CLINICAL TRIAL IN MALAYSIA

Clinical Trial and Compliance Section
National Pharmaceutical Control Bureau
Ministry of Health Malaysia

OUTLINE

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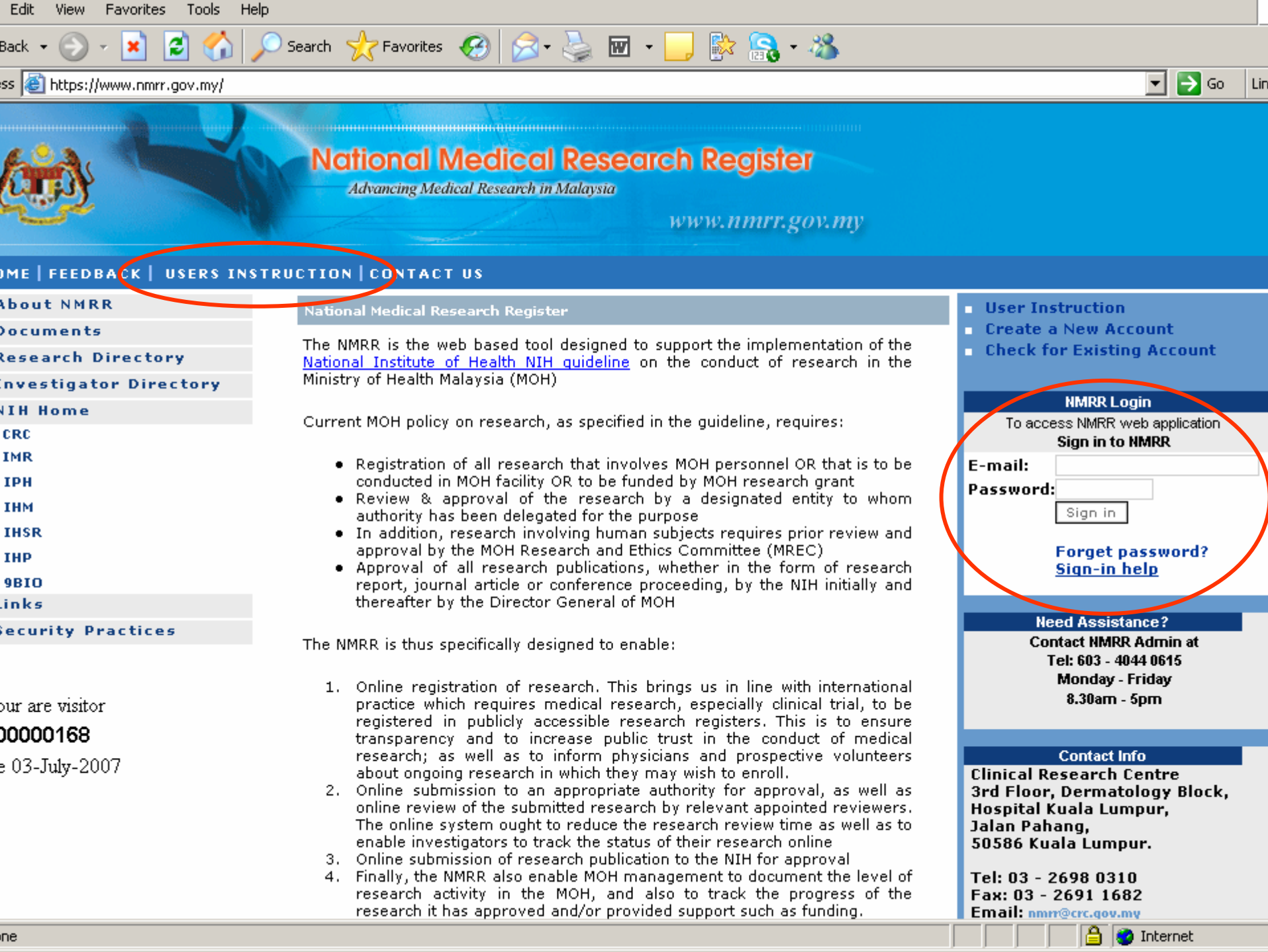
- Regulation and Ethical Oversight of Clinical Trial in Malaysia
- Guidelines and Legal Requirements
- Compliance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National Medical Research Register
The NMRR is the web based tool designed to support the implementation of the National Institute of Health NIH guideline on the conduct of research in the Ministry of Health Malaysia (MOH)
Current MOH policy on research, as specified in the guideline, requires:
Registration of all research that involves MOH personnel OR that is to be conducted in MOH facility OR to be funded by MOH research grant
Review & approval of the research by a designated entity to whom authority has been delegated for the purpose
In addition, research involving human subjects requires prior review and approval by the MOH Research and Ethics Committee (MREC)
Approval of all research publications, whether in the form of research report, journal article or conference proceeding, by the NIH initially and thereafter by the Director General of MOH
The NMRR is thus specifically designed to enable:
1. Online registration of research. This brings us in line with international practice which requires medical research, especially clinical trial, to be registered in publicly accessible research registers. This is to ensure transparency and to increase public trust in the conduct of medical research; as well as to inform physicians and prospective volunteers about ongoing research in which they may wish to enroll.
2. Online submission to an appropriate authority for approval, as well as online review of the submitted research by relevant appointed reviewers. The online system ought to reduce the research review time as well as to enable investigators to track the status of their research online
3. Online submission of research publication to the NIH for approval
4. Finally, the NMRR also enable MOH management to document the level of research activity in the MOH, and also to track the progress of the research it has approved and/or provided support such as funding.
User Instruction
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Check for Existing Account
NMRR Login
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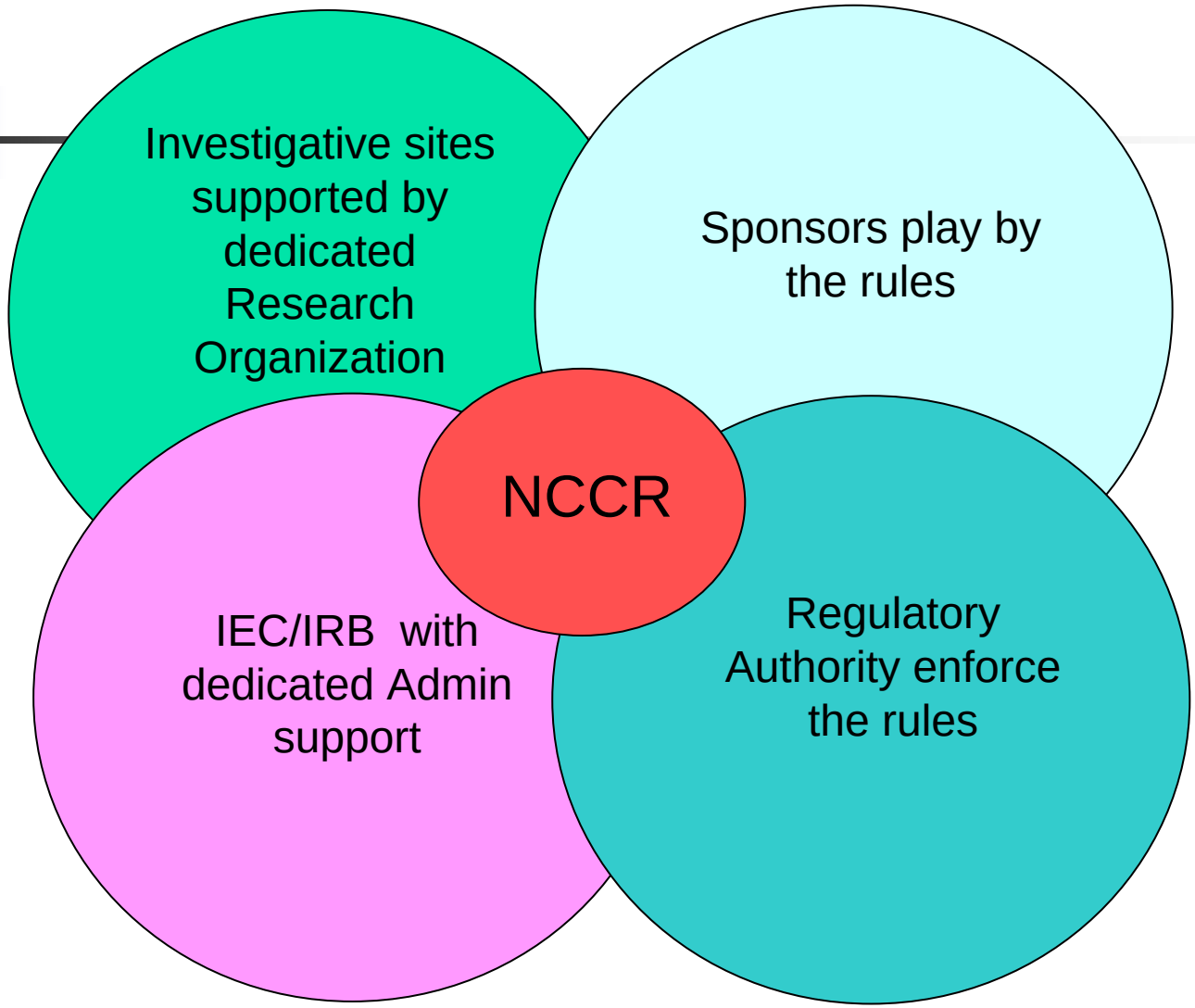
Sign in to NMRR
E-mail:
Password:
Sign in
Forget password?
Sign-in help
Need Assistance?
Contact NMRR Admin at
Tel: 603 - 4044 0615
Monday - Friday
8.30am - 5pm
Contact Info
Clinical Research Centre
3rd Floor, Dermatology Block,
Hospital Kuala Lumpur,
Jalan Pahang,
50586 Kuala Lumpur.
Tel: 03 - 2698 0310
Fax: 03 - 2691 1682
Email: nmrr@crc.gov.my
Internet

Regulation and Ethical Oversight of Clinical Trial in Malaysia

Ensuring Ethical Research: A joint responsibility



1. National Committee for Clinical Research(NCCR)

- Forum for dialogue among all parties: Regulatory authority, IECs, Sponsors, Investigators from MOH/Universities/ Private hospitals
- Promulgate & implement various guidelines:

- GCP, Bioequivalence (BE) studies, GLP, Guidelines for Application For CTIL/ CTX etc

- Training on GCP
- Site-inspection for clinical trials
- Review processes for approval of clinical trials

2. Investigative sites & Research organization

This is where the action is; where investigators enroll patients into the trial

Ethical trial conduct & compliance requires:

- Adequate resources to conduct the trial
- Training, eg GCP certification
- Independent monitoring of trial conduct

3. Sponsors

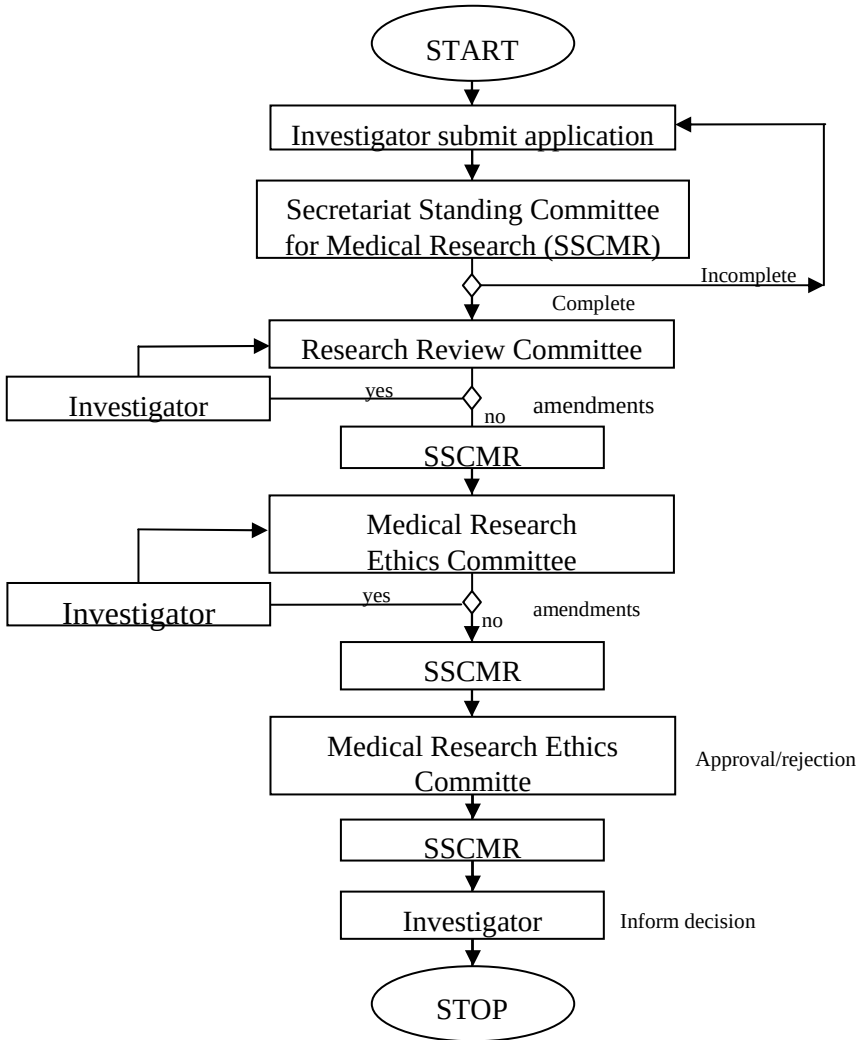
- Sponsor pay for the research, and own the IPR
- Mostly industry sponsors (mostly drug trials) or government grant agency (eg NIH of the MOH, MOSTE)
- Recruitment of well qualified investigators
- Avoid undue influence of investigators and patients
- Independent monitoring /audit by sponsors: common practice for industry

4. IEC/ IRB

"An independent body constituted of medical professionals and non-medical members whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects." ICH GCP 1.27

- In Malaysia, for MOH/private sites, this is the Medical Research & Ethics Committee of the MOH (MREC); universities have their own IECs.

Application for Conduct of Clinical Trial in MOH, Malaysia



5. Regulatory Authority

- Drug Control Authority (DCA)

  An authority established for the purpose of regulating the Control of Drugs and Cosmetics Regulations, 1984
- DCA has a broad public protection mission to ensure the safe use of regulated products that are themselves safe and efficacious
- Ensure Implementation of trial related guidelines and legislation

Guidelines and Legal Requirements

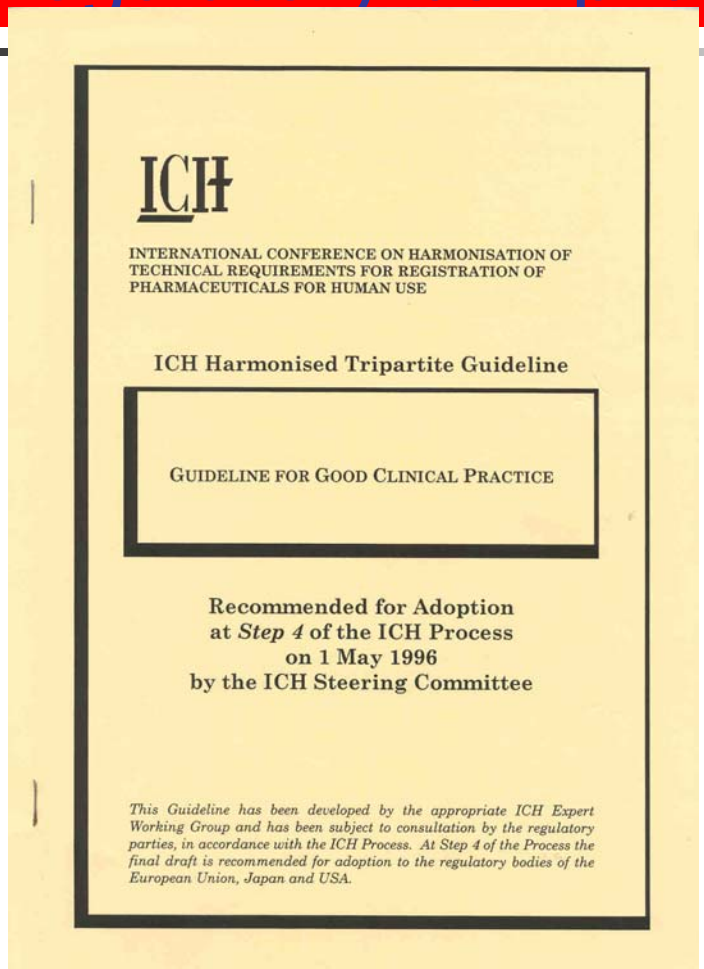
Guidelines:

- Malaysian Guidelines for GCP (Updated 2004)
- Guidelines for Application of CTIL and CTX in Malaysia
- NIH Guideline for Research conduct in MOH

Laws

- Control of Drugs and Cosmetics Regulation 1984
- The Poison Regulation (Psychotropic Substances) 1989
- Sale of Drugs Act 1952

Regulatory compliance



ICH

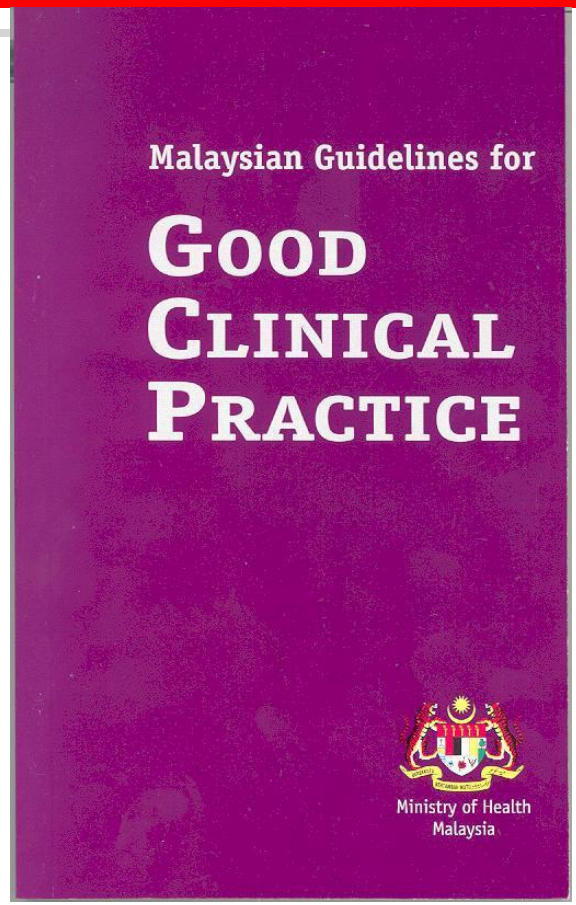
INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

ICH Harmonised Tripartite Guideline

GUIDELINE FOR GOOD CLINICAL PRACTICE

Recommended for Adoption
at *Step 4* of the ICH Process
on 1 May 1996
by the ICH Steering Committee

This Guideline has been developed by the appropriate ICH Expert Working Group and has been subject to consultation by the regulatory parties, in accordance with the ICH Process. At Step 4 of the Process the final draft is recommended for adoption to the regulatory bodies of the European Union, Japan and USA.



Malaysian Guidelines for

GOOD CLINICAL PRACTICE

Ministry of Health
Malaysia

Malaysia GCP Guidelines “5.20.3

The DCA will enforce the rules and punitive action will be decided by the DCA

4.Malaysian GCP
4.1 Investigator's Qualifications and Agreements

4.1.1The investigator (s) should be qualified by education, **approved training in Good Clinical Practice certification** and experience to assume responsibility for the proper conduct of the trial, should meet all the qualifications specified by the applicable regulatory requirement (s), and should provide evidence of such qualifications through up-to-date curriculum vitae and/ or other relevant documentation requested by the sponsor, the IRB/IEC and/or the regulatory authority (ies)

Control of Drugs and Cosmetics Regulations 1984 (Revised 2006)

Regulation 29. Directions

(1) The Director of Pharmaceutical Services

may issue written directives or guidelines to any person or a group of persons as he thinks necessary for the better carrying out of the provisions of these Regulations and in particular relate to-

(a) clinical trials or

(2) Any person to contravenes any **directives or guidelines** issued by the Authority under subregulation (1) commits an offence.

Control of Drugs and Cosmetics Regulations 1984

Regulation 12(1)(c): Clinical Trial Import Licence (CTIL)

A Clinical trial import licence in Form 4 in the Schedule,

- *authorising the licensee to import any product for purposes of clinical trials,*
- *notwithstanding that the product is not a registered product*

Control of Drugs and Cosmetics Regulations 1984

Regulation (15) Exemptions

Regulation 15(5) : Clinical Trial Exemption (CTX)

"Any person who wishes to manufacture any products solely for the purpose of producing samples for registration/clinical trials under these Regulations may on application be exempted by the Authority from the provisions of regulation 7(1)."

Contravention of Regulation 7(1) of the Control of Drugs and Cosmetic Regulations 1984

- The penalty comes under parent acts Section 12, Sale of Drug Acts 1952 (Revised 1989)

CTIL and CTX Application

CTIL Application

- For unregistered products.
- Product when used or assembled (formulated or packaged) in away different from the approved form.
- Form BPFK 442.4
- Fees : RM 500 for each product
- Licence A for Poisons (where applicable)
- DCA approval based on:-
  - approval from IRB/IEC
  - complete information on investigational products

CTX Application

- For unregistered products- manufactured locally.
- Form BPFK 443.1
- Fees : Free of charge
- Licence A for Poisons (where applicable)
- DCA approval based on:-
  - approval from IRB/IEC
  - complete information on investigational products

Factors affecting speed of approval

- How complete is the information submitted?
- How fast sponsor/ PI respond to queries ?
- Adherence to established procedures
- For CTIL and CTX - Ethical Approval given prior to release of CTIL/CTX

Compliance

Who does inspections?

- By the local Regulatory Authority
- External Regulatory Authorities

Don’t just believe what we say

Malaysia’s favorable experience with sponsor’s audit and regulatory inspection

Sponsor pre-qualification or on-study audit

- Pfizer, Sanofi-Aventis, B Braun, Beaufour Ipsen, etc

Regulatory inspection

- EMEA
- FDA

Thank You
For Your Kind Attention

www.bpfk.gov.my