



EXPLORING VIRTUAL CLINICAL TRIALS: *Lessons from Clinical Care*

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Virtual Clinical Trials: Challenges and Opportunities
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Overview

- What is Livongo?
- Challenges of remote chronic condition management
- Real-world Evidence research partnerships
- Use of digital tools for clinical research and medical product development

What is Livongo?

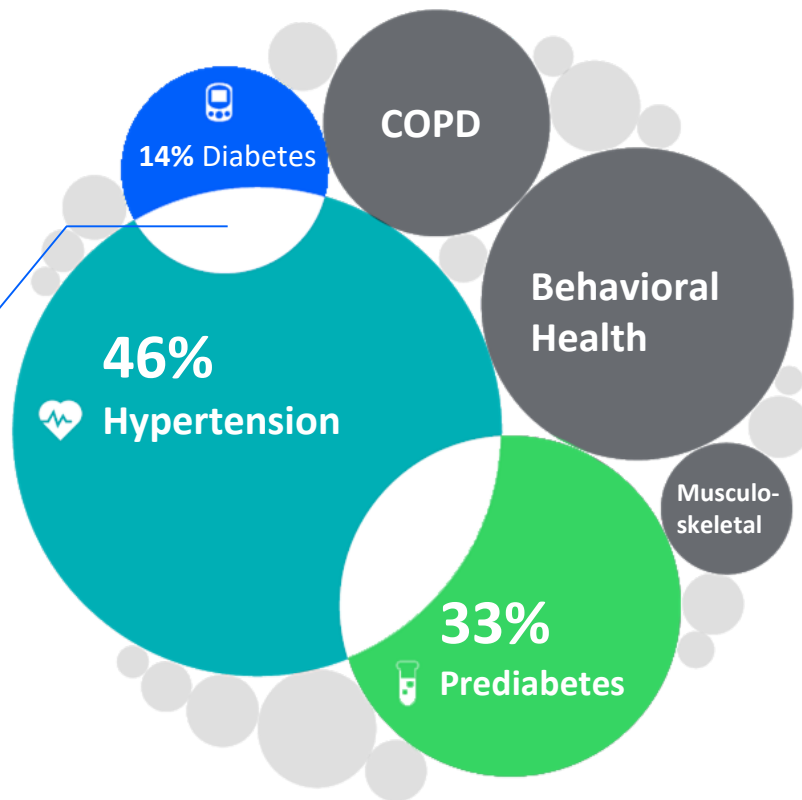
The Health and Cost Impact of Chronic Conditions Is Overwhelming

135 MILLION

Americans have chronic conditions

73%

of people with diabetes also have hypertension



75%

of US healthcare spend is on chronic conditions

\$327_B

Cost of diabetes²

#1 cost driver¹

\$131_B

Cost of hypertension³

\$44_B

Cost of prediabetes⁴

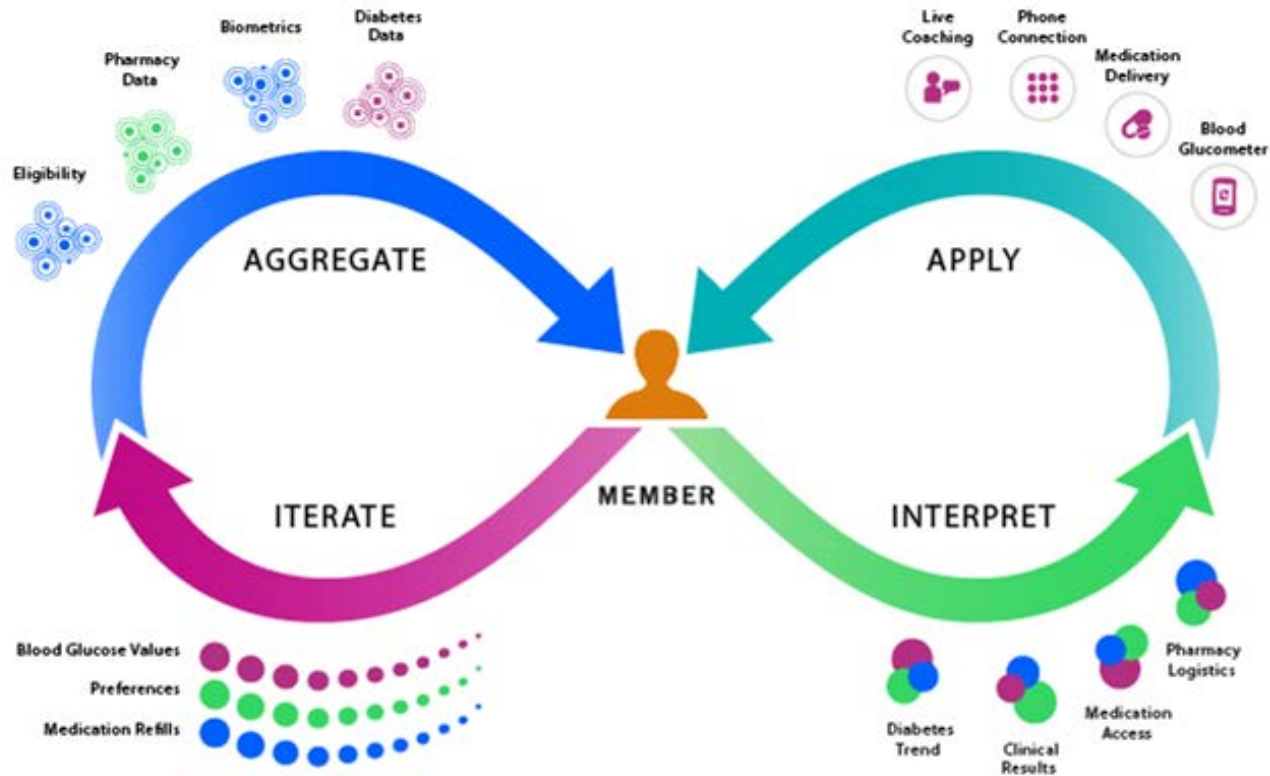
- 1 - [US Spending on Personal Health Care and Public Health, JAMA, 2016](#)
- 2 - [Statistics About Diabetes, American Diabetes Association, 2018](#)
- 3 - [Vital Signs: ...of Uncontrolled Hypertension \(MMWR\), CDC, 2012](#)
- 4 - [Medical Care Expenditures for Individuals with Prediabetes, NCBI, 2017](#)



For many Americans living with chronic conditions the **confusion, complexity, and cost** of the healthcare system is overwhelming and has resulted in them ignoring their health and conditions.

This is Noisy Healthcare.

Applied Health Signals: AI + AI



Livongo Health Programs & Devices



Livongo for Diabetes

2015



Livongo DPP
Powered by Retrofit

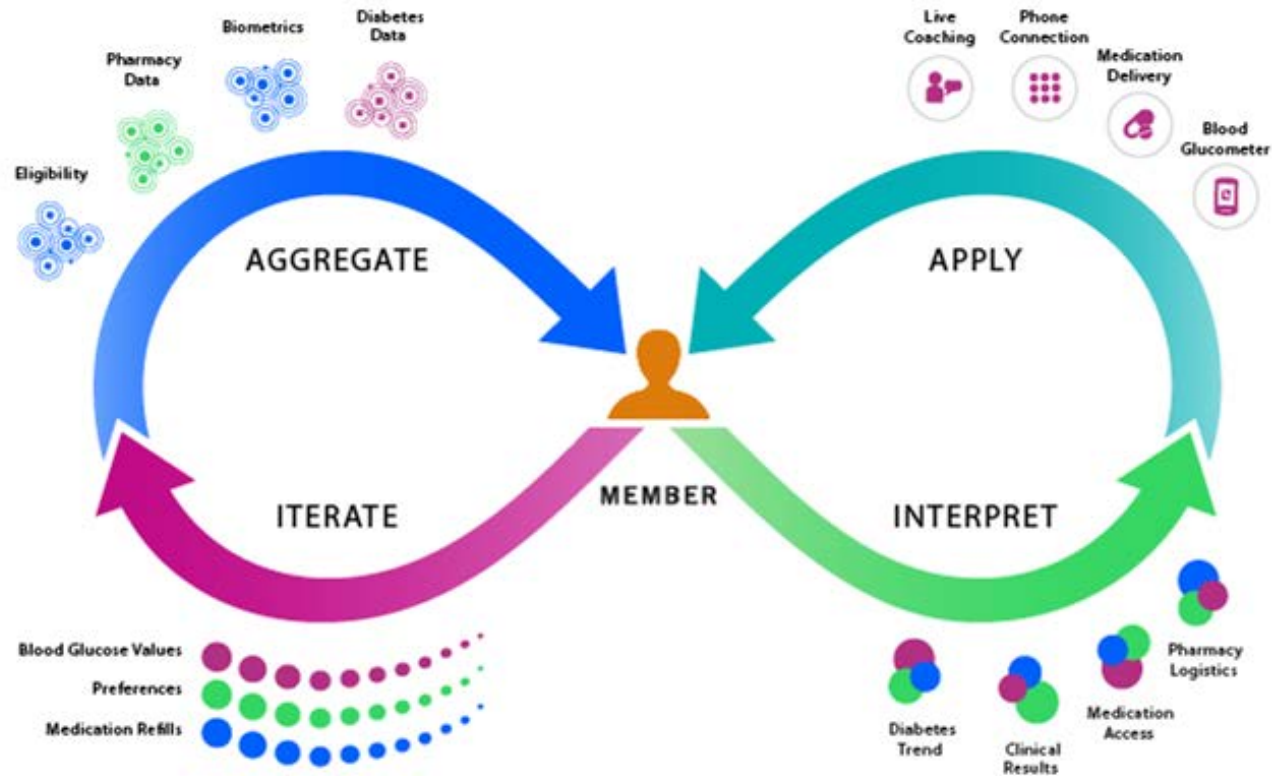
2018



Livongo for Hypertension

2019

Applied Health Signals: AI + AI



We Support All People with Chronic Conditions

People with chronic conditions are very diverse and their needs evolve over time



**Maria (51) T2D,
overweight
Just changed
medications**



**John (54) T2D, HTN
Facing a
complication**



**Britt (42) T2D, HTN
Doesn't think
checking is needed**



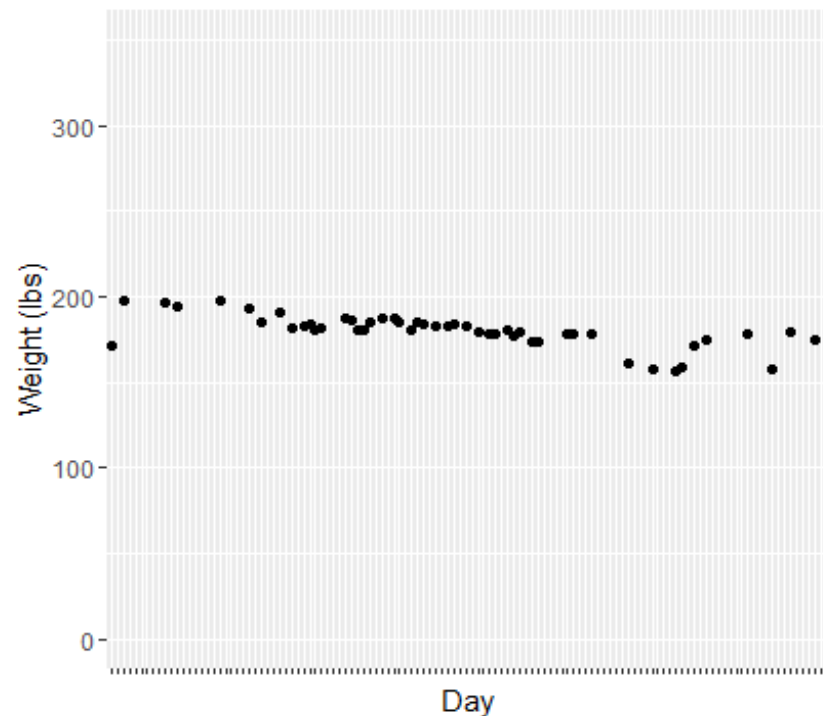
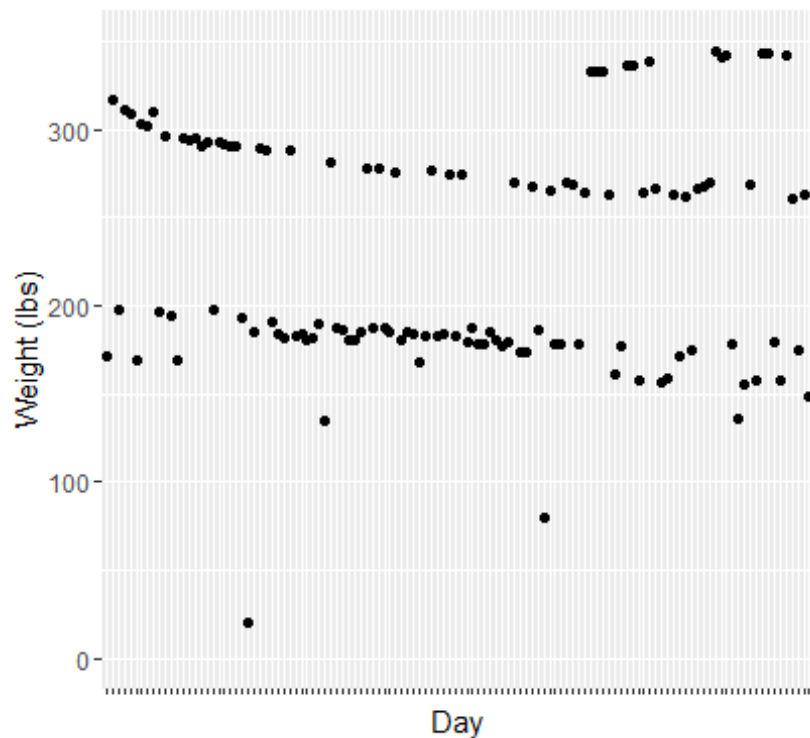
**Max (25) T1D
Diagnosed for 10 years,
feels like an expert**

Over 400+ Organizations Provide Livongo for their Employees/Members

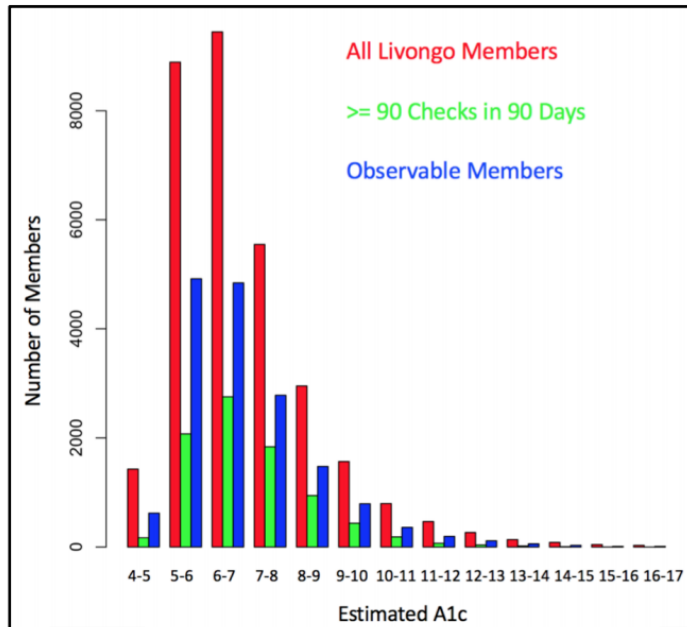


Challenges of Remote Chronic Condition Management

Are We Observing the Right Person?



How Do We Create Meaningful Health Signals?



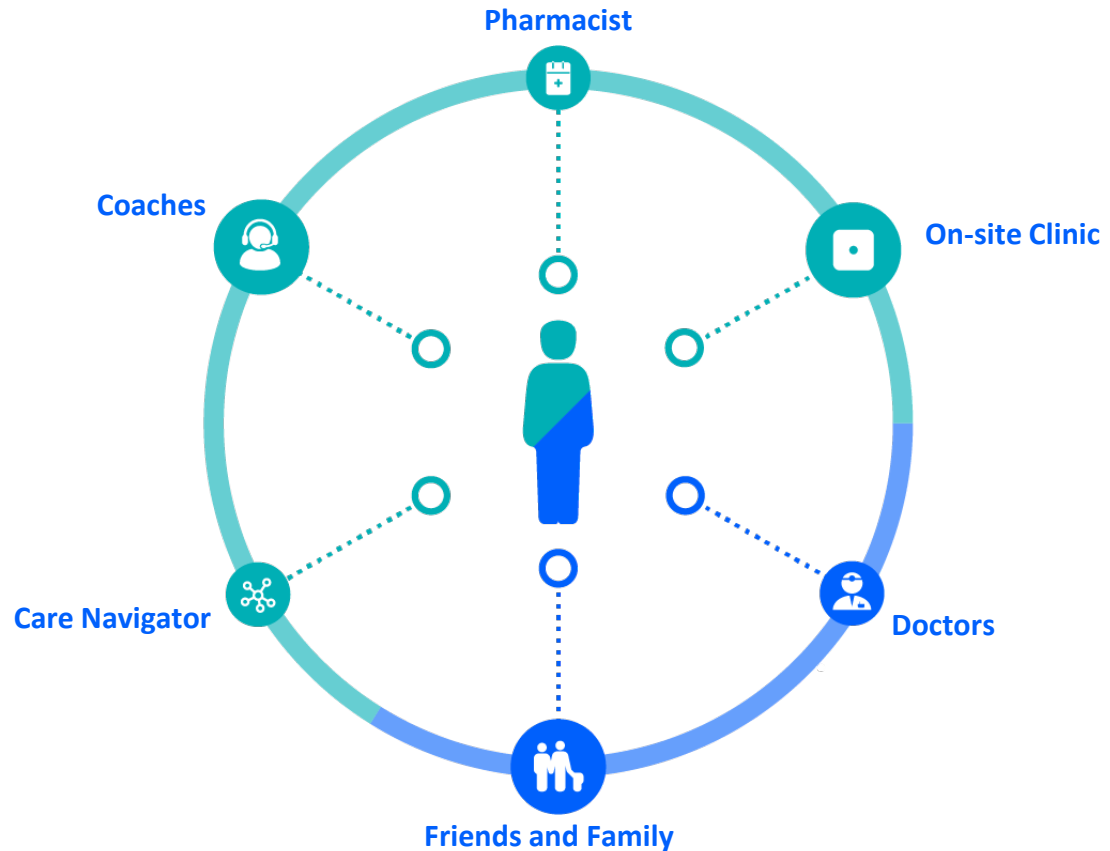
Estimated A1c for Livongo population. Mean BG converted to A1c using ADAG model.

- HbA1c is gold standard lab test for assessing diabetes health status and risk stratification
- Livongo measures individual blood glucose values
- Created concept of “Observability”
- Increased our ability to observe health status of 25% -> 53% of our members

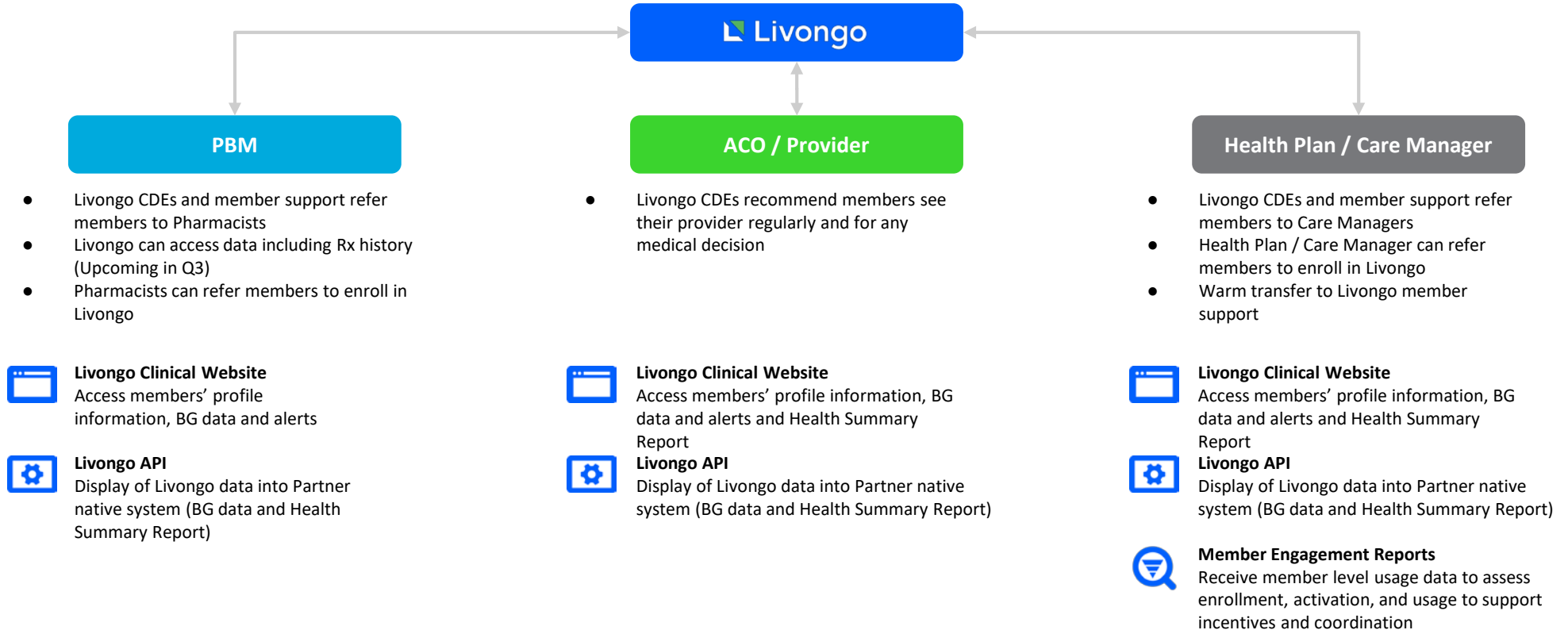
[Data Science Approach to Monitoring Health Status for a Diabetes Population](#),
Oral Presentation, American Medical Informatics Association Summit,
San Francisco, CA - March 15, 2018

How do we best coordinate care for members?

We surround members with the resources to get and stay healthy.



How do we best coordinate care for members?



Real-World Evidence Research Partnerships

What is Real-World Evidence?

The NEW ENGLAND JOURNAL of MEDICINE

SOUNDING BOARD

Real-World Evidence — What Is It and What Can It Tell Us?

Rachel E. Sherman, M.D., M.P.H., Steven A. Anderson, Ph.D., M.P.P.,
Gerald J. Dal Pan, M.D., M.H.S., Gerry W. Gray, Ph.D., Thomas Gross, M.D., M.P.H.,
Nina L. Hunter, Ph.D., Lisa LaVange, Ph.D., Danica Marinac-Dabic, M.D., Ph.D.,
Peter W. Marks, M.D., Ph.D., Melissa A. Robb, B.S.N., M.S., Jeffrey Shuren, M.D., J.D.,
Robert Temple, M.D., Janet Woodcock, M.D., Lilly Q. Yue, Ph.D., and Robert M. Califf, M.D.

The term “real-world evidence” is widely used by those who develop medical products or who study, deliver, or pay for health care, but its specific meaning is elusive. We believe it refers to information on health care that is derived from multiple sources outside typical clinical research settings, including electronic health records (EHRs), claims and billing data, product and disease registries, and data gathered through personal devices and health applications.^{1,2} Key to understanding the usefulness of real-world evidence is an appreciation of its potential for complementing the knowledge gained from tra-

shortage of researchers with adequate methodologic savvy could result in poorly conceived study and analytic designs that generate incorrect or unreliable conclusions. Accordingly, if we are to realize the full promise of such evidence, we must be clear about what it is and how it can be used most effectively, and we must have appropriate expectations about what it can tell us. It is important to distinguish two key dimensions of real-world evidence. The first is the setting in which evidence is generated, which includes the population defined by the data source as well as the specific methods used to collect and curate

“We believe it refers to information on health care that is derived from multiple sources outside typical clinical research settings, including electronic health records (EHRs), claims and billing data, product and disease registries, and data gathered through personal devices and health applications.”

NEJM 375;23, December 8, 2016

Examples of RWE Research

What is the financial impact of a remote diabetes digital management program offering a connected blood glucose meter, digital and in-person CDE coaching at one year?



Other Examples of RWE Research

- Evaluation of Diabetes Patient Empowerment and Diabetes Distress With Real-World Patient Outcomes using the Livongo for Diabetes Platform
- Exploration of Blood Glucose Variability and Medication Use in a Real-World setting for Livongo members with Type 2 Diabetes
- Retrospective *In Silico* Evaluation of Glycemic Pattern Recognition System in the Livongo population Using Insulin

Use of digital tools for clinical research and medical product development

Remote Collection of Health Device Data for Research

- More convenient for research participants
- Less expensive for researchers
- Allows for more frequent assessments
- Consider impact of **Hawthorne Effect** - *the alteration of behavior by study participants due to their awareness of being observed*
 - BG checking patterns are different for some of our members when they are in “airplane mode”
 - Sharing BG values with friends, family, healthcare providers yields improved and sustained outcomes

Thank you!

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