**Independent Group Advising on the Release of Data (IGARD)**

**Minutes of meeting held via videoconference 10 March 2022**

| **IGARD MEMBERS IN ATTENDANCE:** | |
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| **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 |
| Dr. Geoffrey Schrecker | Specialist GP Member / IGARD Deputy Chair |
| **IGARD MEMBERS NOT IN ATTENDANCE:** | |
| Prof. Nicola Fear | Specialist Academic Member |
| Dr. Maurice Smith | Specialist GP Member |
| Jenny Westaway | Lay Member |
| **NHS DIGITAL STAFF IN ATTENDANCE:** | |
| **Name:** | **Team:** |
| Dave Cronin | Data Access Request Services (DARS) (SAT* Observer: item 3.4) |
| Louise Dunn | Data Access Request Service (DARS) (SAT* Observer: item 3.2 - 3.3) |
| James Gray | DigiTrials (Item 3.3) |
| Karen Myers | IGARD Secretariat (Items 1 & 3.1) |
| Dr. Jonathan Osborn | Deputy Caldicott Guardian (Observer: 3.1 – 3.3) |
| Frances Perry | DigiTrials (Items 3.1 - 3.2) |
| Steph Rowley (SR) | Data Access Request Services (DARS) (Observer: items 3.1 – 3.3) |
| Charlotte Skinner | Data Access Request Services (DARS) (Item 3.4) |
| Kimberley Watson | Data Access Request Services (DARS) (SAT* Observer: item 3.1) |
| Vicki Williams | IGARD Secretariat |
| ***SAT** – Senior Approval Team (DARS) | |

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| **1** | **Declaration of interests:**<br>There were no declarations of interest.<br>**Review of previous minutes and actions:**<br>The minutes of the 3rd March 2022 IGARD meeting were reviewed out of committee by IGARD following conclusion of the meeting, and subject to a number of minor changes were agreed as an accurate record.<br>**Out of committee recommendations:**<br>An out of committee report was received (see Appendix A). |
| **2** | **Briefing Notes** |
| **2.1** | <u>Alcohol Dependence Dataset – Briefing Paper (Presenters: Richard Irvine / Frances Hancox)</u><br>The briefing paper was to inform IGARD of the onboarding of the Alcohol Dependence dataset and had been previously discussed at the IGARD business as usual meeting on the 24th February 2022.<br>The NHS Long Term Plan (LTP) sets out commitments in relation to prevention including optimisation of hospital services that support alcohol dependent patients, specifically in the form of Alcohol Care Teams (ACTs), which are liaison services that support hospital patients with alcohol use disorders, mainly those who are alcohol dependent.<br>The dataset will contain record level data about individuals referred to ACTs and include details such as the date of referral and number of interactions with the ACT. The initial intention is to make this dataset available to NHS England/Improvement and Clinical Commissioning Groups (CCGs).<br>The Alcohol Dependence dataset is required in order to monitor the impact and clinical outcomes of alcohol dependence treatment services, as well as the impact on reducing health inequalities. It will also contribute to the evaluation of the programme and drive future policy decisions in terms of further roll out.<br>IGARD noted the importance piece of this work with regard to monitoring care and clinical outcomes.<br>IGARD welcomed the finalised briefing paper and made no further comments.<br>IGARD looked forward to receiving a copy of the finalised briefing paper, and any relevant supporting documents, at a future meeting of IGARD alongside the first of type application at IGARD, as per usual practice. |
| **2.2** | <u>Tobacco Dependence Dataset – Briefing Paper (Presenters: Richard Irvine / Frances Hancox)</u><br>The briefing paper was to inform IGARD of the onboarding of the Tobacco Dependence Dataset and had been previously discussed at the IGARD business as usual meeting on the 24th February 2022.<br>The NHS Long Term Plan (LTP) set out commitments towards the prevention of ill health, including the implementation of the Prevention Programme – NHS funded tobacco dependence treatment services. To deliver these commitments, NHS E/I is investing £150m by 2023/24 through the LTP, specifically to roll out the NHS-funded tobacco dependence treatment services across inpatient, maternity and specialist mental health outpatient/community settings. |

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| | The dataset will contain record level data about individuals eligible for referral to Tobacco Dependence Services and include details such as a person's smoking status and whether they had quit smoking by a certain point in time. The initial intention is to make this dataset available to NHS England/Improvement and Clinical Commissioning Groups (CCGs).<br><br>The Tobacco Dependence dataset is required to monitor the impact and clinical outcomes of tobacco dependence treatment services and the impact on reducing health inequalities. It will also contribute to the evaluation of the programme and drive future policy decisions in terms of further roll out.<br><br>IGARD welcomed the finalised briefing paper and made no further comments.<br><br>IGARD looked forward to receiving a copy of the finalised briefing paper, and any relevant supporting documents, at a future meeting of IGARD alongside the first of type application at IGARD, as per usual practice. |
| **3** | **Data Applications** |
| **3.1** | University of Warwick: Rehabilitation Exercise and psycholoGical support After covid-19 InfectioN (REGAIN) (Presenter: Frances Perry) NIC-629056-F4L4B-v0.3<br><br>**Application:** This was a new application for identifiable Demographics data; for the purpose of identifying potentially eligible participants and inviting them to take part in the REGAIN study.<br><br>The REGAIN intervention is an eight-week online, supervised, home based exercise rehabilitation with behavioural, motivational and mental health support. REGAIN includes individual assessment, supervised home based exercise programme with pre-recorded and live sessions and one-to-one and group online psychological and motivations support and education. The control group is a 'light touch' exercise and behaviour intervention, where participants will receive a single, online, one-to-one, practitioner consultation with general advice on safe and effective physical activities in adults with ongoing COVID-19 sequelae (a condition which is the consequence of having COVID-19) more than three months after hospital discharge (long-COVID).<br><br>Since recruitment started in January 2021, the study has recruited 210 participants of a target of 535 participants primarily from secondary care Trusts. The purpose of the application is to support recruitment to the study. The study aims to inform long term care for COVID-19 survivors and benefit patients and society.<br><br>The legal basis for the flow of data out of NHS Digital, is The Health Service Control of Patient Information (COPI) Regulations 2002.<br><br>**Discussion:** IGARD welcomed the application and noted the importance of the study / research.<br><br>IGARD noted that a special condition had been inserted in section 6 (Special Conditions) that the data would only be provided by NHS Digital up to and including The Health Service (Control of Patient Information) Regulations 2002 (COPI) Notice expiry date (currently the 30th June 2022). However, IGARD queried if the provision of data would have to stop before the COPI Notice expired, since Allied Publicity Services (APS) Group, who would be providing the mail out services to assist with trial recruitment, would not be able to hold the data beyond the COPI Notice expiry date.<br><br>IGARD noted that in relation to the provisions under Regulation 3 COPI that long-covid was **not** a communicable disease* and noted that the research related to treatment of an illness, **not** diagnosing, recognising trends, controlling and preventing spread or monitoring and |

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| | managing outbreaks or incidents of communicable disease. IGARD asked that the Privacy, Transparency & Ethics (PTE) directorate confirm that Regulation 3 COPI was an appropriate legal basis for the flow of confidential data for research into treatment for a non-communicable illness under this data sharing agreement (DSA). In addition, written confirmation from PTE should be uploaded to NHS Digital's customer relationship management (CRM) system, as a future supporting document.<br><br>IGARD noted the inherent risk of NHS Digital flowing data in the absence of case law testing Regulation 3 of COPI and its application to illnesses that were the result of communicable diseases.<br><br>*Communicable diseases are also known as infectious or transmissible diseases.<br><br>There was a lengthy discussion with regard to long covid, and IGARD suggested that it be made clear throughout the application, noting that section 5 (Purpose / Methods / Outputs) of the application summary formed NHS Digital's data uses register, that the definition of long covid requiring a hospital stay was particular to this study. In addition, IGARD asked that it be made clear throughout the application that the definition of long covid was the study's definition only. IGARD asked that section 5(c) (Specific Outputs Expected) and section 5(d) (Benefits) be updated to be clear that the study and its outputs were based on those hospitalised with COVID-19 and would **not** include any participants who may meet other diagnostic criteria for long covid but were not hospitalised.<br><br>IGARD noted the inclusion criteria outlined in section 5(a) (Objective for Processing) was for participants to be 18 years or older, treated in hospital with COVID-19, discharged from hospital at least 3 months ago and that they must be alive, and suggested that a clear justification was provided as to why children and young people were excluded from the study. In addition, IGARD asked how the inclusion and exclusion criteria would work together and that this be explained in section 5 for transparency.<br><br>Noting the age profile of those with long covid and hospitalised, IGARD queried the low expected recruitment rate of 2.5% and that NHS Digital would be inviting circa 20,000 participants over two mailings in order to generate the 325-recruitment target and asked if this was in any way attributable to the need for digital access.<br><br>IGARD noted that there may be a potential study bias stemming from the digital access barriers and suggested that section 5 was updated to be clear that the sign-up mechanism and treatment interventions required digital access which in turn may impact on the cohort characteristics. IGARD also asked that section 5 clearly explained if the study could make any adjustments or mitigating steps in the production of, or explanation of, the outputs in relation to the digital access barriers. IGARD also queried how the study would ensure a representative sample of the population and suggested that where referencing "*monitoring*" of characteristics of the cohort in section 5, that an explanation of the mitigating steps that may be taken to ensure a representative population sample was included.<br><br>IGARD noted that the trial began in January 2021 and queried if the study was looking at specific COVID-19 variants and suggested that section 5 be updated to clarify if different variants were being tracked throughout the study period, for transparency.<br><br>IGARD noted the excellent patient and public involvement and engagement (PPIE), however noted that there may be sensitivities around the intensive treatment and intervention offered as part of the trial and recommended on-going public and patient involvement.<br><br>Noting the potentially impactful and long-running nature of this study, IGARD queried whether the applicant would later seek follow up data. If this is a possibility, IGARD urged the applicant |

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| | to ensure their consent materials included (amongst other aspects) narrative around the potential long-term follow up, the sharing of data with NHS Digital, a description of the type of data that may be gathered, and a description of any possible linkages, since the current restrictive language in their consent materials may preclude NHS Digital providing follow up data linked to the cohort.<br><br>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 time-limited nature of the legal basis.<br><br>**Outcome:** recommendation to approve by a quorum of 4 members, with one specialist member dissenting, subject to the following condition:<br><br>1. In respect of reliance on Regulation 3 of The Health Service (Control of Patient Information) Regulations 2002 (COPI):<br>a. NHS Digital PTE to confirm the Reg 3 COPI is an appropriate legal basis for the flow of confidential data under this DSA, noting that Long covid, the subject of this research, is **not itself** a communicable disease.<br>b. To upload the written PTE confirmation to NHS Digital's CRM system.<br><br>The following amendments were requested:<br><br>1. In respect of long covid:<br>a. To make clear throughout the application that the definition of long covid requiring a hospital stay is particular to this study, and<br>b. To make clear throughout the application that the definition of long covid outlined in the application is the study's definition only, and<br>c. Section 5(c) and 5(d) to be updated to be clear that the study and its outputs are based on those hospitalised with COVID-19 and will not include any participants who may meet other diagnostic criteria for long covid but were not hospitalised.<br>2. In respect of the inclusion and exclusion criteria<br>a. To include a justification in section 5 as to why children and young people are excluded from this study, and<br>b. To provide further clarification in section 5 as to how the inclusion and exclusion criteria work together.<br>3. In respect of any potential study bias stemming from the digital access barriers:<br>a. To update section 5 to be clear that the sign-up mechanism and treatment interventions require digital access, which may impact on the cohort characteristics, and<br>b. To explain in section 5 if the study can make adjustments and take any mitigating steps in the production or explanation of outputs, and<br>c. Where referencing the "*monitoring*" of the characteristics of the cohort population in section 5, to explain any mitigating steps that might be taken to ensure a representative sample of the population is included.<br>4. To note in section 5 if different COVID-19 variants are being tracked throughout the study period.<br><br>The following advice was given:<br><br>1. IGARD noted that there may be sensitivity around the type of treatment and intervention offered and recommended on-going public and patient involvement. |

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| | 2. IGARD queried if the low recruitment rate of 2.5% was in any way attributable to the need for digital access, noting the profile of those who would be usually hospitalised for long covid.<br>3. IGARD noted the potentially impactful and long-running nature of this study and urged the applicant to ensure their consent materials included (amongst other aspects) narrative around the potential long-term follow up, the sharing of data with NHS Digital, a description of the type of data that may be gathered, and a description of any possible linkages, since the current restrictive language in their consent materials may preclude the future use of NHS Digital data being provided for or linked to the cohort.<br>4. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the time-limited nature of the legal basis.<br>5. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the time-limited nature of the legal basis.<br><br>**Risk Factor:** IGARD noted the inherent risk of NHS Digital flowing data in the absence of case law testing regulation 3 of COPI and its application to illnesses that were the *result* of communicable diseases.<br><br>It was agreed the conditions would be approved out of committee (OOC) by IGARD members. |
| **3.2** | <u>AstraZeneca AB: DAPA MI - A Registry-based, Randomised, Double-blind, Placebo Controlled Cardiovascular Outcomes Trial (Presenter: Frances Perry) NIC-433176-J8Q2S-v1.2</u><br><br>**Application:** This was a renewal application to permit the holding and processing of pseudonymised NICOR Myocardial Ischaemia National Audit Project (MINAP) data; and an amendment to **1)** add pseudonymised Civil Registration (death) data; and **2)** to facilitate the linkage of trial participants recruited in Welsh hospitals with their corresponding Welsh data. This linkage will occur alongside the existing linkage to those participants recruited in English hospitals.<br><br>The purpose is for a registry based randomised double-blinded placebo-controlled cardiovascular outcomes trial to evaluate the effect of Dapagliflozin on the incidence of heart failure or cardiovascular death in patients without diabetes with acute myocardial infarction at increased risk for subsequent development of heart failure. Dapagliflozin is a drug that was originally developed for the treatment of type 2 diabetes.<br><br>This application is limited to patients who have consented into the trial and enrolled according to the strict inclusion and exclusion criteria of the trial protocol. The first patients were enrolled in the UK in April 2021 and enrolment is planned for 18 months or until 3,200 cohort members have been recruited.<br><br>**Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 25th March 2021.<br><br>IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 2nd March 2021, 9th March 2021 and 16th March 2021.<br><br>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. |

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| | IGARD noted the description in the protocol, provided as a supporting document (SD), of the Executive Committee detailed in SD 2 section 4.8.1: "*The Executive Committee (EC) will be responsible for the overall design, including the development of the protocol and any protocol amendments, supervision, interpretation and reporting (presentations at international congresses and publications in peer reviewed journals) of the study. The EC will make recommendations to AZ regarding early stopping or modifications of the study based on the information received from the Data Monitoring Committee (DMC). The EC will be comprised of designated international academic leaders and non-voting members of the Sponsor, and will operate under a separate EC charter*." IGARD asked that written clarification of the term "*contracted to*" was provided as well as the meaning, for example if it is a substantive contract of employment or another form of contract. IGARD asked that the written confirmation be uploaded to the NHS Digital customer relationship management (CRM) system and / or section 5 (Purpose / Methods / Outputs) of the application be updated.<br><br>Whether a substantive contract of employment or another contract, the application should be updated to describe how this impacted on the data controllership arrangements, as borne of the facts, and in line with NHS Digital DARS Standard for Data Controllers, including any analysis undertaken by NHS Digital.<br><br>IGARD also noted that a member of the Executive Committee was based in Texas, USA, and noting the permitted territory of use as outlined in section 3 (Datasets Held / Requested) restricted the use to the UK and European Economic Area (EEA), asked that written confirmation was provided that the member based in Texas would **not** have access to any data under this data sharing agreement (DSA), and in line with the NHS Digital DARS Standard for Territory of Use. IGARD asked that the written confirmation be uploaded to the NHS Digital CRM system and / or section 5 of the application be updated.<br><br>IGARD noted the inclusion of a number of technical phrases and words within section 5(a), such as *"Ecodes"*, asked that this public facing section, that forms NHS Digital's data uses register, was amended throughout, to ensure technical terms are defined upon first use, and explained in a manner suitable for a lay audience.<br><br>IGARD noted reference to "…*the data required by AstraZeneca AB is being collected by NHS Digital from NICOR* under a COPI** Direction*…" and suggested this reference be removed since it was not relevant to this data sharing agreement (DSA).<br><br>*National Institute for Cardiovascular Outcomes Research (NICOR)<br><br>**The Health Service (Control of Patient Information) Regulations 2002 (COPI)<br><br>**Outcome:** recommendation to approve subject to the following condition:<br><br>1. In respect of the AstraZeneca Executive Committee:<br>a. To provide written clarification of the term "*contracted to*" and what it meant, for example is it a substantive contract of employment or another form of contractual connection, and<br>b. In either case and subject to the clarification in point 1(a) to describe how this impacts on the data controllership arrangements, as borne of the facts, and in line with NHS Digital DARS Standard for Data Controllers, and<br>c. To provide written confirmation that the Executive Committee member based in Texas (USA) will **not** receive any data under this DSA, noting the permitted territory of use is restricted to UK and EEA, and<br>d. To upload the written confirmation(s) as appropriate to NHS Digital's CRM system, AND / OR |

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| | e. To amend section 5 of application with relevant narrative.<br><br>The following amendments were requested.<br><br>1. To remove reference in section 5(a) to data being collected by NHS Digital from NICOR under a COPI Direction, since it is not relevant.<br>2. As section 5 forms NHS Digital's data uses register, to amend section 5(a) throughout, so technical terms are used only where necessary and explained in a manner suitable for a lay audience, for example *"Ecodes"*.<br><br>It was agreed the conditions would be approved out of committee (OOC) by IGARD members. |
| **3.3** | Imperial College London: A phase I study to determine safety and immunogenicity of the candidate COVID-19 vaccine AZD1222 delivered by aerosol in healthy adult volunteers (COVAXAER01) (Presenter: James Gray) NIC-637092-P9K6S-v0.2<br><br>**Application:** This was a new application to utilise the Permission to Contact Service (PtC) for the purpose of supporting recruitment to participate in a COVID-19 vaccine trial.<br><br>The phase 1 study is to determine the safety and immunogenicity of the candidate COVID-19 vaccine candidate AZD1222 (produced by AstraZeneca) delivered by aerosol in healthy adult volunteers, to investigate its safety, tolerability and capability of boosting immune responses both in the blood and the lung when administered to the respiratory tract in volunteers previously vaccinated by intramuscular COVID-19 vaccination.<br><br>Using standardised methods, the study team will measure immune responses in the blood, nose and lower airway and compare with data from ongoing clinical trials of intramuscular vaccination. By doing this analysis, the study team aim to demonstrate the effect of the delivery method and provide the critical information required to begin further clinical trials to show the efficacy of this needle-free vaccination strategy for booster vaccination.<br><br>The aim of this study is to recruit a total of 27 participants.<br><br>**Discussion:** IGARD had raised a query in advance of the meeting, that it appeared that NHS Digital would identify individuals meeting the relevant criteria and then extract their names, dates of birth, email addresses and postcodes, and queried why the date of birth and postcode were required. NHS Digital confirmed that only the names and email addresses would be passed to NHS Digital's contact centre to mail out to volunteers of the PtC service, and the dates of birth and postcodes were only used to interrogate the extract production services, given that volunteers may be required to be of a certain age or geographical location. IGARD suggested that section 1 (Abstract) and section 3 (Datasets Held / Requested) be updated to clearly state that only those fields allowed for the purpose of contact, such as name and email address, would be listed, rather than the current plethora of fields.<br><br>IGARD noted the special condition in section 6 (Special Conditions) that all Data Controllers should have a completed and published Data Security and Protection Toolkit (DSPT) to demonstrate security assurances for the purpose of this data sharing agreement (DSA); and in line with the NHS Digital DARS Standard for Security Assurance asked that for Imperial College London confirmation be provided that the DSPT was in place and that any requisite amendments to the DSA be undertaken, and before dissemination of data.<br><br>IGARD noted this was a phase 1 study and asked that section 1 and section 5 (Purpose / Methods / Outputs) be updated to clearly outline this fact and that its primary focus was on safety, as this was currently unclear. |

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| | IGARD noted that one of the exclusion criteria listed in section 5 was "*history of serious psychiatric conditions likely to affect participation in the study (e.g. ongoing severe depression, history of admissions to an in-patient facility, recent suicidal ideation, history of suicide attempt, bipolar disorder, personality disorder, alcohol and drug dependency, severe eating disorder, psychosis, use of mood stabilisers or antipsychotic medication*" and asked that a justification was provided for the exclusion of those with a previous psychiatric condition that may not be relevant to participation in the study (for example, a suicide attempt many years ago). IGARD noted that unless there was a suitable justification, there was a risk that NHS Digital may be supporting discrimination against those who had previously suffered from such conditions.<br><br>In addition, IGARD suggested that the exclusion criteria set out in section 5(b) (Processing Activities) be reordered to make clear what the study exclusions are, what the study criteria are, and what the invite selection criteria are, in line with the study protocol, provided as a supporting document, since it was not clear in section 5, which forms NHS Digital's data uses register. IGARD also asked that it be clear those criteria that were applied by NHS Digital and those criteria that were applied by the applicant to create the cohort.<br><br>As previously discussed with Digi-Trials, and noting that NHS Digital had discussed consent materials with the National Institute for Health Research (NIHR) who were the conduit between NHS Digital and the study trials, IGARD noted that the consent materials did not appear to cover confidential patient information being sent to, or handled by, NHS Digital for long-term follow-up. IGARD urged the applicant to ensure their consent materials included (amongst other aspects) narrative around any potential long-term follow up, the sharing of data with NHS Digital, a description of the type of data that may be gathered, and a description of any possible linkages as appropriate.<br><br>IGARD also suggested, separate to this application, that NHS Digital review its Data Protection Impact Assessment (DPIA) to address the possible digital exclusion created by the mechanism of the PtC database, noting that IGARD commented on this aspect when the PtC was set up nearly two years ago. IGARD suggest that further thought was given by NHS Digital as to how participation could be widened to include those with limited access to the Internet, or to explain why it was not possible to include them, for transparency of process.<br><br>**Outcome:** recommendation to approve<br><br>The following amendments were requested:<br><br>1. In respect of the ICL DSPT<br>a. To provide confirmation that the ICL DSPT is in place, and<br>b. To make requisite updates to the application, as necessary.<br>2. To make clear in section 1 and section 3 that only those fields allowed for the purpose of contact, such as name and email address, will be listed, rather than the current plethora of fields.<br>3. In respect of the exclusion criteria:<br>a. To update section 1 and section 5 to clearly outline what a phase 1 study is and that its focus is on safety, and<br>b. To provide a justification in section 5 for the exclusion of those with a previous psychiatric illness, and<br>c. To reorder the exclusion criteria to make clear what the study exclusion are, what the study criteria are, and what selection criteria are, and to distinguish those criteria that are applied by NHS Digital and those criteria that are applied by the applicant to create the cohort. |

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| | The following advice was given:<br><br>1. As previously discussed with Digi-Trials, IGARD noted that the consent materials seemingly preclude confidential patient information being sent to, or handled by, NHS Digital for long-term follow-up. IGARD urged the applicant to ensure their consent materials included (amongst other aspects) narrative around any potential long-term follow up, the sharing of data with NHS Digital, a description of the type of data that may be gathered, and a description of any possible linkages.<br>2. **Separate to this application:** IGARD suggested that NHS Digital review its DPIA to address the digital exclusion created by the mechanism of the PTC database, noting that IGARD commented on this aspect when the PTC was set up nearly two years ago. IGARD suggest that further thought is given by NHS Digital as to how participation could be widened to include those with limited access to the Internet, or to explain why it is not possible to include them.<br><br>**Significant Risk Factor:** Unless there is a suitable justification for the exclusion of those who have previously had a psychiatric condition, there is a risk that NHS Digital will be supporting discrimination against such individuals. |
| **3.4** | Liverpool Heart and Chest Hospital NHS FT: FFRCT In Stable Heart disease & CTA Helps Improve Patient care and Societal costs (FISH & CHIPS) (Presenter: Charlotte Skinner) NIC-460711-S8W6S-v0.13<br><br>**Application:** This was a new application for identifiable Civil Registration (Deaths), Diagnostic Imaging Dataset (DIDs), 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 for the Fractional Flow Reserve derived from Computed Tomography (FFRCT) in Stable Heart disease and Coronary Computed Tomography Angiography Helps Improve Patient care and Societal costs (FISH and CHIPS)<br><br>The study that will be comparing individuals' care who had FFRCT to those that did not. Rapid, early and accurate diagnosis of coronary artery disease (CAD) is essential to allow the appropriate diagnosis and treatment of patients. Coronary Computed Tomography Angiography (CCTA) is now the most used test for investigating patients with suspected CAD. For the two thirds of patients who have CAD, CCTA cannot tell whether the CAD is responsible for the patient's symptoms, this results in patients requiring further tests and sometimes unnecessary invasive tests (angiograms) with an increased risk to the patient and cost to the NHS.<br><br>A new technology, FFRCT, uses the CCTA images to make a 3D model of the heart blood vessels that shows whether there is a limitation in the blood flow to the heart which is causing the symptoms. The National Institute for Health and Care Excellence (NICE) recommends the use of FFRCT in a chest pain pathway, however, use of this new technology remains limited due to funding restrictions and uncertainty as to its benefit.<br><br>The study is relying on s251 of the NHS Act 2006, for the flows of identifiable data.<br><br>**Discussion:** IGARD confirmed that they were of the view that the relevant s251 was broadly compatible with the processing outlined in the application.<br><br>Given the commercial aspect to the study, IGARD queried why the data sharing agreement (DSA) duration was three years and not one year as per the current published NHS Digital DARS Standard for Commercial Purpose. IGARD suggested further discussions be |

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| | undertaken with NHS Digital, separate to this application, with regard to the current DARS Standard and how commercial applications are defined.<br><br>IGARD had a lengthy discussion with regard to HeartFlow Inc who were named on the study grant and who also performed the FFRCT analysis for NHS Trusts. IGARD noted that NICE had published on his website on the 13th February 2017 (last updated 19 May 2021) a medical technical guidance document entitled: "*HeartFlow FFRCT for estimating factional flow reserve from coronary CT angiography*" particularly section 2.1 "*HeartFlow $FFR_{CT}$ (developed by HeartFlow) is coronary physiology simulation software used for the qualitative and quantitative analysis of previously acquired computerised tomography DICOM data. The software provides a non-invasive method of estimating fractional flow reserve (FFR) using standard coronary CT angiography (CCTA) image data. FFR is the ratio between the maximum blood flow in a narrowed artery and the maximum blood flow in a normal artery. FFR is currently measured invasively using a pressure wire placed across a narrowed artery*." IGARD also noted that this technology may be specific to Heartflow suggested by the attempts to protect their software, as noted in the Trademark website and also registered US patents.<br><br>In addition, IGARD noted that DSA NIC-292087-M7V9Q University Hospital Southampton NHS FT had been presented to IGARD on the 23rd January 2020, which was a randomised trial comparing 1400 patients with new onset chest pain who were prospectively assigned to either routine assessment or non-invasive technique using the FFRCT assessment, and where Heartflow had provided the funding to the study and cited as a company who had developed new software that allowed FFRCT. IGARD asked that for transparency, the application was updated throughout to make clear that Heartflow Inc. were the organisation who originally developed the tool (and funded the FORECAST trial which used NHS Digital data under NIC-292087-M7V9Q),<br><br>IGARD noted that unlike in NIC-292087-M7V9Q University Hospital Southampton NHS FT and the study protocol provided for this DSA, Heartflow Inc had not been listed in section 8(b) (Funding Sources) as a funding source and asked that this section be updated. In addition, section 5 (Purpose / Methods / Outputs) should be updated to also include reference to Heartflow Inc as a funder and that section 5(b) (Processing Activites) was also updated to outline the nature of any data received by Heartflow Inc. under this DSA.<br><br>IGARD suggested, and in line with the NHS Digital DARS Standard for Data Controllers, that NHS Digital satisfy itself that Heartflow Inc were not carrying out any Data Controller activities, and to specifically address the facts, for example the references in section 5(c) (Specific Outputs Expected) to Heartflow Inc. "…*have appointed a UK lead for engagement and advocacy who is working closely with NHS Digital and the AAC*…", and Heartflow Inc. UK Lead working closely and NHS England and the link to the accelerated access collaboration (AAC).<br><br>IGARD noted the verbal update from NHS Digital that the current section 5(e) (is the purpose of this application in any way Commercial?) wording would be updated to: "*No NHS Digital data will be shared with the industrial partner. This means the data or any subset of the data provided by NHS Digital under this Data Sharing Agreement including manipulated data, as defined in the Data Sharing Framework Contract. Only aggregated results with small number suppression that has been derived through the processing of NHS Digital data may be shared with the industrial partner*." and in line with the NHS Digital DARS Standard for commercial purpose, asked that section 5(e) be updated as outlined above and that a brief summary be included in section 5(a) (Objective for Processing) of the fully commercial aspects of the |

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| | application. In addition, IGARD suggested that "*industrial partner*" be updated to "*Heartflow Inc*."<br><br>IGARD noted that a data flow diagram had been provided as a supporting document however it was not clear if this was the same data flow diagram provided as part of the pack to Health Research Authority Confidentiality Advisory Group (HRA CAG), and asked confirmation be provided that this had been approved by HRA CAG.<br><br>**Subsequent to the meeting:** IGARD queried if the HRA CAG annual review, due 28th January 2022, had been submitted and accepted, and asked that confirmation be provided in section 1 and that written confirmation from HRA CAG be uploaded to NHS Digital's customer relationship management (CRM) system.<br><br>IGARD noted, in line with NHS Digital's DARS Standard for Security Assurance, that all Data Controllers should have a completed and published Data Security and Protection Toolkit (DSPT) to demonstrate security assurances for the purpose of this data sharing agreement (DSA), alongside the HRA CAG condition of support which stated that "*all staff involved in processing data under section 251 support must have successfully completed local security awareness training before processing any data*", and suggested that this be included as a special condition in section 6 (Special Conditions). In addition, and noting that section 5 forms NHS Digital's data uses register, IGARD asked that it be updated to reflect the HRA CAG conditions of support.<br><br>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 if in accordance with the latest advice from the Privacy, Transparency and Ethics (PTE) Directorate.<br><br>**Outcome:** recommendation to approve for 1 year subject to the following conditions:<br><br>1. To confirm that the data flow diagram provided as a supporting document is the same data flow diagram provided to and approved by HRA CAG.<br>2. In respect of Heartflow Inc. (based in Redwood City, USA):<br>a) To list Heartflow Inc. as a funding source in section 8(b) (as indicated in the protocol provided as a supporting document), and<br>b) To update the application throughout to make clear that Heartflow Inc. were the organisation who originally developed the tool (and funded the FORECAST trial which used NHS Digital data under NIC-292087-M7V9Q), and<br>c) NHS Digital to satisfy itself that Heartflow Inc are not carrying out any Data Controller activities, and in line with the NHS Digital DARS Standard for Data Controllers, and to specifically address the facts for example the references to Heartflow Inc. appointing a UK lead for engagement and advocacy and Heartflow Inc. UK Lead working closely and NHS England and the link to the accelerated access collaboration, and<br>d) To make clear in section 5 that Heartflow Inc are a funder.<br>e) To update section 5b outlining the nature of the data received by Heartflow Inc as set out in section 5e.<br><br>The following amendments were requested:<br><br>1. In line with the NHS Digital DARS Standard for commercial purpose, |

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| | a) to provide a brief summary in section 5(a) of the full commercial aspects of this application, as outlined in section 5(e), and<br>b) to update references to "*industrial partner*" to "*Heartflow Inc*."<br>2. In respect of HRA CAG:<br>a) To include in section 6, the HRA CAG condition of support "*all staff involved in processing data under section 251 support must have successfully completed local security awareness training before processing any data*", and<br>b) To update section 5, which forms NHS Digital's data uses register, to reflect the HRA CAG conditions of support, and<br>c) To provide confirmation that the HRA CAG annual review, due 28 January 2022, had been submitted and accepted, and<br>d) To upload the written confirmation from HRA CAG to NHS Digital's CRM system AND to update section 1 (Abstract).<br>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.<br><br>**Subsequent to the meeting:** the IGARD Chair queried if the HRA CAG annual review, due 28 January 2022, had been submitted and accepted. The Chair asked that this update be added to the outcomes and confirmation provided in section 1 and uploaded to NHS Digital's CRM system for future reference.<br><br>It was agreed the conditions would be approved out of committee (OOC) by IGARD members. |
| **4** | Applications progressed via NHS Digital's Precedent route, including the SIRO Precedent<br><br>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** | NHS England / Improvement<br><br>IGARD noted that at the BAU meeting on the 24th March 2022, NHS Digital presented the Alcohol Dependence Dataset and Tobacco Dependence Dataset Briefing Papers (see section 2).<br><br>The datasets are required in order to monitor the impact and clinical outcomes of alcohol and tobacco dependence treatment services, as well as the impact on reducing health inequalities. It will also contribute to the evaluation of the programme and drive future policy decisions in terms of further roll out.<br><br>Following the comments made by IGARD on the 24th March 2022, and the subsequent updates made to the briefing papers by NHS Digital; NHS Digital had been advised in writing (via the IGARD Secretariat) on the 4th March 2022, that the SIRO had agreed to authorise the flow of these datasets to NHS England / Improvement.<br><br>IGARD noted and thanked NHS Digital for the written update. |
| **5** | Oversight & Assurance<br><br>IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. Due to the volume and complexity of applications at |

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| | today's meeting, IGARD were unable to review any Data Access Request Service (DARS) applications as part of their oversight and assurance role.<br><br>IGARD Members noted that they had not yet been updated on the issues raised at the 27th May 2021 IGARD business as usual (BAU) meeting with regard to previous comments made on the IG COVID-19 release registers March 2020 to May 2021. IGARD noted that in addition, they had not been updated on the issues raised on the IG COVID-19 release registers June 2021 to January 2022.<br><br>IGARD Members noted that the last IG COVID-19 release register that they had reviewed and provided comments on was January 2022.<br><br>IGARD also noted that the NHS Digital webpage Excel spreadsheet was for the period March 2020 to May 2021 and that they had queried for some considerable time with PTE why the COVID-19 (non-DARS) data release register was not being updated in a timely fashion: NHS Digital Data Uses Register - NHS Digital |
| **6** | COVID-19 update<br><br>*No items discussed* |
| **7**<br><br>**7.1** | AOB:<br><br>NIC-68740-X7R2N-v2.5 Barts Health NHS Trust: MR1486 - International Surgical Outcomes Study: Long-term survival & healthcare utilisation (No Presenter)<br><br>The application had been presented to IGARD on the 3rd February and recommended for approval<br><br>The following amendments were requested:<br><br>1. To update section 1 and review the application throughout to remove reference(s) to the *"COVID-19 Inquiry"* as it is not relevant to this application.<br>2. To update the application where relevant to reflect that the data requested will effectively be *"identifiable"* and not "*pseudonymise*d".<br>3. In respect of the honorary contract:<br>a) To provide confirmation that the honorary contract has been extended.<br>b) To upload all appropriate documentation to NHS Digital's CRM system for future reference.<br><br>The following advice was given:<br><br>1. IGARD suggested that this application would be suitable for NHS Digital's Precedent route, including the SIRO Precedent.<br><br>Whilst progressing the amendments, NHS Digital noted that National Data Opt-outs would be applied to the whole cohort for the entire recruitment period and that they had amended section 3(c) (Patent Objections Applied) to state 'Yes". NHS Digital have advised the applicant to ensure the ISOS privacy notice is updated to make it clear to participants that if they had requested NDOs, that their data would not be used for the study.<br><br>IGARD noted and thanked NHS Digital for the written update.<br><br>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 04/03/22

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) |
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| NIC-604851-W0M3S | GRAIL Bio UK Ltd | 13/01/2022 | 1. In relation to the Global Transfer Assessment:<br>a) To provide written confirmation from NHS Digital's PTE that the appropriate Global Transfer Assessment documentation has been approved and in place.<br>b) To upload the written confirmation to NHS Digital's CRM system. | IGARD Chair | Chair's Authority | The IGARD Chair noted that the multi-limbed condition was **not** been met, however under Chair's authority and due process as outlined in our ToR and associated published Standard Operating Procedures, has supported the alternative route proposed, which would be to prevent the data going out of the EEA via special condition, with the following caveats:<br>• I would not support a year's contract. I would suggest this is for **three months** as presumably this GTA issue can be clarified by then. If there is a good reason |

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| | | | | | | provided for a year's contract, I would be happy to reconsider.<br>• the Territory of Use in Section 2c of the DSA must change to EEA. (NB the special condition precludes any organisation outside EEA receiving the data so that means AWS in the US may not store data either. Do all the parties understand this?).<br>• the narrative in the abstract must make it clear that the IGARD condition was **not met**. For GRAIL and any other US entities to receive the data there must be appropriate approvals in place and that has not altered. |

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