Session " Industry QA standards "

QA standards overview and Serono implementation choices and benefits

EGEE'06 Conference
27th September 2006

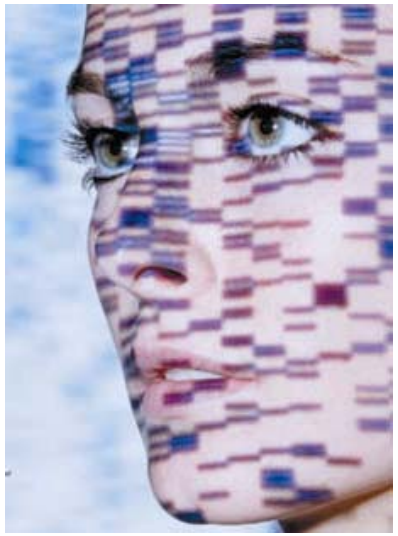
Serge Thorn – IT Research and Innovation

Agenda

- Serono...the company
- IT Governance
- Industry QA's standards
  - Definitions
- Serono's Implementation
  - Components (existing and under evaluation)
  - Relationships between them
  - Choices and Benefits
  - Evolution
- Tools and platforms
- High level Processes
- Questions

Serono Profile

- Fully integrated global biotech company (R&D, Mfg, M&S) with almost 100 years of history in biologic therapies
  - ✓ operate in 44 countries
  - ✓ sales in over 90 countries
  - ✓ 4,750 employees worldwide
  - ✓ 6 recombinant products on the world market
  - ✓ revenues of $2,5 billion in 2005
- Largest biotech company in Europe
- Third largest biotech company worldwide
- Solid and sustained financial performance



A Global Biotech Leader

3rd Biotech worldwide, 1st biotech outside USA

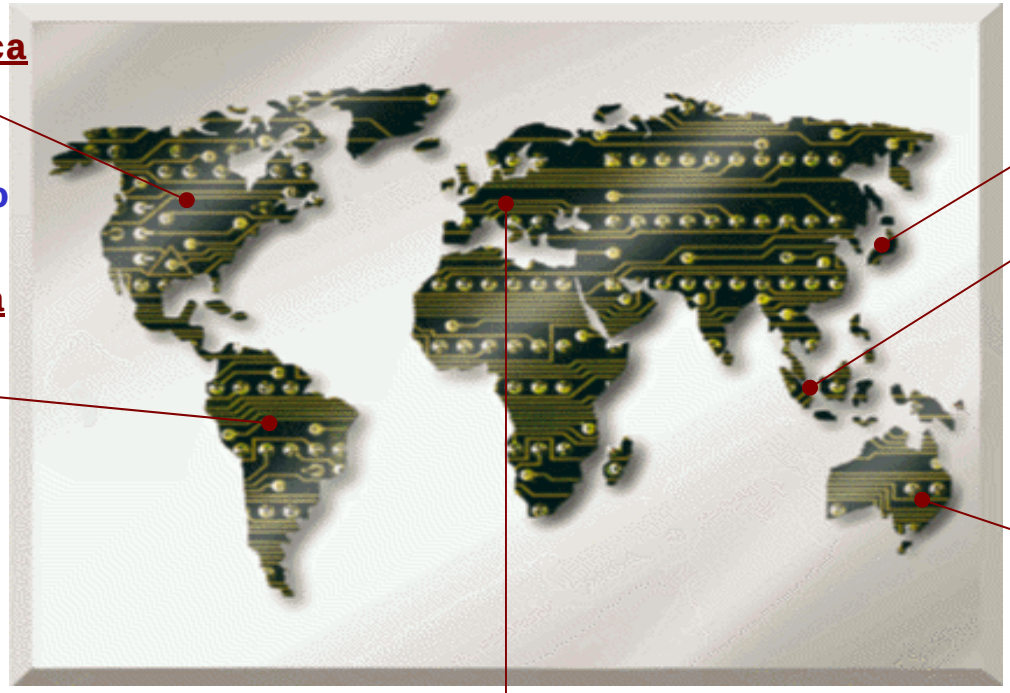
Global Presence

We are a global organisation of 140 employees supporting

4'750 users in more than 60 locations and from 30 different countries in the world.

North America
- Canada
- USA
- Puerto Rico

Latin America
- Argentina
- Brazil
- Uruguay
- Venezuela
- Colombia
- Mexico



Japan

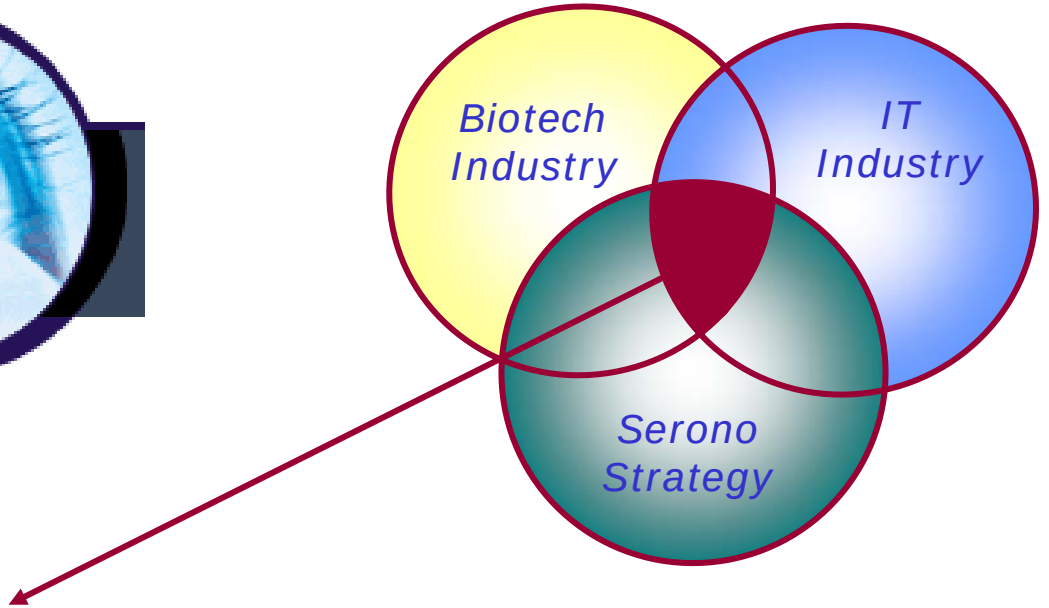
Asia-Pacific
- Singapore
- Korea
- Hong-Kong
- Taiwan
- Thailand
- China

Oceania
- Australia
- New-Zealand

Europe, Middle-East, Africa

- Switzerland
- France
- UK
- Germany
- Austria
- Netherlands
- Sweden
- Danemark
- Finland
- Norway
- Czech Rep.
- Slovakia
- Poland
- Lithuania
- Russia
- Croatia
- Italy
- Spain
- Portugal
- Greece
- Israel
- South Africa
- Egypt
- Tunisia
- Algeria
- Morocco
- Turkey
- Jordan
- Saudi Arabia
- United Arab Em.

Serono IT



At the crossroad of the Biotech Industry trends, the technology opportunities & the company goals to deliver new business capabilities

We sell 4 basic Services

Business case studies & Projects Implementation

Business Applications Secured Hosting & Management

Desktop, MSOffice, e-Mail, VPN & Support Services

Bsnss Applications & Common Desktop Training Programs

We concentrate our forces on three main regions

USA Services

HQ Services

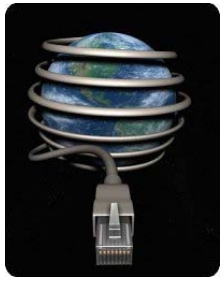
Affiliates Services

Some Statistics

3'000 Desktops
1'500 Laptops

350 Servers

40 Terabytes of Data



120 Telecom Lines

We optimise the running business

100 New projects per year

We invent the future business

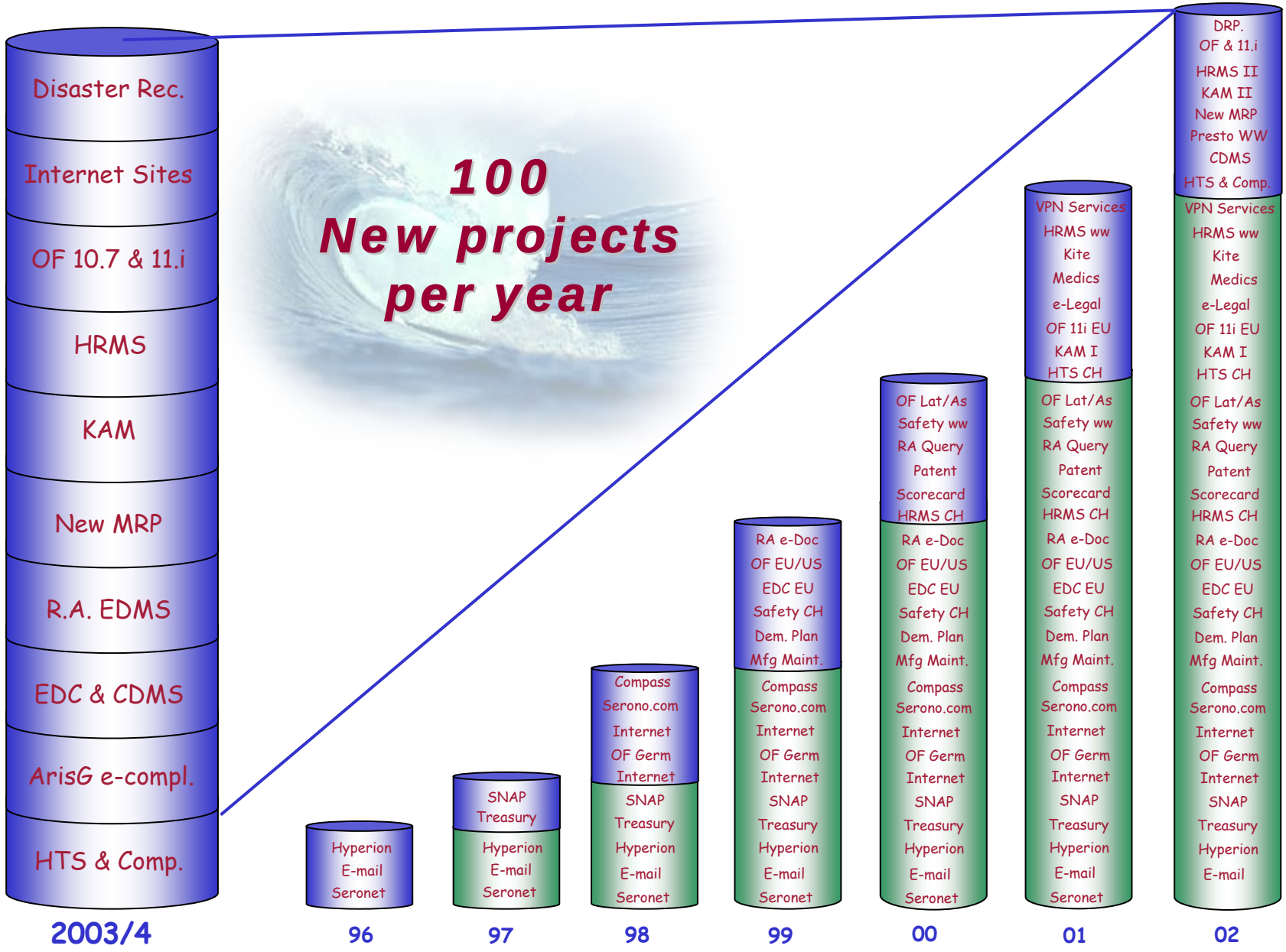
35'000 calls/year

1'500 cyber-attacks/year

500 Applications

20M e-mails/year

Speed Complexity



Business Complexity

Discovery Compounds Inventory and High Throughput Screening

Clinical Dev. Electronic Data Capture, Clinical Trials & Safety Data Management, Medical Call Centers

Regulatory Registration files management

Sarbanes-Oxley
Public Company Accounting Reform and Investor Protection Act

Manuf. Manufacturing Resource Planning suite

FDA

Supply Suply Chain Planning suite

Marketing Patient Registry Databases

Sales Customer Relationship Management

Strategic Plan. Projects and Strategic Documentation Approval Process, Balanced Scorecard Measurement

Business Complexity

Communication Intranet and Internet websites management

Finance Order to cash, Purchase to pay, Reporting and Treasury

Bsnss Dev. M&As approval process

HR Human Resource database management

Legal Contracts management

IP Patents management

Cross-Funct. Datawarehouse and Dashboards

IT A robust and secured platform

We connect the company value chain

What is IT Governance?

"We define IT governance as specifying the decision rights and accountability framework to encourage desirable behavior in IT"

Harvard Business School.

IT governance is the responsibility of the board of directors and executive management. It is an integral part of enterprise governance and consists of the **leadership and organisational structures and processes that ensure that the organisation's IT sustains and extends the organisation's strategies and objectives.**

Board Briefing on IT Governance, IT Governance Institute

Fundamentally, IT governance is concerned about two things: IT's delivery of value to the business and mitigation of IT risks. The first is driven by strategic alignment of IT with the business. The second is driven by embedding accountability into the enterprise. Both need to be supported by adequate resources and measured to ensure that the results are obtained.

Board Briefing on IT Governance, IT Governance Institute

IT Governance is the term used to describe how those persons entrusted with governance of an entity will consider IT in their supervision, monitoring, control and direction of the entity. How IT is applied within the entity will have an immense **impact on whether the entity will attain its vision, mission or strategic goals.**

Robert S. Roussey, CPA, Professor, University of Southern California

IT Governance at Serono

- IT governance is the responsibility of the board of directors and executive management. It is an integral part of enterprise governance and consists of the leadership and organizational structures and processes that ensure that the organization's IT sustains and extends the organization's strategies and objectives.

- IT Governance ensures that
  - IT delivery expectations are fulfilled,
  - IT resources deployment is continuously planned, targeted and optimized ,
  - IT Performance is measurable
  - and that the risks are minimized

Effectiveness	Do the right things
Efficiency	in the right way
Reliability	at the right time

ISO 9000 is a family of generic quality management systems standards.

The International Organization for Standardization (ISO) developed the ISO 9000 in 1987 to establish international standards for quality management. The ISO categorizes the ISO 9000 as a set of generic management system standards, meaning that ISO 9000 can be applied to any organization regardless of size or industry, and the ISO 9000 standards are intended to guide an organization's management of business processes. The ISO defines quality as features of a product or service which is required by the customer. Quality management is defined as what the organization does to ensure that its products conform to customer's requirements.

IT Governance and QA standards
An Overview of the Key Management Frameworks

International Organization for Standardization

Commonly Implemented ISO 9000 Standards

Standards and Guidelines	Purpose
ISO 9000:2000, *Quality management systems - Fundamentals and vocabulary*	Establishes a starting point for understanding the standards and defines the fundamental terms and definitions used in the ISO 9000 family which you need to avoid misunderstandings in their use.
ISO 9001:2000, *Quality management systems - Requirements*	This is the requirement standard you use to assess your ability to meet customer and applicable regulatory requirements and thereby address customer satisfaction. It is now the only standard in the ISO 9000 family against which third-party certification can be carried.
ISO 9004:2000, *Quality management systems - Guidelines for performance improvements*	This guideline standard provides guidance for continual improvement of your quality management system to benefit all parties through sustained customer satisfaction.

Source: Author unknown, “The ISO 9000 Family,” ISO.org, (1 April 2003).

IT Governance and QA standards
An Overview of the Key Management Frameworks

ITIL®

A Process "Recipe Book"

The Information Technology Infrastructure Library (ITIL) provides a set of IT management best practices for the implementation and management of key infrastructure processes such as change management, problem management, etc. (described later)

Six Sigma

A Continuous Improvement Framework

Six Sigma is a rigorous, quantitative methodology that provides a set of tools and project management practices for the identification of and reduction in process variability.

Six Sigma requires companies to perform the following activities to improve underperforming production areas and to resolve quality discrepancies:

- Measure frequency of errors in existing process
- Analyze current performance levels
- Develop procedures to improve quality of existing processes
- Monitor quality performance levels

A Control Framework for IT

Control Objectives for Information and related Technology (COBIT) provides a set of best practices and tools for auditing IT processes and assessing standards compliance, maturity, and associated risks.

IT Governance and QA standards
An Overview of the Key Management Frameworks

- The ISO 27000 series of standards have been specifically reserved by ISO for information security matters. This of course, aligns with a number of other topics, including ISO 9000 (quality management) and ISO 14000 (environmental management).
- As with the above topics, the 27000 series will be populated with a range of individual standards and documents. A number of these are already well known, and indeed, are scheduled for publication. For others, the final numbering and publication details have yet to be determined.
- The following matrix reflects the current known position:

ISO 27001 *This is the specification for an information security management system (ISMS) and replaces the old BS7799-2*	ISO 27002 *This is the potential new standard number of the existing ISO 17799 standard..*
ISO 27004 *This is the designated number for a new standard covering information security management measurement and metrics..*	ISO 27005 *This is the ISO number for an emerging standard for information security risk management..*

IT Governance and QA standards
An Overview of the Key Management Frameworks

	Process Oriented Control and Audit System	Process Improvement Methodology	IT Best Practices
ITIL	○	◑	●
SixSigma	◔	●	◔
COBIT	●	○	○

○ Not Addressed by Framework
● Strength of Framework

IT Governance and QA standards
An Overview of the Key Management Frameworks

- Capability Maturity Model Integration has been developed by the Carnegie Mellon University – Software Engineering Institute
- It is a suite of products used for process improvement
- It consists of best practices that address the development and maintenance of products and services covering the product life cycle from conception through delivery and maintenance
- These Best Practices are used for
  - The development, acquisition and maintenance of products and services
  - Improve delivery of performance, cost, and schedule
  - Implement an integrated enterprise business and engineering perspective
  - Benchmarking an organization against others in a variety of industries

CMMi

- A CCMI model is not a process but describes the characteristics of effective processes.
- CCMI models should be used in conjunction with all companies IT processes found in Service Management (ITIL), COBIT, Project Management (SDLC/Prince 2), Enterprise Architecture (TOGAF), Quality (ISO 9000), Security Management (ISO 17799).
- CMMi allows companies to assess their practices and compare them to those of other companies. The CMMi measures process maturity, progresses through five levels: Level 1 (initial), 2 (managed), 3 (defined), 4 (predictable) and 5 (optimizing).
- CMMi is a new important component of our IT Governance framework and should be considered as a project.

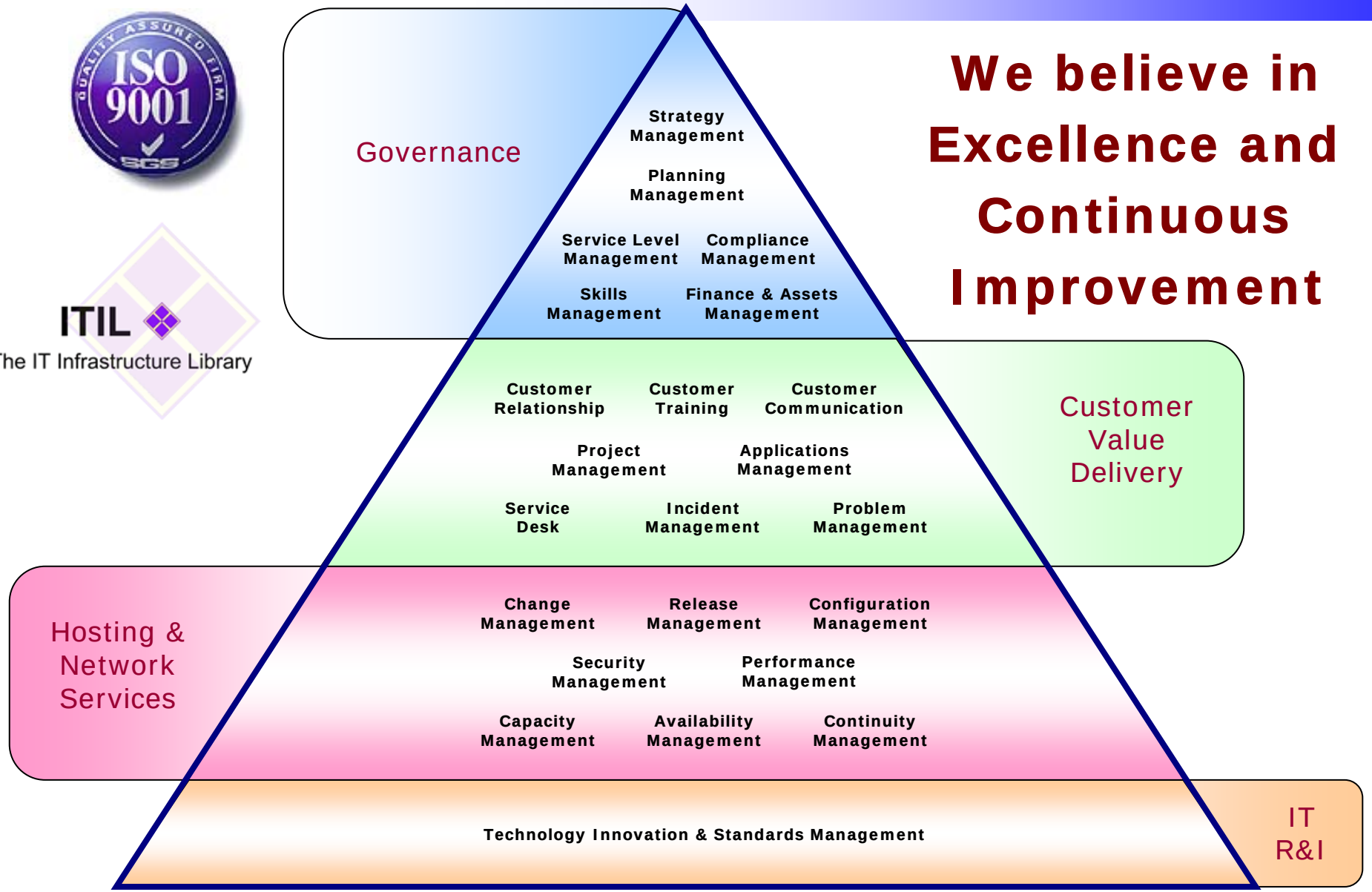
Serono's Quality & Excellence

We are driven by Vision and Excellence

2005 Benchmark of IT Best Practices within the Life Sciences Industry

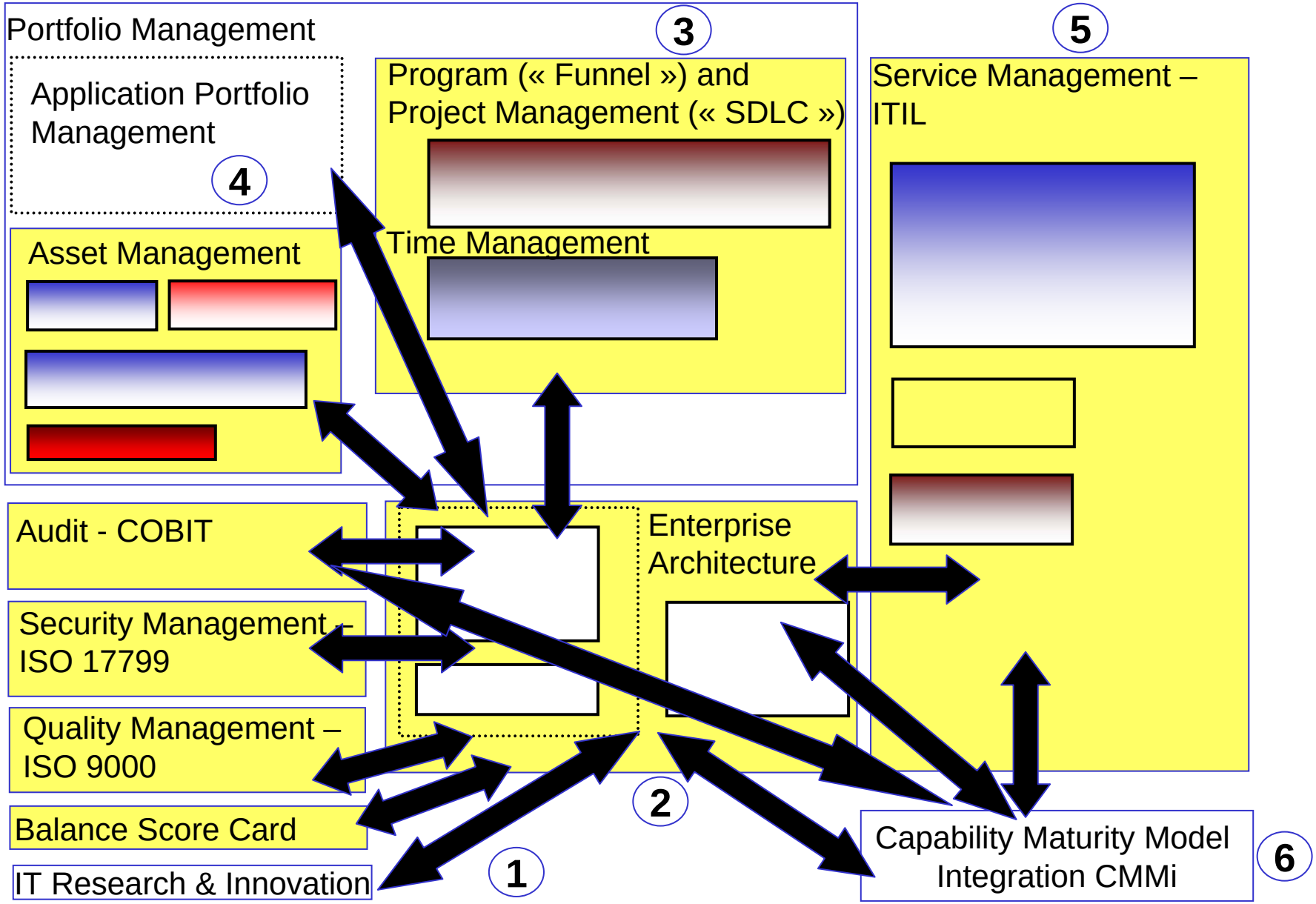
IT Best Practices

ITIL
The IT Infrastructure Library

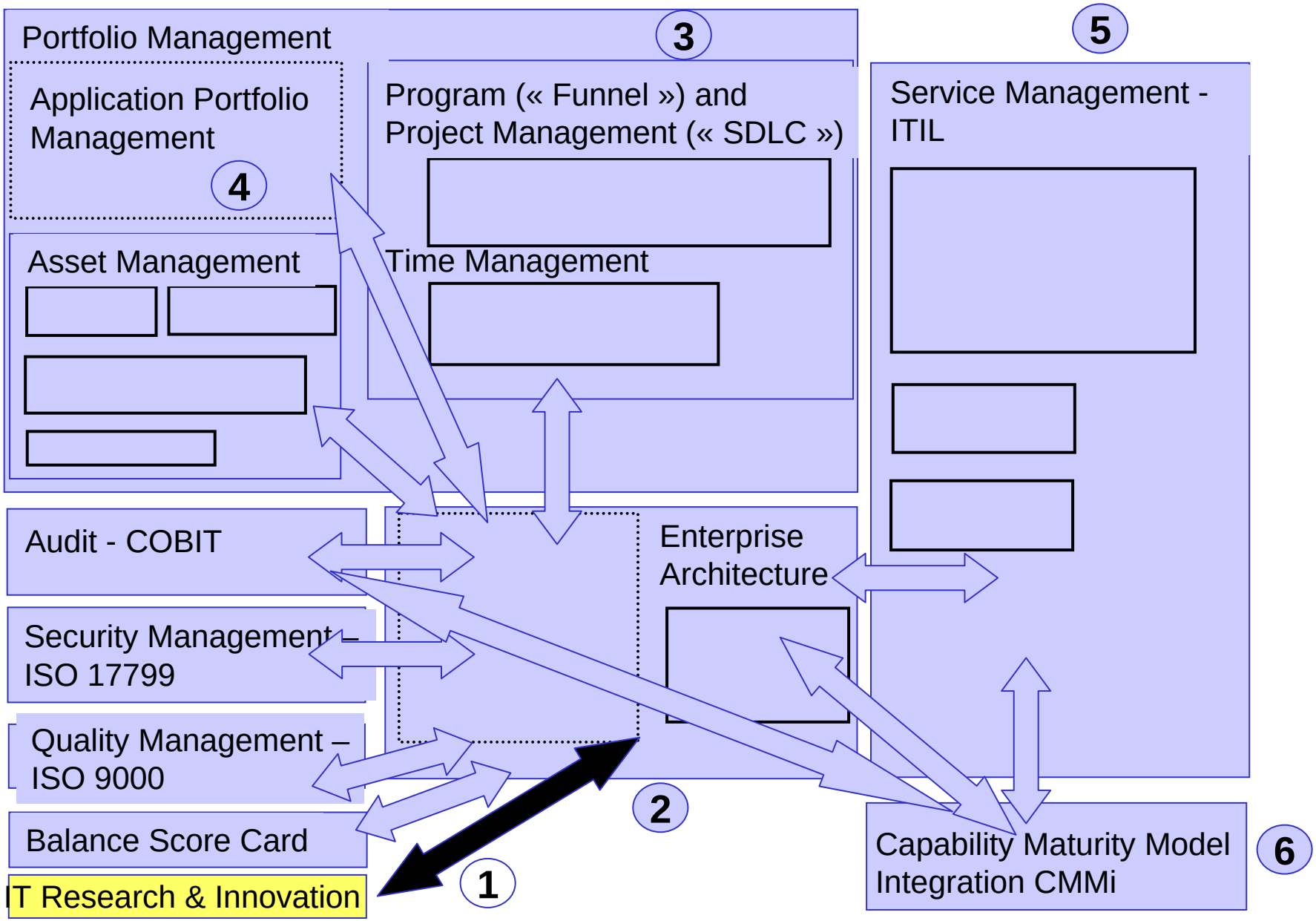


We believe in Excellence and Continuous Improvement

Components


Portfolio Management
3
5
Application Portfolio Management
4
Program (« Funnel ») and Project Management (« SDLC »)
Time Management
Service Management – ITIL
Asset Management
Audit - COBIT
Enterprise Architecture
Security Management – ISO 17799
Quality Management – ISO 9000
2
Balance Score Card
IT Research & Innovation
1
Capability Maturity Model Integration CMMi
6

Components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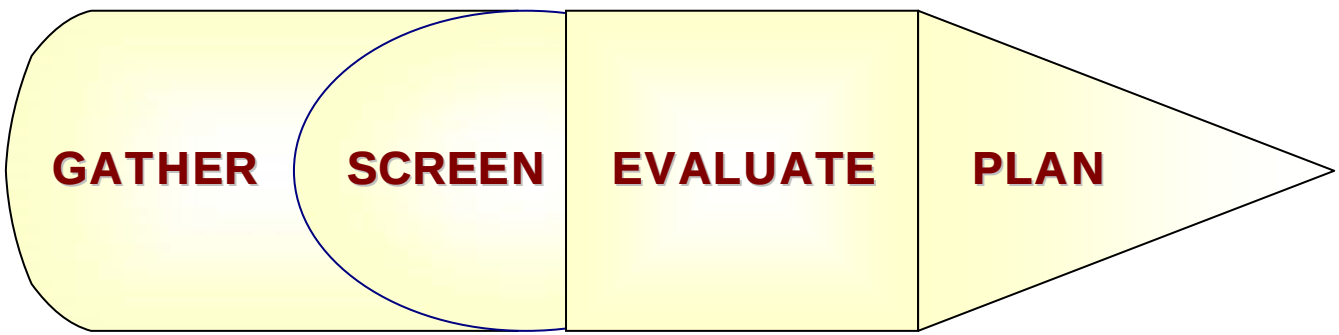
Links with IT Research and Innovation

October 2003: new « R & I » initiative



IT Research and Innovation - Gather

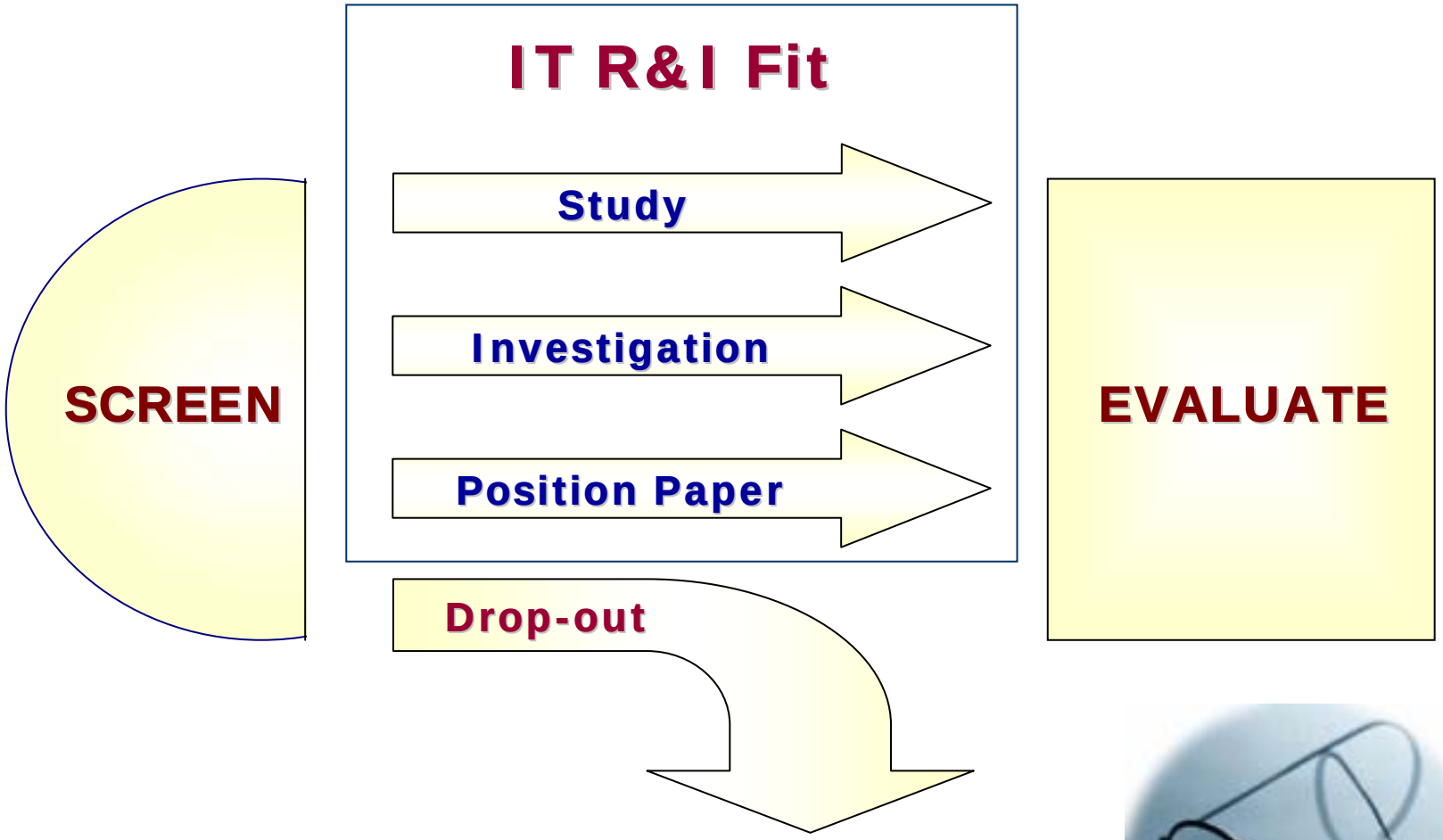
Users Input

IT Experts

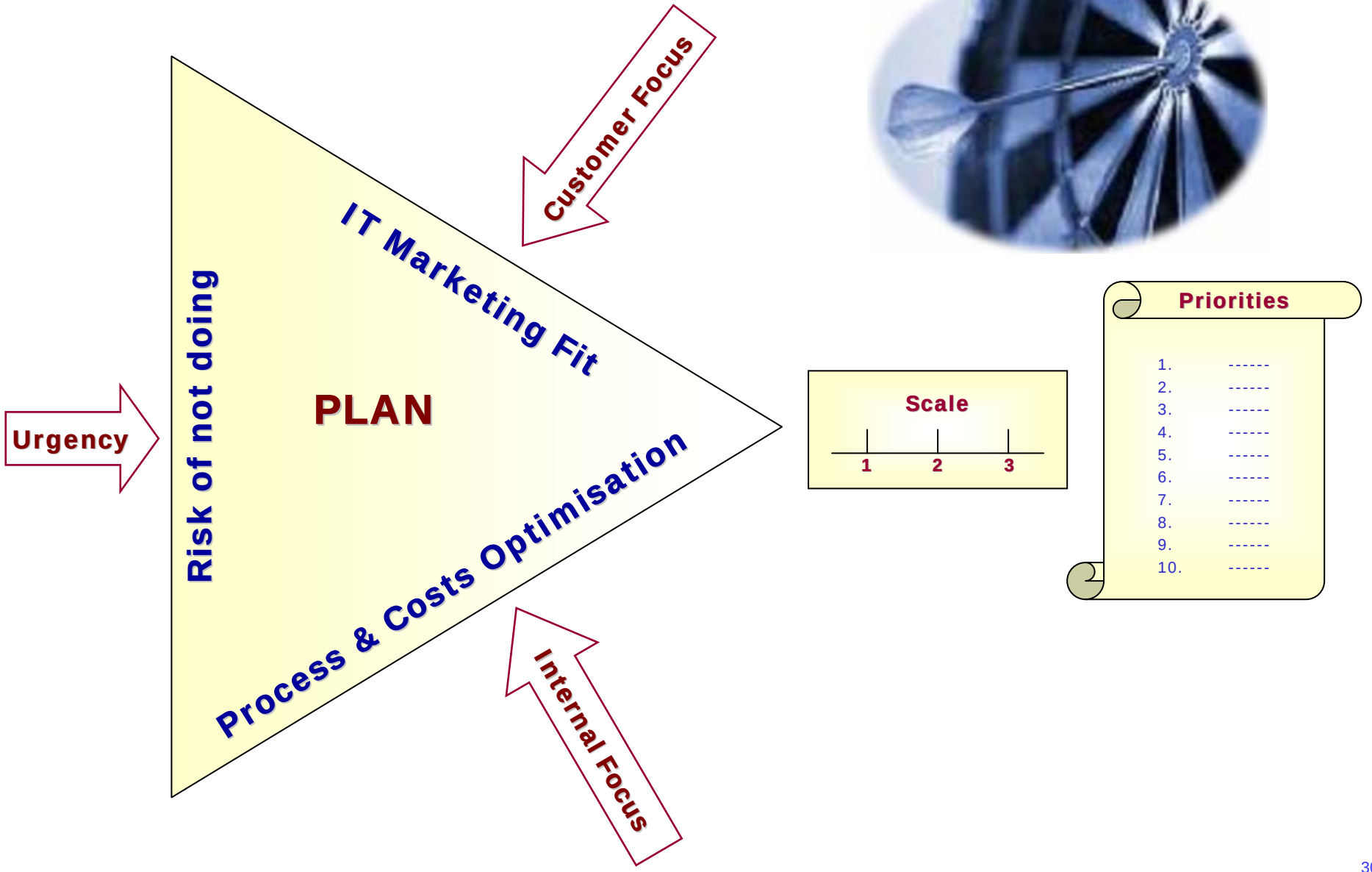
IT Industry Trends

GATHER

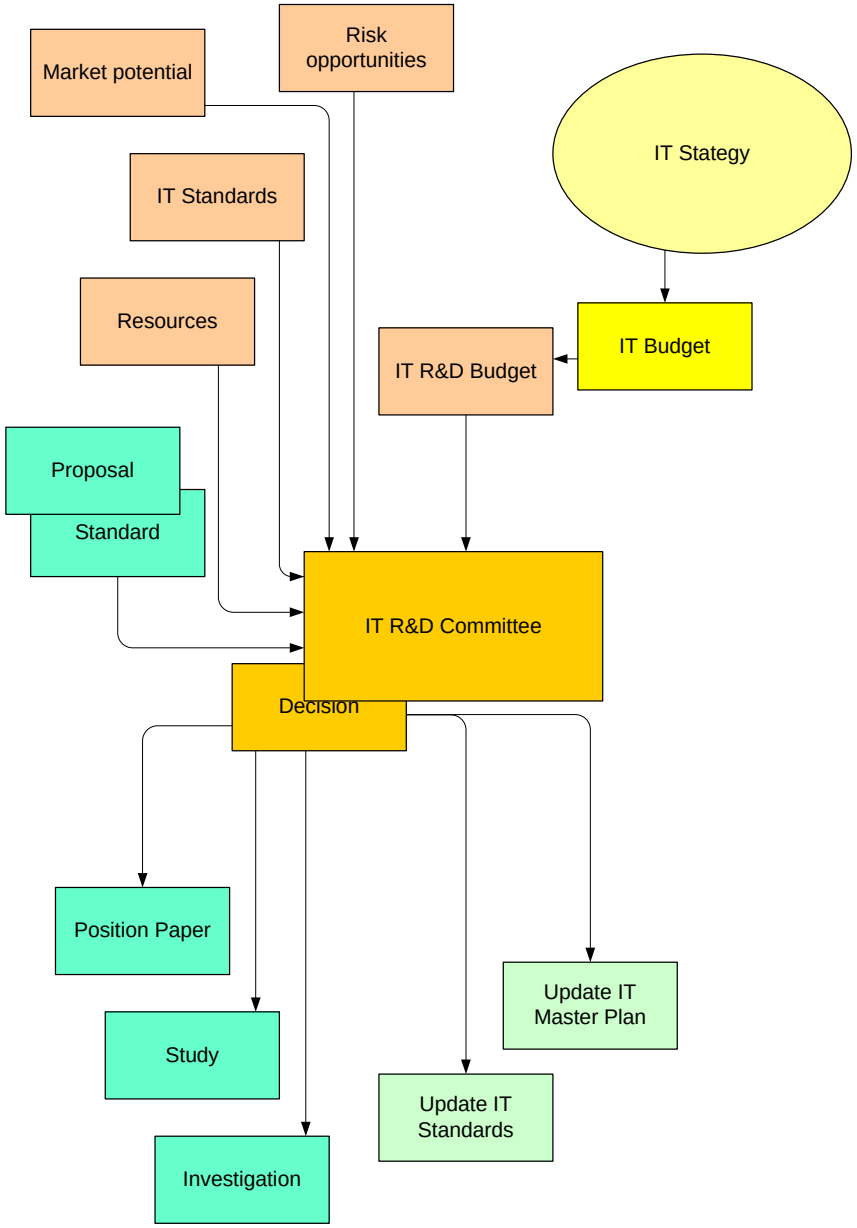
IT Research and Innovation - Screen



IT Research and Innovation - Plan



IT Research and Innovation – Global Process



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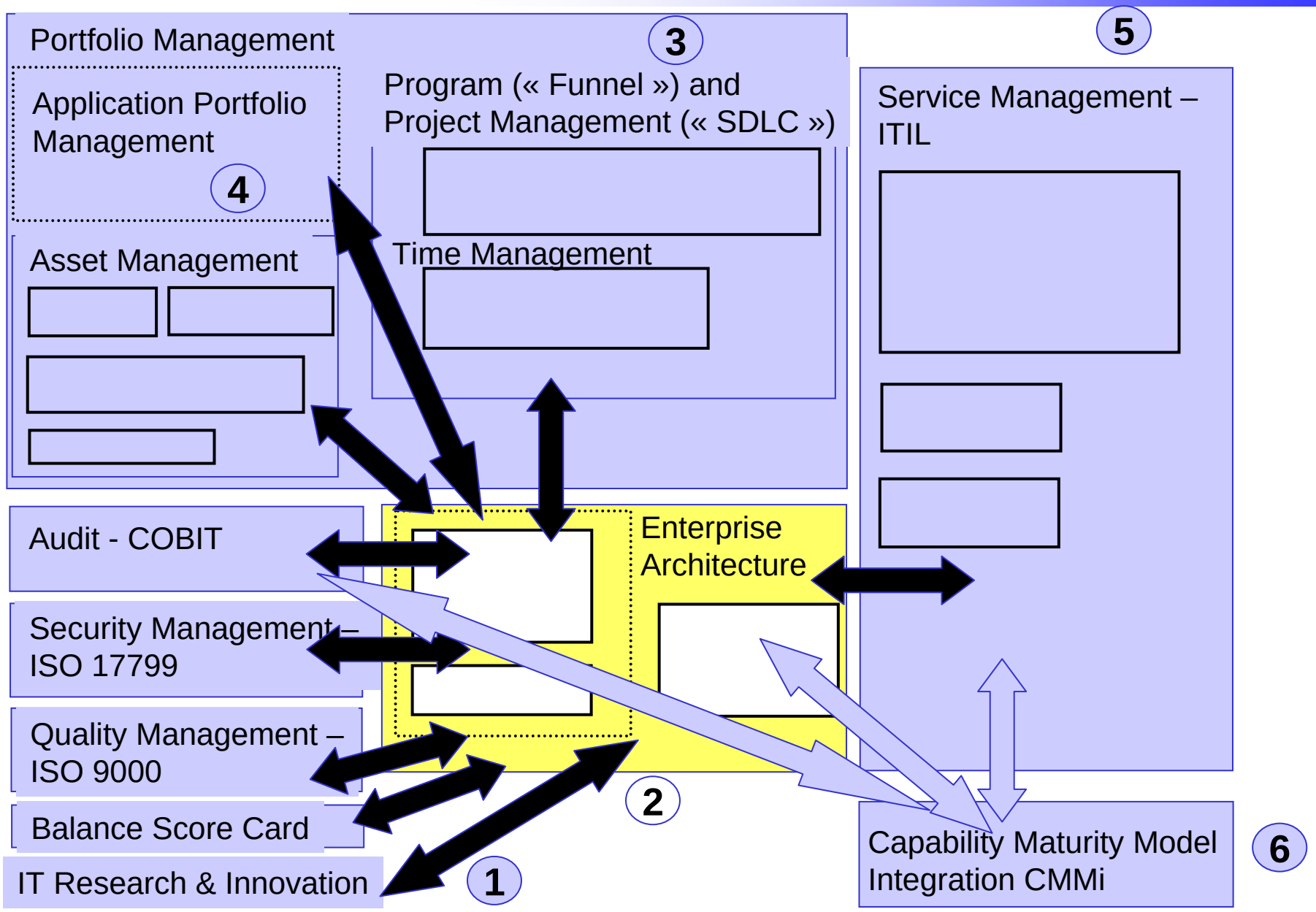
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- One of the key study is linked to Enterprise Architecture
  - Serono wished to evaluate the development process of an Enterprise Architecture in order to re-structure its IT department and improve its relation with the various LOB
  - For these reasons, several workshops were scheduled to:
    - Identify what would be the added value
    - Select and validate an Enterprise Architecture methodology
    - Explore tools and technologies related to Enterprise Architecture, Business Process Management and SOA architecture
    - Define the project scope
    - Define an initial plan

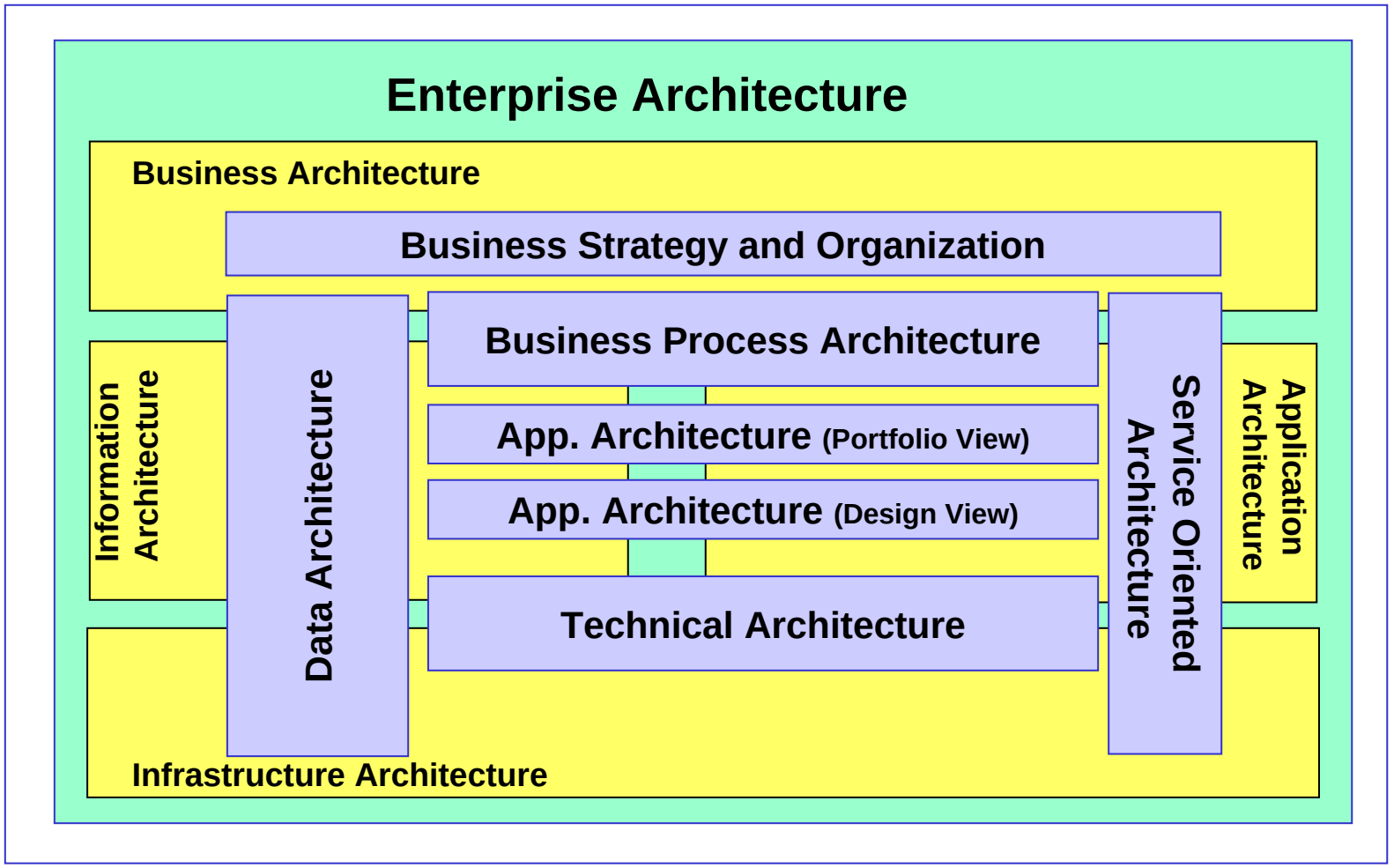
Enterprise Architecture - Definition

- An Enterprise Architecture (EA) consists of the vision, principles, standards and processes that guide the purchase, design and deployment of technology within an enterprise. EA describes the interrelationships between business processes, information, applications and underlying infrastructure for that enterprise, and provides best practices for technology purchase, design and deployment. EA structures and processes govern adherence to an organization's technology strategy and provide a managed environment for the introduction of new technology.

Enterprise Architecture

- Situation
  - Enterprise Architecture did not exist within Serono
- Key Benefits and Value proposition
  - Alignment with the company's Business Model and Strategy
  - Enable business changes, technologically based business opportunities
  - Make easier the introduction of new technologies
  - Allow standardization
  - Information (or data) consolidation
  - Reduce enterprise/application integration complexity
  - Facilitate outsourcing if required
  - Better assets utilization
  - Better assess the impact of changes
  - Reduced time to market

Enterprise Architecture and Business Design Activity

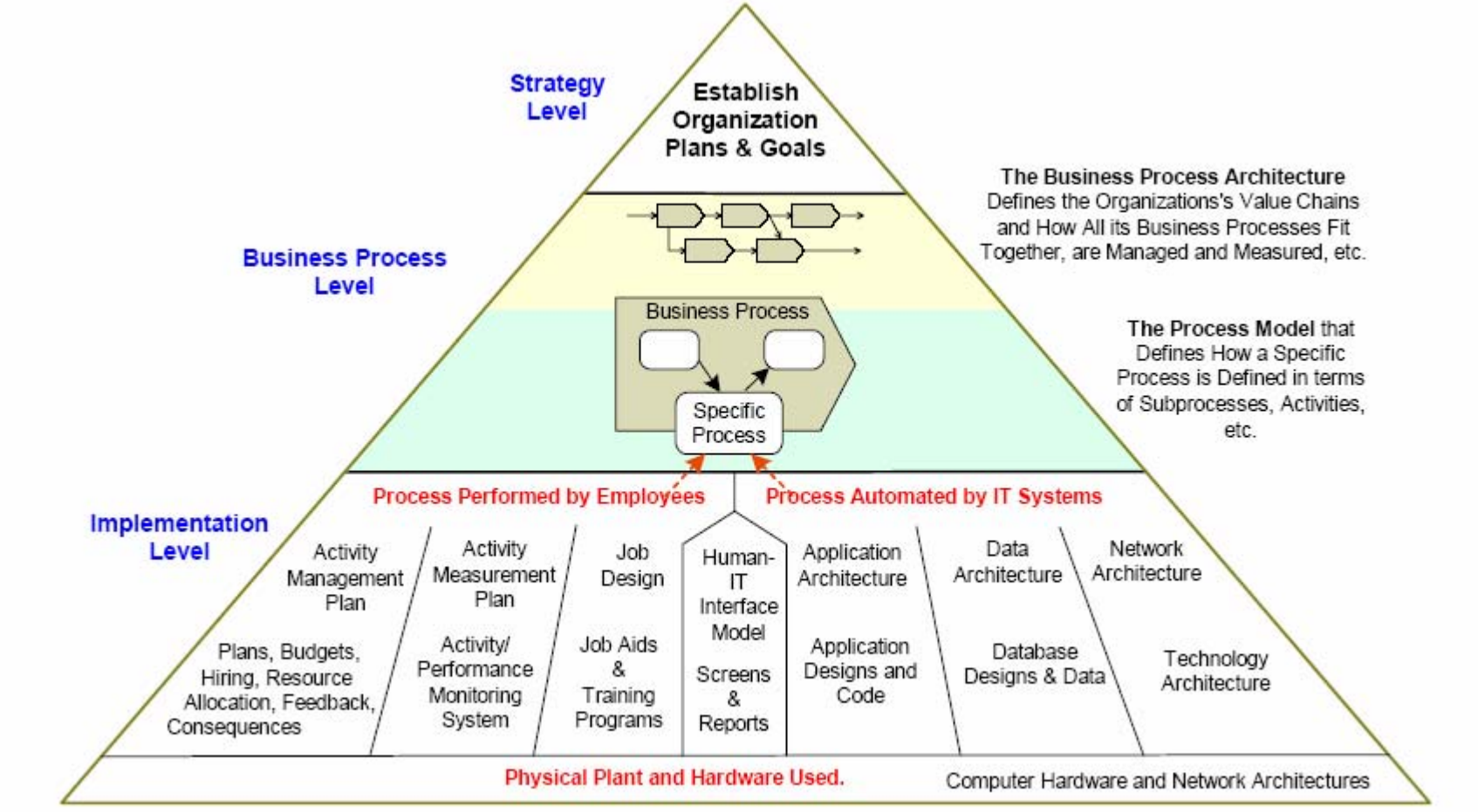


Business Architecture

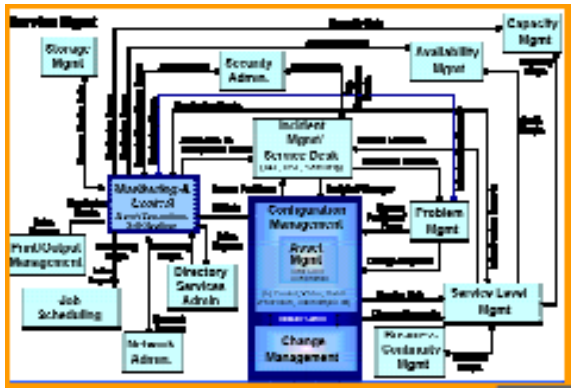
Objectives

- Describe the current Baseline Architecture
- Develop a target Business Architecture describing the product and/or service strategy, and the organizational, functional, process, event, information, and geographic aspects of the business environment
- Analyze the gaps between the Baseline and target Business Architecture

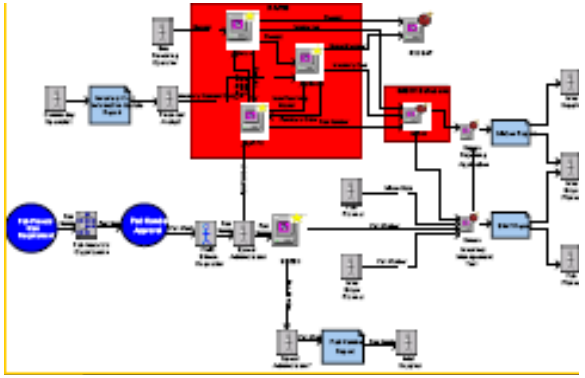
Business Architecture



Enterprise Model consolidates the “4 views”



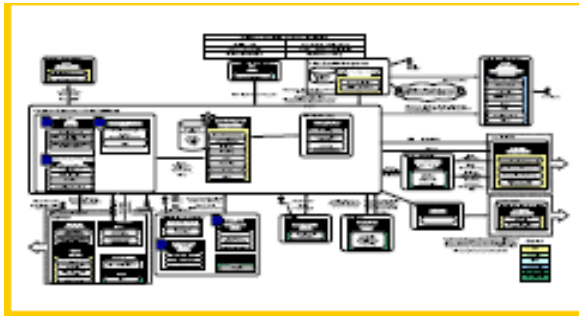
Business Architecture



Information Architecture

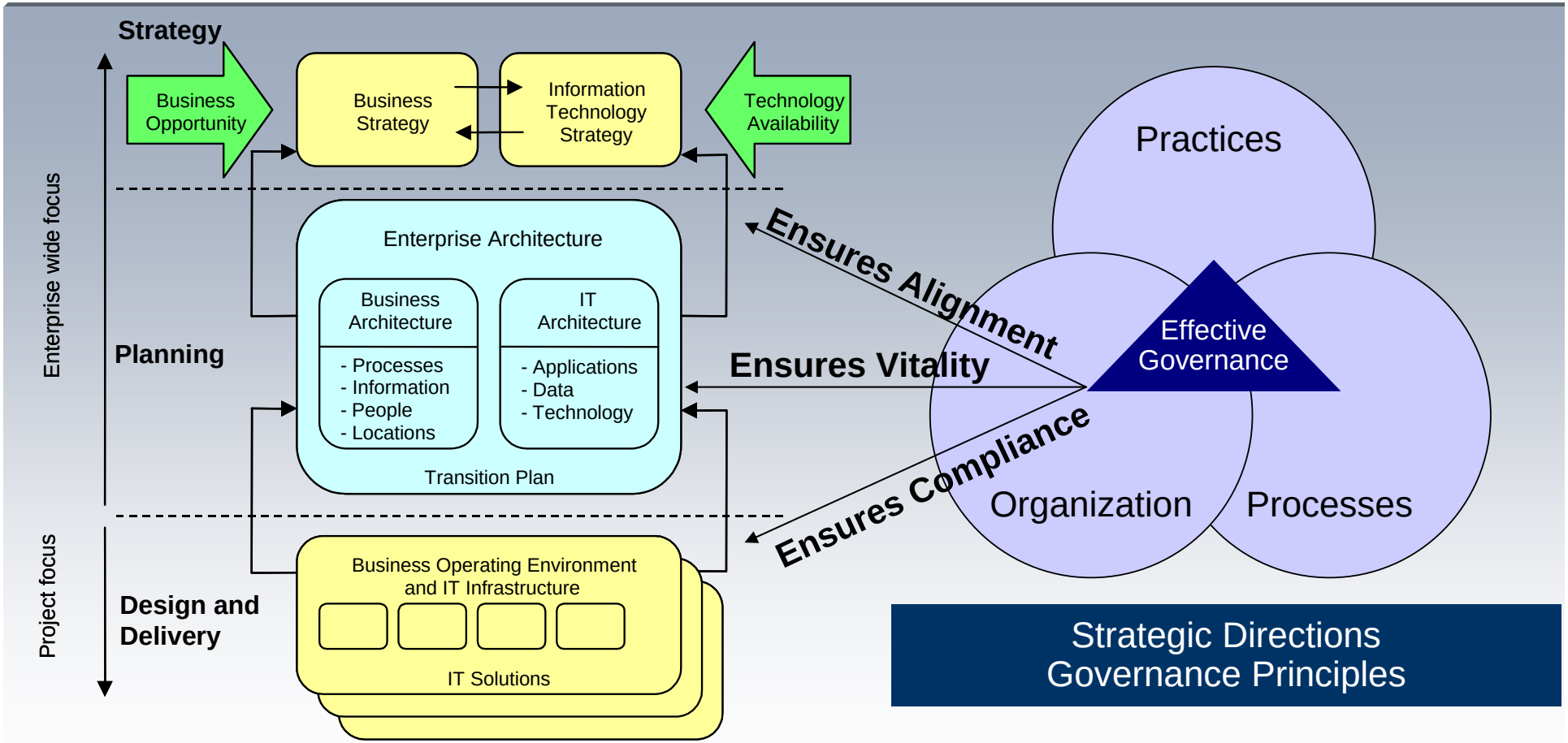
Enterprise Model

Application Architecture



Technical Architecture

Enterprise Architecture Governance Ensures IT Aligns with Business



- Elements of good governance
  - Good documentation
    - Well communicated standards
    - Principles
    - Solution patterns
    - Hardware and software diagrams
  - Strong allies and champions
    - Program and project offices
    - Policy decision makers
    - Purchasing department
    - Legal department
    - Architecture Domain Owners!
  - Solid Processes
    - Ownership
    - Accountability
    - Carrots and sticks

Enterprise Architecture' Frameworks that support objectives

THE Open GROUP
Making standards work™

METAGROUP Return On Intelligence™

Properties

- Customizability
- Correctness
- Compatibility
- Completeness
- Conciseness
- Ability to subset

Properties

- Deliverables
- Methods
- Techniques
- Standards and Practices
- Roles
- Paths

Services

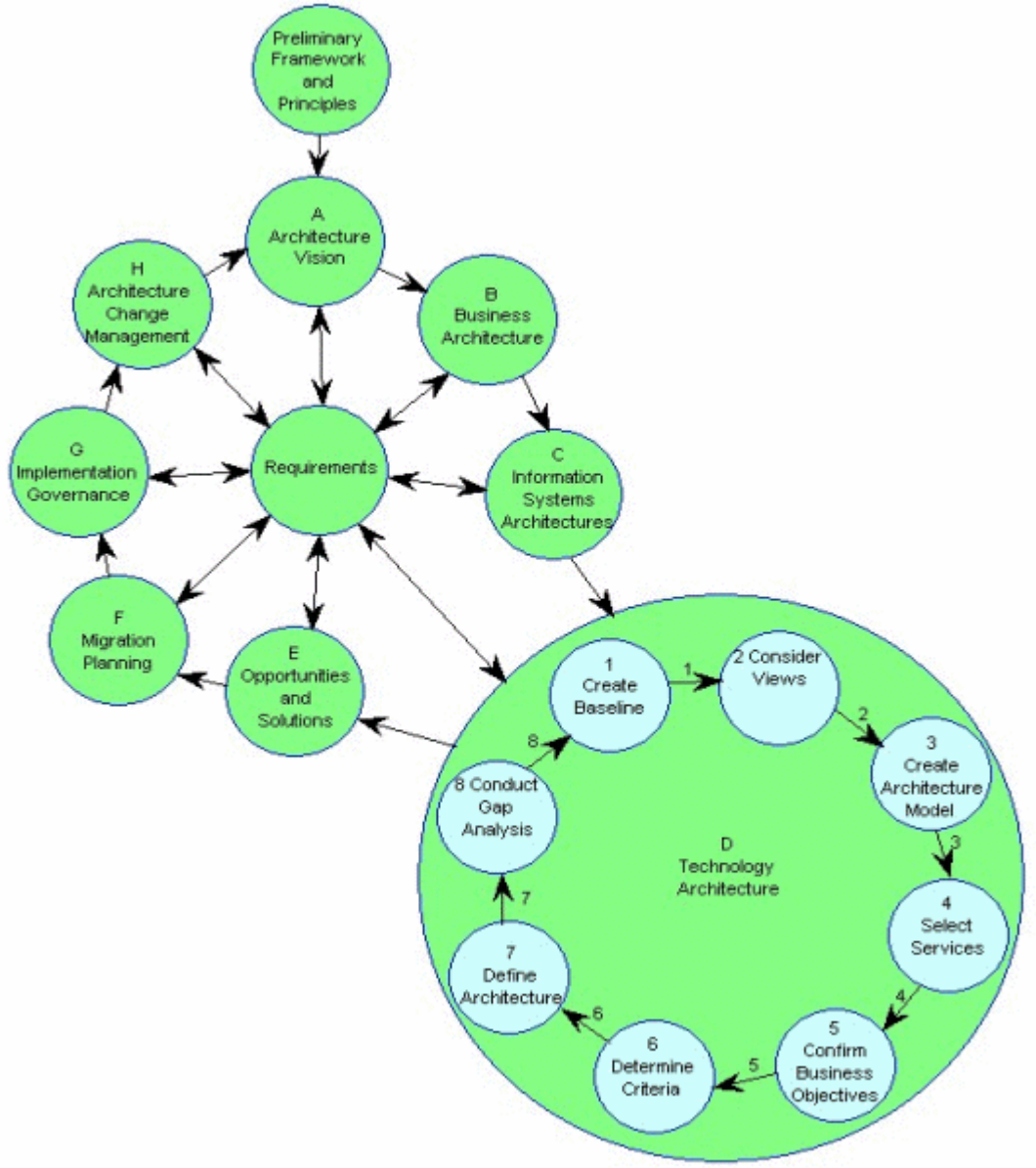
- Education
- Integration
- Demonstration
- Customization
- Implementation

FEAPMO

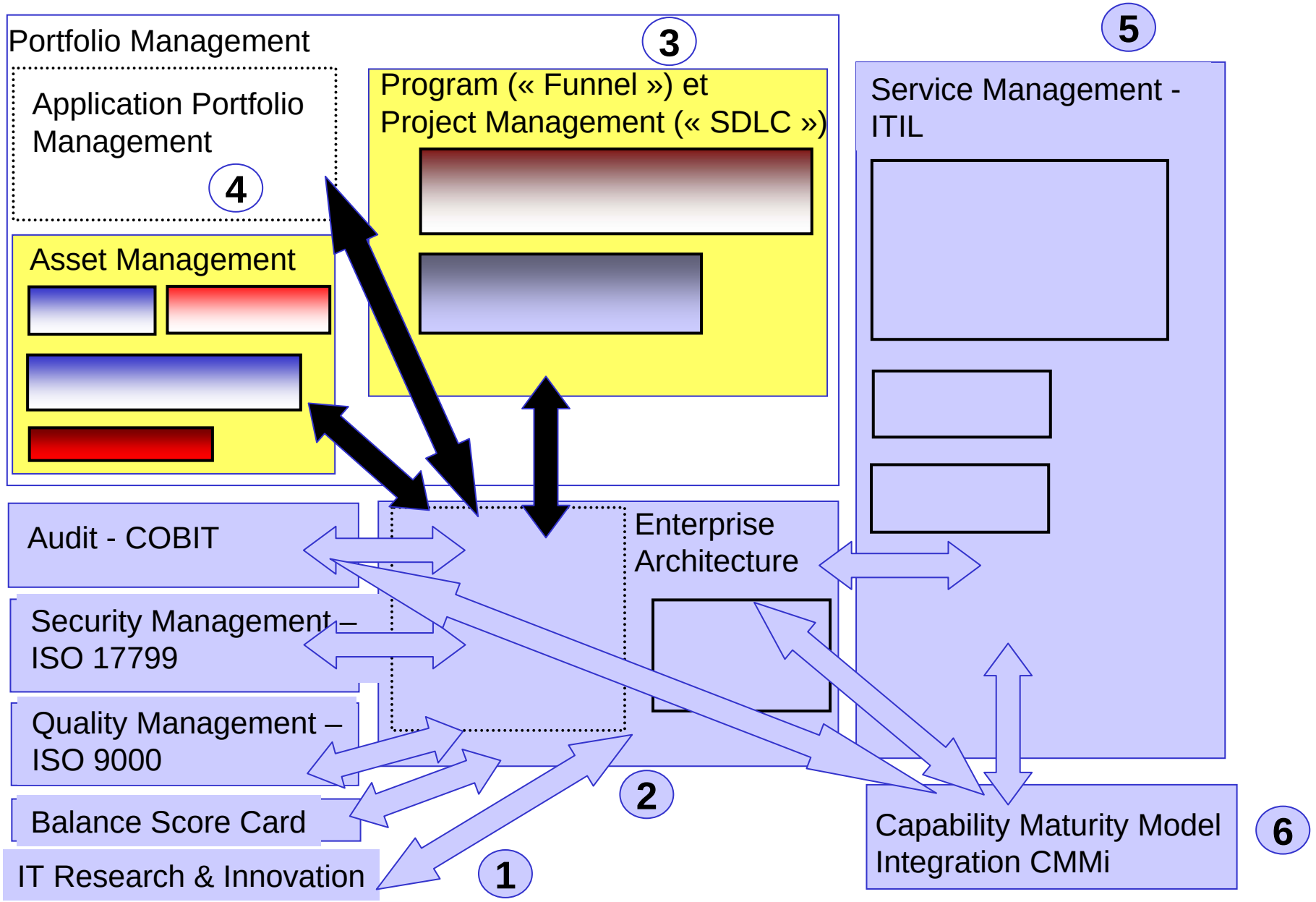
Methodologies and Frameworks: TOGAF 8.1

- Developed by the Open Group in 1995, The Open Group Architecture Framework (TOGAF) provides the most comprehensive methodology for producing architecture deliverables. With its most recent version (version 8), also known as TOGAF Enterprise Edition — TOGAF's Architecture Development Method (ADM) was quite substantially expanded beyond technology architecture to include *business architecture*, *information architecture*, and *application architecture*
- **Under evaluation**

Methodologies and Frameworks: TOGAF 8.1



Components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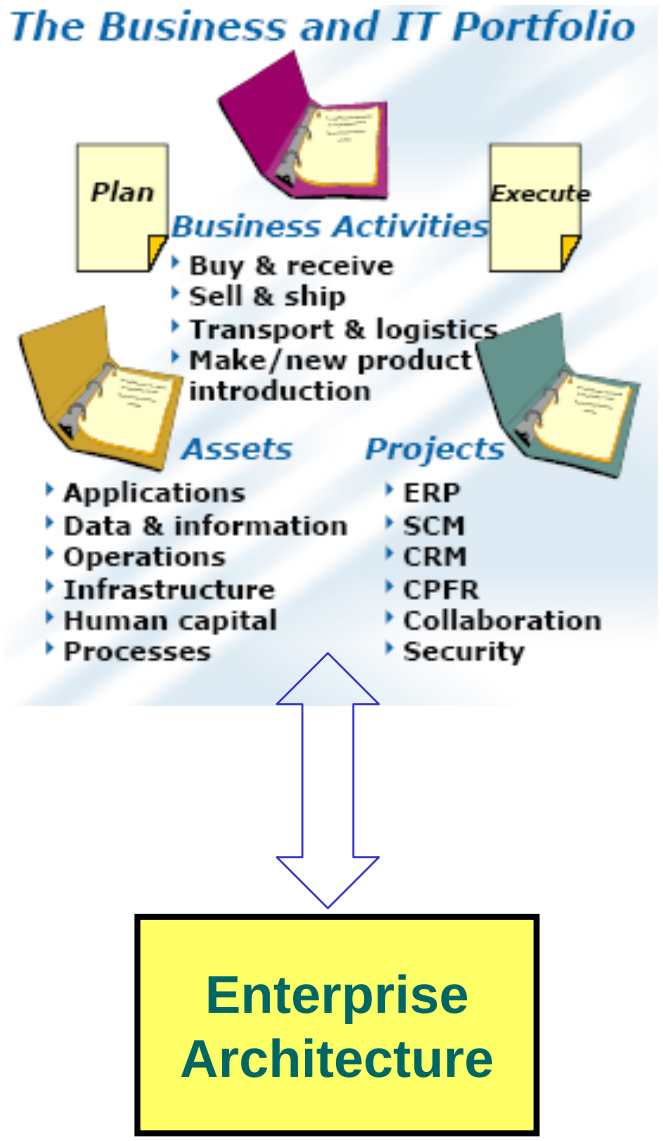
Portfolio management Process

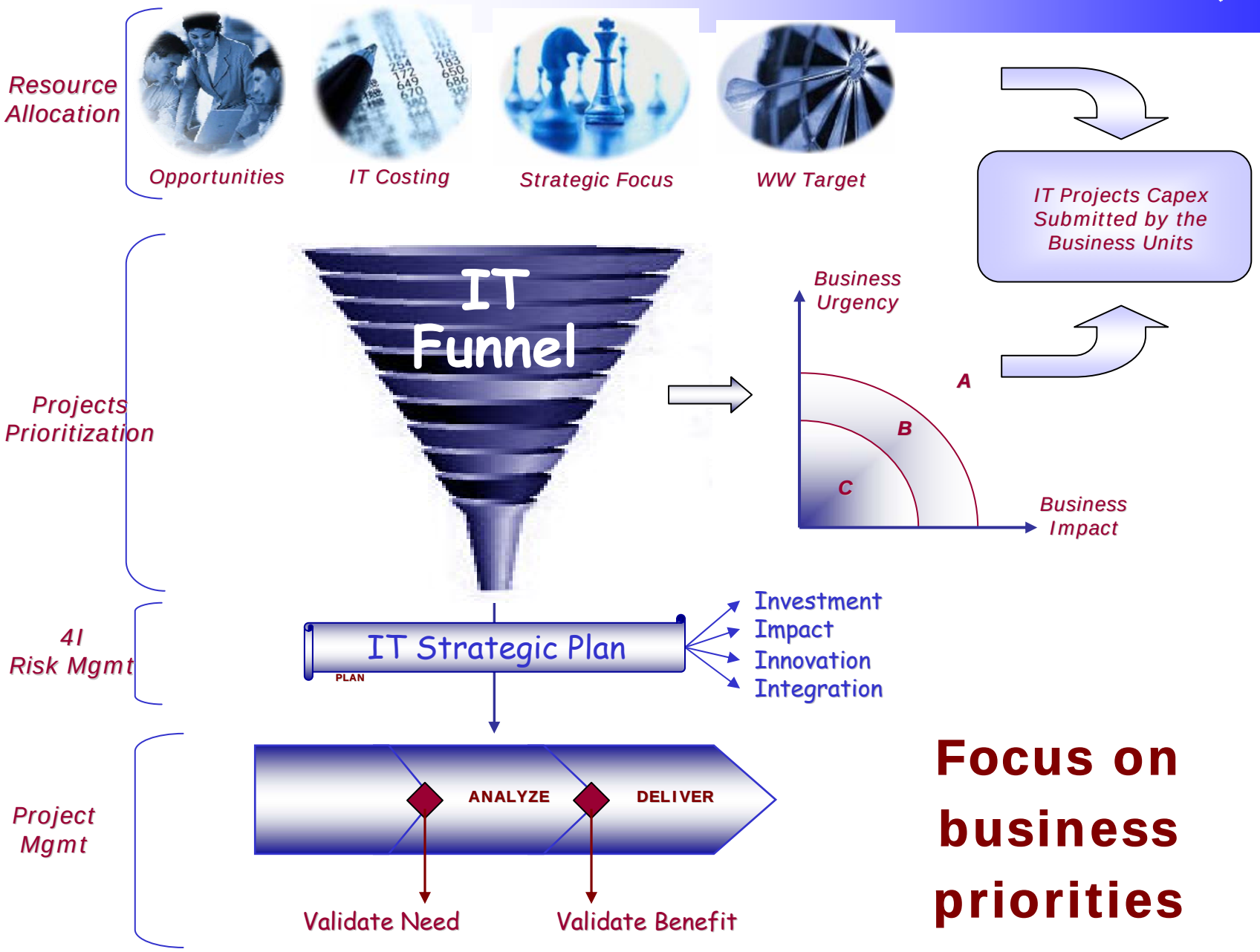
- The portfolio governance process starts when a business user requests or suggests a new capability.
- The request is automatically routed to a gatekeeper, then to a business analyst or team for an initial business case before being routed to the operations council and the architecture standards committee for review and scoring.
- The business team then evaluates the prioritized, ranked projects to determine the proper portfolio mix and whether to accept the recent request.

What is Portfolio management

- A categorization model
- A common language for business and IT to …
  - Support Business strategy
  - Organize investments
  - Evaluate and prioritize IT projects
  - Govern and manage applications portfolio
  - Decide when and how to make changes (opportunities)
  - Understand what can and can not be changed
  - Provide real-time visibility into resources, budgets, costs, programs, projects, and overall IT demand
- A hedge
  - “What if” scenarios enable us to analyze our portfolio and assess the business contribution of each proposal, project, or application to the entire portfolio
  - Triggers, Thresholds



Program Management: Process "Funnel"

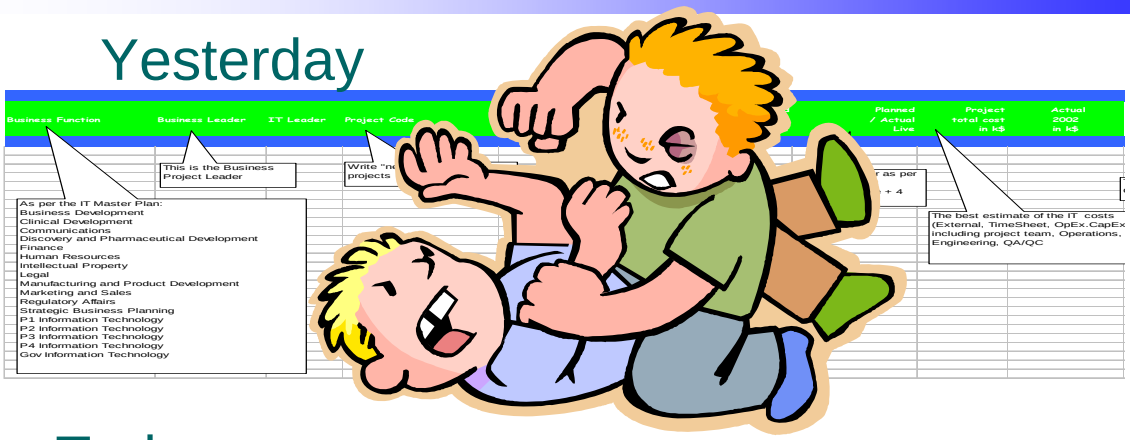


Focus on business priorities

Program Management: Governance Process "Funnel"

- Where are we in the process?
- Is all the information present
- Is the information up to date?
- Who is doing what with it?
- How do I compare the proposals?

Yesterday



Today

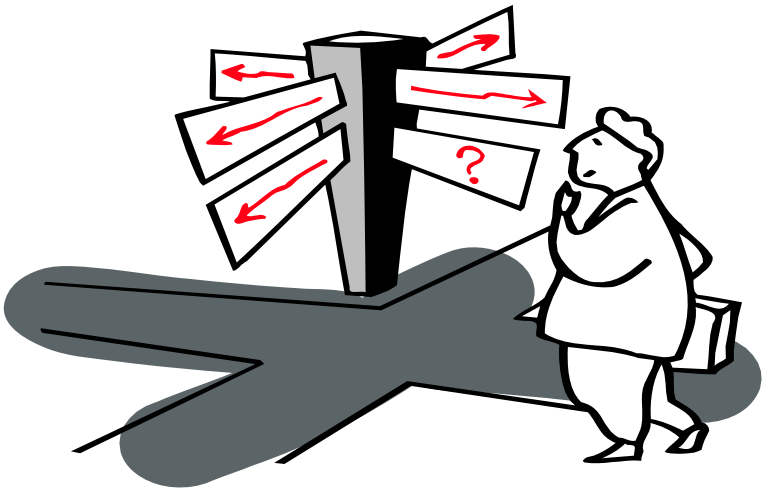
Status

Seq	Workflow Step Name	Step Status	Completed By	Date
1	Submit Proposal	Completed	Admin User	March 22, 2005 10:44:27 AM CST
2	First Review	Approved	Admin User	March 22, 2005 10:44:32 AM CST
3	Rework for First Review			
4	Capacity Analysis	Approved	Admin User	March 22, 2005 10:44:38 AM CST
5	Rework for Second Review			
6	IT Management Review	IT Management Review (View Available Actions)		March 22, 2005 10:44:38 AM CST
7	Rework for IT Management			
8	Validation by the Functions			
9	Finance Review			
10	Rework for Finance			
11	Create Project			
12	Proposal Closed (Approved)			
13	Project Request Rejected			

Expand Steps | Collapse Steps | Graphical View | Approval Details | Transaction Details | Cancel Request

Project Management: Process “SDLC”

- Where are we in the process?
- Is all the information present
- Is the information up to date?
- Who is doing what with it?
- Where is the bottleneck?
- Why can’t I see others Documents?
- Where do I go from here?
- What Document do I need now?
- What do you mean the process has changed again?

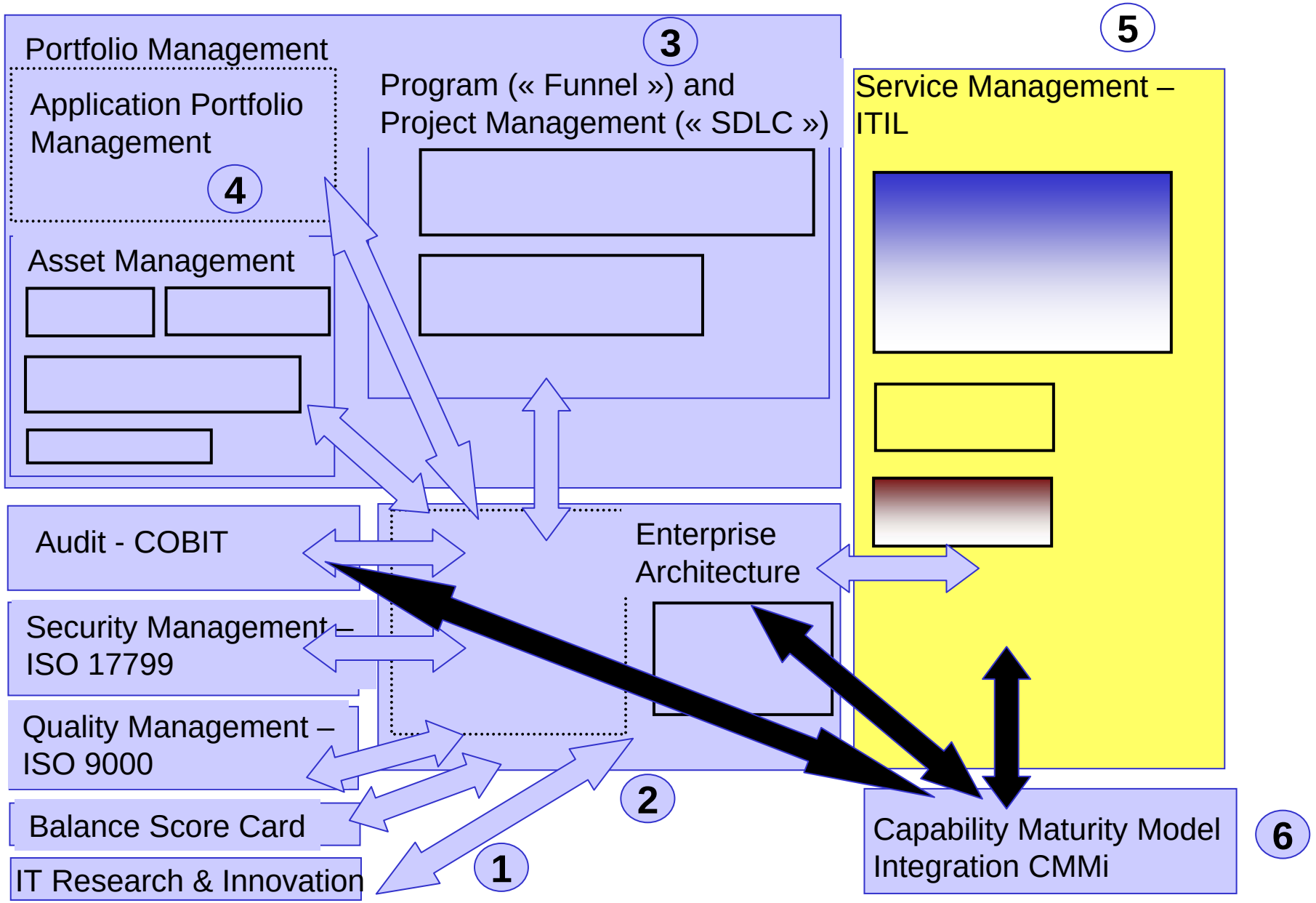


Status

Seq	Workflow Step Name	Step Status	Completed By	Date
1	Check Point 1.5	Completed	Admin User	March 22, 2005 10:02:39 AM CST
2	Check Point 1.5 Approvals	Check Point 1.5 Approvals (View Available Actions)		March 22, 2005 10:02:40 AM CST
3	Check Point 2			
4	Check Point 2 Approvals			
5	Check Point 3			
6	Check Point 3 Approvals			
7	Check Point 4			
8	Check Point 4 Approvals			
9	Check Point 5			
10	Check Point 5 Approvals			
11	End Of Life Project			
12	Create Asset			
13	Project Cancelled			
14	Project Completed			

Expand Steps | Collapse Steps | Graphical View | Approval Details | Transaction Details | Cancel Request

Components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Program (« Funnel ») and Project Management (« SDLC »)
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Service Management – ITIL
Asset Management
Audit - COBIT
Enterprise Architecture
Security Management – ISO 17799
Quality Management – ISO 9000
Balance Score Card
IT Research & Innovation
2
1
Capability Maturity Model Integration CMMi
6

Service Management: What is ITIL?

- ***Information Technology Infrastructure Library***
  - Result of years of analysis and research
  - Currently consists of 7 books providing guidance on the planning, delivery and management of quality IT services to support their business

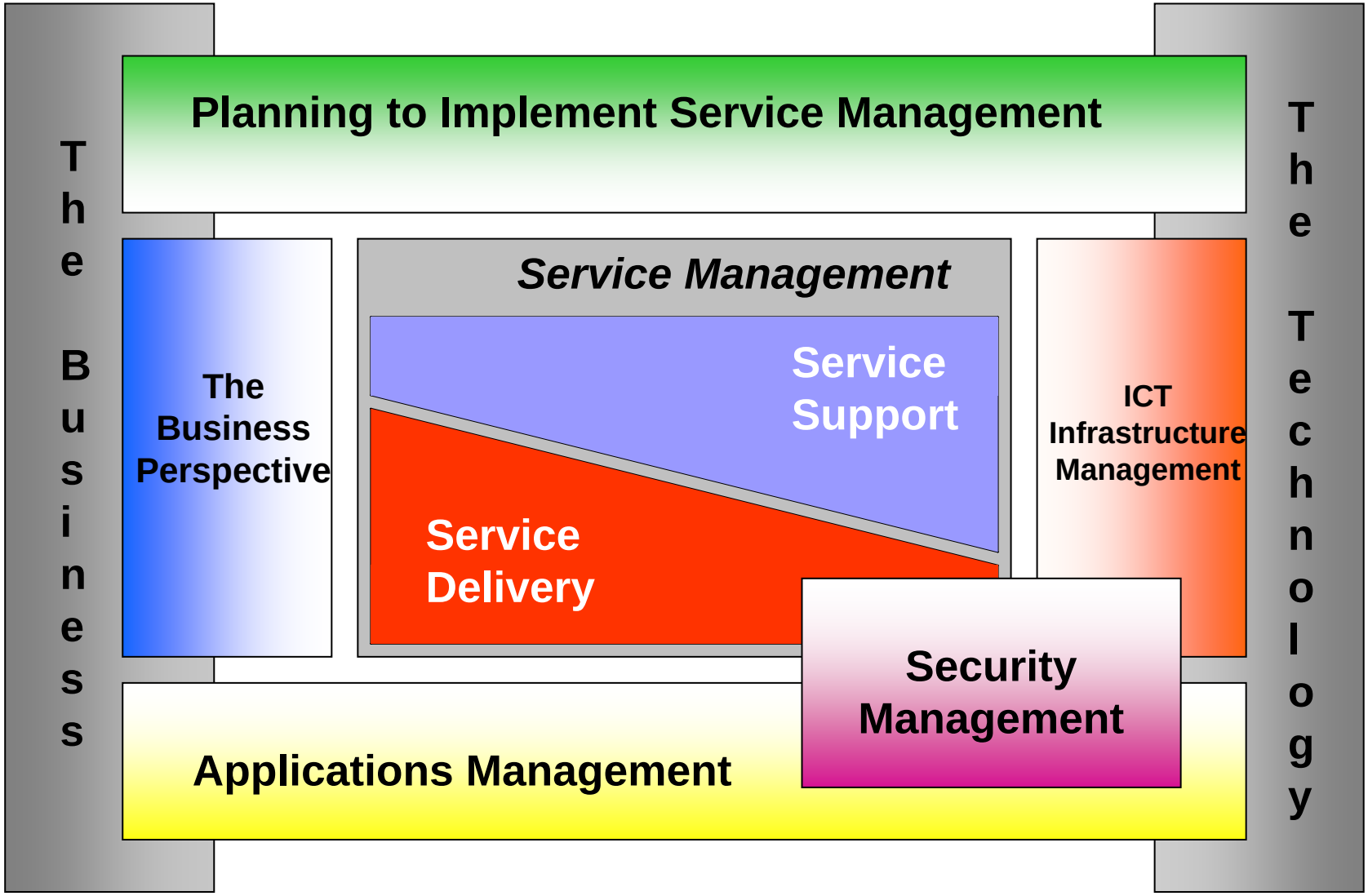
  - Contains codes of practice for quality management of IT services and infrastructure
  - Standardized Approach & Terminology
  - THE de facto global standard of IT Service Management best practices
  - An industry of products, services, and organizations

ITIL®'s Origin and History

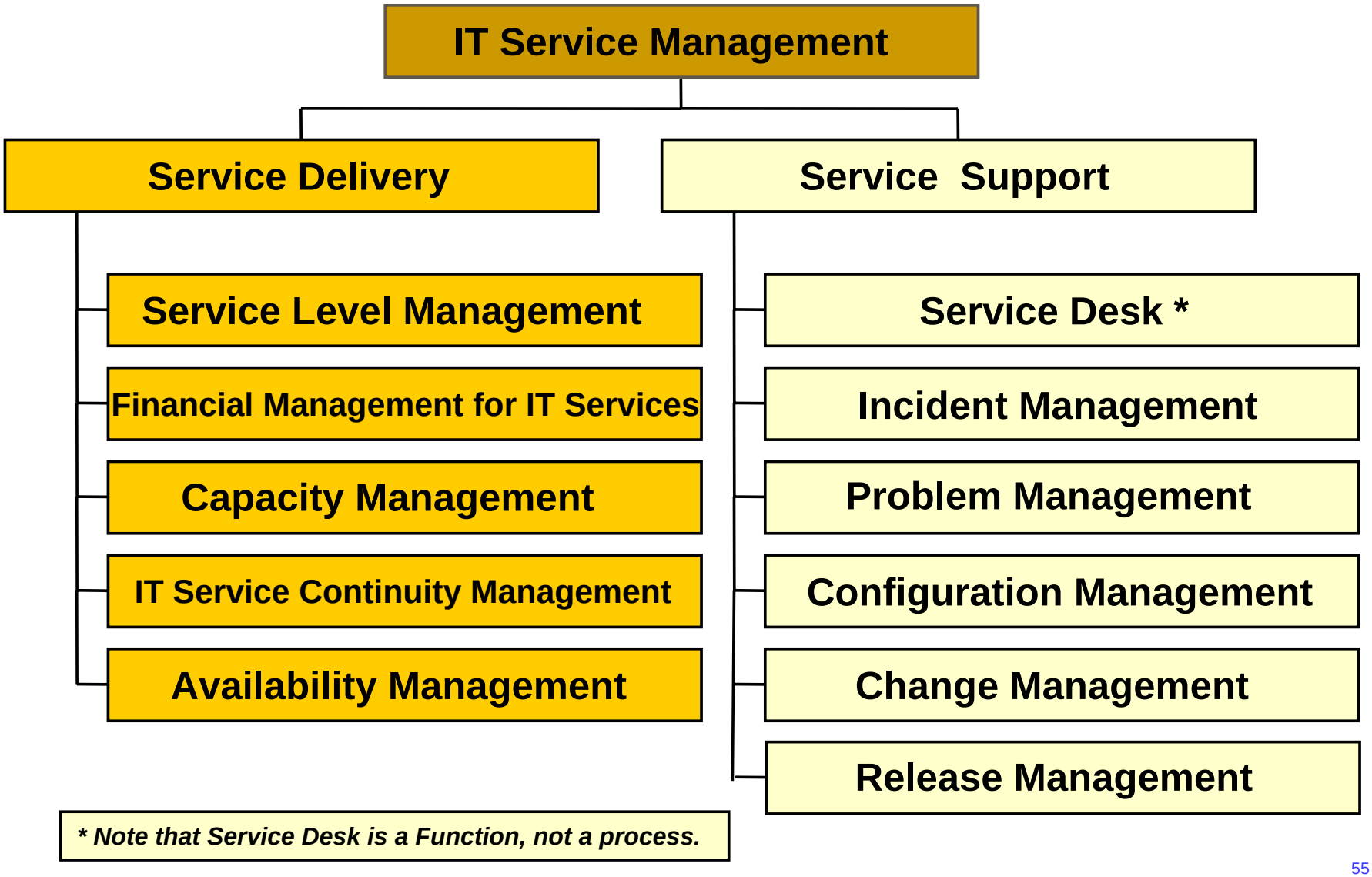
- Developed by the United Kingdom's Office of Government Commerce (OGC) in the 1980's*
- Intended to improve management of IT services in the UK Central Government
- Contributed to by expert IT practitioners around the world

*Known then as the Central Computer and Telecommunications Agency (CCTA)

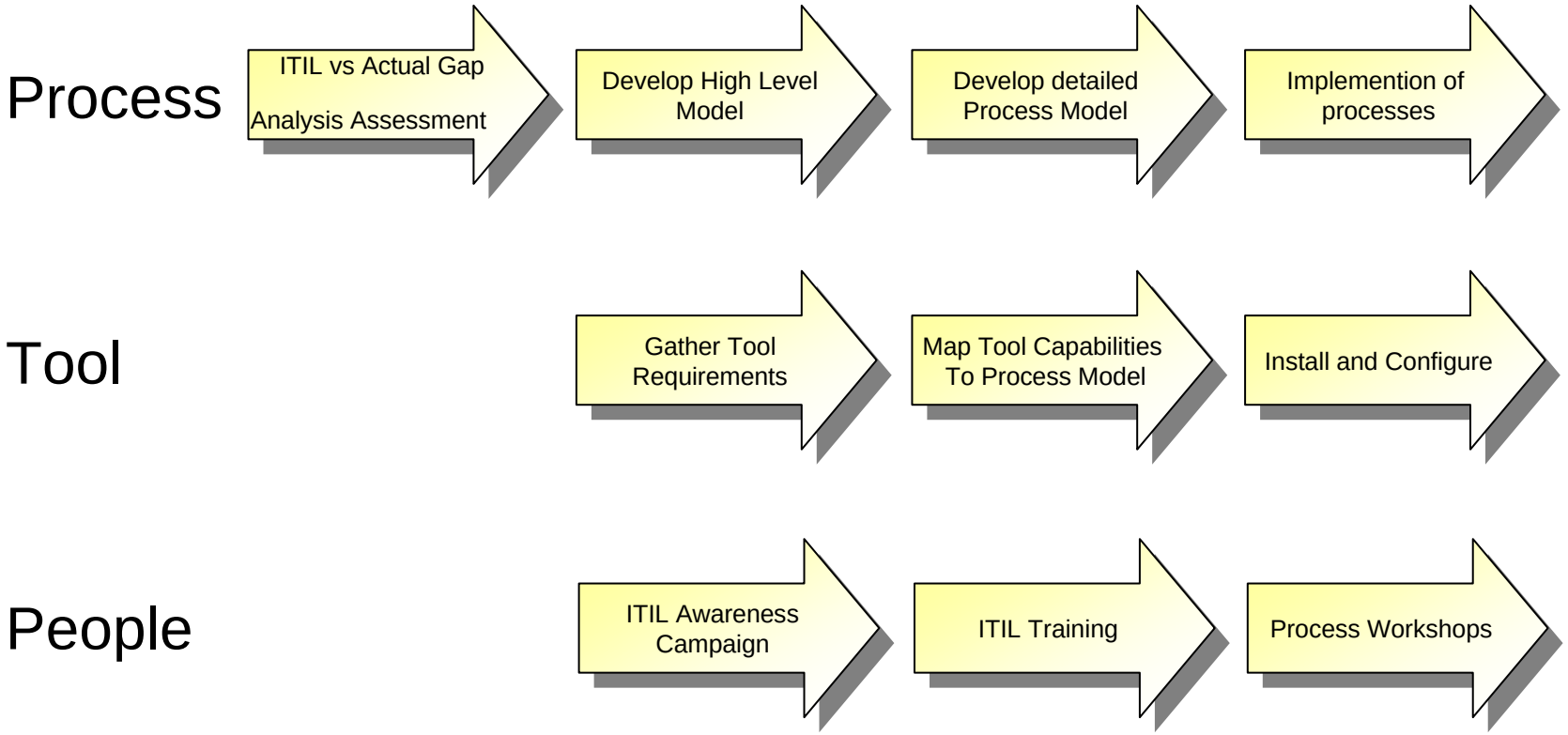
ITIL (Publications map)



Service Management : Core ITIL IT Service Management Disciplines



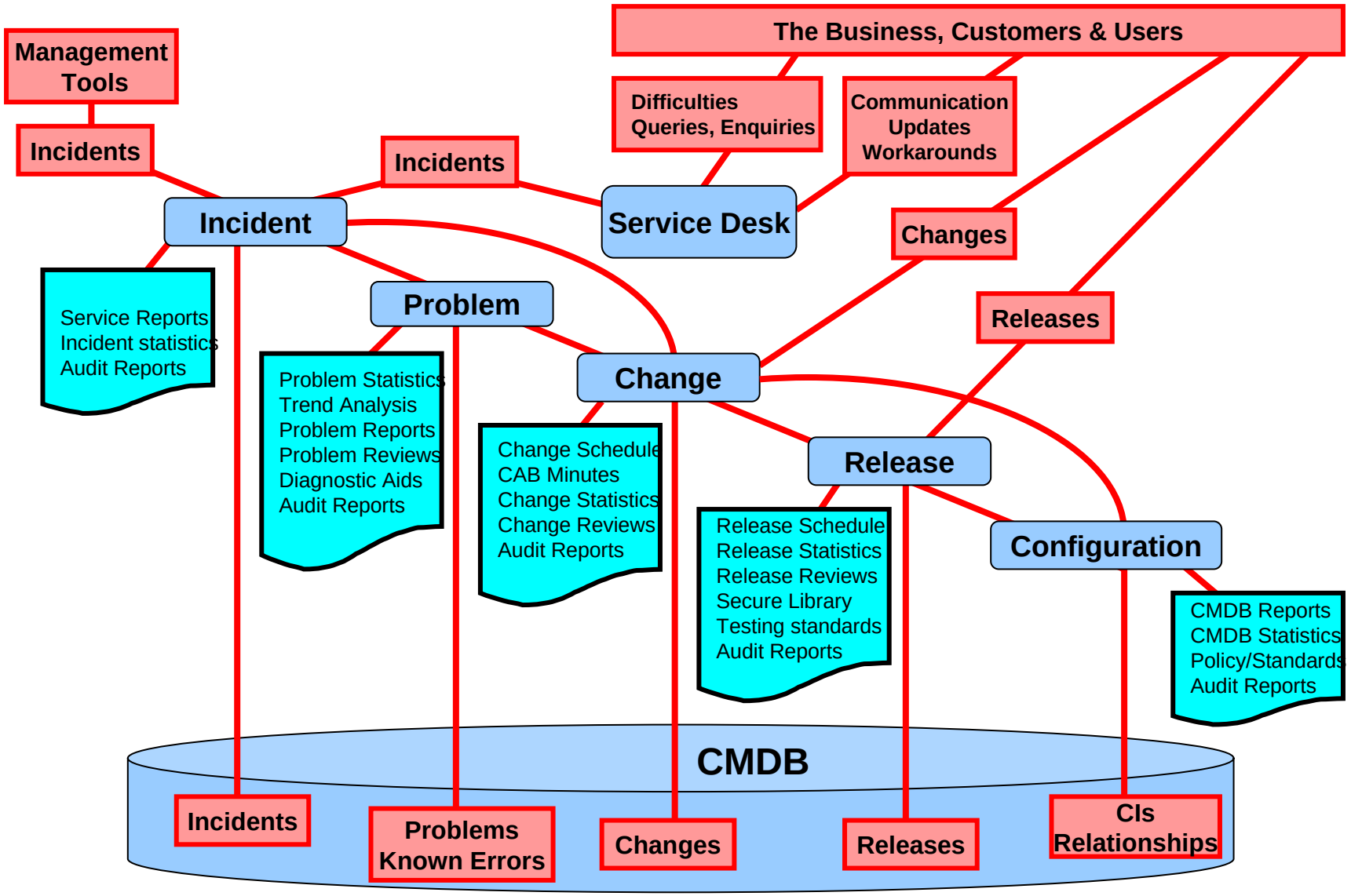
Service Management : Project Approach
It all starts with Process



Systems Versus Services Management

- Systems Management
  - Isolated systems
  - Technology and asset focused
  - Systems monitoring
  - IT perspective
- Service Management
  - Service as experienced and/or consumed
  - Technology transparent to customer
  - From customer perspective

Service Support Process Model



Service Delivery Process Model

The Business, Customers & Users

Queries
Enquiries

Communication
Updates
Reports

SLA's, OLA's, SLR's
Service requests
Service catalogue
SIP
Exception reports
Audit reports

Service Level Management

Requirements
Targets
Achievements

Availability Management

Availability Plan
AMDB
Design Criteria
Targets/Thresholds
Reports
Audit Reports

Capacity Management

Capacity Plan
CDB
Targets/Thresholds
Capacity Reports
Schedule
Audit Reports

IT Financial management

Financial Plans
Types & Models
Costs & Charges
Reports
Budgets & Forecasts
Audit Reports

IT Service Continuity

IT Continuity Plans
BIA & Risk Analysis
Define Requirements
Control Centers
DR Contacts
Reports
Audit Reports

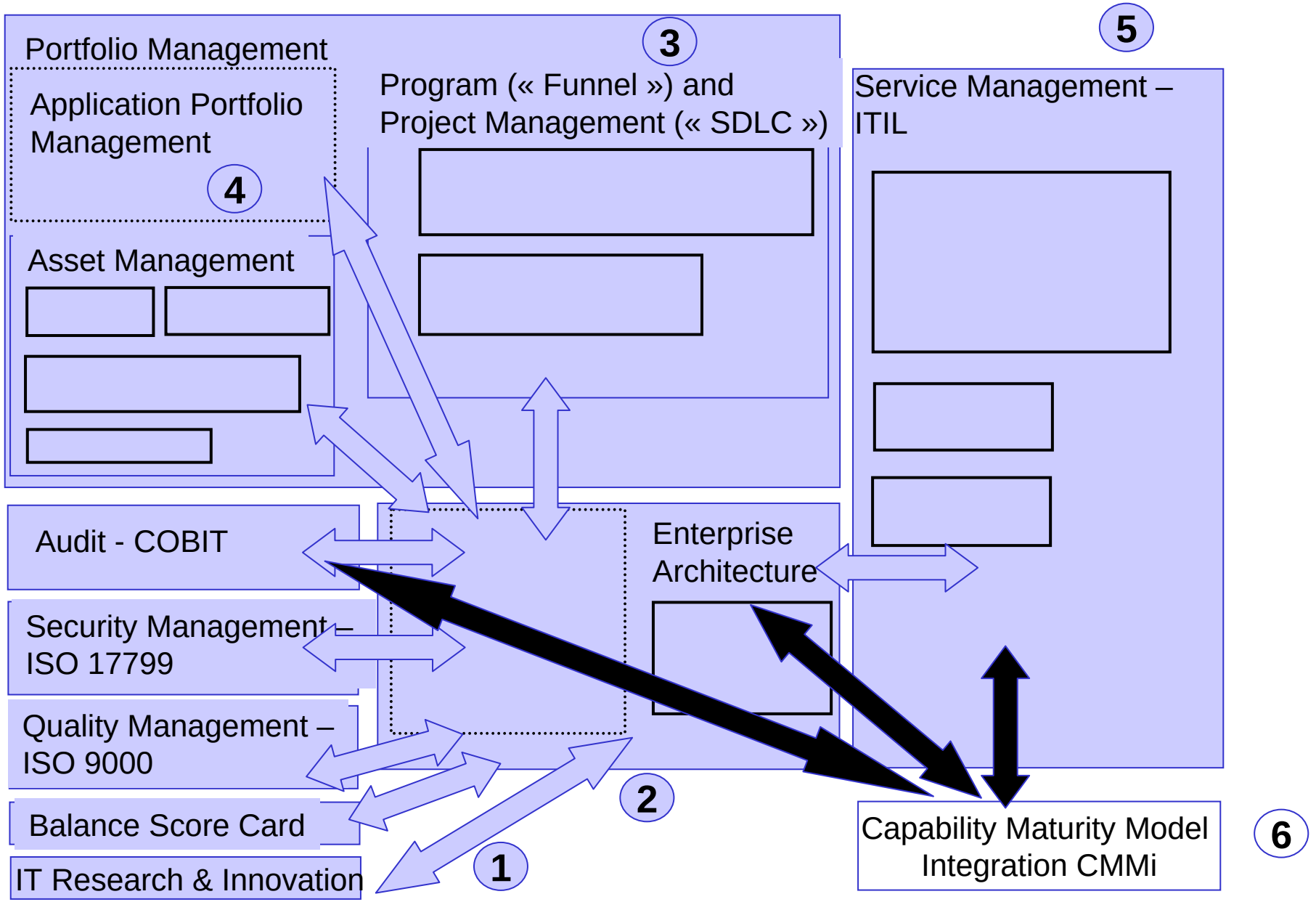
Management Tools

Alerts, Exceptions, Changes

Why use ITIL?

- IT service providers use ITIL concepts and practices to:
  - Increase satisfaction of customers with IT services
  - Enhance communication with customers
  - Achieve higher reliability in mission-critical systems and infrastructure
  - Improve the cost/benefit of services
  - Create a “common sense” among staff

Components


Portfolio Management
3
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Application Portfolio Management
4
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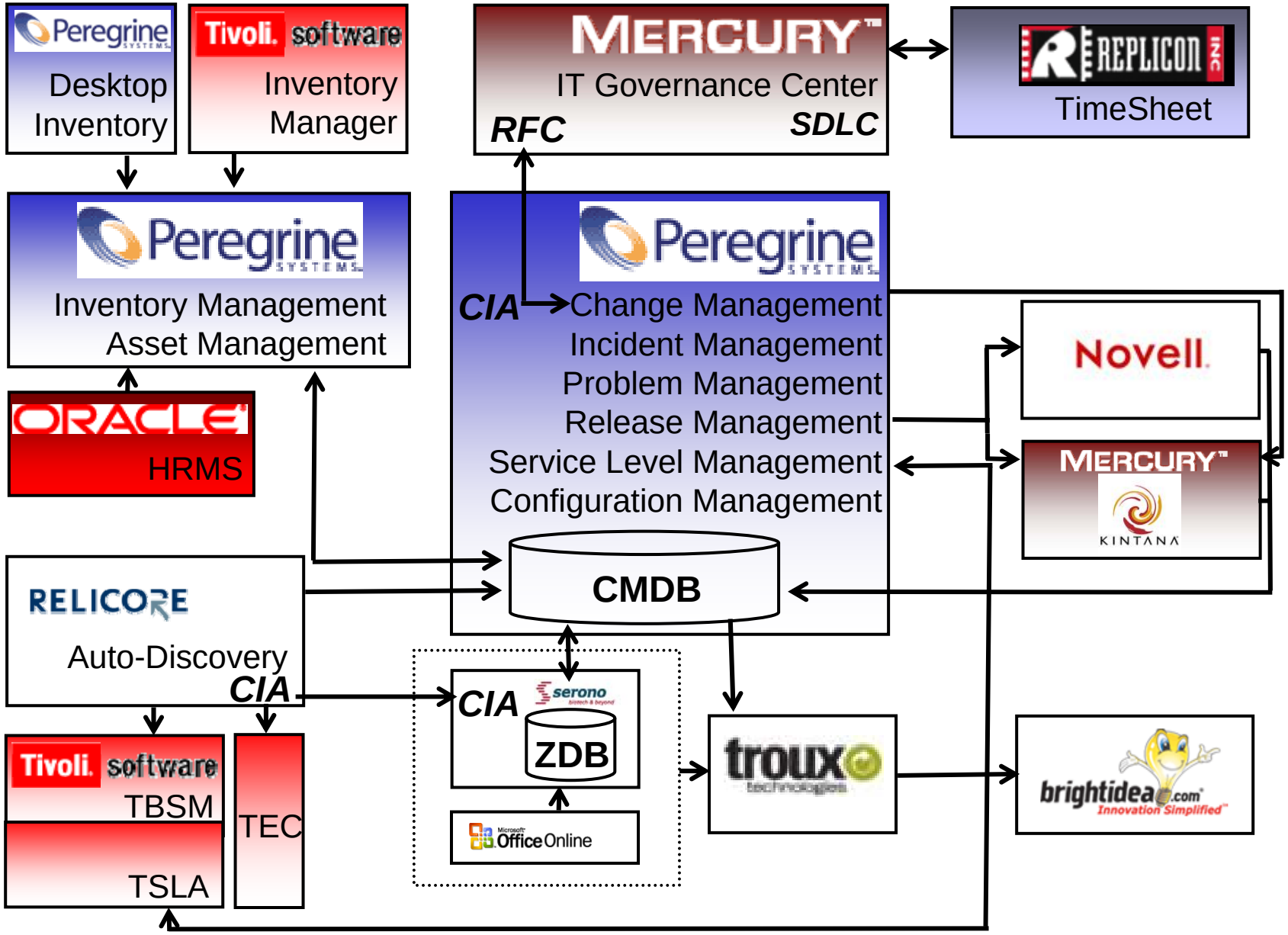
Tools...


Peregrine
Desktop Inventory
Tivoli. software
Inventory Manager
MERCURY
IT Governance Center
RFC
SDLC
REPLICON INC
TimeSheet
Peregrine
Inventory Management
Asset Management
ORACLE
HRMS
Peregrine
CIA
Change Management
Incident Management
Problem Management
Release Management
Service Level Management
Configuration Management
Novell.
MERCURY
KINTANA
RELICORE
Auto-Discovery
CIA
CMDB
CIA
serono
ZDB
Microsoft Office Online
Tivoli. software
TBSM
TSLA
TEC
troux technologies
brightidea.com
Innovation Simplified

Conclusions

- IT Governance at Serono encompass many disciplines within the organization including IT Strategy, Risk Management, IT Service Management and Compliance Management to name but a few
- Understandably this presents a significant challenge for companies seeking to identify a starting point for their IT Governance initiative
- Fortunately best practice governance guidelines and procedures do exist within the industry
- Firms, moving ahead with the adoption of a standard will be well served to utilized a phased implementation project approach and start with elements of the standard that will yield their organization the most benefits.
  - Optimized IT strategy and execution
  - Improve resource utilization
  - Improve planning and resourcing
  - Risk assessment
  - Real-time management reporting (monitoring and control)

Questions?

धन्यवाद
Hindi

多謝
Traditional Chinese

ขอบคุณ
Thai

Спасибо
Russian

Gracias
Spanish

Thank You

شكراً
Arabic

Obrigado
Brazilian Portuguese

Danke
German

Grazie
Italian

多谢
Simplified Chinese

Merci
French

நன்றி
Tamil

감사합니다
Korean

ありがとうございました
Japanese

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Questions

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