EXHIBIT 10.148

CONFIDENTIAL TREATMENT REQUESTED. CONFIDENTIAL PORTIONS OF THIS DOCUMENT HAVE BEEN REDACTED AND HAVE BEEN FILED SEPARATELY WITH THE U.S. SECURITIES AND EXCHANGE COMMISSION

COLLABORATIVE RESEARCH AND LICENSING AGREEMENT

This Agreement is made the 26th day of July 2005

BETWEEN

Medical Research Council, whose principal place of business is 20 Park Crescent, London W1B 1AL ("MRC").

AND

Indevus Pharmaceuticals, Inc., a Delaware corporation whose principal place of business is 33 Hayden Avenue, Lexington, MA 02421-7971 USA ("Indevus").

WHEREAS

MRC is responsible for managing a Microbicides Development Programme based on the MRC Grant number G0100137 entitled 'Vaginal microbicides for the prevention of HIV transmission' (appended at **Schedule 1** to this Agreement).

The MRC Clinical Trials Unit located in London has recognised expertise in the field of clinical trials with the overall objective of developing effective preventive and therapeutic interventions for HIV infection in adults and children and Dr Sheena McCormack of the Unit is one of two Grant Holders (the other being Dr Charles Lacey of Hull York Medical School, University of York) on MRC Grant number G0100137.

Indevus has developed a topical formulation of its naphthalene sulphonic acid formaldehyde condensate antiviral product (PRO 2000) which formulation is under evaluation as a topical microbicide for the prevention of HIV infection and Indevus desires that PRO 2000 shall be included in the Phase III Clinical Trial included in the Programme and in consideration thereof is willing to supply its product and matching placebo to the clinical centres participating in the Phase III Clinical Trial and is willing to have PRO 2000 evaluated in the Phase III Clinical Trial under the terms and conditions set out in this Agreement.

The clinical centres (in Africa and the UK) and the non-clinical centres currently participating in the Programme are detailed in **Schedule 4** to this Agreement. The number and identity of these centres may be amended from time to time by decision of the Programme Management Board ("PMB") or the Programme Liaison Group ("PLG") subject to the terms and conditions set out in this Agreement.

IT IS AGREED AND DECLARED AS FOLLOWS:

DEFINITIONS

"Affiliate":	means (i) any corporation or business entity of which more than fifty percent (50%) of the securities or other ownership interests representing the equity, the voting stock or general partnership interest are owned, controlled or held, directly or indirectly, by a Party; (ii) any corporation or business entity which, directly or indirectly, owns, controls or holds more than fifty percent (50%) (or the maximum ownership interest permitted by law) of the securities or other ownership interests representing the equity, voting stock or general partnership interest of a Party or (iii) any corporation or business entity of which a Party has the right to acquire, directly or indirectly, at least fifty percent (50%) of the securities or other ownership interests representing the equity, voting stock or general partnership interest thereof.
"Analysis Databases":	means the databases held at CTU containing data from the Centres Databases to be used in the main analysis of the Phase III Clinical Trial;
"Analysis Plan":	means the plan agreed by the Trial Steering Committee (which will be amended from time to time as required) indicating the minimum analyses to be carried out relating to the Phase III Clinical Trial for preparation of the Main Master File;
"Background":	means in respect of each party, the Intellectual Property Rights owned and/or Controlled by that party at the Commencement Date and all Intellectual Property Rights which that party may subsequently develop, acquire, own and/or have licensed to it which arise outside and independently of the Programme and which they are free to utilise in accordance with this Agreement;
"the Centres":	means the clinical and non-clinical centres participating in the Programme as detailed in Schedule 4 to this Agreement, as amended from time to time by decision of the Programme Management Board or the Programme Liaison Group;
"Centres Databases":	means all the data which are entered onto computer from the various sources of Trial Data at the Centres;
"CFR":	means the United States Code of Federal Regulations;
"Commencement Date":	means the date of this Agreement;
"Control":	means the possession of the ability to grant a license as provided for herein without violating the terms of any agreement with any third party.
"Confidential Information":	means in relation to each party any information relating to such party's Background, business methods, suppliers, finances, ideas, strategies, concepts, methodologies, inventions, processes, specifications, marketing plans, formulae and/or products;

"CTU":	means the UK MRC Clinical Trials Unit located in London.
"Current Good Manufacturing Practice":	means current Good Manufacturing Practices to the extent applicable to Product (i) as defined in Parts 210 and 211 of Title 21 of the CFR, as may be amended from time to time, or any successor thereto, and (ii) as required by applicable guidelines in countries other than the United States.
"DFID":	means H M Government's Department for International Development;
"Draft First Full Report":	means the draft report based on the Main Master File describing the main objectives of the Phase III Clinical Trial and the outcomes and intended for publication, prepared by a writing group appointed by the Trial Steering Committee;
"Draft Supplementary Reports":	means any draft reports based on any Supplementary Master Files intended for publication subsequent to publication of the First Full Report, prepared by a writing group appointed by the Trial Steering Committee;
"FDA"	means the United States Food and Drug Administration and any successor agency having substantially the same function;
"Field":	means the field of prevention of HIV infection in humans;
"First Full Report":	means the final published report based on the Main Master File describing the main objectives of the Phase III Clinical Trial and the outcomes;
"the Grant":	means MRC Grant number G0100137 entitled 'Vaginal microbicides for the prevention of HIV transmission' (appended at Schedule 1 to this Agreement;
"the Grant Holders":	means Dr Sheena McCormack of the MRC Clinical Trials Unit and Dr Charles Lacey of Imperial College London;
"Independent Data Monitoring Committee":	means the committee responsible for reviewing the accrued safety and efficacy data during the Phase III Clinical Trial, monitoring the overall progress of the trial, and providing advice on the conduct of the Phase III Clinical Trial to the Trial Steering Committee;
"IND":	means Indevus' investigational new drug application (as defined in 21 CFR Section 312.3) number 56962, and any amendments thereto, as filed with the FDA;
"Intellectual Property Rights":	means any patent, copyright, design rights, trademark, Know-How, any rights in respect of any Confidential Information or other industrial and/or intellectual property right (whether registered or unregistered) subsisting

throughout the world and any application and/or right to apply for any of such rights that are necessary or useful for the development, manufacture or commercialization of the Product;

"Investigator":	means the person at each Centre responsible for the conduct of the Programme at that Centre;
"Investigators' Brochure":	means the brochure relating to the Product (and matching placebo) and their use, storage and handling, to be supplied by Indevus to MRC under this Agreement;
"Know-How":	means any confidential know-how, methodologies, formulae, processes, data and/or expertise (including but not limited to any relating to manufacture, production, storage, handling and/or use of Products) that are necessary or useful for the development, manufacture or commercialization of the Product;
"Main Master File":	means a full set of analyses on which the Draft First Full Report and First Full Report for publication shall be based and prepared pursuant to the agreed Analysis Plan and shall include the Protocol and any additional definitions;
"MRC's authorised representative":	means Ian Viney of MRC Centre London, Stephenson House, 158-160 North Gower Street, London NW1 2ND; Tel: +44 (0)20 7670 4625; Fax : +44 (0)20 7670 4690;
"Net Sales":	means the gross amount invoiced by Indevus from sales of Product to Third Parties outside the Territory commencing upon the date of first commercial sale outside the Territory after deducting the following:

(a) credits, allowances, recalls, samples, discounts and rebates to, and chargebacks from the account of, Third Party customers or on account of returned or rejected Product, including allowance for breakage or spoilage;

(b) freight, postage, shipping and insurance costs;

(c) trade discounts, cash discounts, quantity discounts, rebates and retroactive price reductions;

(d) sales, value-added, excise and other taxes incurred in connection with the sale of Product and customs duties, custom broker charges and other surcharges and governmental charges incurred in connection with the exportation or importation of Product;

(e) rebates, chargebacks or similar payments or credits granted to managed health care organizations, wholesalers, distributors, buying groups, health care insurance carriers, pharmacy benefit management companies, health maintenance organizations, or other institutions or health care organizations or to any governmental or regulatory authority in respect of any state, provincial, local or federal Medicare, Medicaid or

similar programs in any country, their agencies and purchasers and reimbursers; and

(f) bad debt expense.

Sales or other transfers by Indevus, its Affiliates or sublicensees in the Territory shall be excluded from the computation of Net Sales and no payments will be payable on such sales or transfers. Sales or other transfers between Indevus and its Affiliates shall also be excluded from the computation of Net Sales and no payments will be payable on such sales or transfers except where such Affiliates are end users, but Net Sales shall include the subsequent sales by such Affiliates to Third Parties outside the Territory.

"Phase III Clinical Trial":	means the Phase III Clinical Trial included in the Programme, the Protocol of which is appended as **Schedule 6;**
"the Product":	means PRO 2000 gel and any other Indevus products derived from or incorporating PRO 2000 to the extent that such products are used in the Phase III Clinical Trial;
"the Programme":	means the Microbicides Development Programme based on the Grant;
"the Programme Liaison Group":	means the body responsible for the overall co-ordination of the Programme on a day to day basis, overseeing finances and administration;
"the Programme Management Board":	means the body responsible for the overall management of the Programme;
"Protocol":	means the Phase III Clinical Trial protocol entitled 'An international multicentre, randomised, double-blind, placebo-controlled trial to evaluate the efficacy and safety of 0.5% and 2% PRO 2000/5 gels for the prevention of vaginally acquired HIV infection', appended as Schedule 6 to this Agreement;
"Royalty Term":	means ten (10) years commencing from the date of first commercial sale of Product outside the Territory with respect to sales by Indevus;
"SAE":	means any serious adverse event as defined in the Phase III Clinical Trial Protocol, including but not limited to death, serious injury, serious adverse reaction and/or any other effect materially adverse to human health and in any event shall have the meaning of Serious Adverse Drug Experience set forth in the ICH Harmonised Tripartite Guideline for Good Clinical Practice;
"Summary of Main Initial Findings":	means a written report comprising a summary of the main findings of the Phase III Clinical Trial and the main conclusions supported by the initial analysis of the Trial Data pursuant to the Analysis Plan and intended for early release pending the preparation of the First Full Report;

"Supplementary Master File":	means a set of analyses on which any Draft Supplementary Reports for publication from the Trial Steering Committee shall be based and prepared pursuant to the agreed Analysis Plan;
"Territory":	means those countries defined from time to time by the World Bank as having "low-income economies" (or a mutually acceptable equivalent list of countries, if such World Bank lists are discontinued) together with additional countries as agreed between the Parties, as listed in **Schedule 5**, provided, however, that if countries that are not listed on **Schedule 5** are subsequently defined as having "low-income economies", the inclusion of such additional countries in the Territory shall be subject to the mutual agreement of Indevus and MRC. The term "Territory" shall permanently include those countries in Africa in which any of the clinical Centres participating in the Programme are situated, regardless of those countries' status on the World Bank list referred to above;
"Trial Data":	means case record forms and related material (including copies of correspondence, hospital and clinic notes and discharge summaries, relevant information from telephone conversations and site visits) on individual participants received from the Centres and laboratory results obtained from the laboratories participating in the Phase III Clinical Trial. All such data will be anonymous;
"Trial Management Group":	means the body charged with the general management of the activities relating to the Phase III Clinical Trial.
"Trial Steering Committee":	means the committee to be established prior to the Phase III Clinical Trial to review progress of the trial.

COMMENCEMENT AND TERMINATION

1. This Agreement will take effect from the 26th July, 2005 and continue until expiration of the Royalty Term unless extended by mutual agreement recorded in writing and signed by authorised representatives of both parties and except to the extent certain provisions herein provide for expiration of such provisions beyond such date.
2. This Agreement may be terminated on thirty (30) days' written notice by either party if the other party:

   (a) fails to make any payment to the other party when due; or

   (b) breaches the terms of this Agreement (and, where the breach is capable of remedy, has not remedied the breach within thirty (30) days of receiving notice requiring the breach to be remedied); or

   (c) persistently breaches the Agreement; or

   (d) suffers a material event of insolvency.
3. This Agreement may be terminated immediately on written notice by either party on the recommendation of the Independent Data Monitoring Committee.

OBLIGATIONS OF INDEVUS UNDER THIS AGREEMENT

(A) General

4. Indevus grants a non-exclusive, non-transferable licence to MRC of Indevus' Intellectual Property Rights in the Product with the right to sub-license to the Centres, solely for the purpose of using the Product in the Phase III Clinical Trial of the Programme at the Centres in the Field pursuant to the Protocol.

5 Indevus shall supply sufficient quantities of the Product and matching placebo required for all the Centres participating in the Phase III Clinical Trial for the duration of the Programme at no cost for the supply of Product or placebo or their shipment to the main storage facility, as specified in the Protocol and any written Protocol amendments submitted as amendments to the IND, up to a maximum number of **[*]** doses of the Product at each strength and **[*]** doses of matching placebo (unless both parties' authorised representatives agree in writing that Indevus shall supply an increased number of doses of Product and/or matching placebo). MRC and Indevus shall be jointly responsible for storing the Product and matching placebo at the main storage facility and distributing the Product and matching placebo to the Centres in accordance with the Protocol and any mutually agreed Protocol amendments submitted as an amendment to the IND with the related responsibilities and obligations of the parties to be set forth in a separate agreement among Indevus and MRC and the main storage facility.The Product and matching placebo shall be shipped in the quantities and at the intervals agreed to by both parties in good faith as quickly as reasonably practicable following receipt by Indevus of all documentation necessary to assure compliance with all applicable laws and regulations. Indevus may refrain from shipment of the Product and matching placebo to the storage facility or to one or more of the Centres if prohibited from doing so by any relevant regulatory authority. Indevus shall ship the Product and matching placebo only to Investigators participating in the Phase III Clinical Trial as referenced in 21 CFR 312.50, and may at its discretion discontinue shipments to Investigators who fail to comply with applicable regulations.

6. Indevus shall supply the Investigators' brochures to the Centres at no cost.

7. If requested by the CTU or by any of the Centres, Indevus shall supply guidance on handling and storage of the Product and matching placebo.

8. When the Programme is completed or is terminated prior to completion the Centres shall arrange either (at Indevus's election) for the destruction (without cost to Indevus) or return to Indevus (at Indevus's cost) of any unused Product and matching placebo in accordance with the Protocol and all applicable legal requirements and the requirements of any relevant regulatory authorities.

9. Indevus agrees to take such steps as it considers in good faith to be commercially practicable and reasonable to assist in ensuring that the Product can become available to all communities who have a need for the Product, including developing countries' markets as well as major commercial markets, subject to the following:

(a) In the case of countries in the Territory, Indevus agrees that:

(i) the Product and/or Indevus' Intellectual Property Rights will be made available under licence to DFID and/or the MRC or their appointed agents solely for distribution and use of the Product in the Field in any countries in the Territory as set forth in the following sentence and in a separate supply agreement to be negotiated in good faith between Indevus and the MRC. The supply agreement will provide that the Product will be made available to DFID and/or the MRC or their appointed agents free on board at Indevus' (or its designee's) manufacturing facility, in

[*] CONFIDENTIAL TREATMENT REQUESTED

exchange for which the MRC or the DFID will pay Indevus an amount equal to Indevus' total cost of goods sold plus **[*]** %, and will include other terms relating to such supply, including terms relating to forecasts, orders, delivery and payments, to be mutually agreed to in good faith.

In the event that Indevus is unable or unwilling to supply sufficient Product to satisfy demand within any country in the Territory, Indevus will, at the request of DFID or the MRC, licence DFID or the MRC or their appointed agents, which may be an aid agency or other appropriate party (the "Proposed Licensee") under Indevus' Intellectual Property Rights the right to manufacture the Product in any country solely for distribution and use of the Product in the Field in the Territory. The terms and conditions of this license will be set forth in a license agreement to be negotiated in good faith between Indevus and the Proposed Licensee, which will include compensation to Indevus in consideration of the grant of such license. In negotiating these terms and conditions, Indevus and the Proposed Licensee will take into account and consider the importance of making the Product available at preferential prices in the Territory as well as a fair return to Indevus.

(b) Indevus' obligations under this Agreement are in all cases subject to receipt of all regulatory authorizations and approvals required in any of the applicable countries to manufacture, use, sell and/or import Product, as required, and are expressly conditioned upon the absence of any adverse condition or event relating to the safety or efficacy of Product, including the absence of any action by any regulatory authority preventing or limiting the development, manufacturing or commercialization of Product.

(B) Subcontracting or transfer of rights and obligations

10. Indevus shall not subcontract any of its activities under the Programme other than to an Affiliate without first notifying the MRC's authorised representative in writing. MRC acknowledges that Indevus has notified MRC that Indevus is subcontracting to third parties the manufacture, shipping, storage and distribution of Product and placebo contemplated by paragraph 5 above. Indevus shall remain liable for the actions and/or any defaults of its subcontractors as if they were the actions and/or defaults of Indevus itself under this Agreement.

11. Indevus shall not assign this Agreement without the advance written agreement of the MRC's authorised representative, such agreement not to be unreasonably withheld or delayed, provided however, that Indevus may assign this Agreement to an Affiliate or in connection with the transfer or sale of its business or all or substantially all of its assets or in the event of a merger, consolidation, change in control or similar corporate transaction, without such consent ("the Proviso"). In the event of a proposed assignment of this Agreement in circumstances other than covered under the Proviso above, the assignee shall assume Indevus's obligations under this Agreement and, provided that such assignee does so, the MRC shall not withhold consent to the assignment.

(C) Warranties and Indemnity

12. Indevus warrants that the Product and matching placebo provided for use in the Phase III Clinical Trial performed under the Programme will be manufactured in accordance with Current Good Manufacturing Practice. TO THE FULLEST EXTENT PERMITTED BY LAW, APART FROM THE FOREGOING WARRANTY, INDEVUS MAKES NO ADDITIONAL WARRANTIES AND HEREBY DISCLAIMS ALL WARRANTIES, REPRESENTATIONS, AND LIABILITIES, WHETHER EXPRESS OR IMPLIED, ARISING FROM CONTRACT OR TORT (EXCEPT FRAUD), IMPOSED BY STATUTE OR OTHERWISE, RELATING TO THE PRODUCT OR MATCHING PLACEBO AND/OR ANY INTELLECTUAL PROPERTY RIGHTS USED OR INCLUDED IN THE

PRODUCT OR MATCHING PLACEBO, INCLUDING ANY WARRANTIES AS TO MERCHANTABILITY, FITNESS, SUITABILITY, USEFULNESS AND/OR SAFETY FOR ANY PURPOSE, OR NON-INFRINGEMENT.

13. Without prejudice to the generality of the foregoing, Indevus does not give any warranty, representation or undertaking as to the efficacy, usefulness, non-toxicity or safety of the Product or matching placebo.

14. Indevus will during and after the period of this Agreement indemnify and hold harmless the MRC and their employees and agents against all liability, damage, costs or expenses which may result from:

    a) a claim by any person participating in the Phase III Clinical Trial alleging injury arising from use of the Product or placebo in accordance with the Protocol;

    b) the gross negligence or wrongful acts or omissions or breach of statutory duty of Indevus, its employees, agents or subcontractors;

    c) any breach by Indevus, its employees, agents or subcontractors of any term of this Agreement, except to the extent such loss, damage, costs or expenses result from the negligence of the MRC, their employees or agents;

    d) the failure of Indevus, its employees, agents or subcontractors to manufacture the Product and/or matching placebo in accordance with the terms of this Agreement;

    e) use of the Product and/or matching placebo pursuant to the Protocol infringing any intellectual property rights of any third party.

Notwithstanding the foregoing, Indevus will not be responsible for and shall not be obligated to indemnify against any loss, claim, or demand, or any costs and expenses arising from any (i) injuries or damages resulting from the negligence or willful misconduct of, or violation of applicable laws, rules or regulations by, MRC or any of the Centres or Investigators or their respective employees, agents, assistants or contractors; (ii) failure to store, handle or administer the Product and/or matching placebo in accordance with the Investigators' Brochure or the Protocol on the part of MRC or any Centre or Investigator, or any of their respective employees, agents, assistants, or contractors; or (iii) activities conducted by MRC or any of the Centres or Investigators or their respective employees, agents, assistants or contractors contrary to the Protocol or the ICH Guidelines for Good Clinical Practice.

15. The MRC agrees to provide Indevus with prompt written notice of any claim, suit, action, demand or judgment for which indemnification is sought under this Agreement. Indevus agrees, at its own expense, to provide attorneys reasonably acceptable to the MRC to defend against any such claim. The MRC shall co-operate fully with Indevus in such defence and will permit Indevus to conduct and control such defence and the disposition of such claim, suit or action (including all decisions relative to litigation, appeal and settlement) provided, however, that Indevus shall not admit fault on MRC's behalf without MRC's advance written permission.

16. Notwithstanding anything to the contrary herein contained, Indevus shall not be liable for any indirect, special, incidental, punitive or consequential damages. In no event shall the liability of Indevus in respect of any damages, costs or expenses under this Agreement exceed the cost of delivery to the Centres of the maximum number of Product and matching placebo to be supplied by Indevus as specified in Clause 5 of this Agreement, except that such limit shall not apply in the case of (i) personal injury or death arising from negligence of Indevus or (ii) fraud by Indevus.

(D) Reporting, accounting and financial auditing

17. Indevus shall render any reasonable assistance requested by the MRC to enable the MRC to provide DFID with reports (both financial and scientific) concerning the Programme as required, subject to confidentiality restrictions.

18. Indevus shall maintain appropriate accounting procedures and practices in respect of supplies of the Product and placebo for the purposes of the Programme.

19. Indevus's accounting records in respect of supplies of the Product and placebo shall be subject during regular business hours to inspection and audit by DFID or the MRC or an independent public accounting firm retained by DFID or MRC, at their expense, upon at least ten (10) business days prior written notice to Indevus, and not more than once each calendar year, for any year ending not more than thirty-six (36) months prior to the date of such request.

(E) Confidentiality, publication of data and intellectual property rights *Confidentiality*

20. Each party shall take all necessary action to ensure that any Confidential Information disclosed by the other party to such party in relation to the Programme (in the case of Indevus) and the Product and matching placebo (in the case of the MRC) (including but not limited to the Trial Data) is treated as confidential by such party's employees, agents or subcontractors, subject to the rights granted under this Agreement. This obligation to maintain confidentiality shall extend for a period of 10 years after termination of this Agreement.

21. Clause 20 of this Agreement shall not apply to any Confidential Information of which either party is the recipient if that information:

    (i) is or was at the time of the disclosure already known to the recipient, free from restrictions on disclosure or use; or

    (ii) is or was at the time of the disclosure already published or generally available to the public; or

    (iii) which after disclosure is published or becomes generally available to the public other than by or as a result of the recipient's breach of its obligations under this Agreement; or

    (iv) was received after disclosure from any third party who had a lawful right to disclose it to the recipient and who did not require the recipient to hold it in confidence; or

    (v) may be required to be disclosed by applicable law or in submission to any regulatory authority; or

    (vi) which the recipient can demonstrate to the satisfaction of the Programme Management Board was independently developed by its employees, agents or subcontractors without the aid, application or use of the Trial Data.

Specific Confidential Information will not be deemed to be within any of the exceptions above merely because it is embraced by more general information which is public knowledge or otherwise lawfully available to the recipient.

Notwithstanding Clause 20, and in addition to any other provision of this Agreement, including paragraphs 35 and 36, enabling a party to use the Confidential Information, either party may use and disclose such Confidential Information (a) in performing its obligations under this Agreement and as otherwise contemplated by this Agreement; and (b) to the extent such disclosure is reasonably necessary, including in filing or prosecuting patent applications, prosecuting or defending litigation hereunder, complying with applicable laws or regulations, conducting other preclinical or clinical studies, or submitting regulatory filings. In addition, Indevus may also make disclosure of this Agreement and the terms hereof in any filings required by the United States Securities and Exchange Commission ("SEC"), may file this Agreement as an exhibit to any filing with the SEC and may distribute any such filing in the ordinary course of its business.

Access to and publication of data

22. The MRC will provide Indevus with a copy of any proposed Protocol amendments and shall not implement any Protocol amendments until such amendments are submitted by Indevus to the FDA. Indevus, as the holder of the IND, shall be responsible for submitting any Protocol amendments to the FDA. The MRC will consult Indevus concerning any provisions of the Protocol or Protocol amendments which may deviate from or fail to meet the standards of the ICH Harmonised Tripartite Guideline for Good Clinical Practice or which affect the Product. Such provisions will only be included with Indevus's agreement.

23. MRC will be responsible for provision of SAE and adverse event data as required to any regulatory authority, other than the FDA, with copies provided to Indevus. Indevus, as holder of the IND, will be responsible for providing SAE and adverse event data as required to the FDA, with copies provided to the MRC. CTU shall collect SAE reports from the centres in accordance with the Protocol and shall forward all such reports to Indevus immediately upon receipt. CTU, in consultation with Indevus and the Investigator, shall decide by the following calendar day whether the SAE meets the criteria for expedited reporting to the FDA. If either the CTU or Indevus believes the SAE meets the criteria for expedited reporting, CTU shall prepare a safety report and forward such report to Indevus within ten calendar days of notification of the SAE. Each Centre will be responsible for reporting to its national ethics committees.

24. The MRC will ensure that the Analysis Databases and the Centres Databases are created and validated and database entries checked in accordance with the ICH Harmonised Tripartite Guideline for Good Clinical Practice.

25. The MRC will permit Indevus (or their designee) to audit the Phase III Clinical Trial data management at CTU. The MRC will use reasonable endeavours to ensure that the Centres permit Indevus (or their designee) to audit the Phase III Clinical Trial data management at the Centres, including such actions as required by Clause 42 and Schedule 7. Such audits are to be permitted on the basis that Indevus provides three months' (or such other period as may be required by applicable regulatory requirements or by agreement between Indevus and MRC) written notice of any such audit and such an audit takes place no more frequently than once per year at any Centre throughout the duration of the Programme. In the event that any Indevus audit identifies a problem requiring rectification, Indevus (or their designee) shall be permitted to make a follow-up visit to CTU/the relevant Centre to assess whether the problem has been adequately resolved, such follow-up visit to be on at least one month's written notice. Audit by any regulatory authority will be permitted as required and Indevus shall promptly receive a copy of any comments by and responses to any regulatory authority in connection with any such audit.

26. Indevus will be represented on the Trial Management Group and will be entitled to attend (although not vote at) Programme Management Board and Trial Steering Committee meetings. Indevus will receive analyses of the Trial Data (blinded) in the normal course of their membership of the Trial Management Group i.e., simultaneously with the clinical investigator members of that Group.

27. Once the Analysis Database has been locked, the MRC will conduct the Phase III Clinical Trial data analysis according to the Analysis Plan.

28. The Draft First Full Report shall be agreed for publication as the First Full Report by the Trial Steering Committee (Indevus shall be entitled to attend but not vote at Trial Steering Committee meetings). It is anticipated that the First Full Report will be finalised ready for submission for publication within six months' of the final

trial participant's follow-up visit. The Draft First Full Report and any Draft Supplementary Reports shall be circulated to the Trial Steering Committee together with a representative from Indevus (who will receive the reports under an obligation of confidentiality). The Trial Steering Committee will specify the deadline for receipt of any comments on the Draft(s) (to be at least 20 days from the date of circulation). The Trial Steering Committee may simultaneously release the Main Master File and any Supplementary Master File to the recipients of the Draft First Full Report (who will receive such documents under the same obligation of confidentiality).

29. In the event that the Trial Steering Committee decides that a Summary of Main Initial Findings will be necessary or desirable in the public interest, then it will prepare such a summary. All revisions of that document and the initial analyses on which it is based shall not be circulated outside the Trial Steering Committee (plus a representative of Indevus) and all recipients shall receive it under an obligation of confidentiality. Recipients of the summary document shall have an opportunity to submit their comments prior to finalisation of the document by the Trial Steering Committee.

30. Indevus may request the MRC's assistance from time to time in providing the regulatory authorities with blinded data from the Analysis Databases and/or additional analyses in advance of publication of the First Full Report. The MRC and Indevus shall agree in writing in advance the scope of the work (and timetable) of any such requested assistance and to reimbursement of the MRC's costs and expenses in doing so (including remuneration in respect of time spent by staff and/or agents both of the MRC and of the Centres). MRC shall provide Indevus with blinded summaries of all adverse events and other data needed to allow Indevus to comply with FDA regulations regarding the IND Annual Report (21 CFR 312.33).

31. Should the analyses included in the Main Master File be insufficient to meet European or USA regulatory requirements, Indevus may request the MRC's assistance to carry out appropriate additional analyses. The MRC and Indevus shall agree in writing in advance the scope of the work (and timetable) of any such requested assistance and to reimbursement of the MRC's costs and expenses in doing so (including remuneration in respect of time spent by staff and/or agents both of the MRC and of the Centres).

32. The MRC will provide Indevus with an electronic copy of the Analysis Databases within 30 days of locking. It is anticipated that locking of the Analysis Database will take place within 6 months of the final participant follow-up visit. Any post-database-lock changes will be notified to Indevus within 30 days. Following locking of the Analysis Databases within 30 days the MRC will provide Indevus with access to the CTU's copies of the data clarifications.

33. The MRC will provide Indevus with the Main Master File in electronic format. Indevus and the MRC shall agree in writing in advance the scope of work (and timetable) and to reimbursement of the MRC's costs and expenses in doing so.

34. The MRC will use its reasonable endeavours to ensure that the Centres permit Indevus (and regulatory authorities) access to the original case record forms, data clarifications and all correspondence with regulatory authorities in respect of any Phase III Clinical Trial participants, including as required by Clause 42 and **Schedule 7**.

35. The Trial Data shall be owned or Controlled by the MRC, subject to the license granted to Indevus in the following sentence. The MRC hereby grants to Indevus an exclusive, worldwide license, including the right to grant sublicenses, under

the Trial Data, the Know-How and any other Intellectual Property owned or Controlled by the MRC that is developed, made or conceived by or on behalf of the MRC during the course of, in furtherance of, and as a result of activities performed pursuant to the Programme (the "Programme IP"), to develop, make, have made, use, offer for sale, sell, import, and distribute Product for any use. In consideration of the foregoing, Indevus shall pay MRC royalties in an amount equal to **[*]** of Net Sales by Indevus, its Affiliates or sublicensees outside the Territory in each year during the Royalty Term if the manufacture, use or sale of Product uses or embodies MRC's Intellectual Property Rights and Indevus's Intellectual Property Rights, provided however, that in the case of sales by a sublicensee of Indevus, royalties payable by Indevus to MRC in any year during the Royalty Term shall not exceed **[*]** of all revenues received by Indevus from such sublicensee during that year.

The parties agree and acknowledge that the royalty provided for in this Clause 35 shall incorporate and supercede any royalties that may otherwise be payable by Indevus under any other agreement pursuant to which MRC provided funding for studies of Product, including the Agreement dated as of October 7, 1996 by and between MRC and Procept, Inc. (a predecessor of Paligent, Inc. and that only one payment shall be due with respect to the same unit of Product.

In the event Indevus is required to make royalty payments to one or more third parties in order to make, use or sell Product, Indevus may offset a total of **[*]** of such third party payments in any royalty period against any royalties that are due MRC in such royalty period, provided that in no event shall the royalty payments to MRC under Paragraph 35 be reduced by more than **[*]** in any royalty period.

36. MRC acknowledges that pursuant to the foregoing license, Indevus may use the Trial Data or any part of it in the following ways:

    (a) for research and development purposes;

    (b) Indevus may disclose the Trial Data or any part of it to any third party with whom Indevus is considering entering into negotiations in respect of a licensing agreement or similar agreement and/or has entered into such an agreement, provided such disclosure is under a duty of confidentiality similar to the confidentiality obligations of Indevus under this Agreement;

    (c) Indevus may disclose and submit the Trial Data or any part of it to any competent regulatory authority in order to discuss and/or apply for or in connection with any regulatory, marketing and/or other applications or approvals; and

    (d) Indevus may use the Trial Data or any part of it in connection with the commercialization of Product, provided that such use be anonymous with respect to individual participants in the Phase III Clinical Trial.

37. It is expected that findings of the Programme will be published in the appropriate scientific literature, whatever the findings show. The Programme Management Board will be responsible for any publication of the Trial Data as set out in clause 38 below. The MRC will use reasonable endeavours to ensure that the Centres do not publish the Trial Data or any part of it without the prior written approval of the Programme Management Board.

38. The MRC will require the Centres to submit draft abstracts and full papers to the Programme Management Board for prior approval not less than 30 days prior to submission for publication. The Programme Management Board will circulate draft abstracts or papers to Indevus for comments within 1 week of receipt from the Centres. Indevus may, within 2 weeks of receipt of the draft abstracts or papers, submit comments to the Programme Management Board for consideration, or request a delay in publication of up to 30 days. An

appropriately worded acknowledgment of Product supplied by Indevus in any publication will be agreed.

39. Indevus may issue press releases in connection with the Programme upon the following conditions:

(i) The full text is provided to the MRC's authorised representative at least twenty-four (24) hours before the intended release; and (ii) The permission of the MRC's authorised representative is obtained prior to any release of information not previously released, such permission not be unreasonably withheld or delayed;

Intellectual property rights

40. For the avoidance of doubt, all Background used in connection with the Programme shall remain the property of the party introducing the same, except as set forth in this Agreement.

41. All Intellectual Property Rights arising in respect of the Trial Data shall be owned by the MRC subject to the provisions of Paragraph 35.

(F) OBLIGATIONS OF THE MRC UNDER THIS AGREEMENT

42. The MRC shall use its reasonable endeavours to ensure that the Confidential Information, the Product and matching placebo shall not be used for any purpose outside the Programme and that the Product and matching placebo shall be handled, stored and used only in accordance with all applicable laws and regulations and in accordance with the requirements of any relevant regulatory authorities, the Investigators' Brochure and any guidance and/or requirements notified by Indevus to MRC.

The MRC will require all Investigators to sign agreements requiring them to comply with the ICH Guidelines for Good Clinical Practice as required by the Protocol. In the event of any conflict between the Protocol and the ICH Guidelines for Good Clinical Practice, the Protocol is to take precedence (any deviations from ICH Good Clinical Practice required by the Protocol are to be agreed in advance with Indevus, as per clause 22 above of this Agreement). The MRC will require Centres to document any instances of non-compliance in an appropriate manner. The MRC shall use its reasonable endeavours to ensure that all Centres comply with the ICH Guidelines for Good Clinical Practice. The MRC will promptly inform Indevus of any significant non-compliance with the ICH Guidelines for Good Clinical Practice as soon as reasonably possible after the MRC becomes aware of such an event of significant non-compliance, and shall consult Indevus as to remedial action to be taken. The MRC shall require each of the Centres to ensure that the investigator responsible for conduct of the Programme has signed the Investigator's Statement (a sample copy of which is appended at **Schedule 3** to this Agreement) and Form FDA 1572 (Statement of Investigator).and shall provide copies thereof to Indevus. With respect to the Protocol, Indevus agrees to transfer, and MRC agrees to accept, some but not all of the obligations specified in CFR Title 21, Part 312 Subpart D "Responsibilities of Sponsors and Investigators". Obligations to be transferred are specified in **Schedule 7** appended to this Agreement.

43. The MRC shall be responsible for informing all investigators of any significant new information on the safety of the Product and/or matching placebo obtained in the course of the Programme.

44. The MRC shall be responsible for monitoring each Centre participating in the Phase III Clinical Trial involving the Product and matching placebo for the quality assurance of all data. Monitoring shall be done in compliance with ICH GCP

Guidelines, and a copy of each monitoring report shall be provided to Indevus within 3 months of completion of the monitoring visit.

45. The MRC shall ensure that any documentation relating to the PRO 2000 and control arms of the Phase III Clinical Trial which is held at CTU will be kept secure until the date two years after the last marketing authorisation has been granted in accordance with European and US regulations; provided that this obligation shall end on the 15th anniversary of publication of the First Full Report.

46. MRC shall arrange, administer and be responsible for all costs associated with the Programme and the Phase III Clinical Trial, except for costs of the supply of Product and placebo as specifically set forth in Clause 5. Except as specifically set forth in this Agreement or unless agreed in writing in advance by authorised representatives of the parties, the MRC will not be responsible for any cost or expense of any kind, incurred for any reason by Indevus in respect of the Programme.

47. MRC shall not subcontract any of its activities under the Programme as defined by this Agreement without first notifying the Indevus' authorised representative in writing. MRC shall remain liable for the actions and/or any defaults of its subcontractors as if they were the actions and/or defaults of MRC itself under this Agreement.

(G) MISCELLANEOUS

Force majeure

48. The parties acknowledge that there may be events beyond either party's reasonable control that may be determined as Force Majeure events. Neither party shall be liable for any delay in performance or failure to perform its obligations under this Agreement if such delay or failure is due to an occurrence beyond its control, including fire, floods, earthquakes, embargoes, war, insurrections, riots, civil commotions, terrorism, strikes, lockouts or other labor disturbances, sabotage, acts of God, failure or delay of transportation, prevention from or hindrance in obtaining energy or other utilities, omissions or delays in acting by any governmental authority, acts of a government or agency thereof or judicial orders or decrees, or circumstances due to the remote location of some of the Centres, local customs or practices or administration procedures, provided that the party in default notifies the other party in writing of the reason for the delay or failure within 5 working days of the due date. If the delay continues for longer than 90 working days after such notification, the other party shall be entitled to terminate this Agreement on thirty (30) days' written notice.

Settlement of disputes

49. MRC and Indevus will attempt to settle by mutual agreement all disputes arising under this Agreement with the assistance of the Programme Management Board.

Governing law

50. This Agreement is to be governed by and adjudicated in accordance with English law.

Entire Agreement

51. This Agreement embodies and sets forth the entire agreement and understanding of the parties and supersedes all prior oral or written agreements, understandings or arrangements relating to the Programme.

Amendment

52. This Agreement shall not be amended, modified, varied or supplemented except in writing signed by duly authorised representatives of the MRC and Indevus.

Form of written notice

53. Any written notice to be given to the MRC's authorised representative under the terms of this Agreement shall be sent by recorded delivery, or express or air mail, or other fast postal service to Ian Viney at MRC Centre London (at the address for MRC Centre London shown in **Schedule 2** appended to this Agreement). A written notice may also be sent by facsimile (to the number shown in **Schedule 2**), provided receipt of it is acknowledged, and provided a confirmatory copy is sent by fast postal service on the same day. Any notice or report required or permitted to be given or made under this Agreement to Indevus shall be in writing, delivered personally or by facsimile or email (and promptly confirmed by personal delivery, U.S. or international first class mail or courier), addressed to Indevus at its address indicated in **Schedule 2,** or to such other address as Indevus shall have last furnished in writing to the MRC.

This Agreement has been executed by duly authorised officers of the parties upon July 26, 2005.

Signed for and on behalf of the Medical Research Council

Signature: /S/ GRAHAM L. WAGNER Date 27 July 2005
Name (Printed): **Graham L. Wagner**
Title: **Deputy Director, Licensing and Agreements, Medical Research Council Technology**

Signed for and on behalf of Indevus Pharmaceuticals, Inc.

Signature: /S/ GLENN L. COOPER Date 7/26/05
Name (Printed) **Glenn L. Cooper, M.D**
Title: **President and Chief Executive Officer**

Signed in the presence of /S/ NOAH D. BEERMAN
Name (Printed)… **Noah D. Beerman**
ECP, Chief Business Officer

Schedule 1: MRC Grant number G0100137 entitled 'Vaginal microbicides for the prevention of HIV transmission'

[*]

[*] CONFIDENTIAL TREATMENT REQUESTED

Schedule 2: Authorised representatives of the parties and Grant Holders' addresses

MRC

Ian Viney
MRC Centre London
Stephenson House
158-160 North Gower Street
London NW1 2ND

Tel: +44 (0)20 7670 4625
Fax: +44 (0)20 7670 4691
Email: iv@centre-london.mrc.ac.uk

Indevus
Dr Albert Profy

Indevus Pharmaceuticals, Inc.
33 Hayden Avenue
Lexington, MA 02421, USA
Tel: 781-861-8444
Fax: 781.863.2564
Email :aprofy@indevus.com

Grant Holders' Contact addresses
Dr Sheena McCormack
MRC Clinical Trials Unit
222 Euston Road
London NW1 2DA

Tel: +44 (0)20 7670 4708
Fax: + 44 (0)20 7670 4815
Email: smc@ctu.mrc.ac.uk

Dr Charles Lacey
Hull York Medical School, University of York,
Heslington, York YO10 5DD, UK

Tel: +44 (0) 1904 725425

Email: charles.lacey@hyms.ac.uk

Schedule 3: Investigator's Statement

I agree to conduct the MDP301 trial according to the final protocol and in accordance with any subsequent protocol amendments and according to the decisions of the Programme Management Board, Trial Management Group and Trial Steering Committee. I agree to comply with the obligations below.

Any changes in procedure will only be made if necessary to protect the safety, rights or welfare of participants.

I agree to conduct in person or to supervise the conduct of the MDP301 trial.

I have read and understood the information in the study protocol and the Investigator Brochure for the study product.

I agree to ensure that all who assist me in the conduct of the MDP301 trial have access to the study protocol plus any subsequent amendments, and are aware of their obligations.

_____	_____	___/___/_____
SIGNATURE OF INVESTIGATOR	NAME OF INVESTIGATOR	DATE

HOSPITAL NAME AND DEPARTMENT/ CLINIC

Obligations of Investigators

Compliance with study protocol and obtaining necessary approvals

To obtain local and national regulatory approval for the MDP301 trial protocol and, under instructions from the CTU, for protocol amendments.

To ensure initial and continuing review and approval of the MDP301 trial by an independent ethical committee constituted in accordance with ICH E6 Good Clinical Practice: Consolidated guidance.

To conduct the MDP301 trial only in accordance with the study protocol and after all necessary approvals have been granted (including ethics approval) and submitted to CTU and Indevus

To ensure that all staff working with study participants are instructed on the study procedures including good clinical practice and voluntary counselling and testing. Full access to the study protocol, any protocol amendments and other related information will be given.

To discuss with the CTU as soon as possible following any deviation from the study protocol to protect a participant's safety, rights or welfare for advice on whether or not the participant is to continue in the study. Any deviation from the study protocol should be recorded on the Case Record Form and documented in a note to file.

No amendment to the study protocol may be made without the approval of the Trial Steering Committee and clarifications for changes kept on file.

Record-keeping

To prepare and maintain complete and accurate case histories including case record forms, medical files and source documents that record all observations and other data pertinent to the investigation for each study participant under the investigator's care.

To retain the study register containing participant identification, medical files and source documents in secure storage for at least 15 years after completion of the study. Should the RHRU become unable to provide secure storage at any time, Professor Helen Rees shall notify one of the Grant Holders and arrange for transfer of the documents to either the CTU or Imperial College.

To keep full records of the dispensing and returns of the study products, including dates, quantities, and use by the study participants.

To certify that the investigator and all subinvestigators under their supervision have no financial interest in the study products or their developers, or to disclose any such interest.

Handling of study products

To follow all protocol procedures in respect of handling, monitoring, labelling and dispensing of study products.

To accept responsibility for delivered study products and to hold these in a secure place in accordance with instructions received from CTU or Indevus.

To use study products only to conduct the study.

To use study products in compliance with applicable legislation, regulations and ordinances.

To abide by standard operating procedures as evidence of measures undertaken to control and monitor the use of study products supplied.

To return remaining study products as requested by Indevus in the event the study is terminated.

Confidentiality, publications and press releases

To treat information on the study products e.g. in the Investigator's brochures, as confidential except to parties undertaking legitimate scientific or ethical review, to clinical staff involved in the study or to participants to enable informed consent to be obtained.

To treat any data or information in relation to the MDP as confidential and to ensure that all other staff do likewise, with the exception of data which fall within the provisions of Clause [ ] to the Agreement between the MRC and RHRU.

To ensure that data generated by other co-applicants or collaborators in connection with the MDP is not used without the advance written consent of one of the Grant Holders.

No data may be disclosed to the public without the approval of the Programme Management Board Joint Chairs/Programme Liaison Group.

To ensure that draft abstracts and full papers intended for publication are submitted to the Programme Liaison Group for prior approval not less than 30 days prior to submission for publication. As a member of the Programme Liaison Group Indevus will receive drafts for comment. The Programme Liaison Group retains the right to require amendment, to refuse permission for publication, or to require delay in submission for publication. The Programme Liaison Group will communicate its decision on publication within 30 days of receipt of the draft.

To consult the Programme Liaison Group/the Joint Chairs of the Programme Management Board for approval of any proposed press release.

Access to Data

Study data will be owned by or held in the custodianship of the MRC.

To permit and facilitate access to the study data and to data on adverse events by Indevus, at the request of the CTU, the Programme Management Board, Programme Liaison Group, and the Trial Steering Committee.

Access to source documentation (including case record forms, data clarifications and adverse event correspondence) will be provided to the MRC or Indevus or to a regulatory authority for the purposes of monitoring and audit. Reports of CTU monitoring visits will be provided to Indevus after the monitoring report has been signed off by the site co-ordinator.

Adverse event reporting

To comply with the procedures for reporting of adverse events specified in the study protocol, including procedures for the reporting of Notifiable Adverse Events to the CTU.

Data management

To take responsibility for the quality of data recorded. This should be a complete and accurate record of participant data collected during the study. A designated representative from the site as listed on the delegation log should sign every Case Record Form.

To send electronically to the CTU twice a month data from the case record forms. To reply promptly to queries raised by the CTU.

To comply with the MRC Guidelines on Personal Information and to ensure that study data is passed to the MRC in linked anonymised form.

Decision-making

To establish a local site management mechanism for decision-making.

To liaise closely with the Programme Liaison Group and to appoint one person as the operational contact for the CTU/the Programme Liaison Group.

To appoint one person from the site to participate actively in the MDP's decision-making structures (that person to appoint a deputy)(Trial Management Group)

Financial and scientific reporting

To undertake or to supervise the completion of the site's quarterly expenditure reports and forecasts and quarterly performance reports.

To assist the MRC in compiling annual scientific reports on the MDP's activities.

Liability for harm to participants

To ensure adequate financial provision is made by the RHRU to compensate study participants for any harm suffered as a result of participating in the study due to the RHRU staff/employees'/agents/contractors negligence, wrongful acts or omissions, breach of statutory duty, or failure to comply with the study protocol.

Schedule 4: Centres participating in the Programme

Clinical Centres
Africa
The Africa Centre for Population Studies and Reproductive Health
Mtubatuba
South Africa

Dept. of Paediatrics and Child Health
School of Medicine & University Teaching Hospital
Lusaka, Zambia

Mwanza Medical Research Centre
National Institute for Medical Research
Mwanza, Tanzania

HIV Prevention and Vaccine Research
Medical Research Council
Durban, South Africa

Reproductive Health Research Unit
Dept of Obstetrics and Gynaecology
Chris Hani Baragwanath Hospital, University of the Witwatersrand
Johannesburg, South Africa

Medical Research Council
Uganda Virus Research Institute
Entebbe, Uganda

Department of Obstetrics and Gynaecology
Nsambya Hospital
Kampala, Uganda

Laboratoire de Santé Hygiène Mobile
Ministry of Health
CHU
Yaoundé, Cameroun

UK
Imperial College of Science, Technology & Medicine
London, United Kingdom

St George's Hospital Medical School
London, United Kingdom

MRC Clinical Trials Unit
London, United Kingdom

Non-clinical centres

Department of Social Statistics
University of Southampton
United Kingdom

London School of Hygiene and Tropical Medicine
Health Policy Unit

Department of Public Health and Policy
London, United Kingdom

Population Services International
London, United Kingdom

Schedule 5 – "Territory"

[*]

[*] CONFIDENTIAL TREATMENT REQUESTED

SCHEDULE 6
PROTOCOL

[*]

[*] CONFIDENTIAL TREATMENT REQUESTED

SCHEDULE 7
TRANSFERRED OBLIGATIONS

Obligations under 21 CFR Part 312 Subpart D to be transferred from Indevus to MRC for Protocol MDP 301:

1. ensuring that the Phase III Clinial Trial is conducted in accordance with the Protocol and any Protocol Amendments contained in the IND, as referenced in 21 CFR 312.50;
2. selecting qualified Investigators, as referenced in 21 CFR 312.53;
3. shipping the Product and matching placebo only to Investigators participating in the Phase III Clinical Trial, as referenced in 21 CFR 312.53(b).
4. obtaining required information and commitments from the Investigators, as referenced in 21 CFR 312.53(c);
5. selecting qualified monitors, as referenced in 21 CFR 312.53(d);
6. informing Investigators of new observations discovered by or reported to MRC, as referenced in 21 CFR 312.55(b);
7. reviewing the ongoing Phase III Clinical Trial, as referenced in 21 CFR 312.56, to include the following:
    a. monitoring the Phase III Clinical Trial, as referenced in 21 CFR 312.56(a);
    b. reviewing and securing Investigator compliance with the signed agreement Form FDA 1572, the Protocol and other investigator responsibilities or, in the alternative, ending the Invesitgator's participation in the Phase III Clinical Trial, as referenced in 21 CFR 312.56(b), and informing Indevus of that decision;
    c. requiring the disposal or return of Product and matching placebo by any non-compliant Investigator whose participation in the Phase III Clinical Trial has been discontinued, as referenced in 21 CFR 312.56(b);
    d. reviewing and evaluating the evidence relating to the safety and effectiveness of the drug as it is obtained from the Phase III Clinical Trial Investigators, as referenced in 21 CFR 312.56(c);
8. maintaining adequate records showing receipt, shipment, or other disposition of the Product and matching placebo, as referenced in 21 CFR 312.57(a);
9. retaining the records and reports required under 21 CFR 312, for two years after a marketing application is approved for the Product, or, if an application is not approved, until two years after shipment and delivery of the Product for investigational use is discontinued, as referenced in 21 CFR 312.57(c);
10. upon request from any properly authorised officer or employee of the FDA, at reasonable times, permiting such officer or employee to have access to and copy and verify any records and reports relating to the Phase III Clinical Trial, as referenced in 21 CFR 312.58(a);
11. upon written request by the FDA, submiting records or reports (or copies of them) relating to the Phase III Clinical Trial, as referenced in 21 CFR 312.58(a);

12. informing Indevus of any Investigator who has failed to maintain or make available records or reports of the Phase III Clinical Trial to the FDA, as referenced in 21 CFR 312.58(a);

13. discontinuing shipments of the Product to any investigator who has failed to maintain or make available records or reports of the Phase III Clinical Trial, as referenced in 21 CFR 312.58(a);

14. assuring the return of all unused Product and matching placebo from each Investigator whose participation in the Phase III Clinical Trial is discontinued or terminated, or authorizing alternative disposition of unused supplies of the Product and placebo provided this disposition does not expose humans to risks from the Product and/or placebo, as referenced in 21 CFR 312.59; and/or

15. maintaining written records of Product and matching placebo disposition, as referenced in 21 CFR 312.59.