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System-Level Approaches to Strengthening Clinical Trials & The OUCRU Nepal CTU Experience

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System-Level Approach to clinical research

What is a System-Level Approach?

- Coordinated support beyond individual trials
- Standardized processes (SOPs, workflows, documentation systems)
- Centralized structures (e.g., CTUs)
- Focus on systems, not just individual studies

Why It Matters?

- Reduces burden on investigators (PIs)
- Improves consistency and quality
- Enables efficient trial implementation
- Supports scalability across multiple studies

What is a Clinical Trial Unit (CTU)?

A centralized institutional structure that provides coordinated support for the planning, implementation, and oversight of clinical trials.

Key Functions and Roles

Standardization	Regulatory & ethics support	Coordination of trial activities	Data & documentation management	Quality assurance & GCP compliance	Support to investigators
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WHO CTU Maturity Framework

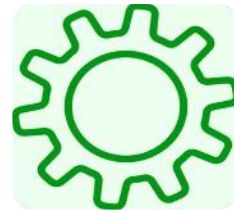
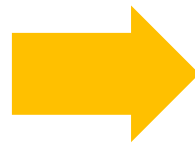
- The WHO CTU Maturity Framework is currently being developed to support assessment and progressive strengthening of clinical trial unit capacity.
- It is intended to help institutions
 - Understand current capabilities
 - Identify gaps in systems and processes
 - Plan stepwise improvement of trial systems
- **Expected Focus Areas** (aligned with WHO guidance on best practices for clinical trials and CTU practices)
 - Governance and leadership
 - Operational systems and processes
 - Quality management and compliance (GCP)
 - Workforce capacity and training

How CTU Systems Develop Over Time



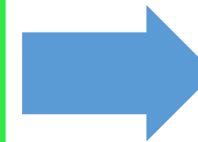
Early Stage

- Investigator driven trials
- Ad hoc processes
- Limited SOPs
- Minimal quality oversight



Developing systems

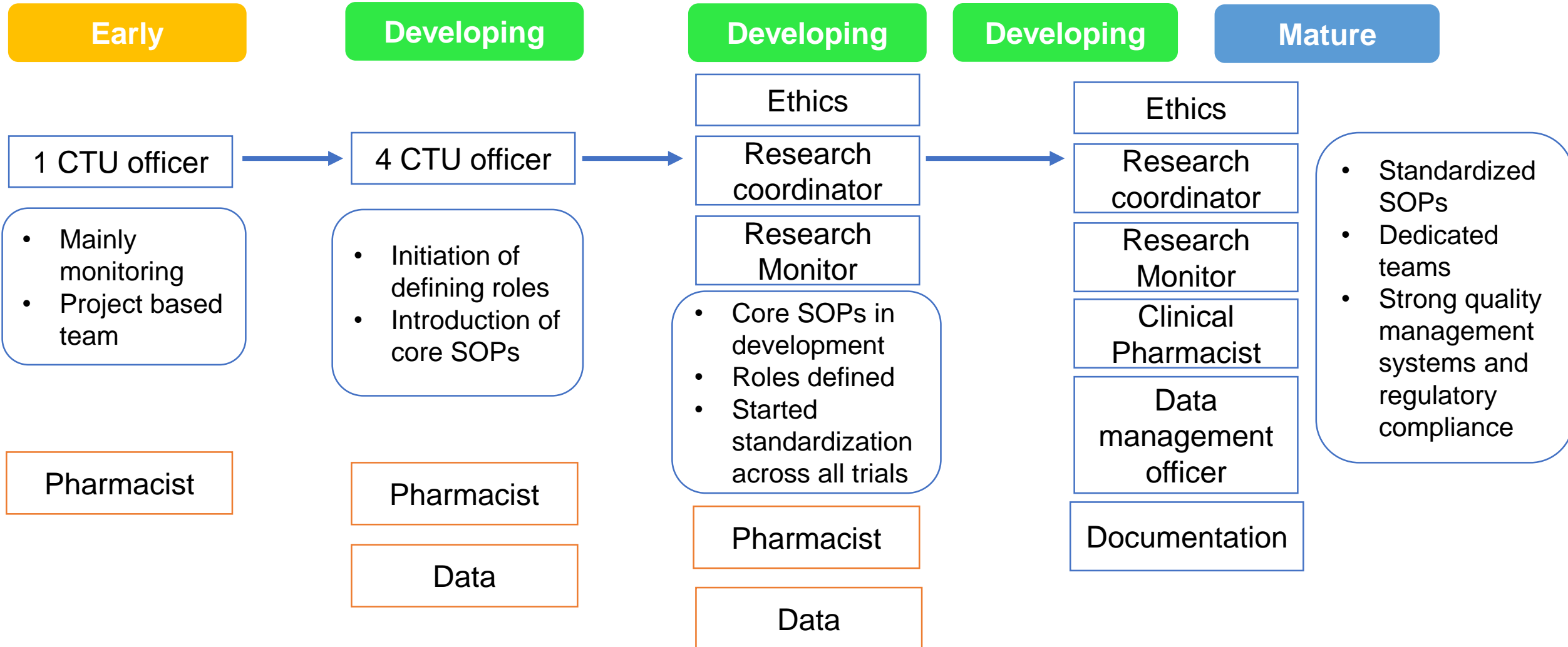
- SOPs and templates introduced
- Emerging CTU support
- Defined roles
- Improving consistency



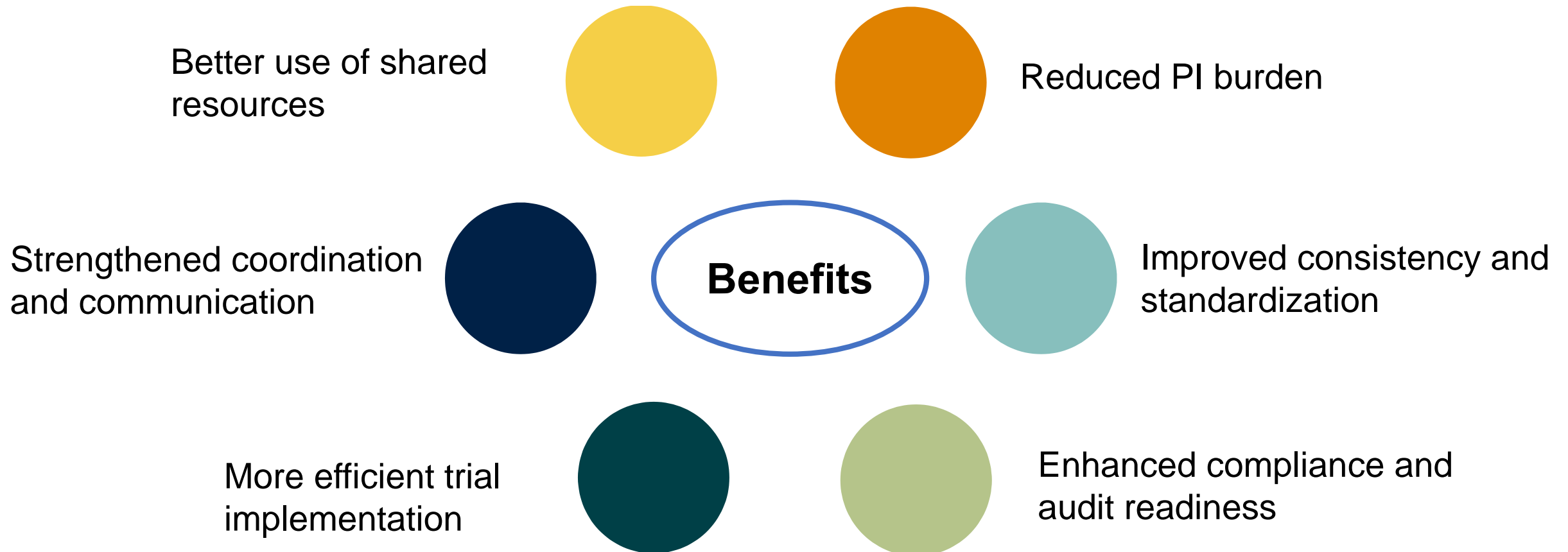
Mature System

- Structured CTU
- Standardized SOPs
- Dedicated teams
- Strong quality and compliance
- Scalable and audit-ready

Evolution of OUCRU Nepal CTU



OUCRU Nepal CTU Experience



Key Takeaways

- System-level approaches strengthen clinical trial quality and efficiency
- CTUs provide structured support that reduces burden on investigators
- Standardization improves consistency, compliance, and oversight
- CTU systems develop progressively
- Investing in people and training is critical for sustainability
- CTU models must be adapted to local context and resources
- WHO framework offers guidance for progressive system strengthening

Thank you