

Landscape of Clinical Trials in Nepal

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Regulatory Framework and Oversight

1 Regulatory Oversight

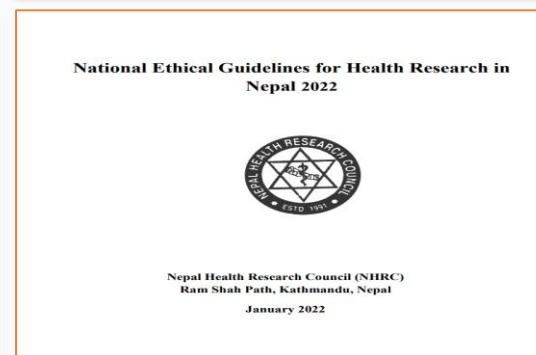
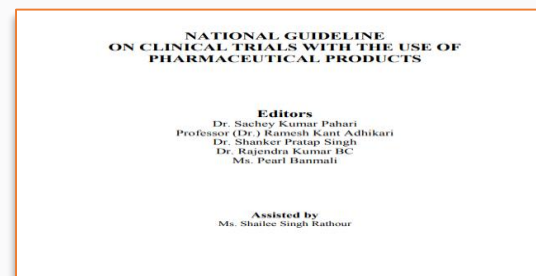
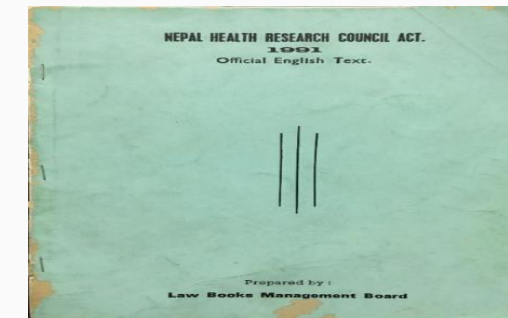
NHRC Act 1991
DDA Act 1978
Cabinet permission in case of Vaccine trial

2 Ethical Review

National Ethical Guidelines 2022
SOPs
ERB recognized by FERCAP
Online submission system
65 IRCs
Initial and post approval review

3 Compliances Monitoring

On-site monitoring
Trial steering committee, DSMB
IRCs, ERB, DDA



औषधि ऐन, २०३५	
प्रमाणीकरण र प्रकाशन मिति	
संशोधन गर्ने ऐन	२०३५/७८
१. औषधि (पहिलो संशोधन) ऐन, २०४५	२०४५/७९०
२. औषधि (दोस्रो संशोधन) ऐन, २०४७	२०४७/७८९४
३. गणतन्त्र सुदृढीकरण तथा केही नेपाल कानून संशोधन गर्ने ऐन, २०६६	२०६६/९०७



Capacity Building for Stakeholders

1

Researcher Training

Providing comprehensive training programs for researchers

Mandatory for researchers /GCP, Researcher qualifications

2

Regulator Capacity

Strengthening the regulatory capacity of government agencies and enhancing their ability to effectively oversee and monitor clinical trials.

Mandatory for Ethics Committee members

3

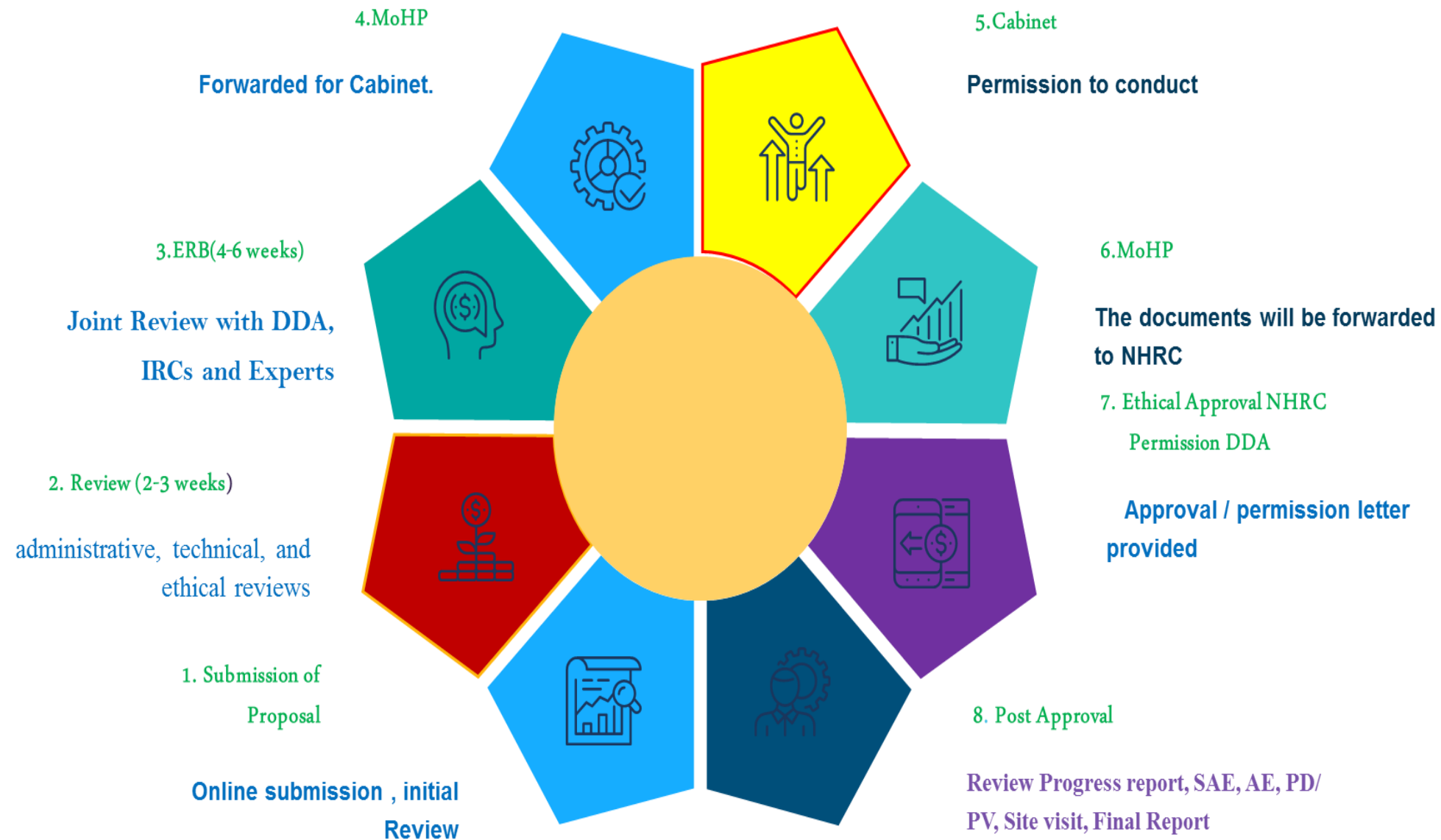
Community Engagement

Educating and empowering local communities to understand the importance of clinical trials and taking ownership as participants / **Community engagement is**

mandatory for trials

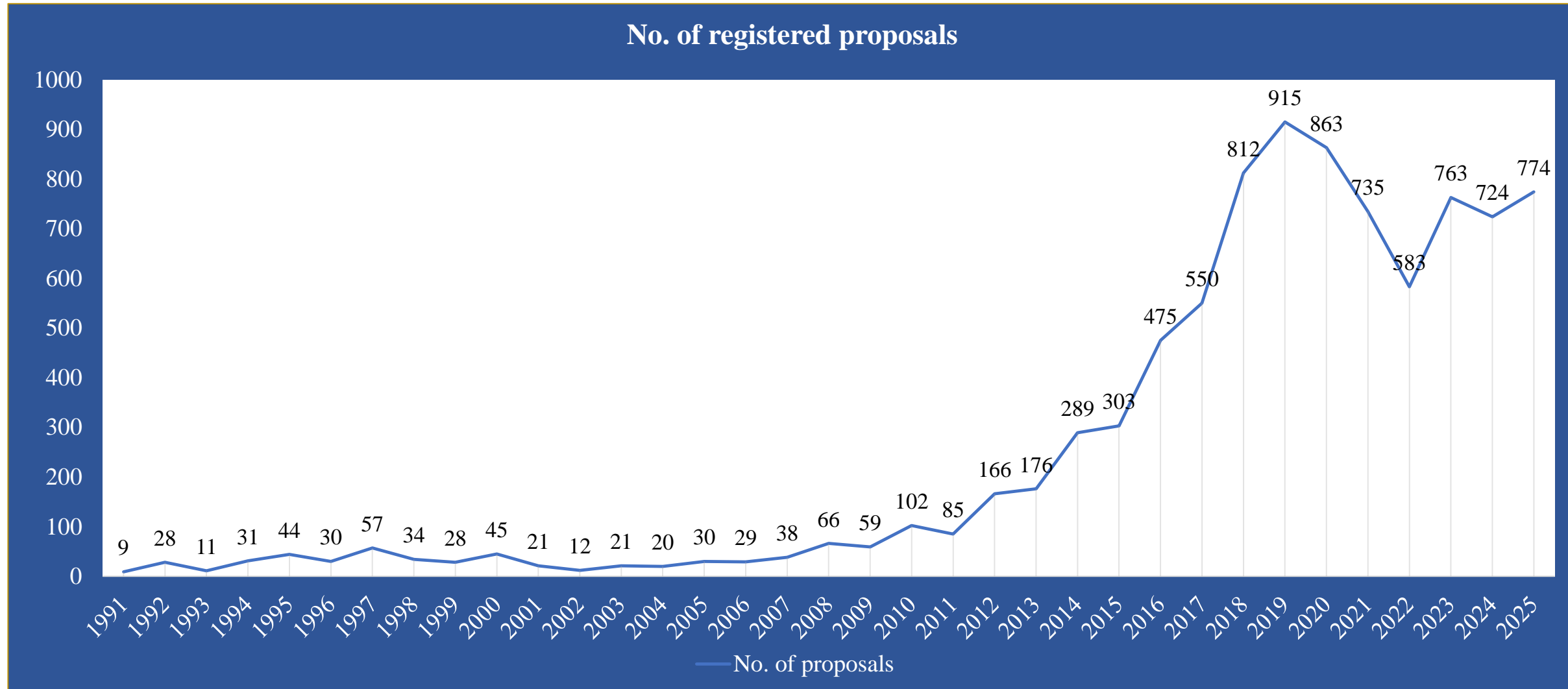


Regulatory Pathway for Vaccine Trials in Nepal



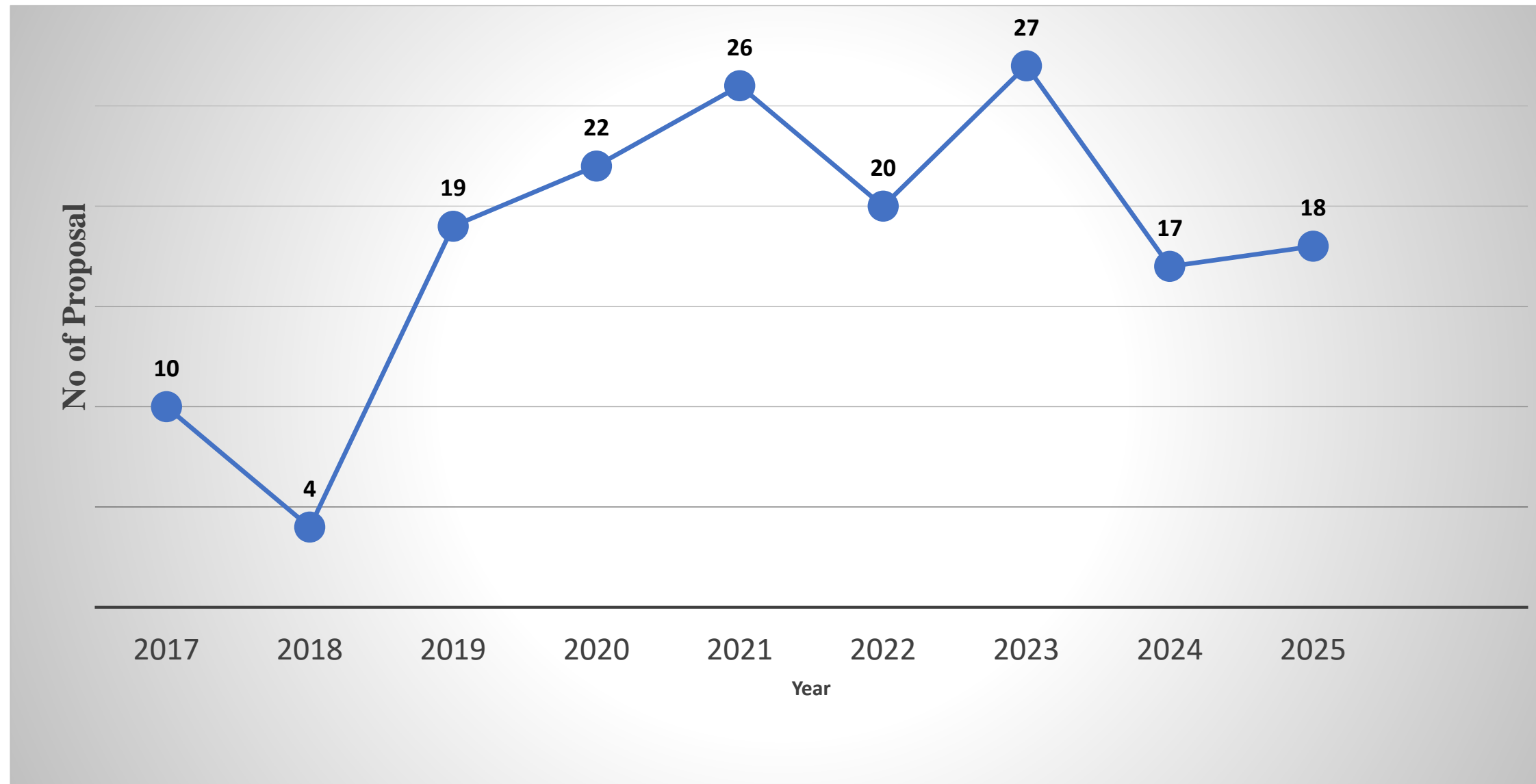


Trend of Research proposals(1991-2025)





Trend of clinical trials from 2017-2025





Types of Trials :



Traditional RCTs

The SOLIDARITY Trial by the WHO evaluated multiple antiviral drugs across countries.

Key feature: These are classic trials with fixed protocols and control groups.

Platform Trials (Multiple treatments in one trial)

The REMAP-CAP Trial evaluates multiple treatments for severe pneumonia (including COVID-19).

Key feature: multiple arms + shared control group.

Adaptive Trials

Parts of the RECOVERY Trial also used adaptive features (adding/removing drugs).

Key feature: Design changes during the trial based on interim results.

Diagnostic/ Device Trials

Procedure Trials



Key Challenges:



Capacity

Traditional versus new trial design

Academic trials/ sponsored trials

AI in trials

Political instability

Limited number of qualified staff in the
Regulatory/ Ethics Committee / Reviewers

Limited number of clinical researchers and
their time allocations, some overloaded
(technical, administrative and clinical)

Limited trial sites, but a lack of
infrastructure/ laboratories

Attention for developing international-level
laboratories

Funding

Lack of sufficient funding
allocations from the government

Processing fee

Managing grant

Building Partnerships: with
international research
institutions and pharmaceutical
companies to secure funding and
share resources

Ethical Concerns

Challenges in taking
consent/assent and retaining
participants, especially from diverse
backgrounds, level of educations

Geographical barriers, peer-
pressure

There are ongoing discussions in
good ethical practices, patient
rights, data sharing and post-study
benefit sharing



Improving the Clinical Trial Ecosystem



Strengthen Capacity

Regularly strengthen the capacity of the regulator, Ethics committee members, Secretariat staff of EC, researchers, clinicians, and support staff involved in clinical trials

Exchange program among /between other regulators

Right person should be promoted

Upgrades Infrastructure

Upgrade a single system for applying a clinical trial

Equipment, research facilities,, and technology to support high-quality clinical trials across Nepal

Regulatory Harmonization

Align clinical trial regulations and guidelines with international best practices to streamline the approval and oversight process.

Promoting Joint review and site monitoring with in country

Promote registry

Collaborative Partnerships

Foster collaborative partnerships with international organizations and academic institutions to facilitate for good practice sharing, joint research projects, and publications

Enhancing communities engagement

Post trial benefit sharing

Promoting use of health system

date and data sharing



Thank you