

Challenges and Perspectives in **Digital Health**

(Pending Publication)

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Overview

- ✓ Definition of Digital Health
- ✓ Why digital health now?
- ✓ Challenges
- ✓ What is next?

Define

DIGITAL HEALTH

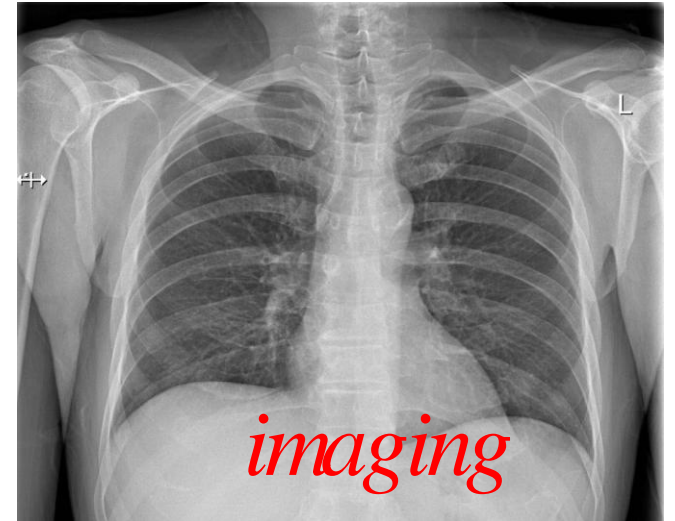
Digital Health

The convergence of the digital revolution with health, healthcare, living, and society.

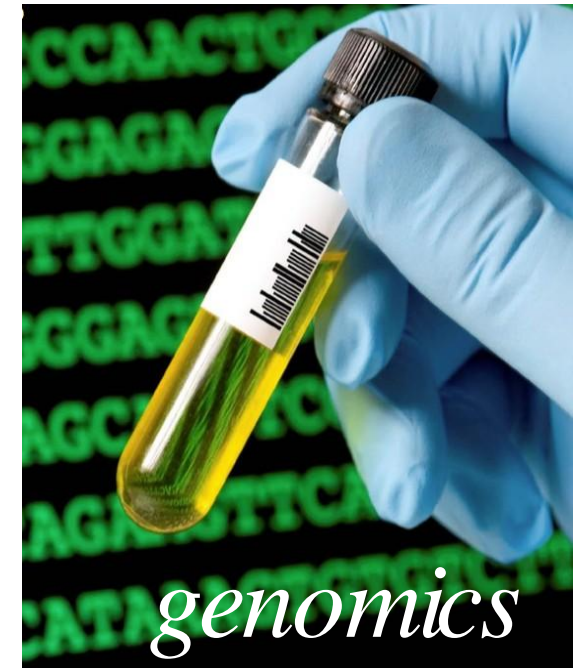
Diversity of digital health data



proteomics



Smart phones



Why digital health now?

DATA

GROWTH OF HEALTHCARE DATA

48% increase annually

(one exabyte = one billion gigabytes)

153
exabytes

2,314
exabytes

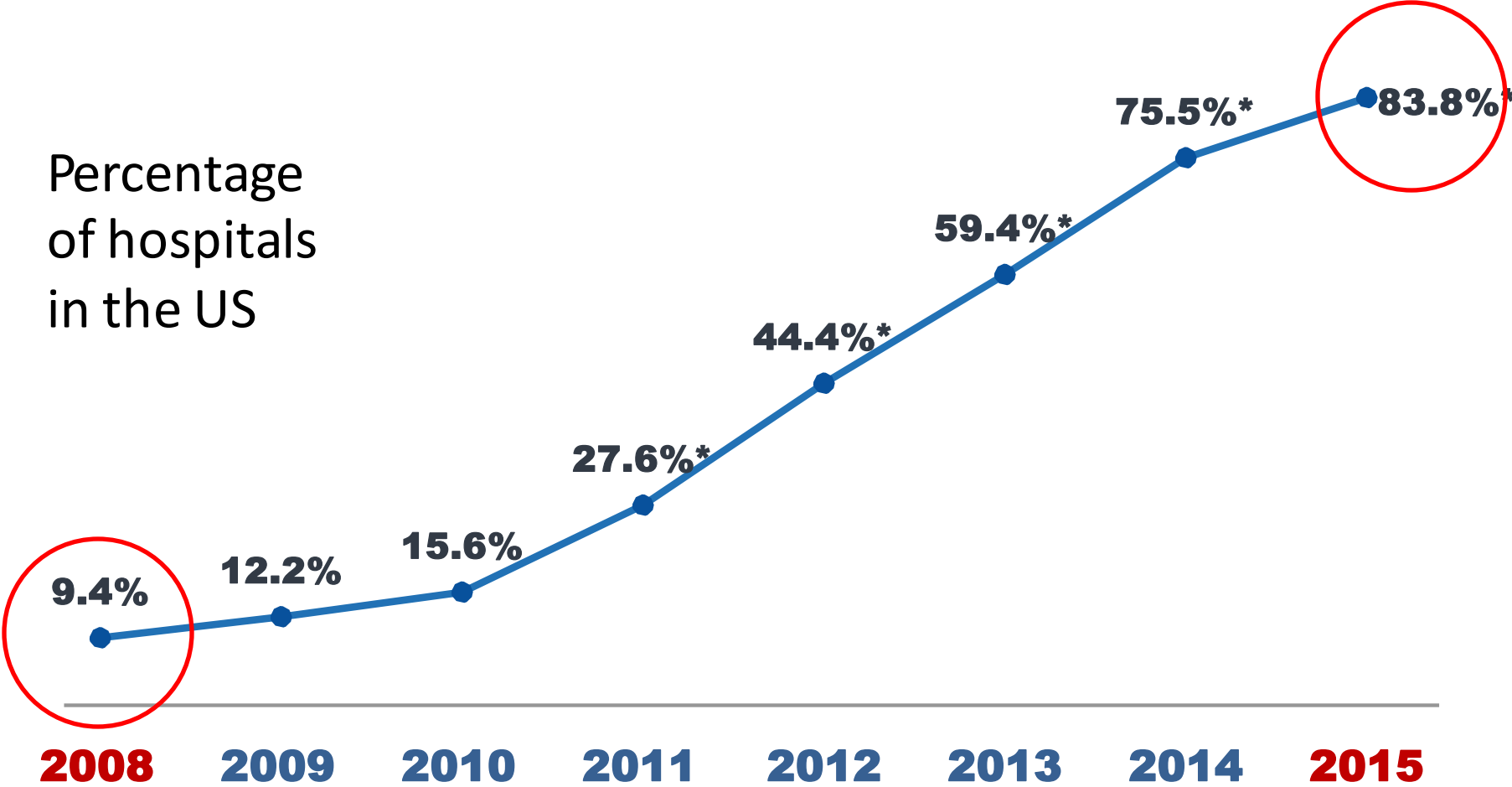
2013

2020

Source: <http://ow.ly/2okF30fti5O>

Addressing the challenges and opportunities of leveraging big data for healthcare, University of Delaware's Population Health Informatics for Healthcare Leaders takes place Oct. 17-18 in Newark 2017.

Adoption of Electronic Health Records has increased **9x** since 2008

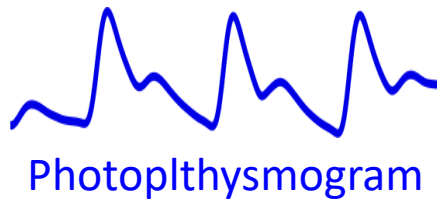


[Henry et al., ONC Data Brief, May 2016]

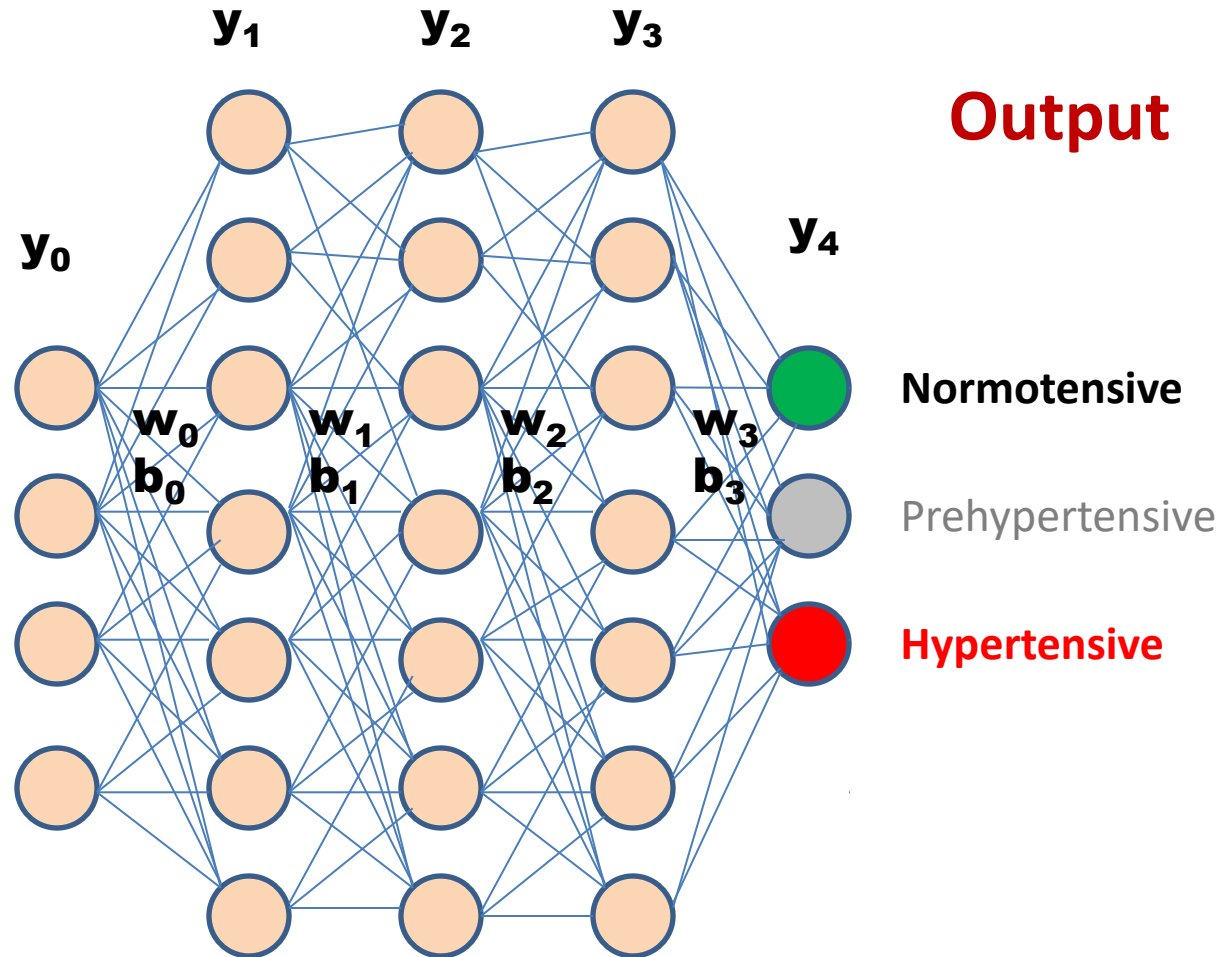
Why now?

ALGORITHMS

Input



Output



$$y_{i+1} = h(W_i y_i + b)$$

Why now?

COMPANIES



106 STARTUPS TRANSFORMING HEALTHCARE WITH AI

PATIENT DATA & RISK ANALYTICS



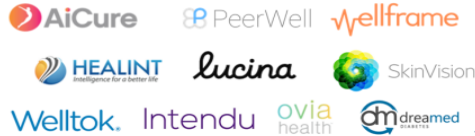
RESEARCH



MEDICAL IMAGING & DIAGNOSTICS



LIFESTYLE MANAGEMENT & MONITORING



NUTRITION



EMERGENCY ROOM & SURGERY



IN-PATIENT CARE & HOSPITAL MANAGEMENT



MISCELLANEOUS



MENTAL HEALTH



DRUG DISCOVERY



VIRTUAL ASSISTANTS



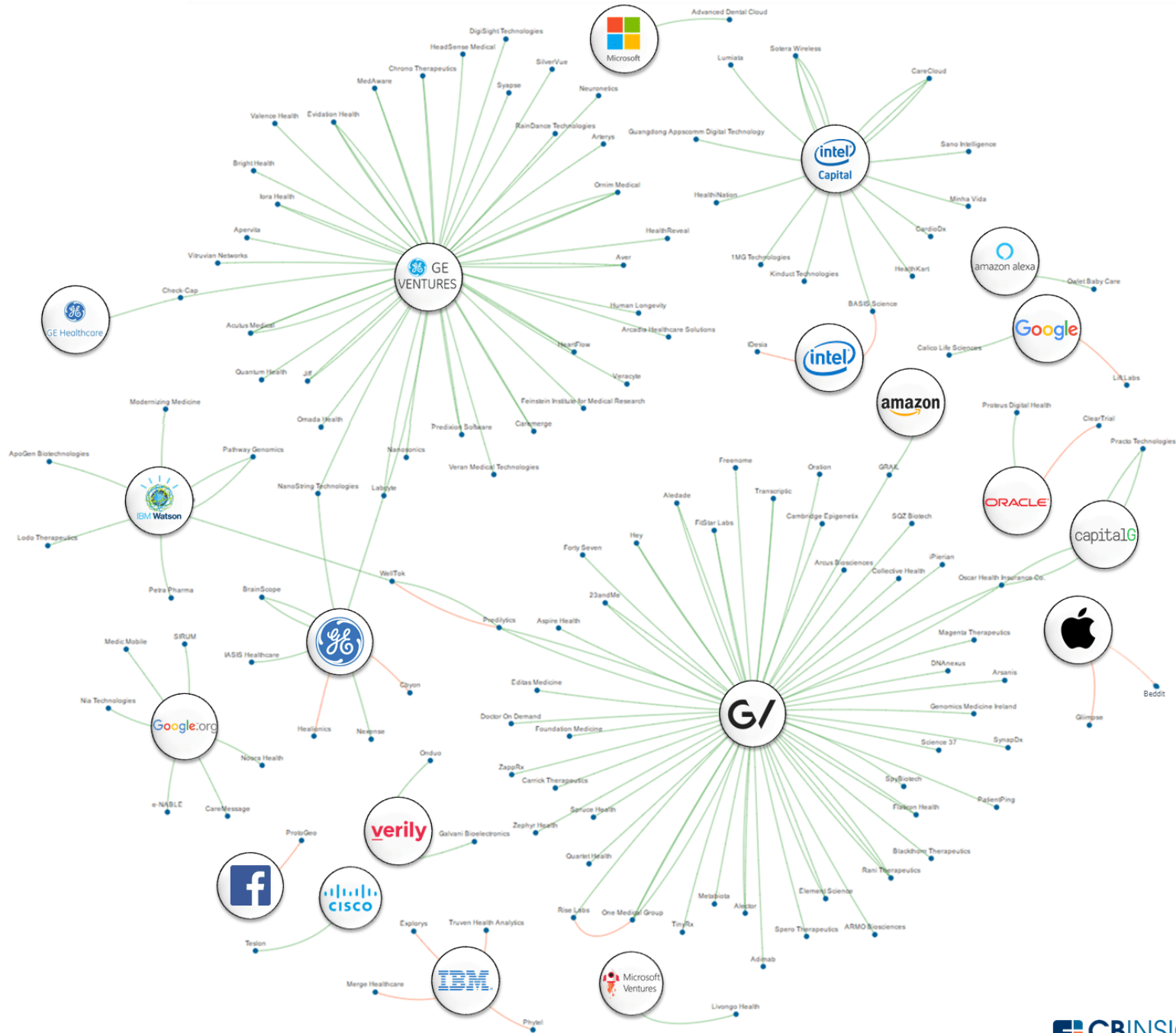
WEARABLES



istock.com/hilch

TECH GIANTS INVESTING IN HEALTHCARE

2012 – 2017 YTD (5/18/2017)

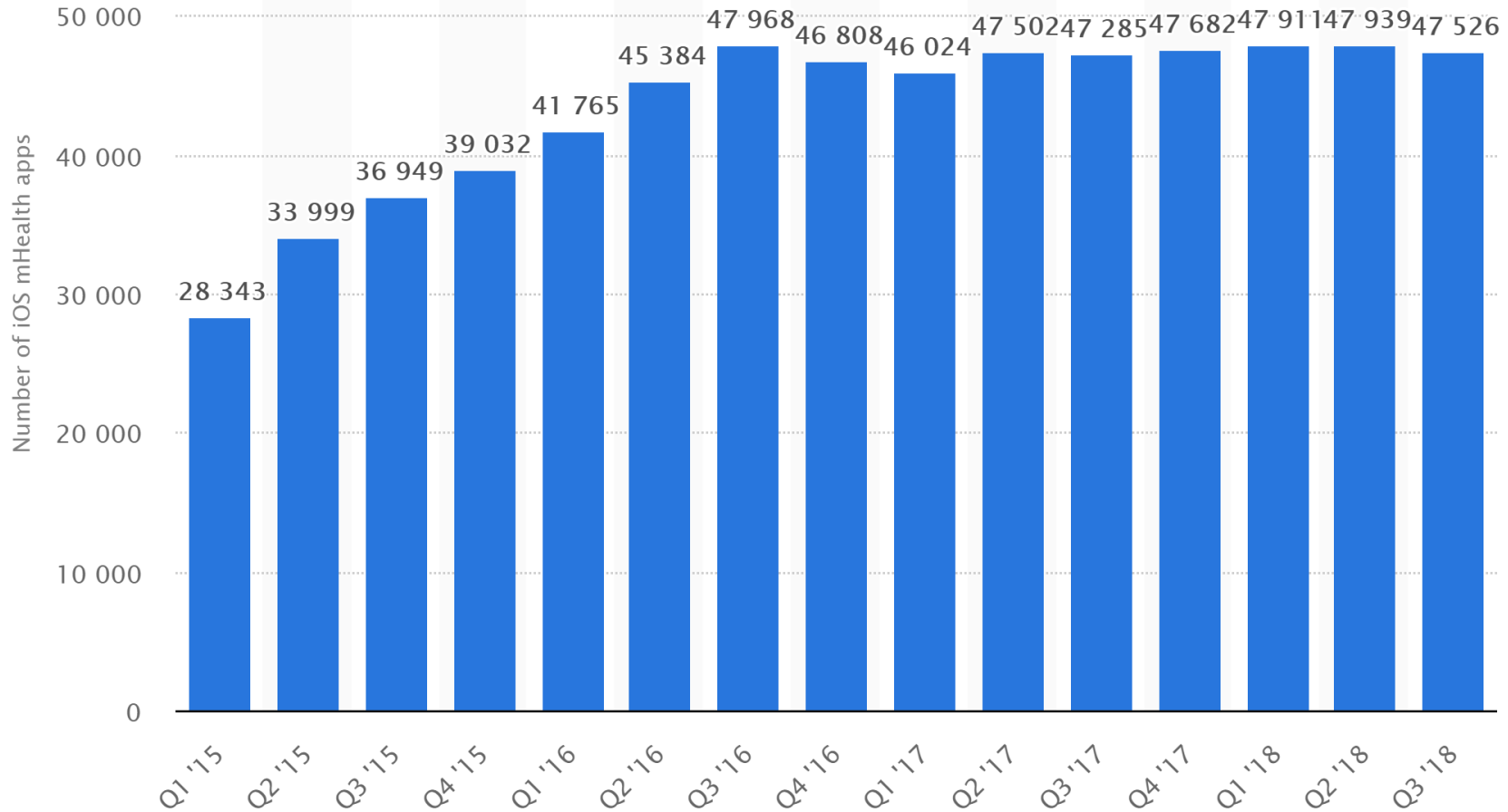


Why now?

APP DEVELOPMENT

Number of mHealth apps available in the Apple App Store

By end of 2018 reached ~ 50,000



<https://www.statista.com/statistics/779910/health-apps-available-ios-worldwide/>

Challenges

APP EVALUATION

Example: App Evaluation

npj | Digital Medicine

Article | [OPEN](#) | Published: 10 August 2018

User experience of instant blood pressure: exploring reasons for the popularity of an inaccurate mobile health app

Timothy B. Plante [✉](#), Anna C. O’Kelly, Bruno Urrea, Zane T. MacFarlane, Roger S. Blumenthal, Jeanne Charleston, Edgar R. Miller, Lawrence J. Appel & Seth S. Martin

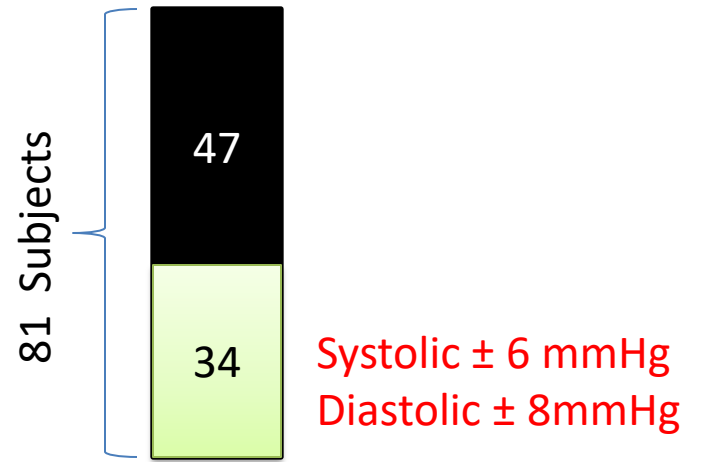
npj Digital Medicine 1, Article number: 31 (2018) | [Download Citation](#) ↓

 **auralife** \$4.99

June 4, 2014 - July 30, 2015






Downloaded >148,000 times

Earned > \$700,000



Aug 7, 2015



-  Do not rely on Instant Blood Pressure for medical advice or diagnosis.
-  Do not use Instant Blood Pressure as a replacement or substitute for a cuff or other blood pressure monitor. It is not as accurate as a cuff or other monitor.
-  Instant Blood Pressure is not suitable for use by individuals whose Systolic or Diastolic blood pressure is outside our supported range of 83-178 (mmHg) or 58-107 (mmHg), respectively.
-  Consult your doctor if you have any health concern. Do not self-adjust medications.
-  Do not use Instant Blood Pressure if you wear a pacemaker or any internal electronic medical device.

Challenges

METHODOLOGY

Example: Method Evaluation



Research | [Open Access](#) | [Open Peer Review](#)

Improving usability and pregnancy rates of a fertility monitor by an additional mobile application: results of a retrospective efficacy study of Daysy and DaysyView app

Martin C. Koch [✉](#), Johannes Lermann, Niels van de Roemer, Simone K. Renner, Stefanie Burghaus, Janina Hackl, Ralf Dittrich, Sven Kehl, Patricia G. Oppelt, Thomas Hildebrandt, Caroline C. Hack, Uwe G. Pöhls, Stefan P. Renner and Falk C. Thiel

Reproductive Health 2018 15:37

<https://doi.org/10.1186/s12978-018-0479-6> | © The Author(s). 2018

Received: 24 April 2017 | Accepted: 18 February 2018 | Published: 2 March 2018



Daysy fertility monitor

March 15 at 12:41pm · 🌐

We have some very exciting news to share!

In our last clinical trial we were able to prove the unique algorithm used by the Daysy fertility tracker to be 99.3% accurate for planning or preventing pregnancy.

Now, with the release of our new clinical trial, we have shown that Daysy, when used in combination with the DaysyView app, is even more effective - 99.4%. Our method safety has jumped one whole point!

Our new study in [collaboration with the University Women's Clinic Erlangen](#) shows that combining the Daysy fertility tracker and the optional DaysyView app helps users to distinguish fertile from non-fertile days with 99.4% accuracy.

According to Dr. Martin C. Koch, the principal author of the study, "combining the Daysy fertility tracker with the app has again improved the safety with [which pregnancies are prevented to 99.4%.](#)"

We are proud to be able to prove that the Daysy fertility tracker and DaysyView app, when used together, provides a highly trustworthy and reliable method for avoiding pregnancy.

Learn more: usa.daysy.me/effectiveness/



DAYSY IS NOT 99.3% EFFECTIVE

DAYSY IS NOW 99.4% EFFECTIVE

Example: Method Evaluation

Commentary | [Open Access](#) | Open Peer Review

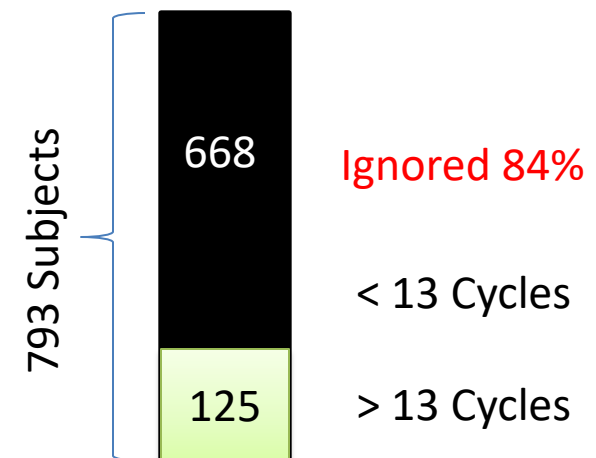
Published analysis of contraceptive effectiveness of Daysy and DaysyView app is fatally flawed

Chelsea B. Polis  

Reproductive Health 2018 15:113

<https://doi.org/10.1186/s12978-018-0560-1> | © The Author(s). 2018

Received: 6 April 2018 | Accepted: 15 June 2018 | Published: 25 June 2018



Under Investigation

Editor's Note

Concerns have been raised with respect to this article; please see the Commentary article at <https://reproductive-health-journal.biomedcentral.com/articles/10.1186/s12978-018-0560-1>. A response has been received from the authors. This is currently under assessment. Appropriate editorial action will be taken once this is complete.

! Daysy tells you when you are in your fertile window and when not. Daysy is not a contraception.

Clarifications concerning the commentary "Published analysis of contraceptive effectiveness of Daysy and DaysyView app is fatally flawed"

Martin C. Koch , Johannes Lermann, Niels van de Roemer, Simone K. Renner, Stefanie Burghaus, Janina Hackl, Ralf Dittrich, Sven Kehl, Patricia G. Oppelt, Thomas Hildebrandt, Caroline C. Hack, Uwe G. Pöhls, Stefan P. Renner and Falk C. Thiel

Reproductive Health 2019 16:83

<https://doi.org/10.1186/s12978-019-0746-1> | © The Author(s). 2019

Published: 17 June 2019


RETRACTED ARTICLE: Improving usability and pregnancy rates of a fertility monitor by an additional mobile application: results of a retrospective efficacy study of Daysy and DaysyView app

Martin C. Koch , Johannes Lermann, Niels van de Roemer, Simone K. Renner, Stefanie Burghaus, Janina Hackl, Ralf Dittrich, Sven Kehl, Patricia G. Oppelt, Thomas Hildebrandt, Caroline C. Hack, Uwe G. Pöhls, Stefan P. Renner and Falk C. Thiel

Reproductive Health 2018 15:37

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 The **Retraction Note** to this article has been published in *Reproductive Health* 2019 16:54

RESEARCH

Open Access



Improving usability and pregnancy rates of a fertility monitor by an additional mobile application: results of a retrospective efficacy study of Daysy and DaysyView app

Martin C. Koch^{1*}, Johannes Lermann¹, Niels van de Roemer², Simone K. Renner¹, Stefania Burghaus¹, Janina Hackl¹, Ralf Dittrich¹, Sven Kehl¹, Patricia G. Oppelt¹, Thomas Hildebrandt¹, Caroline C. Hack¹, Uwe G. Pöhlis², Stefan P. Renner¹ and Falk C. Thiel⁴

Abstract

Background: Daysy is a fertility monitor that uses the fertility awareness method by tracking and analyzing the individual menstrual cycle. In addition, Daysy can be connected to the application DaysyView to transfer stored personal data from Daysy to a smartphone or tablet (IOS, Android). This combination is interesting because as it is shown in various studies, the use of apps is increasing patients' focus on their disease or their health behavior. The aim of this study was to investigate if by the additional use of an App and thereby improved usability of the medical device, it is possible to enhance the typical-use related as well as the method-related pregnancy rates.

Result: In the resultant group of 125 women (2076 cycles in total), 2 women indicated that they had been unintentionally pregnant during the use of the device, giving a typical-use related Pearl-Index of 1.3. Counting only the pregnancies which occurred as a result of unprotected intercourse during the infertile (green) phase, we found 1 pregnancy, giving a method-related Pearl-Index of 0.6. Calculating the pregnancy rate resulting from continuous use and unprotected intercourse exclusively on green days, gives a perfect-use Pearl-Index of 0.8.

Conclusion: It seems that combining a specific biosensor-embedded device (Daysy), which gives the method a very high repeatable accuracy, and a mobile application (DaysyView) which leads to higher user engagement, results in higher overall usability of the method.

Keywords: Female contraception, Fertility monitor, Mobile application, Body basal temperature, Fertility awareness based method, FABM

Plain English summary

The menstrual cycle is one of the characteristic physiological processes of the female body and it is a central indicator of overall health in women of reproductive age. Continuous fluctuations of hormones result in commensurable physiological changes throughout the menstrual cycle. In the last decade, specific biosensor-embedded devices have been developed to assist women in monitoring, measuring and representing these aspects of their

body. For such devices, the typical-use related pregnancy rate is still low but was significantly worse than the method-related pregnancy rate. This implies that usability and understanding of a method plays a major role in a fertility monitoring device and its safe effective use. It is reported, that through the additional use of a mobile application the interest and motivation of a patient's health behavior increases significantly. The contraceptive effectiveness of the fertility monitor (Daysy) has already been demonstrated in an independent trial. The result of the method related Pearl-Index calculation obtained in the present study (0,6) differs only a little from what is reported by Freundl and colleges (0,7). However, if the

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Challenges

REGULATION



****App companies are NOT required to get FDA approval, however, companies prefer to have the FDA “stamp” of approval to make products more sellable**

The FDA **encourages the development** of mobile medical apps that improve health care and provide consumers and health care professionals with valuable health information.

The FDA also has a **public health responsibility** to oversee the **safety and effectiveness** of medical devices – including mobile medical app (**if the companies approach them**)



FDA's mobile medical apps policy **does not regulate** the sale or consumer use of smartphones or tablets.

FDA's mobile medical apps policy **does not consider** entities that exclusively distribute mobile apps, such as the owners and operators of the "iTunes App store" or the "Google Play store," to be medical device manufacturers.

FDA's mobile medical apps policy **does not consider** mobile platform manufacturers to be medical device manufacturers just because their mobile platform could be used to run a mobile medical app regulated by FDA

FDA's mobile medical apps policy **does not require** mobile medical app developers to seek Agency re-evaluation for minor, iterative product changes



Diagnosis in the absence of a legal right to do so is a penal **offense**, potentially making developers susceptible to **fines** and **imprisonment**.

PROHIBITIONS

Controlled acts restricted

27 (1) No person shall perform a controlled act set out in subsection (2) in the course of providing health care services to an individual unless,

- (a) the person is a member authorized by a health profession Act to perform the controlled act; or
- (b) the performance of the controlled act has been delegated to the person by a member described in clause (a). 1991, c. 18, s. 27 (1); 1998, c. 18, Sched. G, s. 6.

Controlled acts

(2) A “controlled act” is any one of the following done with respect to an individual:

1. Communicating to the individual or his or her personal representative a diagnosis identifying a disease or disorder as the cause of symptoms of the individual in circumstances in which it is reasonably foreseeable that the individual or his or her personal representative will rely on the diagnosis.

<https://www.ontario.ca/laws/statute/91r18>



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Notice: Health Canada's Approach to Digital Health Technologies

April 10, 2018

Our file number: 18-104077-808

Given the fast pace of innovation in digital health technologies specifically in relation to medical devices, Health Canada is undertaking an initiative to adapt its approach to support better access to therapeutic products based on healthcare system needs. Under the "[Regulatory Review of Drugs and Devices](#)" initiative, Health Canada is establishing a new division within the Therapeutic Products Directorate's Medical Devices Bureau to allow for a more targeted pre-market review of digital health technologies, to adapt to rapidly changing technologies in digital health, and to respond to fast innovation cycles.

Identified Overall Concerns

- Threat to public health, scientific integrity, and potential consumers
- Apps based on biased publications need to be retracted, or at the very least audited
- Marketing materials are not monitored appropriately, nor are the claims. Where is the appropriate regulation?
- Businesses have direct influence, and to a certain degree control, over consumer/patient/public health behaviors that can consequently interfere with clinical practice and interventions in the public domain
- **Businesses are acting as a healthcare proxy without proper validation or legal authority**

What is

NEXT?

The Way Forward

- ❑ Intentional and focussed efforts to establish a regulatory body and/or assigned positions to monitor digital health technologies
- ❑ Regulatory body, whether it be internal within health agencies or hospitals
 - e.g. “Digital Health Scientist” (**with no conflict of interest**)
 - Focussed on evaluating existing apps for the sole purpose of greater patient good and population health impact
- ❑ Regulation is needed to help minimize future negative effects on patient and population health management, especially when it interferes with clinical recommendations



Let's keep in touch!

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