Mayfield × aws


# Health Innovator Summit 2020


# Thank You for Joining Us!

As venture capitalists with a long history in healthcare — Mayfield was one of the original investors in Genentech and Amgen, among others — we know first-hand how difficult it is for even great entrepreneurs to disrupt this massive, highly regulated, life-or-death part of the economy. The needs and realities of the multiple stakeholders in the ecosystem — payers, providers, regulators — are entrenched and complex. And thanks to an explosion of rapidly-advancing innovations such as artificial medicine and genomic medicine, the challenges are greater than ever.

But so are the potential benefits, in everything from drug discovery to personalized treatments to more effective solutions to address the social determinants of health. Accenture predicts that AI could generate $150 billion in cost savings in the U.S. healthcare system by 2026.[1]

To help unlock these benefits, we partnered with AWS to host a Health Innovator Summit at the JP Morgan healthcare conference in January. More than 300 innovators attended this invite-only event, including technology entrepreneurs, healthcare system executives, FDA CIO Amy Abernethy and AMA CEO James Madara. The gathering, which was also webcast live, provided a forum for these domain experts to step back from the bustle of the conference to discuss real-world ways to accelerate innovation. Our aim was to surface best practices and non-obvious insights from across the ecosystem. Based on the feedback so far, we succeeded. Many attendees said the event was the highlight of their week.

**Photographs by © Marla Aufmuth**

Here are some of the key takeaways from the sessions.

## Fireside Chat with Dr. Amy Abernethy: The Role of the FDA in Enabling Healthcare Innovation

**Real World Evidence will transform economics of drug development.**
The FDA's use of real world data as evidence for drug approval and monitoring can significantly lower the costs and accelerate the speed of clinical trials.

**The FDA is "building muscles" to make the most of real-world evidence.**
The FDA has released a crowdsourcing app called MyStudies that establishes a common interface and definition of the kind of real-world data the Agency wants innovators to collect and share. Another crowdsourcing app, called CureID, lets healthcare providers share results from new uses of drugs to treat difficult-to-treat diseases.

**FDA announced the data challenge for adverse effects.**
To make the most of the data it collects from healthcare providers, patients and other sources, the FDA periodically issues data challenges to engage the world's leading data scientists to work on a particular problem. Amy provided details on the most recent challenge, to find new ways to quickly and accurately identify adverse effects from FDA-approved products.

[1] https://www.accenture.com/fi-en/insight-artificial-intelligence-healthcare

**Abernethy's core focus for 2020 is to make more FDA data available.**
Four months after being appointed Principal Deputy Commissioner in December, 2018, Amy also became CIO to oversee the modernization of the FDA's technology infrastructure to enable it to ingest, share and analyze individualized data at scale. She told attendees that her primary goal for 2020 is increase the amount of data it can open up to industry, both to improve healthcare decisions and to showcase the potential of precision health to Congress.

**The FDA is working on more efficient approval pathways for digital health.**
The FDA recognizes that lengthy drug approval processes are not the best way to regulate fast-changing digital health technologies. One current pilot program focuses on regulating the capabilities of technology companies, rather than each of its products and services.

**For startups, it is never too early to talk to the FDA.**
The FDA is developing a variety of ways to make it easier for start-ups to communicate with the agency, including conferences held on most Fridays where innovators can present their newest solutions to agency staff. Amy urged entrepreneurs to communicate early and often. "Staying away from the FDA probably does you a disservice," she said.

## Atul Butte: The Largest Post-Market Study on the Drugs That Actually Work

**US healthcare providers have spent hundreds of billions of dollars on EHR systems, but almost nothing on making use of the data.**
Doctors and other high-income professionals spend hours each day entering data into EHR systems, but the average byte of data is never looked at again. It would be a "national tragedy" to let this data go to waste.

**Healthcare systems will one day have more information on drugs than their developers.**
With data from 200,000 employees, 250,000 students and 5,000 participating doctors, the University of California's repository of data dwarfs any clinical trial. For example, the UC System has treated more than 10,000 people with Humira, around five times more than the number of people involved in pivotal studies for the FDA.

**The UC is a leader in de-identifying.**
Since it began this work in 2016, Dr. Butte's team has manually de-identified 25,000 notes written by UCSF physicians and used the data to train a machine learning system to de-identify a total of 75 million. The UC has also hired former FTC staffer Cora Han to be its first chief health data officer.

**Find a business reason to mine your EHR data.**
The UC system has saved millions of dollars by using EHR data to get all doctors to only prescribe generic Metformin. It will save millions more by forcing all campuses to standardize on particular drugs and treatment options.

**There are more ways to leverage real-world data than you think.**
Atul and a colleague just published an article in the Journal of Clinical Investigation that identifies 21 ways that real-world data is being used today, by pharmaceutical companies, payors, providers, patients and others.

## Entrepreneurs Panel: The Secrets Behind Built-to-Last Companies

**Create a decision-making framework.**
You'll need an empowered workforce, in which people at all levels of the organization are unafraid to use their expertise and learn. But have a detailed process when serious disagreements crop up, so everyone can disagree and commit to a common course.

**Think platform.**
For years, start-ups that focused on developing a particular molecule or drug were richly rewarded, often with lucrative acquisitions. Going forward, the biggest winners will be companies that establish platforms around breakthrough technologies that allow them to develop multiple products, and carve out a strategic spot in the healthcare ecosystem.

**Get one in the boat.**
Rather than aiming for the most revolutionary or profitable application of a technology, start-ups should de-risk by starting out with a project that is most likely to win FDA approval.

**Overinvest in HR early.**
All the panelists said their worst decisions involved people and culture, such as not hiring or firing a key executive at the right time, not providing enough support to young people starting their careers, or not thinking early enough about inclusion and diversity. They advised bringing on an experienced HR executive early on, and to hold off-sites to thoroughly debate and decide on the company's core values.

**Get smart, tough advisors.**
You're trying to create entirely new technologies, processes and business models, and there will be no lack of skeptics. You need advisors to be 'constructive skeptics,' willing and able to think through unique opportunities and challenges, and who are not looking for the quickest liquidity event.

## Innovation in Care Delivery for Critical Conditions: The Provider POV

**Don't follow the crowd.**
Healthcare executives appreciate innovation that truly solves critical problems, such as cancer treatments. But some problems get far less attention from vendors, such as battling sepsis. While there is a clinical study for every 4,000 cancer deaths, there's one for every 70,000 sepsis-related death.

**High-tech needs to enable high-touch healthcare.**
The new Stanford Hospital was designed so that technology is not front-and-center in the patient's experience, said Lloyd Minor, dean of Stanford Medical School. While each patient gets an iPad with a variety of apps — everything from seeing your daily schedule of procedures, to ordering dinner — he stressed the importance of putting a convertible couch/bed in every room so loved ones can sleep over.

**Help hospitals give more control to patients.**
Consumers are rapidly embracing the chance to take a more active part in their care via mobile apps. The number of hospitals that offer apps based on the FIHR interface will balloon from 340 in late 2019 to 1400 by 2022, says Zak Kohane, chair of the Department of Biomedical Informatics at Harvard Medical School. He predicts that the largest pools of patient-controlled data will no longer be in hospital systems, but on mobile platforms such as Apple's iOS.

**Have reasonable expectations.**
Managing a hospital is almost as complicated as managing a small city, so change takes time. In the fight against sepsis, for example, most hospitals are still focused on trying to get care workers to even wash their hands. Don't expect technology to sell itself.

**Enable lifelong learning.**
Only half of medical students, and even fewer practicing physicians, feel prepared to leverage the benefits of AI and other emerging technologies. Universities need to change their curricula and expose students to other disciplines such as quantitative data science.

## James Madara Fireside Chat with Chrissy Farr: The Role of the AMA in Reducing Barriers to Innovation

**The AMA's top three priorities.**
The first is removing obstacles to care. The second is professional development of physicians and lifelong learning. Last but not least is helping to address chronic diseases, which now consume 85% of the $3.5 trillion the U.S. spends on healthcare each year.

**Better EHRs are key to addressing doctor burnout.**
The average physician spends two hours on paperwork for every hour with patients, and this will get worse should chronic diseases continue to become more prevalent. EHRs need to be better at sharing data between systems, if doctors are to be able to use data to improve care and outcomes.

**Beware the AI hype.**
AI and related technologies will have an important role, but won't completely replace any specialties or sub-specialties. And doctors should be skeptical of what's in the black box, and ask for explanations for how algorithms work before accepting their accuracy and efficacy.

**Patient data should belong to the patients.**
The digital health sector needs regulations so that patients can control who gets their data, and must give their permission for it to be used.

**Doctors need to take a more active public role.**
While lawyers and MBAs impact all aspects of the modern economy, doctors are more likely to spend their time focused on patients. By taking a more active public role, they can have a greater impact on the products and policies that affect an industry that is 20% of the GDP.

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It was delightful to hear so many fresh perspectives that are bound to help the next generation of innovation get to consumers and patients faster. We thank all the participants for engaging in earnest, and for making the event such a success.

Regards,

**Ursheet Parikh & Gamiel Gran, Mayfield**

## The Role of the FDA in Enabling Healthcare Innovation

**Dr. Amy P. Abernethy, M.D., Ph.D. (Principal Deputy Commissioner & CIO, U.S. FDA)**

**Ursheet Parikh (Mayfield)**

**Ursheet Parikh**

Welcome Amy. Before we speak further, I think you have an announcement to make.

**Amy Abernethy**

Hello and thanks for having me. You may have heard over the last six to eight months that we are really focused on technology and data modernization. This is not about getting faster computers. It's about changing our orientation, so we're ready to use data differently now and in the future.

Today we have two announcements that are relevant to this conversation. On Jan. 17th, we announced a new precision FDA data challenge. These challenges have two main goals. First, we want to get the larger community of top notch data scientists working with our data, to teach us how it can be used in the future. And we want to showcase what's happening in the life sciences industry to Congress. This particular challenge will be focused on using FDA data to identify new safety signals.

I also wanted to talk about our MyStudies app, which we announced last week. We want to encourage innovators to collect data on outcomes, but they often don't know where to start. So we built the baseline MyStudies app and made it open source, so the larger community of innovators can run with it. By creating a basic standard interface, we are clarifying the core components that we expect for data that comes in from clinical trials. After that, the way that you update the data to make it more user-friendly for your clinical trial or your corporate needs is all up to you.

And last week we announced a public private partnership with Google, which created a fully clickable version of the app that can be embedded in clinical trials, starting with one at Stanford.

**Ursheet Parikh**

It's extraordinarily exciting that the FDA is going to open up all of its clinical trial data, so that the world can download and analyze it. The second and more interesting thing is that the FDA has created an application that lets you report outcomes of clinical trials into the collective commons. You can use the app to do recruitment, and you can run trials where patients don't have to come to the care setting all the time. It's really a digital transformation about how we build and deliver innovation to the market.

**Amy Abernethy**

One slight edit: the data challenge only involves data that we can currently make available. We hold a lot of confidential information that we cannot disclose, and some types of data are currently structured in a way that is not rapidly analyzable.

**Ursheet Parikh**

The FDA has its skeptics. Yesterday, the New York Times editorial board asked the FDA to slow down innovation. How would you respond to that idea?

**Amy Abernethy**

Not everybody is up to date as to what's possible in 2020 and going forward. So we need to provide the best education and communication we can. But we can't get distracted. I realized as soon as I got to FDA that our mission is to protect and promote public health, and to promote innovation. If we forget that last part we can't accomplish our mission.



**Ursheet Parikh**

You announced another app last week, called CureID. What should we understand about it?

**Amy Abernethy**

It lets healthcare providers who are using antibiotics for novel uses tell us what they're doing, and it also helps us understand the degree to which physicians are willing to participate. While there hasn't been much press on CureID, the physician uptake has also been far greater than I would have expected.

**Ursheet Parikh**

Some of the largest real-world evidence initiatives have been with some of the big healthcare providers. What is the FDA doing to make sure that emerging companies have the same voice?

**Amy Abernethy**

The 21st Century Cures Act has compelled the FDA to understand how we can competently control real-world evidence. This has helped us to start building the muscles internally to use this data, and it lets us communicate to industry what you can do now and in the future.

It's true that the big incumbents have put a lot of money and other resources into this. But we are committed to making sure that everything we learn about real-world evidence is available in a transparent way across the playing field.

**Ursheet Parikh**

Small companies often bring first-in-class technology to market. What are you doing to help them get on the right path to get approval?

**Amy Abernethy**

It used to be kind of hard to talk to the agency, but we're developing all kinds of ways for you to communicate with us, early and often. We have conferences most Fridays, where innovators can present their newest solutions. If you've got a new product, come talk to us, because staying away probably does you a disservice.

We realize that some of our current approaches don't work for everything. For example, we regulate by product category. So we regulate food, we regulate cosmetics, we regulate drugs, devices, animal products. You get the point. However, in the digital health space, products develop much more quickly. We understand that the traditional product pathway may not always work. That's why you've heard us talk probably about a patient pathway. It's now a pilot program to regulate the companies that are developing the product as a way of making things more efficient.

**Ursheet Parikh**

You spent most of your career using data to improve clinical practice. What advice would you give to others who are doing the same?

**Amy Abernethy**

We have a tendency to get emotional about data. We tend to think there's good data and there's bad data. The truth is that all data has value and all data has warts. So you need to look at particular datasets and think about the challenges you need to solve. Can you marry it with other datasets to fill in gaps? Can you find new solutions to clean it up?

**Audience Member**

Late stage venture capital firms don't really have incentive to work on things like anti-fungals, anti-microbials, anti-virals, because of the way they are reimbursed. Has the Agency thought about new ways of developing therapeutics in these areas?

**Amy Abernethy**

This is a really important, very hard problem to solve. The CARB-X initiative is a trans-governmental way of trying to deal with it. As for the FDA, each of the centers is doing its own things, and we're also pulling people together to create a trans-FDA point of view. In the drug center, for example, the infectious disease team looked across the other therapeutic areas and said, "Wait a second. Over there in oncology, they've made really effective, efficient use of accelerated approval processes. What can we learn and bring back and use ourselves?"

Within the animal center for veterinary medicine, we're thinking about how to provide better stewardship around reducing the use of antibiotics for treating animals. In fact, we saw a reduction of about 30%, although that seems to be flattening out. And within the devices center, we're developing new diagnostics to better target antibiotics so we don't just carpet bomb people with antibiotics at scale. So the devices center is working with the CDC and others to create reference libraries for diagnostics.

**Audience Member**

The FDA has a lot of databases — shared, individual, submitted. Which databases will you use?

**Amy Abernethy**

The first set of data that's going to be used for the latest Challenge will be with what's available in openFDA, because we already have the right sharing permissions in place.

But I'm very actively working on how we unlock the massive amounts of information that we maintain internally, while appropriately protecting confidential data from companies in a way that allows us to make better, data-informed decisions, and to showcase what's possible. This is my core focus for the next year.

I realized as soon as I got to FDA that our mission is to protect and promote public health, and to promote innovation. If we forget that last part we can't accomplish our mission.

— Amy Abernethy

## The Largest Post-Market Study on the Drugs that Actually Work

**Atul Butte, M.D., Ph.D., Director of the Bakar Computational Health Sciences Institute, UCSF & Chief Data Scientist, University of California Health System**

We've all heard that the United States spends billions of dollars on electronic health record systems. For example, Sutter Health, our colleagues here in Northern California, has spent $1 billion. Partners, which is Mass General Hospital and Brigham and Women's Hospital, has spent $1.2 billion. Kaiser has spent $4 billion.

But the critical narrative I hope you take home with you is that while the United States has spent hundreds of billions of dollars on these systems, it spends nearly zero on actually using any of that data. Maybe a patient gets readmitted or returns to the clinic, or a doctor looks up an old x-ray. Other than that, the average byte of data is probably never looked at again. And we're paying doctors to type so much of it in, which probably makes this data the most expensive data in America. So I want to convince you that if we don't use this data to improve the practice of medicine — in a safe, respectful way, of course — it will be a national tragedy.

With that, let me introduce you to the University of California. To me it's the most amazing platform for real world clinical data that exists. We have 10 campuses, three national labs, including Lawrence Livermore, which has one the world's fastest supercomputers. We have 200,000 employees, and we have self-funded health plans, so we're actually also a payer for those employees and dependents that get care with us. We have a quarter million students a year, six medical schools, and 12 other health professional schools for disciplines such as veterinary medicine, nursing, dentistry and public health. The University of California trains half the doctors, medical students, and residents in California.

> I still run into people who don't understand what an electronic health record is, never mind that we've spent hundreds of billions of dollars to acquire this data.
>
> — Atul Butte

Several years ago, a new umbrella organization was created, called UC Health, with the 10 year aspiration to become a single accountable care organization for the entire University of California. After a decision like this is made, a health system then needs to decide what exactly is going to be the care it delivers, which is then a great reason to put all the clinical data together. You might have heard that it's so hard to get electronic health record systems to talk to each other. Well it's actually much easier to integrate these systems when you have a business reason to do it. For the University of California, the business reason is to get everyone acting together, in a high performing, high quality way. For example, what if UCSF takes care of kidney transplant patients one way, but UCLA does it another way? Or what if UC San Diego takes care of prostate cancer their way, but at UCSF we do it another way? There eventually should be a "UC Way" of doing things.

So where are we now? We have much of the system built, and we're getting some of the first results. The number I love to start with is 15 million. That's how many patients the University of California has treated in the last 15 years. That's equivalent to 5% of the entire US population. It's an enormous number.

A lot of this is very basic data, because fifteen years ago we didn't have the Epic electronic health record system in place. If we count from when we deployed Epic in 2012, UC Health has seen between five and six million patients, in over 160 million encounters, and performed over 140 million procedures. And we've ordered 680 million medications, everything from Tylenol to CAR T cells. It's essentially the master shopping list of everything we order for patients in the entire health system.

We have different types of health data worth noting. Claims data, or the bills we have been sending to payers for years, is not useless. You get the patient demographics, some disease codes, and perhaps some procedure codes. But electronic health record data is different. Suppose I tell you I love a restaurant that I went to in Napa Valley. Claims data would be as if I showed you the final receipt, so you could see what I paid, but you wouldn't really know what I ordered, or any clue why I liked the restaurant. But with electronic medical record data, you can see exactly what I actually ordered. In healthcare terms, you get the results of lab tests, vital signs and every pulse rate and the pain scores and details about every medication and encounter.

Now how do we safely and respectfully use this data? First of all, we've got to de-identify the data. This has and will remain a hot topic in the press, because a lot of people don't understand that we don't just make up how to de-identify data. The rules are actually specified in federal law, and we have to ensure the users of this data don't break the rules. But to keep a close eye on this, and to promote the right and safe and respectful way to use clinical data, the University of California just hired Cora Han as its first chief health data officer, who is joining us from the Federal Trade Commission.

Why is this data relevant to the pharma industry or the biotech industry? In any given year, the University of California spends billions of dollars on drugs for our patients. As you may have guessed, most of these drugs are biologics. But each of our medical systems often has a choice in these medications. So one can ask why did UCLA use this one and UCSF use that one? And why didn't they even buy them together? And which is the one drug they both should purchase? Work like this are called comparative effectiveness studies, and now health systems would not even need a grant to do this kind of research. It's going to be in their (and our) financial interests to do it. That's the point of having real-world data.

In the first year and a half that we've been up and running, we've already saved the system millions of dollars. For example, in our own self-funded health plan, we noticed that many of our employees were getting prescriptions for brand name Metformin instead of generic Metformin. With the help of primary care physician leads and pharmacists, we now save a million dollars a year, just for that one drug. And we're working on more than a dozen others like this. This fruit is hanging so low, it's almost spoiled.

How has this affected research and clinical trials? Here's an example of how real world data overpowers pivotal study data. If you look at the original pivotal studies done on Humira over a decade ago, around 1,500 to 2,000 patients were treated in those studies. But we've now treated over 10,000 patients with Humira! So here's my prediction: at some point, we as health systems are going to be able to argue that we might know more about these drugs than their originators, because we just keep collecting more and more data on all of these drugs, every day.

In the end, we're enabling all University of California research faculty and staff, not just in the health system, to get to this data in a safe, respectful, and responsible way. So if you want to show how data can improve the US healthcare system, this will be an awesome reason to come work at the University of California.


## The Secrets Behind Built-to-Last Companies

**Anne Wojcicki (Co-founder & CEO, 23andMe)**

**Konstantinos Alataris (Co-founder & CEO, Vorso; Founder & former CEO, Nevro)**

**Stéphane Bancel (CEO, Moderna)**

**Jeff Huber (Founding CEO & Vice Chairman, GRAIL)**

**Chad Robins (Co-founder & CEO, Adaptive Biotechnologies)**

**Anne Wojcicki**

All of you have pioneered areas where there wasn't a defined path forward. I find that the most important thing when you're defining a path forward is how you make decisions. So what do you do to help you make great decisions?

**Chad Robins**

You have to be a good listener and take in as much information and data as you can, but there's a lot of gut that's involved. You can have the best data in the world, but at the end of the day you have to make a call, because there is no perfect answer.

**Anne Wojcicki**

Do people below you feel like they're empowered to make decisions?

**Chad Robins**

Absolutely. If you're talking about company direction, the buck stops with you. But I believe decentralized decision making is the only way a company can grow and scale. You hire smart people and a lot of times just get out of the way and let them make their own decisions. They are the subject matter experts, certainly more than me.

One more point. I think empowered decision making should go all throughout the organization. You have to let people make decisions and also let them fail. You can't have a culture where people are so afraid that if they make a wrong decision, that they can never do anything again either. People need to know they can fail and be okay.

> I wish we'd had a conversation with the government sooner than we did. It feels daunting, but at the end of the day, it's just people on the other end of the table.
>
> — Chad Robins

**Jeff Huber**

I completely agree that really good decision making starts with listening, because there's no way that you can know everything in this business. There's too much science, and too many issues related to business and healthcare. One of the first things we did at GRAIL was to put together a scientific advisory board — a real advisory board. If you look at the top 20 people in the world, probably 15 of them are on our advisory board, and we lean very heavily on them.

At both GRAIL and before that at Google, we use a decision-making framework when real disagreements come up. It's a forum where we can make decisions. You have to write a statement of the problem, a statement of what you disagree about, and you need to show the pros and cons from all perspectives. And you need to agree that once a decision is made, it's binding.

We find that when people go through these steps, in about 95% of cases they figure out what to do without needing a decision to be made for them. And when you do need help, you end up having a very efficient and productive discussion.

**Konstantinos Alataris**

At Nevro, it wasn't so much about procedures or processes, but by a culture that was casually defined by the employees. You have certain people that create the space for a way of working in which everyone feels able to give their opinion. This is essential in a startup. Because if everyone from the CEO to the engineers isn't engaged and aware of what the company is doing and how things are going, you're not going to go anywhere. You should never be surprised if you're at a start-up and it goes out of business. You should have known that was coming six months ago.

**Stéphane Bancel**

One of the most difficult things is to balance technology risk and biology risk, because if you try something with a new technology and with new biology and it fails, you will have no idea if it failed because the biology was incorrect or because the technology was not ready. And since our technology was so new, we decided not to be too cute to think we knew what application would work best. So we did six different applications, and chose to start with the one with the lowest biology risk.

That way if it failed, we could be 100% certain it was because of the technology.

This led us to focus our first product on the flu, where there's very little money to be made. In fact, many people in the biotech industry called us names. But we weren't solving for the drug. We were solving for our platform. Because if we could get one drug to the finish line, we would be able to create thousands of other drugs.

> If everyone from the CEO to the engineers isn't engaged and aware of what the company is doing and how things are going, you're not going to go anywhere. You should never be surprised if you're at a start-up and it goes out of business. You should have known it was coming six months before.
>
> — Konstantinos Alataris

**Anne Wojcicki**

We all make bad decisions. What is the worst decision you've made, and how did you recover?

**Stéphane Bancel**

So I have two buckets of bad decisions. One is around hiring people. Hiring someone you've never worked with is really hard. We've learned that it's better to promote somebody even if you don't think they're quite ready, and figure out how to provide the coaching and structure they'll need to be successful. Because it's very hard to find people who will fit our culture and our pace.

On the business side, I sometimes don't move fast enough. If I could change one thing, I'd go back and create more vaccines earlier. If I'd done that a year or two earlier, we might be a bigger and very powerful company now.

**Konstantinos Alataris**

It's also people for me. Sometimes everything points in the right direction

about someone you've decided to hire, except you have that gut feeling that something's not right. And you say to yourself, "Hey, let's ignore that and focus on all the positives on the other side of the argument."

It's also a real challenge figuring out how to support new people in the startup phase. How do you take a young postdoc or a young kid that has all the talent in the world, and put them in a fast-charging organization that makes decisions quickly when they've never had a job in their lives? We've made mistakes by not having someone there to help people like that. And that takes a lot of work.

**Jeff Huber**

My biggest mistake was failing to recognize what a significant cultural challenge it was to get people from three different cultures to operate as one team. We needed to have the best scientists in the world because we're trying to get biology to elucidate signals that it never has before, to detect cancer at the earliest stages. We needed the best clinical study people, because we're running some of the largest clinical studies that have ever been done. And since we're very ambitious and want to get to the stage where we can treat the entire population, we need great technology people.

There's 100 million people in the US that are over 40 years old that we would like to be able to reach with our test. Since we were generating about half a terabyte for every test we were doing, GRAIL was going to be a zettabyte scale application, in the same league with Amazon, Google, and Facebook.

Making matters more difficult is that we were kind of shot out of a cannon. The company was spun out of Illumina, and on day one had 40 people. We raised $100 million in the A round and almost a billion dollars in the B round. I thought we were okay because we had a clear mission — to detect cancer early when it can be cured — and a very clear statement of purpose, which was to save lives. What I missed was that with people coming from so many cultures, we couldn't just count on a mission and a statement of purpose. We needed to collectively understand our values and our culture. It was only when we got to 120 to 150 people that we really invested in a process to articulate our values.

**Chad Robins**

The biggest mistakes I've made are also around people — in particular blowing through stop signs and hiring someone because they were a big name, but not a cultural fit. We don't let that happen anymore if we can avoid it.

I also wish we had gone in and just had a conversation with the government sooner than we did. It feels daunting, but at the end of the day, it's just people on the other end of the table. I know that based on some of the relationships that I now have, if we had reached out and engaged that we probably could have done the dual track pathway for our first product, to get FDA approval and Medicare approval at the same time.

**Anne Wojcicki**

Another hot topic today is diversity and inclusion. People say, "Oh, it's really hard to find women, it's hard to find minorities." What are you guys doing to change the numbers?

**Chad Robins**

I don't believe it's hard to find good women or good African-Americans or good whatever. There are great people everywhere and some of it is just a matter of not only where you look, but of being open to candidates that may not seem to have the requisite skills on paper, people who can bring a different point of view and skill set and set of experiences to the table. I don't believe in hiring quotas, but I do believe in setting up a culture so that it happens naturally.

> Since our technology was so new, we decided not to be too cute... We did six different applications, and chose to start with the one with the lowest biology risk. That way if it failed, we could be 100% certain it was because of our technology.
>
> — Stéphane Bancel

**Stéphane Bancel**

We have 56 or 57 people, and I wish we had a bit more female representation at the senior leadership level. One of our rules is that for the top three or four levels in the company, you must have a female candidate before you can make an offer. But you just have to work at it. There's no other way around it.

**Jeff Huber**

I have a question for our moderator. 23andMe recently hit a major innovation milestone, with your first drug candidate license. How did you do that, since it seemed like a big departure from where most people thought the business was heading?

**Anne Wojcicki**

Yes, a lot of people were surprised. But even in our Series A document, we talk about the fact that drug discovery could become part of what we do.

But it did take nine years. So one of the most important things, particularly in the sciences where there are so many skeptics, is persistence. In the tech world people are like, "Oh you have a great idea? You want to do it tomorrow?"

**Audience Member**

So as you guys raised capital, did you have recommendations from investors that you had to ignore in order to make sure your companies lasted?

**Stéphane Bancel**

Yes. We always try to be very, very up front about our strategy with everybody, and make it very clear that if you don't believe in it, please don't give us any money because it's not going to end up in a happy place.

**Chad Robins**

As a platform company, there are certain investors that say we should spin things off, or capitalize on them in other ways. But given where we are in the life cycle, with our intellectual capital and shared resources and learnings, I think breaking the company apart would kill us. So we've had to ignore some of those calls.

**Anne Wojcicki**

So this is the last question, and it's on moonshots. How do you guys support big ideas that you really have no idea if they can work? Do you try to cultivate them?

> One of the most important things, particularly in the sciences where there are so many skeptics, is persistence.
>
> — Anne Wojcicki

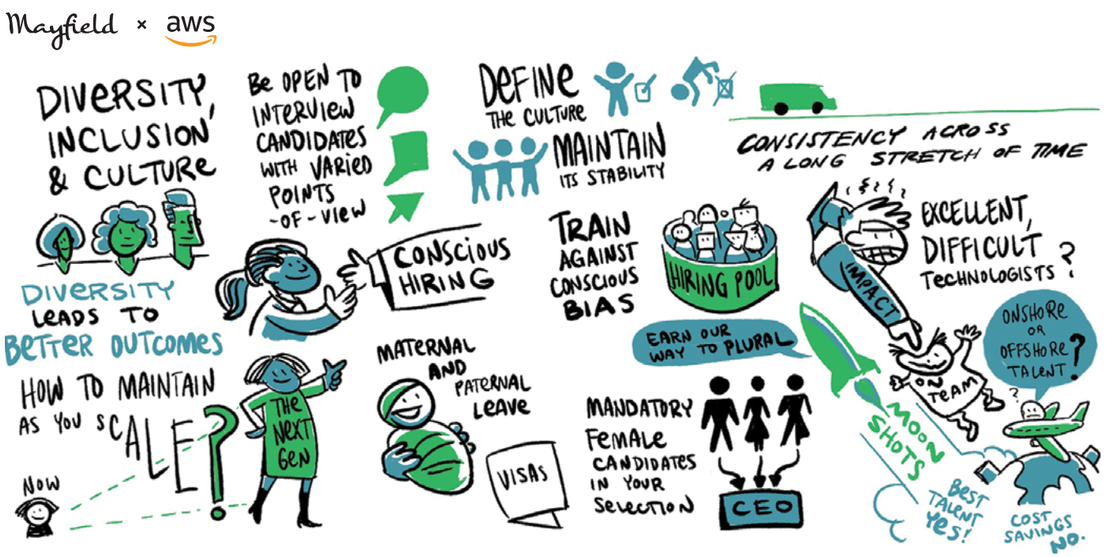
**Chad Robins**

We've got some really big opportunities, but it depends on the stage you're at as to whether they are moonshots or just big meaty opportunities that are going to take some time. Either way, you have to have a patient set of investors, and a patient board that understands how data can be used for clinical decision making, because it's hard to change medical practice.

> We need to earn our way to plural. We need to deliver the first moonshot before we worry about the next ones.
>
> — Jeff Huber

**Jeff Huber**

What we're trying to achieve at GRAIL is a moonshot. But we have one very ambitious board member who always wants to do the next thing and the next thing. So we've had multiple discussions about the fact that we need to earn our way to plural. We need to deliver the first moonshot before we worry about the next ones.

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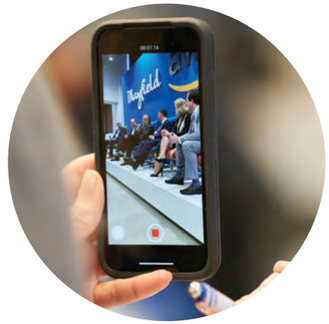



CONVOY

# Innovations in Care Delivery for Critical Conditions: The Provider POV


**Sam Glick (Partner, Oliver Wyman Health and Life Sciences Practice)**

**Albert Chan (Chief of Digital Patient Experience, Sutter Health)**

**Zak Kohane (Professor/Chair, Dept. of Biomedical Informatics, Harvard Medical School)**

**Lloyd Minor (Dean, Stanford University School of Medicine)**

**Lori Morgan (President & CEO, Huntington Hospital)**

**Jason Springs (Co-founder & CEO, Endpoint Health; Co-founder, GeneWEAVE)**


**Sam Glick**

In this panel we've got a disproportionate number of people from legacy healthcare providers, which are the means by which most people will access the innovations we've talked about today and will talk about all week. So this conversation is about how we really make that happen.

Jason, you are one of the few entrepreneurs that is focusing on critical care in hospitals. Why?

**Jason Springs**

Let me paint a picture. There are lots of companies focusing on cancer. For every 3,000 to 4,000 deaths from cancer, you can find about one industry-sponsored interventional trial. That works out to a few hundred drug trials and new therapy trials to cure or extend the life of people that have cancer per year. But there's only one therapeutic trial for every 70,000 deaths from sepsis, which kills one out of every two hospital patients in this country. So we saw a huge unmet need.

**Sam Glick**

Lori, you are CEO of a hospital, but you're also a trauma surgeon. How do you lower the odds that somebody dies from sepsis in your hospital?

**Lori Morgan**

I remember 20 years ago telling a student that by 2020, we'd be able to take a blood test to find out if someone's got type 2A, B, C sepsis, and then pull a bottle off the shelf and make them better. Well, we're not there yet.

I'm almost embarrassed to say this, though I don't think it's really different from other hospitals in the country, but the one thing we've done better in the last two years around sepsis is to get religious about hand washing. Honestly, that's what most hospitals are really trying to focus on.

> I'm almost embarrassed to say this, but the one thing we've done better in the last two years around sepsis is to get religious about hand washing. Honestly, that's what most hospitals are really trying to focus on.
>
> — Lori Morgan

**Sam Glick**

So if it's so hard to get people to wash their hands, what do you say to Jason when he shows up and says, "I have this new AI data-powered tool with a very different approach"?



**Albert Chan**

I tell him to think about workflow. Whenever I hear someone say, "Oh, if you just changed your doctor workflow," I say, "Stop right there." It's not like doctors are afraid of technology. They use CTs or MRIs, right? But it has to make sense in their workflow.

So I would urge him to partner. If you partner with the folks who actually do the work, you're going to get a better understanding of what it actually takes to do that work.

**Sam Glick**

Lloyd, you just built a brand-new hospital. How did you design it differently to be more data and AI-driven?

**Lloyd Minor**

The new Stanford Hospital is designed with technology in mind, but also very much with patients and families in mind. For example, every one of the 368 rooms is private and has a couch that turns into a bed so that relatives and family members can stay with their loved one. Additionally, every patient receives a tablet they can use to monitor their activities for that day. They know when their CT scans or MRI scan will be, and they can order their meals. I think increasingly what we need to focus on is making high tech enable high-touch healthcare.

> Whenever I hear a vendor say, "Oh, if you just changed your doctor workflow," I say, "Stop right there."
>
> — Albert Chan

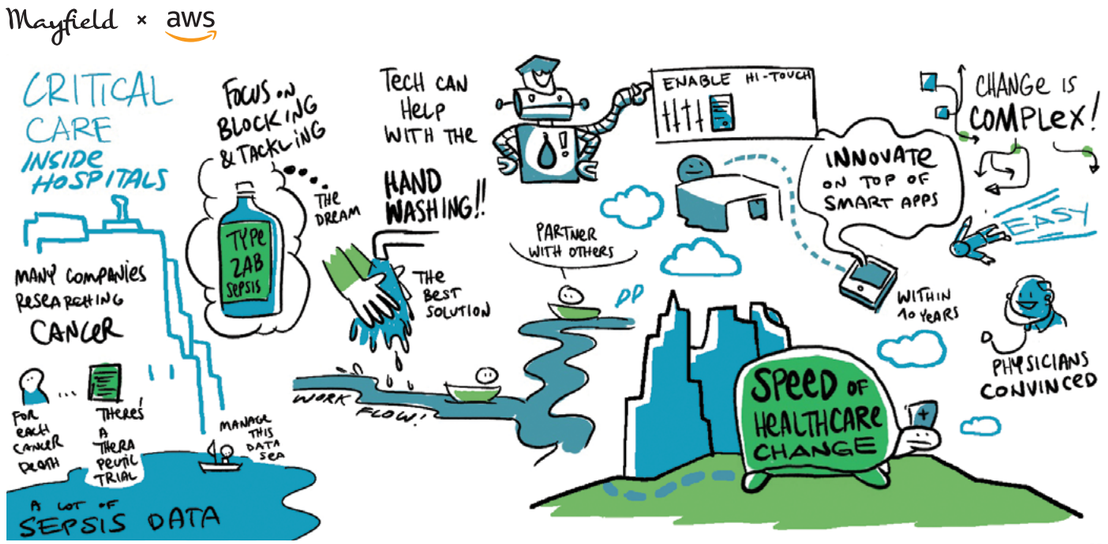
**Sam Glick**

Zak, you spend a lot of time thinking about bioinformatics. What works and what doesn't?

**Zak Kohane**

What doesn't work is expecting the healthcare systems to change at the speed we would like it to. I was listening to my brilliant former student Atul Butte talk about the billions of dollars that we're spending on Epic. Guess what technology Epic was built on? A technology called MUMPS that was a wonder of the world when it was implemented by Massachusetts General Hospital in 1966. The fact that we're paying billions of dollars for something in 2020 that is that old tells us something about the rate of change.

Here's a trend that may take less than 45 years to be the grand slam: activating the patients, who are the ones that care most about our care. We wrote an article in 2009 in the New England Journal of Medicine which was about why Health IT could not be more like the iPhone, because we were worried about expenditures on technology that was state of the art at best from 1980. We got funding for an idea to create apps on top of legacy platforms. This became the SMART-on-FIHR programming interface or API, which started slowly and wasn't a big deal. But what is a big deal is that Ricky Bloomfield at Duke implemented it on top of their Epic System, and was then hired by Apple. And Apple has now implemented the smart FIHR interface at scale.



Two years ago, it was used by a handful of hospitals. Three months ago, it was used in 340 hospitals. Today I just checked, and it's 420 hospitals. In two years, it will be in 1,400 hospitals. This is more data than even Atul has access to from UC. It's not just Fitbit data, which is nice, but actual clinical data. And we now actually think about how to liberate this data so patients or their surrogates can use it to act in the healthcare system.

So if I were to prognosticate where things are going next, I'd say that within a 10-year timeframe, the largest patient-controlled data pools are going to be in this new ecosystem where patients will expect decision support directly out of a device in their hand.

**Sam Glick**

Jason, somebody once said the challenge of working with hospitals is that the doctors blame the administrators, the administrators blame the doctors, and everybody blames Epic. You seem to have broken through some of that. How do you do it?

**Jason Springs**

Let's be honest: any individual hospital, whether it's 100 beds or 1,000 beds, is almost like a city. To get them to change, you need partnerships. Even before we were funded a year ago, we were talking with large academic medical centers. That's where the guidelines are written. That's where people figure out new types of practices.

We are announcing two partnerships soon. One is a clinical trial network specifically focused on figuring out how to deliver precision medicine to hospital patients — not just from a technology standpoint, which is only 10% of the problem, but the full suite of products and services that's required. Maybe it's a text message that reminds someone to wash their hands or run a test, or to make sure they've got the right materials in the ICU to deliver that medicine you believe will save a life. Because if you don't do the whole thing, from admission to discharge, the hospital doesn't save money, and it doesn't save a life. And if you're the vendor, you should be in trouble if you don't think of this.

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> — Jason Springs

> AI right now is not really even as good as a good commonsensical medical student.
> — Zak Kohane

**Sam Glick**

Lloyd, we probably won't see a lot of medical students walking around the JP Morgan conference this week. But it's the students who are in med school today who will be using many of the innovations we're talking about. What has to change about medical education?

**Lloyd Minor**

In our 2020 Health Trends Report, we looked at how prepared the physician workforce is to utilize and leverage the benefits of AI and machine learning and other digital technologies. The results were sobering. Only half of medical students in the United States feel that we're preparing them to really leverage and access the benefits of existing technologies, not to mention what's to come. The proportion of physicians who feel prepared is even less as you get out into years of practice.

What we need to do first is to envision medical education as a lifelong process. For far too long we've thought our responsibility was to the people who are with us at the time, our medical students, postgraduate trainees, and of course, the patients we care for.

Second, we need to provide more flexibility in medical school. In some years, two-thirds of the Stanford medical students take longer than four years to graduate, not because we're failing them or keeping them back, but because they're doing other things in addition to traditional medical education. Often, that includes quantitative data science. We've stayed with the model of having at least two preclinical years before students move full time into the clinics, and for those first two years, we follow the same calendar as the rest of the university. So, students can and do take courses in computer science and other areas of the university.

**Zak Kohane**

There's something very wrong with the fact that everybody in this room probably has a Google reflex to do a search when they want to find something out. But somehow that reflex is absent when it comes to medical care. But the good news — and I wasn't sure it was going to happen — is that our medical students crave that education.

Let me give you a very graphic example. We have a program at Harvard called Pathways, which is in its fourth year. In the first year, students take basic science classes. The second year is what we normally think of as the third year. It's a core of rotations; pediatrics, psychiatry, surgery and so on. And then the students, theoretically having been inspired by their clinical

experiences, go back to the advanced science classes, which will hopefully be much more motivating because they now they have more questions. And they're given the option to focus on various specialties, such as neuroscience, immunology, genetics, pharmacology and so on.

To make a long story short, more students applied for our computationally-enabled medicine course than any of the other specializations, despite the fact that it requires programming and accessing datasets through Amazon Cloud and through Jupyter Notebooks. Every year we have to turn people away.

**Sam Glick**

How do we avoid a world in which the hospitals who can afford innovative technologies are taking great care of people, and the rest are falling farther behind? Sutter is an interesting example, because you serve some of the richest and some of the poorest people in California.

**Albert Chan**

Technology can be a great equalizer if it is done right, but you need to ask leaders who implement technology to actually show their report cards and develop KPIs based on real outcomes. I have a program at Sutter where informatics students and fellows can come work on real world problems and figure out what it actually takes to implement new innovations. That's critical, because I don't remember anywhere in my biomedical education learning about leadership or change management or communication.

**Zak Kohane**

I think technology has a remarkable democratizing effect. For example, dermatologists collaborated with computer scientists to develop a deep learning algorithm that can make a diagnosis from a cell phone photo as accurately as the dermatologists.

> How do we avoid a world in which the hospitals who can afford innovative technologies are taking great care of people, and the rest are falling further behind?
> — Sam Glick

And we're starting to see innovation in the pathology realm. Radiology is ahead, because radiology images are digital to begin with. But it's becoming possible to digitize pathological specimens that are analog. Not every community hospital has a pathologist, much less subspecialty-trained pathologists. So technology can really help address

> What we need to do first is to envision medical education as a lifelong process.
> — Lloyd Minor

some of the disparities that have existed, although it won't be effective on its own.

**Lori Morgan**

I'm going to pick a little bit about technology being democratizing. The number of rural hospitals that are closing, particularly across the South, is going to present quite a crisis in healthcare. Some of that is due to the cost of technology, whether it's the latest CT scanner or PET scanner or EHR technology. In fact, technology costs are probably one of the biggest drivers of hospital consolidation in the last 20 years. So while technology is democratizing in some ways, it would be really great if it came at a really good price point.

**Sam Glick**

How should we regulate AI?

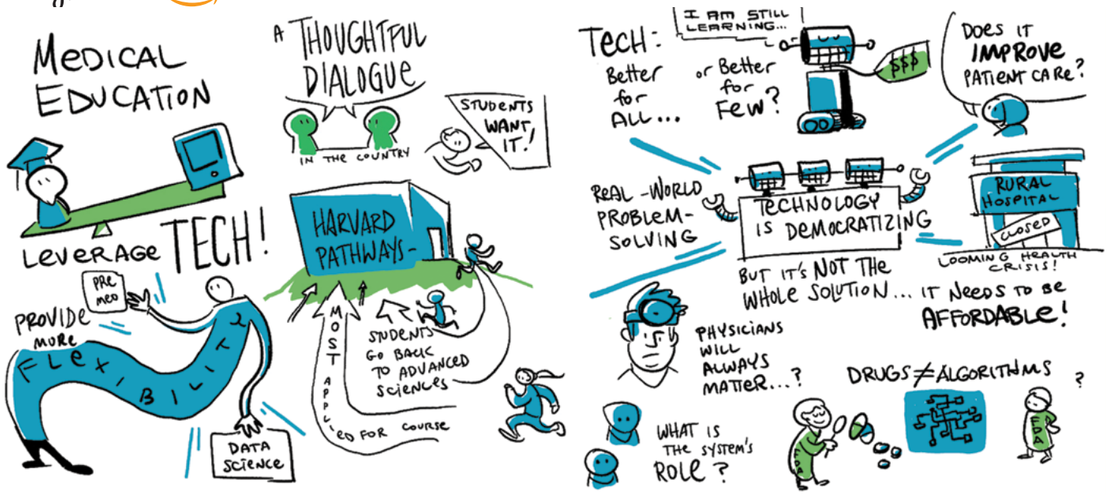
**Zak Kohane**

The problem is that on the one hand, we want to regulate it like a drug, because it can in some cases be just as powerful as a drug. On the other hand, there are things about these technologies that are very un-drug-like. For example, anti-TNF monoclonals are not going to evolve so fast that they will work better or worse in humans ten years from now. But the data that we use to train machine learning models may not actually apply in ten years. This is called data shift, and drugs are not susceptible to it. But algorithms are.

This presents a huge problem. The FDA already has enough trouble just regulating devices and drugs. But think about having to do an ongoing refresh of regulations. So I think we need to have a kind of Consumer Reports that does ongoing assessments of AI regulations, because the healthcare system is more dynamic than biology.

**Sam Glick**

How should we deal with the black box problem? We all have doctors we think are great, in part because they can explain what they're doing and can bring us along on that journey. AI doesn't do that.




**Zak Kohane**

I disagree with your premise. I think the best doctor is the one who's done a procedure the most often, whether they can explain it to me or not. So if AI were to give us enough value, I don't think people would require that much explanation. But this is all in the future. Because AI right now is not really even as good as a good commonsensical medical student.

**Lloyd Minor**

It's also important to remember that social, behavioral, and environmental determinants of health account for roughly 70% of ill health outcomes. So, I agree that if I'm going to have a surgical procedure performed, I want someone with a lot of experience. But to address those determinants, we need to look at the healthcare delivery workforce — nutritionists, lifestyle coaches, and others — who are engaging in a meaningful way with patients. Technology can play a role in this, but this is ultimately how we're going to improve healthcare, particularly in the United States. For three consecutive years, life expectancy in the United States has declined. The last time that happened was during World War I and the Spanish flu. The opioid epidemic contributes to that, but the data strongly suggests that we need to relook at the roles in our healthcare delivery system.

**Sam Glick**

We're coming up on time here, so let's end with this: what's the one thing you'd do to make healthcare better?

**Jason Springs**

I'm doing it.

**Lloyd Minor**

Fix the electronic health record and get it to be more user-friendly, interactive and engaging for both healthcare providers and for patients.

**Zak Kohane**

Get your data to flow with you across hospitals.

**Lori Morgan**

Make electronic health records more functional across the continuum of care, so doctors can spend more time with patients rather than staring at computer screens.

## Evidence-Based Care, the Role of the AMA, and Reducing Barriers to Innovation

**Dr. James Madara (CEO & Executive Vice President, American Medical Association)**

**Chrissy Farr (Health and Technology Reporter for CNBC.com)**

**Chrissy Farr**
We've seen lots of data come out about physician burn-out. How do we get to a place where physicians can really do what they've been trained to do?

**James Madara**
We did a time and motion study showing that for every hour a physician spends with patients, they do two hours of administrative work at the office and another couple of hours at work at home at night. And we have an emerging tsunami of chronic disease that is going to require even more continuous care in the future.

**Chrissy Farr**
Are EHRs helping to address this problem?

**James Madara**
The EHRs we have currently are pretty good for claims and billing and risk mitigation, but not very good for organizing and using clinical data. Administrators may feel that there's interoperability, but if you ask physicians, they don't see it. There's huge amounts of administrative complexity that has nothing to do with patient care.

**Chrissy Farr**
You've talked in the past about "digital snake oil" from technology companies that can't back up their claims with evidence. Is this still a problem?

**James Madara**
Yes. An example is Instant BP, a blood pressure app that was one of the top five most downloaded apps from the Apple Store for two straight years. Well, a group at Johns Hopkins found that its results were wrong more than 50% of the time, for a condition that is the number one killer. That, I would submit, is snake oil.

**Chrissy Farr**
Can patients rely on App Store ratings to help with this problem?

**James Madara**
There are about 300,000 mobile health apps out there, and about 40,000 of those are patient-facing. A group investigators and clinicians and technologists from Harvard picked out about 150 they thought were best and which had good reviews. They found that none of the 150 were usable, or provided appropriate warnings when dangerous trends were detected.

**Chrissy Farr**
Will AI take over any specialties or sub-specialties?

**James Madara**
I think AI is going to play a major role in healthcare, but it doesn't replace jobs. And you have to be careful to understand what's happening in the black box. One project looked at whether AI could look at chest films and identify which lung cancer patients were going to need a lot more care than others. The answer came back that yes, the AI could do it. But when researchers studied the algorithm, they found that the people who would need more care were simply those that needed portable x-rays, because they couldn't be moved to the radiology suite at the time. That wasn't that helpful.

So you can be an optimist or a pessimist on AI, but I'd take a third choice: be an empiricist. What does the data show, and how do we know it? What do we expect to happen next, and does it actually happen?

**Chrissy Farr**
Google's partnership with Ascension Health has led to debate about whether HIPAA needs to be upgraded, to define more clearly how tech players need to protect patients' privacy.

**James Madara**
We believe we need transparency, and an understanding that the data belongs to the patient, and the patient has to give permission to use it. And there needs to be data rights built into electronic transfer. Because while I may agree to release my data to my physician, you can't be sure what will happen to it once the data moves elsewhere. The fact that Ascension and Google made this relationship through a business associate arrangement, which was legal to do, shows that regulation never keeps up with technology.

> You can be an optimist or a pessimist on AI, but I'd take a third choice: be an empiricist.
>
> — James Madara

**Chrissy Farr**
Do doctors need to take a more active voice on issues such as patient rights? Should they unionize?

**James Madara**
Graduates from other professional schools, such as MBAs and JDs, have a huge effect on every industry in the United States, but MDs tend to stick to their knitting. They just see patients, because that's what they like to do. That means we lose their input on a sector of the economy that makes up 20% of the GDP. In particular, I think physicians need to insert themselves more in the development of products. That was a factor in the creation of Health2047 and some other parts of the AMA innovation ecosystem. I sometimes wonder what would have happened if my good friend Judy Faulkner had physicians with her in her garage 30 years ago. Would Epic look any different than it does today?

We don't believe that physicians should be unionized. We don't think that aligns with the best care for patients, or with our aspirations to improve the health of the nation.

**Chrissy Farr**
What would you most love to accomplish in the next 12 months that would make a big difference for doctors?

**James Madara**
The thing that needs to be addressed first is fragmentation of the healthcare system. That's why issues around data — data liquidity, data portability, virtual scribe, social determinants of health — are going to be the hot spots over the next five or 10 years.

Note that all of these topics relate to pre-competitive needs. We're in a national debate now about whether we're going to have a single payer system or a public option or some other set of competitive rules. Who knows what will happen, but I do know this: if these pre-competitive needs are not corrected, it doesn't matter what health system we end up with because it won't work.