EMB – Berlin - 2019

Digital Health Care in Cardiology: patients, biosensors, clinical care

Gerhard Hindricks,

Heart Center Leipzig and Leipzig Heart Institute

Helios

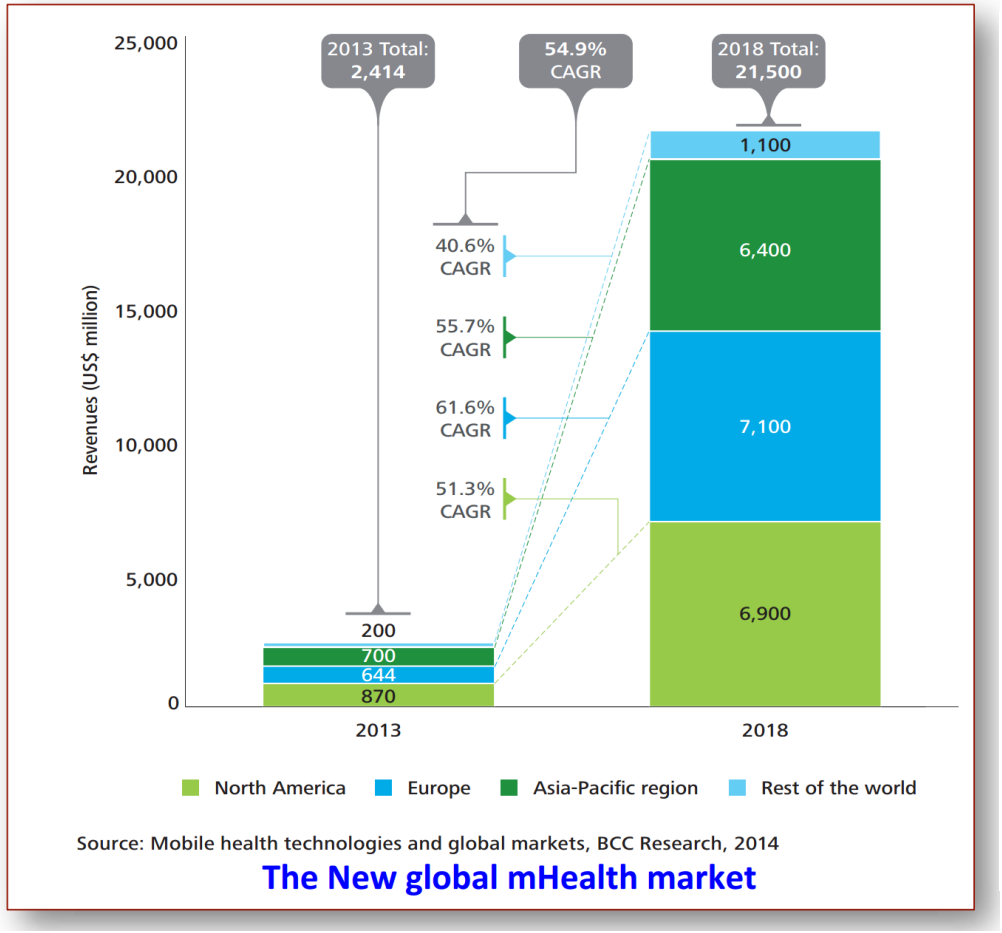
Presenter Disclosure Information

Gerhard Hindricks/Department of Electrophysiology has received scientific grants and research & development grants through the University Leipzig / Heart Center from Abbott, Biotronik, Boston Scientific, Volkswagen Foundation, German Innovation Fond, and the European Commission.

No personal relations to disclose.

Support European Values

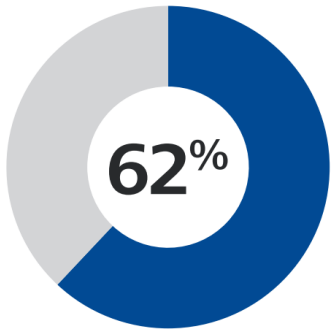
e-health and m-health is disruptive



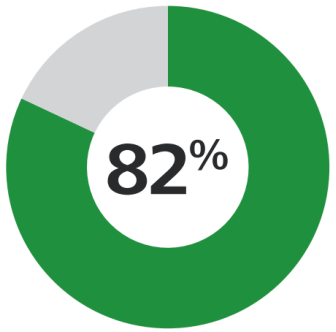
Source: Mobile health technologies and global markets, BCC Research, 2014

The New global mHealth market

Emerging Success Stories



62 per cent of the population of Africa live in rural areas where access to medical facilities is extremely difficult

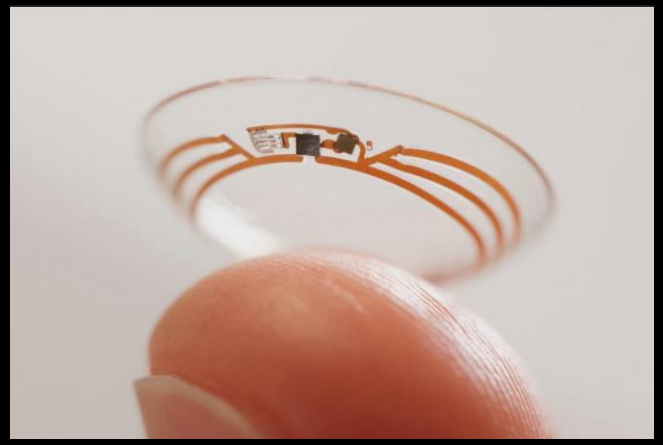


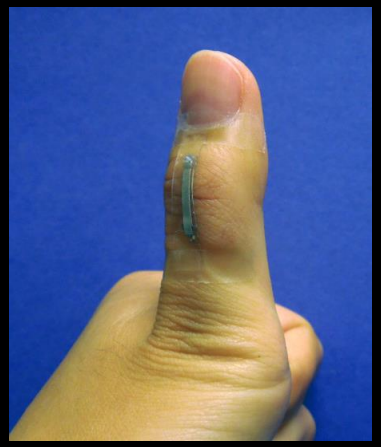
Mobile phone penetration in Africa reached 82 per cent in 2014

- In Kenya, mHealth improved anti-retroviral therapy uptake by 11%
- In Kenya, mHealth reduced government response to malaria outbreak from 4 months to 3 minutes
- In Mali, text messaging to pregnant women has reduced perinatal and maternal mortality by 30%.

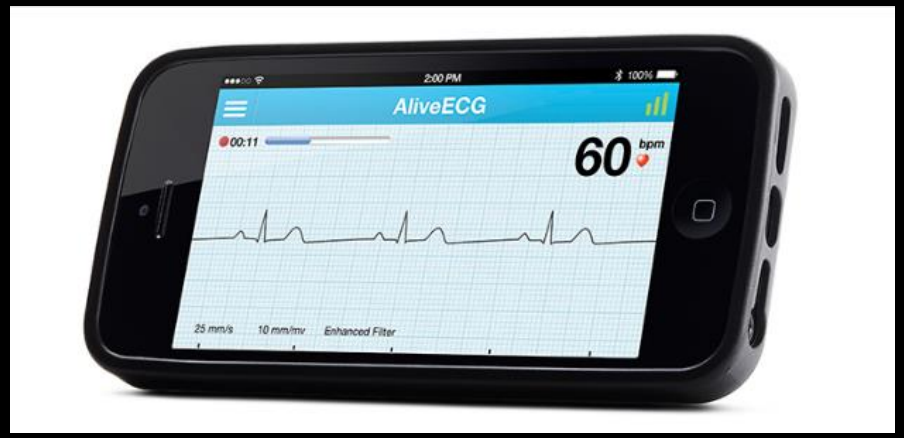
mobile healthcare in Africa, Orange Healthcare, May 2014.

Modified from: Sengupta PP; presented at the 2017 ESC Spring Summit, Sophia Antipolis, France



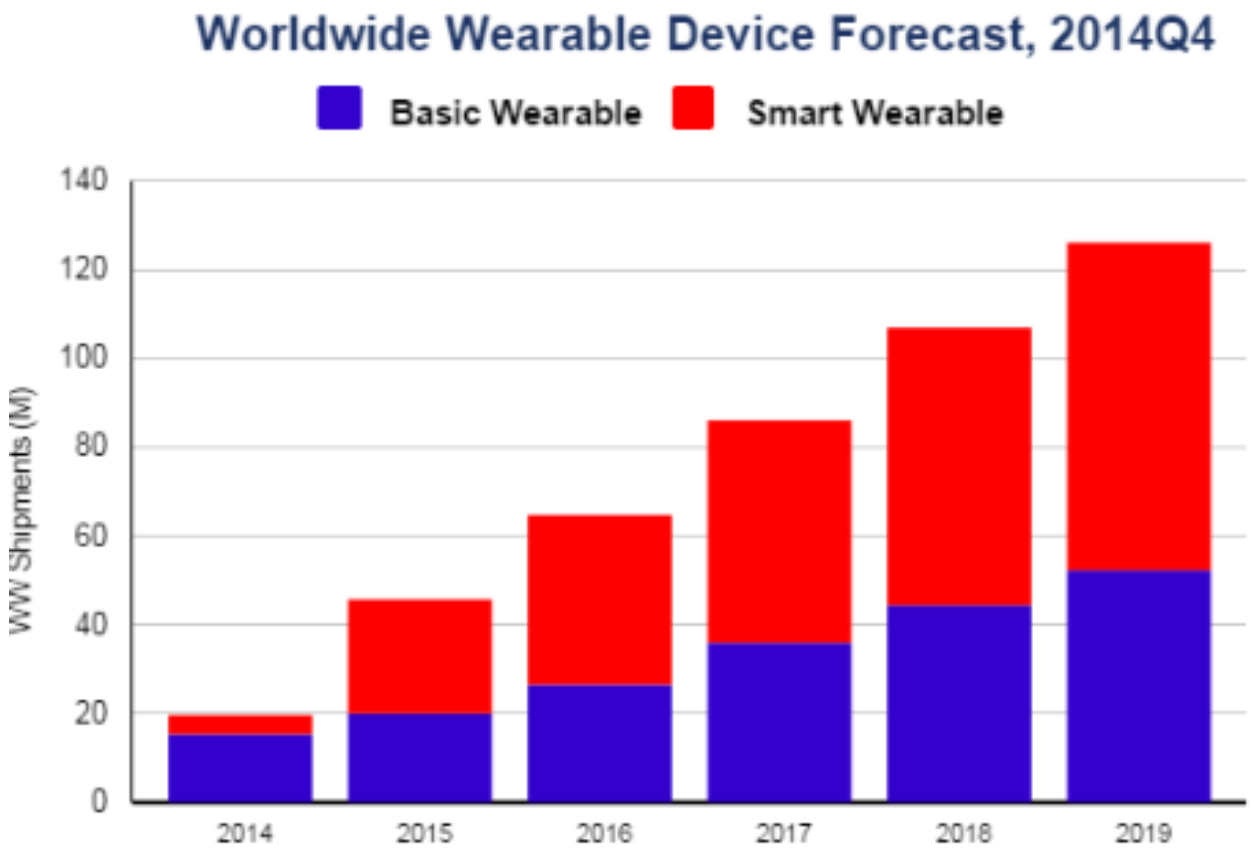


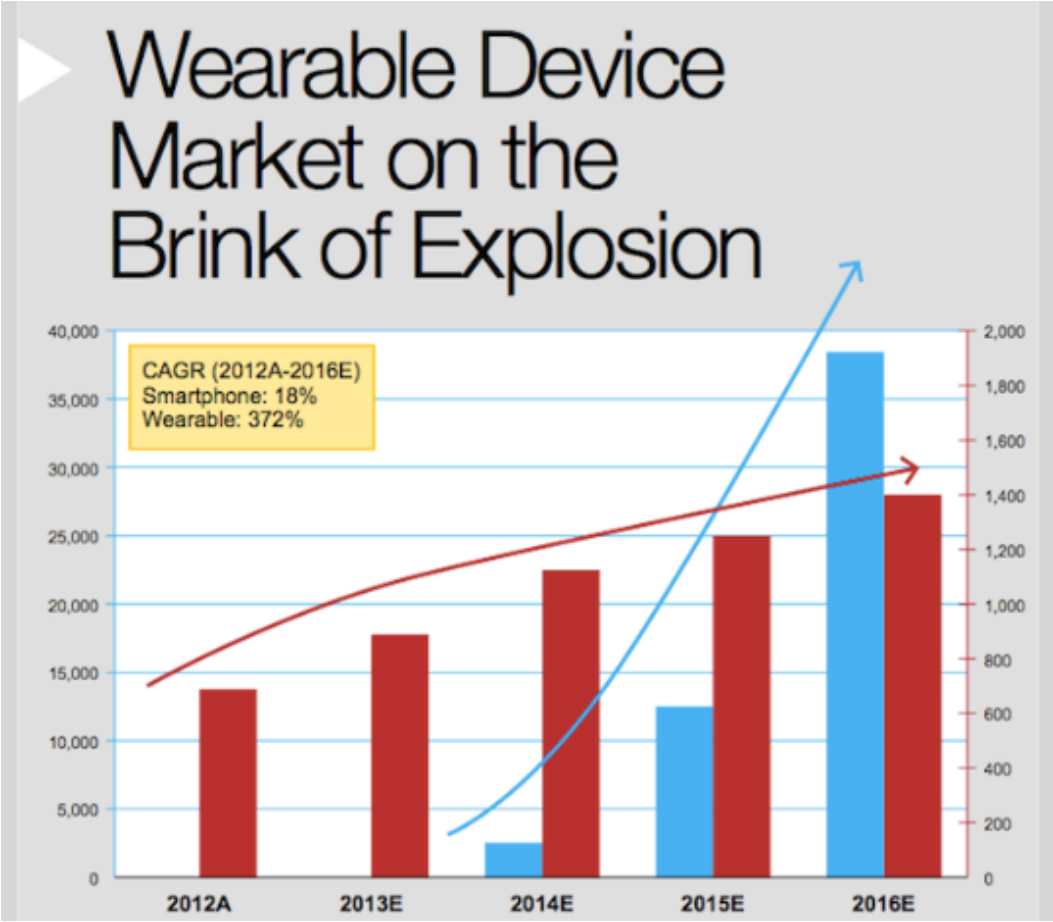

HEAPSYLON

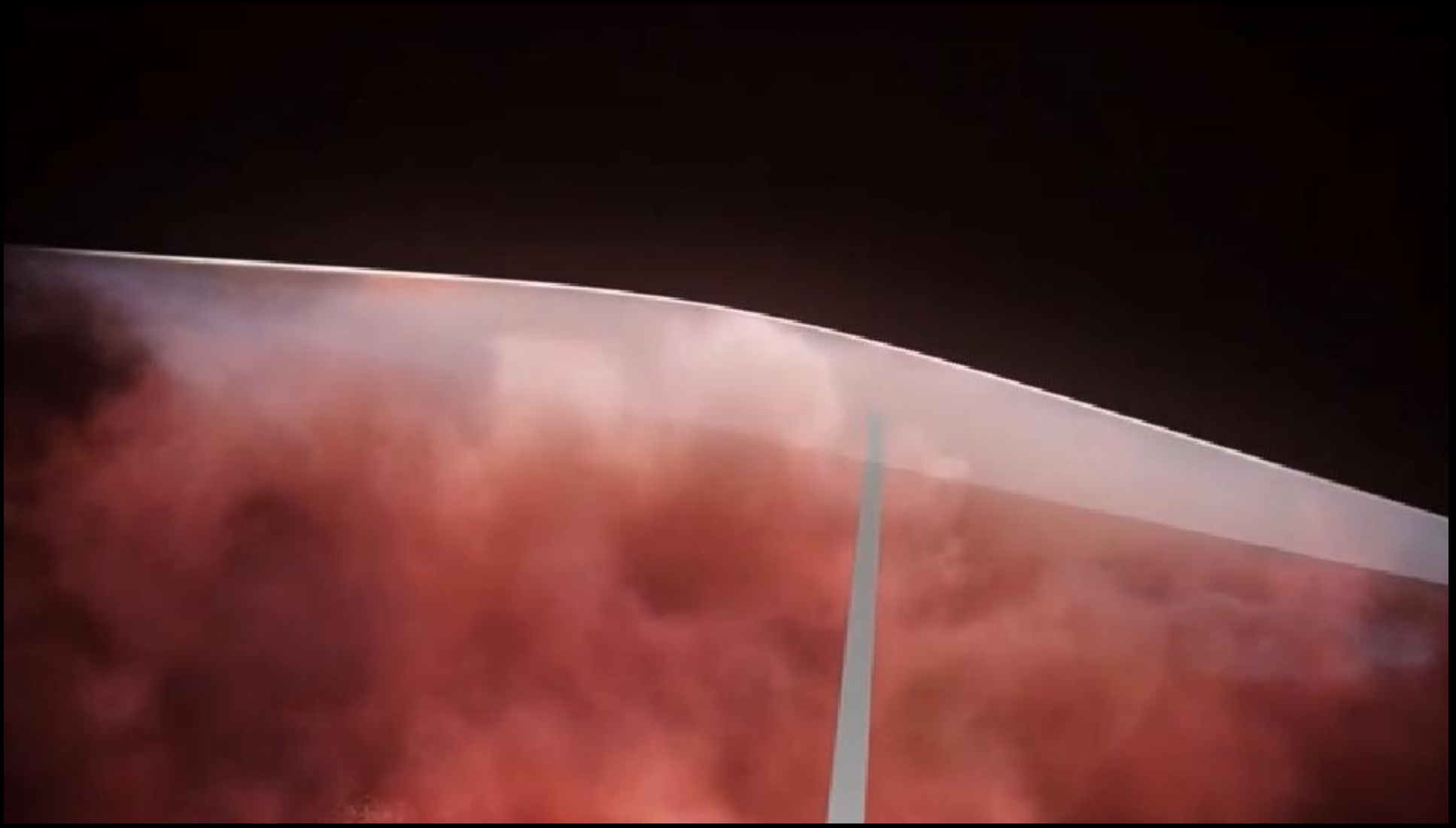

2:00 PM
100%
AliveECG
00:11
60
bpm
25 mm/s
10 mm/mv
Enhanced Filter


WARNING
This is not a diagnostic device.
Please visit http://mobilecg.hu
for an open source diagnostic
electrocardiograph.

Development of the wearable market








Electrocardiogram

Application of wearables: the Apple Heart Study

Rationale and design of a large-scale, app-based study to identify cardiac arrhythmias using a smartwatch: The Apple Heart Study

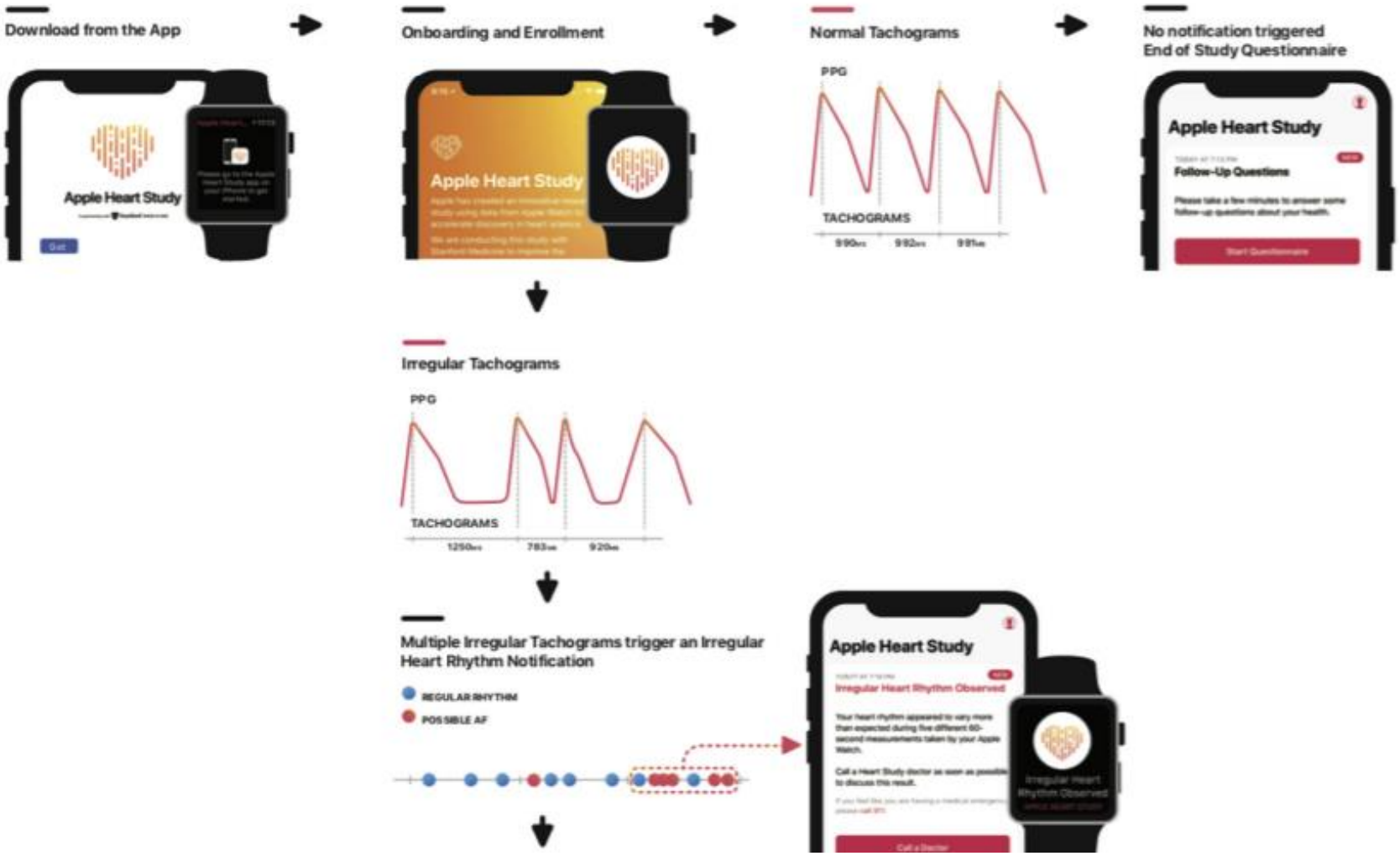
Mintu P. Turakhia, MD, MAS,[a,b] Manisha Desai, PhD,[c] Haley Hedlin, PhD,[c] Amol Rajmane, MD, MBA,[d] Nisha Talati, MBA,[d] Todd Ferris, MD, MS,[e] Sumbul Desai, MD,[f] Divya Nag[f] Mithun Patel, MD,[f] Peter Kowey, MD,[g] John S. Rumsfeld, MD, PhD,[h] Andrea M. Russo, MD,[i] Mellanie True Hills, BS,[j] Christopher B. Granger, MD,[k] Kenneth W. Mahaffey, MD,[d] and Marco V. Perez, MD[l] *Stanford, Palo Alto, Cupertino, CA; Philadelphia PA; Denver Colorado; Camden NJ; Decatur TX; Durham NC*

Background Smartwatch and fitness band wearable consumer electronics can passively measure pulse rate from the wrist using photoplethysmography (PPG). Identification of pulse irregularity or variability from these data has the potential to identify atrial fibrillation or atrial flutter (AF, collectively). The rapidly expanding consumer base of these devices allows for detection of undiagnosed AF at scale.

Methods The Apple Heart Study is a prospective, single arm pragmatic study that has enrolled 419,093 participants (NCT03335800). The primary objective is to measure the proportion of participants with an irregular pulse detected by the Apple Watch (Apple Inc, Cupertino, CA) with AF on subsequent ambulatory ECG patch monitoring. The secondary objectives are to: 1) characterize the concordance of pulse irregularity notification episodes from the Apple Watch with simultaneously recorded ambulatory ECGs; 2) estimate the rate of initial contact with a health care provider within 3 months after notification of pulse irregularity. The study is conducted virtually, with screening, consent and data collection performed electronically from within an accompanying smartphone app. Study visits are performed by telehealth study physicians via video chat through the app, and ambulatory ECG patches are mailed to the participants.

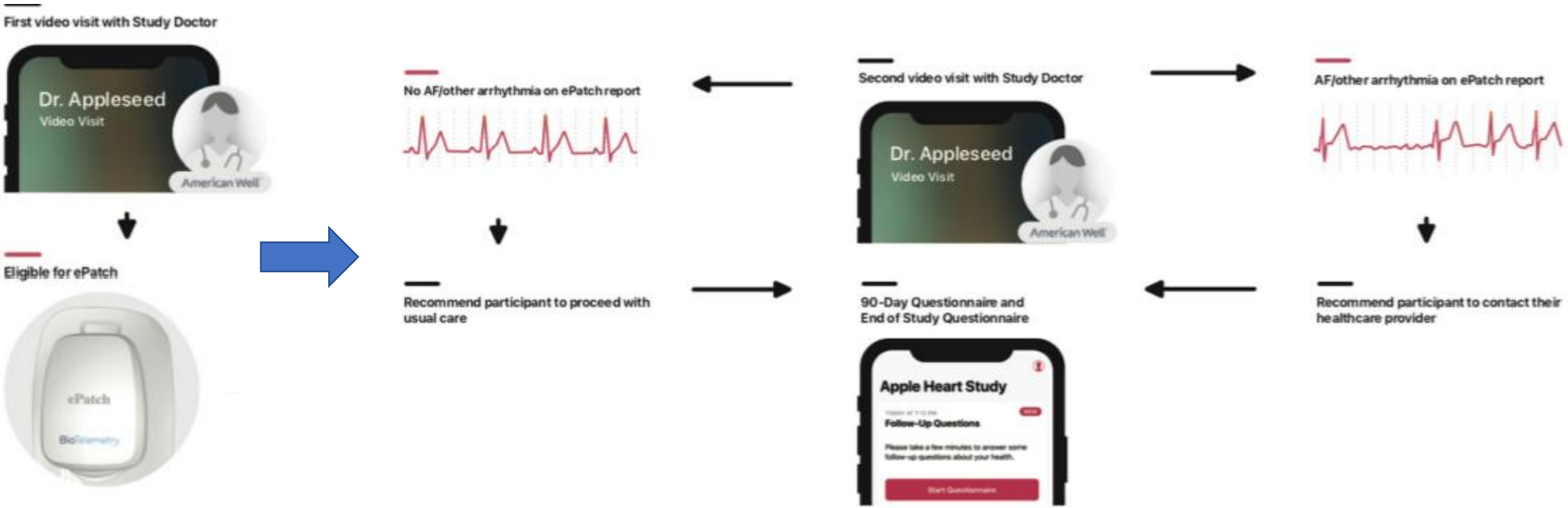
Turakhia M et al.; Am Heart J 2019

Application of wearables: the Apple Heart Study



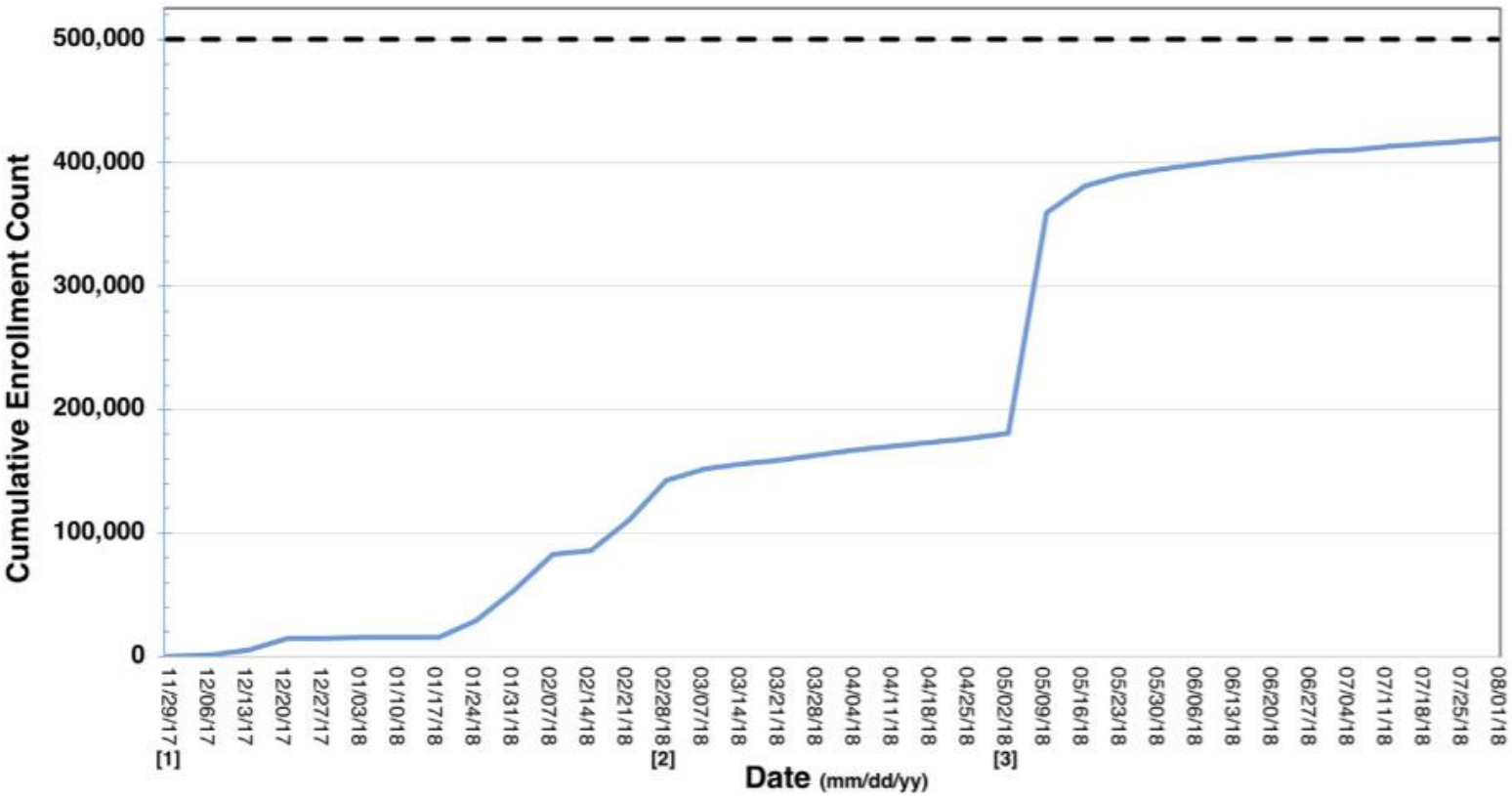
Turakhia M et al.; Am Heart J 2019

Application of wearables: the Apple Heart Study



Turakhia M et al.; Am Heart J 2019

Application of wearables: the Apple Heart Study



Turakhia M et al.; Am Heart J 2019

Application of wearables: the Apple Heart Study

Primary

1. Atrial fibrillation or atrial flutter of greater than 30 seconds duration detected on subsequent ambulatory ECG monitoring for a participant who received an irregular pulse watch notification.
2. Simultaneous ambulatory ECG monitoring indicating an irregular rhythm consistent with atrial fibrillation or atrial flutter during time intervals when the spot tachogram is positive for an irregular pulse among those who received a notification.

Secondary

1. Simultaneous ambulatory ECG monitoring indicating an irregular rhythm consistent with atrial fibrillation or atrial flutter when the Irregular Pulse Notification Algorithm based on multiple tachograms is positive for an irregular pulse among those who received a notification
2. Self-reported contact with a health care provider within 3 months following an irregular pulse watch notification

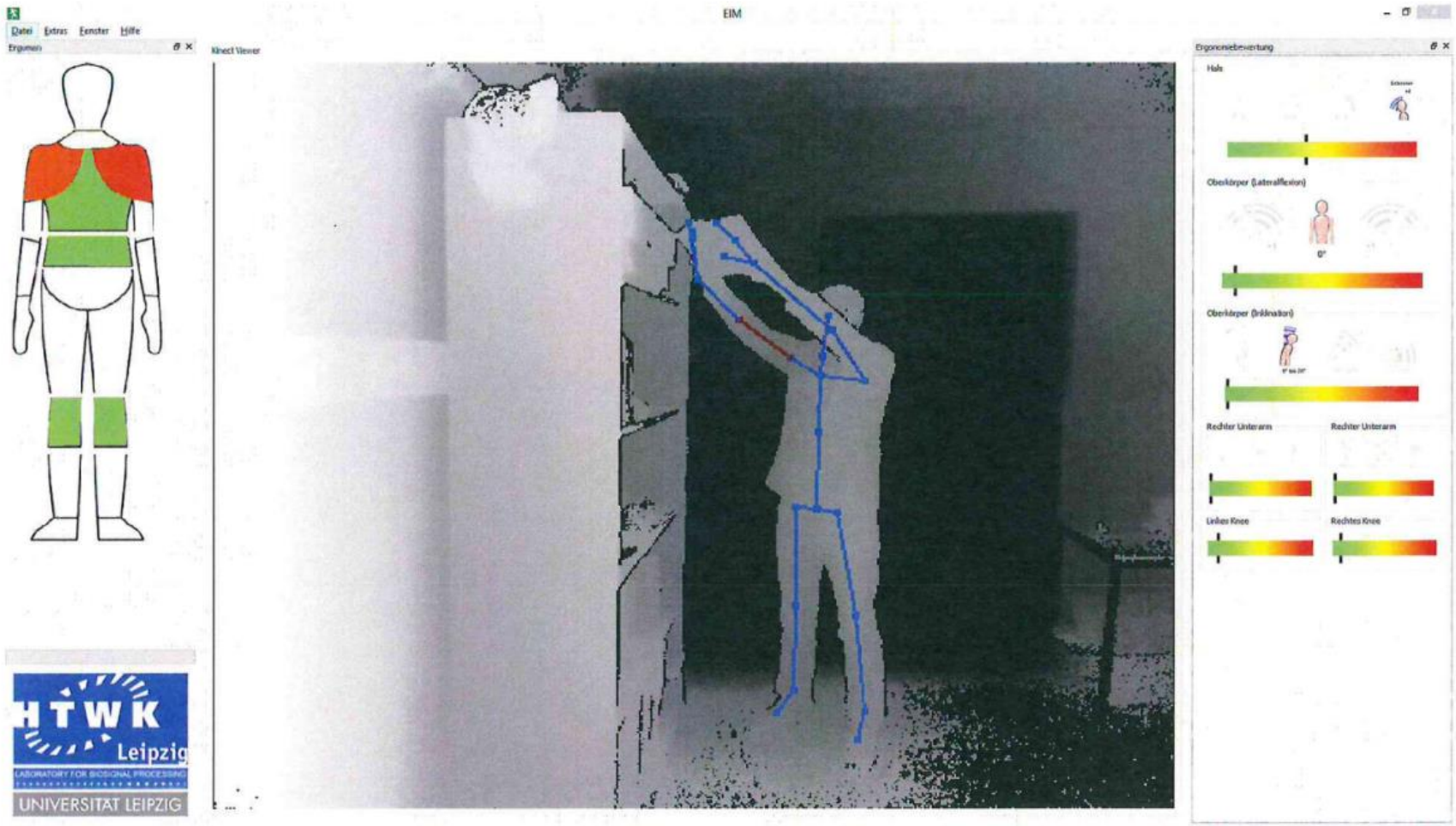
Tertiary

1. Other arrhythmias detected on cardiac patch monitoring.
2. Different durations of atrial fibrillation (6 minutes, 1 hour, 6 hours, 24 hours)
3. Clinical Diagnosis of atrial fibrillation or atrial flutter
4. Therapies for atrial fibrillation or atrial flutter (anticoagulation, antiarrhythmics, rate-controlling meds)
5. Cardioversion by a health care provider.

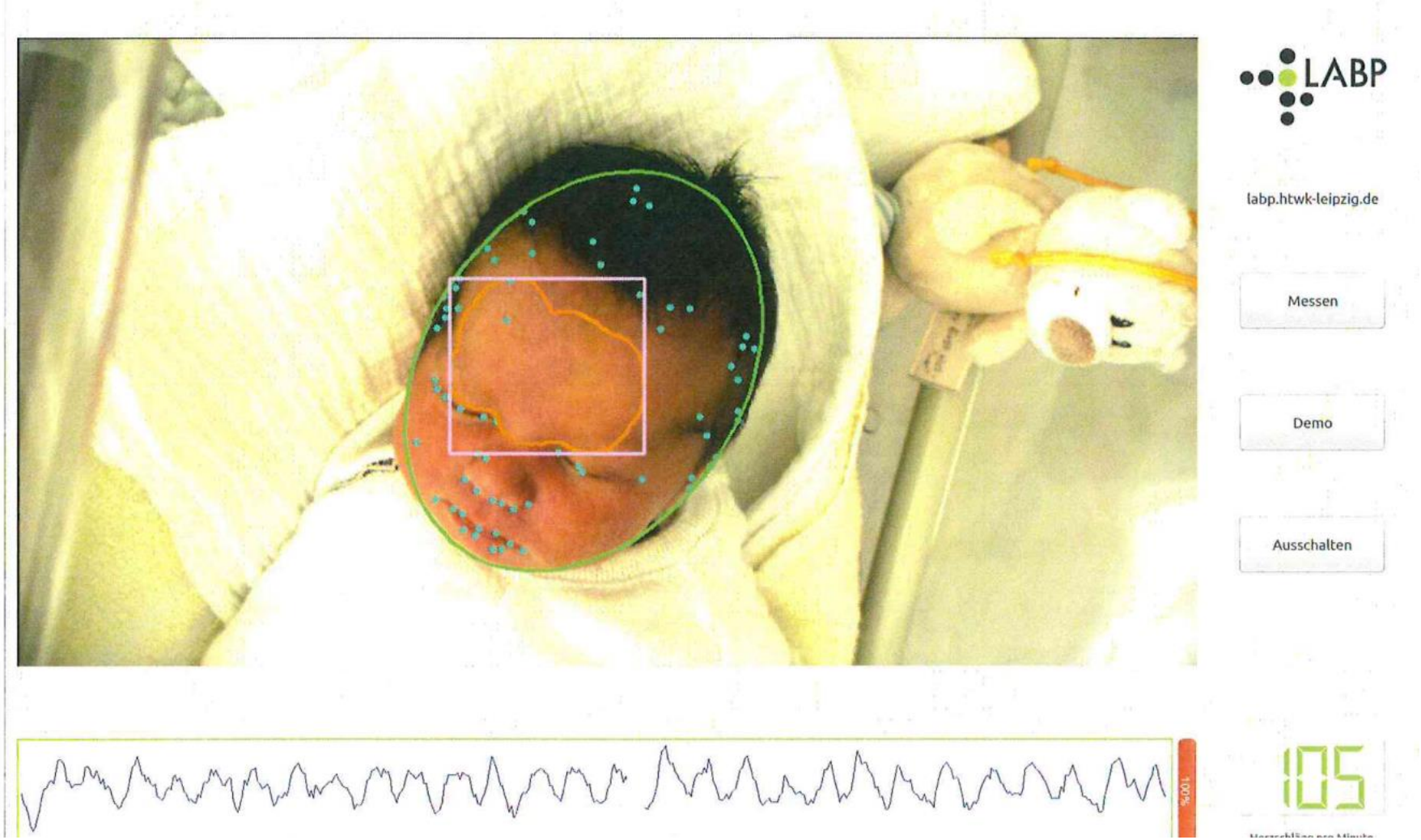
Turakhia M et al.; Am Heart J 2019

The next step: injectables

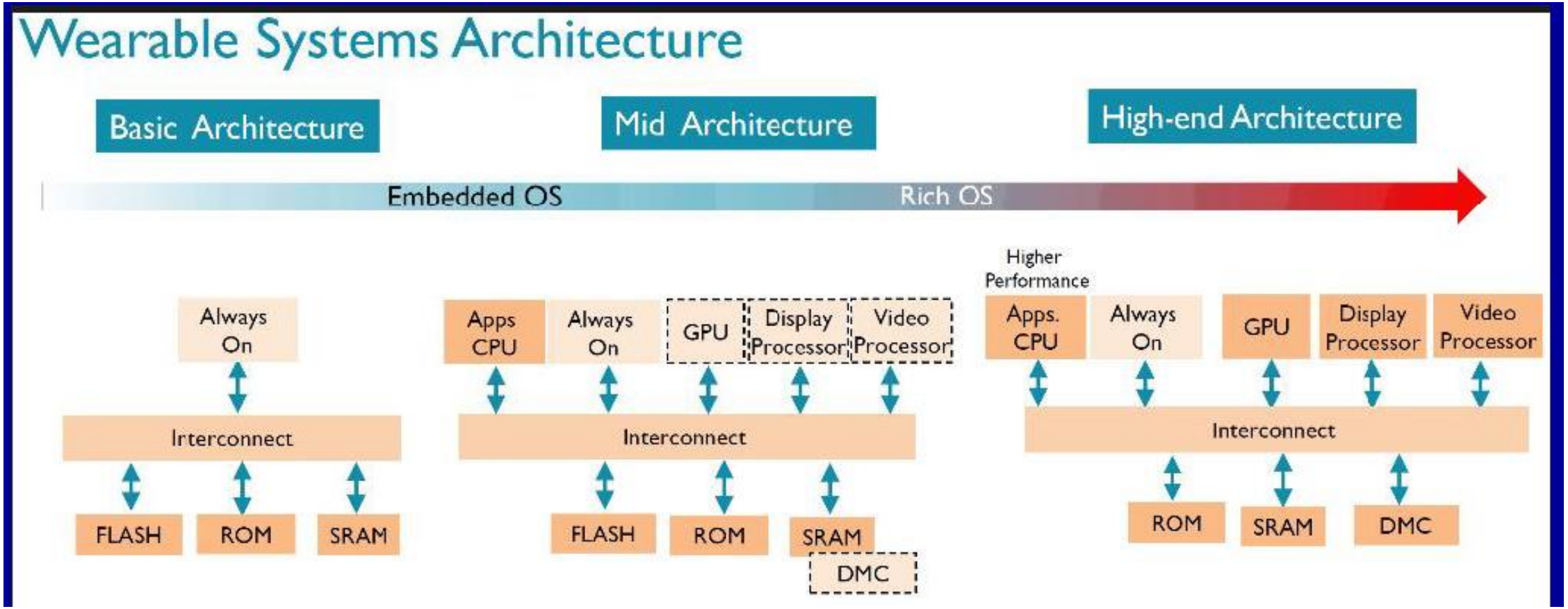
The next step: contactless acquisition of biosignals



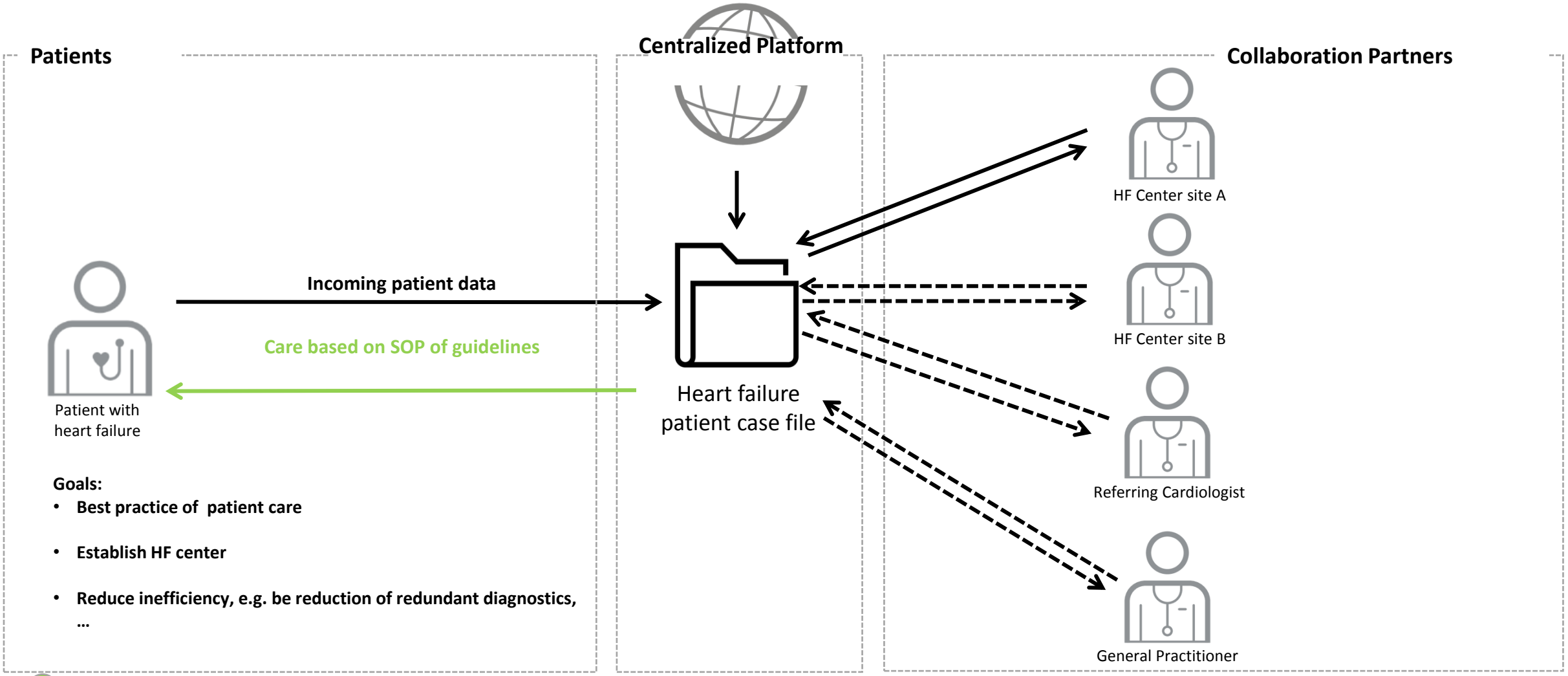
The next step: contactless acquisition of biosignals



Huge ammounts of life style and health data will be generated



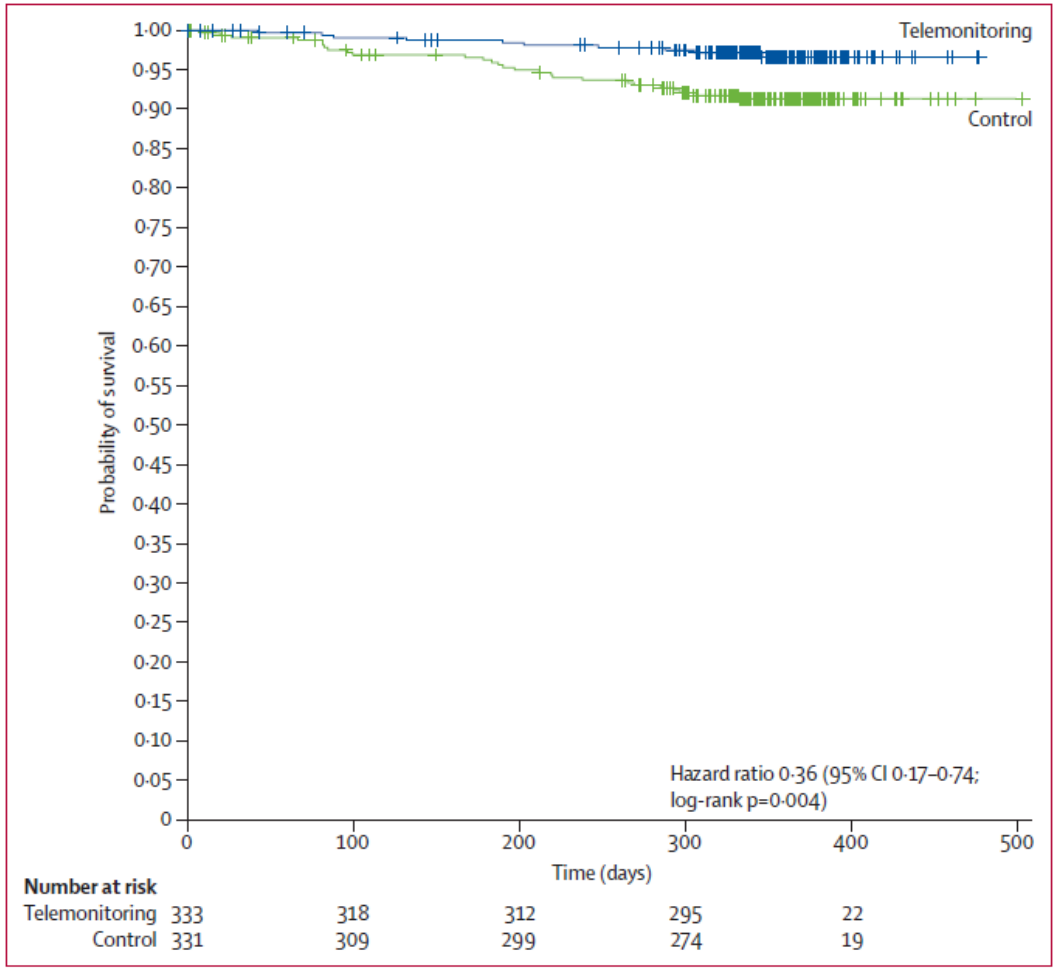
Digitalized Solutions for Value Based Health Care: Example Collaboration Network for heart failure patients

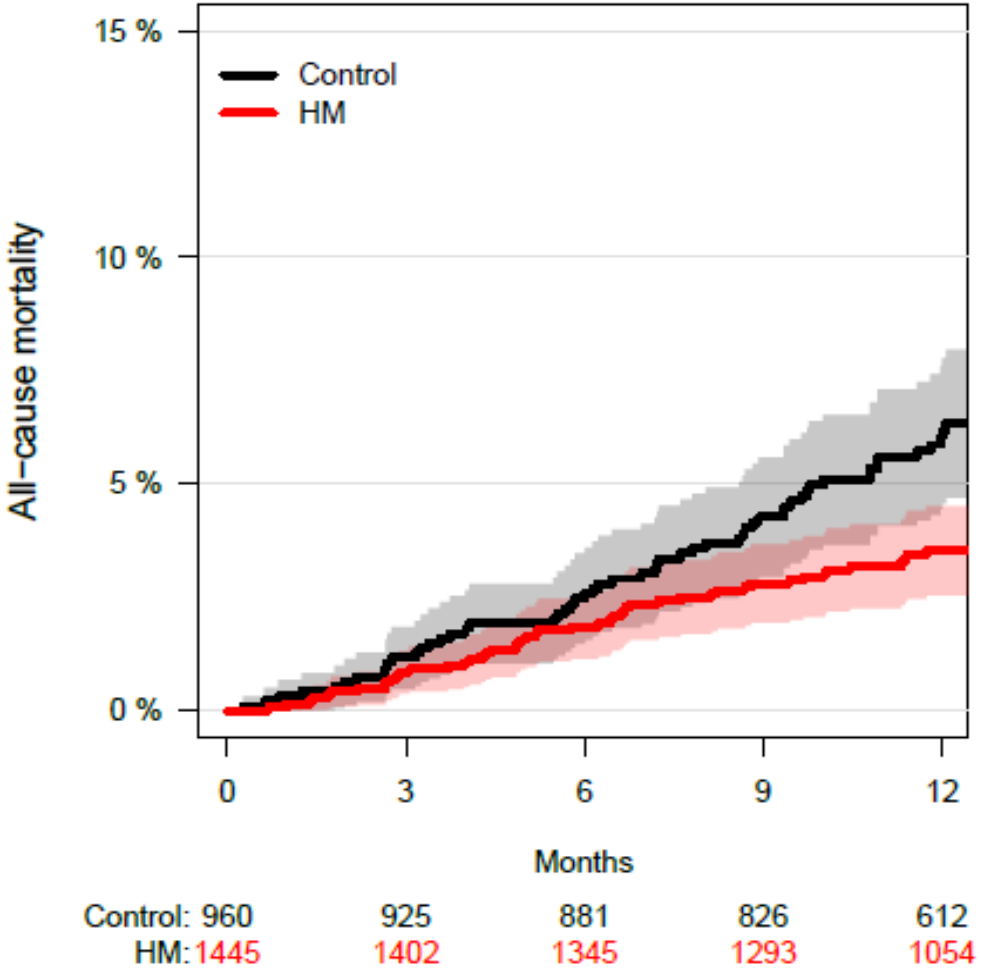


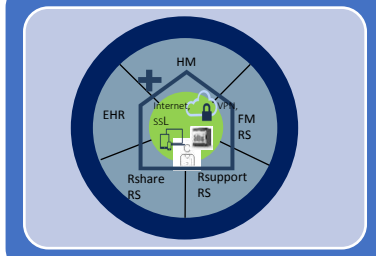
Goals:

- **Best practice of patient care**
- **Establish HF center**
- **Reduce inefficiency, e.g. be reduction of redundant diagnostics, …**

Digital health care: development of SOPs based on clinical trial outcome data







Digitization of clinical pathway (SOP)

- Automation and Integration of the complete cardiac care data into network platform
- Clinical events triggered SOP within the network

inSuiteCardio

Standard Operation Procedures:

Outcome relevant events

↓

automatic process chain

↓

Tasks and responsibilities

↓

automatic documentation

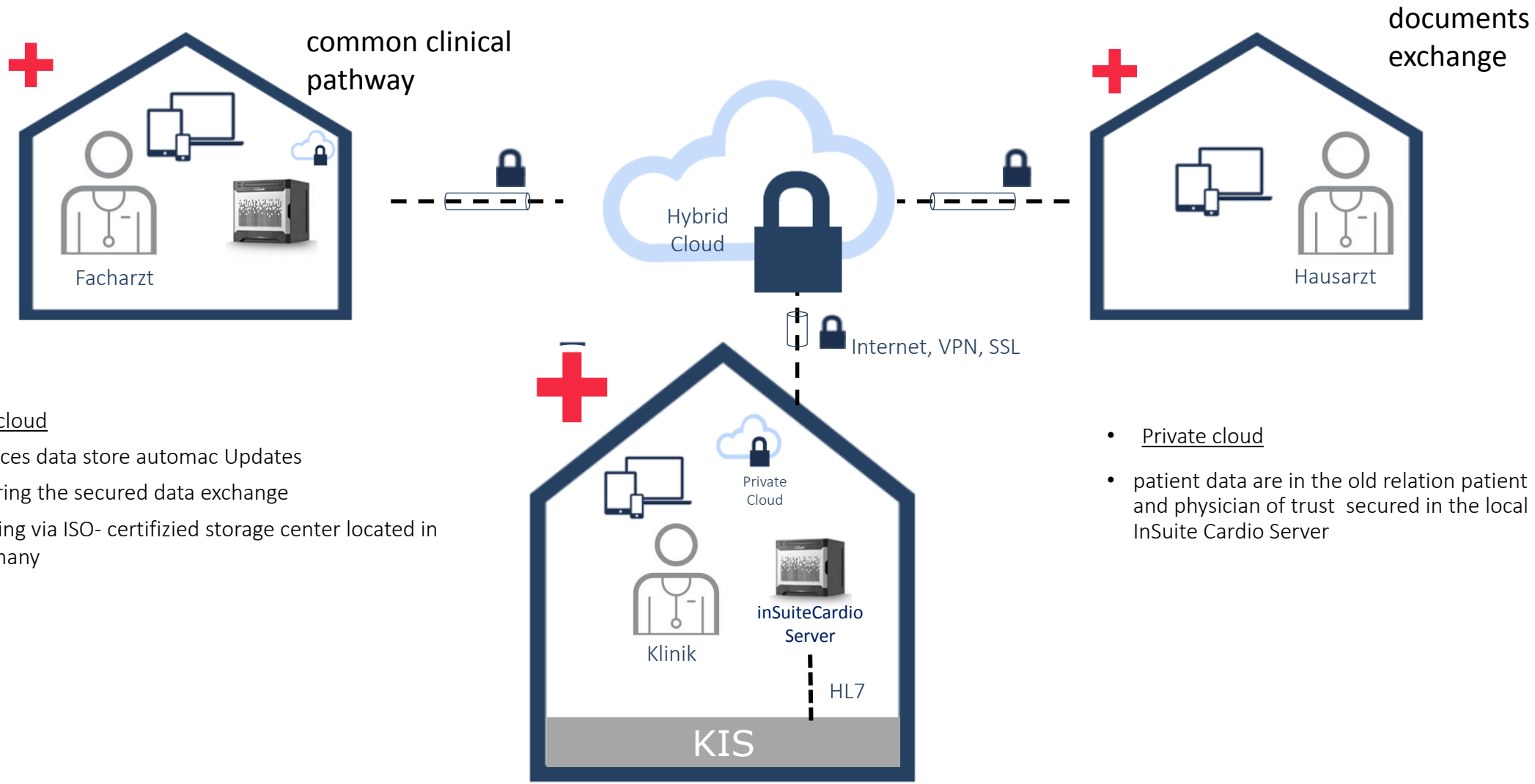
Value Based Health Care Solution

With the solution „inSuite_IN-TIME SOP“ the standard operation procedures (SOP) of the IN-TIME study can effectively and efficiently be used in clinical practice especially in collaboration with different sites and referring physicians:

Outcome relevant events

- activate an automatic process
- assign tasks and responsibilities and
- are automatically documented

The most effective and efficient way of Home Monitoring.

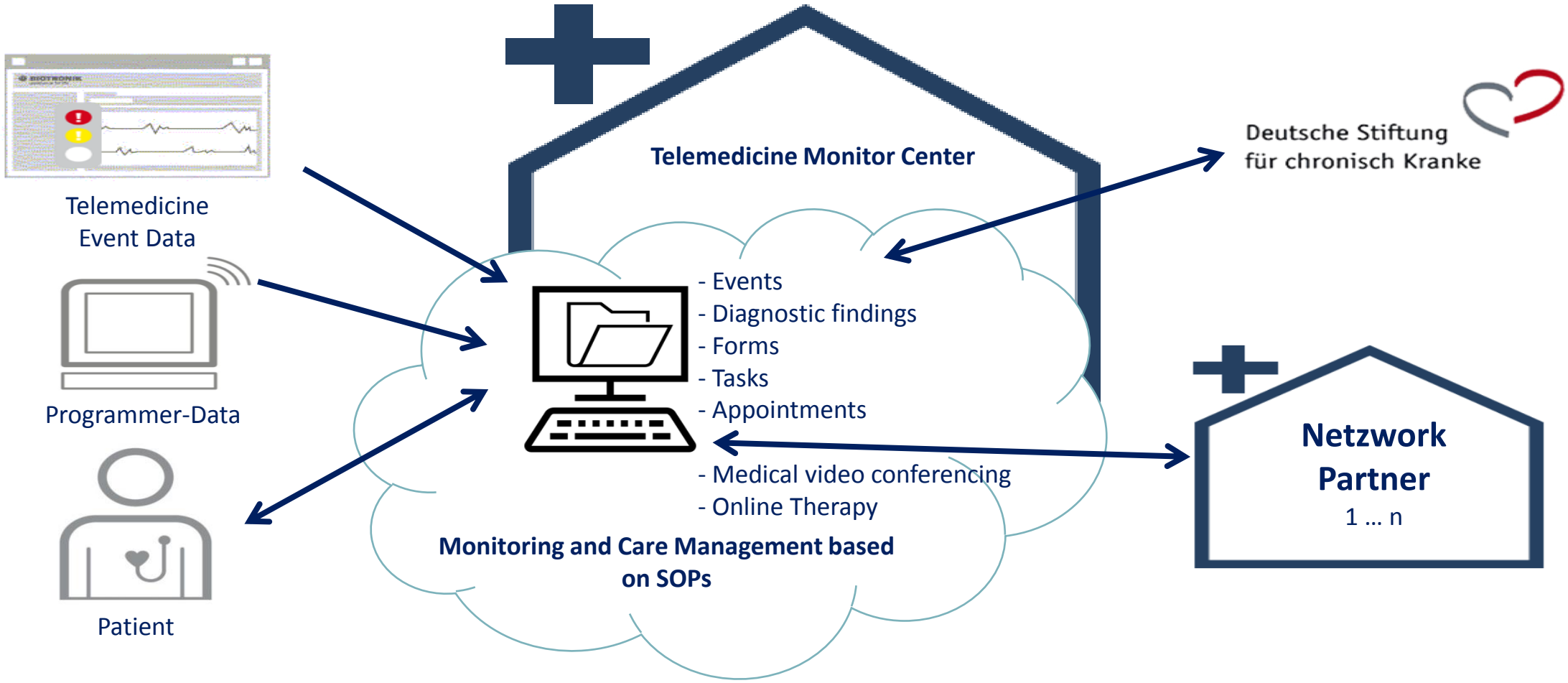


Hybrid cloud

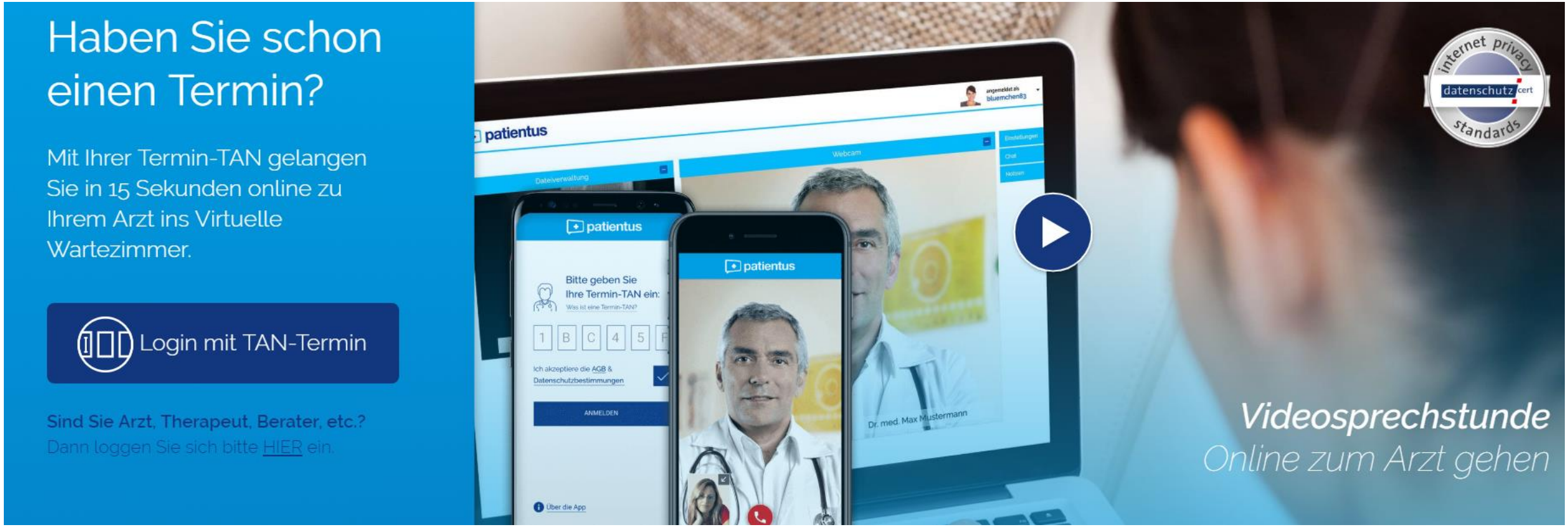
- Services data store automac Updates
- Steering the secured data exchange
- Hosting via ISO- certifizied storage center located in Germany

- Private cloud
- patient data are in the old relation patient and physician of trust secured in the local InSuite Cardio Server

Summary network platform InSuite



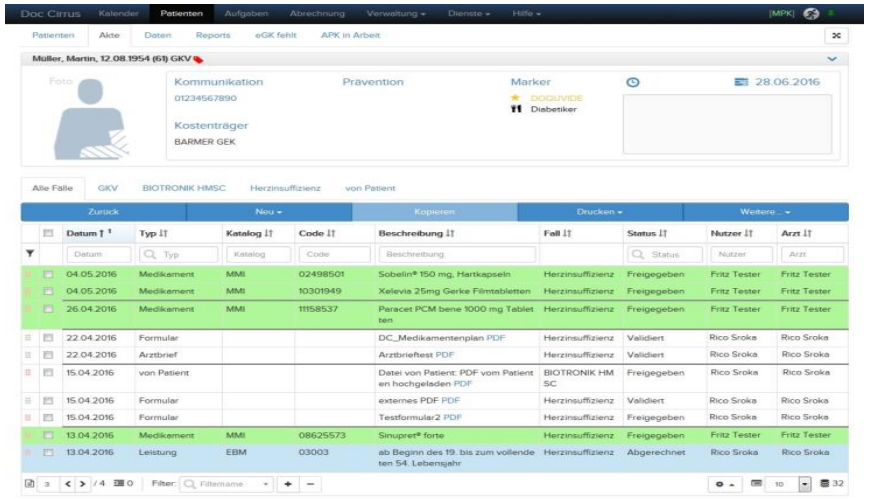
Remote patient management



Technical Details: Medical sectors overlapping Networking on latest technology

- Modular networking software
- Modern web based application for PC, Mac, tablet and smartphone
- No software installation required
- Highly secured local data storage
- Automatic updates
- Standardized interfaces
  - GDT – software for medical practices
  - HL7 – hospital information systems
- Integration of medical devices via DICOM, xDT, HL7, Serial, USB, etc.

Data Safe



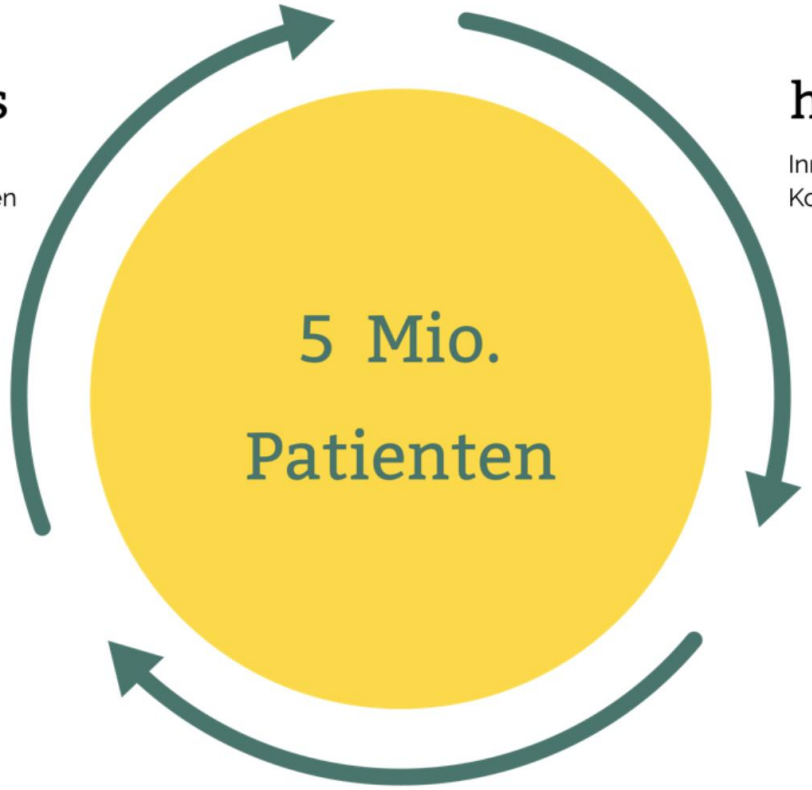
Patient Record

Big data: Helios digital data management program

- HelloHelios Patients portal

- Digital FU

- Remote radiology
- Remote pathology



LifeTime
medexo
M-sense
CardioSecur
Knows your Heart
Hi Doc
Kaiku HEALTH
heartbeat MEDICAL SOLUTIONS
vitabook
HOPPYMED

Big data: outcome asessment and quality control

ESC European Society of Cardiology
European Heart Journal (2018) 0, 1–11
doi:10.1093/eurheartj/ehy528
FASTTRACK CLINICAL RESEARCH
Arrhythmia/electrophysiology

In-hospital mortality of patients with atrial arrhythmias: insights from the German-wide Helios hospital network of 161 502 patients and 34 025 arrhythmia-related procedures

Sebastian König[1,2]*, Laura Ueberham[1,2], Ekkehard Schuler[3], Michael Wiedemann[4], Christopher Reithmann[5], Melchior Seyfarth[6], Armin Sause[6], Jürgen Tebbenjohanns[7], Anja Schade[8], Dong-In Shin[9], Alexander Staudt[10], Udo Zacharzowsky[11], René Andrié[12], Ulrike Wetzel[13], Hans Neuser[14], Carsten Wunderlich[15], Ralf Kuhlen[2,3], Jan G. P. Tijssen[16], Gerhard Hindricks[1,2‡], and Andreas Bollmann[1,2†‡]

[1]Department of Electrophysiology, Heart Center Leipzig - Universitat Hospital, Strümpellstraße 39, 04289 Leipzig, Germany; [2]Leipzig Heart Institute, Russenstraße 69a, 04289 Leipzig, Germany; [3]Helios Kliniken GmbH, Friedrichstraße 136, 10117 Berlin, Germany; [4]Department of Cardiology, Helios Hospital Berlin-Buch, Schwanebecker Chaussee 50, 13125 Berlin, Germany; [5]Department of Internal Medicine I, Helios Hospital München West, Steinerweg 5, 81241 München, Germany; [6]Department of Cardiology, Helios University Hospital Wuppertal, Heusnerstraße 40, 42283 Wuppertal, Germany; [7]Department of Cardiology, Helios Hospital Hildesheim, Senator-Braun-Allee 33, 31135 Hildesheim, Germany; [8]Department of Cardiology, Helios Hospital Erfurt, Nordhäuser Straße 74, 99089 Erfurt, Germany; [9]Department of Cardiology, Helios Hospital Krefeld, Lutherplatz 40, 47805 Krefeld, Germany; [10]Department of Cardiology and Angiology, Helios Hospital Schwerin, Wismarische Straße 393-397, 19053 Schwerin, Germany; [11]Department of Cardiology, Helios Hospital Bad Saarow, Pieskower Straße 33, 15526 Bad Saarow, Germany; [12]Department of Cardiology, Helios Hospital Siegburg, Ringstraße 49, 53721 Siegburg, Germany; [13]Department of Cardiology, Helios Hospital Aue, Gartenstraße 6, 08280 Aue, Germany; [14]Department of Internal Medicine II, Helios Hospital Plauen, Röntgenstraße 2, 08529 Plauen, Germany; [15]Department of Internal Medicine II, Helios Hospital Pirna, Struppener Straße 13, 01796 Pirna, Germany; and [16]Academic Medical Center - University of Amsterdam, Meibergdreef 9, 1105 AZ Amsterdam, Netherlands

patients with main or secondary diagnosis of atrial arrhythmias, n=1,135,697, 85 Helios hospitals, 2010-2017

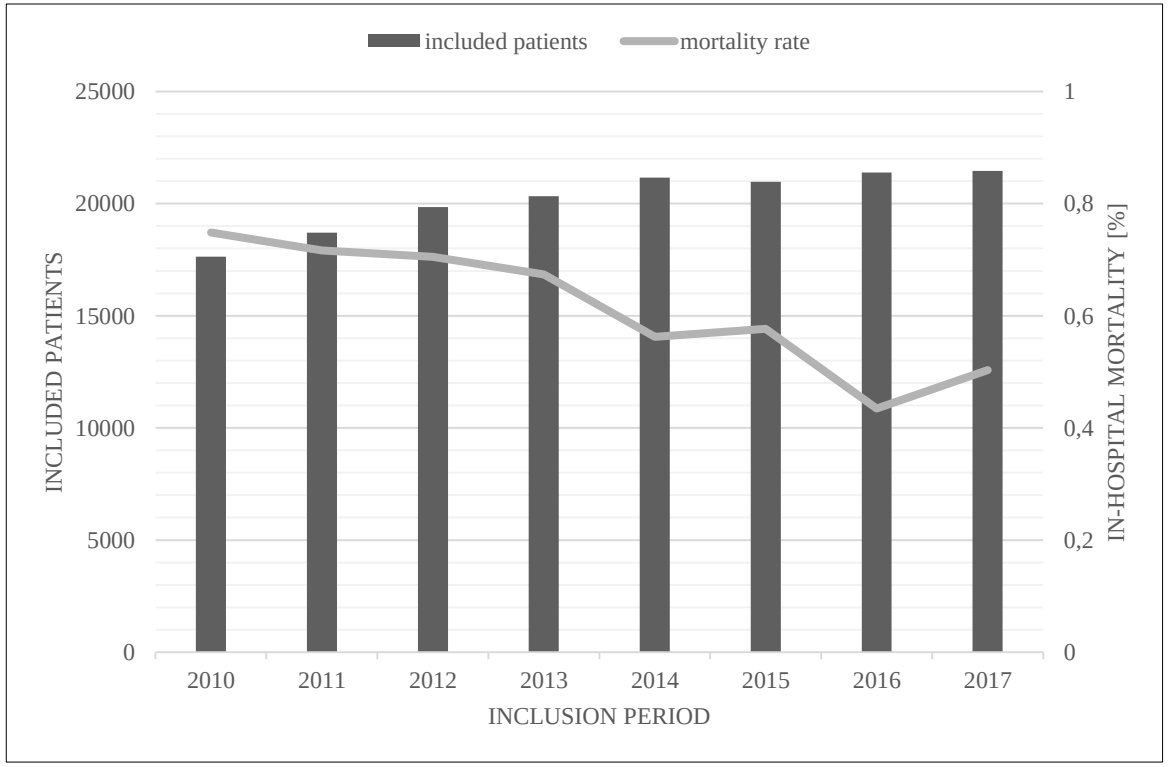
main diagnosis of Afib / Aflut or secondary diagnosis combined with arrhythmia-related procedure, **n=161,502**, 78 Helios hospitals

in-hospital mortality analysis overall and for each arrhythmia-related procedure

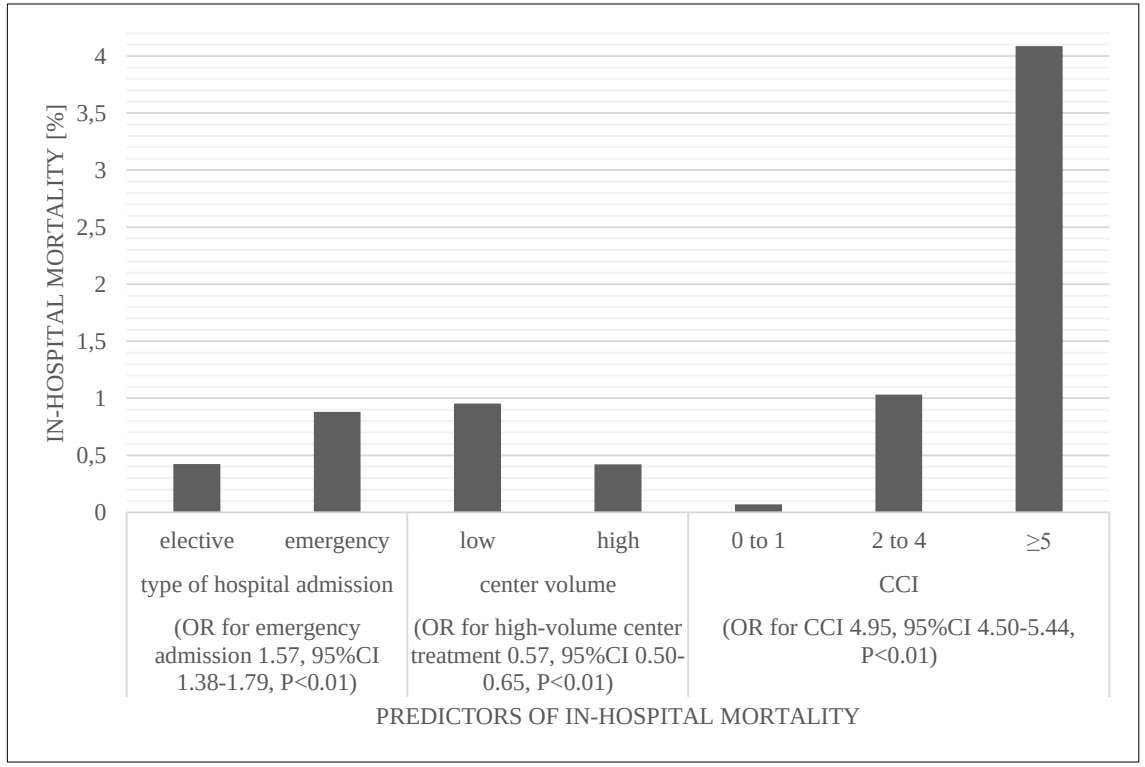
König et al.; Eur Heart J 2018

Big data: outcome asessment and quality control

Mortality data from 161.502 AF/AFLU patients



Predictors for in-hospital mortality



König S et al.; EHJ 2018

Digital health care: final thoughts

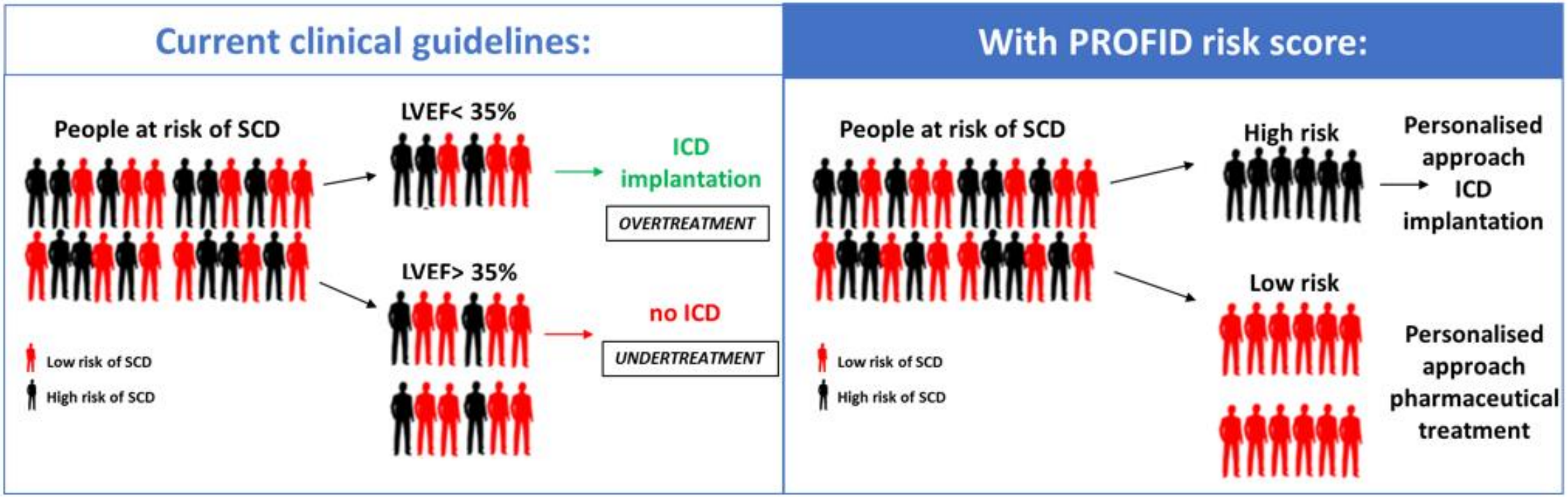
- Digital health care has already changed and improved medical communication pathways, diagnostics, and treatment pathways.
- Implants, wearables, injectables and contactless biomonitoring technology will allow continuous monitoring of various biological signals.
- The connection to AI will be disruptive for the health care system. Algorithms will supplement and partially replace traditional diagnostic and treatment pathways and support patient values, i.e. better and longer life.
- The development and installation of monitoring systems that bridge traditional sectors of the health care system will further improve the quality of care.
- Legal and data safety aspects are currently unsolved and require strong attention.

Personalized SCD risk prediction

***H2020 BHC-25:* Technical annex**

PROFID: Implementation of personalised risk score for sudden cardiac death in post-infarct patients

Personalized SCD risk prediction



Personalized SCD risk prediction

Re-analysis of existing data evidence
- machine learning / deep learning
- artificial inteligence

PROFID Risk Prediction Model
- Continuous adaptation

Randomized clincal trial
- LVEF < 35% non-inferiority design
- LVEF > 35% superiority design

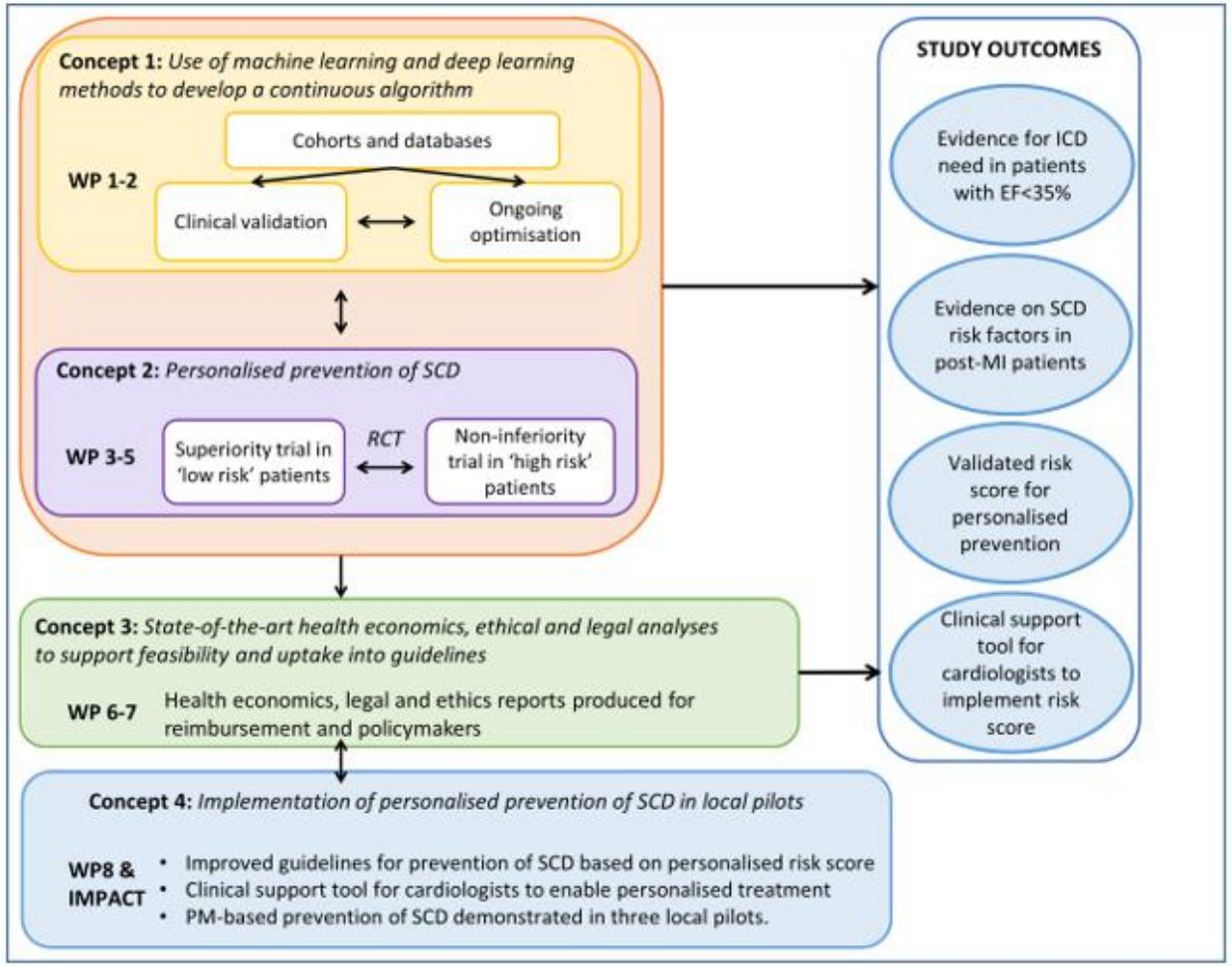


Figure 2: concepts and related approaches planned in this project

Diagnostics and treatment pathways