Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 21st November 2019

In attendance (IGARD Members): Anomika Bedi, Maria Clark, Kirsty Irvine (Chair), Eve Sariyiannidou, Maurice Smith.

In attendance (NHS Digital): Louise Dunn, James Humphries-Hart, Dickie Langley, Karen Myers, Kimberley Watson, Vicki Williams.

Not in attendance (IGARD Members): Sarah Baalham, Nicola Fear, Geoffrey Schrecker.

1	**Declaration of interests:** Maurice Smith noted a family member's professional link with the applicant at University Hospital Southampton NHS Foundation Trust (NIC-292087-M7V9Q), but noted no specific connection with the application or staff involved personally and it was agreed that this was not a conflict of interest **Review of previous minutes and actions:** The minutes of the 14th November 2019 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record of the meeting. **Out of committee recommendations:** An out of committee report was received (see Appendix B).
2	**Data applications**
2.1	<u>NHS England: National Cancer Waiting Times Monitoring Data Set (NCWTMDS) (Presenter: James Humphries-Hart) NIC-192305-X3T0Y</u> **Application:** This was an amendment application to permit NHS England to share aggregate reports containing small numbers with Cancer Alliances, and an additional purpose to track a specific cohort of patients who were identified as having missed a scheduled routine breast screening invitation. This was also a renewal for pseudonymised National Cancer Waiting Times Monitoring DataSet (CWT) for the purpose of monitoring times taken to diagnose and treat patients with cancer and ensure these are in-line with the expectations and rights of patients set out in the NHS Constitution. **Discussion:** As the application was silent on the mechanics of how the individual Cancer Alliances would request, receive, process and derive benefit from the aggregate reports, IGARD queried the actors involved with the work outlined in the application and asked that a diagram was provided outlining who they were. IGARD also asked that the diagram included a further overarching description of the contracting structure, the roles and organisations involved (NHS England, NHS Digital, Cancer Alliances) and details of the flows of data. IGARD also requested that clarification was provided on who had the responsibility for enforcing the contractual arrangements. IGARD had a lengthy discussion with regard to the purpose for the Cancer Alliances to receive the aggregated reports containing small numbers unsuppressed from NHS England and asked that this was clearly articulated, since it was clear that the Cancer Alliances could only get their geographical area and that this report would contain national information; and that confirmation was provided confirming that the individual Cancer Alliances had requested this national report, created by NHS England, to allow them to measure performance against national benchmarks.

	In addition, IGARD discussed what the aggregated reports could offer the Cancer Alliances **in addition** to what was already available to them on the Cancer Waiting Times system and asked that written confirmation was provided outlining additional information the reports were offering and how the reports would be utilised. IGARD queried one of the purposes outlined that stated that the data would be used to *"track patients who were identified as having missed a scheduled routine breast screening invitation…"* and asked how this would be achieved noting that the data requested was pseudonymised. NHS Digital advised that individuals would not in fact be *"tracked"* or followed up, rather that trend analyses would be undertaken. IGARD asked that section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) were updated to make this clear. IGARD noted the statement in section 5(d) (Benefits) ii (Expected Measurable Benefits to Health / and / or Social Care including Target Date) ""*28-day referral to diagnosis – TBC"* and asked that further clarity was provided on what was meant by *"TBC"*. IGARD noted that some of the acronyms within section 5 were not always defined upon first use, for example *"IAO"* and *"SIRO"* and suggested this was updated. IGARD queried the legal basis noted in section 1 (Abstract) under the General Data Protection Regulation (GDPR) and asked that this was reviewed and amended to ensure the correct legal basis was referenced (i.e not for research purposes). IGARD queried information provided in section 1 under the heading *"The Data"* that referred to *"anonymised"* data and asked that this updated and replaced with "*pseudonymised*" data; and that this was reflected where necessary throughout the application. **Outcome Summary:** Recommendation to defer, pending: 1. To provide a diagram outlining the actors involved including description of the contracting structures, roles and organisations (NHS England, NHS Digital, Cancer Alliances), flows of data; and to clarify who has responsibility for enforcing the contractual arrangements. 2. To clearly articulate the need for the Cancer Alliances to receive the aggregated reports containing small numbers unsuppressed and confirmation that the individual Cancer Alliances have requested this data. 3. To provide confirmation what the aggregated reports can offer the individual Cancer Alliances in addition to what is already available to them on the Cancer Waiting Times system. 4. To update section 1 and section 5 for the cohort of patients who were identified as having missed a scheduled routine breast screening invitation, to make it clear that these individuals are not being "tracked" or followed-up, rather that trend analyses is being undertaken. 5. To provide further clarity on the statement in section 5(d) (ii) *"28-day referral to diagnosis – TBC"*. 6. To update section 5 to ensure acronyms are spelt out on first use (for example: *"IAO" and "SIRO"*). 7. To amend section 1 to ensure the correct legal basis under GDPR is referenced (i.e. not research). 8. To update section 1 under the heading *"The Data"* to remove the reference to *"anonymised"* data and replace with *"pseudonymised"* data; and to ensure this is reflected, where necessary, throughout the application.

2.2	University Hospital Southampton NHS Foundation Trust: Fractional Flow Reserve Derived from Computed Tomography Coronary Angiography in the Assessment and Management of Stable Chest Pain: FORECAST TRIAL (Presenter: Louise Dunn) NIC-292087-M7V9Q **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) data for the purpose of a study to determine whether in a population of patients presenting to the rapid access chest pain clinic routine FFRct (Non-invasive technique using CT to determine Fractional Flow Reserve) is better in terms of resource utilisation, (i.e. number and cost of investigational procedure, number of hospital visits etc.) when compared to routine clinical investigations recommended by The National Institute for Health and Care Excellence (NICE). **Discussion:** IGARD welcomed the application and noted the value of the study which had the potential to change the pathways for patients. IGARD noted the various references to a *"Data Controller"* within the application, in the singular, and asked that this was updated throughout to be clear that where there was reference to a Data Controller, that it is specified which of the joint Data Controllers it was referring to. IGARD queried which of the organisation(s) listed in the application would send identifiers to NHS Digital, and which organisation(s) NHS Digital would disseminate the requested data to; and asked that the application was updated throughout to clearly state which organisations was being referenced. IGARD noted the reference in section 5(a) (Objective for Processing) to a *"Data Processor"* and asked that this was updated to expressly state the name of the Data Processor who would be carrying out the activities referenced. IGARD recognised the steps taken by the applicant to simplify the language used in section 5(a) of the application, however asked that this was amended further to ensure this was either written in language suitable for a lay reader or to include a lay summary of the study. IGARD suggested replicating the text that described the study in the patient information sheet (PIS) in order to achieve this. There was a lengthy discussion on the consent materials provided and IGARD asked that the data minimisation column in section 3(b) (Additional Data Access Requested) was updated to ensure this was limited **only** to those members of the cohort that had ticked the 'option 9' box in the various iterations of the consent materials which stated *"I agree to the research team accessing my data via a data warehouse HES (hospital episodes statistics or equivalent) to ensure accurate collection of data for study purposes and for my name, NHS Number or equivalent and date of birth to be stored on the trial database for follow-up purposes.";* and for whom the additional patient flagging up form was completed. IGARD also asked that section 1 (Abstract) was updated to revise the description of the consent material analyses that had been undertaken by NHS Digital to address the point of the cohort numbers. There was a lengthy discussion on the PIS document provided and IGARD asked that further clarity was provided between the inconsistencies in the PIS and the application, where the PIS stated that any data collected by the applicant would not personally identify participants, and that non-identifiable data would be managed by the University of Southampton Clinical Trails Unit (CTU). IGARD also asked that further clarity was provided on the inconsistencies between the PIS, which stated that only anonymised data would be collected, stored and analysed; and the statements in the application that the consent form provided the source of identifiable

information for linkage and that the University of Southampton CTU would send identifiers of the participants to NHS Digital (name, date of birth, NHS number).

IGARD noted the reference within the protocol to the electronic data capture tool 'RAVE'; and asked for clarification on what (if any) NHS Digital data would be on the Tool and its associated server, since it appeared to be based in the USA.

IGARD queried the reference within the protocol to *"Medidata"* and asked for further clarification of what (if any) data that Medidata would have access to.

IGARD noted the reference in section 5(a) that stated *"The Study Team have excluded any mortality, mental health and maternity data…"* and asked for further clarification on mortality data being excluded in light of the statement in section 5(b) (Processing Activities) that referred to *"all cause death"* as a endpoint used to evaluate.

IGARD queried the role of the study funder and asked that further information was provided, in particular, the relation to any participation they may have in the project, if their role was to simply provide funding or if they have any collaboration, services or other contractual agreements with the Data Controller. IGARD asked that dependant on the information provided, various aspects of the application may require further updates, including (but not limited to) commercial use and special conditions sections.

IGARD noted the special condition in section 6 (Special Conditions) that stated *"Heartflow are funding the study and have no influence over the results. They are not permitted to access any record level NHS Digital data."* and asked that this was amended to confirm that no NHS Digital record level data would flow to Heartflow Inc, nor would any data flow to the USA or any other third party.

IGARD queried if supporting document 3.3, version 3 of the study protocol had ethics approval and asked that confirmation was provided.

Outcome Summary: Recommendation to defer, pending:

1. To update the application throughout to be clear that where there is reference to a Data Controller, that it is specifies which of the joint Data Controllers it is referring to.
2. To update the application throughout to clearly state which organisation(s) will send identifiers to NHS Digital and which organisation(s) NHS Digital will disseminate the requested data to.
3. To update section 5 to expressly state the name of the Data Processor who will be carrying out the activities referenced.
4. To amend section 5(a) to ensure this is either written in language suitable for a lay reader or to include a lay summary of the study; and to consider replicating the text describing the study provided in the patient information sheet in order to achieve this.
5. In reference to the consent materials:
    i) To update section 3(b) to ensure the data minimisation column is limited only to those members of the cohort who have ticked the 'option 9' box in the various iterations of the consent materials and for whom the additional flagging up form was completed.
    ii) To amend section 1 to revise the description of the consent material analyses undertaken by NHS Digital to address the point about the cohort numbers.
6. In reference to the patient information sheet:

	i) To clarify the inconsistencies between the patient information sheet and the application where the patient information sheet states that any data collected by the applicant would not identify the participants personally and that non-identifiable data would be managed by the University of Southampton CTU. ii) To clarify the inconsistencies between the patient information sheet which states that only anonymised data would be collected, stored and analysed and statements in the application that the consent form provided the source of identifiable information for linkage and that the University of Southampton CTU would send identifiers of the participants to NHS Digital (name, date of birth, NHS number). 7. To clarify what (if any) NHS Digital data will be on the Rave Tool and associated server. 8. To clarify what (if any) NHS Digital data Medidata will have access to. 9. To clarify the reference in section 5(a) to the mortality data being excluded in light of the statement in section 5(b) referring *"all cause death"*. 10. To provide further information on the funder, in particular in relation to any participation in the project, if they are simply providing funding or if they have any contractual agreements with the Data Controller. Dependent on the information provided, various aspects of the application may need to be updated including (but not limited to) commercial use and special conditions. 11. To amend the special condition in section 6 to confirm that no NHS Digital record level data will flow to Heartflow Inc, nor will any data flow to the USA or any other third party. 12. To provide confirmation if version 3 of the study protocol has ethics approval.
2.3	<u>NHS Bristol, North Somerset and South Gloucestershire CCG: DSfC - NHS Bristol, North Somerset and South Gloucestershire CCG - Comm IV RS (Presenter: Louise Dunn) NIC-186885-Q1T3D</u> **Application:** This was an amendment application to add Microsoft Azure Cloud and a renewal for pseudonymised Secondary Uses Service (SUS+), Local Provider Flows, Mental Health Minimum Data Set (MHMDS), Mental Health Learning Disability Data Set (MHLDDS), Mental Health Services Data Set (MHSDS), Maternity Services Data Set (MSDS), Improving Access to Psychological Therapy (IAPT), Child and Young People Health Service (CYPHS), Community Services Data Set (CSDS), Diagnostic Imaging Data Set (DIDS), National Cancer Waiting Times Monitoring Data Set (CWT), Civil Registries Data (CRD) (Births), Civil Registries Data (CRD) (Deaths), National Diabetes Audit (NDA) and Patient Reported Outcome Measures (PROMs). The purpose is for Invoice Validation (IV) which is part of a process by which providers of care or services are paid for the work they do, Risk Stratification (RS) which is a tool for identifying and predicting which patients are at high risk or likely to be at high risk and prioritising the management of their care; and to provide intelligence to support the commissioning of health services. NHS Digital advised IGARD that the language used in section 5(c) (Specific Outputs Expected) would need reviewing, for example to remove the reference to *"high flyers"*; and that the term *"most expensive patients"* was replaced with *"use of high cost activity"*. **Discussion:** IGARD advised NHS Digital that at the meeting on the 14th November 2019, there was a discussion on NHS Digital's Cloud Standard that was still in draft form and was

	currently with NHS Digital for review. It was noted that section 1 (Abstract) would need amending to use the full wording from the NHS Digital security adviser regarding Cloud Storage, which had been agreed as a temporary measure whilst the Cloud Standard was finalised. IGARD had agreed that they would continue to review Cloud-related applications (with the temporary NHS Digital security adviser assurance in the application abstracts) until the 1st March 2020, by which time IGARD would anticipate that the Cloud Standard would be finalised. IGARD noted inconsistencies within the application when referring to 'Cloud' and asked that the application was amended throughout to ensure that the correct full term was used to correctly refer to *"Cloud storage"*. **Outcome Summary:** recommendation to approve 1. To amend section 1 to revise NHS Digital's Security Advisor's advice on Cloud storage to use the full agreed wording. 2. To update the application throughout to ensure that the full term is used when referring to Cloud 'storage' 3. To review the language used in section 5(c) and remove for example, reference to *"high flyers"*. 4. To review the language used in section 5(c) and amend to replace the term *"most expensive patients"* with *"use of high cost activity"*.
3	<u>Returning Applications</u> IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. • NIC-302604-S7H2N Imperial College London • NIC-359603-D2Q6M Care Quality Commission • NIC-16656-D9B5T University of Liverpool • NIC- 90019-Q8P9K The Health Foundation IGARD welcomed the four applications as part of their oversight and assurance role and noted a number of comments to NHS Digital and suggested that further information and comments be provided in an IGARD Oversight and Assurance Report which would be published separately to the minutes of the meetings, for transparency of process, and on a quarterly basis.
4	<u>AOB:</u> 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.

Independent Group Advising on Releases of Data (IGARD): Out of committee report 15/11/19

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-204531-P5L8G	NHS Scarborough and Ryedale CCG	01/08/2019	1. The NHS Digital IG Advisor to review the applicant's assessment of joint Data Controllership and provide clarification to IGARD why the other members of the Cancer Alliance are not also considered joint Data Controllers	IGARD Chair	OOC by IGARD Chair	
NIC-315419-F3W7K	University of Oxford	03/10/2019	1. To clarify within the application that the education sessions referred to in the application will only use aggregated data, and that should this not be the case that reference to using data for education sessions be removed from the application.	IGARD Chair	OOC by IGARD Chair	

In addition, the following applications were not considered by IGARD but have been progressed for IAO and Director extension/renewal:

- None