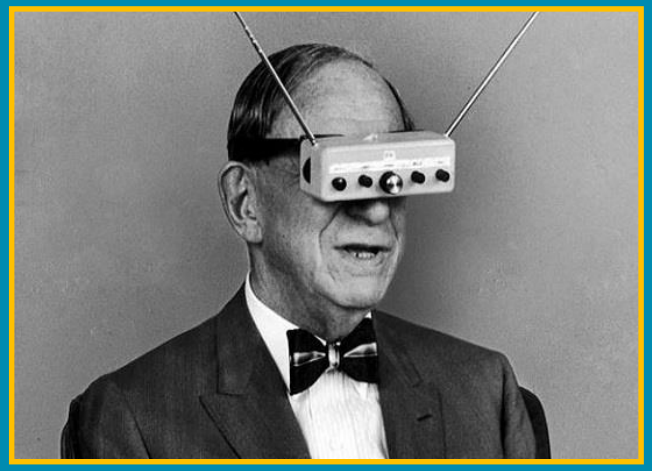
The Role of mHealth Technology in the COVID-19 Pandemic and Beyond …



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Digital Health
& Medical Technologies
120
80
12:32

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Biologically Inspired Engineering

The MGB Center for COVID Innovation

David Walt

Rushdy Ahmad

Gary Tearney

Mass General Brigham
CENTER FOR
COVID INNOVATION

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Direct to Consumer

To aid in the fight against the COVID-19 pandemic, the Direct-to-Consumer (DTC) working group came together to identify rapid diagnostics and mobile health solutions with potential to be deployed within our healthcare system and beyond. An overview of these efforts, which were accomplished through the collective altruism from the researchers, clinicians and staff from across the MGB healthcare system along with collaborators from around the country and the globe, is highlighted below. The full details of this work can be found in this medRxiv manuscript. Results from our clinical evaluations of these products will be posted as they become are available.

COVID-19 Rapid Tests

Contact Tracing Assessment

COVID-19 Rapid Tests

In response to the urgent public health need for accurate, effective, low-cost, and scalable COVID-19 testing technology, the Direct-To-Consumer (DTC) working group within the Mass General Brigham (MGB) Center for COVID-19 Innovation was tasked with identifying viable diagnostic solutions with potential for use as a DTC product. To identify potential products, we performed a deep horizon scan for antigen and serology based diagnostics and down selected to the most promising. Product evaluations are based entirely on company provided data. Those that passed our first scoring algorithm based on Specificity and Sensitivity data were then further evaluated by our second scoring algorithm based on additional technical specifications in combination with data about the company and distribution capacity. The results of these efforts are displayed in the table below. All blank fields represent information we were unable to obtain. The performance metrics for some of the high scoring products are currently being validated in-house through the Diagnostics Accelerator. Once complete, this data will be made available.

Antibody Tests: Horizon Scanning Results

Hide fields | Filter | Group | Sort

	Institution name	Product Name	Response score (max: 10)	Assay metho
1	AccuBioTech Co. Ltd	Accu-Tell COVID-19 IgG/IgM Rapid Test Cassette (CE-IVD)	2	
2	AIVD Biotech Inc.	COVID-19 IgG/IgM Rapid Test (colloidal gold-based) (in development)	3	
3	Alfa Scientific Designs Inc.	DrivenFlow COVID-19 (CE-IVD)	3	
4	Assure Tech. (Hangzhou) Co., Ltd	COVID-19 IgG/IgM Rapid Test Device	3	
5	Autobio Diagnostics Co. Ltd.	Anti-SARS-CoV-2 Rapid Test	3	

mHealth Technology Task Force

IEEE Open Journal of Engineering in Medicine and Biology

Emerging Topics

Can mHealth Technology Help Mitigate the Effects of the COVID-19 Pandemic?

Catherine P. Adans-Dester, Stacy Bamberg, Francesco P. Bertacchi, Brian Caulfield, Kara Chappie, Danilo Demarchi, M. Kelley Erb, Juan Estrada, Eric E. Fabara, Michael Freni, Karl E. Friedl, Roozbeh Ghaffari, Geoffrey Gill, Mark S. Greenberg, Reed W. Hoyt, Emil Jovanov, Christoph M. Kanzler, Dina Katabi, Meredith Kernan, Colleen Kigin, Sunghoon I. Lee, Steffen Leonhardt, Nigel H. Lovell, Jose Mantilla, Thomas H. McCoy, Jr., Nell Meosky Luo, Glenn A. Miller, John Moore, Derek O'Keeffe, Jeffrey Palmer, Federico Parisi, Shyamal Patel, Jack Po, Benito L. Pugliese, Thomas Quatieri, Tauhidur Rahman, Nathan Ramasarma, John A. Rogers, Guillermo U. Ruiz-Esparza, Stefano Sapienza, Gregory Schiurring, Lee Schwamm, Hadi Shafiee, Sara Kelly Silacci, Nathaniel M Sims, Tanya Talkar, William J. Tharion, James A. Toombs, Christopher Uschnig, Gloria P. Vergara-Diaz, Paul Wacnik, May D. Wang, James Welch, Lina Williamson, Ross Zafonte, Adrian Zai, Yuan-Ting Zhang, Guillermo J. Tearney, Rushdy Ahmad, David R. Walt, Paolo Bonato

Abstract* — *Goal: **The aim of this project was to review mobile health (mHealth) technologies and explore their use to monitor and mitigate the effects of the COVID-19 pandemic.** ***Methods:*** **A Task Force was assembled by recruiting individuals with expertise in electronic Patient-Reported Outcomes (ePRO), wearable sensors, and digital contact tracing technologies. Its members collected and discussed available information and summarized it in a series of reports.** ***Results:*** **The Task Force identified technologies that could be deployed in response to the COVID-19 pandemic and most likely would be suitable to address future pandemics. Criteria for their evaluation were agreed upon and applied to these systems.** ***Conclusions:*** **mHealth technologies are viable options to monitor COVID-19 patients and be used to predict symptom escalation for earlier intervention. These technologies could also be utilized to monitor individuals who are presumed non-infected and enable prediction of exposure to SARS-CoV-2, assisting clinicians to prioritize diagnostic testing.**

***Index Terms* — COVID-19, mHealth Technology, Electronic Patient Reported Outcomes (ePRO), Wearable Sensors, Digital Contact Tracing.**

referred to as mHealth [1], has gained the attention of the public at large. mHealth technology could be used to monitor patients with mild symptoms who have tested positive for COVID-19. These patients are typically instructed to self-quarantine at home [2] or undergo monitoring at community treatment centers [3]. However, a portion of them eventually experience an exacerbation, namely the sudden occurrence of severe symptoms, and require hospitalization. In a recent report from South Korea, approximately 2% of those initially experiencing mild symptoms, and hence treated in community centers, were eventually admitted to a hospital as they developed more severe symptoms [3]. In this context, mHealth technology could enable early detection of such exacerbations, allowing clinicians to deliver necessary interventions in a timely manner thus improving clinical outcomes [4]. Smartphone applications enabling self-reports [5], [6] and wearable sensors enabling physiological data collection [7] could be used to monitor clinical personnel and detect early signs of an outbreak in the hospital/healthcare settings [8]. Similarly, in the community, early detection of COVID-19 cases could be achieved by building upon prior studies which

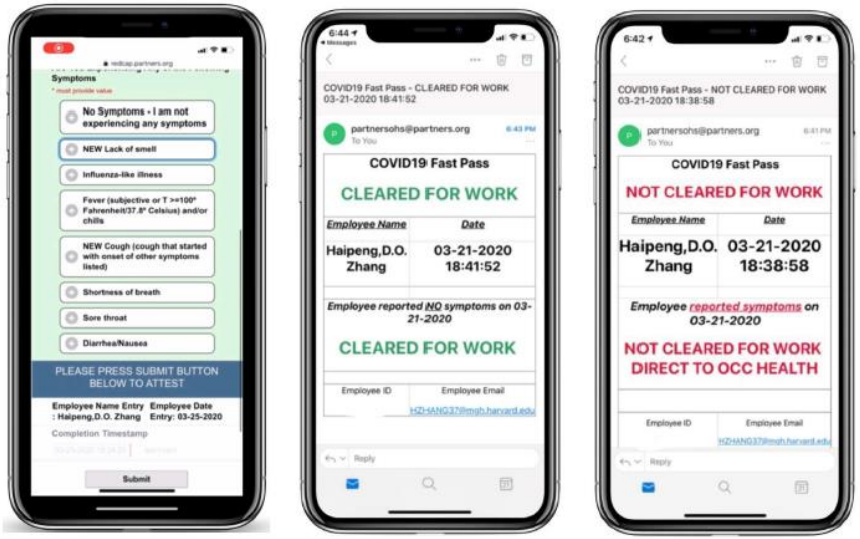
https://ieeexplore.ieee.org/document/9162431

ELECTRONIC PATIENT-REPORTED OUTCOMES

IEEE Open Journal of Engineering in Medicine and Biology

Supplementary Materials

ePRO Solutions to Screen and Monitor COVID-19 Cases



Guillermo
Ruiz-Esparza

Lina
Williamson

ELECTRONIC PATIENT-REPORTED OUTCOMES

The NEW ENGLAND JOURNAL of MEDICINE

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PERSPECTIVE
Are U.S. Hospitals Still "Recession-proof"?

PERSPECTIVE
Rural Matters — Coronavirus and the Navajo Nation

IMAGES IN CLINICAL MEDICINE
Eruptive Mucosal and Ungual Melanoma Metastases

EDITORIAL
Audio Interview: Acute Lung Injury in Covid-19

IMAGE CHALLENGE
What is the diagnosis?

Editor's Note: This letter was published on January 30, 2020, at NEJM.org.

CORRESPONDENCE

Transmission of 2019-nCoV Infection from an Asymptomatic Contact in Germany

666 Citing Articles

TO THE EDITOR:

The novel coronavirus (2019-nCoV) from Wuhan is currently causing concern in the medical

March 5, 2020
N Engl J Med 2020; 382:970-971
DOI: 10.1056/NEJMc2001468
Metrics
Chinese Translation 中文翻译

The NEW ENGLAND JOURNAL of MEDICINE

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PERSPECTIVE
Once Upon a Time...the Hero Sheltered in Place

CASE RECORDS OF THE MGH
Case 23-2020: A 66-Year-Old Homeless Man with Covid-19

EDITORIAL
The Beginning of Genomic Therapies for ALS

ORIGINAL ARTICLE
Pulmonary Vascular Endothelialitis, Thrombosis, and Angiogenesis in Covid-19

PERSPECTIVE
Are U.S. Hospitals Still "Recession-proof"?

Editor's Note: This editorial was published on April 24, 2020, at NEJM.org.

EDITORIAL

Asymptomatic Transmission, the Achilles' Heel of Current Strategies to Control Covid-19

Monica Gandhi, M.D., M.P.H., Deborah S. Yokoe, M.D., M.P.H., and Diane V. Havlir, M.D.

Article Metrics

10 References 69 Citing Articles Letters

TRADITIONAL INFECTION-CONTROL AND PUBLIC HEALTH STRATEGIES RELY heavily on early detection of disease to contain spread. When Covid-19 burst onto the global scene, public health officials initially deployed interventions that were used to control severe acute respiratory syndrome (SARS) in 2003, including symptom-based case detection and subsequent testing to guide isolation and quarantine. This initial approach was justified by the many similarities between SARS-CoV-1 and SARS-CoV-2, including high genetic relatedness, transmission primarily through respiratory droplets, and the frequency of lower respiratory symptoms (fever, cough, and shortness of breath) with both infections developing a median of 5 days after exposure. However, despite the deployment of similar control interventions, the trajectories of the two epidemics have veered in dramatically different directions. Within 8 months, SARS was controlled after SARS-CoV-1

May 28, 2020
N Engl J Med 2020; 382:2158-2160
DOI: 10.1056/NEJMe2009758
Chinese Translation 中文翻译

Related Articles

ORIGINAL ARTICLE MAY 28, 2020
Presymptomatic SARS-CoV-2 Infections and Transmission in a Skilled Nursing Facility
M.M. Arons and Others

CORRESPONDENCE JUL 9, 2020
Screening for Covid-19 in Skilled Nursing Facilities

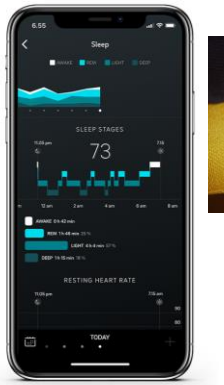
COVID-19 patients may be infectious prior to being symptomatic. This renders the self-report of symptoms meaningless in identifying these cases.

WEARABLE SENSORS

IEEE Open Journal of Engineering in Medicine and Biology

Supplementary Materials

Remote Monitoring of Patients with COVID-19 and Frontline Healthcare Workers Using mHealth Technologies



Ivan
Lee

Jeff
Palmer

WEARABLE SENSORS

Harnessing wearable device data to improve state-level real-time surveillance of influenza-like illness in the USA: a population-based study

Jennifer M Radin, Nathan E Wineinger, Eric J Topol, Steven R Steinhubl

Summary

Background Acute infections can cause an individual to have an elevated resting heart rate (RHR) and change their routine daily activities due to the physiological response to the inflammatory insult. Consequently, we aimed to evaluate if population trends of seasonal respiratory infections, such as influenza, could be identified through wearable sensors that collect RHR and sleep data.

Lancet Digital Health 2020; 2: e85–93
Published Online January 16, 2020
https://doi.org/10.1016/

Stanford Healthcare Innovation Lab

Research Article | Open Access
Volume 2020 | Article ID 6152041 | 8 pages | https://doi.org/10.1155/2020/6152041

Learning from Large-Scale Wearable Device Data for Predicting Epidemics Trend of COVID-19

Guokang Zhu,[1] Jia Li,[1] Zi Meng,[1] Yi Yu,[1] Yanan Li,[1] Xiao Tang,[1] Yuling Dong,[1] Guangxin Sun,[1] Rui Zhou,[1] Hui Wang,[1] **Kongqiao Wang**,[1] and Wang Huang[1]

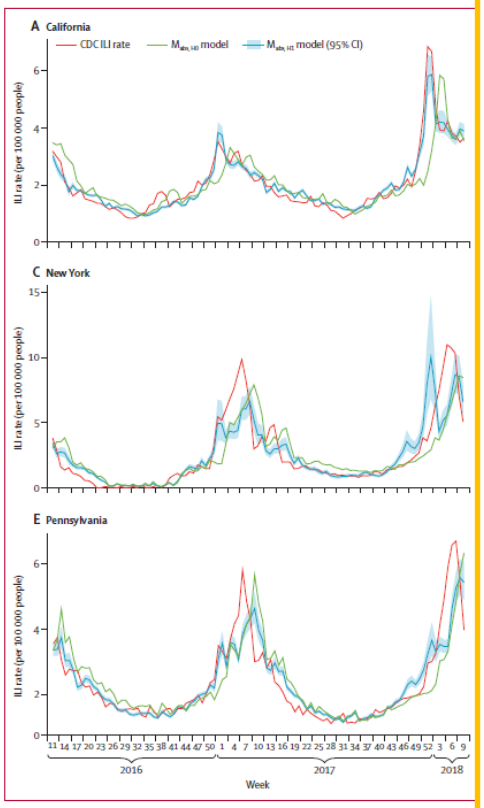


Figure 3: Weekly CDC ILI rates, predicted ILI rates from the baseline $m_{ah,b0}$ model, and predicted ra
Model 1 is used, with the lower heart rate cutoff. Data are from March 16, 2016, to March 1, 2018. CD

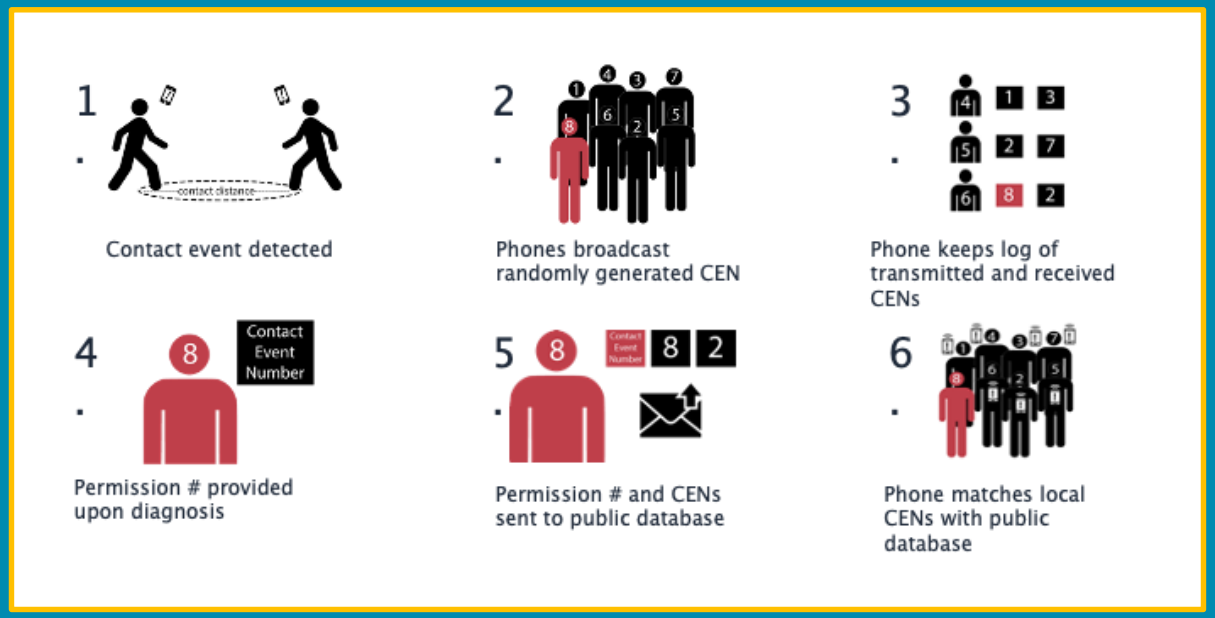
Can population-based results be used to detect infections at the individual level? Are physiological changes specific of COVID-19?

DIGITAL CONTACT TRACING IN THE COMMUNITY

IEEE Open Journal of Engineering in Medicine and Biology

Supplementary Materials

Technology-based Contact Tracing Solutions for Containing the Spread of COVID-19 in the Community



https://www.covid-watch.org/article

Jose Mantilla

Shyamal Patel

mHEALTH SOLUTIONS

ePRO

COVID-19 patients may be infectious prior to being symptomatic. This renders the self-report of symptoms meaningless in identifying these cases.

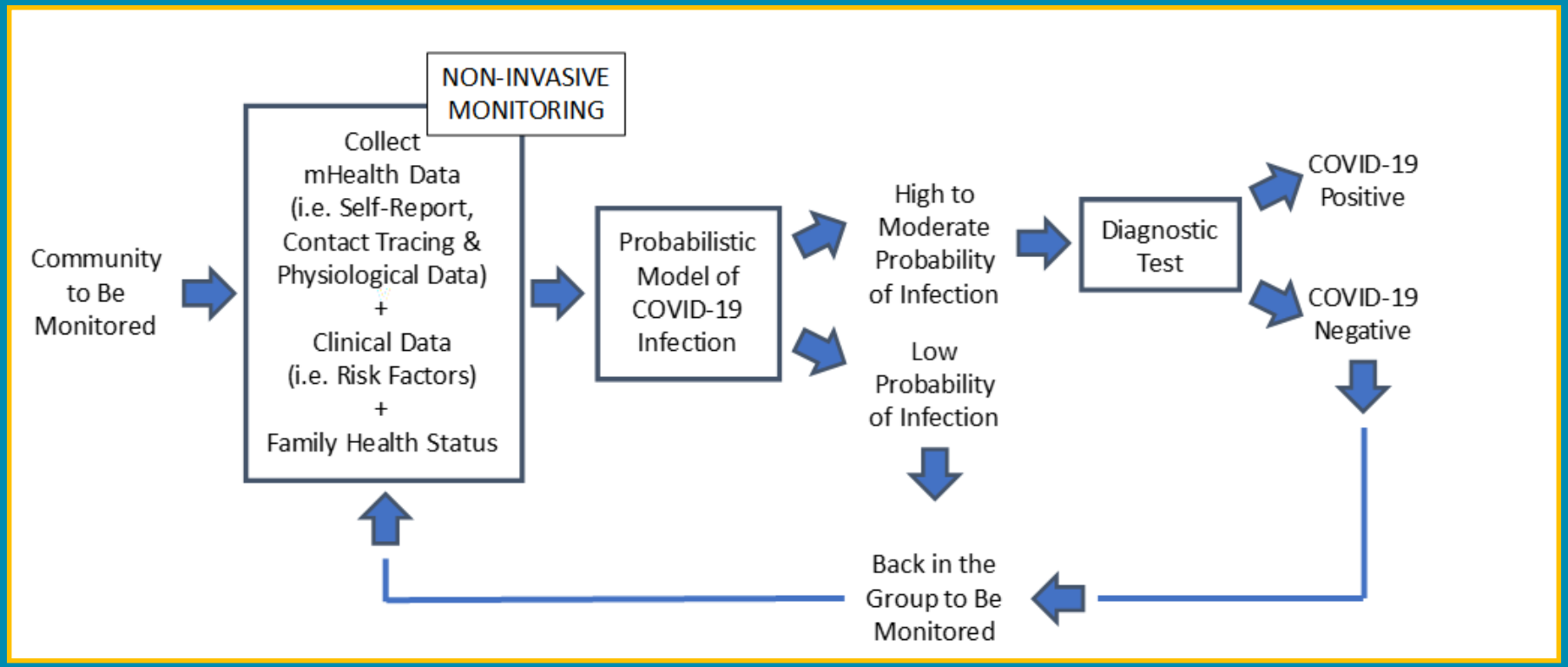
Wearables

Can population-based results be used to detect infections at the individual level? Are physiological changes specific of COVID-19?

Digital Contact Tracing

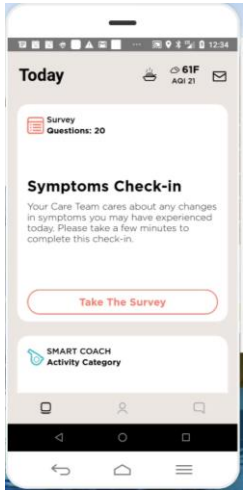
Digital contact tracing can be effective in suppressing the epidemic only if a large portion of the population adopts an app. In addition, being within Bluetooth radio range of the smartphone of a person who have tested positive for COVID-19 does not necessarily imply that a viral transmission took place. Measures of proximity and duration of contact would be relevant in this context. In large metropolitan areas (e.g. among people using public transportation), this approach is likely to lead to a large number of "false positives".

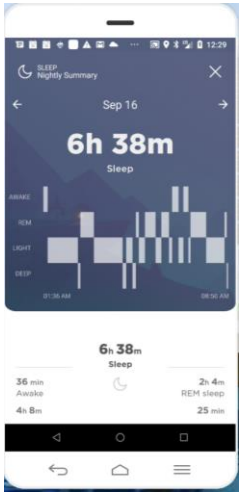
mHealth Technology and Diagnostic Tests

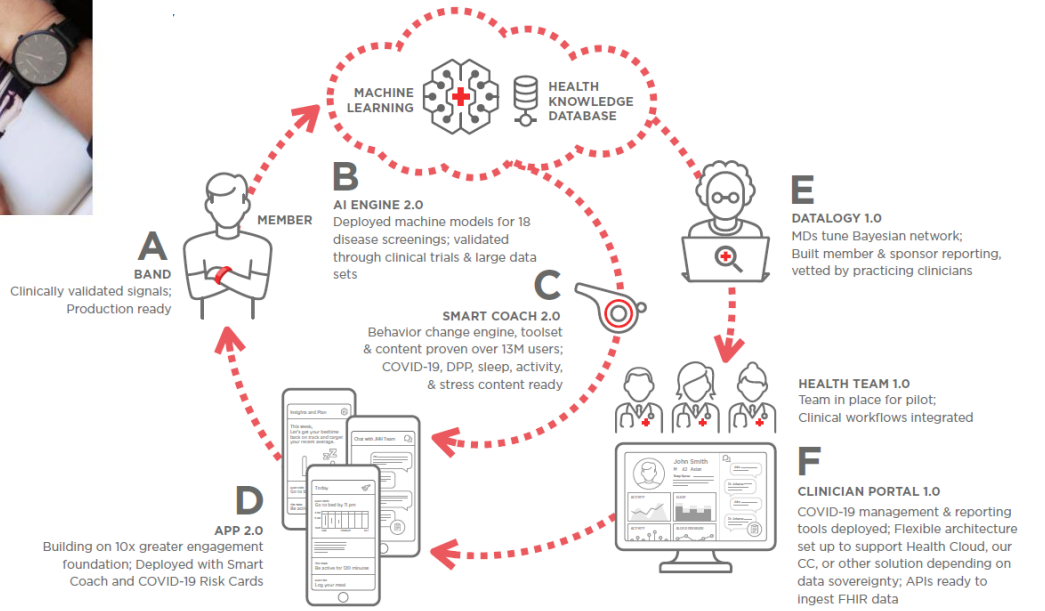


https://ieeexplore.ieee.org/document/9162431

What is Happening Now?







all.health

THE SILVER LINING …

THE LANCET
Digital Health

COMMENT | VOLUME 2, ISSUE 6, E282-E285, JUNE 01, 2020

Virtual care: new models of caring for our patients and workforce

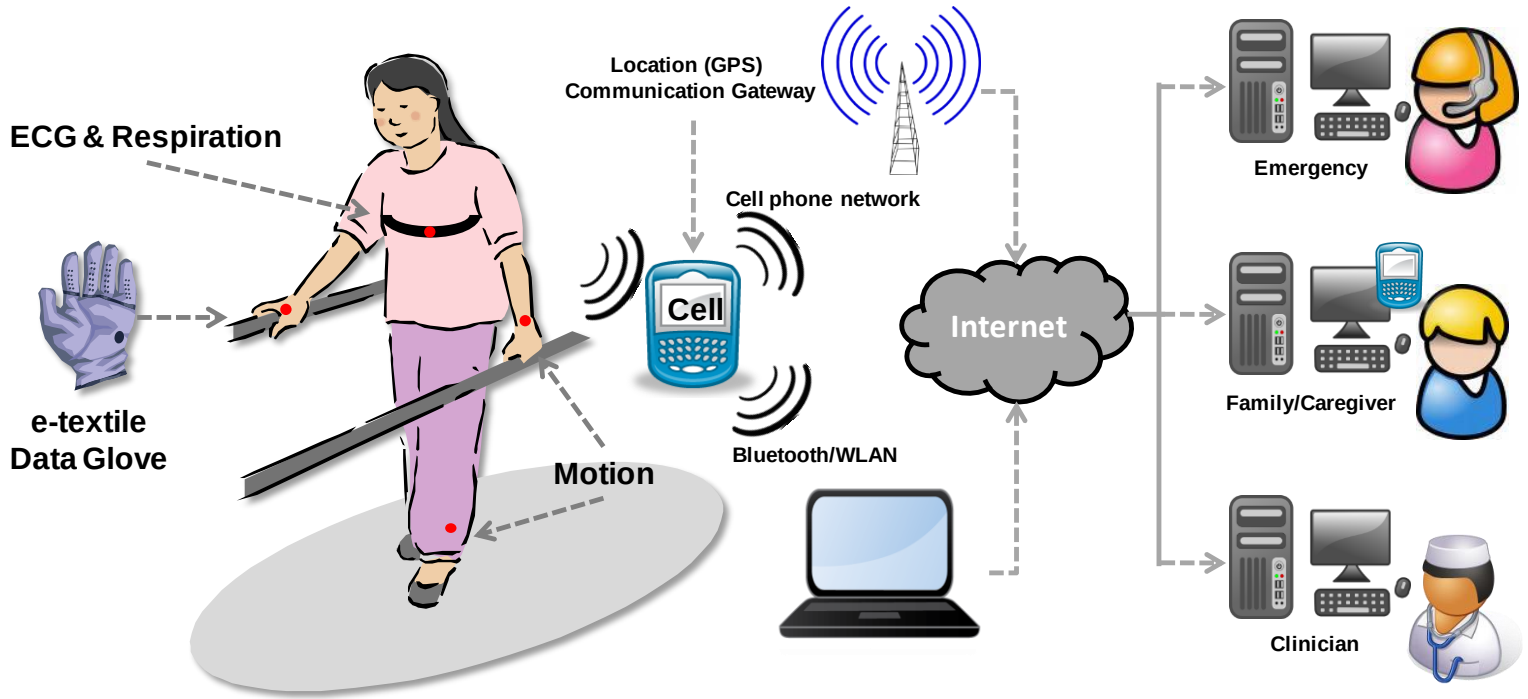
Lee H Schwamm • Juan Estrada • Alistair Erskine • Adam Licurse

Open Access • Published: May 06, 2020 • DOI: https://doi.org/10.1016/S2589-7500(20)30104-7 •

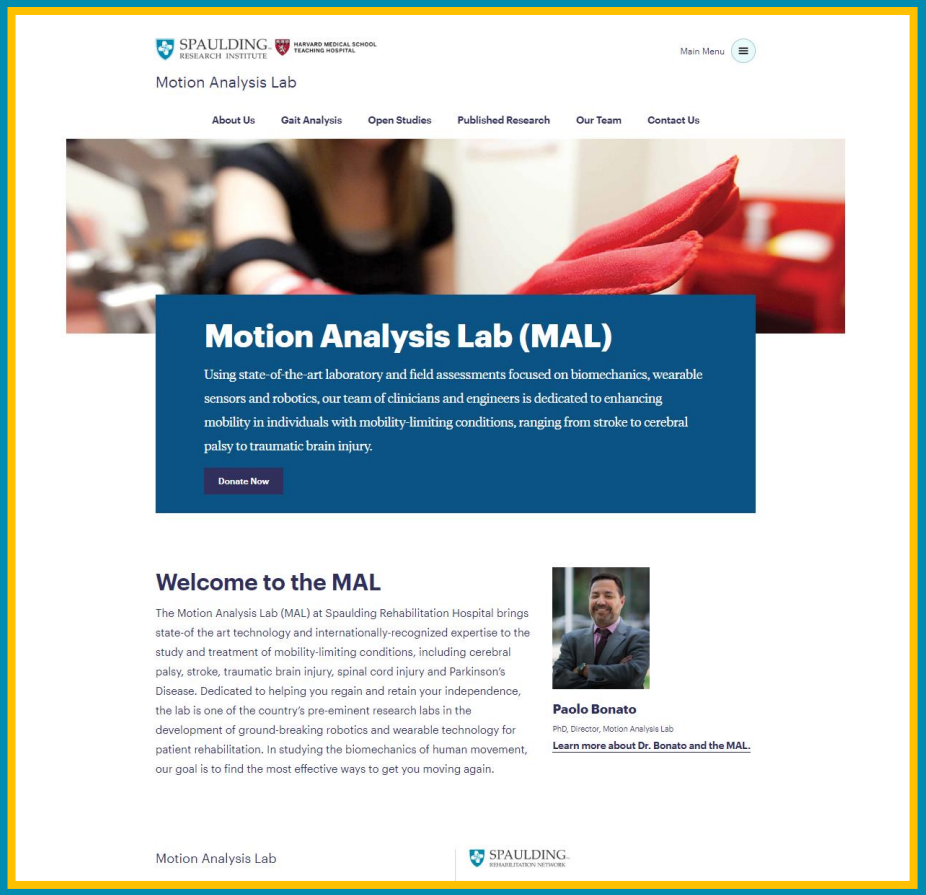
The coronavirus disease 2019 (COVID-19) pandemic has accelerated the widespread adoption of collaboration and communication software to enable medical care at a distance[1] and reduce the risk of transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) between patients and health-care providers from gathering together in hospitals, offices, or clinics. Most virtual care solutions have been implemented to ensure adequate physical distancing between patients and health-care providers, while ensuring that patients without COVID-19 can still access ambulatory care for acute or chronic medical conditions. Although previous efforts to expand virtual care offerings have been met with resistance, the COVID-19 pandemic has highlighted the tremendous value of care delivery at a distance to prevent contagion, but also to provide access to care under these extraordinary circumstances. As a culture, we have learned that many of the patients or providers we had previously deemed too uncomfortable or inept at using technology have actually become quite proficient with videoconferencing for shopping, exercise, socialising, and learning.

For the past two decades, our academic medical centre and others have been building capability in ambulatory virtual visits in specialty care, virtual urgent care for minor complaints, and interfacility emergency virtual consults for time-sensitive conditions like acute stroke.[2, 3, 4, 5] These efforts have been rudimentary at most institutions due to complex technology integration, substantial regulatory barriers, and a lack of reimbursement. One of the greatest criticisms of virtual care in the past has been its depersonalisation of the patient–provider experience, which is too distant for the intimate connection required for good care.[6] Ironically, this attribute of care delivery at a distance is now virtual care's greatest asset. Providers are scrambling to provide options that ensure safe, effective, and equitable access to care for patients in the setting of relaxed regulations and broader reimbursement. Here we describe two innovations in virtual care delivery that have been developed and deployed across our organisation, virtual rounds and a virtual intercom communication system, and give suggestions for how these innovations might be

THE SILVER LINING …



Bonato, IEEE Eng in Med & Biol 2010; 29(3): 25-36
Patel et al, J Neuroeng Rehabil, 2012; 9: 21



https://spauldingrehab.org/research/programs-labs/motion-analysis

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IEEE Entrepreneurship

NEW TECHNOLOGIES, ETHICS AND POLICY ENGAGEMENT FOR SUSTAINABLE DEVELOPMENT: HEALTH & HUMAN WELL-BEING (H&HWB)

Health 4.0 - Transformation of Diagnostic Care for Preventative Medicine

Dr. Ali Tinazli – Chief Commercial Officer – Fluxergy Inc., Irvine, CA

FLUXERGY

Definition of Health

"A state of complete physical, mental and social well-being and not merely the absence of disease or infirmity"

WHO Constitution, April 7th 1948

Megatrends point to transformation in Life Sciences creating Opportunities for Disruption in Healthcare

Infection X

Aging Demographics

Drug resistant "super-bugs"

Wellness Applications

Digital health

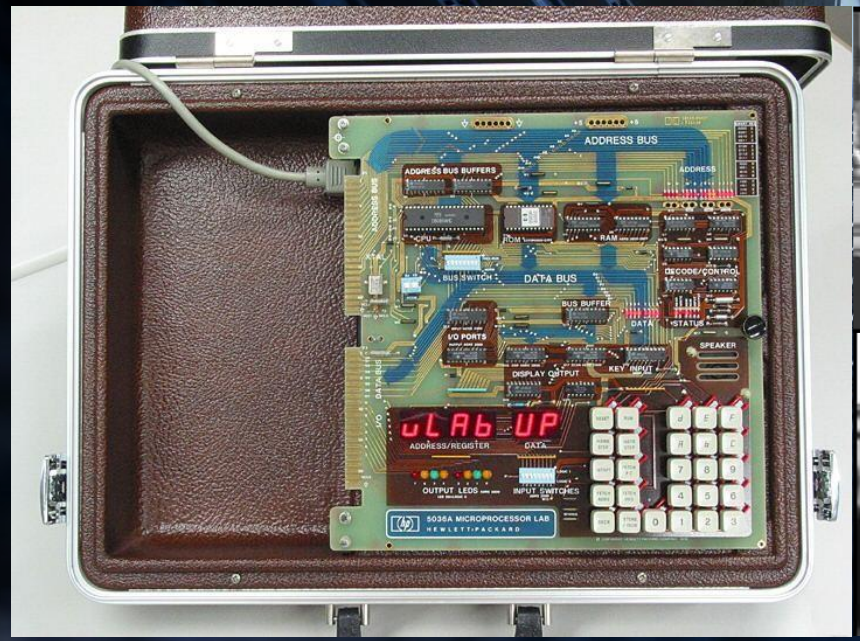
Decentralization of Healthcare

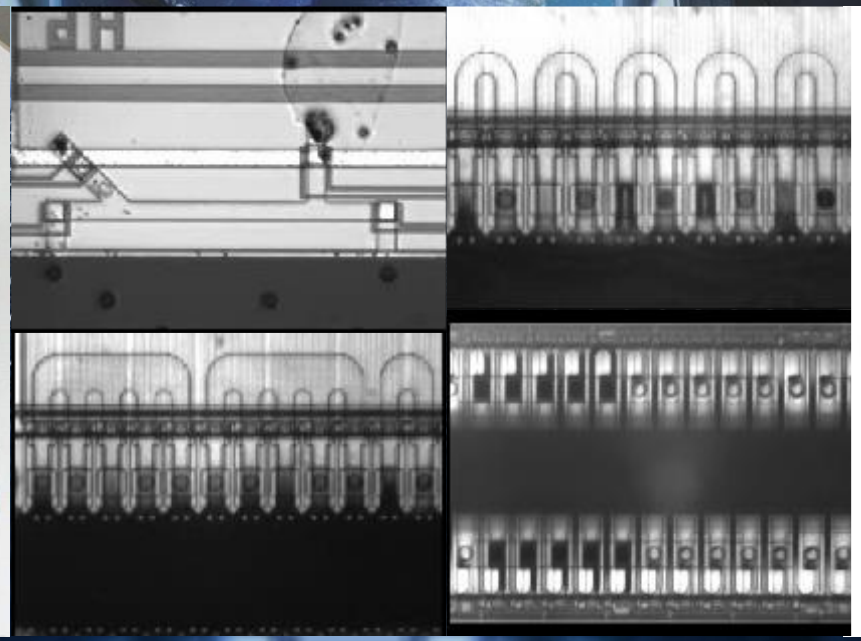
Technology Convergence

PRIMARY TECH IMPLICATIONS:

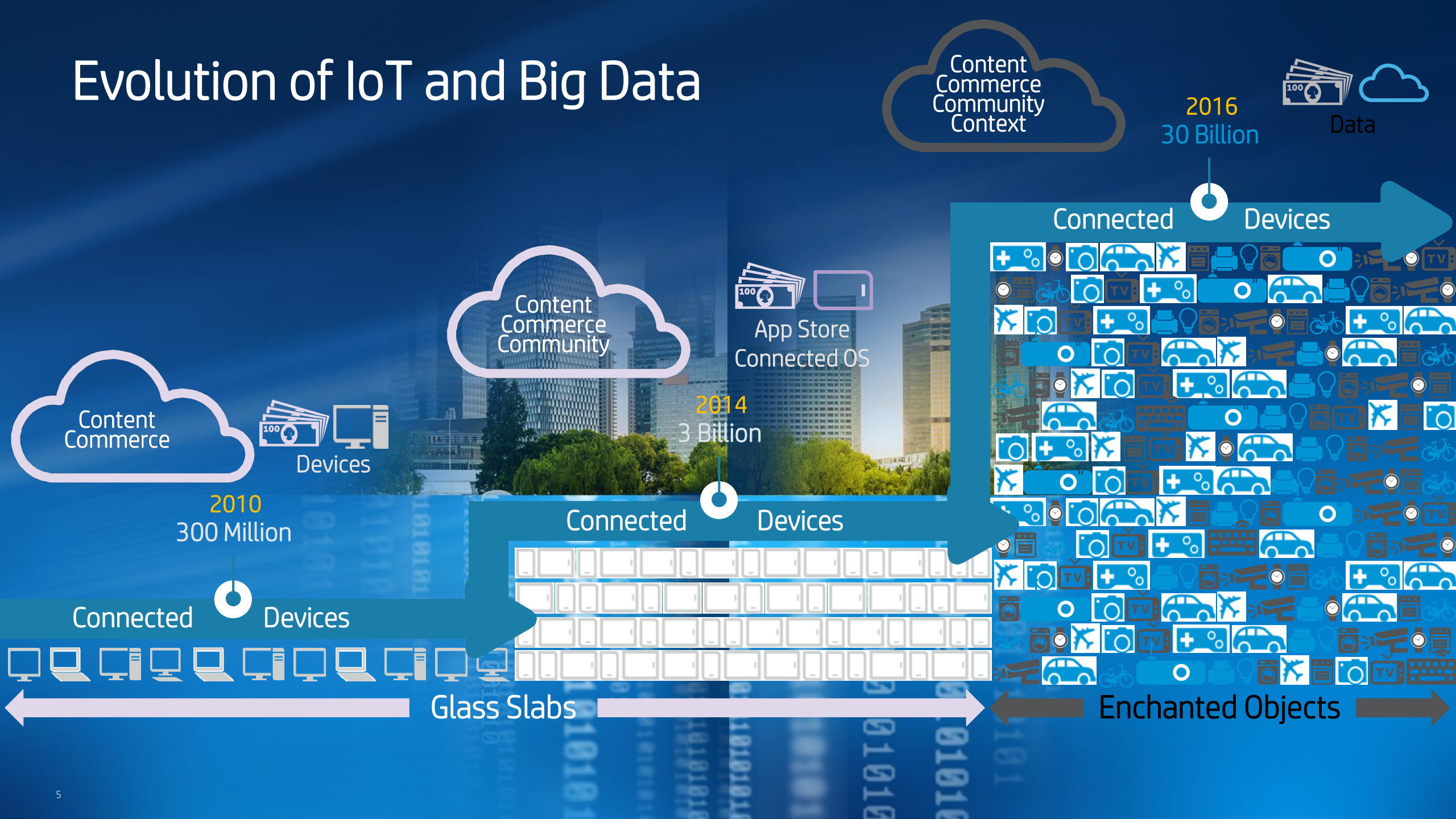
Miniaturization	Digitization
Speed	Precision
Decentralization	Efficiency
High sensitivity	Cost
Personalization	Cybersecurity

We are in the age of technology convergence





Evolution of IoT and Big Data



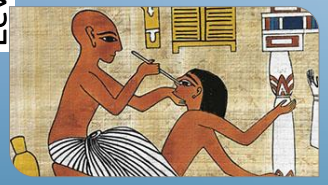
Health 4.0 – Hypermobility & Microfluidics

From a 1-to-1 art to digital mass industrialization & scale, transforming to interconnected & democratized applied science

Healthcare Timeline

Level of Technology

Ancient times

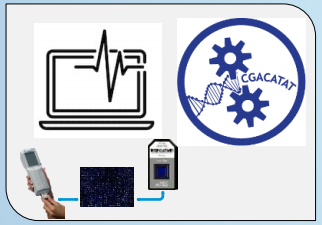


- Health 1.0
  - Rudimentary
  - Highly personal 1-to-1
  - **Access: Exclusive**

Pre 20th Century

- Health 2.0
  - Foundation of modern medicine
  - Shift to scientifically-based medicine
  - **Access: Limited**

20th Century



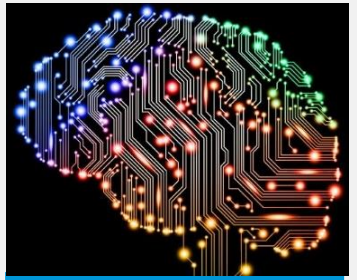
- Health 3.0
  - Industrialization, centralization & standardization
  - Rise of complexity & specialization
  - Technologies challenge healthcare economics
  - **Access: Benefit**

Next

- Health 4.0
  - Decentralization enabled by nano/microtech
  - Focus on prevention
  - Personalized treatments
  - **Healthcare-IoT, Big data, Machine Learning, AI**
  - **Access: Democratized**

Key trends shaping Healthcare

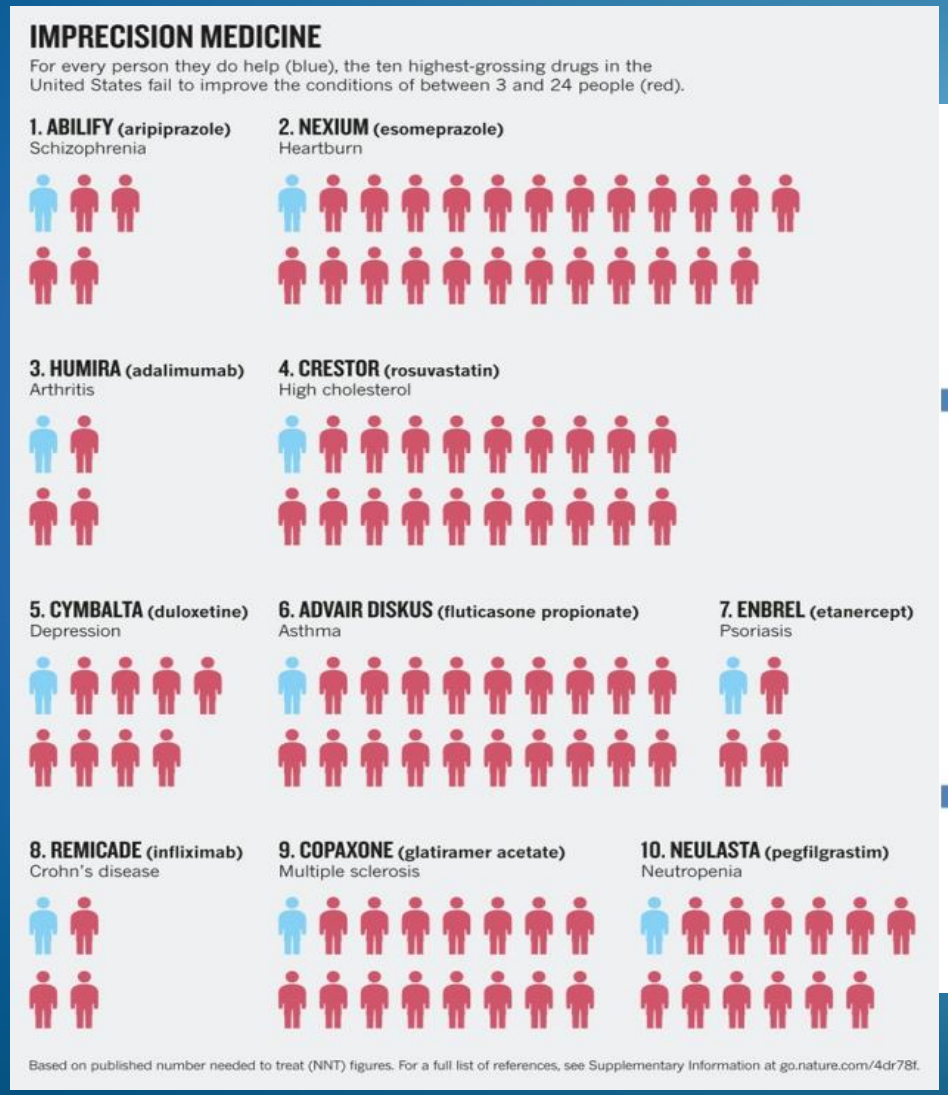
- Convergence of Technologies
- Empowered and engaged customers
- Regulatory changes
- Digital Revolution: healthcare IoT, AI

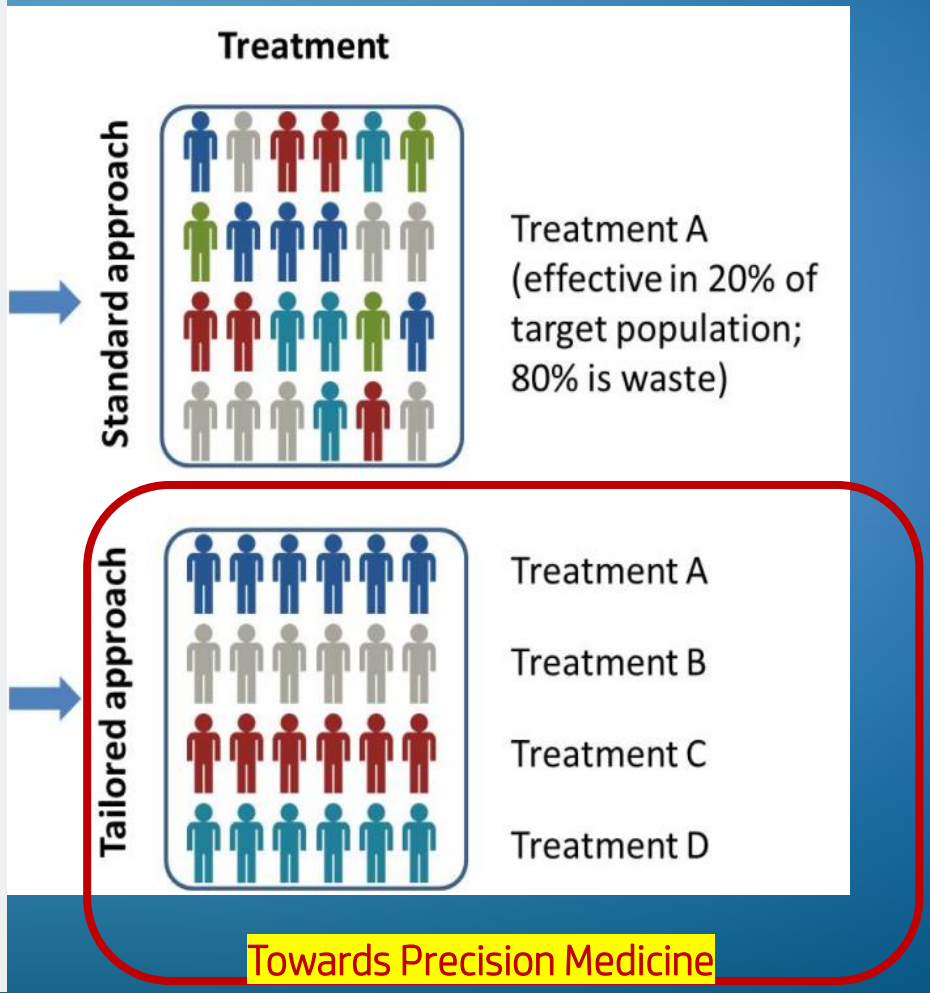


Shift toward decentralized, connected, preventive, and personalized treatment models

Reinventing industries

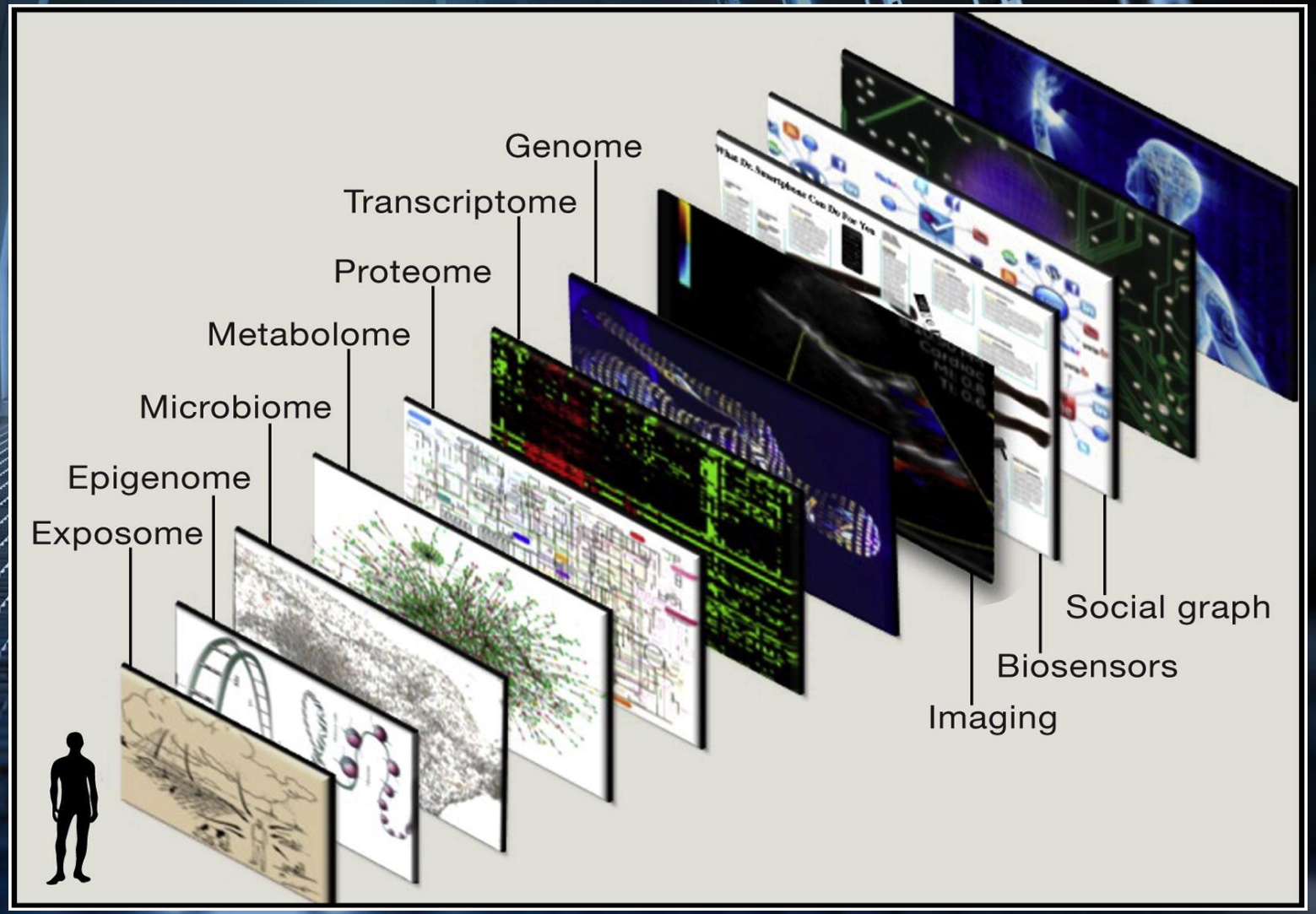
Imprecision Medicine – Do we already have what we need?





Understanding biological complexity

Source: Anna Maria Sybilla Merian, Metamorphosis insectorum Surinamensium. 1705

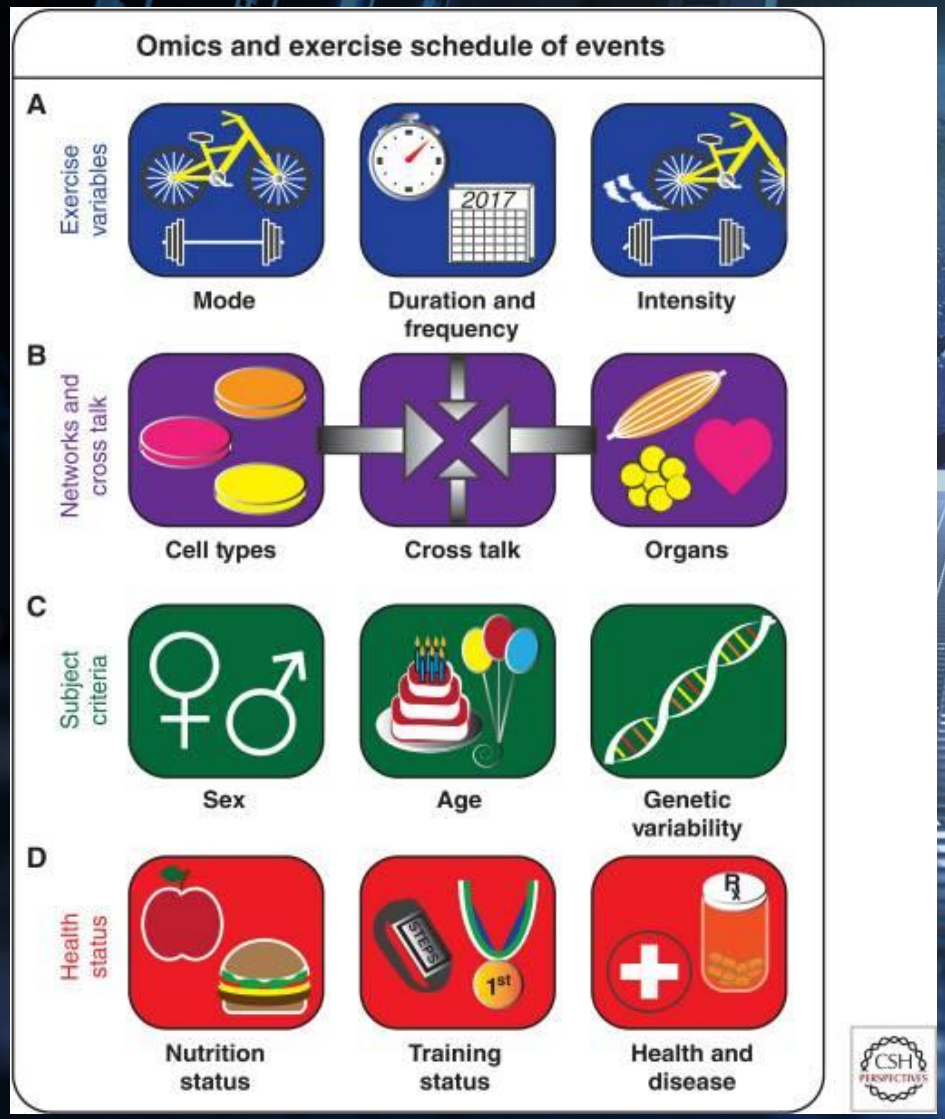


Source: Eric Topol (Cell 2014)

Understanding human physiology and well-being

Source: Cold Spring Harb Perspect Med. 2017 Oct; 7(10): a029884.

Opportunity for DIAGNOSTIC CARE



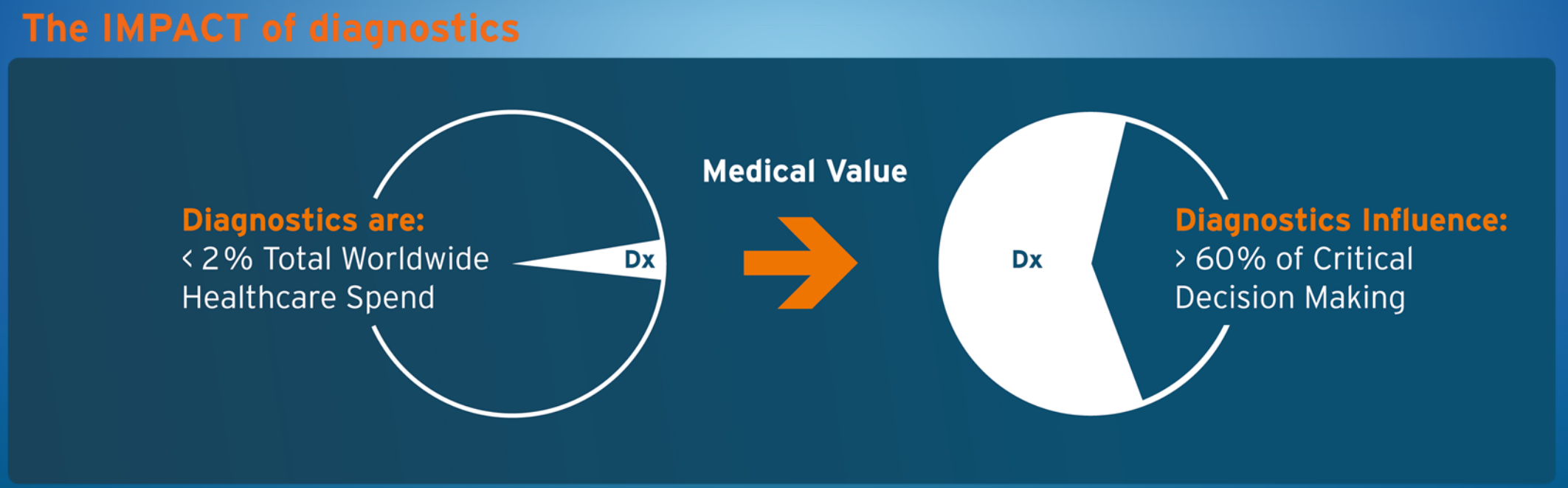
Diagnostics & Preventative Health

→ Diagnostic Care

Source: Cold Spring Harb Perspect Med. 2017 Oct; 7(10): a029884.

DIAGNOSTIC CARE can disrupt the $11T HEALTHCARE MARKET

Assessment of transformative disruption in U.S. healthcare market ($3T) – global impact even at larger scale ($11T)*



Example – Healthcare Testing

From standardized, reactive, and in-person care

To personalized, preventative, and remote care

KEY THEMES:

- Healthcare crisis
- Healthcare anywhere
- Personalized healthcare
- Digital biology

IMPLICATIONS:

Healthcare at the edge

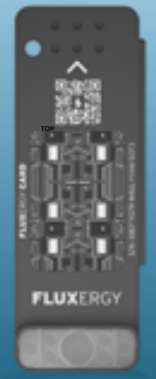
Microfluidics

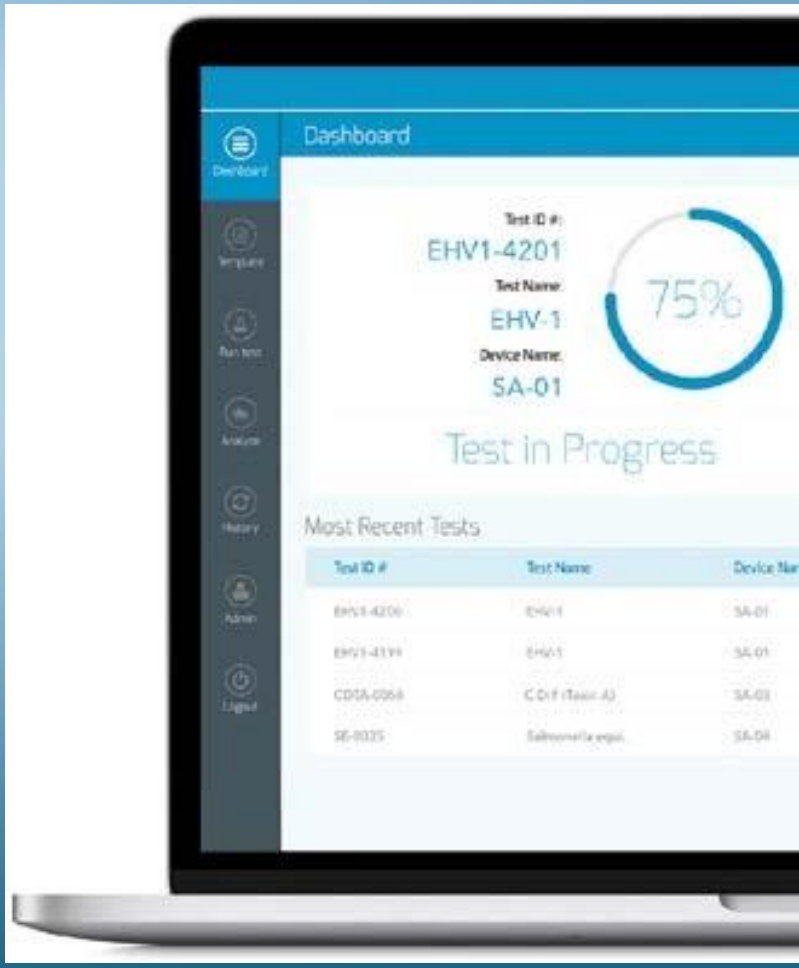
Security of healthcare data and systems

The vision of the Fluxergy platform

Fluxergy is developing a platform* that has the potential to make the below features a reality:

- ✓ **Fast results:** 15-45 minutes
- ✓ **Low Cost:** Disruptive cost structure could enable complete testing at the Point of Care*
- ✓ **Sample-to-Answer workflow**
- ✓ **Multiplex/Multimodal:** Various biomarkers; cells to molecules
- ✓ **Reduced healthcare costs:** 5-30% (est.) through early detection, fewer visits, reduced acute care cases





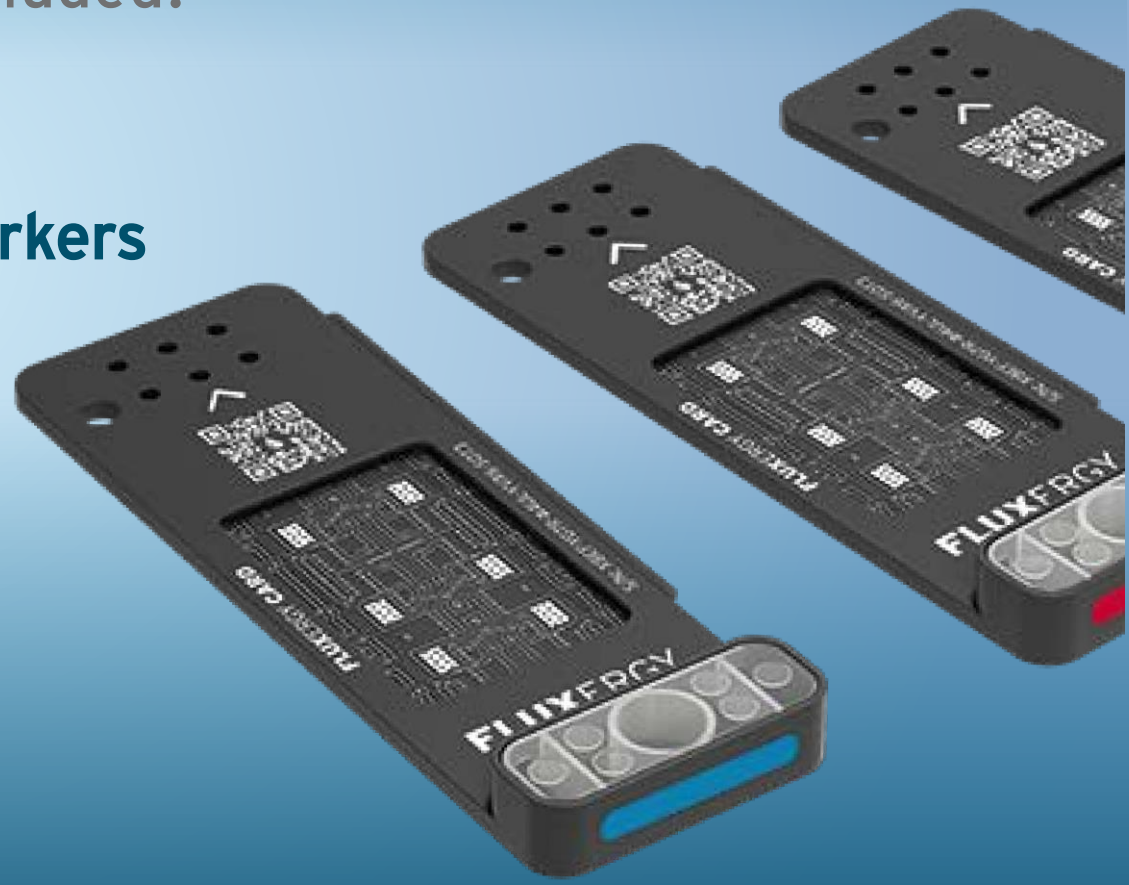
Fluxergy's products are for Research Use Only (RUO) and are not for use in diagnostic procedures. Fluxergy Products have not been evaluated or approved by the FDA or USDA. None of these statements have been endorsed by the FDA or USDA. None of the products discussed in this presentation are currently being sold or offered for sale.

Multiplex and multimodal panels on a single TestCard

Configuration of sub-systems can emulate different laboratory equipment with the FluxergyCard.

The **FluxergyCards** modular nature has the potential to allow for a variety of assays and panels* to be included:

- **PCR Multiplex panels up to 12 targets**
- **Immunochemistry panels with 12+ markers**
- **Chemistry panels with 12+ markers**
- **Cytometry (e.g. cell counting)**
- **Mixed modality panels**



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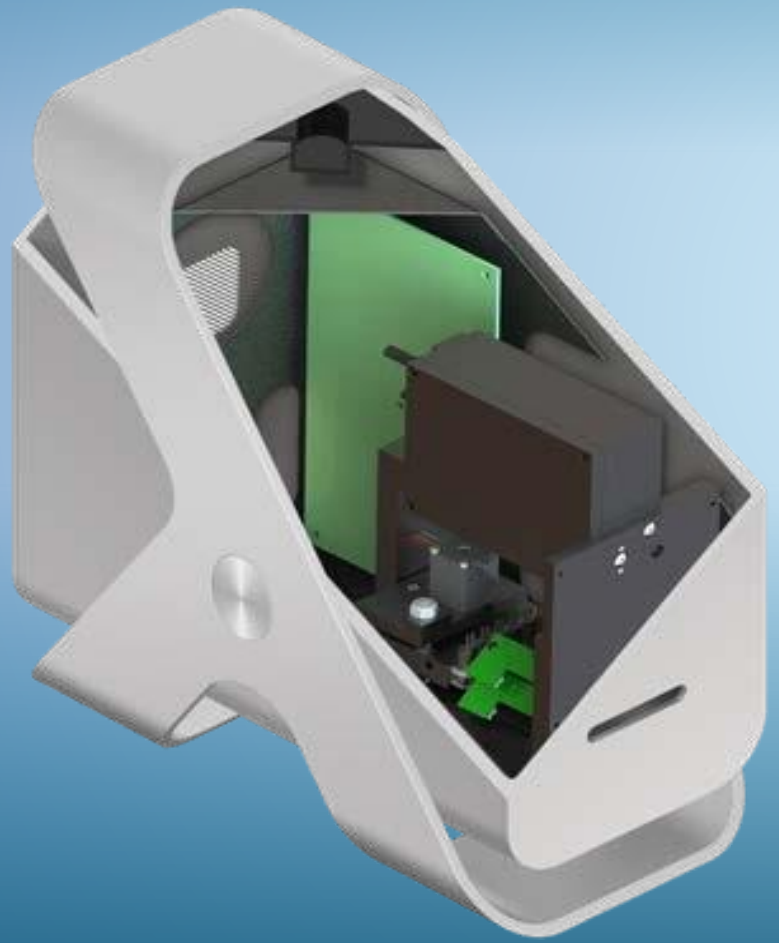
Multiple detection systems in one analyzer

Configuration of sub-systems can emulate different laboratory equipment with the FluxergyCard.



Real-Time PCR

- Fluorescence measurement

Colorimetric Detection

- End-point measurement for immunoassays

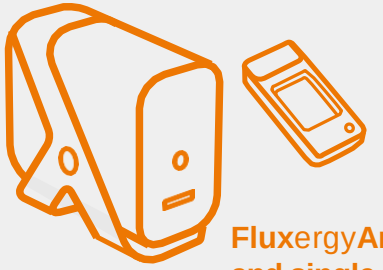
Electrical Potentiometry

- Potential measurement across ion-selective electrodes

Imaging Cytometry

- Image recognition

WE ARE AIMING TO ACHIEVE SCALABLE THROUGHPUT AT THE POINT-OF-CARE THROUGH SMART DEVICE MANAGEMENT



AI/Machine learning

FluxergyAnalyzer and single-use FluxergyCard

Storage

Privacy security (256-bit encryption) HIPAA Compliance

Cloud Platform

Server

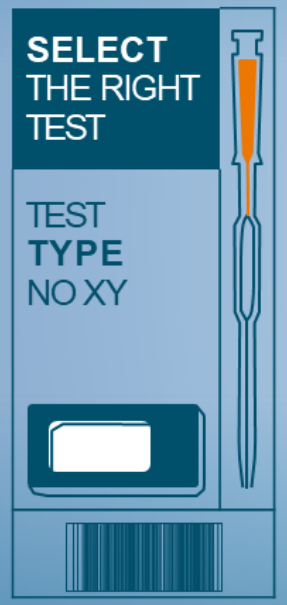
Cloud Management

- Update and optimization/functions
- Technical support
- Extended storage
- Interface w/EMR, Retail Apps, Wearables

SAMPLE-TO-ANSWER* DEVICE INSTEAD OF AN ENTIRE LABORATORY

GENERATION AND MANAGEMENT OF HEALTH DATA VIA EDGE AND/OR CLOUD COMPUTING

Select a test, collect a sample and mix with supplied **Fluxergy Buffer.**



Add sample and buffer mixture to selected **Fluxergy Card.**

15 – 45 MIN

Insert **Fluxergy Card** into the **Fluxergy Analyzer** and run the test.

Upload data, manage, store, analyze

Fluxergy Works
- Storage
- Services
- Big Data analytics
- Cloud connectivity

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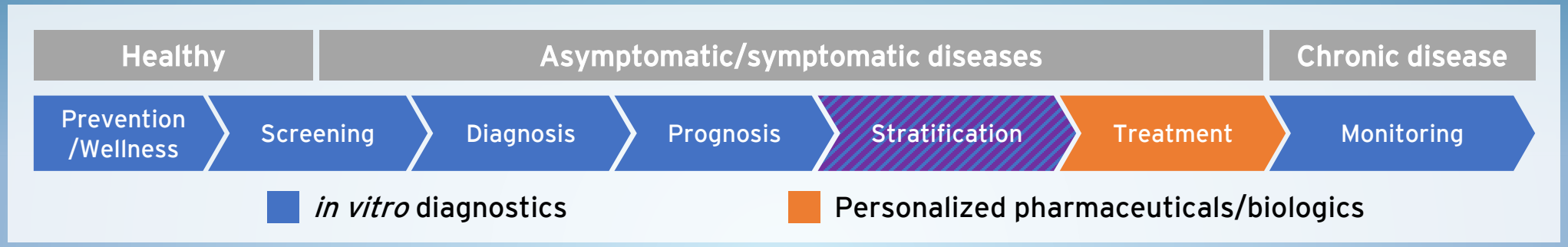
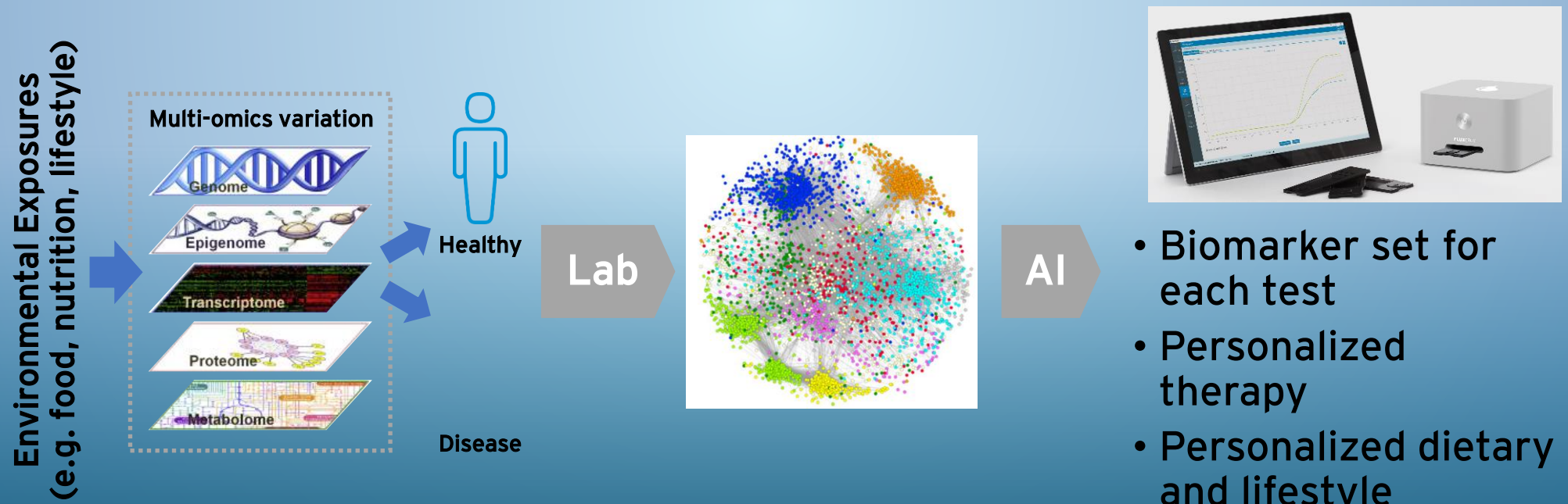
POST-COVID-19

WHAT TO DO WITH THE ESTABLISHED INFRASTRUCTURE FOR DECENTRALIZED HEALTH TESTING?

DIAGNOSTIC CARE FROM WELLNESS TO CHRONIC CONDITIONS: CONTINUUM OF TESTING SOLUTIONS

Substantial opportunity for product solutions from provider to consumer home settings.





- Biomarker set for each test
- Personalized therapy
- Personalized dietary and lifestyle recommendation

Post-COVID-19 World

Infection X

Aging Demographics

Drug resistant "super-bugs"

Wellness Applications

Digital health

Decentralization of Healthcare

Technology Convergence

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Information Resources

Applications of our technology: https://docsend.com/view/eusrgiwtbadmpizg

Investment summary: https://docsend.com/view/asg67xi6wv5ewnsm