

COUNTRY GUIDELINES for

Australia

Proprietary and Confidential
Information of Chubb



This is a two-page Country Guideline – please review both pages for a complete overview.

Country	Are there compulsory insurance requirements for human clinical trials?	Is non-admitted insurance permitted for a clinical trial?*	Local rules, requirements or practices referencing insurance for human clinical trials (Click on name to see regulation)	Can a single aggregate limit apply to multiple trials?	Customary extended reporting period (aka sunset clause) timeframe for a local policy	Compulsory insurance limits for human clinical trials required by regulation	WORLDcert platform does not support the automated issuance of Certificates. Chubb supported limits
Australia	Yes for New South Wales, Victoria and Queensland. No for all other states.	Yes, although the foreign insurer must have Standard & Poors (or equivalent) Rating of A- or better	Victorian Managed Insurance Authority (VMIA) Guidelines New South Wales Department of Health Guidelines Queensland Health Clinical Trial Agreements Guidelines	Yes	Queensland and Western Australia: 6 years All other states: Nil	Victoria: – Per Participant/ Per Occurrence Limit: AUD 10,000,000 – Aggregate Per Trial Limit: AUD 10,000,000 – Per Participant/ Per Occurrence and Aggregate Deductibles: Nil to AUD 25,000 New South Wales: – Per Participant/ Per Occurrence Limit: AUD 20,000,000 – Aggregate Per Trial Limit: AUD 20,000,000 – Per Participant/ Per Occurrence and Aggregate Deductibles: Nil to AUD 25,000	AUD\$10,000,000 AUD \$10,000,000 is the market standard in states with no limit guidelines or requirements



						<p>Queensland:</p> <ul style="list-style-type: none">- Per Participant/ Per Occurrence Limit: AUD 10,000,000- Aggregate Per Trial Limit: AUD 10,000,000- No deductible requirements	
--	--	--	--	--	--	---	--

For website feedback, please e-mail worldcert@chubb.com

Country specific guidance;

Australian clinical trial liability policies are issued on an annually renewable basis only, with renewable premiums payable annually. Issuing an annual policy allows the single aggregate limit to apply to multiple trials for the insured which can be added/included using the same policy.

In order to confirm correct premium and taxes for any policy the following information will need to be provided to the Australian issuing office:

- 1. State (or States) in which clinical trial sites will be operating; and**
- 2. Estimated split of participants sponsor expects to be recruited for each state.**

**WORLDcert platform does not support the automated issuance of Certificates.
For any existing system supported trials contact your underwriter for modifications or extensions.**

* Please review the "Admitted vs. Non-Admitted, Learn About Different Considerations" section of the Worldcert homepage for more information on this topic.

Chubb is the marketing name used to refer to subsidiaries of Chubb Limited, providing insurance and related services. For a list of these subsidiaries, please visit our website, www.chubb.com. Not all insurers do business in all jurisdictions. Actual coverage is subject to the language of the policies as issued. The information in this chart contains confidential and proprietary information of Chubb and is subject to change by Chubb without notice. This chart is descriptive and issued as a matter of information only and confers no rights upon any person or organization. The information provided should not be relied on as legal advice or a definitive statement of the law in any jurisdiction. For such advice, an applicant, insured, listener, or reader should consult their own legal counsel. Neither Chubb nor its employees or agents shall be liable for the use of any information or statements made or contained in any information provided herein.