Project Management in Clinical Research

Module 8 Topic 1

Clinical Research: Project Management

- What is project management in Clinical Research
- PM tools and techniques applied in Clinical Research
- Project Management Plan for Clinical Research
- CRO and SMO Management
- Optimize patient recruitment
- Working with remote and multicultural teams

Project Management Constraints

WHY

6 Mistakes that Mess up a Project
1
Not Understanding the Requirements!
2
Start the project without a Plan
3
Poor Communication
4
Lack of Resources, Skills & Knowledge
5
Fail to Manage and Control
6
Fail to Learn from past

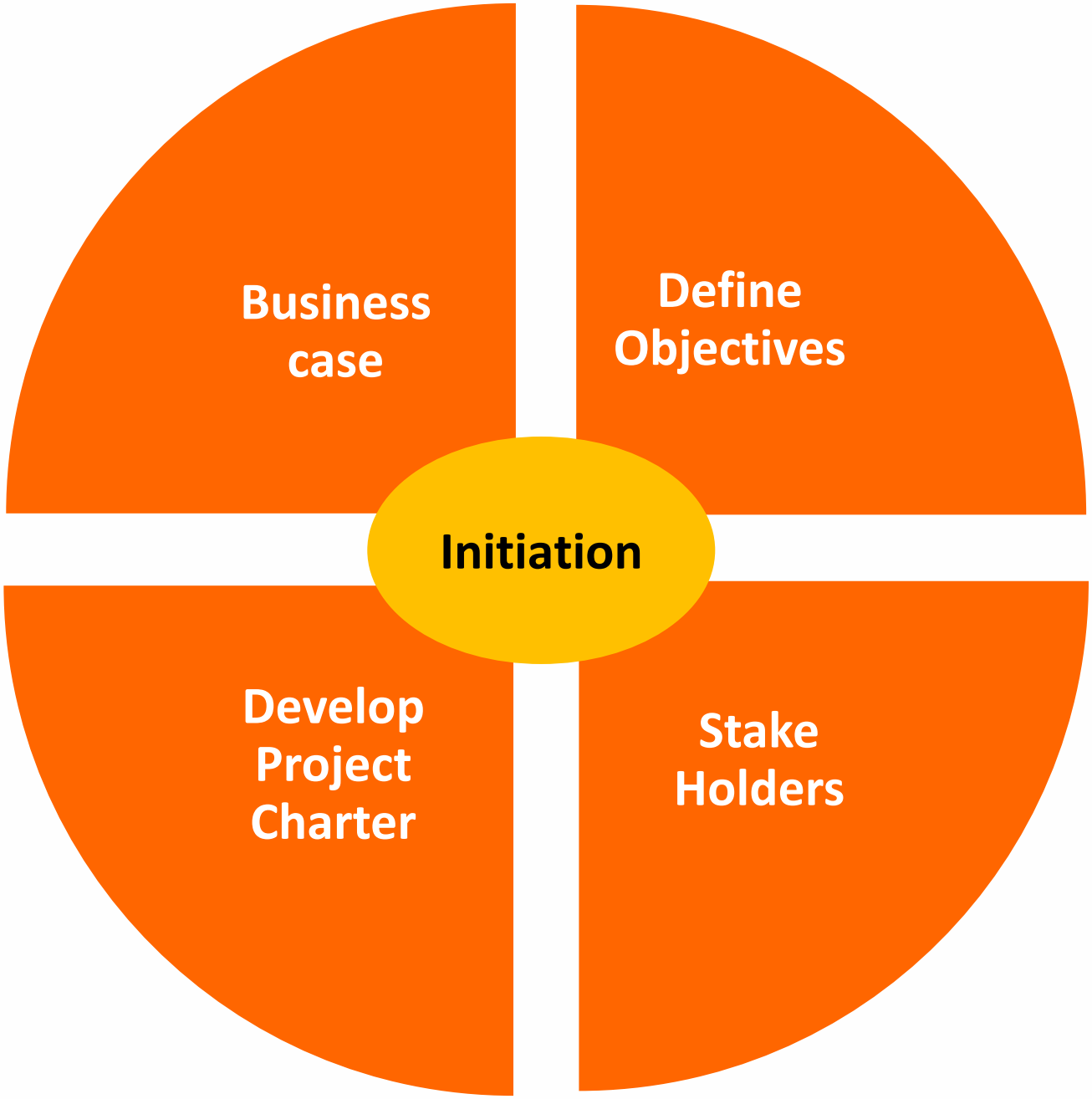
What is Project Management?

"The application of

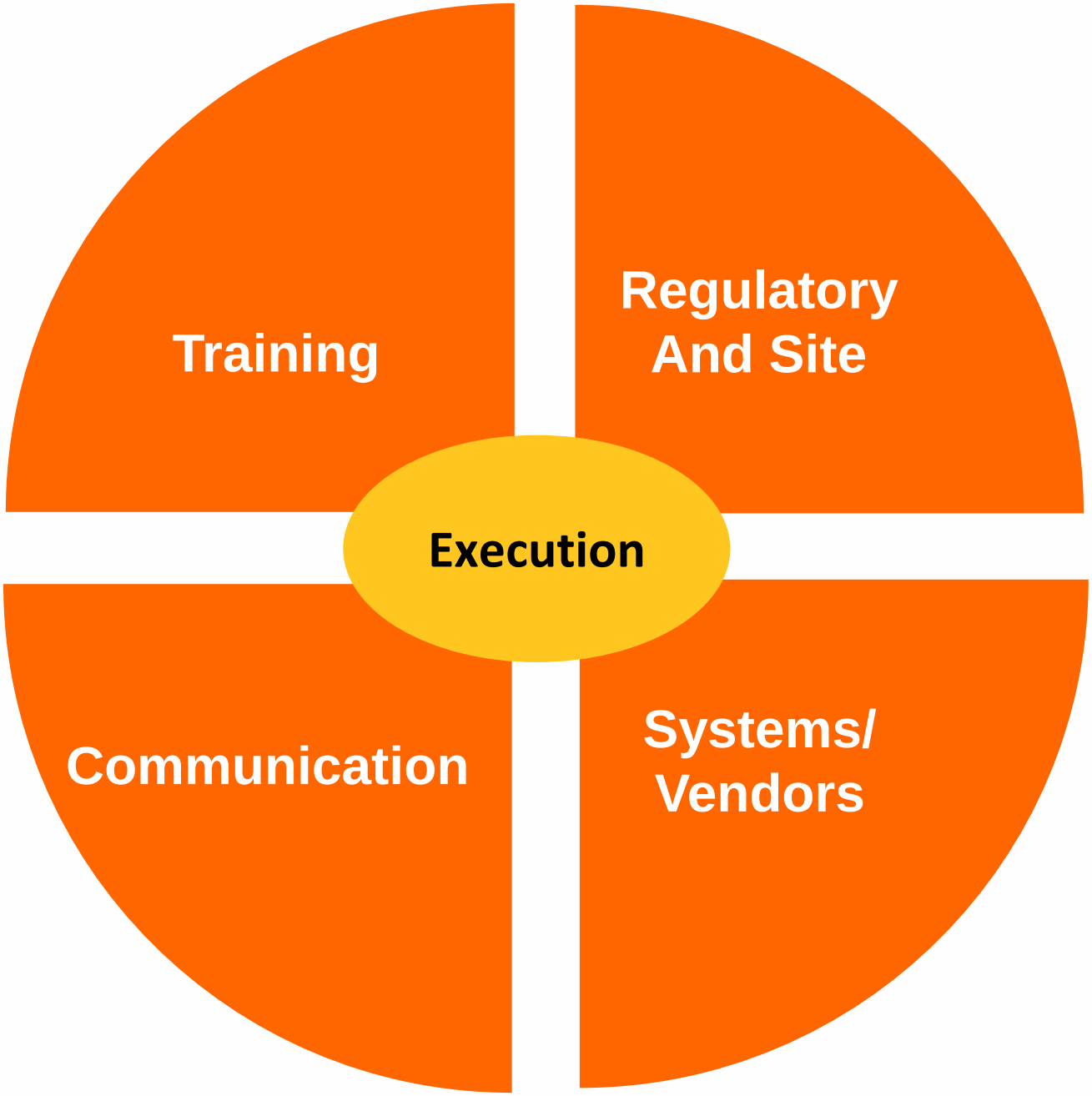
to project activities in order to **meet project requirements**.* "

Project management of a CT

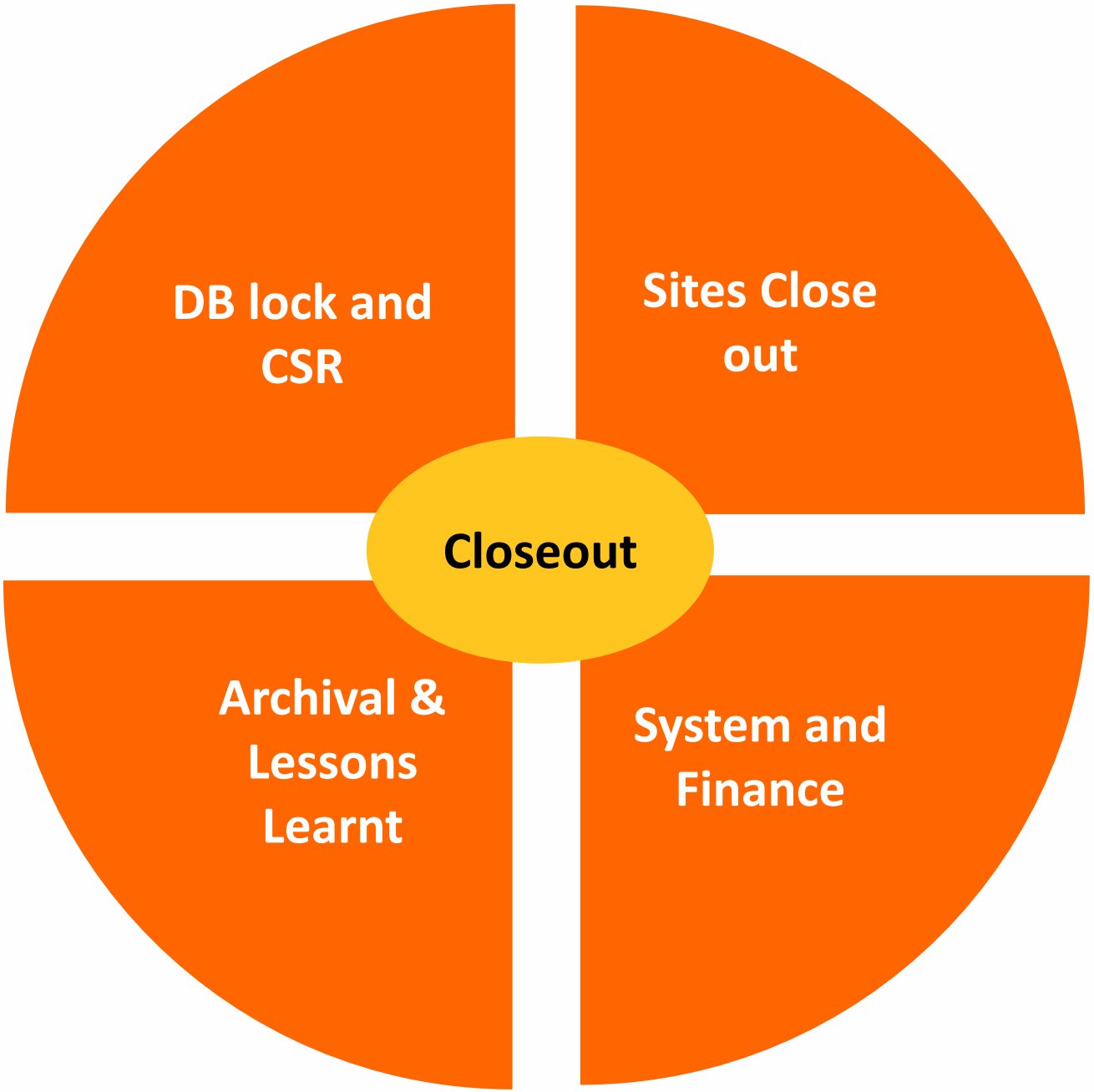
- The following are the steps.
- Important elements to be considered for each step are mentioned in the following slides
- Initiation
- Planning
- Execution
- Monitoring and Control
- Close out


Business case
Define Objectives
Initiation
Develop Project Charter
Stake Holders

Scope Management
Budget/ Milestones
Planning
Kick-Off Meeting
Project Management Plans


Training
Regulatory And Site
Execution
Communication
Systems/ Vendors

Project Performance Review
Change Management
Monitoring and Control
Risk Audit
Stake Holders


DB lock and CSR
Sites Close out
Closeout
Archival & Lessons Learnt
System and Finance

Responsibilities of Project Manager

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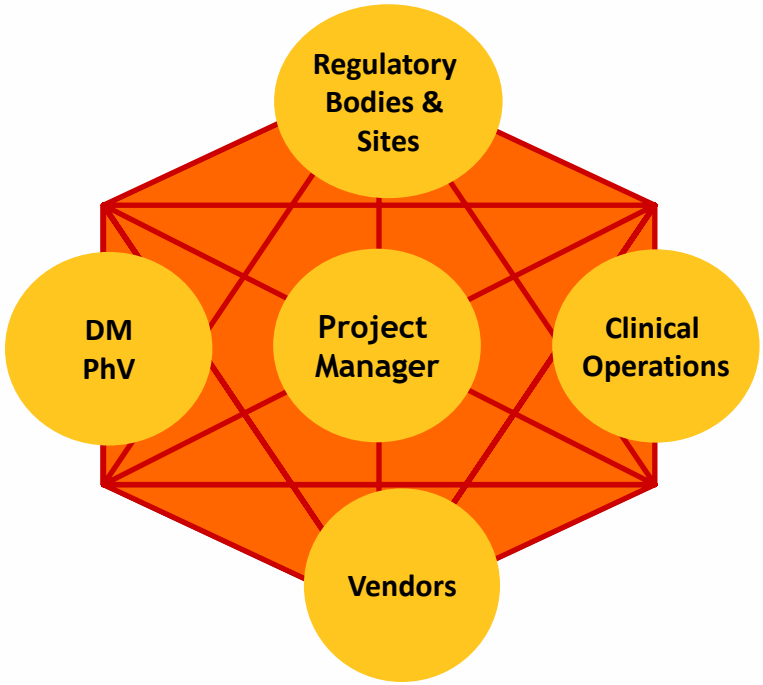
- Coordination, Communication, Escalation
  - Across Functional Areas
  - Across Stakeholders
- Team Motivation and Management
- Status Review/Risk Management
- Financial Management



VENDORS- CRO and SMO Management

Contract Research Organization (CRO) Management

Selection of the CRO

- Therapeutic experience and geographic presence
- Relationship with stake holders
- IT infrastructure
- Education/Experience/Training/Attrition of Key CRO staff

Management KPI and controls

- Weekly/Monthly status review (Start up, Recruitment, Maintenance and Closeout)

Elements in (CRO) Management

Start up

- Feasibility
- Site selection
- EC/Contract
- Regulatory Documents
- Site Initiation

Recruitment

- Site activation
- Patient Recruitment
- Site monitoring

Maintenance

- Patient retention
- Data entry/query resolution
- IP accountability

Closeout

- Site closeout
- IP return
- Archival of study documents

Site Management Organization (SMO) Management

What is needed for selection of an SMO

- Relationship with Investigators/Hospitals/Institutes
- Experience/Training of staff

KPI and controls

- Patient recruitment/retention/compliance
- Data entry/Query resolution
- IP accountability

Working with Remote and Multicultural Teams

Working with Remote and Multicultural Teams

Challenges

- Time zone difference
- Communication style
- Cultural differences (High to Low context)

Working with Remote and Multicultural Teams

Cultural differences

- Thinks, Acts and Reacts differently
- Different approach to tasks
- Varying approach on Relationship Building
- Personal space, Social etiquette and Belief
- Different attitude for conflict, disclosure and negotiation

Working with Remote and Multicultural Teams

Solution

- Global culture/processes/technology
- Harmonize learning and development
- RACI (Responsible, Accountable, Consulted, Informed) matrix
- Links, Sharepoint site, Communicator
- Trust building exercise
  (time zone, geography and culture)
- Flexi work hour