Cancer Trials Australia

Cancer Trials Australia

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Why conduct clinical trials in Australia?

Key reasons:

- Clinical trial quality
- Regulatory speed and flexibility
- Cost efficiencies
- Ethnically diverse population and high volunteer rate

https://www.mtpconnect.org.au

- Australia is recognized as a hub for early-phase clinical trials
- Many international biotech companies have successfully conducted early-phase clinical trials in Australia
- In 2016, out of 13 FDA approved drugs, 7 were trialled in phase 3 in Australia

Clinical trial quality

- Conducive ecosystem
  - Well structured health sector, universities, independent medical research institutes, biobanks, CROs and clinical trial networks
- High quality principal investigators, research nurses and clinical study coordinators
- Acceptance by international organisations
- Strong patent protection
  - Australia ranks 12/128 countries on the International Property Rights Index

Regulatory speed and flexibility

Simplified regulatory framework:

- Unlike the USA, Australia does not require an IND application prior to commencing Phase I clinical trials
- Most commercially sponsored clinical trials in Australia are conducted under the Clinical Trial Notification (CTN) scheme which has reduced the regulatory burden on clinical trial sponsors
    - Ethics committee is the key approver
    - Therapeutic Goods Administration (TGA) does not review the data
    - The CTN scheme eliminates duplication and saves both time and money for sponsors conducting clinical trials in Australia

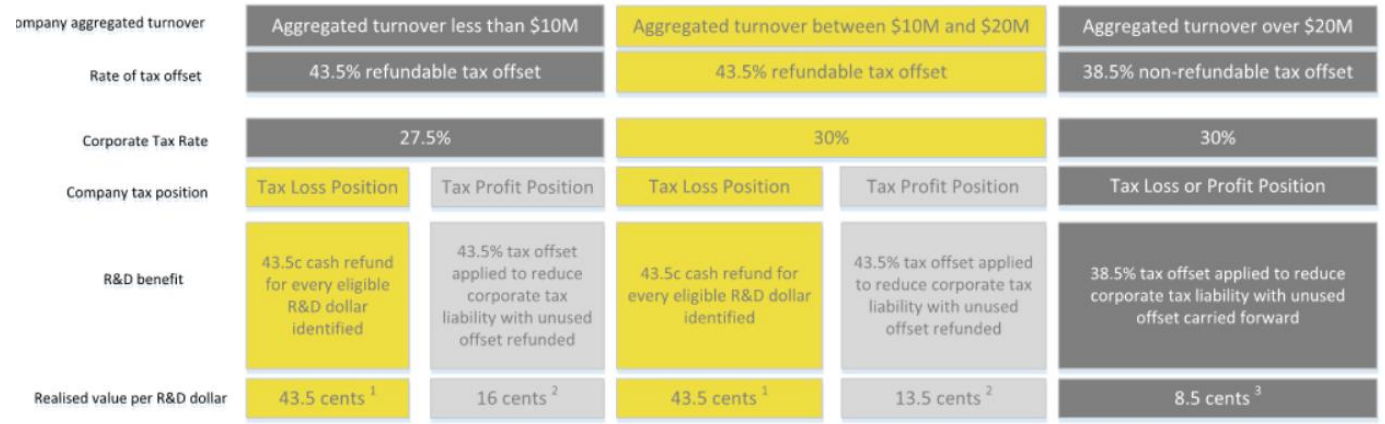
The Australian Government continues to work toward:

- Standardising clinical trial costs to streamline processes and further enhance efficiencies
- Improve coordination across states
- Further enhance clinical trial capability and infrastructure

Cost efficiencies

- Regulatory speed and high recruitment rates help minimise costs

R&D Tax incentive



ompany aggregated turnover	Aggregated turnover less than $10M		Aggregated turnover between $10M and $20M		Aggregated turnover over $20M
Rate of tax offset	43.5% refundable tax offset		43.5% refundable tax offset		38.5% non-refundable tax offset
Corporate Tax Rate	27.5%		30%		30%
Company tax position	Tax Loss Position	Tax Profit Position	Tax Loss Position	Tax Profit Position	Tax Loss or Profit Position
R&D benefit	43.5c cash refund for every eligible R&D dollar identified	43.5% tax offset applied to reduce corporate tax liability with unused offset refunded	43.5c cash refund for every eligible R&D dollar identified	43.5% tax offset applied to reduce corporate tax liability with unused offset refunded	38.5% tax offset applied to reduce corporate tax liability with unused offset carried forward
Realised value per R&D dollar	43.5 cents [1]	16 cents [2]	43.5 cents [1]	13.5 cents [2]	8.5 cents [3]

- Allows for a refundable tax offset if turnover <20 million, and a non-refundable tax offset if turnover >20 million.

- Australia is 28% cheaper than the USA before this tax incentive, and 60% cheaper afterward

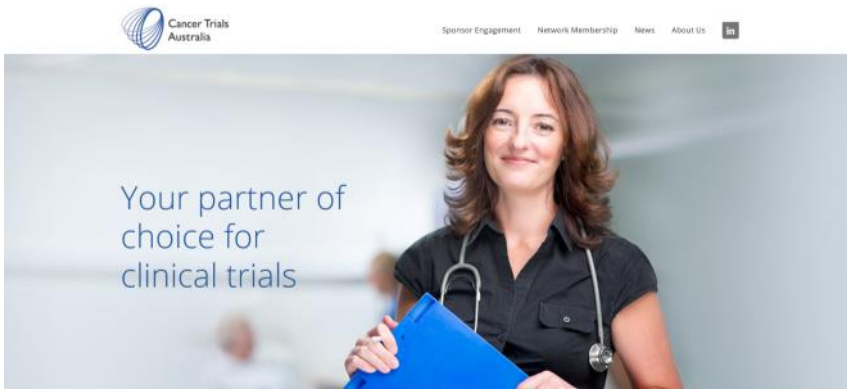
First time in human submission process

- Developed by Cancer Trials Australia in 2006
- Uses CTN not CTX scheme
  - Enables FTIH trial to be performed without an agency- ie FDA approval process/IND number
- Independent Expert Reviewer/s (pharmacology/tox/immunological experience) engaged by Ethics Committee
  - 10 working days for review
- CTA facilitator between Sponsor/HREC secretariat
- Final protocol assessed - comments/concerns are addressed by the PI/Sponsor
- Expert reviewer/s comments and PI response is submitted to HREC with the ethics application

Cancer Trials Australia (CTA)

- 1998 The Centre for Developmental Cancer Therapeutics

- 2003 Cancer Trials Australia established
  - Incorporated
  - Not for profit
  - Member based



- CTA was instrumental and assisted in establishing:
  - 2005 National Mutual Acceptance Program - Ethics
  - 2006 Medicines Australia Standard Clinical Trial Agreement template
  - 2006 First Time in Human (FTIH) / CTN protocol

- CTA continues to be involved in regulatory reform and changes across the health sector, both at Federal and State levels

Victorian Comprehensive Cancer Centre

- The Victorian Comprehensive Cancer Centre (VCCC) was established in 2009 and is a powerful alliance of ten highly successful Victorian organisations
- CTA resides on level 10 of the new $1 billion VCCC facility, purpose-built for cancer research, treatment, care and education in the Melbourne suburb of Parkville
- The VCCC building provides a home to Peter MacCallum Cancer Centre, Melbourne Health and Royal Women's Hospital oncology services
- Our location ensures easy access to our key clinical members
- CTA works in collaboration with the VCCC to support and deliver high-impact cancer research

Cancer Trials Australia

15

Years operating

~~24~~ 25

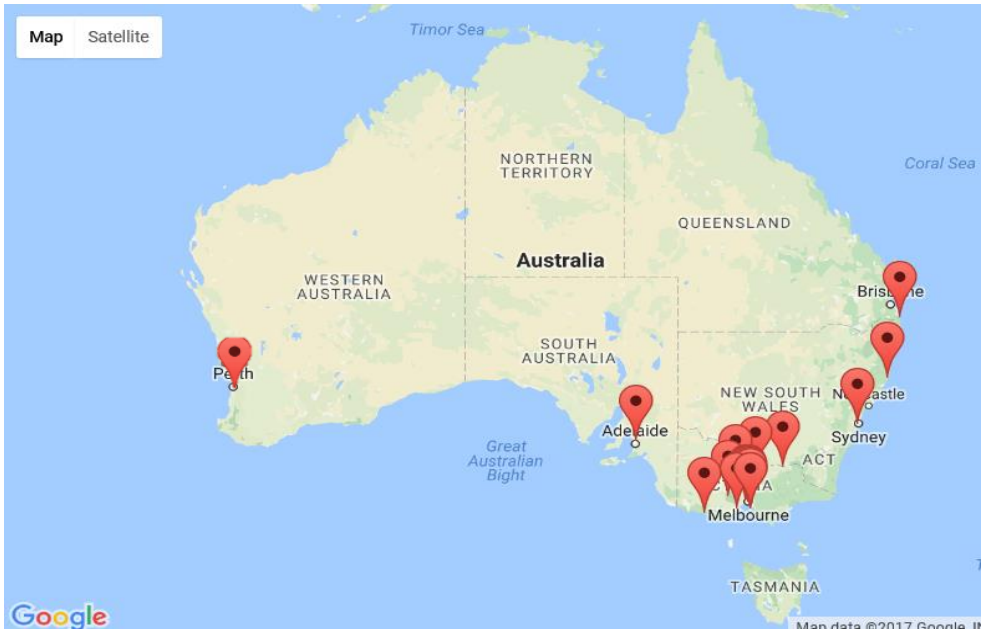
Network members

1,247

Trials opened

7,645

Patients enrolled



Cancer Trials Australia functions

- Clinical trial network
  - Shared expertise, resources, capabilities
  - Tumour groups, monitoring trial performance and supporting cross-referrals
- Clinical trial service provider
  - Ethics and governance start-up and post-approval activities
  - Compilation and negotiation of clinical trial budgets and contracts
  - Financial management
  - Hosting, training and support of a Clinical Trial Management System
    Provide accurate, customised reporting
- Advocacy / policy development
- Strategic partnerships / collaborations

Phase I cancer trial specialists

CTA supports >50% of all Australian Phase I cancer trials

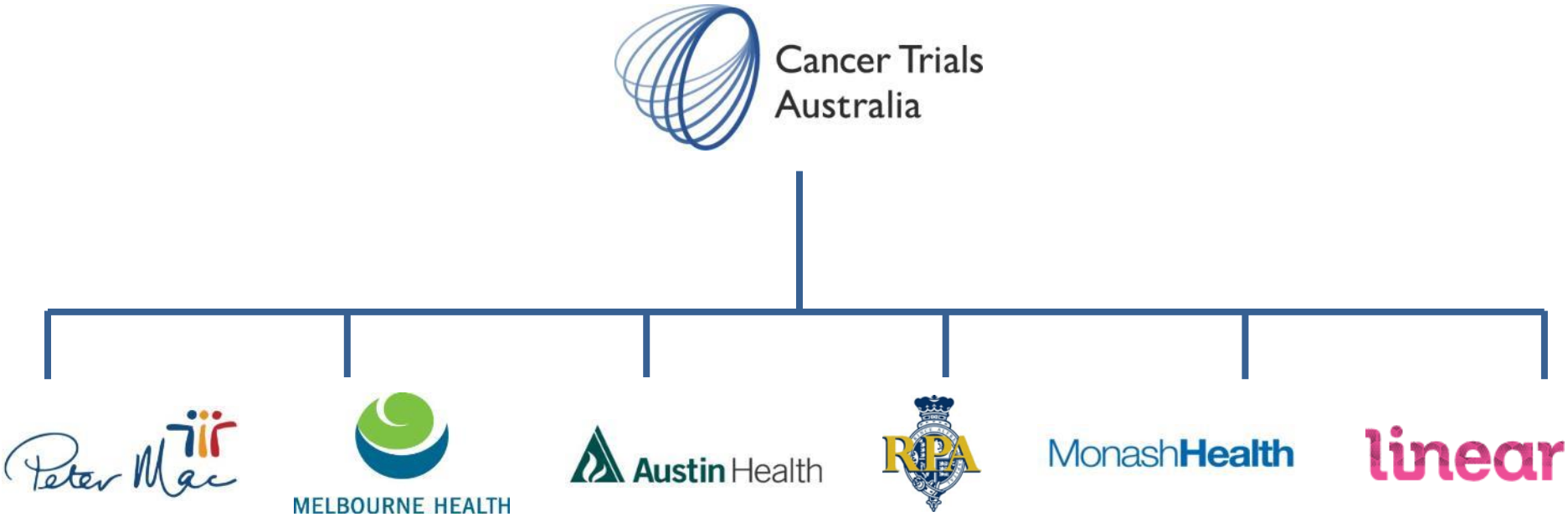
Specialised phase 1 trials group:

- Key opinion leaders in phase I and first-in-human trials
- Specialists provide advice on trial design and translational drug development
- Facilitate protocol development, completion of pharmacokinetic and pharmacodynamic studies and biomarker assays for novel drugs
- Early engagement with biotech to build a long-term partnership

Capable of conducting Phase 1 trials that are:

- Broad studies (all tumour types)
- Tumour specific studies
- Molecular target specific studies

A single point of contact to a wide Phase I network



This Phase 1 network has supported numerous First Time in Human trials sponsored by Chinese biotech companies over 10+ years

Summary

- Australia is a very attractive destination for clinical trials
  - Conducive ecosystem, quality PIs, efficient regulatory processes
  - Government policy and financial incentives

- CTA has a membership across four Australian states
  - Possess particularly strong expertise in Phase I clinical trials
  - Work closely with members to attract trials to member sites
  - Provide necessary services for the administration of clinical trials, as well as:
    - Access to an experienced network of clinical sites
    - Centralised clinical trials management system
  - Our services harmonise processes, enhance speed and decrease costs associated with conducting clinical trials
  - Close relationships with pharma, biotechs and CROs are essential

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