DIGITAL INNOVATION AND TECHNOLOGY FOR ADDRESSING PREVALENT CHRONIC DISEASES

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DISCLAIMER

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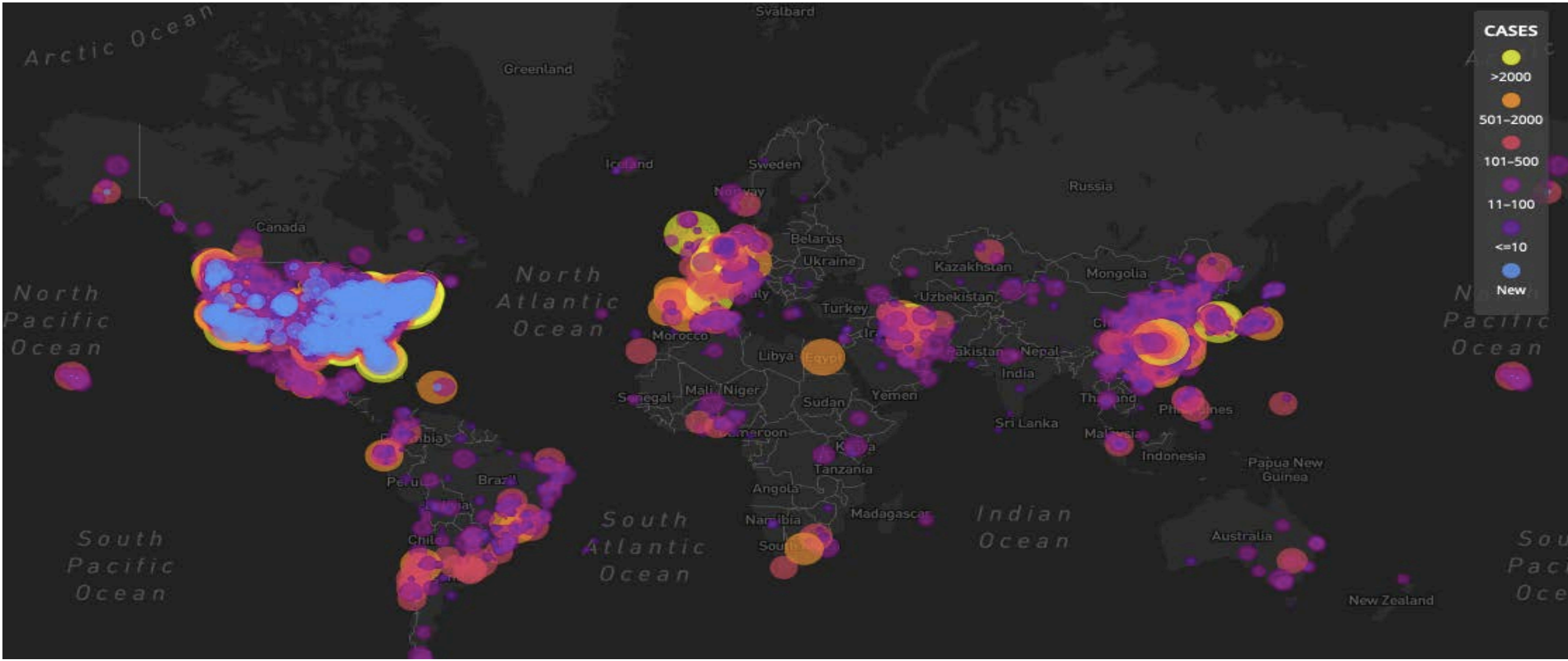
OBJECTIVES

- ***Technology in management of chronic diseases, including understanding the facilitators and barriers***
- ***Technology in clinical research capturing trial data (traditional and decentralized trials)***
- ***Case study: integrative collaborative effort at understanding an unmet need in chronic obstructive pulmonary disease (COPD)***

COVID-19 PANDEMIC

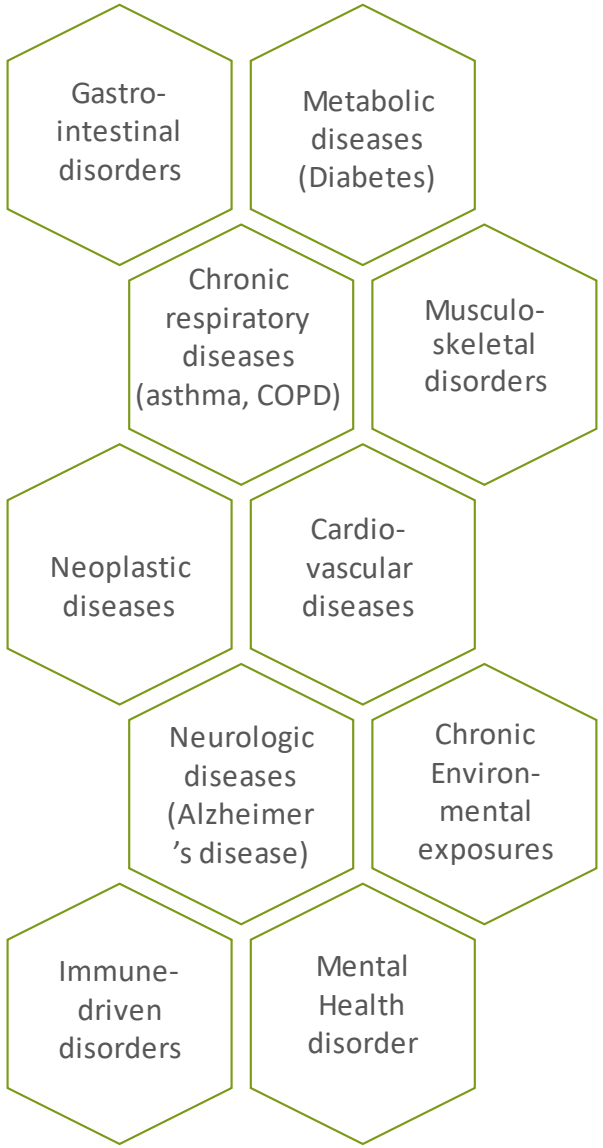
The pandemic has highlighted both health disparities AND health technology



HealthMap COVID-19

April 2020: 2,084,711 Cas

TECHNOLOGY (DIGITAL HEALTH) IN CHRONIC DISEASES DISEASE MANAGEMENT



- **Chronic Diseases in the United States[1]:**
  - 6 in 10 adults suffers from a chronic disease
  - 4 in 10 adults suffers from 2 or more chronic diseases
  - Leading causes of death and disability
  - Drivers of health care utilization and health care costs– $3.8 Trillion

- **Technology for Chronic Diseases Can Facilitate Management[2,3]**
  - Disease monitoring
  - Medication management and adherence
  - Behavior modification
  - Telemedicine/telehealth
  - Patient advocacy and community building
  - Medical record management
  - Comorbidity monitoring and management

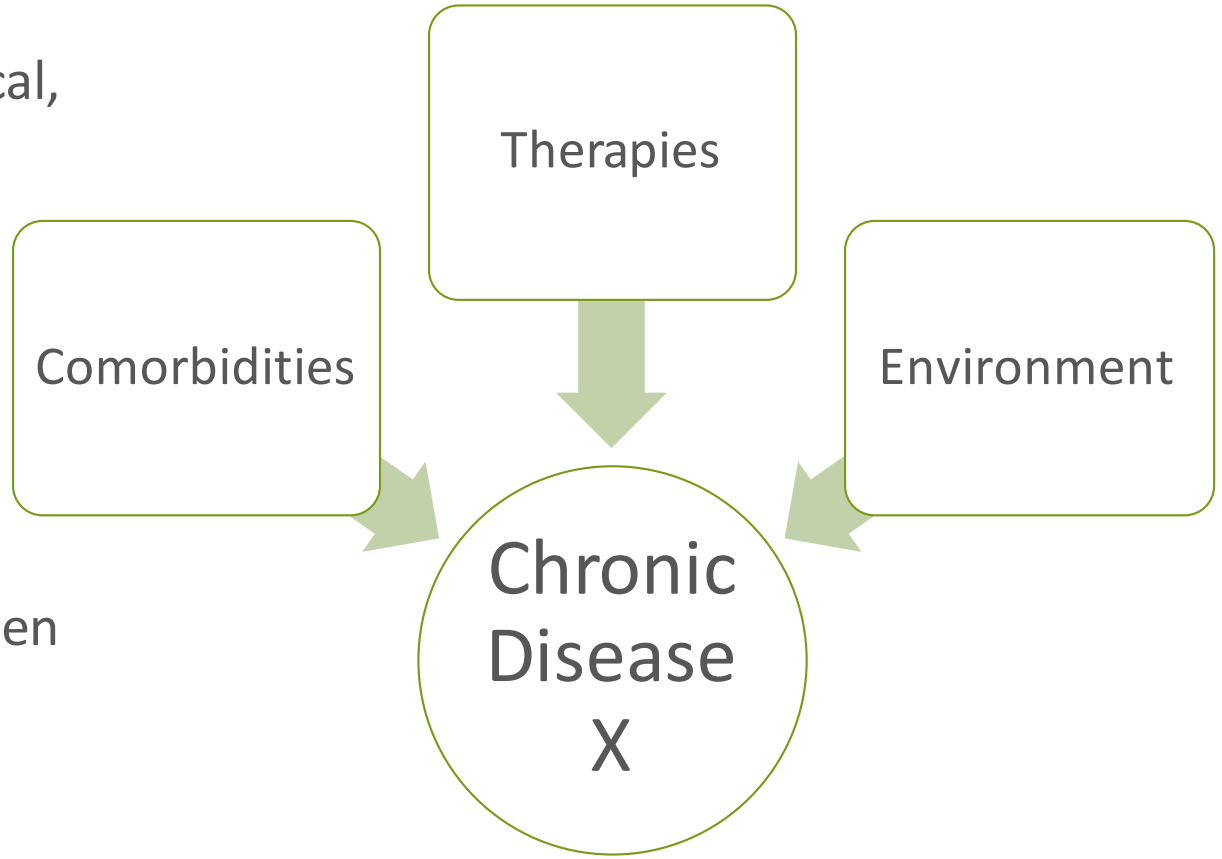
  - *Hospital/provide data management systems*

1) CDC. Chronic Diseases in America. Website: https://www.cdc.gov/chronicdisease/resources/infographic/chronic-diseases.htm. Accessed: 01 Mar 2021. 2) Morton K, et al. Using digital interventions for self-management of chronic physical health conditions: A meta-ethnography review of published studies. Patient Educ Couns. 2017 Apr;100(4):616-635. 3) Bashi N, et al. Digital health interventions for chronic diseases: a scoping review of evaluation frameworks. BMJ Health & Care Informatics 2020;27:e100066.

PATIENT-FACING DIGITAL HEALTH TOOLS FOR CHRONIC DISEASE MANAGEMENT

These tools must sometimes account for the different patient types

- Addresses the needs of the patient: medical, personal, emotional, and functional
- Engages the patient and their family/caregivers
- Achieves patient self-management
- Allows for effective communication between patient and provider
- Increase overall accessibility

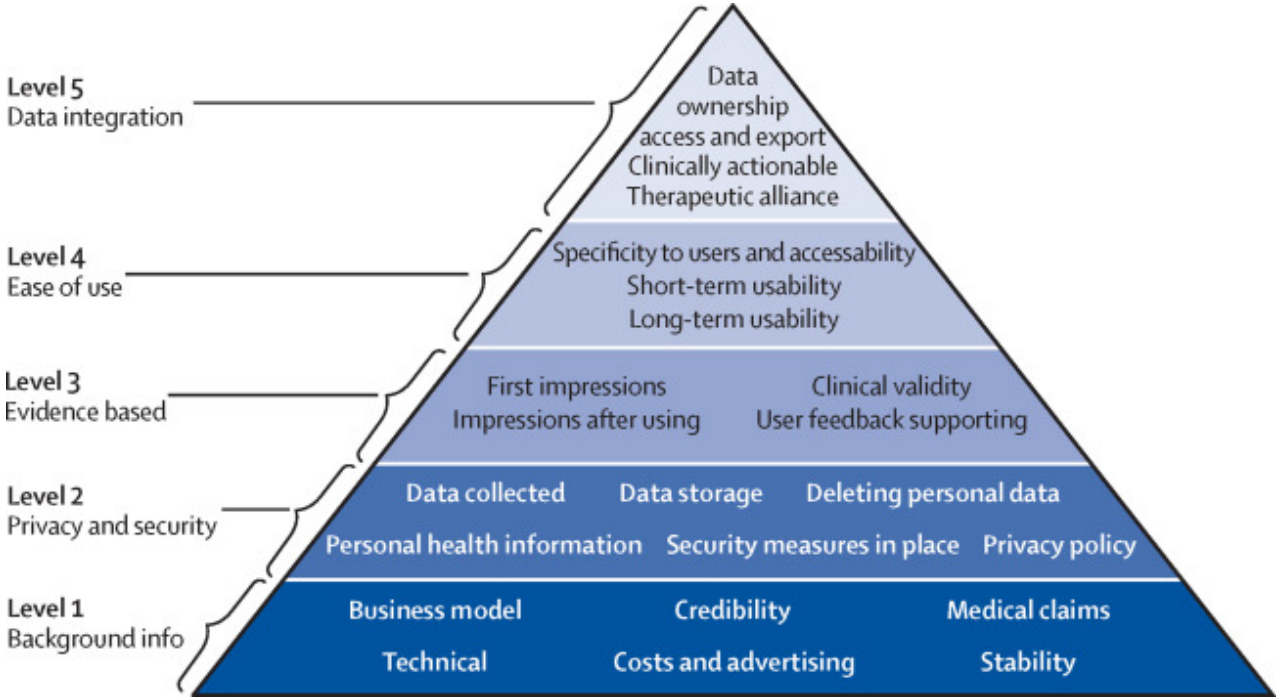


1) Bhattacharyya O, et al. Using Human-Centered Design to Build a Digital Health Advisor for Patients With Complex Needs: Persona and Prototype Development. J Med Internet Res. 2019 May 9;21(5):e10318. 2) Bashi N, et al. Digital health interventions for chronic diseases: a scoping review of evaluation frameworks. BMJ Health & Care Informatics 2020;27:e100066.

THE LIMITLESS NUMBER OF DIGITAL TOOLS CREATE A DILEMMA FOR PATIENTS AND HEALTHCARE PROVIDERS

Barriers to utilization of technology include navigating the complex number of tools available (e.g., websites, apps, wearables)

Pyramid for app evaluation framework[1]

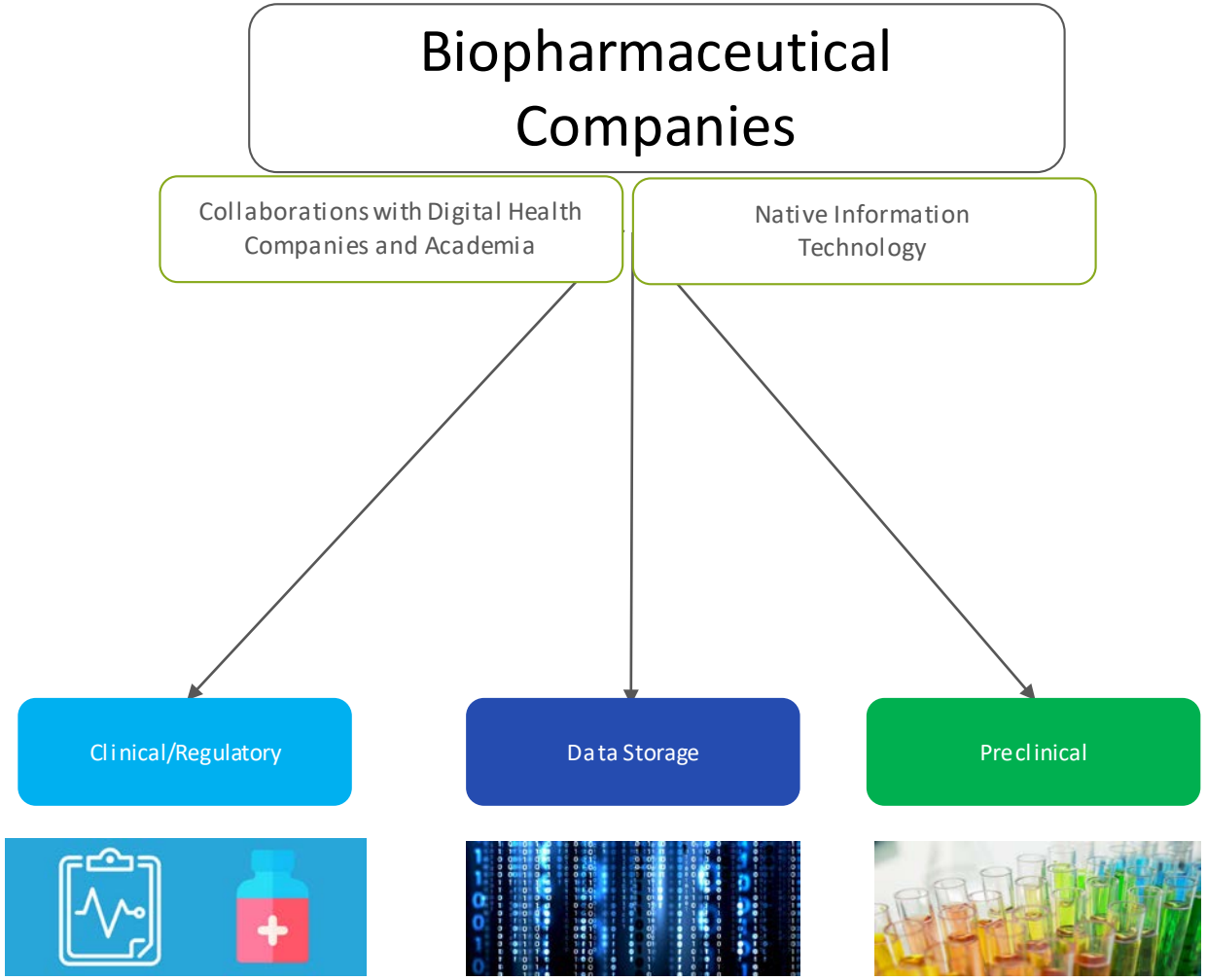


Like medicines, biopharmaceutical industry R&D are using digital tools for the development of drugs and as tools alongside drugs

1) Henson P, David G, Albright K, Torous J. Deriving a practical framework for the evaluation of health apps. Lancet Digit Health. 2019 Jun;1(2):e52-e54. doi: 10.1016/S2589-7500(19)30013-5.
Left: Stock photo.

TECHNOLOGY PARADIGM IN THE BIOPHARMACEUTICAL INDUSTRY

Biopharmaceutical companies also rely on emerging technologies for a variety of functions



Preclinical

- Artificial intelligence
- Automation
- Repositioning

Data Storage

- Centralized, secure cloud-based
- Blockchain

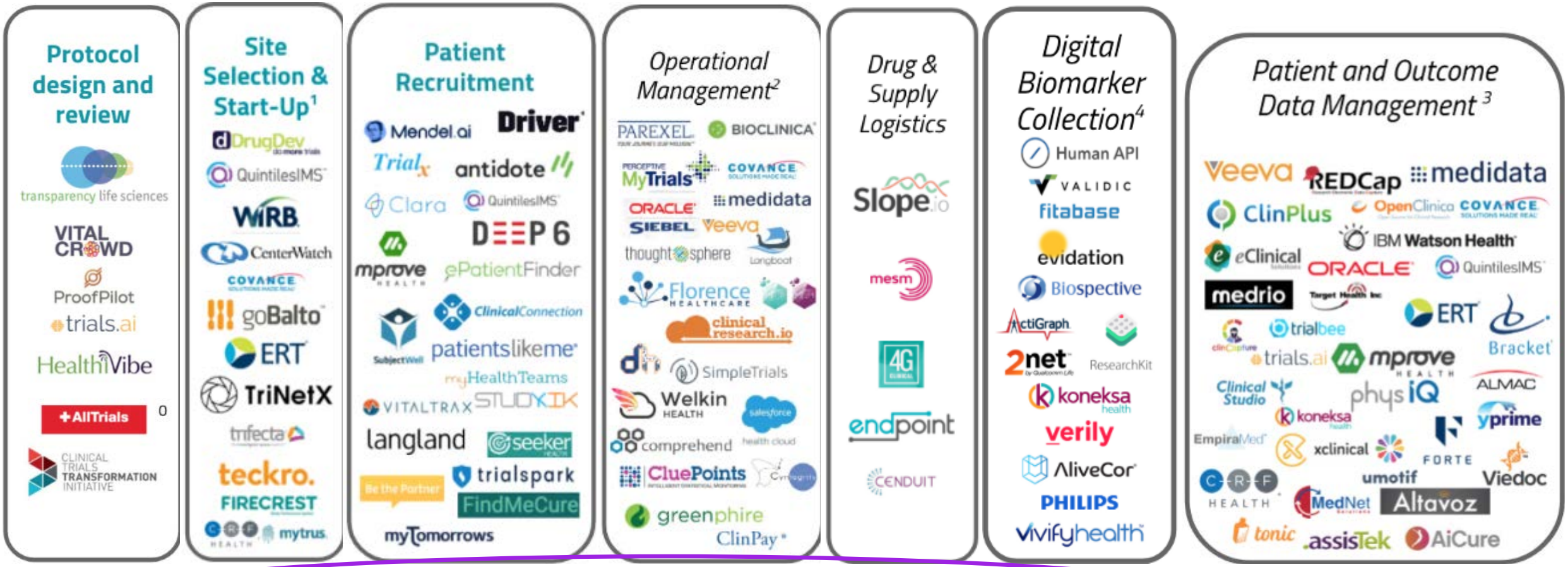
Clinical/Regulatory[1]

- Digital Biomarkers (including data from Wearables; capturing patient reported outcomes)
- Digital Therapeutics
- Study documents and systems (e.g., electronic data capture)
- Health authority submissions
- Real world evidence (e.g., eHR, etc)
- Promotion of Wellness

1) SNS Research. Big Data in the Healthcare & Pharmaceutical Industry: 2018–2030 – Opportunities, Challenges, Strategies & Forecasts. 2018, https://www.snstelecom.com/bigdatahealthcare.
Left: Stock photo.

TECHNOLOGY IMBEDDED IN THE INDUSTRY CLINICAL RESEARCH PROCESS

Vast digital landscape for clinical research with rapid expansion due to decentralized trials



[Coravas, Software Enabled Clinical Trials]

QUESTIONS

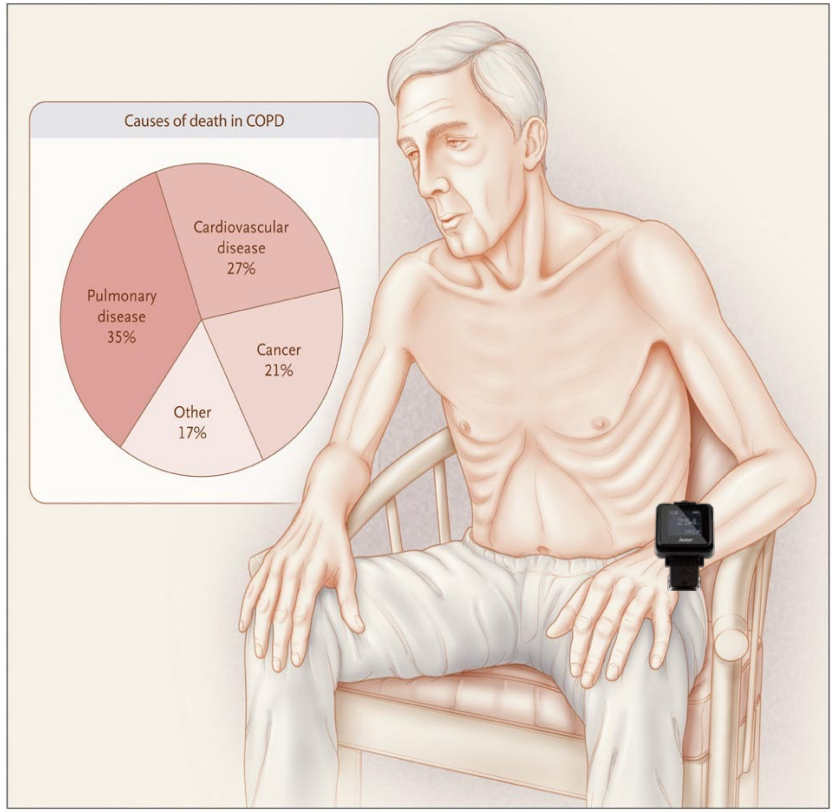
How do we know the technology is effective in capturing important endpoints (e.g., patient reported outcomes)?

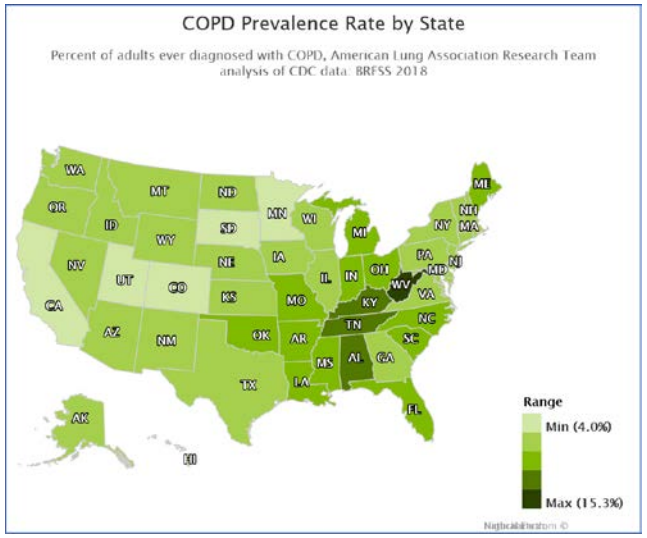
How can we integrate traditional and tech into clinical trials and disease management?

Who leads the way?

CASE STUDY: EXPLORING AN UNMET NEED IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE

CHRONIC OBSTRUCTIVE PULMONARY DISEASE AND PHYSICAL ACTIVITY, AN UNMET CLINICAL NEED





- Chronic obstructive pulmonary disease (COPD) is a progressive illness characterized by persistent airflow limitations; symptoms include chronic cough, sputum, shortness of breath[1]
- In addition to respiratory symptoms, and exacerbations, people with COPD suffer from reduced activity and decline in quality of life[2]
- Estimated healthcare attributable to COPD is $49 billion (2020)[3]
- Current patient-reported outcome tools may underestimate the disease burden related to loss of physical activity and independence[2]
- Can we better capture this data?

1)Halpin DMG, et al. Eur Respir J. 2020;55:1901921; 2. GOLD. Global strategy for the diagnosis, management, and prevention of COPD. 2020
2)Abdulai RM, et al. Deterioration of limb musde function during acute exacerbation of chronic obstructive pulmonary disease. Am J Respir Crit Care Med 2018;197:433–449.
3) Middle Top: American Lung Association COPD Trends by State
Middle Bottom: Centers for Disease Control and Prevention, COPD Costs
Left: Rabe KF. Treating COPD — The TORCH Trial, P Values, and the Dodo. N Engl J Med 2007;356:851-854.

IMI: "RADICAL COLLABORATION" ACROSS SECTORS

Innovative Medicine Initiative (IMI) was founded to improve health and foster innovation

- IMI mission is to improve health by speeding up the development of, and patient access to, innovative medicines, in areas of unmet need
- History of IMI
  - European Technology Platform on Innovative Medicines (2005-2009) with focus on Alzheimer's disease and safety
  - Public-private partnership with key players in health research: universities, research centers, the pharmaceutical and other industries, small and medium-sized enterprises, patient organizations, and medicines regulators
  - Second phase of IMI (IMI2, 2014-2020) had a budget of €3.3 Billion

Achievements

12 years, 158 projects

Over 50% of these projects include a patient partnership

1,234 organization from 46 countries

5,943 publications

IMI projects have a citation impact nearly twice the EU average

28 tools approved by regulators

Digital health and patient-centric evidence generation

Innovative Medicine Initiative 2020
IMI Annual Report 2019

DEVELOPMENT OF THE PROACTIVE TOOL TO CAPTURE AN UNMET NEED

- Physical Activity as a Crucial Patient Reported Outcome in COPD (PROactive) development was an IMI project from 2009-2016
  - Objective was to develop a method to assess physical activity objectively using validated activity monitor, used together with a set of questions, to capture the experience with physical activity in patients with COPD

- Process for the framework of PROactive
  - ✓ Develop a thorough and systematic set of literature reviews to inform the project
  - ✓ Select an appropriate activity monitors capable
  - ✓ Perform extensive qualitative research on how patients experience PA
  - ✓ Confirm the conceptual framework
  - ✓ Validation and delivery of final validated PRO tools in at least 10 languages of the EU

EFPIA companies

- Almirall SA, Barcelona, Spain
- Astrazeneca AB, Södertälje, Sweden
- Boehringer Ingelheim Internationalgmbh, Ingelheim, Germany
- Chiesi Farmaceutici S.A, Parma, Italy
- Glaxosmithkline Research And Development LTD., Brentford, Middlesex, United Kingdom
- Novartis Pharma AG, Basel, Switzerland
- UCB Pharma SA, Brussels, Belgium

Universities, research organisations, public bodies, non-profit groups

- Academisch Ziekenhuis Groningen, Groningen, Netherlands
- European Respiratory Society, Lausanne, Switzerland
- IS GLOBAL - Barcelona Institute For Global Health, Barcelona, Spain
- Katholieke Universiteit Leuven, Leuven, Belgium
- Royal Brompton And Harefield National Health Service Trust, South Kensington, United Kingdom
- The University Of Edinburgh, Edinburgh, United Kingdom
- Thorax Research Foundation, Kolonaki, Athens Greece, Greece
- Universitat Zurich, Zürich, Switzerland

Small and medium-sized enterprises (SMEs)

- Choice Healthcare Solutions Ltd, Hitchin, Hertfordshire, United Kingdom

Patient organisations

- British Lung Foundation, London, United Kingdom
- Netherlands Asthma Foundation, Leusden, Netherlands

FACTS & FIGURES

Start Date	01/09/2009
End Date	31/05/2016
Call	IMI1 - Call 1
Grant agreement number	115011

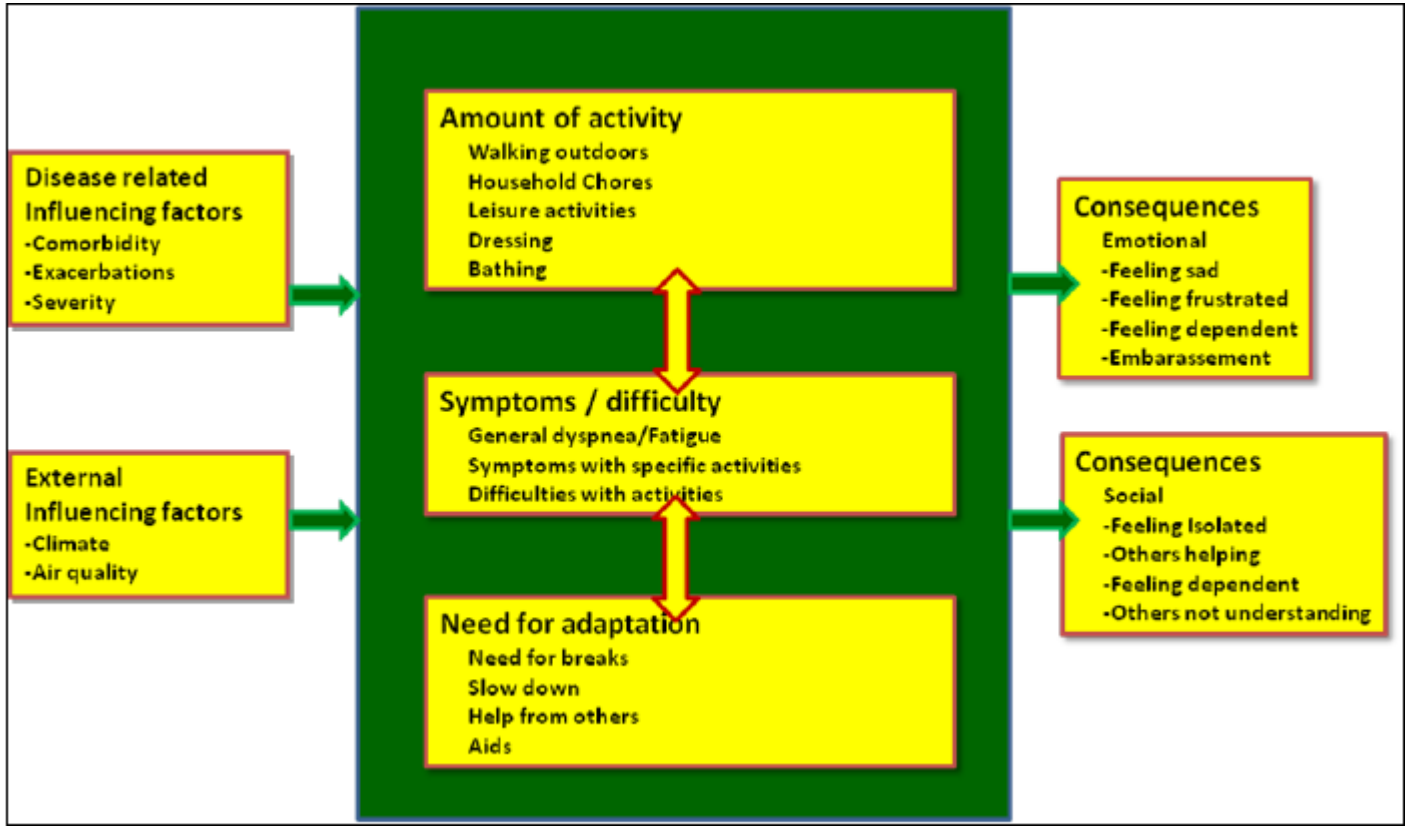
Type of Action:
RIA (Research and Innovation Action)

Contributions	€
IMI Funding	6 767 597
EFPIA in kind	7 230 350
Other	1 637 875
Total Cost	15 635 822

PROactive Final Report 19 Dec 2018
EFPIA: European Federation of Pharmaceutical Industries and Associations

COMPONENTS OF THE PROACTIVE DEVELOPMENT

Creation of a concept of the patient experience of physical activity



Integrations of questionnaires with digital activity monitors

DynaPort MoveMonitor

Actigraph GT3X

PROactive Final Report 19 Dec 2018

Right top: Fokkenrood, HJP. Physical Activity Monitoring in Patients with Peripheral Arterial Disease: Validation of an Activity Monitor. 2014 48194-200
Right bottom: ActiGraph

PROACTIVE TOOL

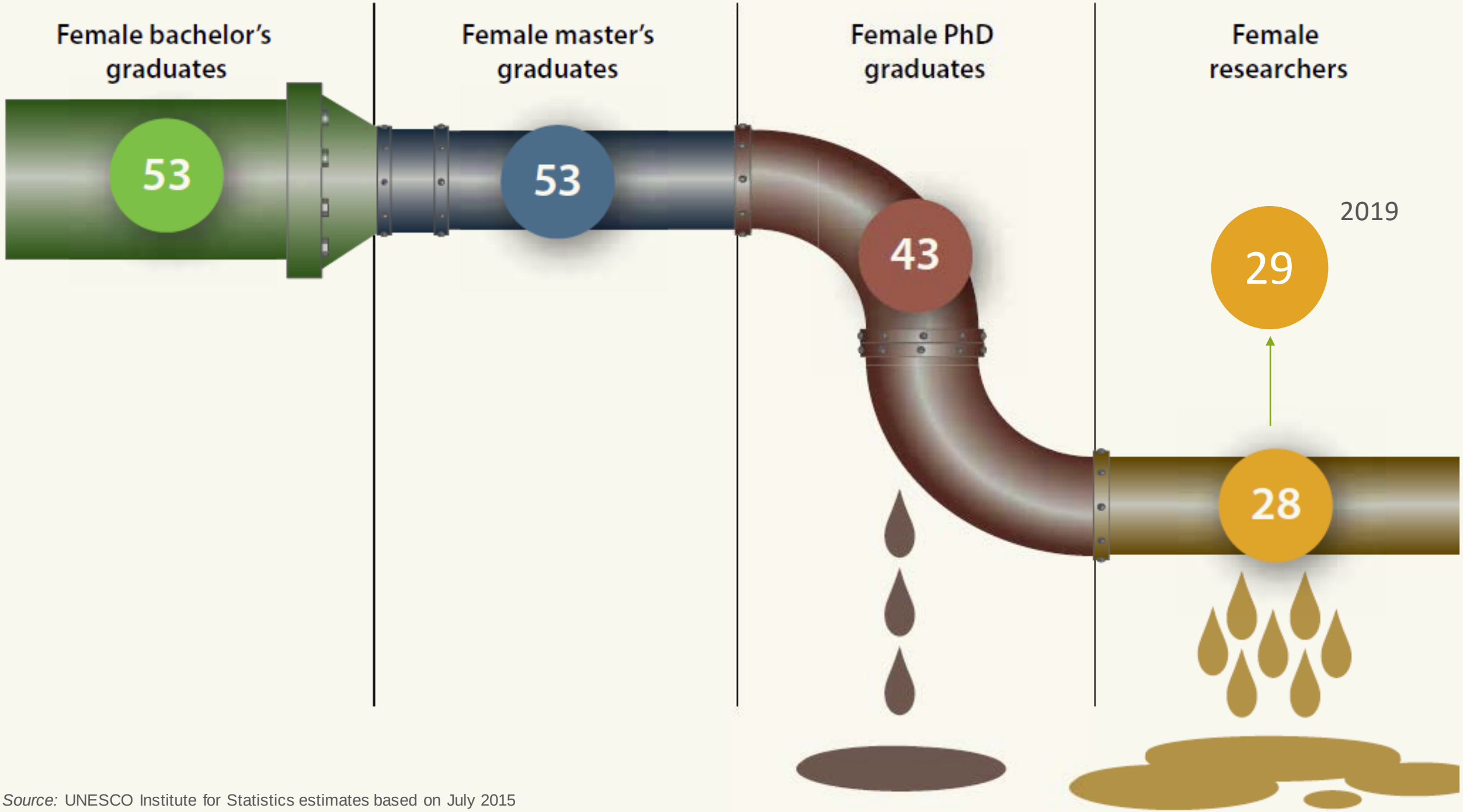
- The consortium two patient reported outcome tools to capture physical activity
  - Daily PROactive Physical Activity in COPD (D-PPAC)
  - Clinical Visit PROactive Physical Activity in COPD (C-PPAC) – 7-day recall
- These tools are a combination of questionnaires and digital monitoring devices to accurately measure the disease burden in an area of unmet need in COPD patients
- They can be used in the clinical trial setting
- Adopted by EMA Committee for Medicinal Products for Human Use (CHMP) in March 2018

PROactive Final Report 19 Dec 2018

CONCLUSION

- Chronic diseases are highly prevalent in the US population and healthcare related costs are impactful
- Digital health tools and other technologies must address multiple personas, which makes it difficult to design effective tools
- Additionally, evaluation the variety of tools available is not intuitive and healthcare providers are not generally trained for these activities
- Biopharmaceutical companies also utilize digital tools in clinical research, and may use them in a clinical trial for development of medicines addressing patient needs
- The IMI's PROactive project demonstrates a "radical collaboration," to address unmet need in COPD patients
- These collaborations can advance medicine and technology for improved patient outcomes

THANK YOU



Source: UNESCO Institute for Statistics estimates based on July 2015
https://www.soroptimistinternational.org/is-the-gender-gap-narrowing-in-science-and-engineering/ on data from its database, July 2015