LIFE SCIENCES SNAPSHOT

A Quarterly Report on Financing Trends

NAVIGATING ARPA-H FUNDING
Q3 2024

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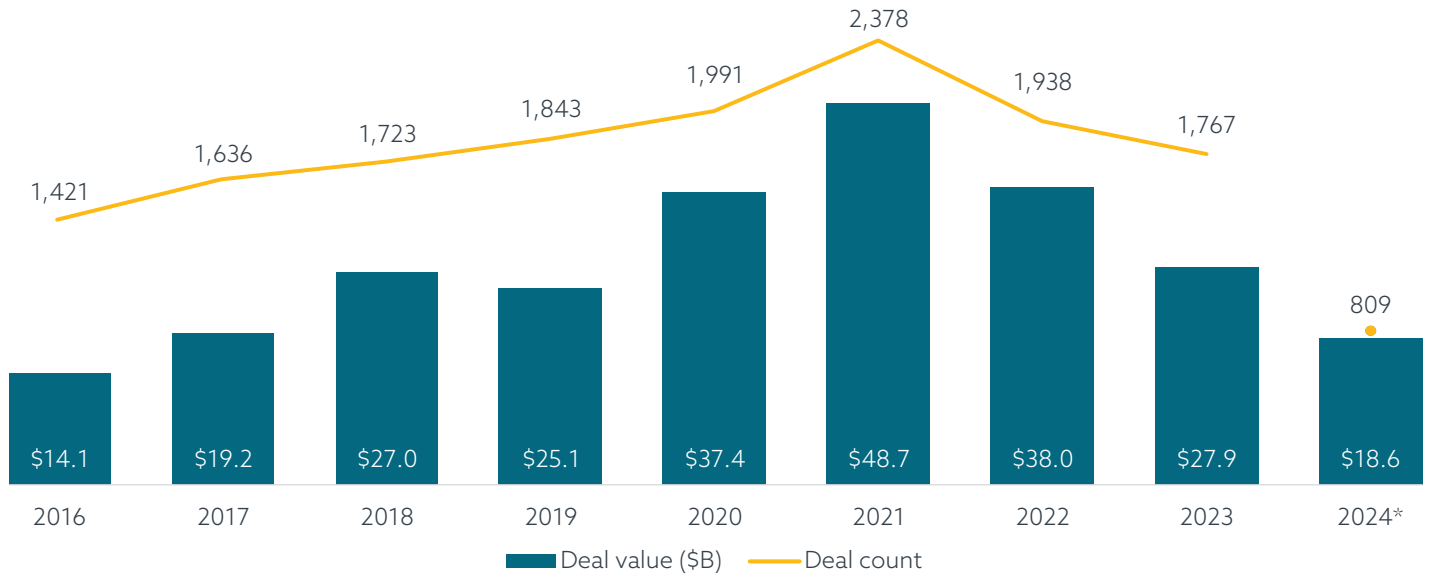
Data provided by

PitchBook

Key Takeaways

Life sciences VC deal activity



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*As of June 30, 2024

This report series examines quarterly trends in life sciences venture investment. Key findings for Q2 2024 include:

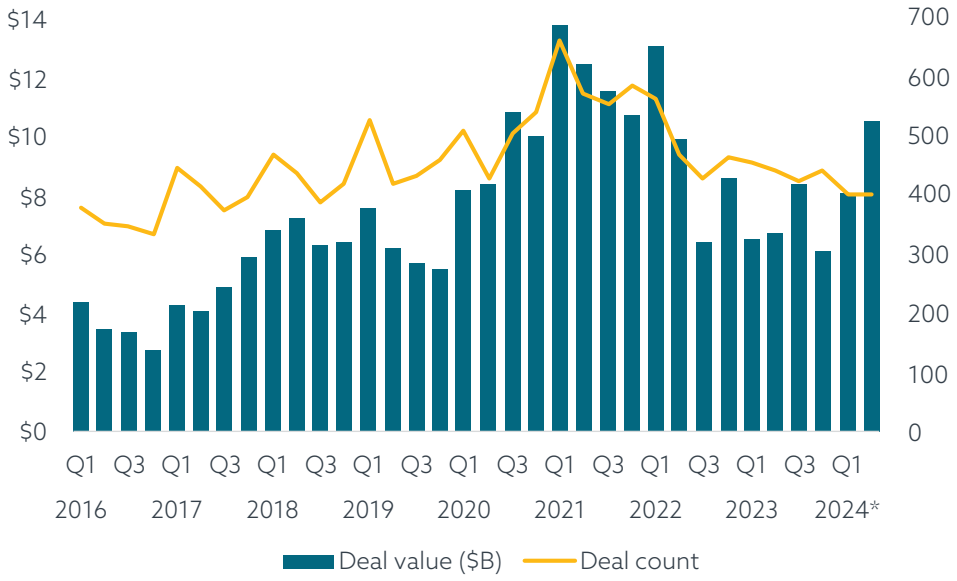
- Life sciences VC deal value reached $10.6 billion in Q2 2024, up more than 30% from Q1, which brings the YTD total to $18.6 billion. In a positive sign for the industry, YTD deal value exceeds that of the same period last year by 40.2%, and it appears that 2024 dealmaking is on track for annual growth after two consecutive years of declines.
- Check sizes and valuations have also trended upward this year, driven in part by selectivity among investors. Larger deals continue to exhibit more durability, with deals over $100 million each driving a larger share of total deal value and count.
- Among the largest deals so far this year, there are several life sciences companies that incorporate AI into their fundamental operations. The technology's potentially transformative applications in areas including drug discovery and protein design continue to draw in top-tier investment firms and corporate backers.
- Exit flow regained some ground beginning in H2 2023, and the industry has maintained this momentum with more than $10 billion in exit value generated in each of the past three quarters. With more than $21.7 billion in exit value already closed YTD compared with $24.0 billion in full-year 2023, the life sciences exit market also appears on track for growth this year.

Market Analysis

Markets held the positive note struck last quarter, with a material upward trend in cumulative life sciences dealmaking for the past three quarters now. The broader outlook for venture has notably improved over the past quarter or so, as valuation resets have largely already been enacted, and federal interest rate cuts are all but guaranteed before the end of 2024. The life sciences industry specifically is benefiting from the AI revolution and weight loss drug surges as well, improving the outlook for future quarters.

Blockbuster deals in Q2 2024 include Xaira Therapeutics' $1.0 billion round in April, which marked the largest individual US deal since 2021. The company uses AI-based approaches to drug development, operating at the intersection of AI and life sciences—an expanding area of interest. Top-tier firms including Sequoia, Lightspeed, and New Enterprise Associates participated, and as investors seek out potentially transformative approaches to drug discovery, diagnostics, and patient care delivery, the number of companies in this area securing VC funding has ticked upward for the past four quarters. Another related deal

Life sciences VC deal activity by quarter



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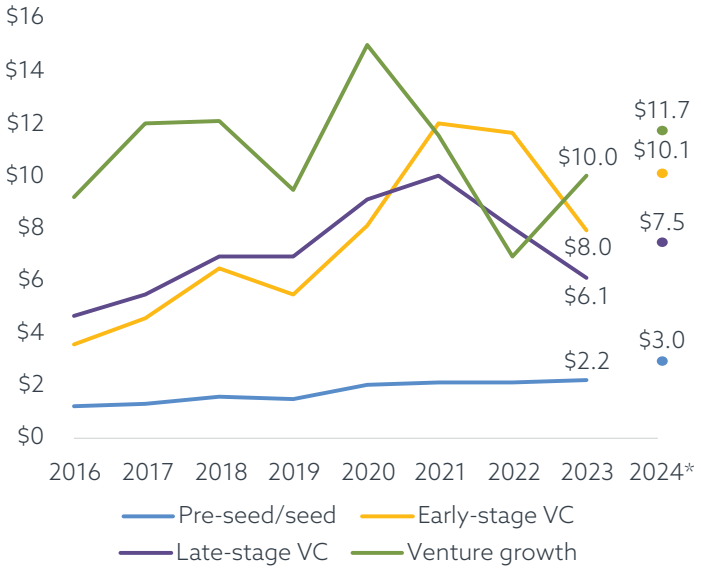
Median life sciences VC deal value ($M) by stage



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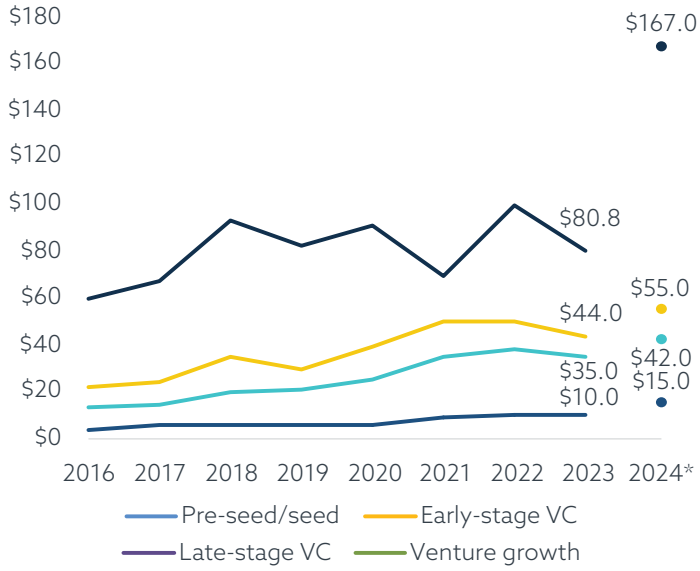
Median life sciences VC pre-money valuation ($M) by stage



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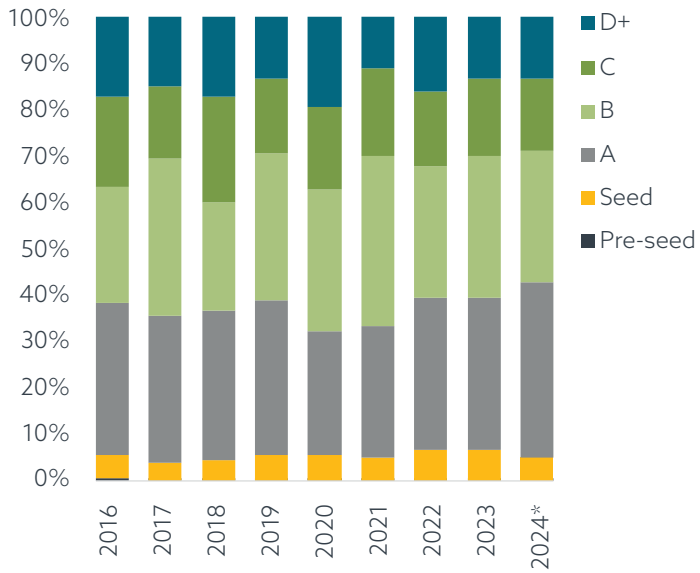
Market Analysis

Share of life sciences VC deal value by series



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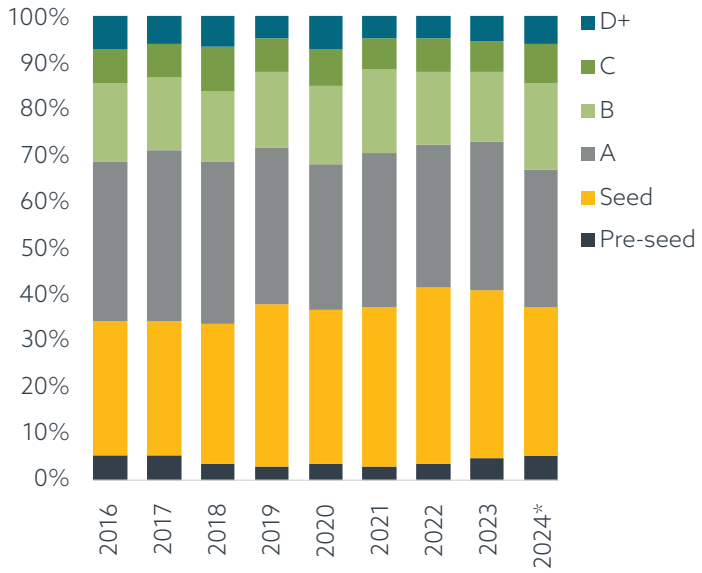
Share of life sciences VC deal count by series



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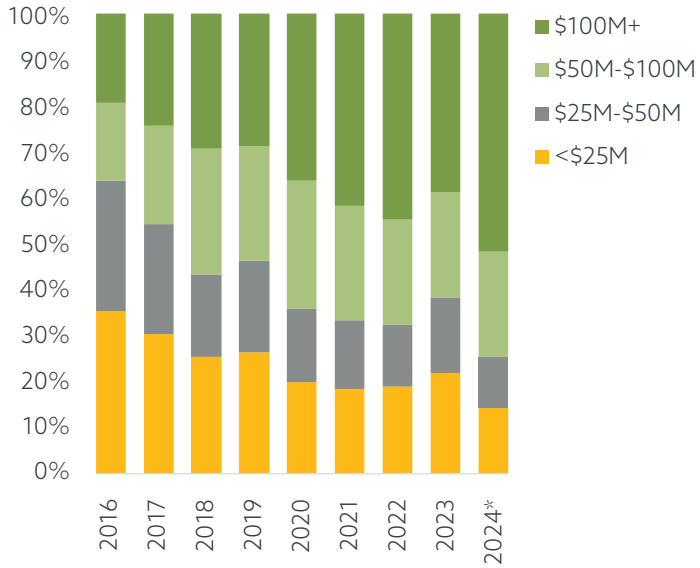
in Q2 was EvolutionaryScale's $142.0 million seed round, which is slated for use in the company's build-out of AI models to generate novel proteins. The company attracted investments from corporate backers including Amazon and NVIDIA in a testament to expanding AI use cases and the tech world's interest in life sciences applications. The second-largest deal in Q2 was secured by Hercules CM, which raised $400.0 million in May. The company has licensed a portfolio of GLP-1 and related weight loss medicines from Chinese drugmaker Jiangsu Hengrui Pharmaceuticals. The surge of interest in the weight loss drug class has hurdled dominant Danish manufacturer Novo Nordisk to the forefront of global headlines, while smaller entrants compete for market share in select markets through licensing agreement channels.

Excitement in these tech and treatment areas continues to carry broader life sciences dealmaking through the recovery stages of the current cycle, but a full resumption of activity has yet to materialize. Investors are demonstrating continued caution as deal count remains below pre-COVID-19 pandemic levels and larger deals continue to draw in a larger slice of the total deal value pie. Deals over $100 million each accounted for 3.5% of total deal count in 2023, but this figure has nearly doubled to 6.4% YTD. Continuing the trend seen last quarter, late-stage VC and venture growth deals command a growing share of total VC count, reaching nearly two-thirds YTD, as investors lean toward established business models and steadier long-term prospects as opposed to riskier, early-stage plays.

Life sciences exit markets are also seeing greater momentum, sustaining a larger amount of cumulative value each quarter since Q3 2023 despite exit counts still reminiscent of the pre-2021 era. Much like dealmaking, the reignition of exit activity is led by fewer, larger exits for the strongest positioned players. The largest exit for Q2 2024 was Tempus AI's IPO of more than $5.6 billion—another example of AI technology prospects for both private and public life sciences investors. This deal drove the total exit value for the IPO category up beyond $10 billion in 2024 after two years of the acquisition category dominating exit prospects for the industry. Four other IPOs closed in the quarter, bringing the total YTD count to more than half of last year's count, signaling slow but steady signs of life for public market entries. Acquisitions remain the more common route, though, and as economic sentiment improves, the number of companies seeking inorganic growth could continue to buoy acquisition count in the coming quarters. The outlook for exits is improving overall, with interest rate cuts much more certain before the end of the year compared with last quarter.

Share of life sciences VC deal value by size bucket



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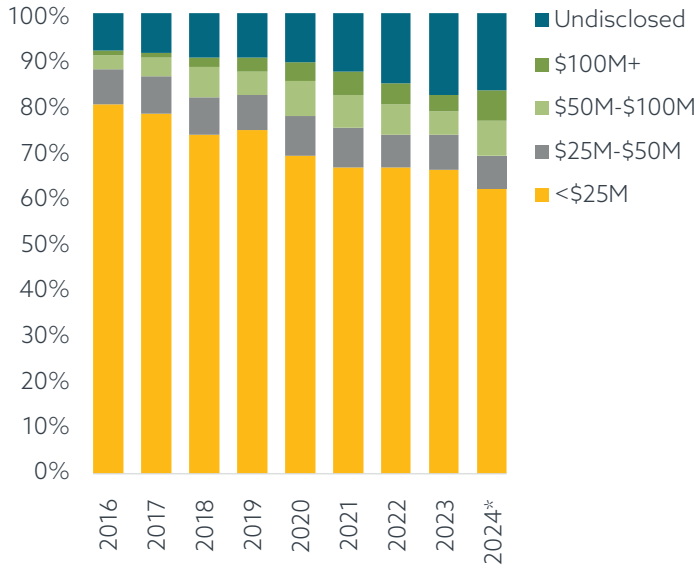

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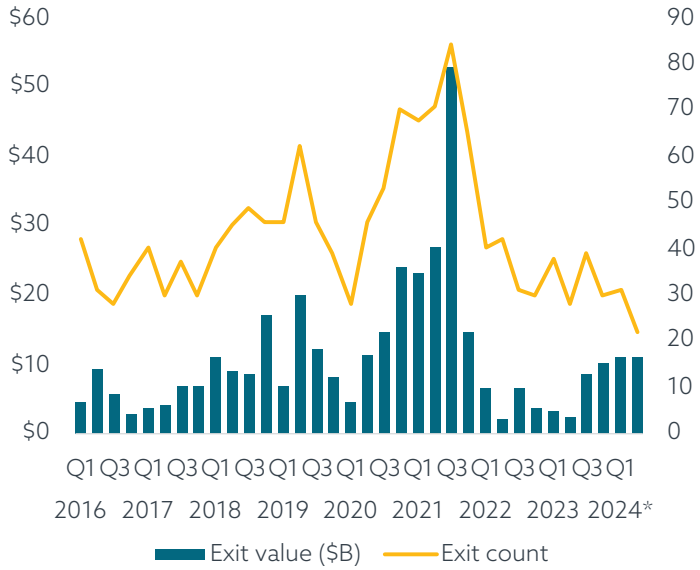
Life sciences VC exit activity by quarter



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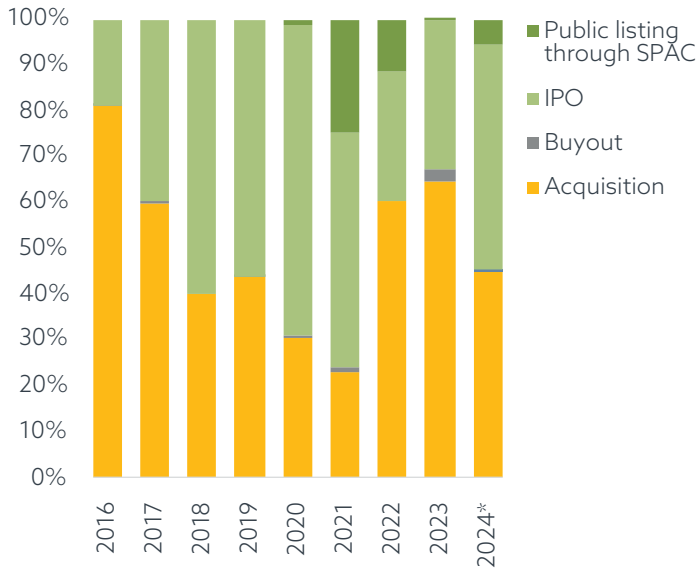
Share of life sciences VC exit value by type



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Roundtable

INTRODUCTION

The Advanced Research Projects Agency for Health (ARPA-H) provides research funding to build high-payoff capabilities or platforms to drive biomedical breakthroughs – ranging from the molecular to societal. As ARPA-H emerges as a key player in health innovation, companies seeking to secure funding are well-served by understanding its processes and strategic priorities. This roundtable explores practices for navigating ARPA-H funding applications, from aligning research with ARPA-H's mission to demonstrating long-term impact potential. We'll also dive into how investors are evaluating companies through the lens of ARPA-H funding, ensuring that investments align with cutting-edge health innovations.

Panel

Contributors

Craig Gravitz
Director, Project Accelerator Transition Innovation Office (PATIO), ARPA-H

Jenica Patterson
Portfolio Lead, Project Accelerator Transition Innovation Office (PATIO), ARPA-H

Maryam Ziaei
Director of Technology Transfer and Transition Services (T3X), Project Accelerator Transition Innovation Office (PATIO), ARPA-H

Misti Ushio
Managing Partner, Digitalis Ventures

Facilitators

Thora Johnson
Partner and Co-Chair of Life Sciences and Healthtech Group, Orrick

Stephen Thau
Partner and Co-Chair of Life Sciences and Healthtech Group, Orrick

Alex Wood
Partner, Tech Companies Group, Orrick

Neel Lilani
Global Head of Tech Clients, Orrick

Neel Lilani: I thought we could kick off with a brief summary from the ARPA-H team with an overview of what the mission of ARPA-H is and a quick summary of the structure and the mandate.

Craig Gravitz: There are four things you need to know about the ARPA business model.

Firstly, program managers. Program managers are the protagonists of our story. They're the people who make all of the technical funding decisions, and all of the work that you see is their vision. The agency isnot top-down priorities pushing forward. It's this bottom-up model where the program managers come in and push forward their ideas.

These program managers are scientists with a lot of gravitas, people who are leaders their field. The typical background or profile of this person is they feel the world has zigged when it should have zagged. And so they come in motivated to solve a problem. And oftentimes the best program managers are people who have a personal stake, not just a professional stake in something. So, they really feel passionately about a topic. They're both domain experts and passionate champions.

Secondly, performers. You're going to hear this term a lot. The program managers don't have labs. Performers are funded R&D entities that essentially implement the vision of a program manager. So they could be start-ups. They could be the skunk works divisions of large companies. They could be academic performers. Really, they respond to solicitations and do the technical work that the program manager is requesting. Performers are sort of where the rubber meets the road.

Thirdly, programs. Programs are collections of performers, and they can either be in direct competition with one another, or they could be part of an integrated solution. The idea is that we want to take a portfolio approach under any particular program with different components. So, for example, our very first program, Nitro, asks: what if joints could heal themselves? There wasn't just one funded performer. There were multiple different performers under that effort. And the idea is that even if one particular performer fails out, overall, the program's vision can still move on and succeed.

And lastly: the vertical is how to understand ARPA-H's business model. It is very, very different than anything else in government. For one, we have really tough technical milestones. We have contracts, not grants. So, if a performer gets funding and they can't meet their technical milestones, they'll get cut and their money would be re-allocated to someone else in that program, or the program can be scoped down and allocated somewhere else. The idea is not, "Hey, we're going to make this bet and see what happened. Let it ride." There's active program management. And I will say that performers under this business model, some of them can thrive because they're like, "Wow, I really like being pushed in a way that I wasn't normally being pushed," but some of them fail out. Doing ARPA work is very different.

There's a sense of urgency that's reflected in the term limits of the program managers and programs. If you don't make your milestones, we move on. Again, it's a very different government business model.

The other thing to know about our business model is that we see ourselves as performing a catalytic function. We don't want to be duplicating anything that's happening elsewhere inside government or the private sector, which is one of the reasons why we work so closely with Misti. If other people are doing work in this space, that's not something that we want to do. It truly should be something that is novel and pre-venture. Something that, but for ARPA-H, it wouldn't have happened. And so that's just sort of a key component to our business model. The first question we always ask ourselves is, "Why ARPA H?" and "Why not someone else?" And if someone else could do it, it's automatically out of scope. We only take on things that other people wouldn't fund.

Stephen Thau: One follow up question: Is the funding in advance of a milestone or in arrears? Do you fund to achieve something?

Craig Gravitz: Every single program is a little bit different. And there are different incentives that you could have. We custom negotiate all of the contracts. But typically, you have to meet your milestone to get paid.

Jenica Patterson: I would say our fifth dimension, and uniqueness of the ARPA-H verse and other ARPAs, is transition. We are very focused on that at ARPA-H. We want to make sure that these programs and the performer teams that are creating these innovations for us reach the hands of people to meet our mission.

Our transition partner is very different from other ARPAs. For example, DARPA, it's the Department of Defense (DoD). So, it remains internal to the government. Whereas at ARPA-H, our transition partner, is external. It's everybody. To meet our mission, we really focus on transition from the beginning.

And that is why we have PATIO, our dedicated transition office, that Craig leads.

Alex Wood: Could you tell us more about PATIO?

Craig Gravitz: This is my passion and why I'm here at the agency. I come from DoD. And one of the things that I observed across the government, not just in DoD, but everywhere, is that there is a lot of great science that was funded that didn't stick the landing. And when I was talking to the people who were on the planning committee for ARPA-H, I came to the agency to help solve the problem that

I didn't think was being addressed well. The health sector is particularly challenging because there's not a colonel somewhere that you can corner and say, " let me explain this great thing," and then he or she puts it into the budget for future years. It's a much more complex environment. And so, the purpose of our office is to gain insights from the private sector to understand what makes this hard.

I met Misti and the other folks at Digitalis very early on when the agency was about 15 people. I took our director to health hotspots around the country. And we really hit it off with Digitalis, thinking about things similarly. "How do you spark these moonshots?" And essentially, what PATIO does is we take that private sector lens, and we apply it to programs from concept development, all the way through performance. PATIO provides a series of managed services through each step of the life cycle of a program where at every step we increase the probability that it's going to actually survive in the wild.

For example, at concept development with Misti and her team, we have this program that we've started called the Transition Mentor program. The transition mentors will sit down with a program manager and work with them to understand, "Wow, if you tweak this one thing, you're going to vastly improve the chances that it'll succeed." The team works in parallel throughout the entire life cycle of the program to make sure that there's a coherent value proposition to investors or other following funders, or the types of people that might license IP.

Misti Ushio: Digitalis Commons, our not-for-profit organization affiliated with Digitalis Ventures, partnered with ARPA-H directly through PATIO to provide early strategic advising, at all levels for transition. We bring our personal experiences and ecosystems of building companies and investing in early-stage innovation companies. The goals of our partnership with ARPA-H is to evaluate the situation where even if the technology works, we ask, "what are all the reasons that this new technology or solution will not reach patients?"

Expanding on this, if we assume the technology works there are still many potential obstacles for the solution not getting to patients. For instance,issues around intellectual property, regulatory path, reimbursement and pricing, manufacturing, etc. We also think a lot about the flow of capital, market forces and the number of options the technology may have to move out of ARPA-H and into the next funding partner.

We work with everyone at ARPA-H, primarily the program managers, but also other dimensions of management, to help think through what we should be doing now, at the earliest stages, to mitigate any decisions that might prevent health innovations from getting to patients. We also think medium and longer term, maybe it's a year from now or two years from now, where something will be the right time to commercialize. The innovation needs to go to the private sector to get to patients. How do we navigate that? One of the things that resonated with us when we met Craig and Renee [Wegrzyn] was that they were already thinking about this, and already very cognizant that the success of the programs really, it's not just technical success. It's actually getting new technology to the U.S. population.

Craig Gravitz: Our mission at ARPA-H is to accelerate better health outcomes for all Americans. For us, it's not enough to just prove that the technology is possible. That's an incremental step. And that's why PATIO is really needed, because there is a gap between the technology development and actual health outcomes, which requires understanding business models, regulatory reimbursement, and other non-technical considerations.

Neel Lilani: Are there generic milestones worth talking about in this context?

Jenica Patterson: It's very bespoke. No program is the same and every organization that's funded under one program typically is reaching a different milestone in terms of technology development.

An example of one thing that could be generalized across a program is, what if you want to develop a benchtop prototype that works on the bench at a certain specificity and sensitivity for whatever you're creating. So, all those organizations that are in that program would be working towards that goal but with their particular solution.

I always use neuroscience as an example because I'm a neuroscientist. Another example is, what if you're creating a benchtop prototype to read and write from the brain. If one company or organization is doing an electrical approach and another is doing an optical approach, you're going to have very different technical requirements for each. However, you're ultimately reaching that same milestone in the program of creating a benchtop prototype.

Typically, at the end of programs, you try to reach a large inflection point. And what I mean by that, I'll give the neuroscience example again, is your really hard challenge, especially in terms of invasive neural interfaces, is reaching to a human. So, what if your big inflection point is receiving that Investigational New Drug (IND) from the U.S. Food and Drug Administration (FDA) to actually do a first in-human clinical trial. That could be a really big inflection point for an organization or a company to reach their next goal of getting into humans.

Stephen Thau: Craig, you mentioned ARPA-H doesn't want to do things that other people are doing or could be doing. But how do you know? Staying with the brain example, there's a lot of stuff happening on computer brain interfaces. Some of which is public. There's been a bunch

of high-profile press, but some of it, maybe not public yet. How do you evaluate those types of questions?

Maryam Ziaei: We typically start with a due diligence process. We look at who's working on the idea in academia and what National Institutes of Health (NIH) grants exist. Then we also look at the commercial landscape. We use Pitchbook and other tools to see who the players are, both on the scientific and commercial side, to help the program managers as they're designing their program.

Jenica Patterson: I'll also add, the program manager's goal when they first walk in the door is to start their market research. So they're talking to people on the outside. Our Director recommends that program managers talk to at least 100 people that work in this industry prior to launching a program. And that's another way that we can push the envelope, understand what the gaps and opportunities are, where ARPA-H can play versus where other funding organizations will play. So I think it's not only on the Transition Office, but it's also a role for the program manager to identify that, too.

Maryam Ziaei: That's where our Transition Mentors that Digitalis Commons provides come in. They are senior industry experts and truly a sounding board in that aspect for the program manager to sit down with and test out their ideas as they're developing it. So they're huge resource . And they truly help program managers as a partner and a mentor.

Craig Gravitz: Our basic view of the case is that the best innovations are interdisciplinary or don't respect the bounds between disciplines. When Thomas Edison invented the record player, he talked to people who were involved in the technology for telephones and telegraphs. And it was the combination of those two things that actually created this new thing. And when you think about the difference between performers, which is one individual group, and programs which is a mix of multiple different groups, that's where the innovation happens. We don't look at a performer-by-performer type of thing. That is important because there's tough technical milestones. But what we're really looking at is the program level, which are the intersections between those disciplines and technologies. But again, a simple version is like a record player is to telephone and telegraph, two totally different technologies combined to make something. We're the people who aim to push those things forward.

Misti Ushio: My other observation comes from sitting on this interface of being not on the inside of ARPA-H, but not on the outside. ARPA-H doesn't fund something that's funded by the NIH, which draws a big line in the sand of what's out of scope. And so, I think you end up with a sophisticated technology with an application for taking it to that next step.

The other thing I wanted to mention is the Digitalis Commons expert network. The Transition Mentors are matched to each program from this curated network. These include investors and entrepreneurs, of course, but also folks with expertise in all areas of development and commercialization from across the biomedical industry. I'll just put a plug in that we're always looking for people. So, if there are people out there who want to participate I think it's a really amazing way for the community at large to help contribute to the mission of ARPA-H. This ensures transition happens and we want to bring people who have been there and done that to help.

Alex Wood: For investors conducting due diligence on companies receiving ARPA-H funding, what are the specific risks or advantages that they should focus on? And how do ARPA-H's milestones align with broader investor criteria?

Misti Ushio: The short answer is: investors are going to look at any opportunity under the same lens. I don't think any investor is going to look at an ARPA-H opportunity differently than anything else that comes into their pipeline. And they shouldn't - everyone has their criteria. I think where ARPA-H is going to have a major impact is they're going to be able to get technology, that no one would invest in whatever dimension in the capital structure, to a point of investment. In short, get it to a point where investors can look at it. That's the value. Technology that may have been off the table for you, venture or other types of capital, ARPA-H will help them get to a point with enough validation and enough forward momentum on the technical side. What we're trying to do with PATIO is to progress the technology on how do you move this into a business. It should dovetail with what investors are going to do anyway. The reality is it's a form of non-dilutive financing, and I think most people will look at it that way. So even though ARPA-H has an SBIR program, I think this just gives technology a much, much longer runway to have success.

Craig Gravitz: I remember the very first question I asked Misti and Geoff [Smith] when I met them two years ago, "What do you wish you could fund but it's just too risky?"

And what was really cool is that Misti and Geoff just started rattling off all of these things where there's no market for it and here's why. But if we were able to have something like ARPA-H doing this, there would be all of these amazing things you could push forward. And it's a question I still ask investors today. But it's a really good way to think about how ARPA-H operates. We work on the things that venture knows about, but thinks are too risky to fund. And if we can take on that technical risk and de-risk it, then it'd be much more likely that someone's going to pick it up on the back end.

Thora Johnson: Are you able to talk about some of the projects that have been funded? Are they far enough along that it's public knowledge?

Craig Gravitz: If you go on our website (https://arpa-h.gov/), you can look at a number of the programs. I think you'd probably get a lot more looking at the publicly posted information. The whole point is that the programs are like the program manager's vision. And they go deep in the tech there.

Misti Ushio: The ARPA-H website has a lot of information . So that would give you a pretty good idea of the diversity and spectrum of what ARPA-H is investing in and what's coming.

Alex Wood: And is it really through PATIO that then the investors can get involved? You're connecting these potential companies with investors. Is that the main route through PATIO?

Craig Gravitz: Yeah. So, one of the other capabilities that we're developing - the capability that Maryam manages, our T3X division, is really mature. We have an impact on between 80 and 88% of program.

For the far end of the pipeline, which is the connection to the outside world, I have another division. It's called ARPANET-H (https://arpa-h.gov/engage-and-transition/arpanet-h). The inspiration was when DARPA created the Internet, the ARPANET. So, we have the ARPANET for health. And while it's not a series of computers, the idea is that we have two basic branches of that. One branch is about customer experience. This is understanding the wants and needs of people. Affordability, accessibility, you know, the patient perspective. We're getting our tentacles in that space. Then the other branch is called the investor catalyst network. And the idea there is trying to pull together people from the investment community in a formal way, so that we're able to create formal structures to be able to push things outside of ARPA-H into the next funder.

Most programs have a five- to ten-year time horizon. We know that we need to build our muscles on that handoff piece. I'm really most excited about a new process that we've created called a sprint. It's how my former programs worked. And we had this really wonderful opportunity to work with the White House. They're really interested in pushing for women's health research. And so, we actually launched a Sprint for Women's Health (https://arpa-h.gov/engage-and-transition/sprint).

But the reason why I bring it up in this context is that we created two tracks. One track was called a spark, and those are the early-stage types of investments that ARPA-H normally makes. But we created a second track called launchpad, which is closer to market. And the idea is by the end of these two years, with these launchpad awardees, they should actually be making those handoffs to investors. And we have a couple of really interesting experiments and capabilities that we're building in order to do that.

Jenica Patterson: We launched our Sprint for Women's Health in February. We had the honor of the First Lady announcing our sprint, committing $100 million to catalyze the ecosystem in women's health. And we did this sprint for three main objectives: to address critical unmet challenges in women's health, champion transformative innovations, and tackle health conditions that uniquely or disproportionately affect women. We wanted to catalyze the ecosystem generally. We wanted to de-risk advancements and create pathways for investors to invest. So what Misti was talking about earlier, where can we break down those barriers and raise these innovations up to a point where an investor could take it on after ARPA-H funding ends. And we wanted to test our new business and contracting model. We have these maximal authorities at ARPA-H to do more of a business-to-business-like experience for proposers, and it's really an opportunity to lower the barrier for non-traditional partners at ARPA-H to work with us.

Once we launched this sprint, we had two funding tracks. First, we had the spark track. It was a $3 million award really focusing on transformative early-stage research efforts. And then we had a launchpad award, a $10 million award. So that's focusing on later-stage R&D efforts to reach the public in two years. We also had program managers raise their hand to help support us. We had five program managers that stepped up to the plate to come up with problem statements in this area in women's health. And we created six topics that we put into a solicitation, and they ranged from women's health at home to objective and quantitative measures of pain to prioritizing ovarian health through midlife to prevent disease. So it was a really vast array of problem statements within the women's health ecosystem.

We're currently still in the state of finalizing our awardees that we hope to announce in the very near future. But I think the unique way that we reached nontraditional performers was number one, we used our investor catalyst hub to help reach throughout our network for submissions. We also had the ability to work with the White House and the FLOTUS team to promote our solicitation. And we had the opportunity to reach an unprecedented number of submissions from 45 States, including the District of Columbia. 34 countries. I didn't even know 34 countries knew about ARPA-H.

And I think the reason is because we lowered the barrier. We only asked for a three-page abstract at the first stage. And then we narrowed those submissions to do in-person, VC-style

pitches. And we brought in an array of subject matter experts through our public-private partnerships to support our program managers. So think regulatory experts, reimbursement experts, equity experts, women's health experts to really help us make better informed decisions across this pipeline. We're now in the negotiation phase. So give us some time, but we're hoping if you talk to us, in maybe a couple of months, we'll be able to announce who we're funding and why we're funding them.

Stephen Thau: I'm curious what you can say about the impact of politics on the whole process here, especially with the election looming.

Craig Gravitz: We are a nonpartisan, non-policy organization. We are a technology funder. We have broad bipartisan support. I don't believe that there's going to be much impact, regardless of who is in the White House, because we're serving a really necessary gap in the biomedical and health funding ecosystem. There is a broad understanding that ARPA-H is a required capability for our nation. There have been probably for the last 10 years, proposals in different administrations for ARPA-H or an ARPA-H-like capability. I have never felt any sort of political pressure to develop anything one way or another. And honestly, we're fiercely independent in terms of the science. We're able to push for the best science, and really, truly, anyone I've ever engaged with is supportive of us taking that. And in terms of the partnership at the White House, they never impeded on any of our technical decision making. Never even asked. Jenica and the other people pushing this forward had complete and total autonomy to push things forward. So I don't feel like there's any political component to anything that we're doing.

Jenica Patterson: Yeah, and I actually want to bring it back to the mission of the sprint. So, we identified this as a huge gap, actually, Renee/our agency director did in the beginning. This is really an opportunity to help catalyze women's health, where it is severely underfunded, as we know. It's also severely under researched. A lot of the information that we have in terms of biology focus is on the male body. We don't even understand truly how the female body works. So this was a really great opportunity for us to catalyze that field. It's also more comprehensive than other government organizations that have taken on this feat, too. But we have a unique way to push it faster, push it forward to really reach people in the next two years or so. I just want to bring it back to where this was an opportunity for us to catalyze an area that has been underfunded for decades.

Craig Gravitz: Yeah. And areas like pain. These are things that matter to everybody, regardless of political affiliation. The types of things that we work on, like ARPA-H's very first program, What if joints could heal themselves, apply to all of us. We all age. We all have these types of things that that happen to us. And ARPA-H is the nation's best capability to help solve for those things.

Thora Johnson: Are there regulatory trends that you are seeing or pitfalls? What are the biggest problems for these new technologies?

Craig Gravitz: Number one: I have to say, FDA is incredibly innovative and incredibly open to working with us. And let me just paint a picture. The more moonshotty the technology you're working on, the less likely it is that there is an existing regulatory path. Traditional regulatory paths are built for incremental advances, and one of the challenges of ARPA-H is that we build moonshots. And so probably on most of the programs that we launch we're going to have to work in very tight coordination with the FDA, including efforts that we've launched in PATIO. One example is that applying AI to medical images is very difficult. It's very difficult for the FDA, because it comes in all different formats, and they're like, "I don't know how to look at this." And then with innovators, they're trying to generate AI solutions there, and they don't know how to put it in a format that is coherent for FDA.

We worked with CRDH and FDA to put together a network survey. We used that nationwide network that I talked about earlier to ask, Hey, why is this hard? And we did that in coordination with the FDA. Identifying there's this gap. It's hard for FDA to understand how to regulate this. It's hard for innovators to understand how to work with FDA. Well, what if we just connected everybody? And so that's a really good example of how both ARPA-H in general, but PATIO specifically, helps close those gaps, and create a pathway where there might not be an existing regulatory pathway. It's a very collaborative relationship.

Maryam Ziaei: As an entrepreneur in the medical device industry, I founded and led an imaging company focused on women's health, successfully guiding it through the FDA approval process. One key lesson I learned was the importance of aligning regulatory efforts with payer coverage requirements. After completing our FDA process and clinical data collection, we discovered that payers required additional clinical data for reimbursement—a factor we hadn't anticipated. This oversight set us back several months and a hefty cost to gather the necessary data.

Had we integrated payer and reimbursement considerations during our initial data collection, we could have avoided this costly delay. Ultimately, while we managed to collect the additional data, which proved helpful for marketing and other areas, the experience reinforced the need to think about these metrics early on.

Now, when advising program managers, I stress the importance of considering factors like user experience, manufacturability, exit strategies, and reimbursement

plans in parallel with technical and regulatory development. This way, when the product is ready for market, there are no unexpected hurdles to overcome.

Neel Lilani: How does receiving ARPA-H funding impact a company's potential exit strategies? Do investors and acquirers view ARPA-H-backed companies differently in terms of risk, growth potential, or strategic alignment?

Misti Ushio: When we first started discussing the different ways to transition with Craig, Jenica, and later Maryam, we realized it wasn't just about starting a new company and raising venture financing. In fact, I would argue that we should aim to leapfrog over venture altogether. When we spoke with Craig and Renee, a light bulb moment occurred: with the capital allocation ARPA-H has, we could bypass venture financing, which is typically expensive and limited in scope. Venture can only invest in a small opportunity space, so wouldn't it be amazing if we didn't need to rely on it at all?

Instead, we could explore alternative paths, like licensing the technology to a larger company or even transitioning it into an existing organization, whether big or small. Starting a new company should be a last resort, only if other options don't exist. This approach gives projects and innovations a much better chance to reach patients without having to navigate the expensive, restrictive venture capital route, which filters out many opportunities.

Of course, if none of these alternatives work, creating a new venture-backed company could be the next logical step. But there are other potential paths, like moving the project into a nonprofit or even back into the government in some cases. We went through a thoughtful exercise about the various transition pathways, and while many projects will likely go into the venture pipeline, I strongly believe that should not be the default strategy. In fact, the goal should be to skip over it entirely, depending on how capital is allocated—though that's a broader discussion for another time.

Ultimately, investors will behave according to their mandates, whether they're venture investors or others. It's not about changing investor behavior, but rather about presenting them with opportunities they wouldn't typically see, such as those backed by ARPA-H funding. That's where the real opportunity lies.

Jenica Patterson: Thanks, Misti! One thing I forgot to mention about the Sprint for Women's Health is that we're still a relatively new agency—just about two and a half years old. I like to call us the "toddlers" of the Federal Government because of how young we are. That said, I encourage everyone to keep an eye on the Sprint for Women's Health Launchpad program.

One aspect we didn't touch on is how we're focusing on transitioning later-stage R&D efforts into the hands of people. We see this as an opportunity to take projects that have reached a certain inflection point—maybe a minimal viable product—and help push them into the market. We're planning to use ARPA-H investment to lower the barriers to transition, bringing in accelerator-like support for organizations, whether they're startups, universities, or something else.

We'll provide wraparound services like manufacturing assistance, reimbursement guidance, and regulatory support—things that are critical for helping innovations transition to market or into the next stage of funding. It could even involve reintroducing projects back into the government.

So, keep an eye out over the next two years and watch how these investments progress. It will serve as a great example of how we're transitioning our innovations out into the world.

Craig Gravitz: Thanks, Jenica, for bringing us back to this point. We saw the Sprint for Women's Health as an opportunity not just to fill a gap, but also to build our "muscle memory" in executing these kinds of initiatives.

The first real successes you'll likely see will come from the Launchpad awards under this initiative. Since these projects are at a slightly different stage of maturity compared to other ARPA-H investments, we've developed a unique strategy for them. As Jenica mentioned, the Launchpad will offer a variety of transition capabilities and wraparound services to support these projects.

We're approaching it similarly to how NIH deployed the RADx model, focusing on performing a needs assessment to determine what each project requires to succeed. From there, we can converge on those key needs and help push them forward in the areas that matter most.

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CONTACT US

Carsten Bernauer
Partner
cbernauer@orrick.com

Tony Chan
Partner
tychan@orrick.com

Ed Dyson
Partner
edyson@orrick.com

Craig Falls
Partner
cfalls@orrick.com

David Gindler
Partner
dgindler@orrick.com

Gregg Griner
Partner
ggriner@orrick.com

Blake Ilstrup
Partner
bilstrup@orrick.com

Scott Iyama
Partner
siyama@orrick.com

Thora Johnson
Partner
thora.johnson@orrick.com

Neel Lilani
Global Head, Tech Clients
nlilani@orrick.com

Ed Lukins
Partner
elukins@orrick.com

Mike O'Donnell
Partner
mike.odonnell@orrick.com

David Schulman
Partner
dschulman@orrick.com

Gargi Talukder
Partner
gtalukder@orrick.com

Stephen Thau
Partner
sthau@orrick.com

Albert Vanderlaan
Partner
avanderlaan@orrick.com