



Key Business Applications What? And Why?

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Agenda

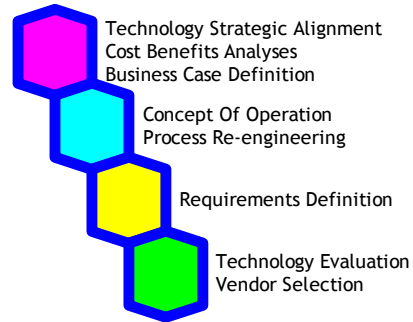
- Why? - Why should you buy?
- When? - When should you buy?
- What? - What should you buy?
- Framework:
 - How do I maximize IT investments?

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Application Selection Process

- Establish Business Case (**Business**)
- Define concept of operation (**Processes**)
- Define requirements (**Resources**)
 - Functional
 - Non-functional
- Select vendor




Why should you spend? Challenges in answering

- Business priorities do not include technology:
 - Financing
 - Patent filing
 - Regulatory filing (IND, NDA)
 - Product efficacy & safety
 - Process validation
 - Adverse Event Reporting
 - Business Development
 - Time to market
- IT receives little guidance

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Why should you spend? Challenges in answering

- Technology selection is hard:
 - Many vendors
 - Many solutions addressing similar needs
 - Technology keeps evolving (java, .NET, open source, XML)
 - No process for decision making

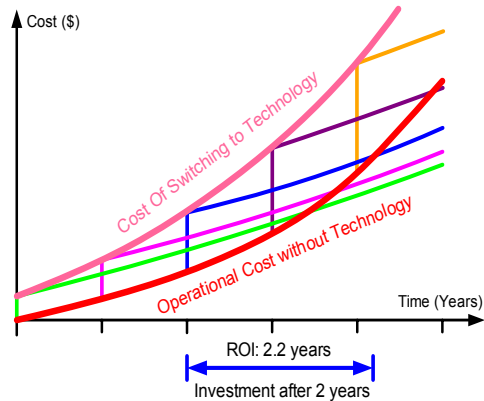
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Why should you spend? Challenges in answering

- Lack of resources
 - No IT expert
- Risky business:
 - IT projects go out of control: scope, costs, timeline
 - Integration is needed to get full benefits

Why should you spend? Challenges in answering

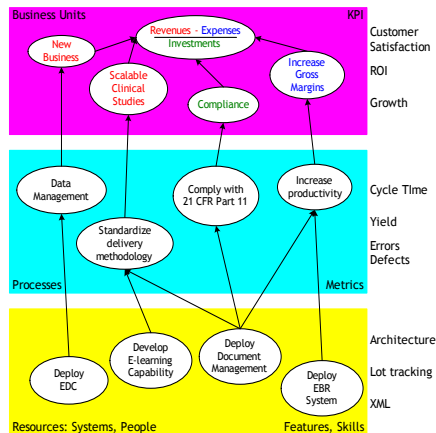
- ROI proposition is unclear
- Application cost is only a small part
- Needs scalable, modular, low cost solution



Web / ASP model: best practices as you go!

Why should you spend? To answer: Strategic Alignment

- Align investments with company objectives
 - Identify cause & effect relationships to link (justify) actionable items (resource commitments) with business objectives
- Three steps:
 - Define **business** goals
 - Define needed **processes**
 - Identify needed **resources**



Why should you spend? Cost of lack of alignment



- FDA retracted Part 11 ruling: narrower scope
- Remains the same:
 - Electronic records maintenance: predicate rule
 - Electronic signatures
- Risk based approach:
 - Computer validation
 - Audit trail
 - Archiving
 - Copies of records
 - Legacy systems

Alignment now possible!
Will save \$\$\$!

Why should you spend? Consider your IT department



- Are all activities justified?
 - Network/infrastructure maintenance?
 - Application development?
 - Report generation?
 - System integration?
 - Application support?
 - Help desk?

Typical
IT budget (AMR):
5% of revenues

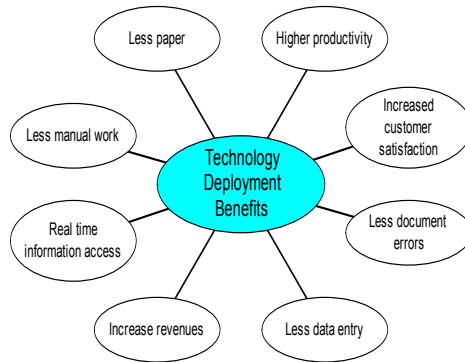
What is the Good Business Reason for doing it?

Why should you spend?

Benefits areas



- Greater Operational efficiency
 - Higher revenues
 - Lower expenses
- Compliance:
 - GxP, Part 11
 - Sarbanes Oxley
- IT Rationalization:
 - Standardization
 - Integration

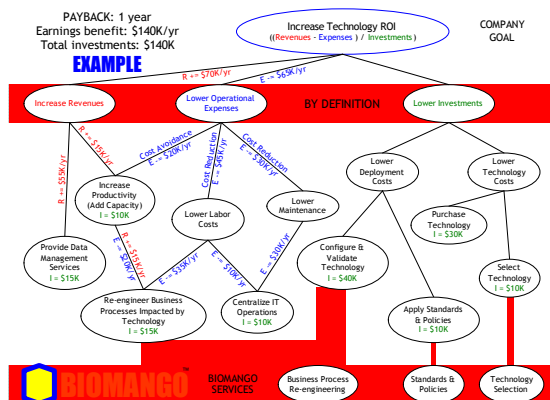


Why should you spend?

To answer: Build Business Case



- Quantify benefits:
 - Compliance
 - Leverage knowledge base
 - Efficiency
- Management & user buy-in
- Measure success (CSF)



When should you spend? Consider future needs & costs

Drug Life Cycle

Business Processes	DISCOVERY	PRE-CLINICAL	PHASES I/II	PHASE III	PRODUCTION
Documentation					
Commercialization					
cGMP Compliance					
Scale-Up					
Manufacturing					
Process Validation					
Inventory Control					
Training					
Data Collection					

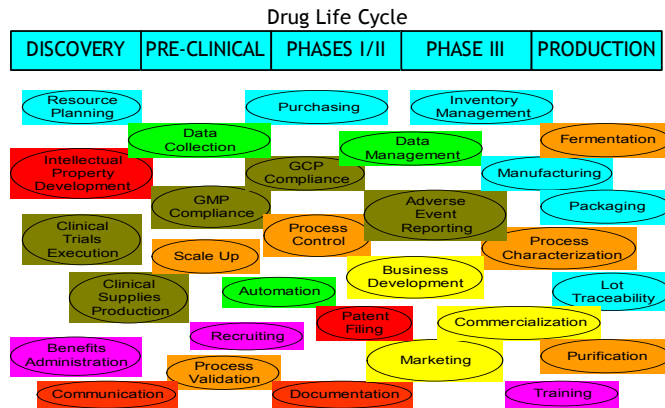
Address critical needs early

What should you buy? Baseline Processes

- Accounting:
 - G/L
 - A/P
 - A/R
 - Payroll
- Communication:
 - IT Infrastructure
 - Network
 - E-Mail (Outlook / Lotus Notes)
- Document generation:
 - Documents (Word)
 - Presentations (Powerpoint)
 - Spreadsheet (Excel)
 - Drawings (Visio)

What should you buy?

Identify business processes!

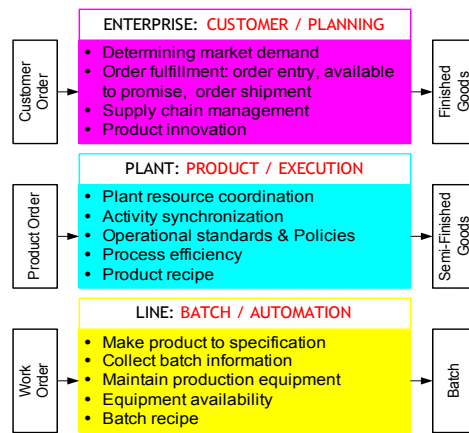


Need: Model / Architecture

What should you buy?

Information model

- Break down organization into layers:
 - Enterprise: Planning
 - Plant: Execution (ISA-S95)
 - Line: Automation (ISA-S88)



What should you buy?

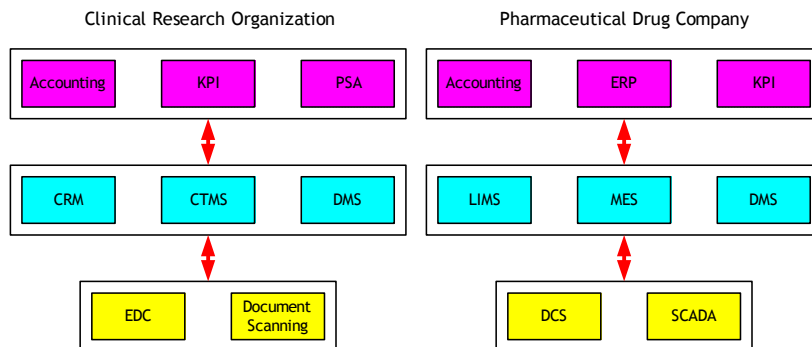
Business Applications

- Enterprise: SCM, ERP, KPI, APS, IPMS
- Plant: MES, EBR, DMS, LIMS, CTMS
- Line: DCS, EDC

<p>ENTERPRISE: CUSTOMER / PLANNING & ANALYSIS</p> <ul style="list-style-type: none"> • SCM: Supply Chain Management • ERP: Enterprise Resource Planning • KPI: Business Intelligence • APS: Advanced Planning & Scheduling • PSA: Professional Service Automation
<p>PLANT: PRODUCT / EXECUTION</p> <ul style="list-style-type: none"> • MES: Manufacturing Execution System • EBR: Electronic Batch Recording • IM: Inventory Management • DMS: Document Management System • LIMS: Laboratory Information Management System • CTMS: Clinical Trials Management System • CSM: Clinical Supply Management
<p>LINE: BATCH / AUTOMATION</p> <ul style="list-style-type: none"> • Batch Control Systems • SCADA: Supervisory Control & Data Acquisition • DCS: Decision Control System • EDC: Electronic Data Capture • OCR: Optical Character Recognition (Imaging)

What should you buy?

Business Applications:



What should I do?

- Biotech / Contract MFG:
 - Intellectual Property Management System
 - Document Management System
 - Inventory Management (tied to accounting system)
- CRO:
 - Document Management System (FDA submissions)
 - Project Management System
 - Clinical Trials Management System

Conclusion

To increase technology ROI:

