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Disrupting the Clinical Research Industry

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By Merging Clinical Trial Software Development and Clinical Trial Delivery

Back in August of 2011 in the Wall Street Journal, Marc Andressen, the famous venture capitalist, said the following in a now classic editorial titled “Why Software is Eating the World”:

“More and more major businesses and industries are being run on software and delivered as online services—from movies to agriculture to national defense. … Over the next 10 years, I expect many more industries to be disrupted by software ...”

Andressen was prescient, and the world has seen many industries “eaten” by software, and then by software’s successor, software-enabled platforms.

Regarding the healthcare and education industries, Andressen stated the following:

“Health care and education, in my view, are next up for fundamental software-based transformation. My venture capital firm is backing aggressive start-ups in both of these gigantic and critical industries. We believe both of these industries, which historically have been highly resistant to entrepreneurial change, are primed for tipping by great new software-centric entrepreneurs.”

As we approach the 8-year mark since Andressen wrote his editorial, what progress has been made towards “fundamental software-based transformation” of the clinical research industry?

Following is a statement from former FDA Commissioner Scott Gottlieb from March 2019:

“But these opportunities [referring to precision medicine] can be delayed or stymied by a clinical research enterprise that is often extraordinarily complex and expensive. Efforts to streamline medical product development based on advancing science can be frustrated by legacy business models that discourage collaboration and data sharing, and the adoption of disruptive technologies that make clinical research more effective. Without a more agile clinical research enterprise capable of testing more therapies or combinations of therapies against an expanding array of targets more efficiently and at lower total cost,

important therapeutic opportunities may be delayed or discarded because we can't afford to run trials needed to validate them."

Clearly, according to the former FDA commissioner, the clinical trial industry in 2019 has not been transformed, and since collaboration, data sharing and disruptive technology are all based in large part on software, it is fair to conclude that the software-based transformation Andressen posited has not taken place in the clinical research industry.

Why is that?

In December of 2018, David Connelly, Founder & CEO of Cmed Group LTD, wrote the following in Applied Clinical Trials.

"We still tend to focus on technology and systems separate from processes. Though there are indications in the market this is now changing, traditionally, clinical service vendors are also separate from clinical trial software vendors. … Who believes we are at the forefront of all industries in applying modern technology and smart processes in clinical trials?"

Connelly is suggesting that one of the root causes of the lack of progress in transforming clinical trials is that the companies that develop clinical research technology/systems are distinct from the companies that utilize those technology/systems to conduct a clinical trial.

Later, Connelly lays out a more specific vision of what this transformed clinical research reality would look like:

"Why not have one purpose-designed system (or systems) with one database that can manage all the data for your clinical trial, rather than have separate systems and tools for eDC, ePRO, esource, lab, safety, econsent, reporting, analytics, etc. Avoid the Frankenstein of patchworked systems, all with their own databases, management, and support systems, and all the costs, inefficiencies, and delays they cause—even when "integrated." Using one system, together with embedded workflow and communication tools commonly in use elsewhere, can unite rather than fragment clinical trial teams, allowing them to operate more easily as one team, including between sponsors, CROs, and sites."

Synthesizing the discussion to this point:

- Software has transformed many industries but not clinical research.
- Combining software development capabilities and clinical research delivery capabilities in the same company could solve a key problem that is impeding the desired industry transformation, as those who use the software to run clinical trials and those who build the software would be tightly and structurally linked.
- The desired output of this marriage would be a single system (platform) that would:

o Gather all clinical trial data into one data structure.

o Use workflow and communication tools commonly in use on other platforms in other industries to unite currently fragmented clinical trial teams.

- The resulting platform would allow for clinically relevant data to be generated quickly and cost effectively, allowing for the validation, and ideally, the commercialization, of an important therapeutic offering that might otherwise remain unexplored due to cost.

If we could find a company that has accomplished the above, then we could presumably build similar companies using the same model, and thus speed up the desired transformation of the clinical research industry.

Let's look at a company that meets these criteria: Virta Health.

Virta Health was founded in 2014 and has raised $82 MM USD in several venture rounds.

Here is a summary statement of what the company does from their Crunchbase entry:

"Virta is an online specialty medical clinic that reverses type 2 diabetes safely and sustainably, without the risks, costs, or side effects of medications or surgery. Our innovations in nutritional biochemistry, data science and digital tools combined with our clinical expertise are shifting the diabetes treatment paradigm from management to reversal. Our mission - to reverse type 2 diabetes in 100 million people by 2025."

Virta builds full stack software. Here is an overview of the responsibilities of a "Senior Software Engineer, Full Stack" at Virta (from the Virta website) that shows the tight linkage between the software platform and clinical activities:

“As a Senior Full Stack engineer, you will make key contributions to the applications, tools, and workflows across the entire patient journey at Virta:

- Creating the cross-platform experience that allows our patients to receive first-class remote care at scale
- Building the next generation healthcare platform that allows our clinical team to serve patients 24/7
- Streamlining the application process that makes applying for medical care as easy as creating a social media account
- Providing the data and insights to employers and health plans that show the efficacy of the Virta Treatment using aggregate patient data in a safe, secure, and respectful way”

Virta has been running an open-label, non-randomized, controlled clinical study on their platform and has published extensively in peer-reviewed journals based on trial data. Here is a summary from an article that appeared this year in Frontiers in Endocrinology:

“At two years of treatment, Virta trial patients still experienced clinically significant improvements in HbA1c %, metabolic syndrome rate, and markers of inflammation. More than half of trial completers met the criteria for diabetes reversal, and a significant portion of those individuals also had partial and complete diabetes remission. Along with these improvements in health outcomes, 67% of diabetes-specific prescriptions were discontinued, and 91% of patients who began on insulin either reduced or eliminated their insulin dosage.”

Finally, due to the positive clinical outcomes and the cost effectiveness of the platform-delivered nutritional program, Virta has now been able to partner with a number of insurers and employers, including the Department of Veteran Affairs in the United States, to bring its treatment to patients.

So, if the right approach is taken, software can “eat” clinical trials.

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