

# Trend Tracking

Gearing up for 2019, we have identified 10 trends ranging from molecule to market that will have a meaningful impact, not just in the near term, but also potentially for disrupting the business of healthcare for years to come.

In this special 2019 Year in Preview issue, more than 100 PharmaVOICE thought leaders address 10 trends that are expected to be part of the changing landscape in the year ahead. These areas of focus cover a variety of disparate topics that range from molecule to market in keeping with our publishing focus and philosophy. What links these trending topics are four threads: technology, innovation, collaboration, and, most importantly, patients.

As this issue was going to press, several events occurred that impact the trends under discussion and the industry at large.

In a first, the FDA granted 23andMe de novo authorization to offer reports on pharmacogenetics, indicating how customers' genetics may influence the way they metabolize certain medications.

According to the company, this is the first authorization of a direct-to-consumer (DTC) report on pharmacogenetics and came through the FDA's de novo classification process. With this authorization, the FDA has classified these DTC pharmacogenetic reports as moderate risk that have special controls to ensure safety, effectiveness, and accuracy. This authorization enables 23andMe to report on numerous variants associated with pharmacogenetic response.

"We've continued to innovate through the FDA and pioneer safe, effective pathways for consumers to directly access genetic health information," says 23andMe co-founder and CEO Anne Wojcicki in a media report. "Pharmacogenetic reports are an important category of information for consumers to get access to and I believe this authorization opens the door for consumers to work with their health providers to better manage their medications."

As part of the authorization process 23andMe had to demonstrate the accuracy of its testing and consumer comprehension of the testing information, including "treatment adherence" and whether or not a customer would continue their prescribed treatment of a medication, or change or stop treatment.

## 2019 Year in Preview Trends

- ▶ 3D and Bioprinting
- ▶ Advanced Diagnostics and Precision Medicine
- ▶ Creating Shared Value
- ▶ Genetic Testing and Human Data Rights
- ▶ Gig Economy
- ▶ Innovative Medicine Launches
- ▶ Multistakeholder Commercial Models
- ▶ Rare Disease Innovation
- ▶ R&D Modeling and Simulation
- ▶ Voice Assistants

Studies showed that more than 97% of users understood that they should not use the report to make any changes to treatment without consulting their doctor.

The authorization allows for the reporting of variants in multiple genes that impact how well an individual metabolizes certain medications, for example clopidogrel, which is commonly prescribed to prevent heart attacks and strokes. These genes are associated with response to more than 50 other commonly prescribed and over-the-counter medications. The authorization allows 23andMe to provide customers with information on whether they are predicted to be fast or slow metabolizers based on their genetics, and when supported by appropriate clinical evidence, whether they may experience reduced efficacy or have an increased chance of side effects from certain medications.

This type of innovation is just one example of how nontraditional players are impacting the overall life-sciences industry. At the same time, big pharma continues to push the envelope in terms of moving the needle.

At the CNS Summit held in November in Boca Raton, Fla., the 2018 CNS Summit Innovation Index, which ranks life-sciences companies based on publicly available information was released. The index takes into consideration three facets of innovation: trial optimization, digital advancement, and innovative partnerships. The index is developed in collaboration with the pharma innovation specialists IDEA Pharma.

Novartis led the ranking, followed by Roche, Amgen, AstraZeneca, and Takeda. The next five on this year's ranking are: Sanofi, J&J, Bayer, GlaxoSmithKline, and Merck & Co.

"The CNS Summit Innovation Index is a data-driven, independent assessment of the innovation leaders within the pharmaceutical industry," says Amir Kalali, M.D., chief curator and scientific program chair of the CNS Summit. Dr. Kalali is also a PharmaVOICE RedJacket. "The goal of the CNS Summit Innovation Index is to objectively assess investments made in innovation, encourage leadership in innovation, and allow companies to benchmark their innovation activities via an objective external source."

Mike Rea, CEO, IDEA Pharma, and another PharmaVOICE Red Jacket, says, "The CNS Summit Innovation Index looks forward to the connection of possibilities, to the intersection of creativity, strategy, and technology, to companies beginning to behave like disruptors, rather than the disrupted."

In addition to the trends identified in this special issue, in the coming year we will be following several other areas of interest to analysts, such as consolidation, which Forester analysts predict will continue across all sectors as well as major disrupters, such as Amazon and Walmart, which are delivering on their promise to provide personal care delivery.

Gartner analysts are keeping an eye on AI, data privacy, diversity, cloud-based technologies, and virtual care.

We will continue to follow these and other emerging trends in 2019. Enjoy.

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By McKesson

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