HDI Global SE - UK

CLINICAL TRIALS INSURANCE
SPECIFIC TRIAL POLICY

(This is a "claims made" Policy)

The HDI Global SE - UK (hereinafter called "the Company") in consideration of the payment of premium by the Insured and subject to all terms and conditions of this Policy and any Endorsement hereon will indemnify the Insured as provided herein

Date 26 July 2017
Signed
For and on behalf of the
HDI Global - UK

Important Notice to the Insured

Please read this policy carefully to ensure that it is in accordance with your requirements and that you understand its terms and conditions.
The Company should be contacted immediately if any correction is necessary

Nothing in this Policy shall confer a directly enforceable benefit on any party other than the Insured
SCHEDULE

Policy Number: 390-01154292-14021

Named Insured: University of Warwick

Trial: Any Trial by or on behalf of the Insured in connection with the Insured’s business

Broker: Marsh Limited

Period of Insurance: From 1 August 2017 to 1 August 2018) Local Standard Time at the Address of the Insured both days inclusive

Retroactive Date: 1 August 2013 Local Standard Time at the Address of the Insured

Policy Territory: Great Britain Northern Ireland the Channel Islands the Isle of Man

Limits of Indemnity: GBP10,000,000 in the aggregate for the Period of Insurance

Deductible: Nil

Premium: GBP29,450.00 plus GBP3,534.00 Insurance Premium Tax

Notice of Occurrence to: HDI Global SE via: Marsh
Charter House
426 Avebury Boulevard
Milton Keynes
UK
MK9 2NS

All Other Notices to: HDI Global SE via: Marsh
Charter House
426 Avebury Boulevard
Milton Keynes
UK
MK9 2NS

Proposal information: Renewal information as provided by the broker

Memoranda applicable at inception: 1&2&3

Examined:
DEFINITIONS

(1) **Bodily Injury** Shall mean personal injury sickness disease or death and shall include but not by way of limitation mental injury or shock

(2) **Claim** shall mean a written demand made against the insured for money or services in respect of Bodily Injury insured by this Policy

For the purpose of this Policy the date of such demand shall represent the date the Claim is first made against the Insured

(3) **Compensation** shall mean compensation payable pursuant to any Compensation Guidelines or pursuant to the procedure set forth in Item 2 of the Conditions of Compensation

(4) **Compensation Guidelines** shall mean any applicable guidelines, which are approved by the Company or required by law applicable to the Trial, relating to a no-fault compensation scheme which specifies the manner and rules determining whether and to what extent Research Subjects should be paid for Bodily Injury arising from participating in a clinical trial or human volunteer study, e.g. the “Clinical Trial Compensation Guidelines” issued by The Association of the British Pharmaceutical Industry, as amended or replaced, or the “Guidelines for Compensation for Injury resulting from participation in a company-sponsored Clinical Trial” issued by Medicines Australia, as amended or replaced

(5) **Compensatory Damages** shall mean any sum which the Insured becomes legally obligated to pay by order or award of a court of competent jurisdiction in respect of Bodily Injury caused by the Research Subject’s participation in the Trial (but excluding any liability which attaches by virtue of any contract or agreement and which would not attach in the absence of such contract or agreement) and shall include any award for related claimant’s costs and expenses

(6) **Deductible** shall mean the amount stated in the Schedule which the Insured must pay in respect of each and every Claim before the Company shall be liable to make any payment

(7) **Final Settlement** shall mean a full and final settlement of the Claim and all causes of action against the Insured and any other person in connection with the Trial

(8) **Independent Lawyer** shall mean a judge retired judge barrister or solicitor

(9) The Insured shall mean and shall include

(a) the Named Insured

(b) any director or partner whilst acting in their respective capacities for the Named Insured

(c) any employee of the Named Insured including Medical Persons but only whilst acting within the scope of their duties

(d) any past employee who acted for the Named Insured and who agrees to be bound by the terms of this Policy

(e) any sub-contractor doctor consultant physician hospital or contract research organisation or nurse who will be performing work for the Named Insured in respect of a Trial covered by this Policy

(f) any Ethics Committee or its members that has approved a Trial which is the subject of this Policy

but only in respect of Claims arising out of a Trial covered by this Policy

(10) **Legal Costs** shall mean all the costs and expenses (including any fees or disbursements of any Independent Lawyer) incurred by or on behalf of the Insured with the written consent of the Company in relation to any Occurrences which may be the subject of indemnity under this Policy

(11) **Medical Persons** shall mean Licensed Physicians Doctors Medical Nurses and Dentists

(12) **Occurrence** shall mean an accident or event including continuous or repeated injurious exposure to substantially the same general conditions which results during the Period of Insurance in Bodily Injury neither expected nor intended from the standpoint of the Insured

(13) **Research Subject** shall mean any person participating in a Trial including any child unborn at the
time of the participation in the Trial

(14) **Trial** shall mean the Clinical Trial or Healthy Volunteer Study stated in the Schedule
COVER

The Company will indemnify the Insured against all sums in excess of the Deductible and subject to the Limit of Indemnity and the Sublimit per Research Subject that the Insured shall become liable to pay as

(a) Compensation or

(b) Compensatory Damages

in respect of any Claim made by Research Subjects for Bodily Injury caused by an Occurrence happening after the Retroactive Date and before the end of the Period of Insurance within the Policy Territory and arising out of the Trial of the Insured as stated in the Schedule

Provided that

(i) such Claim is first made in writing against the Insured during any Period of Insurance and is notified to the Company during or within 30 days after expiry of the same Period of Insurance

And

(ii) all Bodily Injury resulting or alleged to have resulted from the same Occurrence and having occurred during that Period of Insurance in which the first Claim is made against the Insured irrespective of the number of claimants or the period over which such Bodily Injury is likely to result in a Claim or Claims being made against the Insured at some future date
EXTENSIONS

Unless otherwise stated the following Extensions are subject always to the terms of the Policy

(1) NOTIFICATION OF EVENT

If during the Period of Insurance the Named Insured shall give written notice to the Company in accordance with Condition (6)(b) of any specific event which the Company accepts may give rise to a Claim any Claim subsequently made against the Insured arising out of that event shall be deemed to have been first made against the Insured during the said Period of Insurance regardless of when such Claim is actually made.

If the Named Insured fails to give such notice any Claim subsequently made against the Insured arising out of the respective event shall not be covered under this policy.

(2) ETHICS COMMITTEE

The Company will indemnify the Ethics Committee or any member thereof in respect of legal costs and expenses incurred with the Company's written consent in the defence of any criminal proceedings brought (or in an appeal against conviction arising from such proceedings) as a result of manslaughter arising from any event which may be the subject of indemnity under this Policy.

PROVIDED THAT

1 the proceedings relate to an offence alleged to have been committed during the Period of Insurance and in the course of the Trial

2 the Company will not provide indemnity

   (a) for fines or penalties of any kind

   (b) in respect of proceedings consequent upon

   (i) any deliberate act or omission

   (ii) Bodily Injury sustained by any employee of the Named Insured arising out of and in the course of employment by the Named Insured

   (iii) the ownership possession or use by or on behalf of the Insured or any person entitled to indemnity of any mechanically propelled vehicle while being used in circumstances where insurance or security is required by law

(3) EXTENDED REPORTING PERIOD

Notwithstanding anything contained in proviso (i) of the Cover to the contrary it is agreed that the Company will indemnify the Insured in respect of any Claim first made in writing against the Insured and notified to the Company during the Extended Reporting Period specified in this Extension.

Provided that

(i) such Claim would have been admissible under this Policy had such Claim been made in accordance with proviso (i) of the Cover

   and

(ii) the incident giving rise to such Claim occurred after the inception and before the end of
the Period of Insurance

Such Claim shall for the purposes of this Policy be deemed to have been made on the last day of the Period of Insurance.

The Extended Reporting Period shall not reinstate or increase the Limits of Indemnity or extend the Period of Insurance; it may not be cancelled.

The Extended Reporting Period is three (3) years from the end of the Period of Insurance.
EXCEPTIONS

The Company shall not be obliged to indemnify the **Insured** in respect of any **Claim**

1. made as a consequence whether direct or indirect of war invasion act of foreign enemy hostilities (whether war be declared or not) civil war rebellion revolution insurrection military or usurped power

2. made within any country or territory which operates under the laws of the United States of America or Canada or in respect of any order made anywhere in the world to enforce a judgement award or settlement based on those laws either in whole or in part

3. made for **Bodily Injury** of whatsoever nature directly or indirectly caused by or contributed to by or arising from
   
   (a) ionising radiations or contamination by radioactivity from any nuclear fuel or from any nuclear waste from the combustion of nuclear fuel
   
   (b) the radioactive toxic explosive or other hazardous properties of any explosive nuclear assembly or nuclear component thereof

4. arising from Hepatitis or any condition directly or indirectly caused by or associated with Human T-Cell Lymphotropic Virus Type iii (HTLV iii) or Lymphadenopathy Associated Virus (LAV) or the mutants derivatives or variations thereof or in any way related to Acquired Immune Deficiency Syndrome or any syndrome or condition of a similar kind howsoever it may be named

5. arising from any condition directly or indirectly caused by or associated with Transmissible Spongiform Encephalopathy (TSE) Creutzfeldt-Jakob Disease (CJD) variant Creutzfeldt-Jakob Disease (vCJD) new variant Creutzfeldt-Jakob Disease (nvCJD) or Bovine Spongiform Encephalopathy (BSE)

6. arising out of an **Occurrence** the circumstances of which the **Insured** were aware prior to the inception of this Policy

7. made for **Bodily Injury** of whatsoever nature directly or indirectly caused by or contributed to by or arising from
   
   (a) asbestos asbestos fibres asbestos dust or any materials containing asbestos
   
   (b) tobacco or any tobacco products (or ingredients thereof)
   
   (c) Lead

   provided that this Exception shall not apply to **Bodily Injury** where such **Bodily Injury** is not related to the chemical or biological properties of such goods materials products or substances

8. arising out of a **Trial** which does not comply with the statutory requirements or guidelines of the relevant person authority department or public or private body in the country, state or territory in which the **Trial** occurred
CONDITIONS OF COMPENSATION

(1) In the event that Compensation Guidelines apply the Company will indemnify the Insured for any Compensation the Insured becomes liable to pay in accordance with such scheme provided a Final Settlement has been achieved;

(2) In the event that Compensation Guidelines do not apply or in case of doubt about the procedures or liabilities under such Compensation Guidelines the Company will indemnify the Insured for any Compensation which

(i) has been determined on a no-fault basis,
(ii) does take into account the particularities of the Bodily Injury,
(iii) has been determined with reference to the amount of damage awarded in similar cases by the courts of the country where the Trial took place,
(iv) shall be paid in a lump sum;

provided:

(a) the Insured and the Research Subject have agreed upon such Compensation with the consent of the Company within twelve months following the date the Claim has first been made and provided such agreement results in a Final Settlement, or – in case the Insured has made a written offer for a Final Settlement of the Claim in accordance with (a) but the Research Subject has not accepted such offer within the above twelve months period –

(b) the Insured and the Research Subject achieve a Final Settlement in accordance with the following:

(aa) The Compensation shall be determined by an Independent Lawyer experienced in Medical Litigation and acting as an Arbitrator. The choice of Independent Lawyer shall be with the agreement of the Company and Research Subject and in the absence of such agreement the appointment shall be made by the President for the time being of the Law Society of England and Wales and/or the equivalent body of the country in which the Claim is made

(bb) In the event of the appointment of an Independent Lawyer such person shall:

(i) allow the parties a reasonable opportunity to present their cases with both oral and written evidence

(ii) be entitled to obtain independent expert advice

(iii) exercise any power conferred upon an Arbitrator by an Arbitration Statute or other law application in the country in which the Claim is made

(iv) otherwise determine the procedure in order to arrive at a just settlement

(cc) In the event that the Insured and the Research Subject agree to be bound by the decision of the Independent Lawyer and the Research Subject within three months upon the decision of the Independent Lawyer accepts in writing the Final Settlement the Company will pay the reasonable costs of the Research Subject including any legal costs and expenses

(3) Any Final Settlement according to Item (1) or (2) above must – as a pre-condition to the indemnification by the Company – include the following provisions:

(a) the Research Subject waives all rights of action against the Insured in connection with the Trial and

(b) the Research Subject shall sign such release or other documents as the Insured may reasonably require to give effect to (a) of this Item (3) above
(4) In the event that a **Final Settlement** is not reached in accordance with the Items (1) and (2) above the Company shall indemnify the **Insured** for any **Compensatory Damages** which the **Insured** becomes legally liable to pay.
Conditions

(1) This Policy and the Schedule shall be read together as one document and any word or expression to which a specific meaning has been attached in any part of this Policy or of the Schedule shall bear such specific meaning wherever it may appear.

(2) By acceptance of this Policy the Insured agrees that it has been issued in reliance upon the truth of his declarations and representations made to the Company or any of its agents relating to this Insurance.

(3) The terms of this Policy shall not be waived altered or changed in any way except by Endorsement issued by the Company to form a part of this Policy.

(4) If any part of the Deposit Premium is based on estimates furnished by the Insured the Insured shall keep an accurate record containing all relative particulars and shall allow the Company to inspect such record. Within one month of the expiry of the Period of Insurance the Insured shall furnish such information as the Company may require. The Deposit Premium shall thereupon be adjusted and the difference paid by or allowed to the Insured subject to the retention by the Company of any Minimum Premium.

(5) The Insured shall take reasonable precautions to prevent any event which may give rise to liability under this Policy and as soon as possible after discovery cause such additional precautions to be taken as the circumstances may require.

(6) The Insured shall as a condition precedent to their right to be indemnified under this Policy and regardless of any Deductible give immediate written notice to the Company of:

(a) the receipt by the Insured of any Claim.

(b) any specific event which in the opinion of the Insured may give rise to a Claim.

Every Claim writ summons or process shall be forwarded to the Company immediately on receipt.

(7) No admission offer promise payment or indemnity shall be made or given by or on behalf of the Insured without the written consent of the Company. The Company shall be entitled to conduct in the name of the Insured the defence or settlement of any Claim or to prosecute in the name of the Insured for its own benefit any Claim and shall have sole discretion in the conduct of any proceedings and in the settlement of any Claim save as hereinafter provided in Conditions (8) and (9) below and the Conditions of Compensation.

(8) The Insured shall assist and cooperate with the Company in the investigation and defence of all Claims and conduct of legal proceedings arising therefrom as the Company and/or its legal advisers and consultants may require. The choice of Counsel is to be agreed by the Insured and the Company but failing agreement the Company alone shall be entitled to nominate the Counsel of their choice.

(9) In connection with any Claims against the Insured the Company may at any time pay to the Insured the Limit of Indemnity or any less amount for which such Claims can be settled and thereupon the Company shall relinquish the control of such Claims to the Insured and be under no further liability in connection therewith except for costs and expenses which the Company have already agreed to bear in respect of matters prior to the date of such payment.
(10) The insurance afforded by this Policy is excess over and reduced by any other valid and collectable insurance available to the Insured. Valid and collectable insurance includes any self insurance plan which would be applicable to the loss.

(11) The Company may cancel this Policy by sending 30 days notice to the Insured at the Insured’s last known address. The Insured shall thereupon become entitled to a return of premium after deduction of premium at the Company’s short period rates.

(12) This Policy shall be governed by and construed in accordance with the laws of England. The Company and the insured shall submit to the exclusive jurisdiction of the courts of Great Britain, Northern Ireland, the Channel Islands, the Isle of Man over any matter arising under or in connection with this Policy.

Date  26 July 2017

Signed
For and on behalf of the

HDI Global SE - UK
Endorsements attaching to and forming part of Policy No. 390-01154292-14021 in the Name of University of Warwick as stated in the schedule

1. PRIOR NOTIFICATION
It is agreed that this Policy does not apply to the following Trials unless prior to the commencement of such Trial full details of such Trial have been notified to the Company and the Company has agreed in writing to provide an indemnity in respect of such Trial

(1) Trials in which the Insured are the sponsor and which involve the testing of drugs

(2) Trials in which blood-products will be tested

(3) Trials in which artificial implants with skeleton function (e.g. hip-joint, knee-joint or vertebra prosthesis etc) will be tested

(4) Trials in connection with hormone preparations and monoclonal antibodies

(5) Trials in connection with tissue- and cell-technology as well as genetic-technology:
   (a) use of donated cells and/or tissue-transplants:
      (i) allografts (the transplant donor and recipient are not identical, but belong to the same species)
      (ii) xenogenic transplantations (the transplant donor and recipient do not belong to the same species).
   (b) genetic-technology:
      (i) genetic-therapy-studies
      (ii) studies with genetically modified products.

(6) Trials with a planned duration of more than 8 years

(7) Trials in which pregnant women are involved

(8) Trials in connection with contraceptives

(9) Trials in which products are tested which have a potential of addiction and in which the product is given to the patient for a duration of more than two years

(10) Life-Style Clinical Trials (e.g. Viagra, weight loss products, cosmetic surgery)

(11) Clinical Trials in connection with silicone implants (not only breast implants)

(12) Trials involving healthy persons whose health will be impaired for the purpose of the Clinical Trial; e.g. in order to test a remedy afterwards

(13) Trials involving nicotine products

(14) Trials involving immunomodulation (e.g. Interferon, vaccines)

2. TRIALS TO RUN TO NATURAL EXPIRY
Notwithstanding anything herein contained to the contrary it is agreed that the coverage provided for the following Trials which commence during the Period of Insurance shall run to their stated expiry unless otherwise agreed by the Company

3. MALFORMATIONS OF NEW BORN EXCEPTION
It is hereby noted and agreed that from inception date the following amendment is made to the Policy:
4. EXCEPTIONS

The Company shall not be obliged to indemnify the Insured in respect of any Claim:

(9) made in respect of malformations of new born or unborn children where the Trial involves the testing of medicinal products on pregnant women
COMPLAINTS PROCEDURE

HDI Global SE – UK aims to provide its clients with a high standard of service. Consequently, should we fail to meet your expectations, we will aim to resolve your concerns promptly and fairly.

In the first instance, any concerns should be directed to your usual contact or to the manager of the department with which you usually deal. If we cannot resolve your concerns within one (1) working day, we will acknowledge your complaint in writing within seven (7) working days and let you know when an answer might be expected.

If you remain dissatisfied with our response, we have an escalation process for ensuring that a senior member of staff reviews your complaint. You can invoke this by stating to the individual that is handling your complaint that you wish to escalate it.

Alternatively, you may write to:

The Compliance Officer,
HDI Global SE UK,
10 Fenchurch Street
London
EC3M 3BE
Phone:
Fax:

If you are a small business you may have a right of referral to the Financial Ombudsman Service at:

Financial Ombudsman Service,
South Quay Plaza,
183 Marsh Wall,
London
E14 9SR

Phone: 0845 080 1800 or 020 7964 0500
Fax: 020 7964 1001
E-Mail: complaint.info@financial-ombudsman.org.uk
Website: www.financial-ombudsman.org.uk

Your right as a policyholder to take legal action remains unaffected by the existence or use of any complaints procedure referred to above.