

Healthcare Quality in the Age of Artificial Intelligence

Success Factors for QA/RA Professionals

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ASQ Orlando Section Meeting

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AI is already a BIG part of our lives

Hello,
Alexa

Tell Me
a Joke



“By 2022, your personal device will know more about your emotional state than your own family.” [Gartner](#)

Source: <https://www.gartner.com/smarterwithgartner/emotion-ai-will-personalize-interactions/>

Lot more than just weather and jokes



- ✓ Medication reminders
- ✓ Contact the clinic
- ✓ Contact family members
- ✓ Personalized in-home care

50% of average patients do not take their medications as prescribed

700k Americans experience adverse reactions to prescribed drugs that result in a trip to the ER

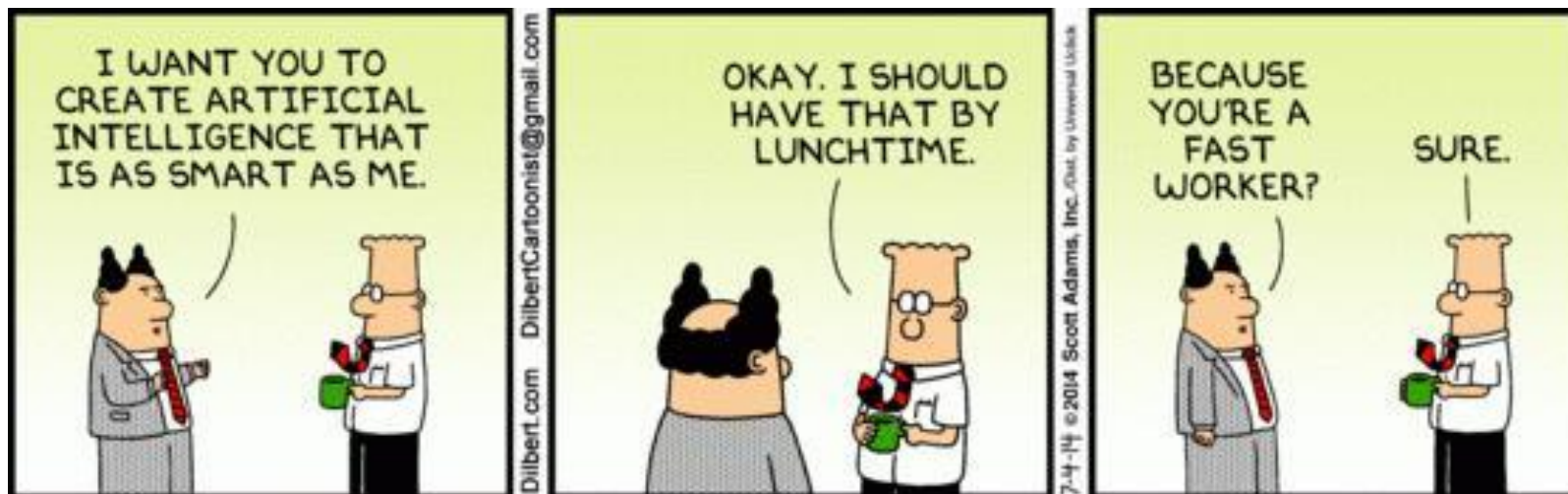
\$29B estimated annual cost of patients not taking their medications as prescribed

Source: CNBC, Orbita

Topics for today

- ❑ **What is Big Data & AI**
- ❑ **Changing Landscape of Medical Industry**
- ❑ **Implications for Quality/Regulatory Professionals**
- ❑ **Looking Ahead and How You can Prepare**

What is Big Data & Artificial Intelligence?



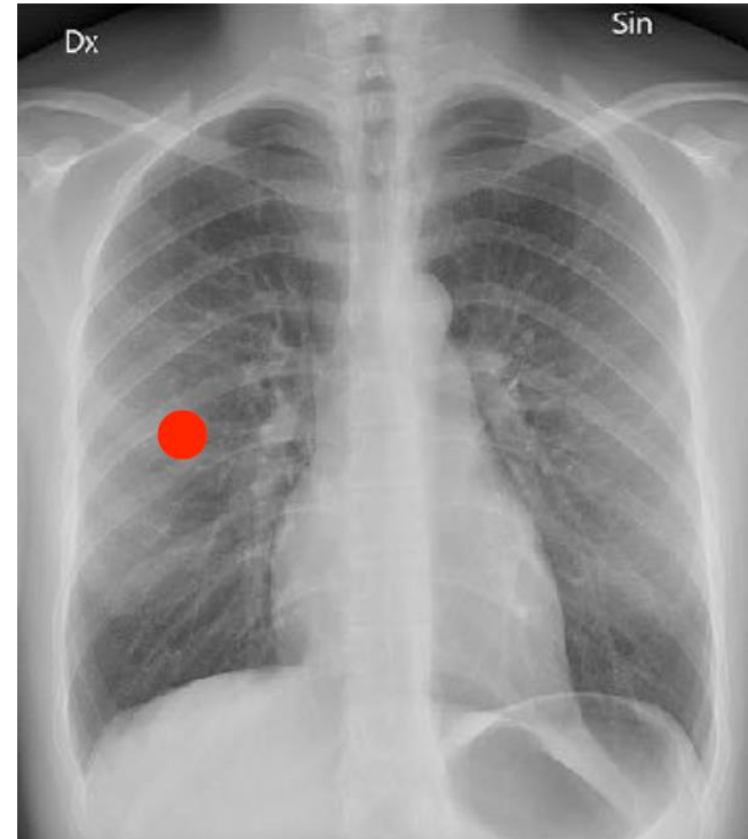
Source: Dilbert.com; Used under provisions of [Fair Use](#)

AI can help answer important questions....

Given this lung x-ray....
What disease, if any?
How confident are we?



Given this lung x-ray....
For every pixel, is there a cancerous tissue?
How confident are we?



Source: Jesse Livezey, Lawrence Berkeley National Lab, Xavier Health AI Summit, Aug 2018

Big Data = Volume, Variety and Velocity

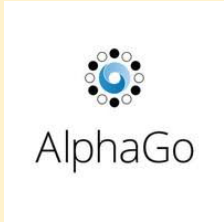
Structured Data



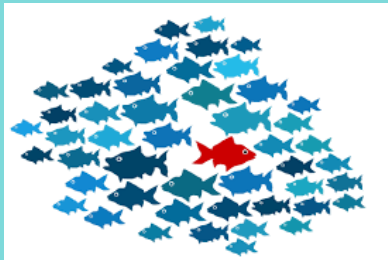
Unstructured Data



Next Frontier - AI > ML > DL

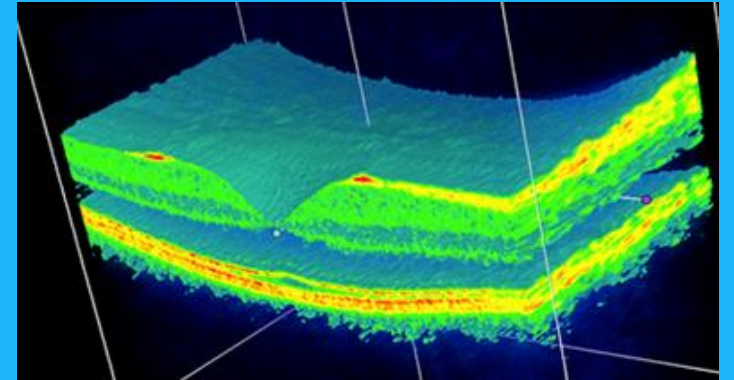


Artificial Intelligence (AI) – enables machines to have human-like intelligence

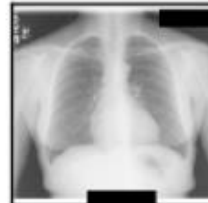


Machine Learning (ML) – enables machines to “learn” with experience

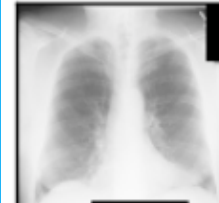
Deep Learning (DL) – enables machines to build a “brain”



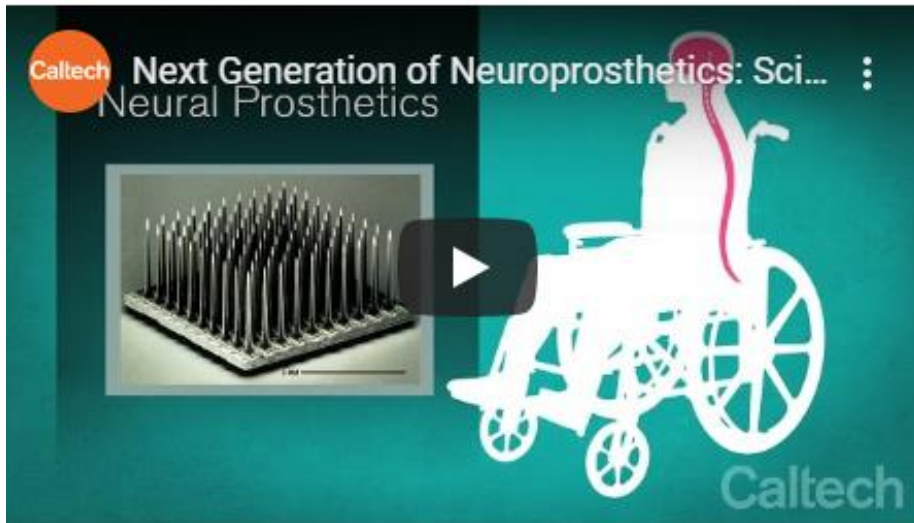
Healthy
93.98%



Cancer
98.98%



Cool Stuff Happening in Healthcare



Next Generation of Neuroprosthetics: Science Explained

Includes animation and narrative



Drinking a Beverage for the First Time

Source: <http://www.vis.caltech.edu/media>

Changing landscape of MedTech

MedTech products span a lifetime of care



Industry is going through a major transition

Acquiring Scale

Acquiring New Capabilities
(AI and 3D Printing)

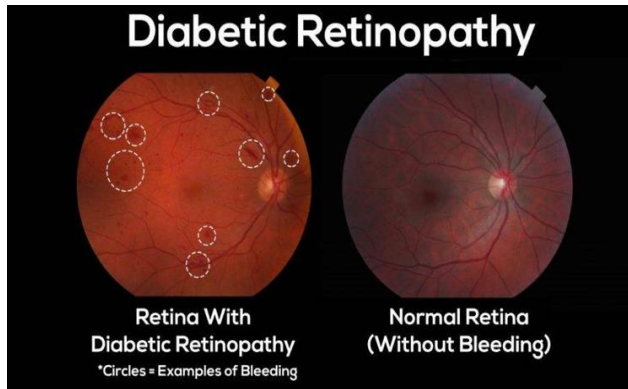
Portfolio Optimization



Wearable Devices

AI based diagnostics

Technology Disruption



Source: <https://www.exeedqm.com/new-blog/tale-of-two-acquisitions>

Disruptive changes ahead in insurance and regulations

Outcome Based

NEW AGREEMENT WITH AETNA REFLECTS SHIFT TOWARDS VALUE-BASED CARE

Medtronic and Aetna – one of the biggest health insurance companies in the U.S. – sign an outcomes-based agreement for patients living with diabetes.

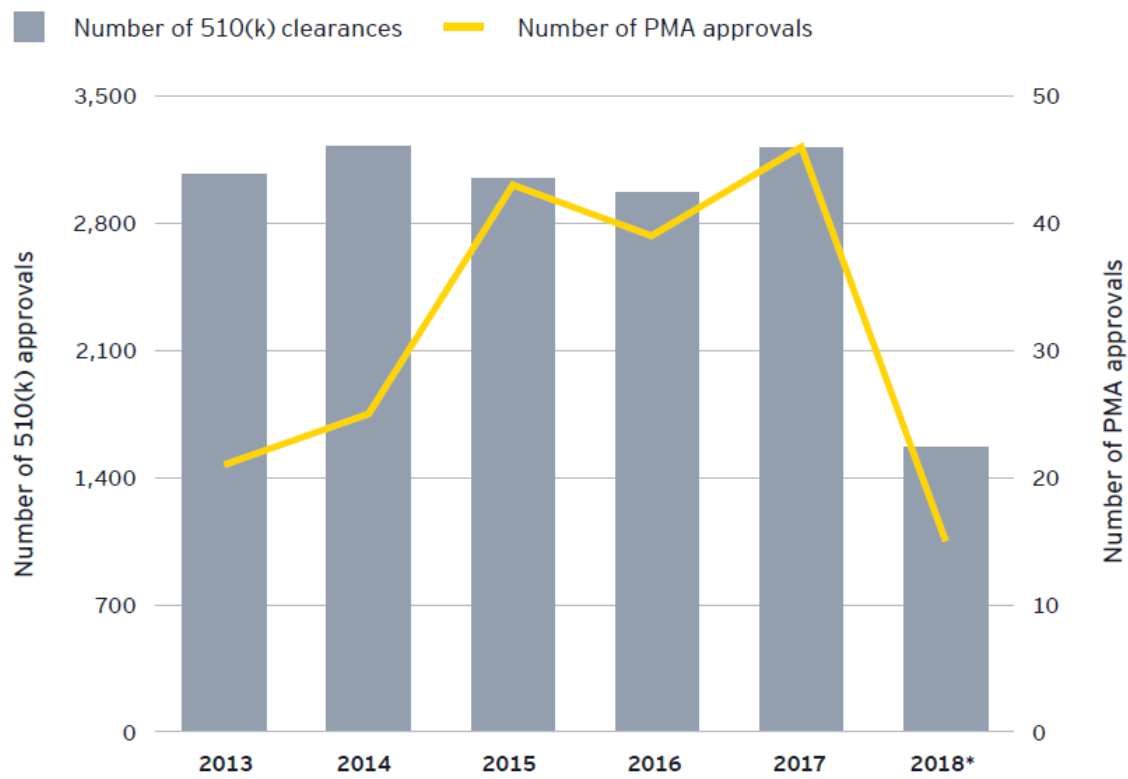


Source: Medtronic.com

New Regulations

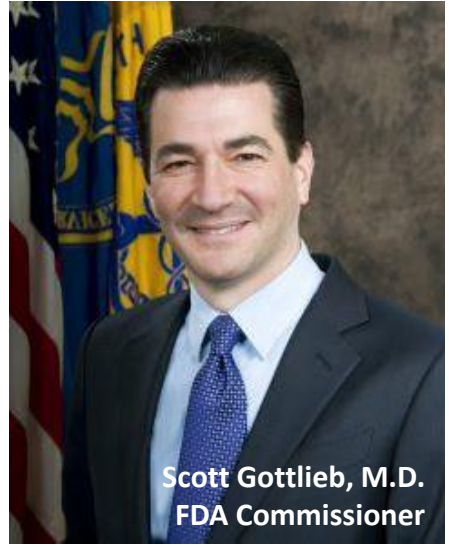


Growing FDA focus on accelerating innovation



Number of 510(k) clearances are shown through 30 June 2018. PMAs are shown through 31 August 2018. Source: US FDA.

Source: EY 2018 Pulse of the Industry Report



“Revolutionary new medical opportunities require FDA to apply an innovative and nimble, regulatory approach to the products we are tasked with evaluating”.

- ✓ National Evaluation System for health Technology (NEST)
- ✓ Breakthrough Devices Program
- ✓ Least Burdensome Approach
- ✓ Digital Health Pre-Cert Program

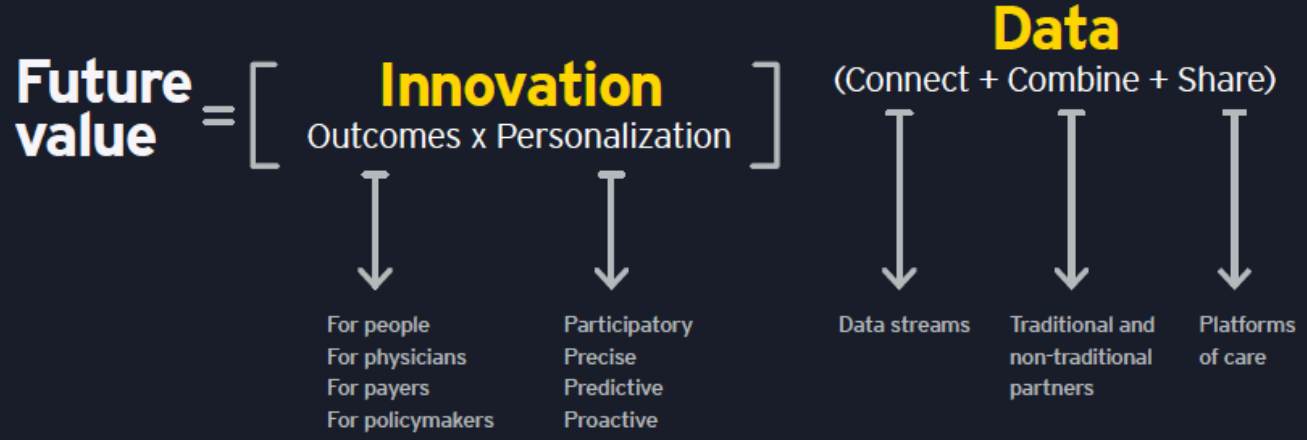
Source: fda.gov

Data will drive the ultimate value in healthcare

New thinking for a new age

Figure 1. A new equation for delivering value

$$FV = IP^D$$



*“Increasingly, medtech’s future growth will be driven by the ability to **connect, combine and share** data quickly and at scale to create secure solutions that deliver clinical and economic benefit”.*

Source: EY 2018 Pulse of the Industry Report



More than 1 million users
expected by 2019!

Source: Abbott Medical

Technology Disruption – Opportunities and Challenges



*“Together with partners like Abbott, our connected pens will give healthcare professionals a better understanding of a patient’s **individual diabetes management** and can help people with diabetes feel more confident in their treatment”*
- CVP, Commercial Innovation, Novo Nordisk

Source: <https://www.abbott.com/corpnewsroom/product-and-innovation/a-better-way-to-manage-diabetes.html>

Disclaimer – for information purposes only; we do not have any affiliations with these companies and products

What does this mean for QA/RA?

Evolving expectations for QA/RA professionals



Not just new skills, a new outlook to achieve success



Internal focus
Compliance
Knowledge
Experience
Certainty



Customer focus
Quality
Problem Solving
Learning Ability
Risk

Looking Ahead and How You can Prepare

The case of customer complaints – Big Data problem?

Complaint means any written, electronic or oral communication that *alleges* deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of a device after it is released for distribution.

§ 820.198(b): Each manufacturer shall review and evaluate *all* complaints to determine whether an investigation is necessary

§ 820.198(d): Any complaint that represents an event which must be reported to FDA *shall be promptly reviewed, evaluated and investigated.*



World as we know it!



Big Data World!

Traditional statistical analysis tools

Descriptive



What happened?

Basic reporting

- Summarize past data
- Mean, median, mode, min, max, variance
- Growth rates
- Compare against benchmarks or goals
- Data distributions, process capability
- Charts, graphs, tables to visualize simple trends

Inferential



Why?

Basic prediction

- Relating sample data to general population
- Finding statistically significant factors
- Regression Analysis
- Correlations
- Hypothesis testing
- DOE, ANOVA, GLM
- Multivariate analysis

Predictive



What could happen?

Forecasting

- Delphi methods
- Trend analysis extrapolation
- Moving averages, data smoothing
- Time series, ARIMA
- Regression analysis

Prescriptive



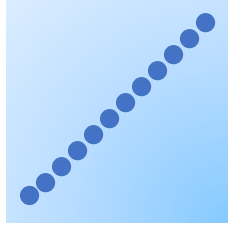
What should we do?

Future outcomes

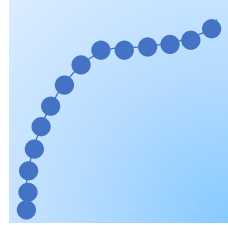
- Data modeling and simulations
- Sensitivity analysis
- What-ifs and probabilities
- Decision tree analysis
- DOE/Robust Design and optimization



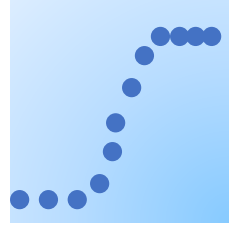
Common ML Algorithms



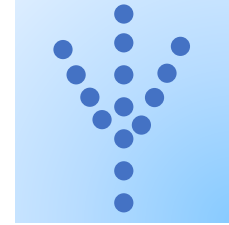
Linear equation
best fit



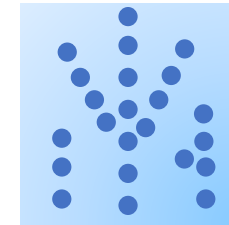
Polynomial equation
best fit



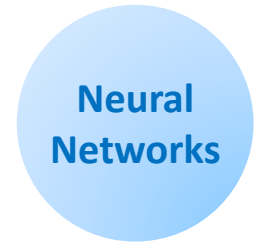
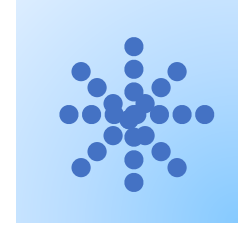
Adapted for yes/no
Uses sigmoid function



Mapping all outcomes
and probabilities



Multiple decision trees
Random sampling



Interconnected layers of
nodes like a human brain



- ✓ Simple calculations
- ✓ Easy to train/validate
- ✓ Numerical prediction
- ✓ Main factors



- X No higher order terms
- X Model optimization issues
- X Feature scaling
- X Overfitting issues

- ✓ Easy to visualize relationships
- ✓ Easy to train/validate

- X Over simplification
- X Limited predictability

- ✓ "Average" of many
- ✓ Fast to train
- ✓ Higher quality output

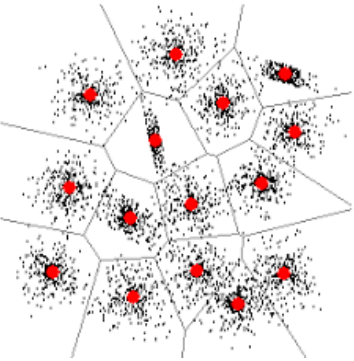
- X Slow to output predictions
- X Difficult to interpret

- ✓ Model complex tasks
- ✓ High accuracy
- ✓ Suitable for deep learning

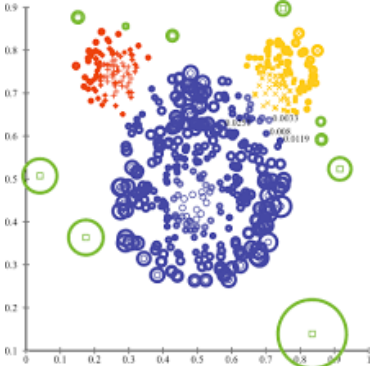
- X Very slow to train
- X Challenging to optimize
- X Nearly impossible to interpret

Case of Complaints – What’s Next?

Cluster Analysis

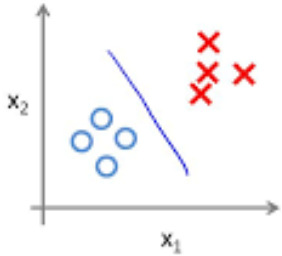


Anomaly Detection

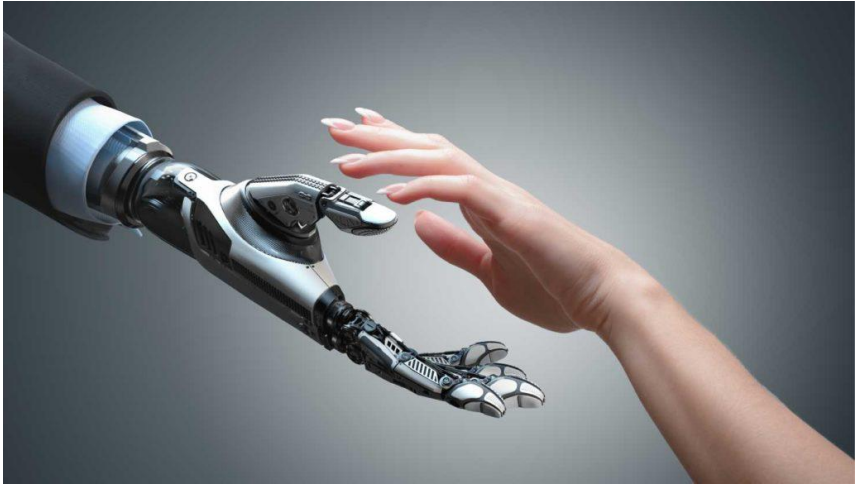
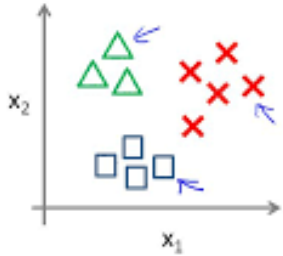


Classification

Binary classification:



Multi-class classification:



Sentiment Analysis



NLP



natural language processing

Data Mining



DATA VISUALIZATION



PATTERN RECOGNITION



Emerging role in Big Data industry

Functional Experts



Statisticians
Engineers
Analysts
Data Scientists
IT professionals



2M - 4M
Projected US
demand over
the next 10
years*

Both Technical and
Business
Management Skills

Senior Business Leadership



Chief Executive Officers
Presidents/VPs
Senior Directors

Source: * McKinsey Global Institute Report – The Age of Analytics, 2016

In Closing....

- ❑ Big Data and Artificial Intelligence are transforming Healthcare
- ❑ New tools are becoming available to analyze large amounts of data
- ❑ Regulatory scrutiny and expectations on the rise
- ❑ Expectations for Quality/Regulatory roles are rapidly evolving
- ❑ New opportunities and roles becoming available for professionals





**Success
Ahead**

All models are wrong, some are useful
George E. P. Box

About Exeed™

Portfolio of Innovative Quality Solutions in 4 Broad Areas



Customer Experience



Regulatory Compliance



Risk Management



Quality Culture

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JANUARY 2019

Meditech Quality Journal

2019 is here, and is already beginning to fly by. I invite you to check out the latest industry news in less than 15 minutes. Please let me know if there are future topics you would like discussed by [contacting me here](#).



- Naveen Agarwal, Ph.D

FEATURE ARTICLE

When Compliance Leaves the Customer Stranded



A paper form that needs to be completed before the plane can leave the gate triggers a sequence of events leading to the flight cancellation.

The Question: Are you stuck with procedures that don't make sense?

[Read More...](#)

REGULATORY NEWS

FDA Wants You to Take a STeP in the Right Direction

The STeP program offers MedTech companies a clear incentive to focus their innovation efforts on improving patient safety. If their devices can claim better safety outcomes, not only do they get faster approval, they can also gain a significant competitive advantage in the market.

The question: Innovating to improve Product Safety can help you gain competitive advantage.

