Australian Government
Department of Health
Therapeutic Goods Administration

TGA Good Clinical Practice Inspection Program (GCPIP)

Guidance for GCP Inspection of Clinical Trial Sites

Dr Tahli Fenner
Risk Management Section
Pharmacovigilance Branch, Medicines Regulation Division
Therapeutic Goods Administration

TGA Health Safety Regulation

Welcome

- This webinar is being recorded for data & analytics only
- Presentation will be made available on the TGA website
- Any relevant links will be broadcasted via the slido app
- Q&A will open midway in the session – we will be using slido tool
- A live Q&A session after the presentation
- Live poll – please let us know how we went

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Webinar overview

- Development of the GCP Inspection Program
- *Guidance for GCP inspection of clinical trial sites for investigational biologicals and medicinal products*
  - published April 2022
- Q&A session

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting clinical trials.

Legislation

- *Therapeutic Goods Act 1989*
  - Regulates access to unapproved goods for use for experimental purposes in humans

- *Therapeutic Goods Regulations 1990*
  - Set out the conditions that therapeutic goods used in clinical trials must comply with in order for the goods to be exempted from the Act
  - Specify inspection powers for trials approved under CTA scheme, and for trials notified to the TGA through the CTN scheme

- *The Therapeutic Goods (Clinical Trials Inspections) Specification (no.2) 2020*
  - Enables the Secretary to release the inspection report to approving authority for the trial site and to the HREC

Development of the GCP inspection program

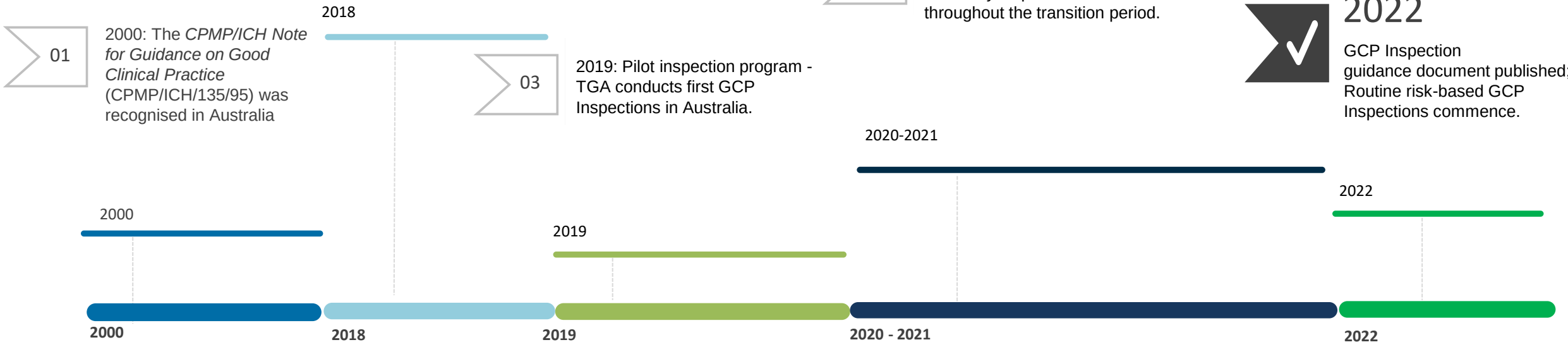
01 2000: The *CPMP/ICH Note for Guidance on Good Clinical Practice* (CPMP/ICH/135/95) was recognised in Australia

02 2018: The TGA annotated *ICH GCP E6R2* version 09 Nov 2016

03 2019: Pilot inspection program - TGA conducts first GCP Inspections in Australia.

04 2020: Endorsement of a routine risk based GCP Inspection Program. Voluntary inspections continue throughout the transition period.

2022 GCP Inspection guidance document published; Routine risk-based GCP Inspections commence.



Note:
ICH stands for International Council for Harmonisation of technical requirements for pharmaceuticals in human use. The Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) is an internationally accepted standard for the designing, conducting, recording and reporting of clinical trials.
ICH GCP E6R2 stands for Integrated Addendum to ICH E6(Revision 1).

GCP inspection program guidance

- Objectives and Scope of GCP Inspection Program
- Inspection Process
  - Inspection Prioritisation
  - Types of Inspection
  - Process of Inspection
- Inspection Follow-up & Close-out
- Compliance and Enforcement

Objectives

1. Education

- provide guidance and work with the site to ensure there are effective systems in place in alignment with Australian legislation and the relevant GCP guideline(s).

2. Compliance check

- verify clinical trial sites are compliant with the GCP standard and have met their clinical trial responsibilities.

Scope

1. Clinical Trials included in the CTN or CTA scheme
   - Risk-based selection of a proportion of eligible clinical trials

2. Types of Investigational Products
   - Medicines or biologicals
   - Not devices

3. Clinical Trial Sites
   - Currently limited to inspections of investigational sites for medicines or biologicals

Inspection prioritisation

1. Risk-based approach to scheduling using combination of:

- risk assessment
- internal and external intelligence

2. Risk assessment of clinical trials:

- risk assessment process as described in the *Risk-based Management and Monitoring of Clinical Trials Involving the Therapeutic Goods*, published in 2018 by National Health and Medical Research Council (NHMRC)
- risk criteria are grouped into 2 categories: the risks associated with

  - investigational medicinal product (IMP)

  - trial conduct, design and methods

GCP inspection types

- Onsite (preferred) vs remote inspections
- Routine
- ‘For cause’
- Announced and unannounced
- Reinspection

GCPIP Process

Pre-inspection → Inspection → Post-inspection

Education & opportunity to ask questions

Pre-inspection (≈28 days)

- Notification, planning and preparation
- Agenda and logistics with trial site
- Drafting and finalisation of Inspection plan

Inspection (≈3 days)

- Opening meeting
- Facility tour
- Documents and source data review
- Closing meeting with presentation of closing summary

Post-inspection

- Issue of the inspection report (≤30 days)
- Initial CAPA* (≤30 days from the issue of the inspection report)
- Evaluation of CAPA and close-out of the inspection

*Note: CAPA stands for Corrective and Preventative Actions

Inspection Topics

Legal and Administrative

Organisational

Informed Consent

Review of Trial Participant Data

Management of the investigational medicinal product (IMP)

Grading of Inspection Deficiencies

- Critical deficiency
- Major deficiency
- Minor deficiency
- Comment

Inspection follow-up & close-out

1. Issue Inspection report and draft close-out record (CAPA)

2. The site continues to work on the close-out record until the response is accepted by the GCP Inspector

Close Out Record

FOR OFFICIAL USE ONLY

TGA to complete	*Organisation to complete*		*TGA to complete*	
Critical/major/minor deficiency	**Organisation's response**	**Proposed completion date**	**Inspector's comments**	**Response accepted Y/N**
	Response date: Identified Root Cause: Corrective action(s) to the Root Cause: Corrections to observed examples:			

Inspection follow-up & close-out

During inspection follow-up stage, the GCP Inspector will:

- **Assess** proposed actions
- **Provide comments** if the initial proposal is not acceptable
- **Monitor** completion of proposed actions through evidence submitted
- **Close out** the inspection

Compliance and enforcement

- GCP inspector, in the first instance, will work with the site to address the deficiencies, for example by providing the site with guidance and education.

- Under the *Therapeutic Goods Act 1989* and the *Therapeutic Goods (Clinical Trials Inspections) Specification (no.2) 2020*, the TGA can release the GCP inspection reports and associated documents to:
  - The approving authority
  - The responsible ethics committee

How did we go?

LIVE POLL

Tahli and the team are currently reading over your submitted questions.

We will be back shortly for Q&A

More Information

TGA website	https://www.tga.gov.au
TGA Facebook	https://www.facebook.com/TGAgovau/
TGA Twitter	https://twitter.com/TGAgovau
TGA YouTube	https://www.youtube.com/channel/UCem9INJbMSOeW1Ry9cNbucw
TGA topics blog	https://www.tga.gov.au/blogs/tga-topics
TGA LinkedIn	https://www.linkedin.com/company/therapeutic-goods-administration/
TGA Instagram	https://www.instagram.com/tgagovau/?hl=en

Questions & Answers

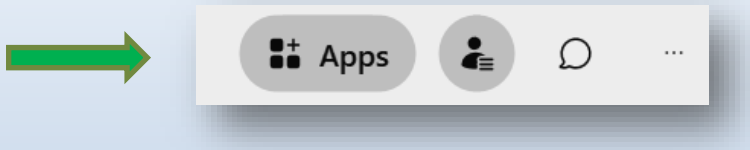
- **Dr Tahli Fenner**
- Director
- Risk Management Section
- Pharmacovigilance Branch
- Medicines Regulation Division

- **Amanda Chan**
- Assistant Director
- Risk Management Section
- Pharmacovigilance Branch
- Medicines Regulation Division

- **Dr Kasia Hoffler**
- Assistant Director
- Risk Management Section
- Pharmacovigilance Branch
- Medicines Regulation Division

How to ask Questions...

Slido App



- Click on Apps + icon
- Select "slido"
- Open Q&A tab to ask questions
- Live Poll (use survey tab when prompt to)

OR

Slido QR

Scan the QR code to access separately on your mobile device

Website and link references

Clinical trials | TGA	https://www.tga.gov.au/clinical-trials
Good Clinical Practice (GCP) inspection program | TGA	https://www.tga.gov.au/resource/good-clinical-practice-gcp-inspection-program
Clinical Trials Toolkit | Australian Clinical Trials	https://www.australianclinicaltrials.gov.au/clinical-trials-toolkit
Learning Modules | Australian Clinical Trials	https://www.australianclinicaltrials.gov.au/_files/elearn/index.html
Resources for Clinical Trials in Australia | Australian Clinical Trials	https://www.australianclinicaltrials.gov.au/resources-clinical-trials-australia
ICH Guideline for Good Clinical Practice | TGA	https://www.tga.gov.au/publication/note-guidance-good-clinical-practice
Department of Health | Clinical Trials	https://www1.health.gov.au/internet/main/publishing.nsf/Content/Clinical-Trials
National Standard Operating Procedures for Clinical Trials | Australian Government Department of Health	https://www.health.gov.au/resources/publications/national-standard-operating-procedures-for-clinical-trials
The National Statement 2018 | NHMRC	https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018
Safety monitoring and reporting in clinical trials involving therapeutic goods | NHMRC	https://www.nhmrc.gov.au/about-us/publications/safety-monitoring-and-reporting-clinical-trials-involving-therapeutic-goods

Contact Us

GCP enquiries
GCP.Inspection@health.gov.au

Australian Government

Department of Health

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