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By email and post - [REDACTED]

15 February 2019

Dear [REDACTED]

FOI Request

Thank you for your email of 29 January 2019 where you requested a copy of our agreement with IQVIA.

We do hold information falling within the terms of your request. A copy of the information which can be disclosed is/attached. The remainder of the information that you requested is exempt from disclosure under section 43 of the Freedom of Information Act 2000 in relation to trade secrets/prejudice to commercial interests and is therefore withheld. That information has been redacted in the attached copy of the agreement we entered into between with IQVIA Limited on 14 September 2018. I would add that the agreement with IQVIA does not in fact enable them to access directly patient data for research and they (like all others) have to go through our standard process for this (approval by Access Review Committee and further agreement) to access de-identified data in our research environment.

With regard to the information that we have redacted we have done so on the basis that the redacted material contains information that is either a trade secret of IQVIA or contains information on internal processes or procedures of IQVIA that would give its competitors a material commercial advantage if it were to be disclosed or otherwise the disclosure of which would prejudice the commercial interests of Illumina in a material way.

In applying the public interest test we have therefore weighed the need for disclosure against the factors set out above and the necessity of being able to implement the collaboration with IQVIA so as to facilitate the free and frank exchange of views between the parties. This is necessary for the collaboration to achieve its aims. We have concluded that with regard to the redacted material the public interest test determines that the information is exempt.

Genomics England Limited (Registered Number 8493132, Registered Office – Dawson Hall, Charterhouse Square, London, EC2M 6BQ)

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of receipt of the response to your original letter and should be addressed to: [REDACTED]
[REDACTED]@genomicsengland.co.uk.

Please remember to quote the reference number above in any future communications.

If you are not content with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision. The Information Commissioner can be contacted at: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF.

Yours sincerely



NICK MALTBY GENERAL COUNSEL
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DATED 14 SEPTEMBER 2018

IQVIA Solutions UK Limited
and
Genomics England Limited

Collaboration Agreement
REDACTED

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Ref: IMS/001/0042

COLLABORATION AGREEMENT

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THIS AGREEMENT is made the 14th day of September 2018

BETWEEN:

- 1 **IQVIA Solutions UK Limited**, a company registered in England, with company number 634325, whose registered office is at 210 Pentonville Road, London, N1 9JY (**IQVIA**); and
- 2 **Genomics England Limited**, a company registered in England, with company number 08493132, whose registered office is at Dawson Hall, Charterhouse Square, London, EC1M 6BQ (**Genomics England**).

BACKGROUND

- A. Genomics England and IQVIA are dedicated to advancing healthcare through the appropriate use of clinical and genomics data.
- B. By working together, it is the view of both parties that they will be able to better serve the growing needs of the life sciences industry and thereby enhance patient benefit through the creation of novel solutions which aid drug discovery, clinical development and the quantification and demonstration of value of treatments to patients, commissioners, and healthcare regulators. Bringing together IQVIA's technologies and services experts with Genomics England's clinical and genomic datasets, technical infrastructure, platform and network to generate, curate and analyse genomics data, the parties intend to be able to encourage greater life sciences investment in the United Kingdom, and increase patients' access to novel therapies.
- C. The parties intend to collaborate to develop and commercialise technology and services products using current and future clinical and genomics data managed by Genomics England, and wish to do so on and subject to the provisions of this Agreement.
- D. The parties wish the collaboration to be a true partnering arrangement under which they will each make available valuable assets, collaborate to develop the service offerings, co-promote the service offerings, make joint decisions about the service offerings and share the risks and rewards in a fair way having regards to their respective contributions and costs.

OPERATIVE PROVISIONS

1. DEFINITIONS AND INTERPRETATION

1.1 In this Agreement:

Agreed Objectives has the meaning given in clause 2.2;

Affiliate means, in relation to either IQVIA or Genomics England, a company which is a subsidiary or holding company of it, or any company which is a subsidiary of any such holding company, "holding company" and "subsidiary" having the meanings ascribed to them in section 1159 Companies Act 2006 and, in the case of Genomics England, the Department of Health and Social Care and any NHS Body;

Airlock Policy means Genomic England's policy for bringing materials into and out of the Genomics England Environment as such policy is amended from time to time and made available from Genomic England's Website;

Analytical Consultancy Services	means the services described in Schedule 2, Part 2;
Annual Review	means the annual review meeting described in clause 5;
ARC	means the access review committee established by Genomics England (to act as an independent decision making body), which approves, declines or amends requests for access to and use of the Genomics England Data;
Business Day	means Monday to Friday, excluding any public holidays in England;
Chairperson	means the individual appointed as such by the parties in accordance with paragraph 2.10 of Schedule 7;
Change	means any change to the provisions of this Agreement;
Clinical Study	means a clinical study, clinical trial, observational study or registry study taking place in the United Kingdom;
Clinical Study Consenting Participant	means a participant in a Clinical Study covered by the Custom Clinical and Genomic Analytical Services that consents to their Participant Sequence / Associated Data being made available for Research in the Genomics England Environment;
Clinical Study Data	means any data collected by or on behalf of IQVIA, its Affiliates or a Customer in relation to a participant in a Clinical Study covered by the Custom Clinical and Genomics Analytical Services;
Collaboration	means the collaboration between Genomics England and IQVIA described in this Agreement;
Commercial Organisation	means any commercial or 'for profit' firm, corporation or organisation;
Competing Third Party	means a commercial entity which has an agreement with Genomics England under which it provides one or more services that compete with one or more of the Services;
Confidential Information	belonging to a party means all information (whether written, oral, in electronic form or otherwise) concerning the business, affairs, operations, customers, processes, budgets, pricing policies, product information, strategies, developments, trade secrets and know-how of that party, its Affiliates and/or its or their customers that the other party obtains or receives as a result of the discussions leading up to or the entering into or the performance of this Agreement, and includes the Genomics England Data which is Confidential Information belonging to Genomics England;

Contract Year	means the twelve (12) month period starting on the Effective Date, and each twelve (12) month period thereafter during the term of this Agreement;
Custom Clinical and Genomic Analytical Services	means the services described in Schedule 2, Part 3;
Customer	means any third party that has entered into both an IQVIA Customer Agreement with IQVIA (or an IQVIA Affiliate) and a Genomics England Data Access Agreement with Genomics England (or a Genomics England Affiliate). For clarity, GeCIP Members are not Customers;
Customer Materials	means all reports, studies, results, documentation, and other materials (in whatever form) created by Customers, or by either party, their subcontractors or Personnel, for Customers as part of the Services;
Customer Personal Data	means any Clinical Study Data that is personal data, and which is provided or made available to Genomics England, or introduced into the Genomics England Environment, by IQVIA, its Affiliates, the Customers, or its or their agents or contractors;
Customer Term	in relation to an IQVIA Customer Agreement, means the period specified in that IQVIA Customer Agreement during which the Customer may access and/or receive the relevant Services;
Data Protection Laws	means: a) Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) including the recitals (GDPR) and any equivalent or implementing legislation; b) the Data Protection Act 2018; and c) all other applicable laws (including judgments of any relevant court of law) and regulations relating to the processing of personal data, data privacy, electronic communications, marketing and/or data security, in each case as from time to time in force and as from time to time amended, extended, consolidated, re-enacted, replaced, superseded or otherwise converted, succeeded, modified or incorporated into law and all orders, regulations, statutes, instruments and/or other subordinate legislation made under any of the above in any jurisdiction from time to time;
Effective Date	means the date of this Agreement;

Force Majeure Event	means any cause not within the reasonable control of a party and which that party cannot reasonably prevent or overcome, as a result of which such party is unable to perform its obligations under this Agreement but shall exclude any delay or failure caused by any supplier or subcontractor unless such supplier or subcontractor is itself affected by an event beyond its reasonable control and which that supplier or subcontractor cannot reasonably prevent or overcome;
Fundamental Business Objectives	has the meaning given in clause 2.1;
GeCIP Member	means an individual who is a member of the Genomics England Clinical Interpretation Partnership;
GeCIP Modules	means those modules of the IQVIA Software which GeCIP Members will be entitled to access and use (in accordance with the terms of the GeCIP Software Licence), as set out in Schedule 8 (GeCIP Modules);
GeCIP Software Licence	means a software licence (in clickwrap or other electronic form) to be entered into by IQVIA, or an IQVIA Affiliate, and each GeCIP Member who is to be granted access to the GeCIP Modules;
Genomics England Data	means any and all genomic, phenotypic, patient and clinical data collected by or on behalf of Genomics England, whether as part of the Project or otherwise; it includes any and all patient-level data generated or collected by or on behalf of Genomics England, whether now or in the future, including genome data, phenotypic data, other sample/patient level administrative data, and linked data to other resources including hospital episode statistics, office national statistics and registry data (including data sourced from Public Health England and NHS Digital); it also includes any data collected by or on behalf of Genomics England in the future such as electronic medical records, patient reported outcomes, whole exome sequencing, biomarker and other -omic data; it does not include any of the foregoing data that is collected by or on behalf of IQVIA, its Affiliates or its or their customers, or any clinical trial data or Clinical Study Data generated or collected pursuant to the Custom Clinical and Genomic Analytical Services;
Genomics England Data Access Agreement	means a data access agreement between Genomics England (or a Genomics England Affiliate) and a customer pursuant to which Genomics England provides the customer with access to Genomics England Services Data for the purpose of accessing and/or receiving the Services;
Genomics England Environment	means the computing environment within which the Genomics England Data is stored by Genomics England and made available for analysis, including the hardware and

	software that is used by or on behalf of Genomics England to manage and operate the data centre;
Genomics England Materials	means Genomics England Services Data and any software, written material, files or other information made available by Genomics England in the Genomics England Environment;
Genomics England Personal Data	means Genomics England Data that is personal data, and any Participant Sequence / Associated Data that is personal data;
Genomics England Project Data	means any Genomics England Data that is collected or generated in the course of the Project;
Genomics England Research Environment	means the computing environment within the Genomics England Environment under which certain Genomics England Data, software, tools and information are made available to third parties who wish to carry out research on such data and within which the IQVIA Software is to be hosted;
Genomics England Security Policy	means the security policy to be finalised by Genomics England in accordance with clause 14.11 as such policy is amended from time to time pursuant to clause 14.11 and provided to IQVIA;
Genomics England Services Data	means the Genomics England Data that is made available in the Genomics England Research Environment;
Genomics England's Website	means the website at www.genomicsengland.co.uk ;
Group Members	means the initial persons appointed by Genomics England and IQVIA to the Groups as set out in Appendix 1 of Schedule 7 and any replacements from time to time agreed by the parties in accordance with paragraph 2.9 of Schedule 7;
Groups	means the Steering Group and the Working Group; and "Group" shall mean either of them;
Implementation Plan	means the implementation plan for the development of the Services and the set-up of the Genomics England Environment attached at Schedule 1, as amended in writing by the parties from time to time;
Information Governance and IT Security Policy	means Genomics England's policy on information governance and IT security as such policy is amended from time to time and made available from Genomics England's Website;
Initial Period	means [REDACTED] years from the Effective Date;

Initial Services	means the Analytical Consultancy Services, the Custom Clinical and Genomic Analytical Services and the Research Feasibility Data Access Services;
Intellectual Property Rights	means patents, trade marks, service marks, trade names, design rights, copyright, database rights, rights in know-how and other intellectual property rights or equivalent forms of protection of whatever nature arising anywhere in the world, whether registered or unregistered and including applications for the grant of any such rights;
IQVIA Customer Agreement	means an agreement between IQVIA, or an IQVIA Affiliate, and a customer pursuant to which IQVIA and/or its Affiliates will provide some or all of the Services;
IQVIA Materials	means any software, data or other material owned by or licensed to IQVIA (other than the IQVIA Software, the Genomics England Materials and any software, data or other material provided or made available by or on behalf of a Customer) and which is brought into the Genomics England Environment by IQVIA;
IQVIA Researcher	means an individual (who may be an employee or contractor of IQVIA, its Affiliates and/or the Permitted Subcontractors) who is nominated by IQVIA to have access to the Genomics England Environment for the purposes of carrying out Research on the Genomics England Services Data and is given access credentials by Genomics England to access the Genomics England Environment;
IQVIA Software	means IQVIA's E360 software, as amended and updated from time to time by IQVIA;
NHS Body	means NHS England, NHS Digital and any NHS Body as defined by the National Health Service Act 2006, as amended, extended or re-enacted from time to time;
Participants	means the individuals that are the subject of the Genomics England Personal Data;
Participant Associated Data	means any data, other than Participant Sequence Data, collected by or on behalf of Genomics England and/or its Affiliates in relation to a Clinical Study Consenting Participant in a Clinical Study covered by the Custom Clinical and Genomic Analytical Services that Genomics England has the right to make available to IQVIA, IQVIA's Affiliates and Customers;
Participant Sequence / Associated Data	means Participant Sequence Data and Participant Associated Data;
Participant Sequence Data	means any genome sequence data collected by or on behalf of Genomics England and/or its Affiliates in relation to a Clinical Study Consenting Participant in a Clinical Study

	covered by the Custom Clinical and Genomic Analytical Services;
Permitted Subcontractor	means (i) in relation to a party, that party's Affiliates, and (ii) any other subcontractor of Genomics England or IQVIA that is permitted by, or approved under, clause 32;
Personnel	means officers, employees, contract staff and consultants;
Project	means the 100,000 genomes project to be delivered by Genomics England;
Project Managers	means the individuals appointed as such by Genomics England and IQVIA in accordance with paragraph 1 of Schedule 7;
Prospective Customer	means any third party that is interested in receiving some or all of the Services but who has not entered into both an IQVIA Customer Agreement and a Genomics England Data Access Agreement in relation to such Services;
Rate Card	means the rate card attached at Schedule 4, as updated from time to time in accordance with clause 19 and/or paragraph 3.3 of Schedule 3;
Regulator	means the Information Commissioner and any other person having regulatory or supervisory authority over all or any part of the Services in relation to the processing of personal data;
Research	means scientific research for healthcare purposes (including to support the development of new medicines, therapies and diagnostic tests);
Research Feasibility Data Access Service	means the services described in Schedule 2, Part 1;
Services	means the Initial Services and any other services which the parties may from time to time agree in writing are to be provided to Customers;
Steering Group	means the body described in paragraph 2.2 of Schedule 7;
Virus	means any program, routine, device or other feature, including a time bomb, automatic shut-down, virus, software lock, drop dead device, malicious logic, worm, Trojan horse or trap or back door, or other harmful code or device which (i) is designed to delete, disable, deactivate, provide unauthorised access to, interfere with or otherwise harm any software, program, data, device, system or service; or (ii) is intended to provide unauthorised access or to produce unauthorised modifications; and
Working Group	means the body described in paragraph 2.4 of Schedule 7.

- 1.2 In the event and to the extent only of any conflict between the clauses and the Schedules this Agreement shall be construed according to the following order of priority:

- 1.2.1 clauses;
- 1.2.2 Schedules.
- 1.3 References to any statute, enactment, order, regulation or other similar instrument shall be construed as references to the statute, enactment, order, regulation or instrument as amended by any subsequent statute, enactment, order, regulation or instrument or as contained in any subsequent re-enactment, modification or statutory extension of any of the above.
- 1.4 Except where the context requires otherwise the singular includes the plural and vice versa; a reference to one gender includes all genders; words denoting persons include firms and corporations and vice versa.
- 1.5 Headings are included in this Agreement for ease of reference only and shall not affect interpretation or construction.
- 1.6 References to clauses and Schedules are, unless otherwise provided, references to clauses and schedules of this Agreement.
- 1.7 Any negative obligation imposed on any party shall be construed as if it were also an obligation not to permit or suffer the act or thing in question and any positive obligation imposed on any party shall be construed as if it were also an obligation to procure that the act or thing in question be done.
- 1.8 The words “include” or “including” shall be construed without limitation to the words following.
- 1.9 References to a party or the parties is a reference to either or both of IQVIA and Genomics England as the context requires.
- 1.10 No rule of construction (including the contra proferentem rule) will apply in the interpretation of this Agreement to the disadvantage of one party on the basis that such party put forward or drafted this Agreement or any provision of this Agreement.
- 1.11 In this Agreement “controller”, “processor” “data subject”, “data subject access request”, “personal data”, “personal data breach”, “supervisory authority” and “processing” shall have the meaning given to those terms in the Data Protection Laws, and “process” and “processed” shall be construed accordingly.

2. OBJECTIVES

- 2.1 The parties acknowledge and agree that Genomics England has the following fundamental business objectives (collectively, the “**Fundamental Business Objectives**”):
 - 2.1.1 to deliver 100,000 whole genome sequences derived from cancer patients and patients suffering from rare genetic diseases together with analyses of such whole genome sequences in order to support patient care and research and improve understanding of early diagnosis and personalised care;
 - 2.1.2 to create opportunities for industry, particularly UK based start-up companies and small and medium-sized enterprises, to develop genome-based knowledge, therapies and tools to drive economic growth;

- 2.1.3 to adopt access models to ensure that Genomics England covers its costs and makes a small surplus for its own purposes, but that any real benefits return to patients and the public in the UK; and
- 2.1.4 to earn and retain the political, ethical and moral trust of the people of the United Kingdom.
- 2.2 The agreed objectives of the parties with respect to this Agreement are as follows (the “Agreed Objectives”):
 - 2.2.1 to collaborate to develop and commercialise technology and services products using current and future clinical and genomics data managed by Genomics England, and the parties wish to do so on and subject Data Protection Laws and to the provisions of this Agreement;
 - 2.2.2 the parties wish the collaboration to be a true partnering arrangement under which they will each make available valuable assets, collaborate to develop the service offerings, co-promote the service offerings, make joint decisions about the service offerings and share the risks and rewards in a fair way having regards to their respective contributions and costs;
 - 2.2.3 to identify risks to the success of the Services and agree mitigation plans;
 - 2.2.4 to enhance communication and information flow between the parties in order to identify:
 - 2.2.4.1 issues early and, by working together, to resolve them;
 - 2.2.4.2 evolving business requirements and agree how to adapt to changing circumstances; and
 - 2.2.5 to keep under constant review the costs of providing the Services and actively seek ways of optimising value for money.
- 2.3 In view of the importance of this Agreement to IQVIA and of the Fundamental Business Objectives to Genomics England the parties shall work individually and collectively with third party suppliers with a view to ensuring that the Services achieve, and do not conflict with, the Fundamental Business Objectives and the Agreed Objectives.
- 2.4 Each party acknowledges and agrees that the Services are collaborative. Notwithstanding the rights and obligations as set out in this Agreement, the parties agree to collaborate and support each other and, in order to ensure that the Services are successful, each party commits to the following behaviours during the term of this Agreement, in each case subject to the other terms of this Agreement:
 - 2.4.1 to act reasonably and in good faith;
 - 2.4.2 to provide cooperation, support, information and assistance in a proactive way and in a spirit of trust and mutual confidence in order to ensure the success of the 100,000 Genomes Project and the smooth-running of the Services;
 - 2.4.3 to adopt a non-combative and non-defensive approach in all dealings with the other party and to make a commitment to mutual success in its relationships with the other party;

- 2.4.4 to take accountability for its actions and choices and use its best endeavours to understand the concerns, intentions and motivations of the other party;
- 2.4.5 to work collaboratively with the other party to identify and provide early warnings of any problems and to solve problems in a quick and constructive manner, particularly where these involve a difference of views or potential conflict of interest;
- 2.4.6 to commit to telling the truth to, and being open and transparent with, the other party; and
- 2.4.7 not to seek to take advantage of the other party through the divulgence of Confidential Information, or through misunderstandings or mistakes.

3. NO EXCLUSIVITY

- 3.1 This Agreement is non-exclusive, and neither party shall be restricted from collaborating or working with others.

4. OPERATION AND MANAGEMENT OF THE COLLABORATION

- 4.1 The parties acknowledge that this Agreement and the relationship between the parties is collaborative and that at the Effective Date there are many aspects of the Collaboration and the Services which are undecided and/or undeveloped. It is therefore not feasible to specify at the Effective Date all aspects of the Collaboration and/or the full range, nature and scope of the Services that the parties may offer to Prospective Customers.
- 4.2 The parties will initially collaborate on the Initial Services however the parties acknowledge that over time the Services will need to be developed and refined in order to ensure that the Services meet customer requirements, the Fundamental Business Objectives and the Agreed Objectives. It may be necessary to add, discontinue and/or change individual Services. The parties further acknowledge that there is no guarantee that the Services will be a commercial or technical success. There are a number of factors the parties will need to take into consideration when developing the Services and which may have an impact on the range, nature and scope of the Services the parties are able to offer to Customers, in particular but without limitation:
 - 4.2.1 Genomics England is the custodian of NHS patient data including sensitive personal data. It is of paramount importance to Genomics England that the confidence and trust of NHS patients and participants in the protection and appropriate use of their data in the Project is maintained and improved. Accordingly, Genomics England must maintain control over that data and have a direct contractual relationship with any Customers that make use of that data. The development and operation of the Services and the Collaboration must not be detrimental to that trust and confidence.
 - 4.2.2 Genomics England needs to seek to agree a suitable new contract with a sequencing provider including provisions that will facilitate the provision of Services as envisaged in this Agreement.
 - 4.2.3 Genomics England needs to seek to enter into suitable contracts with NHS Trusts including provisions that will enable the collection of the bio-specimens required for the Services envisaged in this Agreement.
 - 4.2.4 The Project is scheduled to end at the end of 2018 and thereafter the basis on which Genomics England collects Genomics England Data and its rights to own and use Genomics England Data collected following the end of the Project will change. This

will in part be determined by the structure and operating model of the NHS Genomic Medicine Service which has not yet been finalised.

- 4.2.5 The Genomics England Environment has, at the Effective Date, been developed for academic research use rather than as a platform for a commercial service and Genomics England's contracts with third party service providers in respect of the Genomics England Environment have been entered into on that basis. Accordingly, Genomics England is not able to provide undertakings as to performance, reliability, scalability, latency and disaster recovery that one might expect from a commercial provider of IT services, provided however that this does not affect or limit the scope of Genomics England's obligations or liability in respect of clauses 14.2, 25 or 26.
- 4.2.6 As at the Effective Date, the ARC operates on an individual approval basis such that it considers individual approvals in respect of individual projects to be carried out by individual organisations. As the volume of applications for ARC approvals increases it will be challenging for the ARC to deal with the volumes using the current processes. It is envisaged that as the ARC gains experience in reviewing applications it will be able to provide more umbrella approvals for particular use cases. However, given the independent nature of the ARC, Genomics England cannot guarantee whether or when this change will happen.
- 4.2.7 The basis on which the parties will provide support to Customers has not yet been established and the parties will need to cooperate to work out how best to support Customers.
- 4.2.8 As at the Effective Date, implementation of the Airlock Policy is not automated and necessarily requires human resources and time. As the volume of materials entering and leaving the Genomics England Environment increases it will be necessary to automate the process. However this will be challenging given the strict requirement to prevent identifiable Personal Data from being copied out of the Genomics England Environment.
- 4.3 The parties shall manage the Collaboration in accordance with and comply with the provisions of Schedule 7.
- 4.4 The parties shall use reasonable endeavours to perform their respective obligations set out in the Implementation Plan in accordance with the timetable set out in the Implementation Plan.
- 4.5 Both parties shall pro-actively manage risks relating to the responsibilities allocated to them under the terms of this Agreement.
- 5. ANNUAL REVIEW**
- 5.1 An annual review meeting shall be held each year on a date to be agreed between the parties (the "Annual Review").
- 5.2 The Annual Review shall be attended by the members of the Steering Group and any other persons considered by Genomics England as necessary for the review.
- 5.3 The agenda for the Annual Review shall include (without limitation) the following topics for discussion:
- 5.3.1 overall strategy for the Collaboration;
- 5.3.2 performance of the Collaboration against the Agreed Objectives;

- 5.3.3 the development, marketing and performance of the Services, including demand for the Services;
- 5.3.4 the scope and range of the Services available; and
- 5.3.5 the revenue generated by each of the Services.

6. APPROVAL OF PROSPECTIVE CUSTOMERS

6.1 The use of the Genomics England Services Data for the provision or receipt of the any of the Services shall be subject to:

6.1.1 the approval of the ARC in accordance with clause 10; and

6.1.2 the relevant Prospective Customer entering into:

6.1.2.1 an IQVIA Customer Agreement signed by IQVIA (and/or an IQVIA Affiliate) covering such use (or extending the scope of its existing IQVIA Customer Agreement to cover such use); and

6.1.2.2 a Genomics England Data Access Agreement signed by Genomics England (and/or a Genomics England Affiliate) (if it has not already done so) in respect of the relevant Services.

6.2 [REDACTED], Genomics England shall have absolute discretion over whether or not to grant each Prospective Customer access to the Genomics England Services Data, and therefore whether or not to enter into a Genomics England Data Access Agreement with such Prospective Customer.

[REDACTED]

7. RESEARCH FEASIBILITY DATA ACCESS SERVICES

7.1 The parties shall agree processes and workflow for the onboarding of Prospective Customers for the Research Feasibility Data Access Services. The parties shall keep these processes, workflow and timeframes under regular review, and shall work together to ensure that these processes, workflow and timeframes facilitate the marketing, promotion and sale of the Services to life sciences companies.

8. ANALYTICAL CONSULTANCY SERVICES

8.1 The parties shall agree processes and workflow for the onboarding of Prospective Customers of the Analytical Consultancy Services. The parties shall keep these processes, workflow and timeframes under regular review, and shall work together to ensure that these processes,

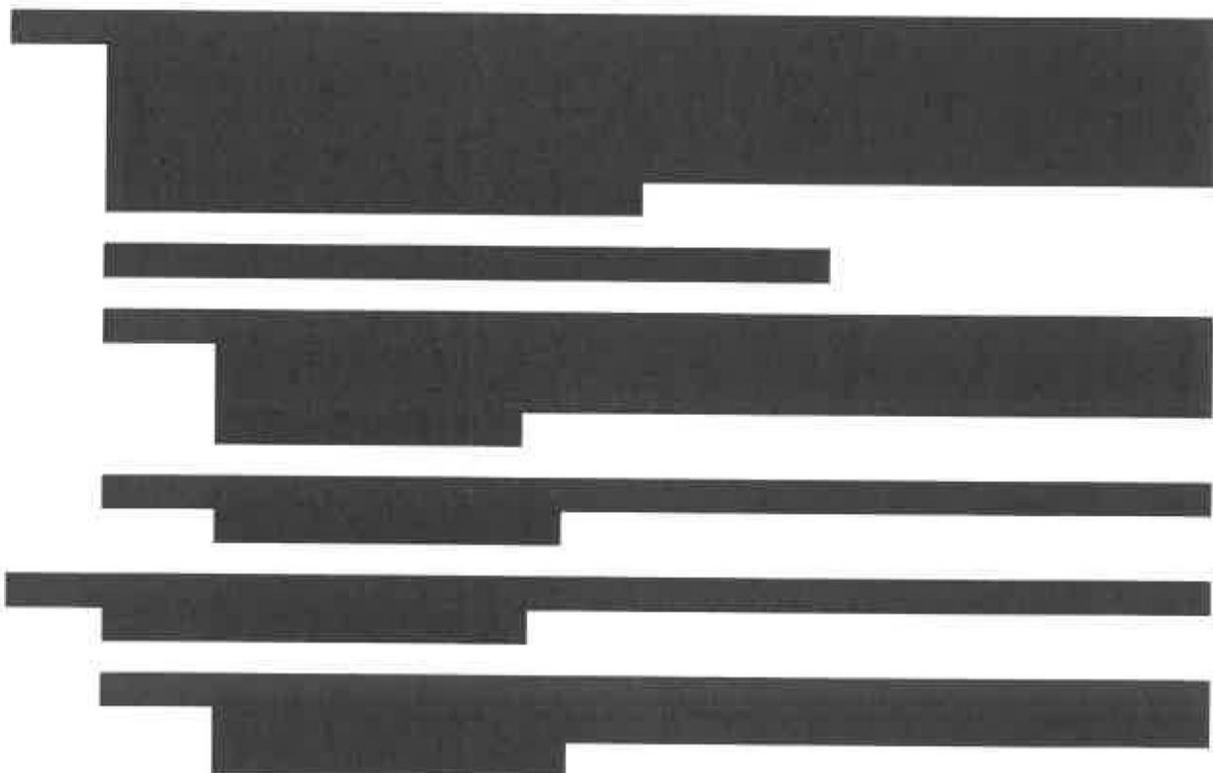
workflow and timeframes facilitate the marketing, promotion and sale of the Analytical Consulting Services to life sciences companies.

- 8.2 If IQVIA wishes to engage Genomics England to provide any of the Analytical Consultancy Services to, or for the benefit of, a Customer, and Genomics England is willing and able to do so within the required timeframe(s), the parties shall agree, in a written statement of work, the nature and extent of the services to be provided by Genomics England, together with any associated timeframes. Genomics England's charges for the provision of those services shall be agreed by the parties in the relevant statement of work, and shall be calculated using the rates set out in the Rate Card. Genomics England shall provide all such services with reasonable skill, care and diligence and in accordance with any agreed timeframes specified in the relevant statement of work.

9. CUSTOM CLINICAL AND GENOMIC ANALYTICAL SERVICES

Genomics tests conducted in parallel with clinical studies

- 9.1 For participants enrolled in current or future Clinical Studies conducted by or on behalf of IQVIA or its Affiliates, IQVIA (or an IQVIA Affiliate) may inform its customers of the option of having a whole genome sequence performed by or on behalf of Genomics England on some or all of those participants, and of having the Participant Sequence / Associated Data of any participants who provide legally valid consent, made available for Research, including Research for the enhancement and development of products and services, within the Genomics England Environment.
- 9.2 The availability and performance of any additional testing or services as described in this clause 9 will at all times be subject to the parties being able to comply in full with their respective legal obligations, including all obligations under Data Protection Laws, and their obligations under clause 26.



[REDACTED]

Service for identification of candidates for clinical study

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

9.16

[REDACTED]

10. THE SERVICES: GENERAL

Access Review Committee

- 10.1 IQVIA acknowledges that access and use of the Genomics England Data is controlled by the ARC.
- 10.2 Any access to and use of the Genomics England Services Data by a Prospective Customer or IQVIA for research must be approved in advance by the ARC unless there is a general ARC approval in place at the relevant time for such access and use.
- 10.3 Genomics England shall be responsible for applying for any approvals by the ARC that is required for the Services and shall use reasonable endeavours to obtain such approvals promptly.
- 10.4 If the ARC wishes to streamline its processes and subject to clause 10.6, Genomics England shall use reasonable endeavours to assist the ARC to update its processes so that approvals can be granted on shorter timescales than is currently the case.
- 10.5 If the ARC wishes to grant a general approval for the provision of the Research Feasibility Data Access Service to Prospective Customers so that ARC approval is not required on an individual basis and subject to clause 10.6, Genomics England shall use reasonable endeavours to assist the ARC to achieve such result.
- 10.6 Nothing in this Agreement shall be construed as requiring Genomics England to compromise the independence of the ARC.

Genomics England Data to Be Made Available for the Services

- 10.7 Genomics England shall not be under any obligation to create or obtain any datasets except to the extent that Genomics England agrees to do so pursuant to clauses 8.2 or 9.
- 10.8 Where any Genomics England Data within the Genomics England Research Environment is made generally available to users of the Genomics England Research Environment, Genomics England shall ensure that such Genomics England Data shall be made available for use in the Services at the same time as it is made generally available to users of the Genomics England Research Environment.
- 10.9 In order to achieve the aims of the Project, Genomics England intends to maximise the amount of Genomics England Project Data that is made available for research (including research utilising the Services) in the Genomics England Research Environment. However, there may be some Genomics England Project Data that Genomics England decides not to make available in the Genomics England Research Environment, including by way of example only, data from small cohorts, data where there is a risk of re-identification of the data subjects, data that is of poor quality and data where there doubt as to whether the proper procedures for the collection of the data have been followed. In all cases, Genomics England shall retain absolute discretion as to which Genomics England Data is made available in the Genomics England Research Environment.
- 10.10 Genomics England hopes to be in a position to make available for the Services, in the Genomics England Research Environment, Genomics England Data that is collected or generated in relation to any replacement or successor to the Project but Genomics England cannot make any binding commitment to do so.

- 10.11 Genomics England does not currently intend to, and does not envisage in the future deciding to, enter into any agreement that would result in Genomics England no longer having the right to include in the Genomics England Research Environment, Genomics England Project Data. However, if Genomics England does decide that it wishes to enter into such an agreement, Genomics England shall inform IQVIA and the parties shall discuss the impact that such an agreement would have on the Services. Genomics England shall consider IQVIA's views but Genomics England shall retain absolute discretion as to whether or not to enter into such an agreement.

Development and Provision of the Services

- 10.12 Each party shall provide the other party with such information, co-operation and assistance as the other party may from time to time reasonably request in connection with the development and provision of the Services.
- 10.13 Except as otherwise agreed between the parties, each party shall bear its own costs incurred in developing, marketing and delivering the Services.

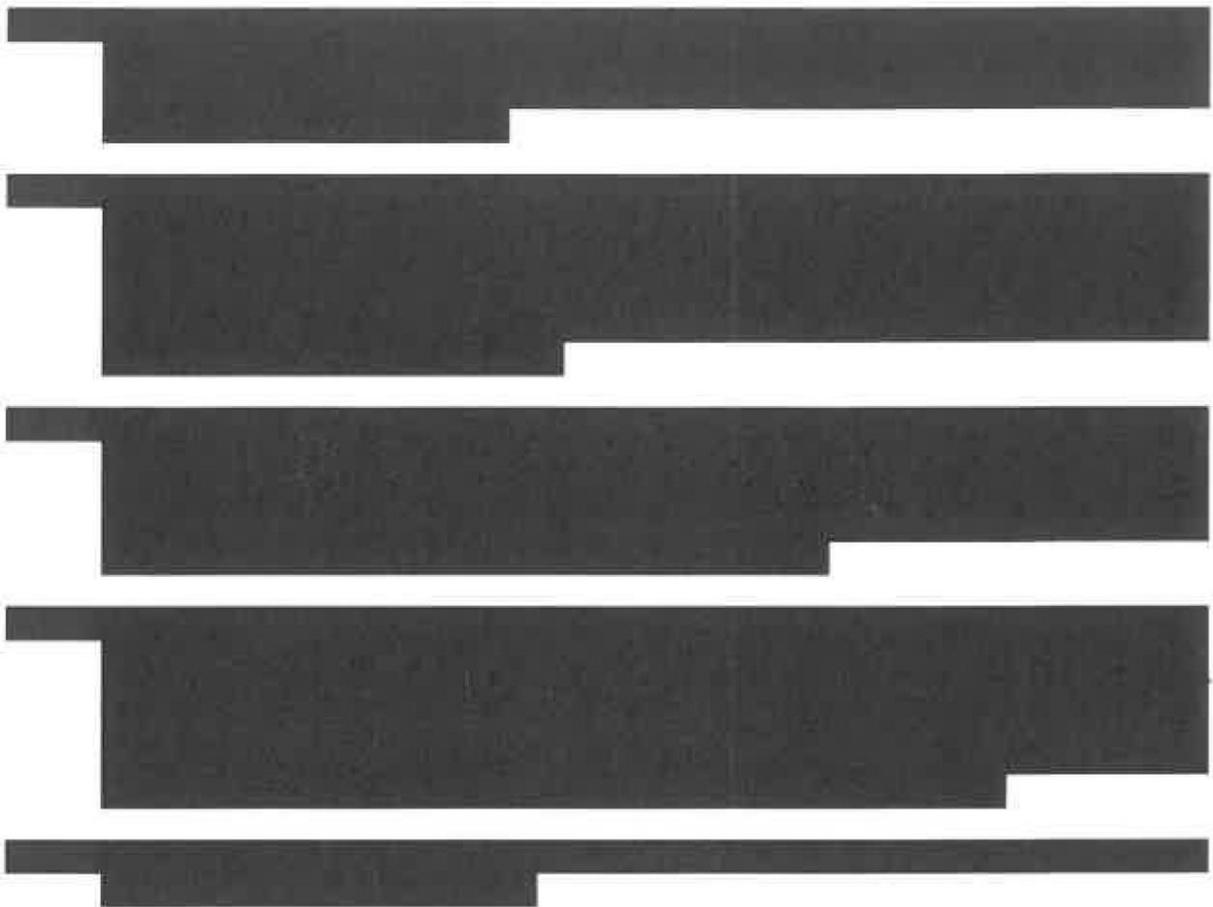
Customer Support for the Services

- 10.14 IQVIA shall provide first level support to Customers in relation to the Services. Where a Customer support request concerns aspects of the Services for which IQVIA is responsible, IQVIA shall be responsible for handling the Customer support request. Where a Customer support request concerns aspects of the Services for which Genomics England is responsible, IQVIA shall at its option, either (i) try to itself resolve the Customer support request, or (ii) refer the support request to Genomics England, in which case IQVIA shall copy the Customer support request to Genomics England and Genomics England shall be responsible for handling the Customer support request.
- 10.15 The parties shall ensure that the IQVIA Customer Agreements and the Genomics England Data Access Agreements do not include provisions that are inconsistent with the support arrangements set out in clause 10.14 above.

11. MARKETING AND PROMOTION OF THE SERVICES

- 11.1 Each party shall have the right, but not the obligation, to market and promote the Services.
- 11.2 IQVIA shall not make any promises or representations or give any warranties or guarantees in respect of Genomics England or the Genomics England Data that have not otherwise been expressly authorised by Genomics England in writing.
- 11.3 Genomics England shall not make any promises or representations or give any warranties or guarantees in respect of IQVIA, the IQVIA Software or the Services that have not been expressly authorised by IQVIA in writing.
- 11.4 IQVIA shall not alter, obscure, remove, interfere with or add to any of the trade marks, trade names, markings or notices contained in the Genomics England Services Data at the time when it is made available to IQVIA.
- 11.5 Genomics England shall not alter, obscure, remove, interfere with or add to any of the trade marks, trade names, markings or notices contained in the IQVIA Software at the time when it is made available to Genomics England.

12. CONTRACTING FOR THE SERVICES



13. GENOMICS ENGLAND DATA

- 13.1 Genomics England grants IQVIA and its Permitted Subcontractors, a non-exclusive, non-transferable licence to access, use and analyse the Genomics England Services Data within the Genomics England Environment, and to access and use the Genomics England Environment, solely for:
- 13.1.1 the purposes of enabling IQVIA and its Affiliates to carry out Research for the purposes of developing and enhancing the Services provided that any enhancement of the IQVIA Software shall be licensed under clause 13.1.3;
 - 13.1.2 the purposes of enabling IQVIA and its Affiliates to provide the Services in accordance with the provisions of this Agreement;
 - 13.1.3 the purposes of enabling IQVIA and its Affiliates to carry out Research which may lead to developments of and improvements to the IQVIA Software provided that such use has been approved by the ARC;
 - 13.1.4 the purposes of carrying out the activities described in clause 9.12 to the extent such activities have been approved by the ARC; and
 - 13.1.5 such other purposes as may be agreed in writing and signed by the duly authorised representatives of both parties provided that such use has been approved by the ARC.

- 13.2 IQVIA acknowledges that neither it nor the Customers shall have access to identified data, and that all exports of results from the Genomics England Environment are regulated by the ARC. Genomics England shall ensure that neither IQVIA nor any of the Customers shall have access to identified data in the Genomics England Environment or via the Services.
- 13.3 IQVIA shall procure that any Affiliate of IQVIA and Permitted Subcontractor of IQVIA that accesses the Genomics England Environment or provides any aspect of the Services complies with the applicable provisions of this Agreement as if such Affiliate or Permitted Subcontractor were party to this Agreement and IQVIA shall be responsible for the activities of such Affiliate and Permitted Subcontractor as if such activities had been carried out by IQVIA under this Agreement.
- 14. GENOMICS ENGLAND ENVIRONMENT**
- 14.1 Genomics England shall host the IQVIA Software and the Genomics England Services Data in the Genomics England Research Environment. Genomics England shall use reasonable endeavours to install the IQVIA Software in accordance with the Implementation Plan.
- 14.2 The parties shall comply with the Genomics England Security Policy.
- 14.3 Each party shall take reasonable steps to ensure that no Viruses are introduced into the Genomics England Environment, and that the access by IQVIA, its Permitted Subcontractors and/or Customers does not cause any Viruses to be introduced into IQVIA's, its Affiliates', Permitted Subcontractors' or Customers' systems, including by installing and using the latest available updates from a reputable anti-virus, software provider.
- 14.4 Subject to the provisions of clauses 10.7 to 10.11 inclusive, Genomics England shall be free to make changes from time to time to the Genomics England Environment including to the range of, and capabilities of, the software analytical tools and data made available in the Genomics England Environment but, for the avoidance of doubt, not the IQVIA Software.
- 14.5 Access to and use of certain third party software and analytical tools made available in the Genomics England Environment may be conditional upon the user agreeing to accept the terms of a user licence.
- 14.6 IQVIA shall:-
- 14.6.1 comply with the Airlock Policy and the Information Governance and IT Security Policy provided that if any changes are made to such a policy, IQVIA shall not be required to comply with the changes unless (i) the changes are reasonable and (ii) IQVIA is informed of the changes in writing a reasonable time before the changes come into effect; and
- 14.6.2 use commercially reasonable endeavours to comply with all commercially reasonable instructions received from Genomics England and co-operate with Genomics England's staff in connection with the use of the Genomics England Environment.
- 14.7 Genomics England shall not make available to IQVIA and/or Customers any Genomics England Material in the Genomics England Environment unless Genomics England has the right under any Intellectual Property Rights to permit IQVIA and the Customers to use the Genomics England Material in the Genomics England Environment in accordance with the terms of this Agreement.

Support

- 14.8 Subject to the Genomics England Security Policy, Genomics England shall provide IQVIA with such access to the Genomics England Environment, as IQVIA may from time to time reasonably require for the purposes described in clauses 9.12, and 13.1, and provide IQVIA with such other information, co-operation and assistance as IQVIA may from time to time reasonably require, in each case for the purposes of the installation and operation of the IQVIA Software in the Genomics England Environment, and the ongoing maintenance and support of the IQVIA Software.
- 14.9 Subject to the Genomics England Security Policy, Genomics England shall provide IQVIA with such support as IQVIA may reasonably require in relation to IQVIA's use of the Genomics England Environment for the provision of the Services.
- 14.10 Genomics England shall provide the support referred to in clause 14.9 by telephone or email between 9:00am and 5:00pm UK time during Business Days.

Genomics England Security Policy

- 14.11 Genomics England shall develop and finalise the Genomics England Security Policy within a reasonable period following the Effective Date. Genomics England shall provide a draft to IQVIA for comments. Genomics England shall consult with IQVIA and consider all reasonable comments made by IQVIA on Genomics England's drafts. Genomics England shall provide IQVIA with a final version of the Genomics England Security Policy as soon as it has been finalised. Genomics England may update the Genomics England Security Policy from time to time provided that if any changes are made to such policy, IQVIA shall not be required to comply with the changes unless and until (i) the changes are reasonable and (ii) IQVIA is informed of the changes in writing a reasonable time before the change comes into effect
- 14.12 From and after the date on which Genomics England provides IQVIA with a final version of the Genomics England Security Policy in accordance with clause 14.11, references in this Agreement to the Genomics England Security Policy shall be deemed to be references to such final version of the Genomics England Security Policy as may be updated from time to time in accordance with clause 14.11.

15. IQVIA RESEARCHERS

- 15.1 Subject to the provisions of this Agreement (and in particular clause 26) and the Genomics England Security Policy, Genomics England shall during the term of this Agreement provide IQVIA Researchers with access to the Genomics England Environment for the purpose of carrying out activities (including the provision of the Services) which IQVIA is permitted to carry out pursuant to clauses 9.12 and 13.1.
- 15.2 IQVIA shall have the right to nominate individuals to be IQVIA Researchers (including replacements for existing IQVIA Researchers) by sending their full names, job title, employment status (i.e. whether the proposed replacement is an employee, full time consultant, part time consultant or other; if the proposed replacement is a consultant, the commencement and expiry of the consultancy contract), their business contact details and such other details as Genomics England may reasonably request.
- 15.3 All IQVIA Researchers must have a working individual email address on the standard email domain of IQVIA, its Affiliates and/or Permitted Subcontractors. Before being provided with credentials necessary to access the Genomics England Environment an IQVIA Researcher must complete Genomics England's standard information governance training to the reasonable satisfaction of Genomics England. Genomics England shall make its standard information governance training available online, and shall provide IQVIA and any individuals nominated to be IQVIA Researchers with access to such information governance training free of charge.

- 15.4 Genomics England shall provide a new IQVIA Researcher with access to the Genomics England Environment within ten (10) Business Days after the IQVIA Researcher has completed Genomics England's standard information governance training to the reasonable satisfaction of Genomics England.
- 15.5 IQVIA shall procure that the IQVIA Researchers comply with the applicable provisions of this Agreement relating to access to the Genomics England Environment as if they were party to this Agreement in place of IQVIA.
- 15.6 IQVIA shall procure that all IQVIA Researchers keep their user names, passwords or other access credentials for the Genomics England Environment secret and do not disclose them to any other person.
- 15.7 IQVIA shall not take any copy of any of Genomics England Materials out of the Genomics England Environment except in compliance with the Airlock Policy. Any such copies of Genomics England Materials shall not include any Genomics England Personal Data except to the extent that such data is processed by IQVIA in accordance with clause 26.

16. IQVIA MATERIALS

- 16.1 If IQVIA wishes to bring any IQVIA Materials into the Genomics England Environment, IQVIA shall follow the procedure set out in the Airlock Policy. Genomics England shall have absolute discretion as to whether or not to permit all or any IQVIA Materials to be brought into the Genomics England Environment, except for IQVIA Materials reasonably necessary to provide the Services.
- 16.2 Genomics England shall have the right to block access and/or delete from the Genomics England Environment at any time any IQVIA Materials other than IQVIA Materials reasonably necessary to provide the Services, but if Genomics England does so, Genomics England shall promptly inform IQVIA that it has done so and give the reason for having done so.
- 16.3 IQVIA shall not bring any IQVIA Material into the Genomics England Environment unless:-
 - 16.3.1 IQVIA has and shall have throughout the term of this Agreement, the right under any Intellectual Property Rights applicable to that IQVIA Material to bring the IQVIA Material into the Genomics England Environment; and
 - 16.3.2 if the IQVIA Material is brought in for use by IQVIA only, that IQVIA has and shall have throughout the term of this Agreement the right under any Intellectual Property Rights to use the IQVIA Material in the Genomics England Environment; and
 - 16.3.3 if the IQVIA Material is brought in for use by Customers, that IQVIA has and shall have throughout the term of this Agreement, the right under any Intellectual Property Rights to permit use of the IQVIA Materials by Customers; and
 - 16.3.4 to the extent that IQVIA Materials include personal data in respect of which IQVIA is the controller, IQVIA has a valid legal basis under Data Protection Laws (including where applicable any necessary notices and legally valid consents), to permit it to bring such IQVIA Materials into the Genomics England Environment and to permit use of such IQVIA Materials by IQVIA, its Affiliates and Permitted Subcontractors.

17. IQVIA SOFTWARE LICENCE

- 17.1 IQVIA grants Genomics England a non-exclusive, non-transferable licence to install and use a copy of the IQVIA Software in the Genomics England Environment solely for the purposes of:

[REDACTED]

17.1.6 [REDACTED]

- 17.2 To the maximum extent permitted by applicable law, Genomics England shall not adapt, reverse engineer, decompile, disassemble, modify, adapt or make error corrections to the IQVIA Software in whole or in part, provided that Genomics England shall be free to configure the IQVIA Software as necessary to host and operate the IQVIA Software in the Genomics England Environment.

- 17.3 Genomics England shall not grant any person access to the IQVIA Software, provided that Genomics England may provide such access to Personnel who are maintaining and supporting the Genomics England Environment solely to the extent necessary for them to maintain and support the Genomics England Environment and host the IQVIA Software in the Genomics England Environment. Genomics England shall procure that any Personnel that access the IQVIA Software comply with the applicable provisions of this Agreement in relation to the IQVIA Software as if such Personnel were party to this Agreement and Genomics England shall be responsible for the activities of such Personnel as if such activities had been carried out by Genomics England under this Agreement.

18. GECIP MEMBERS

- 18.1 Genomics England shall have the right, during the two (2) year period starting on the Effective Date, to provide GeCIP Members with access to the GeCIP Modules solely for the purposes of accessing the Genomics England Services Data, provided that each such GeCIP Member to whom access is to be granted has first entered into a GeCIP Software Licence with IQVIA.

- 18.2 Unless otherwise agreed in writing by the parties, no charges shall be payable by Genomics England or any Genomics England Affiliate to IQVIA in relation to the provision of access to GeCIP Members to the GeCIP Modules during the two (2) year period starting on the Effective Date. Any access by a GeCIP Member after that period shall be subject to agreement in writing by the parties, and shall be subject to payment of charges (on a per GeCIP Member basis, the amount of which will be agreed in writing by the parties) by Genomics England to IQVIA.

- 18.3 The parties shall cooperate to ensure that GeCIP Members do not have any access to any part or functionality of the IQVIA Software other than the GeCIP Modules.

- 18.4 Genomics England shall use reasonable efforts to procure that, if a GeCIP Member makes public any research, analysis or other content that has been created in whole or in part as a result of the use of the GeCIP Modules, that research, analysis or other content shall contain a statement, in a form to be agreed with IQVIA, that it was created using the IQVIA Software.
- 18.5 Both parties wish to ensure that any access to the IQVIA Software that is granted to a GeCIP Member is not abused and in particular is not used for the benefit of a commercial business. If a GeCIP Member is found by Genomics England to (i) have abused his or her access to the GeCIP Modules (including by using such access for the benefit of a Commercial Organisation), or (ii) be a full-time employee or full-time consultant of a Commercial Organisation, Genomics England shall promptly block that person's access to the GeCIP Modules and shall inform IQVIA in writing promptly after it has done so. This shall not affect IQVIA's rights and remedies under the GeCIP Software Licence, including any termination or suspension rights IQVIA may have.
- 18.6 Neither party shall charge GeCIP Members for access to the GeCIP Modules that is granted by Genomics England under this clause 18, without the prior written consent of the other party and agreement in writing between the parties as to how such charges will be shared between the parties.
- 18.7 Genomics England shall provide first line support to GeCIP Members. IQVIA shall not be required to provide any support to GeCIP Members.

19. CHARGES AND PAYMENT

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

19.2.3 [REDACTED]

[REDACTED]

19.3 [REDACTED]

20. TITLE AND RISK

- 20.1 Title to and risk in all equipment and other tangible property supplied or used by Genomics England for the performance of its obligations under this Agreement shall remain with Genomics England.

21. PUBLICATIONS

- 21.1 If IQVIA or any of the IQVIA Researchers publishes any paper based upon research using the Genomics England Environment, the publication must acknowledge the contributions of (i) Genomics England to enabling the research covered by the publication; (ii) the following funders of the Genomics England Environment: the National Institute for Health Research, NHS England, the Wellcome Trust, Cancer Research UK and the Medical Research Council; and (iii) the patients who consented to the use of their data for research purposes and the National Health Service clinicians and healthcare teams that contributed to the data and results covered by the publication. The following is an example of an acknowledgement that would satisfy this requirement:-

“This research was made possible through access to the data and findings generated by Genomics England’s Research Environment and by the patients who consented to the use of their data for research purposes and the National Health Service clinicians and healthcare teams that contributed to the data and results covered by this research. Genomics England’s Research Environment is managed by Genomics England Limited (a wholly owned company of the Department of Health) and is funded by the National Institute for Health Research and NHS England, the Wellcome Trust, Cancer Research UK and the Medical Research Council.”

22. WARRANTIES

- 22.1 Each party hereby warrants and represents to the other that, subject to clause 22.4
- 22.1.1 it has the full capacity and authority and all necessary licences, permits and consents to enter into and to perform its obligations under this Agreement;
 - 22.1.2 this Agreement is executed by a duly authorised representative of that party;
 - 22.1.3 the obligations of that party under this Agreement are valid, binding and enforceable in accordance with the terms of this Agreement;
 - 22.1.4 the execution and delivery of this Agreement and the performance by it of its obligations under it will not:-
 - 22.1.4.1 result in a breach of any provision of its Memorandum or Articles of Association;
 - 22.1.4.2 result in a breach of, or constitute a default under, any instrument agreement or arrangement to which it is a party or by which it is bound; or
 - 22.1.4.3 result in a breach of any order, judgment or decree of any court or governmental agency to which it is a party or by which it is bound.

- 22.2 Except as expressly stated in this Agreement, all warranties, conditions and terms, whether express or implied by statute, common law or otherwise (including but not limited to fitness for purpose and suitability) are hereby excluded to the extent permitted by law. Without prejudice to the generality of the foregoing, Genomics England does not give any warranty, representation or undertaking as to the efficacy, usefulness, performance or technical capabilities of the Genomics England Environment, provided however that this does not affect or limit the scope of either party's obligations or liability in respect of clauses 14.2, 25 or 26.
- 22.3 Each party shall perform its obligations under this Agreement in compliance with all applicable laws, enactments, orders, regulations, and other similar instruments.
- 22.4 No representations or warranties are given by either party in relation to compliance with Data Protection Laws except as set out in clause 26.

23. LIABILITY

- 23.1 Nothing in this Agreement shall exclude or limit either party's liability in respect of any liability that cannot be excluded or limited pursuant to applicable law including, to the extent that they cannot be excluded or limited by law, liability for:
- 23.1.1 death or personal injury caused by negligence; and
 - 23.1.2 fraud or fraudulent misrepresentation.
- 23.2 Except as provided in clause 23.1, in no event shall either party be liable to the other for loss, whether direct or indirect, of profit, business, revenue or goodwill, or for any indirect or consequential loss or damage.
- 23.3 Except as provided in clause 23.1:
- 23.3.1 Genomics England shall have no liability to IQVIA concerning the efficacy, usefulness, performance or technical capabilities of the Genomics England Environment, provided however that this does not affect or limit the scope of Genomics England's obligations or liability in respect of clauses 14.2, 25 or 26;
 - 23.3.2 Genomics England's liability to Customers shall be governed by the terms of Genomics England's Data Access Agreements with each relevant Customer. Genomics England shall have no liability to Customers under this Agreement;
 - 23.3.3 IQVIA's liability to Customers shall be governed by the terms of the IQVIA Customer Agreement with each relevant Customer. IQVIA shall have no liability to Customers under this Agreement;
 - 23.3.4 except in relation to Genomics England's obligations in respect of, or liability arising in relation to, clauses 14.2, 14.7, 17, 19, 25 or 26, which shall be subject to clause 23.4, Genomics England's liability to IQVIA in relation to any claims, demands or actions made against IQVIA or its Affiliates by Customers, shall in no event exceed the lesser of (i) the amounts payable by IQVIA to Genomics England in respect of the Services provided, or committed to be provided, to such Customer, and (ii) £1 million; and
 - 23.3.5 except in relation to IQVIA's obligations in respect of, or liability arising in relation to, clauses 13.1, 14.2, 16.4, 19, 25 or 26, which shall be subject to clause 23.4, IQVIA's liability to Genomics England in relation to any claims, demands or actions made against Genomics England or its Affiliates by Customers, shall in no event

exceed the lesser of (i) the amounts payable by IQVIA to Genomics England in respect of the Services provided, or committed to be provided, to such Customer and (ii) £ [REDACTED].

- 23.4 Except as provided in clause 23.1 and subject to clause 23.2 and 23.3, the aggregate liability under this Agreement of either party for any and all claims in respect of causes of action first arising in any Contract Year shall in no event exceed £ [REDACTED].
- 23.5 Subject to the provisions of clauses 23.2, 23.3 and 23.4, Genomics England shall indemnify IQVIA and its Affiliates from and against any costs, expenses, losses and damages arising out of any claims, demands or actions made against IQVIA or its Affiliates by Customers to the extent that such claims, demands or actions arise as a result of Genomics England or its Affiliate's negligent act or omission, intentional misconduct or breach of this Agreement or any Genomics England Data Access Agreement.
- 23.6 Subject to the provisions of clause 23.2, 23.3 and 23.4, IQVIA shall indemnify Genomics England and its Affiliates from and against any costs, expenses, losses and damages arising out of any claims, demands or actions made against Genomics England or its Affiliates by Customers to the extent that such claims, demands or actions arise as a result of IQVIA or its Affiliate's negligent act or omission, intentional misconduct or breach of this Agreement or any IQVIA Customer Agreement.
- 23.7 Should any limitation or provision contained in this clause 23 be held to be invalid under any applicable statute or rule of law it shall to that extent be deemed omitted but if any party thereby becomes liable for loss or damage which would otherwise have been excluded such liability shall be subject to the other limitations and provisions set out herein.

24. INTELLECTUAL PROPERTY RIGHTS

- 24.1 Any Intellectual Property Right owned by a party that was not generated in relation to this Agreement will remain owned by that party.
- 24.2 The IQVIA Software and all Intellectual Property Rights in the IQVIA Software shall remain owned by IQVIA, and the Genomics England Data and all Intellectual Property Rights in the Genomics England Data shall remain owned by Genomics England.
- 24.3 Genomics England shall own:-
- 24.3.1 any extracts from the Genomics England Data (and any Intellectual Property Rights in respect of such extracts) and any dataset that is derived directly from the Genomics England Data (and any Intellectual Property Rights in respect of such derivative dataset) provided that, in each case, Genomics England shall not own (i) any programming code, interpretive or summary analysis, algorithms or know-how, or (ii) any derivative dataset where the degree of abstraction and amalgamation from the Genomics England Data is such that the derivative dataset no longer contains Personal Data. By way of example only: (a) if IQVIA or a Customer generates a report that includes extracts from the Genomics England Data (such as copies of variant sequences) the report shall be owned by IQVIA or the Customer but be subject to Genomics England's ownership of the extracts of the Genomics England Data; (b) if IQVIA or a Customer realigns a genome sequence contained in the Genomics England Data the realigned sequence shall be owned by Genomics England but any algorithms, techniques and know-how developed by IQVIA or the Customer and used to realign the sequence shall belong to IQVIA or the Customer; (c) if IQVIA or a Customer uses the Genomics England Data to develop prognostic, predictive or descriptive analytics or algorithms, the algorithms, techniques, know-how and

programming code shall belong to IQVIA or the Customer, and the Genomics England Data shall belong to Genomics England.

- 24.3.2 the results (and any Intellectual Property Rights in respect of such results) from any access to or analysis of the Genomics England Data that is not covered by an ARC approval, if ARC approval is required, or is otherwise carried out in breach of the provisions of this Agreement.
- 24.4 The Intellectual Property Rights in any developments and enhancements made to the IQVIA Software shall be owned by IQVIA. Where Genomics England Data is ingested into a form that is compatible with the IQVIA Software, Genomics England shall own the Intellectual Property Rights in the ingested data but shall not own any Intellectual Property Rights in the IQVIA Software or the techniques and processes used to create the ingested form which rights shall be owned by IQVIA.
- 24.5 Except as set out in clauses 24.2 to 24.4 (inclusive) above and 24.6 and 24.7 below:-
- 24.5.1 the Intellectual Property Rights arising out of work carried out by the Personnel of a party will be owned by that party; and
- 24.5.2 the Intellectual Property Rights in any algorithms, models, products and other materials (in any form) created by IQVIA and/or its Affiliates pursuant to clause 13.1 shall be owned by IQVIA.
- 24.6 Except as set out in clauses 24.2 and 24.3, the Intellectual Property Rights in any Customer Materials that are created or generated by IQVIA, its Affiliates, the Customers, shall, as between IQVIA and Genomics England, be owned by IQVIA.
- 24.7 Except as set out in clauses 24.1 to 24.4 (inclusive) above, the Intellectual Property Rights in all Customer Materials that are created or generated by or on behalf of Genomics England, shall be owned as set out in the IQVIA Customer Agreement with that Customer.
- 24.8 Genomics England hereby grants to IQVIA, its Affiliates, its and their agents, subcontractors and customers a worldwide, royalty-free, non-exclusive, transferable, sublicensable, perpetual, irrevocable licence under any Intellectual Property Rights that are created or generated by IQVIA, IQVIA's Affiliates, its and their agents and subcontractors and/or Customers (other than in breach of the provisions of this Agreement) but are owned by Genomics England pursuant to clause 24.3.1 to copy, modify, adapt and otherwise use as if IQVIA, its Affiliates, its and their agents, subcontractors or customers (as applicable) owned such Intellectual Property Rights provided that:-
- 24.8.1 no licence is granted in relation to Intellectual Property Rights that are owned by Genomics England pursuant to Clause 24.3.2; and
- 24.8.2 the Company shall not have the right to disclose to any third party, results that have not been released in accordance with the Airlock Policy.
- 24.9 IQVIA hereby grants to Genomics England a royalty-free, non-exclusive, non-transferable licence to install, store, and operate and maintain the IQVIA Materials in the Genomics England Environment during the term of this Agreement or, if earlier, until the date upon which IQVIA removes, or Genomics England removes on IQVIA's behalf, the IQVIA Materials (or the relevant part of them) from the Genomics England Environment, solely to enable IQVIA and the Customers to use, load, execute, interpret, store, transmit, display, copy, modify, adapt and enhance such IQVIA Materials in the Genomics England Environment during the term of this Agreement.

25. CONFIDENTIALITY

- 25.1 This clause 25 shall be subject at all times to the provisions of clause 26, which shall to the extent of any conflict or inconsistency take precedence over this clause 25 in respect of Confidential Information that is or contains Genomics England Personal Data.
- 25.2 Each of IQVIA and Genomics England hereby undertakes to the other to:
- 25.2.1 keep all Confidential Information given by one party (Disclosing Party) to the other party (Recipient) or otherwise obtained by the Recipient confidential;
 - 25.2.2 implement rigorous security practices against any unauthorised copying, use, disclosure, access, damage or destruction of the Disclosing Party's Confidential Information;
 - 25.2.3 not, without the prior written consent of the Disclosing Party, disclose Confidential Information in whole or in part to any other person save those of its Personnel, subcontractors (including Permitted Subcontractors) and Customers involved in the development, provision or receipt of the Services and who need to know the Confidential Information in question for the development, provision or receipt of the Services;
 - 25.2.4 use the Confidential Information solely in connection with the provision or receipt of the Services or as otherwise permitted under this Agreement;
 - 25.2.5 promptly notify the Disclosing Party if the Recipient suspects or becomes aware of any unauthorised access, copying, use or disclosure in any form or if the Recipient is required by law to disclose any of the Disclosing Party's Confidential Information; and
 - 25.2.6 without limiting any of the foregoing, treat the Confidential Information with at least the same degree of care that it uses for its own confidential information and in the case of Genomics England Personal Data, at least to the standard required under clause 26.
- 25.3 Each of IQVIA and Genomics England hereby undertakes to the other to make all relevant Personnel and subcontractors (including Permitted Subcontractors) aware of the confidentiality of the Confidential Information belonging to the other and the provisions of this clause 25 and, without limitation to this clause 25.3, to take all such steps as shall from time to time be necessary to ensure compliance by its Personnel and subcontractors (including Permitted Subcontractors) with the provisions of this clause 25.
- 25.4 The provisions of clauses 25.2 and 25.3 shall not apply to any information which:
- 25.4.1 is or becomes public knowledge other than by breach of this clause 25;
 - 25.4.2 is in the possession of the Recipient without restriction in relation to disclosure before the date of receipt from the Disclosing Party;
 - 25.4.3 is received from a third party who lawfully acquired it and who is under no obligation restricting its disclosure; and/or
 - 25.4.4 is independently developed without access to any Confidential Information belonging to the other

- except where such information is Genomics England Personal Data.
- 25.5 Subject to clauses 25.6 and 25.7, the Recipient may disclose Confidential Information of the Disclosing Party to the minimum extent required by:
- 25.5.1 any order of any court of competent jurisdiction or any competent judicial, governmental or regulatory body; or
 - 25.5.2 the rules of any listing authority or stock exchange on which the shares of any Affiliate of the Recipient are listed or traded; or
 - 25.5.3 the laws or regulations of the United Kingdom or any EU member state with jurisdiction over the affairs of any Affiliate of the Recipient.
- 25.6 In no circumstances shall IQVIA and/or IQVIA Affiliates disclose Genomics England Personal Data pursuant to clause 25.5.2. In no circumstances shall Genomics England and/or any Genomics England Affiliates disclose pursuant to clause 25.5.2, Personal Data in respect of which IQVIA and/or its Affiliates are a controller provided that this provision shall not apply to Genomics England Personal Data.
- 25.7 Before the Recipient discloses any information under clause 25.5, the Recipient shall (to the extent permitted by law) use its reasonable endeavours to:
- 25.7.1 inform the Disclosing Party of the full circumstances of the disclosure and the information that will be disclosed, and take all such steps as may be reasonable and practicable in the circumstances to agree the contents of such disclosure with the disclosing before making the disclosure;
 - 25.7.2 consult with the Disclosing Party as to possible steps to avoid or limit disclosure and take those steps where they would not result in significant adverse consequences to the Recipient;
 - 25.7.3 gain assurances as to confidentiality from the body to whom the information is to be disclosed; and
 - 25.7.4 where the disclosure is by way of public announcement, agree the wording with the Disclosing Party in advance.
- 25.8 The Recipient shall co-operate with the Disclosing Party if the Disclosing Party decides to bring in any legal or other proceedings to challenge the validity of the requirement to disclose Confidential Information under clause 25.5 (at the Disclosing Party's cost and expense).
- 25.9 If the Recipient is unable to inform the Disclosing Party before Confidential Information is disclosed under clause 25.5, the Recipient shall (to the extent permitted by law) inform the Disclosing Party promptly after the disclosure of the full circumstances of the disclosure and the information that has been disclosed.
- 25.10 Where Genomics England is subject to the provisions of the Freedom of Information Act 2000 (FOIA), Genomics England may disclose IQVIA's Confidential Information if and to the extent required to comply with FOIA, and in accordance with the timelines required by the FOIA.
- 25.11 In relation to any request for disclosure of IQVIA's Confidential Information pursuant to FOIA, acting in accordance with the provisions of the FOIA and all applicable guidance, Genomics England shall:

- 25.11.1 take into account the IQVIA Confidential Information which has been designated as commercially sensitive information in Schedule 6 (**Commercially Sensitive Information**);
- 25.11.2 consider the application of the confidentiality exemption and the commercial interests exemption set out in s.41 and s.43 respectively of FOIA to the Commercially Sensitive Information; and
- 25.11.3 in any event, inform IQVIA, promptly upon receipt, of any FOIA request received by Genomics England for any of IQVIA's Confidential Information and allow IQVIA an opportunity to provide comments to IQVIA on any such request within the permitted timescales pursuant to FOIA prior to releasing any of IQVIA's Confidential Information.

26. PROTECTION OF PERSONAL DATA

- 26.1 Each party shall comply with its obligations under this clause 26 at its own cost.
- 26.2 The parties acknowledge that the factual arrangement between them dictates the role of each party in respect of the Data Protection Laws. Notwithstanding the foregoing, the parties agree that:-
 - 26.2.1 except as provided in clause 26.2.3, Genomics England is the controller of Genomics England Personal Data it collects, holds and otherwise processes;
 - 26.2.2 Genomics England grants the Customer access to Genomics England Personal Data pursuant to a Data Access Agreement. The Customer shall be a separate and independent controller for any Genomics England Personal Data it accesses and processes and IQVIA will be a processor acting on behalf of the Customer; and
 - 26.2.3 in relation to any Customer Personal Data brought into the Genomics England Environment by IQVIA and/or a Customer as contemplated by clause 9.9 and/or a Data Access Agreement, the Customer shall be the controller, IQVIA shall be a processor acting on behalf of the Customer, and Genomics England shall be a processor acting on behalf of the Customer throughout the duration of the relevant Clinical Study. Following completion of the relevant Clinical Study, if the parties and the relevant Customer have agreed in writing that Genomics England will be licensed to use some or all of the Customer Personal Data at the end of the Clinical Study or at a later date, then that Customer Personal Data shall become part of the general dataset available within the Genomics England Environment from the date agreed in writing by the parties and the relevant Customer and, from that point, the Customer and Genomics England shall each be independent controllers in respect of the Customer Personal Data; and
 - 26.2.4 IQVIA shall be a separate and independent controller to the extent that IQVIA is granted access to the Genomics England Personal Data for the purpose of conducting, on IQVIA's own behalf, Research permitted under clause 13.1.
- 26.3 The parties acknowledge and agree that the Customer's access to the Genomics England Personal Data, and the processing of the Customer Personal Data by Genomics England shall be subject to additional terms set out in the data access agreement between Genomics England and the relevant Customer. IQVIA and its Affiliates shall not be in any way liable for any acts or omissions of the Customer in relation to the Genomics England Personal Data or the Customer Personal Data.

- 26.4 The parties acknowledge and accept that the Genomics England Data may constitute personal data notwithstanding that the data has been de-identified.
- 26.5 IQVIA shall not re-identify, attempt to re-identify or knowingly assist or enable any third party to re-identify or attempt to re-identify any Participant from the Genomics England Services Data.
- 26.6 If IQVIA or any of its Personnel or its Affiliates do re-identify any Participant from the Genomics England Services Data or knowingly assist or enable any third party to re-identify any Participant:-
- 26.6.1 IQVIA shall as soon as practicable after becoming aware of the re-identification notify Genomics England that re-identification has occurred and provide Genomics England with a report produced in good faith setting out the circumstances in which the re-identification has occurred;
- 26.6.2 IQVIA shall not and shall procure that its Personnel and its Affiliates do not contact or attempt to contact any re-identified Participant or the institutions or medical practitioners responsible for the medical care of the Participant as a consequence of the re-identification; and
- 26.6.3 IQVIA shall not and shall procure that its Personnel and its Affiliates do not share the identity of that Participant with any third party.
- 26.7 Genomics England warrants that at the Effective Date it has a valid legal basis under Data Protection Laws (including where applicable any necessary notices and legally valid consents) to authorise researchers and clinicians to use the Genomics England Services Data for Research. Genomics England shall notify IQVIA in writing promptly upon becoming aware that it no longer has, or is likely to no longer have, a valid legal basis under Data Protection Laws (including where applicable any necessary notices and legally valid consents) to authorise researchers and clinicians to use the Genomics England Services Data for Research.
- 26.8 IQVIA shall not use the Genomics England Personal Data for the purpose of developing software except to the extent such development constitutes Research.
- 26.9 Each party shall, and shall procure that its Affiliates shall, comply with all applicable provisions of the Data Protection Laws in relation to the activities conducted in connection with this Agreement.
- Genomics England Personal Data – IQVIA and Genomics England as separate and independent controllers**
- 26.10 Where Genomics England grants IQVIA access to Genomics England Personal Data and Genomics England and IQVIA are separate and independent controllers of the Genomics England Personal Data, clauses 26.11, 26.12, 26.13 and 26.14 shall apply.
- 26.11 When processing Genomics England Personal Data:-
- 26.11.1 IQVIA shall take reasonable steps to ensure the reliability of all of its personnel who have access to the Genomics England Environment and ensure that only personnel who require access to the Genomics England Personal Data are given access (and only to the extent necessary) and that such personnel: (i) are informed of the confidential nature of the Genomics England Personal Data; (ii) have received appropriate training on protecting the Genomics England Personal Data; and (iii) are bound by contractual or statutory confidentiality obligations, and ensure that any such access is revoked once no longer required;

- 26.11.2 IQVIA shall inform Genomics England without undue delay, and in any event within thirty-six (36) hours of becoming aware of a personal data breach affecting any Genomics England Personal Data;
- 26.11.3 where pursuant to this Agreement individuals based outside the United Kingdom are to access and/or analyse the Genomics England Personal Data for or on behalf of IQVIA or IQVIA's Affiliates, IQVIA shall put appropriate safeguards in place pursuant to the Data Protection Laws; and
- 26.11.4 IQVIA shall provide such information and documents as Genomics England may reasonably request from time to time to demonstrate its compliance with the obligations in this clause 26.11.
- 26.12 In relation to any Genomics England Personal Data, Genomics England shall, in accordance with the requirements of the Data Protection Laws (including any applicable timeframes), provide data subjects with any information required under the Data Protection Laws and respond to any requests from data subjects to exercise their rights under the Data Protection Laws in respect of Genomics England Personal Data in the Genomics England Environment, including any requests from data subjects that are received by IQVIA in respect of IQVIA's processing of Genomics England Personal Data. IQVIA shall provide such reasonable and timely assistance as Genomics England may require in order to respond to any such requests in respect of IQVIA's processing of Genomics England Personal Data.
- 26.13 Each party shall provide reasonable cooperation, assistance and information to the other party to enable it to comply with its obligations under the Data Protection Laws to (a) carry out any data protection impact assessment; and (b) implement data protection by design and data protection by default principles.
- 26.14 The parties acknowledge and agree that, except where Genomics England Services Data is exported from the Genomics England Environment via the Airlock, the Genomics England Services Data will remain in the Genomics England Environment. Therefore, Genomics England shall:-
- 26.14.1 implement and maintain, in respect of the Genomics England Environment, appropriate technical and organisational measures against unauthorised or unlawful processing of the Genomics England Personal Data and against accidental unauthorised or unlawful processing, loss or destruction of, alteration, or damage to or disclosure of, or access to, the Genomics England Personal Data and ensure that, having regard to the state of technical development and the cost of implementing any measures, such measures will ensure a level of security appropriate to the harm that might result from such unauthorised or unlawful processing or accidental loss, destruction, alteration or damage to or disclosure of or access to and the nature of the Genomics England Personal Data to be protected and shall regularly review and update the technical and organisational measures implemented to keep the Genomics England Personal Data secure and confidential in order to demonstrate that the processing of the Genomics England Personal Data is performed in accordance with the Data Protection Laws;
- 26.14.2 manage any personal data breaches relating to the Genomics England Personal Data in the Genomics England Environment and make any notifications required under articles 33 and 34 of the General Data Protection Regulation, provided that IQVIA shall be free to independently make notifications relating to Genomics England Personal Data in the Genomics England Environment pursuant to article 33 of the General Data Protection Regulation. IQVIA shall promptly inform Genomics

England if it makes a notification under article 33 of a personal data breach relating to the Genomics England Personal Data in the Genomics England Environment;

- 26.14.3 promptly after making a notification under article 33 of the General Data Protection Regulation under clause 26.14.2, inform IQVIA if a personal data breach relating to the Genomics England Personal Data in the Genomics England Environment has occurred which relates to IQVIA's use of the Genomics England Personal Data in the Genomics England Environment and Genomics England reasonably believes that there are steps which IQVIA could take to mitigate the impact of such breach, and provide all necessary information and assistance to enable IQVIA to make its own independent notifications as permitted under such circumstances; and
 - 26.14.4 at the request of IQVIA, provide IQVIA with a copy of Genomics England's security procedures and data breach management process.
- 26.15 Each party shall respond to and comply with any communication, request or correspondence in connection with the processing of the Genomics England Personal Data which it or one of its Affiliates receives from a Regulator in relation to the processing of the Genomics England Personal Data by IQVIA, IQVIA's Affiliates and/or IQVIA's Permitted Subcontractors and shall provide a copy of its response to the other party. Each party shall provide such reasonable cooperation, assistance and information to the other as the other may require to prepare response to the Regulator.

Customer Personal Data

- 26.16 Each of the parties acknowledges and agrees that in respect of any Customer Personal Data, and for the purposes of the Data Protection Laws:
- 26.16.1 the Customer on whose behalf IQVIA is processing the Customer Personal Data is the controller;
 - 26.16.2 IQVIA is a processor on behalf of that Customer; and
 - 26.16.3 Genomics England is a processor acting on behalf of that Customer throughout the duration of the relevant Clinical Study. Following completion of the relevant Clinical Study, if the parties and the relevant Customer have agreed in writing in accordance with clause 9.4.3. that Genomics England will be licensed to use some or all of the Customer Personal Data at the end of the Clinical Study or at a later date, then that Customer Personal Data shall become part of the general dataset available within the Genomics England Environment from the date agreed in writing by the parties and the relevant Customer and, from that point, the Customer and Genomics England shall each be independent controllers in respect of the Customer Personal Data.

27. ANTI-BRIBERY

- 27.1 Each party shall in relation to this Agreement:
- 27.1.1 comply with all applicable laws, statutes, regulations relating to anti-bribery and anti-corruption including but not limited to the Bribery Act 2010 (**Relevant Requirements**);
 - 27.1.2 not engage in any activity, practice or conduct which would constitute an offence under sections 1, 2 or 6 of the Bribery Act 2010 if such activity, practice or conduct had been carried out in the UK;

- 27.1.3 have and shall maintain in place throughout the term of this Agreement its own policies and procedures, including adequate procedures under the Bribery Act 2010, to ensure compliance with the Relevant Requirements and clause 27.1.2, and will enforce them where appropriate;
 - 27.1.4 promptly report to the other parties any request or demand for any undue financial or other advantage of any kind received by it in connection with the performance of this Agreement; and
 - 27.1.5 promptly notify the other parties if a foreign public official becomes an officer or employee of it or acquires a direct or indirect interest in it and warrants that it has no foreign public officials as direct or indirect owners, officers or employees at the Commencement Date.
- 27.2 For the purpose of this clause 27, the meaning of adequate procedures and foreign public official and whether a person is associated with another person shall be determined in accordance with section 7(2) of the Bribery Act 2010 (and any guidance issued under section 9 of that Act), sections 6(5) and 6(6) of that Act and section 8 of that Act respectively.

28. TERM AND TERMINATION

- 28.1 This Agreement shall take effect on the Effective Date and shall continue in force until terminated in accordance with its terms.
- 28.2 Without affecting any other termination rights under this Agreement, either party may terminate this Agreement by giving the other party not less than [REDACTED] notice in writing, such termination to take effect on, or at any time after, the Initial Period.
- 28.3 Either party may, by giving written notice to the other party, terminate this Agreement as of the date specified in the termination notice, provided that such date shall be no later than [REDACTED] of the date upon which the notice is given, if:
- 28.3.1 the other party is in material breach of this Agreement and the other party shall have failed to remedy the breach within [REDACTED] of written notice to the other party specifying the breach and requiring its remedy;
 - 28.3.2 the other party:
 - 28.3.2.1 passes a resolution, or the Court makes an order that the other party be wound up otherwise than for the purpose of a bona fide reconstruction or amalgamation; or
 - 28.3.2.2 a receiver, manager or administrator on behalf of a creditor is appointed in respect of the business or any part thereof of the other party; or
 - 28.3.2.3 circumstances arise which entitle the Court or a creditor to appoint a receiver, manager or administrator or which entitle the Court otherwise than for the purpose of a bona fide reconstruction or amalgamation to make a winding-up order; or
 - 28.3.2.4 the other party is unable to pay its debts within the meaning of Section 123 of the Insolvency Act 1986; or
 - 28.3.2.5 any similar event occurs under the law of any other jurisdiction.

28.4 Without affecting any other termination rights under this Agreement, either party may terminate this Agreement by giving the other party not less than thirty (30) days notice in writing if Genomics England ceases to have a valid legal basis under Data Protection Laws (including where applicable any necessary notices and legally valid consents) to authorise researchers and clinicians to use the Genomics England Services Data for Research.

29. CONSEQUENCES OF TERMINATION

29.1 Where a party has given notice of termination under clause 28.2 or 28.4, IQVIA shall not enter into any new IQVIA Customer Agreements, and Genomics England shall not enter into any new Genomics England Data Access Agreements, in each case that extend beyond the date of termination of this Agreement, and neither party shall agree to extend the duration of any such agreement beyond the date of termination of this Agreement.

29.2 Where a party has given notice of termination under clause 28.3, IQVIA shall not enter into any new IQVIA Customer Agreements, and Genomics England shall not enter into any new Genomics England Data Access Agreements from the date of such notice except that, where notice of termination was provided under clause 28.3.1, the parties may enter into such agreements once (and if) the breach has been remedied in accordance with that clause.

29.3 Notwithstanding any termination of this Agreement, IQVIA shall be entitled to continue to provide any or all of the Services to Customers pursuant to any IQVIA Customer Agreements entered into prior to the date of termination of this Agreement in compliance with the provisions of clause 29.1 and 29.2, and for these purposes the provisions of this Agreement (and each party's rights and obligations under this Agreement) shall continue in force in respect of each such IQVIA Customer Agreement until that IQVIA Customer Agreement has been terminated or has expired.

29.4 Upon termination or expiry of all IQVIA Customer Agreements:

29.4.1 Genomics England shall permanently expunge from the Genomics England Environment, and all other systems operated by or on behalf of Genomics England, all copies of the IQVIA Software, and shall confirm in writing to IQVIA that it has done so; and

29.4.2 IQVIA shall permanently expunge all copies of the Genomics England Services Data in the possession or control of IQVIA and/or IQVIA's Affiliates, and shall confirm in writing to Genomics England that it has done so provided that IQVIA shall not be required to expunge copies of any Customer Materials.

29.5 Any termination of this Agreement for any reason shall be without prejudice to any other rights or remedies a party may be entitled to at law or under this Agreement and shall not affect any accrued rights or liabilities of either party nor the coming into force or the continuance in force of any provision of this Agreement which is expressly or by implication intended to come into or continue in force on or after such termination.

29.6 Upon termination of this Agreement for any reason:

29.6.1 each party shall return to the other, or at the other party's option, permanently expunge, all Confidential Information belonging to the other party, except that IQVIA shall not be required to return or expunge any Confidential Information belonging to Genomics England other than Genomics England Personal Data which (i) it has provided or made available to Customers pursuant to an IQVIA Customer Agreement (including as part of any Customer Materials), or (ii) it reasonably requires in order to fulfil the terms of any IQVIA Customer Agreement entered into prior to the date

of termination of this Agreement, but shall return or expunge such Confidential Information to Genomics England promptly following the relevant Customer Term except that either party may retain a copy of any Confidential Information belonging to the other party that it reasonably considers necessary in order to be able to address any queries raised by external bodies such as Customers and regulators; and

29.6.2 Genomics England shall retain copies of the Genomics England Services Data and the Participant Sequence / Associated Data in accordance with Genomics England's data retention policy from time to time and/or the provisions of the relevant Genomics England Data Access Agreement, and shall, subject to clause 26, provide IQVIA, Customers and/or Regulators with access to the Genomics England Data if requested by a Regulator to do so.

29.7 Upon termination of this Agreement for any reason, all rights and obligations under this Agreement shall cease except that clauses 1, 19 (to the extent any payments are outstanding), 21, 23, 24, 25, 26, 29, 31, 33 and 34, shall survive termination of this Agreement.

30. FORCE MAJEURE

30.1 Subject to the remaining provisions of this clause 30, neither Party to this Agreement shall be liable to the other for any delay or non-performance of its obligations under this agreement to the extent that such non-performance is due to a Force Majeure Event.

30.2 In the event that either party is delayed or prevented from performing its obligations under this agreement by a Force Majeure Event, such party shall:

30.2.1 give notice in writing of such delay or prevention to the other party as soon as reasonably possible, stating the commencement date and extent of such delay or prevention, the cause thereof and its estimated duration;

30.2.2 use all reasonable endeavours to mitigate the effects of such delay or prevention on the performance of its obligations under this Agreement; and

30.2.3 resume performance of its obligations as soon as reasonably possible after the removal of the cause of the delay or prevention.

30.3 A party cannot claim relief if the Force Majeure Event is attributable to that party's wilful act, neglect or failure to take reasonable precautions against the relevant Force Majeure Event, or failure to implement and comply with any business continuity and disaster recovery plan which that party is required to implement and comply with under this Agreement.

30.4 As soon as practicable following the affected party's notification, the parties shall consult with each other in good faith and use all reasonable endeavours to agree appropriate terms to mitigate the effects of the Force Majeure Event and to facilitate the continued performance of this Agreement.

30.5 The affected party shall notify the other party as soon as practicable after the Force Majeure Event ceases or no longer causes the affected party to be unable to comply with its obligations under this Agreement. Following such notification, this Agreement shall continue to be performed on the terms existing immediately prior to the occurrence of the Force Majeure Event unless agreed otherwise by the parties.

31. DISPUTE RESOLUTION PROCEDURE

- 31.1 The parties shall attempt, in good faith, to resolve any Dispute promptly by negotiation which shall be conducted as follows:
- 31.1.1 the Dispute shall be referred, by either Party, first to IQVIA's General Manager, United Kingdom, and Genomics England's Chief Operating Officer for resolution;
 - 31.1.2 if the Dispute cannot be resolved by the representatives referred to in clause 31.1.1 within 14 days after the Dispute has been referred to them, either party may give notice to the other party in writing (Dispute Notice) that a Dispute has arisen;
 - 31.1.3 within seven days of the date of the Dispute Notice, each party shall refer the Dispute to IQVIA's President, North Europe, Middle East and Africa, and Genomics England's Chief Executive for resolution; and
 - 31.1.4 if the representatives referred to in clause 31.1.3 are unable, or fail, to resolve the Dispute within 21 days of the date of the Dispute Notice, or within 14 days of the reference to such representatives pursuant to clause 31.1.3, each party shall refer the Dispute to IQVIA's President, Real World Analytics Solutions, and Genomics England's Chair for resolution.
- 31.2 If the representatives referred to in clause 31.1.4 are unable, or fail, to resolve the Dispute within twenty-one (21) days of the date of the Dispute Notice, or within fourteen (14) days of the reference to such representatives pursuant to clause 31.1.4, either party may commence or continue court proceedings in respect of such unresolved Dispute or issue.
- 31.3 Nothing in this clause 31 shall prevent either party from instigating legal proceedings where an order for an injunction, disclosure or legal precedent is required.
- 31.4 Without prejudice to a party's right to seek redress in court, each party shall continue to perform its obligations under this Agreement notwithstanding any Dispute or the implementation of the procedures set out in this clause 31.

32. TRANSFER AND SUB-CONTRACTING

- 32.1 Except as set out in clauses 32.2, 32.3 and 32.4, neither party shall assign, novate, transfer, sub-contract or otherwise dispose of this Agreement or any rights or obligations under this Agreement without the prior written consent of the other party.
- 32.2 The rights and licences granted to IQVIA under this Agreement shall also enure for the benefit of its Affiliates, provided always that IQVIA shall ensure that such Affiliates comply with any conditions for the exercise of such rights or licences set out herein.
- 32.3 Either party may sub-contract any or all of its obligations under this Agreement to its Affiliates with or without the prior written consent of the other party.
- 32.4 Either party may sub-contract any or all of its obligations under this Agreement to third parties other than Affiliates, save that:
- 32.4.1 IQVIA shall not sub-contract any aspect of the Services that involves the analysis or handling of the Genomics England Services Data or access to the Genomics England Environment to anyone other than its Affiliates without the previous consent in writing of Genomics England, which shall not be unreasonably withheld or delayed; and

32.4.2 Genomics England shall not permit access to the IQVIA Software by the Personnel of a third party, if such Personnel work for an Affiliate, division or business group that (i) owns or licenses out, or otherwise provides access to, a product that competes with the IQVIA Software, or (ii) is a provider of healthcare data. For the avoidance of doubt, this restriction shall not apply to the Personnel of an Affiliate, division or business group of a corporate group if that Affiliate, division or business group (i) does not own or license out, or otherwise provides access to, a product that competes with the IQVIA Software, or (ii) is not a provider of healthcare data.

32.5 If a party sub-contracts any of its obligations under this Agreement to any third party (including an Affiliate), the party sub-contracting shall remain fully responsible to the other party for the proper performance of those obligations in accordance with the provisions of this Agreement and for any act or omission of the third party in relation thereto as if it were an act or omission of that party under this Agreement.

33. PUBLICITY AND ANNOUNCEMENTS

33.1 Neither party shall make any press announcements about this Agreement or, except as reasonably required to market and promote the Services, publicise this Agreement, its contents or its relationship with the other party in any way without the prior written consent of the other party, which may be withheld by the other party at its sole discretion.

33.2 The parties acknowledge that Genomics England is required to publish a statement specifying who has access to the Genomics England Data, and a short lay summary describing the purpose of that access. Genomics England shall be responsible for obtaining all consents needed in order to make this publication. IQVIA hereby consents to Genomics England publishing a statement specifying that IQVIA has access to the Genomics England Data and a short lay summary describing any purposes for which IQVIA will access the Genomics England Data pursuant to clause 13.1, provided that such statement and summary is approved in advance and in writing by IQVIA (such approval not to be unreasonably withheld or delayed).

34. GENERAL

34.1 This Agreement shall constitute the whole of the terms agreed between the parties hereto in respect of the subject matter of this Agreement provided that nothing in this clause 34.1 shall limit a party's liability for fraudulent misrepresentation.

34.2 This Agreement shall be capable of being varied only by a written instrument signed by a duly authorised officer or other representative of each of the parties.

34.3 This Agreement is severable in that if any provision is determined to be illegal or unenforceable by any court of competent jurisdiction such provision shall be deemed to have been deleted without affecting the remaining provisions of this Agreement.

34.4 Nothing in this Agreement shall constitute or be deemed to constitute a partnership, agency or joint venture between the parties hereto or constitute or be deemed to constitute either party the agent of the other for any purpose whatsoever and neither party shall have any authority or power to bind the other or to contract in the name of or create a liability against the other.

34.5 Unless otherwise agreed in writing, no failure by either party to exercise any right or remedy available to it hereunder nor any delay so to exercise any such right to remedy shall operate as a waiver of it nor shall any single or partial exercise of any right or remedy preclude any other or further exercise thereof or the exercise of any other right or remedy.

- 34.6 Any notice to be given hereunder by either party to the other shall be in writing and delivered personally sent by pre-paid recorded delivery or registered post to the addressee at the addressee's registered office for the time being and shall be deemed to be received if delivered personally at the time of receipt if sent by post at the expiration of 72 hours after being placed in the post (having been correctly addressed) whether or not received.
- 34.7 Save as provided in clauses 23 and 26, no third party shall have any rights under the Contracts (Rights of Third Parties) Act 1999 or otherwise in connection with this Agreement. Notwithstanding any rights any third party may have under any of such clauses, the parties may cancel or vary this Agreement in accordance its terms without the consent of any third party.
- 34.8 This Agreement shall be governed and construed in accordance with the laws of England. The parties hereby irrevocably submit to the exclusive jurisdiction of the Courts of England and Wales.

Signed for and on behalf of **IQVIA Solutions UK Limited**

Signed for and on behalf of **Genomics England Limited**

Signed: _____

Signed: _____

Name: _____

Name: _____

Position: _____

Position _____

LIST OF SCHEDULES

No.	Schedule Heading
1	Implementation Plan
2	The Services
3	Pricing, Revenue Share, Charges and Payment
4	Rate Card
5	Specification
6	Commercially Sensitive Information
7	Governance and Contract Management
8	GeCIP Modules

SCHEDULE 1 - IMPLEMENTATION PLAN

1.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

■	[REDACTED]	[REDACTED]
■	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

SCHEDULE 3 - CHARGES

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

5.4 [REDACTED]

SCHEDULE 4 – RATE CARD

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

SCHEDULE 5 - SPECIFICATION

[REDACTED]

[REDACTED]

[REDACTED]

Diagrammatic representation of E360 deployment pipeline for Genomics England

[REDACTED]

SCHEDULE 6 – COMMERCIALY SENSITIVE INFORMATION

1. IQVIA's charges to Customers
2. The charges and payment terms of this Agreement, including the content of Schedule 3
3. The E360 Software
4. Details of the Services and/or the Customers
5. IQVIA's Intellectual Property Rights

SCHEDULE 7 – GOVERNANCE AND COLLABORATION MANAGEMENT

1. APPOINTMENT OF PROJECT MANAGERS

- 1.1 IQVIA and Genomics England shall each appoint a Project Manager for the purposes of this Agreement through whom the Collaboration and the Services shall be managed on a day-to-day basis.
- 1.2 A party may replace its appointed Project Manager at any time by informing the other party of the identity and contact details of its replacement Project Manager.

2. GROUPS

Establishment and structure of the Groups

- 2.1 The Collaboration shall be supervised by a Steering Group and a Working Group which shall be staffed with equal numbers of suitable employees or contractors from each respective Party.

Steering Group

- 2.2 The Steering Group shall be made up of six (6) members, three of which shall be appointed by Genomics England and three of which shall be appointed by IQVIA.
- 2.3 Each party shall ensure that at least one of its members of the Steering Group has sufficient seniority and authorisation on behalf of such party to make decisions arising within the scope of responsibilities of the Steering Group as set out in paragraph 3.

Working Group

- 2.4 The Working Group shall be made up of six (6) members, three of which shall be appointed by Genomics England and three of which shall be appointed by IQVIA.
- 2.5 Each party shall ensure that at least one of its members of the Working Group has sufficient seniority and authorisation on behalf of such party to make decisions arising within the scope of responsibilities of the Working Group as set out in paragraph 4.
- 2.6 Each party shall appoint its Project Manager to be a member of the Working Group.
- 2.7 In relation to each Group, the:
- 2.7.1 Initial Genomics England Group Members;
 - 2.7.2 Initial IQVIA Group Members;
 - 2.7.3 frequency that the Group shall meet (unless otherwise agreed between the Parties);
 - 2.7.4 location of the Group's meetings; and
 - 2.7.5 planned start date by which the Group shall be established,
- shall be as set out in Annex 1.

- 2.8 Any member of the Working Group or Steering Group may designate a substitute to attend and perform the functions of that member at any meeting of the relevant Group. Each party may in its reasonable discretion invite non-member representatives of such party to attend meetings of the Working Group and/or Steering Group, including but not limited to the Project Managers, as a non-voting observer.
- 2.9 Each party may replace any or all of its Group Members at any time provided that at all times each party must ensure that one of its members has sufficient seniority and authorisation on behalf of the applicable Party to make decisions arising within the scope of responsibilities of each Group as set out in paragraphs 3 and 4. In the event that either party wishes to replace any of its appointed Group Members, that party shall notify the other in writing of the change. Notwithstanding the foregoing, it is intended that each Genomics England Group Member has at all times a counterpart IQVIA Group Member of equivalent seniority and expertise.

Group meetings

- 2.10 A chairperson shall be appointed by the parties for each Group (the “Chairperson”). Each Chairperson shall be appointed to serve a six (6) month term. Unless the Parties agree otherwise the right to name the Chairperson shall alternate between the Parties with Genomics England designating the first Chairperson. The Chairperson shall be responsible for:
- 2.10.1 scheduling Group meetings and giving attendees reasonable notice of the relevant Group meeting;
 - 2.10.2 setting the agenda for Group meetings and circulating to all attendees in advance of such meeting;
 - 2.10.3 ensuring all attendees provide such documentation and information as the relevant Group requires in order to discharge its responsibilities;
 - 2.10.4 chairing the Group meetings;
 - 2.10.5 monitoring the progress of any follow up tasks and activities agreed to be carried out following Group meetings;
 - 2.10.6 ensuring that minutes for Group meetings are recorded and disseminated electronically to the appropriate persons and to all Group meeting participants within seven (7) Business Days after the Group meeting; and
 - 2.10.7 facilitating the process or procedure by which any decision agreed at any Group meeting is given effect in the appropriate manner.
- 2.11 Group meetings shall be quorate as long as at least two representatives from each Party are present. Decisions of the Groups shall be on a unanimous basis. If the Working Group is unable to reach a unanimous decision, the issue at hand will be decided upon by the Steering Group. If the Steering Group is unable to reach a unanimous decision, the issue at hand shall be escalated in accordance with clause 31 (Dispute Resolution Procedure).
- 2.12 The Parties shall ensure, as far as reasonably practicable, that all Groups shall as soon as reasonably practicable resolve the issues and achieve the objectives placed before them. Each Party shall endeavour to ensure that Group Members are empowered to make relevant decisions or have access to empowered individuals for decisions to be made to achieve this.
- 2.13 All material decisions of the Groups shall be recorded in writing under the supervision of the Chairperson.

- 2.14 In addition to the meetings of the Groups described in this Schedule, the Parties shall be free to agree and convene ad hoc meetings of each Group from time to time. Each Party shall act reasonably and in good faith when considering a request by the other Party to convene any such ad hoc meeting.

3. ROLE OF THE STEERING GROUP

- 3.1 The Steering Group shall:

- 3.1.1 provide senior level guidance, leadership and strategy for the overall Agreement; and
- 3.1.2 carry out the specific obligations attributed to it in Paragraph 3.2.

- 3.2 The Steering Group shall:

- 3.2.1 ensure that the Collaboration is operated throughout the Term in a manner which is consistent with the Agreed Objectives and Clause 2 ;
- 3.2.2 receive and review reports from the Working Group and review reports on technology, service and other developments that offer potential for improving the Collaboration in a manner which is consistent with the Agreed Objectives;
- 3.2.3 determine strategy for the Collaboration and provide guidance on policy matters which may impact on this Agreement;
- 3.2.4 review, consider and evaluate any potential additional Services the parties could make available under this Agreement;
- 3.2.5 analyse and record the impact of all Changes to this Agreement, specifically whether a proposed Change:
 - a) has an impact on other areas or aspects of this Agreement; and
 - b) will raise any risks or issues relating to the proposed Change; and
- 3.2.6 shall be empowered to create sub teams or sub committees of itself as it may deem necessary or appropriate. Each party shall have equal representation on any such sub team or subcommittee. Each such sub team or subcommittee shall report to the Steering Group.

- 3.3 The Steering Group shall not have the power to make any changes to the provisions of this Agreement.

4. ROLE OF THE WORKING GROUP

- 4.1 The Working Group shall be responsible for the executive management of this Agreement and shall:

- 4.1.1 be accountable to the Steering Group for comprehensive oversight of this Agreement and for the senior management of the operational relationship between the parties;
- 4.1.2 oversee implementation of the Implementation Plan including:
 - a) monitoring progress against the delivery timetable set out in the Implementation Plan;

- b) identifying the resources necessary for implementation of the Implementation Plan;
 - c) identifying issues which may hinder progress towards completing the Implementation Plan and proposing solutions to such issues or escalating such issues to the Steering Committee where appropriate;
 - d) reporting quarterly to the Steering Group on progress to implement the Implementation Plan.
- 4.1.3 review performance of the Collaboration against the Agreed Objectives;
- 4.1.4 review the development, marketing and performance of the Services including:
- a) process and strategy for identifying, and marketing the Services to, Prospective Customers;
 - b) demand for the Services including a review of (i) the status and progress of discussions with Prospective Customers, (iii) the number and identity of any new Customers who have committed to receive Services since the previous meeting of the Working Group, and (iv) the scope of the Services provided to such new Customers;
 - c) reviewing the processes, workflow and timeframes for onboarding of Prospective Customers for the Research Feasibility Data Access Services and the Analytical Consultancy Services;
 - d) reviewing any feedback received from Customers and Prospective Customers regarding the Services and consider whether and how to respond to such feedback;
 - e) reporting to the Steering Group quarterly on the performance of the Services.
- 4.1.5 identify and discuss where necessary any matters arising under the Collaboration for which ARC Approval is required;
- 4.1.6 report to the Steering Group on all issues requiring decision and resolution by the Steering Group;
- 4.1.7 receive and review reports from the Project Managers on matters such as issues relating to delivery of existing Services, and possible future developments; and
- 4.1.8 deal with the prioritisation of resources and the appointment of Project Managers on behalf of the parties.
- 4.2 The Working Group shall identify and manage risks relating the scope and range of the Services available to the performance of this Agreement. The Working Group shall identify the risks to be reported to the Steering Group via regular risk reports.
- 4.3 The Working Group shall not have the power to make any changes to the provisions of this Agreement.

APPENDIX 1

Steering Group Representation and Structure

[REDACTED]	[REDACTED]

Working Group Representation and Structure

[REDACTED]	[REDACTED]

SCHEDULE 8 – GECIP MODULES

