Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 11 November 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Prof. Nicola Fear	Specialist Academic Member
Kirsty Irvine	IGARD Chair
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Maria Clark	Lay Member
Dr. Imran Khan	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Rhys Bowen	Data Access Request Service (DARS) (Observer: items 1 – 3.4)
Dave Cronin	Data Access Request Service (DARS) (Item 5)
Duncan Easton	Data Access Request Service (DARS) (Observer: items 1 – 3.5)
Liz Gaffney	Data Access Request Service (DARS) (Item 7.1)
Dan Goodwin	Data Access Request Service (DARS)
Lucy Harris	Data Access Request Service (DARS) (Item 7.1)
Karen Myers	IGARD Secretariat
Fran Perry	Data Access Request Service (DARS)
Denise Pine	Data Access Request Service (DARS)
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) (Observer: item 3.1)
Vicki Williams	IGARD Secretariat

1	**Declaration of interests:** Prof. Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising the Scientific Advisory Group for Emergencies (SAGE) on COVID-19. Prof. Nicola Fear noted a professional link with King's College London [NIC-44383-L6C0X and NIC-159251-K4Y6Q] but noted no specific connection with the application or staff involved and it was agreed that this was not a conflict of interest. Dr. Geoffrey Schrecker noted professional links to The Clinical Effectiveness Group, hosted by Queen Mary University of London (NIC-422200-Q1K7S) but no specific connection with the application or staff involved and it was agreed that there was no conflict of interest. **Review of previous minutes and actions:** The minutes of the 4th November 2021 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	Royal College of Surgeons (RCS): National Vascular Registration – patient level HEs and Civil Registration Mortality data request (Presenter: Denise Pine) NIC-59669-F6Y3W-v1.9 **Application:** This was a renewal application which expires on the 20th May 2023 and an amendment to **1)** request mortality data for patients who are not registered in the National Vascular Registry (NVR) cohort but have been previously identified by relevant Office of Population Censuses and surveys (OPCS) codes to enable the applicant to determine the long-term mortality for all vascular patients in England and not just those that have been able to be linked to the NVR, and **2**) to permit utilisation of the data to address the impact of COVID-19 on the vascular patients and delivery of the vascular services in the UK. The Registry was established in 2013 and collects data from NHS Trusts providing vascular surgery in order to provide information on patient characteristics, pre-operative care, then range of surgery undertaken, and post-operative outcomes. The inclusion of COVID-19 questions are aligned to the general purpose of the clinical audit. The Audit had been previously advised by the Healthcare Quality Improvement Partnership (HQIP) to contact the Health Research Authority Confidentiality Advisory Group (HRA CAG) to ensure that any additions were covered. HRA CAG advised that if there was no change to the datasets requested then HRA CAG would not expect any amendment to be required as it is expected that these audits would be looking at adverse events, and that is in line with the audit programme of work. The Audit are treating the inclusion of looking at the impact of COVID-19 as part of the general review of the audit data and the impact of any adverse events to the cohort.

	The audit programme is relying on consent **and** s251 of the NHS Act 2006, for the flow of identifiable data out of NHS Digital. It also contains pseudonymised data which is outside the common law duty of confidentiality. The application was previously considered on the 28th October 2021 where IGARD had deferred making a recommendation. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 21st May 2020 and the 28th October 2021. IGARD noted that the application had been updated to reflect all the previous deferral points. IGARD confirmed that they were of the view that the relevant s251 support provided the appropriate legal gateway and was broadly compatible with the processing outlined in the application. IGARD had a lengthy discussion on the structure of the cohorts, and whether the National Data Opt-out (NDO) should be applied to the whole cohort or part of the cohort, noting that there was a combined legal basis (s251 and consent) and a pseudonymised element. NHS Digital advised that due to technical restrictions within NHS Digital, it would not be possible to only apply the NDO to part of the cohort if there was a single flow of data. IGARD noted the verbal update from NHS Digital, and asked that for transparency to those participants within the consented cohort, the relevant transparency materials were updated, to make clear that for those individuals that hold an NDO, their data would **not** flow and form part of the research data set. IGARD also noted to NHS Digital that transparency with regard to the application of the NDOs, for those that had consented to be part of the cohort but have exercised the NDO would be a significant risk, for example, the application was not in keeping with current transparency wording and the National Data Opt-out policy *("The national data opt-out does not apply where a patient has given their explicit consent to a specific use of their data"*). IGARD noted the combined data flows requested in the application and the NDO being applied to both consented and pseudonymised data may have been incentivised by NHS Digital's charging structure, for example, the applicant being charged less for one combined data flow and were advised by NHS Digital that there was ongoing work internally in respect of reviewing the NHS Digital charging structure. IGARD noted the verbal update from NHS Digital, however highlighted the risk in respect of the NDO being applied to both the consented and pseudonymised cohorts, when it was contrary to the NDO policy. IGARD noted c.5%. of the cohort may be lost due to the application of NDOs. On return, IGARD asked that the applicant and NHS Digital should revisit the advice made in respect of separate data flows, once the changes to the NHS Digital charging structure have been implemented. This would address the applicant losing consented members of the cohort and members of the pseudonymised cohort, due to the NDO. IGARD also noted the concern, in respect of the possible transfer and use of data for patients who had declined to participate in the NVR, that an individual who had declined participation in the NVR might be surprised to find that their pseudonymised data was flowing under this DSA combined with data relating to those that had consented; and again reiterated the advice that this could possibly be mitigated by separate data flows. IGARD queried why identifiers needed to flow into NHS Digital to link part of the cohort to the Registry, noting that this was not clear. NHS Digital advised that the audit questions were designed not to duplicate data that could be gathered by routinely gathered datasets, which in turn necessitates the need for identifying data to flow and linkage to take place in order to

	complete the analysis. IGARD noted the verbal update from NHS Digital and asked that this clarification was outlined in section 5(a) (Objective for Processing) for transparency. IGARD noted that the NVR annual report referred to NHS Digital Hospital Episode Statistics (HES) data; and asked that further details of this was added to the yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits) for clarity; and that the yielded benefits that were currently in section 5(d) (ii) (Expected Measurable Benefits) of the application were moved to section 5(d) (iii). 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 General Data Protection Regulation (UK GDPR) legal basis for dissemination and receipt of data; in accordance with the latest advice from the Privacy, Transparency and Ethics (PTE) Directorate. IGARD noted the references throughout section 5 (Purpose / Methods / Outputs) to *"case ascertainment"*, and noting that this was misleading, asked that this was amended to refer to *"cases identified through data held by NHS Digital"*. 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 complexity of the data flow and the yielded benefits. **Outcome:** recommendation to approve The following amendments were requested: 1. To amend the reference in section 5 from *"case ascertainment"* to *"cases identified through data held by NHS Digital"*. 2. To update section 5(a) with clarification that the audit questions are designed not to duplicate data that could be gathered by routinely gathered datasets which in turn necessitates the need for identifying data to flow and linkage to take place in order to complete the analysis. 3. To provide further details in section 5(d) of the yielded benefits accrued to date utilising NHS Digital HES data referred to in the NVR annual report. To consider moving the (yielded) benefits in section 5(d) (ii) to the yielded benefits in section 5(d) (iii). 4. 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. 5. To update the relevant transparency materials to advise those patients who give consent that if they hold an NDO their data will **not** flow and form part of the research data set. The following advice was given: 1. IGARD noted the potential implications of NHS Digital's charging structure, which seems to have incentivised a combined flow of data as outlined in this application. The NDO being applied to both the consented and pseudonymised cohorts contrary to the NDO policy. IGARD noted the verbal update from NHS Digital that work was ongoing in respect of reviewing the charging structure. 2. IGARD noted that the applicant should have separate data flows to enable the appropriate application of NDOs, noting that c.5 per cent of the cohort may be lost with the current approach.

	3. IGARD advised that they would wish to review this application when it comes for renewal, extension or amendment, due to the complexity of the data flows and the yielded benefits. 4. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the complexity of the data flows and the yielded benefits. **Risk areas:** • The possible transfer and use of data for patients who have declined to participate in the NVR. An individual who has declined participation in the NVR might be surprised to find that their pseudonymised data was flowing under this agreement. This risk could possibly be mitigated by separate data flows. • On return, the applicant and NHS Digital should revisit the advice above in respect of separate data flows, once the changes to the NHS Digital charging structure have been implemented. This would address the applicant losing consented members of the cohort and members of the pseudonymised cohort, due to the NDO. • Transparency with regard to the application of the NDOs for those that have consented to be part of the cohort but have exercised the NDO (such application is not in keeping with current transparency wording).
3.2	<u>NHS Bradford District and Craven CCG: DSfC - NHS Bradford District and Craven CCG - IV, RS, Comms (Presenter: Dan Goodwin) NIC-362267-P1W2X-v1.2</u> **Application:** This was an extension and renewal to permit the holding and processing of pseudonymised Secondary Uses Service (SUS+), Local Provider Flows, Mental Health Minimum Data Set (MHMDS), Mental Health Learning Disability Data Set (MHLDDS), Mental Health Services Data Set (MHSDS), Maternity Services Data Set (MSDS), Improving Access to Psychological Therapy (IAPT), Child and Young People Health Service (CYPHS), Community Services Data Set (CSDS), Diagnostic Imaging Data Set (DIDS), National Cancer Waiting Times Monitoring Data Set (CWT), Civil Registration Data (Births), Civil Registration Data (Deaths), National Diabetes Audit (NDA) and Patient Reported Outcome Measures (PROMs). It was also an amendment to add the following datasets for the purpose of commissioning: **1)** e-Referral Service (eRS); **2)** Personal Demographics Service (PDS); **3)** Summary Hospital-level Mortality Indicator (SHMI); **4)** Medicines Dispensed in Primary Care (NHSBSA Data); and **5)** Adult Social Care Data. The overall purpose for this application is for: Invoice Validation (IV) which is part of a process by which providers of care or services are paid for the work they do; Risk Stratification (RS) which is a tool for identifying and predicting which patients are at high risk or likely to be at high risk and prioritising the management of their care; and to provide intelligence to support the commissioning of health services. **Discussion:** NHS Digital noted that the application had not previously been presented at an IGARD business as usual (BAU) or at a Data Access Advisory Group (DAAG) meeting (IGARD's predecessor). IGARD noted within section 1(b) (Processing Activities) that NHS Bradford District and Craven CCG, had not met the Data Security and Protection Toolkit (DSPT) for 2021/21, and that an action plan had been agreed. IGARD asked that written confirmation was provided, for example, an e-mail, that the DSPT action plan has been finalised and that NHS Digital's Security Advisor has expressed satisfaction that the appropriate security was in place; and

	that the written confirmation from NHS Digital's Security Advisor was uploaded to NHS Digital's customer relationships management (CRM) system for future reference. IGARD noted that it was not clear within the application that the Commissioning Support Unit (CSU) was working as a Data Processor on behalf of the GP, who was the Data Controller; and asked that for transparency, section 5 (Purpose / Methods / Outputs) was updated with clarification of this. IGARD queried the information provided in section 5(b) (Processing Activities) that outlined the activities to be undertaken by Liaison Financial Services Ltd and the CSU as joint Data Processors; and noting that both had the same activities listed, asked that clarification was provided why the same activities were being undertaken by both Liaison Financial Services Ltd **and** the CSU, in line with NHS Digital DARS Standard for Data Processors; or, if there was a delineation of work, that further detail was provided; and that any suggestion of duplication of processing was removed. IGARD noted that there was a risk to NHS Digital in respect of Risk Stratification, in that the application of the National Data Opt-out (NDO) and Type 1 objections may affect direct care for individuals who have either of these in place, despite being told that their direct care would not be affected by them. IGARD suggested that the applicant may wish to update their privacy notice, with regards to the statement that the CCG access '*de-identified*' data, to align it with the application, which states that the CCG accesses '*identifying*' data. IGARD noted the examples of re-identification outlined in the application, polypharmacy and high attendance A&E, and suggested these could potentially breach the UK General Data Protection Regulation (UK GDPR) with regard to excessive processing, since the GP was already in possession of data that could be used for these purposes, and therefore did not need the CCG to provide that detail. 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 General Data Protection Regulation (UK GDPR) legal basis for dissemination and receipt of data; in accordance with the latest advice from the Privacy, Transparency and Ethics (PTE) Directorate. IGARD queried the statement in section 5(b) *"All re-id requests will be processed and authorised by the DSCRO on a case by case basis"*, and noting that it was not clear, asked that the statement be updated to confirm if each *"case"* was referring to individual patients or projects. IGARD noted the effort made in populating the yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits), however advised that the volume of information was not all required, and asked that in line with NHS Digital DARS Standard for Expected Measurable Benefits, the first three paragraphs were removed as the information was not relevant. In addition, IGARD asked that applicant provide 2 or 3 specific yielded benefits accrued to date in section 5(d) (iii), to reflect the processing activities as outlined in section 5(a) (Objective for Processing), i.e. Risk Stratification, Invoice Validation and Commissioning, and to ensure these are clear about the benefits to both patients and the health care system more generally, in line with NHS Digital DARS Standard for Expected Measurable Benefits.

	IGARD noted the statement in section 5(b) to *"a different organisation name but has now merged into this CCG"*, and asked that for future reference, section 1 (Abstract) was updated with information on the historical information in respect of the applicant's name change. Noting the forthcoming CCG / ICS transition that was due to be completed by April 2022, prior to the end date of the agreement and the data retention period, IGARD asked that section 1 and section 5 were updated to also include a reference to this for information. **Outcome:** recommendation to approve subject to the following condition: 1. In respect of the security arrangements a) To provide written confirmation (such as an e-mail) that the DSPT action plan has been finalised and that NHS Digital's Security Advisor has expressed satisfaction that the appropriate security is in place. b) To upload the written confirmation from NHS Digital's Security Advisor to NHS Digital's CRM system for future reference. The following amendments were requested: 1. To update section 5 with clarification that the CSU is working as a Data Processor on behalf of the GP (Data Controller). 2. To provide clarification in section 5(b) why Liaison Financial Services Ltd **and** the CSU, who are both listed as joint Data Processors, are doing the exact same activities (or if there is a delineation of work to provide further detail), to remove any suggestion of duplication of processing. 3. To update section 3 to include a UK GDPR legal basis, if deemed relevant, for those datasets that give information about cohort members who are still living, in accordance with the latest advice from PTE. 4. To update the reference in section 5(b) to *"…case by case basis…"*, to confirm if each *"case"* is referring to individual patients or projects. 5. In respect of the benefits and in line with NHS Digital DARS Standard for Expected Measurable Benefits: a) To update section 5(d) (iii) to remove the first 3 paragraphs as the information is not relevant. b) To update section 5(d) (iii) to provide 2 or 3 specific yielded benefits accrued to date, to reflect the processing activities as outlined in section 5(a) are reflected in the yielded benefits. 6. To update section 1 and section 5 with a reference to the forthcoming CCG / ICS transition. 7. To update section 1 to include the historical information in respect of the applicant's name change. The following advice was given: 1. IGARD suggested that the applicant updated their privacy notice, with regards to the statement that the CCG access de-identified data, to align it with the application, which states that the CCG accesses identifying data. **Significant Risk Areas:** • Noting the examples of reidentification outlined in the application, polypharmacy and high attendance A&E, IGARD noted these could potentially breach UK GDPR with regard to excessive processing, since the GP is already in possession of data that can be used for such purposes and does not need the CCG to provide that detail.

	• There is a risk to NHS Digital in respect of Risk Stratification, that the current flows of data, mean that the NDO or Type 1 Opt-out, may affect direct care for individuals who have these opt-outs in place, despite their being told that their direct care would not be affected. It was agreed the condition would be approved out of committee (OOC) by the IGARD Chair.
3.3	<u>NHS North East London CCG: DSfC - NHS North East London CCG - Comm, RS & IV (Presenter: Dan Goodwin) NIC-422200-Q1K7S-v2.2</u> **Application:** This was a renewal to permit the holding and processing of pseudonymised Secondary Uses Service (SUS+), Local Provider Flows, Mental Health Minimum Data Set (MHMDS), Mental Health Learning Disability Data Set (MHLDDS), Mental Health Services Data Set (MHSDS), Maternity Services Data Set (MSDS), Improving Access to Psychological Therapy (IAPT), Child and Young People Health Service (CYPHS), Community Services Data Set (CSDS), Diagnostic Imaging Data Set (DIDS), National Cancer Waiting Times Monitoring Data Set (CWT), Civil Registration Data (Births), Civil Registration Data (Deaths), National Diabetes Audit (NDA), Patient Reported Outcome Measures (PROMs), e-Referral Service (eRS), Summary Hospital-level Mortality Indicator (SHMI), Medicines Dispensed in Primary Care (NHSBSA Data) and Adult Social Care Data. It was also an amendment to **1)** add Optum Healthcare Solutions UK Limited as a Data Processor for the purpose of Commissioning; **2)** to permit the processing of linked GP data (collected by the CCG directly from GP practices); **3)** to add Amazon Web Services Limited as a Cloud Service provider for Optum Health Solutions UK Limited; **4)** to permit Microsoft Limited Azure Cloud usage for Optum Health Solutions UK Limited. The overall purpose for this application is for: Invoice Validation (IV) which is part of a process by which providers of care or services are paid for the work they do; Risk Stratification (RS) which is a tool for identifying and predicting which patients are at high risk or likely to be at high risk and prioritising the management of their care; and to provide intelligence to support the commissioning of health services. **Discussion:** NHS Digital noted that the application had not previously been presented at an IGARD business as usual (BAU) or at a Data Access Advisory Group (DAAG) meeting (IGARD's predecessor). IGARD noted that there may not be a legal basis for the flow of identifiable data from the GP to the CCG and that this was a significant risk; and suggested that the GP's who were the Data Controllers ensured there was a clear legal basis to share the confidential data with the CCG. IGARD noted that it was essential to clarify whether the CCG were acting as a Data Processor for the GP's or acting as a Data Controller in respect of the identifiable data flowing from the GP to the CCG, and ensure the appropriate data processing agreement or data sharing agreements were in place, and as borne out of the facts. IGARD noted the information provided towards the end of section 5(a) (Objective for Processing) that included details on profiling and automated decision making; and asked that section 5 (Purpose / Methods / Outputs) was updated where necessary, to provide further details on the profiling and automated decision making in relation to the Risk Stratification processing activities. IGARD suggested that since only GPs carry out Risk Stratification, that the privacy notice was updated to clarify this point. In addition, noting the use of profiling and automated decision making in relation to the Risk Stratification, IGARD suggested that the privacy notice was

	updated to address all the appropriate UK General Data Protection Regulation (UK GDPR) requirements, in relation to this point. IGARD noted that it was not clear within the application that the Commissioning Support Unit (CSU) was working as a Data Processor on behalf of the GP, who was the Data Controller; and asked that for transparency, section 5 was updated with clarification of this. IGARD noted the examples of reidentification outlined in the application, polypharmacy and high attendance A&E, and suggested these could potentially breach UK GDPR with regard to excessive processing, since the GP is already in possession of data that can be used for such purposes and does not need the CCG to provide that detail. 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 General Data Protection Regulation (UK GDPR) legal basis for dissemination and receipt of data; in accordance with the latest advice from the Privacy, Transparency and Ethics (PTE) Directorate. 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 worked with the applicant to review and consider if the locations could be consolidated. IGARD queried the statement in section 5(b) (Processing Activities) *"All re-id requests will be processed and authorised by the DSCRO on a case by case basis."*, and noting that it was not clear, asked that the statement be updated to confirm if each *"case"* was referring to individual patients or projects. IGARD noted that the benefits in section 5(d) (Benefits) were not clear as to the express benefits that would flow from the GP data linkage in the application; and asked that for clarity, section 5(d) was updated with this information, and in line with NHS Digital DARS Standard for Expected Measurable Benefits. IGARD noted the effort made in populating the yielded benefits in section 5(d) (iii) (Yielded Benefits), however advised that the volume of information was not all required, and asked that in line with NHS Digital DARS Standard for Expected Measurable Benefits, the first three paragraph were removed as the information was not relevant. IGARD noted the statement in section 5(b) to *"a different organisation name but has now merged into this CCG"*, and asked that for future reference, section 1 (Abstract) was updated with information on the historical information in respect of the applicant's name change. Noting the forthcoming CCG / ICS transition that was due to be completed by April 2022, prior to the end date of the agreement and the end of the data retention period, IGARD asked that section 1 and section 5 were updated to also include a reference to this for information. IGARD noted the references in section 5(a) and section 5(c) (Specific Outputs Expected) to *"patient complaint"*, in respect of calls made to 111 system, and noting that this language could be perceived as being negative, asked that the references was updated to refer to *"clinical issue"* or similar. IGARD noted the inclusion of a number of technical phrases and words within section 5(b), such as *"stochastic algorithm"* and suggested that this was updated to be written in a language suitable for a lay reader and technical terms used only where necessary, or further explained upon first use.

	IGARD noted the reference in section 5 to the *"Collaboration for Leadership in Applied Health Research and Care [CLAHRC]"*, which were local partnerships between NHS providers, universities, charities, local authorities, Academic Health Science Networks and other organisations. IGARD noted that the CLAHRCs scheme closed in September 2019 and has now been succeeded by the NIHR Applied Research Collaborations (ARCs) scheme; and asked that section 5 was updated to replace the reference to *"CLAHRC"* with *"A*RC" if appropriate. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 5 to provide further details on the profiling and automated decision making in relation to the Risk Stratification processing activities. 2. To update section 5 with clarification that the CSU is working as a Data Processor on behalf of the GP (Data Controller). 3. To update section 3 to include a UK GDPR legal basis, if deemed relevant, for those datasets that give information about cohort members who are still living, in accordance with the latest advice from PTE. 4. To update the reference in section 5(b) to *"…case by case basis…"*, to confirm if each *"case"* is referring to individual patients or projects. 5. In respect of the benefits and in line with NHS Digital DARS Standard for Expected Measurable Benefits a. To update section 5(d) (iii) to remove the first 3 paragraphs as the information is not relevant. b. To update section 5(d) to provide further details of the express benefits that will flow from the GP data linkage in this application. 6. To update the *references in section 5(a) and section 5(c) from "patient complaint" to "clinical issue"* or similar. 7. To amend section 5(b) to ensure the use of technical jargon is used only where necessary such as *"stochastic algorithm"*. 8. To amend section 5 to replace the reference to *"CLAHRC"* with *"ARC"* if appropriate. 9. To update section 1 and section 5 with a reference to the forthcoming CCG / ICS transition. 10. To update section 1 to include the historical information in respect of the applicant's name change. The following advice was given: 1. IGARD suggested that the Data Controllers ensured there was a clear legal basis to share confidential data. 2. In respect of the privacy notice: a. IGARD suggested that since only GPs do Risk Stratification, that the privacy notice be updated to clarify this point. b. Noting the use of profiling and automated decision making, in relation to the Risk Stratification, IGARD suggested that the privacy notice was updated, to address all the appropriate UK GDPR requirements, in relation to this point. 3. 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. **Significant Risk Areas:**

	• IGARD noted the examples of reidentification outlined in the application, polypharmacy and high attendance A&E, could potentially breach UK GDPR with regard to excessive processing, since the GP is already in possession of data that can be used for such purposes and does not need the CCG to provide that detail. • There may not be a legal basis for the flow of identifiable data from the GP to the CCG.
3.4	<u>NHS Surrey Heartlands CCG: Integrated Commissioning Surrey Heartlands (Presenter: Dan Goodwin) NIC-463170-V2K1Y-v0.2</u> **Application:** This was a new application for pseudonymised Secondary Uses Service (SUS+), Local Provider Flows, Mental Health Minimum Data Set (MHMDS), Mental Health Learning Disability Data Set (MHLDDS), Mental Health Services Data Set (MHSDS), Maternity Services Data Set (MSDS), Improving Access to Psychological Therapy (IAPT), Child and Young People Health Service (CYPHS), Community Services Data Set (CSDS) , Diagnostic Imaging Data Set (DIDS), National Cancer Waiting Times Monitoring Data Set (CWT), Civil Registration Data (Births), Civil Registration Data (Deaths), National Diabetes Audit (NDA), Patient Reported Outcome Measures (PROMs), e-Referral Service (e-RS), Personal Demographics Service (PDS), Summary Hospital-level Mortality Indicator (SHMI), Medicines Dispensed in Primary Care (NHSBSA Data) and Adult Social Care. The purpose is for NHS Surrey Heartlands CCG and Surrey County Council to receive data to provide intelligence to support the commissioning of health services. The data is analysed so that health care provision can be planned to support the needs of the population within the CCG area. NHS Digital noted that the Invoice Validation and Risk Stratification aspect of this application, was covered under NIC-362236-D7W4M, and that Commissioning would be removed from that Data Sharing Agreement (DSA), noting this was now covered under this DSA. **Discussion:** IGARD noted the verbal update from NHS Digital in respect of the Risk Stratification and Invoice Validation being covered under a separate DSA; however, to avoid duplication of data, asked that a special condition was inserted in section 6 (Special Conditions), that no commissioning processing can take place under this DSA, until such time that NIC-362236-D7W4M had been updated to remove commissioning. IGARD noted that there was an issue with the application, in terms of a clear case not being made for re-identification for the purpose of direct care, as part of a commissioning application; and that the application referred to re-identification in exceptional cases with aggregated numbers with small numbers supressed, and that the examples provided were programmes of care involving high number of patients, i.e. A&E usage and polypharmacy, and that both examples could be done already without the CCG / LA needing to identify those patients for them. IGARD noted the role of the NHS North East London Commissioning Support Unit (NEL CSU) in receiving the identifiable data from the GPs and then pseudonymising it; and suggested that the applicant ensured that the appropriate agreements were in place between the GP and CSU, to ensure that confidential data was handled appropriately. IGARD noted that it was essential therefore to clarify whether the CCG / CSU were acting as a Data Processor for the GP's or acting as a Data Controller in respect of the identifiable data flowing from the GP to the CSU, and ensure the appropriate data processing agreement or data sharing agreements were in place, and as borne out of the facts.

	In addition, IGARD asked that for transparency, section 5 (Purpose / Methods / Outputs) was updated to reflect that NEL CSU would be pseudonymising the data on behalf of the GP practices. 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, if deemed relevant, this was updated to include a UK General Data Protection Regulation (UK GDPR) legal basis for dissemination and receipt of data; in accordance with the latest advice from the Privacy, Transparency and Ethics (PTE) Directorate. IGARD queried the benefits outlined in section 5(d) (Benefits), and noted that some of the information provided were outputs, and asked that section 5(d) was updated to remove any outputs, for example, in respect of the annual report extracts and edit to only leave examples that reflect the benefits to the Health and Social Care System; and that the outputs were correctly moved to section 5(c) (Specific Outputs Expected), in line with NHS Digital's DARS Standard for Expected Outcomes. IGARD noted the effort made in populating the yielded benefits in section 5(d) (iii) (Yielded Benefits), however advised that the volume of information was not all required, and asked that in line with NHS Digital DARS Standard for Expected Measurable Benefits, the first three paragraph were removed as the information was not relevant. In addition, IGARD asked that applicant provide 2 or 3 specific yielded benefits accrued to date in section 5(d) (iii), to reflect the processing activities as outlined in section 5(a) (Objective for Processing) were reflected in the yielded benefits, i.e. Commissioning, and to ensure these are clear about the benefits to both patients and the health care system more generally, in line with NHS Digital DARS Standard for Expected Measurable Benefits. IGARD noted the examples of reidentification outlined in the application, polypharmacy and high attendance A&E, could potentially breach UK GDPR with regard to excessive processing, since the GP is already in possession of data that can be used for such purposes and does not need the CCG to provide that detail. IGARD noted a number of acronyms in section 5, and asked that this public facing section, that forms NHS Digital's data uses register, be updated to ensure that all acronyms upon first use were expanded and clearly defined with a supportive explanation in a language suitable for a lay reader, for example *"CQUIN"*, *"SCW"*, *"NMOC"*. IGARD also noted the inclusion of a number of technical phrases and words within section 5 (Purpose / Methods / Outputs) such as *"Wave 2 PHM Optum national programme"* and *"Triple aim analysis",* and suggested that this was updated to be written in a language suitable for a lay reader and technical terms used only where necessary, or further explained upon first use. IGARD queried the statement in section 5(b) (Processing Activities) *"The only identifier available in the data set is the NHS numbers"*, and noting that NHS number were identifiers, and the data requested was pseudonymised, asked that this statement was removed. IGARD noted the reference in section 5(b) to *"consented GP practices"*, and asked that this was replaced with a more accurate description, for example, "*participating GP practices*". Noting the forthcoming CCG / ICS transition that was due to be completed by April 2022, prior to the end date of the agreement and the end of the data retention period, IGARD asked that section 1 and section 5 were updated to also include a reference to this for information. **Outcome:** recommendation to approve The following amendments were requested:

	1. To insert a special condition in section 6 that no commissioning processing can take place under this DSA, until such time that NIC-362236-D7W4M has been updated to remove commissioning. 2. To update section 3 to include a UK GDPR legal basis, if deemed relevant, for those datasets that give information about cohort members who are still living, in accordance with the latest advice from PTE. 3. In respect of section 5(b): a) To update section 5(b) to remove the statement *"The only identifier available in the data set is the NHS numbers"*. b) To update section 5(b) to remove the reference to *"consented GP practices"*, and replace with *"participating GP practices"*. 4. To update section 5 to reflect that NEL CSU will be pseudonymising the data on behalf of the GP practices. 5. In respect of the benefits and in line with NHS Digital DARS Standard for Expected Measurable Benefits a) To update section 5(d) (iii) to remove the first 3 paragraphs as the information is not relevant. b) To remove any specific outputs from section 5(d) and move to section 5(c), for example, in respect of the annual report extracts. c) To update section 5(d) (iii) to provide 2 or 3 specific yielded benefits accrued to date, to reflect the processing activities as outlined in section 5(a) are reflected in the yielded benefits. 6. As section 5 forms NHS Digital's data uses register, to amend section 5 to ensure that all acronyms upon first use be defined and further explained if the meaning is not self-evident, for example *"CQUIN"*, *"SCW"*, *"NMOC"*. *7.* To amend section 5 to ensure the use of technical jargon is used only where necessary such as *"Wave 2 PHM Optum national programme"* and *"Triple aim analysis"*. *8.* To update section 1 and section 5 with a reference to the forthcoming CCG / ICS transition. The following advice was given: 1. IGARD suggested that the applicant ensure the appropriate agreements were in place between the GP and CSU, to ensure that confidential data is handled appropriately. **Significant Risk Area:** IGARD suggested the examples of reidentification outlined in the application, polypharmacy and high attendance A&E, could potentially breach UK GDPR with regard to excessive processing, since the GP is already in possession of data that can be used for such purposes and does not need the CCG to provide that detail.
3.5	NIC-279476-Y8N7J-v0.9: How effective is FITNET-NHS for children and young adults with CFS/ME (Presenter: Fran Perry) University of Bristol **Application:** This was a new application for pseudonymised Hospital Episode Statistics Admitted Patient Care (HES APC), Bridge file: HES to Mental Health Minimum Data Set (MHMDS), Emergency Care Data Set (ECDS) and Mental Health Services Data Set (MHSDS). The purpose is for a research project the 'Fatigue In Teenagers on the interNET in the NHS trial' (FITNET-NHS), which is a large randomised controlled trial which will investigate the clinical and cost-effectiveness of the FITNET-NHS intervention compared with Activity Management, among children and young people aged 11-17 years, with Chronic Fatigue

	Syndrome (CFS) or Myalgic Encephalomyelitis (ME) who do not have a local NHS specialist CFS/ME service. The FITNET-NHS intervention delivers specialist cognitive behavioral therapy for CFS/ME via the internet. Participants and their parents / carers, will work through 21 modules and have e-consultations with therapists. Activity Management is used as the comparator in this study as recommended by the National Institute of Health and Clinical Excellence (NICE) and is currently the best alternative for children / young people in regions without a local specialist CFS/ME service. The research project consists of 314 individuals who have provided consent. NHS Digital advised IGARD that a thorough review had been undertaken of the consent materials, for example a comparison as to what had changed in each version of the materials, and whether the flow of data was compatible with the materials. NHS Digital confirmed that they were content that all versions of the consent materials were compatible with the flow of data. NHS Digital also noted that within the protocol there was reference to co-applicants, for example, the University of Amsterdam; however confirmed that following discussion with the applicant, they were content that the co-applicants listed were not joint Data Controllers / Data Processors. **Discussion:** IGARD noted and commended NHS Digital, in respect of the review undertaken on the consent materials, as per the verbal update provided. IGARD confirmed that they were also 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 noted and thanked NHS Digital for the verbal update on the role of the co-applicants as outlined in the protocol. IGARD noted that section 5 (Purpose / Methods / Outputs) specifically referred to NICE guidelines, for example *"Activity Management is used as the comparator in this study as recommended by NICE"*, however, asked that all references were updated with the relevant reference numbers and dates, for example, *"CG53 Aug 2007"*. IGARD queried if the work undertaken to date had been fed into the new NICE guidelines that were published in October 2021; and noting that this was not clear, asked that the outputs in section 5(c) (Specific Outputs Expected) and the yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits) were updated with clarification. In addition, IGARD asked that if the work to date had not fed into the NICE guidelines published in October 2021, section 5 was updated with further information as to how this important work would feed into the appropriate channels. IGARD noted a number of technical terms in section 5, and asked that this public facing section, that forms NHS Digital's data uses register, was amended throughout, to ensure technical terms were explained in a manner suitable for a lay audience, for example *"net benefit regression"*. IGARD noted the excellent patient and public involvement and engagement (PPIE) outlined in section 5(c), and queried if there had been PPIE in respect of the study design, and asked that if appropriate, section 5(a) (Objective for Processing) was updated with further information. IGARD noted that the outputs for this study were critical, and that dissemination was key, not just to the cohort, but for others who may have an interest in to the study subject.

	Outcome: recommendation to approve The following amendments were requested: 1. In respect of the NICE guidelines: a) To update the references to the NICE guidelines in section 5 with the relevant reference numbers and dates (e.g. CG53 Aug 2007). b) To update section 5(c) and section 5(d) (iii) to clarify if the work to date has fed into the new NICE guidelines, published in October 2021. c) If the work to date has not fed into the NICE guidelines published in October 2021, to provide further detail in section 5 as to how this important work will feed into the appropriate channels. 2. To update section 5 to ensure technical terms are explained in a manner suitable for a lay audience, for example *"net benefit regression"*. 3. To update section 5(a) to clarify the PPIE in respect of the study design, if appropriate.
4	<u>Applications progressed via NHS Digital's Precedent route, including the SIRO Precedent</u> Applications that have been progressed via NHS Digital's Precedent route, including the SIRO Precedent, and NHS Digital have notified IGARD in writing (via the Secretariat). *No items discussed.*
5	<u>Oversight & Assurance</u> IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. 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: IGARD reiterated as an overarching point and as agreed when they moved to their new ways of working on the 1st May 2019 that section 1 (Abstract) was a living document and it was imperative that this was updated when any changes that were made to the application, since IGARD can only review the changes notified to it, and assumes no other material changes have been made to the application unless they are explicitly pointed out in section 1 (Abstract) and / or supporting documentation. IGARD also reiterated that the scope of the oversight and assurance review was to look at the changes made and take note of any additional flagged points raised in the section 1 since its last independent review. IGARD noted that they only reviewed active DSAs, and that DARS had taken the responsibility to add any comments raised in oversight and assurance to the "notes" section of the Customer Relationship Management (CRM) system for action, and that a process should be in place by DARS to review those notes when the application is "unlocked". IGARD also noted as an overarching point that although Section 1 was for internal use only, it was still subject to Freedom of Information (FOI) requests, and that appropriate language should be used in all cases and that section 1 was subject to an oversight and assurance review by a panel of external senior contractors. • **NIC-368020-R5L2K Telstra Health UK ltd (Dr Foster)** - 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 SIRO Precedent, due to the fact that there was no update with regard to the audit that was underway when last reviewed by IGARD in 2019, the Yielded Benefits were not in line with the NHS Digital DARS Standard for Expected Measurable Benefits and there was no evidence in the application of due diligence having been undertaken on Telstra Health who acquired Dr Foster Limited in 2015. IGARD also noted that this narrative also applied to all current active Dr Foster Limited / Telstra Health UK limited DSAs. • **NIC-44383-L6C0X King's College London (KCL)** - IGARD noted that there appeared to be no update in section 1 with regard to previous advice provided to the applicant that on renewal further details of pathways of dissemination for PPIE be provided. IGARD noted that the Yielded Benefits were not in line with the NHS Digital DARS Standard for Expected Measurable Benefits. IGARD also noted that previously they had asked that an amendment be included in section 5(b) that a local version of the STATA MP software tool was being used and not cloud, but that it appeared that data was now being stored in the cloud, via the additional of two cloud storage providers and that the statement in 5(b) now appeared to be incorrect. • **NIC-376603-K2J9R HSCIC / NHS England** **NIC-159251-K4Y6Q King's College London (KCL)** - IGARD queried why the draft precedent for Population Health Management remained outstanding, meaning that APMS applications were still progressing under the SIRO precedent, and suggested that the precedent be finalised. • **NIC-423859-V7S0R NHS England** • **NIC-454669-H0H4X NHS England** • **NIC-370843-R6V8T Imperial College London (ICL)** **NIC-24810-Q6T3B University of Birmingham** - IGARD noted ongoing work in NHS Digital around derived data and suggested a knowledge sharing exercise on this topic. IGARD welcomed the eight applications as part of their oversight and assurance role and noted a number of comments to NHS Digital and suggested that further information and comments be provided in an IGARD Oversight and Assurance Report. IGARD noted that they had requested, an IG COVID-19 release register suite of documents on a particular data release for review by IGARD as part of their oversight and assurance, and as agreed in June 2020 with the Executive Director Privacy, Transparency and Ethics (PTE) when it had been agreed that IGARD review an agreed number per month, by way of a review of all documentation revised by PTE, and as part of continuous improvement and quality. 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 To support NHS Digital's response to COVID-19, from Tuesday 21st April 2020, IGARD will hold a separate weekly meeting, to discuss COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 urgent applications that have been submitted to NHS Digital. Although this is separate to the Thursday IGARD meetings, to ensure transparency of process, a meeting summary of the Tuesday meeting will be captured as part of IGARD's minutes each Thursday and published via the NHS Digital website as per usual process. IGARD noted that due to conflicting priorities for IGARD members and the IGARD Secretariat, the COVID-19 response meeting on Tuesday, 9th November 2021 was cancelled.
7 **7.1**	AOB: Data Uses Register (Presenters: Lucy Harris / Liz Gaffney) Colleagues from the Data Access Request Service (DARS) attended IGARD, to provide an update and overview in respect of ongoing work with the Data Uses Register. IGARD noted and thanked NHS Digital for the helpful update, and looked forward to further updates in due course. 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 05/11/21

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-156334-711SX	University of Cambridge	13/05/2021	1. To provide an action plan as to how the current consent materials will be augmented by way of communication and transparency measures to bring them in line with the NHS Digital DARS Confidentiality Standard.	IGARD members, or in meeting, as may be requested by NHS Digital.	Quorum of IGARD members in the IGARD BAU meeting on the 28/10/2021.	To amend section 1 to state: *"the agreement holder's substantive **employee** will take relevant disciplinary procedures"*

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