

### ***Digital game-changers***

Healthcare leaders believe four digital technologies — artificial intelligence, big data analytics, mobile health (mHealth), and wearables — will be game changers this year, according to Frost & Sullivan. The market research firm predicts that the market for healthcare IT applications using artificial intelligence will reach \$1.7 billion by the end of 2019, growing at 68.5 percent of compound annual growth rate (CAGR) through 2022, reports [HIT Infrastructure](#). In addition, the market for digital health technologies enabling out-of-hospital care will total \$25 billion, growing by 30 percent this year. Key segments include remote patient monitoring devices, telehealth and mHealth platforms, and personal emergency response systems.

### ***The Theranos lesson***

Startups generate hype for their disruptive potential to advance healthcare goals, but few of the most highly valued ones publish evidence to support their claims, according to an analysis by Stanford University researchers, reported by [MedTech Dive](#). The researchers reviewed published research output of 47 "unicorns," or startups valued at more than \$1 billion. Of 18 current unicorns, 10 had no highly cited published medical papers. The rate for exited unicorns was 12 of 29. The lesson? Be wary of "stealth research," that is, data generated internally rather than through peer-reviewed research. Case in point: Theranos, the much-hyped startup that promised to upend conventional diagnostics with low-cost finger prick tests, but then imploded when massive fraud was uncovered.

### ***Loosen up on Stark, hospitals urge feds***

Proposed rules that would make changes to the Stark Law and anti-kickback statute are working their way through the federal review process and could be released this year, Department of Health and Human Services Deputy Secretary Eric Hargan said at a Brookings Institution event on Jan. 30. Last year the American Hospital Association urged the Centers for Medicare & Medicaid Services to create or adapt compensation exceptions to the Stark Law to enable hospitals and physicians to coordinate care and improve patient outcomes, and asked HHS to create new safe harbors under the anti-kickback statute to enable hospitals, physicians and patients "to work together to achieve value-based care and a patient-centered system."

### ***FDA's bragging***

Last year marked a record year for the U.S. Food and Drug Administration, supported by policies, processes and programs to help efficiently promote safe and effective innovation

in medical device development, [according to FDA Commissioner Scott Gottlieb, M.D.](#) and Jeff Shuren, M.D., director of the CDRH. In 2018, the FDA approved 106 novel devices, surpassing the 40-year record set in 2017 of 99 novel device approvals. The agency also approved or cleared nine breakthrough devices following Breakthrough Device Designation requests. Examples of innovative products that came to market in 2018: expanded approval of an automated insulin dosing system to include people with diabetes who are as young as age 7; the world's smallest heart valve for newborns; the first blood test in the world to evaluate mild traumatic brain injury ("concussion"); the first mobile medical app to help treat substance abuse disorders; and technologies using artificial intelligence to detect diabetic retinopathy in adults with diabetes and for aiding providers in the detection of wrist fractures. FDA also approved the first artificial iris in the U.S. and permitted marketing of a new prescription medical device that measures eye movement as an aid in the diagnosis of concussion.

### ***Where the innovators go***

Manufacturers of innovative medical devices, and specialty distributors and independent reps, will convene July 21-23 in suburban Chicago for "The Many Facets of Value," the Annual Conference of IMDA and HIRA. The Conference will feature presentations and workshops around the theme of identifying and demonstrating value to healthcare professionals. In addition, the Manufacturers Forum will offer manufacturers, dealers and representatives an opportunity to view and talk about new products and discuss business opportunities. The Conference will be held at the Eaglewood Resort in Itasca, Ill. For more information, visit [www.imda.org](http://www.imda.org) or [www.hira.org](http://www.hira.org).