

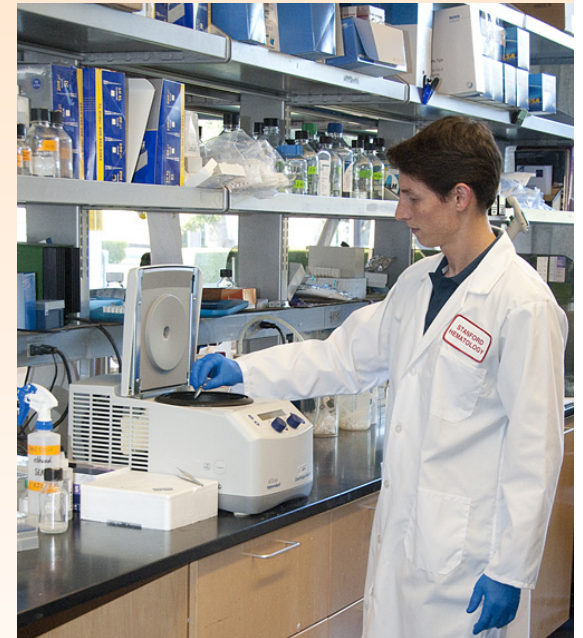
What to Expect in Biotech (and Pharma)

Douglas Kalish, Ph.D.



What you learn as an academic

- **Knowledge is an end in itself**
- **Don't reveal all that you know**
 - In grant applications or publications
- **Today's collaborator can be tomorrow's competitor**
- **The less you depend on other people the faster your research will go**



But to succeed in business, you need to be...

- **Driven by profits**
- **Aware of the needs/characteristics of the market**
- **Focused on products, not interesting science**
- **Collaborative internally**
- **Competitive externally**

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The Important Stuff

- > Online Resources
- > Networking Tips
- > Managing Your Boss
- > Dealing with Difficult People
- > Tricky Situations: Co-Worker Conflicts, Romances, Harassment etc.
- > Surviving an Evaluation
- > Negotiating Salary and Promotions
- > How to Quit

Job Hunting Links

- > Hints for Getting Hired

Making it in the Real World



Read dousguides

- Finding Your First Job
- Who Are These Guys? Working with Other People
- Managing Your Boss and Your Career
- Business Backgrounder

Making the Transition from College to the Real World

Workshops, eBooks, and links to help you survive and thrive in your first job.

Congratulations on leaving or getting ready to leave college, grad school, or your post-doc. You've learned a lot, had fun and made friends. Now you're looking for a job and the reality is sinking in... College hasn't fully prepared you for the Real World. Relax, and welcome to dousguides: a set of eBooks, workshops, and links to help you find a great job with great

Workshops

Feb 9: "Making Meetings and Projects Productive"

California State University at Channel Islands

Feb 22: "Business Bootcamp for Liberal Arts Grads"

University of California, Berkeley

Mar 7: "Working with your Principal Investigator"

University of California, Berkeley

Mar 14: "Finding Your First Real Job"

University of California

The training that BioScientists need (consensus)

- **Overview of drug development process**
- **Business basics (profit requirements)**
- **Team skills**
- **Conflict resolution**
- **And later, management skills,
negotiation, project management,
budgeting**

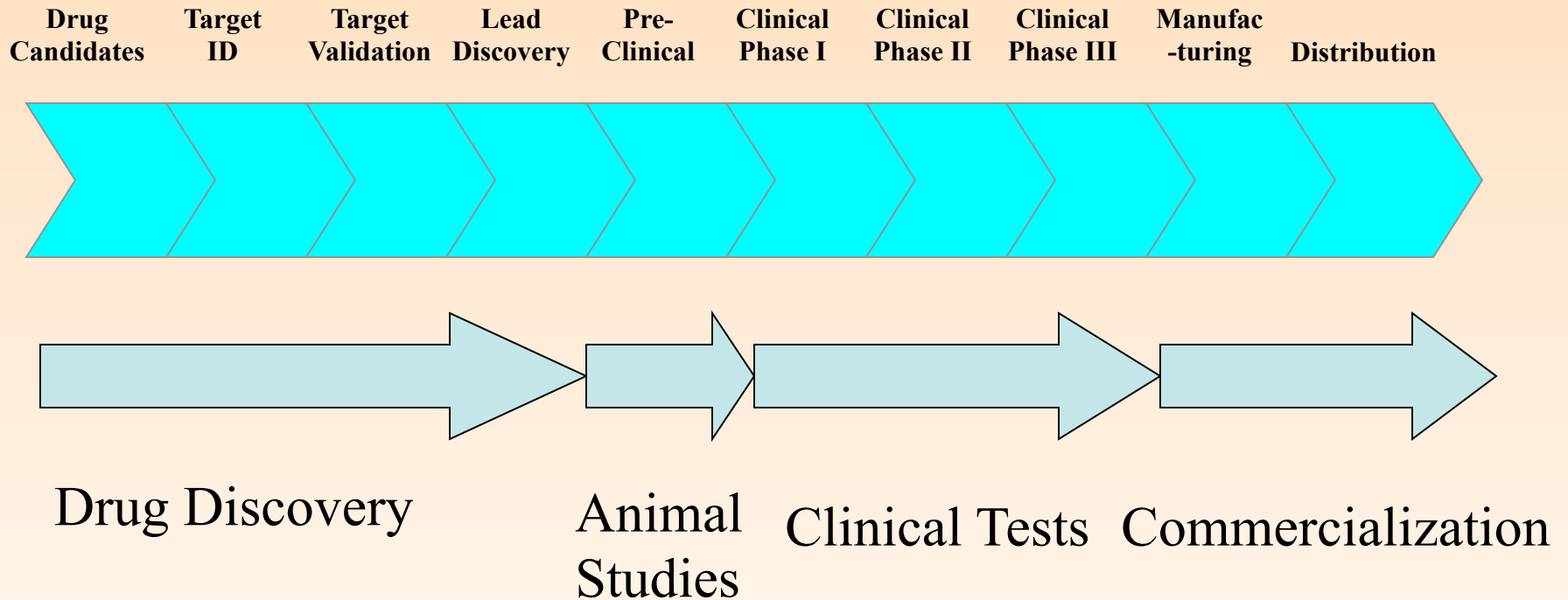
The lack of business vision leads to

“ Scientists wanting to pursue science for knowledge sake... Not advancing our commercial objectives... Falling in love with research program... Unaware of experimental critical path... Results don't affect our commercial path... Wasted time from non-communication... No team orientation; not communicating things that rest of team should know... Not calling for help... People in leadership positions without skills or training.”

Business Survival Skills

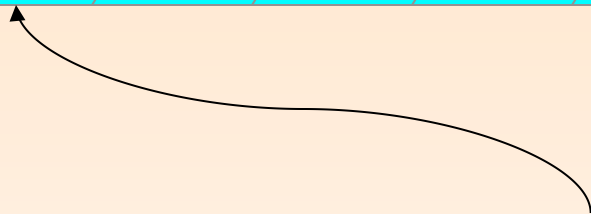
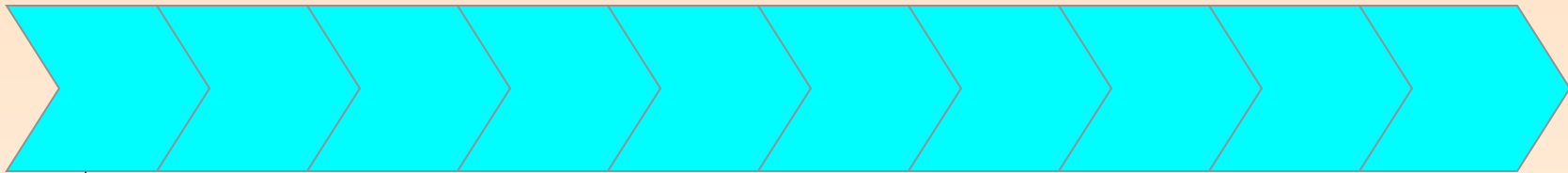
- **Understanding the difference between pure science and drug development**
- **Appreciating how market forces affect development strategies**
- **Understanding the difference between investors (or shareholders) and NIH and NSF**

The Drug Development Process



The Drug Development Process

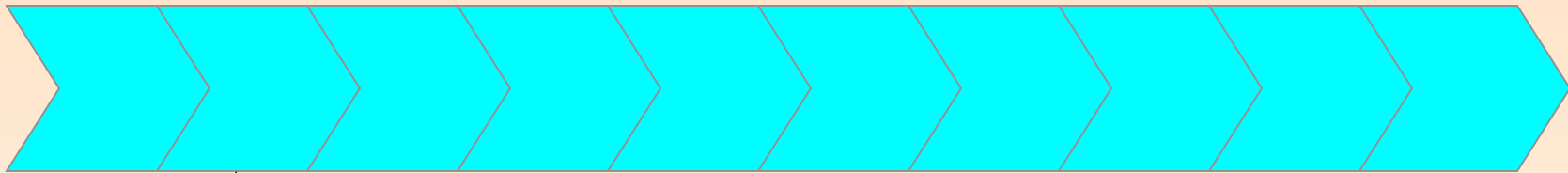
Drug Candidates Target ID Target Validation Lead Discovery Pre-Clinical Clinical Phase I Clinical Phase II Clinical Phase III Manufac-turing Distribution



Entry into the drug development process

The Drug Development Process

Drug Candidates Target ID Target Validation Lead Discovery Pre-Clinical Clinical Phase I Clinical Phase II Clinical Phase III Manufac-turing Distribution



Look for differences (protein, DNA, mRNA, enzyme activity) between normal and diseased tissue

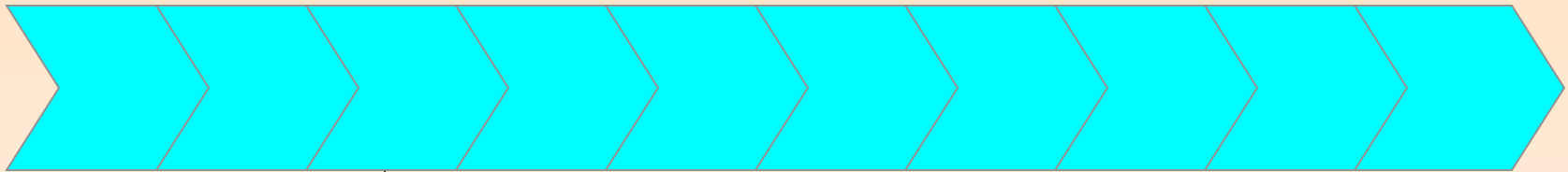
Business Strategies Affect Target Selection

- **Concentrate on disease (cancer, obesity, cardiac)**
- **Concentrate on tissue (lung, breast, brain)**
- **Concentrate on therapies (RNAi, kinases)**

- **Do we have a proprietary technology?**
- **How big is the market?**
- **What is the competition?**
- **What experience do we have?**
- **Is there synergy with our other products?**

The Drug Development Process

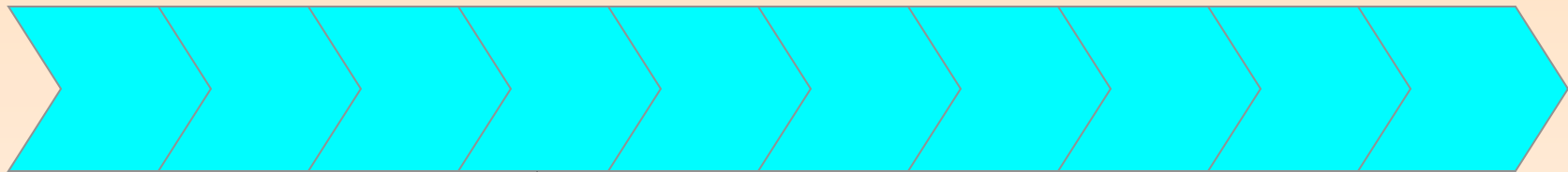
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Verify the involvement of the protein in the disease state.
Understand the protein pathways and interactions.

The Drug Development Process

Drug Candidates Target ID Target Validation Lead Discovery Pre-Clinical Clinical Phase I Clinical Phase II Clinical Phase III Manufac-turing Distribution



Evaluate leads to ‘cure’ the problem, e.g.:

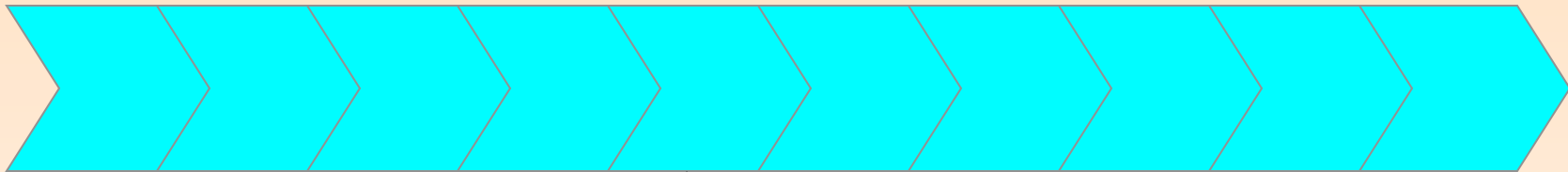
- Replace missing or defective protein with gene therapy
- Anti-sense RNA to prevent protein expression
- Antibody to remove protein
- Stimulation of synthesis to replace protein

Re-visit the Business Issues

- Does the putative therapy fit with our business strategy?
- Exactly what disease(s) will the therapy be directed to?
- What stage(s) of the disease will the therapy target?
- How will the drug be delivered?
- Do we have in-house experience with the technology?
- Will the therapy be better than existing treatments?
- Do we have the expertise to manufacture the drug?
- Do we have the expertise to market the drug?
- What are the expected profits? How much can we charge?
- What are the risks and how can they be mitigated?

The Drug Development Process

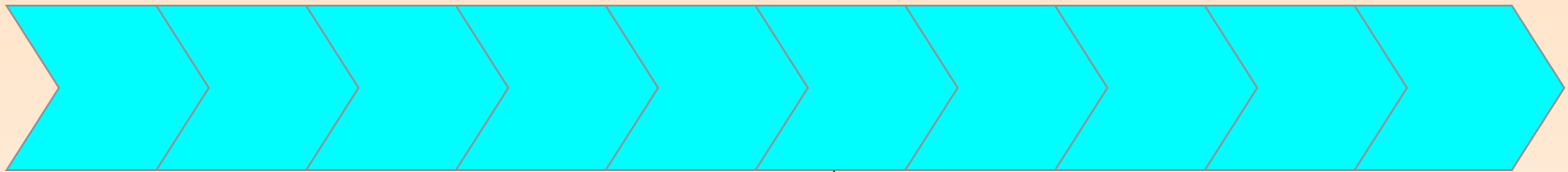
Drug Candidates **Target ID** **Target Validation** **Lead Discovery** **Pre-Clinical** **Clinical Phase I** **Clinical Phase II** **Clinical Phase III** **Manufac-turing** **Distribution**



Animal tests of toxicity and efficacy of therapy

The Drug Development Process

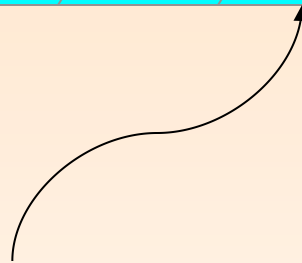
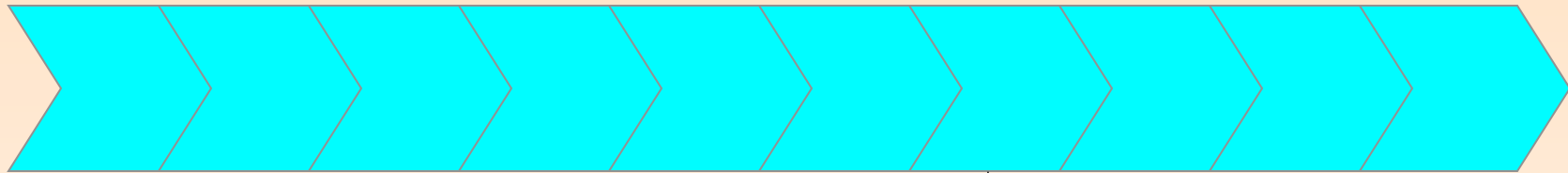
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Small group of healthy volunteers (10' s) to determine safety and toxicity. Maybe some members of target group

The Drug Development Process

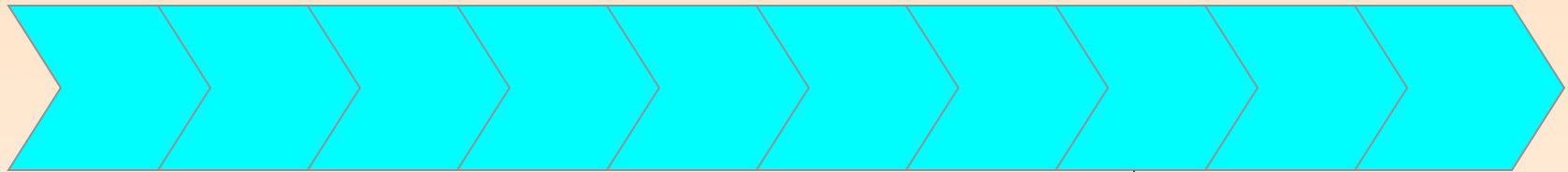
Drug Candidates **Target ID** **Target Validation** **Lead Discovery** **Pre-Clinical** **Clinical Phase I** **Clinical Phase II** **Clinical Phase III** **Manufac-turing** **Distribution**



100' s of patient population to determine dosage, safety

The Drug Development Process

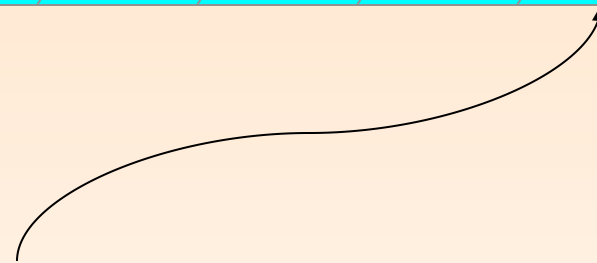
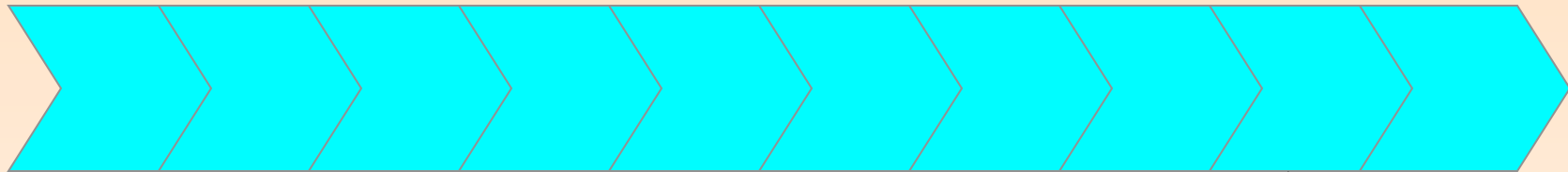
Drug Candidates Target ID Target Validation Lead Discovery Pre-Clinical Clinical Phase I Clinical Phase II Clinical Phase III Manufac-turing Distribution



1000' s of patients to determine efficacy, dosage, safety, side effects, and interactions

The Drug Development Process

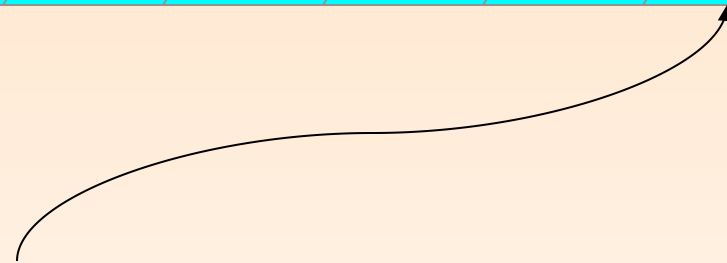
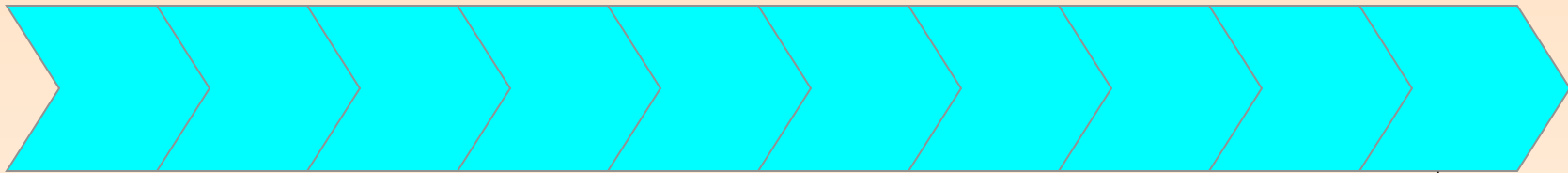
Drug Candidates **Target ID** **Target Validation** **Lead Discovery** **Pre-Clinical** **Clinical Phase I** **Clinical Phase II** **Clinical Phase III** **Manufac-turing** **Distribution**



Scale up to manufacture commercial quantities

The Drug Development Process

Drug Candidates **Target ID** **Target Validation** **Lead Discovery** **Pre-Clinical** **Clinical Phase I** **Clinical Phase II** **Clinical Phase III** **Manufac-turing** **Distribution**



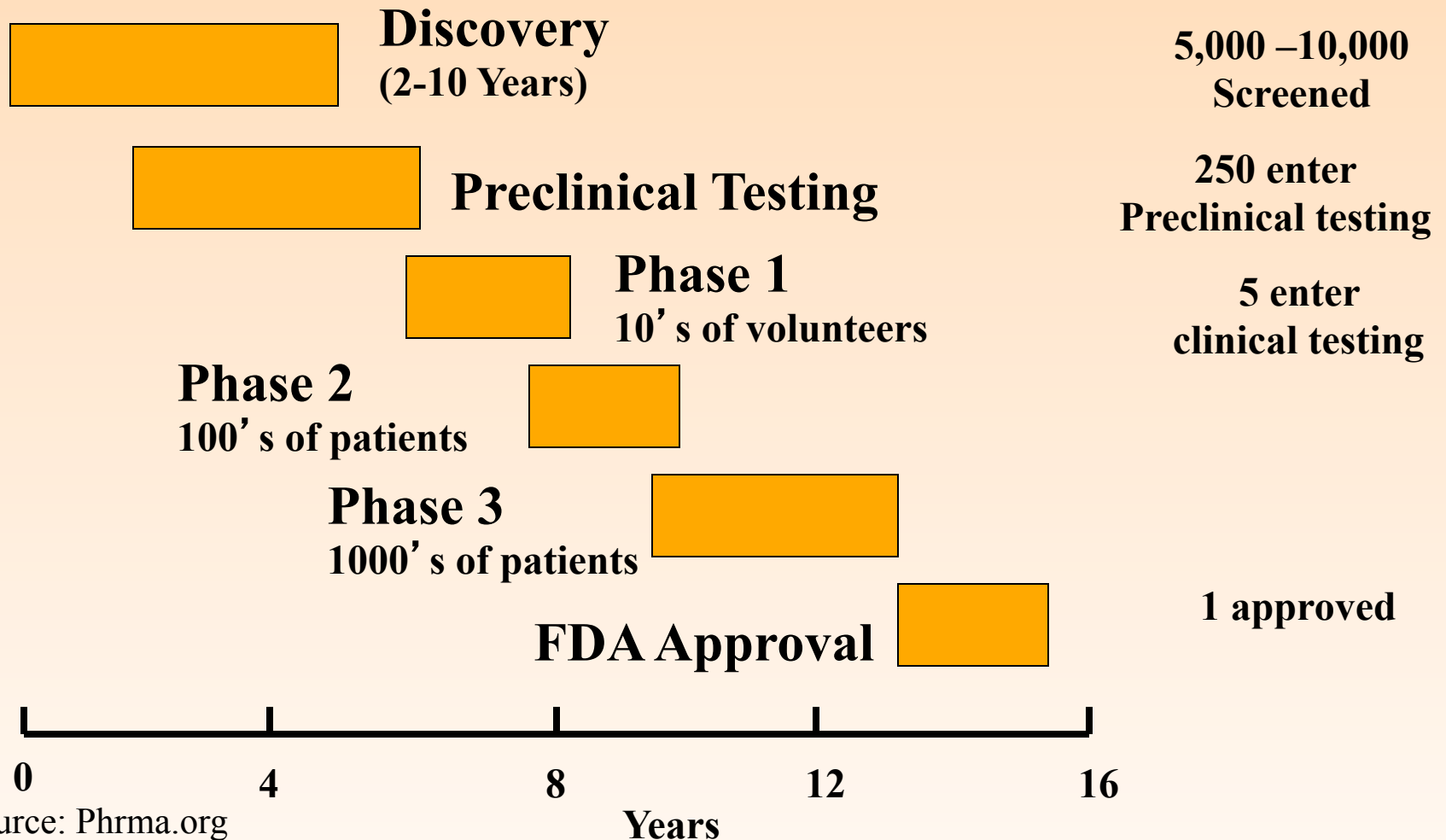
Detailing, advertising and distribution. Insurance company reimbursement

The Dreaded Phase IV: Reporting adverse consequences



Compound Success Rates and Timing by Stage

Success Rates



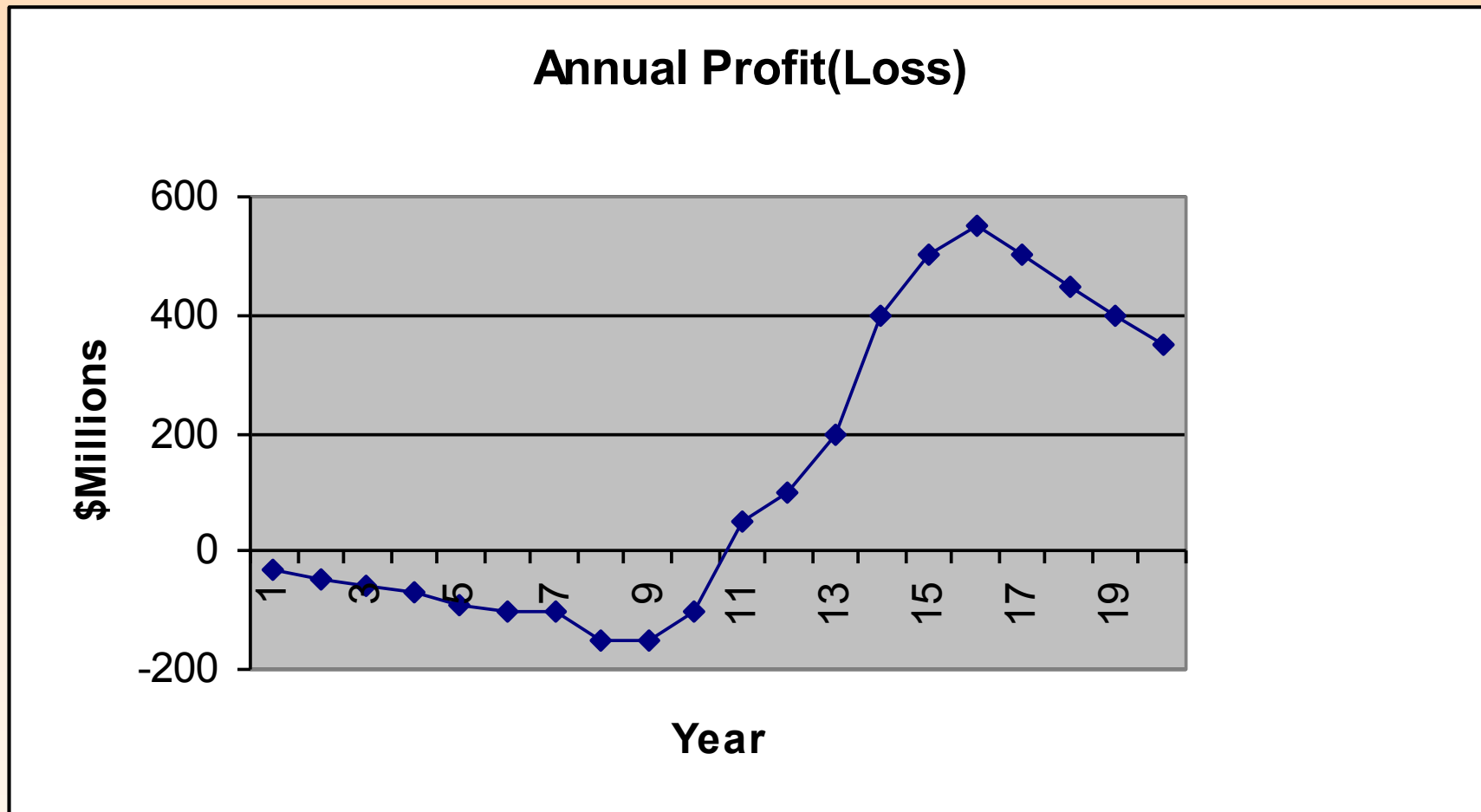
Source: Phrma.org

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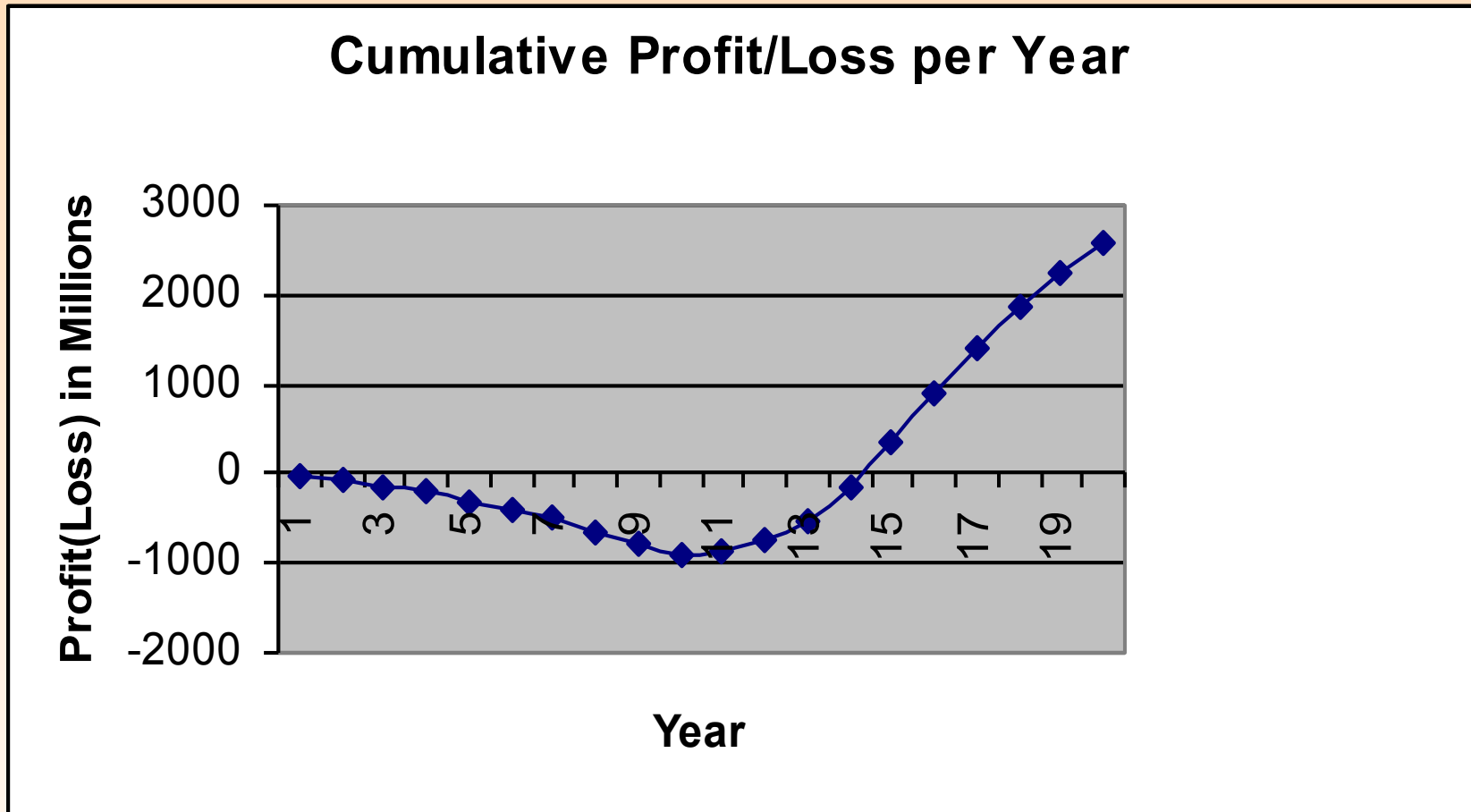
Why don't all targets generate therapies?

- **Just doesn't work (of mice and men)**
- **Similar symptoms from different causes**
- **The cure is worse than the disease**
- **ADME/tox: absorption, distribution, metabolism, excretion/toxicity**
- **Most diseases have complex causes**
- **Diseases have a time course**
- **Individual differences in drug metabolism (pharmacogenomics)**
- **...and so on**

How much does it cost to get a drug approved?



How much does it cost to get a drug approved?



Summary of Drug Development Risks

- **Scientific – Does it work?**
- **Commercial – How big is the market?**
- **Competitive - Does someone else have a better product, now or in the future?**
- **Time to market – How long does your patent have to run?**
- **Intellectual Property position – Do you have all requisite licenses? Have you excluded all others from using the IP?**

Mitigating the Financial Risks in Drug Development

- **Killing unpromising candidates at the earliest opportunity**
- **Maintaining marketing exclusivity as long as possible**
- **Populating a product pipeline**
- **Spreading the risk**

Fully Integrated BioPharma Company (FIBCO)

- **Robust pipeline of products needed at all stages**
- **100-1000x number of expected products entering the pipeline each year**
- **Resources: cash, facilities, expertise at all stages of drug development process**
- **Strong FDA relationships**
- **Strong marketing and distribution functions**
- **Strong IP function to protect and extend exclusivity of products**
- **Ability to forecast drug marketplace**

28

5-10 years out

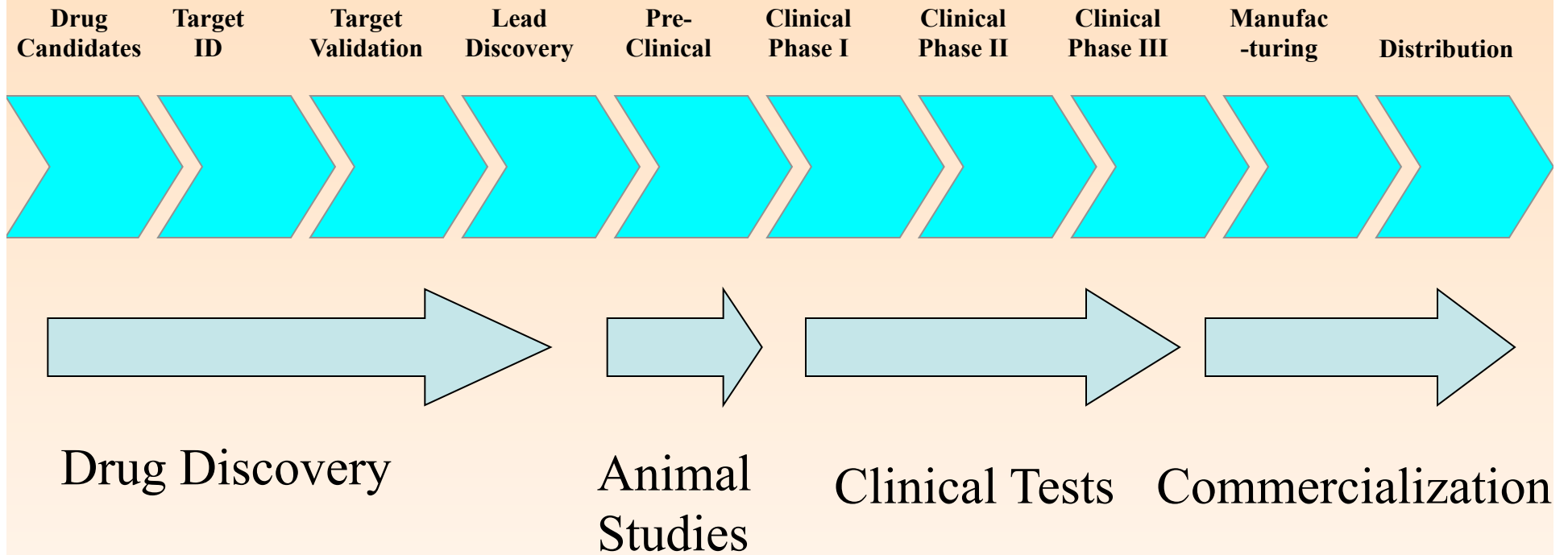
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Realities of the Pharma/Biotech Industry

- **It is extremely difficult to build a new fully integrated biopharma company**
- **Successful companies need portfolio of products in different stages of development**
- **Risks of drug development need to be strategically managed (partnerships, joint ventures, out-licensing)**
- **Successful companies – big and small - need partners in all phases of the drug development lifecycle**
- **Companies are specializing in all phases of the value chain**

Dis-Integration of Drug Discovery



Life at a FIBCO

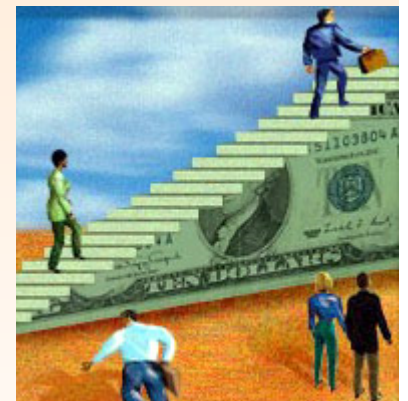
- “Big company” experience, resources, benefits
- Lots of people to learn from
- Well-established policies and bureaucracy
- You will probably be well-removed from the important decision-making
- Mergers, acquisitions, layoffs and retrenching are becoming more common (300,000 jobs lost since 2000; but 40% increase predicted to 2018)



Characteristics of Biotech Companies

- **Primary assets are intellectual not physical**
- **Capital intensive, not labor intensive**
- **Highly skilled labor needed**
- **Long-term paybacks**
- **Legal uncertainty**
- **Hard to value**
- **High burn rates**
- **Global competition**

Equals: High Risk, High Return



Life at a startup

- **There is never enough money**
- **There are never enough people**
- **There is never enough time**
- **Doing one job may not be enough**
- **Uncertainty rules**
- **Perks can be cool**
- **Reality sucks**

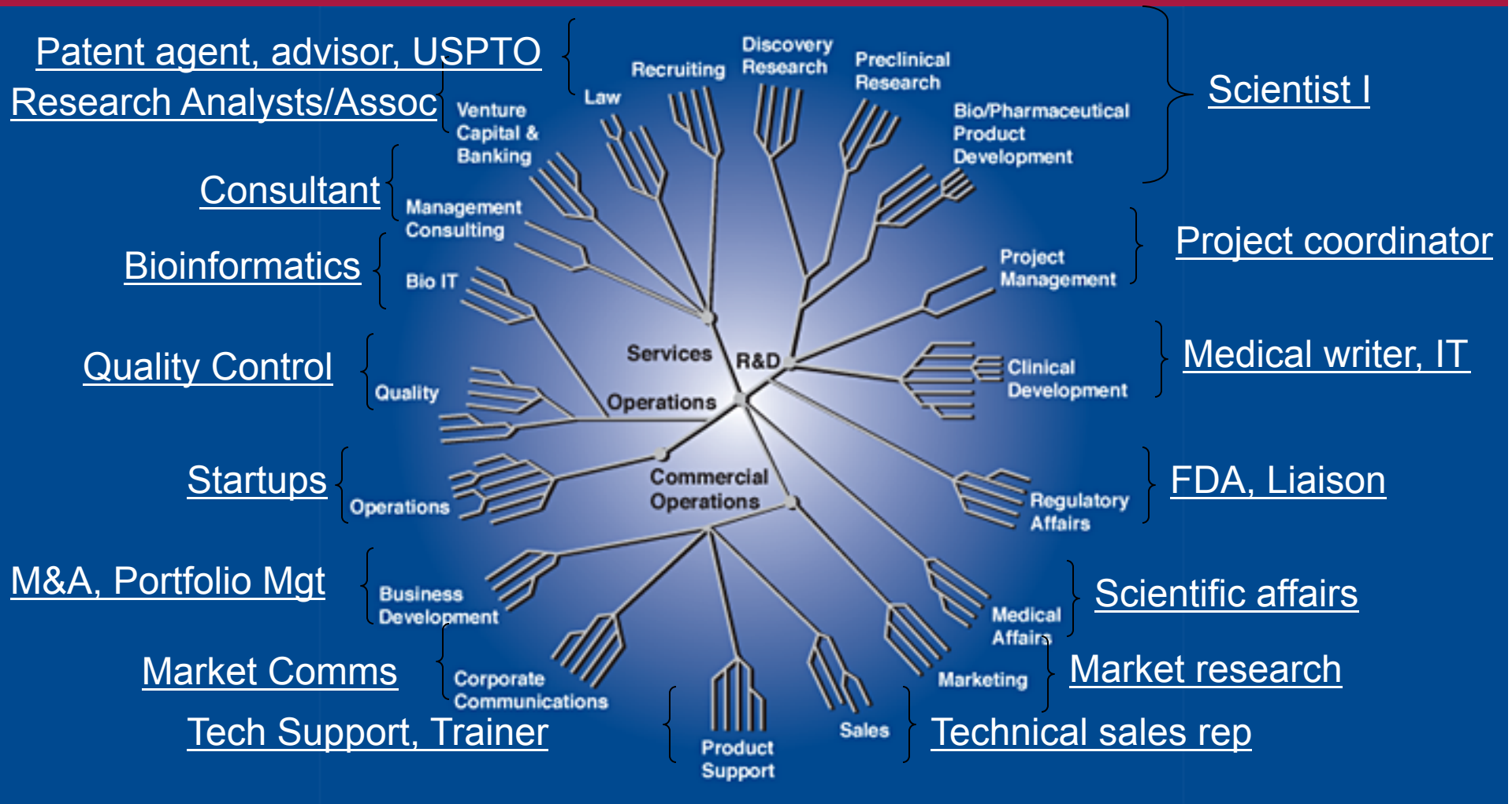


**CAREER OPPORTUNITIES
in BIOTECHNOLOGY
and DRUG DEVELOPMENT**

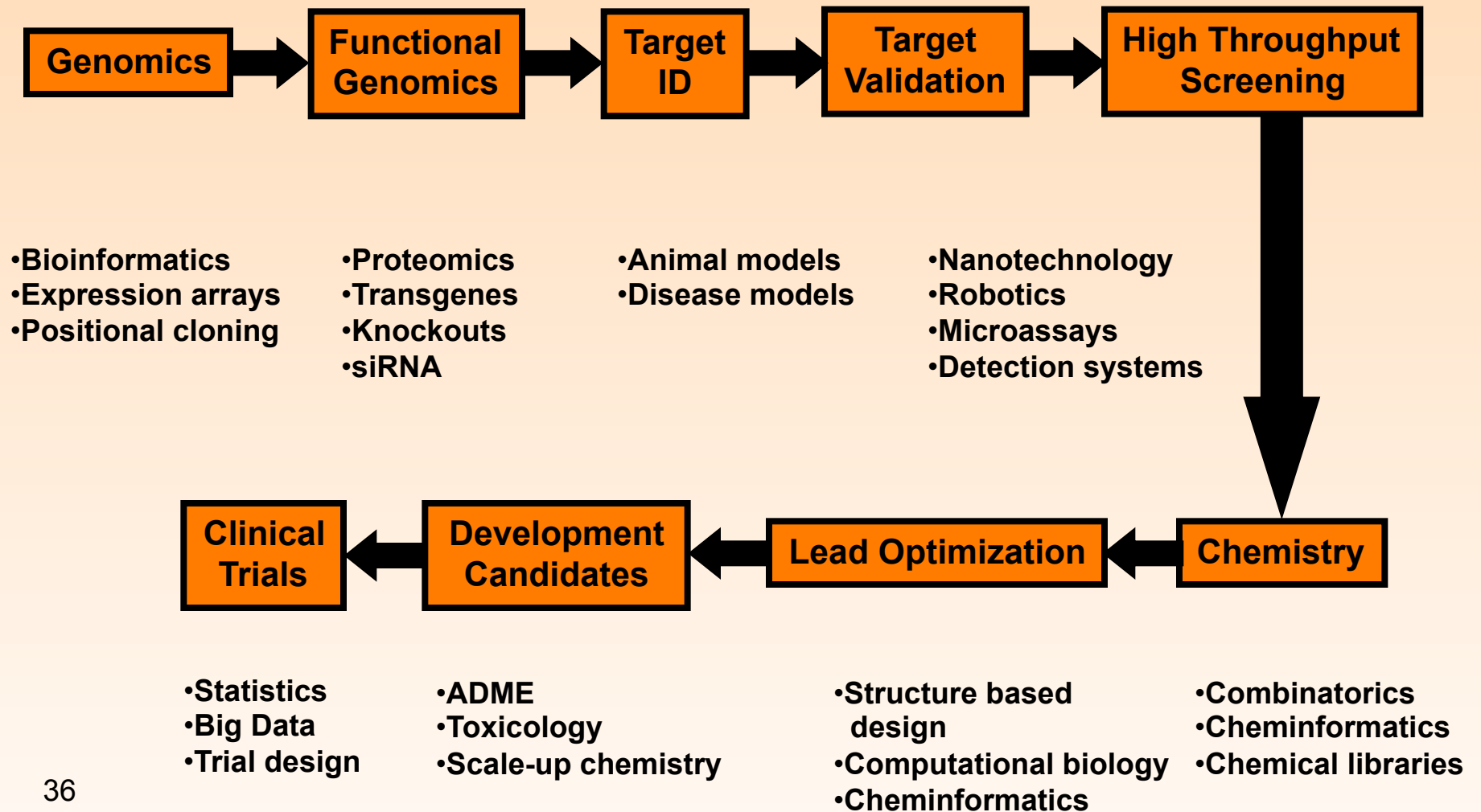
DETAILED
INFORMATION
ON OVER
100 CAREERS

TOBY FREEDMAN

Research and Non-Research Positions for PhDs/Postdocs



Hot tech skills in drug development - today



Don't forget: Non-tech skills are required, too

- **Communication and presentation**
- **Interpersonal skills**
- **Basic understanding of drug development and business**
- **Desire to pursue the product, not the science**



Making yourself desirable

- Find a human disease aspect to your research
- Concentrate on areas of interest to industry
- Acquire technical skills of interest
- Concentrate on the 4 P' s: publications, presentations, posters and patents
- Understand the drug development process
- Understand industry issues: e.g. generics, biosimilarity, assay development (visit pharma.org, bio.org)
- Attend trade conferences

Required Reading

- **Specific industry knowledge**
 - www.bio.org, www.phrma.org, trade journal sites
- **‘How-to-get-a-job’ websites**
 - sciencecareers.sciencemag.org
 - www.dougsguides.com/nowwhat
- **General business knowledge**
 - www.dougsguides.com/businessbasics
- **Presentations and communications**
 - www.toastmasters.org

The Bottom Line

Without a business context, you may do good science...

...but you can't do good drug development

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- > Hints for Getting Hired

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