

Data is the New Black

or How the Fourth Industrial Revolution is Changing Healthcare

or Diagnostics is an Information Business with a Wet Lab on the Side

Mara G. Aspinall

CEO, Health Catalysts Managing Director, BlueStone Venture Partners

Director – Abcam plc, Allscripts, Blue Cross Blue Shield Arizona, Castle Biosciences, GenePeeks, 3Scan, Orasure



•4th Industrial Revolution

• Diagnostics 5.0

•6 Strategies for Improvement







4th Industrial Revolution: Digital Economy







- 1. Artificial intelligence and machine learning
- 2. Internet of things and connected devices
- 3. Blockchain and distributed ledger technology
- 4. Autonomous and urban mobility
- 5. Drones and tomorrow's airspace
- 6. Precision medicine
- 7. Digital trade and cross-border data flows



- Investment
 - Dollars Flowing
 - Start-Ups Growing

- Acquisitions
 - Data Value High
 - Lab Value Low

- Regulation
 - Mobile Apps
 - Personalized Medicine
 - Virtual Clinical Trials

Multiple Mostly Accurate Data Points better than One Very Accurate Data Point



Diagnostics has made great strides



Constantine tastes patients' urine



Urine Test Strip



Blood Glucose Meter



Contact Lens Glucose Meter







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Diagnostics Venture Capital Investments



Health Catalysts Diagnostics Year in Review

Health Informatics Deals Lead the Growth

Investors continued to ramp up their deals to companies aiming to use digital solutions to remedy pain points in the healthcare system.



Artificial Intelligence also Surges Forward







Computational Pathology



Liquid Biopsy



Medical Optics



Next Generation Sequencing



Wearables: incl. Consumer Dx



Artificial Intelligence



Data Integration



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A. Mobile Apps

- A. Clearance of *reSET*
- B. Clearance of Kardia Band
- C. Clearance of Personal Genome Service Personal Health Risk

B. Personalized Medicine

- A. Keytruda
- B. Universal CDx Gene Panels

C. Tech Enabled Clinical Trials

- A. Block Chain
- B. Artificial Intelligence Analysis
- C. BioSimulation
- D. Digital Token Payments



Top 3 barriers to analytics investments and implementation efforts*



While health care is entering the era of big data, insurance companies remain in the dark.

Ernest & Young, The Future of



•4th Industrial Revolution

• Diagnostics 5.0

•6 Strategies for Success



Diagnostics in the Background Today







It is all about the drug but...





Diagnostics Bridge Theory to Therapy





Diagnostic Questions: Dx 1.0 to Dx 5.0



150 years ago – Dx 1.0 *Is there disease?*

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Diagnostic Tools: Dx 1.0 to Dx 5.0



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The So What? Test





Dx 5.0 is Technology & Data Integrated





Diagnostics 4.0 & 5.0 entails :

- Too much data to do anything else
- Multiple Technologies and Multi-Analytes Integrated
- Little time and less patience from MDs
- Companion Diagnostics but the "next gen" of CDx must tackle combination therapy





Diagnostic Lab Technologies sooner or later become broadly available

Recent (and future) advances in Diagnostic Technology create more information that any human can absorb and/or process



Diagnostics is an Information Business with a Wet Lab on the Side



Dx 5.0 Needs Therapeutics



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FDA approves first cancer treatment for any solid tumor with a specific genetic feature

For Immediate Release May 23, 2017

The U.S. Food and Drug Administration today granted accelerated approval to a treatment for patients whose cancers have a specific genetic feature (biomarker). This is the first time the agency has approved a cancer treatment based on a common biomarker rather than the location in the body where the tumor originated.

Keytruda (pembrolizumab) is indicated for the treatment of adult and pediatric patients with unresectable or metastatic solid tumors that have been identified as having a biomarker referred to as microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR).

Proving the Efficacy of Combination Therapy with Data <u>Molecular Analysis for Therapy Choice – MATCH Trial</u>

• Objective

- Assess response rate and progression-free survival following treatment chosen based on presence of specific mutations in patient tumors.
 - Pretreated solid tumors and lymphomas
- Unprecedented Numbers
 - 200 actionable mutations / amplifications / translocations
 - 20 treatment arms
 - 40 pharmaceutical firms

Dx 5.0 Needs Biomarkers for Drug Development Success



Source: Hayashi, K. et al; Impact of biomarker usage on oncology drug development, February, 2013; Journal of Clinical Pharmacy and Therapeutics











Arizona State University

Mission

- Educate healthcare executives to understand and appreciate Diagnostics in clinical medicine and scientific research
- Educate students to be active and impactful members of the healthcare and life science communities through coursework and exposure to industry
- Shape Diagnostic policy worldwide through research and partnerships with industry
- Establish the field of Diagnostics as an independent discipline, distinct yet integral to drug development



Arizona State University

Curriculum

- Science of Diagnostics
- Technology of Diagnostics
- Economics of Diagnostics
- Application of Diagnostics



Arizona State University

• Masters Degree: One Year Online

- 30 course credits
- Applied Project / Field Work

Program Overview

- Student Body
 - Mid Career Executives in Healthcare / Life Sciences
 - Science undergrad majors interested in bioscience careers
- Student Enrollment
- Class of 2015: 24
- Class of 2016: 47
- Class of 2017: 71
- Class of 2018: 102



Thank you

Mara G. Aspinall mara.aspinall@healthcatalysts.com

