

## Abstract

**Abstract:** Many therapeutic assets are struggling to find funding to move past the “Valley of Death.” This is a crucial stage in early drug development, when the value of an opportunity depends on the abundance of its supporting data, the strength of its intellectual property, and the availability of key resources. However, bringing the right assets forward can be a “Catch-22”: Much-needed data takes time and funding to obtain, but the right data package is required to obtain funding. To bridge this gap, a number of public and private funding sources are available—both sequentially and simultaneously—to obtain the complete data package necessary to attract funding and advance these assets forward.

We take a holistic view of the preclinical drug development process through the lens of a “Preclinical Accelerator”. We compare funding sources and organizational structures that move early-stage therapeutic assets past the Valley of Death. We investigate the flow and preference of public and private funds, the emergence of commercially-focused government grant mechanisms, and the developing presence of accelerator and incubator companies and their programs. We use publically-available data to show how these new modalities are emerging and positioning themselves to bridge the funding gap.

We also discuss how the valuation of an opportunity changes during early-stage drug development. Non-dilutive accelerator programs drive ideas at critical times, reaching value inflection points with higher than average return on investment. The right infrastructure and expertise facilitates environments that can make this happen. Not discussed on this poster are the quantifiable screening methodologies, including development team characteristics, and the decision trees that need to be in place for prioritizing projects. The object of this analysis is to compare available routes and requirements for advancing preclinical therapeutic concepts to IND.

## Methods

**Fundraising & Exit Strategy:** We accessed and examined contemporary public records and research reports from VC firms, angel groups, corporations, non-profit organizations, and government agencies. The objectives were to put together a list of funding sources along the development spectrum.

**Valuation & Inflection Points:** We used publically available data from SEC filings, market research reports, government agencies and corporate press releases to break down the follow-through of funds to pinpoint value-enhancing drug development events, called inflection points. Available data was combined to create a sample Net Present Value financial model for a hypothetical therapeutic opportunity.

**Positioning:** Positioning maps and comparison tables were created with publically available information from corporate and non-profit websites, press releases, and industry reports.

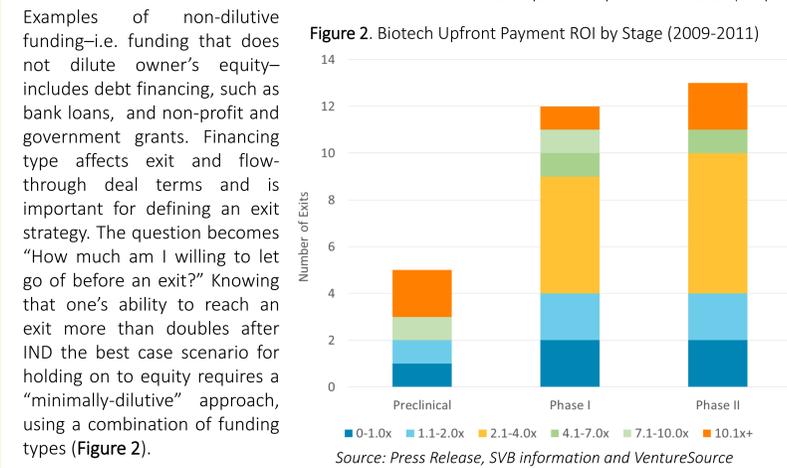
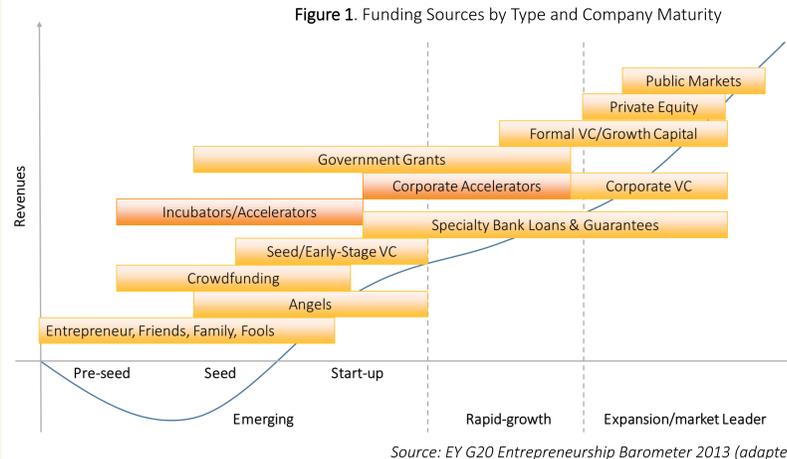
## Key Words

SBIR grant funding; positioning, accelerator, incubator, IND, preclinical, non-dilutive, differentiation, success rates, exit strategy, valuation, inflection, fundraising, de-risking, NIH

## Results

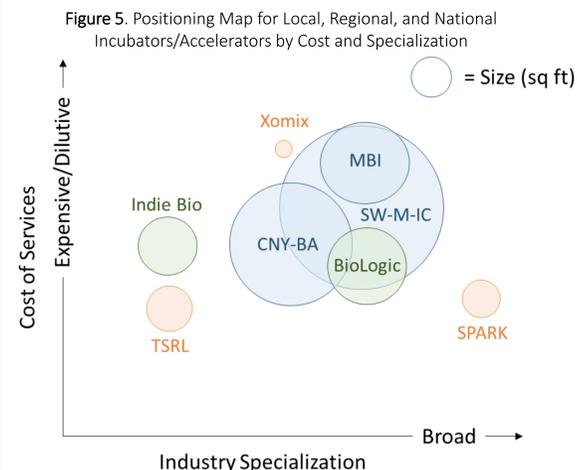
### Fundraising & Exit Strategy

**Fundraising & Exit Strategy:** The type, source and size of fundraising depends on the strength of the opportunity, its risk/reward profile, and availability of capital networks. Incubators and Accelerators are unique, in that they span pre-seed, seed, start-up, and growth stages of young companies (Figure 1).



### Positioning

**Positioning:** Incubators typically offer administrative resources, space, and shared equipment while Accelerators offer capital networks, in-kind services, and mentorship. Differentiation depends on structure, size, breadth of services, specialty, and mission (Figure 5). Preclinical assets often require a highly collaborative environment to thrive.



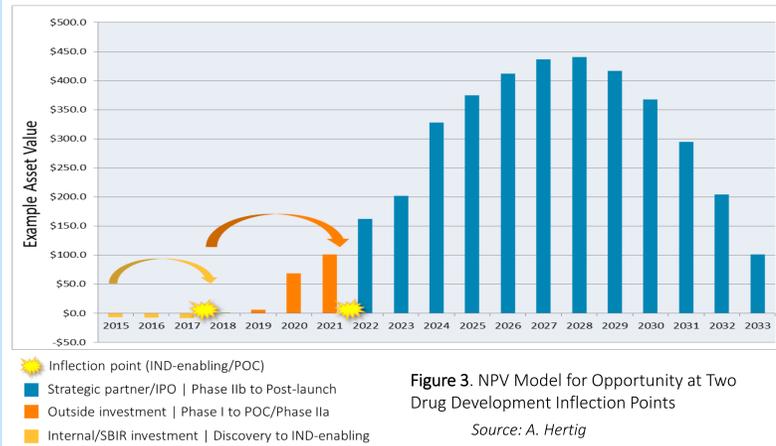
**Table 1. Positioning Map for Local, Regional, and National Incubators/Accelerators**

	SW-M-IC	SPARK	MBI	BioLogic	TSRL, Inc.	CNY-BA	Xomix	Indie Bio
<b>Type</b>	Incubator/Accelerator	Incubator/Accelerator	Incubator	Incubator	Accelerator	Accelerator	Accelerator	Accelerator
<b>Tax Status</b>	Non-Profit	Non-Profit	Non-Profit	For Profit	For Profit	Non-Profit	For Profit	For Profit
<b>Size (sq ft)</b>	69,000	5,000	20,000	15,000	7,200	40,000	None	Varies
<b>Company Stage</b>	Formation	Early to Maturing	Formation	Early Stage	Pre- or Post-Formation	Formation	Pre- or Post-Formation	Pre- or Post-Formation
<b>Funding Provided</b>	None	Debt; Grants; In-Kind	None	None	In-Kind; Grants	N/A	Investment	Investment; Debt
<b>Industry</b>	Life Sciences	Innovation Companies	Life Sciences	Life Sciences	Pharma	Biomedical/Biotechnology	Biomedical/Biotechnology	Synthetic Biology
<b>Mentorship &amp; BD</b>	Counsel; Training; Networks	Networks; Business Support	Counsel; Networks	Grant Management; Networks	Grant Writing; Networks	Counsel; Networks	Counsel; Networks	Counsel; Venture Networks
<b>Other Services</b>	Admin; Lab Space; Core Facilities	Admin; Lab Capital Networks	Lab Space; Core Facilities	Admin; Lab Space; Core Facilities	Lab Space; Equipment; Animal Labs	Admin; Lab; Patient Access; Core Facilities	Fee-for-service; Business Development	Lab Space; Core Facilities
<b>Cost Structure</b>	Monthly Lease	Monthly Lease	Monthly Lease; Equity	Monthly Lease	Monthly Lease; Equity	N/A	Equity; Fee-for-Service	Equity

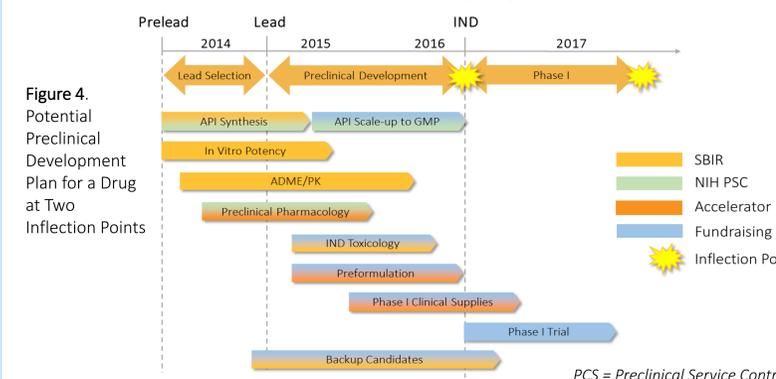
SW-M-IC = Southwest Michigan Innovation Center; MBI = Massachusetts Biomedical Initiatives; CNY-BA = Central New York Biotech Accelerator

Accelerators are uniquely positioned depending on resources required. For instance, well-funded entrepreneurs may not require access to pre-IND funding sources, such as non-dilutive funding, and work well in incubators. Higher-risk projects or emerging entrepreneurs find that highly-engaged Accelerators can offer the guidance and tools needed to reach the next inflection point. If access to external capital is paramount or an exit is in sight, a venture-backed Accelerator is perfect (Table 1).

### Valuation & Inflection Points



**Valuation & Inflection Points:** Drug development programs typically have a negative Net Present Value (NPV) at initiation (Figure 3). Long and costly commercialization timelines stem from clinical trials that ensure drug safety and efficacy for a target patient population. An important inflection point, or value-creation point, is when a drug clears its Investigational New Drug (IND) application and reaches the clinic. The resources required to reach IND, however, is challenging for projects with negative net values (Figure 4). Accelerators provide the infrastructure and expertise for entrepreneurs to become more grant-competitive, as well as in-kind services, to round out successful IND-enabling programs.



## Conclusions

**Conclusions:** There are many ways for entrepreneurs to acquire the resources they need to bridge the preclinical gap, also known as the Valley of Death. Depending the strength of the opportunity and its risk-stage, the options for advancing a single asset or platform vary considerably. Non-dilutive funding sources, coupled with traditional sources from retained earnings and external capital, offer companies a diverse set of tools to advance their therapeutic concepts.

Non-dilutive funding in the form of government grants is ideal for moving lead compounds forward to IND, particularly due to their low cost, availability, and impact on valuation. Preclinical accelerators offer services to contribute to obtaining additional resources, which can be used to obtain more funding at later development stages. Most accelerators are organized according to scope of services provided and industry specialization. It is important for individuals to seek out the services that match their opportunity.

## Future Work

### Measuring Accelerator Success

**Measuring Accelerator Success:** We plan to investigate metrics for the success of accelerators vs. incubators catering to preclinical drug development programs. There are several metrics one can use to determine an Accelerator’s activity and success, including:

- #/% of “graduate” companies or successful exits
- Space utilization or occupancy rate (%)
  - Office space utilization (%)
  - Laboratory space utilization (%)
- # of collaborations
- # of leads → # of screened opportunities
- # of submitted grants → # of awarded grants
- Success rate of each step of conversion process
- Total amount and size of awards
- Sources of revenue (lease/services/licensing)
- Website traffic and social media impact
- Total amount of outside investment

By tying fundraising sources to value inflections, we can track and direct the efficient use of capital toward meaningful early-stage drug development.

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## Acknowledgements

None that apply