Mahidol University
Faculty of Tropical Medicine

CERTIFICATE

OF ATTENDANCE

This is to certify that

Boonying Prathum

Attended the training course

Good Clinical Practice

Completion Date: 28/08/2025

Expiration Date: 27/08/2028

Organized by
Faculty of Tropical Medicine, Mahidol University

Name: Boonying Prathum
Institution Affiliation: Nakhon Si Thammarat Rajabhat University
Email: boonying_pra@nstru.ac.th
Completion date: 28/08/2025
Expiration date: 27/08/2028

Good Clinical Practice

- History and Ethics of Human Subjects Research
- Institutional Review Board (IRB) Composition, responsibility and review process
- Recruitment process, Informed consent process, Reconsent process, Informed opt-out
- Modifications and waivers of informed consent
- Research Involving mothers and child
- Risk and benefit assessment / Risk management
- Conflicts of Interest in Human Subjects Research
- Privacy and confidentiality
- PDPA related to medical research
- Laws and regulations related to research
- Data sharing and material transfer agreement
- Safety report
- Deviation/Violation report
- Overview of International Council for Harmonisation (ICH)
- Sponsor responsibilities / Sponsor obligations in FDA-regulated research
- Audits, inspection, and monitoring of research studies
- Investigator's responsibilities
- Data governance
- Essential documents
- Managing investigational agents according to GCP requirements
- Research Involving Human Subjects