

DECEMBER 2018

Meditech Quality Journal

The holidays are upon us, and with that the start of the New Year. From advancements in technology through artificial intelligence to news of notable mergers and acquisitions, let's take a look at the most relevant industry news in less than 15 minutes. I hope you have a safe and prosperous transition into 2019, and please let me know if there are future topics you would like discussed by [contacting me here](#).



- Naveen Agarwal, Ph.D

FEATURE ARTICLE

How Artificial Intelligence is Shaping FDA's Thinking



Rapid advancement in Artificial Intelligence (AI) is creating tremendous possibilities for innovation in the MedTech industry. As a result, the FDA is evolving its approach to the evaluation of new products for market approval.

The question: Are you prepared to leverage AI in your organization?

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INDUSTRY NEWS

Tale of Two Acquisitions

Mergers and Acquisition (M&A) activity in MedTech remains strong as the big players look for options to grow. Investment in internal R&D remains flat and organic innovation is slowing down.

The question: How you should evolve your M&A strategy?

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REGULATORY NEWS

5 Signs Your Medical Device Could Become a Target of FDA Scrutiny



Last month, the FDA issued a Medical Device Enforcement and Quality Report, providing important clues about factors that can land your medical device in FDA's crosshairs. Here are 5 warning signs that can elevate your risk level.

The question: Could your device be on the FDA's radar?

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RESOURCES

Natural Language Processing (NLP) as a Tool

Medical data is expected to double every 73 days by 2020! There is an exponential increase in the quantity of data from Electronic Health Records, Medical Claims, Scientific Journals and Consumer Wearable Devices. Natural Language Processing (NLP) can be used to automate processing of this data and extraction of insights to accelerate product innovation and monitor product safety. This is a top priority for the FDA.

Natural Language Processing (NLP) in Healthcare

WHAT

A sub-set of **Artificial Intelligence** (AI) capabilities to help machines understand and interpret human language in both written and voice formats

WHY

Exponential growth of healthcare data from Electronic Health Records, Medical Claims, Scientific Literature and Wearable Devices requires automation for cost-effective processing and application

HOW

Application of **Machine Learning** techniques to extract meaning through **lower level tasks** (tokenization, sentence boundary, part-of-speech tagging, word decomposition etc.) and **higher level capabilities** (spelling/grammar errors, near entity recognition, word sense, relationships, part/whole, translation etc.)



Use of real world data (RWD) to help generate real world evidence (RWE) is a top strategic priority for the FDA for approval of new products and monitoring of post-market safety



Scott Gottlieb, M.D. @SGottliebFDA · Dec 6

Use of RWD has the potential to make our medical product development processes more efficient and help lower the cost of development. Our goal is to close the evidence gap between the information we use to make decisions and the evidence collected by the medical community.

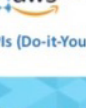
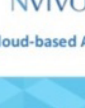


Applications include:

- ✓ Safety surveillance and signal detection from adverse events data, product/disease registries
- ✓ Observational studies using RWD to generate RWE in to derive expanded indications for use
- ✓ Review of scientific literature to accelerate drug discovery, device development
- ✓ Patient monitoring including drug compliance to manage care and reduce cost
- ✓ Automation of medical claims processing



IBM Watson Platform/Service/Consulting



Cloud-based APIs (Do-it-Yourself)

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Download this 1-page overview of how NLP can be used in Healthcare

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We hope your holiday season is filled with quality time with loved ones and we wish you the very best in 2019.

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