)

	Following the last update at the IGARD meeting on the 22nd September 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 noted that work was being refocused and reprioritised, including but not limited to amending a number of the NHS Digital DARS Standards to remove guidance notes and ensure they were "self-contained" and did not refer to other NHS Digital DARS standards. NHS Digital noted that this work may mean that some DARS Standards are retired, and new ones written. The team had forwarded on a number of updated precedents and standards for IGARD's information and observations. 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 21/10/22

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-283774-B9Z6K-v0.19	Imperial College London	18/08/2022	1. In respect of the published HRA CAG Register and HRA CAG support: a) The applicant to confirm with HRA CAG that they are content that even though the applicant has the ability to re-identify the cohort, sufficient controls are in place to satisfy the requirements of the data flowing back being “pseudonymised”, as per the entry on the HRA CAG register; and a) To upload any relevant / supporting documentation to NHS Digital’s CRM system for future reference.	IGARD members	Quorum of IGARD members	*The condition in its current form needs to be set aside as HRA CAG has been contacted and has declined to offer a view, putting the responsibility back on NHS Digital. NHS Digital have, in turn, decided that they are content.* *Separately, HRA CAG has provided advice that they (broadly) believe that a flow of pseudonymised data is still pseudonymised even when the recipient has the means to identify.* *IGARD suggest that this condition is now set aside, but that DARS refer expressly to the verbal advice received from HRA CAG to support that view, or*

						take PTEL advice for the contention that the data is outside of CLDOC

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

GPES Data for Pandemic Planning and Research – Profession Advisory Group

Record of feedback: Wednesday 19 October 2022

Application & application version number: DARS-NIC-400304-S1P1B-v4.1

Organisation name: Briefing Paper - Office for National Statistics (ONS)

Profession Advisory Group Agenda item: 2

PAG thanks the authors of this report for such a comprehensive briefing of the new use case.

Whilst recognising the complex interacting processes and confounding related to cold weather, health, the social determinants of health, workforce and service infrastructure effects, it is clear from the types of analyses you have outlined, as well as the specific one in Annex A, that the studies encompass direct and indirect Covid-19 related purposes (as required by the DPN).

PAG must balance the need to maintain public and professional trust in the appropriate use of the population's GP data with the ability to derive actionable insights to ameliorate winter pressures.

The controls you provide give PAG the necessary reassurances to support this new use case:

1. GDPPR data will be used to create flags relating to patient vulnerability and therefore only fields relating to a patient's current medical state will be used
    a. **Just for clarification - please could ONS explain in more detail what you mean by this providing a "control".**

    No practice level statistics will be created or published. This work is intended to look at national level risk factors and at most will look at regional variation.

    This is a one-off piece of work for this winter; we will reconsult PAG if we wish to repeat this work next winter, and of course, if we wish to add any analysis that does not reasonably fit within the uses described today

    All uses of the GDPPR data will be subject to scrutiny by the National Statistician's Data Ethics Advisory Committee before analysis begins.

ONS submits a 6 monthly report in arrears to PAG about what new analysis has been completed.

Finally, we advise NHS Digital (and ONS) that no studies are undertaken to analyse Covid-19 related factors specifically related to health and social care staff using the GDPPR data; and for the avoidance of doubt, no studies that are aligned to the UK-REACH work unless health and social care staff are offered an opt-out process which is clearly communicated to them.

Attendees	Role	Organisation
Jonathan Osborn	Deputy Chair, Caldicott Guardian	NHS Digital
Amir Mehrkar	GP, Clinical Researcher	RCGP
Mark Coley	Deputy IT Policy Lead	BMA
Duncan Easton	Senior Approvals Team	NHS Digital
Anna Weaver	Senior Case Manager	NHS Digital
Florence Geut	Secretariat	NHS Digital