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Beazley Claims Service

Delivering great claims service is one of Beazley's top priorities. Our Claims Service Standards highlight what our stakeholders can expect when working with our Claims Team – expertise, responsiveness, partnership, fairness, and accountability. Please visit www.beazley.com to read more about our Claims Service Standards under Our Approach to Claims.

Clinical Trials Financial Injury Section

Coverage

Clinical Trials Financial Injury

To pay **loss** resulting from any **claim** first made against any **insured** during the **policy period** for a **clinical trials wrongful act**.

Exclusions from cover

The **insurance company** will not be liable for any **loss** or **claim**:

Contractual Liability

arising out of, based upon or attributable to any contractual liability or obligation, including any breach of contract or agreement, either oral or written.

This Exclusion will not apply to the extent the **insured** would have been liable in the absence of such liability or obligation.

Data Processing Services

arising out of, based upon or attributable to any **insured's** data processing services.

Failure to Pay Bond

arising out of, based upon or attributable to any failure to pay any bond, debt, financial guarantee or debenture, or any interest in connection with the foregoing.

Financial Advice

arising out of, based upon or attributable to any financial or investment advice given, referrals, warranties, guarantees or predictions of future performance made by any **insured** as regards specific and identifiable investment items including but not limited to personal property, real property, stocks, bonds or securities.

Intellectual Property

arising out of, based upon or attributable to any actual or alleged plagiarism, misappropriation of likeness, breach of confidence, or misappropriation or infringement of any intellectual property right, including patent, trademark, trade secret, trade dress and copyright.

Other Insureds

arising out of, based upon or attributable to any **claims** brought against any **insured** by another **insured**.

Personal Injury and Property Damage

arising out of, based upon or attributable to any **personal injury** or **property damage**.

Prior Knowledge and Prior Notice

arising out of, based upon or attributable to:



- (a) any act, error, omission, incident or event committed prior to the inception date if any member of the **control group** on or before such date knew or could have reasonably foreseen that such act, error, omission, incident or event might be expected to be the basis of a **claim** or **loss**; or
- (b) any **claim**, **loss**, incident or circumstance of which notice has been provided under any prior policy of which this Policy is a renewal or replacement.

Recall

arising out of, based upon or attributable to the withdrawal, recall, inspection, repair, replacement, reproduction, removal or disposal of any work product, including when resulting from or incorporating the results of **professional services**.

This Exclusion will not apply to loss of use of such work product resulting from or incorporating the results of **professional services**.

Unapproved Clinical Trials

arising out of, based upon or attributable to any **clinical trial** if:

- (a) such **claim** arises out of any exposure to **biologics, pharmaceuticals, nutraceuticals, medical devices** or any other product or procedure, upon or within human beings, during the **clinical trial** unless the exposure has been approved by the governmental or regulatory authority having jurisdiction over the **clinical trial**; or
- (b) the act, error or omission takes place after any governmental or regulatory authority having jurisdiction over the **clinical trial**:
 - i. places or imposes a hold on the clinical trial;
 - ii. withdraws approval of an Investigational New Drug Application, Investigational Device Exception Application or similar authorization applicable to the clinical trial; or
 - iii. directs or order that the **clinical trial** be discontinued.

Claim Requirements and Information

Notification of Claims

As a condition to coverage under this Policy, the **insured** must give notice to the **insurance company** of any **claim** made against the **insured** as soon as practicable but in no event later than 30 days after the end of the **policy period**.

Notification of Circumstances

The **insured** must during the **policy period** notify the **insurance company** of any fact or circumstance which could reasonably give rise to a **claim**.

Any notice must include:

- (a) the reasons why the **insured** reasonably anticipates that such fact or circumstances could give rise to a **claim**, and
- (b) full particulars of the dates, acts and persons involved (where available).

If a **claim** is made after the end of the **policy period** and arises from a fact or circumstance reported under this provision, then such **claim** will be deemed to have been made at the same time as the fact or circumstance was reported to the **insurance company**.



Related ClaimsAll **related claims**:

- (a) are considered a single **claim** for the purposes of this Policy, irrespective of the number of claimants or **insureds** involved in the **claim**, and
- (b) are deemed to have been made at the time of the first such **claim**, and
- (c) will be treated by the **insurance company** as having been reported when the first of such **claims** was reported or is deemed to have been reported to the **insurance company**.

Notice to the Insurance Company

All notices to the **insurance company** must be sent either by e-mail to or by mail to the address specified in the Declarations.

Defense and Settlement

(a) Duties

The **insurance company** has the right and duty to defend any **claim** against the **insured** seeking amounts which are payable under the terms of this Policy, even if any part of such **claim** is groundless, false or fraudulent.

Defense counsel will be mutually agreed by the **named insured** and the **insurance company** but, in the absence of such agreement, the **insurance company's** decision will be final.

(b) Consent to **defense costs**

The **insurance company** will not be obligated to pay **defense costs** unless it has given prior written consent to such **defense costs** being incurred (except if expressly specified in this Policy that prior consent is not first required).

(c) Settlement of **claims**

The **insured** cannot admit liability, make any payment, assume any obligation, incur any expense, enter into any settlement, stipulate to any judgment or dispose of any **claim** without the prior written consent of the **insurance company**.

If the **insured** refuses to consent to any settlement recommended by the **insurance company** and acceptable to the claimant, the **insurance company's** liability for **loss** will not exceed:

- i. the amount for which the **claim** could have been settled, less the remaining Retention, plus
- ii. the **defense costs** incurred up to the time of such refusal;

or the applicable Limit of Liability, whichever is less, and the **insurance company** will have the right to withdraw from the further defense of such **claim**.

Definitions

The following definitions are applicable to this Coverage:

biologics means any substance or product consisting of or originally derived from a living organism or its by-products (including globulin, serum, blood or blood components, vaccine, protein, antibody, antigen or analogous product) administered orally, topically, or via injection and used in the diagnosis, prevention, mitigation, or treatment of illness or disease subject to United

States Food and Drug Administration regulation or the equivalent of such regulations in any foreign jurisdiction.

claim means:

- (a) a written demand for monetary damages or services (including any request to toll or waive a statute of limitations);
- (b) a civil or administrative proceeding; or
- (c) an arbitration, mediation or other form of alternative dispute resolution proceeding.

clinical trials wrongful act means any negligent act, error or omission or failure in the performance of **professional services** committed by any **insured** or by others on behalf of the **insured organization** while performing clinical investigation and evaluation work in connection with a **clinical trial** that occurs on or before the **retroactive date** and before the end of the **policy period**.

clinical trial means organized studies that adhere to an **institutional review board**-approved written protocol and which provided clinical data for the assessment of the effects of the **biologics, pharmaceutical, nutraceuticals or medical devices**.

damages means judgments (including pre and post-judgment interest), awards and settlements incurred by the **insured**.

damages will not include:

- (a) future profits, restitution, disgorgement of unjust enrichment or profits by an **insured**, or the costs of complying with orders granting injunctive or equitable relief;
- (b) return or offset of fees, charges or commissions charged by or owed to an **insured** for goods or services already provided or contracted to be provided;
- (c) taxes or loss of tax benefits;
- (d) fines, sanctions or penalties;
- (e) punitive or exemplary damages or any damages which are a multiple of compensatory damages, unless insurable by law in any applicable venue that most favors coverage for such damages;
- (f) liquidated damages, but only to the extent that such damages exceed the amount for which the **insured** would have been liable in the absence of such liquidated damages agreement;
- (g) any amounts for which the **insured** is not liable, or for which there is no legal recourse against the **insured**; or
- (h) any amounts deemed uninsurable by law.

defense costs means:

- (a) reasonable legal fees, costs and expenses necessarily incurred by or on behalf of the **insured** in connection with the investigation, defense, settlement or appeal of a **claim**;
- (b) all other fees, costs and expenses incurred by or on behalf of the **insured** with the **insurance company's** prior written consent; and
- (c) premiums for appeal bonds for covered judgments or bonds to release property used to secure a legal obligation, if required for a **claim** against any **insured**. However, the insurance company will have no obligation to appeal or to obtain such bonds.

defense costs will not include the salary of any **insured**, the cost of their time or costs or overheads of the **insured organization**.



independent contractor means any natural person who performs labor or service for the **named insured** pursuant to a written contract or agreement, where such labor or service is under the exclusive direction of the **named insured**. The status of an individual as an **independent contractor** shall be determined as of the date of an alleged act, error or omission by any such **independent contractor**. This coverage shall apply in excess of any other valid and collectible insurance available to any such **independent contractor**.

insured means:

- (a) the **insured organization**;
- (b) a director, executive officer, stockholder, **manager**, administrator or employed physician of the **insured organization**, but only with respect to the performance of his or her duties as such for the **insured organization**;
- (c) an **employee** or volunteer worker of the **insured organization**, but only with respect to the performance of his or her duties as such for the **insured organization**;
- (d) a partner or member if the **named insured** is a partnership or joint venture, but only with respect to his or her liability as such on behalf of the **insured organization**;
- (e) any person who previously qualified as an **insured** under parts (b) and (c) above, but only with respect to the performance of his or her duties as such on behalf of the **insured organization**;
- (f) any **independent contractor** and/or agent of the **named insured**; and
- (g) the estate, heirs, legal representative, trusts, estate planning vehicles or assigns of any **insured** in the event of their death, incapacity or bankruptcy.

institutional review board means:

- (a) a board, committee, group or similar organization; or
- (b) an ethics committee;

designated, directed or requested by an institution or other person or organization to review a **clinical trial** including any:

- i. approval; or
- ii. periodic review;

of any such **clinical trial**.

loss means:

- (a) **damages**; and
- (b) **defense costs**.

medical devices means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, component part or accessory that is:

- (a) subject to United States Food and Drug Administration regulation or the equivalent of such regulations in any foreign jurisdiction;
- (b) intended for use in the diagnosis, cure, mitigation, treatment or prevention of injury, sickness or disease in humans; or
- (c) intended to affect the structure or any function of the human body;

that does not achieve its primary intended purposes through chemical or biological action within or



upon the human body and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

nutraceutical means a dietary supplement as defined by the United States Dietary Supplement Health and Education Act, whether intended for ingestion or topical application.

personal injury means:

- (a) **bodily injury**;
- (b) false arrest, false imprisonment, detention or malicious prosecution;
- (c) libel, slander, defamation of character or invasion of right of privacy, unless arising out of any advertising activities; or
- (d) wrongful eviction from, wrongful entry into, or invasion of the right of private occupancy of a room, dwelling or premises that a person occupies, committed by or on behalf of its owner, landlord or lessor.

pharmaceutical means any substance taken by mouth, injected into a muscle, the skin, a blood vessel, or a body cavity, or applied to the skin to treat or prevent a disease.

professional services means services listed in the Declarations.

related claims means all **claims** arising from the same or a series of related, repeated or continuing acts, errors, omissions or events.