

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 5 April 2018

Members: Sarah Baalham, Joanne Bailey, Anomika Bedi, Jon Fistein, Kirsty Irvine (Chair), Eve Sariyannidou.

In attendance: Rachel Farrand, Denise Pine, Vicki Williams.

Apologies: Chris Carrigan, Nicola Fear.

1	<p>Declaration of interests</p> <p>There were no declarations of interest.</p> <p>Review of previous minutes and actions</p> <p>The minutes of the 22 March IGARD meeting were reviewed and subject to a number of minor changes were agreed as an accurate record of the meeting.</p> <p>Out of committee recommendations</p> <p>An out of committee report was received (see Appendix B).</p> <p>Members were reminded to respond in a timely way to OOC's.</p>
2	<p>Data applications</p>
2.1	<p><u>University of Oxford: ORION-4 (Presenter: Rachel Farrand) NIC-172240-R4R0L</u></p> <p>Application: This was an application for advice on the consent materials to be used in the University of Oxford's research study ORION-4 which is a double blind randomised placebo-controlled trial assessing the effects of inclisiran (an experimental drug for the treatment of familial hypercholesterolaemia) on clinical outcomes amongst people with atherosclerotic cardiovascular disease.</p> <p>NHS Digital suggested that all documentation from the applicant to the participants be clear that this was a 'clinical trial' and IGARD welcomed this approach.</p> <p>Discussion: IGARD welcomed the application noting the importance of the study and that purpose of the trial was well defined within the application and materials provided.</p> <p>NHS Digital noted that they had been working with the applicant and IGARD noted that the applicant should proactively check their consent materials to ensure they met current and future GDPR standards.</p> <p>IGARD suggested that a way forward would be for the applicant to update their consent material and patient information to ensure they meet the GDPR standard of consent since this was a clinical trial. The applicant should set out a clear process for ensuring participants were well informed, be explicit throughout the material how participants can withdraw from the trial, clearly define the actors who will access the data, clearly state that the drug manufacturer will not influence the results or dissemination of the results, clearly outline the role of the Women's Hospital in Boston, USA and the type of data they will receive, and that participants be given clear options about their treatment plan.</p> <p>Outcome: IGARD welcomed the application which came for advice on the consent materials and without prejudice to any additional issues that may arise when the application is fully reviewed. IGARD advised that NHS Digital should consult with senior NHS Digital IG staff and work with the customer on their draft consent materials.</p> <p>Action: IGARD were happy to support NHS Digital in working with the applicant and agreed to provide more detailed feedback to NHS Digital about the consent materials.</p>

2.2	<p><u>University Hospitals Coventry & Warwickshire NHS Trust: What factors lead to palliative care patients being admitted to acute hospitals; can we design services to improve their support at home? (Presenter: Rachel Farrand) NIC-113611-X2Y3H</u></p> <p>Application: This was a new application for a one-off extract of pseudonymised Hospital Episodes Statistics (HES) Admitted Patient Care (APC) and HES Accident and Emergency (A&E) data to consider what factors lead to palliative care patients being admitted to acute hospitals and how services can be designed to improve their support at home.</p> <p>Phase 1 will provide insights into the incidence of admissions, reasons for admissions and clinical outcomes of palliative care patients within the West Midlands and national trends, leading to phase 2. Phase 2 will be a qualitative exploration of palliative care patients and carers' perspectives on reasons for and experience of admission into acute Trusts and the protocols submitted for full ethical review. The findings from both phases will inform the development of appropriate interventions which will be tailored to meet the needs of palliative patient population and the NHS.</p> <p>NHS Digital noted that they had noted a lack of clarity with regard to the individuals processing data and that the application had been updated to include the University of Warwick as a data processor with additional information provided within section 5b.</p> <p>Discussion: IGARD noted the application had been updated but they had not had time to review due to its late circulation to members. IGARD queried if this application was part of the NIHR trial wording, however NHS Digital confirmed that it was not part of the trial.</p> <p>IGARD were not clear if the processing was fully taking place at the University Hospitals Coventry & Warwickshire NHS Trust site and NHS Digital noted that this had been updated within the application. IGARD welcomed NHS Digital's update of the application but asked that the application be updated to clearly outline the individuals involved in processing the data, clarifying where the data was being processed and that the University of Warwick be included as a Data Processor. IGARD also suggested that it be clarified within section 5 of the application the substantive employment details of the individuals involved, where these individuals will access the data and ensure the appropriate restrictions are in place. It was suggested that a special condition be included within the application that the employment details of Dr Peter Kimani as University of Warwick be added and be explicit that the data processing will only be undertaken at the University Hospitals Coventry & Warwickshire NHS Trust.</p> <p>It was noted that IGARD had previously raised an action for NHS Digital to consider how the data processing role of an organisation with this type of arrangement should be reflected within applications and that it be updated to clarify that University Hospitals Coventry & Warwickshire NHS Trust are listed as a Data Controller and that they are processing data, but they are not a Data Processor.</p> <p>IGARD noted that it was not clear within section 5a and 5b how phase 1 and phase 2 of the projects interlinked, if/how the data from phase 1 would be used for phase 2 including any linkages of data, and how NHS Digital data would be used within phase 1 and phase 2. It was noted that section 5 of the application should be updated and to also confirm if phase 2 used the outputs from phase 1 or raw data from NHS Digital. IGARD noted that should the applicant be processing data within phase 2 of the project that ethical consent / approval was in place to enable the applicant to use the data.</p> <p>IGARD queried a reference to a 'letter of permission' within supporting document 2 submitted and asked that a copy of the letter outlining the permission for research be provided in order to check that the applicant was not acting under any parameters or conditions.</p>
-----	---

IGARD suggested that the Data Controller have the appropriate contractual arrangements in place with their Data Processors for the sharing of data.

It was noted that NHS Digital should reference within section 3b and the abstract of the application what the basis for processing data is under GDPR and outline the performance of task.

IGARD noted the supporting document outlining the funding in place for the period 2017/18 but were not clear if new funding was in place for the year 2018/19 and asked for further clarification within section 8. It was also noted that a statement in section 5b be clarified with reference to 'HES data will be presented alongside other data but will not be linked to it' and that statements are easily read by a lay reader that all procedures are in place including how HES data is processed alongside other data.

IGARD noted that the applicant should consider how they disseminate results or conclusions and they may wish to consider maximising the benefits of disseminating outputs via a peer review journal including outside of the region to the lay and patient population.

IGARD queried a reference in section 5a how the Hospital Code was applied, and NHS Digital noted that the Code details where a patient attended not the patient's home address. It was suggested that this be clarified within section 5 of the application.

IGARD suggested that the applicant's DPA registration should be updated to refer to processing data about patients rather than 'our patients'.

Outcome: recommendation to defer, pending:

- Clarification in section 5 the individuals involved in data processing, the place where data processing is being undertaken and consider adding University of Warwick as a Data Processor. To also clarify the substantive employment details of the two individuals involved, where they will access the data and ensure the appropriate restrictions are in place including adding a special condition with the substantive employment details for Dr Peter Kimani as University of Warwick and confirming that processing of data will be only be undertaken at the University Hospitals Coventry & Warwickshire NHS Trust.
- To be clear in sections 5a and 5b how phase 1 and phase 2 interlink, whether and how the data for phase 1 will be used for phase 2 including any linkages, how NHS Digital data is used within the phases and to confirm within section 5 if phase 2 is informed by outputs from phase 1 or use of raw data from NHS Digital.
- To clarify in Section 5b the statement: HES data will be presented alongside other data but not linked to it.
- To clarify in section 5 that if University Hospitals Coventry & Warwickshire NHS Trust is processing data within phase 2 of the project that ethical consent/approval is in place to enable the applicant to use data.
- To update section 5 for a lay reader with regard the use of data and any benefits and clarify for a lay reader that all appropriate procedures are in place including clarifying how HES data is processed alongside other data.
- To clarify within section 5a that the data will only contain the Hospital Code which details the area where the patient attended and not the patient's home address.
- To provide a copy of the letter of permission for research referenced in supporting document 2 to check if the University Hospitals Coventry & Warwickshire NHS Trust are acting under any conditions or parameters.
- Clarification within section 8 if any new funding is in place for the period 2018/19.

	<ul style="list-style-type: none"> • The application should be updated to clarify that University Hospitals Coventry & Warwickshire NHS Trust are listed as a Data Controller and that they are processing data, and they are not a Data Processor. • To reference within section 3b and the abstract what the basis for processing data is under GDPR and outline the performance of task. <p>The following advice was given:</p> <ul style="list-style-type: none"> • IGARD suggested the applicant may wish to consider maximising the benefit of disseminating outputs via a peer review journal via wider routes of dissemination including outside of the region to the lay and patient population • IGARD advised that the applicant should update their DPA registration to refer to processing data about patients rather than 'our patients'. • IGARD noted the Data Controller has a responsibility to ensure they have in place appropriate contractual arrangements with the Data Processor(s).
3	<p>AOB</p> <p>None.</p>

Appendix A: Summary of Open Actions

Date raised	Action	Owner	Updates	Status
20/04/17	IGARD Chair to contact key stakeholder organisations regarding the benefits of uses of data to feed into the IGARD annual report.	IGARD Chair	<p>14/09/17: Ongoing. It was agreed this would be discussed during the educational session.</p> <p>07/12/17: Ongoing. It was agreed to bring the first draft to January's education session.</p> <p>08/02/18: it was agreed the updated draft be brought to the March education session</p> <p>01/03/18: the March education session was cancelled, and it was agreed to take the draft annual report to the April education session.</p> <p>05/04/18: to seek clarification from the Chair if stakeholders have been approached and to bring back the draft to the May education session.</p>	Open
20/07/17	Garry Coleman to provide an update within two weeks on how NHS Digital manage the risk involved in CCGs using South Central and West CSU as a data processor in light of data sharing breaches and recent audits.	Garry Coleman	<p>10/08/17: It was anticipated that a paper on this would be brought to IGARD within the following two weeks.</p> <p>24/08/17: IGARD received a verbal update on the work that had taken place following both audits and verbal assurances that NHS Digital were content with the level of risk involved in this organisation continuing to act as a data processor. IGARD welcomed this update and requested written confirmation.</p> <p>31/08/17: IGARD were notified that the requested written confirmation should be provided within one day.</p> <p>14/09/17: An email response had been circulated on 31 August, and IGARD noted that they were awaiting receipt of the post-audit report.</p>	Open

			05/04/18: IGARD Secretariat had contacted Garry Colman and were awaiting a response.	
31/08/17	Garry Coleman to report back on how cancer registration data was previously described as pseudonymised PDS data within older versions of applications, and present to a future education session on changes to how Medical Research Information Service (MRIS) reports are now shown within applications.	Garry Coleman	22/02/18: IGARD Secretariat to contact Garry Coleman to suggest presentation at the June education session. 05/04/18/18: IGARD Secretariat were awaiting a response.	Open
02/11/17	NHS Digital to consider the responses provided by an applicant (Imperial College London NIC-27085) in relation to the language and terminology used in patient information materials.	Louise Dunn	22/03/18: IGARD Secretariat noted had contacted Louise Dunn and were awaiting a response. 05/04/18/18: IGARD Secretariat were awaiting a response.	Open
15/03/18	Stuart Richardson to provide a briefing note clarifying the contractual arrangements in place, the structure, enforcement strategy and how the agreements worked together so that the data disseminated by NHS Digital would be protected and provide a verbal update to IGARD on the progress of this note by 5 April 2018.	Stuart Richardson	05/04/18: A verbal update was provided that individual Data Sharing Framework Contracts (DSFC) were issued yet Data Sharing Agreements were joint Data Controllership and that DSFC's placed exactly the same terms and conditions upon organisations and NHS Digital believe the position to be acceptable. IGARD noted the verbal update and asked that a briefing note be provided by NHS Digital confirming the arrangements in place by the end of April 2018.	Open
05/04/18	IGARD to provide detailed feedback to NHS Digital with regard to application NIC-172240-R4R0L University of Oxford to support in working with the applicant.	IGARD		Open

Appendix B: Out of committee report

Independent Group Advising on Releases of Data (IGARD): Out of committee report 23/03/18

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-42272-S9J3L	NICOR	22/02/18	<ul style="list-style-type: none"> To provide more specific examples of yielded benefits within section 5 of the application with explicit references to benefits to patients. 	IGARD Chair	Chair of IGARD Meeting (Deputy IGARD Chair)	N/A
GA10b-NW-AMD NIC-170580-K3W3H; NIC-170585-V9Q4L; NIC-170593-N0R4N	NHS Dartford, Gravesham and Swanley CCG; NHS Medway CCG; NHS Swale CCG	25/01/18	<ul style="list-style-type: none"> The fair processing information for CCG's NHS Dartford Gravesham & Swanley CCG, NHS Medway CCG and NHS Swale CCG is updated to meet NHS Digital's nine minimum criteria for privacy notices before data can flow. 	IGARD Chair	Chair of IGARD Meeting (Deputy IGARD Chair)	N/A
NIC-167186-V7J4F	University College London	08/03/18	<ul style="list-style-type: none"> A clearer explanation of avoidable hospital admissions within section 5 of the application with specific examples, and a clearer justification for the amount of data requested, as described in the supporting protocol. 	IGARD Chair	IGARD Chair	N/A
NIC-61042-K9Q3G	University of Hull	08/03/18	<ul style="list-style-type: none"> A clearer explanation of avoidable hospital admissions within section 5 of the application with specific examples, and a clearer justification for the amount of data requested, as described in the supporting protocol. 	IGARD Chair	IGARD Chair	

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

- None notified to IGARD