INTRODUCTION TO ICH GOOD CLINICAL PRACTICE

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DMR

INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE (ICH)

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects.

INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE (ICH)

ICH HARMONISED GUIDELINE

INTEGRATED ADDENDUM TO ICH E6(R1): GUIDELINE FOR GOOD CLINICAL PRACTICE

E6(R2)

Current *Step 4* version

dated 9 November 2016

The guideline was developed with consideration of the current good clinical practices of the European Union, Japan, and the United States, as well as those of Australia, Canada, the Nordic countries and the World Health Organization (WHO).

The objective of this ICH GCP Guideline is to provide a unified standard for the European Union (EU), Japan and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions.

ICH Good Clinical Practice

Historical Background

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) , formerly the International Conference on Harmonisation (ICH) , was established in 1990 .

- is unique in bringing together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration.

ICH MISSION

" To achieve greater harmonisation worldwide to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner "

Harmonisation is achieved through the development of ICH Guidelines via a process of scientific consensus with regulatory and industry experts working side-by-side. Key to the success of this process is the commitment of the ICH regulators to implement the final Guidelines.

The International Council for Harmonisation (ICH), held the inaugural Assembly meetings on 23 October 2015 establishing ICH as an international association, a non-profit legal entity under Swiss law.

Since its announcement of organisational changes, ICH has grown as an organisation and now includes 16 Members and 32 Observers.

ICH
harmonisation for better health

ICH

INTERNATIONAL COUNCIL FOR HARMONISATION of Technical Requirements for Pharmaceuticals for Human Use

- Unique harmonisation initiative for regulators and pharmaceutical industry
- Originally founded in 1990
- Reformed as a non-profit legal entity under Swiss Law on 23 October 2015

Purpose of ICH

Promotion of public health through **international harmonisation** that contributes to:

- Prevention of unnecessary duplication of clinical trials and post market clinical evaluations
- Development and manufacturing of new medicines
- Registration and supervision of new medicines
- Reduction of unnecessary animal testing without compromising safety and effectiveness

Accomplished through **Technical Guidelines** that are implemented by the regulatory authorities.

ICH Members
(as of 6 June 2018)

Members:

- Founding Regulatory:
  - EC, Europe; MHLW/PMDA, Japan; FDA, US
- Founding Industry:
  - EFPIA; JPMA; PhRMA
- Standing Regulatory:
  - Swissmedic, Switzerland; Health Canada, Canada
- Regulatory:
  - ANVISA, Brazil; CFDA, China; HSA, Singapore; MFDS, Republic of Korea; TFDA, Chinese Taipei
- Industry:
  - IGBA; WSMI; BIO

See http://www.ich.org/about/members-observers.html for detai

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ICH Products (as of June 2018)

- Over 60 Guidelines on technical requirements

- Electronic Standards for the Transfer of Regulatory Information (ESTRI, E2B)
- Consideration documents (e.g. participation of women in clinical trials)

See http://www.ich.org/products/guidelines.html for details

E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1)

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

March 2018
Procedural

OMB Control No. 0910-0843 Expiration Date 09/30/2020
See additional PRA statement in section 9 of this guidance.

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GLOSSARY

Good Clinical Practice (GCP)

A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

Clinical Trial / Study

Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.

Investigational Product

A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

Investigator

A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the **principal investigator.**

Sub-investigator

Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions.

Investigator's Brochure

A compilation of the clinical and nonclinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human subjects

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ICH HARMONISED GUIDELINE

INTEGRATED ADDENDUM TO ICH E6(R1): GUIDELINE FOR GOOD CLINICAL PRACTICE ICH E6(R2)

ICH Consensus Guideline

TABLE OF CONTENTS

A total of 8 titles

ICH HARMONISED GUIDELINE

INTEGRATED ADDENDUM TO ICH E6(R1): GUIDELINE FOR GOOD CLINICAL PRACTICE ICH E6(R2)

ICH Consensus Guideline

TABLE OF CONTENTS

THE PRINCIPLES OF ICH GCP

- The principles of GCP are concerned with the safety, rights and wellbeing of participants and the validity and quality of the research data.
- This guideline should be followed when generating clinical trial data that are intended to be submitted to regulatory authorities.
- There are thirteen principles in the 2016 ICH-GCP guidelines

13 Key Principles of ICH GCP

Principle 1

Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement(s).

The Declaration of Helsinki (1964)

The DoH was first adopted in the 1964 World Medical Association (WMA) General Assembly in Helsinki.

- "The well-being of the subject should take precedence over the interests of science and society"
- Consent should be in writing
- Use caution if participant is in dependent relationship with researcher
- Greater access to benefit

World Medical Association Declaration of Helsinki
Ethical Principles for Medical Research Involving Human Subjects

World Medical Association

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the:
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
53rd WMA General Assembly, Washington, DC, USA, October 2002 (Note of Clarification added)
55th WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clarification added)
59th WMA General Assembly, Seoul, Republic of Korea, October 2008
64th WMA General Assembly, Fortaleza, Brazil, October 2013

35 principles
Adopted at 18th WMA General Assembly in June 1964
Amended at 64th WMA General Assembly in Oct 2013
Published in JAMA in Nov 2013

Special Communication

World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects

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59th WMA General Assembly, Seoul, Republic of Korea, October 2008
64th WMA General Assembly, Fortaleza, Brazil, October 2013

Preamble

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.

   The Declaration is intended to be read as a whole and each of its constituent paragraphs should be applied with consideration of all other relevant paragraphs.

2. Consistent with the mandate of the WMA, the Declaration is addressed primarily to physicians. The WMA encourages others who are involved in medical research involving human subjects to adopt these principles.

General Principles

3. The Declaration of Geneva of the WMA binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act in the patient's best interest when providing medical care."

4. It is the duty of the physician to promote and safeguard the health, well-being and rights of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfillment of this duty.

5. Medical progress is based on research that ultimately must include studies involving human subjects.

6. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures, and treatments). Even the best proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.

7. Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights.

8. While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.

9. It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects. The responsibility for the protection of research subjects must always rest with the physician or other healthcare professionals and never with the research subjects, even though they have given consent.

10. Physicians must consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.

11. Medical research should be conducted in a manner that minimizes possible harm to the environment.

12. Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional.

13. Groups that are underrepresented in medical research should be provided appropriate access to participation in research.

14. Physicians who combine medical research with medical care should involve their patients in research only to the extent that this is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.

15. Appropriate compensation and treatment for subjects who are harmed as a result of participating in research must be ensured.

Risks, Burdens and Benefits

16. In medical practice and in medical research, most interventions involve risks and burdens.

    Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects.

17. All medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation.

    Measures to minimize the risks must be implemented. The risks must be continuously monitored, assessed and documented by the researcher.

18. Physicians may not be involved in a research study involving human subjects unless they are confident that the risks have been adequately assessed and can be satisfactorily managed.

    When the risks are found to outweigh the potential benefits or when there is conclusive proof of definitive outcomes, physicians must assess whether to continue, modify or immediately stop the study.

Vulnerable Groups and Individuals

19. Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm.

    All vulnerable groups and individuals should receive specifically considered protection.

20. Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research.

Scientific Requirements and Research Protocols

21. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.

22. The design and performance of each research study involving human subjects must be clearly described and justified in a research protocol.

    The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, potential conflicts of interest, incentives for subjects and information regarding provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study.

    In clinical trials, the protocol must also describe appropriate arrangements for post-trial provisions.

Research Ethics Committees

23. The research protocol must be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins. This committee must be transparent in its functioning, must be independent of the researcher, the sponsor and any other undue influence and must be duly qualified. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration.

    The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. After the end of the study, the researchers must submit a final report to the committee containing a summary of the study's findings and conclusions.

Privacy and Confidentiality

24. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information.

Informed Consent

25. Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it is

A total of 35 General Principles

Principle 2

Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.

Principle 3

The rights, safety and well-being of participants always take precedence over the interests of science and society.

Principle 4

The available nonclinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.

Principle 5

Clinical trials should be scientifically sound, and described in a clear, detailed protocol.

Principle 6

A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/independent ethics committee (IEC) approval/favourable opinion.

Principle 7

The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.

Principle 8

Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).

Principle 9

Freely given informed consent should be obtained from every subject prior to clinical trial participation.

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Principle 10

All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.

This principle applies to all records referenced in this guideline, irrespective of the type of media used.

Principle 11

The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).

Principle 12

Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP). They should be used in accordance with the approved protocol.

Principle 13

Systems with procedures that assure the quality of every aspect of the trial should be implemented.

Aspects of the trial that are essential to ensure human subject protection and reliability of trial results should be the focus of such system.

ICH E6(R2) Addendum

ICH E6(R1) has been amended to encourage implementation of improved and more efficient approaches to clinical trial design, conduct, oversight, recording, and reporting while continuing to ensure human subject protection and reliability of trial results

Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

Principles of ICH GCP (Summary)

Ethics:

1. Ethical conduct of clinical trials
2. Benefits justify risks
3. Rights, safety, and well-being of subjects prevail

Protocol and Science:

4. Nonclinical and clinical information supports the trial
5. Compliance with a scientifically sound, detailed protocol

Credit : MK 190816 GCP IR DMR

Principles of ICH GCP (Summary)

Responsibilities:

6. IRB/IEC approval prior to initiation
7. Medical care/decisions by qualified physician
8. Each individual is qualified (education, training, experience) to perform his/her tasks

Informed Consent:

9. Freely given from every subject prior to participation

Principles of ICH GCP (Summary)

Data Quality and Integrity:

10. Accurate reporting, interpretation, and verification

11. Protects confidentiality of records

Investigational Products:

12. Conform to GMP's and used per protocol

Quality Control/Quality Assurance:

13. Systems with procedures to ensure quality of every aspect of the trial

Credit : MK 190816 GCP IR DMR

ICH GCP TRAINING WORKSHOP

Training Workshop on "International Council for Harmonisation Good Clinical Practice (ICH-GCP) "

(13 - 14 Feb 2020)

General objective

- To strengthen good clinical research practice among clinicians at Medical and Health related Universities under MoHS

Specific objectives

- To promote awareness and understanding of the importance of good clinical practice among clinicians in research involving human subjects
- To encourage conduct of clinical research studies in Myanmar research culture
- To cultivate the application of GCP principles in clinical studies conducted in Myanmar

Expected outcomes

- The workshop will improve the clinician's understanding of the GCP principles, clinical research methods, common ethical problems in clinical research, and build the capacity of faculty in good clinical and research practice. Certificate of training will be provided.

- *This Training Workshop is intended primarily for faculty members and staff engaged in research including those supported by MoHS but is applicable to scholarly research in general*
- *It seeks to provide a practical overview of the rules, regulations, and professional practices that define the GCP*

- *The coverage in this training workshop is not exhaustive and leaves room for continued reading and discussion in the laboratory and classroom, at professional meetings, and in any other setting where faculty and researchers gather to discuss their work*

Conclusion

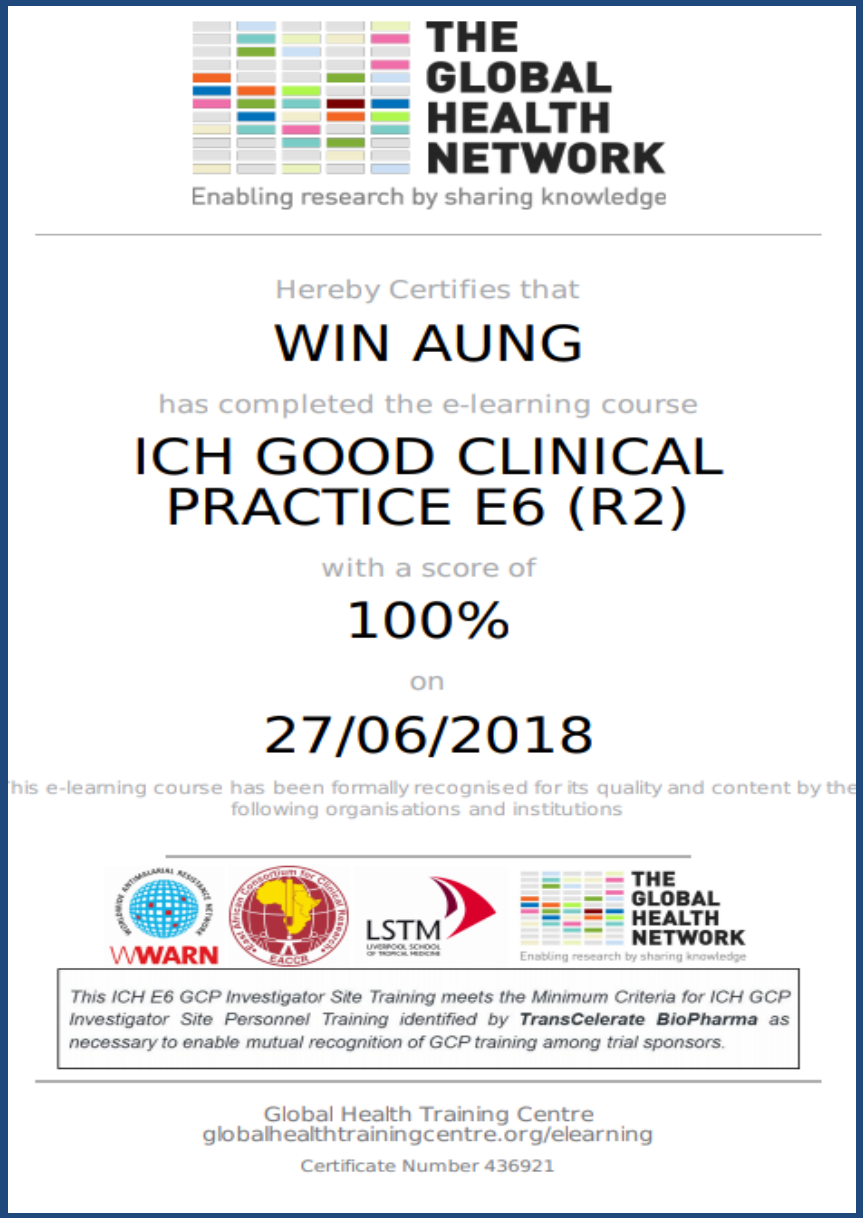
- We hope to encourage faculty, researchers and the academic and research institutions to make a special effort to understand, discuss, and teach others about the ICH-GCP
- This workshop should be seen as the beginning and not the end of learning about this important aspect of our professional life

- *“Coming together is a beginning. Keeping together is progress. Working together is success.”*

  Henry Ford (July 30, 1863 – April 7, 1947)

- ICH official link and ICH GCP E6(R2) : Guideline for GCP document
- https://ich.org/page/efficacy-guidelines>

- ICH GCP online training,.
- https://globalhealthtrainingcentre.tghn.org/ich-good-clinical-practice/>



THE GLOBAL HEALTH NETWORK

Enabling research by sharing knowledge

Hereby Certifies that

WIN AUNG

has completed the e-learning course

ICH GOOD CLINICAL PRACTICE E6 (R2)

with a score of

100%

on

27/06/2018

This e-learning course has been formally recognised for its quality and content by the following organisations and institutions

WWARN · EACCR · LSTM Liverpool School of Tropical Medicine · THE GLOBAL HEALTH NETWORK Enabling research by sharing knowledge

*This ICH E6 GCP Investigator Site Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by **TransCelerate BioPharma** as necessary to enable mutual recognition of GCP training among trial sponsors.*

Global Health Training Centre
globalhealthtrainingcentre.org/elearning

Certificate Number 436921

NIDA Clinical Trials Network

Certificate of Completion

is hereby granted to

Win Aung

to certify your completion of the six-hour required course on:

GOOD CLINICAL PRACTICES

MODULE:	STATUS:
Introduction	N/A
Institutional Review Boards	Passed
Informed Consent	Passed
Confidentiality & Privacy	Passed
Participant Safety & Adverse Events	Passed
Quality Assurance	Passed
The Research Protocol	Passed
Documentation & Record-Keeping	Passed
Research Misconduct	Passed
Roles & Responsibilities	Passed
Recruitment & Retention	Passed
Investigational New Drugs	Passed

Course Completion Date: 27 December 2017

CTN Expiration Date: 27 December 2020

Tracee Williams, Training Coordinator
NIDA Clinical Coordinating Center

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Thank You

For Your Kind Attention !