

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



Project Management Constraints



Timeline

+ US

+++ Asia,
Africa

Cost

+++ US

+ Asia,
Africa

Risk

+ US

+++ Asia,
Africa



Disclaimer: This is just an example, not based on fact

WHY

6 Mistakes that Mess up a Project



What is Project Management?

“The application of



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



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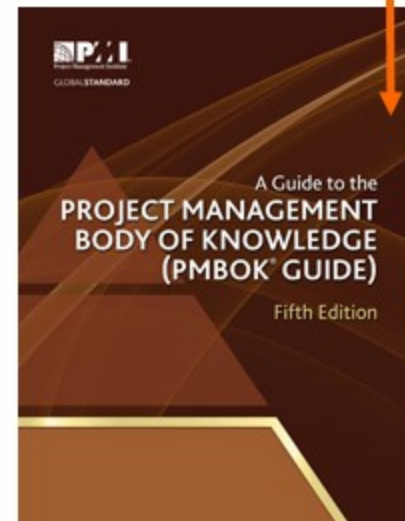
SCIENTIFIC PROJECT MANAGEMENT



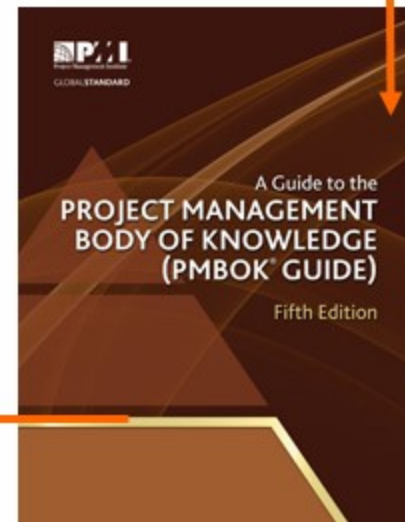
**SCIENTIFIC
PROJECT MANAGEMENT**



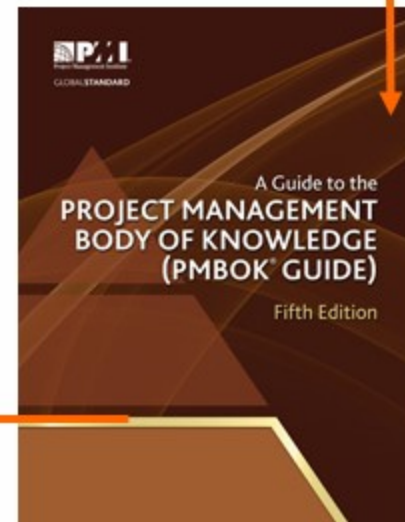
**SCIENTIFIC
PROJECT MANAGEMENT**



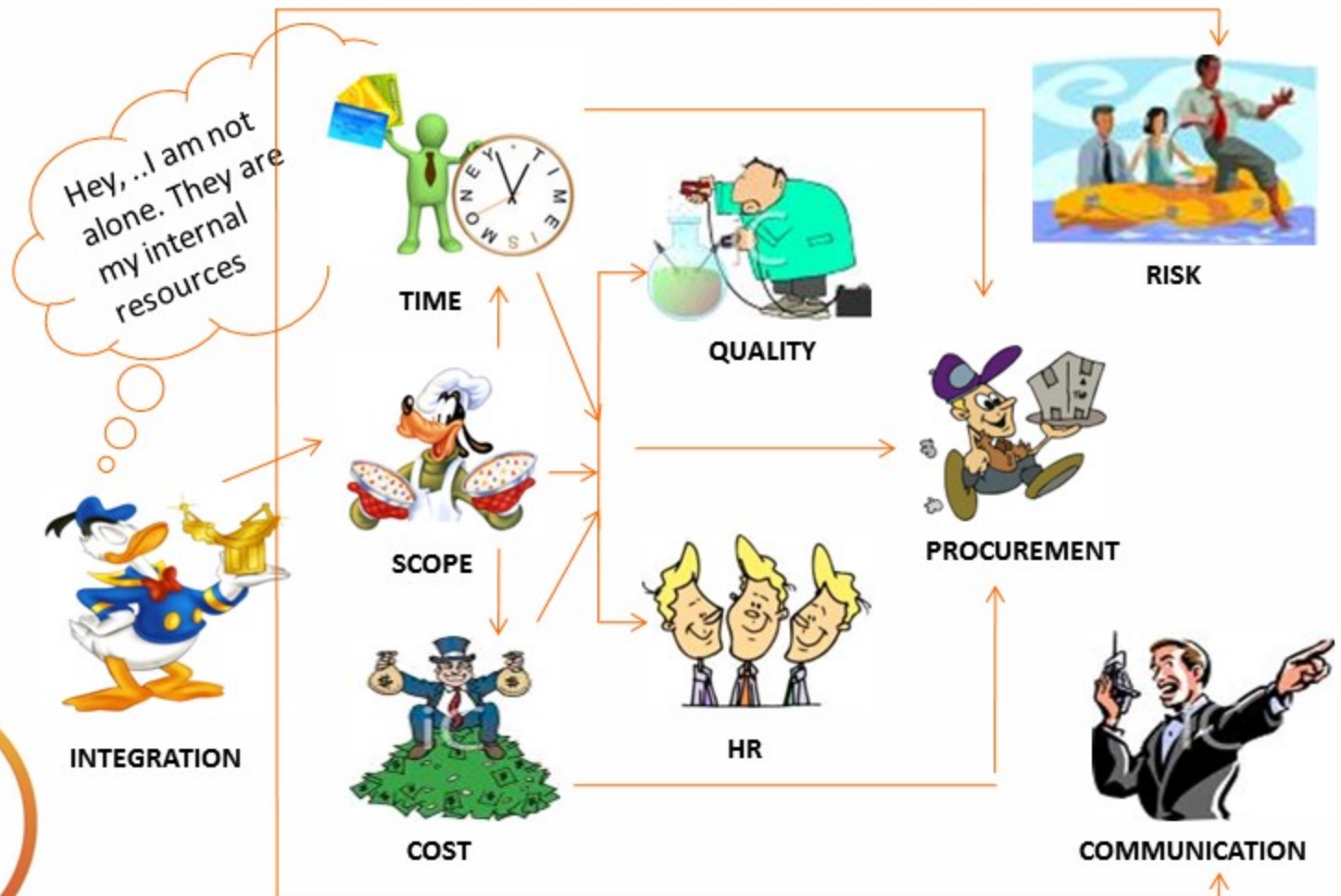
SCIENTIFIC PROJECT MANAGEMENT



SCIENTIFIC PROJECT MANAGEMENT



Knowledge Areas ...



Project Management in Clinical Research



Initiation

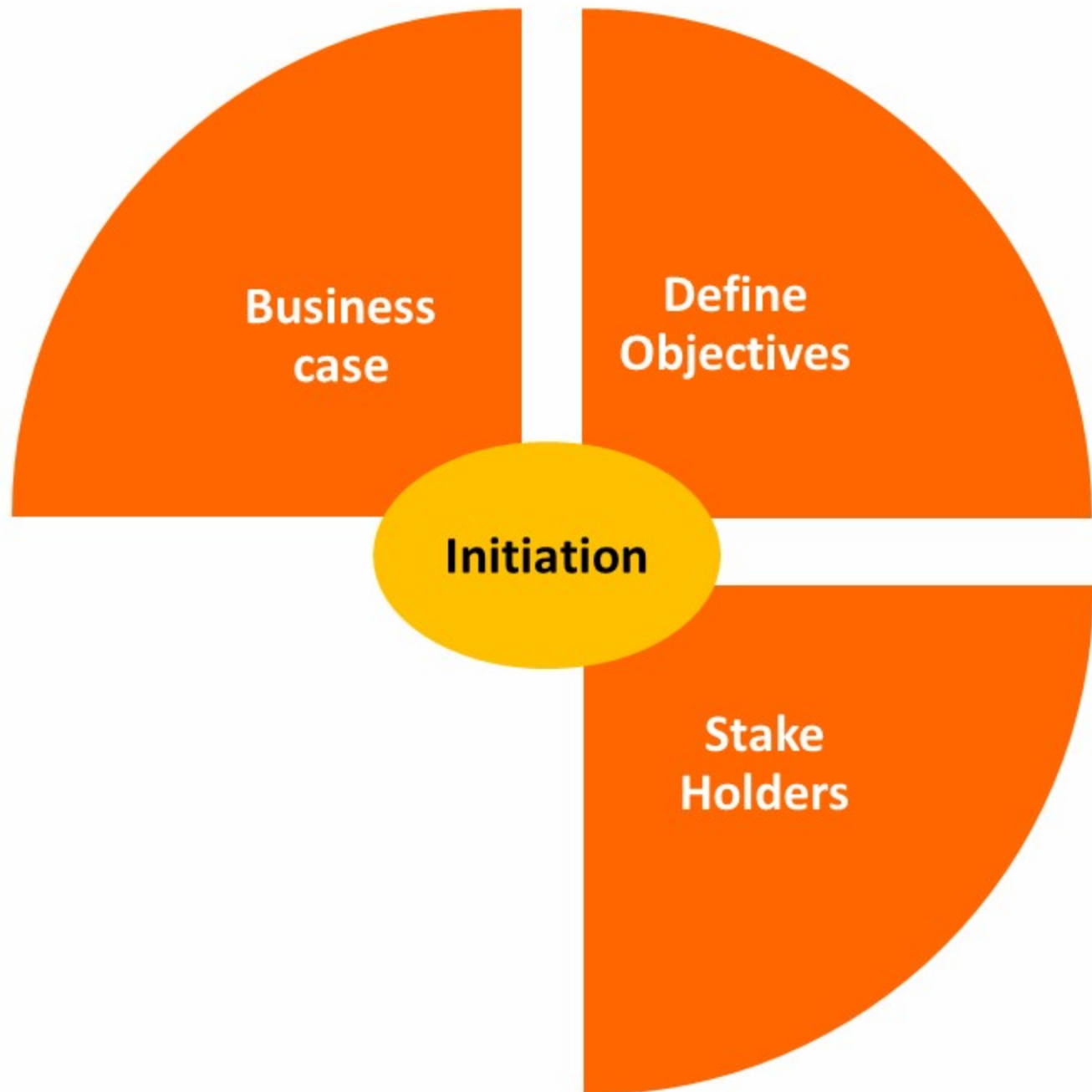


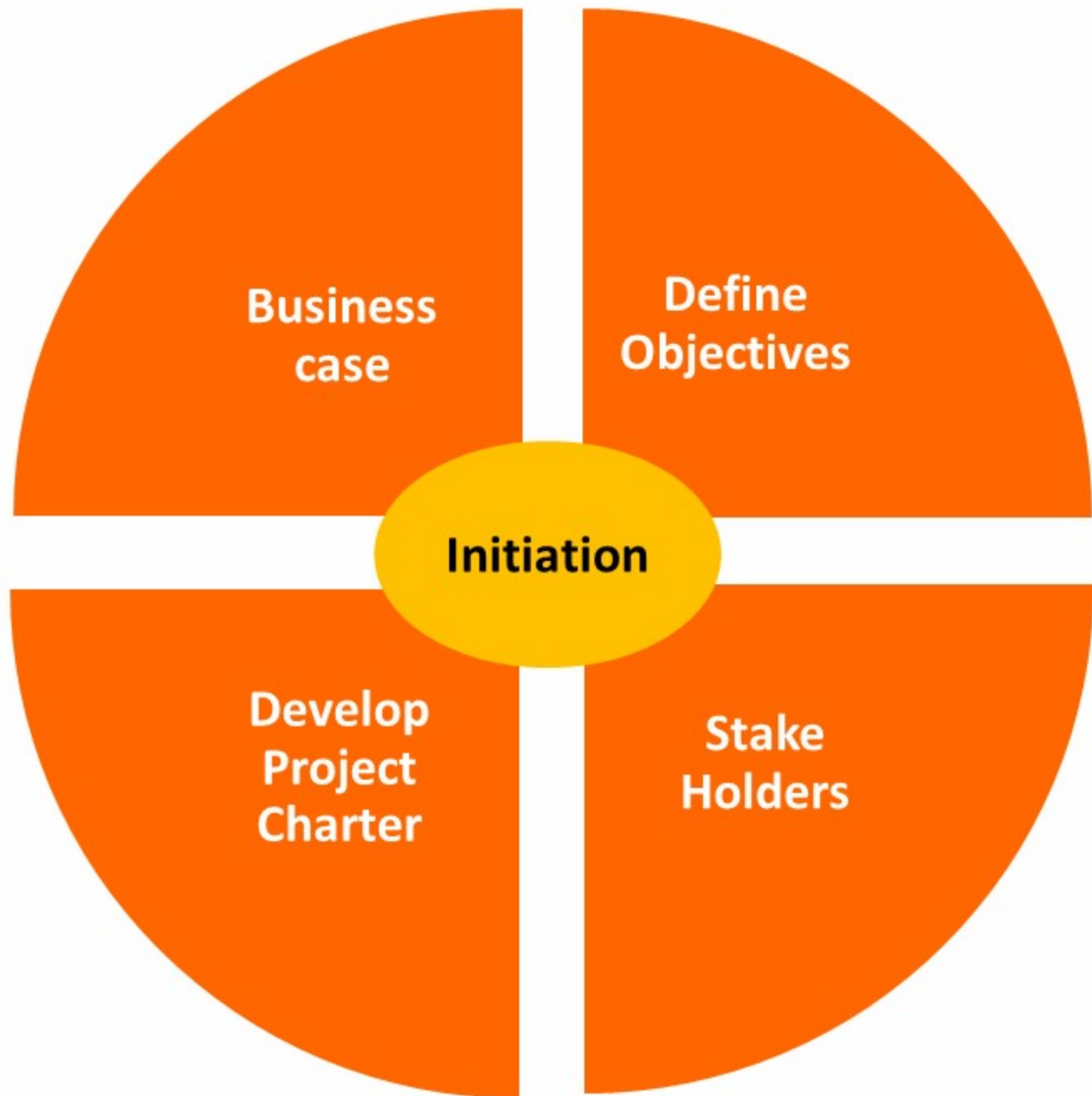
**Business
case**

Initiation









Planning





**Scope
Management**

Planning









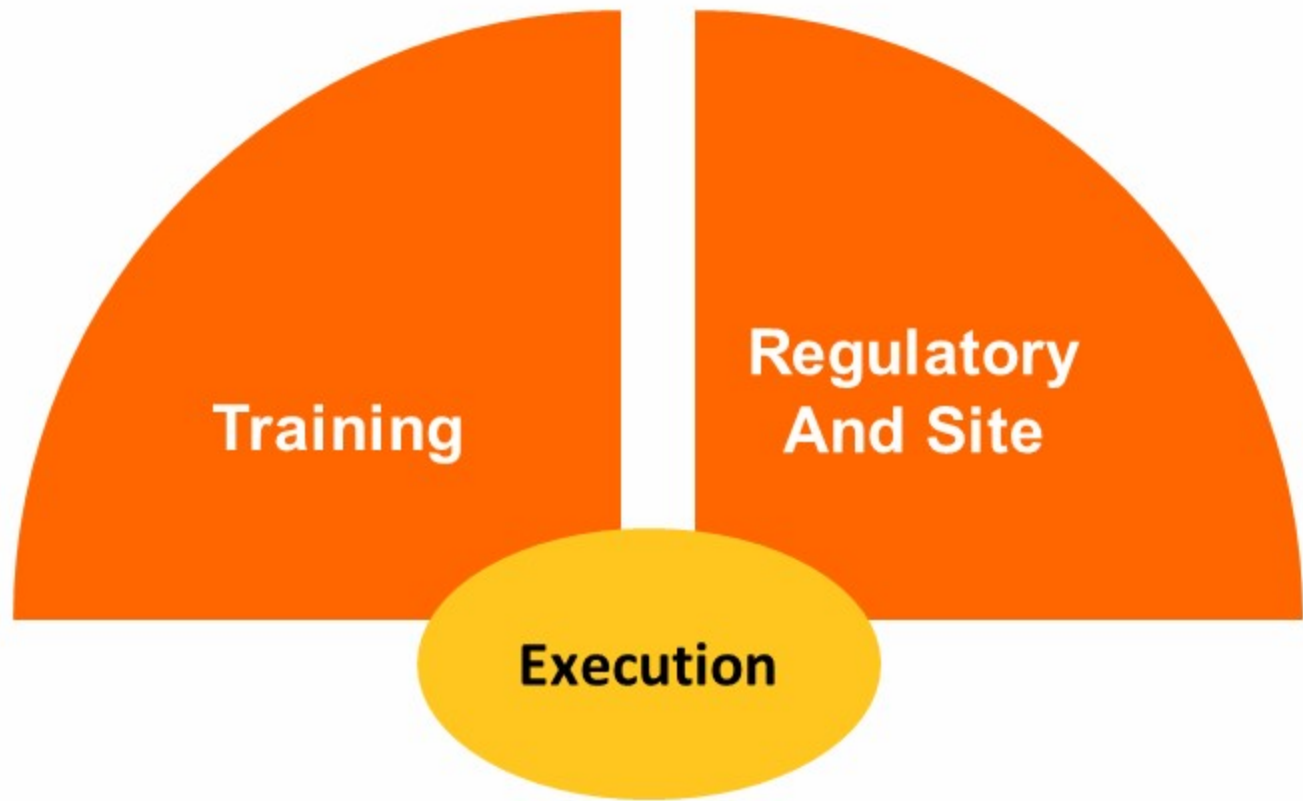
Execution

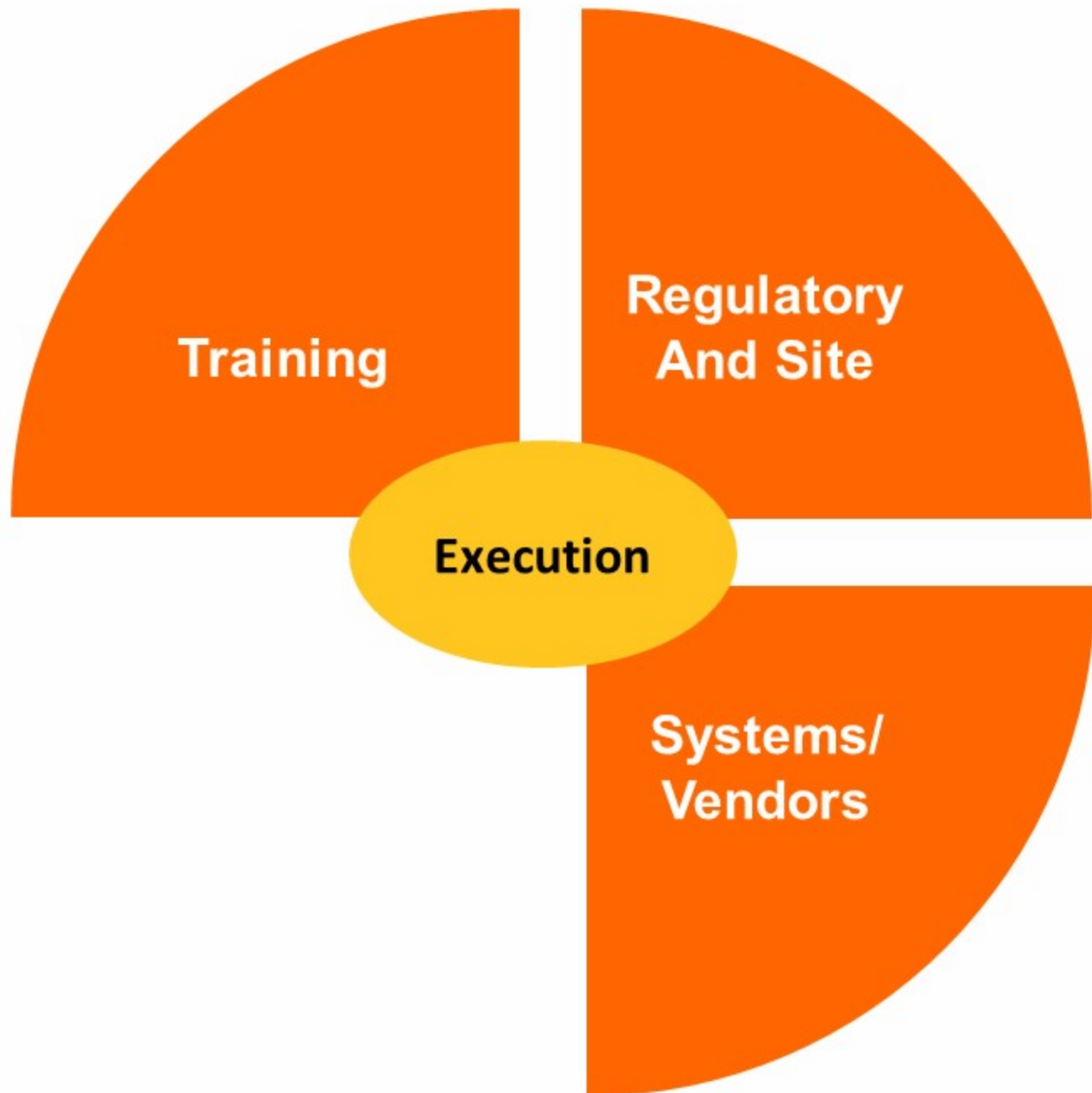


Training

Execution









Monitoring and Control



**Project
Performance
Review**

**Monitoring
and Control**





The diagram consists of two large orange semi-circles at the top, each containing text. Below these is a yellow oval containing text. The entire diagram is set against a white background with a vertical orange bar on the left and a horizontal orange bar at the bottom.

**Project
Performance
Review**

**Change
Management**

**Monitoring
and Control**



**Project
Performance
Review**

**Change
Management**

**Monitoring
and Control**

**Stake
Holders**





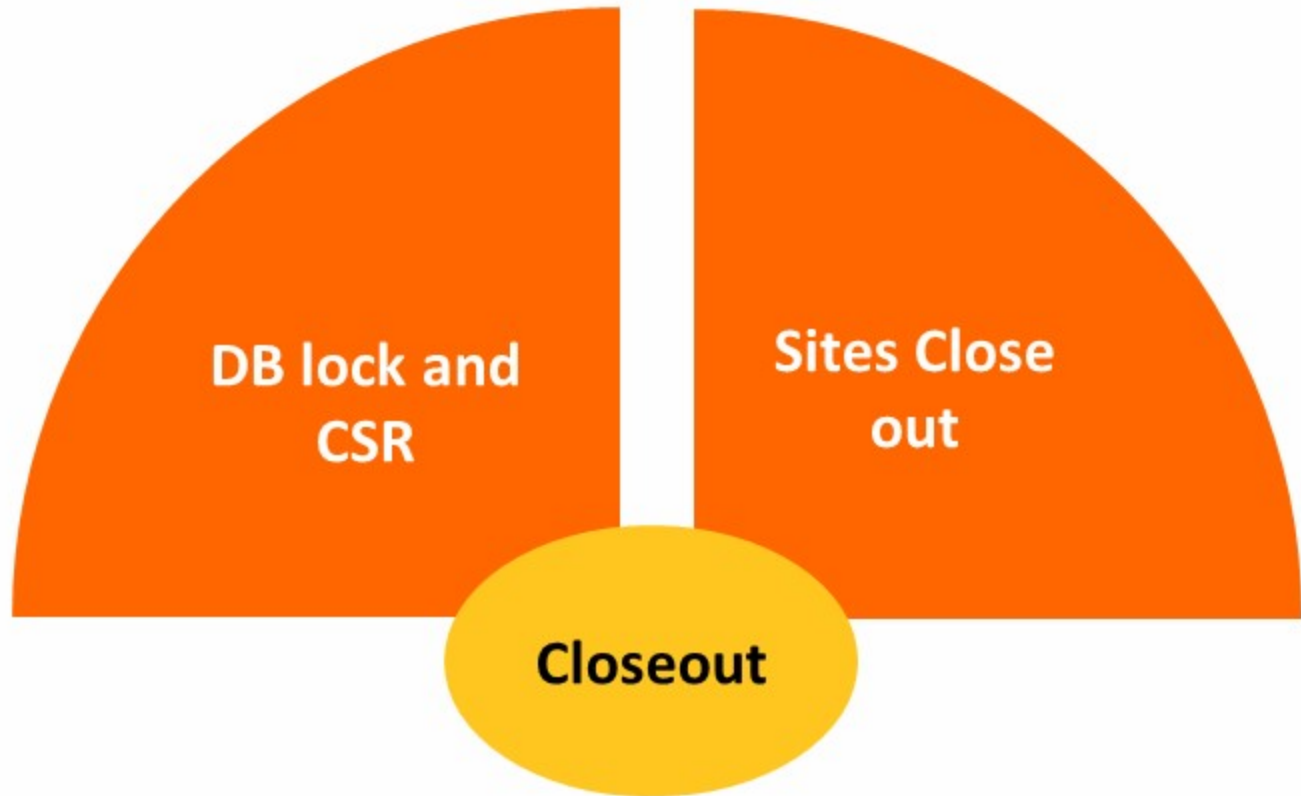
Closeout

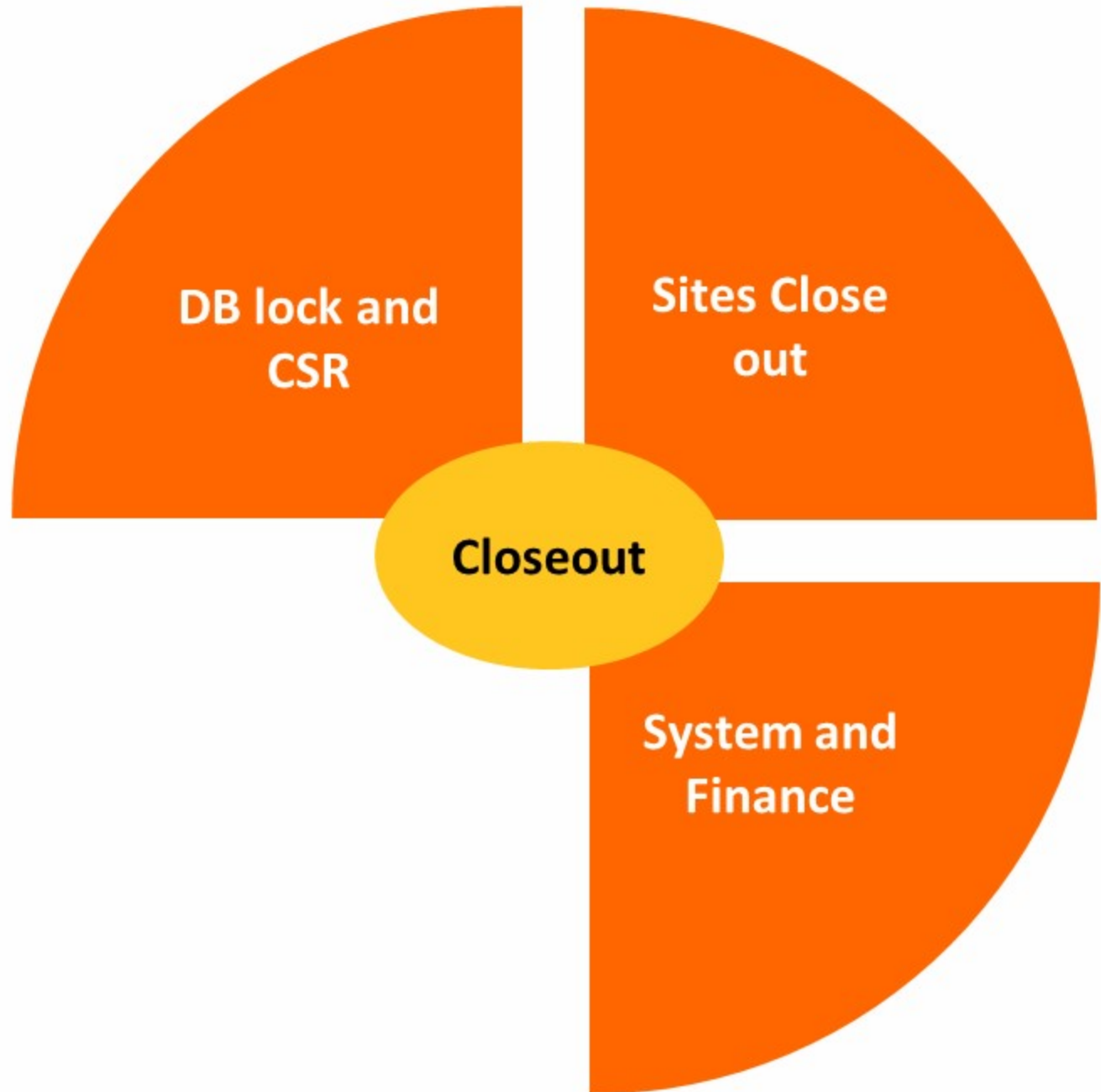


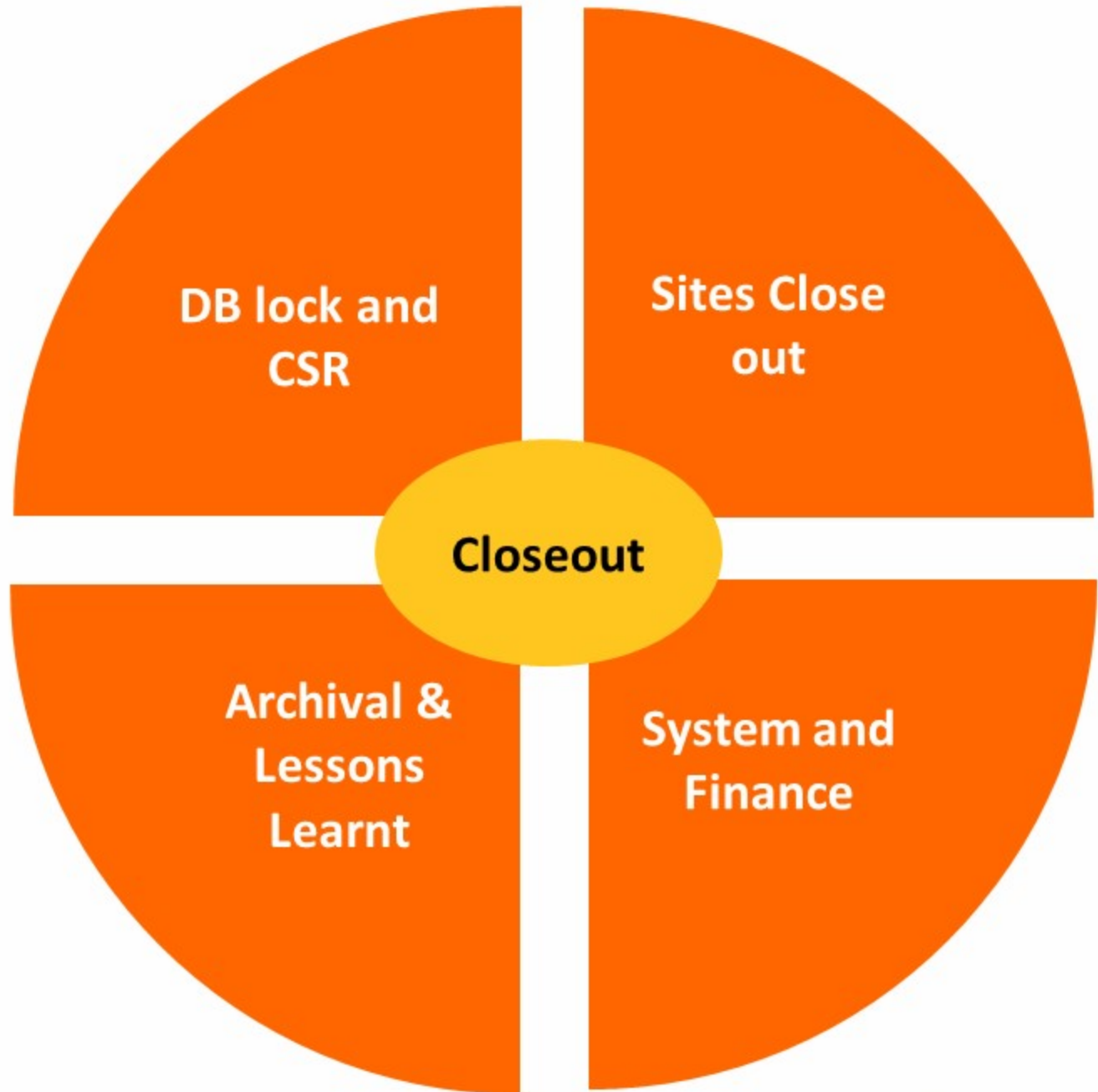
**DB lock and
CSR**

Closeout







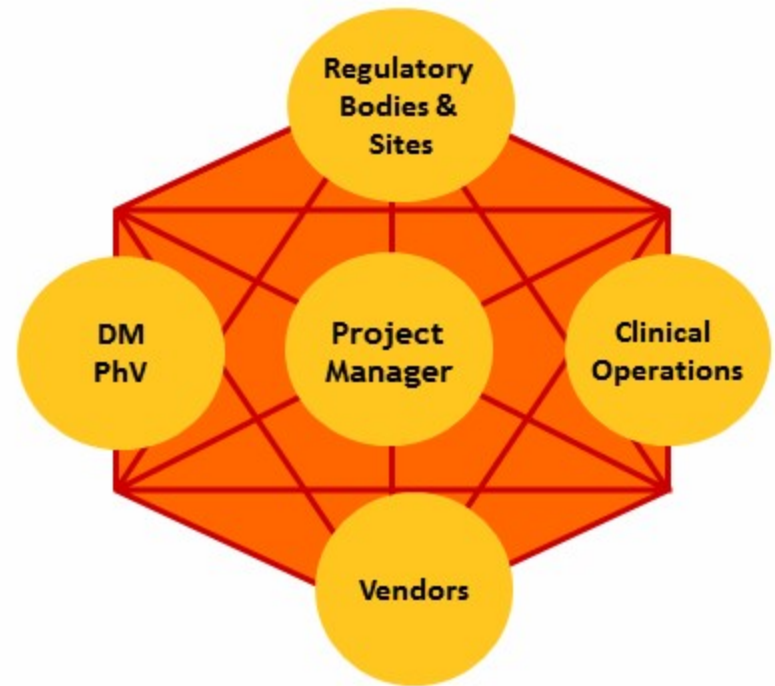


Responsibilities of Project Manager



Responsibilities of Project Manager

- 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

- Therapeutic experience and geographic presence
- Relationship with stake holders
- IT infrastructure

Management/KPI

- Education/Experience/Training/Attrition of Key CRO staff
- Weekly/Monthly status review (Start up, Recruitment, Maintenance and Closeout)



Contract Research Organization (CRO) Management (contd)

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

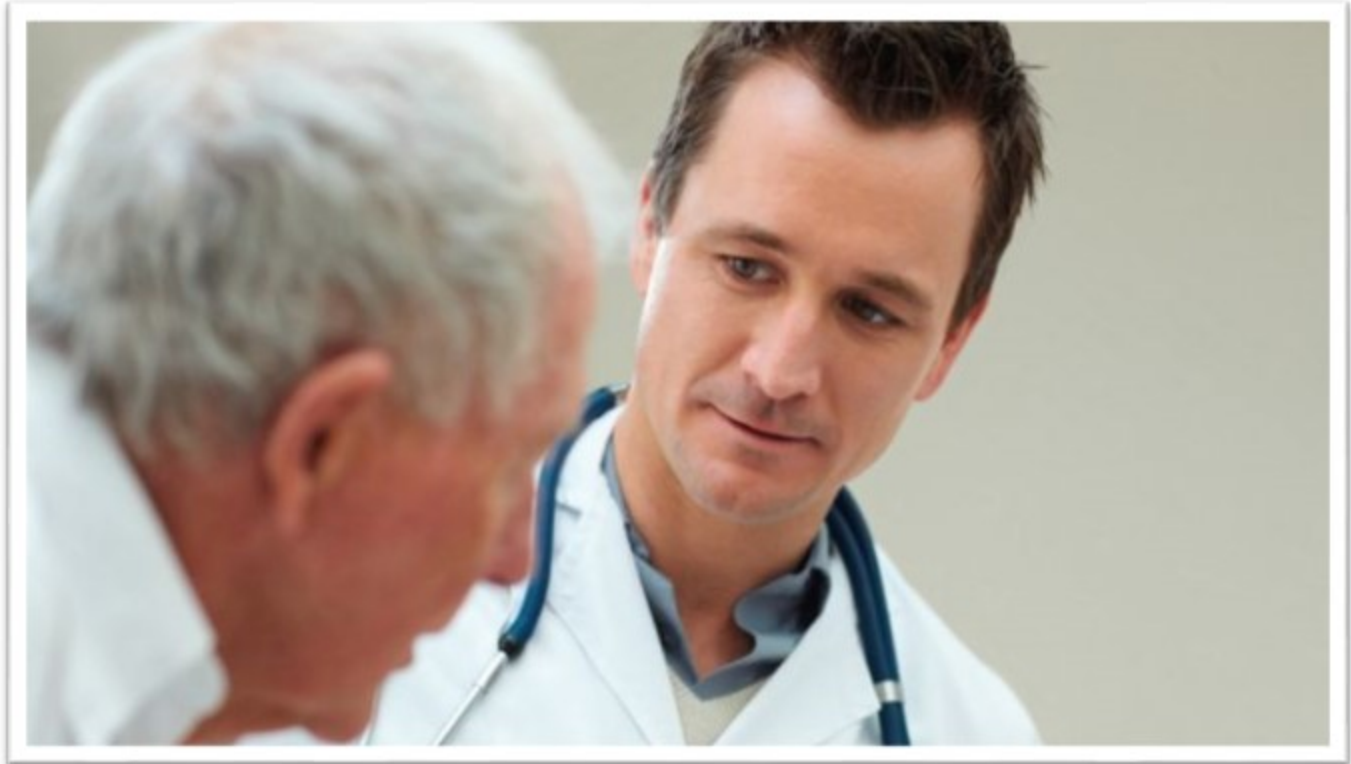
- Relationship with Investigators/Hospitals/Institutes
- Experience/Training of staff

KPI

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



Optimize Patient Recruitment



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

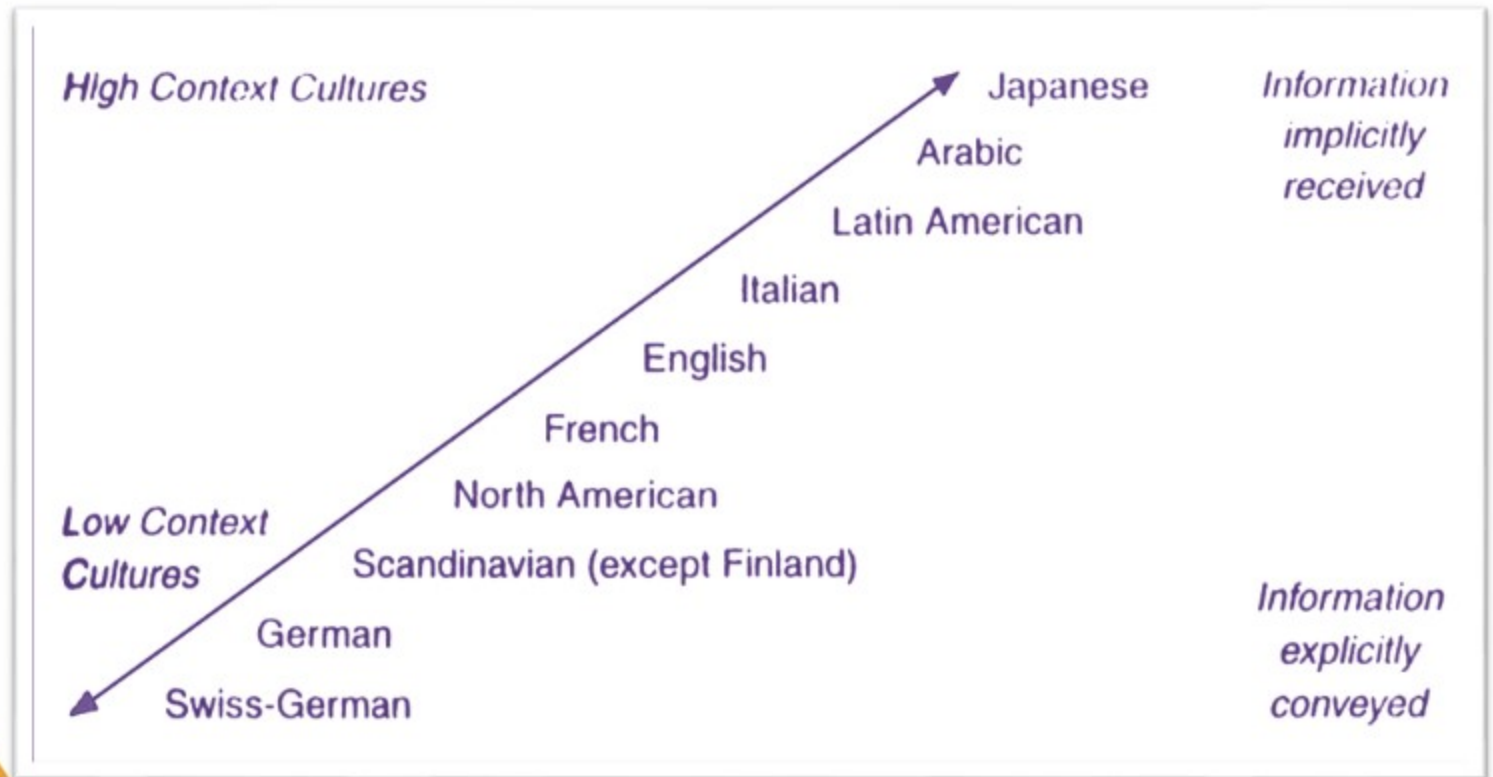


Cultural Differences

	Low Context	High Context
Work Ethics	Task-oriented	Relationship-oriented
Work Style	Individualistic	Team-oriented
Relationship	Many, looser, short-term	Fewer, tighter, long-term
Decision Making	Logical, linear, rule oriented	Intuitive, Relational
Communication	Verbal over non-verbal	Non-verbal over verbal
Knowledge	Explicit, written, formal	Implicit, oral, informal
Sense of Time	Present/Future oriented	Deep respect for past
View of Change	Change over tradition	Tradition over Change



High ContextLow Context



Working with Remote and Multicultural Teams

Solution

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

