Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 24 February 2022

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member
Dr. Robert French	Specialist Academic / Statistician Member (Observer)
Kirsty Irvine	IGARD Chair
Dr. Maurice Smith	Specialist GP Member
Jenny Westaway	Lay Member (Observer)
IGARD MEMBERS NOT IN ATTENDANCE:	
Prof. Nicola Fear	Specialist Academic Member
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Chair
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Vicky Byrne-Watts	Data Access Request Services (DARS) (SAT* Observer: items 3.1 - 3.2, 3.4 - 3.5)
Garry Coleman	Associate Director / Senior Information Risk Owner (SIRO) (Observer: items 2.1 - 2.2)
Catherine Day	Data Access Request Service (DARS) (Items 3.4 - 3.5)
Faris Dean	Data Access Request Service (DARS) (SAT* Observer: item 3.3)
Frances Hancox	Data Access Request Services (DARS) (Items 2.1 - 2.2)
Richard Irvine	Associate Director of Data Optimisation (Items 2.1 - 2.2)
Derrick Lovell	Data Access Request Service (DARS) (Observer: items: 3.1 - 3.4)
Aisha Powell	Data Access Request Service (DARS) (Item 3.3)
Vicki Williams	IGARD Secretariat
Clare Wright	Data Access Request Services (DARS) (Items 3.1 - 3.2)
***SAT** – Senior Approval Team (DARS)	

1	**Declarations of interests:** Dr. Maurice Smith noted that he was a GP working 20 hours per week and that he would be part of the GP workforce dataset being discussed as part of the Health Education England (NIC-440407-T9Q1J-v0.11) application. Dr. Smith noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest and did not preclude Dr. Smith from taking part in the discussions about this application. Dr. Maurice Smith noted a professional link with the Royal College of General Practitioners (RCGP) as a practising GP partner at the Mather Avenue Surgery in relation to comments made by PAG on the National Institute for Health and Care Excellence (NICE) (NIC-610798-N0G8Z-v0.4), but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest. Maria Clark noted a professional link to the National Institute for Health and Care Excellence (NICE) (NIC-610798-N0G8Z-v0.4), but no specific connection with the application or staff involved and it was agreed this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 17th February 2022 IGARD meeting were reviewed, and subject to a number of minor changes were agreed as an accurate record of the meeting. **Out of committee recommendations:** An out of committee report was received (see Appendix A).
2	**Briefing Notes**
2.1	<u>Alcohol Dependence Dataset – Briefing Paper (Presenters: Richard Irvine / Frances Hancox)</u> The briefing paper was to inform IGARD of the onboarding of the Alcohol Dependence dataset. 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. 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). 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. IGARD noted the importance piece of this work with regard to monitoring care and clinical outcomes. IGARD welcomed the draft briefing paper and provided high-level comments including, but not limited to:

	1. IGARD made a general comment that although they welcomed the data collection for alcohol services in hospitals, the vast majority of issues are identified and treated in the community and would be supportive of a similar data collection for community-based activity. 2. Noting the forthcoming CCG / ICS transition, to replace the references to *"CCG"* with *"commissioning bodies"* or similar. 3. To update the briefing paper to be clear that the Direction to collect data was issued by NHS England (not NHS England / Improvement) 4. To remove reference to the "*ICO Code of Practice on Anonymisation*", since this is being revised, and replace with a reference to "*pseudonymised*" data. 5. To establish how the Duty of Confidence is addressed for providers providing information to NHS Digital on a voluntary basis, i.e. not mandated to provide that data. 6. To update the NHS Digital webpages that indicates that patients have to "*consent*" to a privacy notice and give consent to secondary uses as a condition of getting treatment, which would be, inter alia in contravention of the NHS constitution. 7. To remove "*This could include NHS staff who use NHS services as patients*". While correct, this could be said of any data collection about use of NHS services. 8. To ensure that all acronyms upon first use be defined and further explained if the meaning is not self-evident, for example "*NCDR*". 9. To clearly outline what processing is being undertaken under which Article 9 legal basis (noting that this narrative came from the NHS Digital GDPR transparency pages which also needed to be updated). 10. Separate to this application, that NHS Digital follow due process and provide a copy of NHS Digital's DPIA as a supporting document as part of the IGARD review of any new dataset. 11. Separate from the briefing paper, but with a view to the forthcoming applications for use of the data, IGARD noted that NHS England's DPIA would need to be updated to address the processing of fields such as ethnicity and sexual orientation and that the DPIA would need to be updated prior to the processing of this data. IGARD welcomed the draft briefing paper and looked forward to receiving the updated briefing paper, either out of committee (OOC) or at a future meeting, and before any first of type applications were received by IGARD.
2.2	<u>Tobacco Dependence Dataset – Briefing Paper (Presenters: Richard Irvine / Frances Hancox)</u> The briefing paper was to inform IGARD of the onboarding of the Tobacco Dependence Dataset. 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. 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). 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. IGARD welcomed the draft briefing paper and provided of high-level comments including, but not limited to: 1. Noting the forthcoming CCG / ICS transition, to replace the references to *"CCG"* to *"commissioning bodies*" or similar. 2. To update the briefing paper to be clear that the Direction to collect data is issued by NHS England (not NHS England / Improvement). 3. To remove reference to the "*ICO Code of Practice on Anonymisation*", since this is being revised, and replace with a reference to "*pseudonymise*d" data. 4. To update the NHS Digital webpages that indicates that patients have to "consent" to a privacy notice and give consent to secondary uses as a condition of getting treatment, which would be, inter alia, in contravention of the NHS Constitution. 5. To remove "*This could include NHS staff who use NHS services as patients*" . While correct, this could be said of any data collection about use of NHS services. 6. To ensure that all acronyms upon first use be defined and further explained if the meaning is not self-evident, for example "*NCDR*" or "*CQUIN*" 7. To clearly outline what processing is being undertaken under which Article 9 legal basis (noting that this narrative came from the NHS Digital GDPR transparency pages which also needed to be updated). 8. Separate to this application, that NHS Digital follow due process and provide a copy of NHS Digital's DPIA as a supporting document as part of the IGARD review of any new dataset. IGARD welcomed the draft briefing paper and looked forward to receiving the updated briefing paper, either out of committee (OOC) or at a future meeting, and before any first of type applications were received by IGARD.
3	**Data Applications**
3.1	<u>University of Birmingham: Cancer Survivorship Studies (Presenter: Clare Wright) NIC-148313-G56YY-v1.6</u> **Application:** This was an amendment application **1)** that two Medical Research Information Service (MRIS) cohorts are combined MR787 British Childhood Cancer Survivor Study (BCCSS) and MR1262 Teenage and Young Adult Cancer Survivor Study (TYACSS). TYACSS previously existed under NIC-147797-45YH2-v0 agreement which will now be superseded by this application; **2)** The processing details section 5b has been updated to explain how the BCCSS and TYACSS cohorts will be combined into a single cohort; **3)** section 5(a) has been updated to explain how the Centre for Childhood Cancer Survivor Studies (CCCCS):propose to combine the BCCSS and TYACCS cohorts; **4)** To replace the original MRIS reports with Demographics, Civil Registration (Deaths) and Cancer Registration Data; **5)** to request the following additional datasets: Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC), HES Critical Care, HES Outpatients, Emergency Care Data Set (ECDS), Mental Health Services Data Set (MHSDS), Mental Health Minimum Data Set (MHMDS) and Mental Health and Learning Disabilities Data Set (MHLDDS). There is currently no comprehensive national system to monitor adverse health and social outcomes among the entire population of survivors of childhood, teenage and young adult cancer in Britain. However, there already exists two established national population-based

	cohorts of such survivors, which would enable such a comprehensive monitoring system to be created. The British Childhood Cancer Survivor Study (BCCSS) is a national population-based cohort of almost 35,000 individuals who were diagnosed with cancer under the age of 15 years, between 1940 and 2006, in England, Wales or Scotland, and who survived at least 5 years from diagnosis. The Teenage and Young Adult Cancer Survivor Study (TYACSS) is a national population-based cohort almost 201,000 individuals diagnosed with cancer when aged 15 to 39 years inclusive, between 1971 and 2006, in England or Wales and who survived at least 5 years from diagnosis. The Centre for Childhood Cancer Survivor Studies (CCCSS) which was established in 1998 proposes to combine the BCCSS and TYACSS cohorts. The purpose of the application is to establish a system to monitor the risks of adverse health outcomes and related healthcare activity and cost among these survivors, and to determine how observed risks and costs compare with those expected from the general population to determine subgroups of survivors who experience substantially increased risk and who may place a higher demand on services. A related application for tabulated data with small numbers not suppressed for the Cancer Survivorship cohort is being applied for under NIC-461060-D7X5H (item 3.2). The study is relying on s251 of the NHS Act 2006, for the flow of data into and out of NHS Digital. NHS Digital noted, following submission of the application for IGARD review, a number of spelling errors and these will be corrected. **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 the Health Research Authority Confidentiality Advisory Group (HRA CAG) letter of conditional support, provided as a supporting document, stated that "…*support only extends to England and Wales…*" and queried the references within the application to use of Scottish data. IGARD asked that the application was updated throughout to be clear that when referring to "*Scotland*" that the appropriate procedures would be followed with regard to obtaining the legal basis to use Scottish data, for example, but not limited to, explaining the source of the data and any linkage being undertaken. IGARD had raised a query in advance of the meeting, noting that consent was taken for involvement in the original studies and queried if the applicant had reviewed whether there was anything in the original consent materials that barred any of the activities outlined in the application. NHS Digital noted that they had asked the applicant to confirm that this was the original consent form and to check that there wasn't anything else sent out to participants. IGARD asked that for those cohort members who had declined in the past to allow their details to be shared or to take part in the further follow up or processing, which was circa 6% and 8% of those taking part in the study, that the applicant liaise with HRA CAG and ask HRA CAG to confirm that they were covered in the s251 support; or to confirm that s251 support did not include those cohort members. In all cases, a written confirmation of the HRA CAG narrative should be uploaded to NHS Digital's customer relationship management (CRM) system, and in addition that section 5 (Purpose / Methods / Outputs) of the application be updated accordingly.

	IGARD also suggested that the applicant's transparency materials should be updated to clearly articulate how the applicant identifies cohort members to enable them to opt out, and in line with the HRA CAG support provided as a supporting document. IGARD asked that it be clear in section 5(b) (Processing Activities) that re-identification will also occur to identify those members of the cohort who wish to be removed from the cohort. IGARD noted that the intention of the application seemed to be to create a research database and open access to other researchers and queried if this was the intention, noting that section 5(a) (Objective for Processing) mentioned "*sharing anonymised data*"; and suggested that section 5(a) where referencing the future research database, should be clear that this did **not** reference the established databases, but was the future direction of travel and that appropriate procedures would be followed in due course. IGARD were unclear if MRIS data was being more widely shared and suggested that NHS Digital clarify with the applicant whether or not they were sharing MRIS data with other researchers, since this was not covered under this DSA. 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. Noting that section 5 served as NHS Digital's public facing data uses register, IGARD suggested that this is written in a language suitable for a lay reader and in line with the NHS Digital's DARS Standards. IGARD noted the inclusion of a number of technical phrases and words within section 5 such as "*poisson regression*" and "*standardised incidence ratios*" 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 and commended the extensive public and patient involvement and engagement (PPIE) and suggested that the applicant take the opportunity to discuss with the various groups of whether use of the word "*survivor*" or "*survivorship*" should continue in publicity and outputs moving forward. In addition, IGARD suggested that the application be reviewed and updated accordingly with regard to the use of the word "*survivor*" when used as a description of the cohort and instead refer to "*people*" or another neutral term. IGARD asked that the word "*health*" be inserted into the phrase "*mental services*", to be clear it is "*mental health services*". Furthermore, IGARD suggested amending the wording in section 5(a) from "*…who may place a higher demand on services…"* to *"…those service users who require more support…"*. IGARD suggested that the reference to "*PHE*"* be amended to the "*UKSHA*"** or other relevant public body. *Public Health England **UK Health Security Agency **Outcome:** recommendation to approve subject to the following condition: 1. In respect of the HRA CAG support, for the applicant to liaise with HRA CAG and for HRA CAG to confirm that either:

a) those cohort members who had declined in the past to allow their details to be shared or to take part in the further follow up or processing **are** covered in the s251 support, OR
b) the s251 support **does not** include those cohort members, and
c) To upload the written confirmation in relation to point (a) or point (b) above, to NHS Digital's CRM system, and
d) To update the application accordingly.

The following amendments were requested.

1. To update the application throughout when referring to "*Scotland*" to be clear that the appropriate procedures will be following with regard to obtaining the legal basis to use Scottish Data, for example, but not limited to, explaining the source of the data and any linkage being undertaken.
2. To amend section 5(a) where referencing the future research database, to be clear that this application does not refer to the establishment of such a database, but that this is the future direction of travel and that appropriate procedures will be followed in due course.
3. To update section 3 to include a UK GDPR legal basis for those datasets that give information about cohort members who are still living, if this accords with the latest advice from PTE.
4. In respect of the language used throughout the application and in line with NHS Digital's DARS Standards:
   a) Noting that section 5 serves as NHS Digital's public facing data uses register, to ensure this is written in a language suitable for a lay reader,
   b) To revise the references to any technical language used within section 5, including (but not limited to), "*poisson regression*", "*standardised incidence ratios*" and update as necessary with further supportive text.
   c) to consider reviewing the use of the word *"survivor"* when used as a description of patients, and instead refer to "*people*" or other neutral term.
   d) to insert the word "*health*" into the "*mental services*", to be clear it is "*mental health services*".
   e) To amend the wording in section 5(a) from the "*…who may place a higher demand on services…"* to *"…those service users who require more support…"*.
5. To amend the reference to "*PHE*" to "*UKSHA*" (or other relevant public health body).
6. To be clear in section 5(b) that the re-identification will also occur to identify those members of the cohort who wish to be removed from the cohort.

The following advice was given:

1. IGARD suggested that NHS Digital clarify with the applicant whether or not they were sharing MRIS data, since this is not covered under this DSA.
2. IGARD noted and commended the extensive PPIE and suggested that the applicant take the opportunity to discuss with the various groups of whether use of the word "*survivor*" or "*survivorship*" should continue to be used in publicity and outputs moving forward.
3. IGARD suggested that the applicant's transparency materials should be updated to clearly articulate how the applicant identifies cohort members to enable them to opt out and in line with the HRA CAG support.

It was agreed the conditions would be approved out of committee (OOC) by IGARD members.

3.2	University of Birmingham: Cancer Survivorship Studies: national comparator data from routinely collected health service data (Presenter: Clare Wright) NIC-461060-D7X5H-v0.12 **Application:** This was a new application for Aggregated Small Numbers Not Suppressed Emergency Care Data Set (ECDS), Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC), HES Critical Care, HES Outpatients, Mental Health and Learning Disabilities Data Set (MHLDDS), Mental Health Minimum Data Set (MHMDS) and Mental Health Services Data Set (MHSDS). There is currently no comprehensive national system to monitor adverse health and social outcomes among the entire population of survivors of childhood, teenage and young adult cancer in Britain. However, there already exists two established national population-based cohorts of such survivors, which would enable such a comprehensive monitoring system to be created. The British Childhood Cancer Survivor Study (BCCSS) is a national population-based cohort of almost 35,000 individuals who were diagnosed with cancer under the age of 15 years, between 1940 and 2006, in England, Wales or Scotland, and who survived at least 5 years from diagnosis. The Teenage and Young Adult Cancer Survivor Study (TYACSS) is a national population-based cohort almost 201,000 individuals diagnosed with cancer when aged 15 to 39 years inclusive, between 1971 and 2006, in England or Wales and who survived at least 5 years from diagnosis. The Centre for Childhood Cancer Survivor Studies (CCCSS) which was established in 1998 proposes to combine the BCCSS and TYACSS cohorts. The purpose of the application is for a study, with the aim of establishing a system to monitor the risks of adverse health outcomes and related healthcare activity and cost among these survivors, and to determine how observed risks and costs compare with those expected from the general population to determine subgroups of survivors who experience substantially increased risk and who may place a higher demand on services. A related application for the Cancer Survivorship Studies for record level data for the Cancer Survivorship cohort is being applied for under NIC-148313-G56YY (item 3.1). **Discussion:** IGARD noted that the Health Research Authority Confidentiality Advisory Group (HRA CAG) letter of conditional support, provided as a supporting document, stated that "…*support only extends to England and Wales…*" and queried the reference within the application to use of Scottish data. IGARD asked that the application was updated throughout to be clear that when referring to "*Scotland*" that the appropriate procedures would be followed with regard to obtaining the legal basis to use Scottish data, for example but not limited to explain the source of the data and any linkage being undertaken. IGARD queried why small numbers not suppressed had been requested, and NHS Digital explained that the applicant needed to examine rare diseases, which are an important part of the study. IGARD noted the verbal update and asked that a brief explanation be provided in section 5(a) (Objective for Processing), for example referencing rare diseases. In addition, IGARD requested that a clear statement be inserted in section 5 (Purpose / Methods / Outputs) that the researchers would not attempt to re-identify any individual or carry out any other activity that may pick up an individual characteristic that could lead to identification. IGARD also noted that the applicant may not flag members of cohort in the tabulated flow of data and that if they needed to flag members of the cohort, that the applicant discuss the need with NHS Digital, since this may raise issues re identifiability and legal basis.

	Noting that section 5 served as NHS Digital's public facing data uses register, IGARD suggested that this is written in a language suitable for a lay reader and in line with the NHS Digital's DARS Standards. IGARD noted the inclusion of a number of technical phrases and words within section 5 such as "*poisson regression*" and "*standardised incidence ratios*" 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 suggested that the application be reviewed and updated accordingly with regard to the use of the word "*survivor*" when used as a description of patients and instead refer to "*people*" or other neutral term. Furthermore, IGARD suggested amending the wording in section 5(a) from the "*…who may place a higher demand on services…"* to *"…those service users who require more support…"*. **Outcome:** recommendation to approve The following amendments were requested. 1. To update the application throughout when referring to "*Scotland*" to be clear that the appropriate procedures will be following with regard to obtaining the legal basis to use Scottish Data, for example, but not limited to, explaining the source of the data and any linkage being undertaken. 2. To provide a brief explanation in section 5(a) why small numbers unsuppressed has been requested (e.g. reference to rare diseases). 3. In respect of the language used throughout the application and in line with NHS Digital's DARS Standards: a) Noting that section 5 serves as NHS Digital's public facing data uses register, to ensure this is written in a language suitable for a lay reader, b) To revise the references to any technical language used within section 5, including (but not limited to), "*poisson regression*", "*standardised incidence ratios*" and update as necessary with further supportive text. c) to consider reviewing the use of the word *"survivor"* when used as a description of patients, and instead refer to "*people*" or other neutral term. d) To amend the wording in section 5(a) from the "*…who may place a higher demand on services…"* to *"…those service users who require more support…"*. 4. To insert a clear statement in section 5 that the researchers will not attempt to re-identify any individual or carry out any other activity that may pick up individual characteristics that could lead to identification. The following advice was given: 1. IGARD noted that the applicant may not flag members of cohort in the tabulated flow of data and that if they need to flag members of the cohort that the applicant discuss the need with NHS Digital, since this may raise issues re identifiability and legal basis.
3.3	Imperial College London: Imperial College London (HES Amendment, Renewal/Extension) (Presenter: Aisha Powell) NIC-12828-M0K2D-v8.5 **Application:** This was an amendment application to **1)** to remove Dr Foster Ltd as a Data Processor including, removing the processing and storage locations associated with Dr Foster Ltd (Dr Foster Ltd have secured their own direct feed of data from NHS Digital); **2)** to limit the data storage and processing locations to two Imperial College London (ICL) locations; **3)** to remove the identifiable data field, local patient identifier held under the HES APC product; **4)** to

	remove references to the UK General Data Protection Regulation (UK GDPR) legal basis from Article 6(1)(f) 'Legitimate Interests' and replace with Article 6 (1) (e) for the processing of pseudonymised data; **5)** to update the funder from Dr Foster Ltd / Telstra Health UK to National Institute for Health Research (NIHR) Imperial (Biomedical Research Centre)BRC. The purpose is to identify measures of quality and safety in healthcare. Imperial College London Doctor Foster Unit (ICL DFU) research themes around developing and validating indicators of quality and safety of healthcare, particularly by GP practices, consultants, and NHS Trusts. This research finds variations in healthcare performance by unit, patient risk subgroups and risk prediction, risk adjustment and outlier detection for such indicators and variations, and any other methodological aspects as they arise. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the Data Access Advisory Group (DAAG) (IGARD's predecessor) on the 19th July 2016; and the IGARD business as usual (BAU) meetings on the 13th December 2018, 20th June 2019 and 20th June 2020. IGARD welcomed the application and noted the importance of the research. Although IGARD were clear that they did not have any queries with regard to the legal basis or Data Processors, they asked that clarification be sought of any continuing contact or liaison between ICL and Dr Foster Limited and to confirm within section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) that references to *"Dr Foster Unit"* was still an accurate description of the department, within ICL. In addition, and noting that the ICL website was significantly out of date (for example, but not limited to, referring to funding from Dr Foster Ltd), IGARD suggested that the applicant update their website as soon as possible to remove any misleading information. IGARD also suggested that the applicant seek clarification from their Research Ethics Committee (REC) as to whether the significant changes as outlined in the amendment application required an amendment submission, or if the REC were content to receive an update at the applicant's next annual report which was scheduled for May 2022, and that it was for the applicant to address this issue, not NHS Digital. IGARD noted that outputs and benefits cited within the application were NHS Trust orientated and noting that the research themes were around developing and validating indicators of quality and safety of healthcare, particularly by **GP practices**, consultants, and NHS Trusts asked that a justification be provided in section 5(a) (Objective for Processing) as to how the HES data would inform the assessment of the quality of GP practices. In addition, that a justification of the assessment with regard to the quality of GP practices in section 5(a) by using HES alone and to outline the outputs and benefits clearly in sections 5(c) (Specific Outputs Expected) and 5(d) (Benefits) respectively. IGARD noted that if a justification could not be provided, then all references to the assessment of the quality of GP practices should be removed from section 5(a) and throughout the application summary. 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. Noting that section 5 served as NHS Digital's public facing data uses register and in line with the NHS Digital's DARS Standards IGARD noted the inclusion of a number of technical

	phrases and words within section 5 such as "*time series 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 suggested that section 5(a) be updated to remove reference to "*it will*…" or "it can…", and instead use a form of words such as "*it is hoped*…" in reference to "*this dataset **will** enable identification of factors that drive successful treatment of a patient*" to "*it could*". IGARD asked that section 7 (Ethics Approval) was updated to remove the statement "*ethics approval is not required because pseudonymised data only*" since ethics supporting documentation had been provided by the University's REC. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of ICL and Dr Foster Limited: a) To clarify in section 5 of any continuing contact or liaison between ICL and Dr Foster Limited, and b) To confirm that reference to "*Dr Foster Unit*" is still an accurate description of the department. 2. In respect of GP practices: a) To provide a justification in section 5(a) of how the HES data will inform the assessment of the quality of GP practices, and b) To provide a justification of the assessment with regard to the quality of GP practices in section 5(a) by using HES alone and to outline the outputs and benefits in sections 5(c) and 5(d), OR c) If justification of the assessment cannot be provided, to remove its reference from section 5(a). 3. To update section 3 to include a UK GDPR legal basis for those datasets that give information about cohort members who are still living, if this accords with the latest advice from PTE. 4. To revise the references to any technical language used within section 5, including (but not limited to), "*time series analysis*" and update as necessary with further supportive text. 5. To update section 5(a) to use a form of wording such as "*it is hoped* …", rather than "*it will…*" in reference to "*this dataset **will** enable identification of factors that drive successful treatment of a patient*" to "*it could*" 6. To updated section 7 to remove "ethics approval is not required because pseudonymised data only" since ethics supporting documentation has been provided by the University's REC. The following advice was given 1. IGARD noted that ICL website was significantly out of date, for example, but not limited to, referring to funding from Dr Foster Ltd, and suggested that the applicant may wish to update their website. 2. IGARD suggested that the applicant may wish to seek clarification from REC as to whether the significant changes required an amendment submission, or if REC were content to receive an update at the applicant's next report (May 2022).
3.4	Health Education England (HEE): GP Workforce data (Presenter: Catherine Day) NIC-440407-T9Q1J-v0.11

	Application: This was a new application for identifiable General Practice Workforce Data Set. The purpose of the application is to support HEE's statutory function of workforce planning and modelling to predict the numbers needed to train to meet future demand. Each year there is a planning process across HEE and NHS England / Improvement, to estimate future demand, consider future supply routes and direct investment in education and training to close the gap between the two. In the case of GPs, previous planning rounds have identified a shortage, and this is why the Government have set a stretch target for growth and expansion of the training pipeline and the workforce. The Government will wish to monitor progress towards this target, both for training, and for uptake to the workforce. HEE want to be able to see the makeup of the workforce, and any areas where those who are training do not progress, need further support, or can be encouraged back. The key business questions are **1)** what happens to GPs when they qualify; **2)** when do GPs appear on the National Workforce Reporting Service; **3)** what happens to GPs who go into locum posts. **Discussion:** IGARD noted that a briefing paper had previously been presented to IGARD on the 13th February 2020, 26th March 2020, 28th January 2021, and 25th March 2021. IGARD welcomed the application and noted the importance of the study to inform planning. IGARD noted that since this was a first of type application for the use of the GP workforce dataset, that NHS Digital should follow due process and ensure that the briefing paper and any outstanding points previously raised by IGARD were provided alongside the first of type application summary. When the briefing paper was presented most recently in January 2021 and March 2021, IGARD had specifically requested an update on the transparency plan including, but not limited to, feedback from the British Medical Association (BMA) / Royal College of GPs (RCGP) on the simple summary for GP employers to share with their workforce with regard to data collection. IGARD requested that the actions from 2021 were attended to. IGARD noted that a general duty of confidence may be owed by employers to their employees (and by NHS Digital to the employees) not to disclose their confidential information, and queried the Privacy, Transparency and Ethics (PTE) commentary provided to the query raised in advance, which focused on patient confidential information, which IGARD were agreed that this was not. IGARD noted that the common law duty of confidentiality comes into play when there is any information which has a "*necessary quality of confidence*", i.e. not public knowledge, and is imparted in circumstances where one could expect the information to be kept confidential. Noting that the Data Access Request Service (DARS) accept that there was confidential data being handled, the various statues and Directions cited by NHS Digital provide a gateway for NHS Digital to access and process the confidential data, but do not necessarily give HEE the necessary permissions to process confidential data (which is separate from UK General Data Protection Regulations (UK GDPR) since there are UK GDPR grounds for HEE to process the personal data). IGARD therefore asked in respect of HEE's legal gateway to provide confirmation of the legal gateway for HEE to hold confidential workforce data, and to upload the written confirmation to NHS Digital's customer relationship management (CRM) system. In addition, IGARD noted that the Government gateway itself states that employee consent must be sought for keeping ethnicity data: Personal data an employer can keep about an employee - GOV.UK (www.gov.uk), and suggested that the HEE carry out a Data Protection

	Impact Assessment (DPIA) in respect of processing of data, noting the request for ethnicity data. IGARD were unclear as to why the applicant was requesting identifiable data for **all** workers, noting that the linkage project outlined in the application would only be relevant to the GPs and asked that clarification be sought and updated within section 5 (Purpose / Methods / Outputs) of the application. If, on reflection, no linkage was required for any staff other than the GPs, then a justification should be provided in section 5 as to why identifiable GP workforce data was required for all members or staff under this application, and to outline the benefits of processing in respect of all staff, other than GPs, noting that no outputs or benefits had been articulated in sections 5(c) (Specific Outputs Expected) or 5(d) (Benefits) of the application summary presented. IGARD noted that the transparency materials on NHS Digital's website made a statement that no identifiable data would be shared however this statement was incorrect (based on the request in this application) and that **as a matter of urgency** the webpage should be updated and any links to a templated privacy notice should be removed from the public domain. Noting the briefing paper previously presented to IGARD had stated that in relation to the collection there was no right to opt-out as NHS Digital were collecting under legal obligation and that in relation to the dissemination the National Data Opt-out (NDO) was not relevant because it was not confidential patient information, that the application should be updated throughout to reflect to what extent a data subject can opt out or object to the processing of their data, since it was silent on this point. IGARD noted that section 5(a) (Objective for Processing) mentioned "*a data warehouse in Azure*" and queried if Cloud computing was involved. IGARD suggested that reference to Azure data warehouse be removed, or if the mention of Azure was correct, to review the description of the Data Processors in section 1 (Abstract), and review the processing and storage locations in section 2 (Locations) and update the application as appropriate. IGARD noted within section 5(c) that "…*no personal identifiable data will be shared*… *all data within Tableau will be anonymised*…" but asked that it be made clear throughout the application that no personal identifying data will be shared from the Tableau product **and** to remove any suggestion there is no personal identifying data being received by HEE. In addition, IGARD queried the statement "*no identifiable workforce data flows out of HEE. The product is used to inform the planning processes and is shared at an aggregate level with the HEE community*". IGARD asked for clarification in section 5(b) (Processing Activities) as to who was in the "HEE community". **Outcome:** IGARD deferred make a recommendation pending: 1. In respect of the HEE's legal gateway: a. To provide confirmation of the legal gateway for HEE to hold confidential workforce data, and b. To upload the written confirmation to NHS Digital's CRM system. 2. In respect of the GP workforce data: a. To clarify why identifiable data is required for all workers, since the linkage project will only be relevant to GP's, OR b. If no linkage is required for any staff, other than GPs, to provide a justification as to why identifiable data is required for all members of staff under this application, and c. To outline the benefits of processing in respect of all staff, other than GPs, noting that no outputs or benefits have been articulated in sections 5(c) or 5(d).

	3. In respect of "*Azure*": a. To remove the reference to the data warehouse in Azure in section 5(a), OR b. To review the description of the Data Processors, processing and storage locations in section 2 and update as necessary. 4. To update the application throughout to reflect to what extent a data subject can opt out or object to the processing of their data, as outlined in the briefing paper previously presented to IGARD. 5. To make clear throughout the application that no personal identifying data will be shared from the Tableau product **and** to remove any suggestion there is no personal identifying data being received by HEE. 6. To clarify who is in the "*HEE community*". The following advice was given: 1. IGARD suggested that the HEE carry out a DPIA in respect of processing of data, noting the request for ethnicity data. 2. IGARD noted that when the briefing paper was presented most recently in January 2021 and March 2021, that they had specifically requested an update on the transparency plan including, but not limited to, feedback from the BMA / RCGP on the simple summary for GP employers to share with their workforce with regard to data collection. IGARD requested that the actions from 2021 were attended to. 3. IGARD noted that the transparency materials on NHS Digital's website made a statement that no identifiable data would be shared however this statement was incorrect (based on the request in this application) and that **as a matter of urgency** the webpage should be updated and any links to a templated privacy notice should be removed from the public domain. 4. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment. 5. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent.
3.5	National Institute for Health and Care Excellence (NICE): TRE - NICE (Presenter: Catherine Day) NIC-610798-N0G8Z-v0.4 **Application:** This was a new application for access to the following pseudonymised data via NHS Digital's Trusted Research Environment (TRE): Civil Registration (Deaths), Electronic Prescribing and Medicines Administration (EPMA) data in Secondary Care for COVID-19, GPES Data for Pandemic Planning and Research (GDPPR) (COVID-19), HES:Civil Registration (Deaths) bridge, Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC), HES Critical Care, HES Outpatients and Medicines dispensed in Primary Care (NHSBSA data). Work using data from the TRE will be continuous, and the exact data that is required will be dependent on referrals to NICE. The data will be used: during the scoping, development and review of guidance, standards and indicators; to resolve issues of uncertainty and improve access to new innovations for patients; to assess the impact of NICE's products; and to develop guidance tools. **Discussion:** IGARD noted that this application had been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 16th February 2022 (see Appendix B).

	IGARD noted a number of PAG special conditions which had been included in section 6 (Special Conditions) in relation to the use of GDPPR data and requested a discussion with the Chair of PAG and Deputy Chair of PAG with regard to the proforma special conditions that are included in GDPPR data related applications. IGARD noted the work of NICE and that it was well respected around the world. IGARD noted that the purpose of the application was for service evaluation / audit, however there were numerous references to "*research*" within section 5 (Purpose / Methods / Outputs), for example but not limited to "…*driving the research agenda…*", and asked that all references to "*research*" be removed. In addition, and noting the application was utilising the Trusted **Research** Environment (T**R**E) to clearly explain in section 5 how it would be ensured that the data would be used solely for the purpose of service evaluation and audit. Noting that GDPPR and EPMA would only be used for COVID-19 specific purposes, IGARD queried in relation to data minimisation why HES APC had been requested from 1989, HES A&E from 2007, HES critical care from 2008 and HES outpatients from 2003 for COVID-19 purposes. IGARD asked that a justification be provided in section 5 which aligned the NHS Digital DARS Standard for Data minimisation and the general UK General Data Protection Regulation (UK GDPR) principles with regard to excessive processing. Given that all the data will be in NHS Digital's TRE, IGARD asked for further clarification in section 5 as to how the COVID-19 datasets and limited permitted purpose would be managed alongside non-COVID-19 datasets with no restriction on purpose; for example by outlining the effective controls and governance in place, since there would be nothing to stop the applicant from using the GDPPR data across all NICE purposes. Noting that section 5 serves as NHS Digital's public facing data uses register, to update the application throughout to ensure it is written in language suitable for a lay reader and that consideration is given to the patient audience, for example when referring to *"data wranglers".* IGARD also suggested that section 5(a) (Objective for Processing) be updated to remove reference to "*it will*…" or "it can…", and instead use a form of words such as "*it is hoped*…", noting that NICE would "*advocate for improvements*" rather than "*will deliver improvements"*, since NICE are not a regulatory body. IGARD asked that section 7 (Ethical Approval) be updated to correctly reference that ethical support was not required because this was a service evaluation and audit. **Separate to this application:** IGARD requested a discussion with NHS Digital with regard to the post "The Health Service Control of Patient Information (COPI) Notice" exit strategy for data that NHS Digital holds which was gathered under special provisions. **Outcome:** recommendation to approve subject to the following condition: 1. In respect of the purpose of the application (service evaluation/audit): a. To remove any reference to research from section 5 for example "*driving the research agenda*", and b. To clearly explain in section 5 how this application, using a T**R**E, will be limited solely to service evaluation and audit. The following amendments were requested: 1. In respect of data minimisation: a. To provide a justification in section 3 and section 5 of the request to access HES data from 1989 for COVID-19 purposes, and

	b. To align the justification with the NHS Digital DARS Standard for Data minimisation and the general UK GDPR principles with regard to excessive processing. 2. To clarify in section 5 how the COVID-19 datasets and limited permitted purpose will be managed alongside non-COVID-19 datasets with no restriction on purpose; for example the effective controls and governance in place. 3. To insert a clear narrative at the beginning of section 5(a) that there will be specific COVID-19 processing taken place alongside more general processing of data. 4. To update section 7 that no ethical support is required because this is a service evaluation and audit. 5. To update section 5(a) to use a form of wording such as "*it is hoped* …", rather than "*it will…*", noting that NICE would "*advocate for improvements*" rather than "*will deliver improvements*", since they are not a regulatory body. 6. Noting that section 5 serves as NHS Digital's public facing data uses register, to update the application throughout to ensure it is written in language suitable for a lay reader and that consideration is given to the patient audience, for example when referring to *"data wranglers".* Separate to this application: 1. IGARD requested a discussion with NHS Digital with regard to the post "COPI Notice" exit strategy for data that NHS Digital holds which was gathered under special provisions 2. IGARD request a discussion with Chair of PAG and Deputy Chair of PAG with regard to the proforma special conditions that are included in all GDPPR data related applications. 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 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	Oversight & Assurance IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. Due to the volume and complexity of applications at today's meeting, IGARD were unable to review any Data Access Request Service (DARS) applications as part of their oversight and assurance role. IGARD Members noted that they had not yet been updated on the issues raised at the 27th May 2021 IGARD business as usual (BAU) meeting with regard to previous comments made on the IG COVID-19 release registers March 2020 to May 2021. IGARD noted that in addition, they had not been updated on the issues raised on the IG COVID-19 release registers June to October 2021. IGARD Members noted that the last IG COVID-19 release register that they had reviewed and provided comments on was October 2021. 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 timely: NHS Digital Data Uses Register - NHS Digital
6	COVID-19 update NIC-605115-L0W3V-v0.4 - University of Oxford (PANORAMIC) (Presenters: Andy Rees / James Gray) **Background:** This was a verbal update for the Platform Adaptive trial of NOvel antiviRals for eArly treatment of covid-19 In the Community (PANORAMIC), a "sister" application to NIC-411161-G4K7X Platform Randomised trial of INterventions against COVID-19 In older peoPLE (PRINCPLE) which had been previously presented to the IGARD business as usual meeting on the 25th February 2021, and the COVID-19 meetings on the 23rd November 2021, 28th September 2021, 9th February 2021, 10th November 2020 and 27th October 2020. NHS Digital staff sought an initial discussion with IGARD members about the possibility of the information about potential recruits to the trial that is currently provided to the University of Oxford, also being provided to a second recruitment body. This would be in order to support the study's aim of recruiting sufficient trial participants. The following observations were made on the basis of the verbal update from NHS Digital only. **IGARD Observations:** IGARD members noted that due to the nature of the meeting and the fact that they had received no supporting documentation, that should a full review of the application and documentation be required, the full suite of documentation should be presented to a IGARD business as usual (BAU) meeting for a recommendation. IGARD members noted the verbal update from NHS Digital, noting that all previous comments on this application remains live, and made the following high-level observations based on the verbal update only: 1. Data Controllership – ensuring the right parties are signing up to the data sharing agreement (DSA) in the correct capacity (e.g. processor vs controller) 2. Security – ensuring that appropriate security, such as a Data Security and Protection Toolkit (DSPT), is in place 3. Transparency – the transparency to the public and reliance on The Health Service Control of Patient Information (COPI) Notice until June 2022 4. Compatibility with Consent – that NHS Digital may wish to review the consent materials to ensure there was nothing to preclude the proposed actions and/or update materials for new recruits. IGARD suggested that NHS Digital may wish to consider utilising the NHS Digital Senior Information Risk Owner (SIRO) precedent, noting the urgency.
7 **7.1**	AOB: NHS Digital DARS Standard for Ethical Review IGARD noted and thanked NHS Digital for providing commentary on the proposed update to the NHS Digital DARS Standard for ethical review and proposed further discussion with colleagues as a next step.

7.2	NHS Digital DARS Standard for Length of Data Sharing Agreement (DSA) IGARD noted that they had returned comments to NHS Digital with regard to the updated NHS Digital DARS standard for length of DSA and proposed further discussion with the Caldicott Guardian and SIRO. 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 18/02/22

These applications were previously recommended for approval with conditions by IGARD, and since the previous Out of Committee Report the conditions have been agreed as met out of committee.

NIC Reference	Applicant	IGARD meeting date	Recommendation conditions as set at IGARD meeting	IGARD minutes stated that conditions should be agreed by:	Conditions agreed as being met in the updated application by:	Notes of out of committee review (inc. any changes)
NIC-623799-T2J4F-v0.2	Moderna Therapeutics, Inc.	03/02/2022	1. In respect of the ethical approval and in line with NHS Digital's DARS Standard for Ethical Approval: a) To provide written evidence that ethical support is in place. b) To provide written confirmation that all outstanding MHRA queries have been suitably addressed (as per the verbal update from NHS Digital). c) To upload a copy of the written ethical confirmation to NHS Digital's CRM system. 2. In respect of the security arrangements: a) To provide written confirmation (such as an e-mail) that the DSPT assessment has been finalised for Informa UK Ltd; and b) To confirm that NHS Digital's Security Advisor has expressed satisfaction that the appropriate security is in place for Moderna Therapeutics Inc. c) To confirm that NHS Digital's Security Advisor has expressed satisfaction that the appropriate security is in place for Informa UK Ltd.	IGARD members	IGARD Chair under Chair's Authority – with the support of an IGARD Specialist Member.	IGARD Comment: To ensure that the documents uploaded to NHS Digital's CRM system, for example, the security assurance include dates. To add an express statement in the application that Moderna TX, Inc are solely determine the processing and means for this activity for clarity.

			d) To upload the written confirmation from NHS Digital's Security Advisor to NHS Digital's CRM system for future reference. 3. In respect of the description of the entities in relation to data controllership: a) To provide a copy of the document from the Assistant Secretary of Moderna Therapeutics Inc that outlines the descriptions of the entities (as per the verbal update from NHS Digital). b) To ensure the document aligns with the description of the entities in the application, the processing and controllership arrangements and the supporting documents provided. c) To upload a copy of the document from the Assistant Secretary of Moderna Therapeutics Inc to NHS Digital's CRM system for future reference. 4. In respect of the Professor named within supporting document 1.1: a) To provide written confirmation that the Professor has not and does not carry out any controllership activities (e.g. taking any action that may determine the purposes or the means of using the PtC dataset) and therefore their employer is **not** considered, nor fulfils the criteria of, a Data Controller under UK GDPR in respect of the PtC dataset (and in line with NHS Digital's DARS Standard for Data Controllers). b) To provide an analysis in section 1 as to why the Professor is not carrying out any controllership level activities and therefore their employer is not considered a joint Data Controller.			

In addition, a number of applications were processed by NHS Digital following the Precedents approval route. IGARD carries out oversight of such approvals and further details of this process can be found in the Oversight and Assurance Report.

In addition, a number of applications were approved under class action addition of:

Liaison Financial Service and Cloud storage:

- None

Optum Health Solutions UK Limited Class Actions:

- None

Graphnet Class Actions:

- None

Appendix B

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 16th February 2022

Application & application version number: **DARS-NIC-610798-N0G8Z-v0.4** **Organisation name: NICE** **Profession Advisory Group Agenda item: 2**
PAG note a potential conflict of interest from Amir Mehrkar in relation to OpenSAFELY (Amir manages the access to OpenSAFELY for research and analysis purposes and has overseen three NICE audit applications which have all been approved on OpenSAFELY). The committee discussed this and note that it did not have an impact on being part of the discussions for this application. PAG would like further clarification on the projects the applicant is looking to complete and would also like to understand if the applicant is doing service evaluation/audit or research. PAG support the application for service evaluation / audit purposes, however do not support for research purposes without further discussions. Providing that the applicant is using the data for service evaluation / audit purposes PAG support this application.

Attendees	Role	Organisation
Jonathan Osborn	Deputy Caldicott Guardian	NHS Digital
Amir Mehrkar	GP, Clinical Researcher	RCGP
Mark Coley	Deputy IT Policy Lead	BMA
Liz Gaffney	Head of Data Access	NHS Digital
Pam Soorma	Secretariat	NHS Digital
Kimberley Watson	Data Approvals Officer	NHS Digital
Cath Day	Senior Case Officer	NHS Digital