



State of Life Science Entrepreneurship in Tennessee

WE
ELCOME

We at Baker Donelson and Life Science Tennessee are pleased to present this report on the state of life science entrepreneurship in Tennessee. This report offers both objective data and prevailing opinions from thought leaders throughout the State. The information we gathered highlight the challenges and opportunities faced by life science professionals working to commercialize scientific discoveries, secure private and public investment, build a quality workforce and grow successful life science businesses. We gathered feedback from Tennessee's life science community for this report through a written survey instrument as well as four regional focus group discussions that took place in Chattanooga, Nashville, Knoxville and Memphis. Some of the challenges, and opportunities, we found are universal, while some are unique to Tennessee. We hope you find this report as meaningful and interesting as we do, and that it serves as a basis to enhance the growth this important industry sector in Tennessee.

Bruce Doeg

Business Department Chair
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Life Science Tennessee

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Baker Donelson is the nation's 68th largest law firm, with more than 650 attorneys and policy advisors across the Southeast providing informed guidance in more than 30 practice areas, including a specialty focus on the life science sector.



Life Science Tennessee is a member-driven association representing a range of Tennessee-based enterprises as well as educational and clinical research institutions engaged in a wide variety of life science sectors, including biotechnology, pharmaceuticals, medical devices, diagnostics, agricultural biosciences and research.

Sometimes referred to as biosciences, life science is an industry cluster that applies knowledge of the ways in which plants, animals and humans function. The sector is consistently evolving to address the very latest research and scientific discoveries.

SUMMARY

The life science entrepreneurial environment in Tennessee has seen significant success in recent years, and the future remains bright for its continued growth. Both startups and mature companies are creating jobs in all regions of the state, and these include home-grown ventures as well as those attracted to Tennessee from other regions of the country.

The importance of life science companies for the state's economy and for society cannot be overstated. Through cutting-edge innovation Tennessee's life science industry is improving and saving lives. Though scattered and inconsistent by region, life science entrepreneurs have the advantage of operating alongside tremendous resources in Tennessee.

The state has made impressive financial investments in startup companies over recent years. These state-led incentive programs – particularly TNInvestco and INCITE – have been especially helpful in providing vital seed monies to life science entrepreneurs. These businesses face unique regulatory and timeline challenges in taking a product to commercialization, making it sometimes challenging to secure early-stage capital.

Unfortunately, funding for these state incentive programs has now been expended and the likelihood of an additional injection of state support for similar incentives is not expected at this time. The impact of this change is expected to slow progress for life science startups.

Tennessee's life science community has numerous strengths, including its world-class academic research institutions. There are also regional strengths. Memphis has one of the largest clinical medical infrastructures in the nation and houses a premier medical

device cluster. Nashville has the nation's largest network of community-based health care delivery services and access to the health care delivery system's most expert innovators. Vanderbilt University is a top-ten leading recipient of research funding from the National Institutes of Health, receiving more than \$292 million in 2013. East Tennessee boasts a large number of top quality Ph.D. scientists from both the Oak Ridge National Laboratory, the U.S. Department of Energy's largest science and energy lab, and the University of Tennessee. Chattanooga is also bursting with an infectious enthusiasm for collaboration and innovation in the field .

Capitalizing on Tennessee's range of assets can be challenging for life science entrepreneurs, however. For example, much can be done to improve interactions between academic research institutions and their aspiring entrepreneurs. Though some Ph.D. graduate scientists are relocating to the state, the reality is that Tennessee continues to be primarily an exporter of science Ph.D. graduates who go on to launch companies or work elsewhere. Moreover, the dispersion of talent across the state creates challenges to collaboration and community building.

The purpose of this report is to share data and anecdotal information about the startup climate for life science entrepreneurs. Incorporating regional nuances, it highlights the challenges and opportunities faced by life science professionals working to commercialize scientific discoveries, secure public monies, raise capital and build a quality workforce.

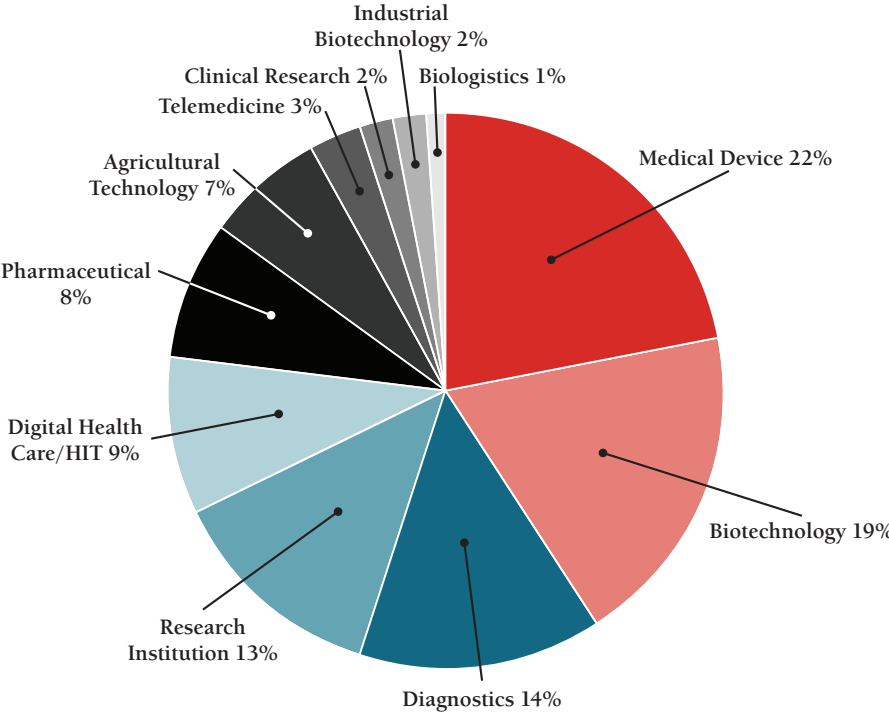
Feedback from Tennessee's life science community was gathered for this report through a written survey and through four regional focus group discussions that took place in Chattanooga, Franklin, Knoxville and Memphis.

The Baker Donelson and Life Science Tennessee 2014 Life Science Survey was completed by nearly 90 professionals representing a wide-range of industry sectors, companies, academic research institutions and venture capital firms from all regions of the State of Tennessee.

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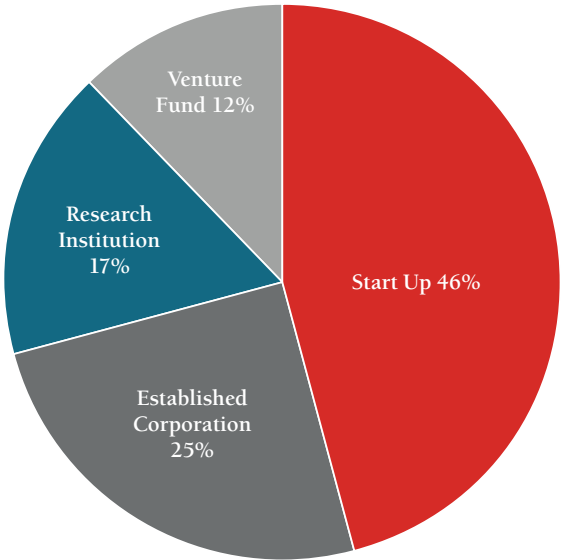
Survey Respondents by Sector

Total: 87



Size and Type of Business Surveyed

Total: 87



Although this report provides detail around challenges in the life science sector and identifies strategies to improve the entrepreneurial environment, it is also important to recognize the growth and success that Tennessee has had in launching and supporting life science businesses. Every region of the state has an active life science community, members of which are launching and running significant companies that improve not just our wellbeing and quality of life, but also provide Tennessee with clear economic benefits.

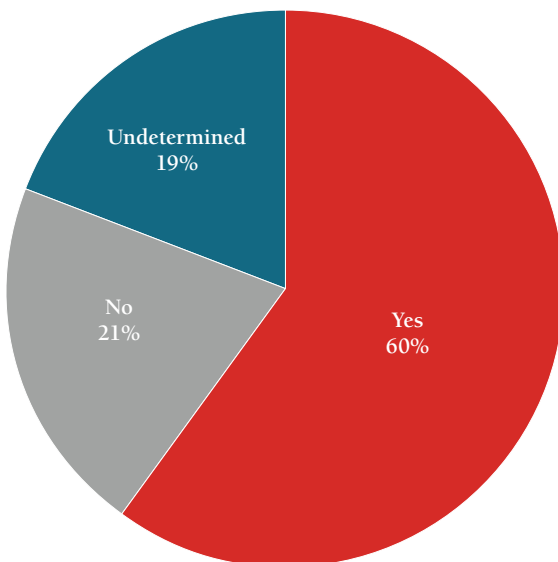
“These are real companies and clearly the velocity has changed,” said one Memphis roundtable participant.

And, despite the hurdles life scientists must overcome to license a product, obtain seed funding and commercialize, the potential for the industry is very positive at this time. More than 60 percent of Tennessee’s life science employers have plans to hire new employees in the next 12 months and almost 80 percent plan to do so within the next five years.

“The tide is rising. Not as fast as we might want, but certainly it’s going in the right direction,” noted a Nashville-based life science entrepreneur and consultant.

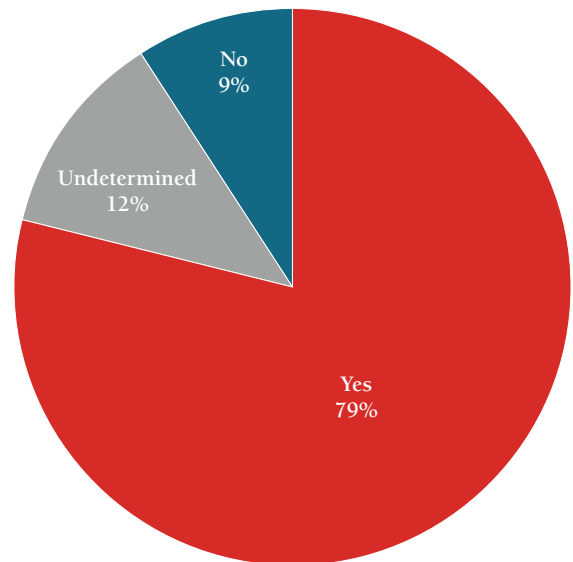
Industry Employers Who Anticipate Hiring New Employees within 12 months

Total: 57



Industry Employers Who Anticipate Hiring New Employees within 5 years

Total: 57



CAPITAL

Access to Capital

Much of the significant growth that Tennessee's life science community has experienced over the past five years can be attributed to soon-to-expire state capital formation programs, particularly TNInvestco and INCITE.

Now fully-allocated, TNInvestco has provided some \$108 million in public seed-funding to startup companies since 200. INCITE, a co-investment fund supporting TNInvestco expenditures, has provided Tennessee entrepreneurs with almost \$30 million in federal matching funds since 2011. Programs such as INCITE and TNInvestco sparked numerous venture deals in the area of life sciences in Tennessee. In 2012, for example, more than \$40 million was invested in the life science industry in Tennessee.

"The appetite is there to fund these state activities, but there are financial impediments," said a Nashville-based participant involved in technology transfer.

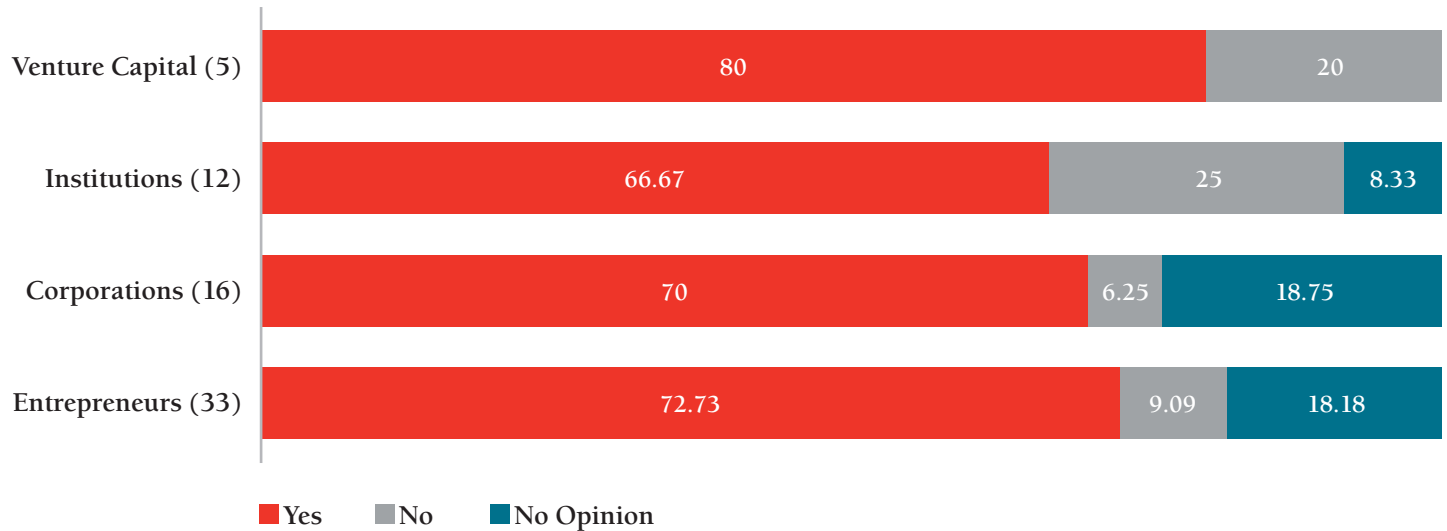
"We have been through several good years in terms of first-stage capital. It makes me nervous not seeing a path for a truly early-stage company. These are companies that are beneath some investor radars. Without programs like TNInvestco, I think we might struggle to get some great companies started," said a roundtable participant who is in technology licensing at a major research institution.

"Never has there been a better time to be an entrepreneur in Tennessee, but a lot of capital is invested because of the seed funding from programs like TNInvestco. Although we have had that funding period recently, I'm a little worried about what the coming years will look like if we don't find a similar program," said a Memphis-based venture capitalist.

In light of the heavy investment required on the front end for any life science startup facing expensive lab and regulatory work before commercialization can take place, it is not surprising that Tennessee's life scientists strongly support state incentive and capital formation programs. Some 73 percent of entrepreneurs and 80 percent of venture capitalists support the programs, which also gain strong support from established corporations (70 percent) and academic research institutions (67 percent).

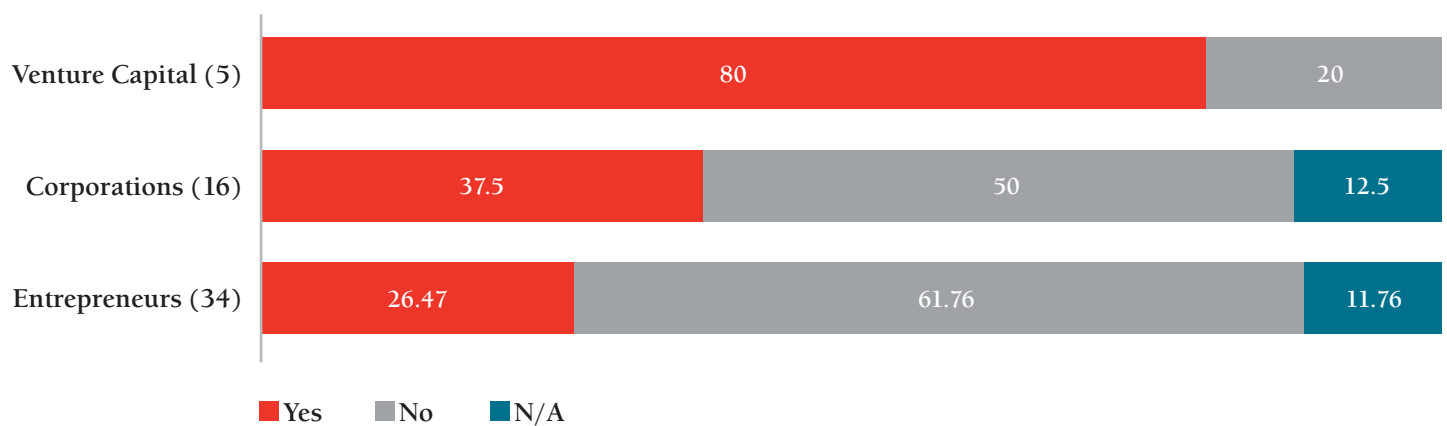
The saturation rate for having participated in such programs is 30 percent for entrepreneurs, almost 40 percent for corporations and 80 percent for venture capitalists. The gap between those entrepreneurs voicing support for state-led incentive programs and their participation indicates strong potential for participation, should the state be in a position to reinvest in these ways in the future.

Do You Believe State Incentive and Capital Formation Programs are Effective in Driving Growth for Life Science in Tennessee?



My Company or I Have Taken Advantage of State-Provided Incentives or State-Led Capital Formation Programs

Total: 34



With the loss of these state funding sources, early-stage life science entrepreneurs must look to alternate sources for seed funding, and many are concerned that the private sector may not be able to sufficiently fill the gap.

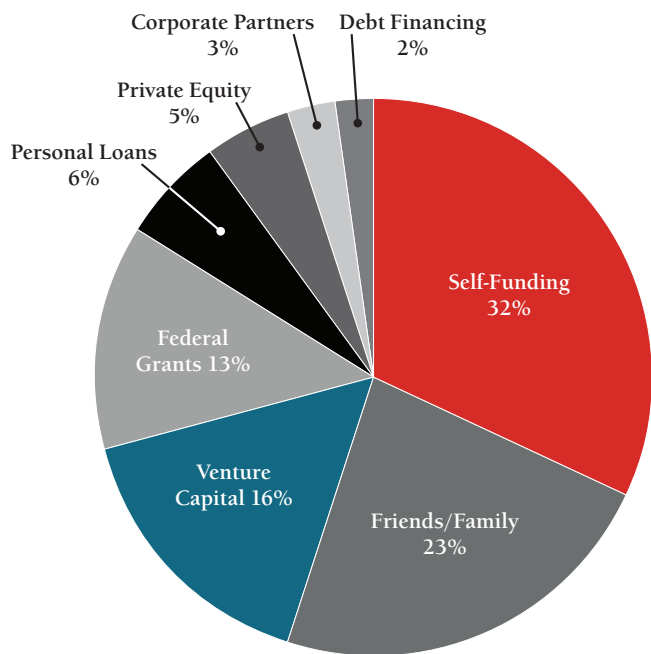
Tennessee's life science entrepreneurs are currently funding their companies from a variety of sources; more than half of these funds come from personal financing, friends and family.

An additional 13 percent is secured in federal grants. These are primarily garnered through the Small Business Innovation Research (SBIR) program which offers grant support to small businesses conducting research and development that has the potential for commercialization.

However, the picture of how entrepreneurs plan to support their ventures in the near term is quite different and, not surprisingly, includes heavier support from private equity, venture capital, corporate partners and federal grants.

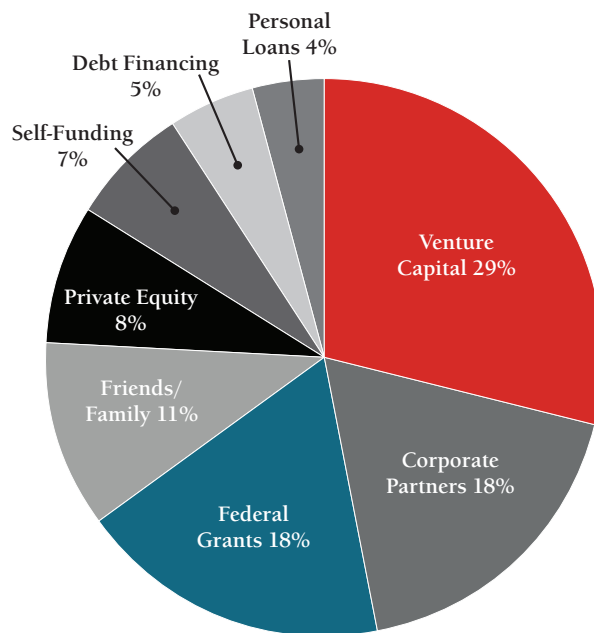
Entrepreneur Funding Sources

Total: 34



Funds Entrepreneurs Plan to Secure

Total: 33



As noted, accessing private funding can be particularly challenging for life science entrepreneurs due to the longer investment time frame, the significant amount of capital needed before commercialization, and the scientific and regulatory risks. Many entrepreneurs have met with a lot of potential funders for whom the entrepreneur's proposal was outside the scope of the fund.

It is also harder for startup companies to find seed funding than it is for established companies with proven management teams and an operational track record. The first round of funding is typically the most difficult to secure and requires intense networking and research.

Though there are some private firms in the state that do a wonderful job investing in early-stage life science companies, there are simply not enough. The majority of seed capital for these companies is not located in Tennessee. Life science entrepreneurs, particularly those located in East Tennessee, must travel extensively to seek out support.

“In Tennessee it is still tough to get the right start. You have to know who to talk to and where to get it,” said a Knoxville-based entrepreneur.

Another entrepreneur, also based in Knoxville, had a similar experience: “We gained Series-A funding out of state, and I would like to have it in-state. I spend a lot of time focused on fundraising like any startup does, but it’s harder for us than if we were in San Francisco because we have to travel.”

While entrepreneurs are hungry to secure early-stage financing, Tennessee’s life science industry is also looking for appropriately staged funding for all companies, including those that have secured seed monies and are ready to take their companies to the next level.

“The specific type of capital we are now having the most difficulty with is in the Series-A range where someone has to now write a \$2 million check,” said a Memphis-based consultant to numerous emerging life science companies. “It’s after seed money to starting the business and scaling up.”

Recommendations:

- Continue to support pitch competitions and other programs that attract and connect funders from outside Tennessee with Tennessee companies and local potential co-investors, such as the Nashville Southland Conference, the TENN, the Life Science Tennessee Venture Forum and the University of Tennessee Venture Summit.
- Provide more forums and networking opportunities for those who develop technology to connect with sources of funding, particularly seed or angel funding, and provide more education for local venture capital firms to gain an understanding of life science funding dynamics, returns and timelines.
- Continue to work with the state on supporting publicly funded incentives.
- Provide SBIR (Small Business Innovation Research) and grant-writing training in targeted markets where startup services are less available.

TRANSFERS

Commercialization and Technology Transfer

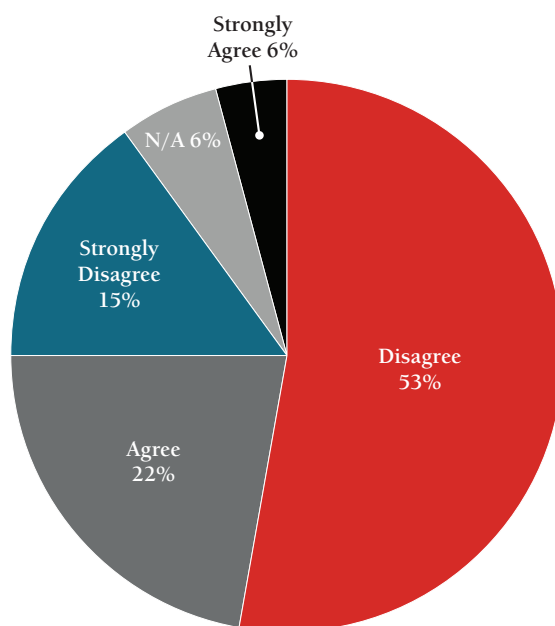
As noted, Tennessee has ample intellectual assets. Oak Ridge National Laboratory is the nation's largest science and energy lab; Vanderbilt University is nationally renowned as a research center and institution of higher education; St. Jude Children's Research Hospital is globally recognized for its pediatric medical research; and the University of Tennessee, University of Memphis, East Tennessee State University, Middle Tennessee State University, Tennessee State University and various private universities are all highly-respected institutions of higher learning.

This academic abundance provides an incredible opportunity for life science business development. These institutions are the bedrock required before capitalizing on any research and intellectual property that academic researchers generate. But the path to achieving this goal is fragmented in Tennessee.

In fact, almost three-quarters of life science entrepreneurs surveyed, as well as 56 percent of corporations and 60 percent of venture capitalists, disagree that Tennessee's research institutions have strong research capabilities and support the commercialization of technologies. While Tennessee's academic research is widely cherished, life scientists in some regions of the state believe the commercialization process of clinical research is lacking.

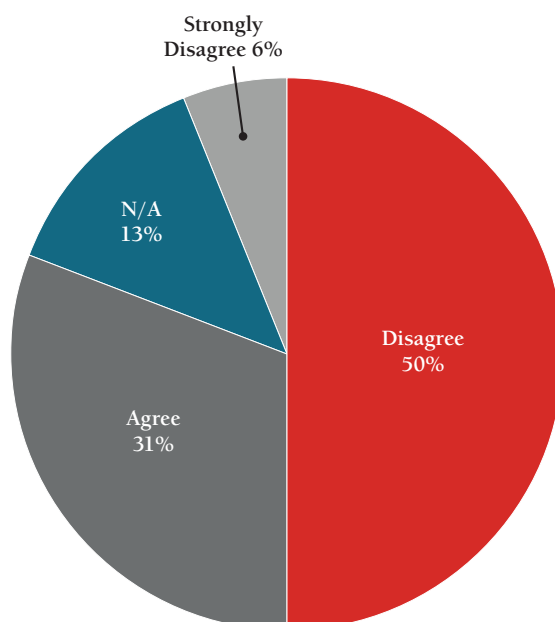
Entrepreneur Response: Do Tennessee Research Institutions Have Strong Research Capabilities and Support the Commercialization of Technologies?

Total: 34



Corporation Response: Do Tennessee Research Institutions Have Strong Research Capabilities and Support the Commercialization of Technologies?

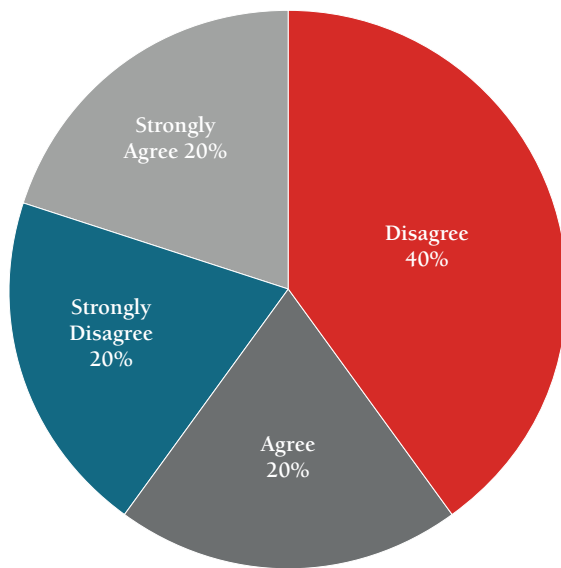
Total: 16



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VC Response: Do Tennessee Research Institutions Have Strong Research Capabilities and Support the Commercialization of Technologies?

Total: 5



Each academic research institution has its own unique commercialization process, and in some regions the environment is viewed with more optimism than in others. Memphis has seen commercialization success due in part to the comparative maturity of the industry in the area, with collaborative networking and the strength of the staff working in the tech transfer offices, as well as at Memphis Bioworks.

“There are three tech transfer offices in Memphis and they have been staffed with the same people for a very long time. A very stable staff and institutional memory in these institutions is an often-unrecognized asset,” said a Memphis-based roundtable participant.

In some circumstances, however, life science professionals in the state feel commercialization and economic development is of secondary importance within their public institutions, and that the culture and infrastructure aren’t always in place to maximize success for either party. The results of this dynamic are unfortunate.

“The perennial issue is Tennessee being a net exporter of engineering and life science talent. We need to figure out how to keep these people here. If we are a net exporter, then someone else is an importer,” said a Nashville participant.

The commercialization process involves moving the discovery rights out of a public lab and into the private marketplace. The innovation involved is typically patented by the research institution and licensed to an entrepreneur for the creation of a company. The licensing is obtained through the negotiation of business terms between the entrepreneur and the research institution. Life scientists believe it is within the terms of these negotiations that relations can improve.

“There is some tension between institutions and their own startup companies. In terms of supporting startups there’s a lot more we can do. Universities need to do more for entrepreneurs. Across the state I think we can make a lot of difference,” said a participant and technology transfer professional.

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The life science community strongly encourages the state's university system to foster policies and practices that enable innovations to be brought to the marketplace. In particular, institutions should be encouraged to adopt a policy whereby the expenses associated with the technology transfer offices are viewed as an investment rather than an operating cost.

Take one startup company's experience as an example. After working on licensing its innovation for two years, its founder explained: "The rules kept changing. It was one thing after another and it was very frustrating. You almost feel like giving up before you get there."

Increased access to specialty and regulatory expertise for entrepreneurs navigating this arena would also improve the conflicts of interest and licensing procedures that present for life scientists housed in academic institutions.

The more Tennessee's academic institutions can do to collaborate with their own faculty members and, despite geographic and transportation difficulties, with other academic institutions across the state, the better the outcomes will be for commercialization and economic development.

"All of our scientists are in Knoxville and the clinicians are here," said a Memphis life science attorney. "It really is a challenge if you aren't on the same campus."

Recommendations:

- Hold roundtables for entrepreneurs on how to work with universities to help commercialize clinical research.
- Continue to work with universities to find ways to effectively translate the investment of ongoing research into businesses.
- Work with academic research institutions to allow researchers time outside the walls of the university.
- Collaborate with tech transfer offices to provide training programs for life science entrepreneurs, including how to negotiate term sheets, listen to customers and bring a product to market.

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Access to Services

Life science professionals who participated in the data gathering process for this report provided us with detailed feedback on the services that are available and unavailable in their markets. All life science practitioners representing all entities and life science disciplines cited access to staged funding as their greatest area of need.

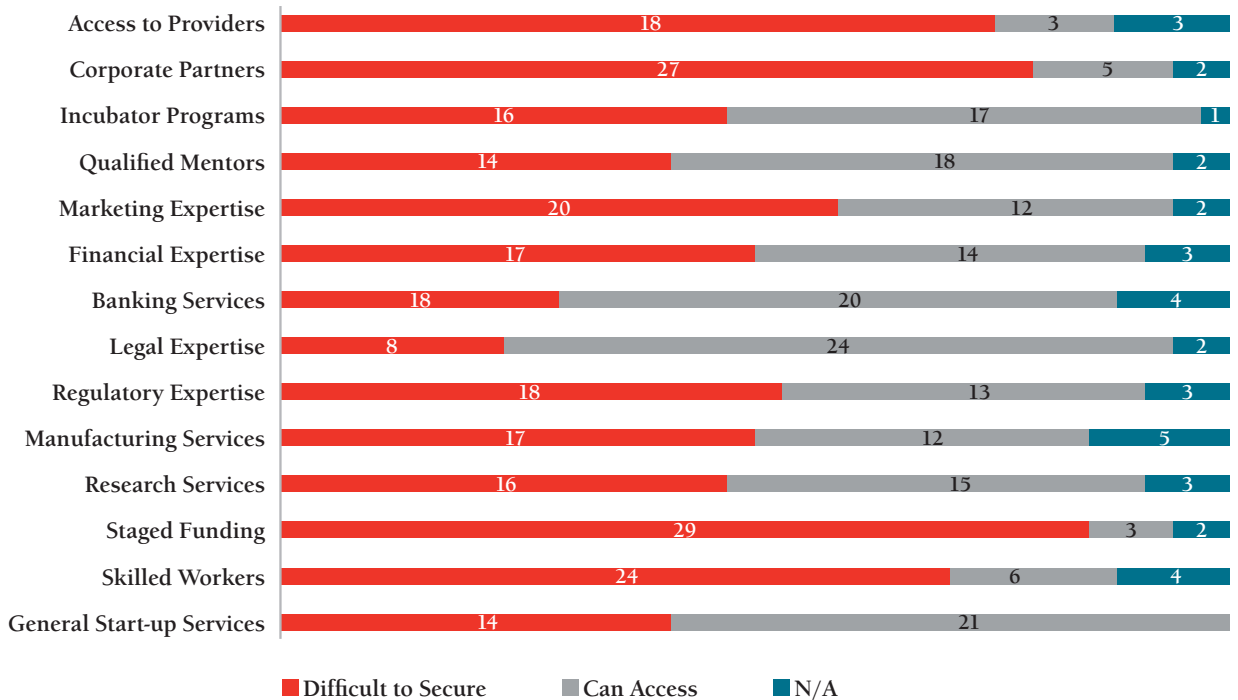
After staged funding, life science entrepreneurs also cited the difficulty in accessing corporate partners, provider partners, skilled workers, skilled marketers and regulatory experts. Entrepreneurs also described challenges accessing biological tissue samples. They expressed a desire to work with Tennessee-based suppliers and partners, but were often not able to identify suitable in-state options.

Other entrepreneurs are struggling to find lab or work spaces. For young life science companies there is a shortage of lab spaces across the state to meet their needs. Campuses such as the Cool Springs Life Science Center, Cumberland Emerging Technologies, the Innovation Center at ETSU and Memphis Bioworks are either full much of the time or not built to handle the existing demand.

A recent development that addresses a concern over the cost of pre-clinical research for these early stage technologies is the launch of TriMetis Life Science in Memphis. TriMetis provides scientists with preclinical services, including access to specialized labs and research expertise.

Entrepreneurs on Availability of Services

Total: 34



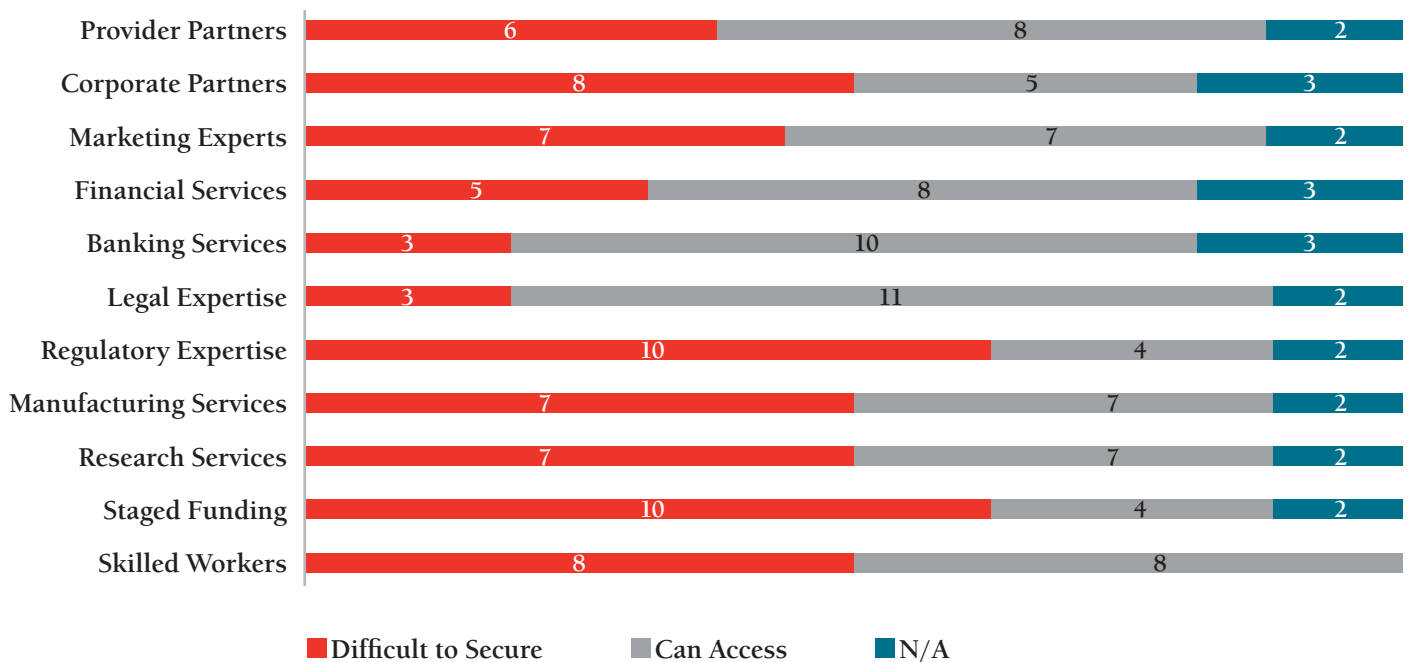
Recommendations:

- Support the continued development of life science campuses with access to services and mentorship support in cluster areas across the state.
- Create an online directory of service providers, similar to an Angie's List for Tennessee's life science companies.

According to the survey, though less significant service gaps appear to exist for established life science corporations, more than half of the corporate respondents noted gaps in regulatory expertise in addition to the need for staged funding.

Corporations on Availability of Services

Total: 16

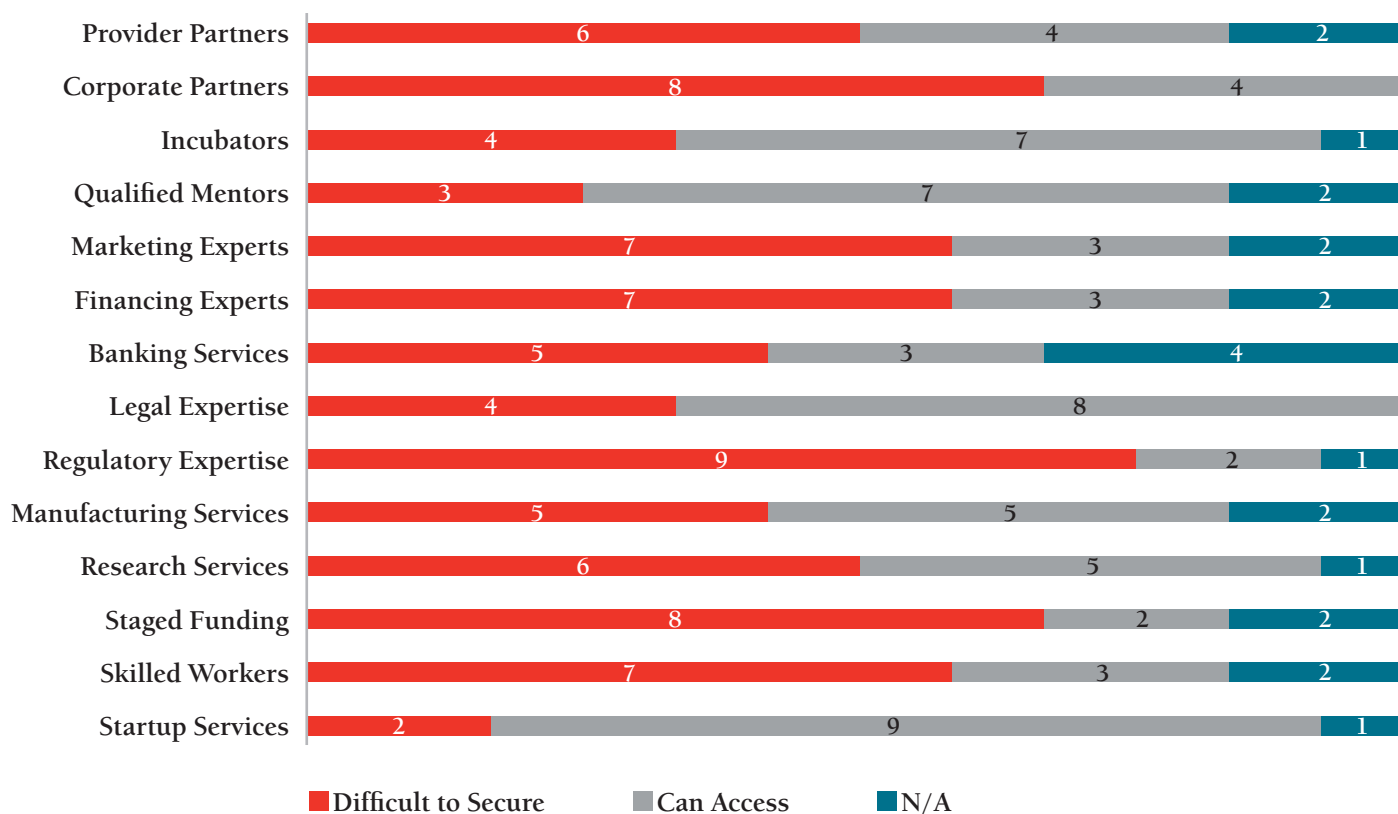


More than half of Tennessee research institutions surveyed are more pessimistic than business leaders about the availability of services for life science startups in their markets. More than

half of academic institutions reported a lack of access to regulatory expertise, corporate partners and skilled workers.

Research Institutions on Availability of Services

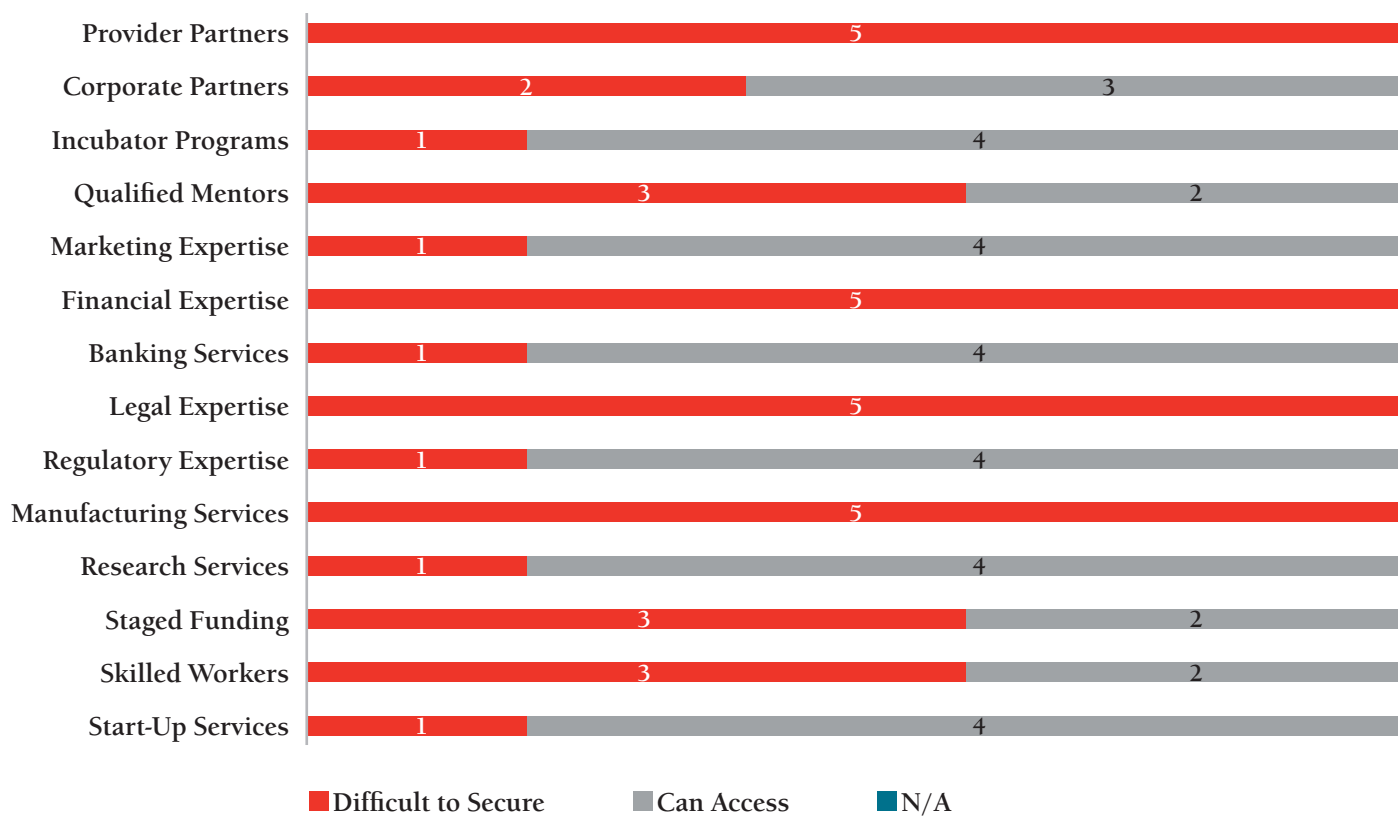
Total: 12



Finally, more than half of venture capitalists operating in the life science space cited a lack of access to skilled workers and qualified mentors.

Venture Capital/Funders on Access to Services

Total: 5



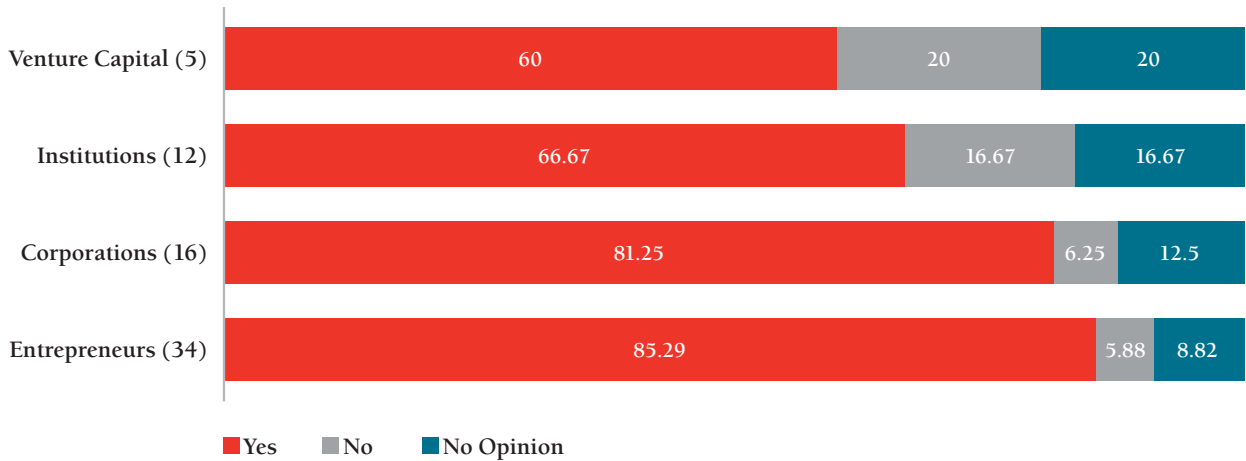
WORKFORCE

Workforce Development

The life science community considers state-incentivized workforce development programs to be highly effective. Some 86 percent of entrepreneurs voiced support for these services along with 82 percent of

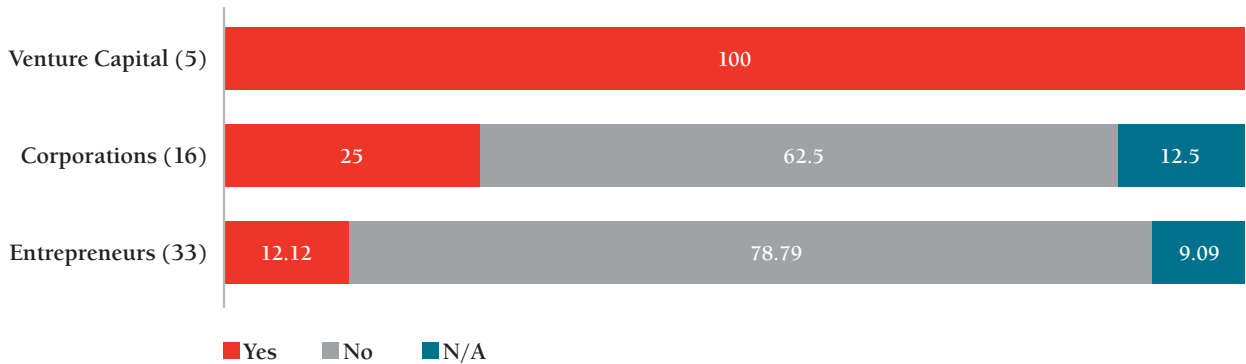
corporations, 67 percent of institutional employees and 60 percent of life science venture capitalists. In contrast, actual participation in state-led workforce development initiatives stands at just 12 percent for entrepreneurs and 25 percent for corporations.

Do You Believe Workforce Development Programs are Effective?



Have You or Your Company Taken Advantage of State-Incentivized or State-Led Workforce Development Programs?

Total: 33



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Improving workforce gaps for life science entrepreneurs is a critical requisite that crosses the full spectrum of salaried and hourly employees. Positions that entrepreneur scientists struggle to fill include, but are not limited to, highly skilled engineers, pharma experts, regulatory gurus, compliance practitioners, clinical chemists, instrument operators, project managers and lower-level laboratory support.

“Workforce is everything, from the guys running the machines to the engineers,” said a Memphis participant.

Life science entrepreneurs are particularly interested in hiring local workers who have the right skills and a startup mentality. In some regions of the state, it is harder to find these than others, and entrepreneurs are outsourcing to fill the gap.

“I scoured for an engineer for several months and just hired one from Connecticut, but I would have really liked to have found one from Tennessee,” said a Knoxville entrepreneur. “I really wanted to find a Ph.D. student and hire them part time, but instead I had to go out of state. When I look at the talent, we have it in this area. It’s not that I can’t find someone here with the skills, I just couldn’t find the interest.”

A Knoxville-based entrepreneur adds, “There are a lot of gaps, and I have been able to find the technical disciplines, but I’ve had a hard time finding someone who gets what a startup is about. I find those tough to find in our region.”

Another concurs: “We need chemical engineering talent with the desire to be involved with a startup. Everyone that’s involved has to want it. We need to keep building that entrepreneurial spirit in Tennessee for emerging life science companies.”

And, as life science companies begin to mature, they commonly experience a host of new workforce challenges around leadership and business management, because it is also challenging to find researchers who can to step out of the lab and change into a highly-skilled corporate business leader.

With regional and sector-specific nuances, particularly in the medical device area, life scientists often need access to quality regulatory expertise around such issues as navigating FDA regulation, basic trademarks or dealing with Medicare requirements.

“The biggest challenge is our friends at the FDA,” said a senior life science executive. “We need access to really good, knowledgeable regulatory advisors.”

It is important to note that the need for regulatory expertise will continue to grow in the future. Despite private funders’ hesitancy to support ventures facing lengthy regulatory approvals and requirements, the nation’s health care delivery system is transforming at a rapid pace. As health care delivery becomes more dependent on new technologies, FDA regulations will be part of the equation much more frequently.

“If it affects the patient, it’s going to be regulated,” said another life science consultant in Nashville. “This is something you are not going to get around as technology continues to make a greater impact on patient care.”

Recommendations:

- Create a clearinghouse that identifies leadership and growth-development programming across the state.
- Provide networking opportunities and discussion forums for special interest groups so people in certain specialties from different companies can come together to share knowledge and resources.
- Continue to support business programs for Ph.D.-level scientists.

MENTORING

Mentoring

One key workforce development strategy to assist any business of any size is to provide an effective mentoring structure. Like other entrepreneurial and life science services across the state, mentoring programs are active in select regions and nonexistent in others.

“Finding mentors specific to the Life Science Tennessee environment and finding the right people to put into the company to start the business is really challenging,” according to a roundtable participant who is also a licensing officer at a research institution.

The Memphis BioWorks Foundation’s ZeroTo510 program is a terrific example of a strong mentoring initiative currently providing networking and support to biotech entrepreneurs in that market. LaunchTN is providing mentoring to its portfolio companies across the state. Structured mentoring programs can also be found in other regions, such as Nashville’s technology accelerator program, JumpStart Foundry, but these are not specifically oriented to the life sciences.

“We need to formalize the mentoring network out there because you can speed up to lightning speed if you know who to reach out to,” said another licensing officer. “This is even more important as TNInvestco funding dries up.”

The majority of life science professionals, particularly entrepreneurs (85 percent), corporations (73 percent) and those housed in institutions (75 percent), strongly support formal mentoring programs. However, only half of life science entrepreneurs and one quarter of corporate employees are participating in them. This participation gap demonstrates the need to provide a structured mentoring program for life science practitioners in select regions of the state.

Though life science entrepreneurs often have mentoring support and some formal programming exists in select regions, there is a desire among life scientists for more formal mentor programming. More than 80 percent of entrepreneurs reported that they already have a mentor but 55 percent also say they would really like another one.

“We could use some growth-type programming to ensure the train stays on the tracks,” said a life science entrepreneurship consultant in Memphis. “There are common growing pains a company sees and we need to help be there when things happen as a company begins to mature.”

Also of note, 60 percent of life science entrepreneurs are interested in serving as a mentor to others.

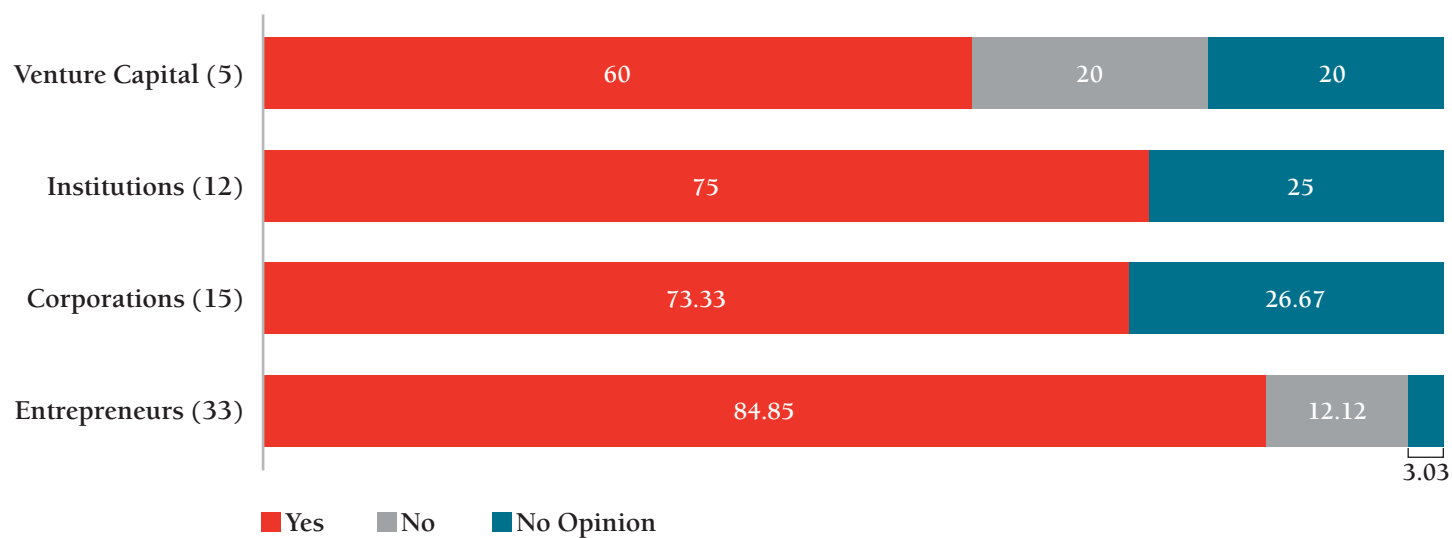
Corporate professionals have less exposure to mentoring programs – with just 25 percent working for a company that participates in formal mentoring – though 40 percent are currently serving as a mentor within their own companies. A further 50 percent of corporate employees would like to have a mentor of their own.

The strength of a formal mentoring program for life science is based on the quality of the participating mentors who must know the life science space and understand how to run a startup business.

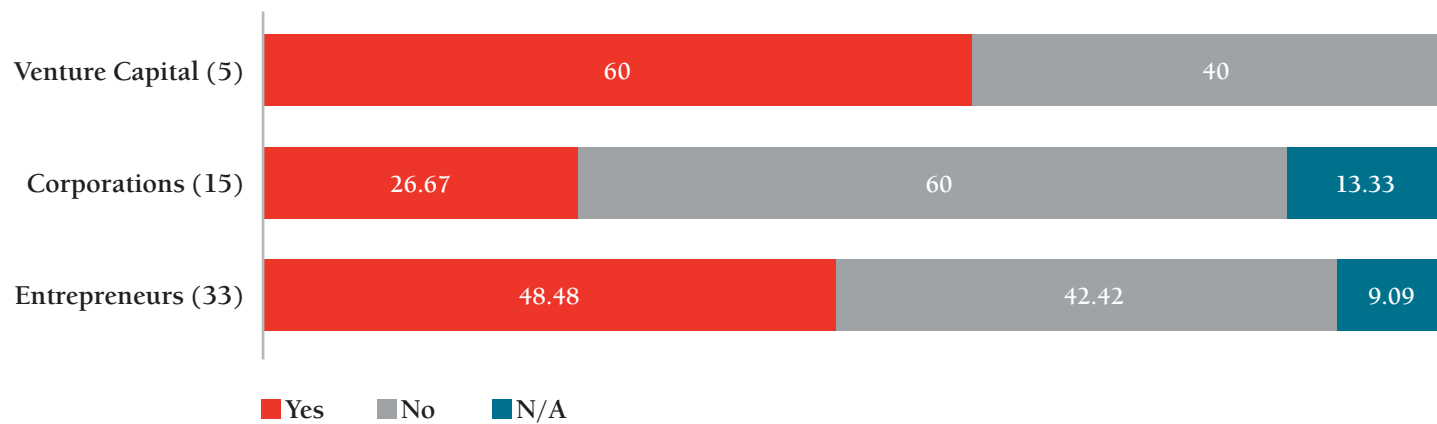
Recommendations:

- Create a clearinghouse that identifies quality mentors.
- Create structured mentoring initiatives across the state that endorse best practices and utilize all disciplines of experienced life science mentors.
- Create growth-development programming across the state.

Do You Believe Formal Mentoring Programs are Effective?



My Company or I have Participated in a Formal Mentoring Program?



Incubator Programs

Another effective strategy supporting life science entrepreneurs is incubator programs. The majority of life science professionals universally believe incubators to be highly effective tools for growing their industry. In fact, more than 50 percent of entrepreneurs, 30 percent of corporations and 60 percent of venture capitalists have participated in an incubator program.

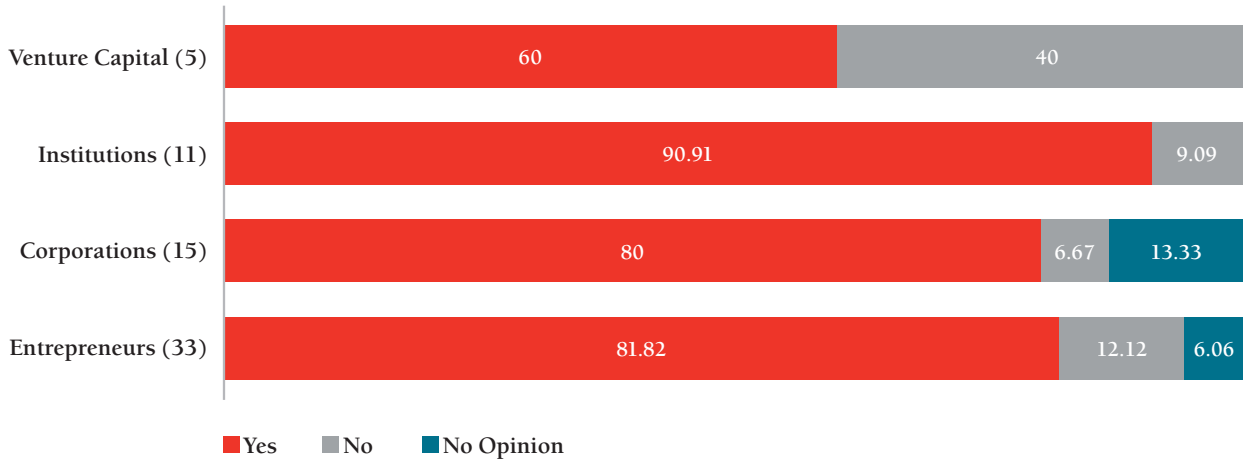
Incubators are especially helpful for startup businesses that are not housed inside academic institutes. Incubator programs provide critical resources for entrepreneurs that can include

office space, wet lab access, research farms, academic partners and shared services. These entities have the potential to make life easier for entrepreneurs to transition from a university to private space. Incubator models are currently available in most regions of the state and should continue to be supported and expanded.

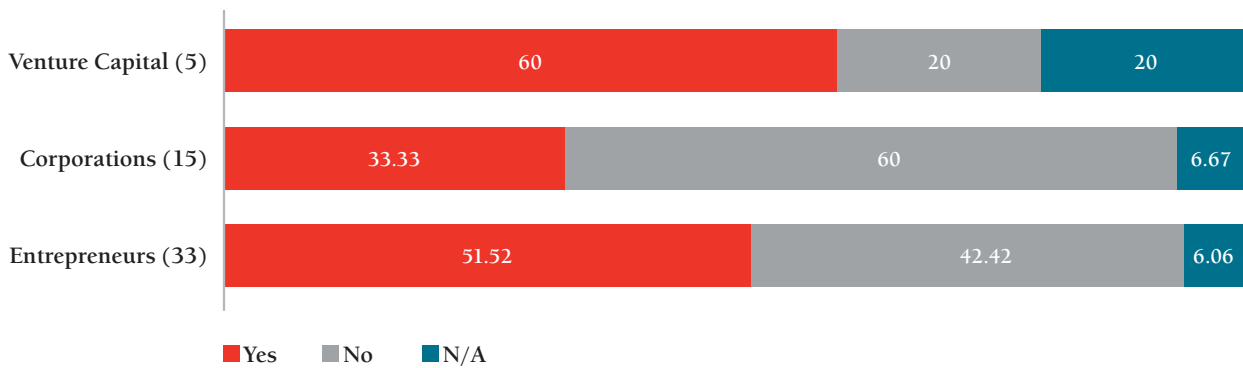
Recommendations:

- Continue to advocate for state support for early-stage incubation programs, and continue to support successful incubators that are creating Tennessee-based startups.

Do You Believe Formal Incubators are Effective?

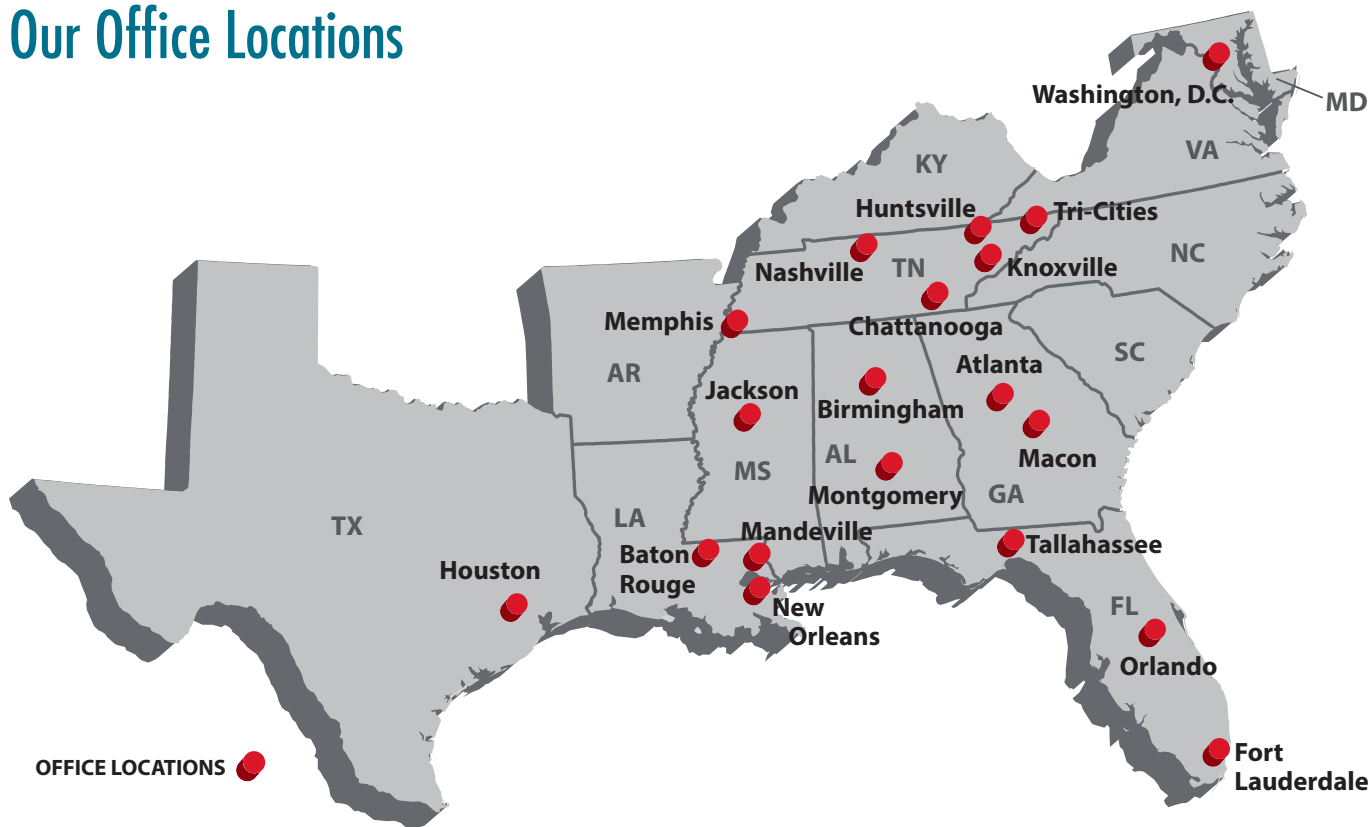


Have You or Your Company Participated in an Incubator?



The production of this report would not have been possible without support from all the life scientist professionals across the state who shared their time and experiences with us. We are also grateful to both LaunchTN and Memphis Bioworks and the large network of organizations across Tennessee, including Vanderbilt University, the University of Tennessee and St. Jude Children's Research Hospital, that have joined us in our work to develop high-growth life science companies. We look forward to continued partnerships and growth for our industry.

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