
Drug Discovery and the Pharmaceutical Industry

Louis Lu

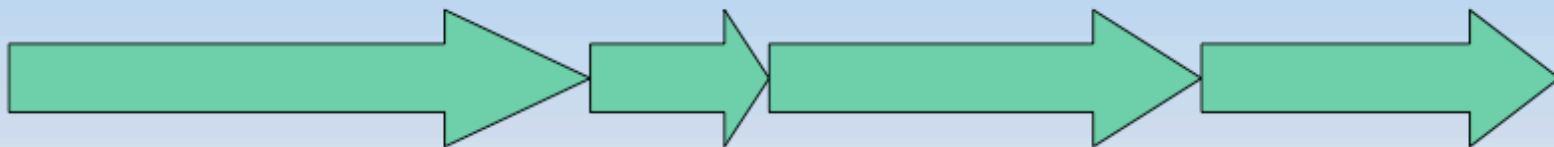
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Genomics and Medicine

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The Pharma Value Chain

Gene Sequencing Target ID Target Validation Lead Discovery Pre-Clinical Clinical Phase I Clinical Phase II Clinical Phase III Manufac-turing Distribution



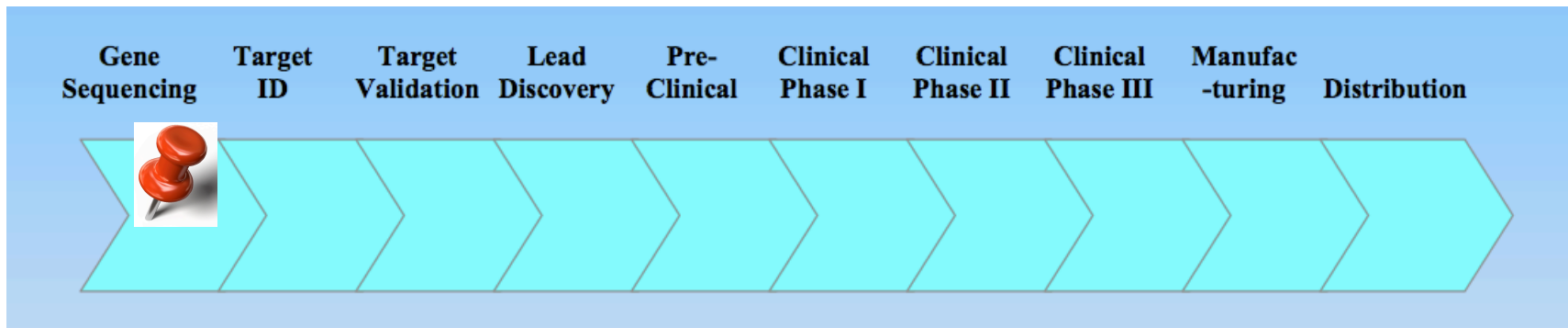
Drug Discovery

Animal Studies

Clinical Tests

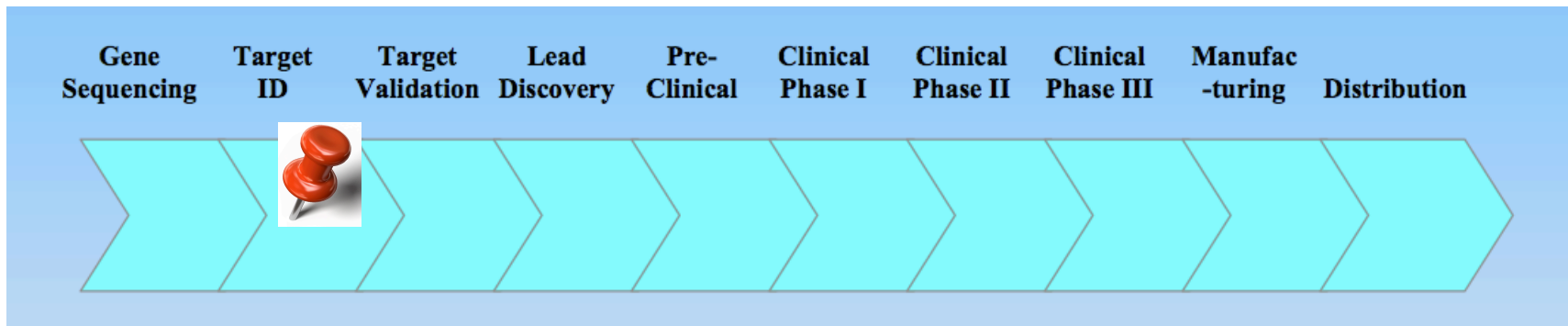
Commercialization

Gene Sequencing



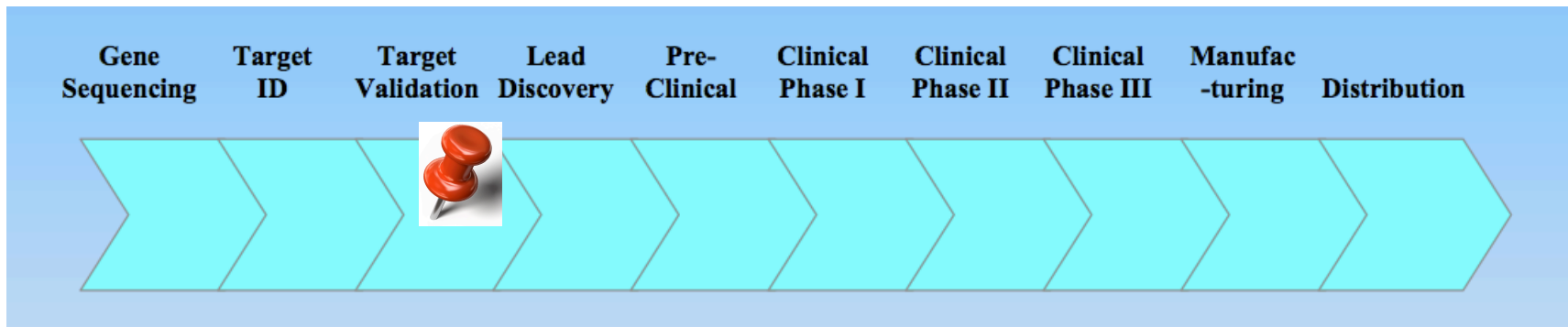
- Human Genome Project
 - Library of DNA sequences
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Target ID



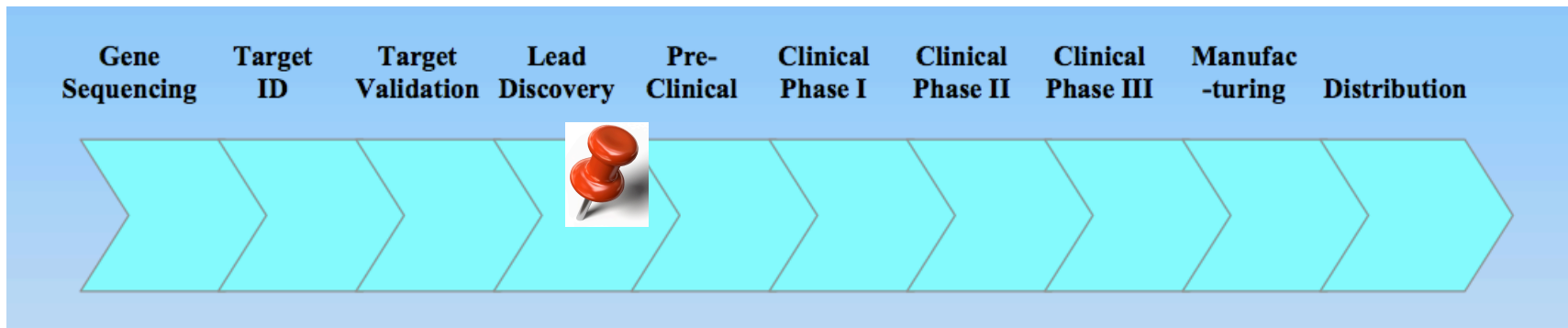
- Pick a disease target
- Proteins or mRNA expressed or not

Target Validation



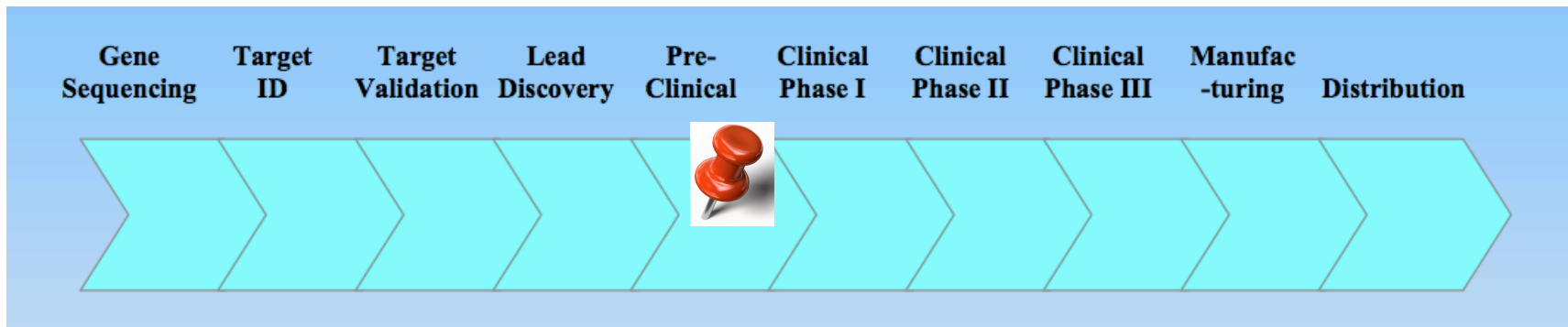
- Involvement of protein
- Understand pathways and interactions

Lead Discovery



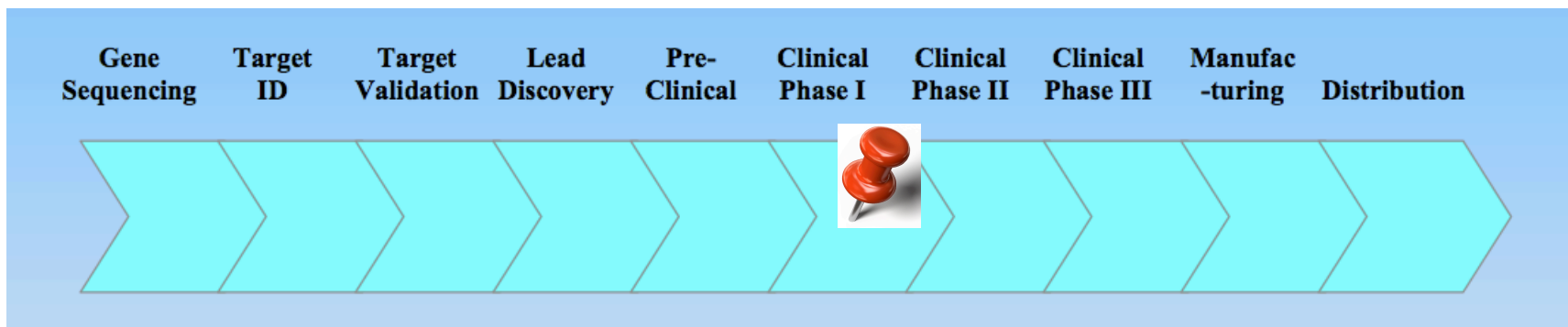
- Evaluate leads
 - Replacing protein?
 - Anti-sense RNA
 - Antibodies
 - Stimulate protein synthesis

Pre-Clinical



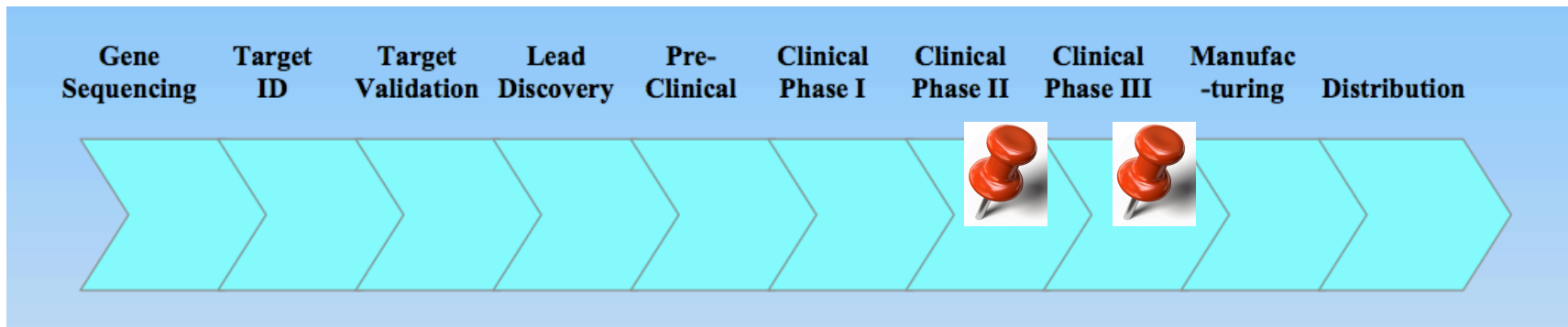
- Animal Tests
 - Toxicity
 - Efficacy

Clinical Phase I



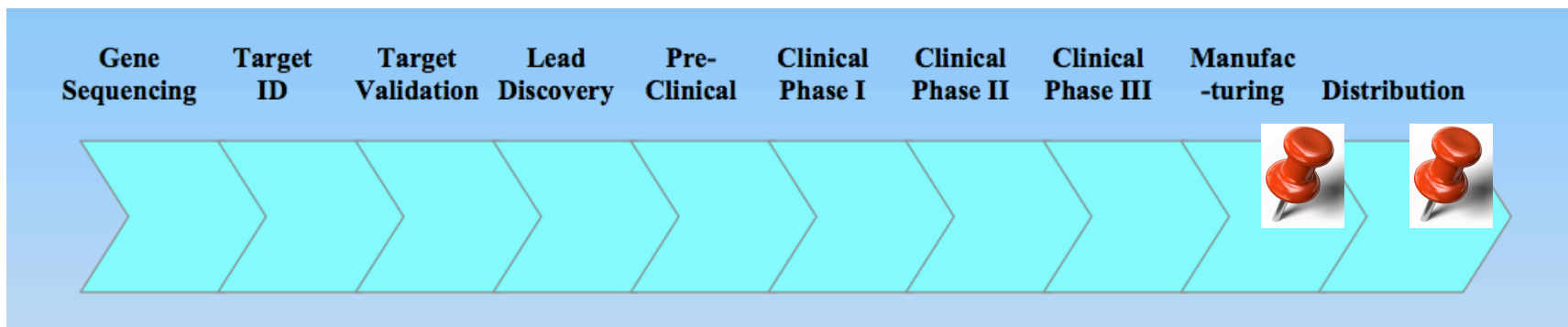
- Small group of healthy volunteers (10's)
 - Safety
 - Toxicity
 - Sometimes use target group patients
 - Example of Gleevec (Chronic Myeloid Leukemia)

Clinical Phases II and III



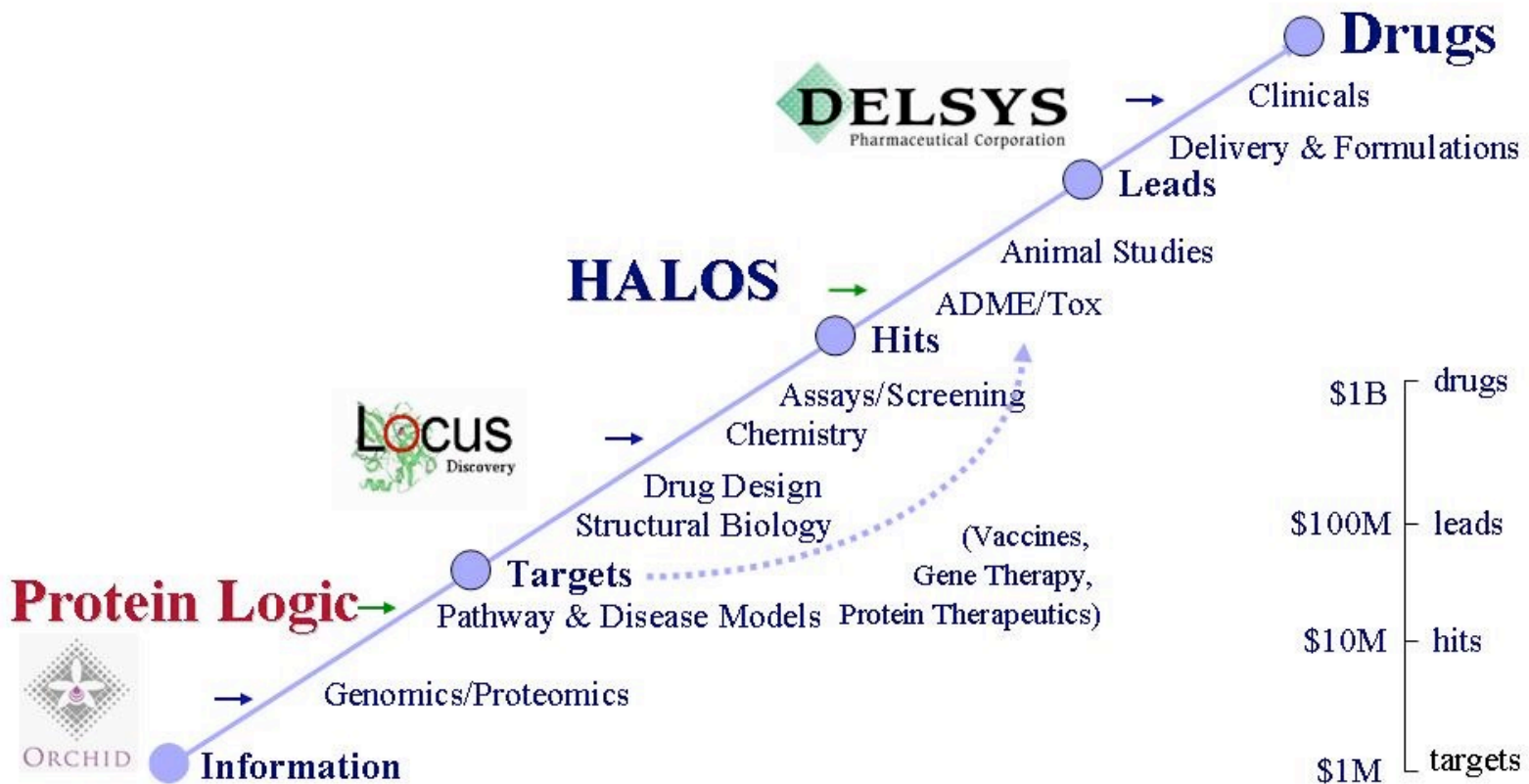
- Phase II: (100's) of patient population, Phase III: (1000's) of patient population
- Determine
 - Efficacy
 - Dosage
 - Safety
 - Side Effects

Manufacturing/Distribution

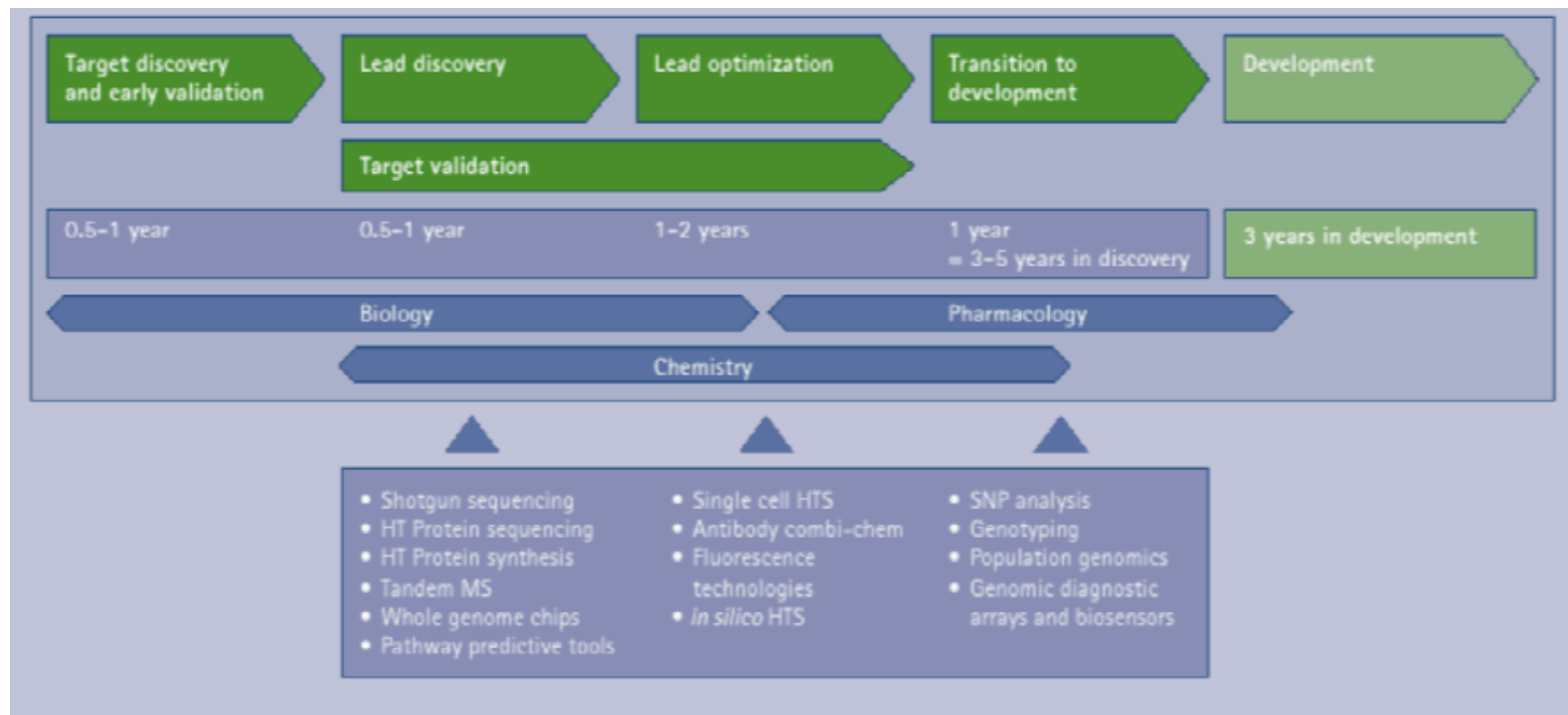


- ❑ FDA Approval
- ❑ Scale up quantities
- ❑ Detailing, advertising, distribution
- ❑ Insurance company acceptance (Example of Vioxx)

Pharma Value Chain

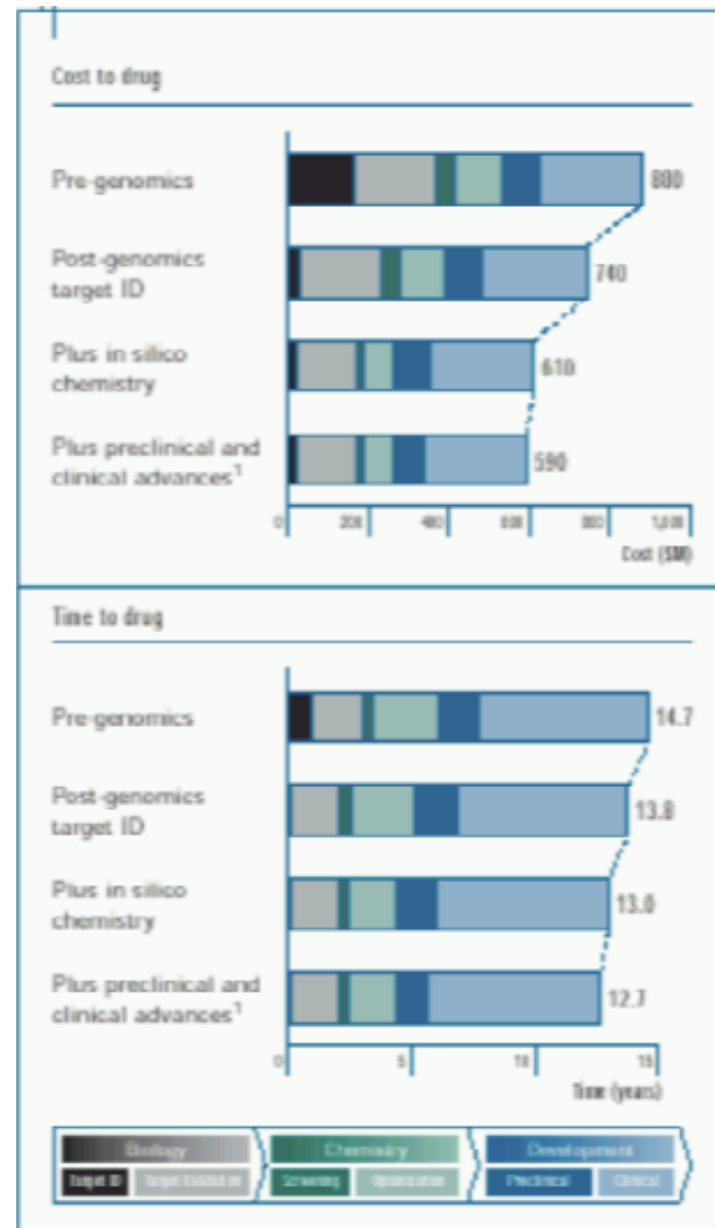


Time Scale



Benefits of Genomics

- Decreases Cost
- Decreases Time



Pharmaceutical Companies



<http://www.duke.edu/web/soc142/team2/shifts.html>

What's the Industry Like Today?

- Time to develop a drug = 10 to 15 years
 - Cost to develop a drug
 - 2006 = \$1.3 billion
 - 2001 = \$800 million
 - 1987 = \$318 million
 - Drugs and Biologics approved in 2008 = 31
 - Only 2 out of every 10 marketed drug ever return revenues that match or exceed R & D costs
 - This year, 2,900 medicines are currently in development
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Bibliography

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 - <http://www.pauljstabile.com/SpawningthePharmaceuticalValueChain.jpg/SpawningthePharmaceuticalValueChain-full.jpg>
 - <http://biochem118/Papers/Drug%20Discovery/Pharmaceutical.pdf>
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