

Beazley | Comprehensive Life Sciences
Insurance

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Beazley Claims Service

The **insurer** will assign a Claims Manager and provide the **insured** with their e-mail address, direct dial telephone number and mobile phone number.

The Claims Manager will endeavour to respond to phone calls within one business day and if the assigned Claims Manager is unable to respond for whatever reason, another Claims representative will contact you.

The Claims Manager, and where applicable the **insurer's** external advisors, will respond in a prompt, professional and transparent manner and will provide straight answers and deliver on commitments.

Claims Managers will be available for meetings to candidly discuss any coverage or claims issues, and will keep an open mind and give any alternative opinions due consideration. Claims Managers work closely with the underwriting teams to ensure that the policy intent is respected.

Schedule

Policy number

Policyholder

Name:
Address:

Policy period

From:
To:
Both days inclusive at the **insured's** address as specified in the Schedule

Limit of liability

Insuring Clauses

(1) Products liability

[local currency] each **claim**
[local currency] in the aggregate during the **policy period**
and separately

(2) Professional indemnity

[local currency] each **claim**
[local currency] in the aggregate during the **policy period**
and separately

(3) Medical malpractice

[local currency] each **claim**
[local currency] in the aggregate during the **policy period**
and separately

(4) Public liability

[local currency] each **claim**
[local currency] in the aggregate during the **policy period**
and separately

(5) No fault compensation for clinical trials

[local currency] each **compensation claim**
[local currency] in the aggregate during the **policy period**
and separately

(6) Legal liability for clinical trials

[local currency] each **claim**
[local currency] in the aggregate during the **policy period**

Sub-limits of liability

sub-limits for the Coverage Extensions stated below will apply in the aggregate during the **policy period** as follows:

- [local currency] Coverage Extension loss of documents
- [local currency] Coverage Extension loss of personally identifiable information
- [local currency] Coverage Extension breach of intellectual property rights
- [local currency] Coverage Extension product recall costs
- [local currency] Coverage Extension research and development restoration costs
- [local currency] Coverage Extension barcode rectification costs
- [local currency] Coverage Extension mitigation costs
- [local currency] Coverage Extension abuse and harassment liability
- [local currency] Coverage Extension medical regulatory costs
- [local currency] Coverage Extension reputation damage costs
- [local currency] Coverage Extension environmental liability costs
- [local currency] Coverage Extension manslaughter defence costs

Policy aggregate limit of liability

[local currency] in the aggregate during the **policy period** for all Insuring Clauses and Coverage Extensions

Retention

(1) Products liability

[local currency] each **claim** or **insured event**

(2) Professional indemnity

[local currency] each **claim** or **insured event**

(3) Medical malpractice

[local currency] each and every **claim** or **insured event**

(4) Public liability

[local currency] each **claim** or **insured event**

(5) No fault compensation for clinical trials

[local currency] each **claim**

(6) Legal liability for clinical trials

[local currency] each **claim** or **insured event**

Retroactive date

- [1] Products Liability [date]
- [2] Professional Indemnity [date]
- [3] Medical malpractice [date]
- [5] No fault compensation for clinical trials [date]
- [6] Legal liability for clinical trials [date]

Extended reporting period

Premium

[local currency] (annual) plus applicable taxes

Territory

Worldwide

THIS POLICY SETS OUT THE TERMS UPON WHICH THE **INSURER** AGREES TO INSURE THE **INSURED** IN CONSIDERATION OF THE PAYMENT OF, OR AGREEMENT TO PAY, THE PREMIUM. THE INSURING CLAUSES AND COVERAGE EXTENSIONS ARE SUBJECT TO ALL TERMS, CONDITIONS, RESTRICTIONS AND LIMITATIONS OF THIS POLICY. ANY WORDS SHOWN IN BOLD TYPE HAVE SPECIFIC MEANINGS IN THE DEFINITIONS SECTION OF THIS POLICY. INSURING CLAUSES 1, 2, 3, 5 AND 6 PROVIDE COVERAGE ON A CLAIMS MADE AND REPORTED BASIS AND APPLY ONLY TO THOSE **CLAIMS** WHICH ARE FIRST MADE AGAINST THE **INSURED** AND REPORTED IN WRITING TO THE **INSURER** DURING THE **POLICY PERIOD** OR THE **EXTENDED REPORTING PERIOD** (IF APPLICABLE). INSURING CLAUSE 4 PROVIDES COVERAGE ON AN OCCURRENCE BASIS AND APPLIES ONLY TO THOSE **PUBLIC LIABILITY INCIDENTS** TAKING PLACE DURING THE **POLICY PERIOD**. THE POLICY CONTAINS IMPORTANT CONDITIONS, THESE ARE D.1(A) CLAIMS AND INSURED EVENTS – FOR CLAIMS MADE COVER; D.1(C) PUBLIC LIABILITY; D.2(D) CONSENT TO SETTLEMENTS; E.3 CHANGE OF CONTROL/ACQUISITIONS; AND E.5 CANCELLATION. PLEASE READ THESE CAREFULLY.

A. Insuring Clauses

1. Products liability

The **insurer** will pay on behalf of the **insured** any **loss** resulting from a **claim** first made against any **insured** during the **policy period** for a **product incident**.

2. Professional indemnity

The **insurer** will pay on behalf of the **insured** any **loss** resulting from a **claim** first made against the **insured** during the **policy period** arising out of a **professional services wrongful act**.

3. Medical malpractice

The **insurer** will pay on behalf of the **insured** any **loss** resulting from a **claim** first made against the **insured** during the **policy period** arising out of a **malpractice incident** or **patient accident**.

4. Public liability

The **insurer** will pay on behalf of the **insured** any **loss** resulting from a **claim** for a **public liability incident** that occurred during the **policy period**.

5. No fault compensation for clinical trials

The **insurer** will pay on behalf of the **insured** any **compensation** resulting from a **compensation claim** first made against the **insured** during the **policy period** for a **clinical trials incident**.

6. Legal liability for clinical trials

The **insurer** will pay on behalf of the **insured** any **loss** resulting from a **claim** first made against the **insured** during the **policy period** for a **clinical trials incident**.

B. Coverage Extensions

GENERAL POLICY COVERAGE EXTENSIONS:

1. Loss of documents

The **insurer** will pay on behalf of the **insured** any **loss** resulting from a **claim** first made against the **insured** during the **policy period** resulting from a loss of **documents**.

2. Loss of personally identifiable information

The **insurer** will pay on behalf of the **insured** any **loss** resulting from a **claim** first made against the **insured** during the **policy period** resulting from a loss of **personally identifiable information**.

3. Breach of intellectual property rights

The **insurer** will pay on behalf of the **insured** any **loss** resulting from a **claim** first made against the **insured** during the **policy period** resulting from a **breach of intellectual property rights**.

4. Additional insured

The **insurer** will pay on behalf of an **additional insured** any **loss** or **compensation** resulting from a **claim** or **compensation claim** first made against the **additional insured** during the **policy period**.

PRODUCTS LIABILITY COVERAGE EXTENSION:

5. Product recall costs

The **insurer** will pay **product recall costs** of the **policyholder**.

6. Research and development restoration costs

The **insurer** will pay **research and development restoration costs** of the **policyholder**.

7. Barcode rectification costs

The **insurer** will pay **barcode rectification costs** of the **policyholder**.

MEDICAL MALPRACTICE COVERAGE EXTENSIONS

8. Mitigation costs

The **insurer** will pay **mitigation costs** of an **insured**.

9. Abuse and harassment liability

The **insurer** will pay on behalf of the **insured** any **loss** resulting from a **claim** first made against the **insured** during the **policy period** resulting from an **act of harassment**.

10. Medical regulatory costs

The **insurer** will pay **medical regulatory costs** of an **insured**.

MEDICAL MALPRACTICE AND PROFESSIONAL INDEMNITY COVERAGE EXTENSION

11. Reputation damage costs

The **insurer** will pay **reputation damage costs** of the **policyholder**.

PUBLIC LIABILITY COVERAGE EXTENSION

12. Environmental liability

The **insurer** will pay **environmental liability costs** of an **insured**.

MEDICAL MALPRACTICE, PUBLIC LIABILITY AND LEGAL LIABILITY FOR CLINICAL TRIALS COVERAGE EXTENSION

13. Manslaughter defence costs

The **insurer** will pay on behalf of the **insured** **manslaughter defence costs** of an **insured** incurred in connection with a **manslaughter proceeding**:

- (a) first made against the **insured** during the **policy period** arising out of a **malpractice incident** or a **clinical trials incident**; or
- (b) arising out of a **public liability incident** that occurred during the **policy period**.

C. Coverage Restrictions

The **insurer** will not be liable to make any payment under this policy for that part of any **loss**:

APPLICABLE TO ALL INSURING CLAUSES AND COVERAGE EXTENSIONS

1. Prior claims and circumstances

arising out of, based upon or attributable to:

- (a) any **claim, compensation claim, insured event**, fact, circumstance, **accident**, act, error or omission, incident or event of which notice has been given under any policy in relation to which this policy is a renewal or replacement or of which any **responsible person** had knowledge prior to the inception of this policy; or
- (b) any matter which taken together with such **claim, compensation claim, insured event**, fact, circumstance, **accident**, act, error or omission, incident or event would constitute a **single aggregated event**.

This Coverage Restriction will not apply to facts or circumstances which have been notified to the **insurer** under any earlier policy but were not accepted by the **insurer** as a valid notification, and where cover has been maintained continuously with the **insurer** from the inception date of that earlier policy until the inception date of this policy.

2. Contractual liability

arising out of, based upon or attributable to any contractual penalty, acceptance by the **insured** of liability for any liquidated damages, or guarantee or warranty provided by the **insured**.

This Coverage Restriction will not apply to the **insured's** failure to perform its duties with reasonable skill and care, provided that the **insurer's** liability will be limited to

such sums as the **insured** would have had to pay in the absence of such contractual penalty, liquidated damages or guarantee or warranty.

3. Dishonesty

arising out of, based upon or attributable to the gaining of profit or advantage to which the **insured** was not legally entitled or any dishonest, malicious or fraudulent act, error or omission or intentional breach of any laws or regulations by the **insured**.

This Coverage Restriction will only apply in the event that any of the above is established by final non-appealable adjudication of a **medical regulatory authority**, a judicial or arbitral tribunal or formal admission by the **insured**.

4. Deliberate or reckless

arising out of, based upon or attributable to any act, error or omission or **accident** that the **insured** knew or ought reasonably to have known was likely to give rise to a **claim** at the time such act, error or omission was committed or **accident** occurred.

5. Duties to employees

arising out of, based upon or attributable to, directly or indirectly, any breach of any obligation or duty owed or purportedly owed by the **policyholder** as a current, former or prospective employer including any liability for **bodily injury** sustained by an employee.

6. Infrastructure

arising out of, based upon or attributable to any failure or malfunction of electrical, data transfer or telecommunications infrastructure or services which are outside the direct control of the **insured**.

7. Cyber

directly or indirectly caused by, resulting from, or arising out of a **cyber act, cyber incident** or **data breach**, including any action taken in controlling, preventing, suppressing or remediating any **cyber act, cyber incident** or **data breach**.

8. Description of the price of goods, products or services

the actual or alleged inaccurate, inadequate or incomplete description of the price of goods, products or services, cost guarantees, cost representations, contract price estimates, or the failure of services to conform with any represented quality or performance.

9. Product recall

arising out of, based upon or attributable to the recall, removal or disposal of any **products**.

This Coverage Restriction does not apply to **product recall costs**.

10. Specific products

arising out of or resulting from the manufacturing, handling, distribution, advertising, labelling, sale, application, ingestion, consumption, testing, exposure to or any use of any product or substance known as, made of or containing any one or more of the following:

- (a) Diethylstilbestrol, or DES, or which has the same chemical formulary, or which is a stilbene derivative, or any other product or substance having substantially similar formulation, structure, or function by whatever name manufactured or marketed as DES;
- (b) Ephedra, Ma huang, Ephedra sinica, Chinese Ephedra, ephedrine, pseudoephedrine, norpseudoephedrine, or any other product or substance having substantially similar formulation, structure or function, by whatever name manufactured, grown or marketed;
- (c) Fenfluramine, Phentermine or Dexfenfluramine;
- (d) Phenylpropanolamine, Phenylpropanolamine Hydrochloride, PPA or any product or drug containing any of these substances;
- (e) any product containing silicone or similar which is in any form implanted or injected in the body;
- (f) tobacco, nicotine, formaldehyde, acetaldehyde, acrolein, nitrosamine, diacetyl or their derivatives or variations or any tobacco or e-cigarette or vaping products (or ingredients of, or used in the manufacture or production of, such products); or
- (g) Opioids, which means natural chemicals prepared from the latex taken from the Papaver somniferum plant (opium poppy), semi-synthetic chemicals synthesised from natural occurring opium products or synthetic chemical made in a lab to emulate the former that interacts with opioid receptors on nerve cells in the body and brain, and reduce the intensity of pain signals and feelings of pain. Opioid includes, but is not limited to heroin, synthetic opioids or opiates such as tramadol, fentanyl and methadone and pain medications available legally by prescription such as oxycodone, hydrocodone, codeine and morphine.

11. Product safety and approval

based upon or arising out of any **products** sold in any country:

- (a) before such **products** have been approved for use or sale; or
- (b) after such **products** have been declared unsafe;

which is deemed in the country of sale to be in violation of any statute, law, ordinance or regulation by the appropriate governmental authority having jurisdiction over such sale.

12. Intellectual property

arising out of, based upon or attributable to the breach of any intellectual property right or misappropriation of a trade secret and including any infringement of a patent or patent rights or misuse or abuse of patent.

This Coverage Restriction does not apply to cover provided for a **breach of intellectual property rights**.

13. Pollution clean up

incurred to test for, monitor, clean up, recycle, remove, recondition, reclaim, contain, treat, detoxify or neutralise pollutants, contaminants, nuclear material or waste of any kind.

14. Intoxication

arising out of, based upon or attributable to the influence of intoxicants, alcohol or drugs knowingly consumed or taken by the **insured**.

This Coverage Restriction will only apply in the event that any of the above is established by final non-appealable adjudication of a **medical regulatory authority**, a judicial or arbitral tribunal or formal admission by the **insured**.

15. Employment practice violation

arising out of, based upon or attributable to any employment-related practice, policy, act or omission, including discrimination (of any kind) or harassment (of any kind). This Coverage Restriction will not apply to the abuse and harassment liability coverage extension.

16. Abuse and harassment

arising out of, based upon or attributable to any actual or alleged conduct, physical act, gesture, spoken or written words of a sexual or violent nature including sexual molestation, sexual or physical assault or battery, sexual or physical abuse or sexual harassment. This Coverage Restriction does not apply to cover provided for an **act of harassment**.

17. Wrongful detention

arising out of or resulting from any wrongful or unlawful detention including breaches of the Mental Health Act 1983 (U.K.) or the Human Rights Act 1998 (U.K.) or the equivalent legislation in any other jurisdiction.

18. War and terrorism

- (a) arising out of, based upon or attributable to, directly or indirectly, war, invasion, act of foreign enemy, hostile operations (whether war has been declared or not), civil war, rebellion, revolution, insurrection, riot or civil commotion amounting to a popular uprising, military or takeover of power or martial law; or
- (b) arising out of, based upon or attributable to, directly or indirectly, terrorism.

19. Property and contamination damage

arising out of, based upon or attributable to, directly or indirectly, loss, damage or destruction:

- (a) of any property whatsoever by reason of wear, tear, gradual deterioration, moth or vermin;
- (b) as a result of looting, or any act of nature;
- (c) arising out of asbestos, silica or lead;
- (d) arising out of heat, smoke or fumes from a fire which becomes uncontrollable or breaks out from where it was intended to be;
- (e) arising out of, based upon or attributable to the actual, potential, alleged or threatened formation, growth, presence, release or dispersal of any fungi, moulds, spores, organic pathogens, organic chemicals, microorganisms or mycotoxins of any kind; or
- (f) arising out of, based upon or attributable to ionising radiation or contamination by radioactivity from any nuclear fuel or from any nuclear waste as a

consequence of the combustion of nuclear fuel, or the radioactive, toxic, explosive or other hazardous properties of any explosive nuclear assembly or nuclear component.

However this Coverage Restriction will not apply in respect of **bodily injury** resulting from the use of ionising radiation in medical imaging including x-ray or as part of the diagnosing or treatment of a specific illness.

20. Retroactive date

arising out of, based upon or attributable to, directly or indirectly, any **professional services wrongful act, malpractice incident, accident, clinical trials incident, act, error, omission, incident, event, conduct, matter, loss of documents or personally identifiable information** occurring prior to the **retroactive date** or has substantially the same originating cause, source of event to any of these.

This Coverage Restriction does not apply to the Public Liability Insuring Clause or the Public Liability Coverage Extensions.

21. Other insureds

arising out of, based upon or attributable to a **claim** made by or on behalf of on any **insured**; but this coverage restriction does not apply to **bodily injury** sustained by any **insured** as a recipient of **professional services**.

APPLICABLE TO PUBLIC LIABILITY INSURING CLAUSE AND PUBLIC LIABILITY COVERAGE EXTENSION ONLY

22. Care, custody and control

arising out of **property damage** to property belonging to the **insured** or which at the time of the damage is in the **insured's** care, custody or control.

This Coverage Restriction does not apply to:

- (a) vehicles or personal belongings of employees and visitors, while they are located at the premises of the **insured**;
- (b) premises rented to the **insured**, for loss or damage not insurable under property insurance policies and for which the **insured** would not be liable other than by the lease or agreement.

23. Work undertaken by the insured

arising out of **property damage** as a result of or in connection with work performed by or on behalf of the **insured**, or materials, parts, equipment used in connection with such work.

24. Professional services

arising out of, based upon or attributable to **professional services**.

25. Bodily injury or property damage to patients

arising out of, based upon or attributable to a **patient accident**.

APPLICABLE TO CLINICAL TRIALS INSURING CLAUSES AND COVERAGE EXTENSION ONLY

26. Product efficacy

arising out of the failure of any product to perform its intended purpose in the **clinical trial**.

For the purpose of determining the applicability of all Coverage Restrictions, the knowledge or act, error or omission of any **insured** will not be imputed to any other **insured**. The knowledge of each **responsible person** will be imputed to the **policyholder** or the relevant **subsidiary**.

D. Claim Provisions

1. Notification

(a) *Claims and insured events – for claims made cover*

The **insured** must give notice to the **insurer** of any:

- (i) **claim** or **compensation claim** made against the **insured** during the **policy period**; or
- (ii) **insured event** occurring during the **policy period**,

as soon as practicable after the **responsible person** first becomes aware of such **claim, compensation claim** or **insured event**, but in no event later than 30 days after the end of the **policy period**.

The **insured** must also give notice to the **insurer** of any intention on the part of the **insured** to incur **mitigation costs** either prior to such costs being incurred, or in respect of a time critical event, within 30 days of such costs being incurred.

If the **insured** does not give notice to the **insurer** in compliance with this provision 1(a) *Claims and insured events*, the **insurer** will have no liability under this policy in respect of that **claim, compensation claim, insured event** or **mitigation costs**.

(b) *Circumstances*

The **insured** must, during the **policy period**, notify the **insurer** as soon as practicable of any fact or circumstances which may in the reasonable opinion of the **responsible person** give rise to a **claim, compensation claim** or **insured event**.

Any notice must include the reasons why the **responsible person** reasonably anticipates that the fact or circumstances may give rise to a **claim, compensation claim** or **insured event** and, where available, full particulars of the dates, acts and persons involved.

Any **claim** which is made or **insured event** which occurs after the end of the **policy period** and which arises from a circumstance notified in accordance with this clause will be deemed to have been made or have occurred at the same time as the circumstance was notified.

(c) *Public liability*

The **insured** must give notice to the **insurer** of any **public liability incident** occurring during the **policy period** as soon as practicable after the **responsible person** first becomes aware of such **public liability incident**.

(d) Related matters

A **single aggregated event** will be treated by the **insurer** as having been notified when the first of such **claims, compensation claim** or **insured events** was notified or is deemed to have been notified to the **insurer**, during the **policy period** or any applicable **extended reporting period** if:

- (i) the **malpractice incident, professional services wrongful act** or **accident** affects two or more persons and it is attributable to a single direct cause;
- (ii) the first **malpractice incident, professional services wrongful act** or **accident** occurs after the **retroactive date** and before the expiration of the **policy period**;
- (iii) the first of such **claims, compensation claims** or **insured events** has been made within the **policy period** or directly relates to circumstances notified within the **policy period**; and
- (iv) the **policyholder** has requested, in writing, within 120 days of the expiration of the **policy period** or any applicable **extended reporting period** the designation of a **single aggregated event** the agreement of which should not be unreasonably withheld by **insurers**.

If the **insured** agrees to designate such **claims, compensation claims** or **insured events** as a **single aggregated event**, then any later related **claims, compensation claims** or **insured events** which are made and notified within 5 years of the expiration date of the **policy period** or any applicable **extended reporting period** are hereby covered under this policy as a **single aggregated event**, and will be deemed to have been notified at the date of the first designated **claim, compensation claim, insured event** or notification and are subject to one **retention** and the limit of liability.

(e) Remedial action

Following the discovery by the **insured** of a **professional services wrongful act, malpractice incident** or **accident**, the **insured** should promptly take all reasonable steps at their own expense (including any positive action as necessary) to prevent or mitigate other or further **bodily injury**, or consequential loss or damage or liability arising out of such **professional services wrongful act, malpractice incident, accident**, or any series of related or repeated or continuing **professional services wrongful acts, malpractice incidents** or **accidents**. If the **insured** fails to comply with this provision, the **insurer** will have no liability under this policy in respect of any subsequent **claims, compensation claims** or **insured events** arising out of such **professional services wrongful acts, malpractice incidents** or **accidents**.

(f) Address for notifications

All notices must be sent either by e-mail to internationalhealthcare.notices@beazley.com or by mail to the address below:

International Healthcare Claims
Beazley Plc
Plantation Place South,
60 Great Tower Street,
London,
EC3R 5AD

2. Defence and settlement

(a) *Duties*

The **insured** has the right and duty to defend and contest any **claim** made against them, or any **insured event** commenced against them, and will take all reasonable steps to prevent or minimise any **loss**.

The **insurer** will be entitled to participate fully in the conduct of the defence, and at its sole discretion and option, to take over conduct of the defence including settlement negotiations, contribution or indemnification proceedings, in consultation with the **insured**.

(b) *Consent to policy costs*

The **insurer** will not be obliged to pay **policy costs** unless the **insurer** has provided prior written consent to such costs being incurred (except where expressly stated in the policy that prior consent is not first required).

If the **insurer's** prior written consent cannot reasonably be obtained before **policy costs** (not including **mitigation costs**) are incurred, then the **insured** will seek **insurer's** consent as soon as practicable and the **insurer** will give retrospective approval for such reasonable **policy costs** necessarily incurred.

(c) *Advancements*

The **insurer** may, at their sole discretion and option, agree to pay **defence costs** or **mitigation costs** prior to coverage being confirmed.

(d) *Consent to settlements*

If an **insured** admits liability or compromises or settles any **claim, compensation claim** or **insured event**, without the **insurer's** prior written consent, this policy will afford no cover in connection with that admission, **claim, compensation claim** or **insured event**.

(e) *Uninsured loss*

The **policyholder** will reimburse the **insurer** as soon as reasonably possible for any payments which are ultimately determined not to be covered under this policy.

3. Allocation

Where a **claim, compensation claim** or **insured event** involves both parties covered and not covered and/or matters covered and not covered by this policy, a fair and proper allocation shall be made between the **insured** and the **insurer**, taking into account the relative legal and financial exposures attributable to the covered matters or persons and the matters or persons not covered by this policy.

4. Cooperation

The **insured** will, as soon as practicable on the **insurer's** request, give all information, documents and assistance to the **insurer** as it may reasonably require to enable it to investigate any matter notified under this policy and cooperate with the **insurer** in responding to any **claim, compensation claim** or **insured event**.

Except where expressly provided for in this policy, these steps will be at the **insured's** own cost.

5. Other insurance

This policy will only pay **loss** that is in excess of any amount recoverable from a more specific civil/professional liability, medical malpractice, products liability, clinical trials liability, public liability or general liability insurance available to the **insured** including insurance or indemnification (including discretionary) provided by any medical defence organisation or Clinical Negligence Scheme for General Practice (CNSG) or any successor or similar scheme available to any **insured**. As excess insurance, this policy will not apply or contribute to the payment of any loss until the amounts of that other insurance or indemnity have been exhausted.

If there is any other such insurance or indemnification (including discretionary) at the time of any event giving rise to a **claim** under this policy the **insured** shall promptly provide the **insurers** in writing with full details of such other insurance, including the identity of the insurer and the policy number, and such further information as **insurers** may reasonably require.

6. Financial interest coverage

The **insurer** will not provide cover for the **loss** of an **uncovered company**. The **insurer** will instead reimburse the **policyholder** for its financial interest in such **uncovered company** by way of agreed valuation calculated as the amount of **loss** which would have been payable to the **uncovered company** under this policy had the **uncovered company** been insured under this policy. However no payment will be made in respect of any Insuring Clause or Coverage Extension which would have covered the **loss** of any **insured person** in respect of their role for the **uncovered company**. For the purpose of this provision the **policyholder** will be deemed to have suffered loss to its financial interest simultaneously with the **uncovered company** which incurred the **loss** for which it would have been entitled to receive cover under this policy.

7. Subrogation and recoveries

Following a payment under this policy, the **insurer** will be subrogated to all rights and remedies available to the **insured** in connection with that payment therefore the **insurer** has the right to seek recovery of that payment from a third party and will be entitled to bring proceedings in the name of the **insured**. The **insurer** has the right to seek recovery from an **additional insured** where liability for the payment is a result of the act, error or omission of the **additional insured**.

Whether before or after payment under this policy, the **insured** will take all steps necessary, or required by the **insurer**, to preserve the rights and remedies which the **insured** may have to recover its **loss**.

The **insured** will provide to the **insurer** any assistance the **insurer** may require to secure the rights and remedies set out above. The **insurer** shall be entitled to take control of all steps taken to recover any **loss**.

Any amounts recovered will be applied in the following order:

- (a) to reimburse costs incurred in bringing proceedings against the third party;
- (b) then to the **insured** for the amount of any **loss** which exceeds the limit of liability;
- (c) then to the **insurer** up to the amount of the **loss** paid by the **insurer** and the limit of liability will be reinstated for such amounts; and
- (d) then to the **insured** to reimburse the **retention**.

The **insurer** agrees not to exercise its rights of recovery against any **insured person** unless the payments made by the **insurer** under this policy are brought about or contributed to by the deliberately dishonest act or omission of that **insured person**.

E. General Conditions

1. Limit of liability

The policy aggregate limit of liability stated in the Schedule is the maximum amount payable by the **insurer** under this policy in respect of all **insureds**, all **loss**, Insuring Clauses and all Coverage Extensions.

The limit of liability stated in the Schedule under each Insuring Clause is the maximum amount for the specific Insuring Clause as listed in the Schedule. These limits are part of, and not in addition, to the policy aggregate limit of liability.

Where any sub-limit is specified in the policy or Schedule, the **insurer** will have no liability in excess of that sub-limit. Any sub-limit will be part of and not in addition to the specific limit of liability for the specific Insuring Clause stated in the schedule.

The **insurer** will not be liable for more than the limit of liability in respect of all **loss** arising from a **single aggregated event**.

Any **loss** paid by the **insurer** under this policy will erode the policy aggregate limit of liability.

If a **claim** triggers more than one Insuring Clause, the limit of liability applied to that **claim** will be the largest limit of liability available under any of the applicable Insuring Clauses.

2. Retention

The **insurer** will be liable only for that part of any covered **loss** which exceeds the **retention**.

Only one **retention**, being the largest, will be applied to the total amount of **loss** arising from a **single aggregated event**.

In respect of **mitigation costs**, a single **retention** will apply to the anticipated **single aggregated event**.

3. Change of control / acquisitions

In the event of a **change of control** of the **policyholder** or a **subsidiary**, no cover under this policy will apply for any:

- (a) **claim** or **compensation claim** against the **policyholder** or that **subsidiary** or their **insured persons**, which arises from a **professional services wrongful act, malpractice incident** or **accident**; or
- (b) **insured event** concerning that **policyholder** or that **subsidiary** or their **insured persons**, which arises out of any conduct,

that occurred after such **change of control**. The **policyholder** will, as soon as practicable, give the **insurer** written notice of any **change of control** which takes place in respect of the **policyholder**.

In the event of an acquisition of a **subsidiary**, no cover under this policy will apply for any:

- (i) **claim** or **compensation claim** against that **subsidiary** or their **insured persons**, which arises from a **professional services wrongful act, malpractice incident** or **accident**; or
- (ii) **insured event** concerning that **subsidiary** or their **insured persons**, which arises out of any conduct,

that first commenced before such acquisition.

4. Clinical trials extended reporting period

If this policy is not extended or replaced, the **insured** will be entitled:

- (a) to an automatic **extended reporting period** for a period specified in the Schedule; and
- (b) to purchase an optional **extended reporting period** for a longer period, provided that written notice is given to the **insurer** by the **policyholder** within 30 days before the end of the automatic **extended reporting period** and any additional premium specified by the **insurer** is paid within 45 days of the end of the automatic **extended reporting period**.

The automatic **extended reporting period** will be part of and not in addition to any optional **extended reporting period** purchased by the **policyholder**.

The **extended reporting period** is non-cancellable and the premium for the optional **extended reporting period** is deemed fully earned at the inception date of the optional **extended reporting period**.

Any **extended reporting period** does not increase the limit of liability, and any payments made with respect to **claims** and **compensation claims** during the **extended reporting period** are part of the limit of liability.

5. Cancellation

If the **insured** has not notified any **claims**, losses or circumstances, then the **insured** may cancel this policy at any time on 30 days' written notice. The **insurer** will provide a pro-rata refund of premium to account for the time on risk.

If a **claim**, loss or circumstance has been notified, the **insured** may cancel this policy at any time on 30 days written notice but no refund of premium shall be given by the **insurer**.

If the premium due under this policy has not been paid to the **insurer** within 60 days of the inception of the **policy period** or, where premium is due to be paid by instalments, by the date on which an instalment is due, the **insurer** will have the right to cancel this policy with effect from inception by notifying the **policyholder** in writing direct or via the insurance broker.

The **insurer** will give not less than 30 days prior notice of such cancellation. If the premium due is paid in full to the **insurer** before the notice period expires, notice of cancellation will automatically be revoked.

If any additional premium due under the terms of this policy or in respect of any amendment to the terms of this policy is not paid within 30 days of the date on which it is due to be paid, the **insurer** will not have any liability in respect of the additional rights which were to have been purchased by the **insured** by payment of the additional premium.

6. Authorisation

The **policyholder** will act on behalf of all **insureds** in connection with all matters relevant to this policy unless the **policyholder** is insolvent in which event the remaining entities will agree with the **insurer** as to which one of them will act on behalf of all **insureds**.

7. Third parties

Nothing in this policy is intended to confer a directly enforceable benefit on any third party other than an **insured**.

8. Assignment

Neither this policy nor any right under it may be assigned without the prior written consent of the **insurer**.

9. Policy interpretation

This policy, its Schedule and any endorsements are one contract in which, unless the context otherwise requires:

- (a) headings and subheadings are descriptive only, solely for convenience, not an aid to interpretation and form no part of the terms and conditions of coverage;
- (b) the singular includes the plural, and the masculine includes the feminine, and vice versa;
- (c) "including" and "include(s)" means without limitation;
- (d) references to specific legislation include amendments to and re-enactments of that legislation and any similar or equivalent legislation in the relevant jurisdiction;
- (e) references to positions, offices or titles will include their equivalents in any jurisdiction;
- (f) if any provision of this policy is or becomes void or illegal, is invalid or unenforceable by a court or other competent body under the law of any applicable jurisdiction, such provision will be deleted. The **insurer** and the **insured** will use their best efforts to agree a replacement for the provision which achieves as far as possible the same effect as would have been achieved by the deleted provision.

10. Governing law

This policy will be governed by and construed in accordance with the laws of England and Wales.

11. Worldwide cover

This policy applies to **claims, compensation claims and insured events or loss** occurring anywhere in the world.

12. Arbitration clause

All disputes and differences between the **insured** and the **insurer** which arise under or in connection with this policy will be referred to arbitration under ARIAS Arbitration Rules (U.K.).

The arbitration tribunal will consist of three arbitrators, one to be appointed by the **insured**, one to be appointed by the **insurer** and the third to be appointed by the two appointed arbitrators.

The third member of the tribunal will be appointed as soon as practicable (and no later than 28 days) after the appointment of the two party-appointed arbitrators. The tribunal will be constituted upon the appointment of the third arbitrator. The arbitrators will be persons (including those who have retired) with not less than ten years' experience of insurance or reinsurance within the industry or as lawyers or other professional advisers serving the industry.

Where the **insured** or the **insurer** fail to appoint an arbitrator within 14 days of being called upon to do so or where the two party-appointed arbitrators fail to appoint a third within 28 days of their appointment, then ARIAS will appoint an arbitrator to fill the vacancy. At any time prior to the appointment by ARIAS the party or arbitrators in default may make such appointment.

The tribunal may in its sole discretion make such orders and directions as it considers to be necessary for the final determination of the matters in dispute. The tribunal will have the widest discretion permitted under the laws of England and Wales when making such orders or directions and the decision of the tribunal will be final. The arbitration will be held in London.

13. Duty of fair presentation

The **insurer** expects the **insured** to comply with its duty to make a fair presentation of the risk in accordance with the Insurance Act 2015 (U.K.). In the event that there has been a breach of the duty of fair presentation, the **insurer** will not exercise any available remedies under the Insurance Act 2015 (U.K.) for any breach that the **insurer** determines was free of any fraudulent conduct or intent to deceive.

The knowledge or act, error or omission of any **insured person** will not be imputed to any other **insured person**. The knowledge of each **responsible person** will be imputed to the **policyholder** or a **subsidiary**.

14. Material changes

The **policyholder** must tell the **insurer** as soon as practicable of any material change or changes in circumstances during the **policy period** that alters the risk covered and/or any material change in the matters declared to the **insurer**. The **insurer** will not provide any cover in respect of liability arising from such material change in the matters declared to the **insurer** unless the **insurer** has agreed in writing to accept the altered risk.

15. Insurer's consent

Where the **insured** is required under this policy to seek the consent of the **insurer**, the **insurer** will not unreasonably withhold, delay or deny such consent.

16. Sanction limitation

The **insurer** will not be liable to provide any cover, benefit or pay any claim under this policy to the extent that the provision of such cover, benefit or payment of such claim would expose the **insurer** to any sanction, prohibition or restriction under United Nations resolutions or the trade or economic sanctions, laws or regulations of the European Union, United Kingdom or United States of America.

17. Complaints

Every effort is made to ensure that a high standard of service is provided. However, if the **insured** is not satisfied with the service it has received or it has any questions or concerns about this policy the **insured** should, in the first instance, contact:

Beazley Complaints
Beazley Group
Plantation Place South
60 Great Tower Street
London EC3R 5AD
Or by telephone – 020 7667 0623
Or by e-mail – beazley.complaints@beazley.com

In the event that the **insured** remains dissatisfied the complaint can be escalated to:

Complaints
Lloyd's
One Lime Street
London EC3M 7HA
E-mail: complaints@lloyds.com
Telephone: 020 7327 5693 Fax: 020 7327 5225
Website: www.lloyds.com/complaints

Ultimately, if the **insured** is dissatisfied with Lloyd's final response, the **insured** may, if eligible, refer the complaint to the Financial Ombudsman Service (FOS). The Financial Ombudsman Service is an independent service in the U.K. for settling disputes between consumers and businesses providing financial services.

The FOS's contact details are as follows:

Financial Ombudsman Service
Exchange Tower
London
E14 9SR
E-mail: complaint.info@financial-ombudsman.org.uk
Telephone: 0300 123 9 123 Website: www.financial-ombudsman.org.uk

18. Compensation

The **insurer** is covered by the Financial Services Compensation Scheme.

The **insured** may be entitled to compensation from the Scheme if the **insurer** is unable to meet its obligations to the **insured** under this contract. If the **insured** is entitled to compensation under the Scheme, the level and extent of the compensation would depend on the nature of this contract.

Further information about the Scheme is available from the Financial Services Compensation Scheme, 10th Floor, Beaufort House, 15 St Botolph Street, London EC3A 7QU, Telephone: 0800 678 1100 or 020 7741 4100 or on their website: www.fscs.org.uk

19. Privacy notice

The **insurer's** Privacy Policy is available at: www.beazley.com/privacy or by requesting a copy from the Data Protection Officer at dpo@beazley.com.

By submitting information to the **insurer** relating to any identifiable individual, the **insured** represents that it has authority to provide that personal information to the **insurer**. With respect to any individual about whom the **insured** provides personal information to the **insurer**, the **insured** agrees: (a) to inform the individual about the content of the Privacy Policy; and (b) to obtain any legally-required consent for the collection, use, disclosure, and transfer (including cross-border transfer) of personal information about the individual in accordance with the Privacy Policy.

F. Definitions

The following definitions are applicable to all sections of this policy:

Accident means an unexpected event or happening including continuous or repeated exposure to substantially the same general harmful conditions.

Act of harassment means any actual or alleged conduct, physical act, gesture, spoken or written words of a sexual or violent nature including sexual molestation, sexual or physical assault or battery, sexual or physical abuse or sexual harassment by the **insured** in the provision of **healthcare services** which occurs on or after the **retroactive date** and before the end of the **policy period**.

Additional insured means any **clinical trials additional insured, research and development additional insured** or **vendor additional insured**.

Barcode error event means an error in printing or illegible printing of the barcode used to code the **products**, on or after the **retroactive date** and before the end of the **policy period**.

Barcode rectification costs means reasonable fees, costs and expenses necessarily incurred by the **policyholder** due to a **barcode error event**:

- (a) to communicate and inform vendors of the **barcode error event**;
- (b) to reimburse vendors for the costs to remove **products** from stock and return them to the **policyholder** or for the costs to re-label the **products**;
- (c) to reprint and provide new labels for the **products**; and
- (d) costs to return the re-labelled **products** to vendors.

barcode rectification costs do not include costs incurred for the repair, reconditioning, modification or replacement of any **product**.

Biologic 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 Medicines and Healthcare products Regulatory Agency (MHRA) regulation or the equivalent of such regulations in any other jurisdiction.

Bodily injury means physical injury, death, mental injury, mental illness, mental anguish, shock, sickness, disease or disability.

Breach of intellectual property rights means any unintentional breach of any intellectual property right or misappropriation of a trade secret including infringement of copyright, trade dress, domain name, title or slogan or the dilution or infringement of trademark or service mark in the performance of or failure to perform **professional services** by any **insured**.

breach of intellectual property rights does not include any breach, infringement or abuse of patents.

Change of control means any one of the following events:

- (a) the **policyholder** consolidates with or merges into or sells all or a majority of its assets to any other person or entity or group of persons and/or entities acting in concert;
- (b) any person or entity, whether individually or together with any other person or persons, entity or entities becomes entitled to exercise more than 50% of the rights to vote at general meetings of the **policyholder** or control the appointment of directors who are able to exercise a majority of votes at meetings of the board of directors of the **policyholder**;

- (c) the appointment of a receiver, liquidator, administrator or other insolvency practitioner in respect of the **policyholder** or a **subsidiary**, but only in relation to the **policyholder** or that **subsidiary**;
- (d) an entity ceases to be a **subsidiary**, or becomes controlled by another entity by virtue of any law.

Claim means:

- (a) a written demand for damages, compensation or non-monetary relief;
- (b) a civil, administrative or regulatory proceeding for damages, compensation or non-monetary relief; or
- (c) a demand for mediation, arbitration or other form of alternative dispute resolution for damages, compensation or non-monetary relief.

Clinical trial (or **clinical trials** where applicable) means an organised study sponsored, investigated or conducted by the **policyholder** in connection with their **professional services** that adheres to an **institutional review board**-approved written protocol and which provides clinical data for the assessment of the effects of the **biologics, pharmaceuticals, nutraceuticals** or **medical devices** via their testing to establish their effectiveness, bioequivalence or safety.

Clinical trials additional insured means:

- (a) any sub-contractor, doctor, consultant, physician, hospital or contract research organisation or site management organisation or nurse who will be performing work for the **policyholder** in respect of a **clinical trial**;
- (b) any **institutional review board** and its members,

if the **policyholder** is required, pursuant to a written contract or agreement executed prior to the date of commencement of the relevant **clinical trial**, to indemnify such person or organisation. This policy does not cover liability which arises out of the **clinical trials additional insured's** own act, error or omission where such act, error or omission is not directly connected to the **policyholder** or is outside the scope of the **clinical trial**.

Clinical trials incident means **bodily injury** (including exacerbation of an existing condition) suffered or allegedly suffered by a **research subject** caused by participation in a **clinical trial** which occurs on or after the **retroactive date** and before the end of the **policy period**.

Compensation means the amount payable by the **policyholder** or an **additional insured** to the **research subject** as determined by the **insurer** or the **independent lawyer** (as applicable) in accordance with the **compensation procedure**. **Compensation** also includes the reasonable fees, costs and expenses of the **independent lawyer**.

Compensation claim means a demand or proceeding for monetary relief made by a **research subject** or the dependents, heirs, executors, administrators and legal representatives of a **research subject**.

Compensation procedure means the procedures described in the Appendix.

Computer system means any computer, hardware, software, communications system, electronic device (including, but not limited to, any smart phone, laptop, tablet or wearable device), server, cloud or microcontroller, including any similar system or any configuration of the aforementioned and including any associated input, output, data storage device, networking equipment or back up facility, owned or operated by the **insured** or any other party.

Cosmetic means a product that is intended to be applied to the human body for altering appearance, beautifying, cleansing or promoting attractiveness, or as defined by the Federal Food, Drug, and Cosmetic Act or the European Union Cosmetics Regulation (EC) No. 1223/2009 or any equivalent legislation in the United Kingdom.

Cyber act means any actual or alleged unauthorised, malicious or criminal act or series of related unauthorised, malicious or criminal acts, or the threat or hoax thereof, regardless of time and place, involving access to, processing of, disclosure of, use of, suspension of or operation of any **computer system** or **data**.

Cyber incident means:

- (a) any actual or alleged error, omission or accident, or series of related errors, omissions or accidents, involving any **computer system**;
- (b) any partial or total unavailability or failure or series of related partial or total unavailability or failures to access, process, use or operate any **computer system**; or
- (c) any actual or alleged violation of any **privacy law** in relation to **data**.

Data means any information, facts, concepts or code that is recorded or transmitted in a form to be used, accessed, processed, transmitted or stored by a **computer system**.

Data breach means the actual or alleged theft, loss or unauthorised disclosure of **data** that is in the care, custody or control of the **insured** or a third party for whose theft, loss or unauthorised disclosure of **data** the **insured** is liable.

Defence costs means the reasonable fees, costs and expenses necessarily incurred by or on behalf of the **insured** in connection with the investigation, defence, settlement or appeal of a **claim**. **Defence costs** includes:

- (a) the reasonable fees, costs and expenses of an accredited expert retained through defence counsel approved by the **insurer** on behalf of the **insured** in order to prepare an evaluation, report, assessment, diagnosis or rebuttal of evidence in connection with the defence of a covered **claim**; and
- (b) up to £500 per day, up to a maximum of £5000, for each day on which a natural person of the **insured** has been required to and has attended court as a witness in connection with a **claim** notified under and covered by this policy. No **retention** will apply.

defence costs does not include the remuneration of any **insured**, the cost of their time or costs or overheads of the **policyholder** or a **subsidiary** (except as provided for in clause (b) above).

Dietary supplement means a product intended for ingestion and to add further nutritional value to supplement the diet, and may be a vitamin, a mineral, a herb or other botanical, an amino acid, a dietary substance supplementing the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, or extract, or any combination thereof.

Document means any physical document but does not include electronic documents or **personally identifiable information**.

Environmental claim means a **claim** first made against an **insured** during the **policy period** arising out of an **accident**, and which arises out of a discharge, dispersal, release, escape, seepage, transportation, emission, treatment, removal or disposal of pollutants, contaminants, nuclear material, or waste of any kind, including any actual or alleged direction, or request to test for, abate, monitor, clean up, recycle, remove, recondition, reclaim, contain, treat, detoxify or neutralise pollutants, contaminants, nuclear material or waste of any kind.

Environmental liability costs means **defence costs** incurred by any **insured** in connection with an **environmental claim**.

Extended reporting period means the period of time following the end of the **policy period** during which notice may be given to the **insurer** of any **claim** or **compensation claim** first made against the **insured** arising out of any **clinical trials incident** committed before the end of the **policy period**.

Good samaritan act means emergency medical services performed without a fee in a medical emergency, accident or disaster by any **insured** who is present either by chance or in response to a general emergency call.

Healthcare services means services provided by an **insured** in the treatment or care of any person including:

- (a) health care, medical care, diagnostic, laboratory, x-ray or other health care treatment services;
- (b) the provision or dispensing of medications, drugs, blood, blood products or tests;
- (c) the provision or dispensing of medical, surgical or dental supplies, equipment, devices or appliances in connection with such care;
- (d) the provision of food or beverages in connection with such care; and
- (e) the handling of or the performance of post-mortem examinations on human bodies.

Independent lawyer means a judge, retired judge, barrister or solicitor with suitable experience in medical malpractice, healthcare, life sciences or clinical trials that is agreed and appointed by the **insurer**, the **insured** and the **research subject**.

Institutional review board means an independent:

- (a) board, committee, group or similar organisation; or
- (b) an Ethics Committee,

designated, directed or requested by an institution or other person or organisation to review a **clinical trial** including any approval or periodic review of any such **clinical trial**.

Insured means:

- (a) the **policyholder**;
- (b) the **insured persons**;
- (c) any natural person acting as a principal, partner, director, Medical Director, member of an Ethics Committee whilst acting within the scope of and in the course of their duties for the **policyholder**;
- (d) any natural person employed by the **policyholder**;
- (e) any student or volunteer that is under the control, direction and supervision of the **policyholder**;
- (f) any **subsidiary**;
- (g) any joint venture to the extent of the **policyholder's** percentage participation;
- (h) a **principal investigator**.

insured does not include contractors, sub-contractors, consultants or locums unless such persons are employed by the **policyholder**.

Insured event means an **act of harassment**, a **barcode error event**, a **manslaughter proceeding**, a **medical regulatory event**, a **product recall event**, a **reputational damage event**, or a **research and development event**.

Insured person means any natural person who was, is, or during the **policy period** becomes:

- (a) a physician, doctor or surgeon qualified and registered with the General Medical Council or other official trade body;
- (b) a dentist qualified and registered with the General Dental Council or other professional body;
- (c) a nurse or midwife qualified and registered with the Nursing and Midwifery Council or other professional body;

employed by the **policyholder**;

insured person includes the estate, heirs, legal representatives or assigns of an **insured person** in the event of their death, incapacity or bankruptcy or the lawful spouse, civil or domestic partner of an **insured person** solely in their capacity as such.

Insurer means Beazley Syndicates 2623/623 at Lloyd's.

Loss means:

- (a) **policy costs**;
- (b) any amount that the **insured** or any **additional insured** is required to pay as a result of a legally enforceable obligation to a third party, for:
 - i) damages, interest and related costs awarded pursuant to a final judgment or award;
 - ii) compensation awarded by a **medical regulatory authority**;
 - iii) compensation pursuant to a settlement negotiated with the **insurer's** prior written consent.
- (c) costs of recompiling, reconfiguring or reconstructing **documents** or **personally identifiable customer information**;
- (d) **compensation**.

loss does not include:

- i) fines and penalties;
- ii) profits, restitution, disgorgement of unjust enrichment or profits by an **insured**;
- iii) non-compensatory, punitive, aggravated or exemplary damages (other than aggravated or exemplary damages awarded in an action for defamation, emotional distress, libel, slander or injurious falsehood)
- iv) multiple damages (except for the single compensatory amount of those damages prior to their multiplication);
- v) employment-related compensation, wages or benefits, or costs or overheads of the **policyholder**;
- vi) taxes;
- vii) fees, commissions or other compensation for any **professional services** rendered or required to be rendered by the **insured**; or
- viii) amounts which are uninsurable.

Malpractice incident means any **bodily injury** to any **patient** caused by a negligent act, error or omission committed by the **insured** in the provision of **healthcare services** or as part of any **good samaritan act** on or after the **retroactive date** and before the end of the **policy period**.

Management control means:

- (a) controls the composition of the board of directors;

- (b) controls more than half of the shareholder voting power; or
- (c) holds more than half of the issued share capital.

Manslaughter defence costs means the reasonable fees, costs and expenses necessarily incurred by or on behalf of the **insured** in connection with the investigation, defence, settlement or appeal of a **manslaughter proceeding**.

Manslaughter proceeding means a proceeding against the **insured** in respect of any offence of manslaughter by a natural person or any offence under the Corporate Manslaughter and Corporate Homicide Act 2007 occurring on or after the **retroactive date** and before the end of the **policy period**.

Medical device 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 any Medicines and Healthcare products Regulatory Agency (MHRA) or United States Food and Drug Administration (FDA), 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.

Medical regulatory authority means any regulator, government, government body, judicial or parliamentary body, governmental or administrative agency, any self-regulatory body recognised in that capacity under applicable law or professional body such as the General Medical Council or General Dental Council.

Medical regulatory costs means reasonable fees, costs and expenses necessarily incurred by an **insured** directly in connection with preparing for, cooperating with or attending interviews in respect of or responding to a **medical regulatory event** first commenced during the **policy period**. **Medical regulatory costs** includes up to £500 per day, up to a maximum of £5000, for each day on which a natural person of the **insured** has been required to and has attended as a witness in connection with a **medical regulatory event** notified under and covered by this policy.

Medical regulatory event means in respect of an **insured person** only any formal or official hearing, examination or investigation by a **medical regulatory authority** that relates to an actual or alleged **malpractice incident**.

Medical regulatory event means in respect of a **policyholder** only:

- (a) any coroner's inquest or inquiry;
- (b) corporate manslaughter proceedings; or
- (c) an investigation or inquiry by the Care Quality Commission,

arising out of an actual or alleged **malpractice incident**.

A **medical regulatory event** does not include routine regulatory supervision, inspection or compliance reviews, or any investigation which focuses on an industry rather than an **insured**.

Mitigation costs means any reasonable payments incurred by the **insured** during the **policy period** and up to 90 days after expiry of the **policy period** (provided **insurer's** consent is obtained before expiry of the **policy period**) in taking action to mitigate the financial consequences of a **malpractice**

incident which the **insured** establishes to the **insurer's** satisfaction would otherwise have reasonably been expected to give rise to a **claim** for which the resulting **loss** would have been covered by the policy. **Mitigation costs** does not include payments incurred after such **claim** is made. **Mitigation costs** does not include payments incurred without the **insured** first obtaining the **insurer's** consent, unless it was not reasonably practicable to obtain consent due to a time critical event and the **insurer** was otherwise notified in writing within 14 days of such payment being incurred.

Nutraceutical means a **cosmetic, dietary supplement or personal care product** as defined by the General Food Law Regulation (Regulation (EC) No 178/2002), Food Standards Agency and Food Safety Act 1990 and the United States Dietary Supplement Health and Education Act, whether intended for ingestion or topical application.

Patient means any person or human body receiving **professional services** as provided under Insuring Clause 3 (Medical Malpractice).

Patient accident means **bodily injury** to a **patient** or **property damage** to a **patient's** property caused by an **accident**.

Personal care product means a non-medicinal consumable product that is intended to be used in the topical care and grooming of the body or hair and is rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied, to a body, human or animal, for cleansing, beautifying, promoting attractiveness, or altering the appearance without affecting the body's structure or functions, and includes products specifically for use in such activities as cleansing, toning, moisturising, hydrating, exfoliating, conditioning, anointing, massaging, colouring/decorating, soothing, deodorising, perfuming, and styling.

Personally identifiable information means any physical or electronic document or information concerning any past, present or prospective patient or **research subject** of the **insured**.

Pharmaceutical means a synthetic or natural chemical recognised by any official regulatory body in the appropriate jurisdiction:

- (a) intended for use in the diagnosis, cure, mitigation, treatment or prevention of injury, sickness or disease in humans and which affects the structure or functioning of the human body; or
- (b) which is a component of any **product**.

Policy costs means **defence costs, environmental liability costs, manslaughter defence costs, medical regulatory costs, mitigation costs, reputation damage costs** and **research and development restoration costs**.

policy costs will not include the remuneration of any **insured person**, the cost of their time or costs or overheads of the **policyholder** or a **subsidiary**.

Policyholder means the entity named in the Schedule.

Policy period means the period specified in the Schedule.

Principal investigator means the individual, or in the case of an investigation by a team of individuals, the leader of that team, who is responsible for ensuring that the **clinical trial** is conducted in accordance with the relevant investigator statement, investigational plan, the written protocol and regulations for protecting the rights, safety and welfare of the **research subjects** under such investigator's care, and who is employed by the **policyholder** or engaged by the **policyholder** subject to a written agreement.

Privacy law means any law or regulation concerning the collection, use, safeguarding, handling, storage, retention or destruction of information.

Product or **products** means any goods or products manufactured, developed, designed, created, tested, leased, licensed, rented, sold, handled, disposed of, distributed, reviewed, installed, maintained or repaired by the **policyholder** or by others trading under its name, including:

- (a) **biologics**;
- (b) **pharmaceuticals**;
- (c) **nutraceuticals**;
- (d) **medical devices**; and
- (e) products that are used, or are intended for use in **clinical trials**, or the providing of **professional services**.

Product incident means **bodily injury** or **property damage** arising out of an **accident** caused by **products** away from the **policyholder's** premises which occurs on or after the **retroactive date** and before the end of the **policy period**.

Product recall costs means reasonable fees, costs and expenses necessarily incurred by the **policyholder** due to a **product recall event**:

- (a) to communicate the recall of the **products**; and
- (b) to undertake the recall of the **products** including transportation, examination, sorting and destruction of the **products** and any overtime costs or costs to hire additional temporary staff that are required to complete the recall in a timely manner.

product recall costs do not include costs incurred for the repair, reconditioning, modification or replacement of any **products** or costs incurred in relation to any voluntary recall by the **policyholder** of **products** that have not been directly impacted by the **product recall event**.

Product recall event means a recall of **products** by the **policyholder** or required by an official governmental or regulatory authority, on or after the **retroactive date** and before the end of the **policy period**, due to:

- (a) unintentional, illegal or malicious contamination, impairment, mislabelling or alteration of **products**, and
- (b) the **insured's** reasonable belief that the **products** have been rendered unfit or dangerous for the use for which they were intended with the potential to result in **bodily injury** or **property damage**.

Professional services means services performed by or on behalf of the **policyholder** including **healthcare services, research and development operations** and any related services, administrative and back office functions, pursuant to an agreement with a third party. **Professional services** do not include the **policyholder** acting as a trustee, fiduciary or administrator of any pension, profit-sharing or employee benefits.

Professional services wrongful act means any actual or alleged negligent act, error or omission in the performance of or failure to perform **professional services** by any **insured** or by any other person for whom the **insured** is legally liable that occurs on or after the **retroactive date** and before the end of the **policy period**. **Professional services wrongful act** does not include a **malpractice incident**.

Property damage means physical damage to, destruction of or loss of use of tangible property.

Public liability incident means **bodily injury** or **property damage** caused by an **accident**. **Public liability incident** does not include a **malpractice incident**, a **product incident**, or a **clinical trials incident**.

Reputation damage costs means the reasonable fees, costs and expenses necessarily incurred by the **insured person**:

- (a) in appointing a public relations firm or consultant, a crisis management firm, a law firm or tax advisor retained by the **policyholder** directly to mitigate the adverse or potentially adverse effect on the **policyholder's** reputation due to a **reputational damage event**;
- (b) in appointing a law firm to effect the **policyholder's** right to be forgotten or right to erasure following a **reputational damage event**.

reputation damage costs do not include the costs incurred to recall any material, publications or products.

Reputational damage event means:

- (a) a **claim** first made against the **policyholder** during the **policy period** arising out of a **malpractice incident** or a **professional services wrongful act**;
- (b) negative publicity posted on internet-based social media platforms or websites of which the **policyholder** first becomes aware during the **policy period** and which could, in their reasonable opinion, give rise to a **claim** arising out of a **malpractice incident** or a **professional services wrongful act**.

Research and development additional insured means any research associate, research consultant, research coordinator, research monitor and **research key person**, if the **policyholder** is required, pursuant to a written contract or agreement executed in relation to the provision of services to the **policyholder** in respect of their **research and development operations** to indemnify such person or organisation. This policy does not cover liability which arises out of the **research and development additional insured's** own act, error or omission where such act, error or omission is not directly connected to the **policyholder** or is outside the scope of the **research and development operations**.

Research and development event means the death of a **research key person** or a **research key person** suffering from an injury or illness which entirely prevents that **research key person** from completing or participating in the **research and development operations** which occurs on or after the **retroactive date** and before the end of the **policy period**.

Research and development operations means the **policyholder's** business which is directly related to or directly supporting the development of new **products** or enhancements of existing **products**.

Research and development property means written, printed or inscribed documents, plans, records or formulas, processes or cultures and resulting products, samples or other materials produced by such processes or cultures and prototypes, if produced and directly associated with the **policyholder's research and development operations**. **Research and development property** does not mean:

- (a) money or securities;
- (b) property including **products** held for sale or held for delivery after sale;
- (c) **products** that the **policyholder** has manufactured which are in their completed state and ready for sale; or
- (d) laptops, mobiles, tablets and other portable electronic devices.

Research and development restoration costs means reasonable fees, costs and expenses necessarily incurred by the **policyholder**:

- (a) to engage temporary replacement cover or to recruit for a permanent replacement for a **research key person** as a result of a **research and development event** for a maximum period of 90 days from the date the **research and development event** occurred; and
- (b) to repeat experiments, to repair or replace **research and development property** up until the point that the research has been recreated to the level it was at before the **research and development event** occurred.

research and development restoration costs do not include the salary of the permanent replacement of the **research key person**.

Research key person means a researcher or a scientist that is vital to the **research and development operations** of the **policyholder**.

Research subject means a human being who is or becomes a participant in a **clinical trial**.

Responsible person means the Clinical Director, Chief Medical Officer, Risk Manager, Insurance Manager, Chairman, Chief Executive Officer, Chief Financial Officer, Chief Operating Officer, Compliance Officer, Head of Audit or General Counsel including any individual in a substantially similar position or with substantially similar responsibilities as those referenced, irrespective of the exact title of such individual, of the **policyholder** or **subsidiary**.

Retention means the amount specified in the Schedule for each Insuring Clause and/or Coverage Extension.

Retroactive date means the date(s) specified in the Schedule.

Single aggregated event means all **claims, compensation claims** and **insured events** arising from the same or series of related or repeated **professional services wrongful acts, malpractice incidents, accidents** or from any continuing **professional services wrongful acts, malpractice incidents, accidents**, irrespective of the number of claimants or **insureds** involved in the **claim**.

Subsidiary means any entity in which the **policyholder** either directly or indirectly through one or more entities obtains **management control** on or before the inception date of this policy. **Subsidiary** will include:

- (a) any new entity which the **policyholder** incorporates during the **policy period** and which, at the time of incorporation, the **policyholder** has **management control**;
- (b) any entity, that the **policyholder** acquires **management control** of during the **policy period** provided that at the time of obtaining that **management control**:
 - i) the revenues of the acquired entity do not exceed 10% of the **policyholder's** total projected annual revenue figure; and
 - ii) the acquired entity is located in the same country or countries as the **insured**.

If a newly acquired entity's revenue exceeds 10% of the **policyholder's** total projected annual revenue figure or is incorporated or domiciled in a different country to the **insured**, the **insurer** will provide cover under this policy for 60 days from the date of acquisition, during which time the **policyholder** will give the **insurer** sufficient information to allow the **insurer** to assess the potential increase in insurance risk. The **insurer** may agree to extend the definition of **subsidiary** to include the newly acquired entity, subject to the **policyholder** accepting any amendment to the terms and conditions of this policy or the charging of a reasonable additional premium that the **insurer** requires.

Uncovered company means any **subsidiary**:

- (a) which is located in a jurisdiction where the applicable law or regulation does not allow the **insurer** to provide cover to that **subsidiary**; or
- (b) which the **policyholder** has elected that the policy will not cover directly but, instead, the policy will cover the **policyholder's** own financial interest in such **subsidiary**.

Vendor additional insured means any person or organisation involved in the distribution or sale of the **products**. This policy does not cover liability, which arises out of:

- (a) any express warranty, unauthorised by the **policyholder**;
- (b) any act of the vendor which changes the composition of the **products**;

- (c) any failure to maintain the **products** in a merchantable condition;
- (d) any failure to make such inspections, adjustments, tests or servicing as the vendor has agreed to make or normally undertakes to make in the usual course of business, in connection with the distribution or sale of the **products**;
- (e) **products** which after the distribution or sale by the **policyholder** have been labelled or relabelled or used as a container, part or ingredient of any other product, thing or substance by or for the vendor; or
- (f) the **vendor additional insured's** own act, error, or omission where such act, error or omission is not directly connected to the **policyholder**.

vendor additional insured does not include any person or organisation from whom the policyholder has acquired such **products** or any ingredient, part or container, entering into, accompanying or containing such **products**.

G. Appendix - No fault compensation procedure for clinical trials

Compensation procedure means the procedures described below that are to be followed when assessing a **compensation claim**. These procedures must be accepted by the **research subject** before the **compensation claim** can commence:

- (a) if in the opinion of the **insurer** on the balance of probabilities the **clinical trial incident** was sustained as result of participation by the **research subject** in the **clinical trial**, the **insurer** will provide authority for the **insured** to make an offer of **compensation** and the **research subject** must agree or reject the offer within 90 days following the date of such offer.
- (b) in the event of (a) occurring but no agreement being reached between the **insured** and the **research subject** after 90 days the amount of **compensation** shall be determined by the **independent lawyer** who will conduct the **claim for compensation** as an arbitration in accordance with the ARIAS Arbitration Rules (U.K.).
- (c) the **independent lawyer** shall in their sole discretion make any orders and directions as permitted by the laws of England and Wales which are necessary to assess the **compensation claim**.
- (d) the **independent lawyer** shall allow the **research subject** and the **policyholder** to present their cases with oral and written evidence.
- (e) the **independent lawyer** should determine:
 - i) if on the balance of probabilities the **bodily injury** (including exacerbation of an existing condition) was caused by the administration to or use by the **research subject** of any **biologic, pharmaceutical, nutraceutical or medical device** involved in the **clinical trial** or was directly attributable to participation in the **clinical trial**;
 - ii) the **compensation** that is appropriate in light of the nature, severity and persistence of the **bodily injury** (including exacerbation of an existing condition). This **compensation** may be determined with reference to either:
 - 1) the clinical trial compensation guidelines as set out by the Association of the British Pharmaceutical Industry (ABPI); or
 - 2) the amount of damage awarded in similar cases by the courts of the country where the **clinical trial** took place;
 - iii) if **compensation** should be reduced or denied because:
 - 1) the negligent acts, errors or omissions of the **research subject** caused, contributed or exacerbated the **bodily injury** (including exacerbation of an existing condition);
 - 2) the **research subject** was adequately warned and informed of the possible adverse reactions and the degree of probability that such adverse reactions may occur; or
 - 3) the **research subject** was advised of the availability and efficacy of alternative treatments available to the **research subject** had the **research subject** not participated in the **clinical trial**.
- (f) once the **independent lawyer** has made a decision as to the amount of **compensation** payable to the **research subject**, if any, the **research subject** has 90 days to agree and accept that decision.

- (g) if the **research subject** accepts the decision:
- i) payment of **compensation** will be made in a lump sum and this will be accepted in full and final settlement of any other actions the **research subject** has against the **policyholder** in respect of the **clinical trials incident**;
 - ii) the **research subject** will assign all rights the **research subject** has to bring a **claim** against any third party as a result of the **clinical trials incident** and the **policyholder** shall receive all help and assistance as the **policyholder** may reasonably require from the **research subject** in exercising and enforcing these rights; and
 - iii) the **research subject** will sign any agreements to give effect to (i) and (ii) above.
- (h) if the **research subject** does not accept the decision of the **independent lawyer**, the **research subject** shall be able to pursue a **claim** against the **policyholder**, any such **claim** will then be covered by Insuring Clause 6.