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Using Project Management Information Systems (PMIS) To Improve R&D Portfolio Decisions

Martin D. Hynes III, Ph.D.
Director, Operations & Quality,
Pharmaceutical Product Research & Development

Lilly Research Laboratories
A Division of Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285 U.S.A.
www.lilly.com



Answers That Matter.

Agenda

- I. Introduction**
- II. Integrated Business Process for Portfolio and Project Management**
- III. Portfolio Management**
- IV. Project Management**
- V. Capacity Management**
- VI. Financial Management**
- VII. Conclusion**

I. Introduction



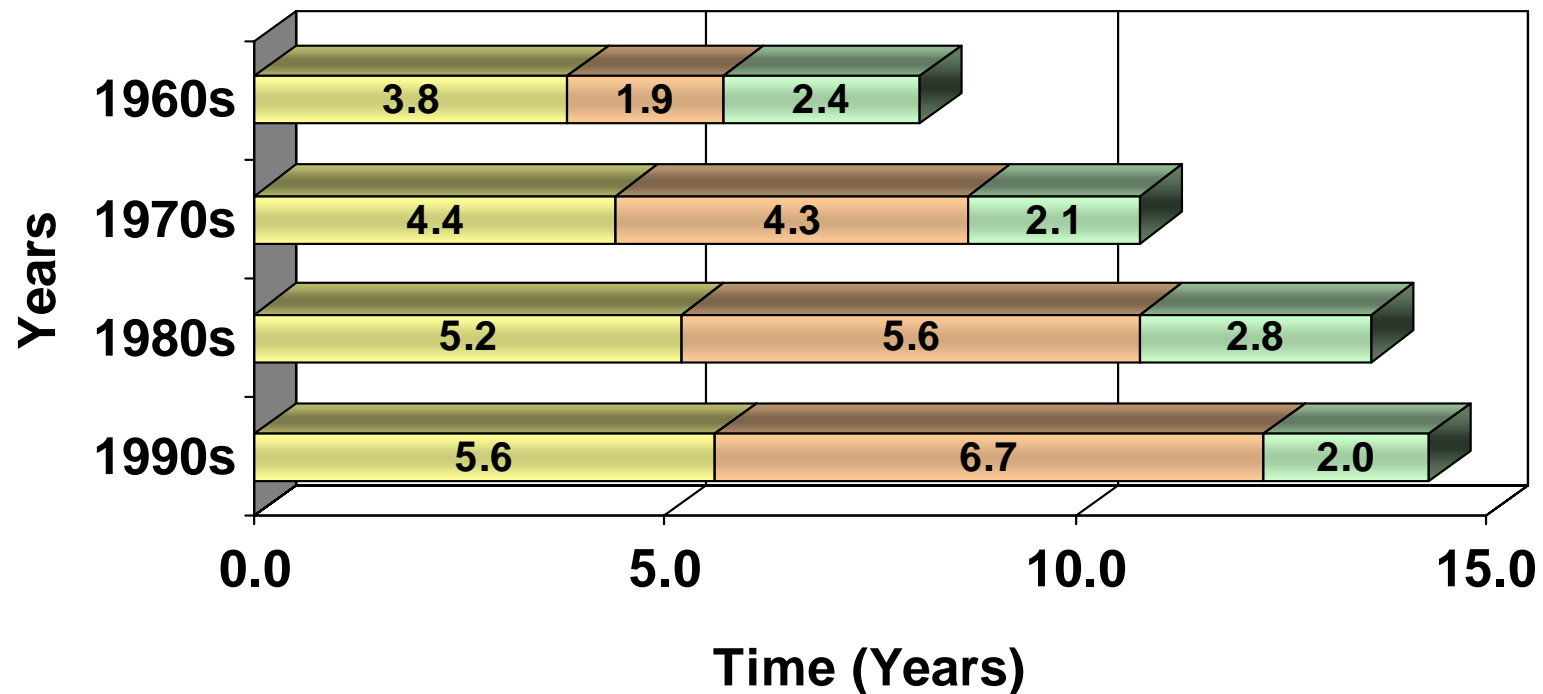
The Challenges of Drug Development

We Are Confronted With

- **Increasing**
 - ▶ **Development time**
 - ▶ **Costs**
- **Low probability of technical success**
- **Hostile political environment**
- **Global development organizations**
- **Unmet medical needs**

Drug Development Cycle Time

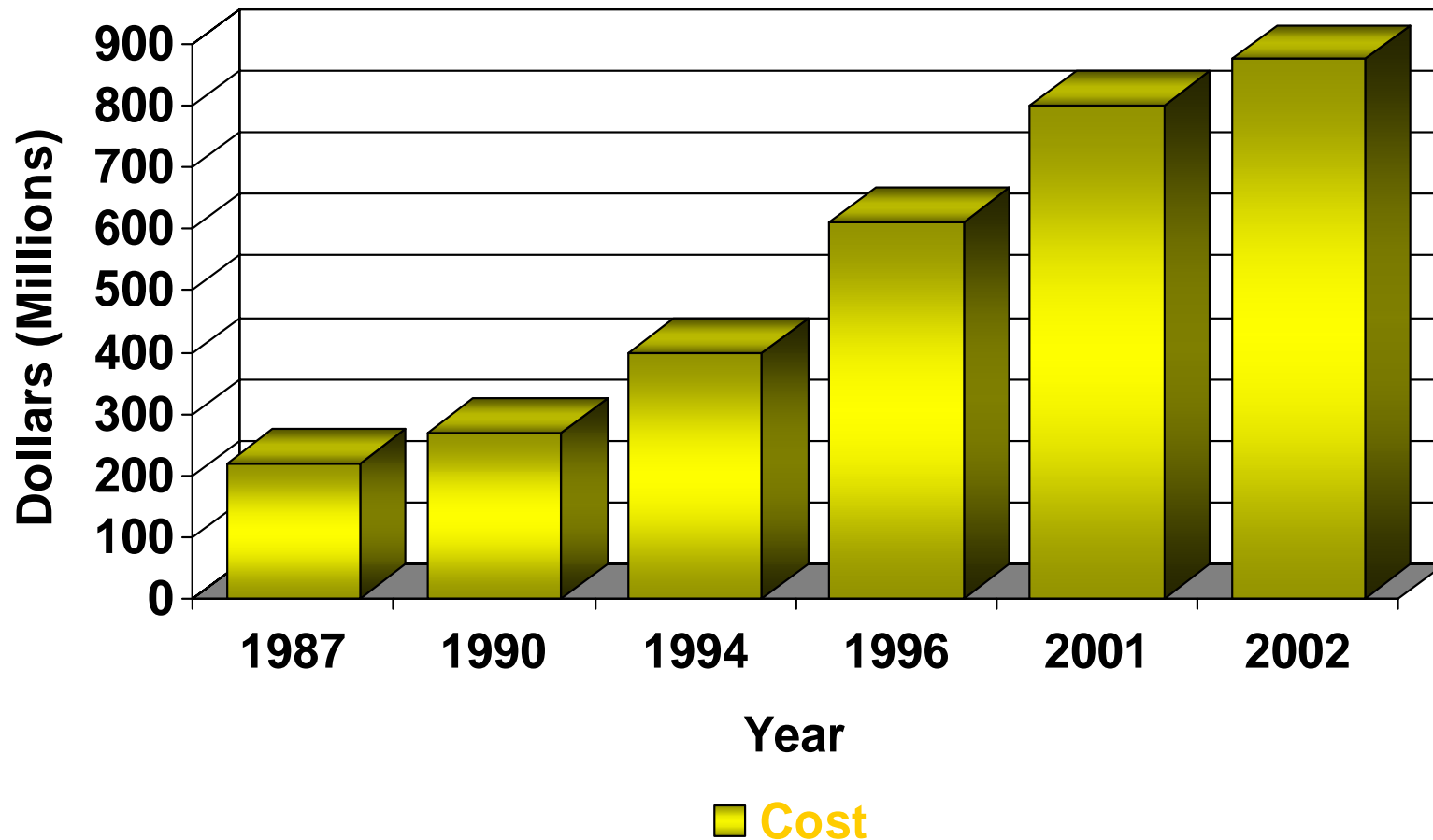
Time from First Pharmacological Testing to New Drug Approval, 1963 - 1997



■ 1st Pharm Testing to IND File ■ IND File to NDA Subm ■ NDA Subm to Approval

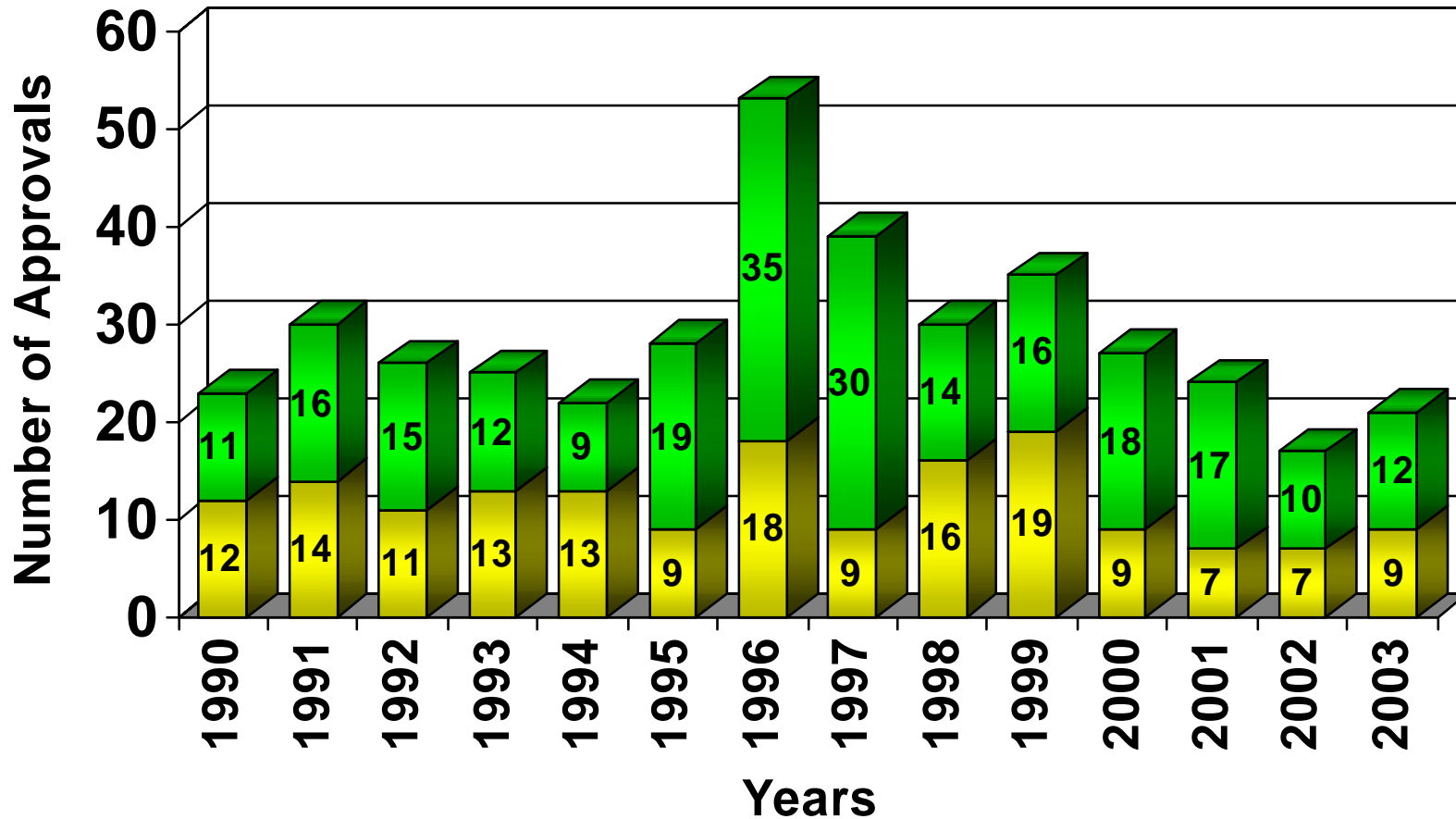
Source: Parexel's Pharmaceutical R&D Statistical Sourcebook, 2002/2003

Rising Cost of New Drug Development



Represents a 250% increase from 1987 – 2002!

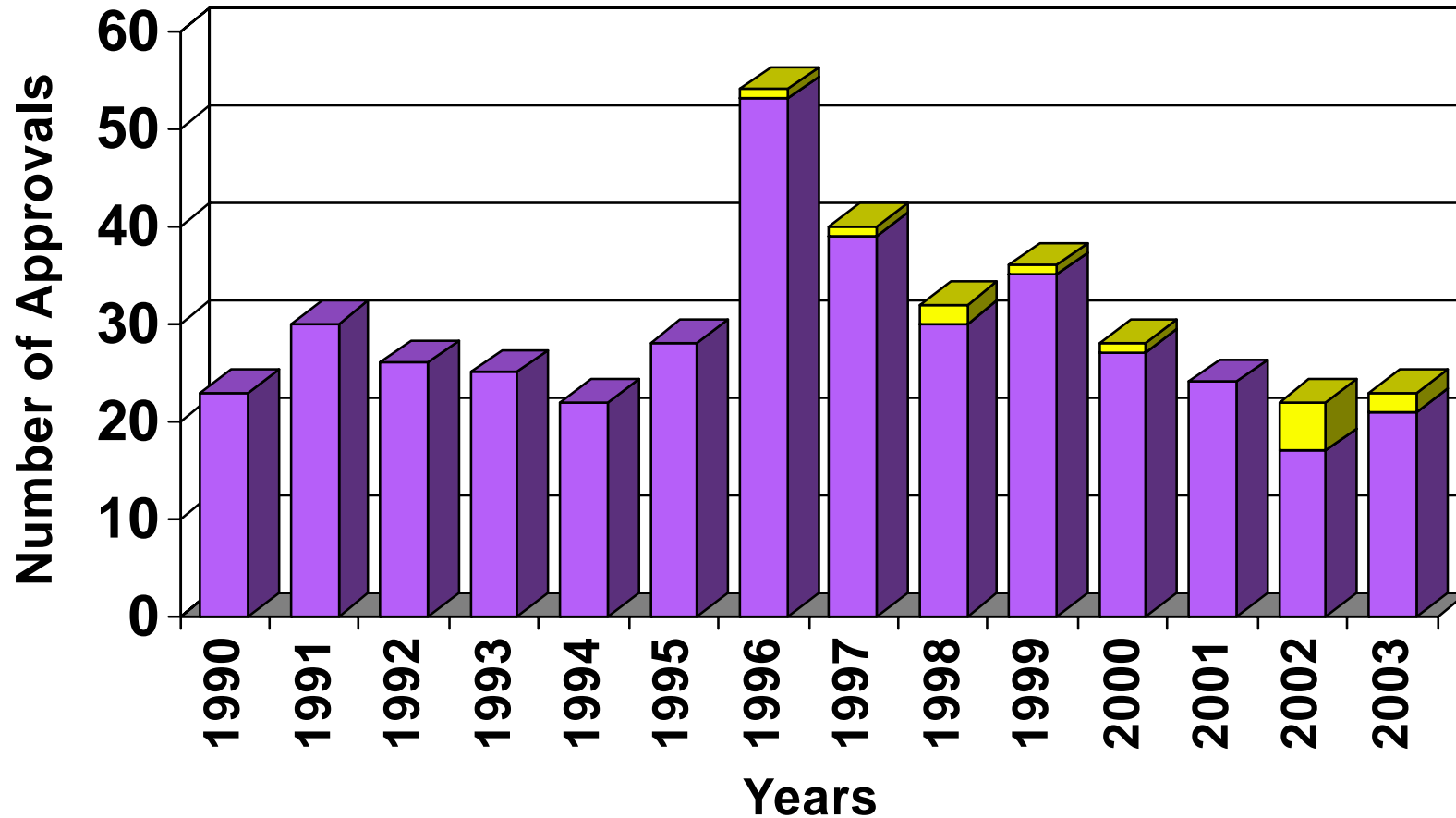
NMEs Approved 1990 - 2003



■ Priority Review ■ Standard Review

www.FDA.gov

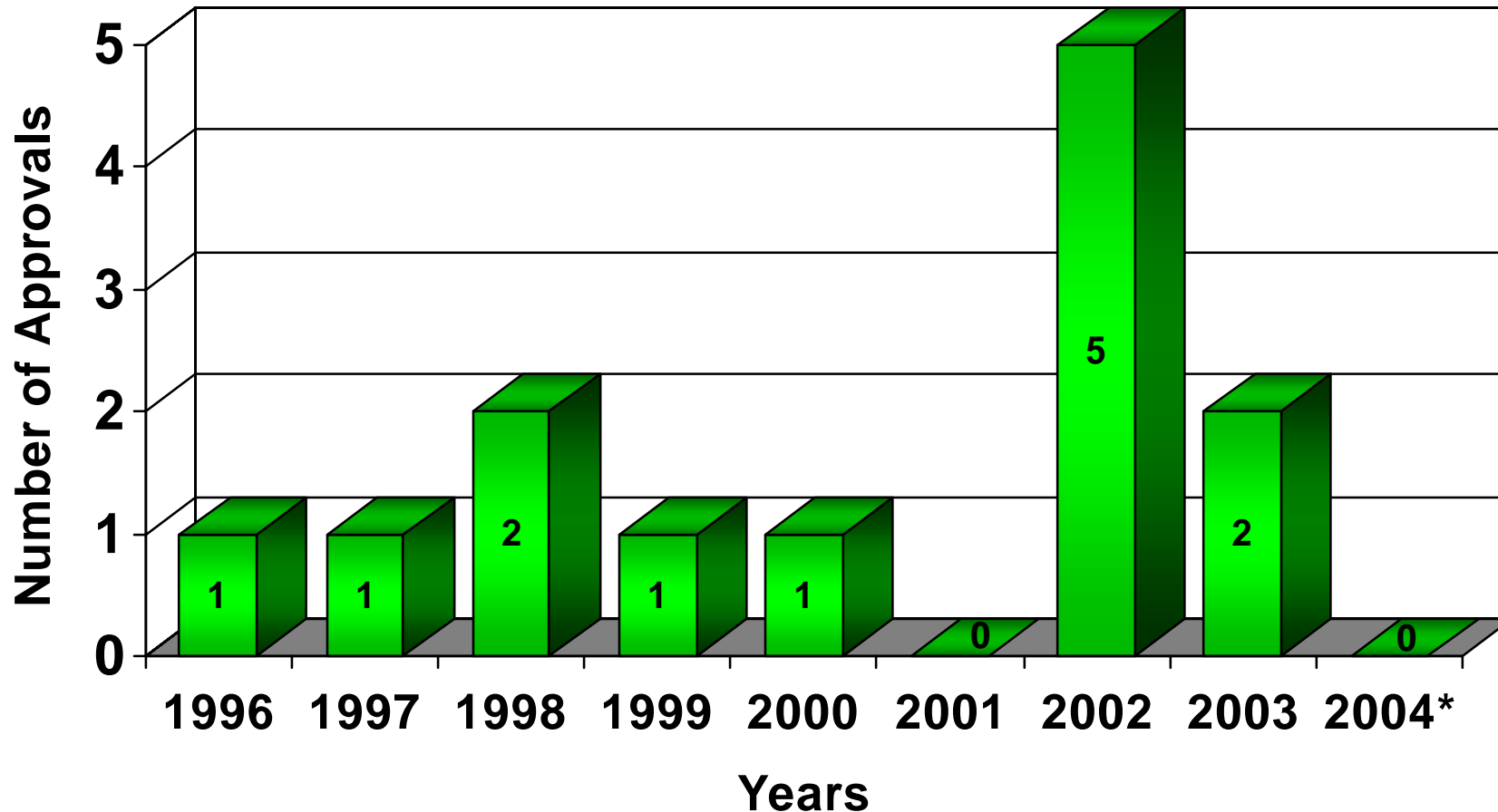
NMEs and BLAs Approved 1990 - 2003



■ New Molecular Entities ■ Biologics License Application

www.FDA.gov

Biologics License Applications (BLA) Approved 1996 - 2004



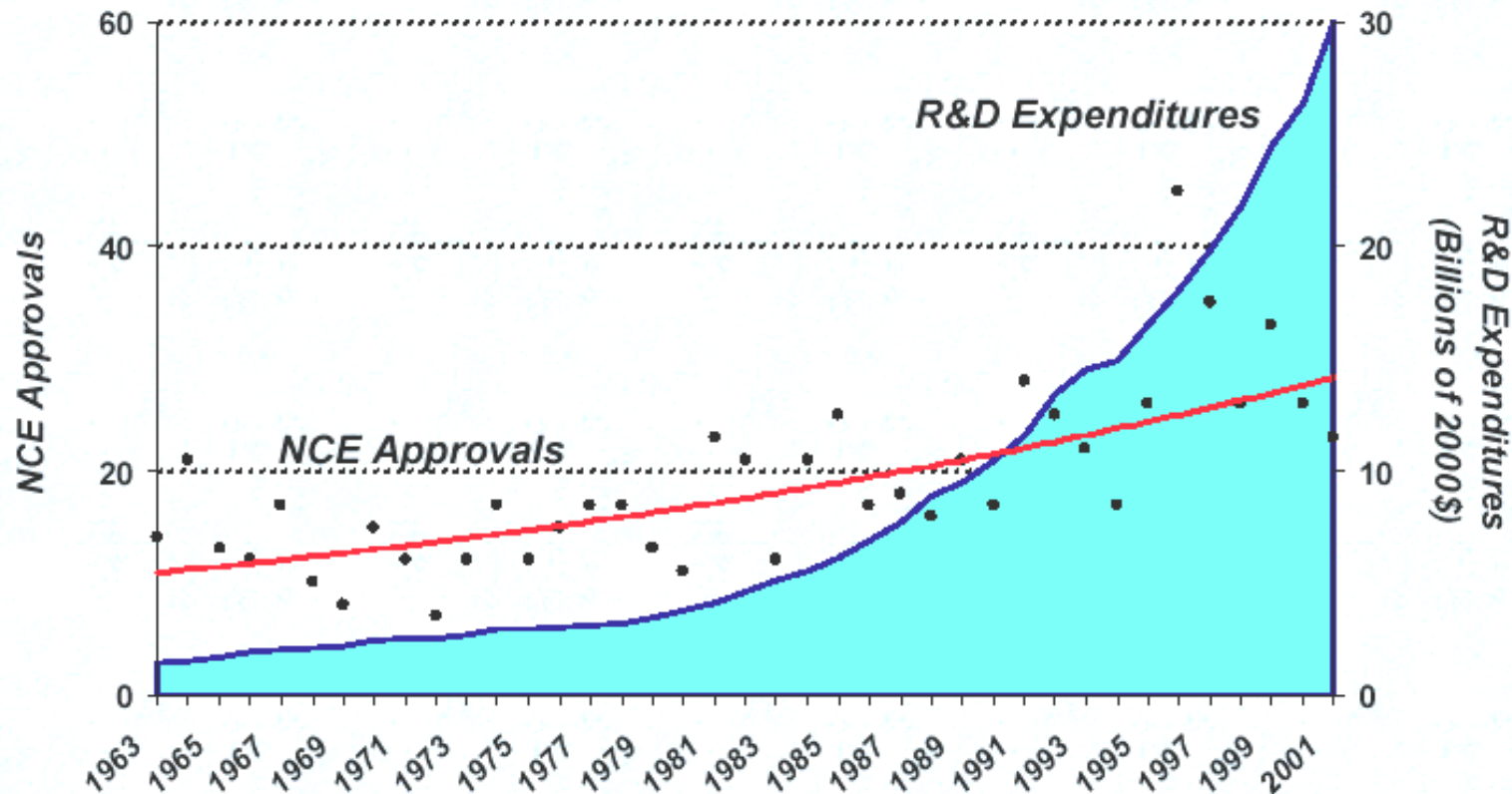
■ Approvals

* As of April 2004

www.FDA.gov

U.S. Pharmaceutical Industry

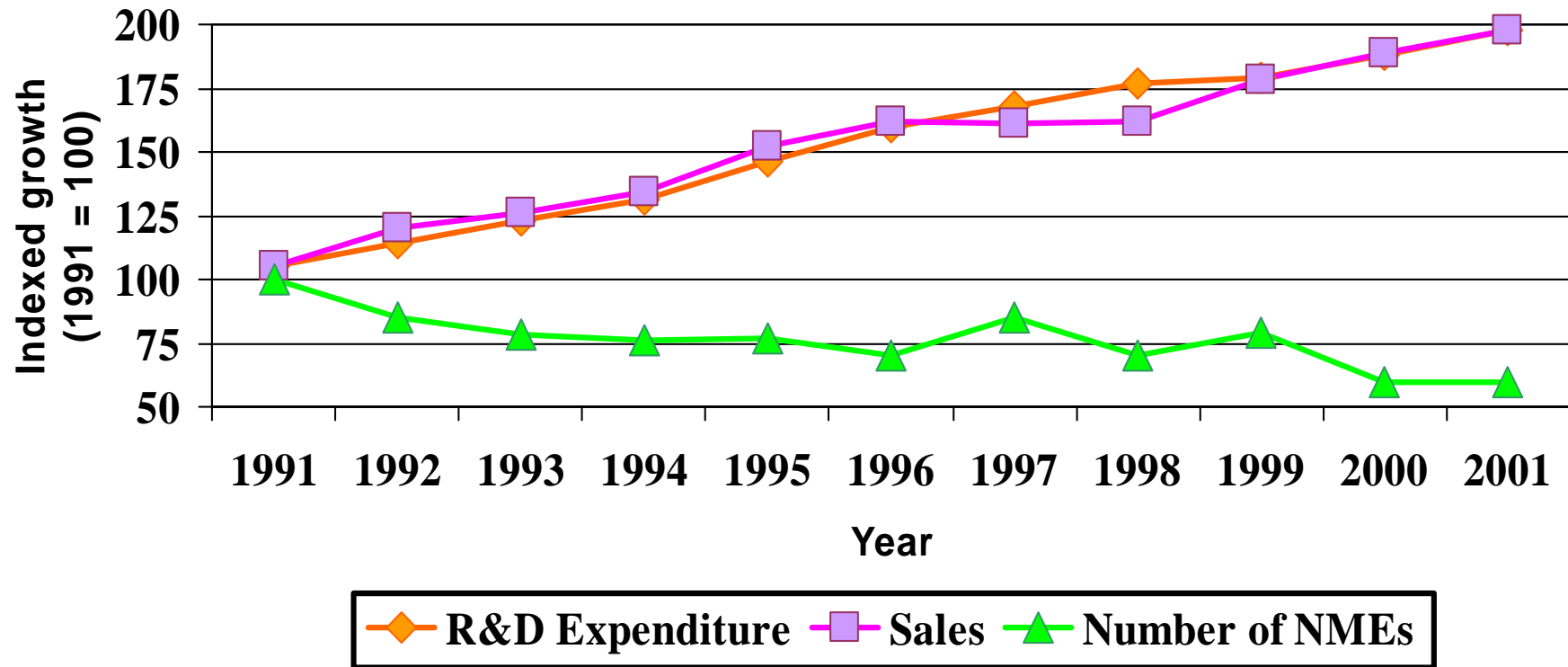
Adjusted R&D Expenditures and NCE Approvals, 1963-2001



Source: Tufts CSDD Approved NCE Database; PhRMA

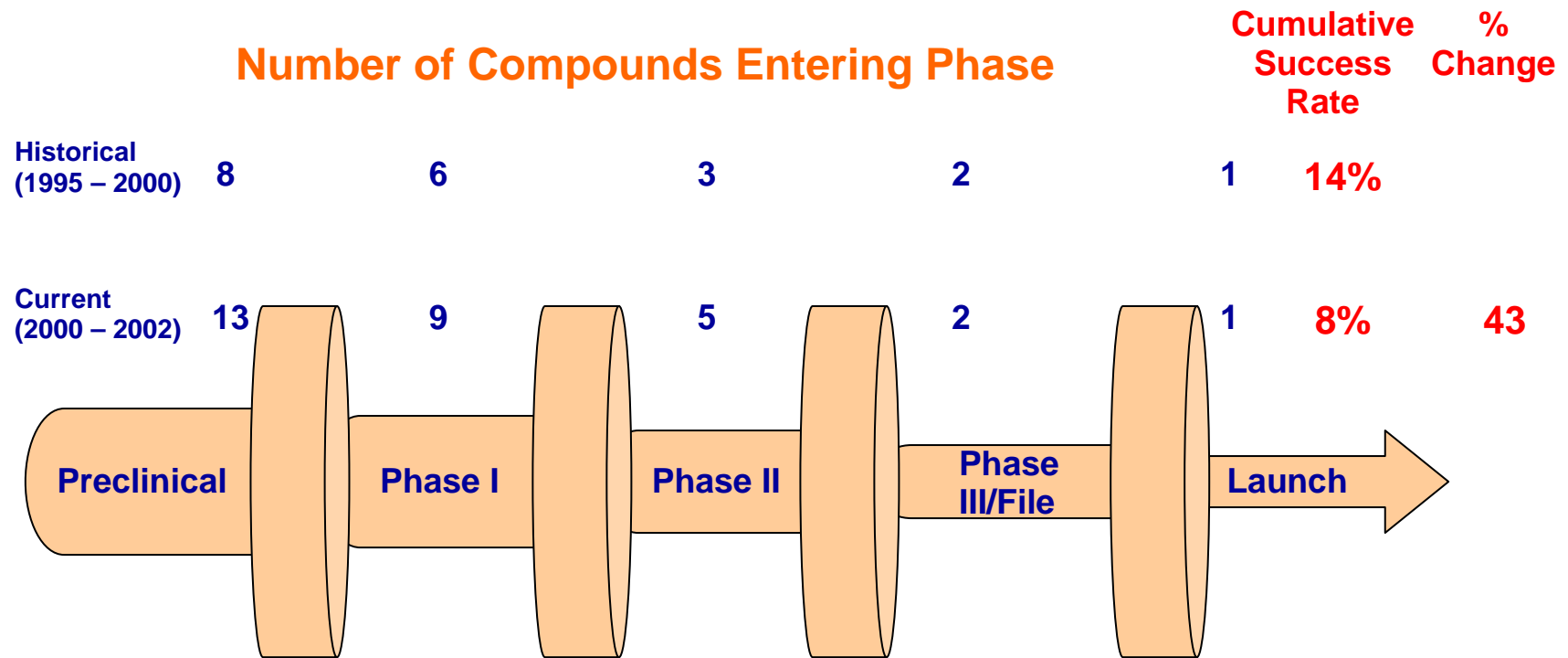


Trends in R&D Expenditure, Sales, and Number of NMEs — 1991 - 2005



Source: News from CMR International, March 2002

Declining R&D Success Rates



Source: Windhover's In Vivo: The Business and Medicine Report, Bain Drug Economics Model, 2003

Safety-Based Market Withdrawals Post-Launch

Withdrawal Year (Approval Year)						
1998	1999	2000	2001	2002	2003	2004
Mibefradil (1997)	Astemizole (1988)	Alosetron* (2000)	Cerivastatin (1997)	—	—	Vioxx (1999)
Bromfenac (1997)	Grepafloracin (1997)	Cisapride (1993)	Rapacuronium (1999)	—	—	—
Seldane (1985)	—	Troglitazone (1997)	—	—	—	—

* Returned to market in 2002 with restricted distribution

www.FDA.gov

Recouping the Cost of Development

- Only 3 out of every 10 drugs brought to market generate enough revenue to recover the average cost of its development

7 out of every 10 drugs brought to market never generate enough revenue to recover the average cost of development

H. Grabowski et.al. 2002

We Are Confronted With Unmet Medical Needs

In the last 40 minutes there have been....

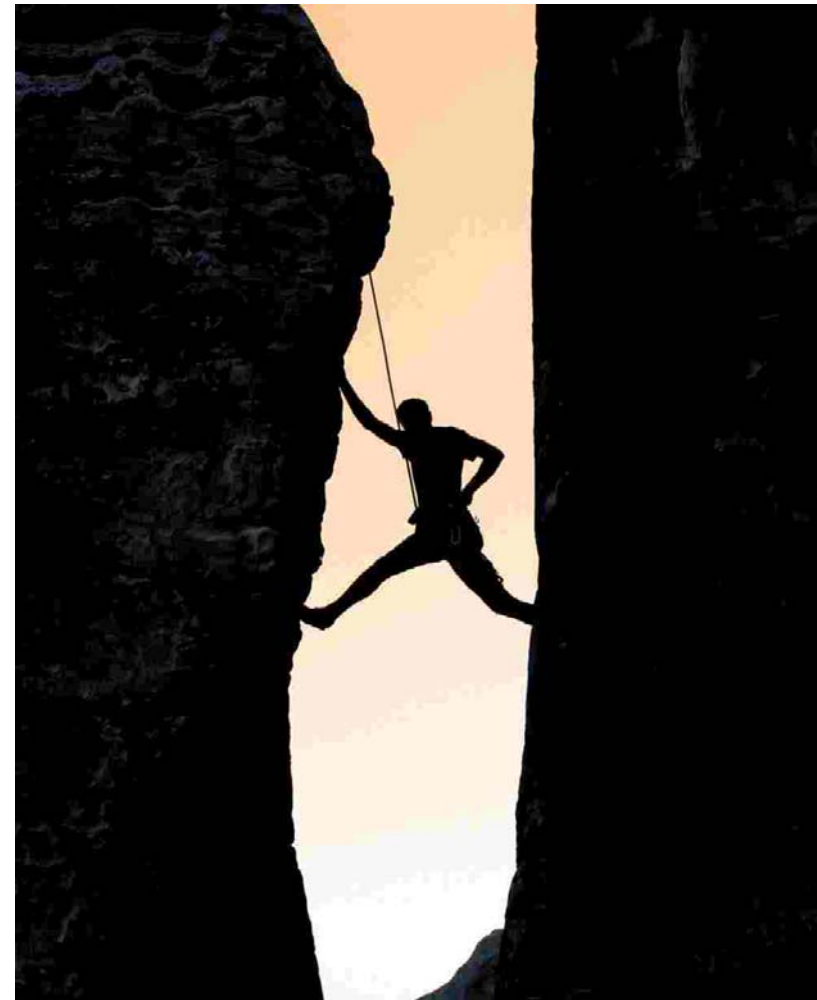
- ▶ **10 new victims of schizophrenia**
- ▶ **132 U.S. cancer deaths**
- ▶ **20 osteoporosis-related hip fractures**
- ▶ **1,296 cases of anxiety disorder**
- ▶ **1,523 procedures requiring pain treatment**
- ▶ **72 U.S. deaths from cardiovascular disease**
- ▶ **365 new cases of HIV/AIDS diagnosed**

There continues to be challenges in medical science

- ▶ **Age-old ailments (cholera, pneumonia, malaria, dysentery, tuberculosis)**
- ▶ **Emerging pathogens (Legionnaires' disease, AIDS, Ebola, SARS, West Nile Virus)**

How Do We Respond to These Challenges?

- **Total despair**
- **Revamp the drug development process**
- **One project at a time**



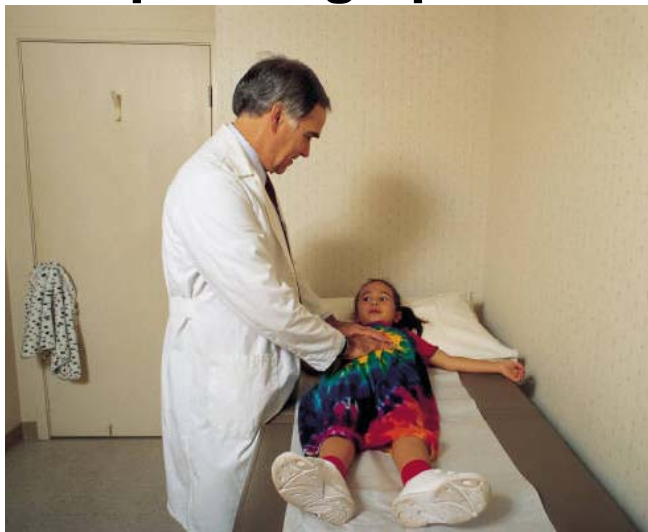
How Do We Respond to These Challenges?

➤ Total despair

Big Pharma sentiment “shifts from pessimism to hopelessness”
— Jami Rubin - Morgan Stanley

▶▶ Not viable

Patients on a global basis are depending upon us



www.thestreet.com

▶▶ Not necessary

Our industry is staffed with bright and creative people



How Do We Respond to These Challenges?

- **Revamp the Drug Development Process?**
 - ▶ **Viable in the long term**



The Critical Path to New Medical Products

On March 16, FDA released a report addressing the recent slowdown in innovative medical therapies submitted to the FDA for approval, "Innovation/Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products." That report describes the urgent need to modernize the medical product development process -- the Critical Path -- to make product development more predictable and less costly.

According to Acting FDA Commissioner Lester M. Crawford, "A new focus on updating the tools currently used to assess the safety and efficacy of new medical products will very likely bring tremendous public health benefits."

Source: www.FDA.gov

How Do We Respond to These Challenges?

- **One project at a time...**
 - ▶ **Viable approach in the near term**



How Do We Respond to These Challenges?

Better management of drug development projects can lead to reductions in cost and cycle time



How Do We Respond to These Challenges?

- **There are interventions that will help, for example:**
 - ▶▶ **Cutting development cycle times by 50% would lower cost by 30%**
 - ▶▶ **Improving clinical success rate by 30% would reduce cost by 22%**
 - ▶▶ **Cutting one year from phase III clinical trial would save an average of \$71 million USD**

How Do We Respond to These Challenges?

You can't manage what you can't measure

➤ **Hence, we need to be able to measure**

▶▶ **Timelines**

▶▶ **Cost**

▶▶ **Probability of technical success**

▶▶ **Value**

for drug development projects as well as the portfolio of projects

➤ **This data should be used to drive:**

▶▶ **On time, on budget, and on scope performance**

▶▶ **Improvements in the drug development process**

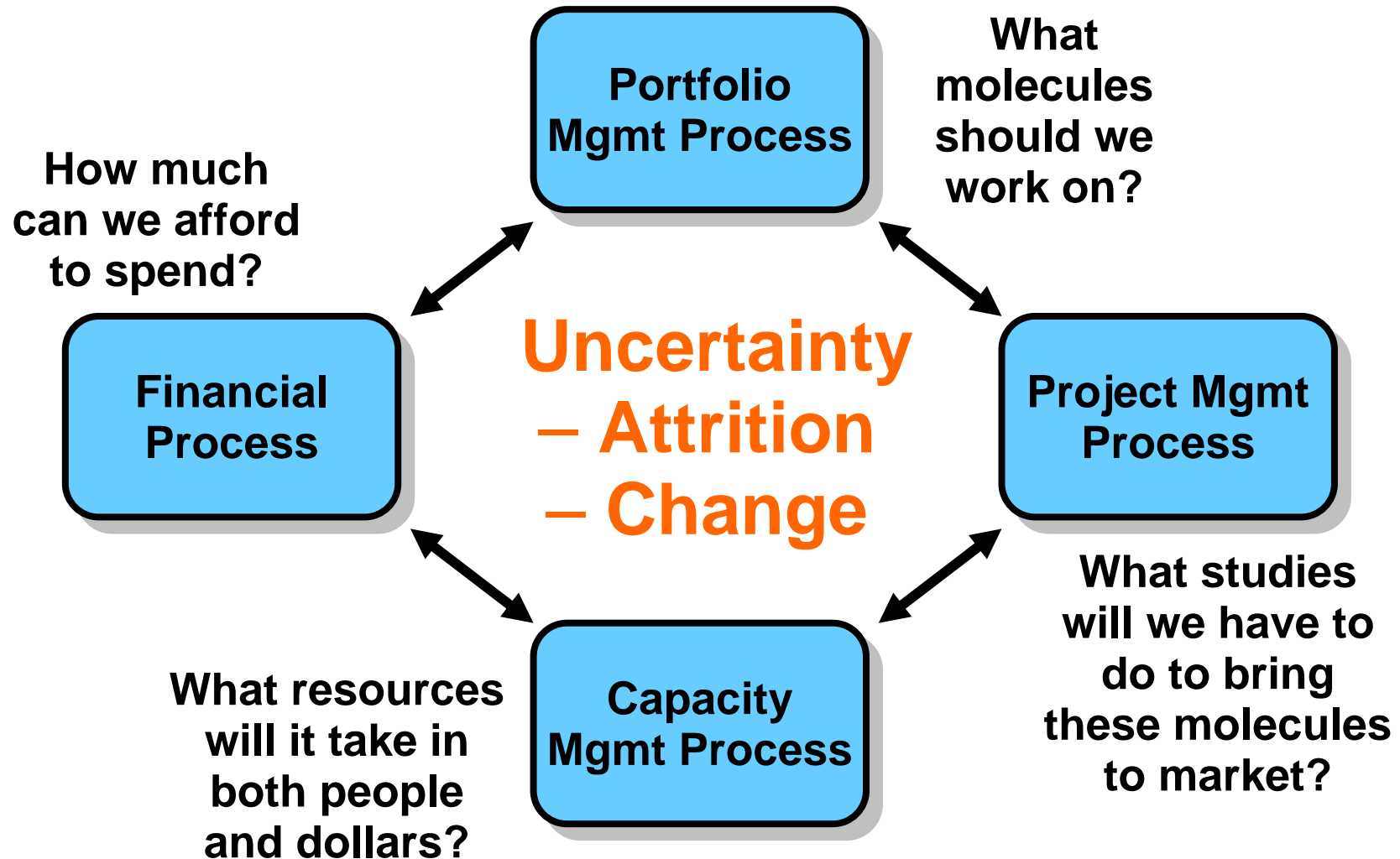
Confronting the Challenges

- **Business processes and supporting tools are needed that will allow us to:**
 - ▶ **Deliver:**
 - ◆ on time
 - ◆ on budget
 - ◆ products that add value
 - ▶ **Increase the probability of technical success**
 - ◆ Allow for the rapid redeployment of resources once a compound fails
 - ▶ **Effectively manage global development projects**

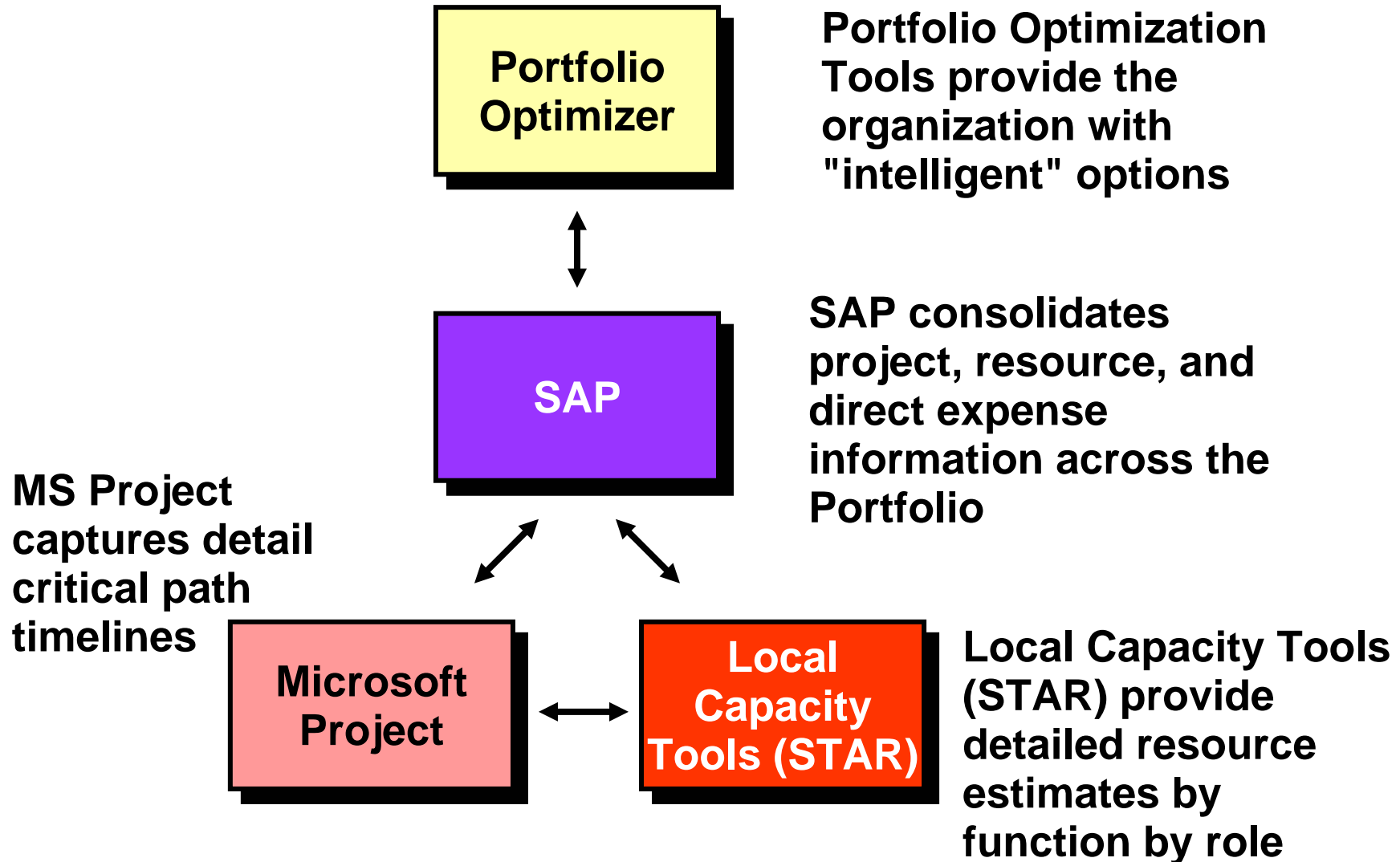
II. Integrated Business Process for Portfolio and Project Management



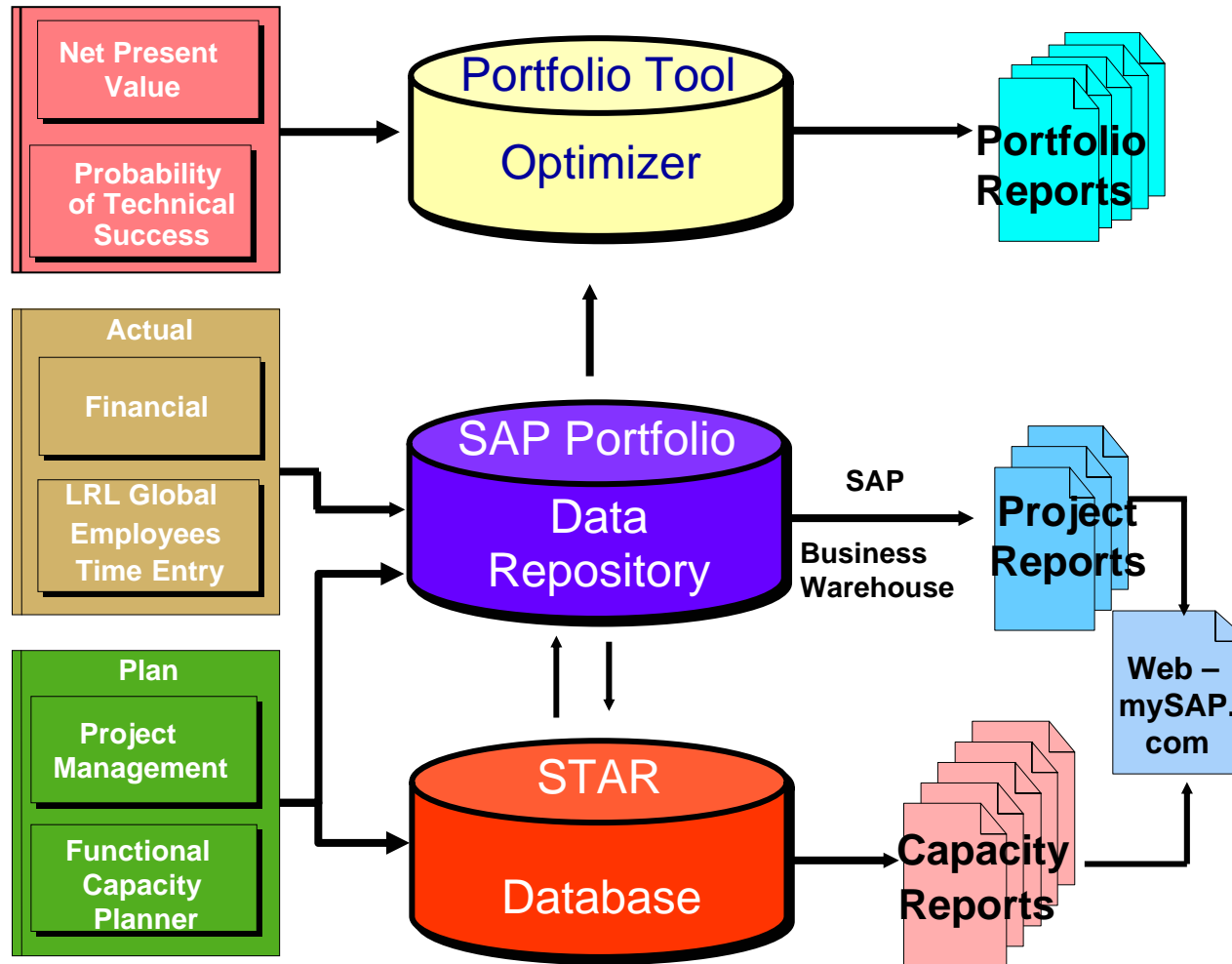
Business Process for Portfolio and Project Management



IT Tools for Portfolio and Project Management



The Project Management Information System

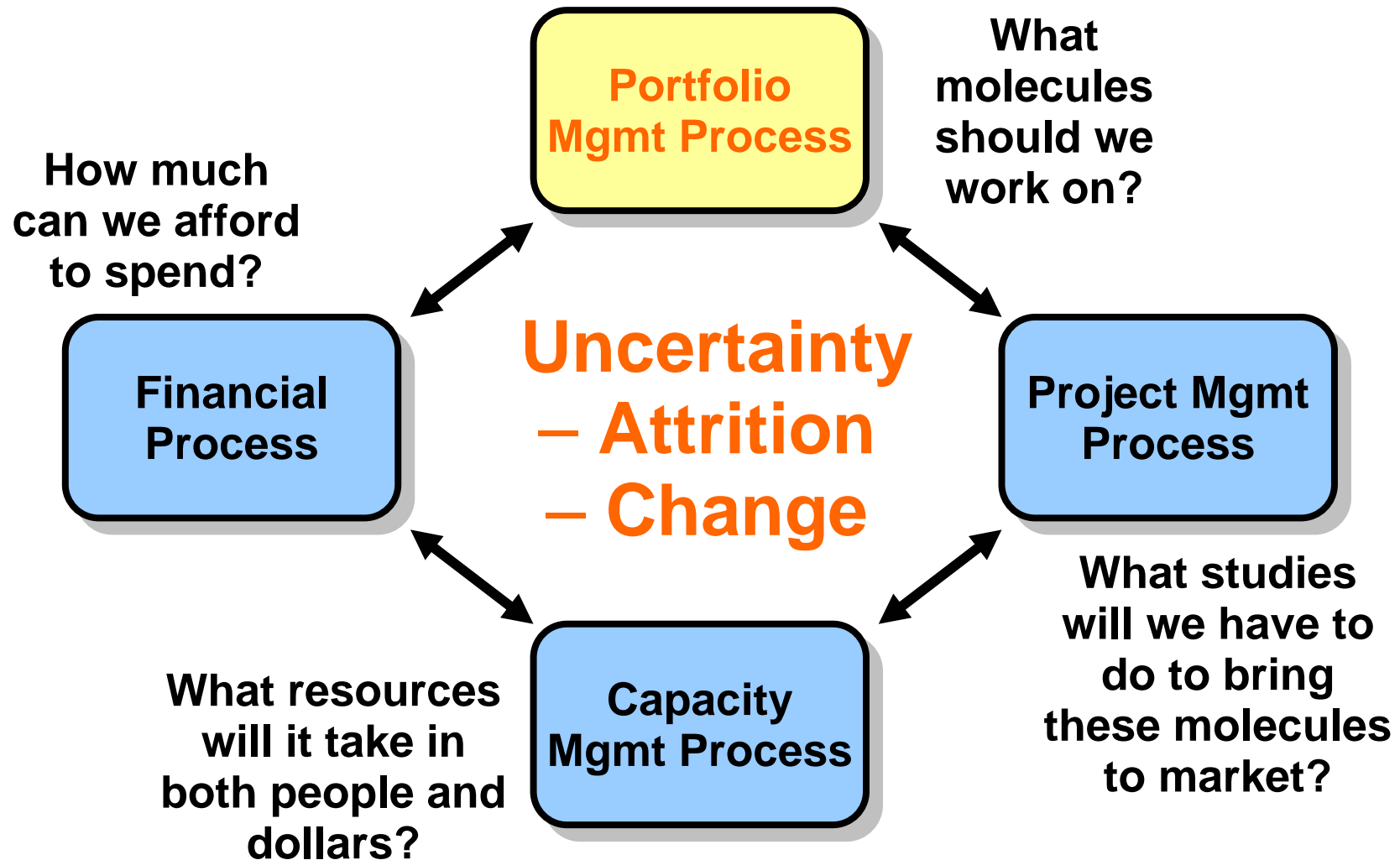


III. Portfolio Management



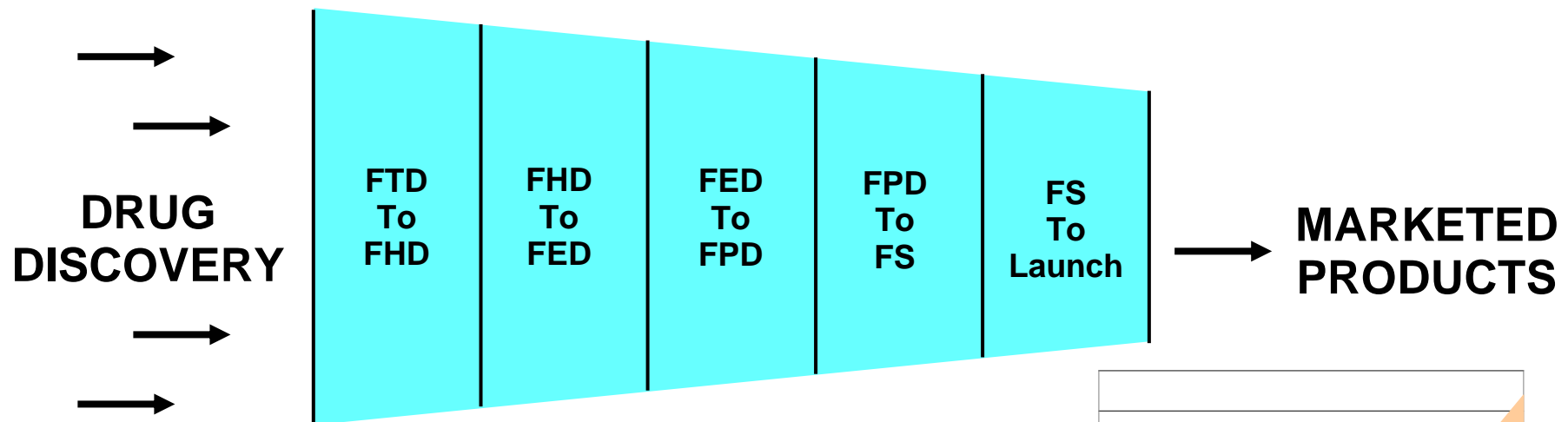
What Molecules Should We Work On?

Business Process Integration

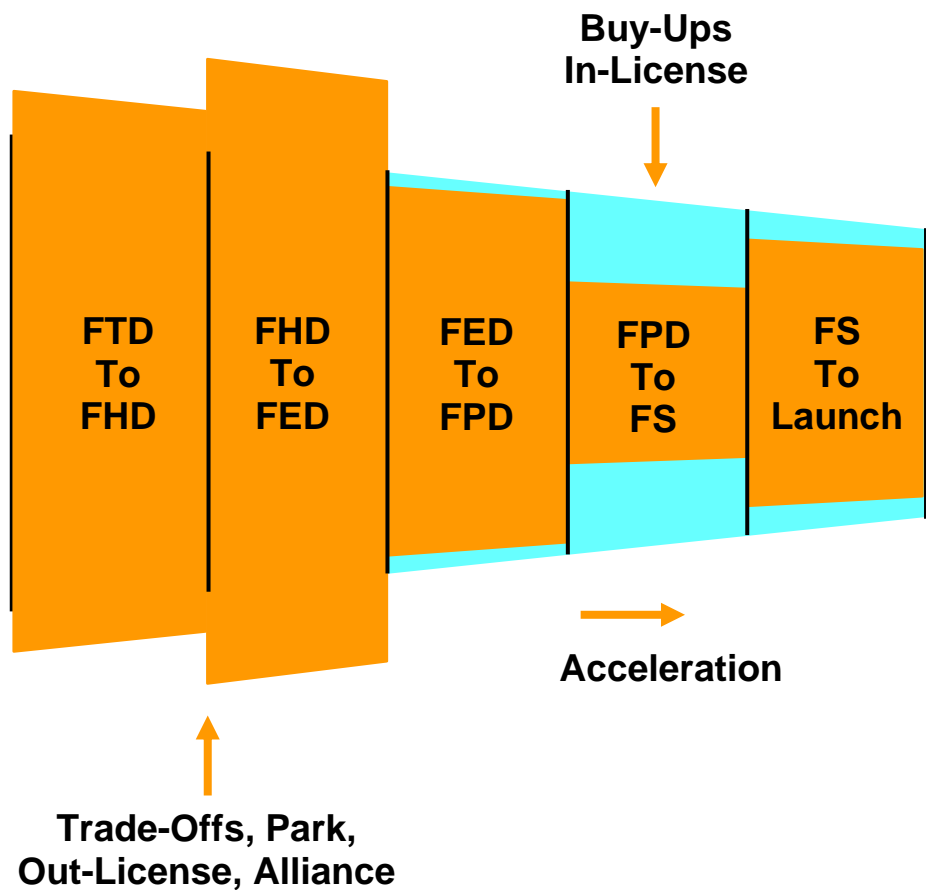


Portfolio Management: R&D Model

- Key question - How many projects need to be in the pipeline to meet corporate growth targets?



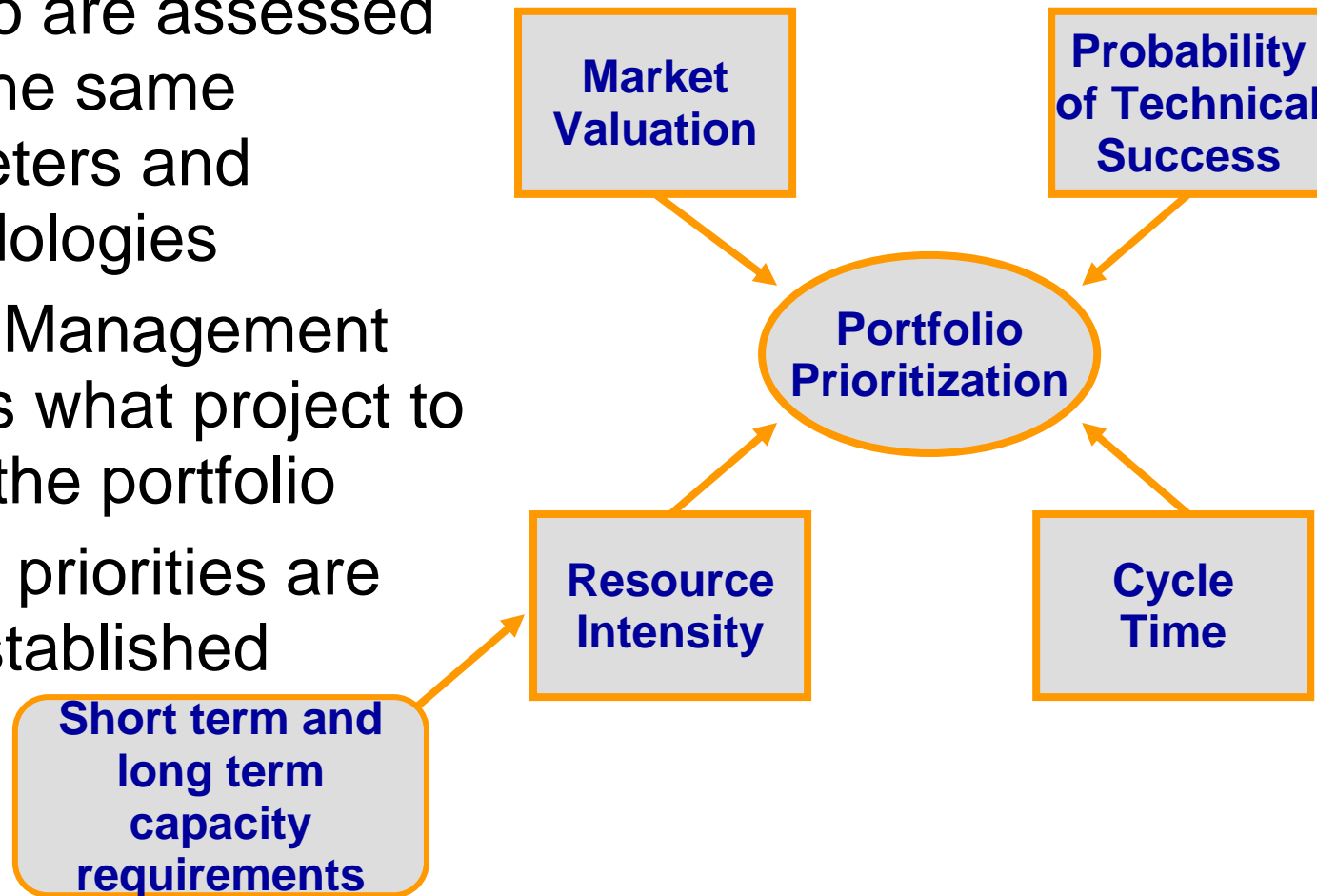
Governance: Review and Approval Process – Balancing Portfolio



- Portfolio and Operational Committees review work-in-progress vs research and development model
- Consider Buy-Up Proposals, Acceleration Strategies, or In-License Opportunities to fill critical gaps
- Make Trade-Offs, Park, Out-Licensing, or Alliance Decisions to moderate phases are over-capacity

Portfolio Governance: Portfolio Review Process

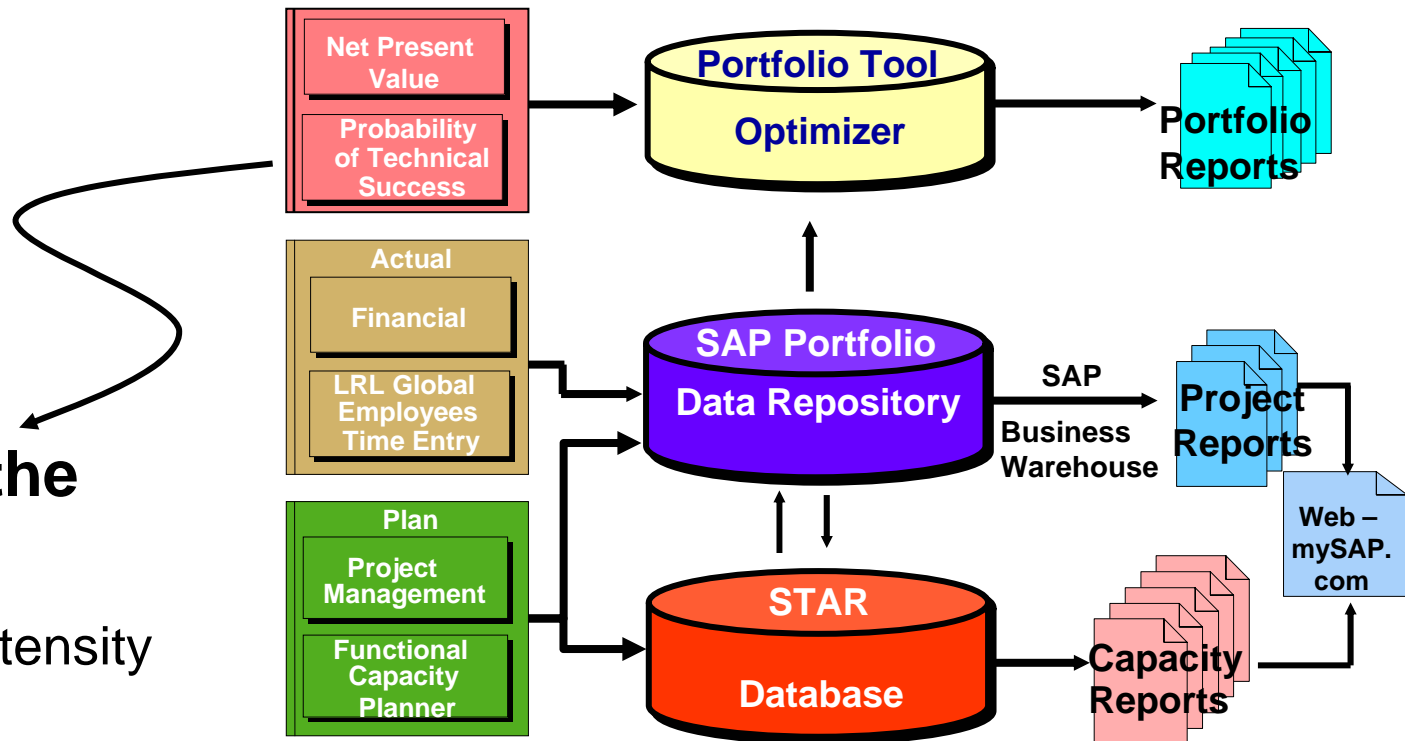
- All projects in the portfolio are assessed using the same parameters and methodologies
- Senior Management decides what project to add to the portfolio
- Project priorities are then established



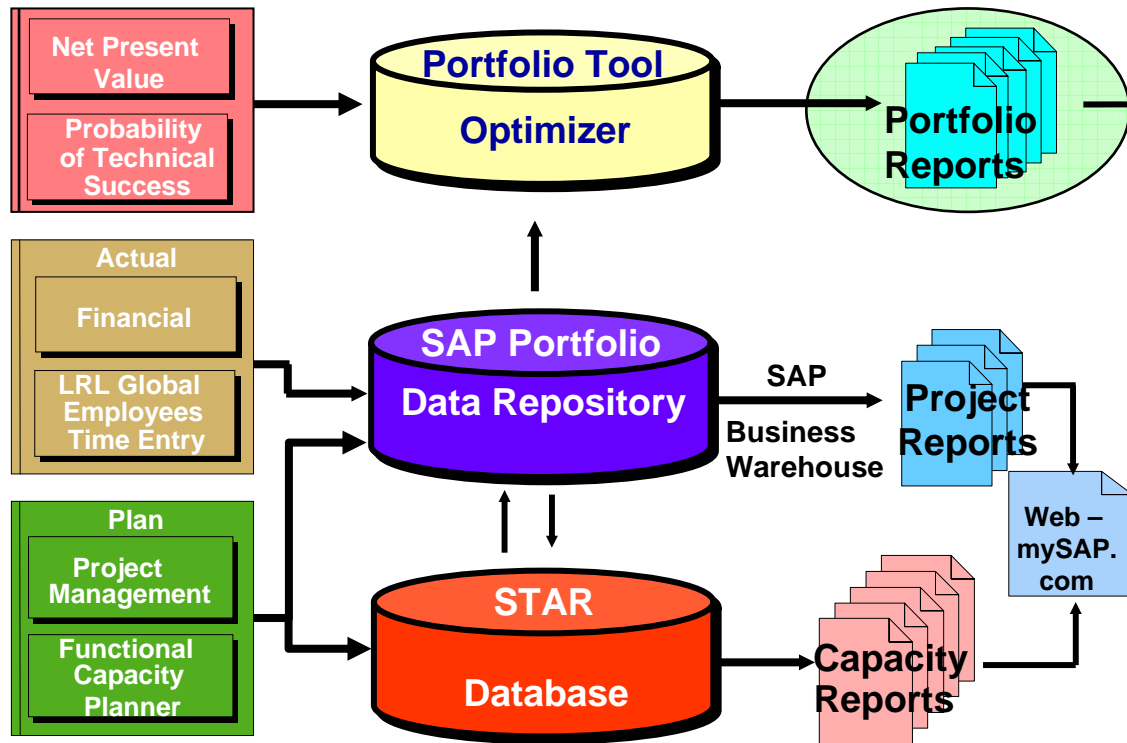
Portfolio Inputs To Project Management Information Systems

Inputs to the Portfolio

- Resource intensity
- Cycle time
- Probability of technical success
- Market valuation



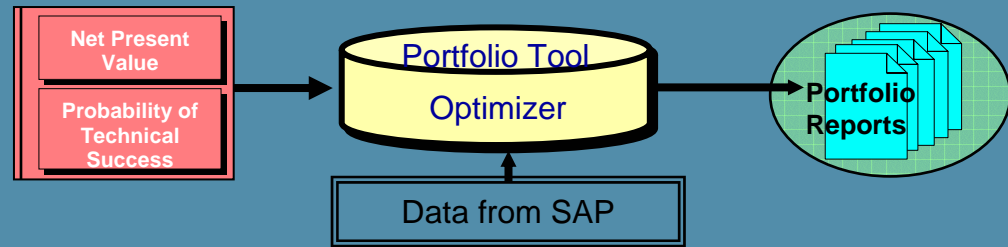
Portfolio Reporting From Project Management Information Systems



Examples of Portfolio Reports

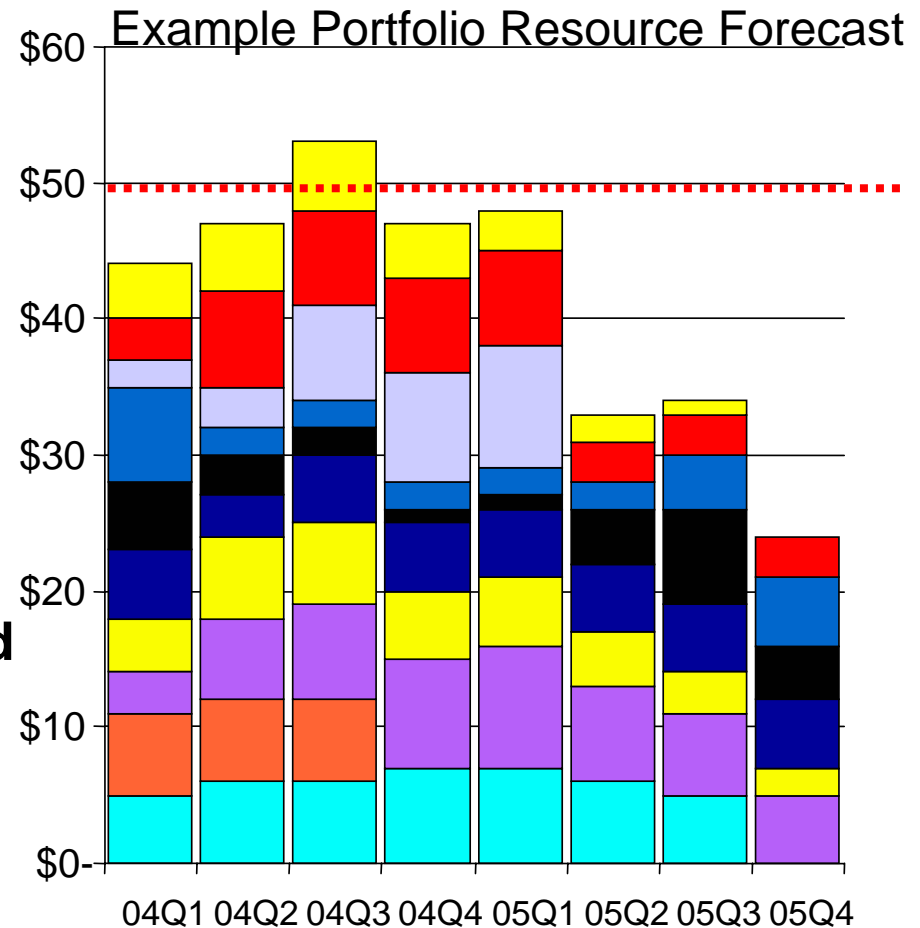
- 8Q Rolling Forecast
- 8Q Forecast – Plan by Project
- Project Milestones, Cost, and Revenues
- Plan vs Actual Spend

Portfolio Reporting

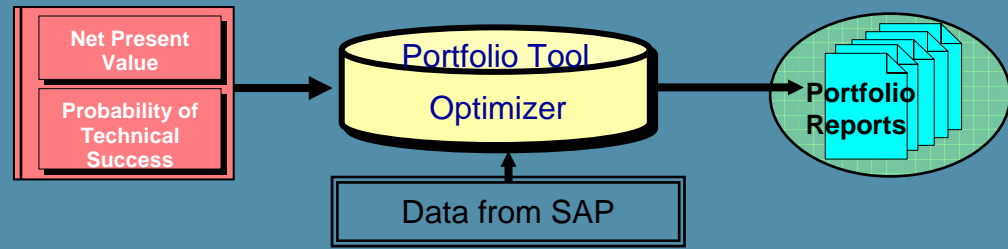


➤ 8 Quarter Rolling Forecast

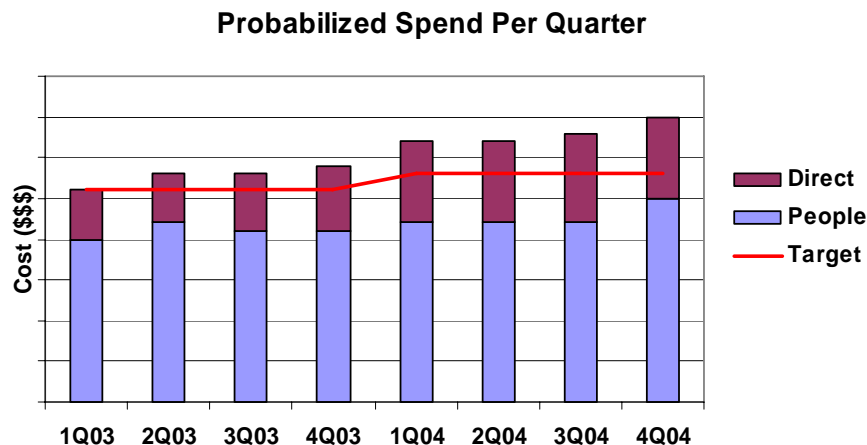
- _ Do we have adequate resources to deliver portfolio?
- _ How are we progressing toward key milestones?
- _ Do we need to slow, stop or accelerate any resource utilization?
- _ Are we appropriately resourcing our priorities?
- _ Do we have the capacity to add new projects?
- _ What are the rate limiting functional areas?



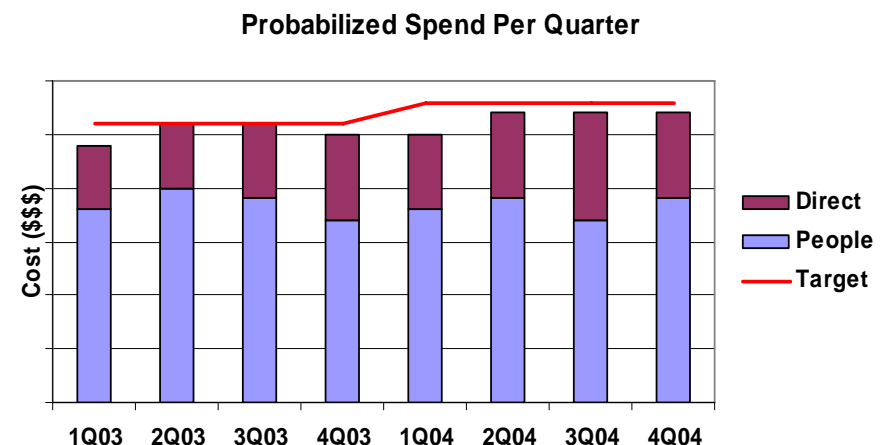
Portfolio Reporting



8 Quarter Forecast: Plan By Project vs Functional Budget



- **Plan By Project (Demand) exceeds Target (Supply)**
- **Trade-offs necessary to meet target**

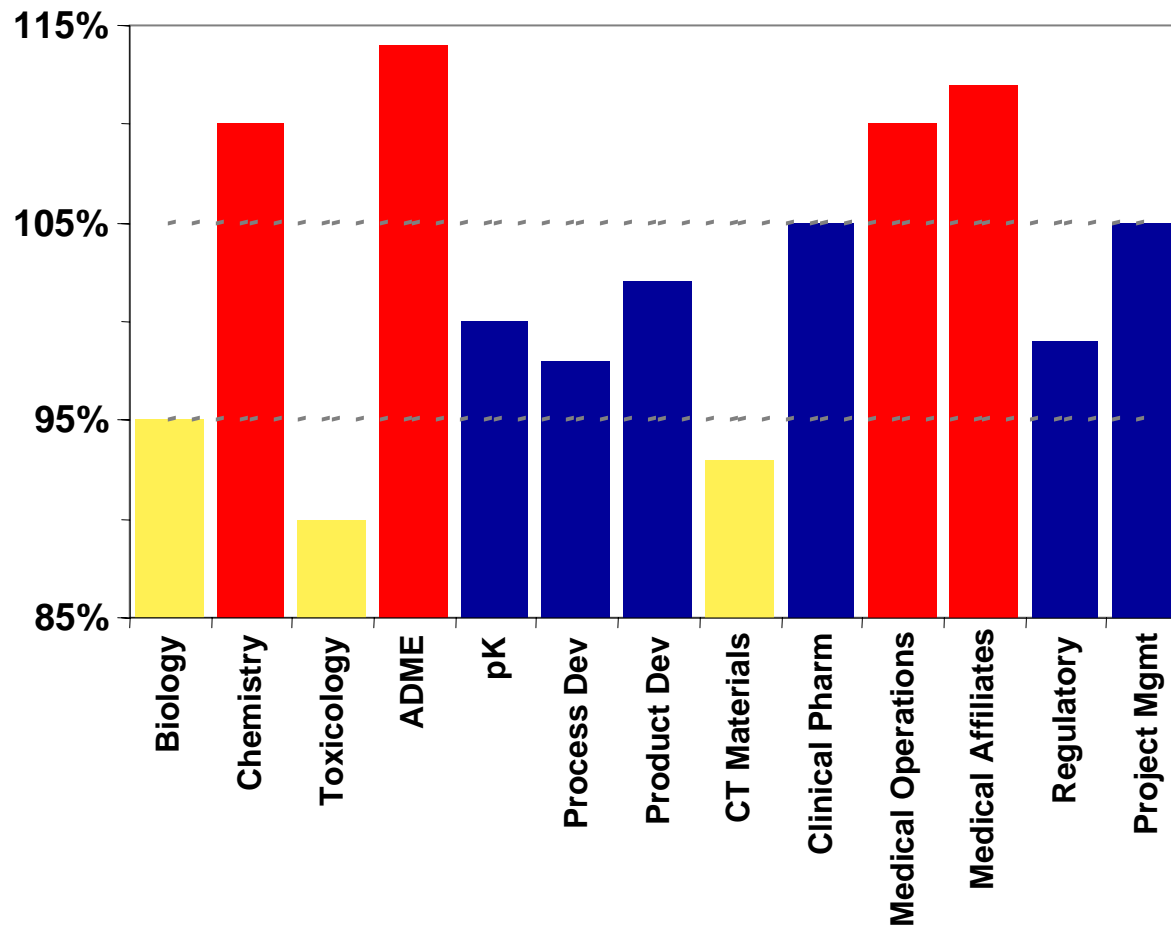


- **Plan By Project (Demand) less than Target (Supply)**
- **Consider additional Buy-Up Opportunities**

Portfolio Capacity Management

Project Demand vs Supply (On-Board Headcount)

Supply vs Demand



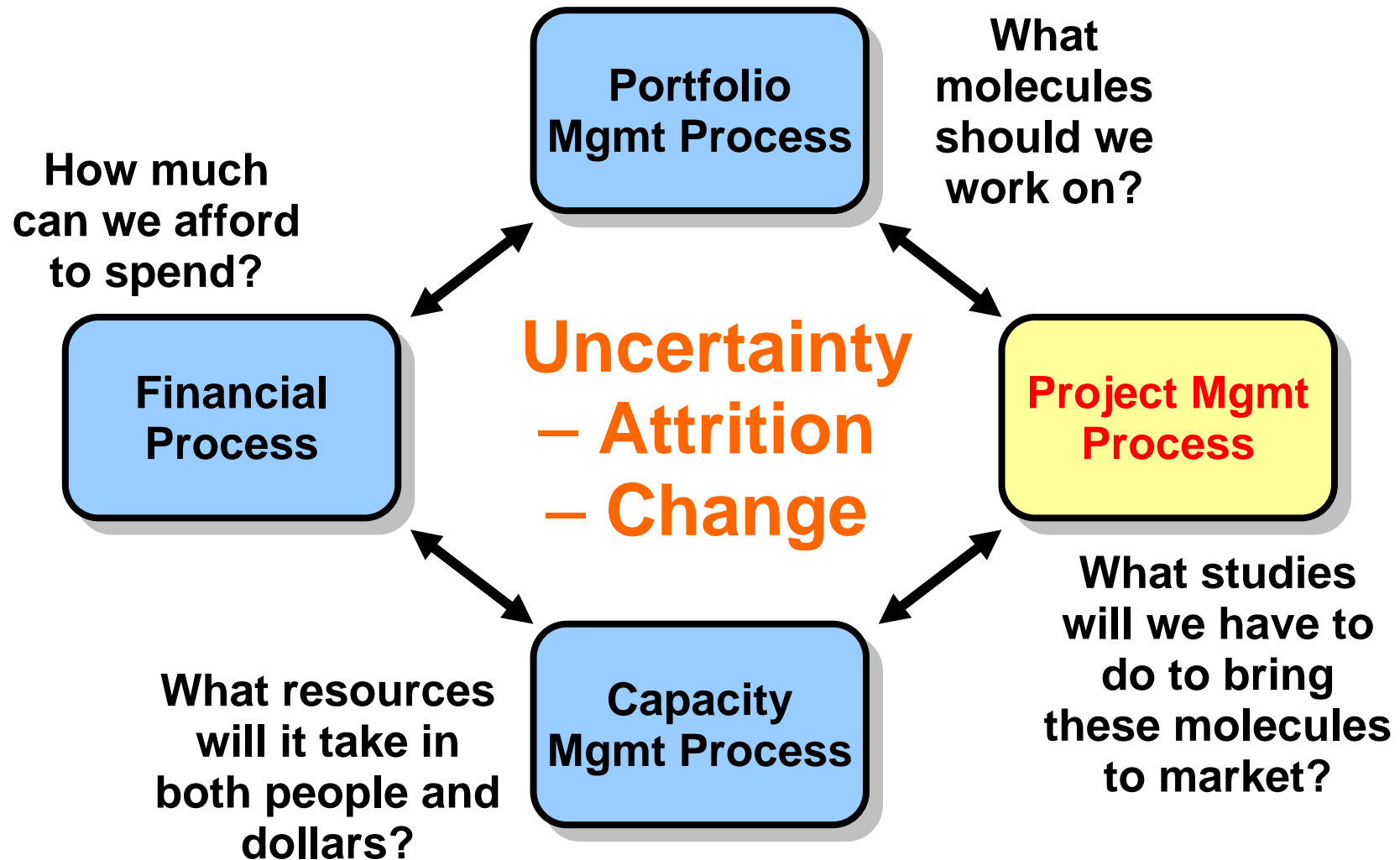
- Compare supply vs demand over periods of time
- Used to identify chronic bottleneck functions
- Is the bottleneck where you want it to be?
- Trade-off decisions, strategic hiring

IV. Project Management

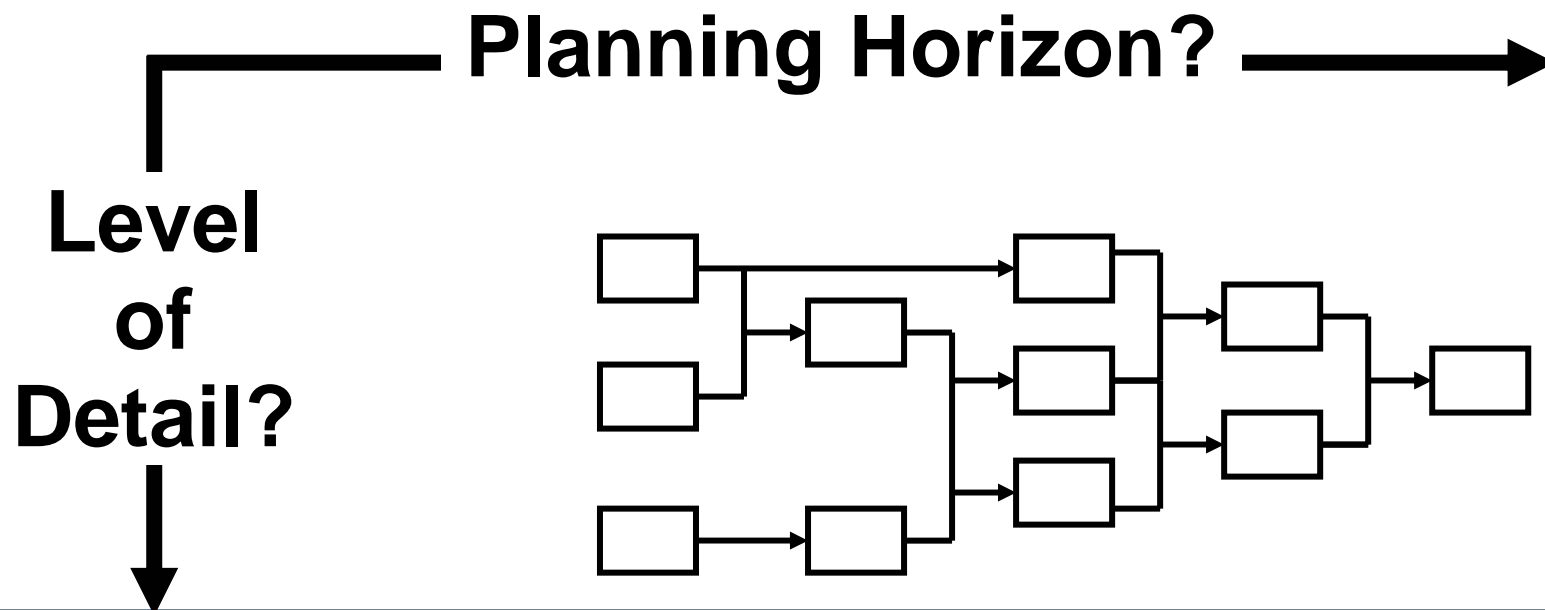
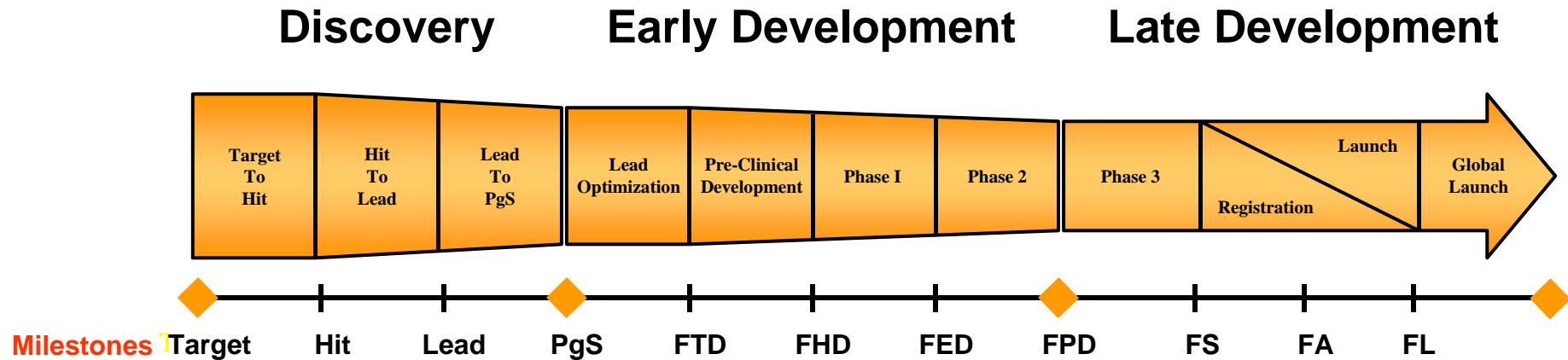


What Studies to Get the Molecules to Market?

Business Process Integration

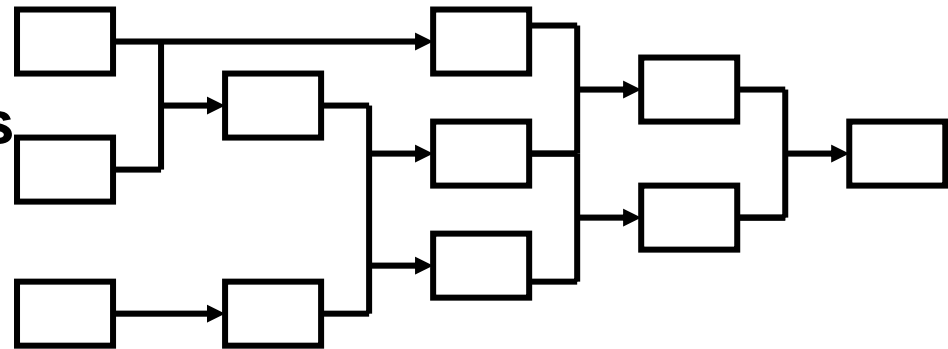


The Project Management Planning Process

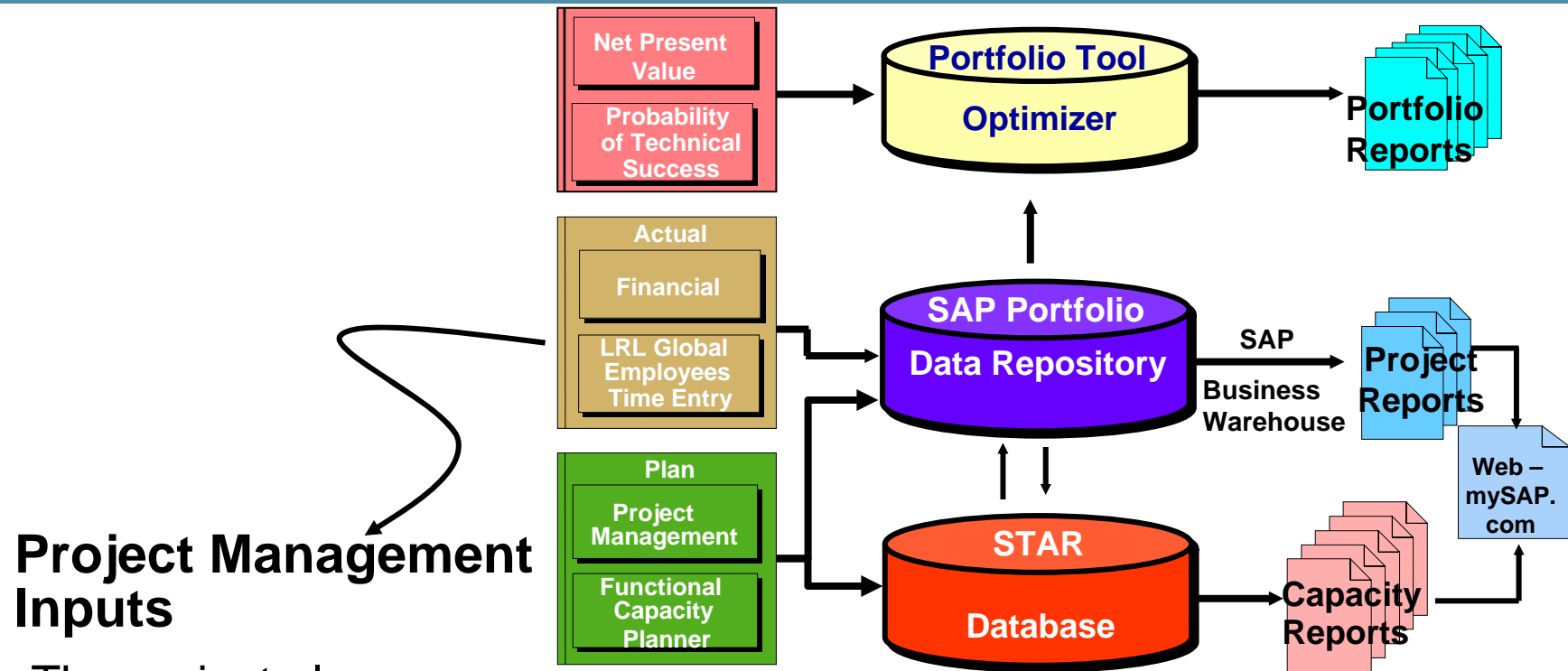


Project Planning Process

- **Utilize Microsoft Project for detailed project planning (timelines)**
- **Utilize SAP project systems for timeline and cost integration**
- **Conduct critical path analysis to optimize cross-functional plan**
- **Use rolling wave methodology across planning horizon**
- **Use phase specific templates as starting point for each phase of development**



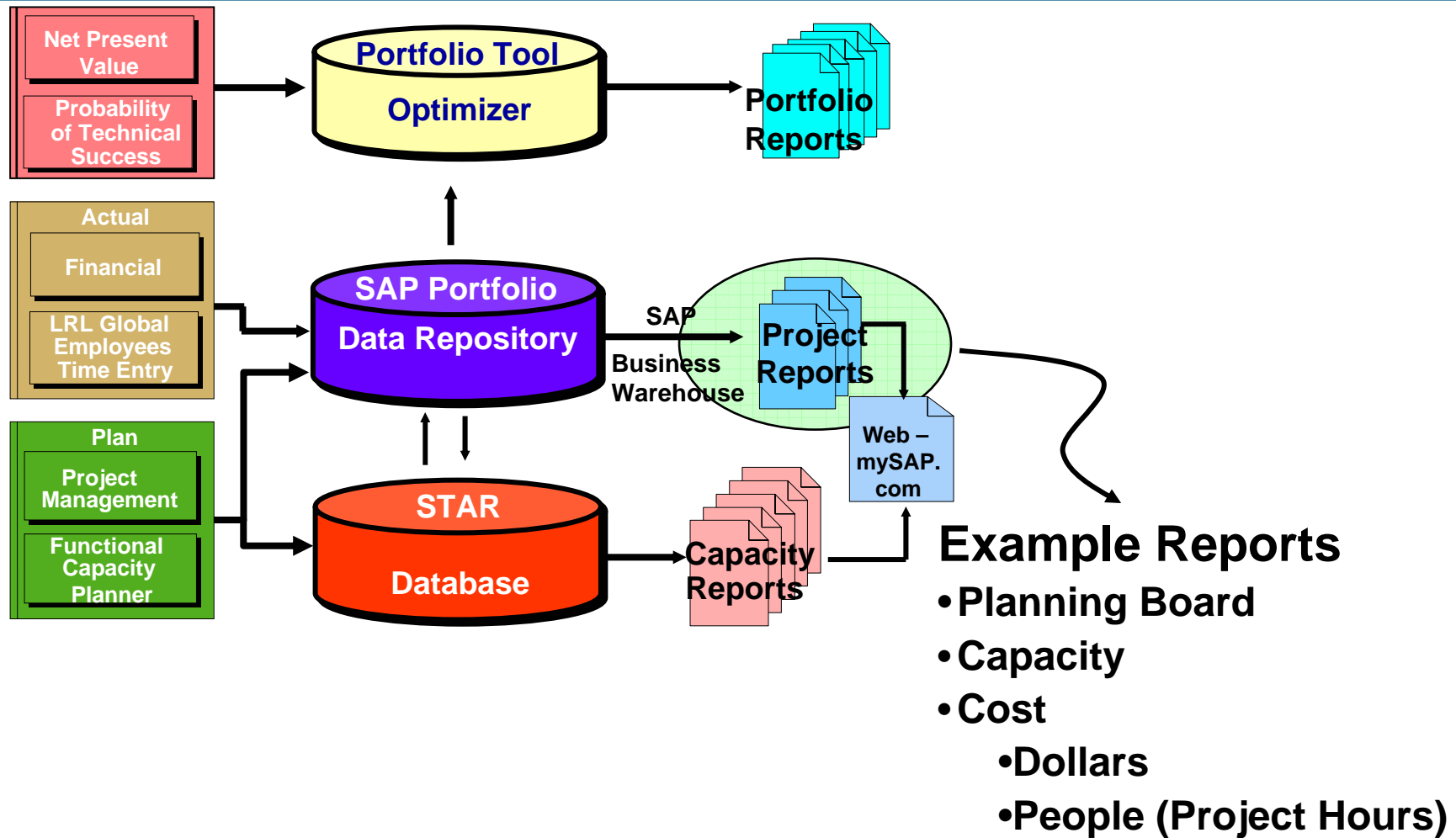
Project Inputs To Project Management Information System



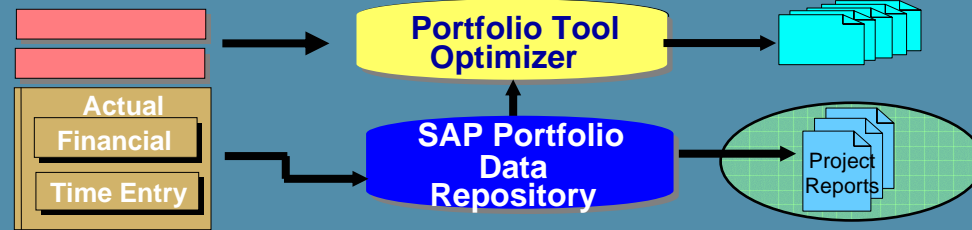
Project Management Inputs

- The project plan
 - Timeline/Milestones
 - Expenses
 - Direct
 - Indirect

Project Reporting From Project Management Information Systems



Project Reports



Project Edit Goto Details Settings Extras System Help

Project: Change

Project: 130-0001 Human Phase Project #1

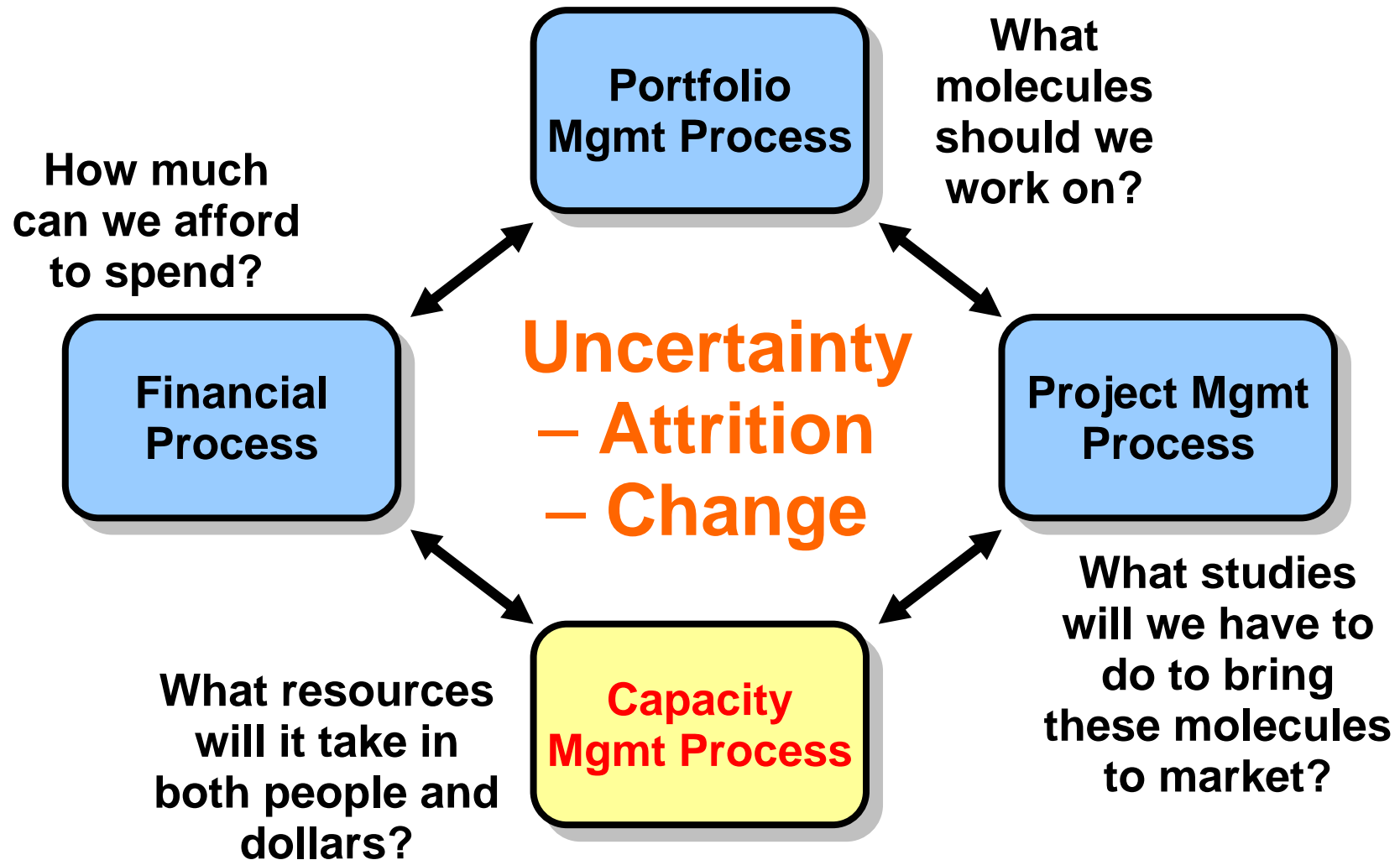
S	Hid	Le	Description	Duratr	Work	Actual wor	Project cost plan	Actual costs
			Human Phase Project #1	728.0 DAY			2,090,000.00 USD	
		1	NCE	728.0 DAY			2,090,000.00 USD	
		2	Pre-Clinical	168.0 DAY			315,000.00 USD	
		3	CM&C	47.0 DAY			101,000.00 USD	
			API -1 Development for FHD				2,000.00 USD	
			Chemical Processing		20.0 H		2,000.00 USD	
			NDP Development for FHD	45.0 DAY			10,000.00 USD	
			PPD		100.0 H		10,000.00 USD	
			API Methods for FHD	30.0 DAY			6,000.00 USD	
			PPD		30.0 H		3,000.00 USD	
			Chemical Processing		30.0 H		3,000.00 USD	
			GMP NDP MFG / Packaging for Phase 1	30.0 DAY			53,000.00 USD	
			CT OPs		30.0 H		3,000.00 USD	
			Misc Analytical Support for Phase 1	30.0 DAY			20,000.00 USD	
			Chemical Processing		100.0 H		10,000.00 USD	
			PPD		100.0 H		10,000.00 USD	
			NDP Methods for FHD	30.0 DAY			10,000.00 USD	
			PPD		100.0 H		10,000.00 USD	
		3	Toxicology	92.0 DAY			50,000.00 USD	
			Acute Tox	90.0 DAY			10,000.00 USD	
			Toxicology		100.0 H		10,000.00 USD	
			Repeat Dose tox + TK (1 Month)	90.0 DAY			20,000.00 USD	

V. Capacity Management



What Resources Will It Take?

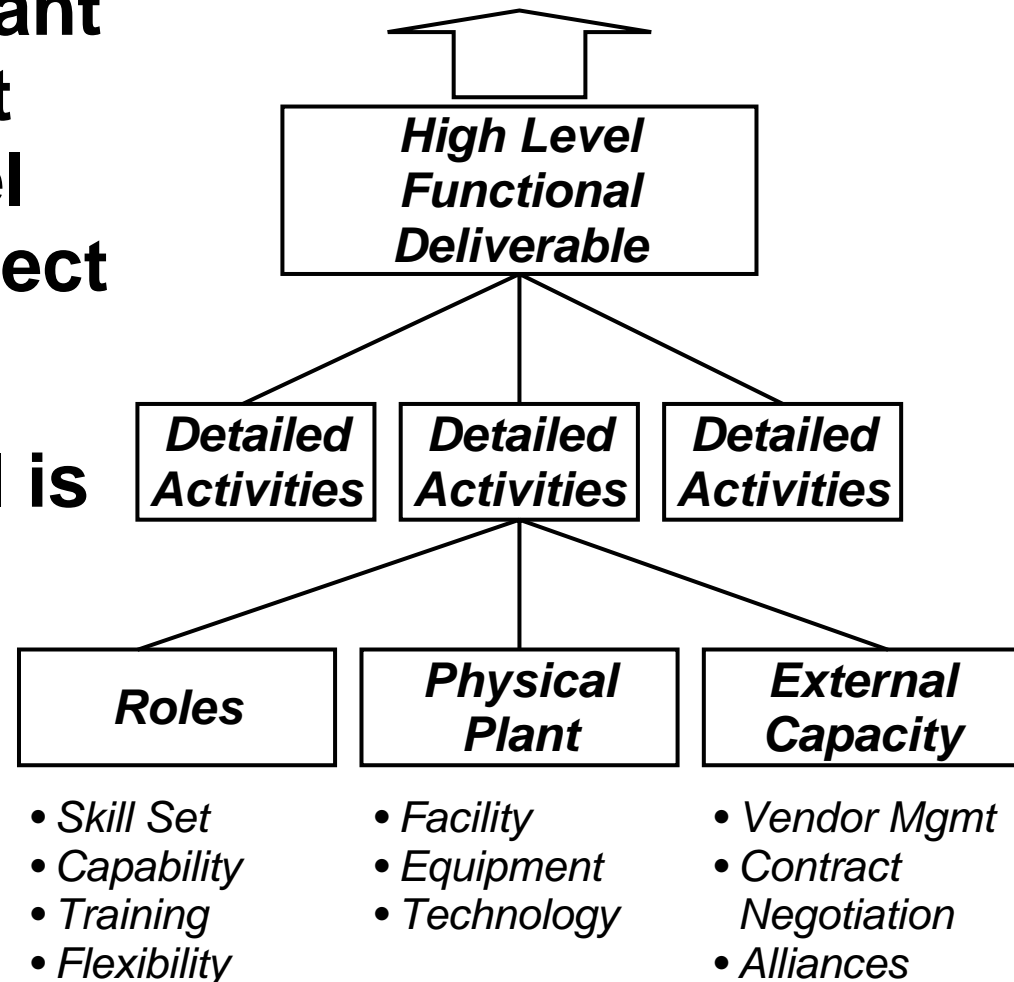
Business Process Integration



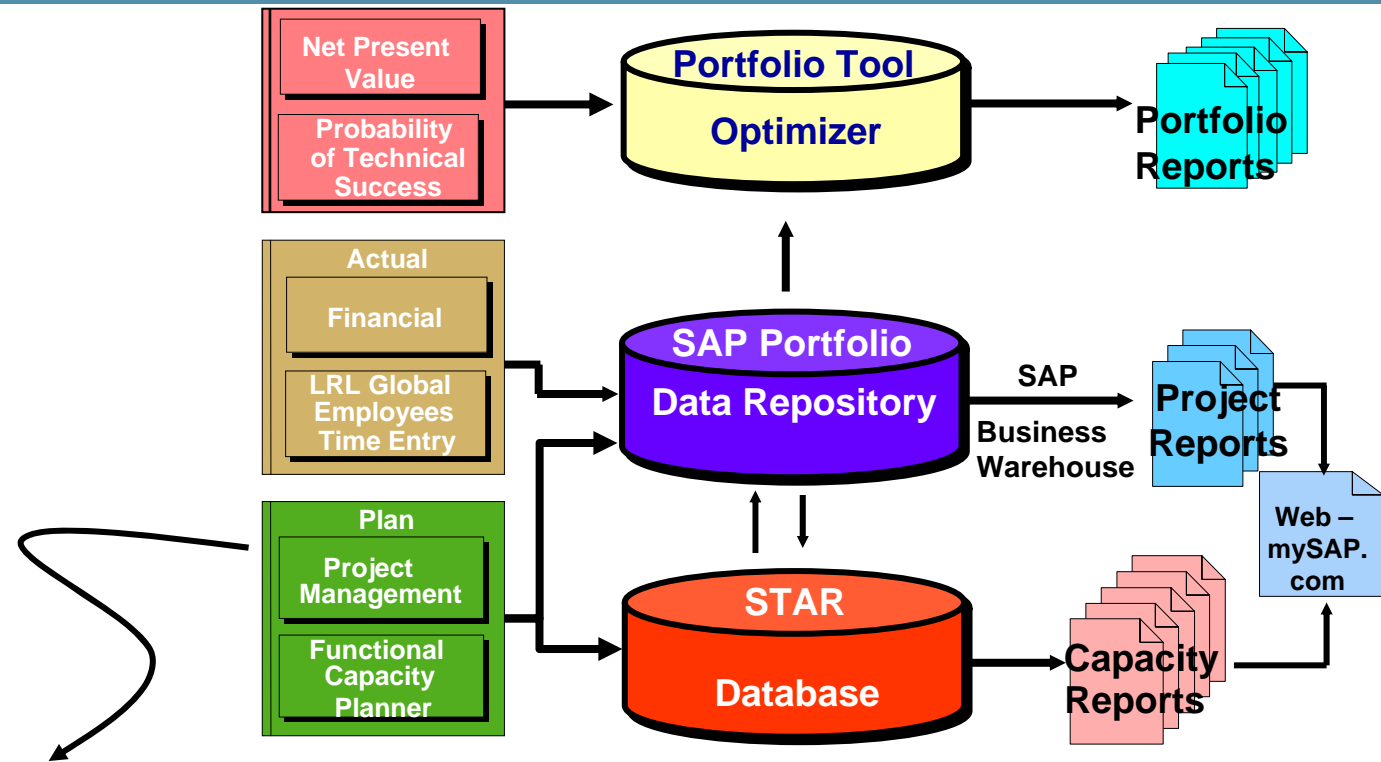
Functional Capacity Management

- There is a significant amount of detail at the functional level that feeds the Project Level information
- This level of detail is managed at the functional level

Project Level Planning



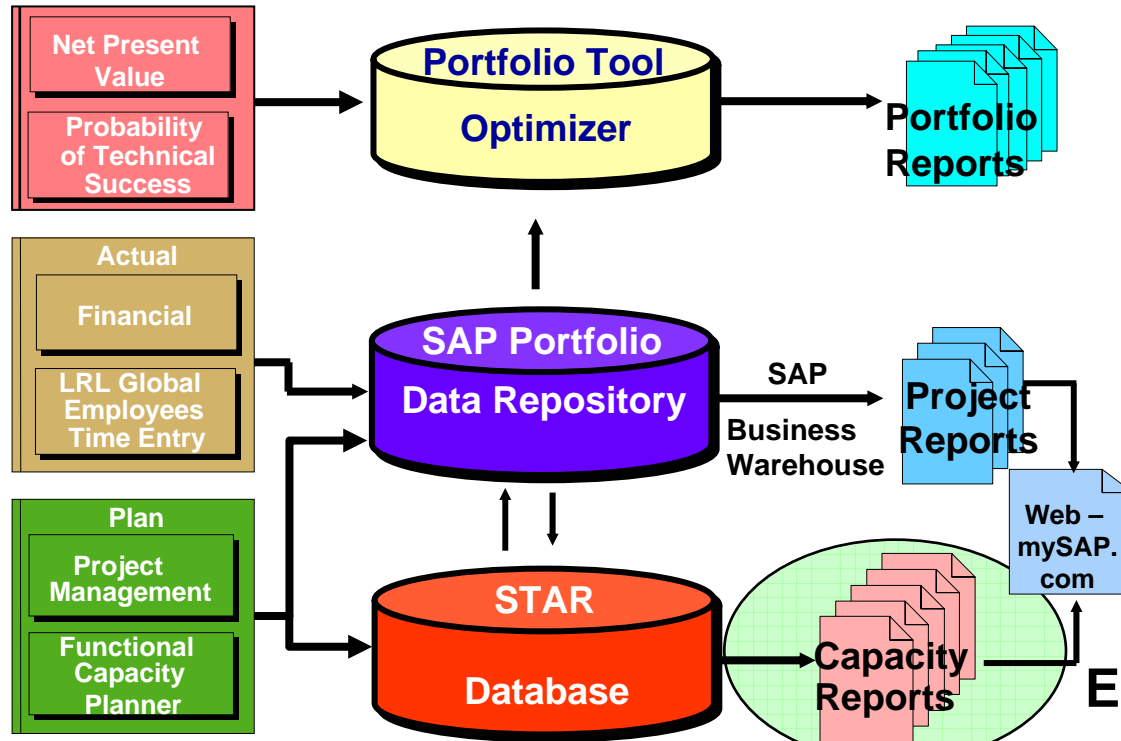
Capacity Management Inputs To Project Management Information Systems



Functional Capacity Inputs

- Project plans
- Capacity plans

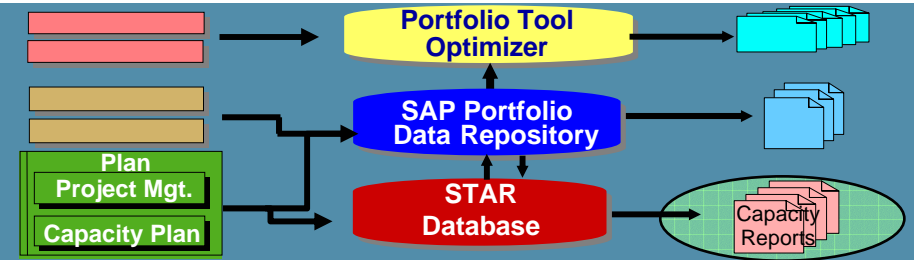
Capacity Management Reporting To Project Management Information Systems



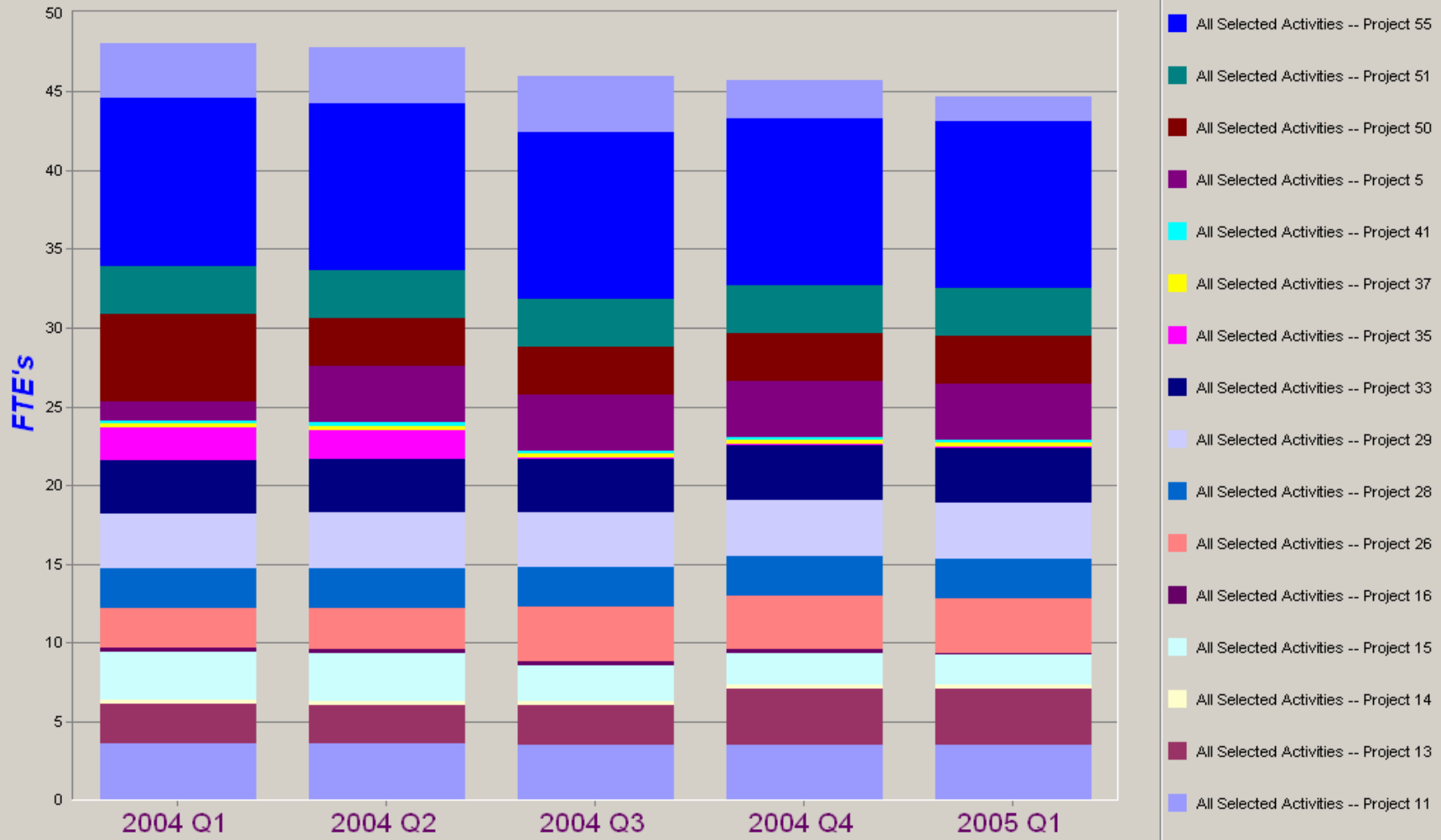
Example Reports

- Plan, Actual, and Forecast for:
 - each project
 - the portfolio of projects
 - function
 - division

Capacity Reports From PMIS



Formulation Demand by Project

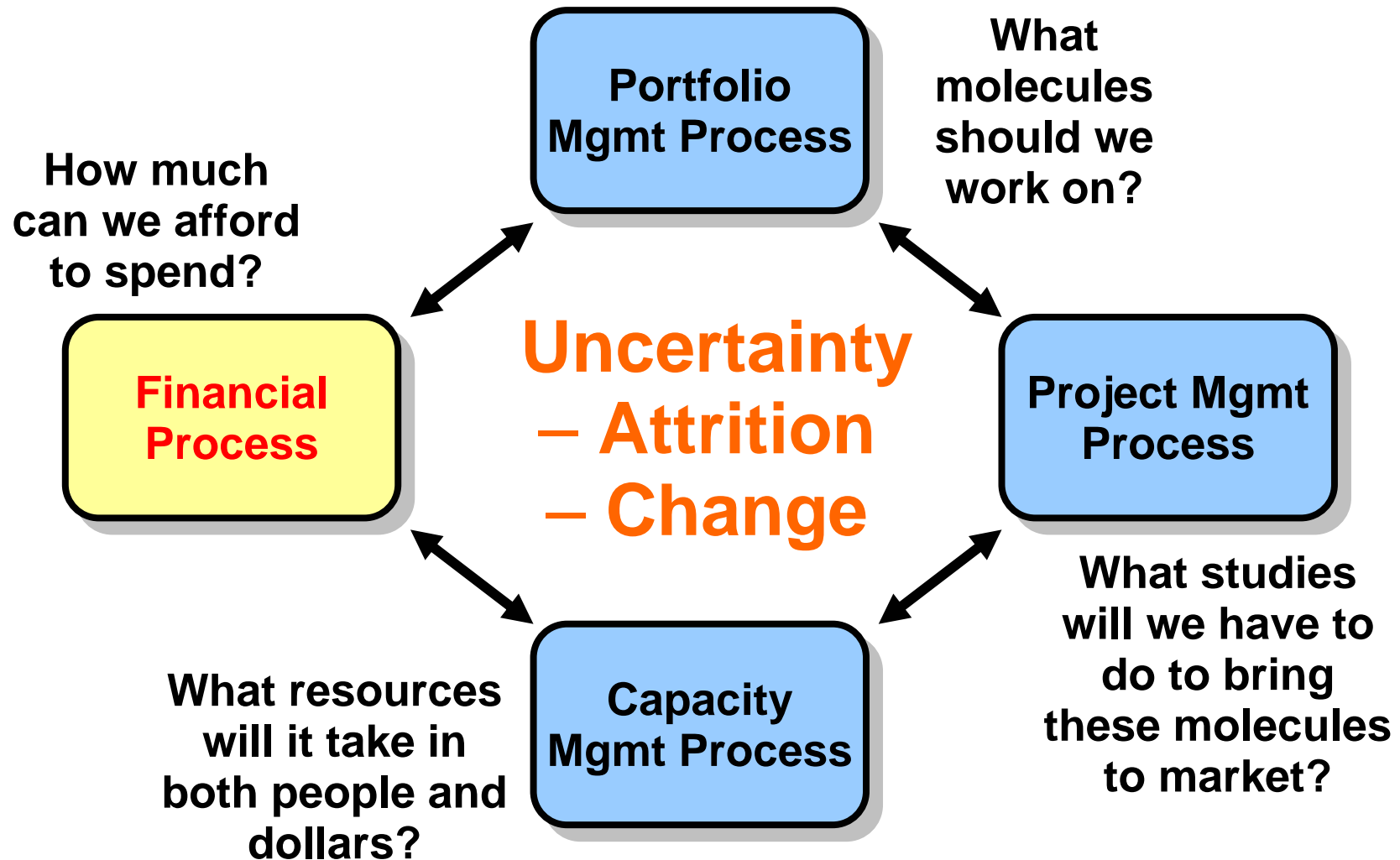


VI. Financial Management



How Much Can We Afford to Spend?

Business Process Integration

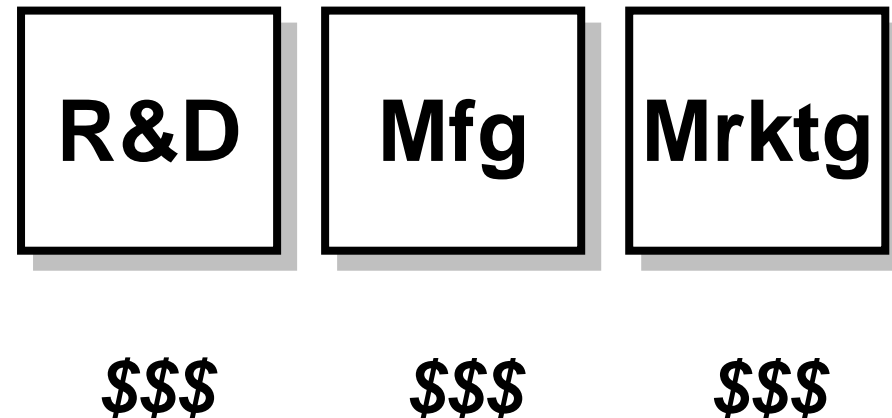


Financial Process

- The corporate budgeting process defines the R&D budget

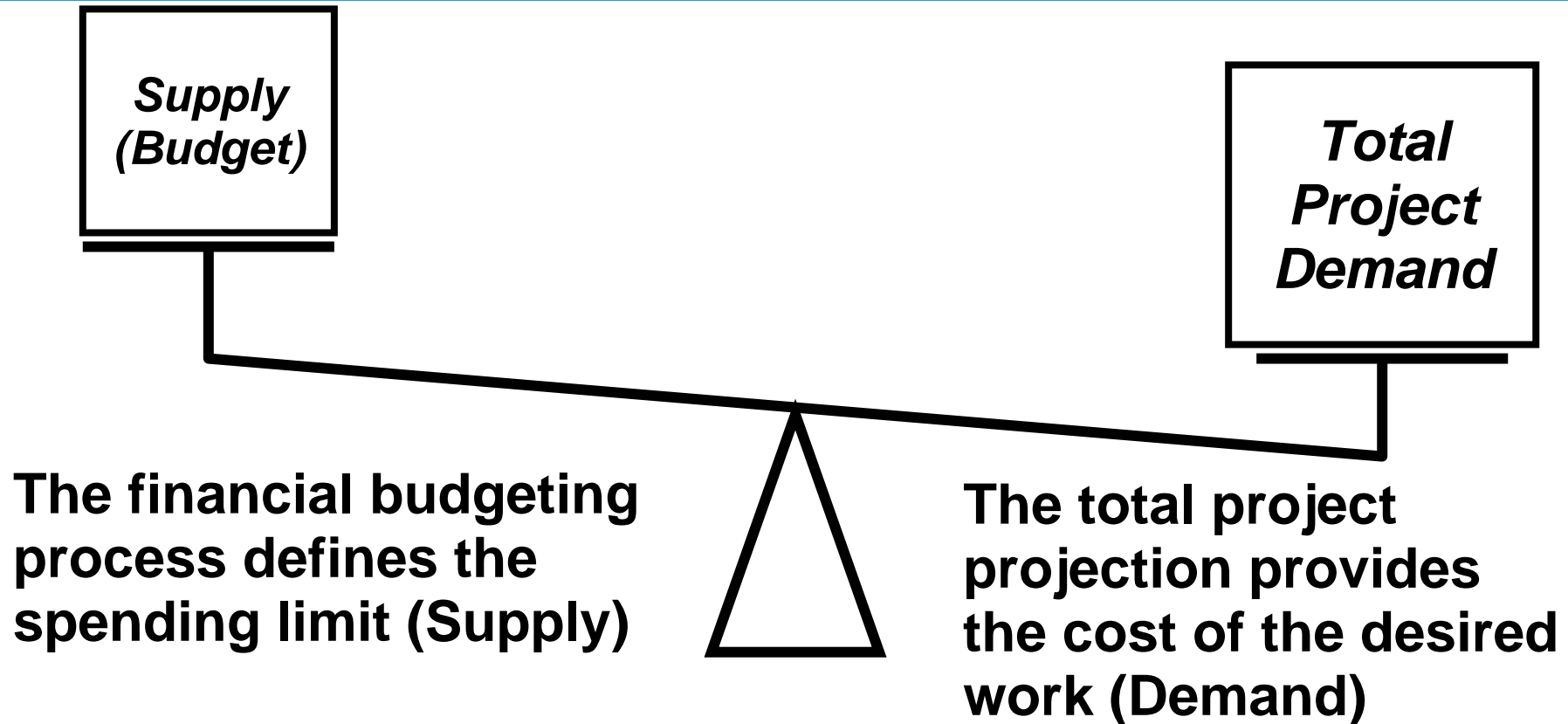
Total Budget

- Fiscal process to establish annual budget for upcoming year



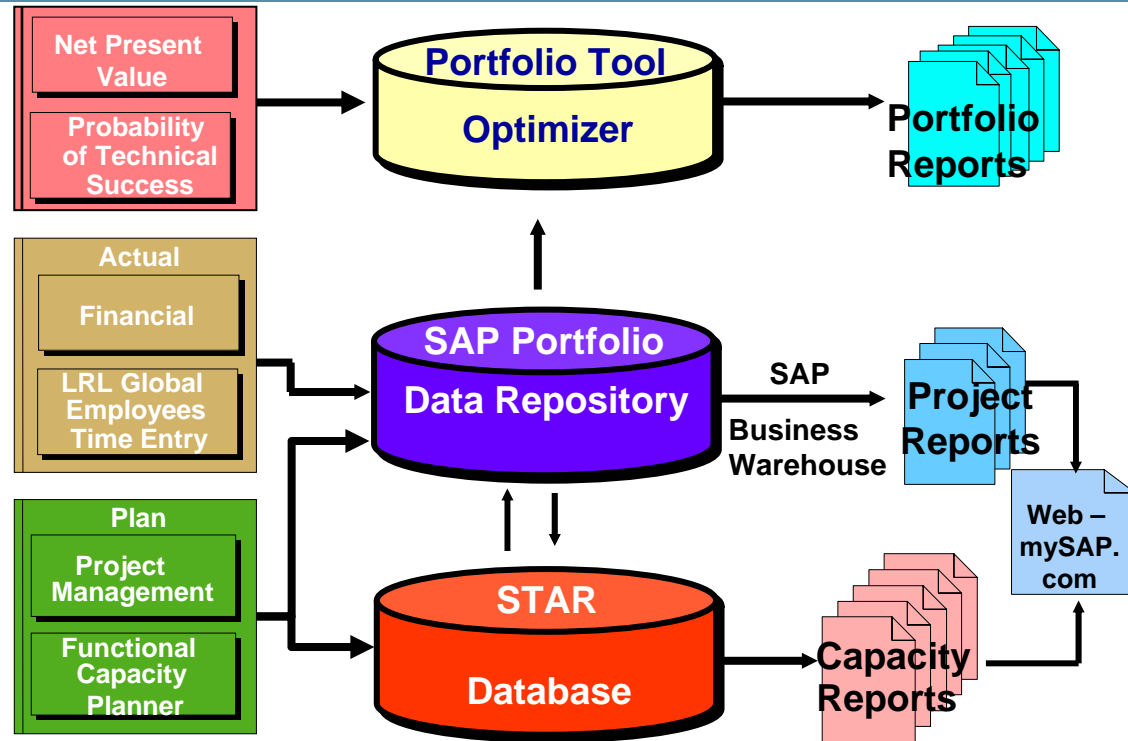
- 8 quarter forecasting process for refinement throughout the year

Budget Reconciliation



Reconciliation of Supply and Demand through "Buy-Up" and "Trade-Off" Processes

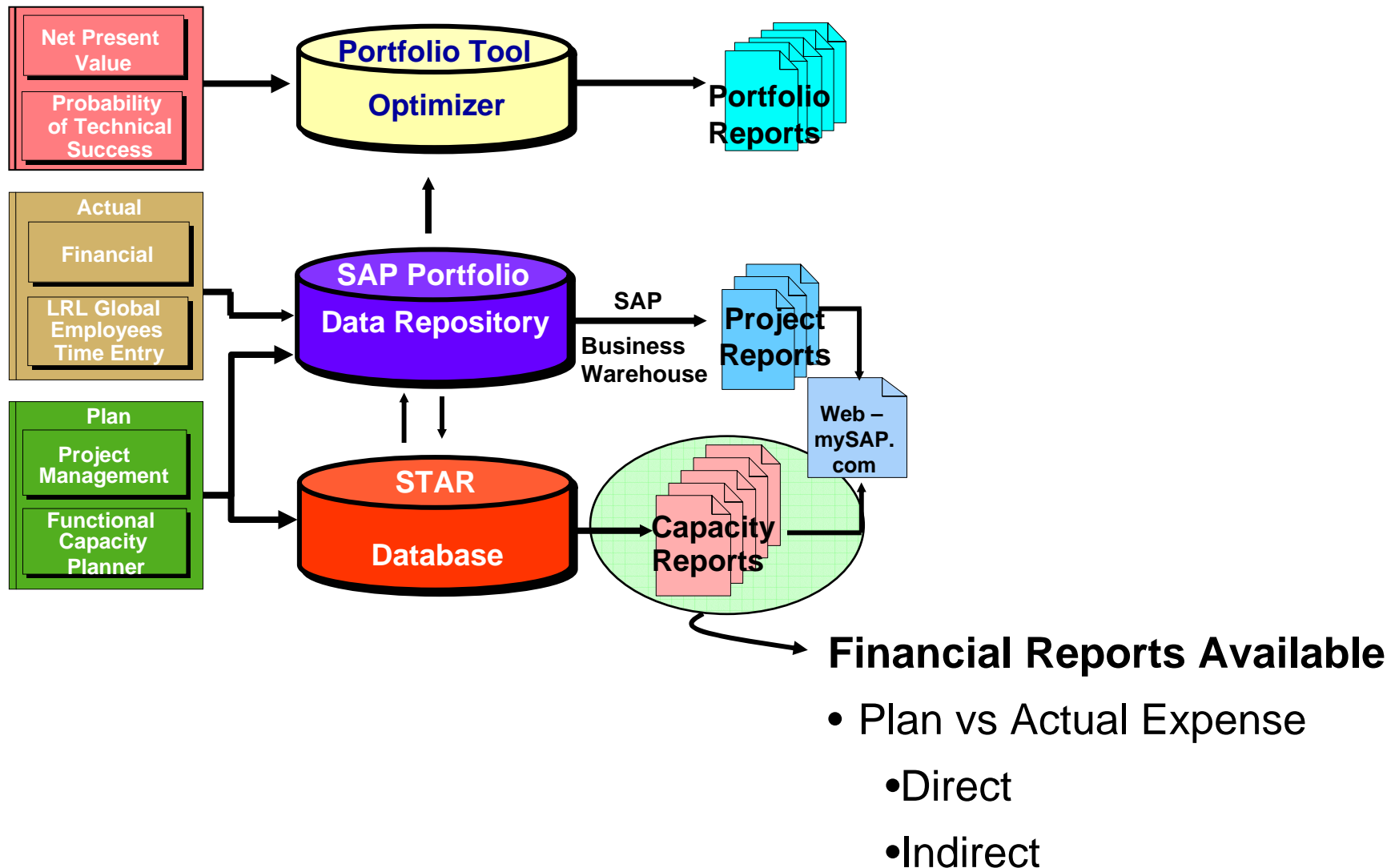
Financial Inputs



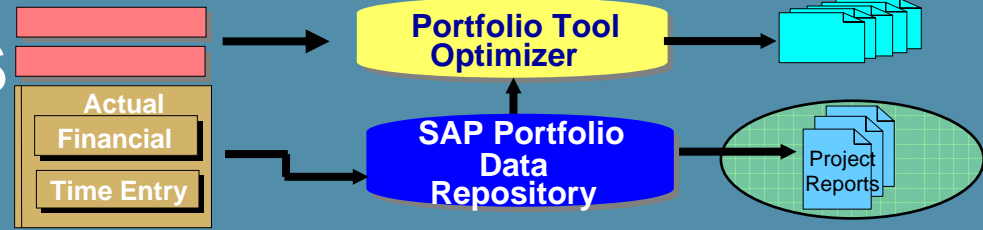
Inputs to Financial Process

- The project plan
- Time entry data
- Global cost project data
- Clinical trial data

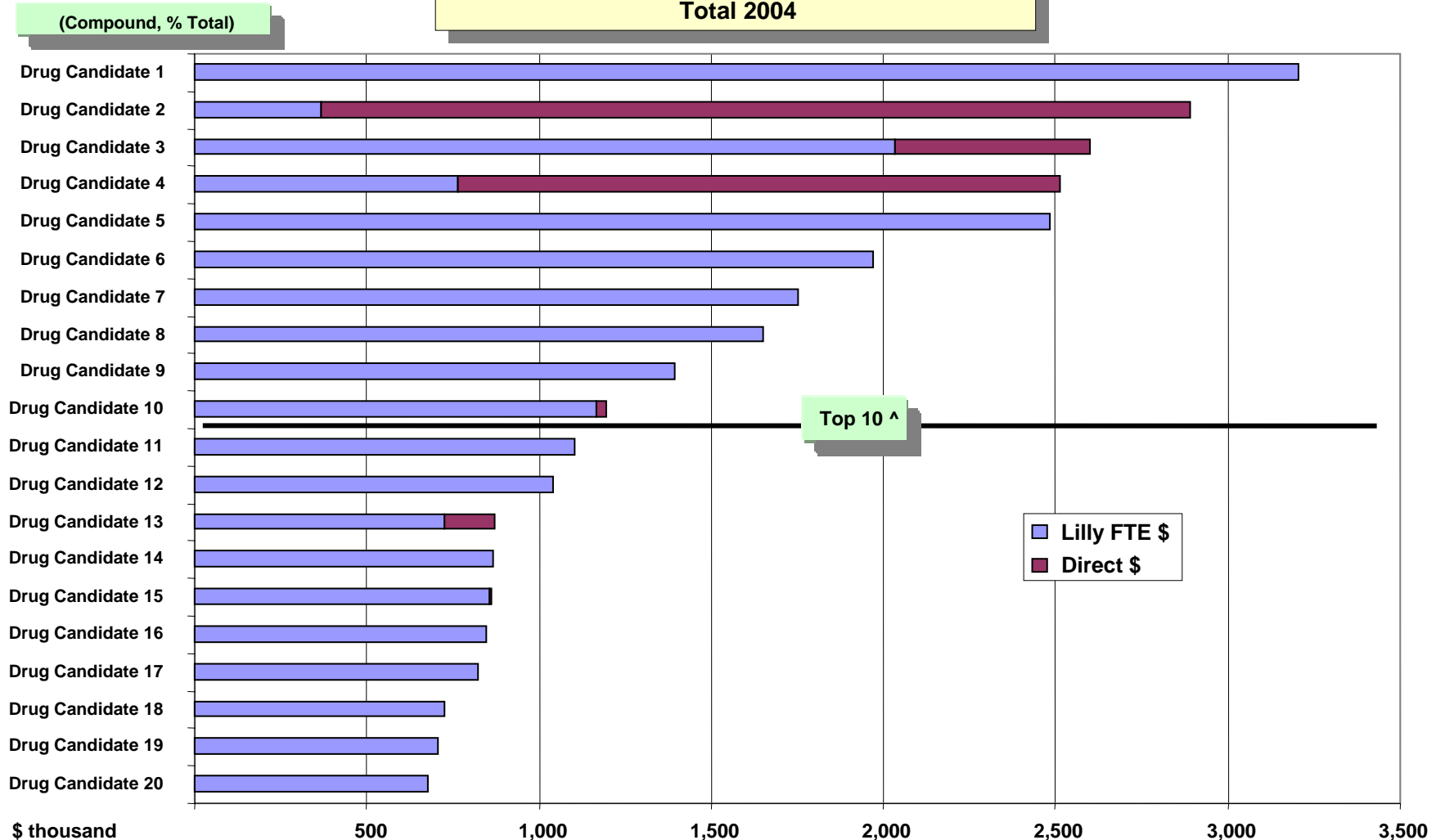
Financial Reporting From Project Management Information Systems



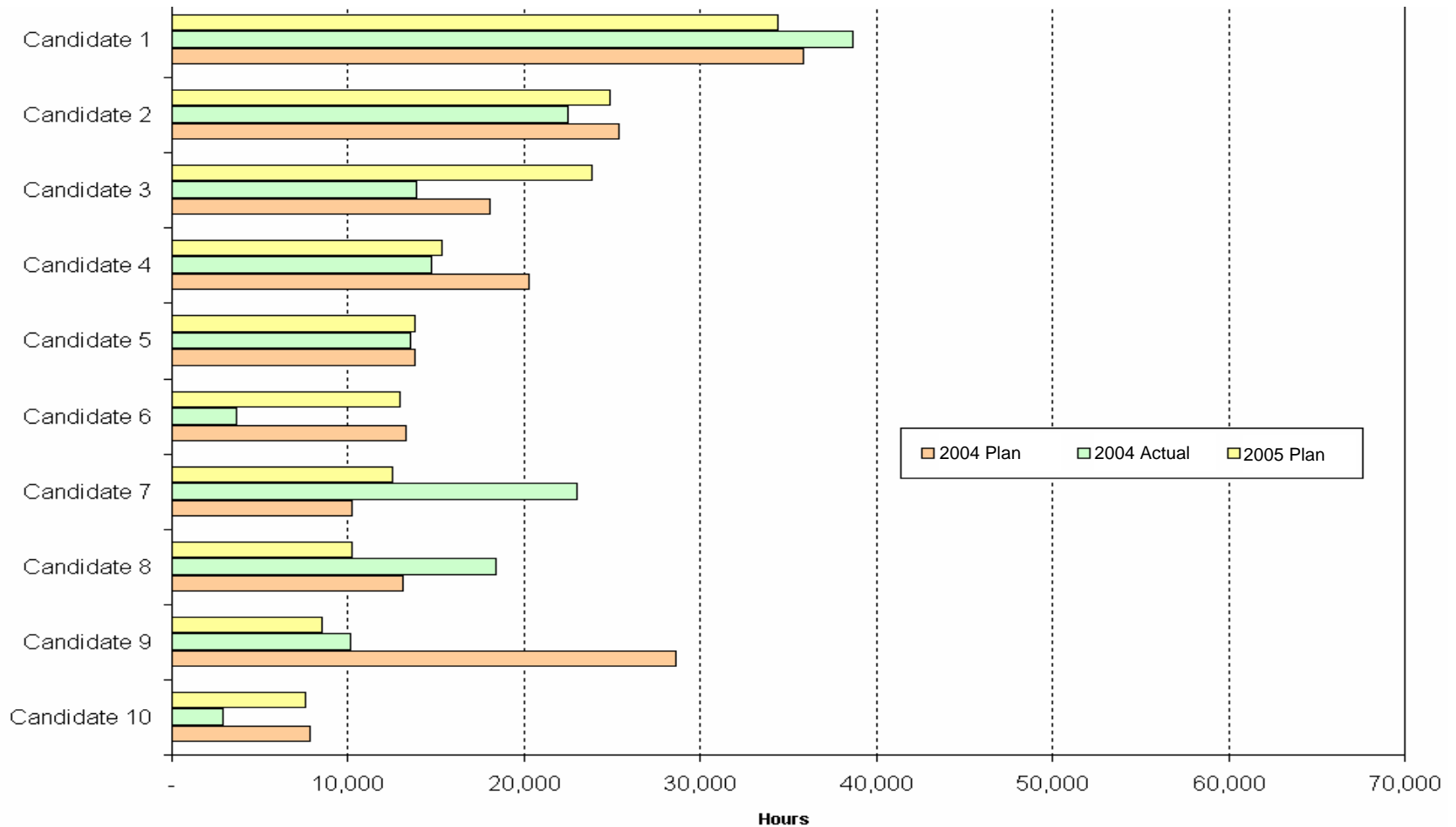
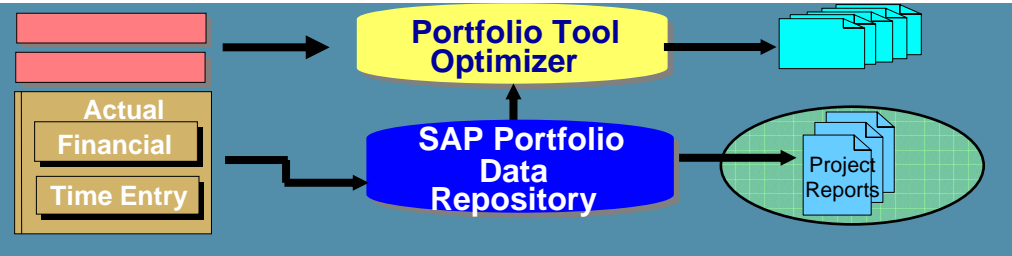
Financial Reports From PMIS



**Top 20 Compounds by Spend
Total 2004**



Financial Reports From PMIS



VII. Conclusion



The Benefits of Project Management Information Systems to the Project Manager

- **Consolidated source of project information:**
 - ▶▶ **More timely and consistent information for controlling projects**
 - ▶▶ **Information more appropriate for cross project comparison**
 - ◆ **Senior Management reporting**
 - ▶▶ **Fewer tools to maintain**
 - ▶▶ **Reduced risk of different data**

The Benefits of Project Management Information Systems to the Financial Process

- **Provides Project and Financial Manager with integrated financial management tool:**
 - ▶ **Utilizing data provided by the function**
 - ▶ **Plan and Actuals tied to Project Plan**
 - ▶ **Cost and resource information more visible to:**
 - ◆ **Project Manager**
 - ◆ **Global Research Organization**
 - ▶ **Better, more current information for controlling projects**

Benefits of Project Management Information Systems to the Portfolio Management Process

- **SAP Project Systems has provided more accurate, comprehensive, and timely information collected in a consistent manner for decision makers.**
- **Better data should lead to better decisions:**
 - ▶ **Decisions made by people**
 - ▶ **Dependent upon on the quality of the inputs**
- **Facilitates the consideration of**
 - ▶ **Buy-ups and in-licenses**
 - ▶ **Trade-offs and out-licenses**

Key Question

➤ **Can small companies benefit from this type of approach?**

Yes

- ▶▶ **Significant benefit is derived from**
 - ◆ **Project management tools**
 - ◆ **Business process**

Project Management Tools

- **Can a small company afford the tools for portfolio, project and capacity management?**
 - ▶▶ **Can you afford not to measure?**
 - ◆ **Probably not**
 - ◆ **Significant choice of tools at a variety of costs**

Project Management Tools

➤ **Types of tools available to small pharmaceutical and biotech companies**

▶▶ **Examples**

◆ **Project management tools**

- **Excel**
- **Microsoft Project**
- **Microsoft Project Server Edition**
- **Artemis**
- **Scitor**
- **Primavera**

◆ **Reporting/ Communication tools**

- **PowerPoint**
- **Web sites**
- **Lotus Notes database**

Business Process

- **Significant benefit can be derived from**
 - ▶ **Establishment of a business process for:**
 - ◆ **Project management**
 - ◆ **Portfolio management**
 - ◆ **Resource / capacity management**
 - ◆ **Project governance / gate reviews / project charters / approvals**
 - ▶ **Establishment of a dictionary for key terms**
 - ◆ **Examples -**
 - **First Human Dose**
 - **Submission**
 - ▶ **Establish a common language**

Business Process

- **Significant benefit can be derived from**
 - ▶ **Making data driven decisions**
 - ◆ **Projects**
 - ◆ **Portfolio**
 - ◆ **Function**
 - ◆ **Disciplined execution**
 - ◆ **Proactive risk management**
 - ◆ **Frequent communication**

Conclusion

➤ **As an industry, we need to continue to adapt by:**

▶ **Reinventing the drug development process**

◆ **FDA's Critical Path initiative**

▶ **Controlling drug development cost and cycle times**

◆ **Project management**

◆ **Capacity management**

◆ **Resource management**

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Thank You

Using Project Management Information Systems (PMIS) To Improve R&D Portfolio Decisions

Martin D. Hynes III, Ph.D.
Director, Operations & Quality,
Pharmaceutical Product Research & Development

Lilly Research Laboratories
A Division of Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285 U.S.A.
www.lilly.com



Answers That Matter.