

Funding For-Profit Organizations

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May 29, 2006



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Outline: Tales from IP Research*

- Brief intro: role of commercial sector in therapy development
- Federal Models (scope/strategy/evaluation)
- State Models
- Foundation Models
- Commonalities/differences
- Challenges

* An early snapshot

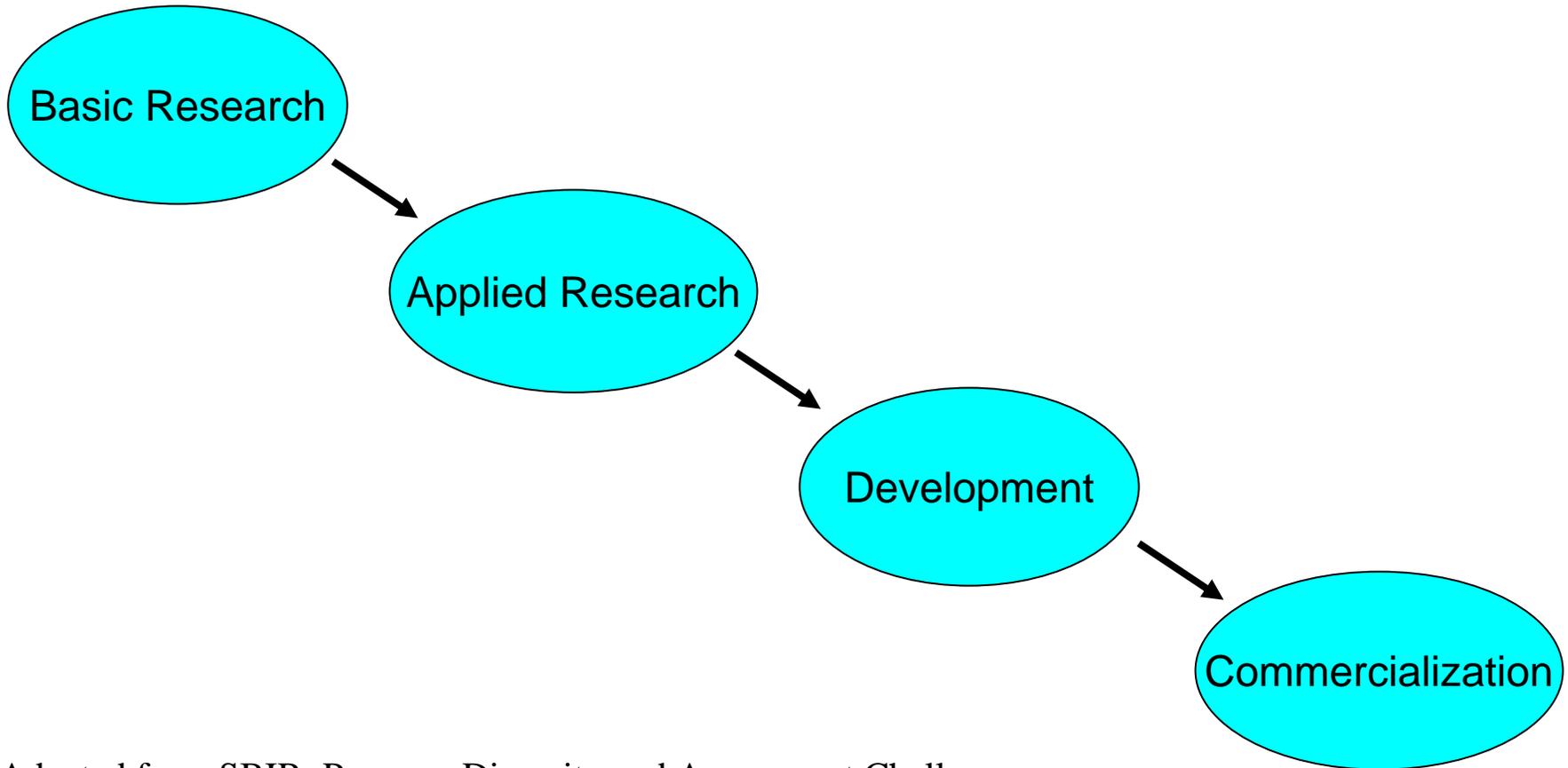


California Stem Cell Research and Cures Act (Proposition 71)

- Authorizes \$295M per year for 10 years to fund stem cell research at California research institutions
- Assures that research is done safely and ethically
- Prohibits the use of funds for reproductive cloning
- Benefits the California economy
- Advances the California biotech industry to world leadership



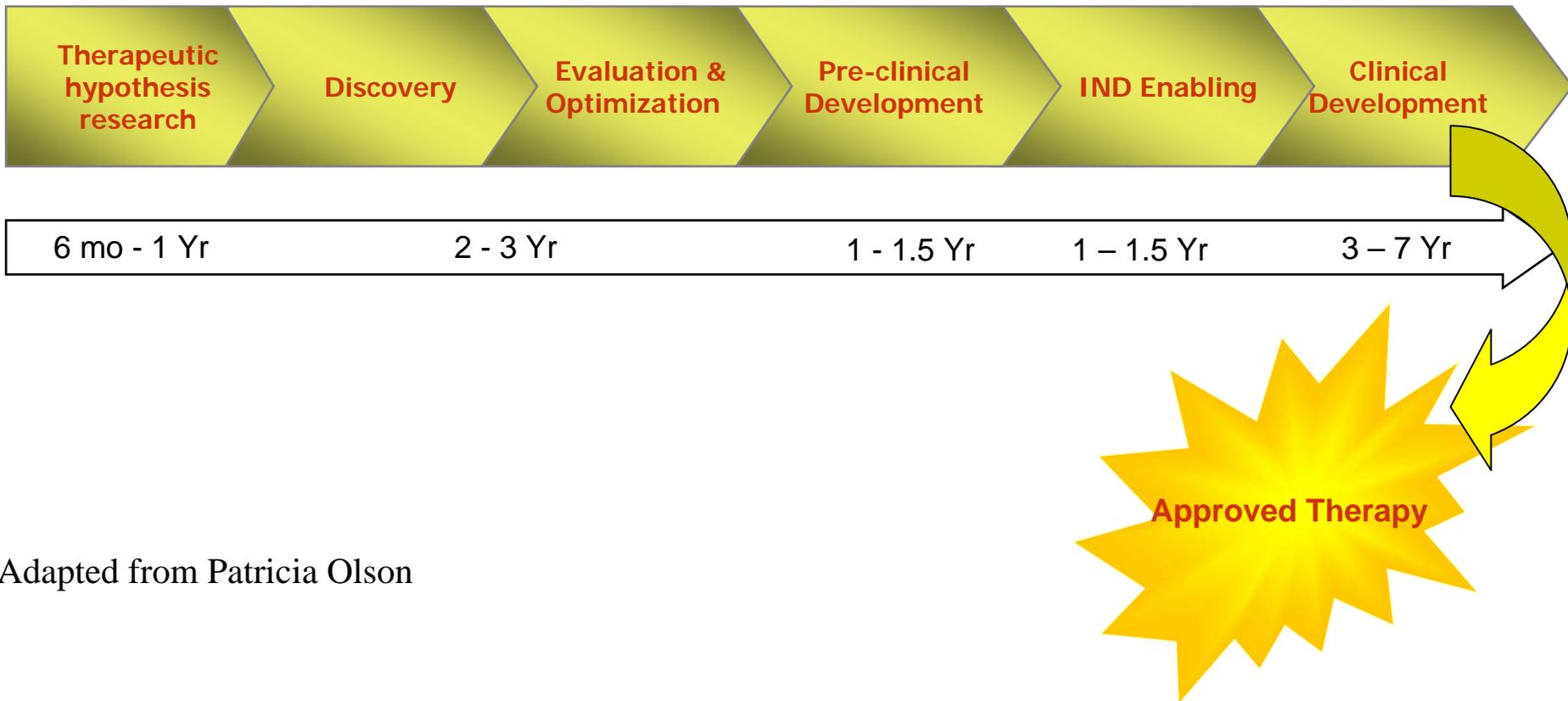
The Stages of Innovation



Adapted from SBIR: Program Diversity and Assessment Challenges



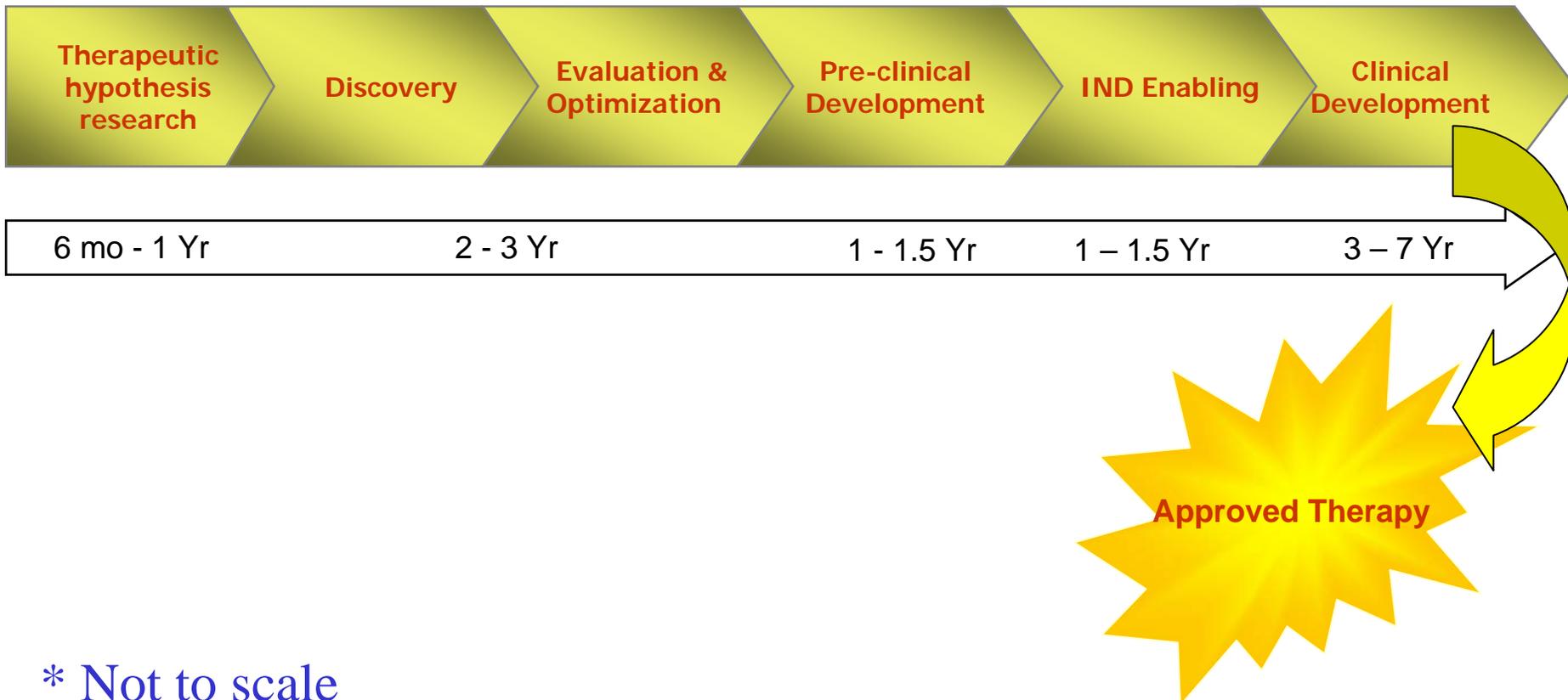
Generic therapy timeline



Adapted from Patricia Olson

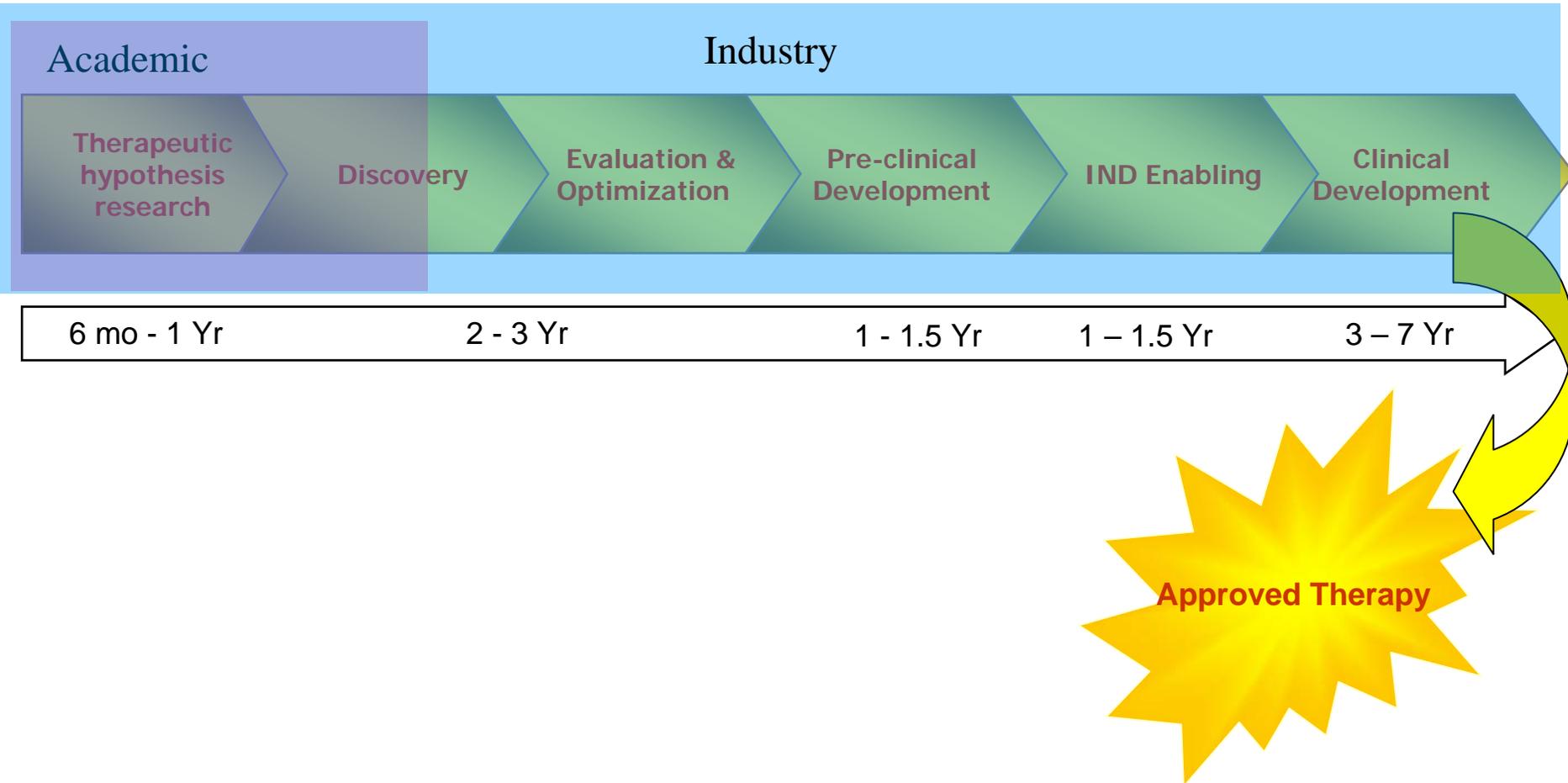
Generic costs*

Costs escalate with progression



* Not to scale

Research roles



CIRM strategic planning: the commercial sector

- How to decide how much of the ~\$295M/yr will go to companies?
- Should CIRM play a role in helping to fill funding gaps for early stage companies focused on hESC therapeutic indications?
- What types of CIRM funding opportunities will be available to companies? (*grants, loans, contracts*)
- Review:
 - Should the review process be blinded as to applicant?
 - Should there be a separate process for companies?
- Should funding for the commercial sector be “back-end loaded” to support clinical development?



Federal Models: SBIR & ATP

Small Business Innovation Research (1982)

&

Advanced Technology Program (1992)

- 1) Technology development is inherently valuable; translate discovery into public good through commercialization*
- 2) Early stage financial support for high-risk technologies*
- 3) No dilution of ownership or repayment required*
- 4) Intellectual property is the property of the grantee or awardee*



SBIR: \$2B/year, 50 programs (23 NIH)

- *2.5% set aside for federal agencies with R&D budgets over \$100M to help achieve agency missions*
- *Only for small companies (500 people)*
- *3 phases with varying award amounts:*
 - *Phase 1 ~ \$100,000: establish scientific promise*
 - *Phase 2 ~ \$750,000: further develop feasibility*
 - *Phase 3 no federal funds: move technology to prototype stage and to market*



ATP: \$2.1B over 14 years

- *Competitive requirements:*
 - Highly innovative and high risk (50% chance of success)?
 - Does R&D plan feature feasible means of overcoming high technical risk?
 - Is sufficient funding unlikely?
 - Will technology provide broad-based economic benefits in U.S. with high spillover potential?
 - Is there a clear commercial pathway to economic benefits?
- *Single company and joint company (at least 2) programs*
- *Awards capped at \$2M, 3 year duration, direct costs only*
- *No follow-on awards*
- *Matching funds required*
- *Robust evaluation practices up to 6 years post-funding:*
 - *\$4.1B invested = \$60B public benefit*



State Models:

- ***Maryland – TEDCO*** (*Technology Development Corporation*)
 - Assist in transferring to the private sector and commercializing the results and products of scientific research conducted by universities and in the private sector
 - 39 finished projects, \$2.2B invested, raised \$60.7B in downstream funding
 - Grants and loans (rates at or below market)
- ***Pennsylvania – Ben Franklin Tech. Partners***
 - Improve the economic well-being of the people of the Commonwealth through growth of technology-based small companies
 - Matching funds required (1:2 or 1:3)
 - Payback required
- ***California – UC Discovery Grants***
 - To strengthen and expand California's economy through jointly sponsored industry-university research partnerships
 - Grants range from \$50,000 to \$3M +



Foundation Models:

- *Outcome-based*: impact from research requires commercial engagement
- *Flexibility*: be mindful of burdening companies from attracting other investments needed to realize potential of research
- *Range of funding*:
 - \$50,000 to \$22M + (so far)
 - companies of all stages are targets
 - grants and loans provide flexibility and options for revenue-sharing



Foundations:

- *Strategic programs:*
 - Grants, loans in response to perceived need:
 - Scientific research
 - Policy research
 - Translation of early discoveries
 - Academic/industry consortia: build tools for drug discovery
- *“Response mode” programs*
 - Bring ideas forward in any area with prospects for public good



Some common themes in funding the commercial sector:

- *Commercial sector research costs more*
- *Review includes due diligence steps:*
 - Evaluation of senior management & business plan
 - Oral presentation (via teleconference)
- *Commitment to tend and monitor projects:*
 - Frequent site visits
 - Participation in company board meetings
- *Shared decision-making in “go” and “no go” project stages*
- *Continued evaluation of performance metrics and cautious view of “success”*
 - Determination of impact of funding and creation of public benefit



Some differences:

- *Some foundations are spinning out commercial funding arms while some are fully integrating them* (and dedicating to them as much as 15% of overall budget)
- *Disease-based foundations appear to have multiple directed strategic initiatives for commercial sector*
- *Annual meetings for all awardees vs. invitation only “superstar” meetings*
- *Funding of small companies (vs. any company) not universal*
- *Expectation of repayment not universal*



Ongoing challenges

- Tracking - companies fail, merge
- Liability – clinical trials/healthy volunteers
- Small companies lack (expensive!) clinical infrastructure until commercial promise is apparent – often later than needed
- Agreements – organizational restructuring can violate
- Stem cell trials – costs are likely to be high



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