

Session 3: Deep Innovation Dive in Health Equity: Truveta (“*Saving Lives with Data*”)

Summary of Proceedings by McKaylin Hughes

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Speaker: Dave Heiner, Chief Policy Officer and General Counsel, Truveta

Abstract: This session is a “deep dive” into health equity and research via a moderated discussion with Truveta, a new data partnership company poised for research breakthroughs in the healthcare sector. In it, Dave Heiner, General Counsel and Chief Policy Officer for Truveta, discusses the company’s healthcare-centered mission and the key role that data plays in the healthcare field.

I. Introduction

Moderator and Seattle University School of Law Professor, Steven Tapia, and Truveta’s General Counsel and Chief Policy Officer, Dave Heiner, first met sitting across from one another when Tapia was interviewing for a position at Microsoft over 26 years ago. Since then, Tapia and Heiner have worked together on and off for about 15 years in a variety of different contexts.

Professor Tapia opens the session by briefly introducing Dave Heiner. Expanding on this introduction, Heiner explains that he started his career at Wall Street law firm Sullivan & Cromwell. While at this firm, Heiner provided legal advice on intellectual property issues related to technology and anti-trust issues. In the early 1990’s, one of Sullivan & Cromwell’s clients was then-young company Microsoft. In 1994, Heiner left Sullivan & Cromwell and became an anti-trust attorney for Microsoft, where he then worked for 21 years. There, Heiner worked directly with then-CEO, Bill Gates, and other notable names at Microsoft, including Steve Ballmer and Brad Smith. After about 19 years, Heiner took over leading the Regulatory Affairs Team at Microsoft. Heiner explains that the team dealt with a range of regulatory issues on a global basis, including privacy, telecommunications, financial services, human rights, and Internet safety. Internet safety includes Internet bullying, harassment and child pornography, among other things.

It was while doing this work that it became apparent to Heiner that data was going to become the next big thing. Then, within a few years, everyone began talking about artificial intelligence.

Since Heiner had already focused on data through his privacy work at Microsoft, he was one of their first lawyers tasked with thinking through the legal issues surrounding artificial intelligence. Heiner spent two years at Microsoft specially focused on public policy issues around artificial intelligence. He also helped start up and serve as a legal representative on the Artificial Intelligence Ethics Advisory Board at Microsoft. The board was established to determine how Microsoft should deal with the interesting issues that artificial intelligence raises, including facial recognition and the like.

In November 2019, Heiner retired from his successful career after 25 years at Microsoft. Then, in March 2020, the Covid-19 pandemic shut down the United States and any plans Heiner had for a fun-filled retirement. After a very short-lived retirement, Heiner began working at Truveta later in 2020.

Truveta was founded by Terry Myerson in September 2020. One morning, Heiner was drinking coffee and reading about Truveta, the data it was compiling, and their healthcare-focused mission. Heiner was familiar with Truveta CEO Myerson through their work at Microsoft, where Myerson served as the former head of Microsoft's Windows and Devices Group during Heiner's employment there. Not much later in the year, Heiner was hired as General Counsel and Chief Policy Officer for Truveta.

II. What is Truveta Up To?

Dave Heiner explains that sector after sector of the economy is being transformed by data. He says, "Google and Facebook collect our data and use it to target ads more effectively than any newspaper or magazine could do, upsetting the traditional economics of that whole industry."

However, there are two sectors that are continuously lagging: education and health care. For years, a question among top leaders in the healthcare field has been, "how can we make better use of healthcare data?" Heiner explains that the healthcare sector can be slow to move and implement changes. As an example, he states that it was not until about 2010 that electronic medical records, instead of printed medical records, became normalized across the United States. However, there are numerous issues that dramatically complicate the use of healthcare data, including the fact that the data comes in many different formats and is stored on numerous platforms, in addition to endless data privacy issues.

Heiner states that "when Covid came along, it was just so obvious right from the start that there was insufficient data to understand Covid." In addition to this problem, there was also a problem with conflicting messages and misinformation broadcasted by political leaders. It was these problems that forced the health care systems to come together and work with entrepreneurs in the Seattle area to create and identify a model for a company, which would later become Truveta. This company would be owned by the healthcare systems so they can act as a consortium together to pool all their Covid-related data.

Truveta collects patient data via electronic health records and other records, anonymizes that data, and then pools it into one data set. According to Heiner, "today, already, we have patient data that accounts for 16% of all patient care in the United States across 42 states." This data set then becomes available to researchers who can utilize the data sets in various ways. Truveta has information on every disease and everything that is going on at the hospitals. The information is updated on a regular basis and is made available to researchers for a fee. The fees are then given as royalties to the healthcare systems to advance their business models. Since most of the hospitals are non-profits, the royalties considerably help these hospitals pursue their healthcare missions.

Dave Heiner explains that Truveta is in the early stages of developing a platform to allow the same healthcare data sets to become available on a community level. The platform would enable researchers to come to the website where they can utilize various tools to engage in data analysis with the data sets. On the website, researchers could conduct research in private, or they could choose to contribute to a study, almost like an open-source model. Then, the community could comment on it, copy parts of it, duplicate the study, or try the study a different way and report back on their results.

III. Why Seattle? Is There Something Unique About Seattle That Makes it a Great Place for Truveta to Call Home?

In answering the question, “why did Truveta decide to call Seattle home,” Dave Heiner states that it is simply because of the vast technology talent and community available in the Seattle area, in large part due to Bill Gates bringing Microsoft to Redmond, Washington, just outside of Seattle. Now, Seattle is home to many huge technology companies, including Amazon, Google, and Facebook, among many others.

A. Seattle as a Place that is Willing to Push the Envelope and Pursue Innovative Ideas

Some people are more willing to take risks than others. Heiner wonders if in any part, being more willing to take risks is genetic? Since the United States has been a leading engine of innovation into the 21st century, Heiner posits if this could reflect the fact that people who chose to come to America were risk takers: people who left the world they knew behind, in search of something better in America.

Professor Tapia expanded on Heiner’s insights, adding that the people who chose to come to the United States in the 17th Century self-selected. Tapia explains that these people were extremely willing to find the best in whatever situation they were in, including packing up their families and embarking to a new and unknown land. Tapia wonders if this created a genetic proclivity for being adventurous.

B. Seattle-based Company, Remote Workers

Since Truveta was founded in September 2020, during the Covid-19 pandemic, all of the employees were hired remotely and work remotely. Heiner explains that the company is leaning into the remote work approach. Currently, Truveta is a national company with 30% of the employees located outside of the Seattle area.

V. Impersonalizing Data: How Can Medical Information Can be Separated from Individual Patients?

Heiner explains that under the current HIPAA model, when patients go to the hospital and sign the consenting forms, part of what they are consenting to is allowing the hospital to use those records for healthcare operations. This includes administration, financial, legal, quality improvement, treatment and care, etc. The hospital can then contract with others to process the data and create data sets for healthcare operations.

This is what Truveta does. Truveta contracts as a service provider with each individual healthcare system to process their systems healthcare data. The first step is for the healthcare systems to send Truveta their data. Truveta then normalizes the data. “Normalizing data” means that Truveta reformats the data in a way that makes it accessible and useful for every hospital. Since different healthcare systems use different formats for their data, normalization assures that the data is accessible to all users. Once all the data is inputted, it is put in a common model using artificial intelligence.

Next, the data is anonymized. HIPAA provides two ways to anonymize data. The first is called the Safe Harbor Method, which entails stripping out the name of the patient in addition to 17 other identifiers to ensure that a patient could not be tracked based on any of the remaining available information. The second method, currently used by Truveta, uses a range of statistical techniques to either delete data, change, or mask certain data. Then a 3rd party expert comes in to analyze and certify the data. Once the data is fully anonymized, the data is moved to the Truveta platform. Here, the data is combined with data from the other healthcare systems and made available for hospitals and healthcare systems.

“For most of the research on the Truveta platform, the researchers do not need to see individual records. They are dealing with cohorts of patients to see patterns,” says Heiner. In addition to medical data, there is some socioeconomic data in the platform, so for example, a researcher could determine if the data set they are analyzing shows any changes among patients based on their socioeconomic status.

VI. HIPAA and The Control or Ownership of Medical Data

Heiner states that because of how HIPAA is set up, once the patient’s data is anonymized, the patient no longer has an interest in their data and it can then be used for any purpose. Truveta’s purpose is to improve healthcare research and is a digital form of what was happening in the analog world.

“When you go to see your doctor, you are relying on the experience of your doctor, which is based on his or her medical training, and 10, 20, or 30 years of seeing patients,” says Heiner, “and those are all data points... that the doctor is bringing to bear when s/he treats you.” He goes on to say that “[Truveta] is basically telling the research community: let’s bring that at scale. Let’s let everyone learn from all of the experience of all the doctors, and then the outcomes of all the patients.”

Heiner explains another point of view—that of the individual patient, who might think “I don’t want to participate in all of this, I don’t want my data being used even if it is anonymized. Is my data really anonymous? Is there really zero risk of reidentification?” Heiner explains that one of the things Truveta is looking at doing is attempt to build a system where individuals could opt-out of participating in the system. This technology, however, is still in the works.

“The privacy community talks about ‘my data,’ but the concept of actual ownership of that data, which implies the right to hold it, or to monetize it, isn’t really there under U.S. privacy laws,”

says Heiner. He talks about different theorists who are discussing the ways in which people might be able to come together to pool their data. Then, as a group, they would have some ownership of their data.

Heiner explains that the European Commission recently drafted a proposal for what they term the “European Health Data Space,” a platform that would make healthcare data available to anyone who wants to study health care, at the cost of providing the data. Here, data is being seen as a public good.

VII. Will a System like Truveta Make it Easier or More Difficult for Lawyers to Request Clients’ Medical Records for a Case?

Heiner states that in his opinion, Truveta will not make it any easier or more difficult for attorneys requesting clients’ medical records for their cases. Heiner explains that the way Truveta is set up, the patient’s data is only identified when it is still with the patient’s healthcare system, who Truveta is acting as a service provider to. For example, if Truveta was given a subpoena to turn over a specific person’s medical records, Truveta would try to get the treating patient’s healthcare system to release the patient’s medical records, since they are still the owners of the data.

VIII. Mental Health: Distinguishing Between the Personal and Public Good at Truveta

Heiner explains that there are special provisions in HIPAA that relate to mental health data and Truveta does not have much mental health data. He further explains that Truveta is just starting to work with “clinical notes,” so if a patient did express to the doctor that they were “depressed” or experiencing another mental health condition, that would be in the clinical notes and passed along to Truveta. This is a currently a known problem that Truveta is working on solving within their platform. Their main concern is how to de-identify these clinic notes.

IX. What Safety Mechanism(s) Does Truveta Envision for Extreme Situations Where the Popular “Public Good” Perspective Might Be the Extermination of Disabled, Transgender, or Indigenous Peoples?

Part of the mission of Truveta is promoting health equity for all people. Truveta is focused on identifying the disparities in health care that are a function of income, racial groups, religion, etc. Then, there is the question of “what can you do with the data in the Truveta platform?” Responding to the overarching question, what Truveta could as a safety mechanism is to limit the use of their data to only hospitals and healthcare research.

Heiner goes on to say that “research” is a very broad term. Questions that Heiner and the Truveta legal team are currently thinking about include, are there “questions that should not even be asked on Truveta? Is there research Truveta does not want to have conducted on their platform?” Then, they also need to think through the next set of related issues, such as “when some areas of research are questionable and reasonable people differ dramatically – what should Truveta do? Are there areas of research where a company like Truveta should say, ‘We’re not open for that kind of research, we don’t want our data used in that way?’”

X. How Does Truveta Ensure that Information is Not Leaked from their Platform to Insurance Companies?

Heiner's response to this question was that Truveta does not deal with any insurance companies. "This is core to the mission of the whole company; this is core to the people that we will do business with," says Heiner, "[and] Truveta is only about healthcare."

XI. What is Your Role as General Counsel at Truveta? What Do You Do?

Heiner is General Counsel at Truveta and his official title is Chief Policy Officer. Heiner spends a lot of his time thinking about policy and policy-related questions like, "what ethical pitfalls does Truveta need to be on the lookout for? Where does Truveta need to insert themselves? What is Truveta's responsibility?"

Heiner explains that as a lawyer and Chief Policy Officer, he needs to frame up the issues. He asks, "what is it that the company needs to think about?" Then, he brings the framework of the issues to the senior leadership team. As a company, Truveta then establishes a point of view, which is then presented to the healthcare systems. Within the healthcare system, the issue is then presented to many different groups, including research advisors, ethics advisors, and privacy and security advisors, among others, who will give their input on the issue.

XII. What is Your Advice to Law Students?

Be curious all your life and keep learning. Go for a breadth of experience as you move through your career, because you never know when you're going to want to change careers and a range of experience will help you move onto the next chapter.