

CLINICAL TRIAL AGREEMENT FOR PHARMACEUTICAL AND BIOPHARMACEUTICAL  
INDUSTRY SPONSORED RESEARCH IN GENERAL PRACTICE

[Name – Clinical Trial]

This agreement dated .....

is between

[... insert name of General Practice....] , of [...insert address....]  
(Hereinafter known as the “Practice”)

[AND

[...Insert name of Investigator...]  
(Hereinafter known as the “Investigator”)]

AND

[...insert name....], of [...insert address....]  
(Hereinafter known as the “Sponsor”)

NOW

**WHEREAS** the Sponsor is a pharmaceutical company involved in the research, development, manufacture and sale of medicines for use in humans

**WHEREAS** the Sponsor is developing new treatments and therapies in the field of [...insert field....]

**WHEREAS** the Practice which is a [insert practice’s legal structure e.g. company, partnership][and the Investigator] [is/are] concerned with the diagnosis, treatment and prevention of disease and clinical research for the improvement of healthcare

**WHEREAS** [the Practice][the Practice and the Investigator][delete as appropriate] [has/have] a particular interest and expertise in [...insert area of expertise....]

[WHEREAS the Investigator is a General Medical Practitioner with a particular interest in

[...insert area of interest...][delete if Investigator not a Party]

**WHEREAS** the Sponsor wishes to contract with the [the Practice] [the Practice and the Investigator][delete as appropriate] to undertake a sponsored clinical trial entitled:

“ [ ..... insert title and EUDRACT number or Unique Identifier number.....] ”

It is agreed that [the Practice][the Practice and the Investigator][delete as appropriate] and Sponsor shall participate in the aforementioned clinical trial in accordance with this Agreement.

## **1. DEFINITIONS**

### **1.1 The following words and phrases have the following meanings:**

“Affiliate” means any business entity which controls, is controlled by, or is under the common control with the Sponsor. For the purposes of this definition, a business entity shall be deemed to control another business entity if it owns, directly or indirectly, in excess of 50% of the voting interest in such business entity or the power to direct the management of such business entity.

“Agent[s]” shall include, but shall not be limited to, any person (including any nurse or other health professional), any such person’s principal employer in the event it is not the Practice and where such person is providing services to the Practice under a contract for services (commonly known as an honorary contract) or otherwise, and/or any contracted third party providing services to a Party under a contract for services or otherwise, and/or any third party involved in the recruitment of Clinical Trial Subjects .

“Agreement” means this agreement comprising its clauses, schedules and any appendices attached to it.

“Auditor” means a person being a representative of the Sponsor who is authorised to carry out a systematic review and independent examination of Clinical Trial related activities and documents to determine whether the evaluated Clinical Trial related activities were conducted, and the data were recorded, analysed and accurately reported according to the Protocol, the Sponsor’s Standard Operating Procedures, ICH GCP and the applicable regulatory requirements.

“Clinical Trial” means the investigation to be conducted at the Trial Site in accordance with the Protocol numbered [...insert identification number...].

“Clinical Trial Subject” means a person recruited to participate in the Clinical Trial.

“Clinical Trial Authorisation” means a clinical trial authorised in accordance with Part 3 of the Medicines for Human Use (Clinical Trials) Regulations 2004.

“Confidential Information” means any and all information, data and material of any nature belonging to [the Practice] [the Practice or to the Investigator][delete as appropriate] or to the Sponsor and/or its Affiliates which [either][any] Party may receive or obtain in connection with this Agreement which is Personal Data or Sensitive Personal Data (as both terms are defined in the Data Protection Act 1998) which relates to any patient of [the Practice][the Practice and the Investigator][delete as appropriate] or his or her treatment or medical history, or other information, the release of which is likely to prejudice the commercial interests of [the Practice][the Practice and the Investigator][delete as appropriate]

## NHS-ABPI-BIA Primary Care mCTA (2013 - Wales)

or the Sponsor, or which is a trade secret, including Know How.

“ICH GCP” means the ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) together with such other good clinical practice requirements as are specified in Directive 2001/20/EC of the European Parliament and the Council of 4 April 2001 relating to medicinal products for human use and in guidance published by the European Commission pursuant to such Directive.

“IND” means the Investigational New Drug application process by which the United States Food and Drug Administration exempts pharmaceutical companies from the Federal statute that prohibits an unapproved drug from being shipped in interstate commerce.

“Inspector” means a person, acting on behalf of a Regulatory Authority, who conducts an official review of documents, facilities, records and any other resources that are deemed by the Regulatory Authority to be related to the Clinical Trial and that may be located at the Trial Site.

“Intellectual Property Rights” means patents, trade marks, trade names, service marks, domain names copyrights, moral rights, rights in and to databases (including rights to prevent the extraction or reutilisation of information from a database), design rights, topography rights and all rights or forms of protection of a similar nature or having equivalent or the similar effect to any of them which may subsist anywhere in the world, whether or not any of them are registered and including applications for registration of any of them.

“Investigational Medicinal Product” means the study drug or control material as defined in the Protocol.

“Investigator” means Dr [...insert name of Investigator .. who is a signatory to this Agreement.][... insert name of Investigator][delete as appropriate] and who will take primary responsibility for the conduct of the Clinical Trial at the Trial Site on behalf of the Practice, or any other person as may be agreed from time to time between the Parties as a replacement. Additional General Practitioners participating in the Clinical Trial at the Trial Site will be referred to as Trial Site Team Members (defined below).

“Joint Position” means the ‘Joint Position on the Disclosure of Clinical Trial Information Via Clinical Trial Registries and Databases’ agreed by the innovative pharmaceutical industry and published by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) in January 2005.

“Know How” means all technical and other information which is not in the public domain (other than as a result of a breach of confidence), including but not limited to information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, procedures, designs for experiments and tests and results of experimentation and testing, processes, specifications and techniques, laboratory records, clinical data, manufacturing data and information contained in submissions to regulatory authorities, whether or not protected by Intellectual Property Rights or any applications for such rights.

## NHS-ABPI-BIA Primary Care mCTA (2013 - Wales)

“Liability Insurance” means a contract of insurance or other arrangement made for the purpose of indemnifying the Practice or Investigator.

“Party” means [the Practice][the Practice or the Investigator][delete as appropriate] or the Sponsor and “Parties” shall mean [all][both] of them.

“Practice” means the [... insert name ...] General Practice that is a signatory to this Agreement.

“Protocol” means the description of the Clinical Trial (a copy of which is at Appendix 1 and signed by the Investigator) and all amendments thereto as the Parties may from time to time agree in accordance with clauses 4.7, 10.2 and 14.2 and which have also been signed by the Investigator. Such amendments will be signed by the Parties and form a part of this Agreement.

“Regulatory Authority” means any relevant authority which regulates any aspect of the Clinical Trial, including without limitation the UK Medicines and Healthcare products Regulatory Agency, the U.S. Food and Drug Administration, the European Medicines Agency and the General Medical Council.

“Site File” means the file maintained by the Investigator containing the documentation specified in section 8 of ICH GCP (edition CPMP/ICH/135/95).

“Sponsor” means the pharmaceutical company that is a signatory to this Agreement.

“Timelines” means the dates set out in Appendix 2 hereto as may be amended by agreement between the Parties and Timeline shall mean any one of such dates.

“Trial Monitor” means one or more persons appointed by the Sponsor to monitor compliance of the Clinical Trial with ICH GCP and to conduct source data verification.

“Trial Site(s)” means any premises approved by the Practice in which the Clinical Trial will be conducted.

“Trial Site Team Members” means the persons who will undertake the conduct of the Clinical Trial at the Trial Site(s) on behalf of [the Practice][the Practice and the Investigator][delete as appropriate].

- 1.2 Any reference to a statutory provision, code or guidance shall be deemed to include reference to any subsequent modification or re-enactment of it.
- 1.3 The headings to clauses are inserted for convenience only and shall not affect the interpretation or construction of this Agreement.
- 1.4 Where appropriate, words denoting the singular shall include the plural and vice versa and words denoting any gender shall include all genders.

## 2. INVESTIGATOR AND TRIAL SITE TEAM MEMBERS

- 2.1 The Practice represents that this Agreement has been duly authorised, executed and delivered.

2.2 [Alternative clauses – delete as appropriate]

[When agreement is between Sponsor and Practice]

The Practice represents that the Investigator holds the necessary registration and has the necessary expertise, time and resources to perform the Clinical Trial as an investigator and it shall ensure the Investigator is aware of and acknowledges the obligations applicable to the Investigator set out in Appendix 6 and elsewhere in this Agreement and it shall ensure the performance by the Investigator of such obligations.

[When agreement is between Sponsor, Practice and Investigator]

The Practice and the Investigator each represent that the Investigator holds the necessary registration and has the necessary expertise, time and resources to perform the Clinical Trial as an Investigator and the Investigator is aware of and acknowledges the obligations applicable to the Investigator set out in Appendix 6 and elsewhere in this Agreement.

2.3 The [Practice][Practice and the Investigator each][delete as appropriate] represent[s] that no Trial Site Team member, including the Investigator, is, or has been, involved in any misconduct, litigation or investigation by any Regulatory Authority and none has ever been debarred or sanctioned by any internationally recognised global or national drug or health authority. No data produced by any Trial Site Team Member, including the Investigator, in any previous clinical research study have been rejected because of concerns as to their accuracy or because they were generated by fraud. In the event that the Investigator, during the term of this Agreement, becomes debarred, suspended, excluded or otherwise receives any sanctions from Regulatory Authorities, or receives notice of an action or threat of action with respect to any such debarment, suspension, exclusion, sanction or ineligibility, the [Practice] [Practice and the Investigator each][delete as appropriate] agree[s] to notify the Sponsor immediately.

2.4 [Alternative clauses: delete as appropriate]

[For use when agreement is between Sponsor and Practice]

The Practice shall notify the Sponsor if the Investigator ceases to be associated with the Practice or is otherwise unavailable to continue as Investigator, and shall use all reasonable endeavours to find a replacement acceptable to all Parties, subject to the Practice's and Investigator's overriding obligations in relation to Clinical Trial Subjects and individual patient care. If no mutually acceptable replacement can be found the Sponsor may terminate this Agreement pursuant to clause 12.3 below.

[For use when agreement is between Sponsor, Practice and Investigator]

The Practice and the Investigator shall notify the Sponsor if the Investigator ceases to be associated with the Practice or is otherwise unavailable to continue as Investigator, which shall entitle the Sponsor to terminate this Agreement pursuant to clause 12.3 below.”

2.5 The [Practice][Practice and the Investigator][delete as appropriate]shall procure

the performance of the obligations of the Trial Site Team Members as set out in this Agreement

### **3. CLINICAL TRIAL GOVERNANCE**

- 3.1 The Sponsor shall inform the Practice and the Investigator of the name and telephone number of the Trial Monitor and the name of the person who will be available as a point of contact. The Sponsor shall also provide the Investigator with an emergency telephone number to enable adverse event reporting at any time.
- 3.2 The Parties shall comply with all relevant laws of the EU if directly applicable or of direct effect and all relevant laws and statutes of the UK country in which the Trial Site is located including but not limited to, the Human Rights Act 1998, the Data Protection Act 1998, the Human Medicines Regulations 2012, the Medicines for Human Use (Clinical Trial) Regulations 2004, and with all relevant guidance relating to medicines and clinical trials from time to time in force including, but not limited to, the ICH GCP, the World Medical Association Declaration of Helsinki entitled 'Ethical Principles for Medical Research Involving Human Subjects' (1996 version), the NHS Research Governance Framework for Health and Social Care in Wales (Second Edition 2009). In addition, where the Clinical Trial is conducted as part of an IND, the Practice and Investigator will comply with any other relevant requirements notified by the Sponsor to the [Practice][Practice and Investigator][Investigator] [delete as appropriate].
- 3.3 The Sponsor shall comply with all guidelines from time to time in force and published by The Association of the British Pharmaceutical Industry in relation to clinical trials and in particular those entitled "Clinical Trial Compensation Guidelines" (1991) a copy of which is set out in Appendix 3.
- 3.4 The Sponsor shall not commit (and warrants that in entering into the Agreement it has not committed) any of the following acts:
- 3.4.1 provide or offer to provide to any person in the employment of or in the service of the Practice or Investigator any gift or consideration not contemplated by the financial arrangements set out at clause 10 below in relation to the negotiation or performance of this Agreement or the Clinical Trial;
- 3.4.2 make payment or agree to make payment of any commission to any person in the employment of or in the service of the Practice or Investigator in relation to this Agreement or the Clinical Trial.
- 3.5 If the Sponsor or any of his employees, Agents or sub-contractors, or any person acting on their behalf, commits any of the acts referred to in clause 3.4 above or commits any offence under the Bribery Act 2010 in relation to this Agreement or the Clinical Trial, [the Practice][the Practice and the Investigator][delete as appropriate] shall be entitled, acting reasonably, in addition to any other remedy available, to terminate this Agreement with immediate effect, taking into consideration the potential effects of termination on the health of the Clinical Trial Subjects. If the Sponsor or any of his employees, Agents or sub-contractors, or any person acting on their behalf, commits any offence under the Bribery Act 2010, in relation to any other agreement with [the Practice][the Practice and the

Investigator][delete as appropriate] or an authority that is a health service body within the meaning given by Section 7(4) of the National Health Service (Wales) Act 2006, [the Practice][the Practice and the Investigator][delete as appropriate] shall be entitled, acting reasonably, in addition to any other remedy available, to terminate this Agreement with immediate effect, provided that before so doing, they shall have considered all of the circumstances of the case in consultation with the Sponsor and shall, in particular, have considered the potential effects of termination on the health of the Clinical Trial Subjects.

- 3.6 Should there be any inconsistency between the Protocol and the other terms of this Agreement, or any other document incorporated therein, including the Sponsor's Standard Operating Procedures, the terms of the Protocol shall prevail to the extent of such inconsistency except insofar as the inconsistency relates to clauses 5, 6, 8 and/or 9 of this Agreement.

#### **4. OBLIGATIONS OF THE PARTIES**

- 4.1 The Sponsor shall be responsible for obtaining and maintaining all favourable opinions from the relevant research ethics committee where required for the conduct of the Clinical Trial and the Sponsor shall keep the Practice and Investigator fully apprised of the progress of any ethics committee submissions as required.
- 4.2 The Sponsor shall submit the Clinical Trial for listing in a free, publicly accessible clinical trial registry within 21 days of initiation of patient enrolment.
- 4.3 Neither the Practice nor the Investigator shall register either the Clinical Trial, or the results, on any publicly accessible clinical trial registry.
- 4.4 The Sponsor shall ensure that the results of the Clinical Trial will be published on a free, publicly accessible clinical trial results database within one year after the Investigational Medicinal Product is first approved and made commercially available in any country, or for a post-approval Clinical Trial, within one year of Clinical Trial completion. In respect of a Clinical Trial that is under review by peer-reviewed journals that prohibit disclosure of results pre-publication, the results will be posted at the time of publication.
- 4.5 The Parties shall conduct the Clinical Trial in accordance with:
- 4.5.1 the Protocol a copy of which is attached at Appendix 1 to this Agreement;
  - 4.5.2 the current marketing authorisation for the Investigational Medicinal Product or, as the case may be, the Clinical Trial Authorisation granted by the [relevant Regulatory Authority][Medicines and Healthcare Products Regulatory Agency][delete as appropriate]; and
  - 4.5.3 the terms and conditions of the favourable opinion of the relevant [...insert name...] research ethics committee
- 4.6 Until the Sponsor has obtained all required documentation from the Regulatory Authority and a favourable opinion from the research ethics committee it shall not supply the Investigational Medicinal Product to the Practice or Investigator. [The Practice][The Practice and the Investigator][delete as appropriate] shall ensure



that neither administration of the Investigational Medicinal Product to any Clinical Trial Subject nor any other clinical intervention mandated by the Protocol takes place in relation to any such Clinical Trial Subject until ~~it is~~~~they are~~~~delete as appropriate~~ satisfied that all relevant regulatory approvals and a favourable opinion from the research ethics committee have been obtained.

- 4.7 In the event of any substantial amendments (relating to any of the matters referred to in the definition of “substantial amendment to the Clinical Trial Authorisation” in regulation 11 of the Medicines for Human Use (Clinical Trial) Regulations 2004) being made to the Protocol, the amendments shall be signed by the Investigator and shall be implemented by the Trial Site Team Members as required by the Sponsor. The Sponsor shall initiate simultaneously the change control procedures set out in clause 14 below.
- 4.8 The Sponsor shall make available to the Investigator copies of the documentation referred to in clause 4.5.1 and evidence of grant of the authorisations listed in clause 4.5.2 above and the Investigator shall include such documents together with the favourable opinion of the research ethics committee in the Site File.
- 4.9 The Investigator shall make any necessary disclosures of financial interests and arrangements as specified by the Sponsor and for the purposes of these obligations the Sponsor shall advise the Investigator in writing of the completion date of the Clinical Trial.
- 4.10 Neither the Practice nor the Investigator shall permit the Investigational Medicinal Product to be used for any purpose other than the conduct of the Clinical Trial and upon termination or expiration of this Agreement all unused Investigational Medicinal Product shall, at the Sponsor’s option, either be returned to the Sponsor or disposed of in accordance with the Protocol or the Sponsor’s written instructions.
- 4.11 The Practice and Investigator shall use their best endeavours to ensure that the Investigator recruits ~~[...insert number...]~~ Clinical Trial Subjects to participate in the Clinical Trial and the Parties shall conduct the Clinical Trial in accordance with the Timelines.
- 4.12 In the event that the Clinical Trial is part of a multi-centre clinical trial (which for the purposes of this Agreement shall mean that at least one other institution is taking part) the Sponsor may amend the number of Clinical Trial Subjects to be recruited pursuant to clause 4.11 above as follows:
- 4.12.1 if in the reasonable opinion of the Sponsor recruitment of Clinical Trial Subjects is proceeding at a rate below that required to enable the relevant Timeline to be met the Sponsor may by notice to the ~~[Practice]~~~~[Practice and the Investigator]~~~~delete as appropriate~~ require recruitment at the Trial Site to cease and the terms of the Agreement shall relate thereafter to the number of Clinical Trial Subjects who have been enrolled in the Clinical Trial at the date of such notice; or
- 4.12.2 if recruitment of Clinical Trial Subjects is proceeding at a rate above that required to meet the relevant Timeline the Sponsor may with the agreement of the Practice and Investigator increase the number of Clinical Trial Subjects to be recruited.



## NHS-ABPI-BIA Primary Care mCTA (2013 - Wales)

- 4.13 The following provisions relate to access, research misconduct and Regulatory Authorities
- 4.13.1 The Practice and Investigator shall permit the Trial Monitor and any Auditor or Inspector access to all relevant clinical data of Clinical Trial Subjects for monitoring and source data verification, such access to be arranged at mutually convenient times and on reasonable notice. Such monitoring may take such form as the Sponsor reasonably thinks appropriate including the right to inspect any facility being used for the conduct of the Clinical Trial and to examine any procedures or records relating to the Clinical Trial, in accordance with the provisions of clause 6.2 of this Agreement. The Sponsor will alert the [Practice][Practice and the Investigator][delete as appropriate] promptly to significant issues (in the opinion of the Sponsor) relating to the conduct of the Clinical Trial.
- 4.13.2 In the event that the Sponsor reasonably believes there has been any research misconduct in relation to the Clinical Trial, the Practice and the Investigator shall provide all reasonable assistance to any investigation into any alleged research misconduct undertaken by or on behalf of the Sponsor, the results of which the Party on whose behalf the investigation was undertaken shall, subject to any obligations of confidentiality, communicate to the Practice and Investigator. In the event that the Practice and Investigator reasonably believes there has been any research misconduct in relation to the Clinical Trial, the Sponsor shall provide all reasonable assistance to any investigation into any alleged research misconduct undertaken by or on behalf of the Practice and Investigator, the results of which shall, subject to any obligations of confidentiality, be communicated to the Sponsor.
- 4.13.3 The [Practice][Practice and the Investigator][delete as appropriate] shall promptly inform the Sponsor of any intended or actual inspection, written enquiry and/or visit to the Trial Site by any Regulatory Authority in connection with the Clinical Trial and forward to the Sponsor copies of any correspondence from any such Regulatory Authority relating to the Clinical Trial. The [Practice][Practice and the Investigator][delete as appropriate] will use all reasonable endeavours to procure that the Sponsor may have a representative present during any such visit.
- 4.13.4 The [Practice][Practice and the Investigator][delete as appropriate] will permit the Sponsor to examine the conduct of the Clinical Trial and the Trial Site upon reasonable advance notice during regular business hours to determine that the Clinical Trial is being conducted in accordance with the Protocol, ICH GCP and the applicable regulatory requirements.
- 4.14 The [Practice][Practice and the Investigator][delete as appropriate] shall ensure that any clinical biological samples required to be tested during the course of the Clinical Trial are tested in accordance with the Protocol and at a laboratory approved by the Sponsor.
- 4.15 Upon completion of the Clinical Trial (whether prematurely or otherwise) the Investigator shall co-operate with the Sponsor in producing a report of the Clinical Trial detailing the methodology, results and containing an analysis of the results and drawing appropriate conclusions.

- 4.16 Subject to the Practice's and the Investigator's overriding obligations in relation to Clinical Trial Subjects and individual patient care, neither the Practice nor the Investigator nor Trial Site Team Members shall during the term of this Agreement conduct any other trial which might hinder the Practice's or Investigator's ability to recruit and study the required cohort of Clinical Trial Subjects.

## **5. LIABILITIES AND INDEMNITY**

- 5.1 In the event of any claim or proceeding in respect of personal injury made or brought against the Practice or Investigator by a Clinical Trial Subject, the Sponsor shall indemnify the Practice and Investigator, its servants, Agents and employees in accordance with the terms of the indemnity set out at Appendix 4 hereto.
- 5.2 Nothing in this clause 5 shall operate so as to restrict or exclude the liability of ~~either~~~~any~~ Party in relation to death or personal injury caused by the negligence of that Party or its servants, Agents or employees or to restrict or exclude any other liability of ~~either~~~~any~~ Party which cannot be so restricted or excluded in law.
- 5.3 In no circumstances shall ~~either~~~~any~~ Party be liable to the other ~~Party~~~~Parties~~ in contract, tort (including negligence or breach of statutory duty) or otherwise howsoever arising or whatever the cause thereof, for any loss of profit, business, reputation, contracts, revenues or anticipated savings or any special, indirect or consequential damage of any nature, which arises directly or indirectly from any default on the part of ~~the~~~~any~~ other Party.
- 5.4 Subject to clauses 5.2 and 5.5, the liability of the Practice and Investigator to the Sponsor arising out of or in connection with any breach of this Agreement or any act or omission of the Practice or Investigator in connection with the performance of the Clinical Trial shall in no event exceed the amount of fees payable by the Sponsor to the ~~Practice~~~~Practice and the Investigator~~~~delete as appropriate~~ under this Agreement. In the case of damage to equipment loaned to the ~~Practice~~~~Practice and the Investigator~~~~delete as appropriate~~ for the purposes of the Clinical Trial, the ~~Practice's~~~~Practice's and the Investigator's~~~~delete as appropriate~~ liability arising from its negligence shall exclude fair wear and tear and shall not exceed the value of the equipment.
- 5.5 In respect of any wilful and/or deliberate breach by the Practice or Investigator, or any breach of clauses 6, 8 and/or 9, the liability of the Practice and Investigator to the Sponsor arising out of or in connection with the breach shall not exceed twice the value of the contract.
- 5.6 The Sponsor will take out appropriate insurance cover or will provide an indemnity satisfactory to the Practice and Investigator in respect of its potential liability under clause 5.1 above and such cover shall be for a minimum of £~~...~~~~insert amount...~~ in respect of any one occurrence or series of occurrences arising from one event. The Sponsor shall produce to the Practice and Investigator, on request, copies of insurance certificates, together with evidence that the policies to which they refer remain in full force and effect, or other evidence concerning the indemnity. The terms of any insurance or the amount of cover shall not relieve the Sponsor of any liabilities under this Agreement.

- 5.7 The Practice and the Investigator represent that they each have an indemnity or Liability Insurance that includes the testing of pharmaceutical products and undertake to maintain such indemnity or Liability Insurance until the completion of the clinical trial.

## **6. CONFIDENTIALITY, DATA PROTECTION AND FREEDOM OF INFORMATION**

### **6.1 Medical Confidentiality**

The Parties agree to adhere to the principles of medical confidentiality in relation to Clinical Trial Subjects involved in the Clinical Trial. Personal data (as defined in the Data Protection Act 1998) shall not be disclosed to the Sponsor by the Practice or the Investigator save where this is required to satisfy the requirements of the Protocol or for the purpose of monitoring or adverse event reporting, or in relation to a claim or proceeding brought by the Clinical Trial Subject in connection with the Clinical Trial. The Sponsor shall not disclose the identity of Clinical Trial Subjects to third parties without prior written consent of the Clinical Trial Subject, except in accordance with the provisions of the Data Protection Act 1998 and the principles set out in "Confidentiality: Code of Practice for Health and Social Care in Wales (August 2005)", unless in relation to a claim or proceeding brought by the Clinical Trial Subject in connection with the Clinical Trial.

- 6.2 [Each party][All Parties] shall comply with the Data Protection Act 1998 ("the 1998 Act") and any other applicable data protection legislation. In particular where a Party is acting as the data processor of another Party ("data controller"), the Party processing data on behalf of the [other][others] agrees to comply with the obligations placed on the data controller by the seventh data protection principle ("the Seventh Principle") set out in the 1998 Act, namely:

6.2.1 to maintain technical and organisational security measures sufficient to comply at least with the obligations imposed on the data controller by the Seventh Principle;

6.2.2 only to process Personal Data for and on behalf of the data controller, in accordance with the instructions of the data controller and for the purpose of the Clinical Trial and to ensure the data controller's compliance with the 1998 Act;

6.2.3 to allow the data controller to audit the processing party's compliance with the requirements of this clause on reasonable notice and/or to provide the data controller with evidence of its compliance with the obligations set out in this clause 6.2;

6.2.4 the processing party shall obtain prior agreement of the data controller to store or process Personal Data at sites outside the European Economic Area (comprising the countries of the European Community, Norway, Iceland and Liechtenstein).

- 6.3 [Both][All] Parties agree to use all reasonable efforts to assist [each other][the others] to comply with the 1998 Act. For the avoidance of doubt, this includes providing [each other][the others] with reasonable assistance in complying with subject access requests served under Section 7 of the 1998 Act and consulting with [each other][the others] prior to the disclosure of any Personal Data created

in connection with the conduct or performance of the Clinical Trial in relation to such requests.

#### **6.4 Freedom of Information**

The Sponsor acknowledges that the Practice is subject to the Freedom of Information Act 2000 ("FOIA") and the Codes of Practice issued under the FOIA as may be amended, updated or replaced from time to time.

6.4.1 If the Practice receives a request under the FOIA to disclose any information that belongs to the Sponsor or its Affiliates, it will notify the Sponsor in accordance with clause 16 as soon as is reasonably practicable, in any event, not later than five (5) working days after receiving the request and will consult with the Sponsor in accordance with all applicable guidance.

6.4.2 The Sponsor acknowledges and agrees that:

(a) subject to clause 6.2.8(b), the decision on whether any exemption applies to a request for disclosure of recorded information under the FOIA is a decision solely for the Practice;

(b) where the Practice is managing a request as referred to in clause 6.2.7, the Sponsor shall co-operate with the Practice and shall use its reasonable endeavours to respond within ten (10) working days of the Practice's request for assistance in determining whether or not an exemption to the FOIA applies.

6.4.3 Where the Practice determines that it will disclose the Confidential Information, notwithstanding any objections from the Sponsor, it will notify the Sponsor in writing, giving at least two (2) working days notice of its intended disclosure.

#### **6.5 Confidential Information**

6.5.1 Each Party shall ensure that only those of its officers, Agents and employees (and in the case of the Sponsor those of its Affiliates) directly concerned with the carrying out of this Agreement (which shall include, without limitation, any third party involved in the recruitment of Clinical Trial Subjects) have access to the Confidential Information of the other Party. Each Party undertakes to treat as strictly confidential and not to disclose to any third party any Confidential Information of another Party, save where disclosure is required by a Regulatory Authority or by law. The Party required to make the disclosure shall inform the other within a reasonable time prior to being required to make the disclosure (and, where appropriate in accordance with clause 6.5), of the requirement to disclose and the information required to be disclosed. Each Party undertakes not to make use of any Confidential Information of the other Party, other than in accordance with this Agreement, without the prior written consent of the other Party.

6.5.2 The obligations of confidentiality set out in this clause 6.5 shall not apply to Confidential Information which is (i) published or becomes generally

available to the public other than as a result of a breach of the undertakings hereunder by the receiving Party, (ii) in the possession of the receiving Party prior to its receipt from the disclosing Party, as evidenced by contemporaneous written evidence, and is not subject to a duty of confidentiality, (iii) independently developed by the receiving Party and is not subject to a duty of confidentiality or (iv) obtained by the receiving Party from a third party not subject to a duty of confidentiality.

6.5.3 In the event of a Party visiting the establishment of the other Party, the visiting Party undertakes that any further Confidential Information which may come to the visiting Party's knowledge as a result of any such visit, shall be treated as Confidential Information in accordance with this sub-clause 6.5.

6.5.4 This clause shall remain in force without limit in time in respect of Confidential Information which comprises Personal Data or which relates to a patient, his or her treatment and/or medical records. Save as aforesaid and unless otherwise expressly set out in this Agreement, this clause shall remain in force for a period of ten (10) years after the termination or expiry of this Agreement.

## **7. PUBLICITY**

7.1 The Sponsor will not use the name of the Practice, nor of any member of the Practice's staff, nor the Investigator, in any publicity, advertising or news release without the prior written approval of an authorised representative of the Practice or Investigator, such approval not to be unreasonably withheld. Neither the Practice, nor the Investigator, nor any Trial Site Team Member will use the name of the Sponsor or of any of its employees, nor the name of the Clinical Trial, nor the name of the Investigational Medicinal Product, in any publicity, advertising or news release without the prior written approval of the Sponsor, such approval not to be unreasonably withheld.

7.2 Neither the Practice nor the Investigator will issue any information or statement to the press or public, including but not limited to advertisements for the enrolment of Clinical Trial Subjects, without, where appropriate, its review and the delivery of a favourable opinion by the research ethics committee and the prior written permission of the Sponsor.

## **8. PUBLICATION**

8.1 The Sponsor recognises that the Investigator has a responsibility under the Research Governance Framework for Health and Social Care to ensure that results of scientific interest arising from the Clinical Trial are appropriately published and disseminated. The Sponsor agrees that employees of the Practice and the Investigator shall be permitted to present at symposia, national or regional professional meetings, and to publish in journals, theses or dissertations, or otherwise of their own choosing, methods and results of the Clinical Trial, subject to this clause 8 and any publication policy described in the Protocol, provided any such policy is consistent with the Joint Position. If the Clinical Trial is multi-centred (as defined in clause 4.12 above), any publication based on the results obtained at the Trial Site (or a group of sites) shall not be made before the first multi-centre publication. If a publication concerns the analyses of sub-sets of

## **NHS-ABPI-BIA Primary Care mCTA (2013 - Wales)**

data from a multi-centred Clinical Trial the publication shall make reference to the relevant multi-centre publication(s).

- 8.2 Upon completion of the Clinical Trial, and any prior publication of multi-centre data, or when the Clinical Trial data are adequate (in Sponsor's reasonable judgement), the Investigator may prepare the data derived from the Clinical Trial for publication. Such data will be submitted to the Sponsor for review and comment prior to publication. In order to ensure that the Sponsor will be able to make comments and suggestions where pertinent, material for public dissemination will be submitted to the Sponsor for review at least sixty (60) days (or the time limit specified in the Protocol if longer) prior to submission for publication, public dissemination, or review by a publication committee.
- 8.3 The Practice and Investigator agree that all reasonable comments made by the Sponsor in relation to a proposed publication by the Investigator will be incorporated by the Investigator into the publication.
- 8.4 The Practice and Investigator acknowledge that the Sponsor may present at symposia, national or regional professional meetings, and publish in journals, theses or dissertations, or otherwise of their own choosing, methods and results of the Clinical Trial and in particular, but without limiting the foregoing, post a summary of study results in on-line clinical trials register(s) before or after publication by any other method. In the event the Sponsor coordinates a multi-centre publication, the participation of the Investigator as a named author shall be determined in accordance with the Sponsor's policy and generally accepted standards for authorship. If the Investigator is a named author of the multi-centre publication, such person shall have access to the Clinical Trial data from all Clinical Trial sites as necessary to participate fully in the development of the multi-centre publication.
- 8.5 During the period for review of a proposed publication referred to in clause 8.2 above, the Sponsor shall be entitled to make a reasoned request to the Investigator that publication be delayed for a period of up to six (6) months from the date of first submission to the Sponsor in order to enable the Sponsor to take steps to protect its proprietary information and/or Intellectual Property Rights and Know How, and the Practice and the Investigator shall not unreasonably withhold their consent to such a request. The Practice and the Investigator shall not unreasonably withhold or delay their consent to a request from the Sponsor for an exceptional additional delay if, in the reasonable opinion of the Sponsor, the Sponsor's proprietary information and/or Intellectual Property Rights and Know How might otherwise be compromised or lost.

## **9. INTELLECTUAL PROPERTY**

- 9.1 All Intellectual Property Rights and Know How owned by or licensed to the Sponsor prior to and after the date of this Agreement other than any Intellectual Property Rights and Know How arising from the Clinical Trial are and shall remain the property of the Sponsor.
- 9.2 All Intellectual Property Rights and Know How owned by or licensed to the Practice or Investigator prior to and after the date of this Agreement other than any Intellectual Property Rights and Know How arising from the Clinical Trial are and shall remain the property of the Practice or Investigator.

## NHS-ABPI-BIA Primary Care mCTA (2013 - Wales)

- 9.3 All Intellectual Property Rights and Know How arising from and relating to the Clinical Trial, the Investigational Medicinal Product (including but not limited to its formulation and use alone or in combination with other drugs) or the Protocol, but excluding any clinical procedure and improvements thereto that are clinical procedures of the Practice or Investigator, shall vest in the Sponsor in accordance with clauses 9.4 and 9.5 below.
- 9.4 In accordance with clause 9.3 above, the Practice and Investigator hereby assign their rights in relation to all Intellectual Property Rights and in all Know How, falling within clause 9.3 above, to the Sponsor, and at the request and expense of the Sponsor, the Practice and Investigator shall execute all such documents and do all such other acts as the Sponsor may reasonably require in order to vest fully and effectively all such Intellectual Property Rights and Know How in the Sponsor or its nominee.
- 9.5 The Practice and the Investigator shall promptly disclose to the Sponsor any Know How generated pursuant to this Agreement and falling within clause 9.3 above and undertake not to use or disclose such Know How other than for the purposes of this Agreement.
- 9.6 Nothing in this clause 9 shall be construed so as to prevent or hinder the Practice and Investigator from using Know How gained during the performance of the Clinical Trial in the furtherance of their normal business activities, to the extent such use does not result in the disclosure or misuse of Confidential Information or the infringement of any Intellectual Property Right of the Sponsor.

## 10. FINANCIAL ARRANGEMENTS

- 10.1 Arrangements relating to the financing of this Clinical Trial by the Sponsor are set out in Appendix 5 hereto.
- 10.2 In the event that amendments to the Protocol require changes to the trial financing arrangements, an amended financial schedule will be signed by the Parties pursuant to clause 14.2 below and attached as a supplement at Appendix 5 of this Agreement.
- 10.3 All payments will be made according to the schedule contained in Appendix 5 on presentation of an invoice (with the addition of VAT if appropriate) to the Sponsor by the [Practice][Practice and Investigator][Investigator][delete as appropriate].
- 10.4 The Sponsor shall promptly respond to any reasonable request for invoicing data received from [Practice][Practice and Investigator][Investigator][delete as appropriate] within 45 days of the close-out of the Trial Site. The [Practice][Practice and Investigator][Investigator][delete as appropriate] will send its final invoice, (or, as the case may be, issue a credit note and make repayment of any monies previously paid for work not completed), to the Sponsor as soon as possible and, in any event, within 45 days of receipt of the said data where such a request has been made, or within 45 days of study close-out in all other circumstances unless there is a written agreement between [Practice][Practice and Investigator][Investigator][delete as appropriate] and the Sponsor to extend these periods.
- 10.5 The Sponsor shall make payment within forty five (45) days of the date of receipt



of the invoice mentioned in clause 10.3 above.

10.6 Any delay in the payment of the payee invoices by the Sponsor will incur an interest charge on any amounts overdue of 2 per cent per month above the National Westminster Bank plc base rate prevailing on the date the payment is due.

**11. TERM**

This Agreement will remain in effect until completion of the Clinical Trial, close-out of the Trial Site and completion of the obligations of the Parties under this Agreement or earlier termination in accordance with this Agreement.

**12. EARLY TERMINATION**

12.1 [Either][Any] Party (the “Terminating Party”) may terminate this Agreement with immediate effect at any time if [the][another] Party (the “Defaulting Party”) is:

12.1.1 in breach of any of the Defaulting Party’s obligations hereunder (including a failure without just cause to meet a Timeline) and fails to remedy such breach where it is capable of remedy within twenty eight (28) days of a written notice from the Terminating Party specifying the breach and requiring its remedy;

12.1.2 declared insolvent or has an administrator or receiver appointed over all or any part of its assets or ceases or threatens to cease to carry on its business.

12.2 A Party may terminate this Agreement on notice to the other [Party][Parties] with immediate effect if it is reasonably of the opinion that the Clinical Trial should cease in the interests of the health of Clinical Trial Subjects involved in the Clinical Trial.

12.3 [Alternative clauses – Delete as appropriate]

[When agreement is between Sponsor and Practice]

The Sponsor may terminate this Agreement on notice to the Practice if the Investigator is no longer able (for whatever reason) to act as Investigator and no replacement mutually acceptable to the Parties can be found.

[When agreement is between Sponsor, Practice and Investigator]

The Sponsor may terminate this Agreement on notice to the Practice and Investigator if the Investigator is no longer able (for whatever reason) to act as Investigator.

12.4 The Sponsor may terminate this Agreement immediately upon notice in writing to the Practice and Investigator for reasons not falling within clauses 12.1.1, 12.2 or 12.3 above. In all such circumstances the Sponsor shall confer with the Investigator and use its best endeavours to minimise any inconvenience or harm to Clinical Trial Subjects caused by the premature termination of the Clinical Trial.

## NHS-ABPI-BIA Primary Care mCTA (2013 - Wales)

- 12.5 In the event of early termination of this Agreement by the Sponsor, pursuant to clauses 12.2, 12.3 and 12.4 and subject to an obligation on the Practice and the Investigator to mitigate any loss, the Sponsor shall pay all costs incurred and falling due for payment up to the date of termination, and also all expenditure falling due for payment after the date of termination which arises from commitments reasonably and necessarily incurred by the Practice or Investigator for the performance of the Clinical Trial prior to the date of termination, and agreed with the Sponsor.
- 12.6 In the event of early termination, if payment (whether for salaries or otherwise) has been made by the Sponsor to [Practice][Practice and Investigator][Investigator][delete as appropriate] in advance for work not completed, such monies shall be applied to termination related costs and [Practice][Practice and Investigator][Investigator][delete as appropriate] shall issue a credit note and repay the remainder of the monies within 45 days of receipt of written notice from the Sponsor.
- 12.7 At close-out of the Trial Site following termination or expiration of this Agreement the [Practice][Practice and Investigator][Investigator][delete as appropriate] shall immediately deliver to the Sponsor all Confidential Information and any other unused materials provided to the Practice and the Investigator pursuant to this Agreement.
- 12.8 Termination of this Agreement will be without prejudice to the accrued rights and liabilities of the Parties under this Agreement.

### 13. RELATIONSHIP BETWEEN THE PARTIES

- 13.1 [Neither][No] Party may assign its rights under this Agreement or any part thereof without the prior written consent of the other [Party][Parties], such consent not to be unreasonably withheld or delayed, and [no][neither] Party may sub-contract the performance of all or any of its obligations under this Agreement without the prior written consent of the other [Party][Parties], such consent not to be unreasonably withheld or delayed. Any party who so sub-contracts shall be responsible for the acts and omissions of its sub-contractors as though they were its own.
- 13.2 Nothing shall be construed as creating a joint venture, partnership, contract of employment or relationship of principal and agent between the Parties.

### 14. AGREEMENT AND MODIFICATION

- 14.1 Any change in the terms of this Agreement shall be valid only if the change is made in writing, agreed and signed by the Parties.
- 14.2 Any amendment to the Protocol pursuant to clause 4.7 ("Protocol Amendment") shall be managed by means of the change control procedure set out in this clause 14.2
- 14.2.1 For the purposes of this Agreement a "change request" is a request to change the obligations of the Parties arising from a Protocol Amendment.
- 14.2.2 Where the Sponsor originates a change request, [Practice][Practice and Investigator][Investigator][delete as appropriate] shall provide the

## NHS-ABPI-BIA Primary Care mCTA (2013 - Wales)

Sponsor, within thirty five (35) days of receiving the change request, details of the impact which the proposed Protocol Amendment will have upon the costs of carrying out the Clinical Trial and the other terms of this Agreement.

14.2.3 A change request shall become a “change order” when the requirements of the change control procedure have been satisfied and any necessary change to this Agreement is signed by the authorised representatives of both Parties.

14.2.4 An amended financial schedule shall be signed and appended to this Agreement according to clause 10.2 above.

14.3 This Agreement including its Appendices contains the entire understanding between the Parties and supersedes all other agreements, negotiations, representations and undertakings, whether written or oral of prior date between the Parties relating to the Clinical Trial, which is the subject of this Agreement. Nothing in this Agreement will, however, operate to limit or exclude any liability for fraud.

## 15. FORCE MAJEURE

[Neither][No] Party shall be liable to [the other][any other] Party or shall be in default of its obligations hereunder if such default is the result of war, hostilities, terrorist activity, revolution, civil commotion, strike, epidemic, accident, fire, wind, flood or because of any act of God or other cause beyond the reasonable control of the [Party][Parties] affected. The Party affected by such circumstances shall promptly notify the other [Party][Parties] in writing when such circumstances cause a delay or failure in performance (“a Delay”) and where they cease to do so. In the event of a Delay lasting for four (4) weeks or more a non-affected Party shall have the right to terminate this Agreement immediately by notice in writing to the other [Party][Parties].

## 16. NOTICES

Any notices under this Agreement shall be in writing, signed by the relevant Party to this Agreement and delivered personally, by courier or by recorded delivery post.

Notices to the Sponsor shall be addressed to:

[...insert address....]

Notices to the Practice shall be addressed to:

[...insert address....]

[Notices to the Investigator shall be addressed to:

[...insert address....]]

## 17. RIGHTS OF THIRD PARTIES

Nothing in this Agreement is intended to confer on any person any right to enforce any

**NHS-ABPI-BIA Primary Care mCTA (2013 - Wales)**

term of this Agreement which that person would not have had but for the Contracts (Rights of Third Parties) Act 1999 (“Third Party Rights Act”). Any right or remedy of a third party which existed or is available apart from the Third Party Rights Act is not affected; in particular, without limitation, any right of any Clinical Trial Subject to claim compensation in accordance with the Clinical Trial Compensation Guidelines referred to in Appendix 4.

**18. WAIVER**

No failure, delay, relaxation or indulgence by any Party in exercising any right conferred on such Party by this Agreement shall operate as a waiver of such right, nor shall any single or partial exercise of any such right nor any single failure to do so, preclude any other or future exercise of it, or the exercise of any other right under this Agreement.

**19. DISPUTE RESOLUTION**

19.1 In the event of a dispute arising under this Agreement, authorised representatives of the Parties will discuss and meet as appropriate to try to resolve the dispute within fourteen (14) days of being requested in writing by any Party to do so.

19.2 In the event of failure to resolve the dispute through the steps set out in clause 19.1 the Parties agree to attempt to settle it by mediation in accordance with the Centre for Effective Dispute Resolution Model Mediation Procedure.

19.2.1 To initiate a mediation, a Party shall give notice in writing (ADR Notice) to the other [Party][Parties] requesting mediation in accordance with this clause 19.2. The Parties shall seek to agree the nomination of the mediator, but in the absence of agreement he shall be nominated by the President for the time being of the British Medical Association. The mediation will start no later than twenty (20) days after date of the ADR Notice.

19.3 If the dispute is not resolved within thirty (30) days of the ADR Notice, any Party shall be entitled to submit to the exclusive jurisdiction of the courts of England and Wales.

19.4 Nothing in this Agreement shall prevent any Party from seeking an interim injunction in respect of a breach of this Agreement. For the avoidance of doubt nothing in this clause shall amount to an agreement that any of the Parties is entitled to an interim injunction.

**20. SURVIVAL OF CLAUSES**

The following clauses shall survive the termination or expiry of this Agreement:-

- 1.1 Definitions
- 3.2 to 3.6 (inclusive) Clinical Trial Governance
- 4.3, 4.4, 4.13 Obligations of the Parties and the Investigator

**NHS-ABPI-BIA Primary Care mCTA (2013 - Wales)**

|                          |   |
|--------------------------|---|
| 5                        | Liabilities and Indemnity   |
| 6                        | Medical Confidentiality, Data Protection and Freedom of Information |
| 7                        | Publicity   |
| 8                        | Publication   |
| 9                        | Intellectual Property   |
| 12.5 to 12.8 (inclusive) | Early Termination   |
| 13 to 21 (inclusive)     | Miscellaneous provisions  |

Subject to clause 6.5.4, clause 6.5 (Confidential Information) shall survive the termination or expiry of this Agreement for a period of ten (10) years commencing on the date of such termination or expiry.

**21. GOVERNING LAW**

This Agreement shall be governed and construed in accordance with the laws of England and Wales.

Signed on behalf of the:

**SPONSOR:** .....

.....

Date:

.....

(Print name and position of authorised signatory)

Signed on behalf of the:

**PRACTICE:** .....

.....

Date:

.....

(Print name and position of authorised signatory)

**NHS-ABPI-BIA Primary Care mCTA (2013 - Wales)**

Signed on behalf of the:

**INVESTIGATOR:** .....

.....

Date:

.....

(Print name)

**APPENDIX 1**

**The Protocol**



APPENDIX 2

TIMELINES FOR PARTIES

| Milestone  | Sponsor responsibility | Site responsibility | Target date |
|--|------------------------|---------------------|-------------|
| Provision of materials for Ethics Committee submission | X                      |                     |             |
| Ethics Committee submission                            | X                      |                     |             |
| Trial Site initiation visit                            | X                      | X                   |             |
| First Clinical Trial Subject recruited                 |                        | X                   |             |
| Last Clinical Trial Subject recruited                  |                        | X                   |             |
| All CRF queries submitted                              | X                      |                     |             |
| All CRF queries completed                              |                        | X                   |             |

**APPENDIX 3**

**CLINICAL TRIAL COMPENSATION GUIDELINES**

Preamble

The Association of the British Pharmaceutical Industry favours a simple and expeditious procedure in relation to the provision of compensation for injury caused by a participation in clinical trials. The Association therefore recommends that a member company sponsoring a clinical trial should provide without legal commitment a written assurance to the investigator – and through him to the relevant research ethics committee – that the following Guidelines will be adhered to in the event of injury caused to a patient attributable to participation in the trial question.

1. Basic principles

- 1.1 Notwithstanding the absence of legal commitment, the company should pay compensation to patient-volunteers suffering bodily injury (including death) in accordance with these Guidelines.
- 1.2 Compensation should be paid when, on the balance of probabilities, the injury was attributable to the administration of a medicinal product under trial or any clinical intervention or procedure provided for by the protocol that would not have occurred but for the inclusion of the patient in the trial.
- 1.3 Compensation should be paid to a child injured in utero through the participation of the subject's mother in a clinical trial as if the child were patient-volunteer with the full benefits of these Guidelines.
- 1.4 Compensation should only be paid for the more serious injury of an enduring and disabling character (including exacerbation of an existing condition) and not for temporary pain or discomfort or less serious or curable complaints.
- 1.5 Where there is an adverse reaction to a medicinal product under trial and injury is caused by a procedure adopted to deal with that adverse reaction, compensation should be paid for such injury as if it were caused directly by the medicinal product under trial.
- 1.6 Neither the fact that the adverse reaction causing the injury was foreseeable or predictable, nor the fact that the patient has freely consented (whether in writing or otherwise) to participate in the trial should exclude a patient from consideration for compensation under these Guidelines, although compensation may be abated or excluded in the light of the factors described in paragraph 4.2 below.
- 1.7 For the avoidance of doubt, compensation should be paid regardless of whether the patient is able to prove that the company has been negligent in relation to research or development of the medicinal product under trial or that the project is defective and therefore, as the producer, the company is subject to strict liability in respect of injuries caused by it.

2. Type of Clinical Research Covered

- 2.1 These Guidelines apply to injury caused to patients involved in Phase II and

## NHS-ABPI-BIA Primary Care mCTA (2013 - Wales)

Phase III trials, that is to say, patients under treatment and surveillance (usually in hospital) and suffering from the ailment which the medicinal product under trial is intended but for which a product licence does not exist or does not authorise supply for administration under the conditions of the trial.

- 2.2 These Guidelines do not apply to injuries arising from studies in non-patient volunteers (Phase I), whether or not they are in hospital, for which separate Guidelines for compensation already exist.<sup>1</sup>
  - 2.3 These guidelines do not apply to injury arising from clinical trials on marketed products (Phase IV) where a product licence exists authorising supply for administration under the conditions of the trial, except to the extent that the injury is caused to a patient as a direct result of procedures undertaken in accordance with the protocol (but not any product administered) to which the patient would not have been exposed had treatment been other than in the course of the trial.
  - 2.4 These guidelines do not apply to clinical trials, which have not been initiated or directly sponsored by the company providing the product for research. When trials of products are initiated independently by doctors under the appropriate Medicines Act 1968 exemptions, responsibility for the health and welfare of patients rests with the doctor alone (see also paragraph 5.2 below).
3. Limitations
    - 3.1 No compensation should be paid for the failure of the medicinal product to have its intended effect or to provide any other benefit to the patient.
    - 3.2 No compensation should be paid for injury caused by other licensed medicinal products administered to the patient for the purpose of comparison with the product under trial.
    - 3.3 No compensation should be paid to patients receiving placebo in consideration of its failure to provide a therapeutic benefit.
    - 3.4 No compensation should be paid (or should be abated as the case may be) to the extent that the injury has arisen:
      - 3.4.1 through a significant departure from the agreed protocol;
      - 3.4.2 through the wrongful act or default of a third party, including a doctor's failure to deal adequately with an adverse reaction; or
      - 3.4.3 through contributory negligence by the patient.
  4. Assessment of compensation
    - 4.1 The amount of compensation paid should be appropriate to the nature, severity and persistence of the injury and should in general terms be consistent with the quantum of damages commonly awarded for similar injuries by an English Court

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<sup>1</sup> Guidelines for medical experiments in non-patient human volunteers, ABPI March 1988, as amended May 1990.

in cases where legal liability is admitted.

- 4.2 Compensation may be abated, when certain circumstances excluded, in the light of the following factors (on which will depend the level of risk the patient can reasonably be expected to accept):

4.2.1 the seriousness of the disease being treated, the degree of probability that adverse reactions will occur and any warnings given; or

4.2.2 the risks and benefits of established treatments relative to those known or suspected of the trial medicine.

This reflects the fact that flexibility is required given the particular patient's circumstances. As an extreme example, there may be a patient suffering from a serious or life-threatening disease who is warned of a certain defined risk of an adverse reaction. Participation in the trial is then based on an expectation that the benefit/risk ratio associated with participation may be better than that associated with alternative treatment. It is, therefore, reasonable that the patient accepts the high-risk and should not expect compensation for the occurrence of the adverse reaction of which he or she was told.

- 4.3 In any case where the company concedes that a payment should be made to a patient but there exists the difference of opinion between company and patient as to the appropriate level of compensation, it is recommended that the company agrees to seek at its own costs (and make available to the patient) the opinion of a mutually acceptable independent expert, and that his opinion should be given substantial weight by the company in reaching its decision on the appropriate payment to be made.

## 5. Miscellaneous

- 5.1 Claims pursuant to the Guidelines should be made by the patient to the company, preferably via the investigator, seeking out details of the nature and background of the claim and, subject to the patient providing on request an authority for the company to review any medical records relevant to the claim, the company should consider the claim expeditiously.

- 5.2 The undertaking given by a company extends to injury arising (at whatever time) from all administrations, clinical interventions or procedures occurring during the course of the trial but not to treatment extended beyond the end of the trial at the instigation of the investigator. The use of unlicensed products beyond the trial period is wholly the responsibility of the treating doctor and in this regard attention is drawn to the advice provided to doctors in MAL 302 concerning the desirability of doctors notifying their protection society of the use of unlicensed products.

- 5.3 The fact that company has agreed to abide by these Guidelines in respect of a trial does not affect the right of a patient to pursue a legal remedy in respect of injury alleged to have been suffered as a result of participation. Nonetheless, patients will normally be asked to accept that any payment made under the Guidelines will be in full settlement of their claims.

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2 MAL30 A guide to the provisions affecting doctors and dentists, DHSS, revised June 1985.

## **NHS-ABPI-BIA Primary Care mCTA (2013 - Wales)**

- 5.4 A company sponsoring a trial should encourage the investigator to make clear to participating patients that the trial is being conducted subject to the ABPI guidelines relating to compensation for injury arising in the course of clinical trials and have available copies of the Guidelines should they be requested.

**APPENDIX 4**

**FORM OF INDEMNITY**

1. The Sponsor indemnifies and holds harmless the Practice and Investigator and their employees and Agents against all claims and proceedings (to include any settlements or ex gratia payments made with the consent of the Parties hereto and reasonable legal and expert costs and expenses) made or brought (whether successfully or otherwise):
  - 1.1 by or on behalf of Clinical Trial Subjects and (or their dependants) against the Practice and Investigator or any of their employees or Agents for personal injury (including death) to Clinical Trial Subjects arising out of or relating to the administration of the Investigational Medicinal Product under investigation or any clinical intervention or procedure provided for or required by the Protocol to which the Clinical Trial Subjects would not have been exposed but for their participation in the Clinical Trial;
  - 1.2 by the Practice or Investigator, their employees or Agents or by or on behalf of a Clinical Trial Subject for a declaration concerning the treatment of a Clinical Trial Subject who has suffered such personal injury.
2. The above indemnity by the Sponsor shall not apply to any such claim or proceeding:
  - 2.1 to the extent that such personal injury (including death) is caused by the negligent or wrongful acts or omissions or breach of statutory duty of the Practice or Investigator, their employees or Agents;
  - 2.2 to the extent that such personal injury (including death) is caused by the failure of the Practice or Investigator, their employees, or Agents to conduct the Clinical Trial in accordance with the Protocol;
  - 2.3 unless as soon as reasonably practicable following receipt of notice of such claim or proceeding, the Practice or Investigator shall have notified the Sponsor in writing of it and shall, upon the Sponsor's request, and at the Sponsor's cost, have permitted the Sponsor to have full care and control of the claim or proceeding using legal representation of its own choosing;
  - 2.4 if the Practice or Investigator, their employees, or Agents shall have made any admission in respect of such claim or proceeding or taken any action relating to such claim or proceeding prejudicial to the defence of it without the written consent of the Sponsor such consent not to be unreasonably withheld provided that this condition shall not be treated as breached by any statement properly made by the Practice or Investigator, their employees or Agents in connection with the operation of the Practice's internal complaint procedures, accident reporting procedures or disciplinary procedures or where such a statement is required by law.
3. The Sponsor shall keep the Practice and Investigator and their legal advisors fully informed of the progress of any such claim or proceeding, will consult fully with the Practice and Investigator on the nature of any defence to be advanced and will not settle any such claim or proceeding without the written approval of the Practice and Investigator (such approval not to be unreasonably withheld).

## **NHS-ABPI-BIA Primary Care mCTA (2013 - Wales)**

4. Without prejudice to the provisions of paragraph 2.3 above, the Practice will use its reasonable endeavours to inform the Sponsor promptly of any circumstances reasonably thought likely to give rise to any such claim or proceeding of which it is directly aware and shall keep the Sponsor reasonably informed of developments in relation to any such claim or proceeding even where the Practice decides not to make a claim under this indemnity. Likewise, the Sponsor shall use its reasonable endeavours to inform the Practice of any circumstances and shall keep the Practice reasonably informed of developments in relation to any such claim or proceeding made or brought against the Sponsor alone.
5. The Practice and the Sponsor will each give to the other such help as may reasonably be required for the efficient conduct and prompt handling of any claim or proceeding by or on behalf of Clinical Trial Subjects (or their dependants) or concerning such a declaration as is referred to in paragraph 1.2 above.
6. Without prejudice to the foregoing if injury is suffered by a Clinical Trial Subject while participating in the Clinical Trial, the Sponsor agrees to operate in good faith the guidelines published in 1991 by The Association of the British Pharmaceutical Industry and entitled "Clinical Trial Compensation Guidelines" and shall request the Investigator to make clear to the Clinical Trial Subjects that the Clinical Trial is being conducted subject to the Association Guidelines.
7. For the purpose of this indemnity, the expression "Agents" shall be deemed to include without limitation any nurse or other health professional providing services to the Practice and Investigator under a contract for services or otherwise and any person carrying out work for the Practice and Investigator under such a contract connected with such of the Practice's facilities and equipment as are made available for the Clinical Trial.



**APPENDIX 5**

**FINANCIAL ARRANGEMENTS**

[When utilising a 'Hub and Spoke' approach to patient recruitment, the financial arrangements for participating practice sites acting as Spokes MUST be included in the payment schedule]

**APPENDIX 6**

**CONDITIONS APPLICABLE TO THE INVESTIGATOR**

- (a) The Investigator is free to participate in the Clinical Trial and there are no rights which may be exercised by or obligations owed to any third party which might prevent or restrict his performance of the obligations detailed in this Agreement.
- (b) The Investigator is not involved in any regulatory or misconduct litigation or investigation by any Regulatory Authorities. No data produced by him in any previous clinical study has been rejected because of concerns as to its accuracy or because it was generated by fraud.
- (c) The Investigator is satisfied that facilities appropriate to the Clinical Trial are available to him at the Trial Site and that he is supported, and will continue to be supported, by medical and other staff of sufficient number and experience to enable him to perform the Clinical Trial efficiently and in accordance with its obligations under the Agreement.
- (d) During the Clinical Trial, the Investigator will not serve as an investigator or other significant participant in any clinical trial for another sponsor if such activity might adversely affect his ability to perform his obligations under this Agreement.