

The Pharma/Biotech Innovation Conundrum: R & D Spending Up, Number of Drugs Down

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Agenda

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- Purpose
- Industry Trends
- Innovation Conundrum
- Innovation Deficit: Strategic Issues
- “I” Shaped Hierarchical Departments
- Value Networks: Innovation Pathways
- Innovation Pathway Challenge
- Innovation Pathway Solution
- What’s the Solution to the Innovation Conundrum? - Discussion

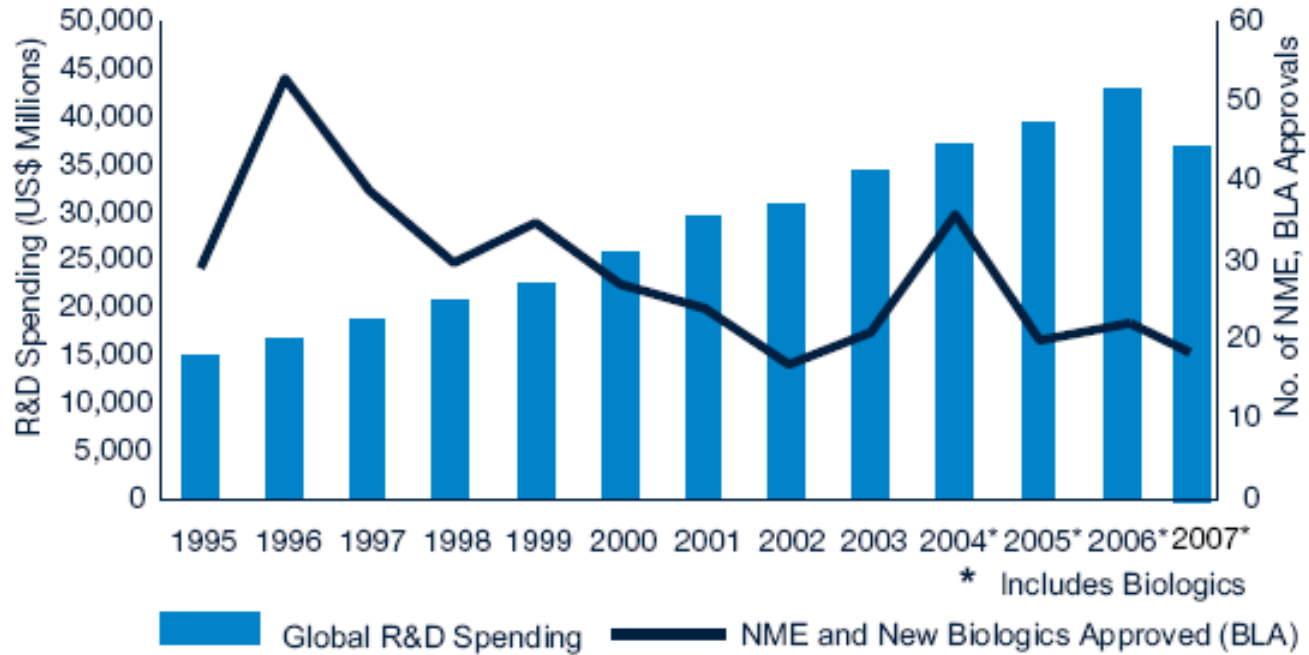
Purpose

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- Offer insights into the innovation challenges faced by the pharma/biotech industry
- Share ideas on how innovation networking can contribute to the innovation development process, increasing R & D productivity
- Discuss how innovation management can play a role to solve the conundrum.

- R & D Cycle – Long – 7 to 10 yrs, Costly \$1.2 B Avg. (Tufts CSDD 2007)
- Regulatory – FDA increasingly focused on reducing patient risk
- Efficacy - Most therapies work on average of 40 % of patients
- Science – Discovering the ‘right’ biotech therapy to increase efficacy
- Safety – Sophisticated therapies are high risk causing drug complications, interactions
- Pricing - increased patient, provider and government scrutiny
- Competition – 10 Major Pharma/Biotech Companies – in Oncology last year there were almost 400 new therapies announced in Phase 1 – 3 trials
- Clinical Research – US clinics are saturated with trials, ltd capacity
- Innovation Deficit – R & D investment is not producing NMEs at the rate of investment

The Innovation Conundrum: R & D Spending Up 2x, Drugs Launched Down 50 %



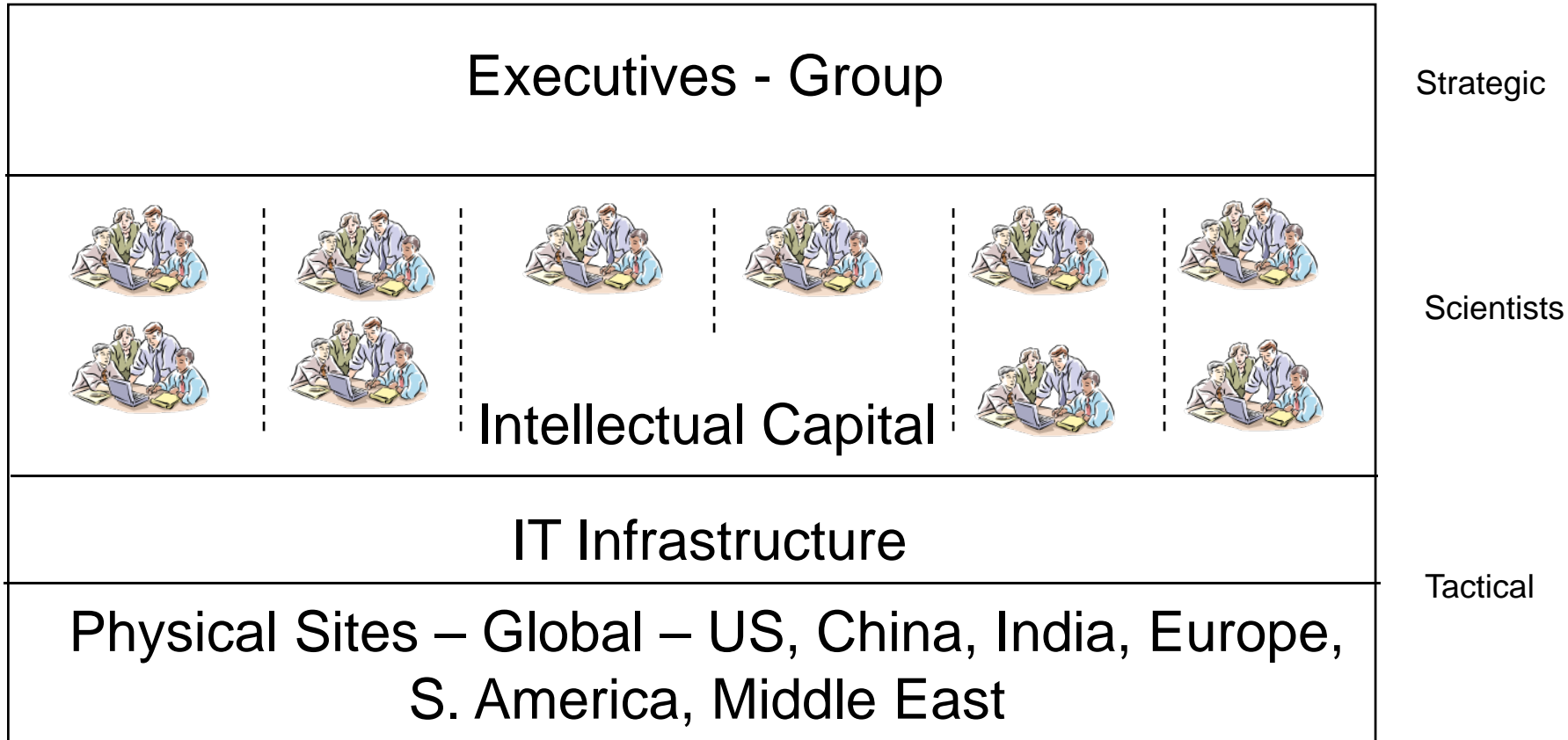
NME:
 New chemical or biological prescription therapeutic: excludes vaccines, antigens and combination therapies which do not include at least one new constituents

Source: FDA CDER, PhRMA and PricewaterhouseCoopers analysis

The Innovation Deficit : Major strategic impact on Pharma/Biotech Companies with Key Issues

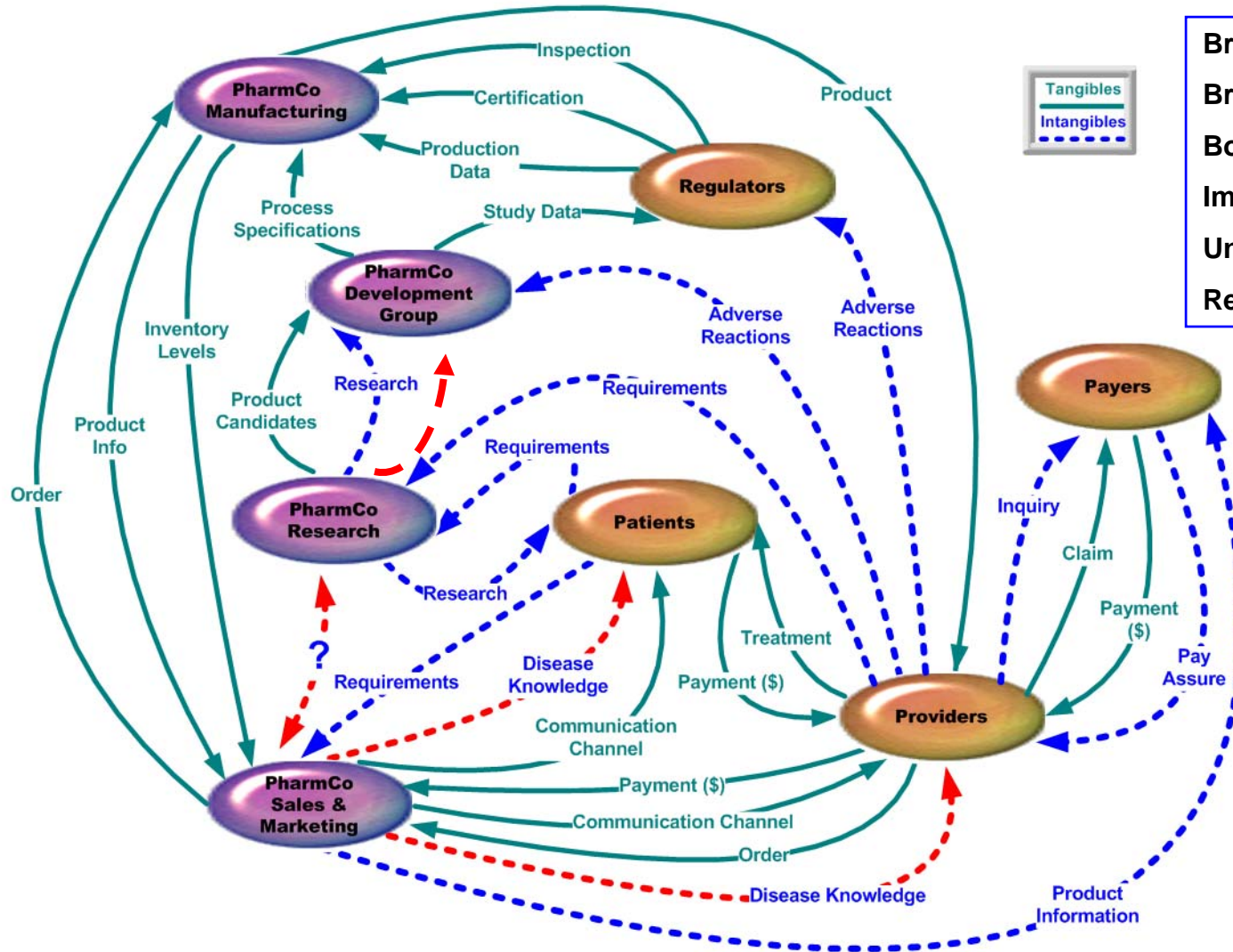
- Scientific Issues : Better understanding of the human body to be understood at the molecular level, and the pathophysiology of disease
- Leadership Issues: Understanding the patient point-of-view, in providing a total solution from a cost/benefit perspective, work with regulators in 'parallel' for targeted solutions
- Technology Issues: Greater use of technology to virtualize the research and development process, integration of global content
- Collaboration Issues: Increase collaboration, expertise sharing, 'how to' knowledge – between scientists, academics, government,

Today: “I” Shaped Hierarchical Departments for R & D – How to connect scientists for optimal innovation?



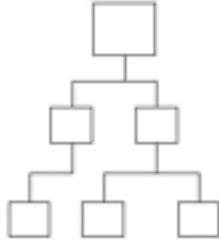

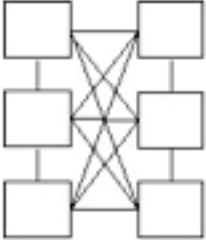
Value Networks: Map Innovation Pathways

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Verna Allee, Value Networks LLC

Value Networks: Match Innovation Pathways to Strategy Goal

	Production Network	Development network	Innovation Network
Illustration			
Structure	Vertical	Horizontal	Diagonal
IC function	Implement knowledge	Transfer knowledge	Create knowledge
Knowledge environment	Mechanic	Organic	Dynamic
Flows between staff	Tangible (i.e. products, money) Intangible (i.e. production related information)	Intangible (transferable firm specific information, know-how)	Tangible (i.e. innovation related products, money) Intangible (i.e. research knowledge, experimental knowledge, know-how)

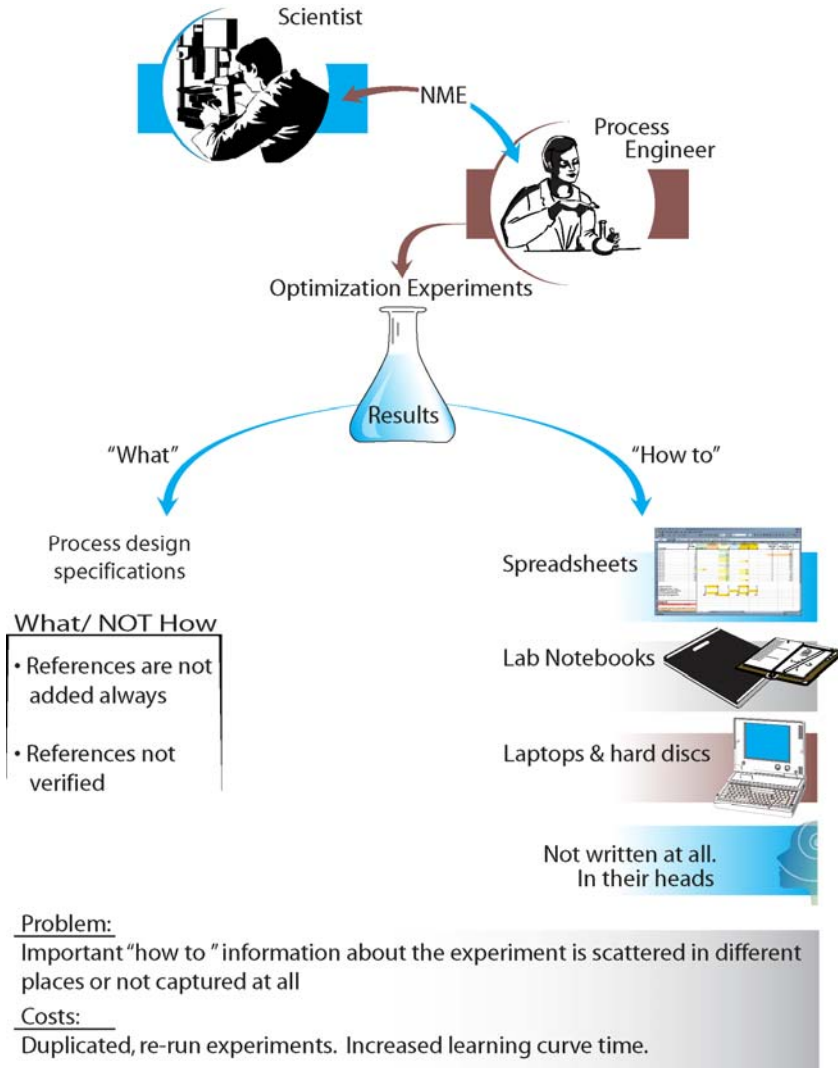
Stahle, Gronoroos 2000, Poyhonen & Smedlund, 2004

Value Networks: Require Different Leadership Models

Knowledge environment	IC function	Knowledge and competence	Relationships	Information flow	Management and leadership method	Biotech
Innovation (Dynamic)	Create knowledge	Intuitive, potential	Spontaneous, abundant	Chaotic, sporadic	Personal networking skills, relinquishing power	Research
Transform (Organic)	Transfer knowledge	Experiential, hidden, tacit	Reciprocal, seeking consensus	Multi-way, horizontal	Dialogue, empowerment	Development
Productivity (Mechanic)	Implement knowledge	Defined, explicit	Determined by hierarchy	One-way, top-down	Orders, direct use of power	Process Mfg

Stahle, Gronoroos 2000, Poyhonen & Smedlund, 2004

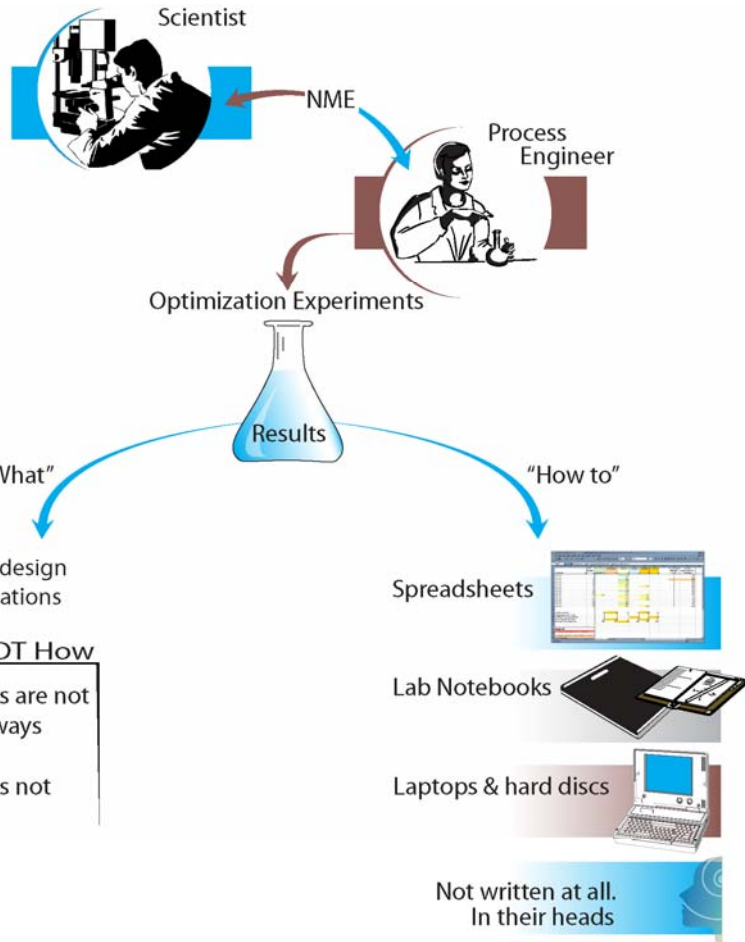
Innovation Pathway Challenge: Example



- Knowledge sharing is an informal process that is often done on an ad hoc basis
- The organization is effective at capturing and communicating specific versions of manufacturing processes, i.e. the "What"
 - Experiment Results
 - Tech References
 - Process Descriptions
 - Process Specs
 - Detailed process versions
 - Critical parameters
 - Equip. requirements
- However, the "Why" and "How To" information on developing and improving manufacturing processes between versions is not always captured or is captured in many different places
 - Rationale behind experiments
 - Process / analytical drivers for improvements
 - Campaign history / use in clinical program
 - Lessons learned

Innovation Pathway Challenge: Knowledge Sharing Solution

Today



What/ NOT How

- References are not added always
- References not verified

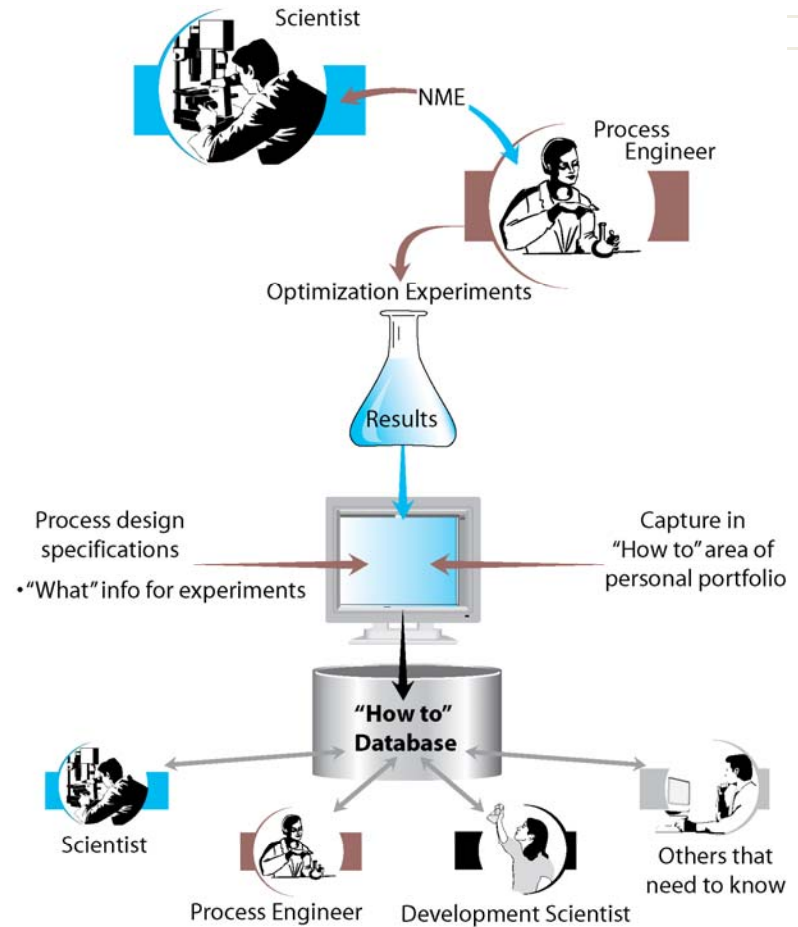
Problem:

Important "how to" information about the experiment is scattered in different places or not captured at all

Costs:

Duplicated, re-run experiments. Increased learning curve time.

Future



Solution: Shared structural "how to" information to all

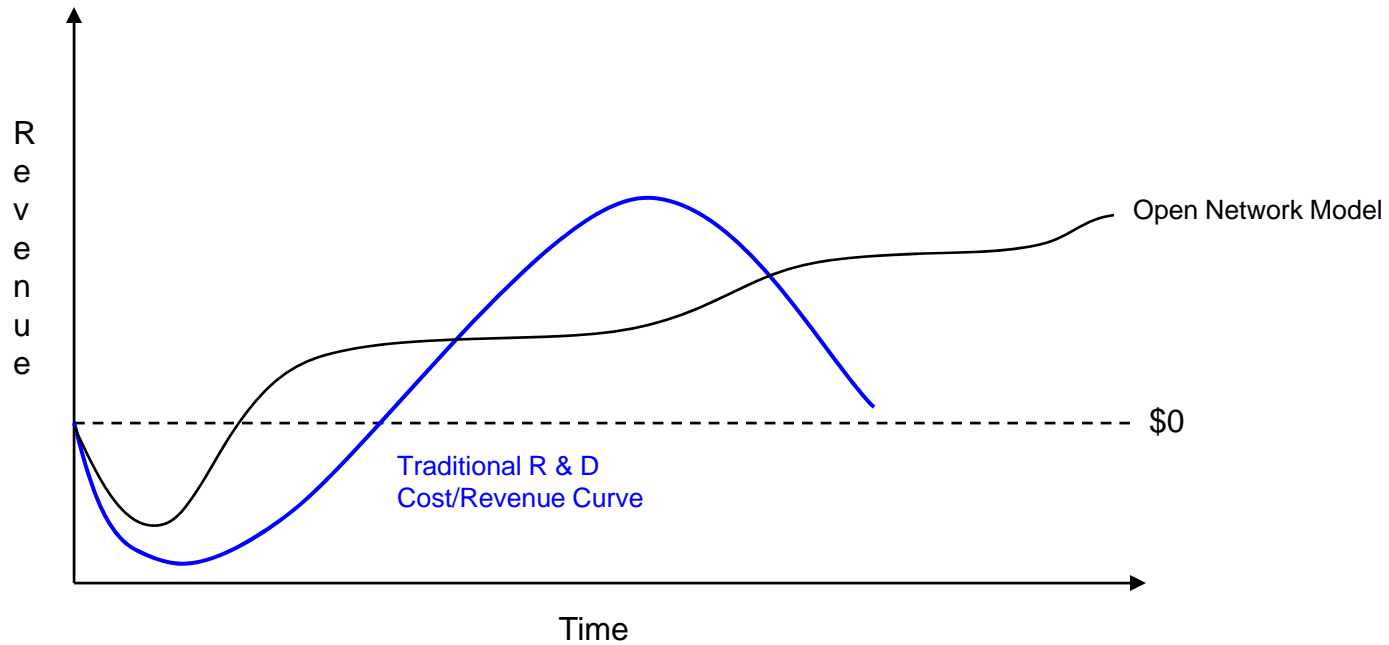
Benefit: Reduced development time

What is the solution to the Innovation Conundrum?

Questions for Discussion:

- What role does organization structure, leadership play?
- How can IT hinder or encourage solutions?
- How open innovation business models help?
- What factors need to change in the science innovation environment to foster more effective or faster innovation?
- What do we know about collaboration services, systems that can help us in solving this problem?
- How would parallel, iterative, collaborative value streams reduce the time to market launch?

New Model to Accelerate R & D Development Time



Adapted from Price Waterhouse Coopers – “Pharma 2020: Virtual R & D, Which Path Will You Take? 2008