



Australian Government  
Department of Health and Ageing  
Therapeutic Goods Administration

# Current Regulation of Clinical Trials in Australia

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# Therapeutic Goods Legislation

- Forms the legal basis for a national system for supply\* of therapeutic goods in Australia by providing:
  - Standards for therapeutic goods
  - Registration of therapeutic goods
  - Licensing of therapeutic goods manufacturers

\*import, export, manufacture or marketing





# Exemptions from Registration

- Provisions for supply of unregistered therapeutic goods\* exist for:
  - Individual Patients
  - Clinical Trials
- This is essentially the role of the TGA as a regulator with respect to clinical trials.





# Clinical Trials in Australia

- Two operational Schemes:
  - Clinical Trials Notification (CTN) scheme
  - Clinical Trials Exemption (CTX) scheme





## CTN and CTX scheme

- Covers medicines and devices
- Currently Biological agents are regulated as medicines
- Separate Biologicals\* framework currently being considered

\*Human Cells and Tissues (HCT)





## Features of CTN scheme

- Notification only
- Decision from TGA not required
- Decision to pursue a route (CTN/CTX) rests with the sponsor in consultation with the ethics committee
- Suitable for most drugs which have successfully completed initial human experiments





## Features of CTX scheme

- Assessment and decision required from TGA
- 30–50 day evaluation cycle
- Trial cannot proceed if TGA raises an objection
- Approval is in the form of 'Usage Guidelines'
- Suited to first trials in humans and trials involving high-risk or unconventional therapies





# Role of HRECs in Clinical Trials

- Initial Ethical & Scientific approval, as well as ongoing monitoring, is the responsibility of Human Research Ethics Committees (HRECs)
- Applies to all Clinical Trials (CTX/CTN) whether or not reportable to TGA
- HRECs need to be NHMRC approved
- HoMER initiative by NHMRC





## The TGA & Clinical Trials

- Provides a legal avenue for supply of unapproved therapeutic goods
- Avenue to report Adverse Drug Reactions and Safety Information
- Report any changes to the scientific conduct or research governance
- Ability to seek further information
- Ability to stop the trial on public health grounds
- Compliance with GCP and GMP





# Good Clinical Practice

- ICH guideline is fully adopted
- Further local requirements / standards for research set by the National Statement from NHMRC
- GMP required for all Investigational Medicinal Products
- Auditing for GCP being integrated with GMP auditing function





# Additional requirements potentially applicable to Clinical Trials

- Products involving 'dealings' with GMOs
- Need reporting to OGTR by the sponsor
- Separate process from TGA
- Role of CTAC of NHMRC





# TGA guidance documents

- ARGPM
- TGA adopted European Guidelines
- TGA adopted European Guidelines -  
Biologicals
- Access to unapproved therapeutic  
goods – clinical trials in Australia
- Clinical Trials Handbook





## New directions

- Expected changes in legislation, structure of the organisation and business procedures
- Requirements for conduct of clinical trials – not expected to change significantly
- Changes in consultation with external stakeholders
- Review of guidelines and current documents relating to clinical trials, especially with Biologicals





# Summary of Clinical Trials Regulation

- Deregulated environment since the introduction of CTN scheme
- Central role of Ethics Committees
- Compliance with GCP and GMP





## Further Information

- Experimental Drugs Section, Office of Prescription Medicines – info line:
  - [eds@tga.gov.au](mailto:eds@tga.gov.au)
- Blood & Tissues Unit, Office of Devices, Blood and Tissues – info line:
  - [bloodandtissues@tga.gov.au](mailto:bloodandtissues@tga.gov.au)

