### Independent Group Advising on the Release of Data (IGARD) Minutes of meeting held 19<sup>th</sup> December 2019

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

**In attendance (NHS Digital):** Stuart Blake, Louise Dunn, James Humphries-Hart, Dickie Langley, Karen Myers, Vicki Williams, Robyn Wilson.

Not in attendance (IGARD Members): Sarah Baalham, Anomika Bedi, Nicola Fear.

**Observers:** Dan Goodwin, Joanna Geisler, Tracey Taylor.

#### 1 Declaration of interests:

There were no declarations of interest.

#### Review of previous minutes and actions:

The minutes of the 12<sup>th</sup> December 2019 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record the meeting.

#### Out of committee recommendations:

An out of committee report was received (see Appendix B).

#### 2 Data applications

#### 2.1 IQVIA Briefing Paper (Presenter: Louise Dunn)

The briefing paper was to inform IGARD of the organisation changes within the IQVIA group, which affected a number of active Data Sharing Agreements (DSA).

The IQVIA UK group is consolidating the majority of its UK businesses within IQVIA Ltd and will be transferring the business and assets (including contracts) of IQVIA Solutions UK Limited and IQVIA World Publications Ltd into IQVIA Ltd.

As a result of these changes, NHS Digital have proposed a number of actions, including adding IQVIA Ltd as a Data Controller and amending section 1 (Abstract) and section 5(a) (Objective for Processing) within the existing active IQVIA DSA's with standard wording to reflect the changes outlined.

IGARD welcomed the briefing paper and made the following additional comments:

- 1. To ensure that throughout the briefing paper, each individual IQVIA company is referred to individually and to be explicitly clear as to the role of each entity and what data controllership and data processing duties each one is carrying out.
- 2. To include a clear statement explaining which IQVIA companies are becoming 'dormant' (and ultimately dissolved) and which organisation will be absorbing the assets and employees of the dormant companies.
- 3. To update section 1.1 to expand the information provided on IQVIA's active Data Sharing Agreements, and to outline current Data Controllers and new Data Controllers against each NIC number.

<u>Technology Services Ltd: HES data for IQVIA clinical trial site identification (Presenter: Louise Dunn) NIC-210151-K9C7G IQVIA</u>

**Application:** This was an amendment application to add IQVIA Ltd as a Data Controller and a Data Processor. The purpose of the application is to use pseudonymised Hospital Episodes Statistics (HES) data to analyse estimated patient populations at all hospitals in the UK; and

compare these with similar estimates of patient populations in other countries in which IQVIA and its Affiliates undertake Clinical Trial Site Identification (CTSI) (using data sources specific to those countries). This information helps clients of IQVIA and its Affiliates to select suitable countries in which to recruit patients into clinical trials, in order to develop new medicines and treatments for patients.

**Discussion:** IGARD noted the organisational changes within the IQVIA UK group and that this application had been brought to IGARD to reflect this. Following a discussion on the data controllership following the organisational changes, IGARD advised NHS Digital that data controllership was not a legal status that could be transferred by contract and that it would have to be clearly referenced that the companies would become dormant with the intention of being dissolved.

IGARD queried which of the IQVIA companies would become 'dormant' and ultimately dissolved and which organisations would absorb the assets and employees of these dormant companies; and asked that section 5 was updated with this information; including clarification of which, if any IQVIA companies not being absorbed have live Data Sharing Agreement's (DSA) or joint Data Controller arrangements in place. IGARD also advised NHS Digital that the number of employees may increase following the re-organisation of the IQVIA companies.

IGARD also asked that a special condition was added to section 6 confirming that if there was a change in status of the dormant IQVIA companies, then NHS Digital must be notified of this immediately, noting that this could impact on live DSA's.

IGARD noted the number of IQVIA entities that were referred to throughout the application, however also noted the numerous references to "IQVIA" and asked that the appropriate use of the various IQVIA entities named were clearly delineated throughout the application; and to be clear which of the parties were Data Controllers and for which of the processing activities outlined.

IGARD noted that section 5 (Purpose / Methods / Outputs) did not specify the territory of use, and since this was an international company, asked that this was updated to add an explicit statement that the territory of use was England and Wales.

In addition, IGARD also asked that the special condition in section 6 (Special Conditions) that stated ""IQVIA staff are permitted to work remotely including at home…" was updated to make it clear that this must be within the territory of use, England and Wales.

IGARD noted the statement in section 5(b) (Processing Activities) that stated "Affiliates will only access the HES data where it is aggregated with small numbers suppressed…" and asked that this statement was replicated wherever 'Affiliates' access to data' was discussed.

IGARD queried the special condition in section 6 that incorrectly stated IQVIA Ltd would be the sole Data Controller and asked that this was amended to reflect the correct information.

IGARD noted the statement in section 5(b) that stated "Relevant Extracts of HES data will be used by employees of IQVIA or its Affiliates..." and asked that this was removed as it was not relevant.

In light of the re-organisation that had been outlined, IGARD suggested that NHS Digital may wish to consider auditing this organisation in relation to these applications / DSA's.

IGARD advised NHS Digital 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. To ensure the appropriate use of the various IQVIA entities named throughout the application are clearly delineated and to be clear which parties are Data Controllers for which processing activities.
- 2. To add an explicit statement in section 5 that the territory of use is England and Wales.
- 3. To update section 5 with an explicit statement naming the IQVIA companies that are becoming 'dormant' (and ultimately dissolved) and which organisation will be absorbing the assets and employees of the dormant companies and to clearly state which, if any IQVIA companies not being absorbed have live DSA's or joint Data Controller arrangements in place.
- 4. To add a special condition in section 6 confirming that if there is a change in status of the dormant IQVIA companies, then NHS Digital must be notified immediately.
- 5. To update the special condition in section 6 that states "IQVIA staff are permitted to work remotely including at home..." to make it clear that this must be within the territory of use, namely England and Wales.
- 6. To replicate the statement in section 5b that states "Affiliates will only access the HES data where it is aggregated with small numbers suppressed..." wherever Affiliates' access to data is discussed.
- 7. To amend the statement in section 6 (Special Conditions) that IQVIA Ltd will be deemed as the sole data controller.
- 8. To remove the statement in section 5b that extracts of HES data will be used by employees of IQVIA or its affiliates.

The following advice was given:

- 1. In light of this re-organisation, IGARD suggested that NHS Digital may wish to consider auditing this organisation in relation to these applications / data sharing agreements.
- 2. IGARD advised that they would wish to review this application again when it comes up for renewal.

It was agreed the conditions would be approved Out of Committee (OOC) by the IGARD Chair.

2.2 Guys & St Thomas NHS FT: Transforming Cancer Services Team for London access to

National Cancer Waiting Times Monitoring Data Set (NCWTMDS) from the Cancer Wait Times

(CWT) System (Presenter: James Humphries-Hart) NIC-228903-Z0F4V

**Application:** This was a new application for pseudonymised National Cancer Waiting Times Monitoring Dataset (CWT) for the Transforming Cancer Service Team London, hosted by the applicant, to access data (previously supplied by NHS England) to provide London-wide support for improving cancer services and in terms of cancer waiting times, provide all the pan-London analysis across London, working with the Cancer Alliances to improve waiting times.

The application was been previously considered on the 14<sup>th</sup> November 2019 when IGARD had deferred pending: to redraft the application throughout to reflect that <u>only</u> Guy's and St Thomas' NHS Foundation Trust on behalf of the Transforming Cancer Services Team (TCST) London will have access to the data; and to remove any reference to CCG's accessing the data; to confirm if Guy's and St Thomas' NHS Foundation Trust hold any extracts of data that replicate data held on the I-View Plus Tool and if so to provide clear written justification for the retention of the data extract or to provide written confirmation of destruction; to ensure that the stated outcomes and project benefits outlined in the application are realistic for example, but not limited to, providing further clarification of how "equity of access" will be achieved.; to amend section 1 to ensure the correct legal basis is referenced; to update section 1 on Article 9 to make reference to section 11 of the DPA.

**Discussion:** IGARD noted that the application had been updated to reflect all of the comments previously made.

IGARD noted that there appeared to be remaining CCG terminology within the application, for example in Section 1 (Abstract) when detailing how Guys and St Thomas Trust meets the Data Protection Act (DPA) requirements; and asked that this was removed unless it was deemed relevant.

IGARD queried a statement in section 5(b) (Processing Activities) that stated "The user will be able to access the provider extracts from the portal for any provider where at least 1 patient for whom they are the registered CCG for that individuals GP practice appears in that setting" and asked for further clarity on the meaning of this statement.

#### Outcome Summary: recommendation to approve

- To remove any remaining CCG terminology from the application (for example in the abstract when detailing how Guys and St Thomas Trust meets the DPA requirements), unless deemed relevant.
- To provide further clarity on the statement in section 5(b) that states "The user will be able to access the provider extracts from the portal for any provider where at least 1 patient for whom they are the registered CCG for that individuals GP practice appears in that setting.

# 2.3 Cambridge Centre for Health Services Research (Based at the University of Cambridge): BRACE NIHR Rapid Evaluation Centre (Presenter: James Humphries-Hart) NIC-243359X4T5M

**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 'Birmingham RAnd and CambridgE' (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.

**Discussion:** IGARD had a lengthy discussion on the funder and funding arrangements for the programme of work outlined in the application, noting that it clearly stated both within the application and the supporting documents provided that the funder was the National Institute for Health Research (NIHR). IGARD asked that further consideration was given as to whether NIHR, noting the level of control they had over the programme should be a joint **or** sole Data Controller for the overarching programme; with the currently named Data Controllers potentially becoming Data Controllers with the appropriate approvals in place for subordinate project-level Data Sharing Agreement (DSA) / applications.

IGARD also queried if NIHR funding was still in place and continuing and asked that appropriate evidence was provided clarifying this. IGARD also noted that the evidence should also acknowledge the other organisations involved with the programme and the scope of the projects and that this should align with the processing that was outlined in the application.

IGARD noted that within both the application and support documentation provided that various RAND organisations were referred to but that it was not clear which RAND organisation was being specified as noted on the UK Government's Companies House website, and noted that a number of RAND organisations were listed as being located at the same building address and queried the Data Controllers outlined in supporting documents 6 and 7, the study protocols; and asked that these were reviewed and given further consideration to determine if any

additional Data Controllers should also be added to the application, in light of the co-location arrangements.

IGARD asked that references in the application to "RAND" be updated to explicitly stated which RAND organisation(s) was being referred to; and to clarify which RAND organisation(s) would be undertaking the data controllership and data processing activities.

IGARD queried the Legitimate Interest Assessment (LIA) that had been completed and asked that an LIA was completed by **each** of the relevant RAND organisations, and that particular attention was paid to the balancing test and that there was a requirement to respond appropriately to all sections of the LIA. IGARD also asked that a clear Privacy Notice was provided by the relevant organisation(s) clearly outlining their roles, responsibilities and processing activities in the context of the programme.

IGARD queried the length of the study and the time frame of the activities that were being proposed and asked that section 5 (Purpose / Methods / Outputs) was updated outlining this.

IGARD noted the first paragraph in section 5(a) (Objective for Processing) outlined some potential 'contentious' issues in relation to the health and care system and suggested that this was updated to remove the specific examples provided.

IGARD queried why both the HES A&E data **and** the Emergency Care Data Set had both been requested, noting that they appear to be the same or provide similar data and asked that further clarity was provided.

#### Outcome Summary: Recommendation to defer, 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).
- 2. To 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.
- To 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.
- 4. To 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.
- 5. To 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.
- 6. To update section 5 outlining the length of the study and the time frame of the activities being proposed.
- 7. To update the first paragraph in section 5(a) to remove the specific examples provided of current 'contentious' issues.

8. 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.

# 2.4 University of Manchester: MR806: BSPAR Enbrel Cohort Study (BSPAR EN) (Formerly: BSPAR, BNDR (Biologics and New Drugs Registry) for Juvenile Idiopathic Arthritis (JIA) patients) (Presenter: Stuart Blake) NIC-179285-7RS6G

Application: This was a renewal and extension application for identifiable Medical Research Information Service (MRIS); and an amendment to add the British Society for Rheumatology as an additional Data Controller and to change the purpose for processing to reflect the long-term aims of the study. The purpose of the long-term observational study is to monitor the safety of the biologic therapy Enbrel, and all Etanercept biosimilars, prescribed for juvenile idiopathic arthritis (JIA) in routine healthcare, specifically to understand if these new drugs increase the risk of developing serious infection, cancer or premature death above that of what would be expected in a population with similar disease characteristics not receiving these therapies.

**Discussion:** IGARD welcomed the application which came for advice on the consent materials and section 5(a) (Objective for Processing) without prejudice to any additional issues that may arise when the application is fully reviewed.

IGARD noted and endorsed most of the conclusions outlined in the analyses provided by NHS Digital in supporting document 3.0, the consent review. IGARD asked that going forward the assent process was formally and robustly recorded and that the consent materials were updated as appropriate to reflect this, and that the process complied with the relevant updated EU Clinical Trials Regulation. IGARD advised that the "2012 individual" cohort of those aged under 16 consented in 5.3(iii) were withdrawn, unless it could be shown that parental consent had been obtained, since under 16's were unable to provide assent / consent in clinical trials and could not therefore be part of the clinical trial. Finally, IGARD advised NHS Digital that the appropriateness of consent materials in the context of the duty of confidence was dependent on further clarification as to which study requested the data.

IGARD queried the purpose of the application noting the inconsistent references within the application and supporting documents to either an "adolescent study" or a "paediatric study" as well as the British Society for Paediatric and Adolescent Rheumatology Etanercept Cohort Study (BSPAR ETN) and asked for clarification as to which was correct, or if both were correct asked that the consent materials correctly aligned following the review of the consent materials and the study outlined in the application.

IGARD noted the statements made by the applicant that it often processed the same data for the studies covered by different Data Sharing Agreements (DSA's) and asked that a further explanation was provided explaining the relationship between the relevant studies, cohorts and the data processed.

IGARD endorsed NHS Digital's comments and queried the decision-making process outlined in supporting document 8, the e-mail trail between NHS Digital and the applicant; and asked that further information was provided on **all** aspects of the decision-making process.

IGARD also asked that the information provided in the latest version of the Protocol was reviewed, in view of the statements made by the applicant with regard to the Data Controllership, particularly any ongoing involvement of the University of Birmingham.

IGARD queried if all of the research ethics approvals and all protocols provided as supporting documents had received a favourable opinion from an ethics committee, and

asked that evidence was provided of this, noting that this was a requirement of The Medicines for Human Use (Clinical Trials) Regulations.

IGARD queried if the study outlined had ongoing funding and asked the evidence was provided; and requested further details of the pharmaceutical company who had previously provided funding and clarification as to why this funding had now ceased.

IGARD noted the reference in section 5 (Purpose / Methods / Outputs) and the study protocol to a "control group" and asked that further information was provided on this group; with details of the age of this group and how they were recruited, including if they were part of the original consented group.

IGARD suggested that the statement in section 5(a) that stated "...there are no moral or ethical issues..." was removed since it was not necessary to include in the application.

IGARD noted the information in supporting document 8 that the applicant processes aggregated data and asked that further clarity was provided within the application, on the type of data that was being processed and asked that the terms were used consistently throughout the application.

IGARD endorsed NHS Digital's comments and noting the outputs outlined in SD8 and asked for further clarification of these.

**Outcome Summary:** IGARD welcomed the application which came for advice on the consent materials and section 5(a) and without prejudice to any additional issues that may arise when the application is fully reviewed.

- 1. In relation to NHS Digital's analysis of the consent materials provided in SD 3, IGARD endorsed the conclusions reached with three caveats:
  - To ensure that going forward the assent process is formally and robustly recorded and to update the consent materials as appropriate to reflect this, complying with the relevant updated Regulations.
  - ii. To exclude from the "2012 individual" cohort those aged under 16 consented in 5.3(iii) (unless it can be shown parental consent was obtained) as they are unable to provide consent in clinical trials.
  - iii. The appropriateness of consent materials in the context of the duty of confidence is dependent on further clarification as to which study requests the data.
- 2. IGARD queried the purpose of the application, namely, if this is the "adolescent study" or a "paediatric study" or both, noting the conflicting information in the application and supporting documents provided; and to ensure the consent materials correctly align with this.
- To clarify the statements made by the applicant that it processes the data for the studies covered by different DSAs and to explain the relationship between the relevant studies, the cohorts and the data processed.
- 4. To clarify all aspects of the decision-making process as outlined in SD8.
- 5. To review the information provided in the latest version of the Protocol (SD8) in view of the statements made by the applicant with regard to the Data Controllership (particularly any ongoing involvement of the University of Birmingham).
- 6. To provide evidence of all research ethics approvals and all protocols that have received a favourable opinion from an ethics committee as this is a requirement of The Medicines for Human Use (Clinical Trials) Regulations.

- To provide evidence of ongoing funding and to provide further details of the pharmaceutical company who previously provided funding and why this funding has now ceased.
- 8. To provide further information on the "control group" referenced in section 5 and the protocol outlining the age of this group and how they were recruited.
- 9. To remove from section 5(a) reference to 'there are no moral or ethical issues".
- 10. To provide further clarity within the application on the type of data that is being processed and to use the terms consistently throughout the application, in view of the comments made by the applicant in SD8 that it processes aggregated data.

To provide further clarifications of the outputs as outlined in SD8.

### 2.5 NHS Herts Valleys CCG: DSfC - NHS Herts Valleys CCG IV & Comm (Presenter: James Humphries-Hart) NIC-55752-D6X5Y

**Application:** This was an amendment application to add GP data linkage for commissioning by Arden and Greater East Midlands Commissioning Support Unit (CSA). 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; and to provide intelligence to support the commissioning of health services.

NHS Digital advised IGARD that there would be a period of 3-months dual running for Arden and Greater East Midlands CSU and North East London CSU from the start of the Data Sharing Agreement (DSA), and that after this 3-months, North East London CSU would cease to receive and process data for the CCG under this DSA and would complete a Data Destruction Certificate and submit this to NHS Digital. During this 3-month period **only** Arden and Greater East Midlands CSU would have access to the GP data.

**Discussion:** IGARD noted the update from NHS Digital on the temporary period of dual running for Arden and Greater East Midlands CSU and North East London CSU and that only Arden and Greater East Midlands CSU would have access to the GP data.

IGARD noted that it was not clear within section 1 (Abstract) of the application what amendments had been made to the application and asked that this was updated to reflect this information.

IGARD queried the information provided in section 5(a) (Objective for Processing) and section 5(b) (Processing Activities) in relation to the objective for GP data linkage; and asked that both section of the application were updated to clearly highlight this.

Separate to this application, IGARD queried the legal basis for the flow of the identifiable GP data and requested an update from NHS Digital on the ongoing work on the transparency and duties of GP practices. **ACTION**: NHS Digital to present to a future IGARD meeting.

Outcome Summary: recommendation to approve

The following amendments were requested:

- 1. To update section 1 to clarify the amendments that have been made to this application.
- 2. To highlight the objective for GP data linkage in sections 5(a) and 5(b).

#### 2.6 Adult Social Care Surveys – Briefing Paper (Presenter: Robyn Wilson)

The briefing paper was to inform IGARD of two data sets that are due to be made available through the Data Access Request Service (DARS), the Adult Social Care Survey (ASCS) and the Survey of Adult Carers in England (SACE).

Both of the surveys had previously been available to external customers, however this was outside of DARS processes. Historically, Adult Social Care Surveys have been managed and disseminated by NHS Digital's Adult Social Care Statistics Team.

Access to the Adult Social Care survey data is required for all Councils with Adult Social Services Responsibilities (CASSRs), for the purpose of: answering Freedom of Information (FOI) requests; benchmarking against other Councils; measuring / monitoring local performance; service development; planning and improvement; and management information, local reporting, accountability.

IGARD welcomed the updated draft briefing paper and made the following additional comments, and looked forward to receiving the updated briefing paper at a future IGARD meeting:

- To provide a clear statement outlining who are the Data Controllers and who are the Data Processors, and to consider if NHS Digital should also be included as a Data Controller or Data Processor.
- 2. To provide further clarity on the purpose of the processing.
- 3. To provide further details outlining the processing activities.
- 4. To clarify the distinct legal bases for NHS Digital to collect, process and disseminate the data including any restrictions that may apply, since there may be different legal bases for collecting, processing and disseminating the data.
- 5. To amend the letter template for a lay audience to clarify that patients cannot be **directly** identified and ensure the only reference to "anonymised" is in relation to published outputs (as the data accessed by researchers will not be anonymised and, if linked to other data, may allow for indirect identification).

#### 3 Returning Applications

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 37191 P5S9S University College London
- NIC 67135 G7D9V University of Dundee
- NIC 309751 G8D4H King's College London

IGARD welcomed the three 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** AOB:

#### 4.1 <u>Eve Sariyiannidou</u>

Both IGARD and NHS Digital noted that this was Eve Sariyiannidou's final meeting and wished to extend their sincere thanks for her significant contribution over the last 8 years during her tenure on IGARD, its predecessor the Data Access Advisory Group (DAAG), and the General Practice Extraction Service Independent Advisory Group (GPES IAG).

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 13/12/19

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-192767- R0S9V	Group Application for 3 CCGs	28/11/2019	To remove reference to the ICS and amend the application throughout to ensure the application is specific to the CCG's and their joint data controllership.	Quorum of IGARD members	Quorum of IGARD members	N/A
NIC-338789- M0T3Q	Group Application for 3 CCGs	28/11/2019	To remove reference to the STP and amend the application throughout to ensure the application is specific to the CCG's and their joint data controllership.	Quorum of IGARD members	Quorum of IGARD members	N/A
NIC-295342- W3Z6L	University of Oxford	14/11/2019	To revise the application throughout to align with the stated research aims outlined in the study protocol, including the purpose, outputs and benefits.	Quorum of IGARD members (Chair and 2 medical specialist members)	Quorum of IGARD members (Chair and 2 medical specialist members)	N/A
NIC-157211- T8B2M	University College London	17/10/2019	<ol> <li>To revise the Protocol or to provide suitable Protocol-standard wording that clearly sets out the scientific justification for processing the data for the cohort age group from 30 to 45 years old.</li> <li>Confirmation from NHS Digital that they are satisfied that the revised contracts with the students are fit for the proposed purpose (for example using a Code of Conduct agreement rather than an "Honorary Contract"), and for such agreement to cover</li> </ol>	Quorum of IGARD Members	Quorum of IGARD members	The abstract, could be amended so that it satisfies the specifics of condition 2, namely: "NHS Digital is satisfied that the revised contracts with the students are fit for the proposed purpose and that the contracts provide appropriate protections such as

off appropriate protections such as sanctions for misuse of data, and that the parties involved have been clearly identified.	sanctions for misuse of data, and that the parties involved have been clearly identified."
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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 quarterly Oversight and Assurance Report.