

What is Project Management? cvg

NIH Principles of Clinical Research

Charles Grudzinskas, Ph.D.

NDA Partners LLC

Center for Drug Development Science (CDDS)
UCSF—Washington Center

Drug Development Consultant
Annapolis

WHAT IS PROJECT MANAGEMENT ? cvg

- *What Is A Project ?*
- *Process & Content*
- *7 Elements Of Project Management*
- *Evolution Of Project Management*

Cost of Poor Management cvg

- *\$ 899 MM/Each New Drug*
- *Opportunity Costs*
- *Failed Drugs*
- *Marketing & Sales Costs*
- *The Patients are Still Waiting*

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Benefit of Good Management

- Higher NPVs
- More Products per \$
- Identify Losers Sooner
- More Successful Projects
- Faster Reviews

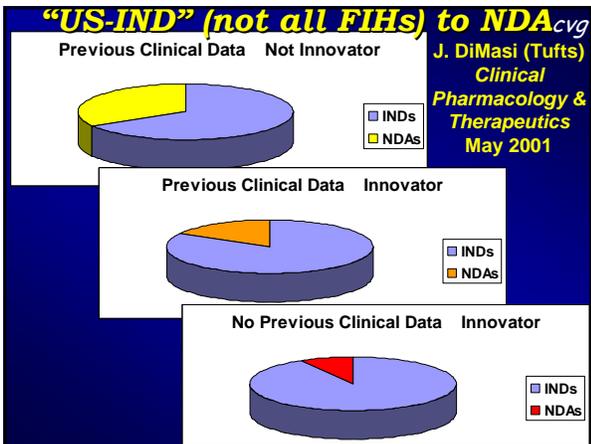
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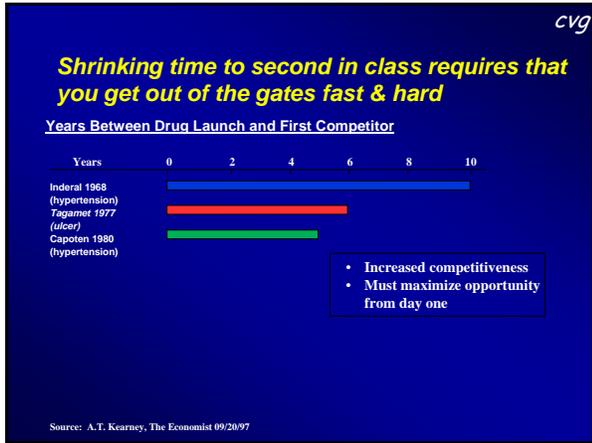
Many Are Treated, but Few Are Cured

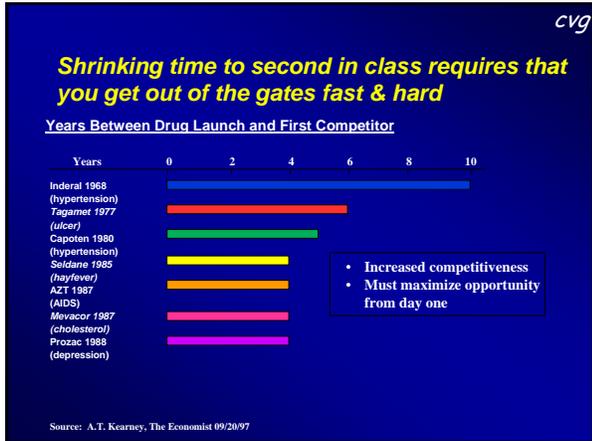
From within the ranks of the Pharmaceutical Industry, Statistics on the Low Percentage of Individuals Helped by Medications & Drugs.

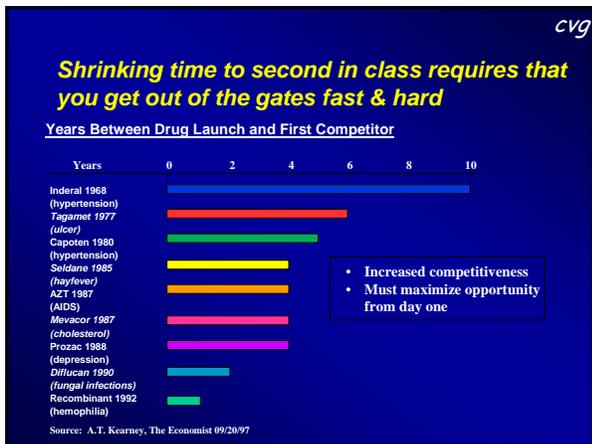
The solution? Pharmacogenomics

Glaxo chief: Our Drugs do not Work on Most Patients









Differentiation: Oncology^{cvg}

- Better **effectiveness** profile
 - Imatinib Mesylate (Gleevec™)
- Better **safety** profile
 - Epirubicin (Ellence™)
- Better patient **compliance**
 - Less chair-time?
 - Oral paclitaxel?

Tools for Success^{cvg}

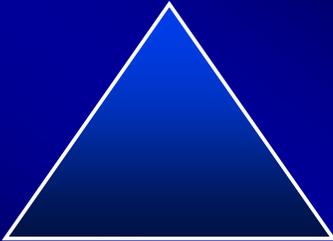
- Target Product Profile (TPP)
- Target Package Insert (TPI)
- Comparative PI elements
 - Marketed
 - In development

Target Product Profile^{cvg}

- Meets ICH guidances
- ↑ The “Optimal” target
- ↓ The “Threshold”-
 - Below which we will not launch
- Must be measurable

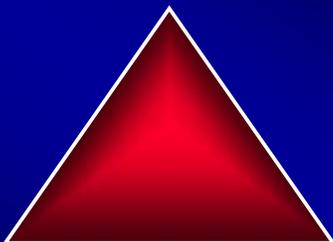
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A PROJECT IS...



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A PROJECT IS...



SPECIFICATIONS
(QUALITY AND QUANTITY)

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PROJECT OBJECTIVES

- *GO / NO GO Criteria*
- *Barn Door Forecasting ?*

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Barn Door Forecasting

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Barn Door Forecasting

BANG!

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Barn Door Forecasting









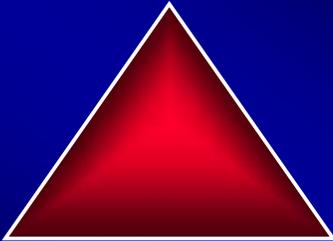






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A PROJECT IS...



SPECIFICATIONS
(QUALITY AND QUANTITY)

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A PROJECT IS...

- *Unique Chemical (or Combo), Biological, or Device*
- *Single Indication(s)*
- *Single Formulation*
- *Single Package Style*

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A PROJECT IS...

- *Unique Chemical (or Combo), Biological, or Device*
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INTERNAL FORCES

**YOUR
PROJECT**

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INTERNAL FORCES

Team

↓

**YOUR
PROJECT**

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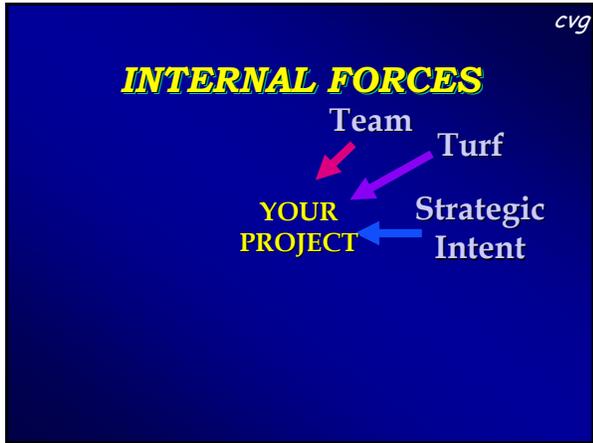
INTERNAL FORCES

Team

Turf

↓ ↓

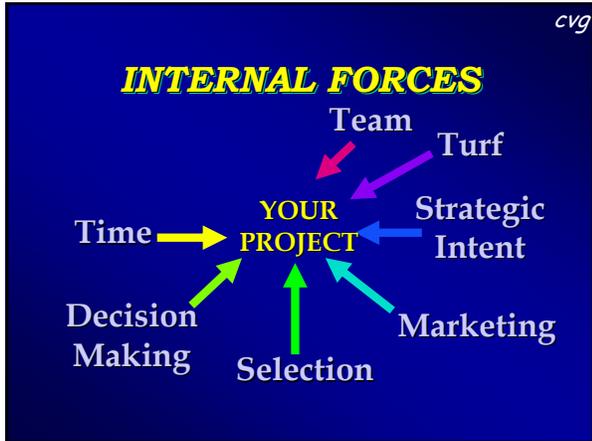
**YOUR
PROJECT**









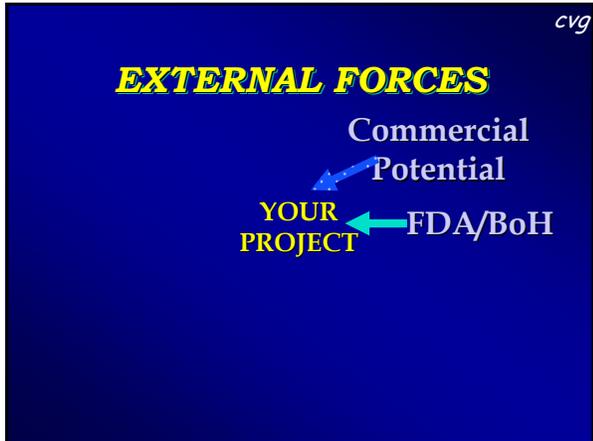
















EXPANDED REIMBURSEMENT cvg

“HCFA Reimbursement For Epogen, Takeover Talk Help Amgen Grow in June”

- “A second increase in the Health Care Financing Administration reimbursement rates for Epogen has aided in increasing the valuation of Amgen in the financial community.”
- “On June 19, HCFA issued a program memorandum to payors that directed payment of claims for Epogen (erythropoietin alfa) in patients whose hematocrit levels reach as high as 37.5%”

“The Pink Sheet” 7/6/98 page 20

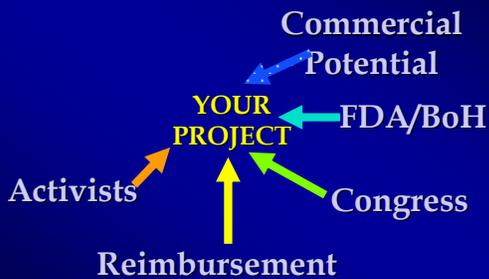
EXPANDED REIMBURSEMENT cvg

“HCFA Reimbursement For Epogen, Takeover Talk Help Amgen Grow in June”

- On June 24, Gruntal & Co. analyst David Saks predicted that the new reimbursement policy could result in a 10% increase in use; Epogen sales in 1997 were about \$1.07 bil. And Amgen’s total revenues were \$2.4 bil. Gruntal upgrades Amgen from “buy” to “strong buy.”

“The Pink Sheet” 7/6/98 page 20

EXTERNAL FORCES







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What is Project Management?

PMBOK

“Project management is the application of knowledge, skills, tools, and techniques to project activities in order to meet or exceed stakeholder needs and expectations from a project.”

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What is Project Management?:

Knowledge

- Drug development process & benchmarking
- Science/Medicine (therapeutic area)
- Regulations
- Business
- Portfolio management
- Alliance Management
- Risk management
- Project time management
- Project cost management
- Organizational dynamics
- International & corporate culture

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What is Project Management?:

Skills

- Interpersonal
- Network planning
- Strategic thinking
- Negotiation
- Meeting management
- Communication (written & oral)
- Conflict management
- Issue resolution
- Monitoring
- Contractor management

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What is Project Management?:

Tools

- Planning software
- PERT charts
- Gantt (bar) charts
- Dashboards
- Decision trees & network
- Meeting minutes
- Spreadsheets
- e-Mail
- Word processor
- Teleconference
- Videoconference

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What is Project Management?: Techniques

- What if analyses
 - *Cajoling*
 - *Nagging*
 - *Begging*
- Critical path analyses
- **Brainstorming**
- **Challenging (devil's advocate)**

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OBJECTIVES (Results)

PROCESS

- *Communicate Strategy*
- *"White Space"*
- *Integrate Plan*
- *Facilitate*
- *Resolve Conflicts*
- *Report on Progress*
- *Business Decisions*

CONTENT

- *Establish Strategy*
- *Science/Technology*
- *Study Design/Execution*
- *Report/Recommend*
- *Scientific Decisions*
- *Business Decisions*

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WHAT IS PROJECT MANAGEMENT ?

- *Portfolio Design, Planning & Management*
- *Planning*
- *Scheduling*
- *Resource Allocation*
- *Human Factors (Teams)*
- *Decision Making Process*
- *Process Leadership & Benchmarking*



“Sure, we need more research in alchemy, necromancy, and sorcery, but where is the money going to come from?”

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WHAT IS PROJECT MANAGEMENT ?

- **PORTFOLIO DESIGN, PLANNING & MANAGEMENT**
 - *Doing the Right Research*
 - *Doing the Research Right*

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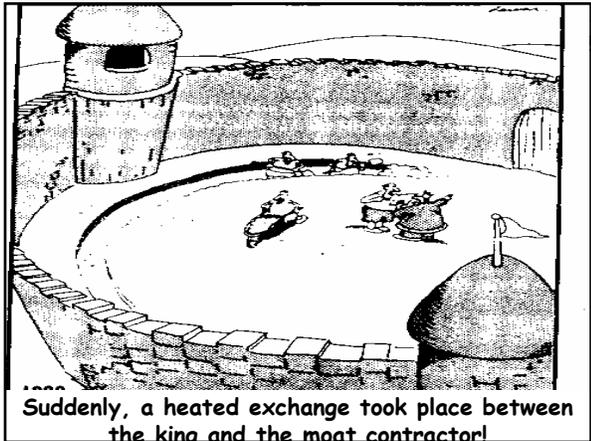
WHAT IS PROJECT MANAGEMENT ?

- **PORTFOLIO DESIGN, PLANNING & MANAGEMENT**
 - **Design and Plan**
 - *Vision*
 - *Design*
 - *Plan*

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WHAT IS PROJECT MANAGEMENT ?

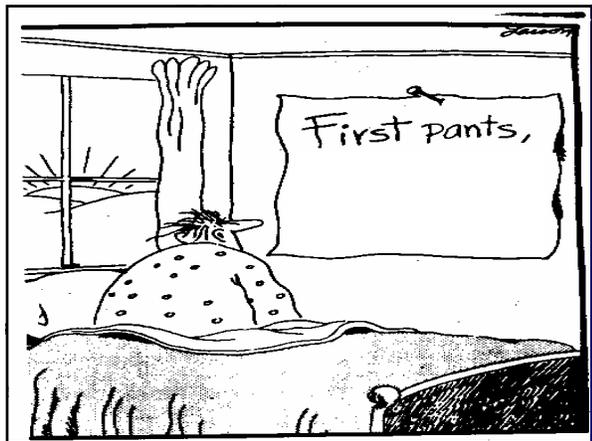
- **PORTFOLIO DESIGN, PLANNING & MANAGEMENT**
 - **Manage**
 - **Prioritize**
 - **Decision Effectiveness**

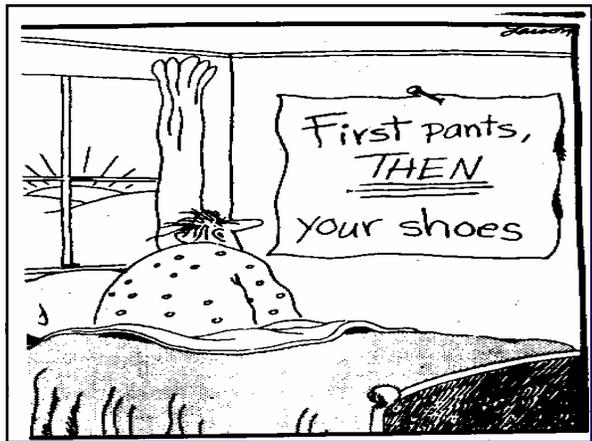


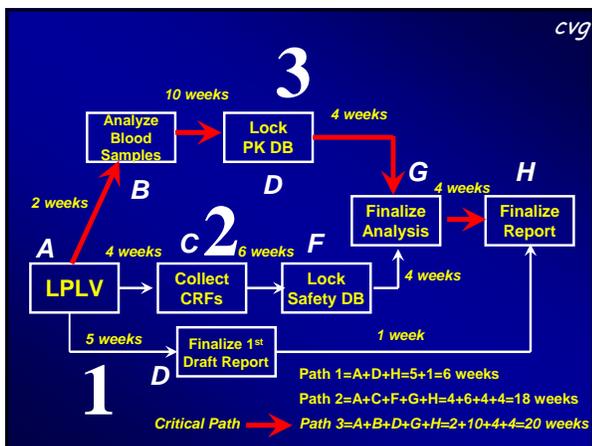
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WHAT IS PROJECT MANAGEMENT ?

- **PLANNING**
 - **Objectives**
 - **Strategy**
 - **Tactics**
 - **Go/No Go Criteria: *prespecified***
 - **Integration**
 - **Budgeting (Finance)**



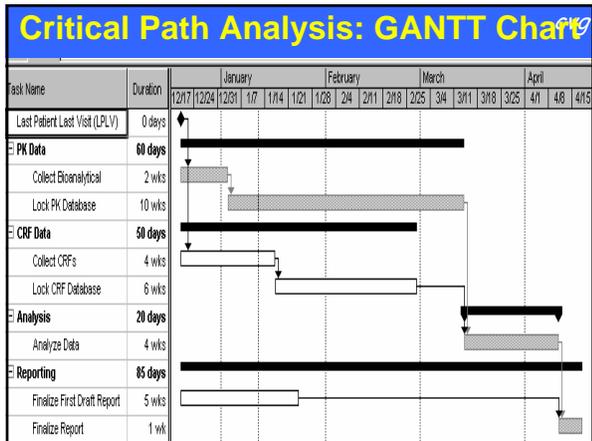




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WHAT IS PROJECT MANAGEMENT ?

- **SCHEDULING**
 - **Deadlines**
 - **Velocity**
 - **Acceleration**
 - **Tradeoffs**

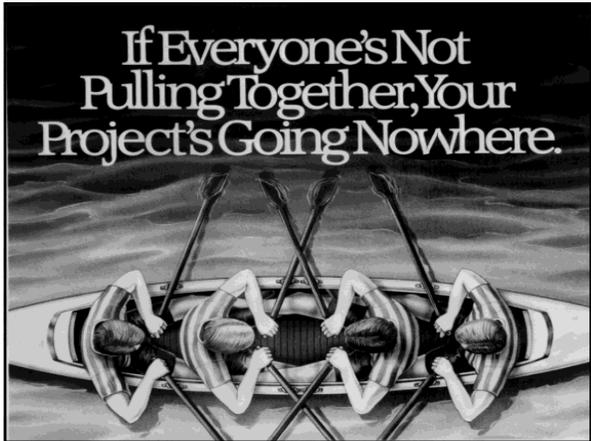




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**WHAT IS PROJECT
MANAGEMENT ?**

- **RESOURCE ALLOCATION**
 - *Capacity*
 - *Relative to timing needs?*
 - *Financial*
 - *Budget (Forecast)*
 - *Accounting (Status)*



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**WHAT IS PROJECT
MANAGEMENT ?**

- **HUMAN FACTORS (TEAMS)**
 - *Communication*
 - *Transformation*
 - *Leadership*

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WHAT IS PROJECT MANAGEMENT ?

- **HUMAN FACTORS (TEAMS)**
 - *Team Building*
 - *Team Leadership*
 - *Matrix Teams & Core Teams*
 - *High Performance*
 - *Heavy-weight Teams*
 - *Education: Core Competencies*

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WHAT IS PROJECT MANAGEMENT ?

- **FACILITATING DECISIONS**
 - *Selecting Clinical Candidates*
 - *Implementing*
 - *Tracking*
 - *Reporting*
 - *Completing /Terminating*

Adapted from "How to Keep R&D Projects on Track!"--Robert

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WHAT IS PROJECT MANAGEMENT ?

FACILITATING DECISIONS

```

    graph TD
      Report --> Decide
      Decide --> Complete_Terminate[Complete/Terminate]
      Complete_Terminate --> Initiate
      Initiate --> Monitor_Track[Monitor/Track]
      Monitor_Track --> Report
  
```

Adapted from "How to Keep R&D Projects on Track!"--Robert

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WHAT IS PROJECT MANAGEMENT ?

- **PROCESS LEADERSHIP AND BENCHMARKING**
 - *Knowledge of the Overall Process*
 - *Knowing What is Needed Next*
 - *Knowing How Long it Should Take & How Much It Costs*

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PM EVOLUTION

LINE DRIVEN

PROJECT DRIVEN

Notes

1975 1980 1985 1990 1995 2000

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PM EVOLUTION

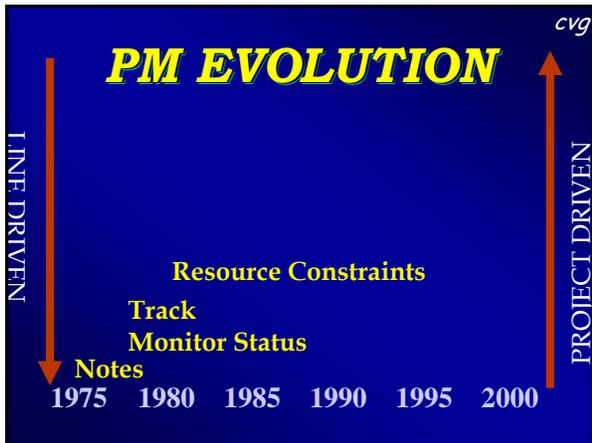
LINE DRIVEN

PROJECT DRIVEN

Track
Monitor Status

Notes

1975 1980 1985 1990 1995 2000



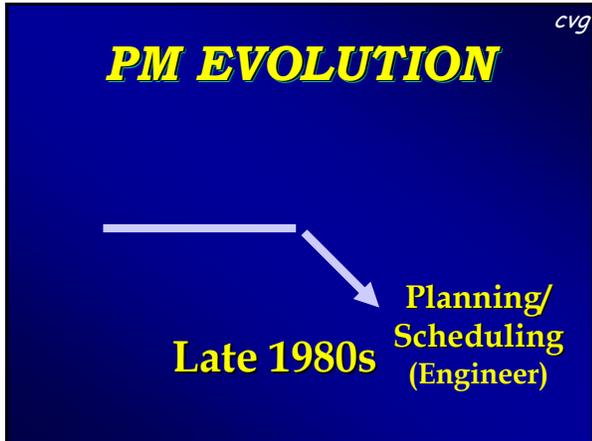


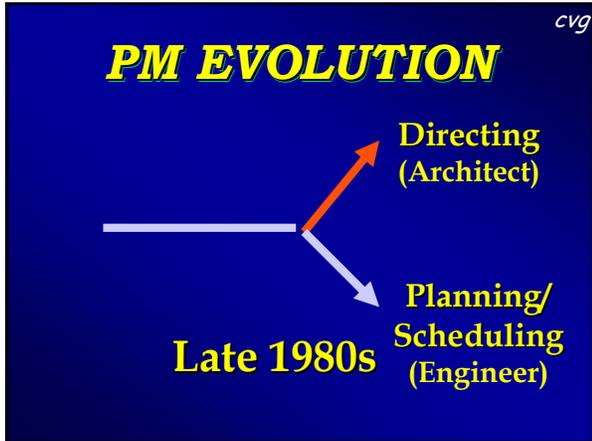












- cvg*
- ### **Project Initiation**
- *What are the expected outcomes?*
 - *When are they needed?*
 - *How much will they cost?*
 - *What resources will you need?*
 - *Who do you need?*
 - *What the project isn't (out of scope)*

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Project Initiation

- *What are the expected outcomes?*
 - *Deliverable*
 - *Results (work product)*
 - *Measurable*
 - *Target Product Profile*
 - *Target Package Insert*
 - *Emerging: Draft Package Insert*

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Project Initiation

- *Weight reduction drug*
 - *To generate the data needed to support global registrations for the weight reduction drug.*
 - *The product will be a once/week formulation.*

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Project Initiation

- *Weight reduction drug*
 - *The development program will be designed to demonstrate a sustainable (24 months) 20% reduction in weight.*

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Project Initiation

- **Weight reduction drug**
 - **The development plan will support a 12/05 NDA submission and 03/06 European submissions.**

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Project Initiation

- **Weight reduction drug**
 - **The projected budgets are:**

■ Proof of concept	\$20M
■ Dose and dose regimen	\$50M
■ Animal safety for NDA	\$45M
■ Phase 3 clinical program	\$75M
■ TOTAL	\$190M

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Project Initiation

- **When are objectives needed?**
 - **Timing drives resources?**
 - **Resources drive timing?**
 - **Deadline driven?**
 - **Competition driven?**

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Project Initiation

- *What resources will you need?*
 - *People*
 - *Facilities*
 - *Equipment*
 - *Supplies*
 - *Animals, receptors, etc.*

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Project Initiation

- *Who do you need?*
 - *In your area*
 - *In collaborative areas*
 - *In other areas of the government*
 - *Collaborators (JV)*
 - *Outsourcing (contracts)*

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Project Initiation

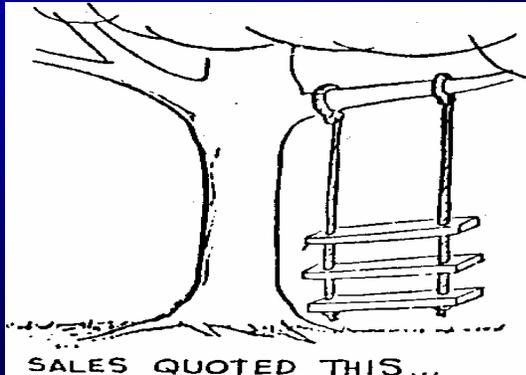
- *How much will it cost?*
 - *Green dollars*
 - *Grants*
 - *Equipment*
 - *Supplies*
 - *Animals/receptors/etc.*
 - *Blue dollars*
 - *People*
 - *Facilities*

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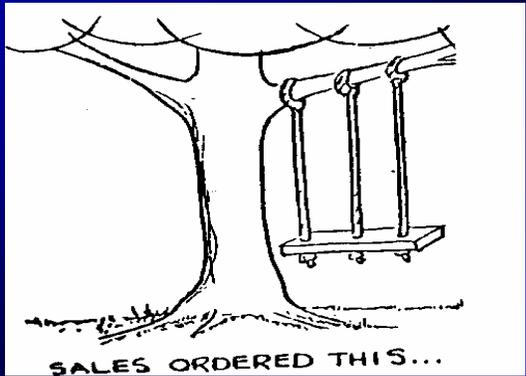
Project Initiation

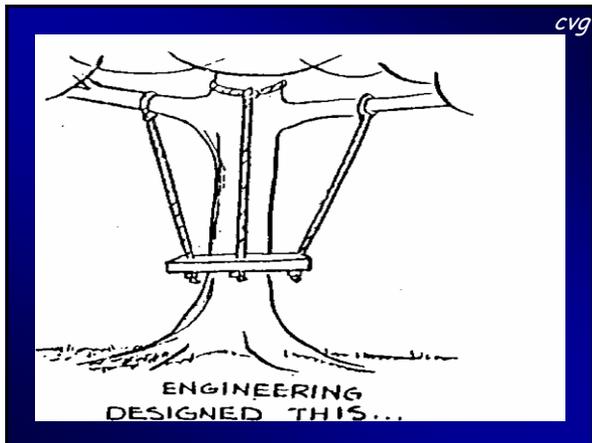
- What the project **is NOT**
 - Out of scope
 - Defines the bounds (triangle)
 - Used to track project modifications

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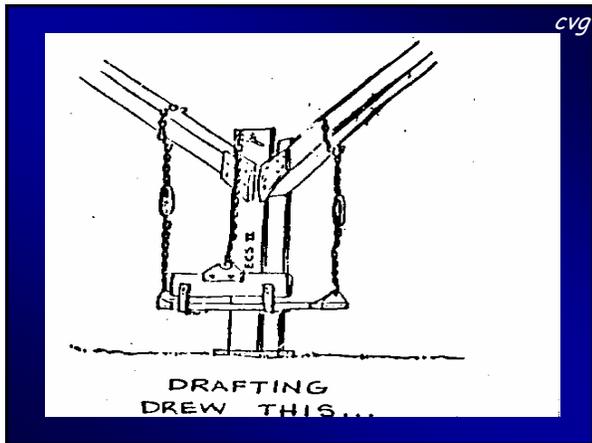


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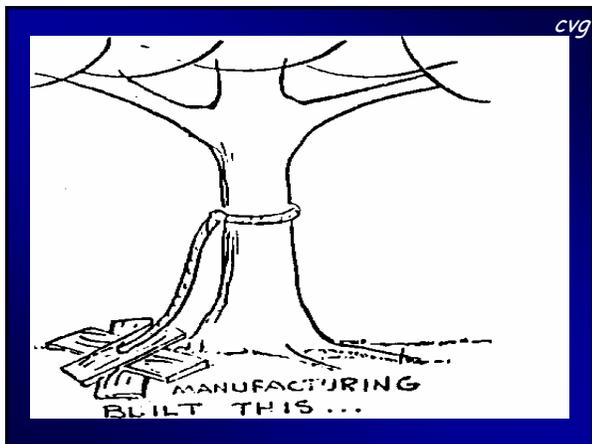




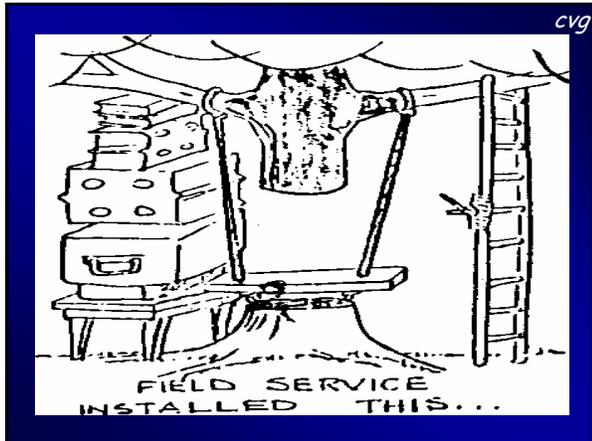
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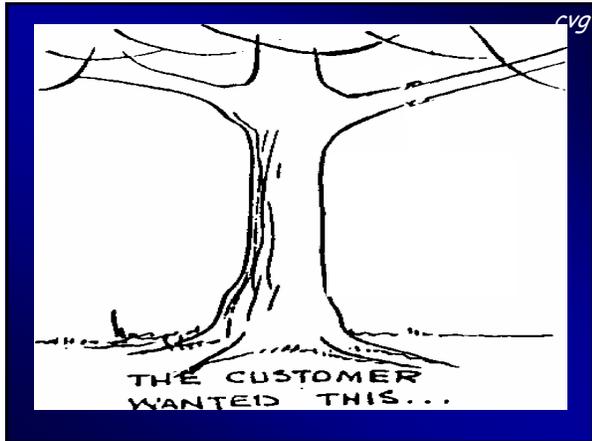


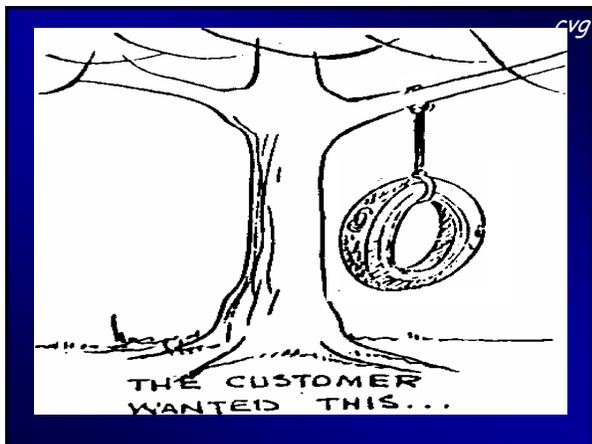
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WHAT IS PROJECT MANAGEMENT ?

- **1. PORTFOLIO**
 - *Design & Planning*
 - *Management*

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WHAT IS PROJECT MANAGEMENT ?

- **2. PLANNING**
 - *Objectives*
 - *Strategy*
 - *Tactics*
 - *Integration*
 - *Budgeting/Finance*

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WHAT IS PROJECT MANAGEMENT ?

- **3. SCHEDULING/TIMING**
 - *Deadlines*
 - *Velocity*
 - *Acceleration*
 - *Tradeoffs*

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**WHAT IS PROJECT
MANAGEMENT ?**

- **4. RESOURCE ALLOCATION**
 - *Capacity*
 - *Financial*
 - *Budget (Forecast)*
 - *Accounting (Status)*

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**WHAT IS PROJECT
MANAGEMENT ?**

- **5. FACILITATE DECISIONS**
 - *Selection*
 - *Initiation*
 - *Tracking*
 - *Reporting*
 - *Completion/Termination*

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**WHAT IS PROJECT
MANAGEMENT ?**

- **6. HUMAN FACTORS**
 - *Leadership*
 - *Team Building*
 - *Matrix/ Heavy-weight Teams*
 - *Communication*
 - *High Performance*
 - *Education*

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WHAT IS PROJECT MANAGEMENT ?

- **7. PROCESS LEADERSHIP AND BENCHMARKING**
 - *Knowledge of the Overall Process*
 - *Knowing What is Needed Next*
 - *Knowing How Long it Should Take & How Much It Costs*

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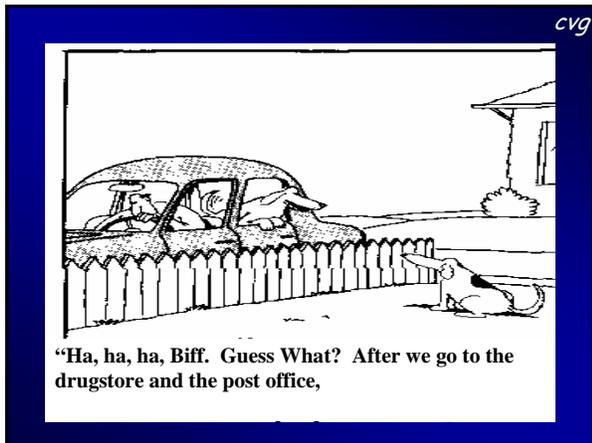
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- *Scheduling*
- *Resource Allocation*
- *Human Factors (Teams)*
- *Decision Making Process*
- *Process Leadership & Benchmarking*

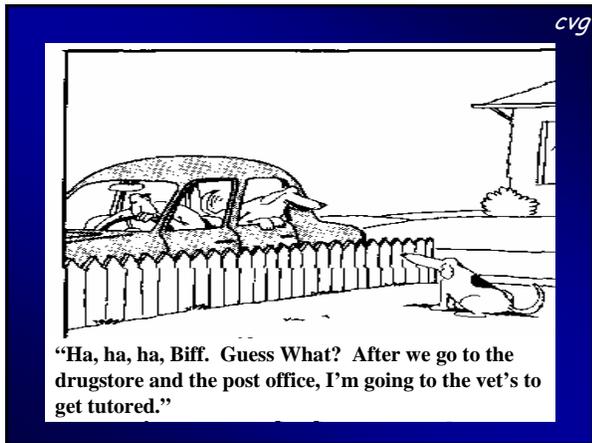
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WHAT IS PROJECT MANAGEMENT ?

- *What Is A Project ?*
- *Process And Content*
- *Evolution Of Project Management*
- *7 Elements Of Project Management*



"Ha, ha, ha, Biff. Guess What? After we go to the drugstore and the post office,



"Ha, ha, ha, Biff. Guess What? After we go to the drugstore and the post office, I'm going to the vet's to get tutored."

