International Clinical Trials and Liability Insurance - The Challenges and their Solutions

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QBE EO Medical Liability

QBE Medical liability

- Maximum capacity of EUR 85 million for pharmaceutical liability
- Maximum capacity of EUR 85 million for clinical trials (per individual protocol)
- Scope of cover:
  - Pharmaceutical public, products and pollution liability
  - Clinical trials

Who we are

- World's 25th biggest insurance group, founded in Australia 125 years ago.
- Standard & Poor's and Fitch A+, A.M. Best A rating.
- Strong pharmaceutical / life science / biotech / clinical trials brand.
- Long term commitment to pharmaceutical industry with dedicated pharmaceutical team in London and support from QBE European offices
- High level of knowledge / expertise both in London and the Branches
- The largest pharmaceutical line size in the Lloyds market
- The largest medical liability book in the London market
- Significant claims expertise in Pharmaceuticals in Europe, the Americas and Asia Pacific

International Liability Programmes

Programme Structure

Local Policies

- Where admitted insurance required by law;
- Where there are fiscal advantages in having one;
- Where evidence of local insurance in local language is desired;
- As a comfort factor for local subsidiary;
- As an instrument for local premium collection.

Master Policy

- Provides difference in conditions cover, assuring uniform scope of cover worldwide;
- Provides difference in limits cover to ensure adequacy in the event of a catastrophic loss anywhere in the world.

Clinical Trials

Clinical Trials Scope of Cover

Cover is provided in accordance with the legal requirements or requirements of ethics committees in countries where these are defined, for example

- No Fault Compensation and Legal Liability insurance to sponsors of clinical trials and research studies conducted in Switzerland;

- Hybrid cover in accordance with § 40 (3) Arzneimittelgesetz in Germany.

In countries where the requirements are not defined, cover is provided in accordance with local practice or subject to specific agreement.

Cover on a difference in conditions, difference in limits basis may be provided under a separate central master policy.

Clinical Trials Covered

We cover:

- Human volunteer studies, bioequivalence studies, clinical trials of new drugs, medical devices, treatments, procedures etc. or alternatively existing drugs, medical devices, treatments with new uses / indications etc.
- Clinical trials in all phases of up to 5 years' duration.

We will consider, subject to profile:

- Products for which it is difficult to get cover such as ephedrine, statins, selective serotonine reuptake inhibitors, etc.

We do not cover:

- Clinical trials of permanently invasive devices;
- Clinical trials in the USA for companies whose parent company is domiciled in the USA.

Multi Territory Clinical Trials

Key aspects:

- Speed is of the essence. Of all the factors that need to be considered in organising a clinical trial, insurance is often the last – and then it's urgent!
- Policy documentation must be issued immediately upon receipt of an order.
- Access to local policy wordings which are compliant with local legislation, issued in local language and have been previously agreed by local ethics committees is critical.
- Many clinical trials are moving to more cost efficient territories (e.g. Latin America, Eastern Europe) where bespoke policy forms are required.
- Latin America is a particularly challenging insurance climate, due to licensing and reinsurance restrictions.

Multi Territory Clinical Trials

- Ability to write business in about 70 countries, which include Europe, North America, Asia Pacific and Latin America.
- QBE Group, QBE Lloyd's syndicate and selected partners provide local service (where QBE / Lloyd's do not have licence).
- Centralised approach for policy documentation.
- All policies are fully compliant with local legislation, issued in local language where required, and have been previously agreed by local ethics committees.
- All policies comply with statutory discovery / extended reporting periods.
- In house policy documentation means that where possible paperwork is produced in a timely and efficient manner.
- Potential to write clinical trials sponsored by pharmaceutical companies of all sizes, hospitals, etc.

Since inception of the facility one and a half years ago, QBE has written over 750 individual policies. To date none have been rejected by a local ethics committee.

Multi Territory Clinical Trials

Europe / Middle East

Austria	Czech Republic	Hungary	Luxembourg	Slovakia
Albania	Denmark	Iceland	Macedonia	Slovenia
Belgium	Estonia	Ireland	Moldova	Spain
Bulgaria	Finland	Israel	Netherlands	Sweden
Bosnia & Herzegovina	France	Italy	Norway	Switzerland
	Georgia	Kosovo	Poland	Turkey
Croatia	Germany	Latvia	Portugal	UAE
Cyprus	Greece	Lithuania	Romania	UK

North America

Canada	USA

Multi Territory Clinical Trials

Latin America

Brazil	Colombia	Guatemala	Mexico	Peru
Chile	Ecuador	Honduras	Paraguay	

Asia Pacific

Australia	India	Macau	Philippines	Taiwan
China	Indonesia	Malaysia	Singapore	Thailand
Hong Kong	Japan	New Zealand	South Korea	Vietnam

Africa

Egypt	South Africa

Notes:

1. *These are the countries where we have detailed arrangements in place to issue policies. We are, of course able to accommodate various other countries as well.*
2. *Whilst this list of countries is accurate at the date this presentation was prepared, laws and regulations are constantly changing, with the result that our ability to service a particular country may change in a positive or negative sense.*

Further information

- QBE Insurance Group
  - www.qbe.com
- QBE Europe
  - www.qbeeurope.com
- QBE Casualty
  - www.qbeeurope.com/casualty
- QBE Europe - Financial reports and accounts
  - www.qbeeurope.com/credentials/financials
- QBE Europe - Financial strength ratings analysis
  - www.qbeeurope.com/credentials/rating-analysis

Plantation Place, QBE Europe headquarters