Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 20 January 2022

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member
Dr. Robert French	Specialist Academic / Statistician Member (Observer)
Kirsty Irvine	IGARD Chair
Dr. Imran Khan	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Prof. Nicola Fear	Specialist Academic Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Chair
Dr. Maurice Smith	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Garry Coleman	Associate Director / Senior Information Risk Owner (SIRO) (Observer: item 3.4)
Dave Cronin	Data Access Request Service (DARS) (Items 5, 7.2 – 7.5) (SAT Observer: item 3.5)
Faris Dean	Data Access Request Service (DARS) (SAT Observer: item 3.2)
Louise Dunn	Data Access Request Service (DARS) (Item 3.3) (SAT Observer: item 3.1)
Liz Gaffney	Head of Data Access, Data Access Request Service (DARS) (Item 7.1)
Dan Goodwin	Data Access Request Service (DARS) (item 3.3)
Colleen Jones	Data Access Request Service (DARS) (Observer: items 3.1 - 3.3)
Karen Myers	IGARD Secretariat
Tania Palmariellodiviney	Data Access Request Service (DARS) (SAT Observer: item 3.4)
Frances Perry	DigiTrials (Items 3.1 - 3.2, 7.6)
Denise Pine	Data Access Request Service (DARS) (Items 3.4 - 3.5)

Emma Russell	Data Access Request Service (DARS) (Item 5)
Joanna Warwick	Data Access Request Service (DARS) (Item 5)
Kimberley Watson	Data Access Request Service (DARS) (SAT Observer: Item 3.3)
Vicki Williams	IGARD Secretariat
SAT – Senior Approval Team (DARS)	

1	**Welcome and Introductions:** IGARD welcomed Dr. Robert French to the meeting as an observer, as part of his new role on IGARD as a Specialist Academic / Statistician Member. **Declaration of interests:** Paul Affleck noted professional links to AIMES Management Service (NIC-280606-N9Z7W), but no specific connection with the application or staff involved and it was agreed that there was not a conflict of interest. Dr. Imran Khan noted a professional link to the North of England Commissioning Support Unit (NIC-371243-H1P5T), but no specific connection with the application or staff involved and it was agreed this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 13th January 2022 IGARD meeting were reviewed, and subject to a number of minor amendments were agreed as an accurate record of the meeting. **Out of committee recommendations:** An out of committee report was received (see Appendix A).
2	**Briefing Notes**
	There were no briefing papers submitted for review.
3	**Data Applications**
3.1	King's College London: Standard versus Accelerated initiation of Renal Replacement Therapy in Acute Kidney Injury (STARRT-AKI) trial: UK arm of a multi-centre randomized controlled trial (Presenter: Frances Perry) NIC-280606-N9Z7W-v0.13 **Application:** This was a new application for pseudonymised record level Civil Registration (Deaths) data, Emergency Care Data Set (ECDS), Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC), HES Critical Care and HES Outpatients. This was an application for King's College London and Guy's and St Thomas' NHS Foundation Trust, for an international multi-centre randomised control trial (RCT) designed to address the clinical question of the optimal timing of initiation of renal replacement therapy (RRT) in patients in critical care with acute kidney injury. The purpose of this application is to provide data on secondary care services received by patients enrolled in the UK arm of the trial and in the observational cohort study in order to allow quantification of the overall cost of each

	patient's care. This will determine the impact of accelerated versus standard initiation of renal replacement therapy on total costs of care as well as outcomes of care which will facilitate an economic evaluation. The study will determine the incremental cost and the incremental health benefits, in terms of quality adjusted life-years of accelerated initiation of renal replacement therapy compared to standard initiation. The UK arm of the study, consists of two cohorts, both of which were consented between 2018 and 2021: **1)** a cohort of 191 participants with acute kidney injury randomised to accelerated or standard renal replacement therapy will provide data to both the UK study and the international trial; and **2)** the UK data will be supplemented with a separate cohort of 568 patients meeting the inclusion criteria for the trial but not randomly assigned to treatment. The second group consists of patients eligible, but not enrolled in the trial due to a clinician decision that either accelerated or standard initiation of renal replacement therapy was in the patient's best interest. **Discussion:** IGARD noted and commended NHS Digital on the quality of the information provided within section 1 (Abstract) of the application, which supported the review of the application by Members. IGARD confirmed that they were of the view that the most recent consent materials provided the appropriate gateway and were broadly compatible with the processing outlined in the application. IGARD and NHS Digital had a discussion on the identifiability of the data flowing, noting that the application stated the data was *"pseudonymised"*. IGARD queried if this was correct, noting the data also containing study IDs, which would enable the applicant to identify individuals. Noting that this was a consented study, IGARD asked that the applicant updated the application where relevant, to reflect that the data requested would effectively be *"identifiable"* and not "*pseudonymise*d". NHS Digital also noted that section 1 contained information that stated King's College London's Clinical Trials Unit (KCTU) would be collecting identifiable data; and confirmed that this was incorrect, and would need updating. IGARD noted the verbal update from NHS Digital, and supported the update to section 1, to outline the correct processing responsibilities, that aligned within the information within the supporting documents provided. IGARD noted that Article 9(2)(j) of the UK General Data Protection Regulation (UK GDPR) was cited as the legal basis for the processing, however asked that section 1 and section 5 (Purpose / Methods / Outputs) were updated, to correctly list the Data Protection Act (DPA) 2018 Schedule 1 Part 1 references, and to clearly describe how the schedule conditions are met. IGARD suggested that NHS Digital draw the applicant's attention to Article 26(2) of the UK GDPR, which states that they must convey the essence of the joint data controllership arrangements to their data subjects. IGARD noted and agreed with the analysis provided by NHS Digital that a National Data Opt-out (NDO) should take precedent over consultee advice; however, advised that consent should take precedent over an NDO. IGARD queried if it was possible to only apply the NDOs to the consultee advice cohort. NHS Digital advised that this had been discussed with the applicant and an offer made to utilise NHS Digital's NDO cleansing service to understand how this would impact the cohort. However, the applicant responded that they were unable to flag who was consented and who was under consultee advice. IGARD noted the verbal update

	from NHS Digital and suggested that the applicant should take steps to ensure that they knew which cohort members had been recruited via consultee advice and which via consent. IGARD queried the statement in section 3(b) (Additional Data Access Requested) that *"GDPR does not apply to data solely relating to deceased individuals"*, however, noting that the status of those patients that are still alive would be revealed, asked that this was updated to include a UK GDPR legal basis for dissemination and receipt of data if in accordance with the latest advice from the Privacy, Transparency and Ethics (PTE) Directorate. IGARD noted the helpful references to patient and public involvement and engagement (PPIE) in the application, however suggested that the applicant may wish to consider involving the relevant charities, for example, Kidney Care UK, and any other relevant public groups, as early as possible, and not just at the end of the study; in line with HRA guidance on Public Involvement. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 1 and section 5 in respect of the UK GDPR Article 9(2)(j) legal basis to correctly list the DPA 2018 Schedule 1 Part 1 references and clearly describe how the schedule conditions are met. 2. To update section 3 to include a UK GDPR legal basis for those datasets that give information about cohort members who are still living, if this accords with the latest advice from PTE. 3. To update the application where relevant to reflect that the data requested will effectively be *"identifiable"* and not "*pseudonymise*d". 4. To update section 1 to correctly outline the processing responsibilities (as per the verbal update from NHS Digital). The following advice was given: 1. IGARD suggested that NHS Digital draw the applicant's attention to Article 26(2) UK GDPR, which states that they must convey the essence of the joint data controllership arrangements to their data subjects. 2. IGARD suggested that the applicant should take steps to ensure that they have reference to those cohort members who have been recruited via consultee advice. 3. IGARD noted the helpful references to PPIE in the application, however suggested that the applicant may wish to consider involving the relevant charities, for example, Kidney Care UK, and public groups as early as possible, and not just at the end of the study; in line with HRA guidance on Public Involvement.
3.2	University of Glasgow: Data linkage request for 'Effectiveness of Intravenous iron treatment vs standard care in patients with heart failure and iron deficiency: a randomised, open-label multicentre trial (IRONMAN)' (Presenter: Frances Perry) NIC-433923-Z0V8D-v0.17 **Application:** This was a new application for pseudonymised record level Cancer Registration Data, Civil Registration (Deaths) and Hospital Episode Statistics Admitted Patient Care (HES APC) data. The purpose of the application, is for a study looking at whether there is evidence that the addition of Intravenous (IV) iron to standard care is of benefit; and will utilise a Prospective, Randomised, Open-label, Blinded Endpoint (PROBE) design, in that, the participants will be randomised to normal care or intravenous iron therapy with the participants and their physicians being aware of the treatment received. Participants will be assigned to receive IV

	iron or not, in addition to guideline-indicated care. Participants assigned to IV iron will receive repeated doses sufficient to ensure iron repletion for the duration of the study. It is an event-driven trial, but it is expected that participants will be treated for between six months and five and a half years. The study commenced in 2016 and is ongoing; the recruitment to the study was completed in October 2021, and the study follow up is expected to complete in March 2022. Long-term follow up will be for up to 10 years after recruitment ended. The study team will be sending a consented cohort of 1,400 patients to NHS Digital from England and Wales. **Discussion:** IGARD noted that NHS Digital had provided a verbal update in respect of this application at the IGARD business as usual (BAU) meeting on the 25th November 2021. IGARD confirmed that they were of the view that the most recent consent materials provided the appropriate gateway and were broadly compatible with the processing outlined in the application. In addition, IGARD suggested that the application be updated throughout to correctly cite *"consent"* as the legal basis, as this was currently not clear. IGARD asked that section 5(a) (Objective for Processing) was updated and in line with NHS Digital DARS Standard for Commercial Purpose, and that a brief summary was provided in section 5(a) of the commercial aspect of the application, as outlined in section 5(e) (Is the Purpose of this Application in Anyway Commercial). IGARD also noted that a representative from Pharmacosmos had been invited to attend the Trial Steering Committee (TSC) meetings as an observer, and suggested that further detail be provided to the exact nature of the observer status of the funder, for example could they contribute to the TSC meetings. IGARD noted that Article 9(2)(j) of the UK General Data Protection Regulation (GDPR) was cited as the legal basis for the processing, however asked that section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) were updated, to correctly list the Data Protection Act (DPA) 2018 Schedule 1 Part 1 references, and to clearly describe how the schedule conditions are met. IGARD queried the statement in section 3(b) (Additional Data Access Requested) that "*GDPR does not apply to data solely relating to deceased individuals*", however, noting that the status of those patients that are still alive would be revealed, asked that this was updated to include a UK GDPR legal basis for dissemination and receipt of data if in accordance with the latest advice from the Privacy, Transparency and Ethics (PTE) Directorate. IGARD noted the statement in section 5(c) (Specific Outputs Expected) that "*if the study provides clear evidence of benefit of IV Iron treatment for heart failure patients then then the results of the study maybe submitted by the University of Glasgow to the regulators of drugs in the UK, European (EU) and elsewhere*"; however suggested that section 5(c) and section 5(d) (Benefits) (iii) (Yielded Benefits) be updated to ensure that results of the study, even those that do not show a *"benefit"* of using this treatment were submitted to regulators in the UK, EU and elsewhere. IGARD noted in section 1 that *"the co-sponsors have legally amended the co-sponsorship agreement between the two parties* to reflect that the University of Glasgow is the sole data controller for the purposes of data linkage*…"; and suggested that the narrative from section 1 be removed that suggested that the parties had determined apportionment of data controllership by way of a contractual agreement, when controllership is borne out of the facts and in line with the NHS Digital's DARS Standard for Data Controllers.

	IGARD commended the applicant in sending the study results to the study participants and noted the patient and public involvement and engagement (PPIE) outlined in the application. IGARD queried whether there could be was any more active involvement by participants in the study, for example, by way of input into the summary document or distribution mechanism, and in line with the HRA guidance on Public Involvement. If such activity had already been undertaken, the applicant should take the opportunity to update section 5 accordingly, since this formed NHS Digital's Data Use Register. IGARD noted that section 3(b) incorrectly stated that the Cancer Registration Data, Civil Registration (Death) data and the HES APC data was "*pseudonymised*", and asked that this was updated to correctly reflect that it was "*identifiable*". IGARD advised that this application would be suitable for NHS Digital's Precedent route if all qualifying Data Access Request Service (DARS) Standards were met. **Outcome:** recommendation to approve The following amendments were requested: 1. In line with the NHS Digital DARS Standard for commercial purpose, to provide a brief summary in section 5(a) of the commercial aspect of this application, as outlined in section 5(e), including, but not limited to, providing detail of the exact nature of the observer status of the funder (for example can they contribute to meetings). 2. To update section 1 and section 5 in respect of the UK GDPR Article 9(2)(j) legal basis to correctly list the DPA 2018 Schedule 1 Part 1 references and clearly describe how the schedule conditions are met. 3. To update section 3 to include a UK GDPR legal basis for those datasets that give information about cohort members who are still living, if this accords with the latest advice from PTE. 4. To update section 5 (c) and 5(d) (iii) to ensure that results of the study, even those that do not show a "benefit" of using this treatment are submitted to regulators in the UK, EU and elsewhere. 5. To update the application where relevant to reflect that the data requested will effectively be *"identifiable"* and not "*pseudonymise*d". 6. To update the application throughout to ensure the legal basis is correctly cited as *"consent"*. 7. To remove the narrative from section 1 suggesting that the parties had determined apportionment of data controllership by way of a contractual agreement, when controllership is borne out of the facts and in line with the NHS Digital's DARS Standard for Data Controllers. The following advice was suggested: 1. IGARD commended the applicant in sending the study results to the study participants and noted the PPIE outlined in the application, but queried whether any more active involvement by participants in the study by way of input into the summary document or distribution mechanism could be sought in line with the HRA guidance on Public Involvement. If such activity had already been undertaken, the applicant should take the opportunity to update section 5 accordingly. 1. IGARD advised that this application would be suitable for NHS Digital's Precedent route if all qualifying NHS Digital's DARS Standards are met.

3.3	NHS North and East London Commissioning Support Unit: HES data for all CSUs and NHS England 2020/21 (Presenter: Dan Goodwin) NIC-371243-H1P5T-v8.1 **Application:** This was an amendment application to update the purpose for processing. The purpose of the application, is to allow Commissioning Support Units (CSU) (which are part of NHS England), to use this data to support Clinical Commissioning Groups (CCGs), other commissioning bodies and Local Authorities to meet their statutory duty, and to support health economy wide transformation projects. They do this by providing benchmarking and comparative information to their customers to support their needs. NHS Digital noted that IGARD had raised a query prior to the meeting, in respect of the statement in section 5(a) (Objective for Processing) *"Tools are available on a subscription-basis to NHS organisations, internally within the CSUs through specialist support teams, by CCG member practices, local authorities and* ***other CSU clients****."*; in particular querying who the *"other CSU clients"* were. NHS Digital gave an example from the applicant of a commercial company based in the USA, who would receive aggregated with small numbers suppressed data to enable a comparison with data pertaining to the United Arab Emirates (UAE) for a UAE client. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the Data Access Advisory Group (IGARD's predecessor) / IGARD business as usual (BAU) meetings on the 10th November 2015, 30th August 2018 and the 29th August 2019. IGARD noted the verbal update from NHS Digital in respect of the *"other CSU clients"* referenced within the application, and the example provided by the applicant, in respect of the outputs flowing to a commercial company based in the USA. Noting that this information (the nature of the clients/potential clients and scope of work) was not explicit within the application or supporting documents provided, IGARD asked that, for transparency, a written explanation was provided of the nature of the *"other CSU clients"*; and that clarity was also provided on any restrictions as to who could be a client of the CSU; any commercial companies who may be a client of the CSU; and any commercial companies who may be a client of the CSU who were located outside England and Wales. IGARD noted that when the application had been previously presented in 2018 and 2019, IGARD had advised that NHS Digital may wish to consider auditing this organisation in relation to this application / data sharing agreement (DSA). Noting that an audit had not been undertaken, IGARD reiterated the advice, and strongly suggested that NHS Digital should consider auditing this organisation in relation to this application / DSA, due to the quantum of national data flowing and the unique processing arrangements. IGARD noted the large number of storage and processing locations in section 2 (Locations), and noting this may cause difficulty for NHS Digital in respect of auditing, suggested that NHS Digital work with the applicant to review and consider if the locations could be consolidated; and noting the discussion at the workshop at the business as usual (BAU) meeting on the 18th November 2021. IGARD suggested the applicant carried out a Data Protection Impact Assessment (DPIA), due to the large-scale processing and in light of explaining the applicant's contractual arrangements. IGARD also noted that the DPIA exercise could help inform the applicant's transparency to the public, for example explaining the applicant's contractual arrangements. If a DPIA had already been produced, IGARD suggested that this was updated to reflect the amendments outlined in this application.

	IGARD noted that the yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits) had not been updated since 2018 and in line with the NHS Digital DARS Standard for Expected Measurable Benefits; and observed that these should be updated. In addition, IGARD noted the reference in section 5(d) (iii) to the demand management *"Good Practice Guide"* and suggested that this reference should be removed, noting this had generated substantial controversy within the GP profession and suggested that it would not be advisable for NHS Digital to have this initiative as a yielded benefit in the published NHS Digital Data Uses Register. IGARD noted the benefits outlined in section 5(d), however ,suggested that these were also updated, to reflect the additional purposes and wider scope of the application, including, but not limited to, the services provided for the "*other CSU clients"*; and in line with the NHS Digital DARS Standard for Expected Measurable Benefits. IGARD noted the reference in section 5(c) (Specific Outputs Expected) to *"frequent flyers"* when referring to benchmarking and comparative analysis, and asked that this was reworded with a less pejorative form of words such as *"high utilisation of services"*. **Outcome:** Recommendation to defer, pending: 1. IGARD reiterated previous advice made in 2018 and 2019; that NHS Digital should consider auditing this organisation in relation to this application / DSA, due to the quantum of national data flowing and the unique processing arrangements. 2. IGARD noted the large number of storage and processing locations, and, noting this may cause difficulty for NHS Digital in respect of auditing, suggested that NHS Digital worked with the applicant to review and consider if the locations could be consolidated. 3. In respect of the *"other CSU clients"*: a) To provide written explanation of the nature of the *"other CSU clients"*. b) To provide clarity as to any restrictions as to who can be a client of the CSU. c) To provide clarification on any commercial companies who may be a client of the CSU. d) To provide clarification on any commercial companies who may be a client of the CSU who are located outside England and Wales. 4. IGARD suggested the applicant carried out a Data Protection Impact Assessment (DPIA), due to the significant volume of data flowing, the large-scale processing and in light of explaining the applicant's contractual arrangements If a DPIA has already been produced, IGARD suggested that this was updated to reflect the amendments outlined. 5. To reword the reference to *"frequent flyers"* in section 5(c) with a less pejorative form of words such as "high utilisation of services". 6. To update the outputs in section 5(c) to reflect the additional purposes and wider scope of the application (including services provided for "other CSU clients"). 7. To update the benefits in section 5(d) to reflect the additional purposes and wider scope of the application (including services provided for "other CSU clients"). 8. IGARD noted that the yielded benefits had not been updated since 2018 and in line with the NHS Digital DARS Standard for Expected Measurable Benefits, and observed that these should be updated. In particular, the reference to the demand management *"Good Practice Guide"* should be removed, noting this has generated substantial controversy within the GP profession. IGARD suggested that it would not be advisable for NHS Digital to have this initiative as a yielded benefit in the published NHS Digital Data Uses Register. **Subsequent to the meeting:**

	NHS Digital shared with the IGARD Chair (via the IGARD Secretariat) written confirmation of the verbal update provided at the meeting on the 20th January 2022, in relation to the *"other CSU clients"*. Noting the significant information contained within this correspondence, the IGARD Chair asked that for future reference, section 1 of the application was updated with this information.
3.4	Department for Transport: HES and STATS19 One-to-one linkage project (Presenter: Denise Pine) NIC-381383-Z9F2P-v4.4 **Application:** This was a short-term three-month extension to the Data Sharing Agreement (DSA) which expired on the 31st July 2021, to hold but not process pseudonymised Hospital Episode Statistics Accident and Emergency (HES A&E) and HES Admitted Patient Care (APC). The purpose of the application is to understand the types of injuries sustained by people injured in road traffic accidents; and to use the analysis to show the number of patients admitted to hospital following a road accident, in the first few months of the year of 2020. This will support policy colleagues in understanding road safety during the COVID-19 period so far and in preparing for users to return to roads. The Senior Information Risk Owner (SIRO) had requested on the 18th November 2021 that the application be brought to IGARD in light of the potential breach of the data sharing agreement (DSA) and that the privacy notice condition that had not been complied with. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 8th November 2016, 24th January 2017, 20th June 2019 and the 30th July 2020. IGARD welcomed the approach in respect of an IGARD review as per the SIRO request, but queried why the application had not been submitted for a more timely review, following the request of an independent review by the SIRO back in November 2021. IGARD suggested that internal processes within NHS Digital be reviewed to mitigate any similar issues in the future. IGARD noted that the application should be updated throughout to align with NHS Digital's DARS Standard(s) and before it was presented to a future business as usual (BAU) meeting of IGARD. On return to a BAU meeting, IGARD advised that they would expect that **all** previous points raised by IGARD were adequately addressed; and that the application was updated accordingly. Noting the breach of DSA, IGARD suggested that the applicant look at their own internal processes to ensure that no further storage or processing location changes were made without notification to the research team, in order for them to update their application with NHS Digital. **Outcome:** IGARD welcomed the application, which came for advice at the request of the SIRO and without prejudice to any additional issues that may arise when the application is fully reviewed. 1. IGARD noted that application should be updated to align with the relevant NHS Digital DARS Standard(s). 2. IGARD advised the upon return, the applicant should ensure that all points previously raised by IGARD have been adequately addressed.

	3. The applicant may wish to ensure that internal processes are in place to ensure that no further storage or processing location changes are made without notification to the research team in order for them to update their application with NHS Digital.
3.5	Methods Analytics Ltd: Standard Extract Subscription (Presenter: Denise Pine) NIC-09519-D5G0R-v17.2 **Application:** This was a renewal and extension application, to permit the holding and processing of pseudonymised Civil Registration (Deaths) Secondary Care Cut, Emergency Care Data Set (ECDS), Hospital Episode Statistics Admitted Patient Care (HES APC), HES Outpatients, HES:Civil Registration (Deaths) bridge and Secondary Uses Service Payment By Results Episodes (SUS PbR). It was also an amendment to **1)** add the Cloud service provider, Redcentric, PLC as a joint Data Processor; and **2)** reduce the dissemination of the data from monthly to quarterly. The aim is for data to be used to help inform improvement in NHS services. The effect of using this data, analysed securely and then provided to NHS decision makers / providers to the NHS in Methods' tools which helps decision makers visualise and understand what changes they need to make to their organisations and services to enhance the quality, safety and efficiency of health and care. The three objectives of processing are **1)** bespoke tools and analysis; **2)** The NHS England / Improvement Getting it Right First Time Programme (GIRFT); and **3)** SWORD, which is a programme for a number of specialist surgical societies (registered charities) to provide an intelligence tool for only their Consultant Surgeon members. **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 March 2016, 28th June 2016, 23rd March 2017, 28th September 2017, 8th November 2018, 13th December 2018 and the 18th March 2021. The application was also discussed as part of oversight and assurance at the IGARD BAU meeting on the 23rd January 2020. IGARD queried what contractual arrangements or other controls were in place for the data flow with GIRFT; and noting that this was not clear and asked that for transparency, section 5(b) (Processing Activities) was updated with a brief narrative. In addition, IGARD asked that a special condition was inserted in section 6 (Special Conditions), setting out what the contractual arrangements or other controls were for the aggregated data with small numbers unsuppressed, as part of the GIRFT data flow. IGARD noted the information provided in section 5(d) (Benefits), however suggested that in respect of the benefits and yielded benefits, the applicant may wish to seek feedback from the appraisers who have used the SWORD Tool and include any reported qualitative benefits, for example, as to how it may have improved the accuracy and / or fairness of the assessments; and in line with NHS Digital DARS Standard for Expected Measurable Benefits. In addition, noting that the Methods Analytics data and input was key to the GIRFT programme, IGARD suggested that applicant update the yielded benefits in section 5(d) (iii) (Yielded Benefits) with any readily available information or narrative about the benefits and yielded benefits of GIRFT which can be attributed to Methods work either in whole or in part; and in line with NHS Digital DARS Standard for Expected Measurable Benefits. **Outcome:** recommendation to approve

	The following amendments were requested: 1. To update section 5(b) to include a brief narrative about the contractual or other controls on the unsuppressed small numbers data (as part of the GIRFT data flow). 2. To insert a special condition in section 6 setting out what the controls are for the unsuppressed small numbers data (as part of the GIRFT data flow). The following advice was given: 1. IGARD suggested that in respect of the benefits and yielded benefits, the applicant may wish to seek feedback from the appraisers who have used the SWORD Tool and include any reported qualitative benefits as to how it may have improved the accuracy and/or fairness of the assessments. 2. Noting that the Methods Analytics data and input is key to the GIRFT programme, IGARD suggested that applicant update the yielded benefits with any readily available information or narrative about the benefits and yielded benefits of GIRFT which can be attributed to Methods work either in whole or in part.
4	Applications progressed via NHS Digital's Precedent route, including the SIRO Precedent Applications that have been progressed via NHS Digital's Precedent route, including the SIRO Precedent, and NHS Digital have notified IGARD in writing (via the Secretariat).
4.1	NIC-148369-8PPWK-v3.5 University of Oxford (No Presenter) The purpose of this application was for a long-running study to determine mortality, disability, psychological morbidity, cognitive decline and cost of care; following a stroke, transient ischaemic attack (TIA), Acute Coronary Syndrome (ACS) and acute peripheral vascular events, in patients registered in one of eight GP practices in Oxfordshire. IGARD noted that this application was last reviewed at the IGARD business as usual meeting on the 2nd May 2019. IGARD noted that on the 13th January 2022, NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had agreed to authorise a renewal for a period of 6-months. In addition, an update was provided in respect of the ethics approval, patient notifications, transparency, s251 support and the latest protocol. IGARD noted and thanked NHS Digital for the written update and asked that the next iteration should be brought to a future IGARD BAU meeting.
4.2	NIC-456088-R0H0V-v1.5 University Hospital Southampton NHS FT (No Presenter) The purpose of this application was for the CovBoost trial, that is looking at giving boosters to the those in the population aged over 70 or health care workers, a minimum of 3 months after their second dose of either the AstraZeneca or Pfizer vaccination. IGARD noted that this application was last reviewed at the IGARD – NHS Digital COVID-19 response meeting on the 18th May 2021. IGARD noted that on the 7th January 2022, the SIRO had advised in writing (via the IGARD Secretariat) that due to the urgency, a one-year Data Sharing Agreement had been approved. IGARD noted and thanked the SIRO for the written update and asked that the next iteration should be brought to a future IGARD BAU meeting.

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. IGARD agreed, that from the 22nd July 2021, where substantial issues / significant risks are raised in respect of the returning applications, that a high-level summary of these points would be included within the published minutes for transparency and audit purposes: • **NIC-177392-B8T1Z University of Oxford** IGARD noted that it should be clear within section which precedent the application had been approved under, since two were cited: simple amendment / extension and renewal. IGARD reiterated previous comments that changes to applications should be "date stamped" so that it was clear when updates had been made to the application summary. • **NIC-195235-Q0B5T University of East Anglia** IGARD noted comments previously made that language within the application summary relating to consultee advice being "consent" was incorrect and that it was important that the applicant knew who was in the cohort under consent and who was in the cohort through consultee advice, since those participants would need to be consented when they were well enough. In addition, IGARD noted that the consent was for 7 years and that a note should be included on CRM to flag should the DSA be extended or renewed beyond this time period. • **NIC-236925-Y5R9M Health Education England** • **NIC-177523-N8J2S University College London** IGARD noted that the governance pathway for APMS data had not been updated to correctly reference when applications for APMS should come via IGARD. IGARD asked that internal processes be updated accordingly. IGARD noted that section 5(d) had not been updated and therefore did not meet the NHS Digital DARS standard for expected measurable benefits. • **NIC-58603-S6Z1B London School of Hygiene & Tropical Medicine** IGARD reiterated previous comments that changes to applications should be "date stamped" so that it was clear when updates had been made to the application summary. • **NIC-327369-T1M7M University of Nottingham** 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. IGARD Members noted that the last IG COVID-19 release register that they had reviewed and provided comments on was July 2021.
6	COVID-19 update Deep Dive request for IG release 00517 Following the review of IG Release 00517, NHS National Services Scotland (NSS) / Public Health Scotland which had been previously circulated and reviewed out of committee by members, the comments had been shared with the Privacy, Transparency and Ethics Directorate and a summary of the points raised are noted below:

	• Alternatives to transferring data to Scottish entities - IGARD suggested that the alternatives considered were documented and all purposes outlined. • Other border patients - IGARD suggested that arrangements for other nations were referenced. • Vital interests – IGARD suggested not referring to "vital interests" vis a vis the duty of confidence and harmonising the exact ground for setting aside the duty of confidence. • Citing of multiple legal bases under UK GDPR – IGARD suggested ICO guidance is followed, and it is made clear what activities fall under particular bases. • Supporting Document 5 – IGARD suggested that it was clearly documented whether or not the conditions were met.
7	AOB:
7.1	Head of Data Access Update The Head of Data Access attended (part of) the meeting as part of her regular catch-up with IGARD. In addition and following discussion at the 4th November 2021 IGARD BAU Meeting, the Head of Data Access gave a verbal update with regard to NIC-433629-H3M0G NHS England which had been a new application which had progressed via the NHS Digital SIRO precedent route. NHS Digital noted that due to the urgency of the application it had progressed under SIRO precedent, since there was a relevant Direction and Memorandum of Understanding (MoU) in place. The Head of Data Access had asked that IGARD be updated, however this had not taken place. IGARD thanked the Head of Data Access for attending to update members and asked the relevant internal processes be updated.
7.2	Date of Death discussion (Presenter: Dave Cronin) IGARD noted that discussions with regard to where mortality data is supplied as part of a pseudonymised datasets and whether that inclusion makes the data more identifiable had been ongoing with NHS Digital since 2018 / 2019. IGARD noted the update from NHS Digital with regard to providing a process document for DARS and suggested that since this will form an artefact that it be mapped back to the original National Data Guardian (NDG) advice received in March 2019, thereby preserving the back and forth of the conversation. IGARD noted that discussions with regard to the UK GDPR legal basis for those datasets that give information about cohort members who are still living were still ongoing. IGARD noted that DARS had requested in early 2021 for PTE advice on this topic, and noting that they had still not had sight of the legal question asked or the legal answer provided, asked that a copy of that advice be provided to IGARD and that a further discussion be included on a future IGARD BAU meeting agenda.
7.3	"Review requested by IGARD" on the application summary (Presenter: Dave Cronin) IGARD noted that there had been multiple previous instances where the "review requested by IGARD" in section 1 of the application summary had defaulted to "no" when in fact IGARD had requested to see the application again. NHS Digital noted that since the current field and process were not fit for purpose they were exploring better processes / functionality to address the issue or whether it would be simpler to remove the field altogether. NHS Digital noted that IGARD should be assured that even if the review box is ticked "no" applications were still

	being brought to IGARD and that the correct procedures were being followed. IGARD noted the update from NHS Digital.
	<u>Outputs / Benefits section containing "will" and "can" (Presenter: Dave Cronin)</u>
7.4	NHS Digital noted that IGARD were consistently giving feedback that statements in section 5(c) and 5(d) should not project certainty on outcomes where such outcomes are uncertain. NHS Digital noted that applications would continue to be reviewed to remove such declarative statements in the short term, however the longer-term intentions were to produce clearer guidance on how to structure benefit statements. IGARD thanked NHS Digital for the update and reminded them of the forthcoming NDG guidance on benefits which was due to be published later this year.
	<u>Security Assurance for Cloud Storage (Presenter: Dave Cronin)</u>
7.5	IGARD had been requesting, through amendments to the application summary, that section 1 be updated to include the full agreed wording by the NHS Digital security advisor on Cloud storage. NHS Digital noted that the DARS process should ensure that applications involving Cloud storage were subject to the appropriate checks, involving review by the NHS Digital security consultant and only submitted for approval once the full application complies with the security assurance data sharing standard and that IGARD should be assured that this process has been undertaken and no such commentary will be included in section 1. However, if an application is to be amended to include Cloud storage where it has previously not been permitted, a note will be included in section 1 under "points to note". NHS Digital noted that guidance on what to include in section 1 of the application summary across different types of applications was in development and would be shared with IGARD members for comments before being launched internally.
	<u>'Use of the terms Sex' and 'Gender' (Presenter: Frances Perry)</u>
7.6	Following discussion at IGARD on the 9th December 2021, and a previous request by IGARD in August 2021 where IGARD had asked NHS Digital to respond to a query of how DARS and Data Production deal with 'sex' (a person's physical characteristics at birth) versus 'gender' (the socially constructed roles, behaviours, expressions and identities) as data fields and a means of linking and extracting data IGARD welcomed and thanked the author of the paper and a member of the DARS Senior Approval Team to attending to discuss further. IGARD reiterated previous comments made on this topic that it was not about challenging the definition of 'sex' or 'gender', it was about ensuring that each dataset clearly described whether it contained 'sex' data, 'gender' data or both sets of data, since the terms were not interchangeable. NHS Digital noted that more work was required to discuss with each IAO of every dataset what was contained. IGARD noted the verbal update but impressed upon NHS Digital that it was not for IGARD to adjudicate on this topic, however, it was within IGARD's remit to raise the issue that applicants may be receiving the wrong type of data since the terms were used inconsistently and that in turn this may affect the outcomes of a research study, for example efficacy of medication which may affect the results if the researcher was getting 'gender' data rather than 'sex' data.

	IGARD suggested that NHS Digital investigate this subject further, noting that a growing proportion of (often) younger members of society identify as non-binary or as a gender different from the sex assigned to them at birth. Accordingly, it was important that NHS Digital was clear on whether the datasets NHS Digital held contained accurate sex or gender data fields, or both. In addition, IGARD suggested that an education session be undertaken by NHS Digital to ensure that DARS and others were clear on the terms and what was covered by 'sex' and 'gender' and why it matters to researchers and case studies. 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 14/01/22

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-612092-Q0Y6F-v0.2	Home Office	16/12/2021	1. In respect of Data Controllers: a) To add the Cabinet Office as a joint Data Controller, in line with the NHS Digital DARS Standard for Data Controllers / UK GDPR or otherwise clarify why their commissioning role does not create a controllership role. b) Where the University of Hull are described in section 5, to be clear that they are not considered, nor fulfil the criteria of, a Data Controller under UK GDPR. 2. In respect of the dissemination of data under s261 of the Health & Social Care Act: a) To insert a clear statement in section 5(a) as to why this study is important from a public health perspective for example to mention that knife crime is a **serious public health problem** that can impact on the **provision of health services**. b) To update section 5(d) to be clear that the benefits are in line with the NHS Digital DARS Standard for Expected Measurable Benefits and satisfy the legal obligations to disseminate data under s261 of the Health and Social	IGARD members	Quorum of IGARD members	None

			Care Act for the benefit of health and / or care.			

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:

- DARS-NIC-197669-K8J6D-v4.4 DSfC - NHS Basildon and Brentwood CCG - Comm - Mid & South Essex STP

Graphnet Class Actions:

- None