Technical Perspectives on Mobile Sensing in Mental Health

Jakob E. Bardram, PhD

Professor, Dept. of Health Technology
Adjunct Professor, Dept. Public Health, University of Copenhagen
Director, Copenhagen Center for Health Technology

DTU Technical University of Denmark

cachet | Copenhagen Center for Health Technology

UNIVERSITY OF COPENHAGEN

Outline

BACKGROUND

- Digital Phenotyping
- Copenhagen Research Platform (CARP)

CHALLENGES

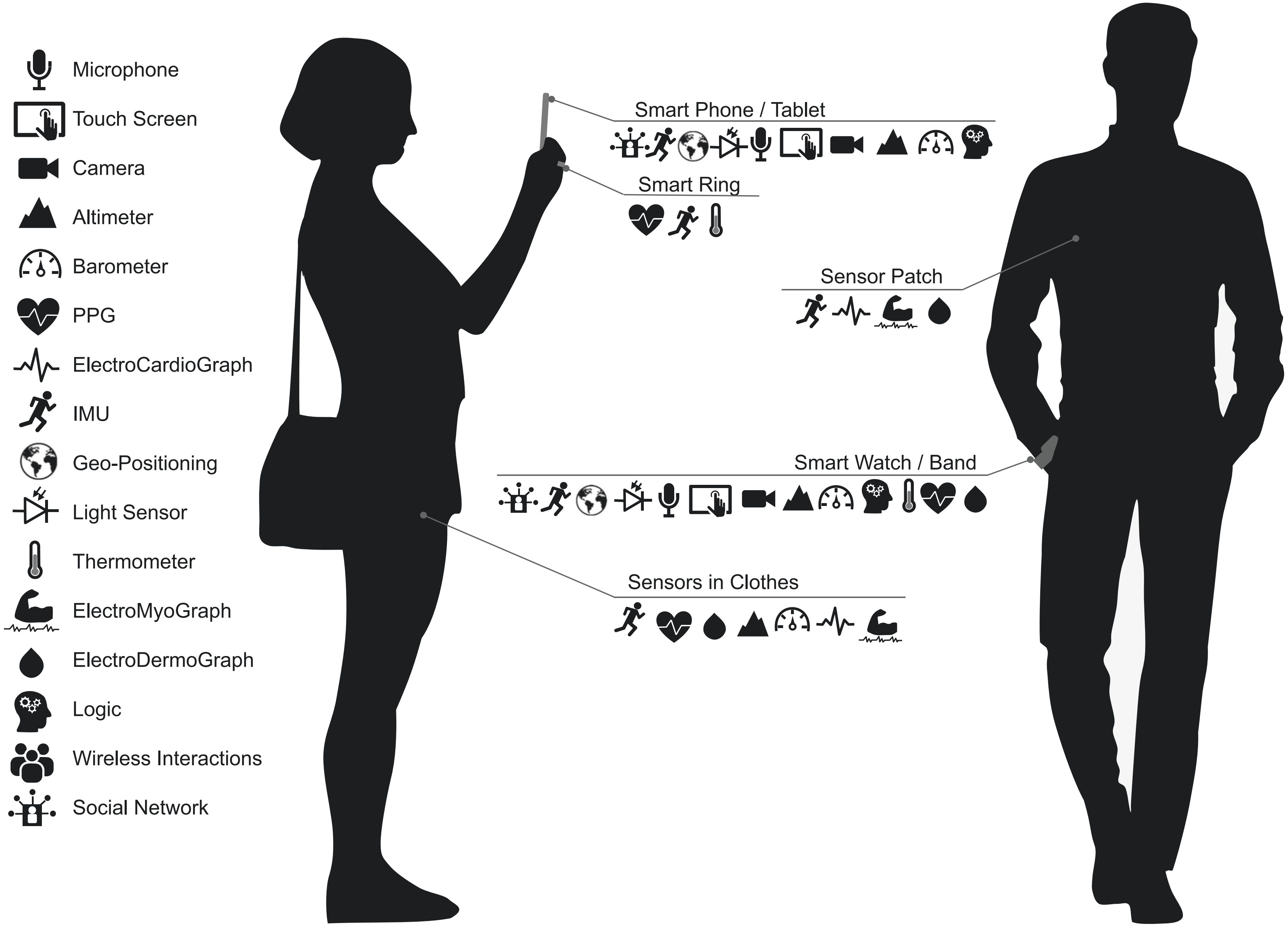
- (Technical) Challenges in Mobile Sensing (in Mental Health)
- ... and what to do about them

LOOKING AHED

- What is coming
- How do I see the future of mobile sensing in Mental Health?

BACKGROUND

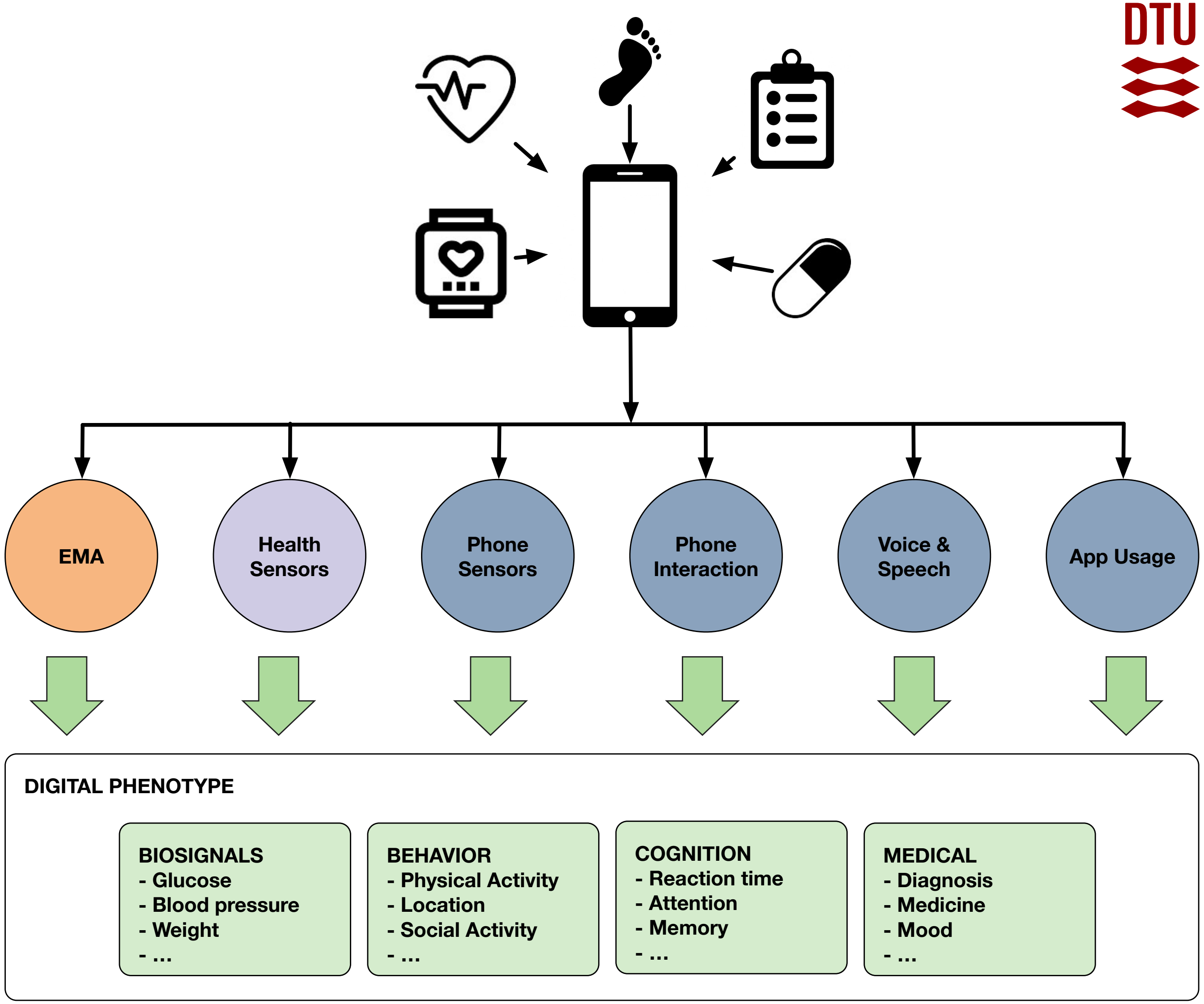
Digital Phenotyping & The Copenhagen Research Platform (CARP)



Kourtis, L. C., Regele, O. B., Wright, J. M., & Jones, G. B. (2019). Digital biomarkers for Alzheimer's disease: the mobile/wearable devices opportunity. *NPJ digital medicine*, *2*(1), 9.

Digital Phenotyping

- **Continuous**
  - 24/7, longitudinal,
- **Ambulatory**
  - “in-the-wild”, at home, …
- **Unobtrusive**
  - consumer / everyday technology
  - mobile / wearable sensing
- **Large N’s**
  - large-scale deployment
  - “cheap” technology
- **Inference & Insights**
  - behavior, cognition, health, …
  - based on health data science (AI/ML)



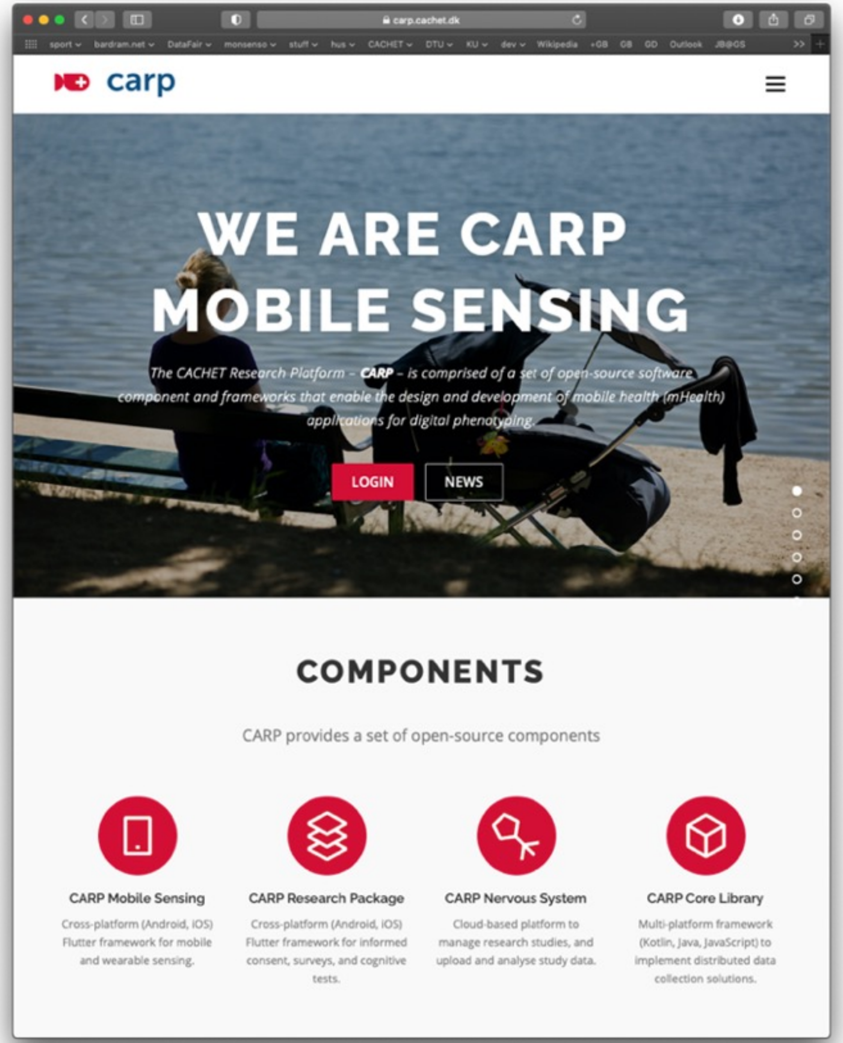
- JP Onnela & SL Rauch (2016). Harnessing Smartphone-Based Digital Phenotyping to Enhance Behavioral and Mental Health. *Neuropsychopharmacology*. 41(7): 1691–1696.
- SH Jain, BW Powers, JB Hawkins & JS Brownstein (2015). The digital phenotype. *Nat Biotech*, 33(5), 462–463.
- TR Insel (2017). Digital phenotyping: Technology for a new science of behavior. *JAMA*, *318*(13), 1215–1216.

Copenhagen Research Platform – CARP

carp.cachet.dk

Large-scale data science platform for digital phenotyping and personal health technology

- **Open source [programming] framework**
  - multi-project platform used in many mHealth applications
  - developed and shared w industry partners
- **Sharing**
  - multi-study platform
  - analysis of data across multiple studies
- **Privacy & Security**
  - enabling privacy & security as part of platform (GDPR)
  - secure local hosting @ DTU Computerome
- **Standardization**
  - part of open international standards
  - FHIR, IEEE 1752, ORK, ORS, ...



CARP Components

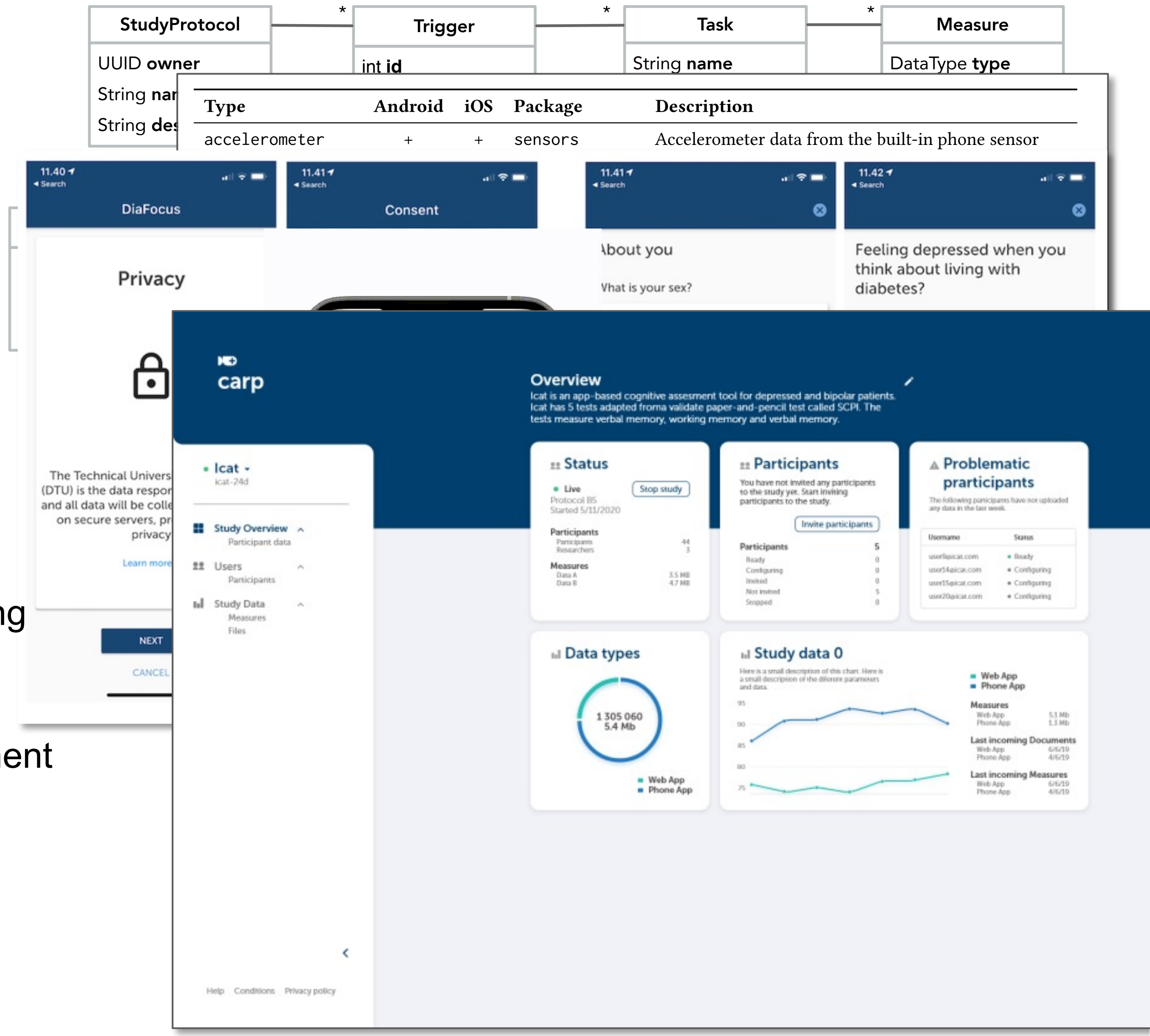
CARP Core
- domain model and standards

CARP Mobile Sensing (CAMS)
- mobile & wearable sensing framework

CARP Research Package
- informed consent & survey framework

CARP Cognition Package
- 14 pre-made cognitive test & API for extending

CARP Web Services (CAWS)
- cloud-based infrastructure for data management



Data Collection

Physiological
- weight, height, ...
- ECG, HR, HRV, blood pressure...
- Blood glucose

Behavioral
- physical activity (steps, movement, ...)
- social activity (communication, calendar, messaging, ...)
- phone usage (screen, connectivity, ...)

Contextual
- location (geo-position, geofence, ...)
- weather, air quality

Patient-Reported
- surveys
- ecological momentary assessments (EMA)
- audio & video

Cognition
- 8 Neurocognitive domains
- 14 validated gold-standard cognitive tests

Cross-platform Mobile Sensing

Type	Android	iOS	Package	Description
accelerometer	+	+	sensors	Accelerometer data from the built-in phone sensor
gyroscope	+	+	sensors	Gyroscope data from the built-in phone sensor
pedometer	+	+	sensors	Step counts from the device on-board sensor
light	+	-	sensors	Ambient light from the phone's front light sensor
device	+	+	device	Basic device information
battery	+	+	device	Battery charging status and battery level
screen	+	-	device	Screen event (on/off/unlock)
memory	+	-	device	Free memory
connectivity	+	+	connectivity	Connectivity status
bluetooth	+	+	connectivity	Scanning nearby bluetooth devices
wifi	+	+	connectivity	SSID and BSSID from connected wifi networks
location	+	+	context	Request the location of the phone.
geolocation	+	+	context	Listens to location changes.
activity	+	+	context	Activity as recognized by OS
weather	+	+	context	Current weather and weather forecasting
air_quality	+	+	context	Local air quality from land-based air pollution stations
geofence	+	+	context	Entry/dwell/exit events in circular geofences
audio	+	+	audio	Records audio from the device microphone
noise	+	+	audio	Detects ambient noise from the device microphone.
phone_log	+	-	communication	Log of phone calls in/out
text_message_log	+	-	communication	Log of text messages (sms) in/out
text_message	+	-	communication	Text message (sms) events when received
calendar	+	+	communication	All calendar events from all calendars on the phone
apps	+	-	apps	List of installed apps
app_usage	+	-	apps	App usage over time
survey	+	+	survey	User surveys via the Flutter `research_package`
movisens	+	-	movisens	ECG-related data from the Movisens EcgMove4 device.
esense	+	+	esense	Sensor and button events from eSense devices.
health	+	+	health	Wearable device data from Apple Health / Google Fit.

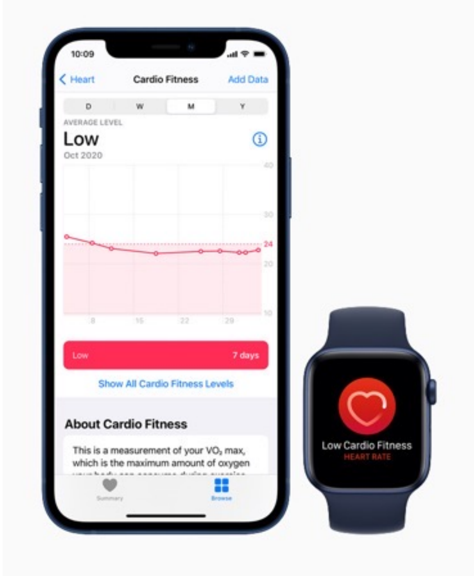
- Bardram, J. E. (2020). The CARP Mobile Sensing Framework--A Cross-platform, Reactive, Programming Framework and Runtime Environment for Digital Phenotyping. *arXiv preprint arXiv:2006.11904*
- Bardram, J. E. (2022). Software Architecture Patterns for Extending Sensing Capabilities and Data Formatting in Mobile Sensing. *Sensors*, *22*(7), 2813

Devices

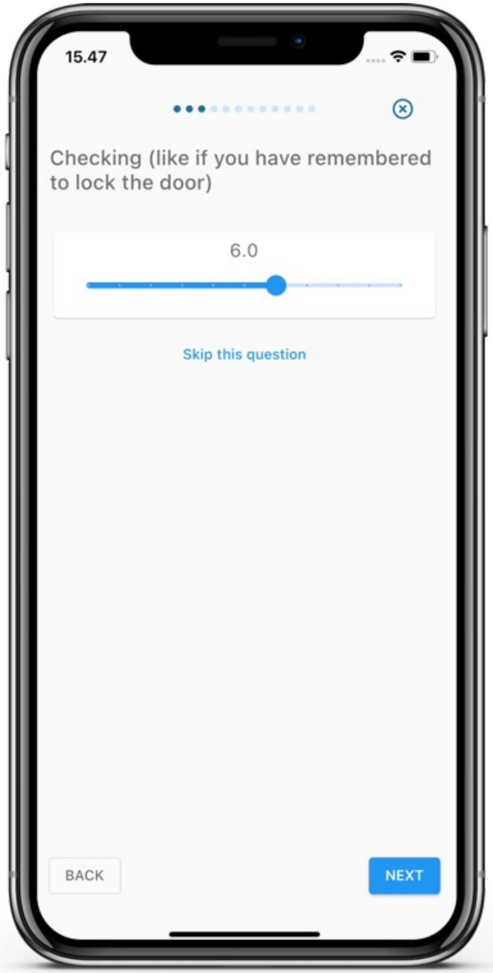
- Movisens Move4 (activity)
- Movisens EcgMove4 (activity, ECG)
- Nokia Bell Labs eSense (noise, activity)
- Polar Sense & H10 (HR/ECG)
- Empatica E4 (HR, GSR, activity)

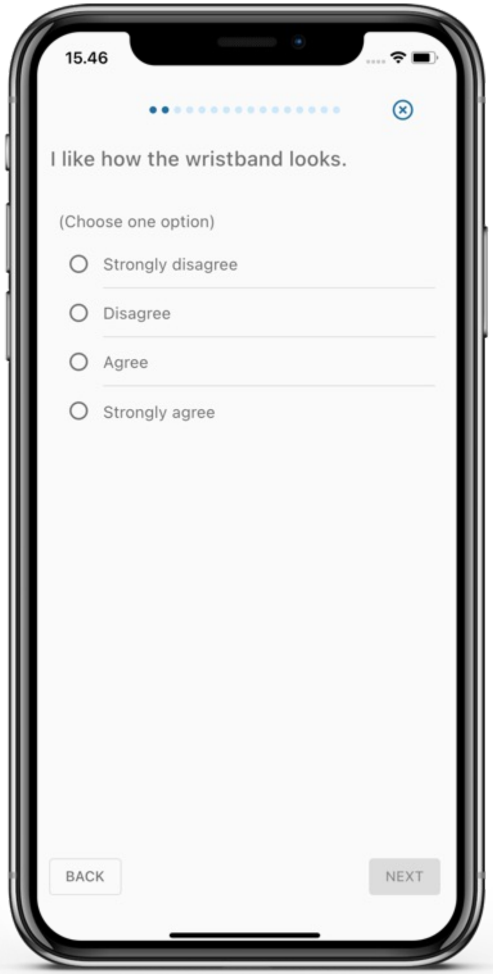
- Apple Health
- Google Fit / Health Connect

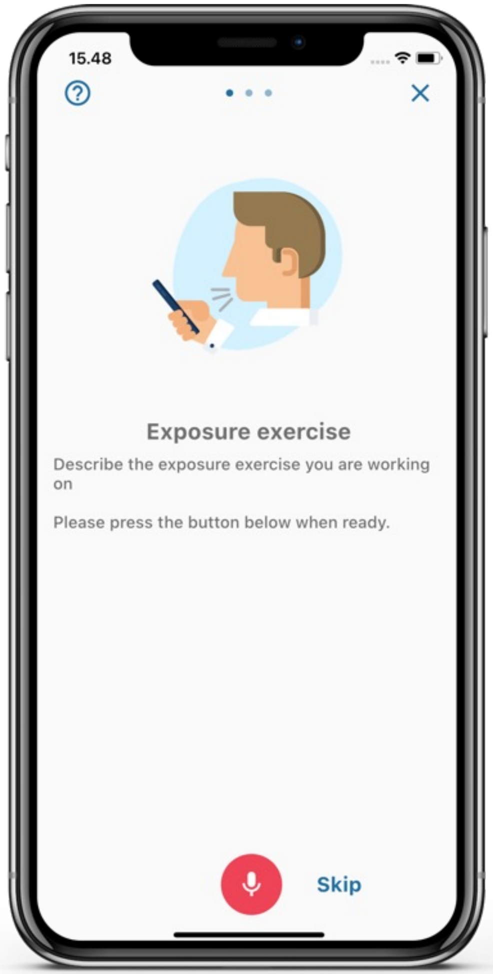
- Dexcom (CGM)
- Garmin (activity, sleep, HR, ...)
- Fitbit (activity, sleep, HR, BP, ECG, weight,
- Withings (activity, sleep, HR, BP, ECG, weight, ...)

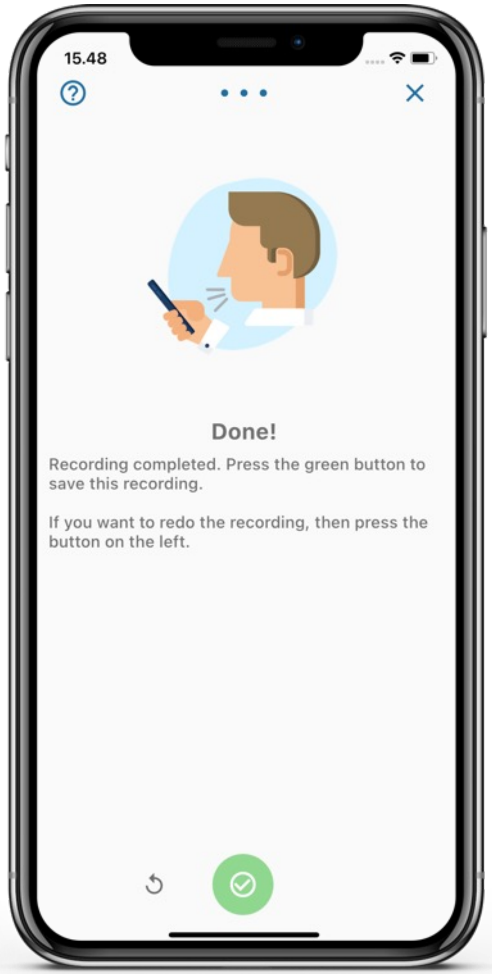


Patient Reported Data (PRO)



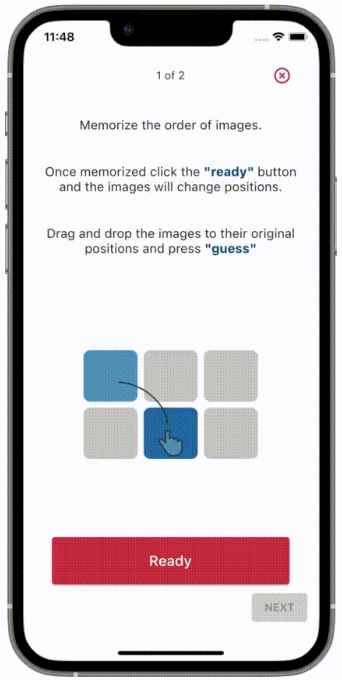




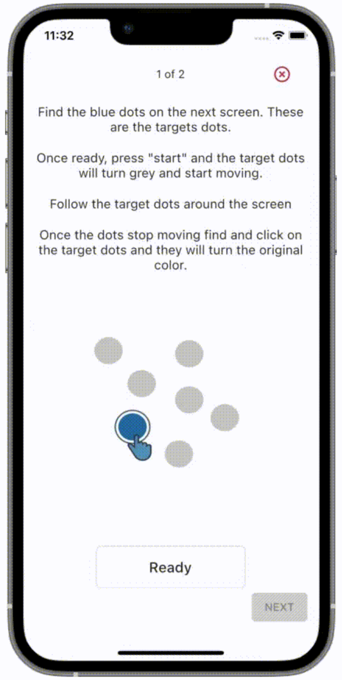


Cognition

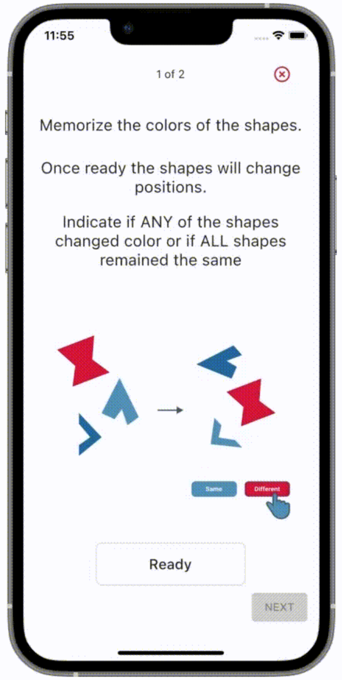
- 14 validated gold-standard cognitive tests
- 8 Neurocognitive domains
  - Sensation
  - Perception
  - Motor skills and construction
  - Attention and concentration
  - Memory
  - Executive functioning
  - Processing speed
  - Language and verbal skills



Picture Sequence Memory



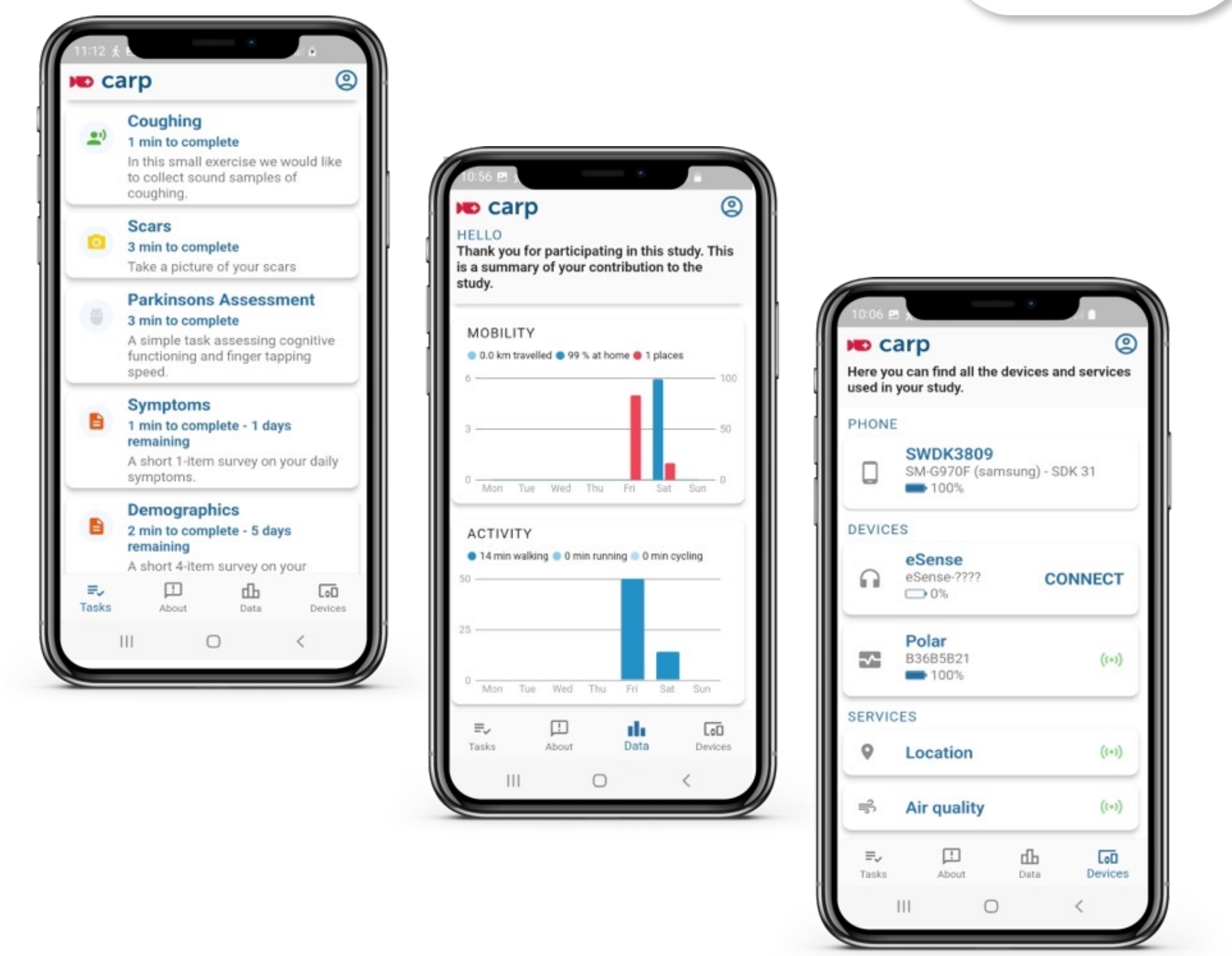
Multiple Object Tracking



Visual Array Change

“CARP Studies” App (standard, out-of-the box)

- Triggering of **user tasks**
  - surveys, cognitive tests, EMAs
  - notifications
- **Sensor** data collection
  - on-board mobile sensing
  - wearable devices
- Informed Consent (**eConsent**)
- On-going study **information**
- **Internationalization** (DA, EN, ES, FR, …)
- **Cross-platform** (Android & iOS)
- Infrastructure-independent (**upload** data to any backend server)



CHALLENGES

(Technical) Challenges in Mobile Sensing (in Mental Health)

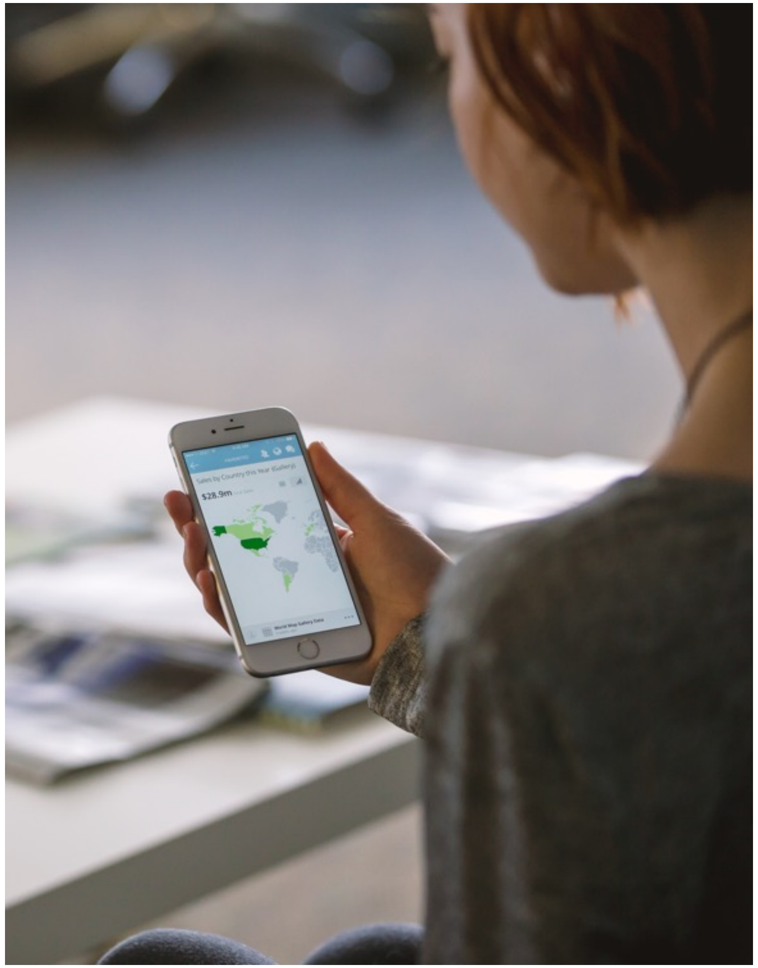
(Technical) Challenges in Mobile Sensing

#1 The **Fallacy** that Smartphones are Ubiquitously Available

#2 Accessing **Sensors**

#3 (Background) **Sensing**

#4 **Adherence** to Sensing



#1 – The "Ubiquitous" Computing Platform

Smartphones as Mobile Healthcare Sensors

From a
fer a pr
tions in
In deve
one mo
lion use
to deve
for leve
where,

F Gravenhorst, A Muaremi, JE Bardram, ... (2015) "Mobile phones as medical devices in mental disorder treatment: An overview," *Personal and Ubiquitous Computing*. 19 (2)53.

Common networked devices like the smartphone (e.g., GPS, keyboard touches, phone use, and communication patterns) and wearables can provide a continuous stream of the data about an individual's behaviors, psychological states, and environments, forming a picture of their lived experience[1]. This sensing
technolog
patterns,
condition
potential
individua
treatment
beginning
more eng
standard
stand-alo
populatio
and inter
innovations have le
are beginning to be
their dissemination.

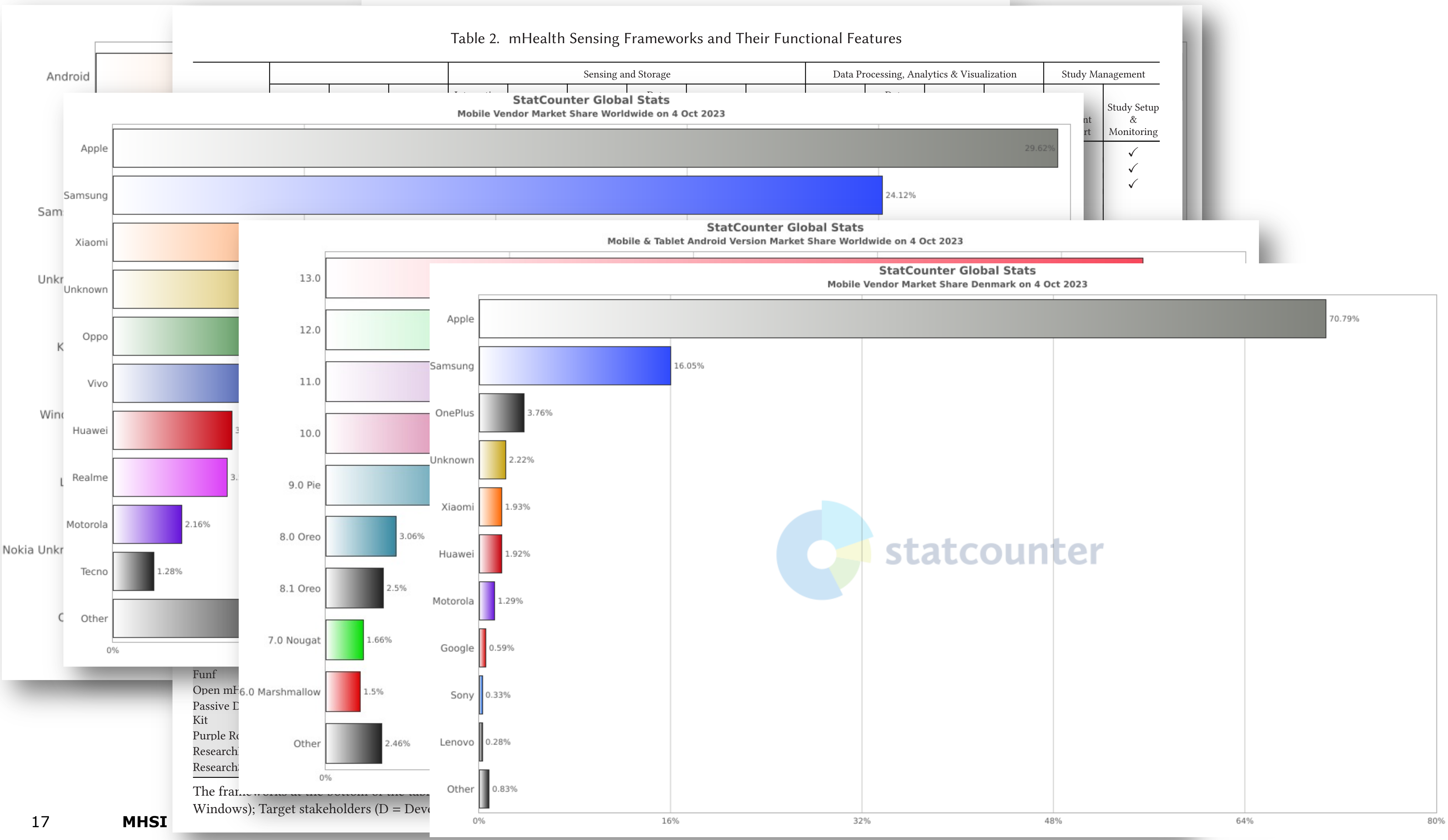
DC Mohr, K Shilton & M Hotopf (2020). "Digital phenotyping, behavioral sensing, or personal sensing: names and transparency in the digital age". *NPJ digital medicine*, 3(1), 45.

With the global trend toward increased smartphone ownership (44.9% worldwide, 83.3% in the UK) and wearable device usage forecast to reach one billion by 2022[8], this new science of "remote sensing", sometimes referred to as digital phenotyping or personal sensing[9] presents a realistic avenue for the management and treatment of depression. When combined with the completion of questionnaires, remote sensing may generate more objective and
frequen
disorde
or parti

V De Angel, ... & M Hotopf. (2022). Digital health tools for the passive monitoring of depression: a systematic review of methods. *NPJ digital medicine*, 5(1), 3.

Due to increasing ubiquity and cost-effectiveness, smartphones and wearable devices, compared to medical devices, allow researchers to monitor personalized daily behaviors and physiology over time for large and diverse populations[5–7]. Combined with scalable data collection platforms, these technologies provide high-fidelity multimodal behavior sensing capabilities[8].

Y Zhang, ... & RADAR-CNS consortium. (2023). "Long-term participant retention and engagement patterns in an app and wearable-based multinational remote digital depression study". *NPJ digital medicine*, 6(1), 25.



agoni (2020).
works for
systematic
uting for

G Marcu
ment system:
ystem for
the 2nd ACM
atics

Cross-Platform Sensing

- There is a fundamental need for cross-platform support across
  - hardware | OS | versions | countries

ID	Sex	Age	YwD	Days	Phone	Interview
P1	F	71	27	125	iOS	✓
P2	M	48	15	58	iOS	✓
P3	M	67	10	41	iOS	✓
P4	F	65	16	108	iOS	✓
P5	M	71	25	104	iOS	✓
P6	M	73	N/A	7	iOS	–
P7	F	44	1	14	Android	✓
P8	M	71	20	88	iOS	✓
P9	M	64	N/A	3	iOS	–
P10	M	69	12	110	iOS	✓
P11	F	67	8	38	iOS	✓
P12	M	71	6	124	iOS	✓
Overall	4/8 (F/M)	65 ± 9.3	14 ± 8.3	68 ± 46	11/1 (i/A)	10/12 (83%)

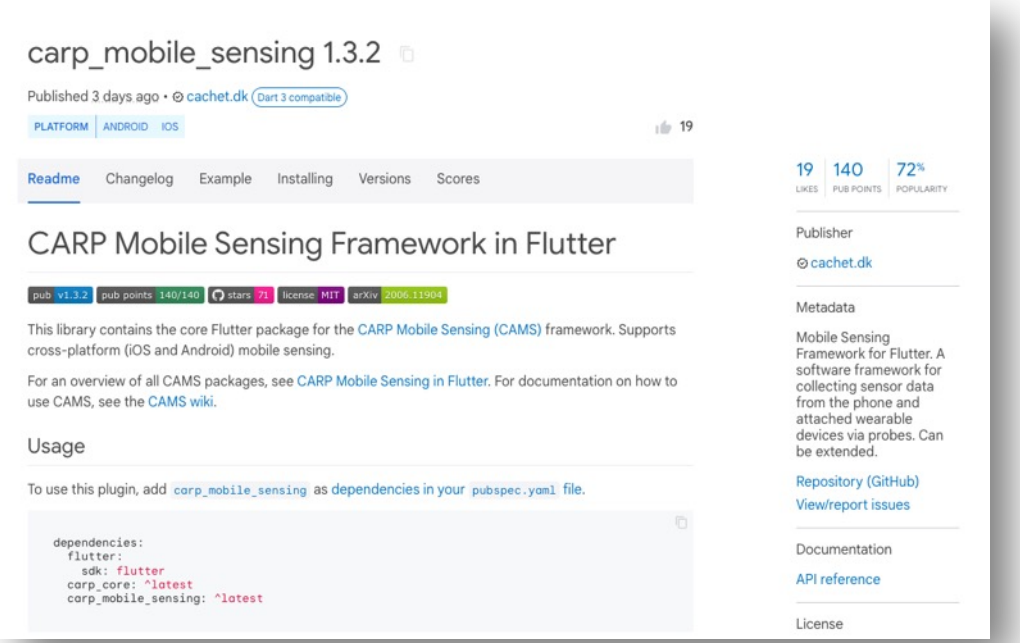
Table 2. Participants demographics. YwD: Years with T2D. Days: Days active in the study.

JE Bardram, C Cramer-Petersen, A Maxhuni, …(2023). "DiaFocus: A Personal Health Technology for Adaptive Assessment in Long-Term Management of Type 2 Diabetes". *ACM Transactions on Computing for Healthcare,* 3(2).

CARP Mobile Sensing

The CARP Mobile Sensing (CAMS) **Flutter package** is a **programming framework** for adding **digital phenotyping** capabilities to your mobile (health) **app**.

CAMS is designed to collect research-quality **sensor data** from the smartphone **on-board** sensors and attached **off-board** wearable devices.



Flutter

Cross-platform framework

- Android & iOS (web, Windows, ...)
- UI framework (write once!)
- compiles natively (fast!)
- OS-level plugins (hackable!)

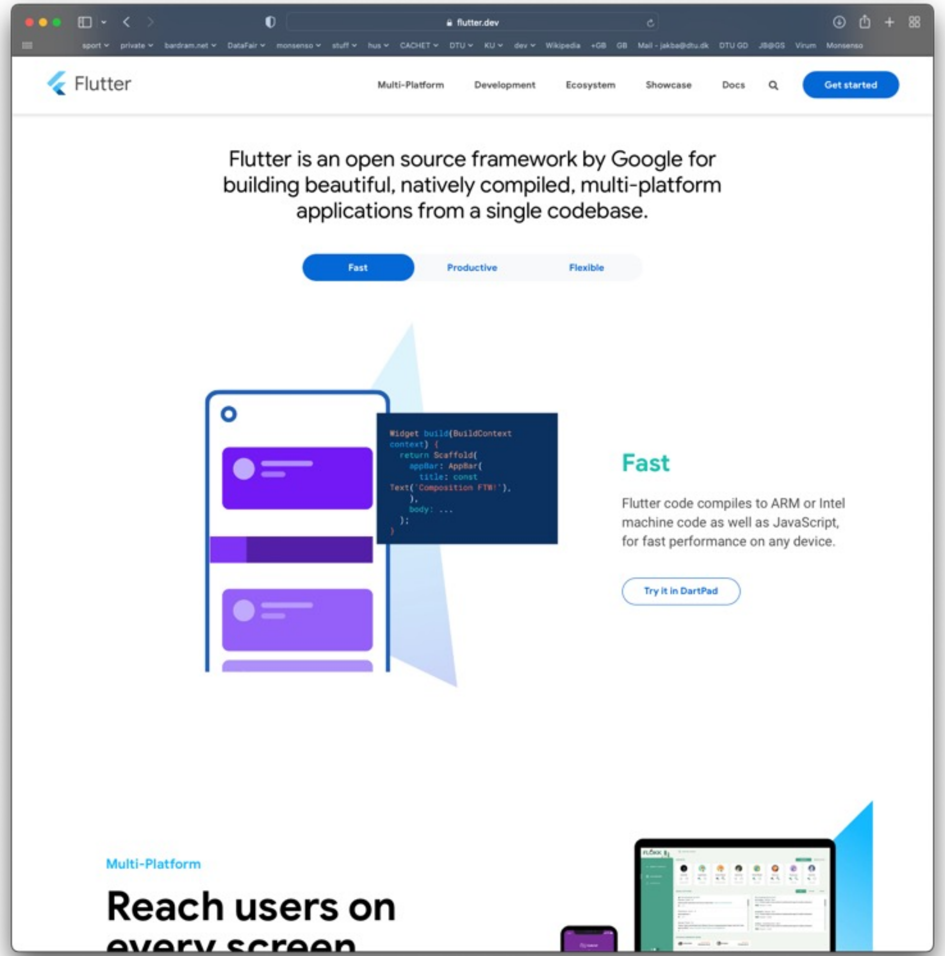
Dart programming language

- modern, reactive, ... (like Swift)

Significant traction

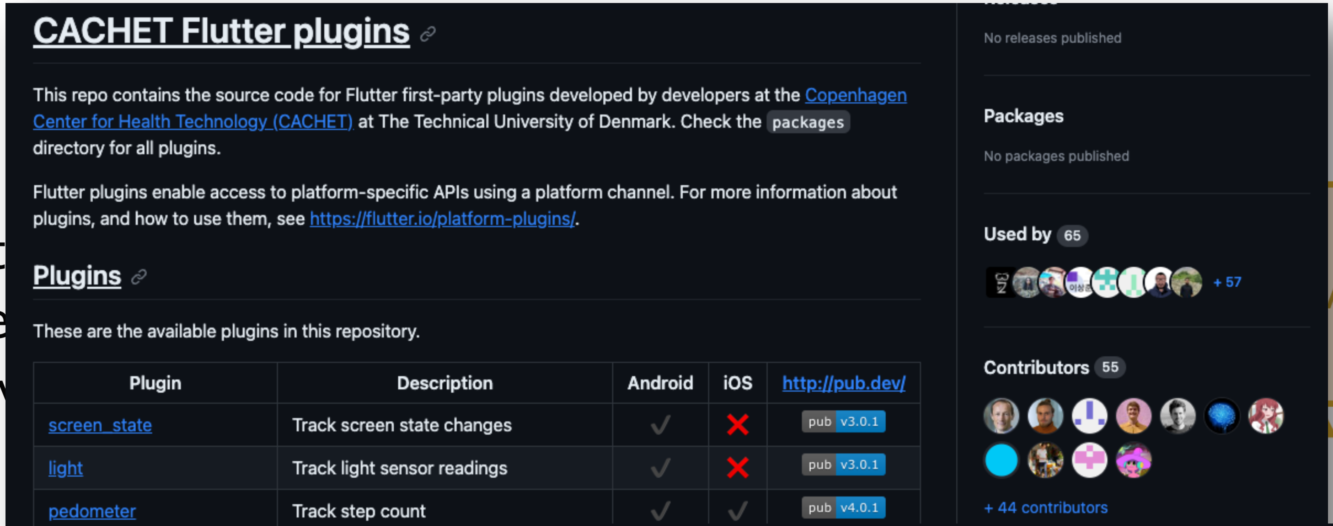
Large number of 3rd party packages and plugins

- `pub.dev`



Plugin Arc

- Allow for access t
  - ... across diffe
  - access to nativ



CACHET Flutter plugins

This repo contains the source code for Flutter first-party plugins developed by developers at the Copenhagen Center for Health Technology (CACHET) at The Technical University of Denmark. Check the `packages` directory for all plugins.

Flutter plugins enable access to platform-specific APIs using a platform channel. For more information about plugins, and how to use them, see https://flutter.io/platform-plugins/.

Plugins

These are the available plugins in this repository.

Plugin	Description	Android	iOS	http://pub.dev/
screen_state	Track screen state changes	✓	✗	pub v3.0.1
light	Track light sensor readings	✓	✗	pub v3.0.1
pedometer	Track step count	✓	✓	pub v4.0.1
noise_meter	Read noise level in Decibel			
app_usage	Track usage of all applications or phone.			
weather	Get current weather, as well as forecasting using the OpenWeatherMap API.			
air_quality	Get the air quality index using the WAQI API.			
notifications	Track device notifications.			
movisens_flutter	Movisens sensor communication			
esense_flutter	eSense ear sensor plugin.			
health	Apple HealthKit and Google Fit interface plugin.			
activity_recognition	Activity Recognition			
audio_streamer	Stream audio as PCM from mic			
mobility_features	Compute daily mobility features f location data			
carp_background_location	Track location, even when app is ... the background	✓	✓	pub v4.0.0
flutter_foreground_service	Foreground service for Android	✓	✗	pub v0.4.1

No releases published

Packages

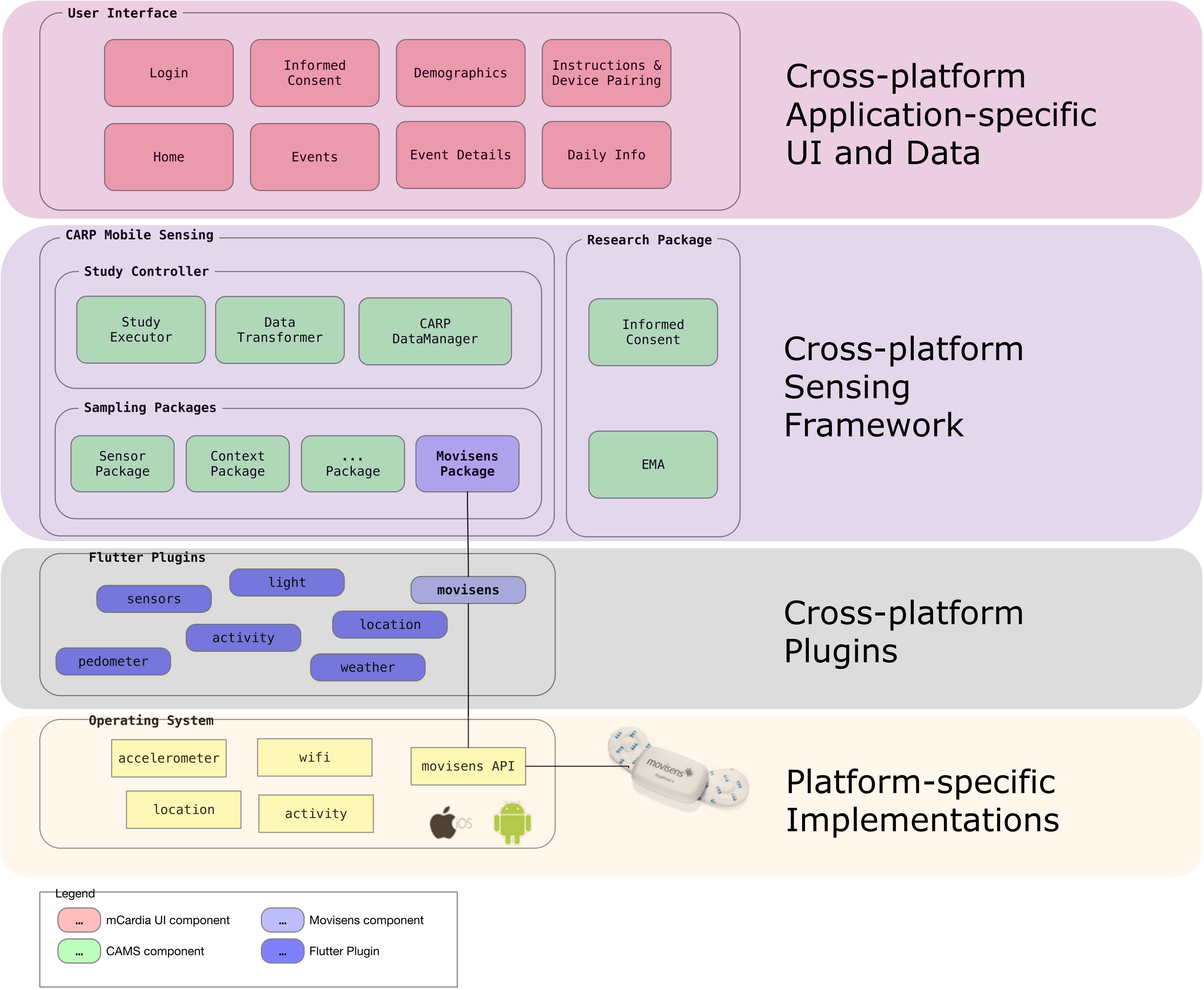
No packages published

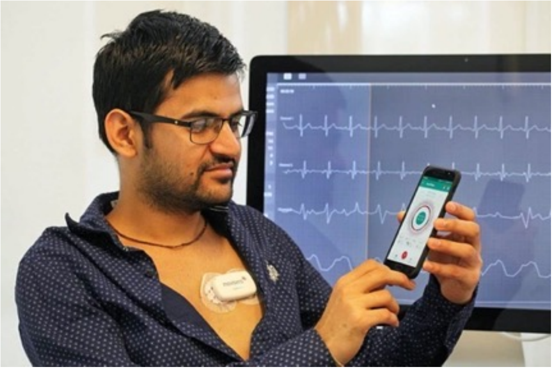
Used by 65

+ 57

Contributors 55

+ 44 contributors





D Kumar, R Maharjan, A Maxhuni, H Dominguez, A Frølich & JE Bardram (2022). mCardia: A Context-Aware ECG Collection System for Ambulatory Arrhythmia Screening. *ACM Transactions on Computing for Healthcare*, 3(2), 1-28.

#2 – A

Common netw
keyboard touc
wearables can
individual's be
forming a pi
technology ca
patterns, activi
conditions[2]. Th
potential to i
individuals an
treatments. Be
beginning to b
more engaging
standard psych
stand-alone o
populations of
and interventio
innovations ha
are beginning
their dissemina

CACHET Flutter plugins

This repo contains the source code for Flutter first-party plugins developed by developers at the Copenhagen Center for Health Technology (CACHET) at The Technical University of Denmark. Check the `packages` directory for all plugins.

Flutter plugins enable access to platform-specific APIs using a platform channel. For more information about plugins, and how to use them, see https://flutter.io/platform-plugins/.

Plugins

These are the available plugins in this repository.

Plugin	Description	Android	iOS	http://pub.dev/
screen_state	Track screen state changes	✓	✗	pub v3.0.1
light	Track light sensor readings	✓	✗	pub v3.0.1
pedometer	Track step count	✓	✓	pub v4.0.1
noise_meter	Read noise level in Decibel	✓	✓	pub v5.0.2
app_usage	Track usage of all applications on ph			
weather	Ge for Op			
air_quality	Ge WA			
notifications	Tra			
movisens_flutter	Mo			
esense_flutter	eS			
health	Ap interface plugin.			
activity_recognition	Activity Recognition	✓	✓	pub v5.0.0
audio_streamer	Stream audio as PCM from mic	✓	✓	pub v4.0.0
mobility_features	Compute daily mobility features from location data	✓	✓	pub v4.0.1
carp_background_location	Track location, even when app is in the background	✓	✓	pub v4.0.0
flutter_foreground_service	Foreground service for Android	✓	✗	pub v0.4.1

No releases published

Packa

No pack

Used

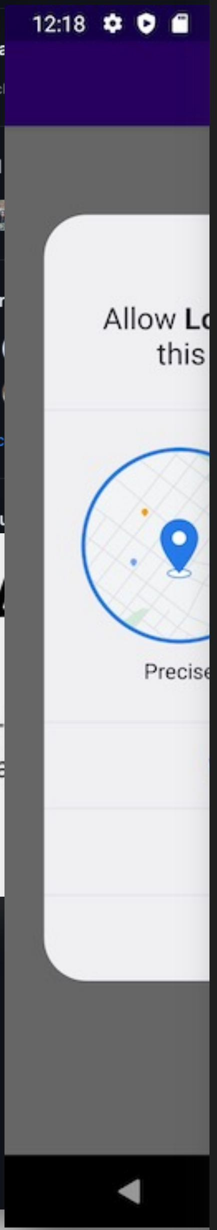
Contr

+ 44 c

Langu

Location updates in A

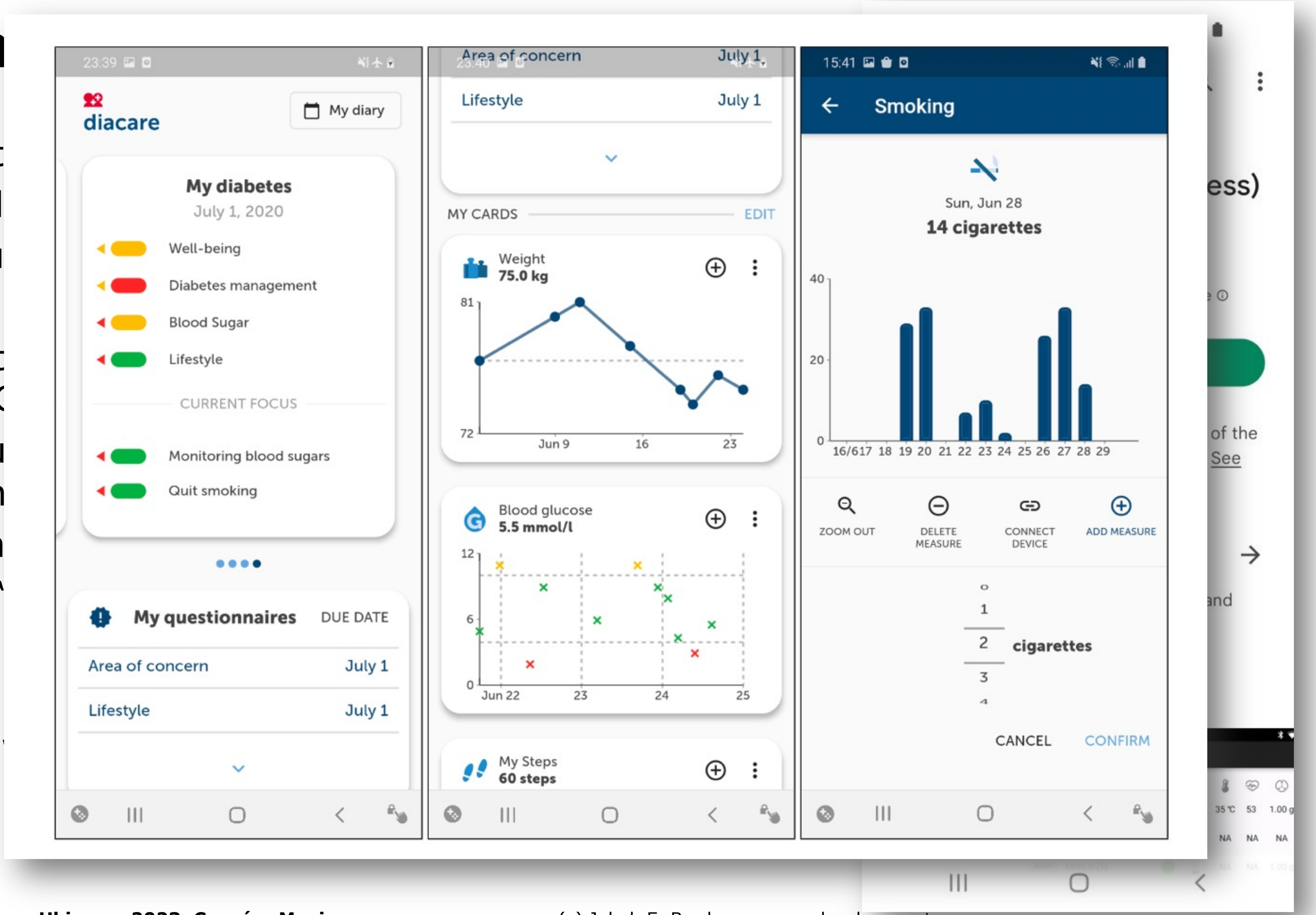
To further protect user privacy, Android 11 adds one-
users grant background location access. These upda
and higher.



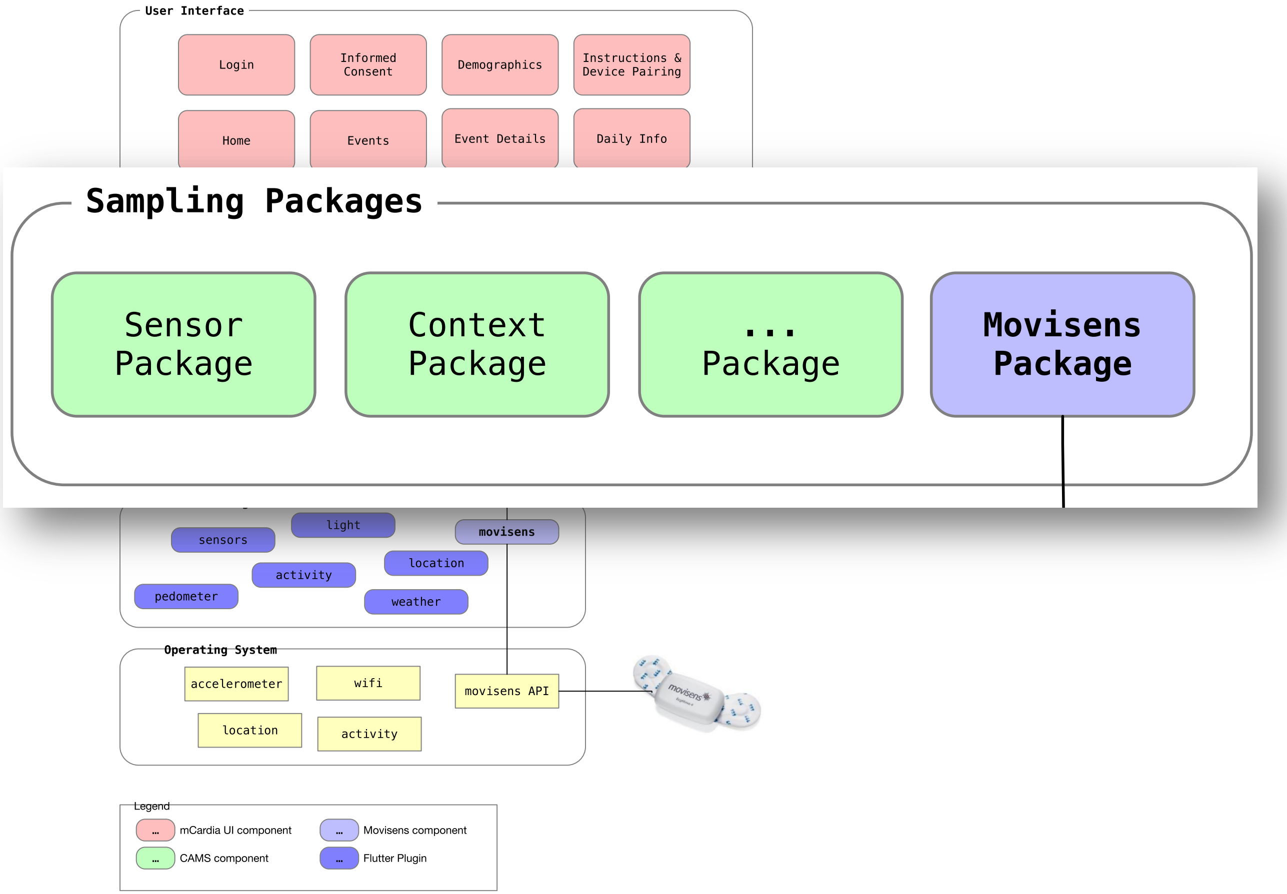

```
/// Returns a list of all possible [PermissionGroup] values.
static const List<Permission> values = <Permission>[
  calendar,
  camera,
  contacts,
  location,
  locationAlways,
  locationWhenInUse,
  mediaLibrary,
  microphone,
  phone,
  photos,
  photosAddOnly,
  reminders,
  sensors,
  sms,
  speech,
  storage,
  ignoreBatteryOptimizations,
  notification,
  accessMediaLocation,
  activityRecognition,
  unknown,
  bluetooth,
  manageExternalStorage,
  systemAlertWindow,
  requestInstallPackages,
  appTrackingTransparency,
  criticalAlerts,
  accessNotificationPolicy,
  bluetoothScan,
  bluetoothAdvertise,
  bluetoothConnect,
  nearbyWifiDevices,
  videos,
  audio,
  scheduleExactAlarm,
  sensorsAlways,
];
```

Handlin

- ... is a night
  - for the **d**
  - for the **u**
- ... and most AppStore / G
  - numerou publishin
  - mental h
  - generic "
- Not allowed
  - location
  - children



Sampling Package Architecture



- A sampling package is responsible for
  - implementing **access to sensors**
  - handling **permissions**
- **Unified architecture** for
  - on-board sensors (e.g., location)
  - wearable sensors (e.g., ECG)
- **Modulization**
  - only include "sensors" that are relevant to your domain
  - which you can get approved

JE Bardram (2022). Software architecture patterns for extending sensing capabilities and data formatting in mobile sensing. *Sensors*, *22*(7), 2813.

#3 – Background Sensing?

- The core assumption in mobile sensing is that this runs “**continuously**”
  - 24/7
  - in the “Background”, i.e., when the user doesn’t use the app or the phone

- … “**unobtrusively**”
  - doesn’t disturb the user or require him/her to ”do” anything
  - with minimal resource drain
    - battery | network | data plan (money)

- … “**collecting**” data
  - from on-board sensors and the OS
  - from connected devices (BLE)

Don't kill my app! GET IT ON Google Play

Our mission API Press

Our r

Smartphon
are always t
release.

#1 Samsu
especially af

#3 Huaw
except Nexu

Developer News Discover Design Develop Distribute Support Account

Developer Forums

Search by keywords or tags

Post

Can iOS kill an application in background in battery saving mode

2.4k

Hello there,

I developed an iOS application that is connected to a BLE device.

My application has the background mode activated because I need to listen to ble events. Sometimes I put my app in background for a few hours and the app disappear from the apps in background.

Yes.
iOS will kill off backgrounded apps, based on various factors (which are hard to predict).
You could expect this to happen more agressivily in low power mode.

Posted 1 year ago by robnotyou

modifying Android in ways that break core functionality. The default behavior of these devices is to forbid newly installed apps to send/receive broadcasts, acquire wakelocks, start services, set alarms, etc. in certain conditions (e.g. screen off), unless the user explicitly whitelists the app.

The problem with this approach is that users are not very savvy and unaware of this. The blame is therefore directed to developers. We explicitly need to detect the manufacturer, and guide the user to whitelist their app. Maintaining this for all manufacturers is a nightmare.

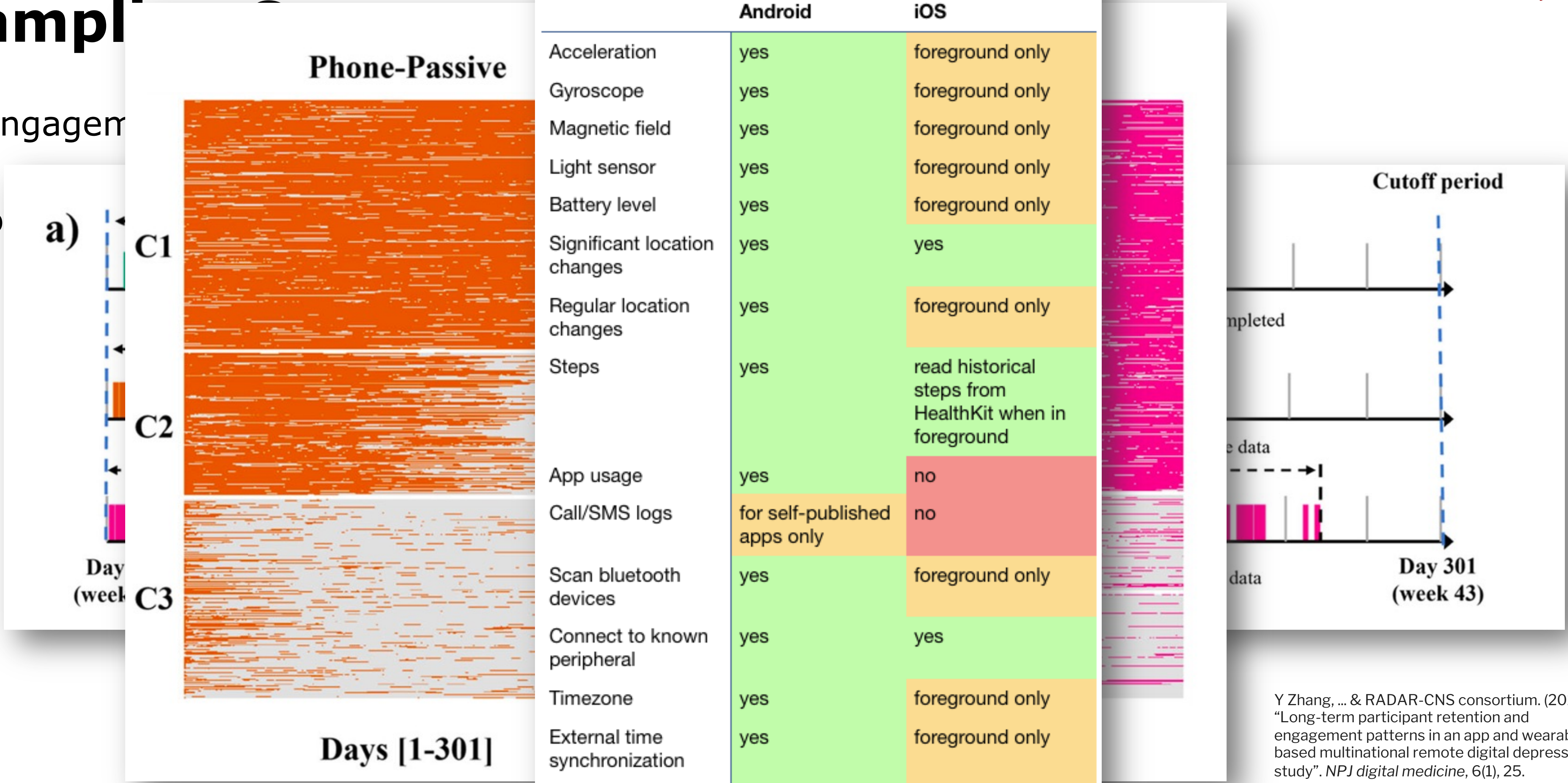
Additionally, these OEMs preload (and remotely configure) a whitelist of packages that are allowed to freely perform said actions. How is this fair to the rest of us?

Honestly, how is Google certifying these devices when the core functionality does not work out of the box?

Android SM-A320FL - API 26
air_quality
Android SM-G970F - API 29
air_quality
0.58 0.83 0.92
iPhone 11 Pro, OS 13.7
activity
air_quality
device
location
weather
wifi
Android API 30 - part 1
air_quality
0.67 0.87
Android API 30 - part 2
air_quality 1 0.67 0.6 0.57 0.37 0.23 0.33 0.6 0.33 0.47
light 1 0.27 0.017 0.017 0.033 0.017 0.017
location 1 0.68 0.6 0.62 0.37 0.23 0.32 0.6 0.35 0.45
memory 1 0.68 0.6 0.62 0.37 0.23 0.3 0.6 0.35 0.45
noise 1 0.68 0.6 0.6 0.38 0.23 0.38
screen 0 0.05 0.13 0.1 0.17 0.23 0.05 0.05
weather 1 0.67 0.6 0.57 0.37 0.23 0.33 0.6 0.33 0.47
measure
07:00 08:00 09:00 10:00 11:00 12:00 13:00 14:00 15:00 16:00 18:00
hour
1.0 0.8 0.6 0.4 0.2 0.0

Sampl

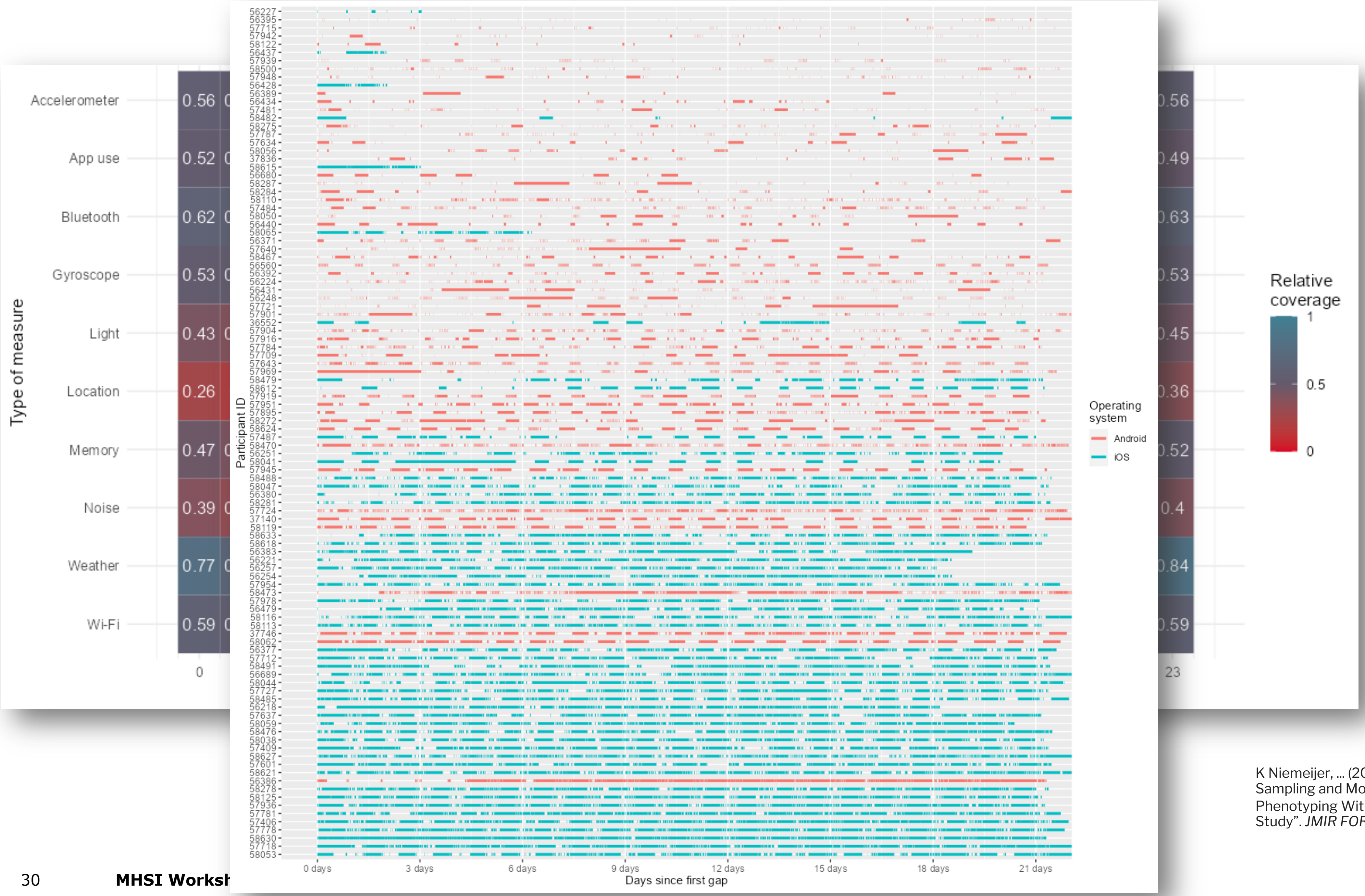
- “Engagem
- To



Sensors per phone type

	Android	iOS
Acceleration	yes	foreground only
Gyroscope	yes	foreground only
Magnetic field	yes	foreground only
Light sensor	yes	foreground only
Battery level	yes	foreground only
Significant location changes	yes	yes
Regular location changes	yes	foreground only
Steps	yes	read historical steps from HealthKit when in foreground
App usage	yes	no
Call/SMS logs	for self-published apps only	no
Scan bluetooth devices	yes	foreground only
Connect to known peripheral	yes	yes
Timezone	yes	foreground only
External time synchronization	yes	foreground only
Weather	yes	foreground only
Data sending	always	when activated only

Y Zhang, ... & RADAR-CNS consortium. (2023). “Long-term participant retention and engagement patterns in an app and wearable-based multinational remote digital depression study”. *NPJ digital medicine*, 6(1), 25.



K Niemeijer, ... (2023). "Combining Experience Sampling and Mobile Sensing for Digital Phenotyping With m-Path Sense: Performance Study". *JMIR FORMATIVE RESEARCH*, 7(e43296).

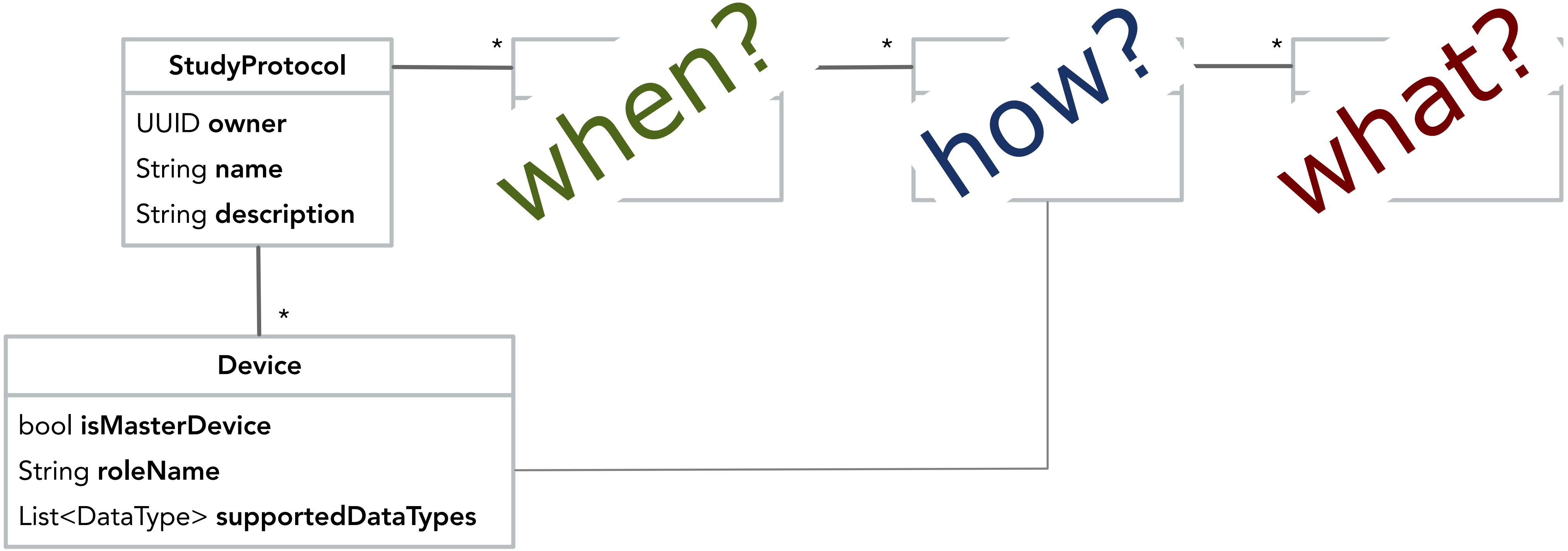
Sampling Coverage

- “Engagement” | “Compliance” | “Adherence”

- To what degree do we collect the data we expect?

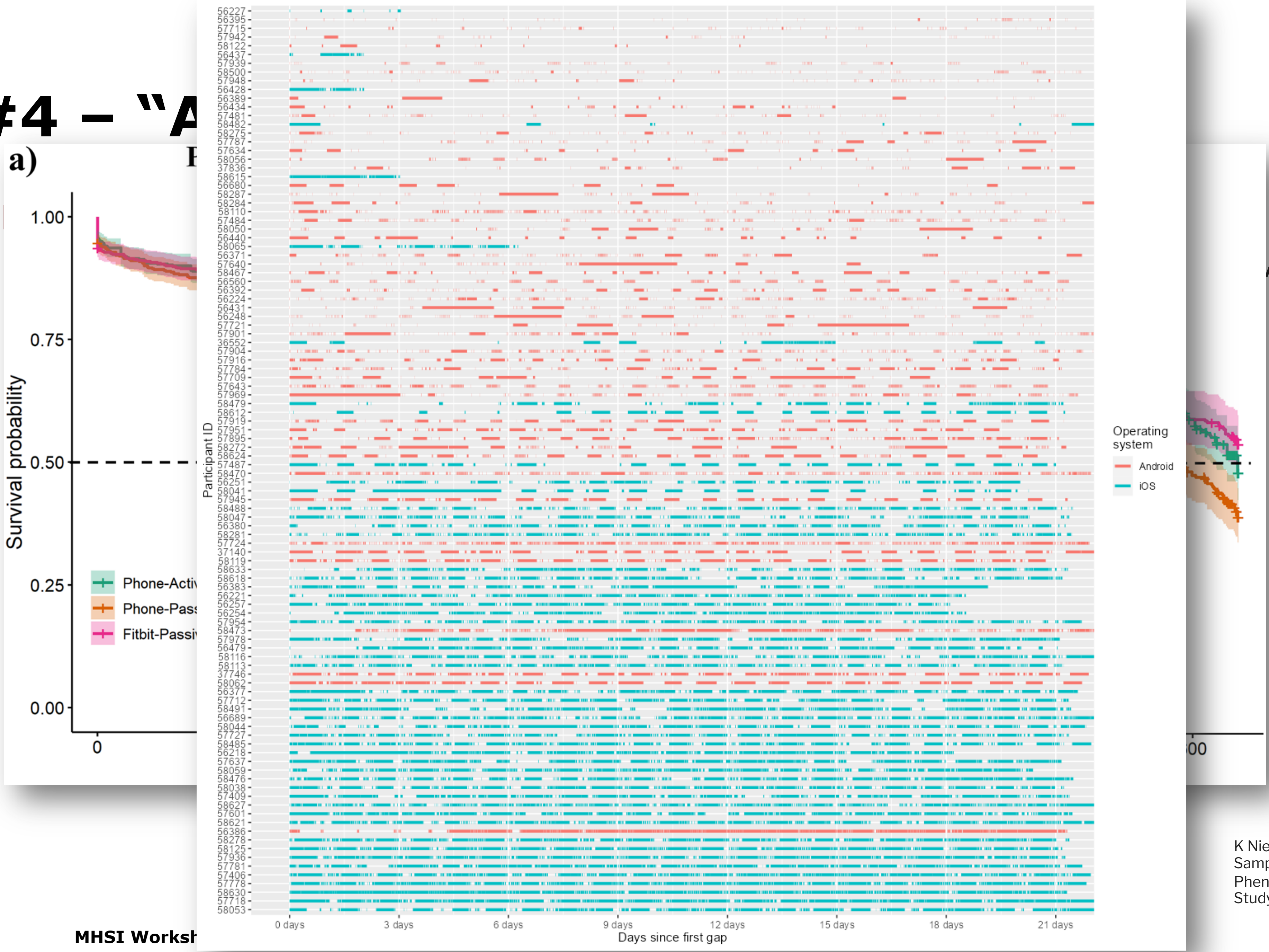
- This requires us to **standardize** what we mean by
  - collect
  - data
  - expectation

CARP Study Protocol



#4 – "A

● ve sensing



Y Zhang, ... & RADAR-CNS consortium. (2023). "Long-term participant retention and engagement patterns in an app and wearable-based multinational remote digital depression study". *NPJ digital medicine*, 6(1), 25.

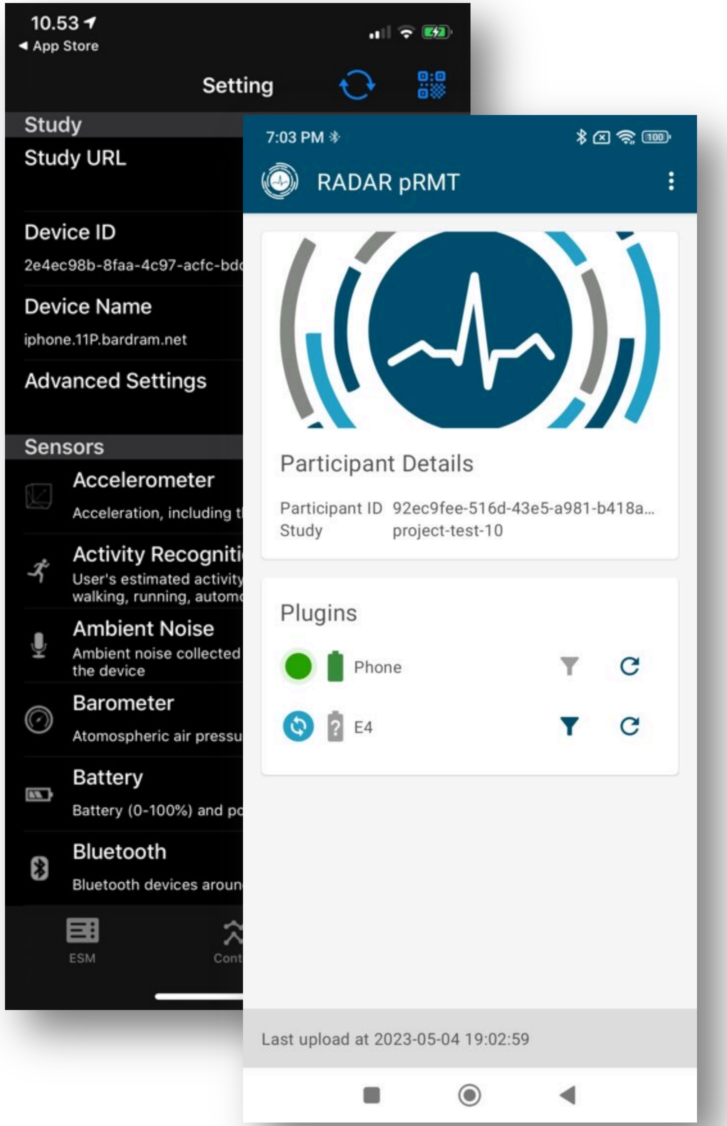
K Niemeijer, ... (2023). "Combining Experience Sampling and Mobile Sensing for Digital Phenotyping With m-Path Sense: Performance Study". *JMIR FORMATIVE RESEARCH*, 7(e43296).

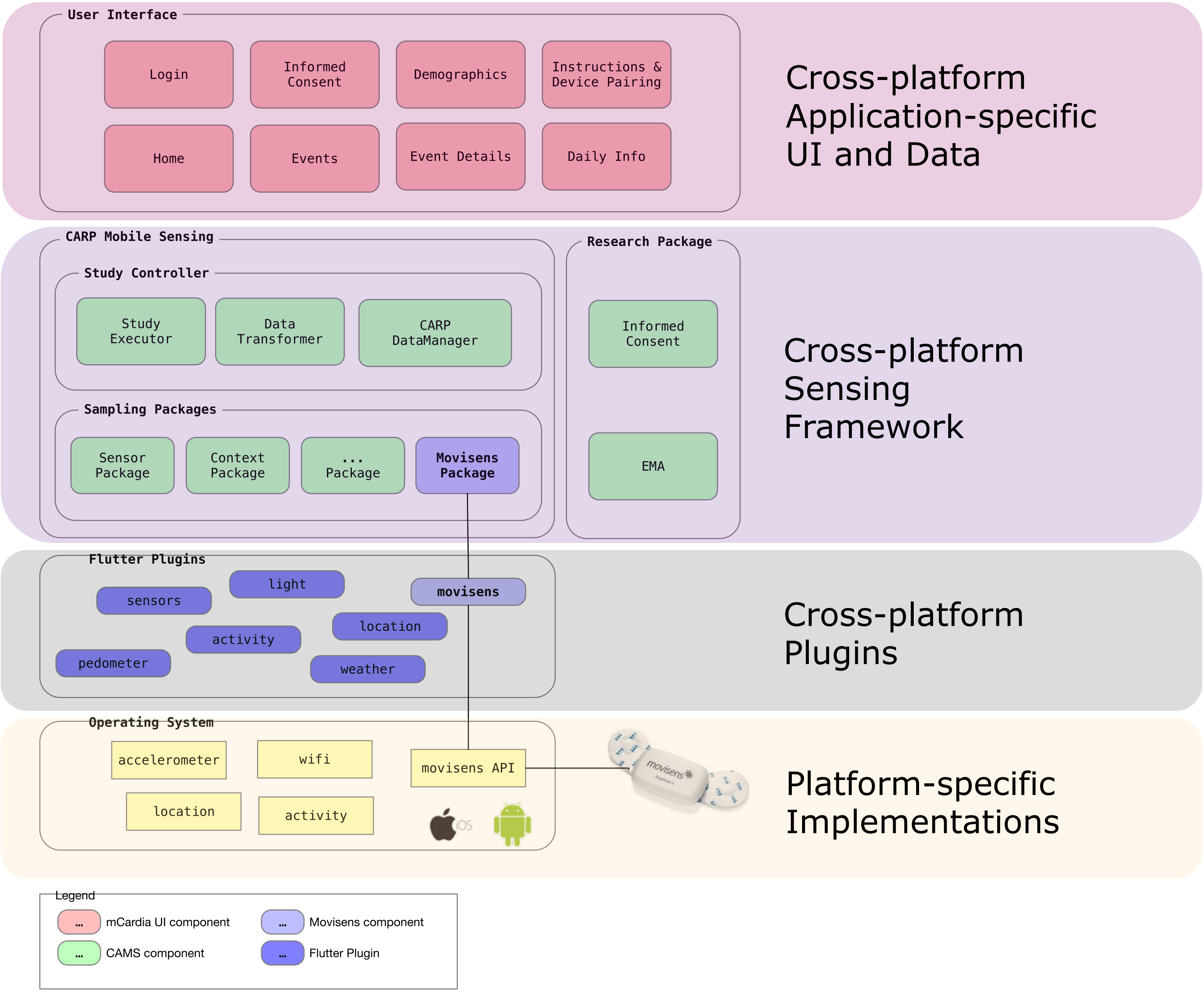
Domain-specific Applications

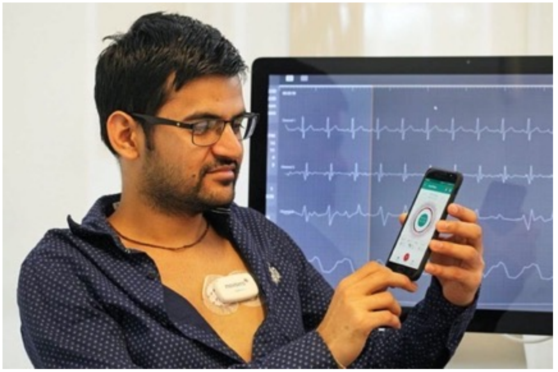
- Rather than having generic "sensing" apps ...

- ... we should allow for the design of domain-specific apps that ensure **engagement**
  - can undergo a UX design process – "participant-centric design"
  - provides "something" for the participant
  - allow for "human-in-the-loop"
  - allow for "disease-targeted recruitment"

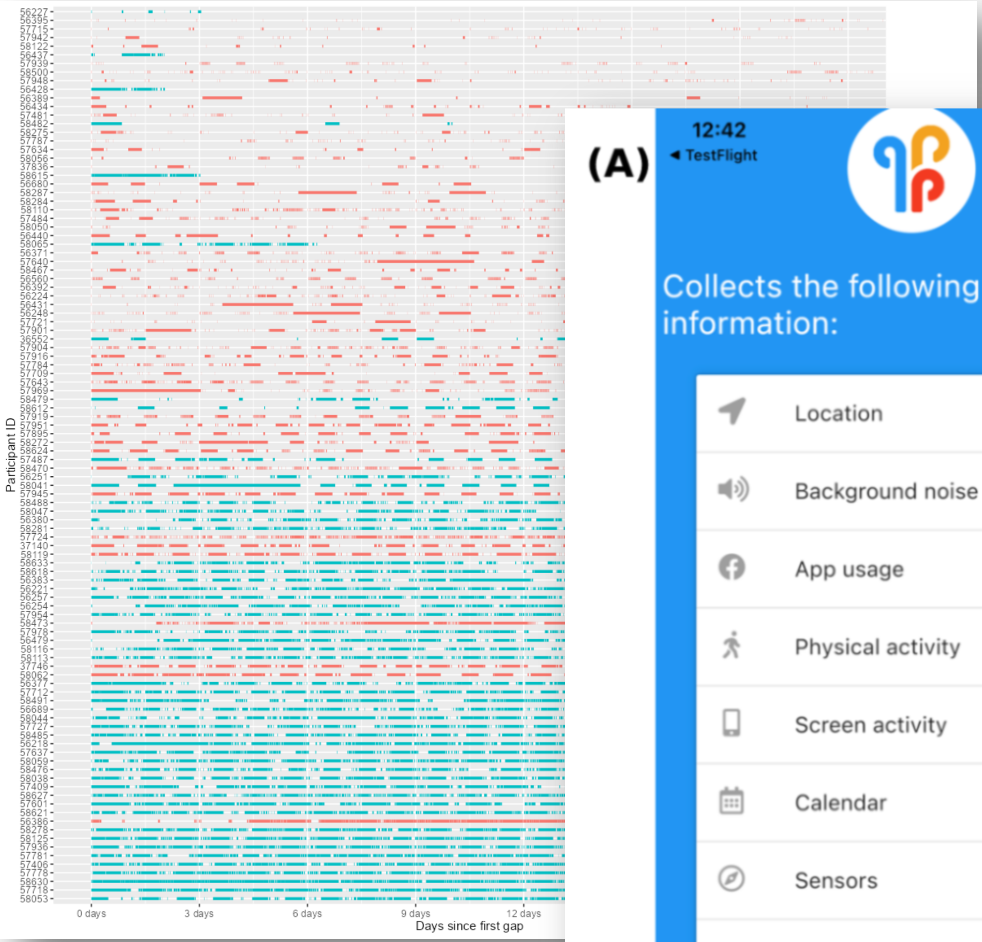
- .. and can be **approved** in the app stores

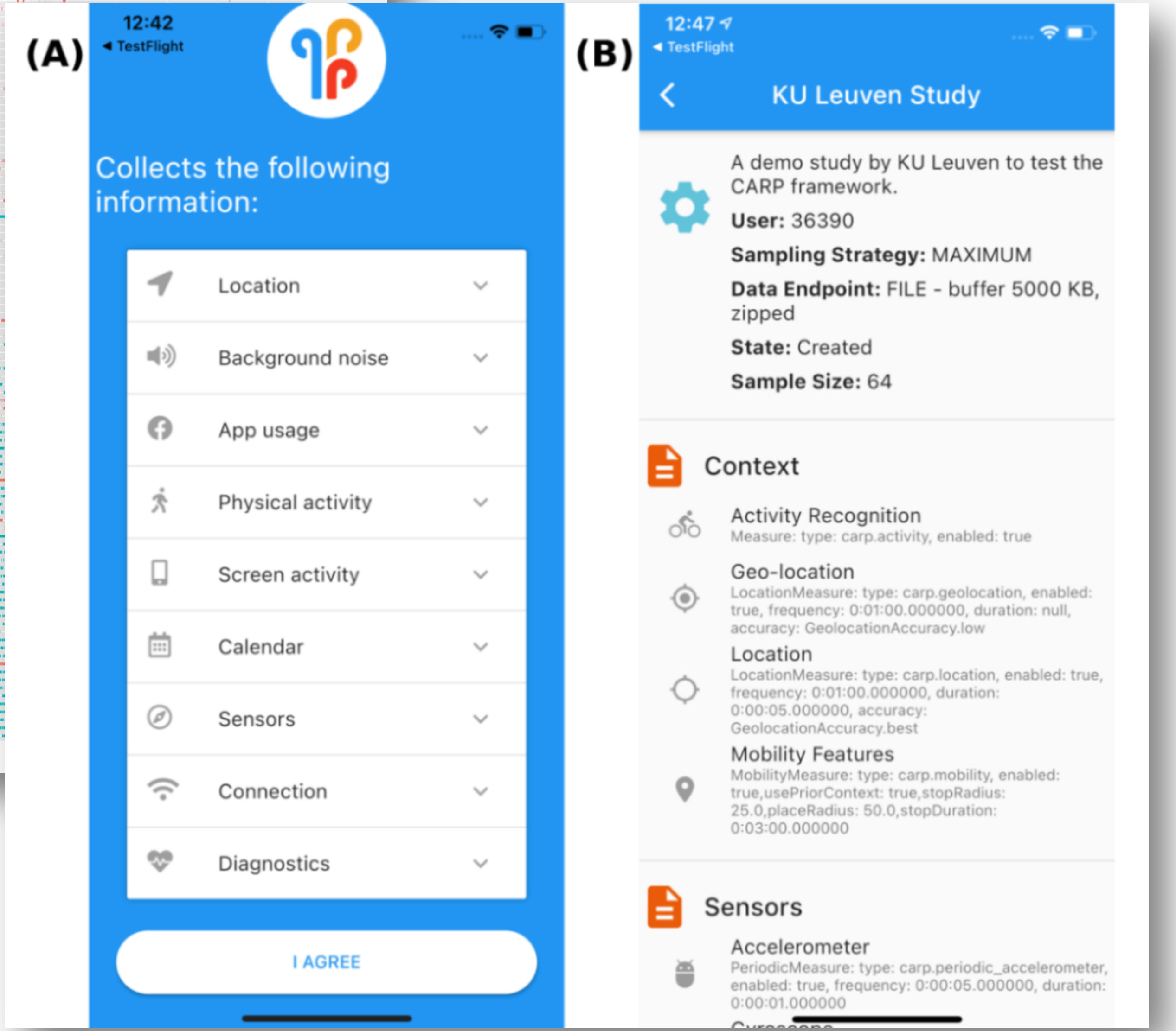




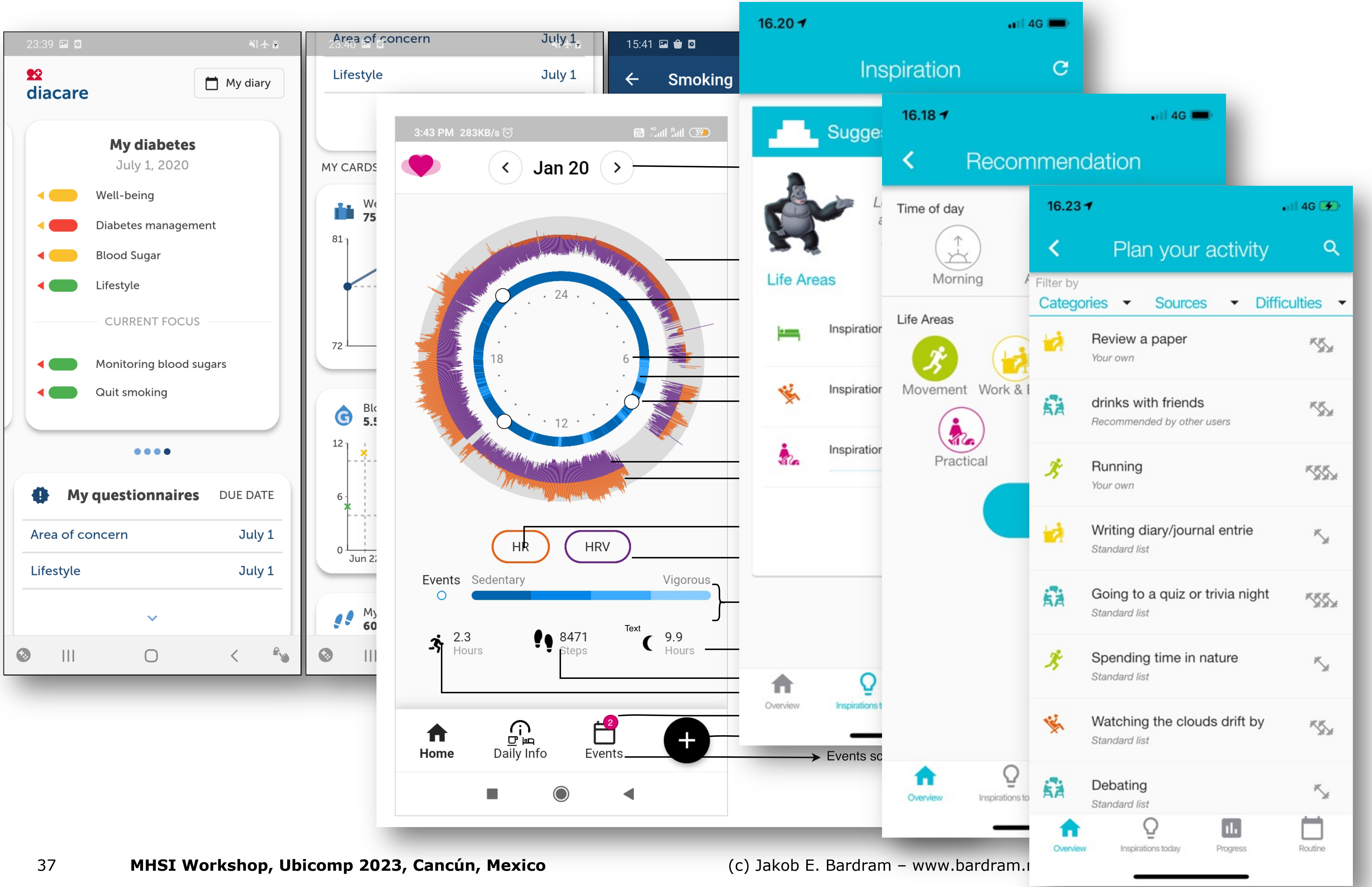


D Kumar, R Maharjan, A Maxhuni, H Dominguez, A Frølich & JE Bardram (2022). mCardia: A Context-Aware ECG Collection System for Ambulatory Arrhythmia Screening. *ACM Transactions on Computing for Healthcare,* 3(2), 1-28.





K Niemeijer, ... (2023). "Combining Experience Sampling and Mobile Sensing for Digital Phenotyping With m-Path Sense: Performance Study". *JMIR FORMATIVE RESEARCH*, 7(e43296).


diacare
My diary
My diabetes
July 1, 2020
Well-being
Diabetes management
Blood Sugar
Lifestyle
CURRENT FOCUS
Monitoring blood sugars
Quit smoking
My questionnaires
DUE DATE
Area of concern
July 1
Lifestyle
July 1
MY CARDS
Smoking
Jan 20
24
18
6
12
HR
HRV
Events
Sedentary
Vigorous
2.3
Hours
8471
Steps
Text
9.9
Hours
Home
Daily Info
Events
Events sc
Inspiration
Sugges
Life Areas
Inspiration
Inspiration
Inspiration
Overview
Recommendation
Time of day
Morning
Life Areas
Movement
Work &
Practical
Plan your activity
Filter by
Categories
Sources
Difficulties
Review a paper
Your own
drinks with friends
Recommended by other users
Running
Your own
Writing diary/journal entrie
Standard list
Going to a quiz or trivia night
Standard list
Spending time in nature
Standard list
Watching the clouds drift by
Standard list
Debating
Standard list
Overview
Inspirations today
Progress
Routine

LOOKING AHEAD

Where is Digital Phenotyping in Mental Health Heading?

What can we use sensing in mental health for?

Correlation

- self-reported mood
- mobility
- social activity
- physical activity
- voice
- ...

Classification

- disease classification
- state (e.g., manic/depressive episodes)

Prediction

- mood forecasting (1-5 days)
- relapse / remission
- readmission

What can we use sensing in mental health for?

Monitoring – overcoming the “snapshot” problem

- ambulatory, in-the-home, contextual, ”in-the-wild”, ...
- long-term, trends, deviations, ...
- continuously, real-time, ...

Diagnosis

- ambulatory
- early
- more precise

Research – clinical | industrial

- (digital) biomarkers ~ digital phenotyping
- clinical evidence, real-world evidence
- phase 5 studies

What can Digital Phenotyping be used for?

DIGITAL HEALTH

- **Medical Product** as part of the patient's life (Digital Therapeutics (DTx))
- **Patient-generated Health Data** collected from digital health technologies allows us to understand patient behavior in the context of their daily lives

STUDY MEDICAL PRODUCTS

- Can transform how we **study medical products –** pharmacological & medical device technology
- De-centralized **clinical trials**
- Capture **real-world evidence** (RWE)

www.fda.gov/digitalhealth

Enable Remote Data Collection in Decentralized Clinical Investigation
- More frequent or continuous monitoring compared to traditional methods
- Longitudinal view of participant's health status
- Improved recruitment and retention of participants leading to less missing data

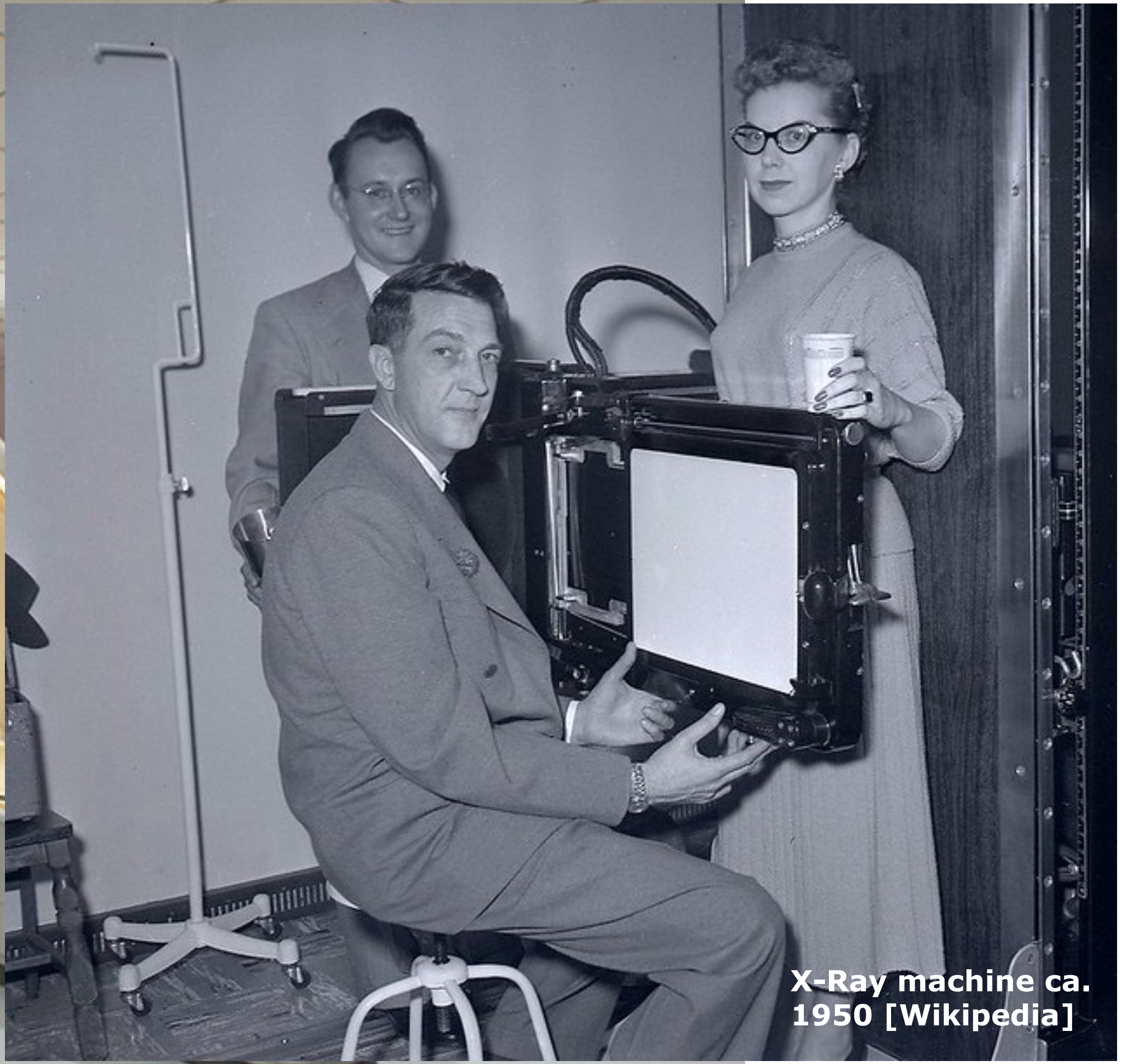
Improve Access to Clinical Investigations
- Meet a participant where they are at for a clinical investigation
- Fewer visits to a study site places less burden on participants
- Reach a more diverse population, advancing health equity

Facilitate Innovative Clinical Investigation Endpoints
- New types of data to inform novel endpoints
- Complementary to other forms of data used to support a regulatory submission

Capture Real-World Data (RWD) and Patient-Generated Health Data (PGHD)
- Data reflects a participant's daily life
- Remote and longitudinal follow-up with participants beyond the clinical investigation
- More detailed picture of the impact of a medical product on a participant

www.fda.gov/digitalhealth 10

MRI Scanner - Northern Lincolnshire and Goole NHS Foundation Trust



X-Ray machine ca. 1950 [Wikipedia]

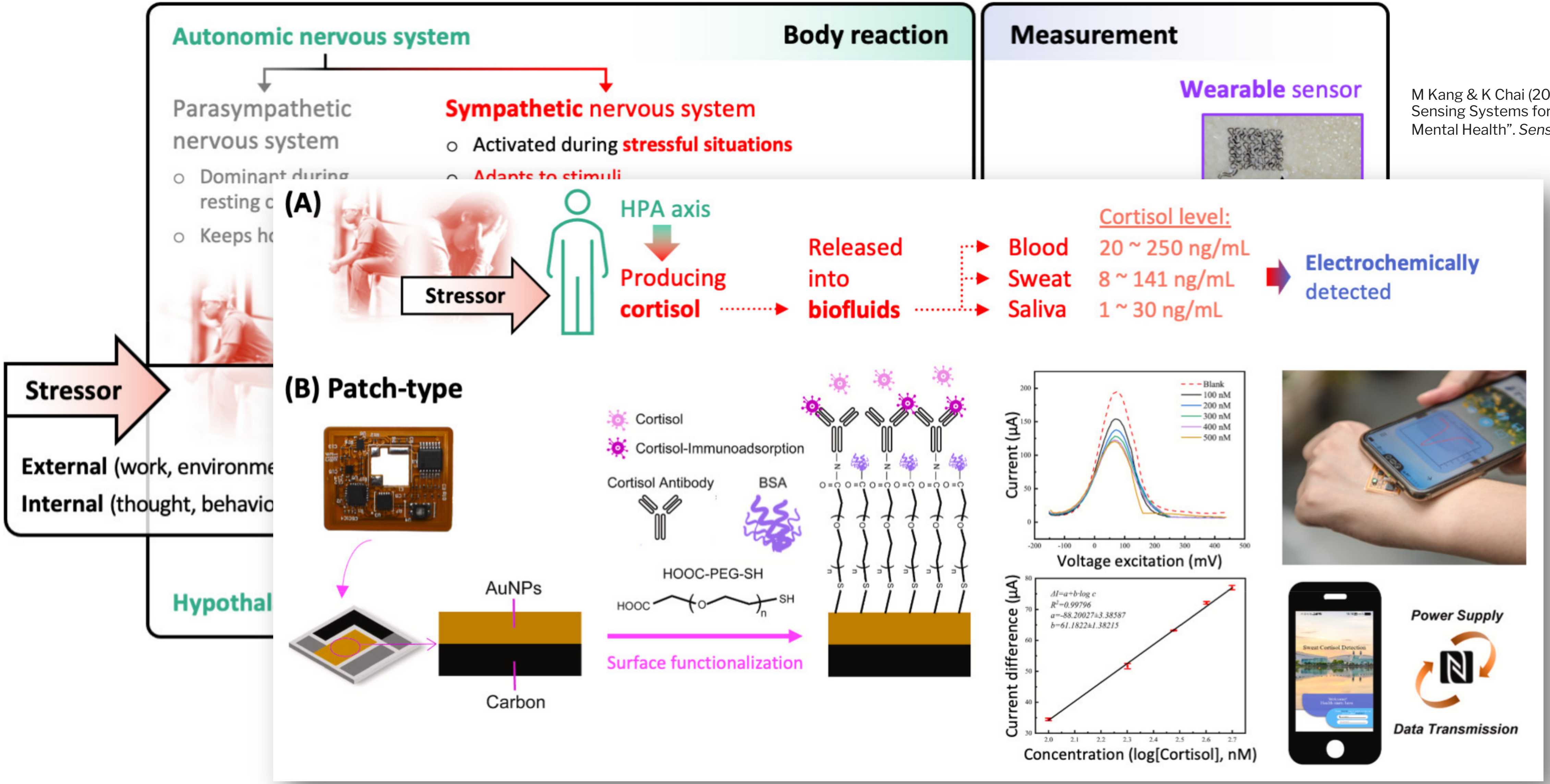

Early Holter Monitoring
setup [Wikipedia]


10:09
Back
ECG Detail
0s
1s
2s
Sinus Rhythm
88 BPM Average
This ECG does not show signs of atrial fibrillation.
Export a PDF for Your Doctor
If you believe you're having a heart attack or a medical emergency, call emergency services.
SAMPLE DETAILS
Start Time
12 Sep 2018 at 10:08:31 AM
End Time
12 Sep 2018 at 10:09:01 AM
Source
ECG
Today
Health Data
Sources
Medical ID
ECG
10:09
Hold your finger on the crown.

Open Questions

- Is the **Smartphone** a good **hardware / sensor platform** for mental health?
  - maybe there is a need for **dedicated** hardware and devices?
  - with dedicated sensors for health (and not piggybacking on other sensors designed for other purposes)
  - which would be much more application- / **health-specific**
  - could be regulated as a **medical device**
  - not controlled by the **monopoly** of Apple & Google

- **Wearable** and/or **implantable** biomedical / physiological sensors
  - Heartrate (HR) & electrocardiograph (ECG)
  - Electroencephalography (EEG)
  - Electrodermal Activity (EDA)
  - Electrochemical (e.g., Cortisol, Dopamine)



M Kang & K Chai (2022). "Wearable Sensing Systems for Monitoring Mental Health". *Sensors*, 22(994)

From Sensing to Acting

Novel Technological Topics

- Actuator Hardware & Technology
- Operating Systems & Programming APIs
- AI & ML Models
- UI Technology and UX

Challenges

- Safety
- Autonomy
- Accountability

THEME ARTICLE: GRAND CHALLENGES

From Sensing to Acting—Can Pervasive Computing Change the World?

Jakob E. Bardram, *Technical University of Denmark, 2800, Lyngby, Denmark*

Computing technology has indeed become pervasive. Taking a quick look around me, I see computing systems in literally everything—in the cars, televisions, smartphones, restaurants, ski-lifts, heating systems, sports trackers, medical devices, etc. This has been realized by a tremendous development in hardware and software technology in terms of CPUs, memory, sensors, operating systems, network, display, etc. However, looking back at this technology development—and the research done in the field—it strikes me that something is missing. One of the grand visions was to make the computer "invisible," as framed by Weiser. But it seems like instead of computing becoming more invisible, it is taking up more of the user's attention. In this article, I argue that this is because (pervasive) computing has only come halfway. Much effort has been done in terms of sensing *and* understanding *the world around the user, while much less effort has been put into helping the user actually* doing *anything. By providing examples mostly taken from the medical domain, this article discusses if moving from "sensing" and "thinking" to actually "doing" something is possible and what challenges are associated with this movement.*

Pervasive and ubiquitous computing builds on the idea of trying to integrate computing into the "fabric" of human life and make computers more aware of, and integrated into the physical world and the activities of people. Going back to the initial research on "context-aware" computing in the seminal paper on "Context-Aware Computing Applications," Bill Schilit, Norman Adams, and Roy Want[18] wrote that "context-aware software adapts according to the location of use, the collection of nearby people, hosts, and accessible devices, as well as to changes to such things over time. A system with these capabilities can examine the computing environment and react to changes to the environment." [p. 85]. Since then, almost 30 years of research and development have brought forth a fantastic set of technologies in the Ubicomp family: Advanced mobile phones with powerful processing power, memory, network connectivity, sensors, and interactive displays; wearable computers, including smartwatches with similar powerful resources; wireless networking technology from low-power networks to high-speed cellular and wireless networks; and interactive displays in all sizes and forms. In addition, the software in terms of operating systems, programming application programming interfaces (APIs), and user-interface software technology has seen a similar development in the Ubicomp space. And the recent revival of artificial intelligence (AI) and machine learning (ML) has provided the field with new opportunities for analyzing data collected via these devices.

Despite these fantastic and promising achievements within the Ubicomp family of hardware and software technology, it still seems like something is missing. To me, it seems like we have only come half the way. We have been very good at collecting data and deriving some level of understanding from this. We are, however, not very good at using this for anything. It is worth noting that in the original definition of context-aware computing previously, the words "adapts" and "reacts" are used, thus assuming some active action from the computer's side. Take the smartphone, for example. The smartphone is the Ubicomp device *par excellence*. But the whole device is

1536-1268 © 2022 IEEE
Digital Object Identifier 10.1109/MPRV.2022.3182489
Date of publication 7 July 2022; date of current version 20 September 2022.

Bardram, Jakob E. "From Sensing to Acting — Can Pervasive Computing Change the World?." *IEEE Pervasive Computing*21.3 (2022): 17-23.

CLOSING

Technical Perspectives on Mobile Sensing in Mental Health

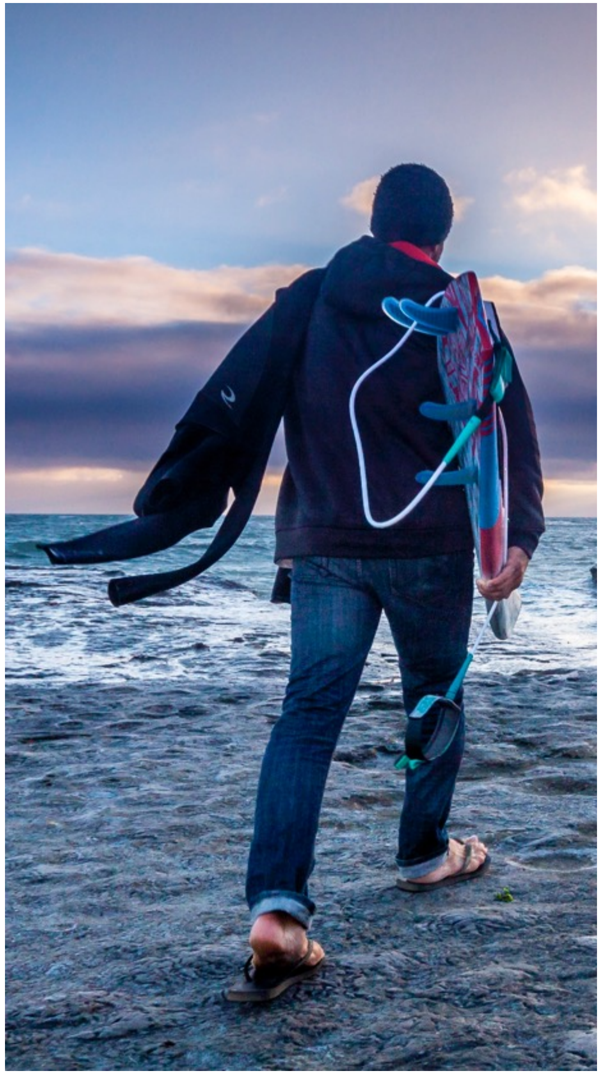
Outline

BACKGROUND
- Digital Phenotyping
- Copenhagen Research Platform (CARP)

CHALLENGES
- (Technical) Challenges in Mobile Sensing (in Mental Health)
- ... and what to do about them

LOOKING AHED
- What is coming
- How do I see the future of mobile sensing in Mental Health?

Questions



Technical University of Denmark

cachet | Copenhagen Center for Health Technology

UNIVERSITY OF COPENHAGEN

DTU

BACKUP SLIDES

Diagnosis…. or Overdiagnosis?

Overdiagnosis is a huge problem
- … especially in mental health

Medical technology
- diagnostic tools
- wearable devices / smartwatches
- apps
- big data / AI / personal medicine

… is a major source for over-diagnosis
… and may even worsening (e.g., rumination)
… which again leads to high **inequality** in healthcare

***caveat** :: this is spoken from a Danish, Scandinavian, publicly funded healthcare system*

Sensing Dev

U.S. FOOD & DRUG
ADMINISTRATION

September 11, 2018

Apple Inc.
% Donna-Bea Tillman
Senior Consultant, Biologics Consulting Group
Biologics Consulting Group, Inc.
1555 King St, Suite 300
Alexandria, Virginia 22314

Re: DEN180044
Trade/Device Name: ECG App
Regulation Number: 21 CFR 870.2345
Regulation Name: Electrocardiograph software for over-the-counter use
Regulatory Class: Class II
Product Code: QDA
Dated: August 13, 2018
Received: August 14, 2018

Dear Donna-Bea Tillman:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the ECG App, an over-the-counter device under 21 CFR Part 801 Subpart C, with the following indications for use:

> The ECG app is a software-only mobile medical application intended for use with the Apple Watch to create, record, store, transfer, and display a single channel electrocardiogram (ECG) similar to a Lead I ECG. The ECG app determines the presence of atrial fibrillation (AFib) or sinus rhythm on a classifiable waveform. The ECG app is not recommended for users with other known arrhythmias.
>
> The ECG app is intended for over-the-counter (OTC) use. The ECG data displayed by the ECG app is intended for informational use only. The user is not intended to interpret or take clinical action based on the device output without consultation of a qualified healthcare professional. The ECG waveform is meant to supplement rhythm classification for the purposes of discriminating AFib from normal sinus rhythm and not intended to replace traditional methods of diagnosis or treatment.
>
> The ECG app is not intended for use by people under 22 years old.

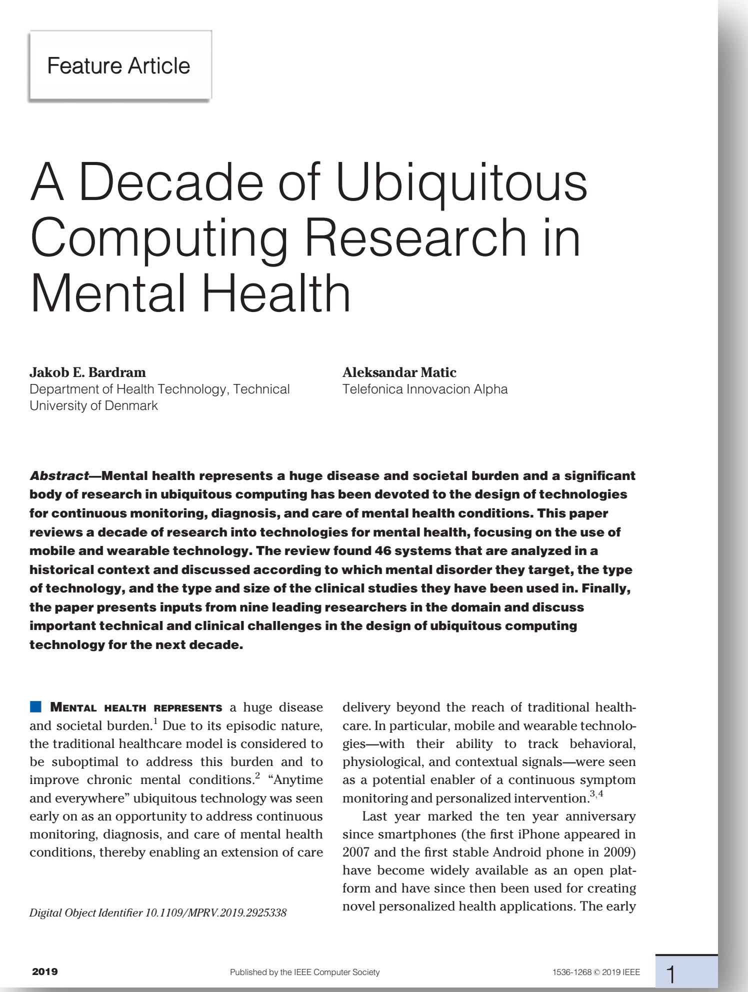
FDA concludes that this device should be classified into Class II. This order, therefore, classifies the ECG App, and substantially equivalent devices of this generic type, into Class II under the generic name electrocardiograph software for over-the-counter use.

What has been designed?

- Systematic review of technologies (not studies!)
  - as published in peer-reviewed literature
  - 2009-2019
  - mobile & wearable technologies (‘ubicomp’)
  - severe mental illness (SMI) as defined by ICD-10

- Results
  - 45 systems – 32 clinical | 13 non-clinical

- “Typology”
  - sensing
  - clinical assessment
  - predictive modelling
  - intervention models
  - user interaction


Feature Article

A Decade of Ubiquitous Computing Research in Mental Health

Jakob E. Bardram
Department of Health Technology, Technical University of Denmark

Aleksandar Matic
Telefonica Innovacion Alpha

***Abstract*—Mental health represents a huge disease and societal burden and a significant body of research in ubiquitous computing has been devoted to the design of technologies for continuous monitoring, diagnosis, and care of mental health conditions. This paper reviews a decade of research into technologies for mental health, focusing on the use of mobile and wearable technology. The review found 46 systems that are analyzed in a historical context and discussed according to which mental disorder they target, the type of technology, and the type and size of the clinical studies they have been used in. Finally, the paper presents inputs from nine leading researchers in the domain and discuss important technical and clinical challenges in the design of ubiquitous computing technology for the next decade.**

MENTAL HEALTH REPRESENTS a huge disease and societal burden.[1] Due to its episodic nature, the traditional healthcare model is considered to be suboptimal to address this burden and to improve chronic mental conditions.[2] “Anytime and everywhere” ubiquitous technology was seen early on as an opportunity to address continuous monitoring, diagnosis, and care of mental health conditions, thereby enabling an extension of care delivery beyond the reach of traditional healthcare. In particular, mobile and wearable technologies—with their ability to track behavioral, physiological, and contextual signals—were seen as a potential enabler of a continuous symptom monitoring and personalized intervention.[3,4]

Last year marked the ten year anniversary since smartphones (the first iPhone appeared in 2007 and the first stable Android phone in 2009) have become widely available as an open platform and have since then been used for creating novel personalized health applications. The early

Digital Object Identifier 10.1109/MPRV.2019.2925338

2019 Published by the IEEE Computer Society 1536-1268 © 2019 IEEE 1

J. E. Bardram and A. Matic, “A Decade of Ubiquitous Computing Research in Mental Health,” *IEEE Pervasive Computing*, p. 1–11, 2020.

A All ages

Leading causes 1990	Percentage of DALYs 1990
1 Neonatal disorders	10·6 (9·9 to 11·4)
2 Lower respiratory infections	8·7 (7·6 to 10·0)
3 Diarrhoeal diseases	7·3 (5·9 to 8·8)
4 Ischaemic heart disease	4·7 (4·4 to 5·0)
5 Stroke	4·2 (3·9 to 4·5)
6 Congenital birth defects	3·2 (2·3 to 4·8)
7 Tuberculosis	3·1 (2·8 to 3·4)
8 Road injuries	2·7 (2·6 to 3·0)
9 Measles	2·7 (0·9 to 5·6)
10 Malaria	2·5 (1·4 to 4·1)
11 COPD	2·3 (1·9 to 2·5)
12 Protein-energy malnutrition	2·0 (1·6 to 2·7)
13 Low back pain	1·7 (1·2 to 2·1)
14 Self-harm	1·4 (1·2 to 1·5)
15 Cirrhosis	1·3 (1·2 to 1·5)
16 Meningitis	1·3 (1·1 to 1·5)
17 Drowning	1·3 (1·1 to 1·4)
18 Headache disorders	1·1 (0·2 to 2·4)
19 Depressive disorders	1·1 (0·8 to 1·5)
20 Diabetes	1·1 (1·0 to 1·2)
21 Lung cancer	1·0 (1·0 to 1·1)
22 Falls	1·0 (0·9 to 1·2)
23 Dietary iron deficiency	1·0 (0·7 to 1·3)
24 Interpersonal violence	0·9 (0·9 to 1·0)
25 Whooping cough	0·9 (0·4 to 1·7)
27 Age-related hearing loss	0·8 (0·6 to 1·1)
29 Chronic kidney disease	0·8 (0·8 to 0·9)
30 HIV/AIDS	0·8 (0·6 to 1·0)
32 Gynaecological diseases	0·8 (0·6 to 1·0)
34 Anxiety disorders	0·7 (0·5 to 1·0)
35 Other musculoskeletal	0·7 (0·5 to 1·0)

Leading causes 2019	Percentage of DALYs 2019	Percentage change in number of DALYs, 1990–2019	Percentage change in age-standardised DALY rate, 1990–2019
1 Neonatal disorders	7·3 (6·4 to 8·4)	–32·3 (–41·7 to –20·8)	–32·6 (–42·1 to –21·2)
2 Ischaemic heart disease	7·2 (6·5 to 7·9)	50·4 (39·9 to 60·2)	–28·6 (–33·3 to –24·2)
3 Stroke	5·7 (5·1 to 6·2)	32·4 (22·0 to 42·2)	–35·2 (–40·5 to –30·5)
4 Lower respiratory infections	3·8 (3·3 to 4·3)	–56·7 (–64·2 to –47·5)	–62·5 (–69·0 to –54·9)
5 Diarrhoeal diseases	3·2 (2·6 to 4·0)	–57·5 (–66·2 to –44·7)	–64·6 (–71·7 to –54·2)
6 COPD	2·9 (2·6 to 3·2)	25·6 (15·1 to 46·0)	–39·8 (–44·9 to –30·2)
7 Road injuries	2·9 (2·6 to 3·0)	2·4 (–6·9 to 10·8)	–31·0 (–37·1 to –25·4)
8 Diabetes	2·8 (2·5 to 3·1)	147·9 (135·9 to 158·9)	24·4 (18·5 to 29·7)
9 Low back pain	2·5 (1·9 to 3·1)	46·9 (43·3 to 50·5)	–16·3 (–17·1 to –15·5)
10 Congenital birth defects	2·1 (1·7 to 2·6)	–37·3 (–50·6 to –12·8)	–40·0 (–52·7 to –17·1)
11 HIV/AIDS	1·9 (1·6 to 2·2)	127·7 (97·3 to 171·7)	58·5 (37·1 to 89·2)
12 Tuberculosis	1·9 (1·7 to 2·0)	–41·0 (–47·2 to –33·5)	–62·8 (–66·6 to –58·0)
13 Depressive disorders	1·8 (1·4 to 2·4)	61·1 (56·9 to 65·0)	–1·8 (–2·9 to –0·8)
14 Malaria	1·8 (0·9 to 3·1)	–29·4 (–56·9 to 6·6)	–37·8 (–61·9 to –6·2)
15 Headache disorders	1·8 (0·4 to 3·8)	56·7 (52·4 to 62·1)	1·1 (–4·2 to 2·9)
16 Cirrhosis	1·8 (1·6 to 2·0)	33·0 (22·4 to 48·2)	–26·8 (–32·5 to –19·0)
17 Lung cancer	1·8 (1·6 to 2·0)	69·1 (53·1 to 85·4)	–16·2 (–24·0 to –8·2)
18 Chronic kidney disease	1·6 (1·5 to 1·8)	93·2 (81·6 to 105·0)	6·3 (0·2 to 12·4)
19 Other musculoskeletal	1·6 (1·2 to 2·1)	128·9 (122·0 to 136·3)	30·7 (27·6 to 34·3)
20 Age-related hearing loss	1·6 (1·2 to 2·1)	82·8 (75·2 to 88·9)	–1·8 (–3·7 to –0·1)
21 Falls	1·5 (1·4 to 1·7)	47·1 (31·5 to 61·0)	–14·5 (–22·5 to –7·4)
22 Self-harm	1·3 (1·2 to 1·5)	–5·6 (–14·2 to 3·7)	–38·9 (–44·3 to –33·0)
23 Gynaecological diseases	1·2 (0·9 to 1·5)	48·7 (45·8 to 51·8)	–6·8 (–8·7 to –4·9)
24 Anxiety disorders	1·1 (0·8 to 1·5)	53·7 (48·8 to 59·1)	–0·1 (–1·0 to 0·7)
25 Dietary iron deficiency	1·1 (0·8 to 1·5)	13·8 (10·5 to 17·2)	–16·4 (–18·7 to –14·0)
26 Interpersonal violence	1·1 (1·0 to 1·2)	10·2 (3·2 to 19·2)	–23·8 (–28·6 to –17·8)
40 Meningitis	0·6 (0·5 to 0·8)	–51·3 (–59·4 to –42·0)	–57·2 (–64·4 to –48·6)
41 Protein-energy malnutrition	0·6 (0·5 to 0·7)	–71·1 (–79·6 to –59·7)	–74·5 (–82·0 to –64·5)
46 Drowning	0·5 (0·5 to 0·6)	–60·6 (–65·2 to –53·6)	–68·2 (–71·9 to –62·8)
55 Whooping cough	0·4 (0·2 to 0·7)	–54·5 (–74·6 to –16·9)	–56·3 (–75·6 to –20·3)
71 Measles	0·3 (0·1 to 0·6)	–89·8 (–92·3 to –86·8)	–90·4 (–92·8 to –87·5)


Global Health Metrics

Global burden of 369 diseases and injuries in 204 countries and territories, 1990–2019: a systematic analysis for the Global Burden of Disease Study 2019

Summary