

Australia – Destination of Choice for Clinical Trials: Corporate Structuring & R&D Incentives

Luis Silva, Regional Business Development Manager, Acclime

Tokyo, Japan.

May 2024

ACCLIME.

AUSTRALIA

Destination for Clinical Trials

- Speed
- Cost
- Quality
- Heterogeneous population

WHAT ARE THE BENEFITS AVAILABLE?

**Global group
turnover
< AU\$20m**

43.5%
Cash Refund

- 43.5% benefit in a tax loss position
- Up to 16% benefit in a tax payable position

**Global group
turnover
> AU\$20m**

38.5%-46.5%
Tax offset

- Reduces tax payable (not refundable)
- Tax offset can be carried forward and offset against future tax liabilities

WHO IS ELIGIBLE?

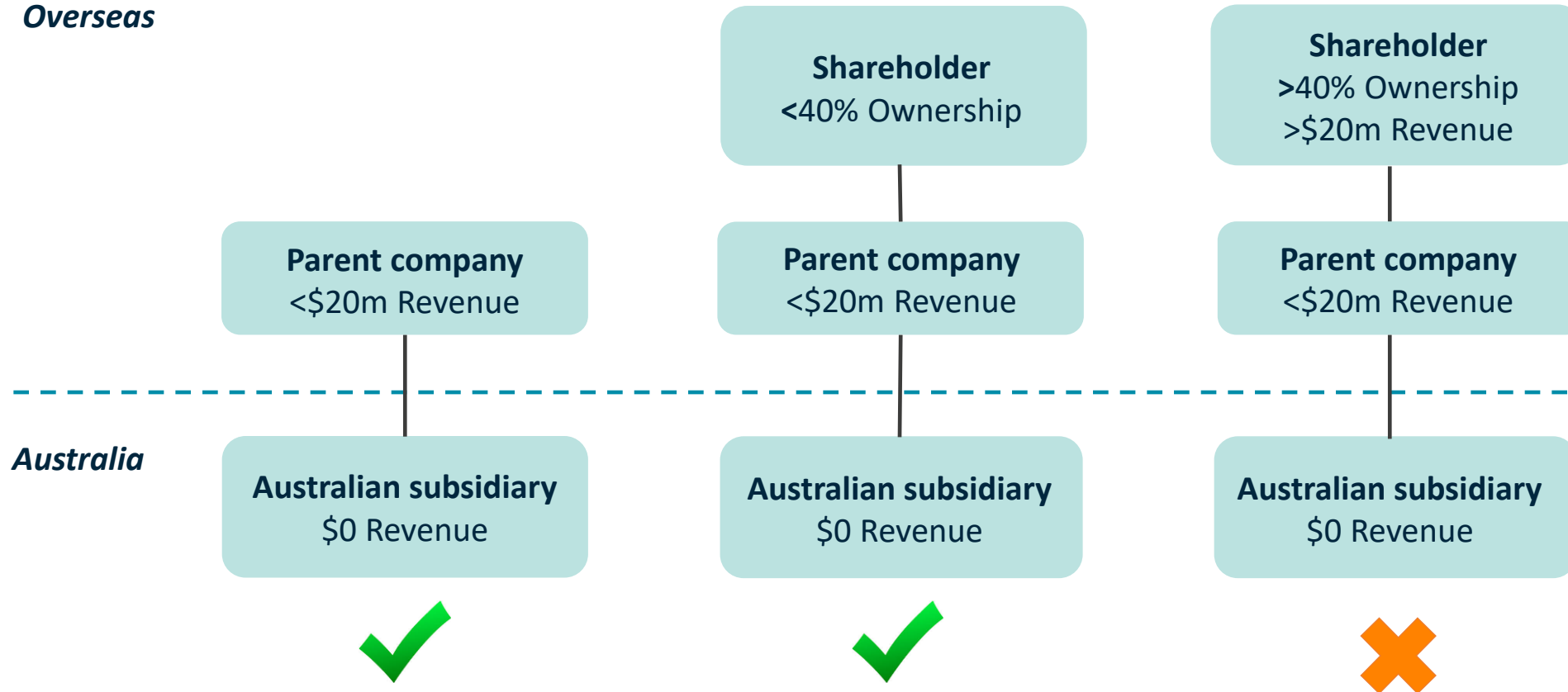
The application requires **a registered legal entity in Australia**

- Australian subsidiary can be **100% foreign-owned** (If you have a foreign government shareholder(e.g. SOE Stated Owned Enterprise) with >20% holding, you must apply for approval.
- Minimal capital requirements (Min. capital of 1 share = AU\$1, unless significant debt in Australian entity)
- Resident Director / Resident Public Officer
- Registered Address in Australia

R&D TAX INCENTIVE – CASH REFUND ELIGIBILITY

Combined turnover (revenue) for Australian subsidiary, parent company and all **connected & affiliated** entities **must not exceed A\$20 million in a financial year.**

Overseas



WHO IS ELIGIBLE?

Parent company should ideally be located in a country with a Double Tax Agreement with Australia (over 40 countries):



Includes: Taiwan, Singapore, China, Korea, **Japan**, Denmark, Sweden, Germany, USA, Canada, UK, etc. Does not include Hong Kong



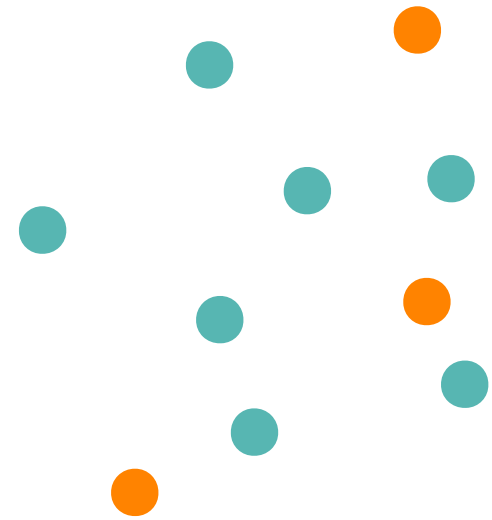
Does not include: TAX HAVENS – Cayman Islands, BVI, Barbados, etc.

WHAT ACTIVITIES ARE ELIGIBLE?

CORE R&D ACTIVITY

Eligible R&D projects must contain 1 minimum Core Activity with the following attributes:

- Experiment generates new knowledge - outcome is not known or cannot be determined in advance
- Follows scientific method
- Examples include:
 - Clinical trials
 - Pre-clinical studies



WHAT ACTIVITIES ARE ELIGIBLE?

SUPPORTING R&D ACTIVITIES

Can also be included provided they are:

- directly related to the core activity; or
- for the dominant purpose of supporting the core activity

Examples include:

- Manufacturing of drug material
- PK/PD laboratory analysis
- PK/PD biostatistical analysis
- Patient recruitment
- Project management
- Protocol development

R&D TAX INCENTIVE – LEGAL STRUCTURING

Documentation of the legal arrangements between the parent company and the Australian subsidiary is a requirement of the R&D Tax Incentive.

There are two primary models to the structure:

AGENCY MODEL
(AGENCY AGREEMENT + TRANSFER PRICING
MEMO)

ENTERPRENEURIAL MODEL
(IP LICENCE + COMMERCIAL RATIONALE)

R&D TAX INCENTIVE – APPLICATION PROCESS

R&D Tax Incentive Application lodged with **Department of Industry, Science, Energy & Resources** (within 10 months of year-end).

Applications are filed along with the **Australian Taxation Office**, completion of the Australian subsidiary's annual financial statements, and income tax return.

Rebate is usually paid within 8-12 weeks after filing the Income Tax Return.

Funds received can be retained in Australia for further R&D activities.

Self-assessment program, subject to review. Evidence must be on hand in the event of a review.

R&D TAX INCENTIVE – OVERSEAS FINDINGS

Avenue for claiming costs incurred on R&D activities **conducted overseas**

- **Subject to strict criteria:**
 - Must not be able to conduct the activities in Australia
 - Must have a significant scientific link with the Core Activity in Australia
 - Overseas expenditure must be less than Australian expenditure
- **Pre-approval required**
- **Significant practical hurdles to obtain approval**

As the conditions are strict there are no guarantees that activities would be eligible.

CONTACT

For further information please contact us.
We are happy to answer any of your questions



Luis Silva

Regional Business Development Manager

m: +66 96 807 6077

e: L.Silva@acclime.com

ACCLIME.

**Thank
you.**

ありがとう
ございます。

ACCLIME.