

The Quest for Efficient and Cost-Effective Pharma R & D

Rashmi H. Barbhैया, Ph.D.

Advinus Therapeutics

Bangalore, India

WHO, Geneva -May 30, 2005

Key Issues affecting Pharmaceutical R&D In the US and Europe

- ***Bottlenecks*** in drug discovery and development
- Too much ***idle Intellectual Property*** and occasional to frequent difficulties in initiating / supporting ***backup programs***
- Drug candidates with high probability of success and desirable commercial potential compete with those with unknown commercial potential and probability of success – ***all candidates are treated equally***
- Ever ***increasing timelines*** for drug development
- ***Flat R&D productivity*** as judged by the numbers of INDs and NDAs filed in the last 15 years
- Exponential increase in R&D budgets – ***huge cost of innovation and drug development***
- ***Heavy focus on diseases with high potential for returns on investment*** – ***diseases of poor countries are essentially neglected***

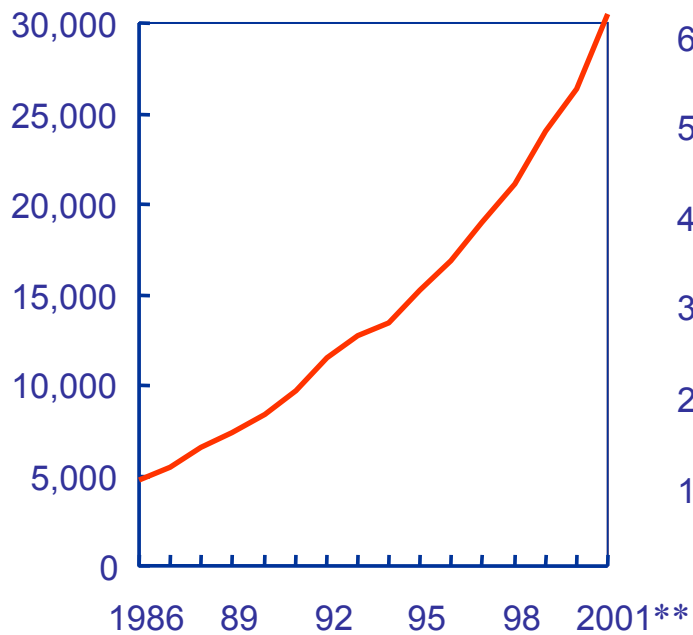
NUMBER OF PHARMA PRODUCTS FLAT DESPITE INCREASE IN R&D INVESTMENT

R&D spending has increased
5 fold . . .

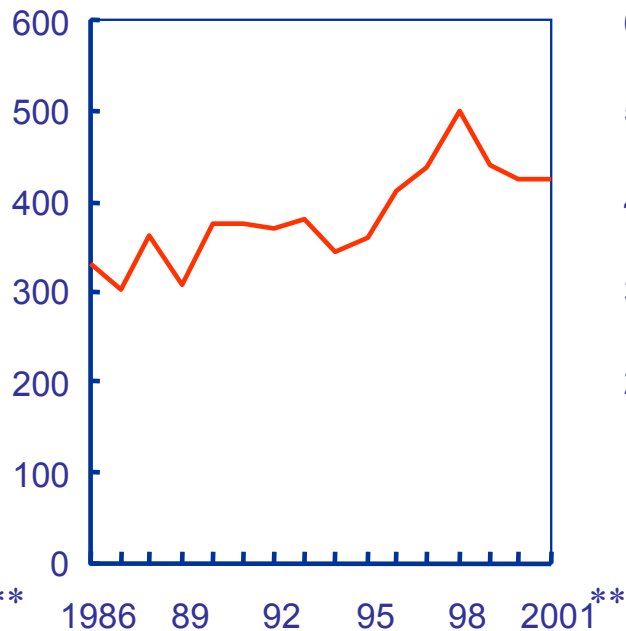
. . . while IND submissions
have increased modestly . . .

. . . and NCEs are essentially
flat

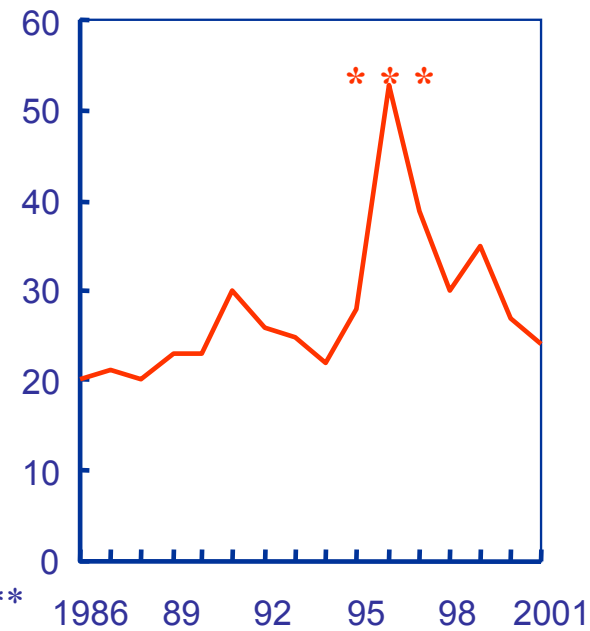
R&D spending*
\$ Millions 1986-2001



Commercial IND submissions
1986-2001



NCEs approved per year
1986-2001



* Global R&D expenditures by U.S. research based pharmaceutical companies

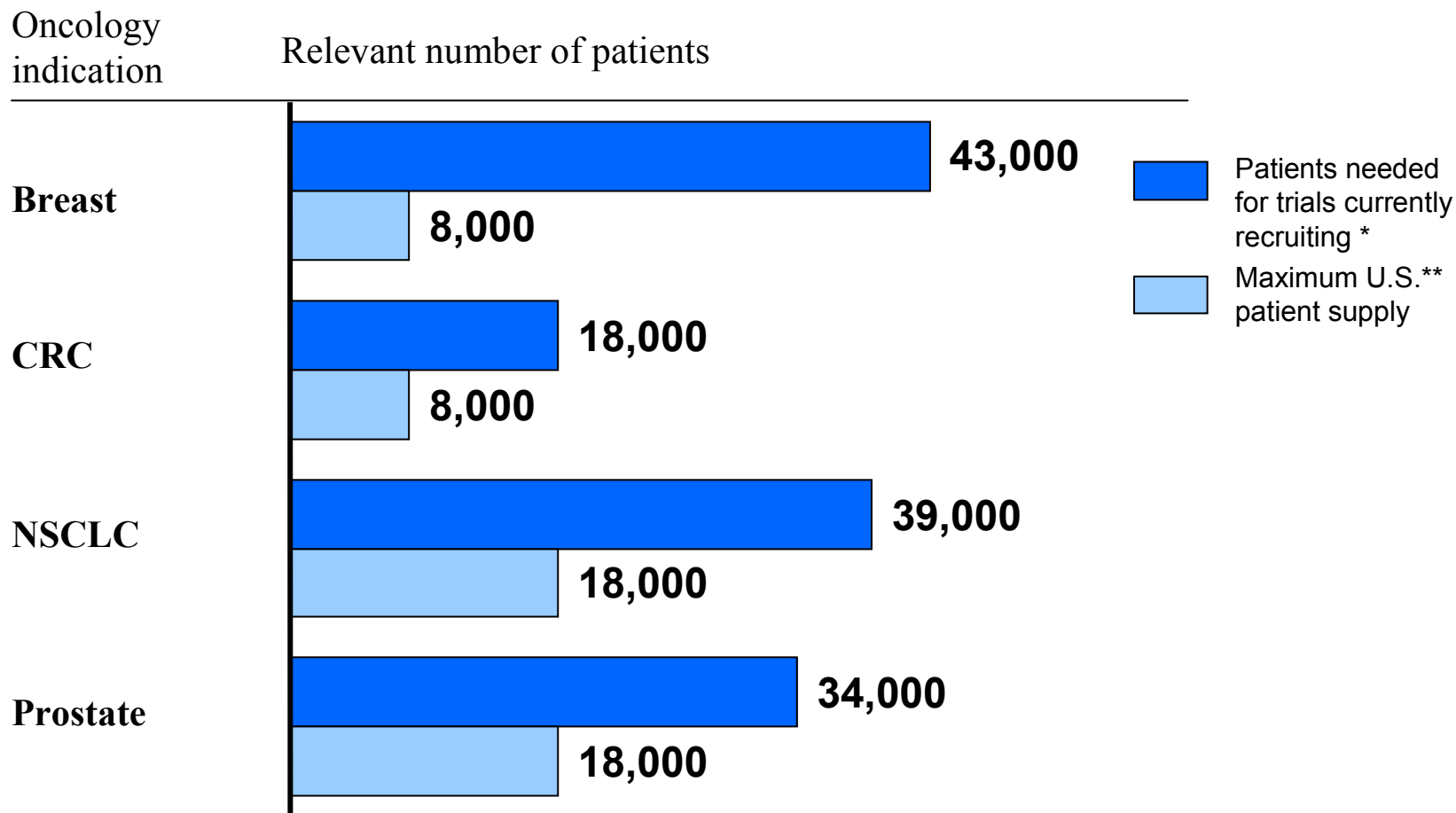
** Estimates

*** Spike was likely a one time increase in approvals due to adoption of user fees for faster FDA approval

Source: Pharma Annual Survey, 2000; U.S. Regulatory Reporter, 2001

CURRENT REALITIES IN N. AMERICA

“WAR FOR PATIENTS” – ONCOLOGY EXAMPLE



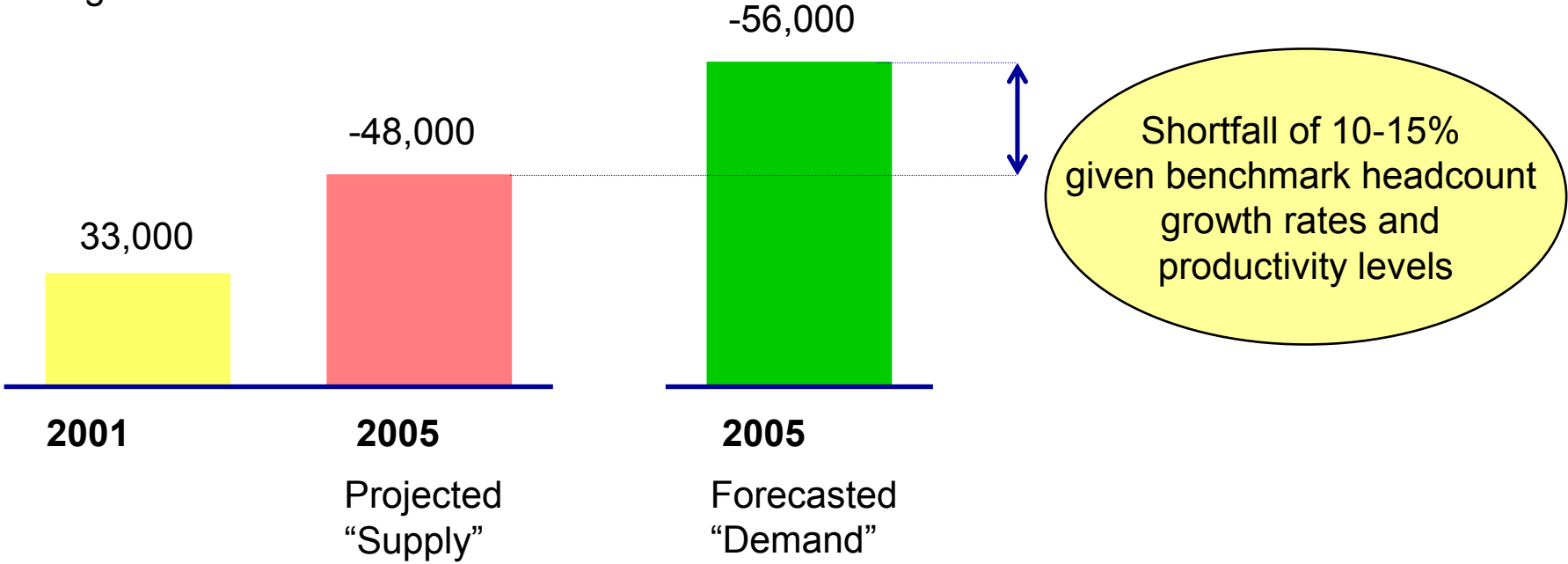
* Total trials in advanced disease, compiled from NCI and CenterWatch database

** Assuming 10% of eligible patients are the maximum supply. Eligible patients are Stage IV of breast/prostate, Stage IIIB/IV lung, Duke’s D CRC

Source: NCI; CenterWatch; Decision Resources; ASCO; team analysis

SHORTFALL OF INVESTIGATORS EXPECTED IN MANY WESTERN COUNTRIES

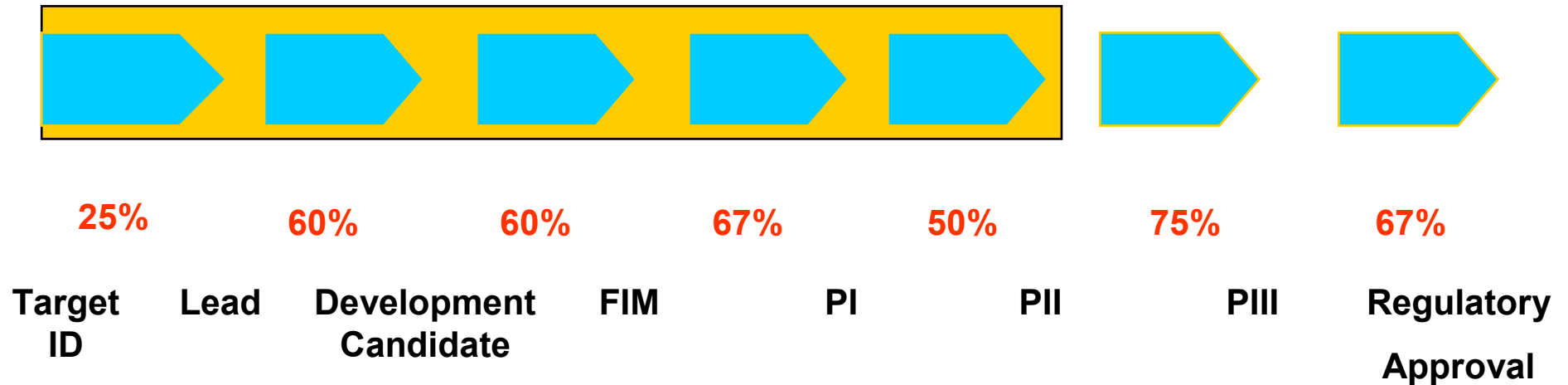
Example U.S., Number of principal investigators



Source: FDA Center Watch Analysis (published in Parexel R&D Statistical Yearbook 2002/2003)

Pharma R & D: Failure is a Norm!

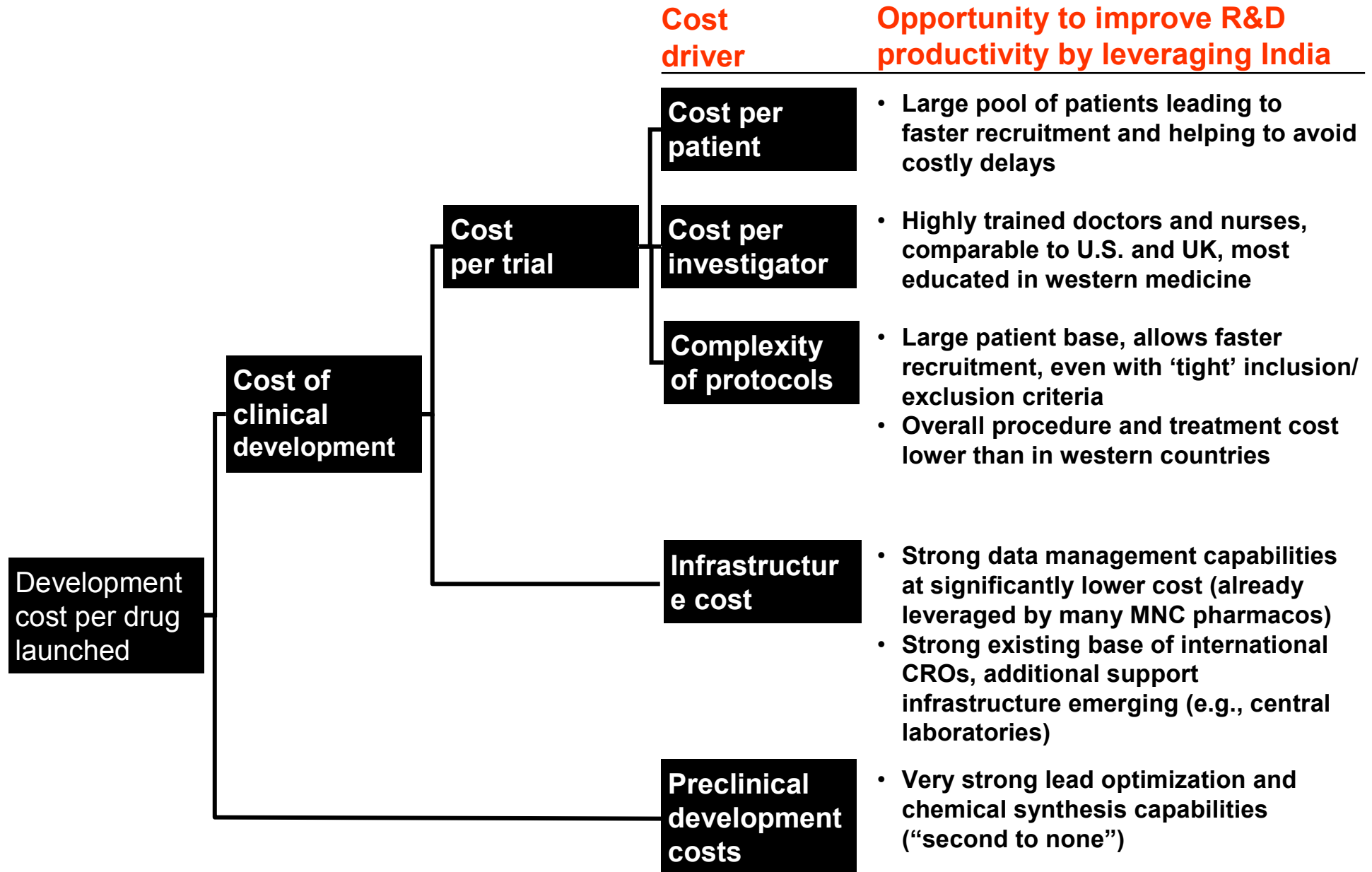
Pipeline Success Rate



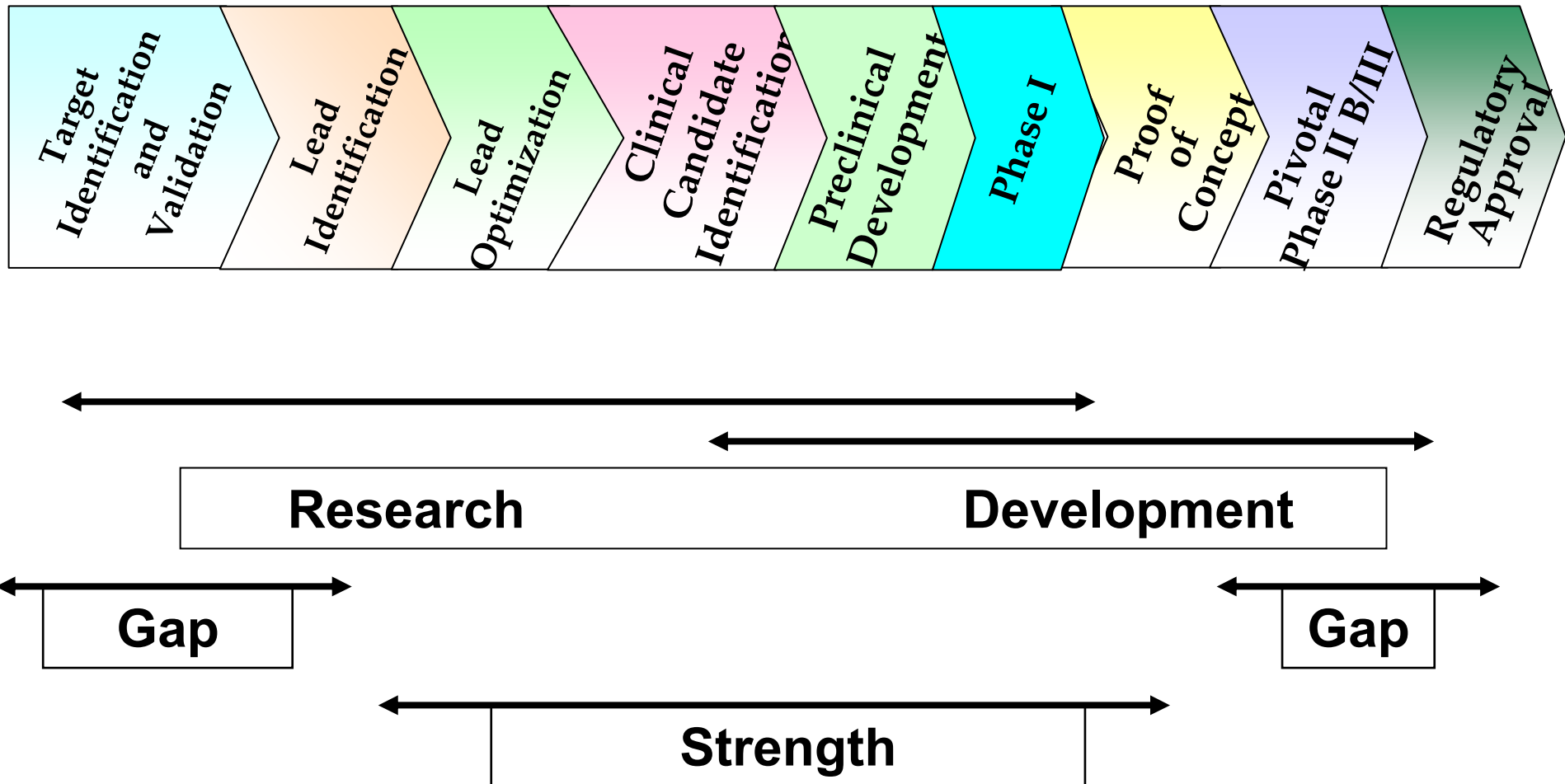
Cumulative Success Rate for a Program: 1.5%

Opportunities for improving success rate, speed up development while leveraging the cost-effectiveness paradigm

CAN INDIA BE THE TUGBOAT?



The Process of Drug Discovery & Development: Opportunities for PPP



Why India? Why Now?

Emerging Positive Trends in India

- **Availability of talent pool hungry to prove**
 - **Chemistry and biological sciences**
 - **Clinical sciences**
 - **IT**
- **IPR post January 2005**
- **Availability of large number of patient pool for practical all diseases, including treatment naïve patients**
- **English as an official business language**
- **IT infrastructure as good as any in the world**
- **Contributions of Non-Resident Indians (NRIs)**
- **Good infrastructure being developed in some parts of India**
- **Proven track record in the generic field, a natural transition**
- **Opportunities for R & D on neglected diseases**

PPP for Neglected Diseases: A Win/Win Alliance with an Indian Company

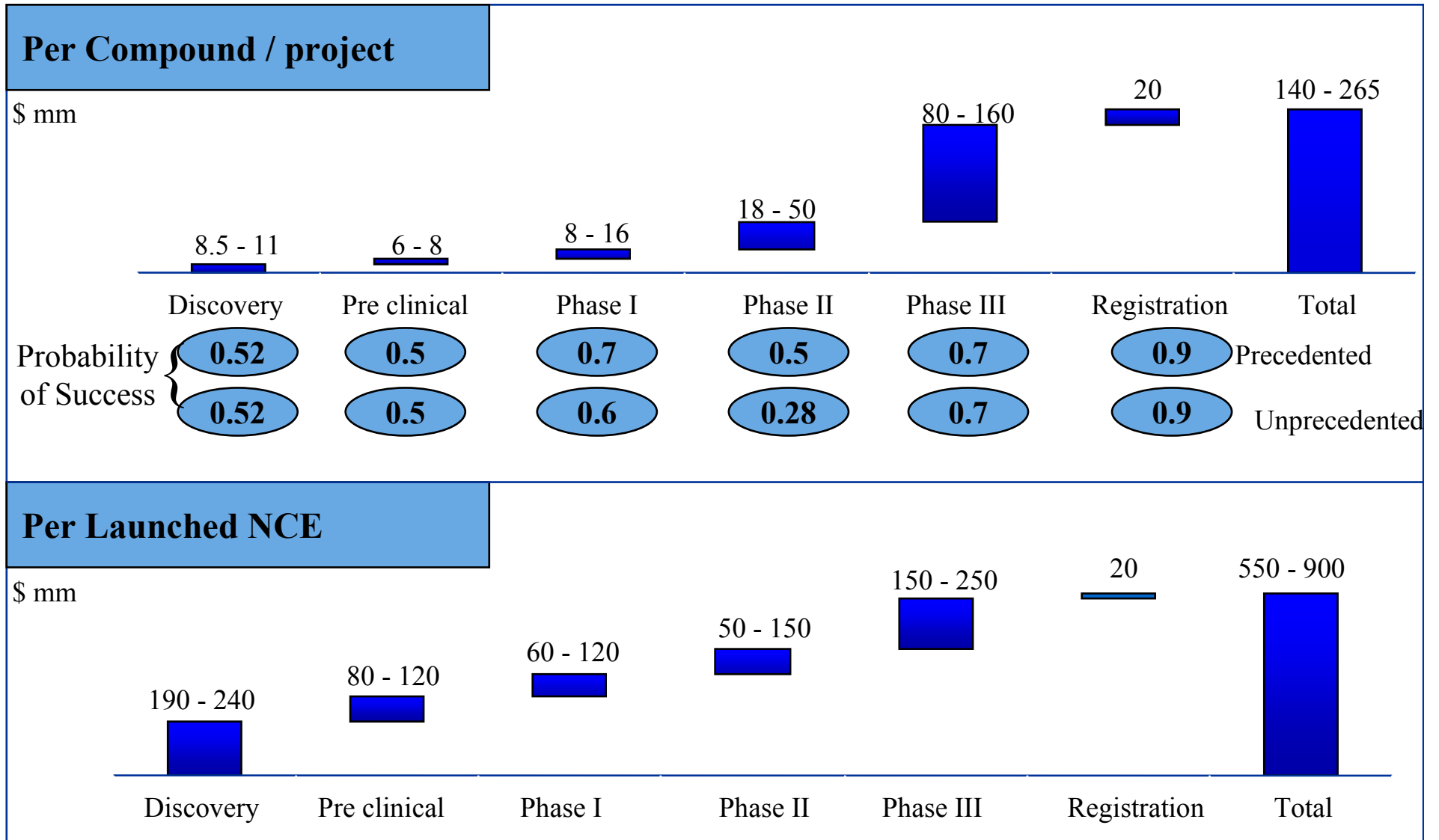
Neglected Diseases

- An ideal partner for not-for-profit organizations
- Coexistence of public health problems and talent pool for R & D
- Discovery and Development at a fraction of the cost – more shots at the goal and bring affordable medicine to needy patients
- Proof of concept in humans & clinical trials
- Shared risk and rewards

An Indian Company

- Access to late stage discovery candidates
- Funding for R & D
- Opportunity for conducting R & D in disease areas neglected by MNCs
- Opportunity to develop an NCE
- Opportunities for young Indian scientists to gain valuable experience
- Image building

The Cost of Developing a Drug for Big Pharma is High & Varies From \$550-900 Million: Can India Help Reverse This Trend?

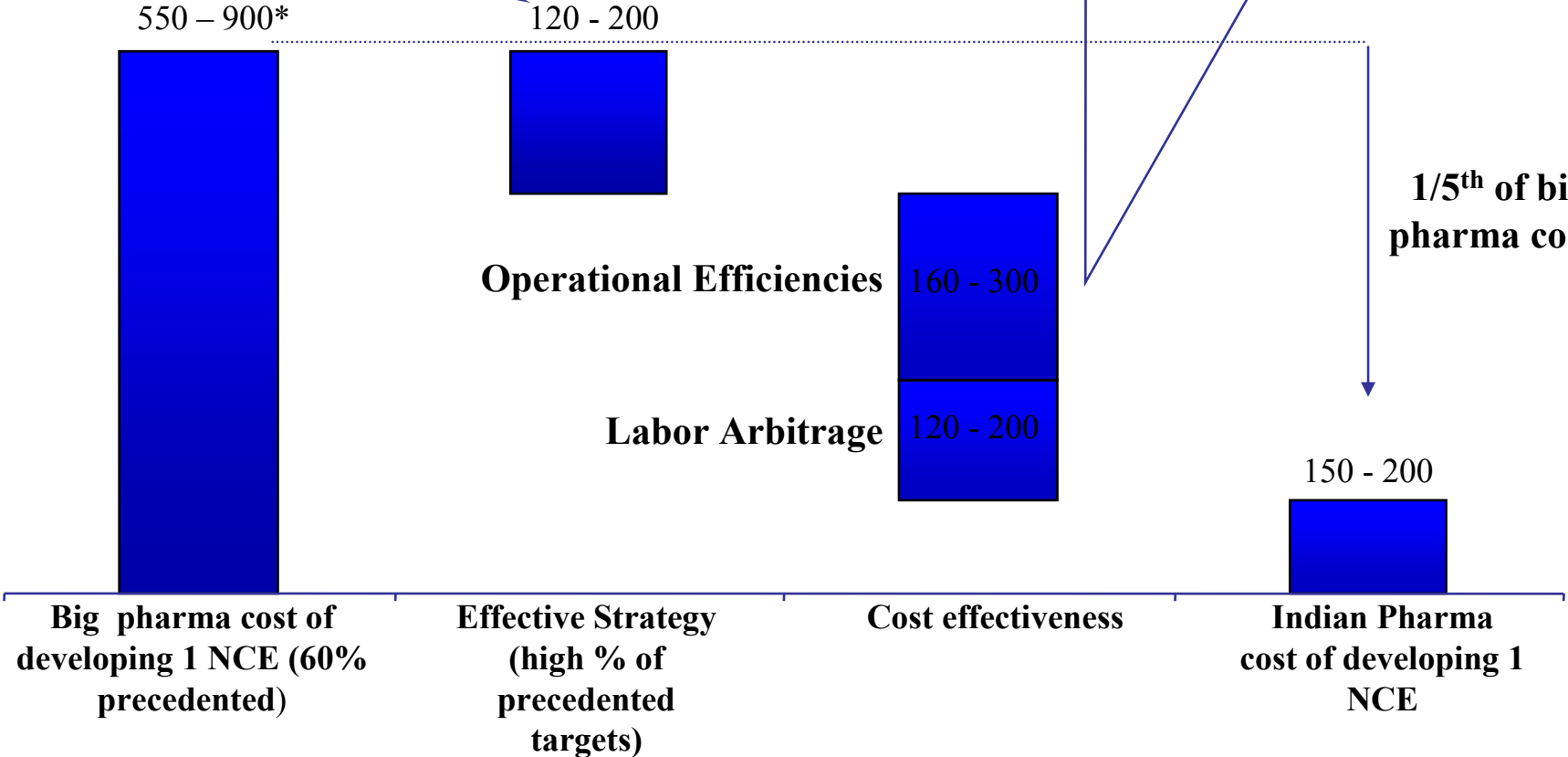


Cost Reduction Leveraging the India-Advantage

\$ MM

- Effective Strategy**
- Higher share of precedented targets
 - Clinically superior TAs
 - Fail fast with reduced cost of development

- Cost Effectiveness: Leveraging the India-advantage to achieve a 3-4 fold reduction in costs through**
- Aggressive management of resources, material, information and drug development
 - Process efficiency and rigorous decision making processes



Key Attributes to Look for in an Indian Partner

- **A leadership team with a proven track record and complementary skills**
- **Drug discovery team with medicinal chemistry expertise backed by strong biology and pre-clinical optimization teams**
- **Understanding and appreciation of “business norms” in the US & Europe**
- **Ability to solve day to day as well as strategic issues**
- **Credibility and contacts with the pharma and biotech industries**
- **Pure drug discovery environment**
- **Effective and rapid decision making – in a non- hierarchical organizational mindset**
- **A “winning” senior leadership team capable of building an organization with superior talent**
- **Track record of delivering goods – quality, timelines coupled with cost-effectiveness**

The Quest for Efficient and Cost-Effective Pharma R & D

- PPP for neglected diseases
- Win/Win R & D between academia, biotech/large pharma companies and Asian companies – blending technology, talent, efficiency and cost-effectiveness
- Process efficiency and rigorous decision making
- Conduct all the phases of R & D at least up to the end of Phase II in a country where cost of innovation and development is significantly lower than that in developed countries – reduce cost of failure and time to reach key decision points
- Fail fast strategy and speed up development