

**Strategic  
Framework  
and  
Implementati  
on Roadmap  
for  
Accelerated  
OSD Generic  
Drug  
Development  
in Emerging  
Markets**

- Akanksha Pal
- MBA (Pharmaceutical Management)
- IIHMR University, Jaipur
- Guide: Dr. Rahul Sharma
- Year: 2025

# Introduction

Focus on accessible,  
affordable  
medications in  
emerging markets

OSD generics are cost-  
effective and widely  
used

Challenges: regulatory  
hurdles, supply chain  
issues, cost, and time  
constraints

Strategic project  
management is crucial  
for success



# Objectives & Hypotheses

- Develop a strategic roadmap for OSD generic drug development
- Hypotheses:
  - Project management enhances timeline & budget adherence
  - Regulatory engagement expedites approvals
  - Supply chain practices reduce delays
  - Collaboration improves project outcomes

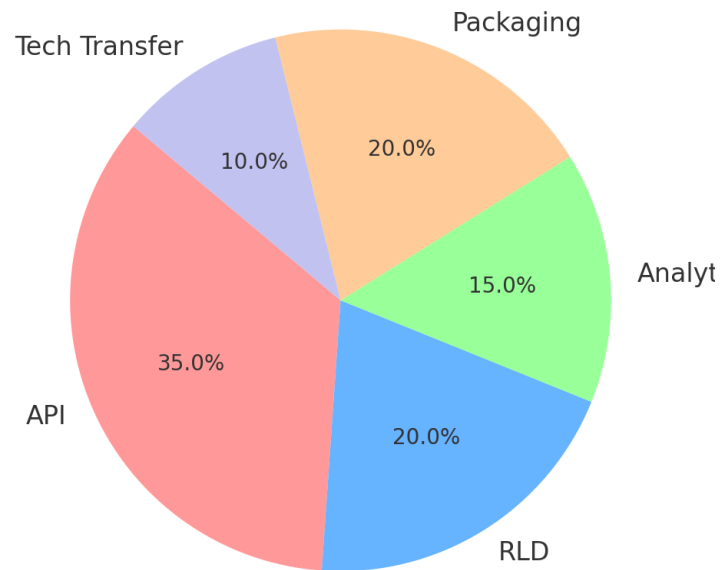
# Methodology

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- Mixed-methods approach
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- Data from interviews, literature, and project documentation
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- Stakeholders: RA, R&D, sourcing, BD, manufacturing
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- Analyzed NPD framework, costs, risks, and timelines

# Challenges & Strategic Solutions

- Regulatory: Engage early, follow regional guidance
- Supply Chain: Diversify vendors, robust QA
- Budgeting: Accurate estimates, contingency planning
- Timelines: Set realistic milestones, track KPIs
- Collaboration: Cross-functional alignment, communication tools

# Cost Estimation Breakdown



# Conclusion & Recommendations

- Strategic project management enables cost-effective, timely OSD drug development
- Cross-functional collaboration ensures regulatory and supply alignment
- Future focus: digital tools, regional regulatory harmonization, innovation in sourcing



THANK YOU