



# **Activity Report**

Workshop: Introduction to Good Clinical Trials –
Using the Good Clinical Trials Collaborative (GCTC)
Guidance

November 25 & 26, 2024



Region: Latin America and the Caribbean - MÉXICO -

### 1. General Information

Workshop Title: Introduction to Good Clinical Trials, using the Good Clinical Trials
 Collaborative (GCTC) Guidance

• Dates: November 25–26, 2024

Format: In-person

#### Venue:

Public Library of the State of Jalisco "Juan José Arreola", Periférico Norte Manuel Gómez Morín No. 1695, Col. Belenes, Zip Code 45100, Zapopan, Jalisco, Mexico

Fee: No cost (requires prior registration)

#### Moderator:



Netzahualpilli Delgado Figueroa
PRISM TGHN LAC Coordinator – The Global Health Network
Email: netzahualpilli.dfigueroa@academicos.udg.mx

#### Guest panelists:



#### Daniela Morelli (TGHN LAC HUB)

Nurse and researcher with expertise in clinical effectiveness, committed to research capacity building and nursing empowerment across Latin America.



#### **Bryain Maradiaga-Mendoza**

Global health advocate and AI coordinator, experienced in research, clinical training, and international medical collaboration across the Americas.



#### **Luis Felipe Arias Soto**

Clinical psychologist focused on mental health, research ethics, digital health, and implementation science in low-resource Latin American settings.

#### **Fernando Rubinstein**

Physician and epidemiologist specializing in public health research, training, and clinical methods. Leads TGHN's global training initiatives and capacity-building efforts.

### 2. Participation

- Total attendees: 34 participants over the two-day workshop
- Working language: Spanish
  - Printed and digital materials were provided in Spanish
  - Presentations were fully translated during the sessions
  - Mixed format: in-person and remote collaboration

### 3. Workshop Objectives

- Provide fundamental knowledge on Good Clinical Practice in controlled trials
- Develop skills in ethical protocol design, particularly for vulnerable populations
- Train participants in quality management and effective monitoring of clinical trials
- Promote ethical and transparent communication of clinical trial results

### 4. Topics Covered

- Capacity-building and cooperation opportunities through TGHN
- Developing a strong clinical research question
- Ethical protocol design for vulnerable populations
- WHO 2024 Guidance for Best Practices in Clinical Trials
- · Risk-proportionate trial design and conduct
- Strengthening the global clinical trials ecosystem
- Quality management and trial monitoring

### 5. Workshop Activities and Outcomes

**Participatory Exercise: Identifying Barriers and Facilitators** 

Participants collaboratively identified **key barriers and facilitators** for the implementation of good clinical trials in Latin America and the Caribbean:

### **Barriers and Facilitators**

#### **Barriers**

#### Dissemination

- Limited disseminiation of guidance and practices
- Lack of translation and accessible language
- Difficulties with local adaptation

#### Researchers

- Investigators with limited or no clinical trial experience
- Weak institutional support
- Low motivation or recognition
- Prevalent "publish or perish" culture

#### **Ethics Committees**

- Overloaded with protocols
- Delayed or inconsistent evaluations
- Lack of standardized processes

#### Political/Regulatory

- Role ambiguity of regulatory bodies
- Fragmented or nontransparent-procedures

#### **Facilitators**

# Training & Capacity Building:

- Updated training in Spanish
- National and regional research networks
- Local facilitators trained with GCTC resources
- Clinical trial workshops

## Institutional & Political Support

- Greater inclusion in national research agodas
- Institutional commitment and investment
- Clear and supportive regulations

#### Resources

- Open-access fools and platforms
- Sharing of successful protocols and case studies

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# 6. Dissemination and Follow-up

Positive social media feedback from participants

- Event updates shared via:
  - Global Health Trials
  - o <u>Latin America Hub The Global Health Network</u>

#### 7. Photo Gallery and Videos of the activities:

Videos of the activities Video1 and Video2



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