FDA approves stroke-detecting AI software

The US Food and Drug Administration (FDA) has cleared a deep-learning algorithm that analyzes images to detect potential strokes. The computer-aided image software system from San Francisco-based AI-health firm Viz.ai, identifies suspected large vessel occlusion (LVO) strokes, and sends a notification by text message to specialists, who can view the results on their phone and decide whether to initiate emergency treatment. The approval is the first for a newly introduced regulatory classification for computer-aided triage software, within the FDA's 510(k) pathway. "The Viz.ai LVO Stroke Platform is the first example of applied artificial intelligence software that seeks to augment the diagnostic and treatment pathway of critically unwell stroke patients," said Chris Mansi, neurosurgeon and chief executive officer of Viz.ai, in a press release. In addition to the FDA's go-ahead in February, the Viz.ai LVO Stroke System received a CE Mark by the EU in January, confirming its compliance with health, safety and environmental regulations. The system analyses computed tomography (CT) scans and sends an alert in approximately 6 minutes if it identifies a suspected LVO. According to Viz.ai, a study involving 300 CT scans comparing the performance of the software with that of neuroimaging specialists resulted in faster detection by the software in more than 95% of cases and saved an average of 52 minutes, an improvement that could slash the time to intervention that is critical for stroke recovery. According to the American Stroke Association, almost 800,000 people in the US have a stroke each year. There has been growing interest in the use of AI to assist clinicians' diagnoses. (*Nat. Biotechnol.* **35**, 604–605, 2017).

"I had this whole rationale for why these three [DNA variants] would have an effect. But let's cut to the chase: We didn't replicate that study, we didn't even come close." Christopher Gardner, Stanford co-investigator on a study of the effect of genes on dieting, admits they were unable to replicate preliminary studies that suggested DNA could predict who would succeed on low fat versus low carb diets. (*STAT*, 20 February 2018)

"Gilead gives CRISPR the Zinc finger." EP Vantage tweeted about how Gilead chose to sign a deal with Sangamo, the zinc finger company, for developing T-cell therapies, unlike Novartis and Celgene, which hooked up with CRISPR companies. (*@EPVantage*, 22 February 2018)

Roche. Others have tried to tackle the challenge of messy records with artificial intelligence and machine learning approaches. San Francisco-based Mendel Health for instance has developed an artificial intelligence (AI) platform to identify patients from unstructured electronic health records and match them for clinical trials, though search results are first checked by a staff of oncologists before they are reported to users. It relies in part on methods designed for recognizing Arabic characters and translating them into English. Though that application differs from Flatiron's, the problem they address is the same, finally tackling the cumbersome task of making all existent data gathered on cancer patients useful. Flatiron's approach has been to start with careful human curation, and then layer in AI for very specific data abstraction tasks using the resulting data quality as a guide as to when AI is or is not good enough.

Some see Flatiron's nationwide operation and data cleaning tools as unrivalled. "Every company that wants to use machine learning to clean up data ignores the fact that at the end of the day you have to do the tough stuff," says Abernethy. "That we have been willing to take it on and do the real work has been important." The work devoted to documenting every individual data point has allowed Flatiron to create high-quality datasets clean enough to satisfy the expectations of regulators, peer-reviewed journals and skeptical clinical researchers.

Those data points have already greased Roche's path to regulatory approval. The company relied on Flatiron data to expand the label for Alecensa (alectinib), a treatment for people with non-small-cell lung cancer, to 20 countries. Regulators outside the US wanted more information on controls, and it might have taken Roche a year to satisfy those requirements through another route. In addition, Flatiron is working on tailoring its IT tools for clinical trials in order to make them more efficient, as well as to create "technical highways" to enable complex trials, where designs are altered after the trials have commenced.

Having Roche's financial backing will accelerate Flatiron's progress, no doubt, but Roche must allow Flatiron to remain independent, to reassure the oncologists who input data into OncoEMR, as well as the pharma firms that pay to partner with Flatiron, that Roche will not use those relationships to market its therapies or eavesdrop on rivals' drug development programs.

Roche's spokesperson Patrick Barth reiterated the firm's respect for Flatiron's independence, likening the acquisition to its relationship with Foundation Medicine, which continues to independently offer its menu of genomic tests for circulating and solid cancers, and trades on the NASDAQ stock exchange. "As autonomous companies, it is critical that this work continues without disruption," Barth says.

Foundation Medicine and Flatiron have also been collaborators since 2014. In 2016, they rolled out a clinico-genomic database containing information on roughly 20,000 patients, pairing Flatiron's electronic health records with Foundation Medicine's cancer sequencing data. Gaurav Singal, vice president of data strategy and product development at Cambridge, Massachusetts–based Foundation Medicine, says the database is currently used by a variety of pharma companies and academic researchers. "It's also scalable and continuously updated," he added.

Although Roche, Flatiron and Foundation Medicine all insist that following the completion of Roche's acquisition of Flatiron, things will remain business as usual for the three firms, Singal acknowledges that the common ownership of Flatiron and Foundation Medicine could certainly result in some "data synergies" going forward, though he did not elaborate.

The other company in the mix is Syapse, a firm that offers a menu of software tools for oncologists to store, share and access patient information. Although its remit is similar in concept to Flatiron's, the two companies differ on the types of data they collect, making their databases more complementary than competitive. Roche and Syapse are jointly developing software and analytics for oncologists, including tools for decision making, health economics and matching patients to clinical trials. Roche Venture Fund also invested in Syapse's $30-million series D financing last year, as did Amgen, Merck and GE, among others.

Syapse CEO Ken Tarkoff says he wasn't surprised by Roche's planned acquisition of Flatiron. Instead, he says the deal "validates what we have believed for a long time," that the "entire healthcare ecosystem" must cooperate to advance precision medicine for cancer patients. Flatiron's Abernethy similarly says that Roche's investments in Flatiron Medicine, Foundation Medicine and Syapse, showed the pharma has adopted a multipronged approach to gain access to the best data and tools it can to advance its drug making and diagnostics programs.

"If you are Roche, frankly you should have a lot of shots on goal," Abernethy says of Roche's relationships with the trio of companies. "This is an example of having many shots on goal."

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