Advancing Clinical Trials in Nepal: Overcoming Challenges and Implementing Solutions

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Introduction

- Clinical trials important assessing safety and efficacy of health interventions
- Well-designed trials generate evidence that address health needs.
- In developing countries, trials often face challenges like limited infrastructure and limited experience in conducting trials
- Building capacity for scientifically and ethically sound trials is vital.

Objectives

- To identify common challenges and discuss practical solutions for improving clinical trial feasibility and effectiveness.
- To share best practices and successful strategies for conducting high-quality clinical trials.
- To enhance understanding of the regulatory and ethical requirements for clinical trials in Nepal.
- To foster collaboration and communication among various stakeholders involved in clinical trials.

METHODS

OUCRU Nepal organized a one day symposium, which featured series of:

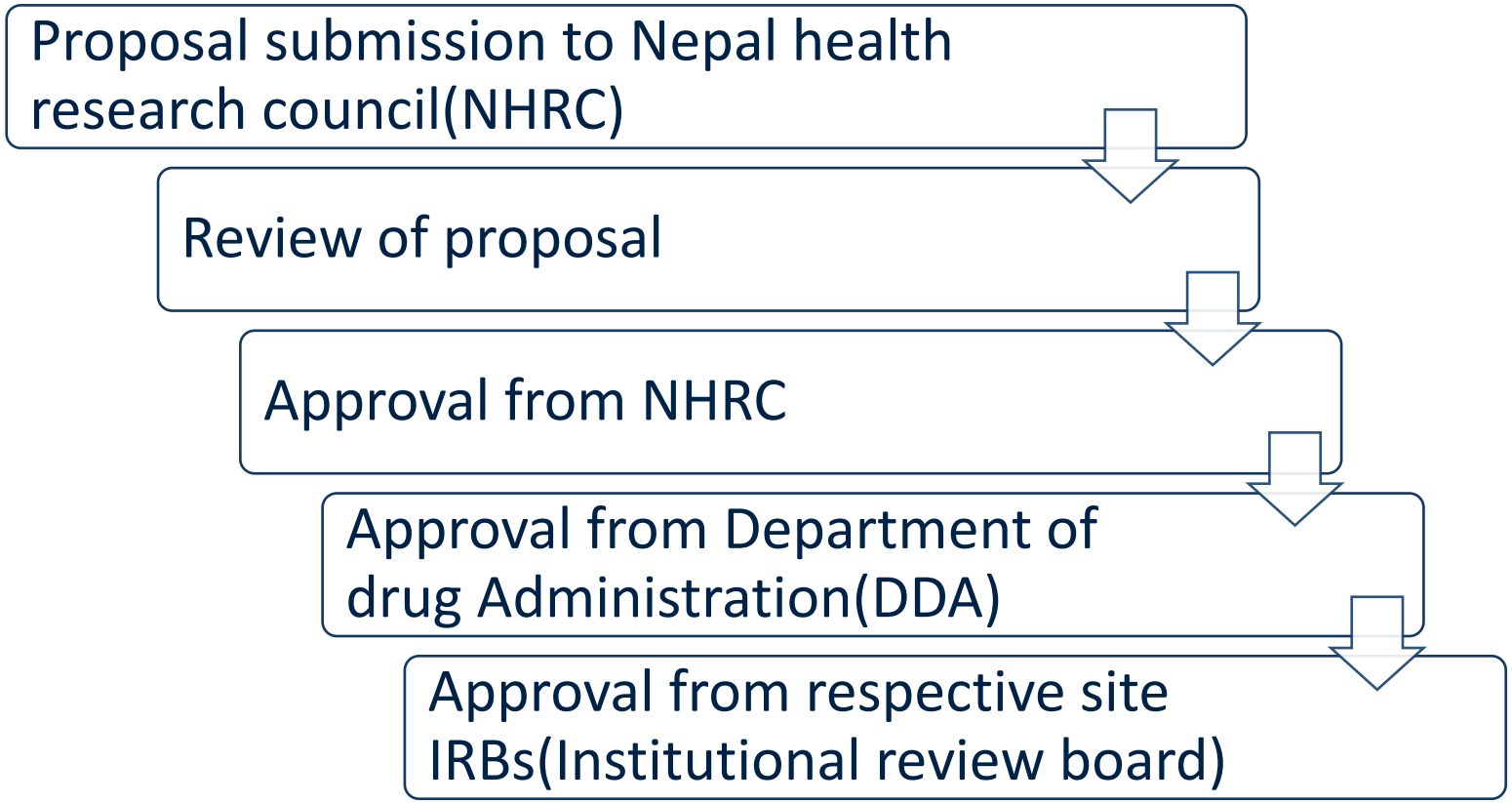
- **Presentations**
- **Panel discussions**
- **Group Discussions**

Discussions

Presentations

- Ethical regulation process and importance of monitoring
- Regulatory Roles of DDA and regulatory challenges in conducting clinical trials
- Scope of Clinical Trials/Future Clinical Trials in Nepal

Ethical regulation process in Nepal



Ethical regulation process and importance of monitoring

Major ethical concerns

- Limited number of Clinical researchers and their time allocations
- Challenges in taking consent/assent
- Lack of infrastructure like laboratories in trial sites
- Ensuring data quality, privacy and security

Importance of monitoring

- Monitoring important for **protocol adherence, data integrity, and participant safety.**

- The need for training research teams to understand the objectives of monitoring to avoid mistrust between researchers and ethical bodies.

Regulatory Roles of DDA

- The Department of Drug Administration (DDA) is a regulatory authority responsible for oversight of **clinical trials in Nepal** as per the Drug Act 1978
- Clinical trial inspection guideline(2023)
- Regulatory audit process
- Initiation of in-site inspection program

Regulatory challenges in conducting clinical trials in Nepal

- The need for frequent reapplication due to the one-year license duration for the same study

- The requirement to reapply for adaptive trial designs as a new trial when study drugs are added or removed which is time consuming and researchers run out of study period.

Current Scope of clinical trials in Nepal

- Establishment and amendment of guidelines to enhance compliance with international standard
- National and global grant opportunities
- Collaborative research projects

Challenges

- The lack of time of clinicians due to clinical duties
- Insufficient exposure to research-related training and mentorship
- Lack of funding
- Limited job opportunities in clinical research

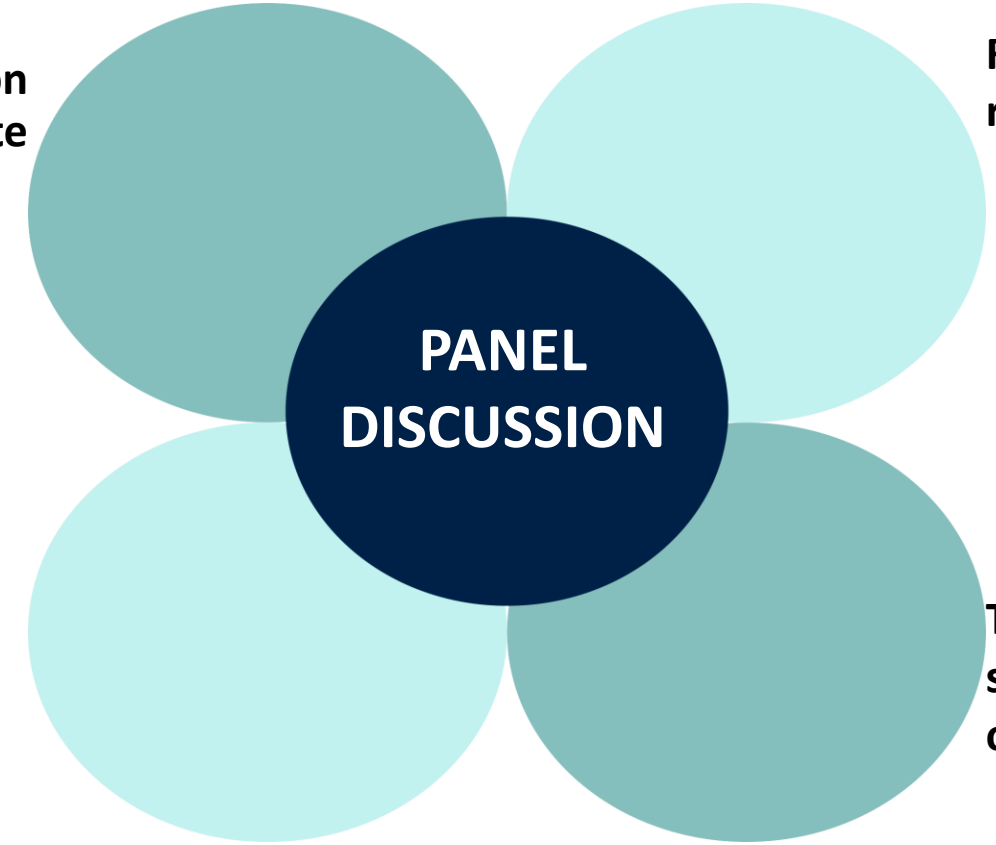
Recommendations

- Structured research training programs
- Periodic amendments of national guideline to align with global standard
- Upgrade single system for application of clinical trial
- Foster collaboration with national and international organizations

Enhancing Clinical Trial Site Feasibility: Strategies and Best Practices

Important factors in selection of clinical trial site

Role of Institutional review committee



Difficulties of trial site in successful clinical trial operation

The best practices for smooth implementation of clinical trials.

Important factors in selection of clinical trial site

Key points

Factors to be considered :

- amount of quality data that can be captured
- Infrastructure and resources at site for smooth operation
- supportive environment from IRB and hospital administration
- ethical aspects like transparency of fund, availability of qualified investigator

Role of institutional review committee (IRC)

Key points

- The workload of ERB can be decreased if reviewer of the IRC is capable enough to review trial protocols.

- IRC can review the protocol and give feedback on feasibility of conducting clinical trial in that site.

- IRC can have different team to address ethical issues and technical part of research separately

Difficulties trial site encounter for smooth operation of clinical trial

Key Points

Recruitment and retention problem due to various factors like

- Counselling patients to enroll
- Lack of motivation of trial site staff
- Limited resources

Best practices for smooth implementation of clinical trials

- Multidisciplinary team needed to implement the trial at site
- Adherence to ethical guideline and proper documentation of clinical trial data
- Timely monitoring of the research at trial site by IRC

Group Discussion

- Challenges of conducting clinical trials in Nepal and strategies for addressing Them
- Improving patient recruitment and retention strategies in clinical trials

Challenges of Conducting Clinical Trials in Nepal and Strategies for Addressing Them

Challenges

- Limited funding
- High regulatory and ethical costs
- Limited opportunities for research training and mentorships
- Lack of comprehensive clinical trial guidelines.

Strategies

- Streamlining the regulatory process through joint review mechanisms, regular updates to guidelines
- Capacity building for regulators, ethics committee members, and researchers.
- Integration of research into clinical practice to establish research friendly environment

Improving Patient Recruitment and Retention Strategies in Clinical Trials

Barriers to recruitment

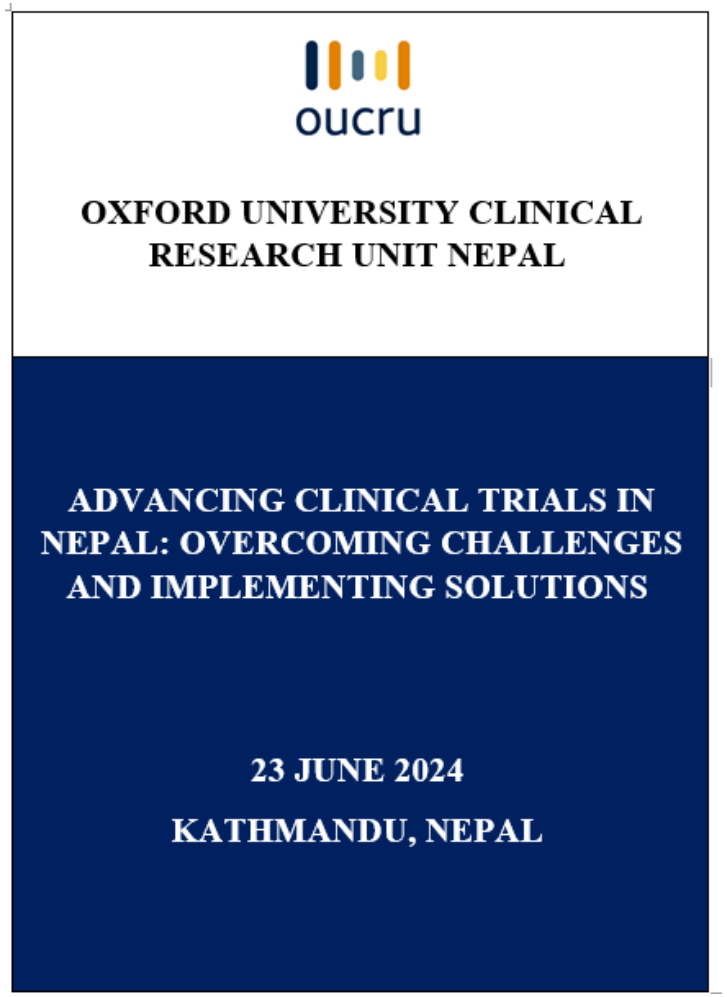
- Difficulties in understanding trial aspects for informed consent
- Language barriers
- Research stigma
- Fear of interventions
- Frequent follow-up visits.

Strategies to improve recruitment

- Proper counseling involving family members
- Compensation for lost wages, travel and research related harm
- Community engagement programs
- Building rapport with participants, providing teleconsultation
- Offering medical services during the study period.

Conclusion

- **Good governance and leadership** crucial for continuous improvement of clinical trial ecosystem in Nepal
- Development of **competent researchers** through capacity building
- Encouragement of clinicians to dedicate time for research in hospitals
- Regulatory organizations were urged to facilitate and monitor trials for smooth conduction rather than controlling them.



Acknowledgement

- Speakers , panelists and all participants

Speakers	Panelists
Dr. Diptesh Aryal, MD, Research Physician	Dr. Hari Prasad Dhakal, Chair, Institutional Review Board, Nepal Cancer Hospital
Prof. Dr. Ramesh Kant Adhikari, Chairman, Ethical Review Board, Nepal Health research Council	Dr. Roshan Kumar Jha ,Site PI (RECOVERY TRIAL)Nepal APF hospital
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Narayan Dhakal, Director General, Department of Drug Administration	Dr. Ajit Rayamajhi , Chair, Institutional Review Board, National Academy of Medical Sciences
Dr.Rajeev Shrestha, Dhulikhel Hospital	Dr. Mohan Raj Sharma, Director of Research, Institute of Medicine,
	Dr Olita Shilpakar ,Clinical lead,OUCRU Nepal