

DRAFT (1):

# Single Study Dataset Agreement

between

The Secretary of State for Health

Acting through the GPRD Group of the MHRA

and

relating to

Production and Supply of a Dataset from the General  
Practice Research Database for use in a Single Study

## CONTENTS

1.	Interpretation .....	1
2.	Production and Delivery of Dataset.....	4
3.	Licence .....	4
4.	Permitted Use.....	5
5.	Payment of Fee and Invoicing Arrangements .....	5
6.	Consequences of Late Payment .....	5
7.	Restrictions on Use of Dataset.....	6
8.	Changes to Study .....	7
9.	Intellectual Property Rights .....	7
10.	Warranties and Indemnity by Customer .....	8
11.	Audit of research .....	8
12.	Liability of the GPRD Group for Failure of the Dataset DVD .....	8
13.	Limitation of Liability and Disclaimer .....	9
14.	Force Majeure .....	9
15.	Suspension and Termination.....	10
16.	Consequences of Expiry or Termination .....	11
17.	Alternative Dispute Resolution .....	11
18.	Notices .....	12
19.	Entire agreement.....	12
20.	Assignment.....	12
21.	Variation .....	12
22.	Severability.....	13
23.	Waiver .....	13
24.	Survival.....	13
25.	Execution.....	13
26.	Applicable law and Jurisdiction .....	13
	SCHEDULE .....	15



**THIS AGREEMENT** is dated      and made

**BETWEEN:**

- (1) **THE SECRETARY OF STATE FOR HEALTH**, (the "GPRD Group"), acting through the GENERAL PRACTICE RESEARCH DATABASE GROUP within the MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY of 151 Buckingham Palace Road, London SW1W 9SZ of the one part; and
- (2) ***[Please Insert]***, (the "Customer"), whose registered office is ***[Please Insert]*** of the other part.

**WHEREAS:**

- (1) The Crown acting through the General Practice Research Database Group within the Medicines and Healthcare products Regulatory Agency (an Executive Agency of the Department of Health) has developed and controls all rights to the Database and is making it available for non-profit-making research in accordance with the terms and conditions referred to below.
- (2) The Customer desires access to certain extracts of the Data contained within the Database to conduct a single study for non-profit-making medical and health research purposes, as specified in a protocol which has received approval from the Independent Scientific Advisory Committee.
- (3) The GPRD Group has agreed to produce the Dataset for and to grant a licence to use the Dataset to the Customer in accordance with the terms and conditions set out in this Agreement.

**NOW IT IS HEREBY AGREED AS FOLLOWS:**

1. **Interpretation**

- 1.1 In this Agreement unless the context otherwise requires, the following expressions shall mean:

Affiliated Companies	Any company controlling, controlled by or under common control with the Customer by ownership, directly or indirectly, of 50% or more of the total ownership, or by the power to control the policies and actions of such company;
Data	Data from time to time obtained from contributing general medical practices as are contained in the Database, or any such data as are added to the Database by the GPRD Group, or any part of such data;
Database	The General Practice Research Database containing an electronic and relational record of

anonymous patient data, collected, aggregated and developed by the GPRD Group and as may be amended or updated with Data by the GPRD Group from time to time;

Dataset	The extracts of the Data to be supplied by the GPRD Group to the Customer under this Agreement as described in the Schedule hereto referred to either as the entire extract of Data or as part of the entire extract as the context may require;
Delivery Plan	The estimated time or date when the GPRD Group intends to deliver the Dataset as specified in the Schedule;
Effective Date	The date on which the GPRD Group delivers the Dataset to the Customer;
Fee	The fee payable by the Customer for the production of and right to use the Dataset as specified in the Schedule;
Force Majeure	Any event or occurrence which is outside the control of the Party concerned and which is not attributable to any act or failure to take preventative action by the Party concerned, including but not limited to acts of God, war, riot, civil commotion, malicious damage, computer viruses or other malicious software or program code, inability to obtain supplies, accident, breakdown of plant or machinery including telecommunications equipment, interruption to electricity supply, explosions, fire, flood, storm, default of suppliers, strikes, lockouts or other industrial disputes except where such strikes, lockouts or other industrial disputes occur within either of the Parties' organisations;
Intellectual Property Rights	Patents, trademarks and service marks, present and future copyrights, topography rights, design rights and database rights (including, without limitation, rights of extraction), whether or not any of them are registered and including applications for registration of any of them, trade secrets and rights of confidence, and all rights or forms of protection of a similar nature or having equivalent effect to any of them which may subsist anywhere in the world;
Independent Scientific Advisory Committee or ISAC	The body or any successor body nominated by the GPRD Group to review the scientific acceptability of studies;
Licence Period	A period of 12 months from the Effective Date, unless such period is extended at the Customer's

request and as may be agreed and confirmed in writing subject to the GPRD Group's sole discretion;

Medical and Health Research Purposes Population-based studies in health outcomes, drug safety, health economics, drug utilisation, public health research, drug formulary research and disease management, or such other purposes as are authorised by the GPRD Group;

Non-profit-making Not having the object of making a profit year on year;

Parties The GPRD Group and the Customer or their successors in title, each of them being referred to as a "Party";

Protocol The protocol approved by the Independent Scientific Advisory Committee set out in Annex B in accordance with which the Study is to be conducted;

Study The single study for non-profit-making Medical and Health Research Purposes which the Customer wishes to carry out with the Dataset under this Agreement as described in the Schedule and the Protocol;

Territory The world.

1.2 In this Agreement:

(A) the headings are included for convenience only and shall not affect the construction of this Agreement; and

(B) the Interpretation Act 1978 shall apply to this Agreement in the same way as it applies to an enactment.

## 2. **Production and Delivery of Dataset**

2.1 Subject to the terms of this Agreement, and in consideration of the payment by the Customer of the Fee, the GPRD Group shall use reasonable endeavours to produce and supply the Dataset to the Customer in accordance with the Delivery Plan. Subject to that timescale, and on receipt of the payment from the Customer in accordance with clause 5, including any VAT thereon, the GPRD Group shall deliver the Dataset to the Customer.

2.2 The Customer shall inform the GPRD Group by way of a notice within 14 days of delivery if it considers that any modification needs to be made to the Dataset in order to conduct the Study, together with its reasons. The GPRD Group shall review any such request for modification and, if it considers it appropriate, shall modify the Dataset and re-deliver it to the Customer within such period as the Parties may agree in writing. For the avoidance of doubt, the Licence Period shall be suspended during any such period in which the GPRD Group carries out alterations to the Dataset.

2.3 The GPRD Group shall retain any computer files and supporting records created during the course of production of the Dataset for a minimum period of 5 years (or such longer

period as may be agreed by the Parties in writing) following delivery of the Dataset to the Customer.

### 3. **Licence**

3.1 Subject to the terms of this Agreement, the GPRD Group grants the Customer a limited, non-exclusive and non-transferable licence to use the Dataset during the Licence Period.

3.2 This Agreement shall operate for the benefit of the Customer provided that:

(A) it is the responsibility of the Customer to ensure that any Affiliated Companies or their staff who are granted access to the Dataset are aware of and comply with the obligations and any restrictions in respect of the access and use of the Dataset as set out in this Agreement;

(B) the Customer provides to the Affiliated Companies together with the Dataset a copy of the Protocol and ensures that the Affiliated Companies and their staff are aware of and comply with any obligations and restrictions in respect of the access and use of the Dataset that the Protocol sets out;

(C) any act or omission of any Affiliated Company or other third party which would have been a breach of the terms of this Agreement if any such Affiliated Company or third party had been a party hereto shall be treated as a breach by the Customer for which the Customer shall be liable, and the GPRD Group shall have the right to obtain injunctive relief in addition to any other legal or financial remedies to which the GPRD Group may be entitled;

(D) the Customer notifies the GPRD Group of the access to the Dataset and the details of the Affiliated Companies and their own staff given such access;

(E) pursuant to section 1(2) of the Contracts (Rights of Third Parties) Act 1999, the Parties do not intend that any term of this Agreement may be enforced by any Affiliated Companies or third parties.

3.3 The Customer shall be entitled to make and use copies of the Dataset during the Licence Period and in accordance with the terms of this Agreement at as many sites operated by the Customer or its Affiliated Companies as the Customer sees fit throughout the Territory.

3.4 No provision of this Agreement shall be deemed to restrict or limit the GPRD Group's right to use, market, sell, distribute, display or otherwise provide access to the Data directly or indirectly anywhere in the world.

### 4. **Permitted Use**

4.1 The licence granted in clause 3.1 is subject to:

(A) payment of the Fee in accordance with clause 5;

(B) the use of the Dataset or any other information obtained by the Customer or its Affiliated Companies (if any) in accordance with this Agreement being restricted to carrying out the Study for Medical and Health Research Purposes on a non-profit-making basis, which, for the avoidance of doubt, shall not prevent the Customer from recovering its reasonable direct operating costs associated with that research

and any other use of the Dataset, that is not expressly specified in the Protocol, is strictly prohibited save that the Customer is entitled to produce its own independent reports, studies, papers and statistical tables in connection with the use of the Dataset;

(C) the Customer and its Affiliated Companies (if any) complying with the restrictions set out at clause 7;

4.2 In the event the Customer has doubts as to the scope of the licence granted in clause 3.1 it shall contact the GPRD Group for clarification.

## 5. **Payment of Fee and Invoicing Arrangements**

5.1 Payment of the Fee shall be on receipt of an invoice from the GPRD Group with payment due within 30 days of the date of the invoice.

5.2 The invoice shall be sent to the Customer at the following address

***[Please insert invoicing address]***

5.3 The sponsor shall, if subject to VAT, pay VAT on the Fee at the rate applicable at the time payment is made as specified on the GPRD Group's invoice.

## 6. **Consequences of Late Payment**

6.1 If any payment is not made within 30 days of the date of the invoice interest shall accrue thereafter on the amount unpaid at the rate of 4% above the prevailing base rate of Barclays Bank Plc per year accruing on a daily basis from the date on which payment became due until the date on which payment has been received.

6.2 If at the end of a further period of 30 days the payment together with interest accrued has not been received by the GPRD Group, the GPRD Group may immediately suspend the Customer's licence set out in clause 3.1 without notice until payment (including interest) is made. The Licence Period shall not be extended to take account of the period of any such suspension of access. Whether or not the GPRD Group chooses not to suspend the Customer's licence in accordance with the provisions of this clause, interest shall continue to accrue on the amount unpaid at the rate specified at clause 6.1 above.

6.3 If any payment due under this Agreement is outstanding for more than 8 weeks after the initial 30 day period from the date of the invoice for payment has expired, the GPRD Group may terminate this Agreement without further notice.

## 7. **Restrictions on Use of Dataset**

7.1 The Customer shall not use or attempt to use the Dataset whether on its own or in conjunction with any other data in any other form, for:

(A) identifying, contacting or targeting patients;

(B) identifying, profiling, contacting or targeting general medical practitioners or general medical practices; or



(C) studying the effectiveness of advertising campaigns or sales force,

and the Customer shall ensure that all reports, papers or statistical tables that are published or released to third parties as a result of use of the Dataset cannot be used to identify or enable others to identify patients, contributing general medical practitioners or contributing general medical practices. If at any time the Customer considers that there is information in the Dataset which could be used to identify any individual, general medical practitioner or general medical practice, the Customer will inform the GPRD Group immediately in writing by way of a notice delivered in accordance with clause 18.

- 7.2 The Customer shall not sell, transfer (except as permitted under this Agreement to Affiliated Companies), trade, or otherwise dispose of the Dataset or parts thereof save that, with the written permission of the GPRD Group, extracts of the Dataset may be supplied to regulatory authorities by the Customer for audit purposes.
- 7.3 The Customer shall not permit any third party to access, study, analyse, refer to or otherwise use the Dataset or parts thereof (with the exception of Affiliated Companies), or permit any third party to reproduce it.
- 7.4 The Customer shall not reproduce or modify the Dataset in any way (otherwise than as permitted by clause 3.3) for the purpose of creating and/or distributing the Dataset or parts thereof in another database or form.
- 7.5 The Customer will effect and maintain adequate security measures to prevent unauthorised use or copying of the Dataset or parts thereof.
- 7.6 The GPRD Group may require the suspension of use of, or the return of the Dataset to comply with any law, regulation, court order, or other governmental request or order, or to protect the GPRD Group from any legal liability, or if it considers it in the public interest to do so. No compensation will be paid nor will the Fee be rebated for any such suspension of use. But, if the GPRD Group requires the return of the Dataset to the extent that the Customer will be unable to conduct or complete the Study, the Fee shall be refunded in full less a reasonable charge for the cost and administration incurred in producing the Dataset, and this Agreement shall be terminated.

## 8. **Changes to Study**

- 8.1 If during the Licence Period the Customer wishes to alter the Study in any way the Customer shall give notice of the proposed changes to the GPRD Group delivered in accordance with clause 18.
- 8.2 If the proposed changes fall outside the scope of the Protocol the Customer shall re-submit the revised Protocol to ISAC for review. The Licence Period shall be suspended pending ISAC's decision. The decision of the GPRD Group under this clause shall not be interpreted as the views of the UK Licensing Authority acting via the GPRD Group. The Agreement will then either be varied or terminated as appropriate. For the avoidance of doubt, if the Agreement is varied (which may include but is not restricted to any changes that may be required to the Dataset) the Fee payable under the Agreement may also be varied to cover any incremental costs associated with the changes, and if the Agreement is terminated no rebate in the Fee shall be payable except at the sole discretion of the GPRD Group.

8.3 If during the Licence Period the Customer wishes to alter the Study in a way which falls within the scope of the Protocol the Agreement may be varied at the sole discretion of the GPRD Group and, for the avoidance of doubt, any such variation (which may include but is not restricted to any changes that may be required to the Dataset) may include a variation to the Fee payable under the Agreement to cover any incremental costs associated with the changes.

## 9. **Intellectual Property Rights**

9.1 The Crown is the maker of the Database, copyright in the Database is Crown copyright and any database rights in the Database belong to the Crown. Intellectual Property Rights in the Dataset and/or the Database or any part thereof, including the manner in which the Data are presented or appear in the Dataset shall remain the property of the Crown and the Customer shall not acquire any title, copyright or other Intellectual Property Rights therein under this Agreement.

9.2 Copyright in the Study, or any other Intellectual Property Rights arising from the Study, shall belong to the Customer but any publication arising from use of the Data shall include the statement *"This study is based in part on data from the General Practice Research Database obtained under licence from the UK Medicines and Healthcare products Regulatory Agency. However, the interpretation and conclusions contained in this study are those of the author/s alone"*. The Customer will ensure that the description of the Database in such publications is accurate and current, and agrees to request publication of a correction to any published description which the GPRD Group deems to be inaccurate if so requested by the GPRD Group.

9.3 The Customer shall send a copy of any publication including any abstract arising from use of the Dataset under this Agreement to the GPRD Group within 2 weeks of publication.

9.4 The Customer may not remove, suppress or modify in any way any proprietary marking, including any trademark or copyright or database right notice on or in the Dataset or on the DVD or other means by which the Dataset is delivered to the Customer or which is visible during the access or use of the Dataset. If the Customer copies the Dataset as per clause 3.3, it shall ensure that any such proprietary or rights notices are fully reproduced in any copies.

9.5 The Customer shall notify the GPRD Group immediately if the Customer becomes aware of any unauthorised access to, use or copying of any part of the Dataset by any person.

## 10. **Warranties and Indemnity by Customer**

10.1 The Licensee warrants to the Licensor that:

- (A) the Licensee has the requisite power and authority to enter into and perform its obligations under this Licence; and
- (B) this Agreement constitutes binding obligations of the Licensee in accordance with its terms.

10.2 The Customer shall indemnify the GPRD Group, and keep the GPRD Group fully and effectively indemnified against all losses, claims, costs, charges, expenses, liabilities, demands, proceedings and actions which the GPRD Group may sustain or incur, or which may be brought or established against it by any third party which arise out of a breach of

this Agreement by the Customer or its Affiliated Companies, including, but not limited to, any infringement or alleged infringement of Intellectual Property Rights held by any third party.

11. **Audit of research**

11.1 At all times during and after the Licence Period, the Customer will allow the GPRD Group access to the results of the research carried out under this Agreement for the purpose of enabling the GPRD Group to satisfy itself that all use of the Dataset is being undertaken in accordance with the terms of this Agreement.

11.2 For the purposes of clause 11.1 above the Customer shall upon reasonable notice grant the GPRD Group access to its premises subject to the GPRD Group agreeing to comply with any usual security procedures adopted by the Customer.

12. **Liability of the GPRD Group for Failure of the Dataset DVD**

12.1 The Dataset shall be supplied on a DVD or such other media as the GPRD Group may elect. The GPRD Group warrants that the DVD or such other media are free from defective workmanship. If the DVD or such other media are defective then the GPRD Group's liability arising in contract, tort (including negligence) or otherwise, shall be limited to the value of the retail price of such media as available from its manufacturer and the Customer's sole remedy shall be to have a new copy of the Dataset supplied after return of the old Dataset to the GPRD Group.

12.2 This clause 12 states the entire liability of the GPRD Group with respect to any failure of the media as described in clause 12.1.

13. **Limitation of Liability and Disclaimer**

13.1 Except as specified in this Agreement, the provisions of this clause 13 specify the entire liability of the GPRD Group arising out of this Agreement whether arising in contract, tort (including negligence) or otherwise.

13.2 The Customer acknowledges that, although the Dataset shall be produced by the GPRD Group based on the specification in the Schedule attached, it is the Customer's responsibility to ensure that the nature of the Data and the Dataset meet the Customer's requirements for conducting the Study. In addition, the Customer acknowledges that the GPRD Group does not accept any liability for any errors, omissions or inaccuracies in the contents of the Data as recorded by and received from the contributing general medical practitioners. Only data which have been assessed as meeting the GPRD Research Standards (i.e. are from acceptable patients in up-to-standard practices) will be used in the production of the dataset. These data are regarded by the GPRD Group as suitable for the scientific purposes of the protocol for the study approved by ISAC.

13.3 Subject to clauses 12 and 13.5 the GPRD Group shall not be liable under this Agreement (whether in contract, tort or otherwise) for direct, indirect or consequential loss or damage, or financial losses, loss of contracts or opportunity, loss of operation time, loss of data, wasted management time, damage to goodwill, or loss or damage claimed by any clients of the Customer, arising out of or in connection with the use of the Dataset.

13.4 Subject only to clause 13.5 and notwithstanding anything else in this Agreement to the contrary, the total liability of the GPRD Group in contract and tort (including, without

limitation, negligence) shall not exceed in aggregate the amount of the Fee paid by the Customer under this Agreement.

- 13.5 Notwithstanding clauses 12, 13.1, 13.2, 13.3 and 13.4 above, the liability of each Party to the other for death or personal injury resulting from its own negligence shall not be limited.
- 13.6 The Customer acknowledges and agrees that the allocation of risk and liability contained in this Agreement is reasonable in all the circumstances.

#### 14. **Force Majeure**

- 14.1 Neither Party shall be liable to the other by reason of any failure or delay in performing all or any of its obligations under this Agreement (except for payment obligations) which is due to Force Majeure where there is no reasonably practicable means available to the Party concerned to avoid such failure or delay.
- 14.2 If either Party becomes aware of any circumstances of Force Majeure which give rise to any such failure or delay, or which appear likely to do so, that Party shall give notice of those circumstances as soon as reasonably practicable thereafter and shall inform the other Party of the period for which it estimates that the failure or delay will continue. However, failure to provide such a notice shall not prevent that Party from relying on the remaining provisions of this clause.
- 14.3 Where a Party is unable to perform any or all of its obligations (except for payment obligations) under this Agreement due to Force Majeure its duty to perform shall be suspended for so long as the circumstances continue and for such time after they cease as is necessary for that Party, using all reasonable endeavours, to recommence its affected operations in order to perform its obligations. For the avoidance of doubt, unless otherwise agreed by the Parties in writing, the Licence Period will not be extended by any such period during which a Party is unable to perform its obligations, nor shall the Fee be rebated.
- 14.4 If any event of Force Majeure continues for a period exceeding 60 days either Party shall be at liberty to terminate this Agreement immediately on written notice to the other Party.

#### 15. **Suspension and Termination**

- 15.1 If the GPRD Group reasonably believes that the Customer may be using the Dataset for any purpose not authorised by this Agreement the GPRD Group may suspend the licence in clause 3.1 or terminate this Agreement immediately. Upon the GPRD Group being satisfied that the Customer's use of the Dataset is for an authorised purpose the GPRD Group may, if the Agreement was not terminated, reinstate the licence in clause 3.1 and may at its discretion extend the Licence Period by the period for which the licence in clause 3.1 was suspended.
- 15.2 If the Customer commits any other breach of any of the terms of this Agreement (other than those relating to payment or those which provide for immediate termination of the Agreement) which, being capable of remedy by the Customer acting alone, is not remedied within 30 days after written notice by the GPRD Group requiring the same, the GPRD Group may terminate this Agreement.
- 15.3 If the Customer enters into liquidation, other than for the purposes of effecting a solvent reconstruction, whether compulsory or voluntary, or compounds with its creditors, or has a

receiver or administrative receiver or administrator appointed over all of its assets, or takes or suffers any similar action in consequence of a debt, or for any reason ceases to carry on business the GPRD Group may terminate the Agreement forthwith by notice in writing to the Customer.

- 15.4 Termination of this Agreement shall be without prejudice to the rights of either Party which shall have accrued by reason of, or be subsisting at, the date of termination.
- 15.5 If the GPRD Group terminates this Agreement under this clause, or under any other clause herein which provides for termination, save where explicitly stated the GPRD Group shall not be obliged to repay the Customer any proportion of the Fee.
- 15.6 These restrictions on access and use shall survive the termination, variation or expiry of the Agreement.

#### 16. **Consequences of Expiry or Termination**

- 16.1 On the expiry or termination for any reason of this Agreement the Customer will return to the GPRD Group within 4 weeks the Dataset in the form in which it was issued and shall destroy any copies including, without limitation, any back-up and disaster recovery copies of the Dataset or parts thereof which the Customer and any of its Affiliated Companies may have made under the provisions of this Agreement, save that the Customer will be entitled to retain the analysis dataset (datasets used for statistical analyses) in order to complete the Study or for record keeping and regulatory or audit purposes. The Customer shall issue a certificate within 6 weeks of expiry or termination of this Agreement that it has fully complied with its obligations under this clause 16.1.
- 16.2 Upon the expiry or termination of this Agreement the Customer and its Affiliated Companies shall forthwith cease to use the Dataset or parts thereof except under the express instructions of the GPRD Group and the Customer and its Affiliated Companies will cease to use any back-up copies of the Dataset or parts thereof, subject to the provisions of clause 16.1 above, and will not thereafter knowingly access any back-up copies without the prior written consent of the GPRD Group.
- 16.3 The Customer shall be free to use the results of its Study after the termination of the Agreement or on its expiry for any purpose permitted by the Agreement.

#### 17. **Alternative Dispute Resolution**

- 17.1 In the event of any dispute arising between the Parties in connection with this Agreement which is not resolved by initial correspondence, senior representatives of the Parties shall, within 21 days of a written request from either Party to the other, meet in good faith to attempt to resolve the dispute.
- 17.2 If the dispute is not resolved at the meeting referred to in clause 17.1 either Party may propose to the other within 21 days of its conclusion that the matter be referred for either an expert determination, if the matter is within the expertise of a technical expert, or a mediation, if the dispute is of a more general nature, and the other Party may accept or reject that proposal. If that proposal is rejected either Party may refer the matter to the courts in accordance with clause 26.2.
- 17.3 If the Parties agree that an expert or a mediator should be appointed but are unable to agree on the person to be appointed within 21 days then the Parties shall by agreement

refer the matter to the head of an appropriate professional body to appoint such an expert or to the Centre for Dispute Resolution, London or such other body as the parties may agree from time to time to appoint such a mediator.

- 17.4 The Parties shall, within 14 days of the appointment of such an expert or mediator, meet with the expert or mediator to agree a programme for the exchange of any relevant information and the structure to be adopted during the alternative dispute resolution process.
- 17.5 The Parties agree that the decision of any expert appointed shall be final and binding (except on any points of law as opposed to fact) and that if any mediation results in a resolution of the dispute, such agreement shall be placed in writing and, once signed by the duly authorised representatives of both Parties, shall be final and binding (except on any points of law as opposed to fact).
- 17.6 The Parties shall bear their own costs arising from any such expert determination or mediation but shall share equally the costs of the expert or mediator.
- 17.7 The Parties agree that all negotiations connected with the dispute that do not result in a formal resolution of the matter shall be conducted in confidence and without prejudice to the rights of either Party in any future court proceedings.
- 17.8 Notwithstanding any dispute arising which is referred to a means of alternative dispute resolution under this clause or to the courts, the Agreement shall continue in force for the Licence Period, as shall the obligations on the Parties under this Agreement, unless the dispute concerns a matter which entitles the GPRD Group to terminate the Agreement under the provisions herein.
- 17.9 Notwithstanding the above provisions of this clause 17 the Licensor has the right to seek and obtain such urgent or interim relief as the Licensor deems appropriate in any court of competent jurisdiction.

## 18. **Notices**

- 18.1 All notices and other communications between the GPRD Group and the Customer relating to this Agreement shall be given by personal delivery or recorded delivery, or by facsimile transmission provided that a hard copy is subsequently sent by personal or recorded delivery, sent to the Parties' addresses as set out in the Schedule to this Agreement, or such other address as has been notified in writing to the other Party in accordance herewith.
- 18.2 Any notice delivered personally shall be deemed to have been received at the time of delivery, any notice given by recorded delivery shall be deemed to have been received two working days after the date of posting, and any notice given by facsimile transmission shall be deemed to have been received at the time when the sender's equipment records successful despatch.

## 19. **Entire agreement**

- 19.1 This Agreement and the Schedule hereto (over which the Agreement takes precedence) constitute the entire agreement between the GPRD Group and the Customer and supersede all prior negotiations, representations and undertakings, whether written or oral,

except that this clause shall not exclude liability in respect of any fraudulent misrepresentation.

20. **Assignment**

20.1 The Customer may not assign or otherwise sub-license or transfer its rights or obligations under the terms of this Agreement.

21. **Variation**

21.1 No amendments to this Agreement shall be effective unless made in writing and signed by duly authorised representatives of both the GPRD Group and the Customer, such variations to be agreed at the sole discretion of the GPRD Group.

22. **Severability**

22.1 If any part of any provision of this Agreement shall be held by a court of competent jurisdiction to be to any extent invalid or unenforceable that shall not affect the validity or enforceability of the remainder of that provision or of any other provision herein which shall continue in full force and effect as if this Agreement had been executed with the invalid or unenforceable provision or part eliminated.

22.2 In the event of a holding of invalidity so fundamental as to prevent the accomplishment of the purpose of this Agreement, the GPRD Group and the Customer shall immediately commence negotiations in good faith to remedy the invalidity.

23. **Waiver**

23.1 The failure of either of the GPRD Group or the Customer to exercise any right or remedy shall not constitute a waiver of that right or remedy.

23.2 No waiver shall be effective unless it is communicated in writing and notice delivered in accordance with clause 18 above.

23.3 A waiver of any right or remedy arising from a breach of this Agreement shall not constitute a waiver of any right or remedy arising from any other breach of this Agreement.

24. **Survival**

24.1 In addition to the restrictions on use in clauses 4 and 7, terms of this Agreement which from their nature or context it is contemplated that they are to survive termination, expiry or variation shall remain in full force and effect notwithstanding the termination, expiry or variation of this Agreement.

25. **Execution**

25.1 This Agreement shall be executed by first being signed by a duly authorised representative of the Customer, and then being signed by a duly authorised representative of the GPRD Group.

25.2 The date at which this Agreement is signed on behalf of the GPRD Group shall be the date of execution of the Agreement and that date shall be entered by the GPRD Group's signatory on the front page of this Agreement.

26. **Applicable law and Jurisdiction**

26.1 The law of England and Wales shall be the law applicable to this Agreement.

26.2 In relation to any legal action or proceedings to enforce this Agreement or arising out of or in connection with this Agreement ("proceedings") each of the Parties irrevocably submits to the exclusive jurisdiction of the English courts and waives any objection to proceedings in such courts on the grounds of venue or on the grounds that the proceedings have been brought in an inappropriate forum.

**IN WITNESS WHEREOF** this Agreement has been executed as an Agreement.

**Signed** on behalf of  
**The Secretary of State for Health**  
by its duly authorised officer:

---

Name (please print): Mr J Ford  
Date:

**Signed** on behalf of  
**the Customer**  
by its duly authorised officer:

---

Name (please print):  
Date:



## SCHEDULE

### SCHEDULE TO AGREEMENT FOR PRODUCTION, SUPPLY AND USE OF DATASET FROM THE GENERAL PRACTICE RESEARCH DATABASE FOR A SINGLE STUDY

1. **Description of the Dataset to be supplied under the Agreement**

1.1 The GPRD Group shall produce and supply a Dataset for the Customer's use solely under the terms of this Agreement which is described at Annex A.

2. **Nature of the Study**

2.1 The Customer shall, on receipt of the Dataset and in accordance with the terms of this Agreement, conduct a Study in accordance with the Protocol number xxxx submitted to and approved by ISAC (a copy of which is appended hereto as Annex B) as follows:

3. **Delivery Plan and costs**

Delivery of data n date or 20 working days after licence signed date, whichever is later.

**Cost of study**

4. **Notices**

4.1 The addresses to which notices may be given by the Parties under the provisions of clause 18 of the Agreement are as follows:

(A) For the GPRD Group

Address:

The GPRD Group,  
Medicines and Healthcare products Regulatory Agency,  
151 Buckingham Palace Road,  
London, SW1W 9SZ,  
United Kingdom.

For the attention of: Jon Ford

Facsimile number:  
+44 020 3080 6041

Email address:  
jon.ford@gprd.com

(B) For the Customer

Address:

***[Please Insert]***

For the attention of:

***[Please Insert]***.

Facsimile number: (***[Please Insert]***)

E-mail: ***[Please Insert]***

4.2 In cases of emergency the Parties may be contacted by telephone as follows:

(A) For the GPRD Group:

GPRD Group Reception: +44 020 3080 6206

(B) For the Customer: ***[Please Insert]***

## **ANNEX A: Description of Data to be Provided**

## **Annex B – ISAC Protocol**