Ruth Adewuya, MD (host):

Hello, you're listening to Stanford Medcast, Stanford's CME Podcast where we bring you insights from the world's leading physicians and scientists. This podcast is available on Apple Podcast, Amazon Music, Spotify, Google Podcast, and Stitcher. If you're new here, consider subscribing to listen to more free episodes coming your way. I am your host, Dr. Ruth Adewuya. This episode is part of our pediatric pulse miniseries. And today we will be hearing from Charlette Stallworth in a little bit of a unique episode, which is a combination of a previously recorded webinar and some questions that I have for her. Charlette Stallworth is a Vice President of business Development Innovation at Stanford Medicine Children's Health. She has been involved in healthcare innovation for over a decade. Working with innovative physicians and scientists and other healthcare professionals in developing devices, therapeutics, diagnostics, and other healthcare tech.

To start off our conversation, could you define innovation?

Charlette Stallworth, MBA (guest speaker):

Innovation is more than just a word. While many definitions exist, the National Science Foundation sums it up well by saying, "Innovation is a process that begins with imagination and results in the creation of something of value for society." Innovation provides solutions to the problems we face. History is rich with innovation, including the first pulley crane developed in 6th century BC. Later the printing press, which improved communications vastly, and to the drones of the 21st century. And of course many more. Healthcare is also rich in innovation. Revolutionary innovation described new technologies often accompanied by high cost and uncertainty, and create transformational change. Examples include discovery of penicillin, completion of the human genome project, and surgical robots. Evolutionary or incremental innovations, on the other hand, tend to build upon existing technologies and typically have low to moderate costs. And offer competitive advantage in the market. So healthcare innovation is not just about doing something new, but also doing something better, which leads to improved care and delivery of care to our patients.

Ruth Adewuya, MD (host):

Can you talk about your interest in innovation and what drew you in?

Charlette Stallworth, MBA (guest speaker):

I am really passionate about innovation and facilitating innovation. I really enjoy making those connections and creating something new. And healthcare innovation is especially rewarding because you're making a positive impact, or attempting to make that positive impact, on the health and lives of children and adults. In my first career, I was an army officer, and my last job in the army was at their test and experimentation command. And in that role I was responsible for working with Raytheon and Lockheed Martin in satellite systems they were developing for the Department of Defense. And it was really important that we had rigorous tests and metrics to determine whether or not those systems met the standards of the Department of Defense, because lives were at stake.

And the same is true in healthcare. We have to be very rigorous in the testing that we do to ensure that the technologies we're bringing to the marketplace, and to individuals, are safe and reliable. So there a lot of different types of innovation processes that are in place today to help ensure that we're iterating. And that we're bringing the customer or the end user in upfront so that we really target and make the most effective tech, and diagnostic, and healthcare devices that we can make.

Ruth Adewuya, MD (host):

Can you unpack the process a little bit more? Where would you go to start a potential innovation? So let's say that someone has an idea for a healthcare app, how can they get started?

Charlette Stallworth, MBA (guest speaker):

That's really interesting. I think the smartphones are the catalyst for innovation because there's so many ways to use that as a platform for innovation. So with that smartphone, you have an idea for a healthcare app. I would say first is to do a little bit of due diligence. So go to the internet and search just to determine if that app already exists. And if it exists, but your idea is something different from that? Totally fine, that's great. But if your exact idea already exists, you might want to spend time working on something else versus creating a me too app. So consider that your app has some features that the apps in the market don't have, or there's nothing like it out there.

Ruth Adewuya, MD (host):

It sounds like the first step is to make sure that your exact idea doesn't really exist. So let's say that their idea is very new and original, and they get the all clear. What are the next steps? And what is the process of progressing forward and starting to work with more parties?

Charlette Stallworth, MBA (guest speaker):

So technology transfer is the movement of an invention from the inventor to a secondary party for the purpose of further research and development, or commercialization. It is the movement of an invention from the mind to the market. This process can consist of several phases. The cycle begins when an inventor informs the organization of their idea, which is then evaluated. If the invention meets most of the criteria, then it would be appropriately protected, marketed and developed and commercialized, typically via license. When a licensee is found that has the capability to take the product to market, a deal will be executed. And they're actively managed to ensure milestones are met, and royalties and other funds are distributed. Now, this is sort of an ideal scenario that I've just described. Most inventions don't follow this perfect path. Typically, several steps are repeated. They occur simultaneously, out of order, or not at all.

For example, for product development, it's often an iterative process. And many innovation concepts like design thinking, agile software development, seek the customer's perspective upfront and often. So in some cases you could start with product development and then disclose. It depends on the technology and sometimes even just where the inventor is when they learn about the next steps in the process. Most academic medical centers, and tech companies, and pharmaceutical companies have a technology transfer office. Tech transfer offices typically are staffed by professional licensing associates with expertise in their fields and in IP. This office is a primary resource to innovation managers and inventors as it manages the process of evaluating and protecting inventions, and advising on development and commercialization. As you understand the functions and process, you can build a customized framework for supporting innovation and tech transfer at your organization.

Ruth Adewuya, MD (host):

I think you've highlighted a really important thing here, which is that clinicians that have ideas should look internally first. And look at the resources that they have available to them, and reach out to their technology transfer offices for support and for the framework to move forward. What are some of those steps that a tech transfer office can do to elevate the idea to the next level?

Charlette Stallworth, MBA (guest speaker):

The technology transfer office evaluates the technology's potential. And would consider these questions, does the invention solve a problem? Is the invention novel or unique? And what stage of development is the invention process? We assess the market size and likely competitors, timeline and cost to get to market, and any potential barriers or challenges. This includes meeting with the inventor to learn more about the invention in greater detail. Inventors may provide drawings or prototypes of their technologies that help them express their idea.

Ruth Adewuya, MD (host):

As you progress with an idea, I imagine that legal protections also come into play. Could you talk more about this and what rights innovators have?

Charlette Stallworth, MBA (guest speaker):

You can say that intellectual property are the rights protecting the creations of the mind or human intellect. And there are four types of IP. So patent and there are three types of patents. Copyright protects authorships, such as writing and art. Trademark for words, symbols, to distinguish your company and your goods. Trade secret are information that you want to keep secret that gives you an advantage in the marketplace. That could be like a secret chocolate chip recipe for a cookie company. Other types of protection are non-disclosure agreements, material transfer agreements, data use agreements. Legal protection is not necessarily a prerequisite to commercialization. It really depends on the technology and your goal. Maybe you think the world would be a better place if everyone slept more deeply. So you did create a great app that reads bedtime stories to adults to encourage nighttime routine and better sleep. You could post that app to app stores for free download and achieve your goal. On the other hand, if you need investors, you probably want to pursue a patent application.

Ruth Adewuya, MD (host):

At a high level, what are some of those requirements to get a patent? And what is the general process of keeping one?

Charlette Stallworth, MBA (guest speaker):

You must disclose. You can't receive the patent if you don't disclose the invention. The invention must be novel, useful, and non-obvious. And what protection is provided, is that it may prevent others from making, using, selling, and offering for sale your invention. And this allows the commercial opportunity. And the duration of the patent? If it's a utility or plant patent, 20 years from filing. Or a design, 15 years from issue. And the costs vary with each application, typically starting around $5,000 to $15,000. But also, once you start the process, if you're continuing to develop and to maintain the patent protection, additional costs are incurred throughout the life of the patent.

Ruth Adewuya, MD (host):

Going back to this pretend innovative idea, what would the next steps be? After getting green flags in all of these stages and obtaining the proper legal protections.

Charlette Stallworth, MBA (guest speaker):

The technology transfer office recommends marketing the technology. The goal is to determine how and to whom the technology should be promoted. This includes writing technology summaries,

collecting pictures and videos. As well as identifying companies that may have a need for, or interest in, the product. Once we've developed our marketing plan and materials, we begin pitching the invention to commercial targets. Regardless of who we're engaging, the general marketing process includes sharing non-confidential information. If there is keen interest, you would then execute a non-disclosure agreement, and then share a confidential information. The marketing process can be one of the longer phases of technology transfer cycle. But if your invention is very specific, say like a incremental improvement on an existing device, then the manufacturer of that existing device might be your one and only marketing target.

Ruth Adewuya, MD (host):

So now we have an idea, we have the patents, we have the appropriate audience or market. What does the actual product development phase itself look like?

Charlette Stallworth, MBA (guest speaker):

This phase consists of building and improving the technology. This process can involve several different activities. Fundraising, prototyping, testing, regulatory approvals. For example, as the innovation manager at a small organization, you might hire a local engineering company to build a prototype of a technology. This allows the inventor to review their invention at a tangible state, and potentially identify additional design changes that may enhance the technology's value. A prototype might also be used to obtain proof of concept, be incorporated into marketing activities, or used for demonstration purposes when meeting with prospective investors or partners. The product development phase often occurs concurrently with other steps in the tech transfer process, will be different for each respective technology.

Ruth Adewuya, MD (host):

What you described not only sounds like an iterative process, but also sounds like it can be very expensive. What are some of the places where funding is normally needed? And what are some of these sources for getting these funds?

Charlette Stallworth, MBA (guest speaker):

Funding may be needed for many reasons, including patent application fees or marketing expenses, prototype design bench and clinical research, or obtaining proof of concept through product testing. Funding sources include venture capital firms, angel or individual investors, government funding programs, charitable donations, as well as grants and department funds. The type of funding to pursue, and odds of securing such funds, depend largely on the stage and commercial potential of the invention. Historically, late stage products with some proven success are more likely to be funded. Also, disruptive tech is appealing to certain venture capital funds. If the technology is being managed externally, such as by a licensee, then the licensee typically will be responsible for fundraising.

Ruth Adewuya, MD (host):

So if I develop a medical innovation, I imagine that I can't release that straight away into the market. There must be some sort of checks and balances, and regulations involved. Can you spend some time unpacking those and expanding on these regulations?

Charlette Stallworth, MBA (guest speaker):

As medical inventions are developed, regulatory approvals and clearances may be necessary. The FDA categorizes devices into three classes. Class 1, typically low risk devices, like tongue depressors. While Class 3 involve more complex, high risk technologies, like implantable defibrillators. Class 2 falls in the middle. Most class one devices are exempt from FDA regulatory clearance. However, these devices still must meet quality and safety standards. Class 2 and 3 devices on the other hand, must meet specific requirements and approvals before entering the market. The process begins with the manufacturing of a clinical grade device. Once made, the device must be clinically studied to ensure it has the desired effects. Using a new device in a clinical study requires an Investigational Device Exemption, or IDE. IDEs are approved by your Institutional Review Board, IRB. And sometimes also the FDA if the device risk is high.

Clinical device studies allow the researcher to gain device safety and efficacy data. If the study is successful, the data gain will be used for a 510(k) applications and pre-market approval, also called PMA applications. The 510(k), or PMA, is necessary before a device can be marketed for public use. The 510(k)s are typically associated with Class 2 devices, and the PMAs are associated with Class 3 devices. The therapeutic regulatory path is a lot more complex and has longer timeline than that of devices. In order to transition a drug from animal to human subjects, an Investigational New Drug or IND application must be approved by the FDA. The IND application must include certain safety data such as the results of animal tests, how the drug is made, what it's made of, the plan for proposed clinical trials. And investigator information, including experience and qualifications.

If the drug is successful through clinical trials, then a New Drug Application or NDA would be filed with the FDA. NDAs must be approved before the drug can be marketed to the public. The information required in an NDA is supposed to tell the drug's whole story. Including what happened during clinical trials, how the drug behaves in the body. And how it is manufactured, processed, and packaged. An FDA committee will review the NDA to determine whether the drug should be cleared for public use. The two types of NDA reviews include standard, which takes about 10 months. Or a priority, which is only about six months. And is used when a drug would provide significant treatment improvement. There is high risk in pursuing drug development. Only a very few, maybe one out of 10,000 compounds that start on the regulatory path, will gain FDA approval.

Ruth Adewuya, MD (host):

And this just makes me curious. When creating a device and trying to get it approved, how does the pediatric innovation process differ from adult innovation?

Charlette Stallworth, MBA (guest speaker):

That's a good question, because children are not just small adults. They require a different focus and approach. Pediatric medical device development for [inaudible 00:16:39] technology created for adults due to economic challenges and related to differences in market size. So development of pediatric therapeutics also face similar challenges. So fortunately, the FDA recognizes these challenges and they've established the framework for five pediatric device consortiums throughout the continental United States. And those consortiums are led by various academic institutions. And they have a mandate from the FDA to provide funding and coaching for people who are developing the pediatric innovative devices.

Ruth Adewuya, MD (host):

I know that this is a very quick and high level overview about the innovation process, and I have one more question for you. But I also wanted to let our listeners know that Charlette is hosting a webinar

coming up in the fall, September. So save the date and sign up for the Stanford CME newsletter to learn more about that fall 2023 webinar. But as we wrap up, I'm wondering about the inventor ownership portion of this. Working with technology offices and outside parties, I imagine, that this can add levels of ownership. So let's say I'm creating a startup coming from Stanford Medicine. What happens to my original ownership as the inventor who engages in these processes that we have just talked about?

Charlette Stallworth, MBA (guest speaker):

You as a creative person coming up with a innovative idea that is causing you to want to launch a startup. That is your idea as the inventor. But if it is a healthcare idea, it needs to be assessed. Likely it is the ownership of that idea. And if that technology is Stanford, your employer, and this is common in the United States. When you work for a company, as part of your employment arrangement, the technology and ideas, IP, that you create belongs to the employer. Fortunately, we have intellectual property, IP, policies in place at Stanford Medicine that allow you, as the inventor, to participate in revenues generated from your invention. So definitely when you disclose your idea to your employer, there's a framework and assistance or patentability, so there are costs that you don't have to bear as an individual.

Ruth Adewuya, MD (host):

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