



Biotechnology
Innovation Organization

Biotechnology Entrepreneurship Boot Camp

Presented by:

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June 1-2, 2024

[#BIO2024](#) [#StandUpForScience](#)

The strategic importance of forming alliances in this industry:

- Money
- Development expertise
 - ✦ Preclinical
 - ✦ Clinical
 - ✦ CMC
 - ✦ Regulatory
- Commercial capacity and capabilities

Bottom line: You will never cross the finish line without a development partner

Build
Buy
or
Outsource



What big pharma CEOs think when it comes to ensuring innovation and rebuilding pipelines

Prefer outsourcing innovation (buying individual licenses or entering into partnerships)	41%
Buying whole companies is the best approach, especially in the biotech area	39%
In-house R&D is the most efficient source of future innovations	20%

A few basic principles...

- ❑ Ask “why not?”, even if there is a cast-in-stone corporate strategy.
- ❑ Behind every licensing or collaboration deal, there is one fairly obsessed individual, aka champion .
- ❑ Simplicity- the rationale/ value proposition must be clear.
- ❑ Try, try again- make persistence a competitive advantage
- ❑ Appreciate that it’s risky business- Creating something new takes risk (probability of technical and regulatory success) to a new level, especially if it’s first-in-class and requires a completely new road map
- ❑ Synergy is necessary in a partnership. A great team is greater than the sum of its parts.

Long-term considerations to appreciate:

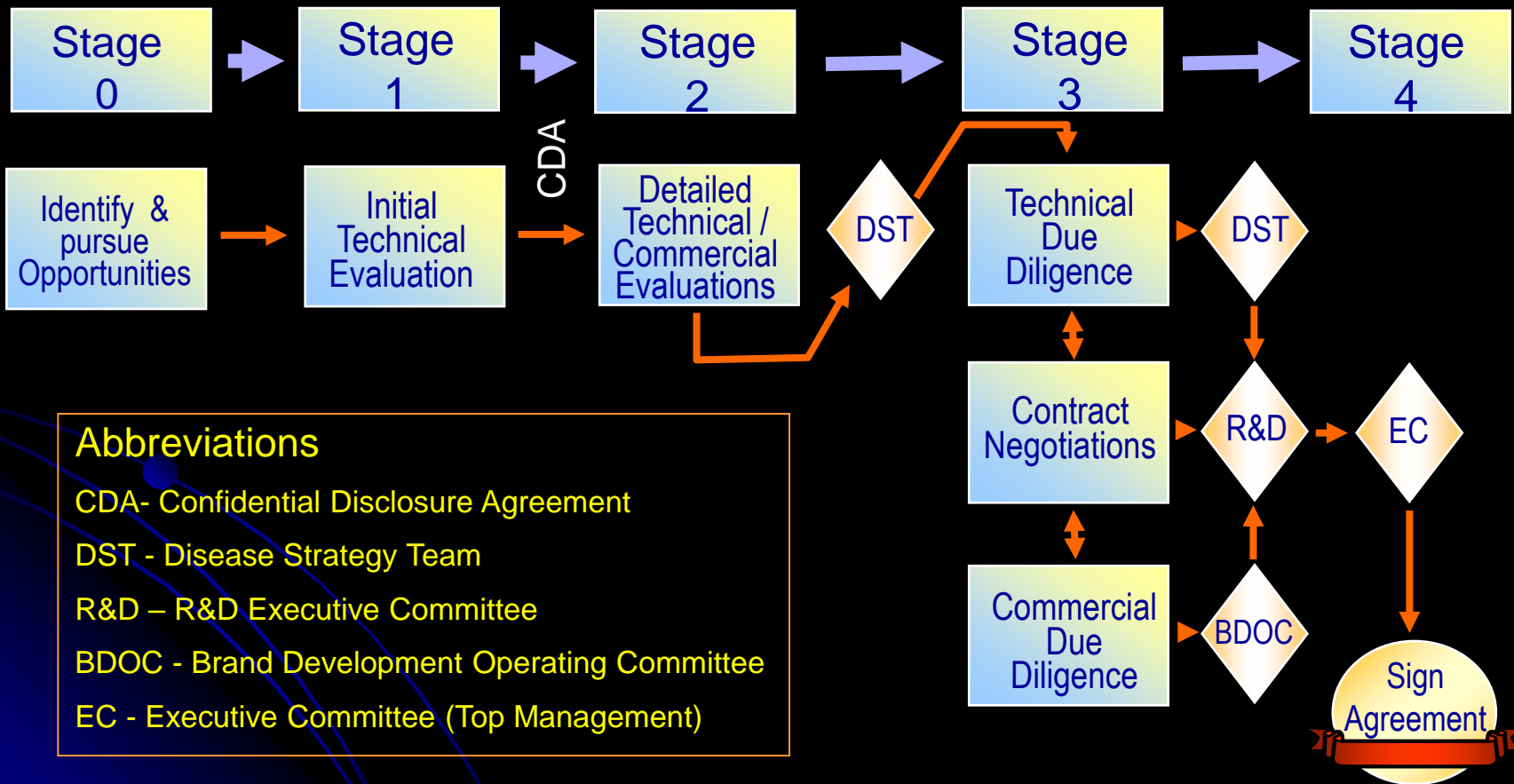
- Big pharma and investors see a lot of deals and can only do a few. Understand their therapeutic and discovery strategies and pick a short-list on which to concentrate from the beginning.
 - Later-stage (Phase 3-ready and beyond) assets make the most sense and are the easiest to get done.
 - Early-stage assets have significantly more technical and regulatory risk and require \$\$\$\$\$\$\$\$ in capital. These are the purview of venture capitalists.
 - The good news- Biotech discovery is important for the future of Big Pharma pipelines- 70% of novel NME FDA approvals are for partnered assets. This will not change.
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Partnering REALITIES you have to understand

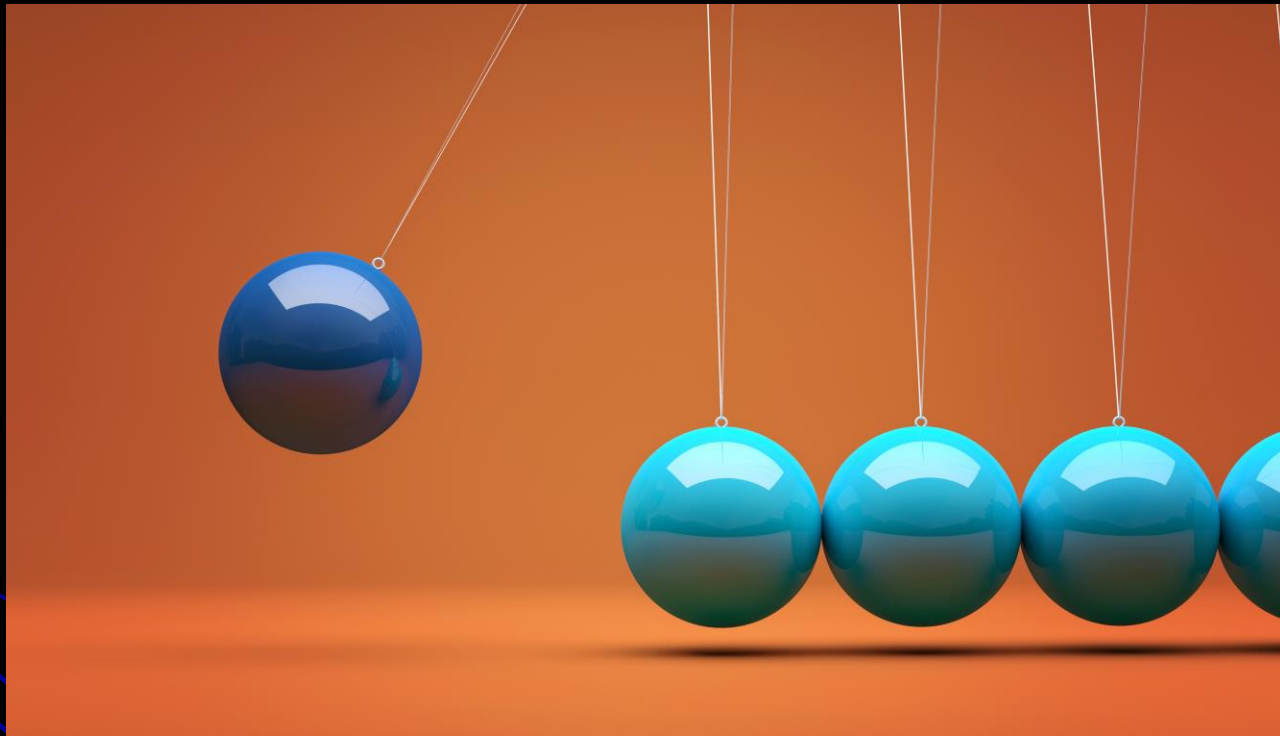
- It's not enough to be innovative, a new drug also has to be cost-effective
- It's not enough to get FDA approval- you also have to make sure that payers will reimburse it
- The FDA is asking for superiority to standard of care (comparative efficacy)
- Life is really expensive and bang for the buck is important
- Companies most likely to get funded today are those that embrace an early partnering strategy from the outset.



In-licensing process



PATENT REVIEW COMES FIRST



The gate keepers in big pharma: The scientific/commercial jury

- Sr. VP, Regulatory
- Sr. VP, Preclinical research
- Sr. VP, Clinical Research
- Sr. VP, Development
- Chief Marketing Officer
- Sr. VP, Project Management
- Sr. VP, Global Pharmaceuticals
- Sr. VP, Business Development
- President, US Pharmaceuticals
- President, Manufacturing
- President, Pharmaceuticals (ex-US)
- CFO/ Corporate Controller
- Sr. VP, Corporate Council/ Legal Affairs



Understand there are a lot of hurdles on the way to success

- **Know what you don't know. Surround yourself with those that do.**
- **Understand the difference between a “science project” and a “company”.**
- **Scientist founders should not be CEOs.**
- **Develop a connected and involved BOD/SAB.**
- **Plan for the future- think ahead in everything.**
- **Try not to take stupid shortcuts- science rules.**
- **Focus.**

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