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

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Director – Abcam plc, Allscripts, Blue Cross Blue Shield Arizona, Castle Biosciences, GenePeeks, 3Scan, Orasure
Agenda:  4 – 5 – 6

• 4\textsuperscript{th} Industrial Revolution

• Diagnostics 5.0

• 6 Strategies for Improvement
The Industrial Revolutions

1st Industrial Revolution

Urbanization

2nd Industrial Revolution

Factory Automation

3rd Industrial Revolution

Communications

4th Industrial Revolution

Data
4th Industrial Revolution: Digital Economy
4th Industrial Revolution: Healthcare

- 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
Data, Data, Everywhere

- 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
Data, Data, Everywhere

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Multiple *Mostly Accurate* Data Points better than One *Very Accurate* Data Point
Diagnostics Venture Capital Investments

Value of Investments

<table>
<thead>
<tr>
<th>Year</th>
<th>Value (in Millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>$952</td>
</tr>
<tr>
<td>2015</td>
<td>$975</td>
</tr>
<tr>
<td>2016</td>
<td>$827</td>
</tr>
<tr>
<td>2017</td>
<td>$1,246</td>
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Number of Investments

<table>
<thead>
<tr>
<th>Year</th>
<th>Angel &amp; Seed</th>
<th>Early Stage VC</th>
<th>Later Stage VC</th>
<th>Total</th>
</tr>
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<tbody>
<tr>
<td>2014</td>
<td>132</td>
<td>422</td>
<td>114</td>
<td>132</td>
</tr>
<tr>
<td>2015</td>
<td>130</td>
<td>446</td>
<td>114</td>
<td>130</td>
</tr>
<tr>
<td>2016</td>
<td>118</td>
<td>414</td>
<td>112</td>
<td>118</td>
</tr>
<tr>
<td>2017</td>
<td>109</td>
<td>412</td>
<td>112</td>
<td>109</td>
</tr>
</tbody>
</table>

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

Sources: Brookings and CB Insights
Artificial Intelligence also Surges Forward

Source: Nature: “There is a blind spot in AI Research”, October 13th, 2016
Diagnostic Tech $ shift away from MDx to Data Related

- Computational Pathology
- Liquid Biopsy
- Medical Optics
- Next Generation Sequencing
- Wearables: incl. Consumer Dx
- Artificial Intelligence
- Data Integration
Data, Data, Everywhere

- Investment
  - Dollars Flowing
  - Start-Ups Growing

- Acquisitions
  - Data Value High
  - Lab Value Low

- Regulation
  - Mobile Apps
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**Multiple Mostly Accurate** Data Points better than **One Very Accurate** Data Point
FDA Actions

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
Barriers to using Data and Data Analytics

![Graph showing top 3 barriers to analytics investments and implementation efforts.]

- **Data quality**: 22% (Ranked #1), 22% (Ranked #2), 16% (Ranked #3)
- **Tools and technology**: 11% (Ranked #1), 18% (Ranked #2), 24% (Ranked #3)
- **Access to skilled resources**: 18% (Ranked #1), 16% (Ranked #2), 7% (Ranked #3)
- **Funding**: 18% (Ranked #1), 9% (Ranked #2), 11% (Ranked #3)
- **Culture and politics**: 13% (Ranked #1), 11% (Ranked #2), 18% (Ranked #3)
- **Data access**: 13% (Ranked #1), 4% (Ranked #2), 13% (Ranked #3)
- **C-suite sponsorship/leadership**: 2% (Ranked #1), 11% (Ranked #2), 4% (Ranked #3)
- **Fragmented ownership**: 2% (Ranked #1), 9% (Ranked #2), 4% (Ranked #3)
While health care is entering the era of big data, insurance companies remain in the dark.
Agenda: 4 – 5 – 6

• 4\textsuperscript{th} Industrial Revolution

• Diagnostics 5.0

• 6 Strategies for Success
Diagnostics in the Background Today
It is all about the drug but...
Diagnostic Questions: Dx 1.0 to Dx 5.0

150 years ago – Dx 1.0
Is there disease?

50 years ago – Dx 2.0
What disease?

Today – Dx 3.0
What sub-type?

Tomorrow – Dx 4.0
Identify risk?

Dx 5.0
Pre-empt disease?
Diagnostic **Tools**: Dx 1.0 to Dx 5.0

- **150 years ago – Dx 1.0**
  - MD’s 5 Senses

- **50 years ago – Dx 2.0**
  - Manual

- **Today – Dx 3.0**
  - Automated Systems

- **Tomorrow – Dx 4.0**
  - Algorithms

- **Dx 5.0**
  - Integration: Dx, Rx & Data
Dx 5.0 is Not Just for Diagnosis

Diagnostics 5.0

Am I at risk?
Am I sick?
What disease?
What sub-type?
How long do I have?
Which treatment – at what dose?
Is treatment working?

The So What? Test
**Dx 5.0 is Technology Agnostic**

<table>
<thead>
<tr>
<th>Technology</th>
<th>Image</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Chemistry</td>
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<tr>
<td>FISH/ISH</td>
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<tr>
<td>Cytogenetics</td>
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<tr>
<td>NGS</td>
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<tr>
<td>Mass Spec</td>
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</tr>
<tr>
<td>PCR</td>
<td><img src="image10" alt="PCR" /></td>
</tr>
</tbody>
</table>
Dx 5.0 is Technology & Data Integrated

- Integrated summary of patient data
- Patient History
- Clinical Dx
- NGS
- Consumer Apps
- Imaging
- Clinical Trials
- Tissue Diagnostics
- Drug Interactions
- POC Dx

Emergence of the Data Interpreter
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

Dx 5.0 Needs Clinical Algorithms
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.
Detailed diagnosis essential for effective therapy

Many
More treatment Options
None

Prognosis only
Comprehensive diagnosis

More treatment Options

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Hospitals in the Future
Mechanism-Based Treatment Paradigm

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FDA News Release

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).
• 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**

**Oncology NME’s 1999-2008**

- **No Biomarkers**
  - 23% P(success)
  - 76.4% Phase I
  - 50.8% Phase II
  - 58.5% Phase III

- **With Biomarkers**
  - 53% P(success)
  - 90.4% Phase I
  - 69.0% Phase II
  - 85.0% Phase III

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

Past & Today
We have a Drug
Find me Patients

Today & Tomorrow
We have A Patient
Find me Drugs
Create the Future: 6 Steps

1. Educate on Diagnostics
   - Genomics
   - Kinetics

2. Educate on Pharmaco:

3. Publish on System Economics

4. Integrate Protocols into Industry Standards

5. Shift Medical Education & Boarding to include PGx / Dx / PK

6. Reward Outcomes not Process
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
Curriculum

- Science of Diagnostics
- Technology of Diagnostics
- Economics of Diagnostics
- Application of Diagnostics
Program Overview

- Masters Degree: One Year Online
  - 30 course credits
  - Applied Project / Field Work

- 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

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