

Draft:

Research Services Agreement

between

The Secretary of State for Health

Acting through the GPRD Group of the MHRA

and

[enter legal name].

as Customer

relating to

Production and Supply of a Report of a Study conducted
using the General Practice Research Database

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THIS AGREEMENT is made

BETWEEN:

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

Background:

- (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 offering to conduct non-profit-making research using the Database in accordance with the terms and conditions referred to below.
- (2) The Customer wishes to engage the GPRD Group to conduct a single study for non-profit-making Medical and Health Research Purposes using Data from the Database to be conducted in accordance with a protocol approved by the Independent Scientific Advisory Committee.
- (3) The GPRD Group has agreed to conduct the Study and produce a Report setting out the results of the Study for the Customer and the Customer will be licensed to use the Report thereafter in accordance with the terms and conditions of this Agreement.

NOW IT IS HEREBY AGREED as follows:

1. **Interpretation**

- 1.1 In this Agreement (the "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 using VAMP Medical (also known as VM) software or Vision software 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;
Effective Date	The date set out in Section 2 of Schedule 1 for commencement of the Study;
Fee	The fee payable by the Customer for the production of and right to use the Report of the Study as specified in Schedule 1;

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;
Marketing Authorisation Holder	The holder, in one or more countries, of an authorisation, licence or approval necessary to market or place on the market a medicinal product in one or more countries, including without limitation the United Kingdom or the European Union;
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 ISAC and annexed to the Schedule in accordance with which the Study is to be conducted;
Report	The results of the Study which are to be provided to the Customer in writing by the GPRD Group under this Agreement as described in the Schedule hereto;
Independent Scientific Advisory	The body or any successor body nominated by the GPRD Group to review the scientific acceptability of

Committee or ISAC	studies at the GPRD Group's request;
Study	The single study for non-profit-making Medical and Health Research Purposes which is to be performed by the GPRD Group under this Agreement as described in the Schedule;
Work Plan	The timing, sequence and work schedule for the Study as set out in Section 2 of Schedule 1.

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. **Scope of Agreement**

- 2.1 Subject to the terms of this Agreement and in consideration of the payment in full by the Customer of the Fee the GPRD Group shall conduct the Study, produce the Report and deliver it to the Customer for use all in accordance with the Work Plan, the tables and information described in Schedule 2, and the licence in clause 7.
- 2.2 The Parties acknowledge that the times and dates specified in the Work Plan are indications only and the GPRD Group shall not be liable in any form whether in contract, tort (including negligence) or otherwise for any delay in conducting the Study or producing or delivering the Report.

3. **Conduct of Study and Production of Reports**

- 3.1 The GPRD Group will use reasonable endeavours to commence work on the Study on or after the Effective Date.
- 3.2 The GPRD Group will use reasonable endeavours to conduct the Study and deliver the Draft Report to the Customer in accordance with the Work Plan.
- 3.3 The format of the draft Report will be agreed in advance in writing by the Parties. The Customer shall provide the GPRD Group with any comments which it may have upon the first draft of the Report or, if it has no comments, shall inform the GPRD Group to that effect, within 15 working days of receipt. If the Customer provides any such comments on the draft Report content the GPRD Group shall be entitled, at its sole discretion, to amend the Report as it sees fit and re-submit the revised Report to the Customer. The GPRD Group will make changes to the format of the Report as reasonably requested by the Customer.
- 3.4 The Customer acknowledges and agrees that the Report shall not represent the opinions or conclusions of the Medicines and Healthcare Products Regulatory Agency as an Executive Agency of the Department of Health as executive arm of the UK Licensing Authority and the contents of the Report

will be non-binding on the Medicines and Healthcare Products Regulatory Agency in this capacity.

- 3.5 The GPRD Group shall retain any computer files or datasets used during the conduct of the Study and the production of the Report for a minimum of 5 years following their completion for reference purposes in the event that the Customer during that period raises any queries concerning them.

4. **Changes to Study**

- 4.1 If during the course of the Agreement the Customer wishes to alter the Study in any way the Customer shall give notice to the GPRD Group of the proposed change.

- 4.2 The GPRD Group shall advise the Customer within a reasonable time of receiving the Customer's request for a change and in its sole discretion whether the proposed change falls outside the scope of the Protocol and if it considers the proposed change to fall within the scope of the Protocol of the anticipated additional work, costs and impact on the Work Plan. The Customer shall within a reasonable time of the response from the GPRD Group, indicate, whether:

(A) in the case that a proposed change falls outside the scope of the Protocol it wishes the GPRD Group to proceed with an application to ISAC to amend the Protocol or wishes to abandon the proposed change;

(B) in the case that a proposed change falls within the scope of the Protocol it wishes to proceed with the change and amend the Work Plan and Fee accordingly or wishes to abandon the proposed change.

- 4.3 If the Customer wishes to pursue a change that requires a change to the Protocol, the GPRD Group shall, on the Customer's behalf, re-submit a revised Protocol to ISAC for review. The GPRD Group shall advise the Customer within a reasonable time of receiving a decision from ISAC, whether the proposed change to the Protocol has been approved by ISAC or not and if the change has been approved the anticipated additional work, costs and impact on the Work Plan. The Customer shall within a reasonable time of the notice from the GPRD Group, indicate, whether:

(A) in the case that a proposed change has been approved by ISAC, it wishes to proceed with the Study on the basis of the amended Protocol or wishes to abandon the proposed change; or

(B) in the case that the proposed change has not been approved by ISAC, whether it wishes to abandon the proposed change or proceed on the basis of the unamended Study.

- 4.4 If the Customer wishes to proceed with the Study amended pursuant to either clause 4.2 or clause 4.3 the Study, the Work Plan and the Fee shall be amended accordingly.

4.5 The Customer acknowledges that whether or not the proposed change results in a change to the Study, the GPRD Group shall be entitled to payment for all time and expenses incurred as a result of or in connection with a proposed change on the basis of the calculation of additional fees for the Study, which shall be added to the Fee.

4.6 The GPRD Group's obligations under clause 3.2 above shall be suspended pending ISAC's decision and the Agreement shall then either continue without any change or be varied or terminated as appropriate. For the avoidance of doubt, if the Agreement is varied the Fee payable and the time periods for delivery of the Report under the Agreement may also be varied. Notwithstanding the provisions of clause 4.4 above, in the event that ISAC approves the proposed change to the Protocol under clause 4.3, the GPRD Group shall be under no duty to re-commence its work hereunder unless and until an amended Fee is agreed between the Parties.

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

5.1 The Customer shall make the payment of the Fee upon receipt of an invoice from the GPRD Group, with payment due within 30 days of the receipt of an invoice.

5.2 The Customer 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. Invoices shall be made as specified in Schedule 1, Sections 2.3 and 2.4 which shall be modified in the event of a change in the applicable legal requirements.

6. **Consequences of Late Payment**

6.1 In the event of a delay in payment, interest after due date will be charged at a rate of 0.25% above the London Interbank Offered Rate (LIBOR). The date of the payment order will be taken to be the day of payment.

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 granted under clause 7.1 without notice until payment (including interest) is made. Whether or not the GPRD Group chooses 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 45 day period from the date of the invoice for payment has expired, the GPRD Group may terminate the licence granted under clause 7.1 and this Agreement without further notice.

7. **Use of Report**

7.1 Subject to clause 7.2 the GPRD Group grants the Customer an exclusive and perpetual licence to use and make copies of the Report and to sublicense Affiliated Companies and other third parties to use and make copies of the

Report, solely for Medical and Health Research Purposes on a non-profit-making basis, without payment of any copyright royalties to the GPRD Group, which, for the avoidance of doubt, shall not prevent the Customer (a) from recovering its reasonable direct operating costs associated with that research and (b) from recovering a profit from any application of the results in the report provided that such profit is only attributable to the value added by the Customer in its further analysis or interpretation of the Data in the report.

7.2 The licence granted under clause 7.1 is subject to the following restrictions and conditions:

- (A) it is the responsibility of the Customer to ensure that any of its Affiliated Companies or any other third party to whom it grants access to the Report are aware of and comply with the obligations and the restrictions in respect of the use of the Report as set out in this Agreement;
- (B) the Customer shall not and shall ensure that its Affiliated Companies and any other third parties shall not make any adaptation of the Report (an "Adaptation") or, save as permitted pursuant to clause 7.1, issue to the public or otherwise publish any work reproducing the Report or any part of it or any Adaptation;
- (C) the Customer shall not permit the Affiliated Companies or any third party to do any of those acts described in clause 7.2(B);
- (D) any act or omission of any Affiliated Company or other third party which would have been a breach of this Agreement if such Affiliated Company or other 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; and
- (E) the Customer, if a Marketing Authorisation Holder in respect of any product which is the subject matter of the Report, shall discharge fully any of its statutory, legal or regulatory reporting requirements world wide and indemnify the GPRD Group from any liability it may incur from the Customer's failure to fully discharge such statutory, legal or regulatory duties world wide in respect of any findings in the Report and in particular in respect of any pharmacovigilance requirements.

7.3 The GPRD Group may suspend or terminate with immediate effect the licence granted under clause 7.1 and require the return of the Report and all copies thereof:

- (A) 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; or
- (B) if the GPRD Group reasonably believes that the Customer, its Affiliated Companies or any third parties to whom the Customer has distributed the Report may be using the Report for any purpose not

authorised by this Agreement. If the GPRD decides to suspend the licence granted under clause 7.1 such suspension will be lifted on the GPRD Group being satisfied that the Report has not been used for an unauthorised purpose; or

- (C) if any invoice is not paid within 45 days pursuant to clause 5.1; or
- (D) in any circumstances under which the GPRD Group has the right to terminate this Agreement pursuant to clause 13.

7.4 Subject to clause 7.5 no compensation will be paid by the GPRD Group nor will the Fee be rebated for any suspension of the licence granted under clause 7.1.

7.5 The restrictions on using and copying the Report shall survive the termination, variation or expiry of the Agreement (subject to clause 7.3).

8. **Confidentiality**

8.1 Subject to the rights granted under clause 7 and the provisions of clauses 8.2 and 9.2 below, the GPRD Group shall not without the prior written consent of the Customer release or otherwise make available to third parties information relating to the Agreement or the Study.

8.2 Each Party shall at all times use its best endeavours to keep confidential (and to procure that its employees and agents shall keep confidential) any information which is marked as confidential or stated to be confidential by the other Party which it or they may acquire during the course of this Agreement in relation to the business and affairs of the other Party, and shall not disclose such information except with the consent of the other Party, or where expressly ordered to do so by a court of competent jurisdiction, or under any governmental request, law or regulation, or in connection with any legal proceedings arising out of this Agreement, or where such disclosure may otherwise be lawful.

8.3 The obligations of each of the Parties contained in clause 8.2 above shall continue without limit in point of time, save that they shall cease to apply to any such information which comes into the public domain otherwise than by a breach by either Party of its obligations under this clause.

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, including copyright, in the Data, the Study and/or the Report, or any part thereof, 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, save to the extent that the Customer is granted the right to use, copy and distribute the Report under clause 7.

9.2 The GPRD Group shall have the right, to submit for publication the Study findings after delivery of the final Report to the Customer,. Journal requirements on disclosure of funding sources will be adhered to by the

GPRD Group. The GPRD Group will send a copy of any such publication, including any abstract, to the Customer, at least 30 working days before the proposed date of submission for publication, for the Customer's comment. All Customer comments shall be considered before submission, and GPRD agrees to reasonably delay any such publication upon Customer's reasonable request (e.g. preparation of own publication etc.). Nothing in this Agreement shall be interpreted as precluding the GPRD Group from conducting research on the same topic as is covered by the Study as may be commissioned by other parties.

- 9.3 Copyright in any independent reports produced by the Customer, or any other Intellectual Property Rights, arising from the Customer's use of the Report in accordance with this Agreement shall belong to the Customer. However, prior to seeking publication of any document arising from use of the Report the Customer shall seek the consent of the GPRD Group, such consent not to be unreasonably withheld. If no comments are provided by the GPRD Group within 30 working days of receipt of the draft report the Customer may proceed with the publication. Any such publication shall include the statement *"This report has been produced with reference to a study conducted, and a report produced, by the General Practice Research Database Group within the UK Medicines and Healthcare products Regulatory Agency using the General Practice Research Database. However, the interpretation and conclusions contained in this report are those of the author/s alone"*.
- 9.4 The Customer shall send a copy of any publication including any abstract arising from use of the Report under this Agreement to the GPRD Group within 2 weeks of publication.
- 9.5 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 Report. If the Customer copies the Report pursuant to clause 7.1, it shall ensure that any such proprietary or rights notices are fully reproduced in any copies, and it shall procure that any Affiliated Companies or other third parties who copy the Report as per clause 7.1 fully reproduce any such proprietary or rights notices in any copies.
- 9.6 The Customer shall notify the GPRD Group immediately if the Customer becomes aware of any unauthorised use or copying of any part of the Report by any person.

10. **Warranties and Indemnity by Customer**

- 10.1 The Customer warrants to the Licensor that:
- (A) The Customer has the requisite power and authority to enter into and perform its obligations under this Agreement; and
 - (B) This Agreement constitutes binding obligations of the Customer 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 out of a breach caused by the act or omission of any of the Customer's Affiliated Companies or any third party, including, but not limited to, any failure to draw any third party's attention to the notice set out in clause 9.3 and the disclaimer in clauses 11.2 and 11.3 or any infringement or alleged infringement of Intellectual Property Rights held by any third party.

11. Limitation of Liability and Disclaimer

11.1 Except as specified in this Agreement, the provisions of this clause 11 specify the entire liability of the GPRD Group arising out of this Agreement whether arising in contract, tort (including negligence) or otherwise.

11.2 Subject to clause 11.7, the Customer acknowledges that, although the Report shall be produced by the GPRD Group based on the specification in the Schedule, it is the Customer's responsibility to ensure that the nature of the Data meet the Customer's requirements for conducting the Study. The GPRD Group does not give medical or other professional advice and the Report does not constitute such advice. The GPRD Group does not accept any liability for any decisions the Customer makes in consequence of or in connection with the Report whether in respect of its business, operations, medical analyses or otherwise and the Customer accepts sole responsibility and liability for any actions it chooses to take in consequence of or in connection with the Report.

11.3 Subject to clause 11.7 the Customer acknowledges that the Report made available under this Agreement is provided "as is", without any representation or endorsement made and, to the extent permitted by law, without warranty or condition of any kind, whether express or implied, statutory or otherwise, including but not limited to implied terms of satisfactory quality, fitness for a particular purpose, or as to the use of reasonable skill and care, as may be appropriate. In particular, 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 which may affect the Study, nor does it warrant that any such errors, omissions or inaccuracies will be corrected.

11.4 Subject to clause 11.7 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 the Customer or any clients of the Customer arising out of or in connection with the use of the Study and/or the Report.

11.5 Subject to prior written agreement on the format of the Report as indicated in Article 3.3. herein above, the GPRD Group shall be entitled to supply the Report in such electronic form as the GPRD Group may in its sole discretion elect. If the GPRD Group so elects, the GPRD Group warrants that the electronic form supplied is free from defective workmanship. Subject to clause 11.7, if the electronic form is 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 form as available from its manufacturer and the Customer's sole remedy shall be to have a new copy of the Report supplied after return of the old Report to the GPRD Group.

- 11.6 Subject to clause 11.7 and notwithstanding anything 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 part of the Fee paid by the Customer in respect of time spent in preparing the Report but excluding any part of the Fee relating to the use or licensing of the Data.
- 11.7 Notwithstanding clauses 11.1 to 11.6 above, the liability of each Party to the other for death or personal injury resulting from its own negligence shall not be limited.
- 11.8 The Customer acknowledges and agrees that the allocation of risk and liability contained in this Agreement is reasonable in all the circumstances.

12. **Force Majeure**

- 12.1 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.
- 12.2 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.
- 12.3 Where a Party is unable to perform any or all of its obligations under this Agreement (except for payment obligations) 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 the licence fees shall not be rebated.
- 12.4 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.

13. **Termination**

- 13.1 If the Customer commits any 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.

13.2 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 this Agreement forthwith by notice in writing to the Customer.

13.3 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.

14. **Consequences of Suspension or Termination**

14.1 If this Agreement is terminated or the licence granted under clause 7 is terminated for any reason the Customer will return the Report and any other information obtained by the Customer or its Affiliated Companies under this Agreement to the GPRD Group within 4 weeks and destroy any copies which it or its Affiliated Companies may have made of the Report and any other information obtained by the Customer or its Affiliated Companies under this Agreement, and shall use reasonable endeavours to have returned all copies of the Report which it may have distributed to any third parties, or authorised any third parties to make. Unless otherwise expressly agreed by the GPRD Group, the Customer agrees that following termination or suspension as described above it will make no further use of the Report and shall obtain written confirmation from its Affiliated Companies and any third parties to whom it may have distributed the Report that they will not thereafter use the Report or any of its contents. The Customer shall issue a certificate within 6 weeks of termination that it has fully complied with its obligations under this clause 14.1.

14.2 If the GPRD Group terminates this Agreement under clause 13, 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 and the Customer shall pay the GPRD Group on the basis of time and materials together with all reasonable costs and expenses duly justified and expended up to and including the date of termination, calculated on the reasonable rates and charges charged by the GPRD Group for its services.

15. **Alternative Dispute Resolution**

15.1 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.

15.2 If the dispute is not resolved at the meeting referred to in clause 15.1 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 25.2.

- 15.3 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.
- 15.4 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.
- 15.5 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).
- 15.6 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.
- 15.7 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.
- 15.8 Notwithstanding any dispute arising which is referred to a means of alternative dispute resolution under this clause or to the courts, this Agreement shall continue in force, 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.
- 15.9 Notwithstanding the above provisions of this clause 15 the GPRD Group has the right to seek and obtain such urgent or interim relief as the GPRD Group deems appropriate in any court of competent jurisdiction.

16. **Notices**

- 16.1 All notices and other communications between the Parties relating to this Agreement shall be given by recorded delivery or by facsimile transmission provided that a hard copy is subsequently sent by 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. A copy of any such notice issued by the GPRD Group shall be sent to the Customer's Legal Department, at the address set out in the schedule to this Agreement.

16.2 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 dispatch.

17. **Entire agreement**

17.1 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.

18. **Assignment**

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

19. **Variation**

19.1 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.

20. **Severability**

20.1 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 the Agreement had been executed with the invalid or unenforceable provision or part eliminated.

20.2 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.

21. **Waiver**

21.1 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.

21.2 No waiver shall be effective unless it is communicated in writing and notice delivered in accordance with clause 16 above.

21.3 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.

22. **Survival**

22.1 In addition to the restrictions on use in clause 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.

23. **Execution**

23.1 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.

23.2 The date at which the 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.

24. **Contracts (Rights of Third Parties) Act 1999**

24.1 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 other third parties.

25. **Applicable Law and Jurisdiction**

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

25.2 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.

London, _____
Signed on behalf of
The Secretary of State for Health
by its duly authorised officer:

Name Jon Ford

Signed on behalf of
[enter company name].
by its duly authorised officer:

Name (please print):

3. **Description of the Report to be supplied under the Agreement**

To be supplied

4. **Notices**

4.1 The addresses to which notices may be given by the Parties under the provisions of clause 16 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:

Email address:

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

(A) For the GPRD Group:

GPRD Group Reception: +44 20 3080 6206

For the Customer: Phone