Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 12th March 2020

In attendance (IGARD Members): Sarah Baalham, Anomika Bedi, Kirsty Irvine (Chair), Eve Sariyiannidou.

In attendance (NHS Digital): Victoria Byrne-Watts, Dave Cronin, Louise Dunn, Karen Myers, Vicki Williams.

Not in attendance (IGARD Members): Maria Clark, Nicola Fear, Geoffrey Schrecker, Maurice Smith.

Observers (NHS Digital): Michael Ball, Lizzie Cherry.

1	**Declaration of interests:** There were no declarations of interest. **Review of previous minutes and actions:** The minutes of the 5th March 2020 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	University of Dundee: Data linkage request for 'Allopurinol and cardiovascular outcomes in patients with ischaemic heart disease ALL-HEART' study (Presenter: Dave Cronin) NIC-369348-H6H8B **Application:** This was a renewal application for identifiable Hospital Episode Statistics (HES) and Medical Research Information Service (MRIS) data; and an amendment to permit the University of Glasgow to share pseudonymised data with the University of Dundee and for the University of Dundee to store and otherwise process that data. The application has therefore been amended to a) add the University of Dundee as a Data Processor and a storage and processing location; b) update section 5 to reflect the process involving the University of Dundee; c) update section 5 to meet the relevant NHS Digital Standard and d) adding an additional data item, GP Practice code to the specification. The purpose is for a study aiming to improve the treatment of patients with Ischaemic Heart Disease, by investigating whether adding allopurinol up to 600mg daily to these patients' usual medications, will reduce their risk of having a stroke, heart attack or of dying due to cardiovascular disease. **Discussion:** IGARD had a lengthy discussion with regard to Data Controllership. IGARD noted that the University of Dundee was listed as the sole Data Controller and queried the roles of the other study partners, the University of Glasgow and the University of Nottingham, in light of the information that was outlined within the study protocol and the consent materials; and asked that further information was provided clarifying why the University of Dundee was considered the sole Data Controller. IGARD noted that the table in section 3(b) (Additional Data Access Requested) did not contain the standard text usually provided to reflect that the data would be limited to the cohort size; and asked that the text was updated accordingly, specifically in relation to the HES APC data. IGARD queried information provided in section 1 (Abstract) that implied that that there was

	explicit consent to use the GP Practice Codes; and asked that this was reviewed to correctly state that the use of the GP Practice Codes was *compatible* with the consent. IGARD noted the reference in supporting document 1.1, the amended study protocol to *"implicit consent"* and suggested that this was reviewed to reflect current best practice IGARD advised that they would wish to review this application again when it comes up for renewal. **Outcome Summary:** recommendation to approve subject to the following condition: 1. To clarify why the University of Dundee is considered the sole Data Controller and the other study partners (the University of Glasgow and the University of Nottingham) are not also considered as joint Data Controllers, in light of the information provided in the study protocol and consent materials. The following amendments were requested: 1. To update section 3(b) to reflect that the HES APC data will be limited to the specific cohort number. 2. To review section 1 to ensure this does not imply that there is *explicit* consent to use the GP Practice Codes; but that the use of GP Practice Codes are *compatible* with the consent. The following advice was given: 1. IGARD suggested that the reference to *"implicit consent"* within the revised protocol was reviewed to reflect current best practice 2. IGARD advised that they would wish to review this application again when it comes up for renewal. It was agreed the condition would be approved Out of Committee (OOC) by IGARD members.
2.2	<u>University of Glasgow: MR1462 - Data linkage request for the Febuxostat versus Allopurinol Streamlined Trial (FAST) (Presenter: Dave Cronin) NIC-72180-R2L5Y</u> **Application:** This was an amendment application to the existing Data Sharing Agreement (DSA) to a) add the University of Dundee as a Data Processor and a storage and processing location; b) update section 5 to reflect the process involving the University of Dundee; c) updating section 5 to meet the relevant NHS Digital Standard(s). The purpose is for a study designed to find out whether febuxostat is safer, less safe or just as safe as allopurinol for long term use in practice. The FAST study will focus on the cardiovascular safety profile of allopurinol, when taken for an average of 3 years in patients aged 60 years or older with chronic hyperuricaemia, in conditions where urate deposition has already occurred. The secondary study objectives are to evaluate other cardiovascular adverse events for both products. **Discussion:** IGARD had a lengthy discussion with regard to Data Controllership. IGARD queried who was in the 'Study Team' that was referred to within the application and how they were involved in the study, and asked that further clarity of this was provided. IGARD queried if the 'Study Team' comprised only the University of Dundee staff. IGARD requested that the application be amended to clearly articulate why the University of Dundee was the sole Data Controller. In addition, they suggested that the current language was revised throughout the application to reflect this, for example by removing reference(s) to the 'Study Team'. NHS Digital advised that the University of Glasgow would be acting on the instruction of the University of Dundee and with no discretion as to how the data was analysed and did not form

	part of the 'Study Team'; IGARD noted this and asked that an express statement was included within the application clarifying this. NHS Digital also advised that no other Universities, other than the University of Glasgow, Dundee and the University of Nottingham were involved in the study; IGARD noted the information and asked that section 5 (Purpose / Methods / Outputs) was updated with an express statement to reflect this. IGARD also asked that a special condition was inserted in section 6 (Special Conditions) to state that any NHS Digital data being made available to any third parties outside of the University of Dundee and the University of Glasgow would be in aggregated form with small numbers supressed. IGARD asked that a special condition was inserted in section 6 (Special Conditions) for the Data Controller to provide to NHS Digital a process flow of the steps that would be taken by the Data Controller to ensure that any such data released to third parties complied with the terms of the NHS Digital Data Sharing Framework Contract (DSFC) and Data Sharing Agreement (DSA). In addition, IGARD also asked that a further special condition was inserted in section 6 stating that the Data Controller would implement the process flow (referred to in the previous paragraph) before any NHS Digital data was released to third parties. IGARD discussed the study funder, the pharmaceutical company Menarini Pharma SAS and asked that section 5(e) was revised to reflect NHS Digital's Commercial Purpose Standard 5(e) including (but not limited to) drawing attention to the fact that Menarini was entitled to a royalty free licence of the study results and aggregated report as referenced elsewhere in the application. IGARD queried if Menarini had any connection with any of the drugs being studied as referenced in the application, since information provided on their website appeared to show that the funder may have a connection; and asked that this was clearly outlined. IGARD also noted the reference in section 5(b) Processing Activities) to the contractual obligations to Menarini ("to provide data listings to the study funders….") and asked that section 5(a) (Objective for Processing) was updated to reflect this as well so that section 5(a) accurately reflected Menarini's interest with the study. IGARD advised that they would wish to review this application again when it comes up for renewal. Subsequent to the meeting, IGARD clarified that a process flow diagram should include a checklist. The checklist should set out the criteria that will be considered in assessing whether any data (including study results or reports) to be disseminated (i) does NOT contain any NHSD data; and (ii) complies with the applicant's Data Sharing Framework Contract and Data Sharing Agreement with NHS Digital. **Outcome Summary:** recommendation to approve subject to the following conditions: 1. In relation to data controllership to: a) To provide clarity of who is in the 'Study Team'. b) If the Study Team comprises only the University of Dundee to clearly articulate the case for the University of Dundee being the sole Data Controller; and to revise the current language within the application to reflect this, for example by removing reference to the 'Study Team'. c) To include an express statement in the application that the University of Glasgow acts on the instruction of the University of Dundee; and with no discretion to how the data is analysed; and does not form part of the Study Team.

	d) To update section 5 to add an express statement that no other Universities form part of the Study Team or are involved in the study in any other way. 2. In respect of Menarini Pharma SAS to: a) To revise section 5(e) to reflect NHS Digital's Commercial Purpose Standard 5(e) including (but not limited to) making reference to Menarini's royalty free licence as referenced elsewhere in the application. b) To clearly outline any connection Menarini may have with any of the drugs being studied. c) To amend section 5(a) to ensure this accurately captures Menarini's interest with the study, particularly with reference to contractual obligations (as outlined in section 5(b)). The following amendments were requested: 1. To insert a special condition in section 6 to state that any NHS Digital data being made available to any third parties (outside of the University of Dundee and University of Glasgow) would be in aggregated form with small numbers supressed. 1. To insert a special condition in section 6 for the Data Controller to provide to NHS Digital a process flow of the steps taken in terms of checking that any such data released to third parties complies with the terms of the DSA. The checklist should set out the criteria that will be considered in assessing whether any data (including study results or reports) to be disseminated i. (does NOT contain any NHSD data; and ii. complies with the applicant's Data Sharing Framework Contract and Data Sharing Agreement with NHS Digital 2. To insert a special condition in section 6 stating that the Data controller will implement the process flow before any NHS Digital data is released to third parties. The following advice was given: 1. IGARD advised that they would wish to review this application again when it comes up for renewal. It was agreed the condition would be approved Out of Committee (OOC) by IGARD members.
2.3	<u>Northgate Public Services (UK) Ltd: Beyond Compliance (Presenter: Victoria Byrne-Watts) NIC-351761-F8Z6V</u> **Application:** This was a new application for pseudonymised Patient Reported Outcome Measures (PROMs) for the purpose of service evaluation. The objective is for Northgate Public Services to provide the Beyond Compliance Advisory Committee and implant manufacturers with the mechanism to assess the patient reported outcomes of patients receiving an implant (within the Beyond Compliance service) in comparison to the national average procedure-specific scores to monitor implant performance, and to flag any areas where patient outcomes report to be statistically significantly worse than the expected. A previous iteration of this application was presented to IGARD under NIC-58668-V5C0L on the 1st March 2018 where IGARD recommended for approval; and was later presented to IGARD for advice on the consent materials on the 11th July 2019; and reviewed on the 5th December 2019 where IGARD had been unable to recommend for approval due to there being no additional information received to change IGARD's previous recommendations and advice on the substantive points raised when previously reviewed. NHS Digital advised IGARD that all comments / feedback from previous IGARD reviews had now been addressed. **Discussion:** IGARD discussed the history of the application, noting the previous iterations that

	had been submitted to IGARD for review / advice. IGARD queried if all NHS Digital data previously held by the applicant had now been destroyed and were advised by NHS Digital that all data had been destroyed and that NHS Digital had received the relevant data destruction certificate(s) confirming this. IGARD welcomed the application and acknowledged the effort that had gone into the revised version but did highlight that while the new application prima facie complied with the legal requirements there might be a challenge that destroying the data and then reapplying for the same data might not be in the spirit of the legislative framework. NHS Digital advised IGARD that they had reviewed the updated application and that noting the clear benefits outlined, that the study was in the public interest. IGARD noted NHS Digital's assessment and was happy to proceed in light of that analysis. IGARD discussed the cohort numbers for the study, in particular in relation to the numbers quoted in the previous iteration of the application and asked that clarity of the cohort numbers was provided in section 1 (Abstract). IGARD queried if the cohort outlined in this application was *"cohort 2"* as outlined in the previous iteration and were advised by NHS Digital that this was correct. NHS Digital advised, however, that in this application, they would not be referred to as *"cohort 2"*. IGARD asked that to support the historical information and for future audit purposes, the history of the previous application was also clearly set out within section 1 including reference to any previous NIC numbers. In addition, IGARD also asked that clarification was provided of who was in the cohort and the dates from when they were consented from; and that all cohort information was confirmed within section 3(b) (Additional Data Access Requested). IGARD queried how much data was required by the applicant **now** and asked that this was clearly distinguished within the application from any future data that may be requested as the cohort increased. IGARD noted the references within the application to *"Beyond Compliance"* and queried who they were, for example an advisory group, a service etc; and asked for further clarity including a consistent narrative was provided throughout the application when referring to them. IGARD noted and supported the conclusion that Northgate Public Services was the sole Data Controller and asked that the application was updated throughout to remove any reference(s) to them *"acting as"* a Data Controller. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. IGARD advised that they would wish to review this application again when it comes up for renewal. **Outcome Summary:** recommendation to approve subject to the following conditions: 1. In relation to the cohort numbers: a) To provide clarity of the cohort numbers within section 1. b) To set out in the abstract that the cohort relates to *"cohort 2"* from NIC-58668. c) To clarify who is in the cohort and the dates from which they were consented from. d) To confirm the cohort within the table in section 3(b). 2. To clarify what *"Beyond Compliance"* is, for example an advisory group, a service etc; and to provide a consistent narrative throughout the application. The following amendments were requested: 1. To clarify how much data is required by the applicant now and to distinguish from future data that may be requested as the cohort increases.

	2. To update the application throughout to remove any reference(s) to Northgate Public Services "*acting as*" a Data Controller. The following advice was given: 1. IGARD advised that they would wish to review this application again when it comes up for renewal. It was agreed the condition would be approved Out of Committee (OOC) by IGARD members.
2.4	<u>Optum Health Solutions UK Ltd: Bespoke Extract Request for producing benchmarks within products (Presenter: Louise Dunn) NIC-277499-D3D0X</u> **Application:** This was a renewal application for pseudonymised Payment by Results (PbR) data; and an amendment to add two additional products of tools, the *"the Horizon Tool"* and *"* Population Health Management (*PHM) Strategic Modelling Tool"*. The purpose is for the development of four Optum Health Solutions UK Ltd products Product 1: the population health analytics tool Health Population Manager (HPM), Product 2: the Commissioning & Contracting suite (CCA), Product 3: the Horizon Tool and Product 4: the PHM Strategic Modelling Product. The typical use for the four tools are by organisations that have a statutory commissioning function, for example NHS organisations, and non-NHS organisations working with Sustainability and Transformation Partnership (STP) group's and Integrated Care Systems (ICSs). **Discussion:** IGARD queried the terminology within the application, in relation to the variety of references to 'Optum', for example *"Optum UK"* and *"Optum Health Solutions UK Limited";* and asked that for consistency the application was updated **throughout** to ensure the full company name of *"Optum Health Solutions UK Limited"* was correctly referred to and as referred to on the Companies House website. IGARD noted the reference in section 5(b) (Processing Activities) to *"role based access controls"* and asked that this was amended to address both role **and task** based access controls. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. IGARD suggested that NHS Digital may wish to establish whether the 'Tools' would be used in other countries outside of England and Wales since it was not clear within the application and in order to understand any benefits accruing to those countries, noting that the tools could not use NHS Digital data. IGARD advised that they would wish to review this application again when it comes up for renewal. **Outcome Summary:** recommendation to approve subject to the following condition: 1. To update the application throughout to ensure the full company name 'Optum Health Solutions UK Limited' is correctly referred to. The following amendment was requested: 1. To amend the reference to controls in section 5(b) to address both role **and task** based access control*.* The following advice was given: 1. IGARD suggested that NHS Digital may wish to establish whether the Tools will be used in other countries outside of England and Wales. 2. IGARD advised that they would wish to review this application again when it comes up

	for renewal. It was agreed this condition would be approved OOC by the IGARD Chair.
2.5	<u>Cambridge Centre for Health Services Research (Based at the University of Cambridge): BRACE NIHR Rapid Evaluation Centre (Presenter: Louise Dunn) NIC-243359-X4T5M</u> **Application:** This was a new application for pseudonymised Hospital Episodes Statistics (HES) data and Emergency Care Data Set (ECDS) for the purpose of supporting the quantitative evaluation work of '**B**irmingham **RA**nd and **C**ambridg**E**' (BRACE) Rapid Evaluation Centre, who will carry out rapid evaluations of promising innovations in the organisation and delivery of health and care services. The study aim is to determine whether or not these innovations have significant potential to impact on indicators such as levels of emergency or avoidable admissions to hospital, and reductions in health care utilisation. The application was been previously considered on the 19th December 2019 when IGARD had deferred pending: in light of the level of control of the funder, NIHR, as described in the application and supporting documents, to consider if NIHR should be joint or sole Data Controller for the overarching programme (with the currently named Data Controllers becoming Data Controllers with the appropriate approvals in place for subordinate project-level DSA / applications)**; t**o ensure that where *"RAND"* is referred to, that the application explicitly states which RAND organisation is being referred to and who is undertaking the data controllership and data processing activities**; t**o review the Data Controllers outlined in the study protocol documents provided (supporting documents 6 and 7) and clarify if additional Data Controllers should be added in light of the co-location of the various RAND organisations listed at the same address**; t**o ensure a Legitimate Interest Assessment is completed by the relevant RAND organisation(s), paying particular attention to the balancing test and the requirement to respond appropriately to all sections of the LIA and to ensure a clear Privacy Notice is provided by the relevant RAND organisation(s) clearly outlining their roles, responsibilities and processing activities in the context of the programme**; t**o provide evidence that the NIHR funding (i) is in place and continuing (ii) acknowledges the other organisations involved and (iii) details the scope of the project such that it aligns with the processing outlined in the application**; t**o update section 5 outlining the length of the study and the time frame of the activities being proposed; to update the first paragraph in section 5(a) to remove the specific examples provided of current 'contentious' issues; to provide clarity on why both the HES A&E data **and** the Emergency Care Data Set have been requested, since they appear to be the same or similar data. **Discussion:** IGARD noted that the application had been updated to reflect most of the comments previously made. IGARD noted the reference to *"RAND Europe"* within the application and asked that this was reviewed and updated throughout to ensure that the correct legal entity 'RAND Europe Community Interest Company' was correctly referenced in full where deemed relevant; and that any references to RAND Europe were removed. IGARD also asked that in addition, a special condition was inserted in section 6 (Special Conditions) to clarify that 'RAND Europe Community Interest Company' was the only RAND entity that would be handling NHS Digital data. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. IGARD suggested that NHS Digital may wish to consider auditing this organisation in relation to this application / Data Sharing Agreement. IGARD advised that they would wish to review this application again when it comes up for

	renewal. IGARD suggested that the applicant may wish to review the information published on their website to correctly reflect the RAND company names as reflected on the Companies House website. **Outcome Summary:** recommendation to approve subject to the following condition: 1. To update the application throughout to ensure the correct legal entity 'RAND Europe Community Interest Company' is correctly referenced in full where deemed relevant (and remove the shortened version of RAND Europe). The following amendment was requested: 1. To insert a special condition in section 6 to clarify that 'RAND Europe Community Interest Company' is the only RAND entity that will be handling NHS Digital data. The following advice was given: 1. IGARD suggested that NHS Digital may wish to consider auditing this organisation in relation to this application / data sharing agreement. 2. IGARD advised that they would wish to review this application again when it comes up for renewal. 3. IGARD suggested that the applicant may wish to review the information published on their website to correctly reflect the RAND company names as reflected on the Companies House website. It was agreed this condition would be approved OOC by the IGARD Chair.
2.6	<u>University of Surrey and RCGP: Secondary data linked to the Royal College of General Practitioners (RCGP) Research and Surveillance Centre's (RSC) primary care sentinel data for the purposes of infectious and respiratory diseases surveillance in England (Presenter: Louise Dunn) NIC-21083-B6C5J</u> **Application:** This was a new application for identifiable Hospital Episodes Statistics (HES) and Civil Registrations data for the use in studies, done in parallel with Public Health England surveillance, focussing on the impact of influenza and other infections. The data will support a robust database and reporting system using up to-data primary and secondary care data at individual patient level that can be easily queried in order to answer a wide range of research questions covering; Upper respiratory infections (URTI), Lower respiratory infections (LRTI) (pneumonia and acute bronchitis), Asthma and Chronic Obstructive Pulmonary Disease (COPD). The application was been previously considered on the 30th January 2020 when IGARD had been unable to recommend pending: 1) In respect of data controllership: a) To add Public Health England (PHE) as a Data Controller as the supporting documents provided establish that the surveillance and efficacy testing is required to be carried out in order to fulfil a statutory duty on PHE; b) to reconsider the role of the University of Surrey as a Data Controller on the basis of the information provided; c) to review the role of the University of Oxford as a Data Controller; d) to review the role of the RCGP in terms of Data Controller and Data Processor; e) to update section 5 throughout to reflect the correct data controllership facts. To provide further information of the study as part of a wider programme of work, what is the study, what is the wider programme, and who is in the cohort for of each. To update the application to reflect that the ability of PHE to utilise Regulation 3 Health Service (Control of Patient Information) Regulations 2002 to set aside the duty of confidence clearly limits the processing to surveillance and monitoring of vaccine efficacy and that an alternative legal basis would need to be articulated for the proposed third purpose which relates to more

	general research. To update the application to clarify why PHE does not need to seek s.251 support as a matter of process. **Discussion:** IGARD noted that the application had been updated to reflect all of the comments previously made. IGARD noted the references throughout the application to *"research"*; and asked that this was amended to remove these references, in order to ensure that the application reflected the parameters laid out by Regulation 3 of the Health Service (control of Patient Information) Regulations 2002, in that research **cannot** be undertaken with data that was supplied in reliance on that Regulation. In addition, IGARD also asked that a special condition was inserted in section 6 (Special Conditions) expressly stating that the data provided under this Data Sharing Agreement was only to be used as set out by Regulation 3, Health Service (Control of Patient Information) Regulations 2002 and therefore cannot be used for research purposes. IGARD noted that the Article 9 legal basis of the General Data Protection Regulation (GDPR) for the University of Surrey, was inconsistent with the other Data Controllers listed; and asked that the application was revised to ensure this aligned with the Article 9 legal basis referenced for the other Data Controller(s). IGARD queried the statement in section 5(b) (Processing Activities) *"The data will not be linked with any record level data."* and were advised by NHS Digital that this was incorrect and would need amending to remove this reference. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. IGARD advised that they would wish to review this application again when it comes up for renewal. **Outcome Summary:** recommendation to approve subject to the following condition: 1. To amend the application throughout to ensure there is no reference to 'research' in order to ensure the application reflects the parameters laid out by Regulation 3, Health Service (Control of Patient Information) Regulations 2002, in that research cannot be undertaken with data supplied in reliance on that Regulation. The following amendments were requested in: 1. To insert a special condition in section 6 expressly stating that the data provided under this Data Sharing Agreement is only to be used as set out by Regulation 3, Health Service (Control of Patient Information) Regulations 2002 and cannot be used for research purposes. 2. To revise the University of Surrey Article 9 legal basis to ensure this aligns with the Article 9 legal basis referenced for the other joint Data Controllers listed. 3. To amend section 5(b) to remove the reference to the data **not** being linked. The following advice was given: 1. IGARD advised that they would wish to review this application again when it comes up for renewal. It was agreed this condition would be approved OOC by the IGARD Chair.
2.7	<u>Queen Mary University of London: MR1488: Prognostic Factors in Prostate Cancer for Patients Treated by Watchful Waiting (TAPG) (Presenter: Louise Dunn) NIC-245768-V0N2T</u>

	Application: This was a new application for identifiable Medical Research Information Service (MRIS) data for the purpose of a study which was established to examine the hypothesis that through a detailed retrospective analysis of outcome in a group of men with clinically localised prostate cancer at diagnosis, variables such as biological, pathological and clinical markers, could be identified that might accurately predict the prognosis of clinically localised prostate cancer. The analyses of the study will also enable the research community and patients to make more informed decisions on treatment pathways for prostate cancer, potentially avoiding unnecessary, highly invasive and toxic radical treatment. **Discussion:** IGARD had a lengthy discussion with regard to data controllership and data processing and queried if Barts Cancer Centre should be considered as a joint Data Controller or Data Processor, in light of the information provided in the application and supporting documents of their role with the study; and asked that an analyses was provided outlining this. IGARD noted that Barts Cancer Centre was referenced under the Queen Mary University London (QMUL) Data Processor description; and asked that a further explanation was provided to further explain this or to amend if required. IGARD queried the role of the Sloan Kettering Hospital in New York, noting that they were the 'other collaborator' of the initial study when it commenced, and asked that an explanatory narrative was provided in section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) why they were no longer involved. IGARD queried the inconsistencies with the study cohort numbers stated within the application and asked that correct cohort size of 3,500 was consistently referenced throughout the application. IGARD also noted that section 5(a) (Objective for Processing) did not specifically reference the size of the cohort (3,500) and asked that this was updated to reflect this information. IGARD noted that yielded benefits had been included within section 5(d) (Benefits) (iii) (Yielded Benefits) and asked that this was amended to make it explicitly clear that the yielded benefits outlined had been achieved prior to receiving any NHS Digital data. In addition, IGARD suggested that upon return that section 5(d) (iii) should be updated to make it explicitly clear the yielded benefits that had been generated following receipt of NHS Digital data. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. **Outcome Summary:** recommendation to approve subject to the following conditions: 1. In respect of Barts Cancer Centre: a) To provide an analysis of whether Barts Cancer Centre should be considered as a joint Data Controller or Data Processor. b) To further explain the reference to Barts Cancer Centre under the QMUL data processor description. 2. To provide an explanatory narrative in section 1 and section 5 setting out why the other collaborator of the initial study is no longer involved. The following amendments were requested: 1. To ensure the **correct** size (3,500) of the study cohort is consistently referenced throughout the application. 2. To update section 5(a) to specifically reference the size of the cohort. 3. To amend section 5(d) (iii) to make explicitly clear that the yielded benefits outlined have been achieved prior to receiving any NHS Digital data.

	The following advice was given: 1. IGARD suggested that upon return that section 5(d) (iii) should be updated to make it explicitly clear the yielded benefits that have been generated following receipt of NHS Digital data. It was agreed the condition would be approved Out of Committee (OOC) by IGARD members.
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-17649-G0X4B University of Leeds • NIC-121849-W0T5C University of Birmingham IGARD welcomed the two 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 **4.1**	<u>AOB:</u> <u>NHS e-Referral (e-RS) dataset – Briefing Paper</u> The briefing paper was previously discussed at IGARD on the 27th February 2020 and this updated version was provided to reflect comments provided at this meeting. The briefing paper was to inform IGARD about the NHS e-Referral Service (e-RS) dataset, which NHS Digital have been directed to establish and operate by the Secretary of State for Health and Social Care. The NHS e-RS went live in June 2015 and is a national IT system that enables patient referrals, primarily from GPs to first hospital or clinic appointments, to be booked into health care services at a location, date and time to suit the patient. GPs and hospitals are obliged, via their respective contracts, to ensure that all GP to consultant referrals are made via e-RS. The primary purpose of processing e-RS data is to enable the correct operation of the e-RS system, subsequent processing transforms the data into appropriate extracts for recipients. IGARD welcomed the updated briefing paper and confirmed they had no further comments to make. 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 06/03/20

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-186893-W6V1H	NHS East Berkshire CCG	30/01/2020	1. To provide a clear narrative with regards to the involvement of Graphnet Healthcare Ltd and to explain why this is not considered parallel / excessive processing. 2. To either update section 5(a) to reflect the parties outlined within the data flow diagram; or to update the data flow diagram to reflect the facts outlined in section 5(a).	IGARD Chair	OOC by IGARD Chair	None
NIC-315134-L9Z6B	IQVIA Solutions UK Limited	06/02/2020	1. To ensure there is reference within section 5(e) to the themes covered in the NHS Digital published 5e Commercial Purpose Standard; and ensure the relevant points outlined in the Standard are addressed, particularly that the benefits to the public are proportionately balanced against the commercial benefits accruing to the pharmaceutical company (Sanofi Genzyme Ltd). 2. To amend the Legitimate Interest Assessment to reflect the specific processing in relation to the specific project outlined in the application.	IGARD Chair	OOC by IGARD Chair	None

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 notified to IGARD