Value of Ethics Committee Audits on Ongoing Studies: Ensuring Compliance and Participants Safety

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Short Biography

Dr Ami Fazlin Syed Mohamed is currently the Director of the Institute for Medical Research (IMR), National Institutes of Health Malaysia (NIH Malaysia). She has a medical degree (University of Adelaide, Australia), MSc in Clinical Pharmacology (University of Glasgow, UK) and PhD in Pharmacometrics (Uppsala University, Sweden). She is involved in natural product development at both the preclinical and clinical level. She is the Test Facility Manager for the in vivo GLP Laboratory IMR and chairs the Main Committee for the Malaysian Herbal Monograph/Pharmacopeia and the Preclinical and Clinical Cluster apart from being a member in the Main Committee of the National Research and Development of Herbal Medicine and others. She is the Deputy Chairman of the Medical Research Ethics Committee in the Ministry Of Health Malaysia and serve as a member of the Scientific Review Panel for Phase I study. She plays a significant role in development of guidelines for herbal medicine research and is a familiar presence in regulatory settings. As the director of a biomedical research institute for the Ministry of Health Malaysia, she lead eight centres that looked into different areas of research namely communicable and non-communicable disease, environmental health. The institute concentrate on research for the betterment of human health leading to policy changes, innovations, training and consultancies.

Introduction to MREC

MREC was established in 2002

to provide an independent ethical review on health research or other research protocols that involve human subjects and are conducted in MOH facilities or using data/ patient/ personnel from the MOH.

The constitution of MREC is in accordance with

- ‘Malaysian Guidelines for Good Clinical Practice (GCP)’
- Declaration of Helsinki,
- International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS)
- ICH Guideline of Good Clinical Practice

Introduction to Compliance Audits

As per MCGP 3.2.2 - The IRB/IEC should perform its functions according to written operating procedures, should maintain written records of its activities and minutes of its meetings, and should comply with GCP and with the applicable regulatory requirement(s).

MREC conducted compliance reviews to ensure safety and rights of study participants are always protected according to MGCP

MREC Compliance Review as per SOP MREC 3-3.

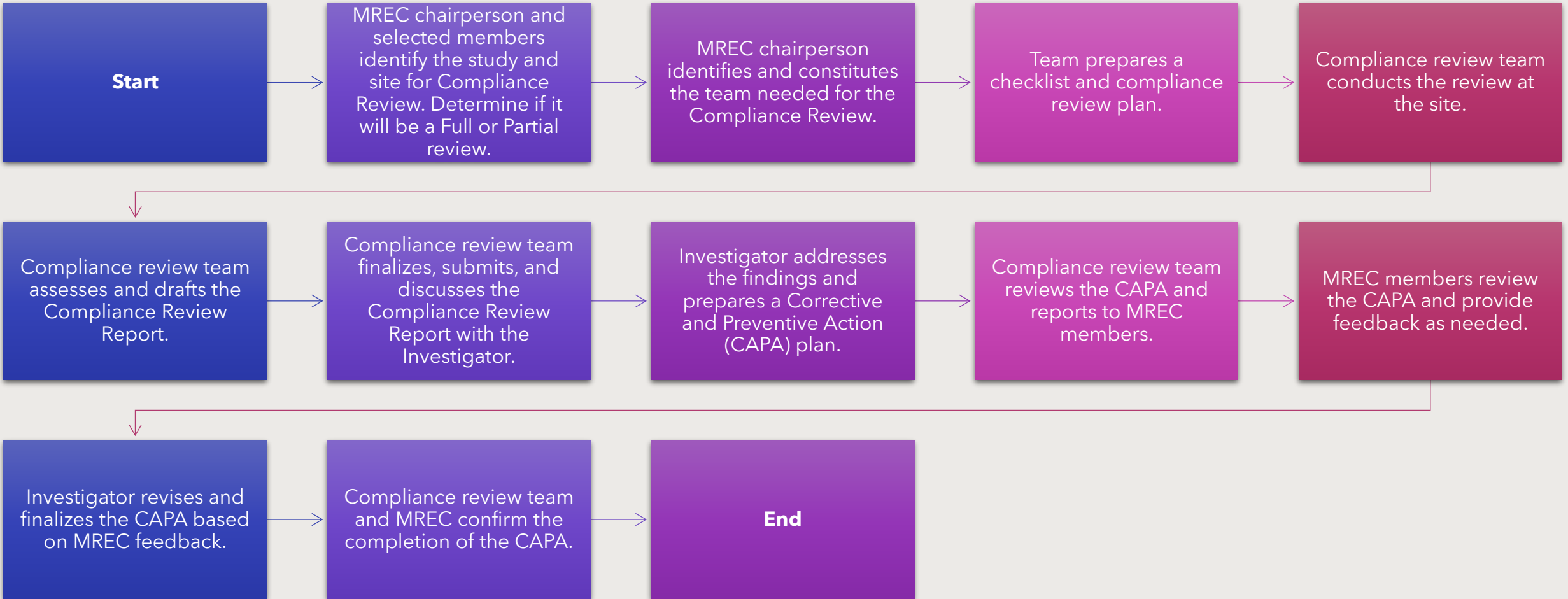
Purpose of Compliance Audits

a. Confirm if the Principal investigator (PI) is complying with protocol and regulatory requirements. Assist the PI in complying with Regulations and Protocol.

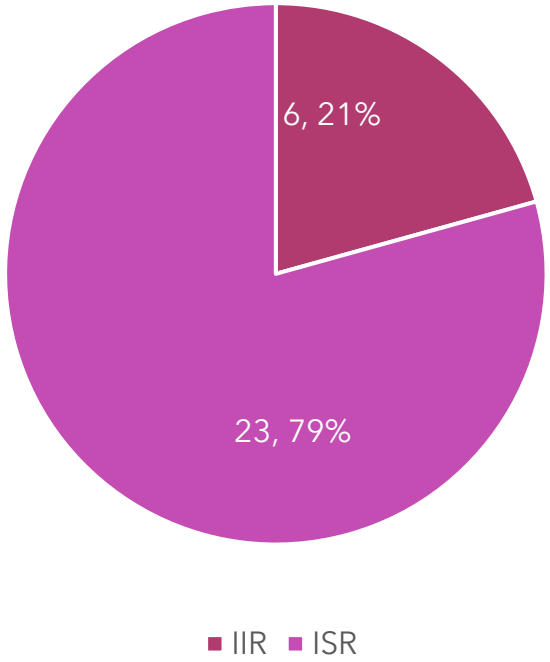
b. Confirm if the PI is taking appropriate and timely action to ensure protection of the rights, safety and well-being of research subjects at all times.

c. Provide assurance to the public as well as to the Ministry of Health Malaysia that MREC is providing the continued oversight of studies and ensuring that rights, safety and well-being of research subjects are safeguarded.

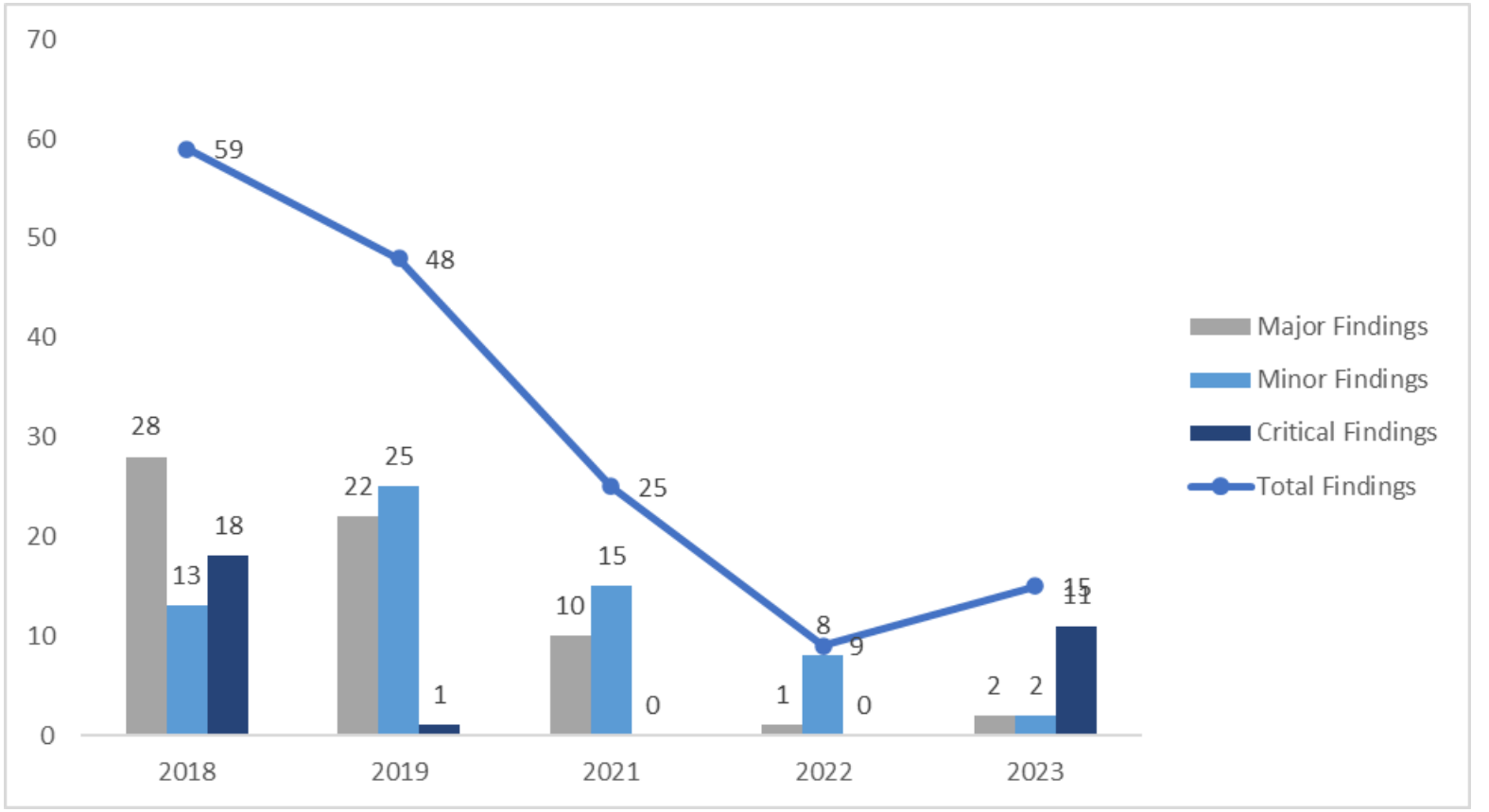
Audit Process



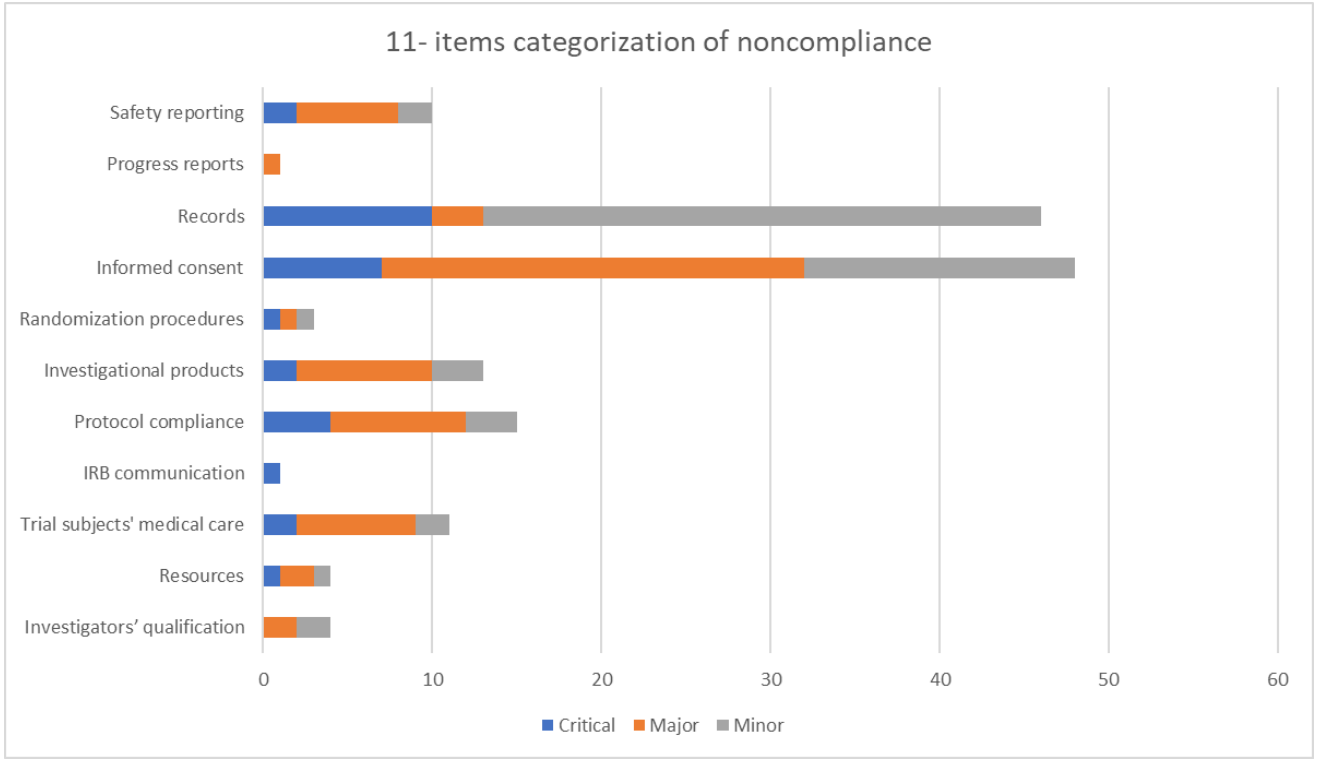
Types of Studies Audited



Number of non-compliance findings from 2018-2023



Common Findings from Compliance Audits



Highest non-compliance:

Informed consent - 48

Records related to trial- 46

Protocol compliance- 15

Case Study 1 – PI Availability and Role of Co-Investigators

- In some compliance audits, it is found that there is only 1 Principal Investigators available and issues arise from unavailability of PI

- In one compliance audit, it was found that the study is not initiated due to PI transferred out and no one taking over the study.

- **Change of Policy : Now it is required to have at least 1 Co-Investigators for clinical trial or high risk interventional study to ensure the safety and well-being of trial participants.**

Case Study 2 – Dispensary Issues

Compliance audits found issues of IP accountability, prescription of prohibited medication, wrong IP kit dispensed are mainly due to lack of delegated pharmacists in the study team

Change of Policy : It is encouraged to have Pharmacist in the team to assist IP dispensary and accountability. One of the site is withhold from conducting further trials until a pharmacist is added into the study team to ensure patients' safety

Case Study 3 – Medical Records

•During compliance audits, it was identified that some sites were not utilizing a trackable system for managing medical records, which posed challenges in maintaining accurate and complete patient documentation. A trackable system is crucial for logging entries, updates, and revisions in medical records to ensure transparency and accountability.

•Post-audit: PI understands the need to key in the medical records in the EMR and not keeping her own print out as source documents which has no time stamp and entry log.

Policy Changes Stemming from Audit Findings

Mandating postgraduate students who run clinical trials/interventional studies to include specialist who is supervising their activities in hospital to be the Principal Investigators

Mandating clinical trials to have at least 1 co-investigator in the study team to ensure the availability of investigators to attend to trial participants when PI is not at site.

Highlight the importance of pharmacist involvement in the trial to ensure the IP accountability and dispensary as per the protocol and regulatory requirement

Benefits of Regular Compliance Audits

Enhanced Participant Safety and Welfare

- Regular audits help ensure that clinical trials prioritize participant safety by verifying that protocols are followed accurately and that any potential risks are identified and mitigated promptly.

Improved Adherence to Good Clinical Practice (GCP)

- Audits reinforce adherence to GCP standards, helping sites consistently meet ethical and regulatory requirements, which in turn strengthens the credibility and reliability of clinical trial data.

Early Detection and Resolution of Compliance Issues

- By regularly monitoring studies, audits can uncover and address compliance issues early, preventing minor problems from escalating and impacting trial outcomes or patient safety.

Increased Accountability and Transparency

- Regular audits promote accountability among researchers, ensuring transparency in trial processes and documentation, which builds trust with regulatory authorities, participants, and the broader community.

Other Benefits of Regular Compliance Audits

Opportunity for Continuous Learning and Improvement

Encouragement of Consistent Documentation Standards

Adaptation to Evolving Regulatory and Ethical Standards

Increased Confidence for Stakeholders

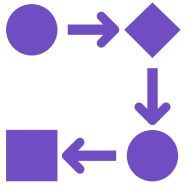
Strengthening of Site Preparedness for External Inspections

Promotion of a Culture of Compliance and Ethical Research

Future Directions and Ongoing Commitment

Annual Compliance Audits as a Standard Practice:

MREC is committed to conducting annual compliance audits at sites across Malaysia, ensuring that clinical trials meet the highest standards of ethical and regulatory compliance. These audits provide ongoing support to investigators and trial sites, reinforcing adherence to Good Clinical Practice (GCP) and safeguarding participant rights and well-being.



Proactive Adaptation to Emerging Research Needs:

As the research landscape evolves, MREC's audit approach will adapt to address new methodologies, technologies, and trial designs, including innovations like decentralized trials, AI integration, and adaptive designs. This flexibility allows MREC to respond to challenges posed by novel clinical trial frameworks while maintaining rigorous ethical standards.

Expansion of Audit Scope to Include Health Clinics Conducting Trials:

Recognizing the increasing role of diverse clinical settings, MREC will extend its audit reach to include health clinics involved in clinical research. This will ensure that all sites—whether large hospitals or community health clinics—uphold the same level of ethical integrity and compliance, promoting equitable and reliable research practices across all settings.

Conclusion

Compliance review can be used by researchers as an important input to improve professional research conduct.

Compliance review is crucial for regulatory bodies to evaluate the effectiveness and efficiency of the research governance process.

While clinical trials provide advancement in healthcare's next frontier, compliance review of clinical trials remains a crucial part of health research governance to ensure patient’s safety and wellbeing.

It is recommended for the ethics committees to conduct compliance review regularly to ensure safety and rights of study participants are always protected.

Thank you