DIGITAL HEALTH REPORT

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Machine Learning and Digital Health Applications

By Suzanne Bell and Sean Withall

The use of artificial intelligence (AI) algorithms to solve complex problems has risen dramatically in the last several years. In 2017, Gartner identified more than 1,000 application and platform vendors claiming to offer some form of AI in their products.[1] Start-ups and established companies in nearly every industry have driven this growth by finding creative ways to apply machine learning, a technique that involves using large data sets to train algorithms to assist with tasks that until recently were exclusively performed by humans.

Applications of machine learning hold particular promise for businesses that sell digital health devices and software, as well as for healthcare providers and health insurance companies. For example, digital health companies can use machine learning algorithms to spot early signs of diabetes using data collected from an Apple Watch,[2] help fitness bands learn
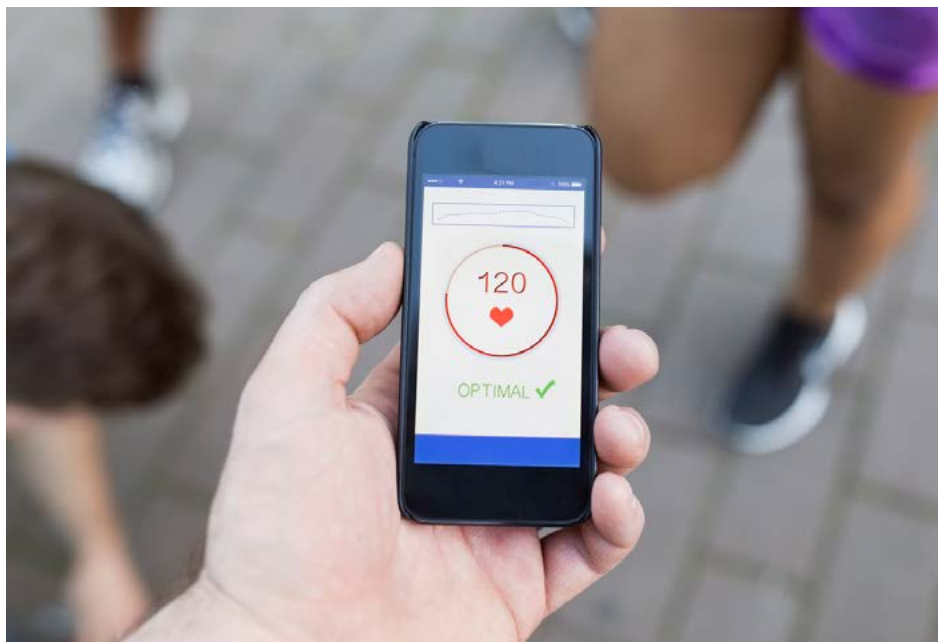
a wearer's exercise routine,[3] and detect mental illness using data gathered from social media accounts[4] and peoples' interactions with their smartphones.[5]

Healthcare providers have also developed machine learning algorithms to spot the early signs of cognitive decline that show up in MRI scans[6] and classify cancers using photographs.[7] Health insurance companies can deploy algorithms that make more accurate actuarial assumptions, offer health suggestions tailored to a person's top risk factors,[8] and root out fraudulent insurance claims[9] using data from sources like social networking sites and marketing databases.

Companies train these algorithms by feeding them large amounts of data, which

enables the algorithms to analyze new inputs. A machine learning algorithm's performance is only as good as the data it is trained on, so its developer needs access to large, high-quality data sets. Identifying the right data set is only half the challenge, however. Companies that want to use data for machine learning purposes must also be sure they have secured the rights necessary to train an algorithm with that data. At a minimum, this means thinking through the following four questions:

(1) Does the data contain personally identifiable information (PII)? PII is typically defined as information that can be used to identify an individual, either alone or when combined with other information linked to that individual.

Machine Learning and Digital Health Applications . . . *(continued from page 1)*

If a data set might include PII, then a company that wants to use the data should do two things. First, the company should make sure that its use of the data will comply with all applicable laws and regulations, such as the Health Insurance Portability and Accountability Act (HIPAA), state-specific privacy laws, and international laws and regulations like the European Data Protection Directive. Second, the company should check the privacy policy of the site or service that collected the PII. If the privacy policy says the data will not be used for "commercial purposes" or similar, then it probably cannot be used to train an algorithm that will be part of a commercially available product or service.

(2) Is the data publicly available?

Although the internet has made large amounts of useful data available to the public, companies cannot necessarily collect and use this data without restriction. While published government reports and census data are generally not protected by copyright, trademark, or trade secret laws, other publicly available data, such as social media posts, are often covered by terms of service that restrict their collection and use. For example, the terms of service of many major social networks (including Facebook,[10] Twitter,[11] and Google[12]) include provisions that prohibit or otherwise discourage companies from scraping publicly available data from their websites. Companies wishing to access and use social media data to train machine learning algorithms may therefore need to negotiate a separate license with the applicable data provider before collecting and using the data.

(3) Is the license to the data limited?

When reviewing or negotiating a license to use a data set, companies should carefully consider whether the scope of the license will permit them to use the data for their intended machine learning purposes. Typically, this means that companies should secure the right to use and reuse the data, incorporate the data into other works, and use the data to develop new commercial

products. Conversely, data that is licensed only for "internal purposes" or "non-commercial purposes" probably cannot be used to train an algorithm for a commercial product. However, even licenses that allow commercial use of the data may restrict the field or purposes for which the data may be used. Companies should think carefully about the license scope and ensure that such limitations will not prevent them from using the data to train an algorithm, or from using the trained algorithm in their products.

(4) Where did the data come from?

A company should conduct some basic due diligence before relying on a license to data in order to make sure that the source of the data actually has the right to grant the necessary license. For example, if a developer plans to license demographic data from a data broker for use in a digital health application, then the developer should make sure that: (a) the data was collected in compliance with all applicable privacy laws and privacy policies (see question 1); and (b) the broker has the right to grant a license to the data that enables training of algorithms (see questions 2 and 3).

Machine learning algorithms—and by extension, the companies that rely upon them—live and die by the availability of good-quality training data. It can be tricky to secure the rights needed to use this data, and companies that take a disciplined approach to data harvesting, use, and licensing stand to avoid costly legal claims for damages or injunctions based on unauthorized use of data.

Patent-Eligible Subject Matter in Digital Health

By Jackie Stroncek

Consider this: you have a new machine learning algorithm for processing genetic data and want to obtain a patent. You file a patent application with the United States Patent and Trademark Office (USPTO). The USPTO then informs you that, under the *Alice/Mayo* framework, your invention is not of the right subject matter for which a patent may be granted.

In the past five years, the interpretation of the *Alice/Mayo* framework at the USPTO has presented a new hurdle for obtaining patents, particularly for inventions of algorithms and software in the digital health space, including bioinformatics. Understanding the basics of the current patentable subject matter doctrine and how it may be construed by the USPTO is essential for productive patent prosecution in these fields.

What is patentable subject matter?

By statute, patentable subject matter can be any one of a "process, machine, manufacture, or composition of matter."[1] However, these categories are subject to certain exceptions created by the Supreme Court, called judicial exceptions. Judicial exceptions were created to prevent abstract ideas, laws of nature, and natural phenomena from being monopolized, which could hinder innovation, rather than advance it.[2] A claimed invention is not patent-ineligible though simply because it *involves* a judicial exception.[3]

The complexity of interpreting what is or is not patentable subject matter stems from determining whether a claimed invention merely involves versus monopolizes a judicial exception. Courts have not

SUBJECT MATTER ELIGIBILITY TEST FOR PRODUCTS AND PROCESSES

ESTABLISHED THE BROADEST REASONABLE INTERPRETATION OF THE CLAIM AS A WHOLE

THE STATUTORY CATEGORIES

Step 1
IS THE CLAIM TO A PROCESS, MACHINE, MANUFACTURE OR COMPOSITION OF MATTER — NO

YES

CAN CLAIM BE AMENDED TO FALL WITHIN A STATUTORY CATEGORY?

CAN ANALYSIS BE STREAMLINED?

WHEN VIEWED AS A WHOLE, THE ELIGIBILITY OF THE CLAIM IS SELF-EVIDENT

A

THE JUDICIAL EXCEPTIONS

Step 2A
IS THE CLAIM DIRECTED TO A LAW OF NATURE, A NATURAL PHENOMENON (PRODUCT OF NATURE), OR AN ABSTRACT IDEA? — NO

B

YES

THE INVENTIVE CONCEPT

Step 2B
DOES THE CLAIM RECITE ADDITIONAL ELEMENTS THAT AMOUNT TO SIGNIFICANTLY MORE THAN THE JUDICIAL EXCEPTION? — YES / NO

C

CLAIM QUALIFIES AS ELIGIBLE SUBJECT MATTER UNDER 35 USC 101

CLAIM IS NOT ELIGIBLE SUBJECT MATTER UNDER 35 USC 101
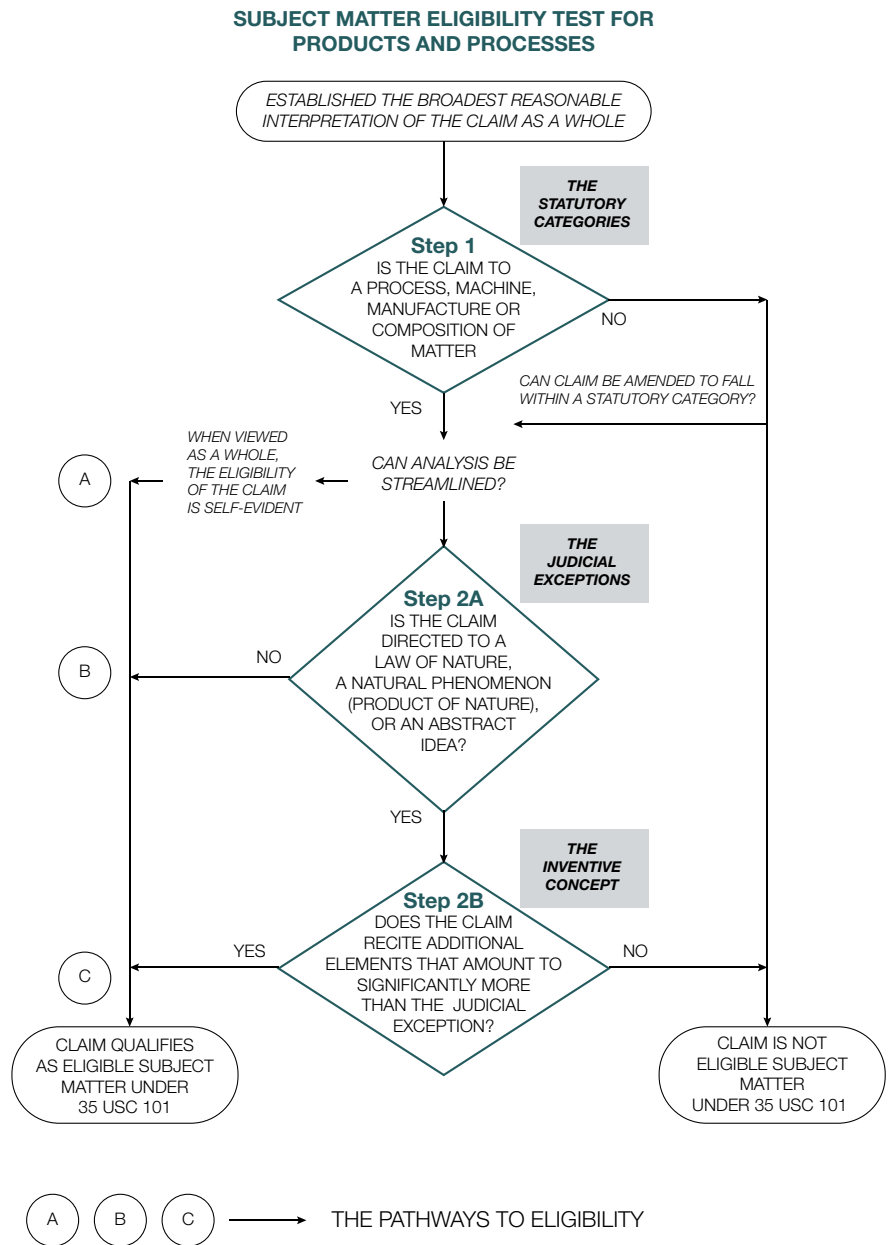
A B C → THE PATHWAYS TO ELIGIBILITY

Fig. 1 illustrates pathways to subject matter eligibility. First, whether the claim meets the threshold requirements of section 101 is determined. Adapted from *Manual of Patent Examining Procedure (MPEP) 2106, Patent Subject Matter Eligibility.*

Patent-Eligible Subject Matter in Digital Health *(continued from page 3)*

provided definitions for each judicial exception. For guidance, patentees must rely on courts' distinctions between inventions that have been found to be patent-eligible and those that have been found to be patent-ineligible.

The *Alice/Mayo* framework is currently used to guide distinctions between patentable subject matter and non-patentable subject matter. This framework is applied after establishing that a claim is to a process, machine, manufacture, or composition of matter (Fig. 1, Step 1). Once established, then the two-step *Alice/Mayo* analysis is applied (Fig. 1, Step 2A-B). First, the USPTO determines whether the claims are directed to a judicial exception. If the claim is not directed to a judicial exception, then the claim is patent-eligible. If, however, the claim is directed to a judicial exception, then the second step applies. In the second step, the claim is analyzed to determine whether it recites significantly more than a judicial exception itself. Determining whether a claim is directed to a judicial exception or recites significantly more requires comparing the claimed subject matter to other inventions that the courts have determined recite patent-eligible (or patent-ineligible) subject matter.

Relevance to Digital Health Software

For inventions in digital health, patentable subject matter issues may arise based on current case law and USPTO examination guidelines. Claims that recite bioinformatics methods, for example, are often rejected as allegedly directed to an abstract idea, without significantly more.

In responding to these rejections, software-related case law and USPTO guidance are frequently the most factually relevant and persuasive authorities to show that a claimed invention is patent-eligible. For instance, the patent-eligible claims of *McRO v. Bandai Games*[4] can be closely analogized to software method claims. In *McRO*, the claims-at-issue recited a method of computer animation with specific rules for lip synchronization and facial expression. The rules improved upon the existing technological processes, were necessarily implemented on a computer, and were specific enough to avoid preemption. In applying *McRO* to software claims, parallels can be drawn between the structure of the *McRO* claims and a claimed software invention, which may similarly recite specific rules that present technological improvements, be necessarily implemented on a computer, and be specific enough to avoid preemption.

How to Address Challenges in Patent Prosecution

Subject matter eligibility issues can be addressed before a patent application has been filed and even while it is undergoing examination (prosecution). Before prosecution, when drafting the application, careful attention should be paid to highlighting inventive concepts in the specification and the claims:

- Applications specifications should provide support for how digital health software can be implemented on hardware and provide detail-rich examples that highlight inventive

attributes. This language may be referenced in prosecution to show that claims are non-conventional and/or present improvements to the technical field (e.g., recite significantly more).

- The specification should discuss features that enable improvements of the claimed invention in a given technical field.

- Inventive aspects of the claims should be commensurate in scope with any improvements described in the specification.

- If an invention involves an *in silico* component of an assay with non-conventional wet-lab procedures (e.g., novel sample preparation techniques), claims can be drafted to emphasize the non-conventional, non-abstract wet-lab procedures.

During prosecution, ongoing discussions with the USPTO may provide valuable insights on how an application might progress to allowance:

- Examiner interviews may provide opportunities to understand an examiner's perspective and possible concerns.

- The claims may be revised to address an examiner's concerns. This is where language from the specification may be helpful.

- The claimed invention may be analogized to cases that the courts have found to be patent-eligible.

Utilizing Inventive Concept to Overcome Patentable Subject Matter Challenges

By Josh Mack and Doug Carsten

Digital health companies are more and more reliant on patents to protect their diagnostic testing and computer-based inventions. However, since the Supreme Court's landmark decision in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*,[1] the patentability of such inventions has been a considerable area of confusion and concern for digital health companies. Recent decisions by the Federal Circuit on patentable subject matter have provided guidance digital health companies can use to help protect these inventions from invalidation in future litigations.

Mainly, the Federal Circuit has held that whether or not a claim contains an inventive concept is a factual issue, which needs to be resolved by a jury at trial. Therefore, it is important for digital health companies to include an inventive concept in the patent specification and claims during patent prosecution. And during litigation, digital health companies should have an early understanding of the inventive concept captured by the claims, and find the best expert possible to support these arguments. Such strategies should increase the likelihood that diagnostic and computer-related patents survive legal challenges during litigation.

Patentable Subject Matter

Congress has codified patentable subject matter in 35 U.S.C Section 101, which provides that patentable subject matter includes "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof . . . ." The Supreme Court has identified three categories of inventions that are not eligible for patent protection: laws of nature, physical phenomena, and abstract ideas.[2] Whether or not an invention contains patentable subject matter is a two-step process that distinguishes "patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent eligible applications of those concepts."[3]

In the first step, the court "determine[s] whether the claims at issue are directed to one of those patent-ineligible concepts."[4] If the patent claims are directed to a patent-ineligible concept, the court turns to step two—the search for an inventive concept—i.e*.,* an element or combination of elements that is 'sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.'"[5] In searching for an inventive concept, the court "consider[s] the elements of each claim both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application."[6]

This patentable subject matter standard, which was first articulated by the Supreme Court in 2012, has led to the invalidation and rejection of a large number of diagnostic and computer-based patents on the grounds that the claims are not patent-eligible as a matter of law.[7] Until recently, it was thought that a jury could have no role in determining whether or not a patent claimed patent-eligible subject matter.[8] Yet, in 2018 the Federal Circuit has shown that a jury can have a role in this determination.

The Federal Circuit Provides Guidance on Inventive Concept

Recent Federal Circuit decisions have shown that patent eligibility can be a question of fact, surviving purely legal challenges during litigation, when the patent specification and claims include an inventive concept.[9] Accordingly, a jury, rather than court, can decide whether or not a diagnostic and computer-based patent claims patent-eligible subject matter. This development in the case law could improve the chances that these patents survive pre-trial legal challenges that have invalidated many of these types of patents.

In *Berkheimer v. Hewlett-Packard Co.*, the district court invalidated a patent directed to digitally processing and archiving files on summary judgment because the court found that the claims were not directed to patent-eligible subject matter.[10] While the Federal Circuit agreed with the district court that the claims were directed to non-patentable subject matter, the Federal Circuit found that there was a factual dispute as to whether the patent claimed an inventive concept.[11] The Federal Circuit reasoned that because the patent specification described an inventive feature that eliminated redundancies and improved efficiency, and certain claims captured that feature, whether or not these claims "perform well-understood, routine, and conventional activities to a skilled artisan is a genuine issue of material fact making summary judgment inappropriate with respect to these claims."[12] Accordingly, the Federal Circuit remanded these claims back to the district court for trial.

Strategically Using Inventive Concept in Patent Prosecution and Litigation

The *Berkheimer* case shows that patent claims directed to diagnostic and computer-based inventions can survive patentable subject matter legal challenges and reach a jury if the "inventive concept" of the invention is described in the specification and captured by the

Utilizing Inventive Concept to Overcome Patentable . . . *(continued from page 5)*

claims. As a result, whether or not these inventions claim patentable subject matter becomes a battle of the experts, and the jury will decide whether the claims include an inventive concept or merely "perform well-understood, routine, and conventional activities."

During the patent drafting process, digital health companies can improve the chances that their patents survive patentable subject matter challenges by making sure the inventive concept of the invention is clearly articulated in the patent specification and captured by the

claims. During litigation, the jury's decision on patentable subject matter may come down to which expert the jury finds more credible and believable. So the choice of expert and litigation counsel could be the key factors in determining whether or not a company's patent is invalidated.

Healthcare Innovations Venture Investment Forum

"The human mind has an instinct, so why not transfer that instinct to a machine and make it intuitive. Think about it, we know when our friend is sad, angry, or happy." This notion and countless other examples of innovative thinking recently drew entrepreneurs and investors to the Healthcare Innovations Venture Investment Forum, a program created by Wilson Sonsini Goodrich & Rosati, and hosted by the Dell Medical School in Austin, Texas on December 6-8, 2017.

More than 150 innovative life sciences companies from across the country met privately with more than 50 top-tier life sciences investors. Company representatives also had the chance to network with investors during breakfast, lunch, and receptions over the three-day event.

The 2017 event in Austin was the third Healthcare Innovations Venture Investment Forum presented by WSGR. WSGR hosted its first venture forum in Palo Alto in 2016, and a second forum in Boston in Spring 2017 in conjunction with the Harvard Innovation Lab.

"Investment in life sciences is tremendously robust, and great ideas can be well-financed today," said Vern Norviel, a WSGR partner in the firm's patents and innovations practice who represents life sciences companies. "This investment environment is creating the opportunity to make enormous advances. Technologies such as immunotherapy, gene editing, cell therapy, and inexpensive DNA sequencing are enabling treatment options that were unimaginable a few years ago."

Therapeutics made up 40 percent of the more than 370 company submissions to the forum, followed by medical devices at 33 percent, and digital health at 26 percent.

The Next Generation of Innovations

NeuroLex Diagnostics

The intuitive machine suggestion mentioned previously was that of Jim Schwoebel, CEO of NeuroLex Diagnostics (NeuroLex). His passion for improving health care was inspired by his brother who was examined by primary care

doctors 11 times and six different specialists only to learn that he had been diagnosed with schizophrenia through an acute psychotic hospitalization.

Schwoebel's company analyzes speech patterns, such as syntax and intonation, to diagnose psychiatric and neurological diseases early. NeuroLex then offers a referral to an appropriate psychiatrist for a confirmed diagnosis and treatment.

"What's happening is that most of these psychiatric and neurological patients are treated only after advanced symptoms appear, leading to poor outcomes—in the case of my brother a longer duration of untreated psychosis and over $15,000 of wasted medical tests," Schwoeble argues. "This kind of testing should be mandated in hospitals or as part of regular lab work to help drive down costs, improve outcomes, and lower readmission rates."

As part of the conference, he met one-on-one with DigiTx Partners, a digital health investment company, which teams up with those driving change in behavioral health through meaningful data.

Siemens Healthineers

Dean Simcoe, vice president of business development for Laboratory Diagnostics at Siemens Healthineers, compared the forum to a successful speed-dating event.

"It's important to have both true financial investors and strategic partners, because the strategic partner can provide guidance and support to commercialize the product or innovation," said Simcoe.

Ari Nowacek, MD, PhD, principal at ARCH Venture Partners, the premier provider of seed and early-stage venture capital for technology firms, added that networking is essential to teaming up with the right investor.

ARCH Venture Partners

"Ideally, you want an investor who does not just commit capital to your company, but someone who also commits their attention and effort to help it succeed," said Nowacek. The 150-plus companies that participated in the forum were selected from a larger pool of healthcare start-ups, based on a submission process.

"The selected companies are evidence that really interesting technology doesn't have to originate from either the Northeast or California. WSGR's forum provides an opportunity for investors to connect with these innovative and growth-minded companies," said Michael Hostetler, a partner at WSGR who represents life sciences and healthcare clients.

UT Austin

In addition to companies, individuals developing early technologies from Dell Medical School and UT Austin also received a chance to meet with investors. "Opening the event up to university technologies that may not be actively fundraising is a huge value-add," said Nishi Viswanathan, Director of Texas Health Catalyst, a program at the school that helps accelerate the translation of innovations to the clinic. "Such interactions usually happen much later and by then, it is hard to shape a product based on industry feedback."

ARK.one Health

From big data to disease management and wearables, much of the success for the life sciences industry now is rooted in value-based care solutions, often through digital technologies. CEO and Co-Founder of Ark.one Health, Shawn Dastmalchi, offers predictive analytic solutions for health systems with the goal of working towards value-based care.

"All health systems feel the need to take on more financial risk for sustainability," said Dastmalchi. "They have to reinvent themselves."

Sirenas

Sirenas, a San Diego biotech company with partners like Bristol-Meyers Squibb, The Bill & Melinda Gates Foundation, and Calibr, is at the forefront of big data. They harness computational approaches to discover therapeutics derived from the global microbiome.

"Our mission is to take molecules from Point A and generate meaningful data into novel potential medicines through our drug discovery platform (ATLANTIS) to identify immuno-modulatory drugs," said Jake Beverage, Pharm.D., CEO of Sirenas.

Conclusion

Schwoebel acknowledges his lab, may be too innovative for investors now, but he is willing to take the risk and present data from what he calls "the largest lab in the world" of its kind. Taking risks is exactly what hopeful inventors need to do when they meet with investors.

"Know why your therapy works, why it will be different from something already available, and demonstrate the data that supports it," he said.

A fourth Healthcare Innovations Venture Investment Forum is planned for 2018. Details are pending as to the date and location. For more information about the firm's forums or its life sciences or digital health practice, visit www.wsgr.com.

To view the complete listing of endnotes for this report, please visit
https://www.wsgr.com/email/Digital-Health-Report/2018/footnote_winter2018.pdf

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