

# Developing the clinical trial process in a rapidly changing environment

-The common information space-

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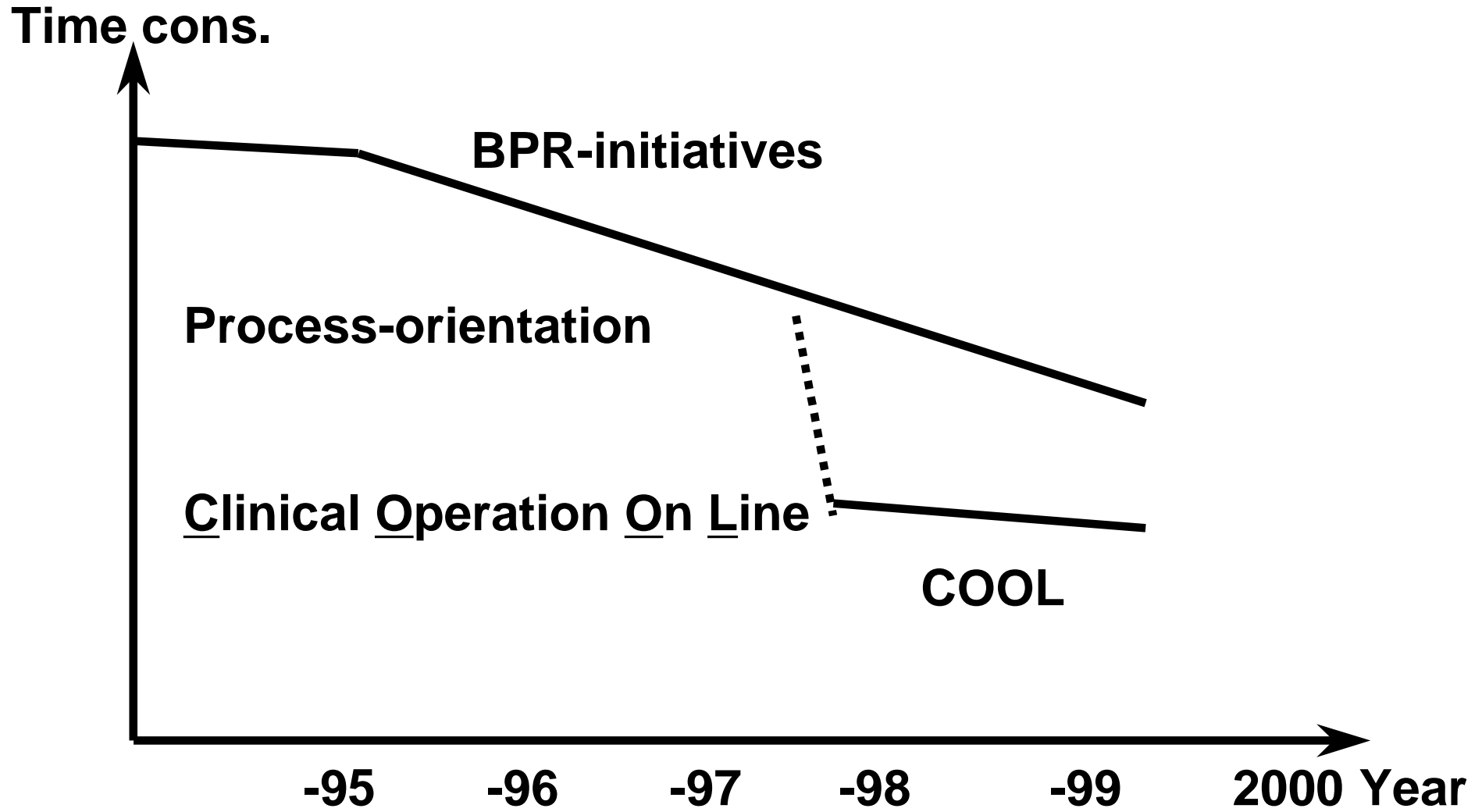


# Disposition

- Challenges for pharmaceutical industry
- Four scenarios for IT and organization infrastructure
- Alternative ways of using IT: Semi-RDC and COOL
- IT and organizational context
- Summary
- Conclusions



# Time reduction for clinical studies



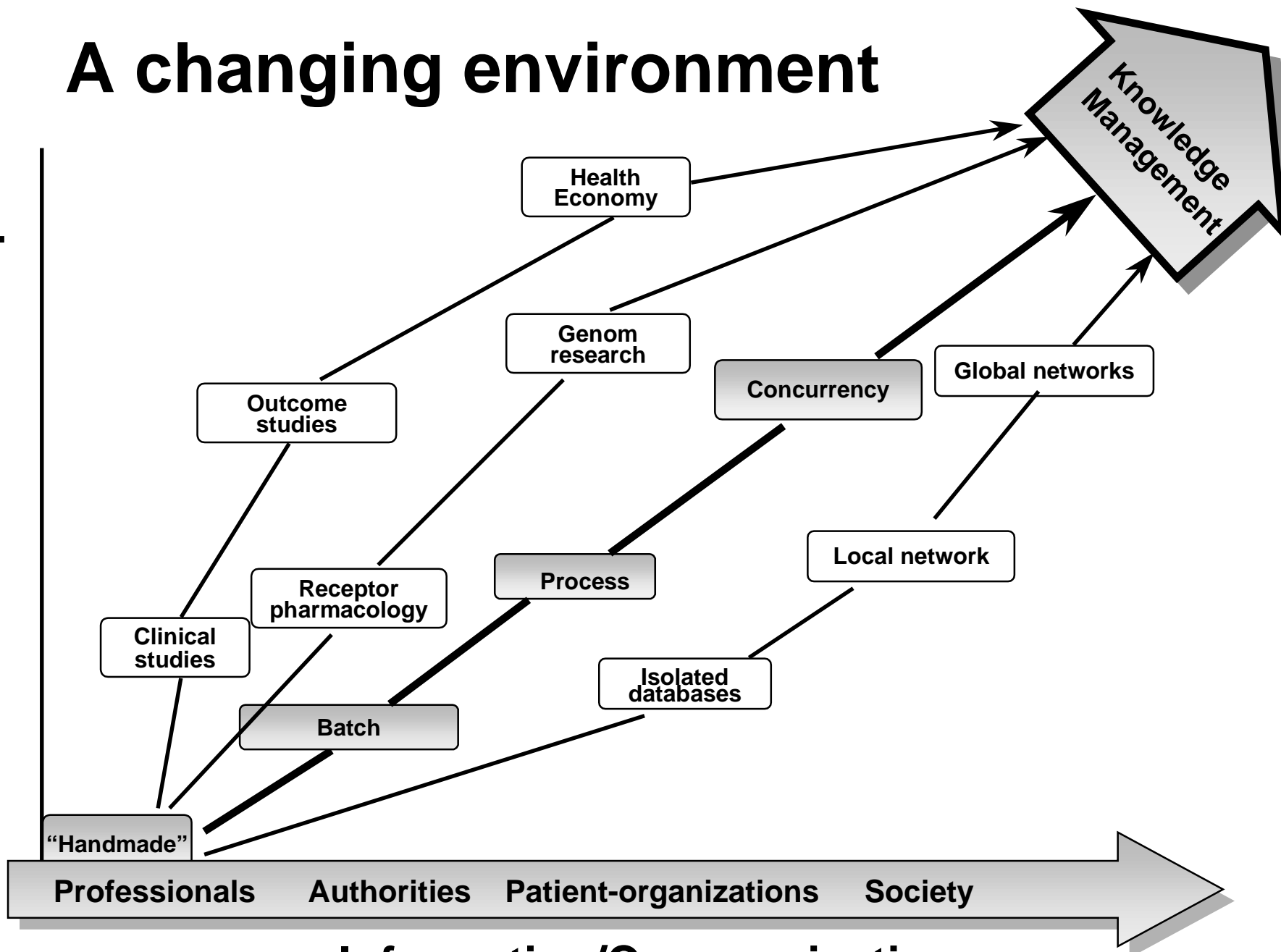
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# A changing environment

Scientific/Technical development

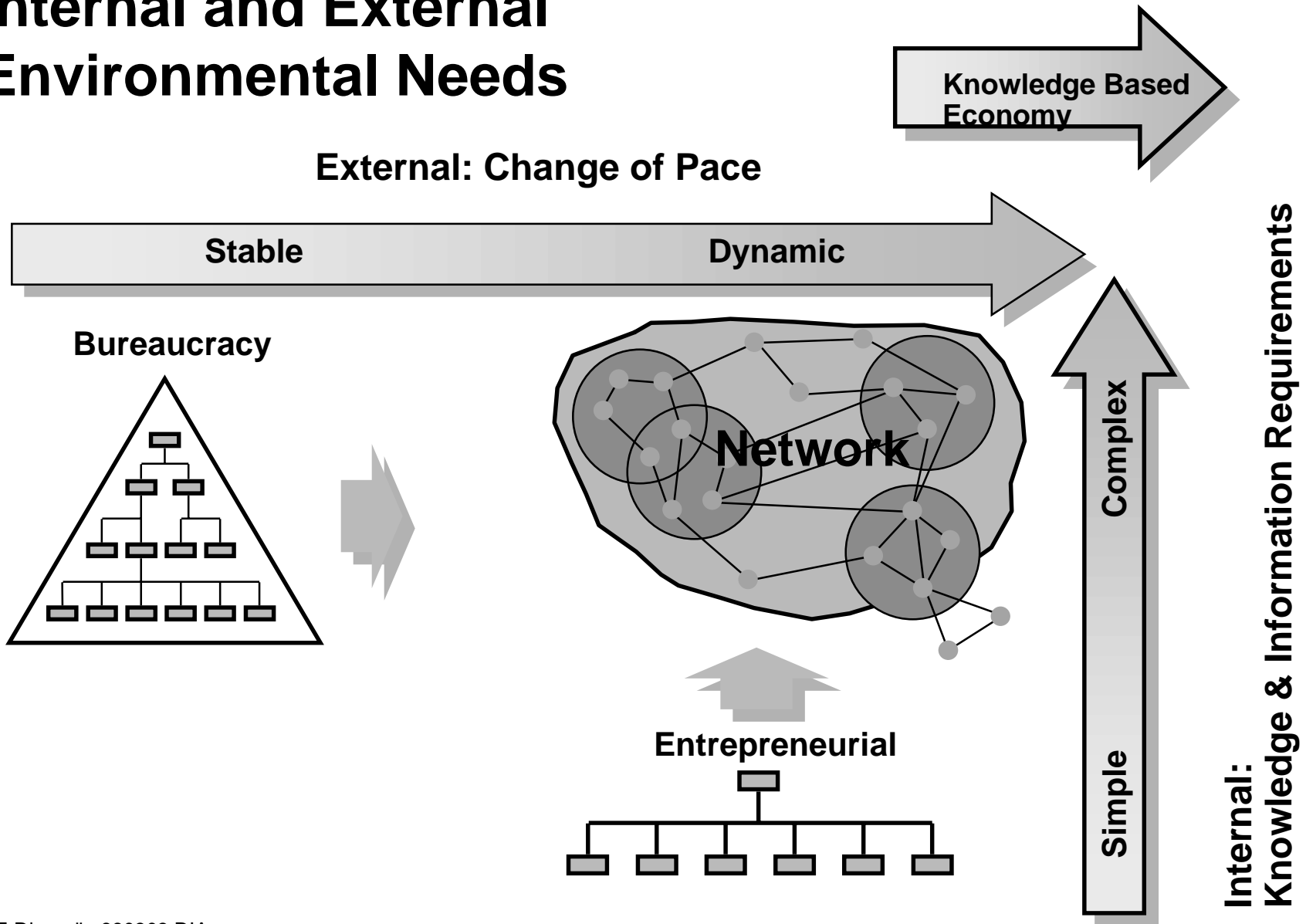


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Information/Communication

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# Internal and External Environmental Needs

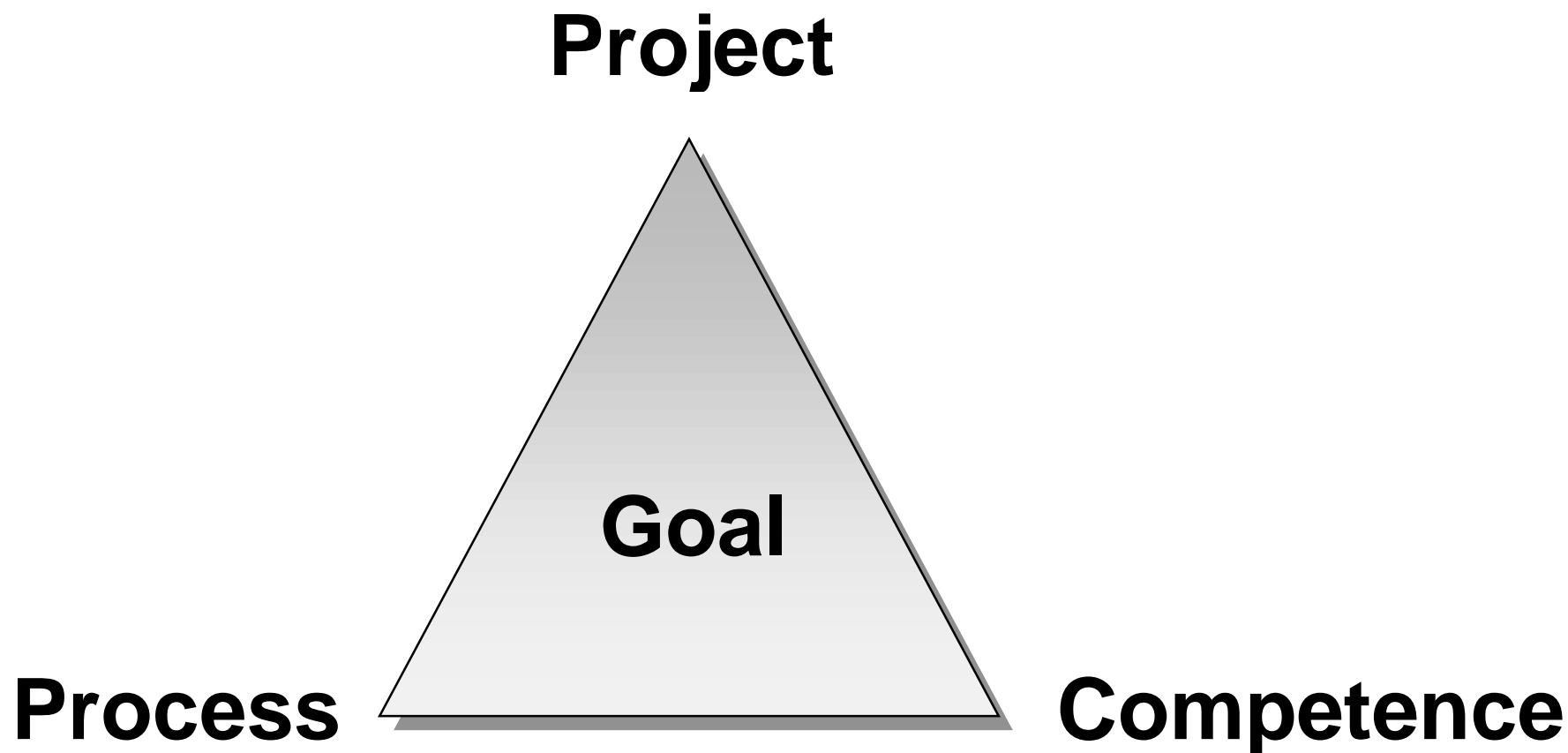


# Challenges for the pharmaceutical industry

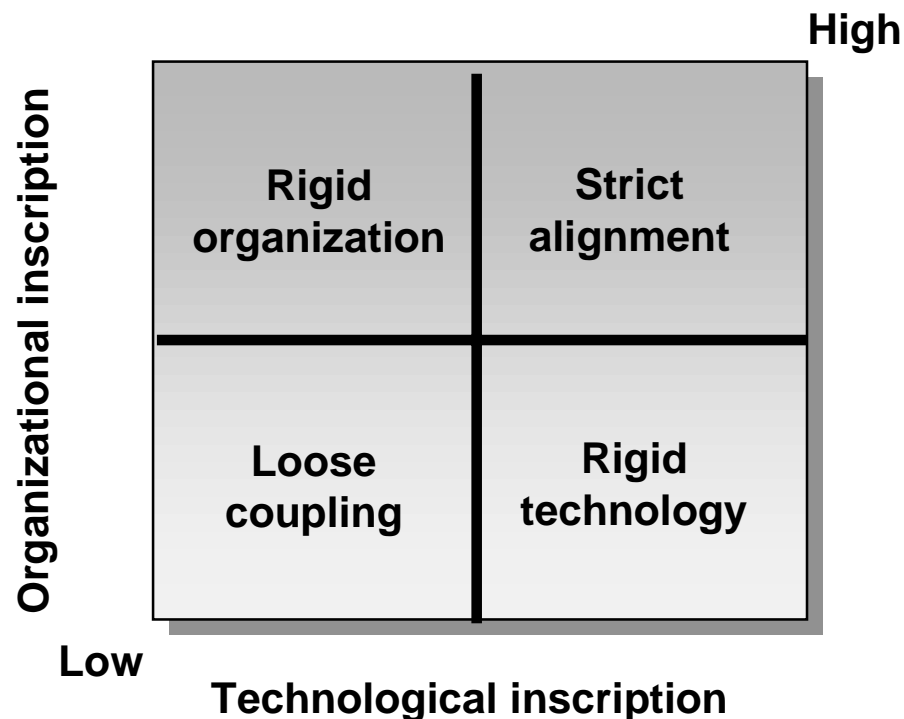
- Globalisation
- Increased external contacts (Authorities, CRO)
- Technological development
- Increased need for documentation
- Shift from functional to network organizations
- Continuous competence development
- Continuous change in organizations
- Cross-functional process-oriented workflow



# Organizational structure



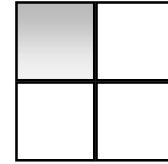
# Four scenarios for IT and organization infrastructure



- **No prescriptive model for infrastructure or selection organizational optimization**
- **Explanatory model for**
  - understanding of the interactions between technology and organization
  - outlining characteristics of the infrastructure in use



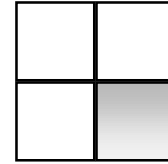
# Rigid Organization



- **Organizational procedures defined globally**
- **Technology use can be modified**
- **Infrastructure is characterized by**
  - different local technologies or**
  - local variations in IT-use**



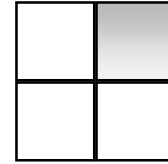
# Rigid Technology



- **Technology does not permit changes in use**
- **Organizational procedures open for local adaptation**
- **Infrastructure is characterized by tension between global and local organization procedures**



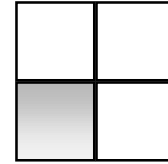
# Strict alignment



- **Design of organizational procedures -no room for local adaptation**
- **Rigid technology: Can't use outside defined context**
- **Infrastructure characterized by**
  - **standardization of technology**
  - **organizational procedures**
  - **strict alignment between these elements**



# Loose coupling



- **Organizational procedures and technology use can be redefined and adapted locally**
- **Infrastructure- typical of Knowledge intensive organizations allowing adaptation to Internal and environmental situations**



# Alternative ways of using IT

## COOL

- **Open in use**
- **WWW-based for RDC**
- **Data entry by site**
- **Low functionality**
- **Adaptable to any process design**

## Semi-RDC

- **Rigid in use**
- **2-tier client server for semi-RDC**
- **Data entry by monitors at study center**
- **High functionality**
- **Based on pre-defined process-design**



# Quantitative measures

## COOL

- Reduced cycle times
- Increased quality
- Costs?

## Semi-RDC

- Reduced cycle times
- Increased quality
- Increased costs



# Qualitative aspects

## COOL

- **Infrastructure**  
Starts at loose coupling  
Facilitates different scenarios
- **Common information space**  
On-line planning
- **Ease of use**
- **On line planning**
- **Adaptable to local routines**
- **High acceptance**

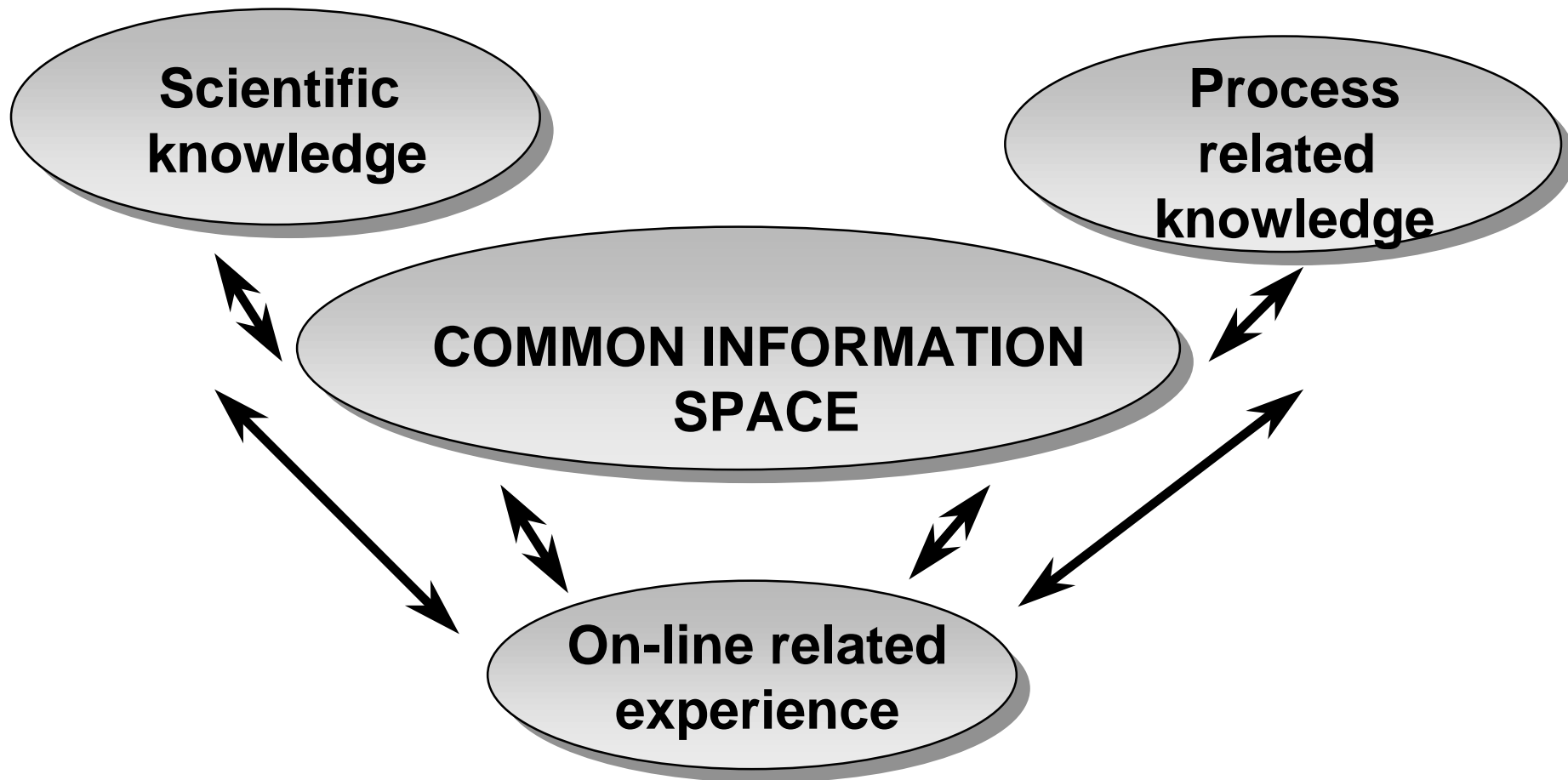
## Semi-RDC

- **Infrastructure**  
Starts at strict alignment  
Use modifies scenarios
- **Information sequentially handled**
- **Complex training**
- **Sequential planning**
- **Strict roles & task distribution**
- **Poor acceptance**



# Knowledge management

## Common information space



# Clinical R&D

## Common information space



- Distributed responsibility for the adaptation of process to projects
- Knowledge feedback from project management to process development.



- Managing knowledge between process, projects and competence
- Provide the advanced IT-support required

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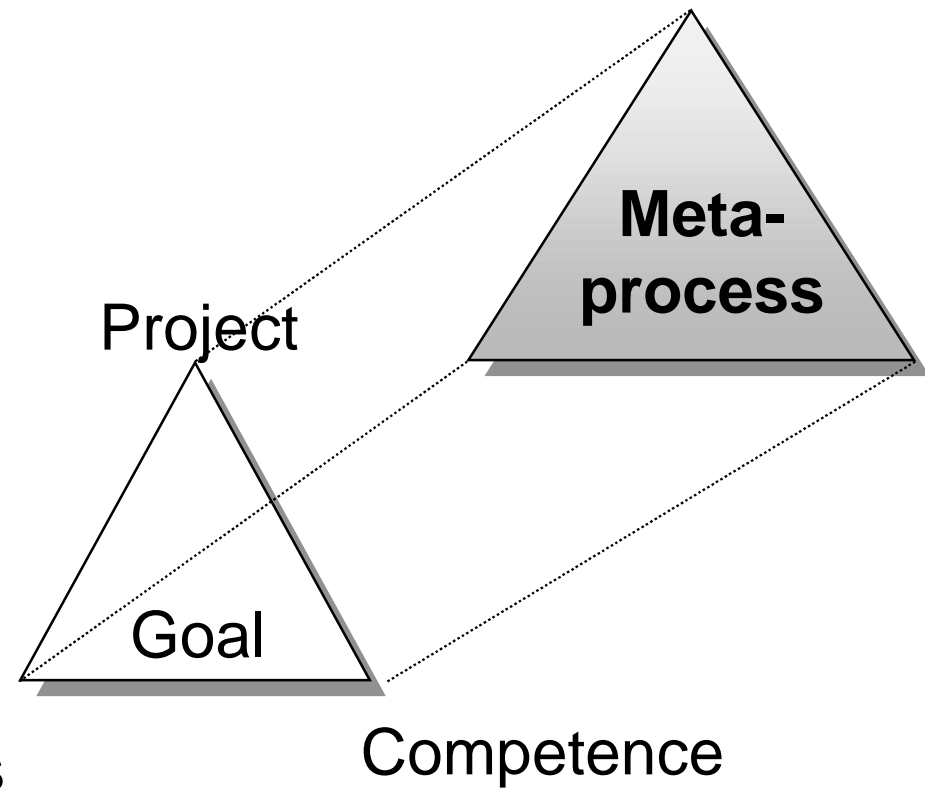


# Knowledge Management Process development

Given the complexity for a process-based environment over time in a multicultural and geographically spread organization a META-process need to be established and continuously managed.

It contains:

- Business model
- Common methods
- Portfolio of tools



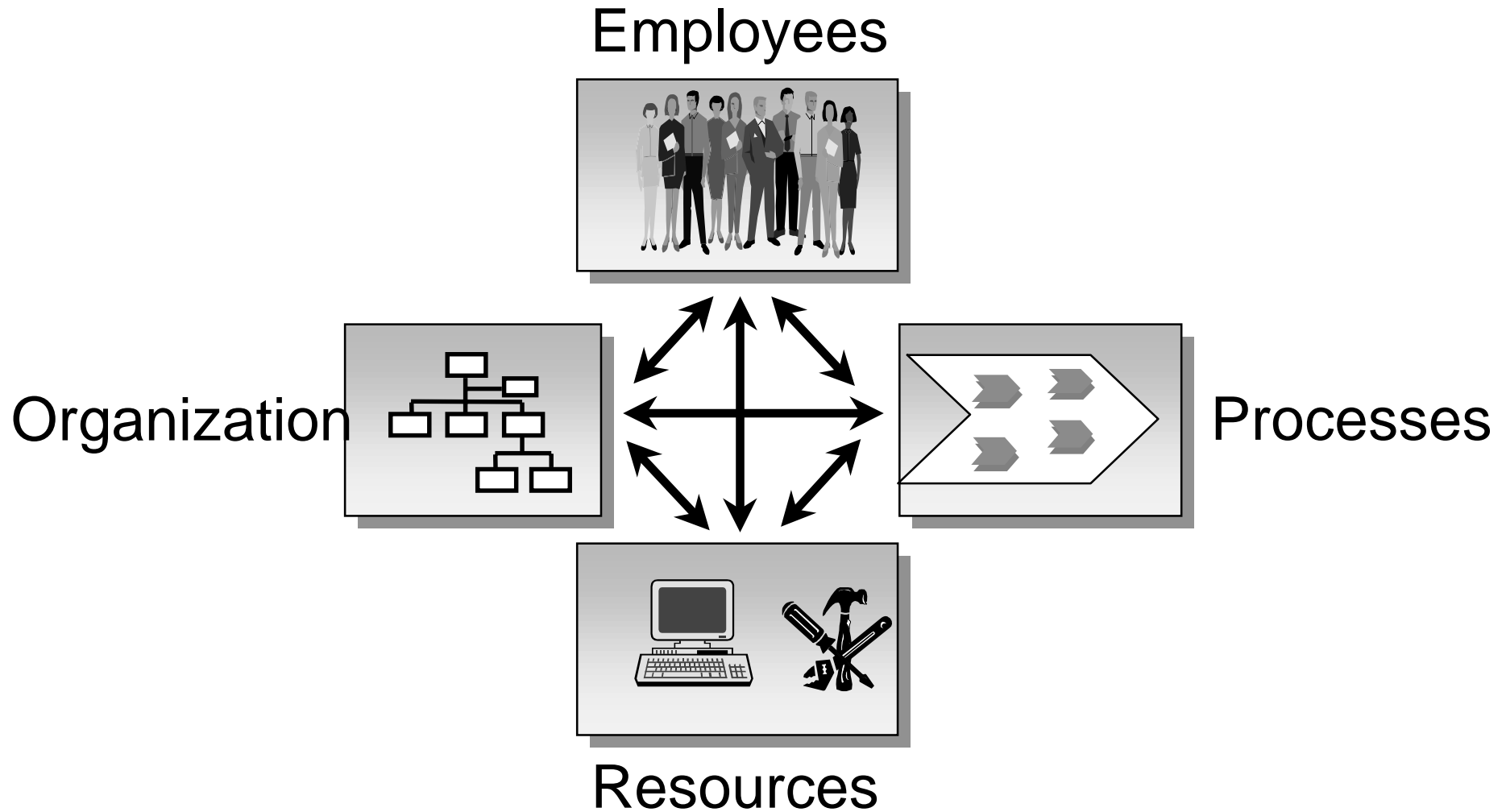
# Meta-process

**The Meta-process is:**

**A model of the companies strategy, goals, business processes and information where processes are analyzed, simulated, effectively operated and controlled, supporting the company business process development.**



# Meta process dimensions



# Summary

- **Clinical research undergoing dramatic changes**
- **Successful strategy open to changes**
- **Qualitative aspects in process development important to consider**
- **Deal with the complexity**
  - Standardized infrastructure and definitions**
  - Flexibility in technology and organization**
  - Development of an effective meta-process**



# Conclusion

**“It is not the most powerful  
nor the most intelligent  
but the one most responsive to change  
that will survive.”**

**C Darwin**

