

CHDR

Centre for Human Drug Research



At home monitoring of subjects in early phase clinical drug trials

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Psychiatry

- Pharmacological treatment of unipolar mood disorders is characterized by (partial) ineffectiveness
- Assessing pharmacodynamics effects in trials (gold standard) → Questionnaires
- Several limitations
- Objective biomarkers

Psychiatry

CLINICAL
STATE

Depression

Anxiety

Other clinical constructs

Mohr, David C. Personal sensing: understanding mental health using ubiquitous sensors and machine learning. *Annual review of clinical psychology*, 2017, 13: 23-47.

CHDR MORE application

- Bring Your Own Device (BYOD)
- Compatible with all Android devices with Android 5.0 or higher
- Continuous monitoring of all device sensors
 - Microphone (openSMILE by audEERING)
 - Gyroscope
 - Accelerometer
 - Light sensor
 - GPS
 - Network
- Continuous monitoring of phone usage (calls, text, app usage, battery level)



Parameters

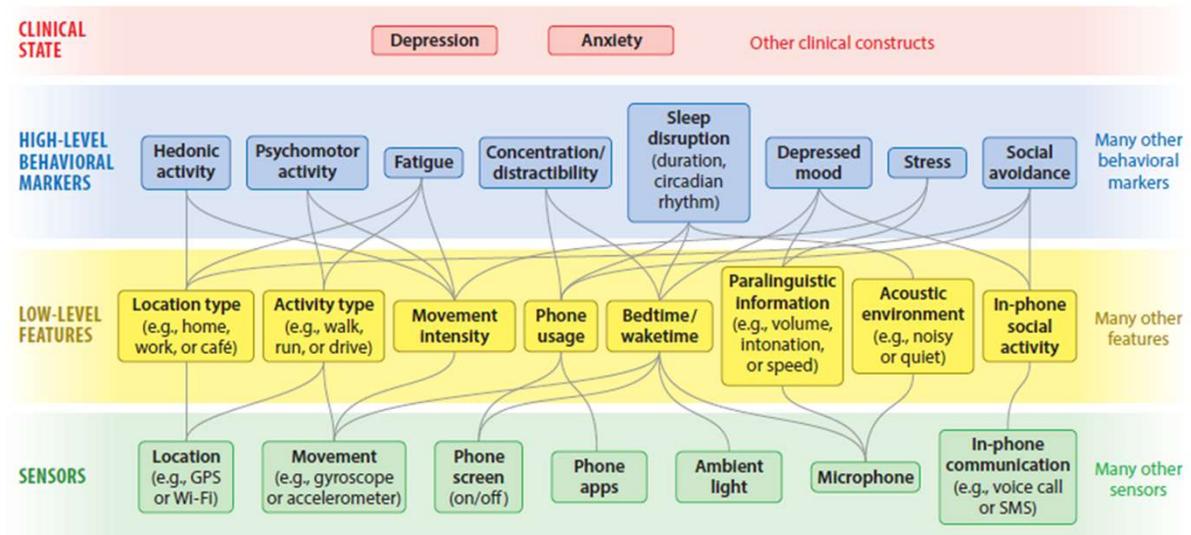
CHDR MORE will collect all data from the Android device:

Social activity

- Voice activation (probability of human voices in proximity)
- Phone (length of call, last 3 digits of phone number, number known/unknown)
- SMS (amount of characters, last 3 digits of phone number, number known/unknown)
- App usage (categories of apps, start time, running in background/foreground)
- Light sensor

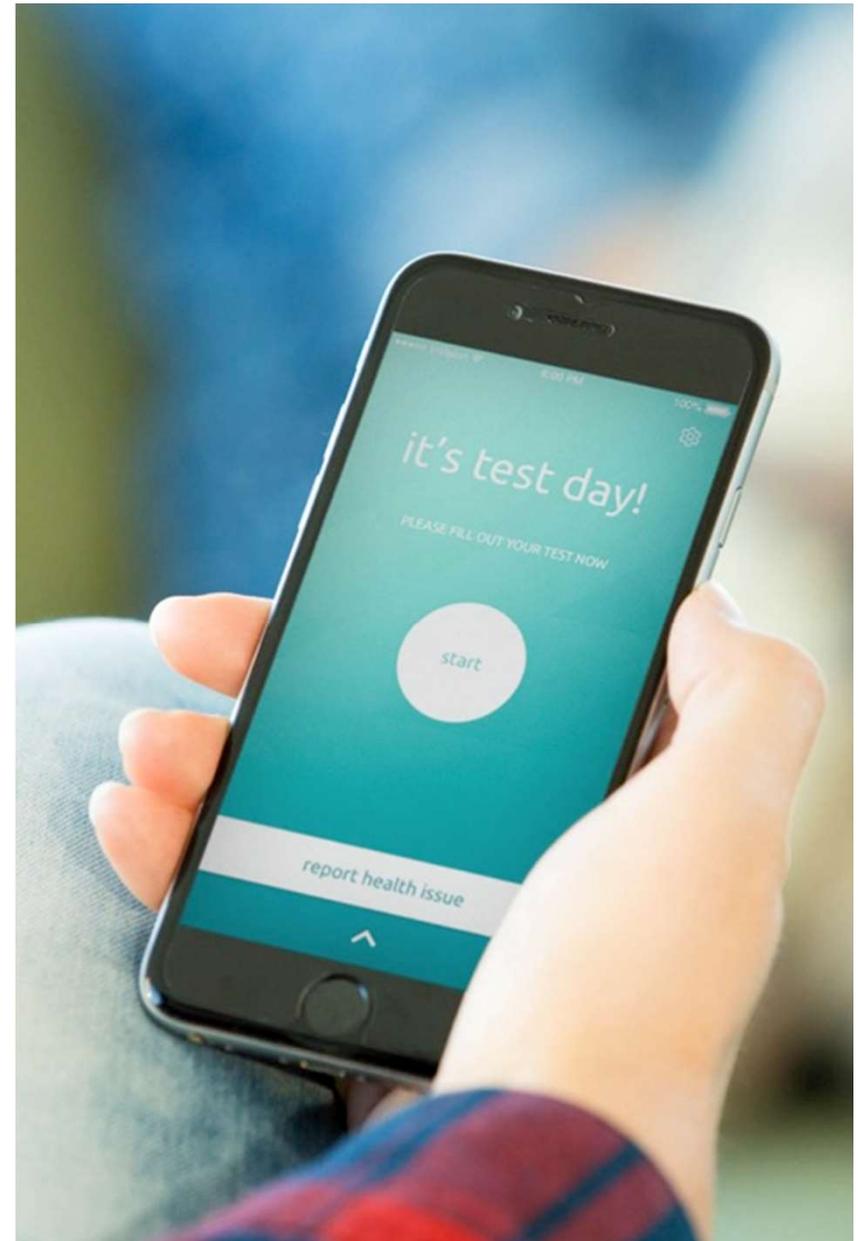
Movement and location

- Acceleration
- Gyroscope
- Magnetic field
- Step count
- Google Places
- Relative location



ePRO Application

- Application for the assessment of questionnaires at home
- Scheduled questionnaires → notifications
- Time windows for user input → compliance



Wearable integration

- Withings Health platform
 - Heart rate
 - Blood pressure
 - Sleep
 - Weight
 - Steps
 - Temperature



Other use cases

- Pediatrics
 - Pediatric clinical trials are rare
 - Invasive
 - Recruitment/inclusion difficult
 - Little known about time to recovery
- Dermatology
 - Compliance
 - E-Diary
- Neurology
 - Neuromuscular diseases
 - Parkinson's tremor assessment
 - Cognitive tasks at home
- ENT
 - Impact of Cochlear Implant

Challenges

- BYOD
 - Exclusion of subjects with Apple devices
 - Unexpected incompatibilities with all the different Android skins
 - Android updates
- Data analysis
 - Huge amounts of data
 - Machine learning
- Privacy
 - GDPR
- Ethical approval process may take longer
 - New methods
 - More EC questions
 - Studies involving children or other vulnerable patient groups

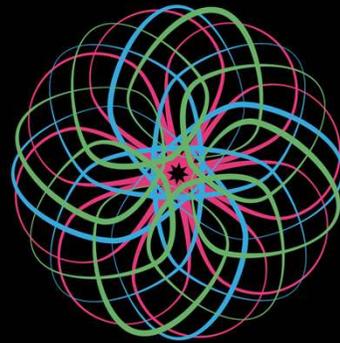
Summary

- At home monitoring allows for 24/7 monitoring of subjects
- Low burden
- 'Fun'
- Real-life data
- Continuous device monitoring
- High resolution
- Patient-centricity

Future work

- eConsent





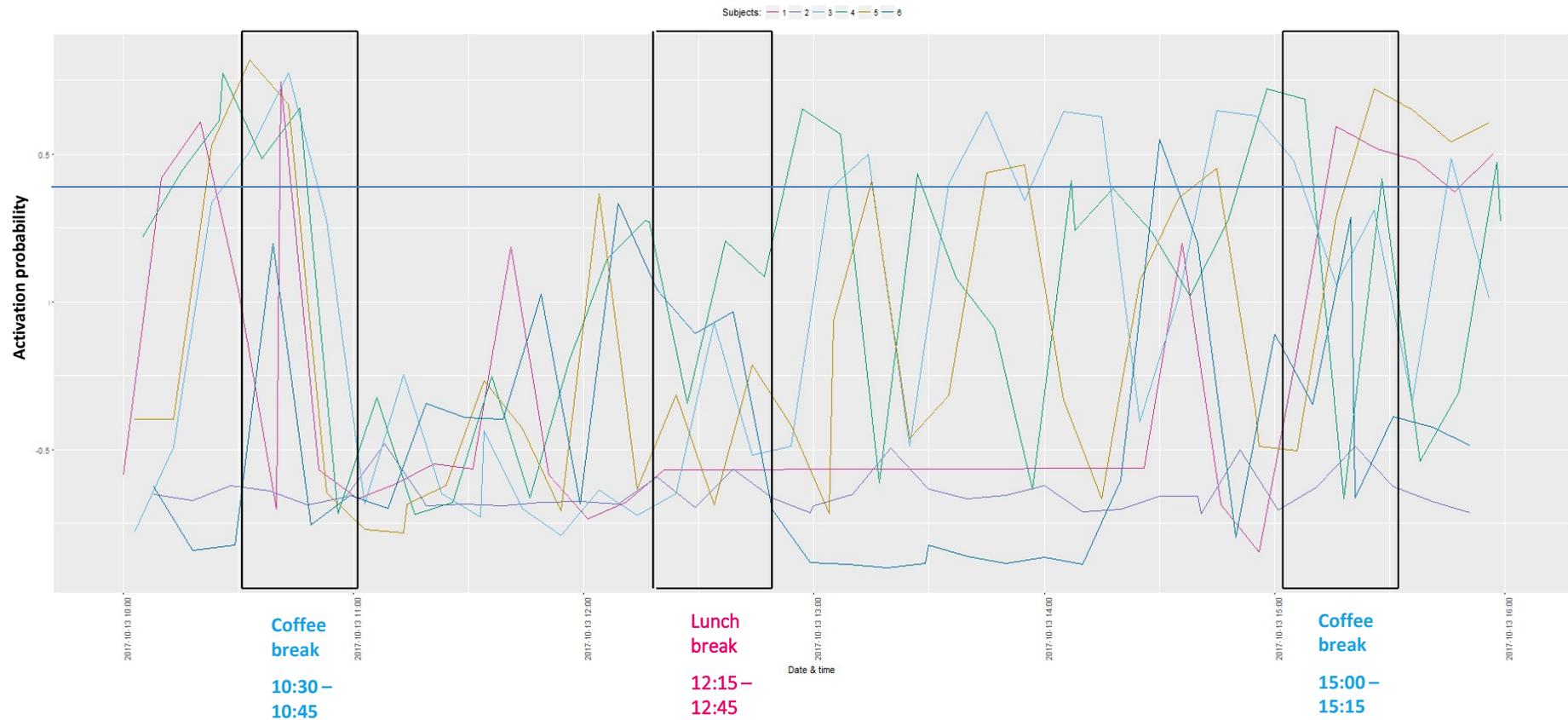
CHDR

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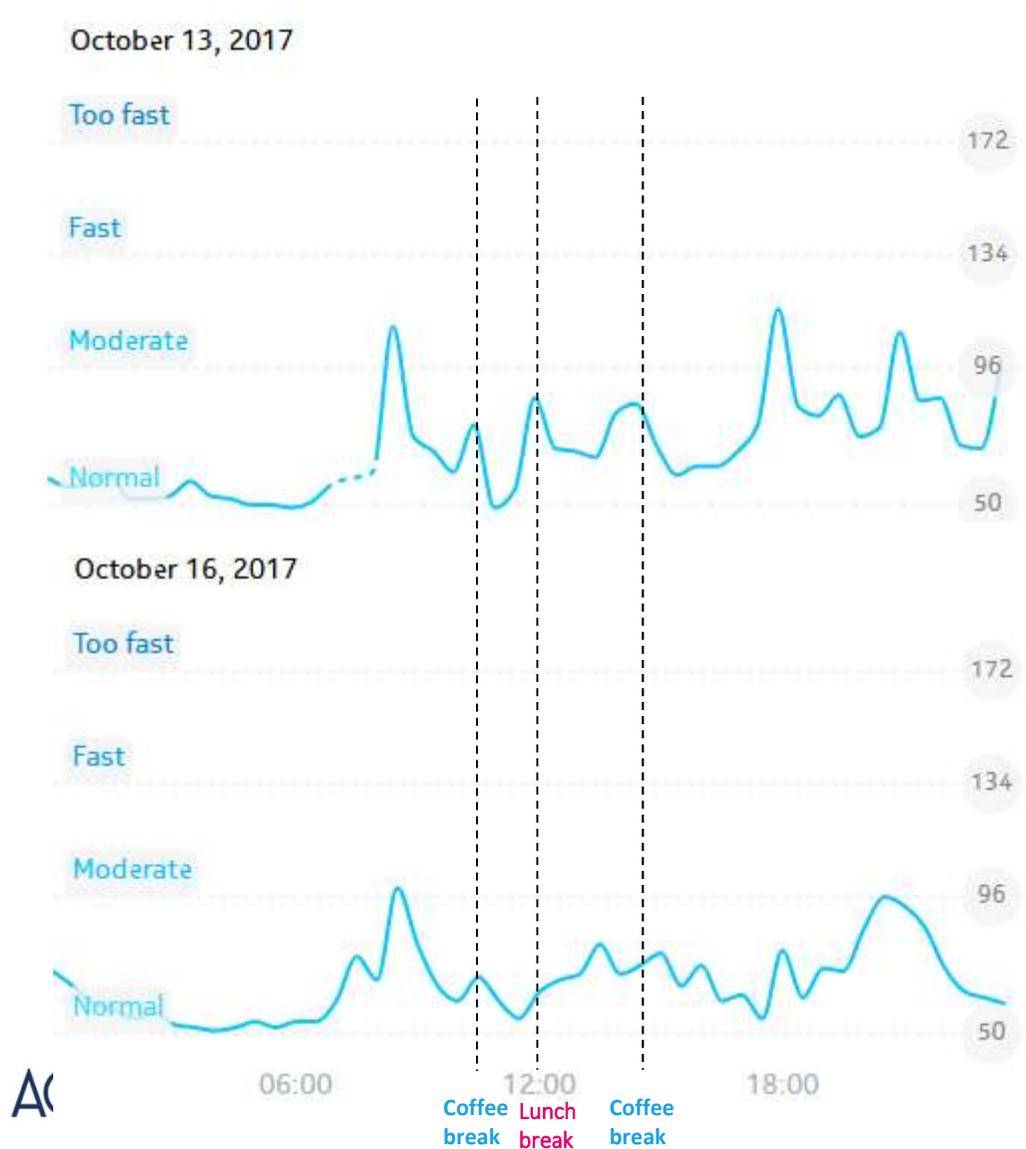
ACRON



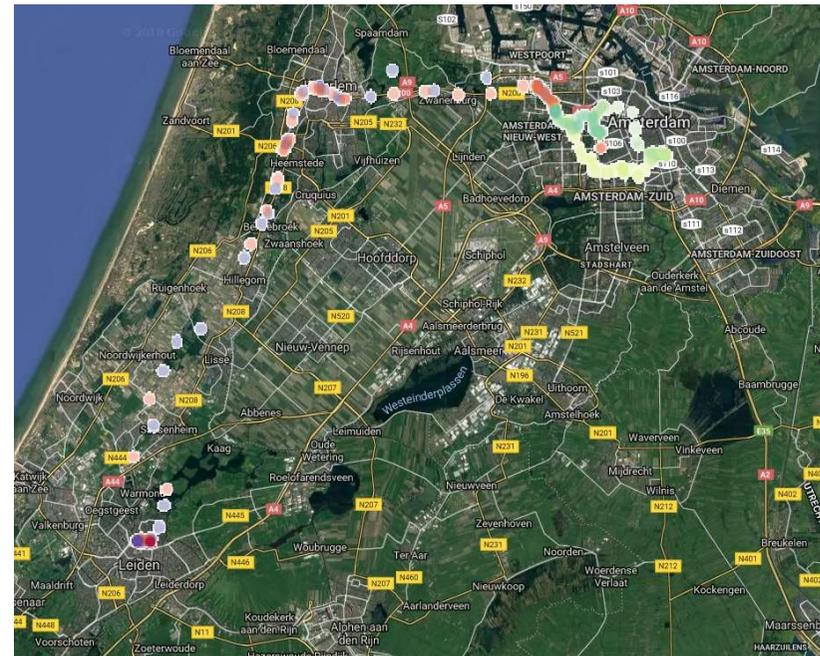
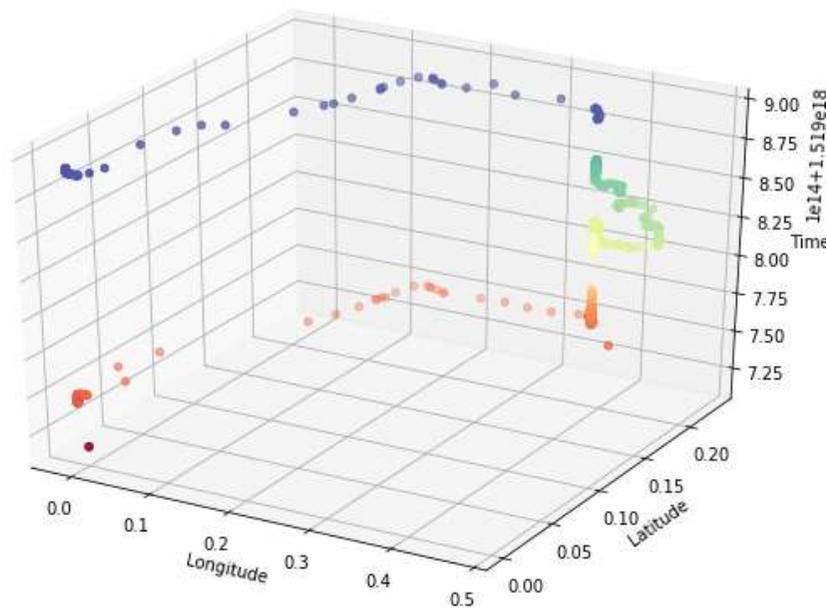
Results – Voice activation



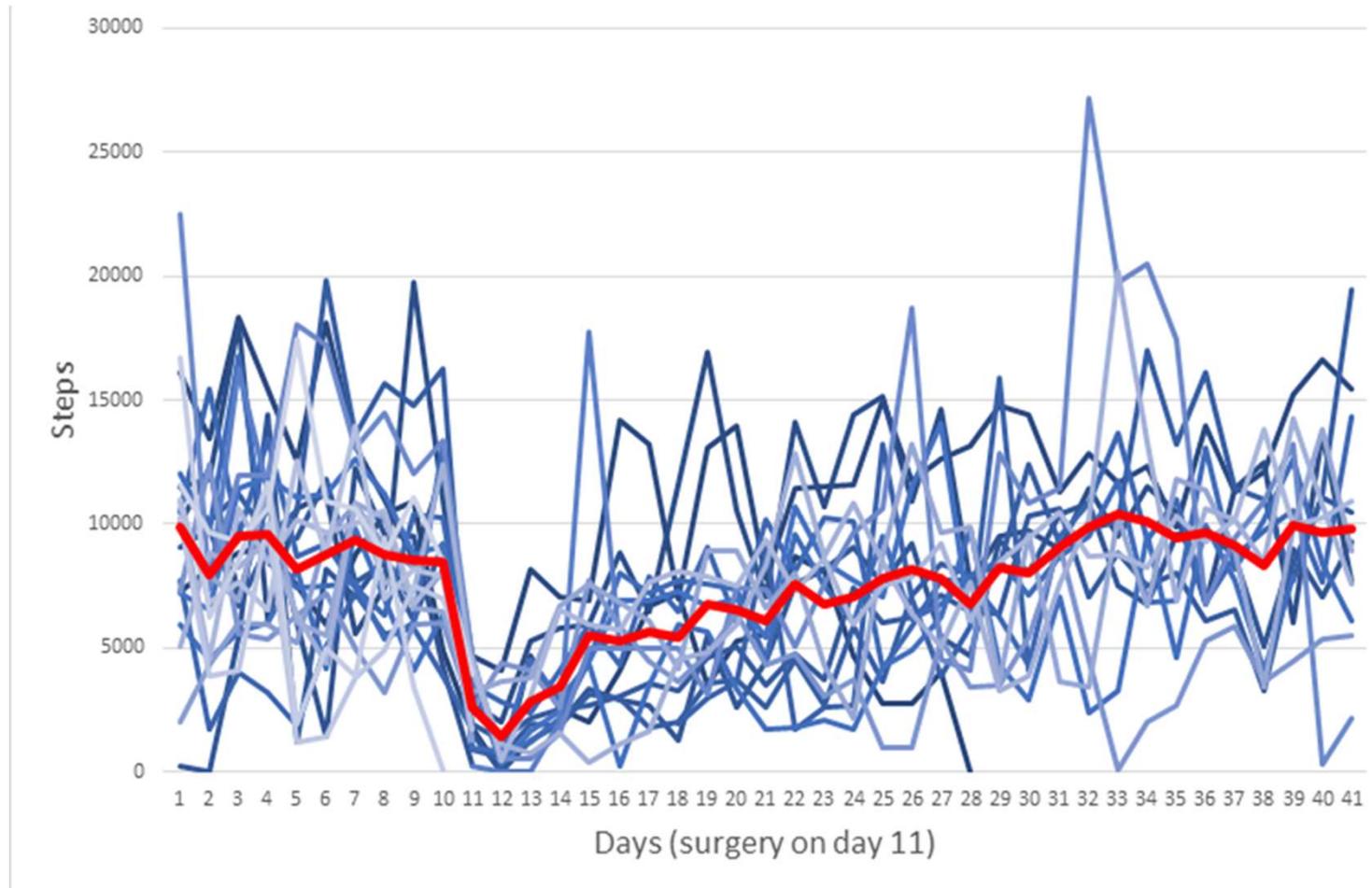
Results – Heart rate



Results - Location

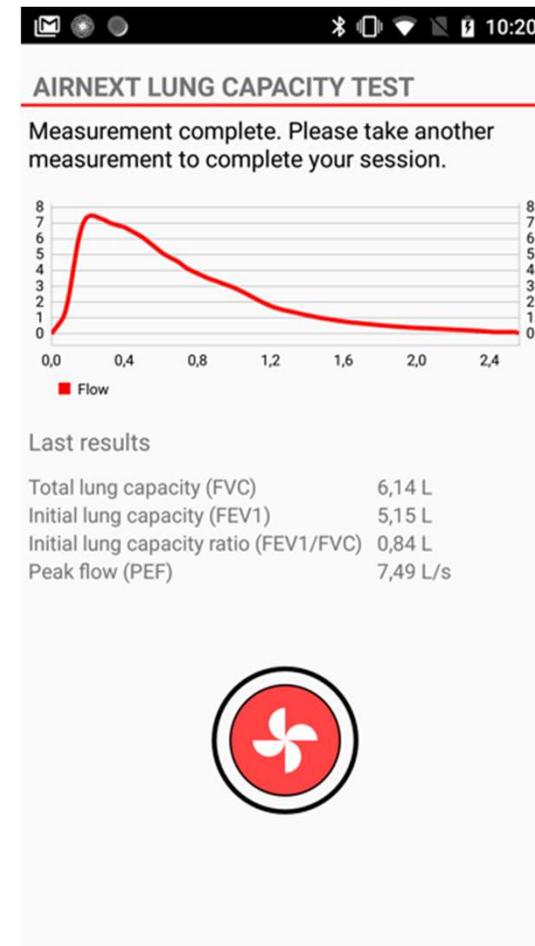


Results – Pilot pediatrics



User Interface – NuvoAir

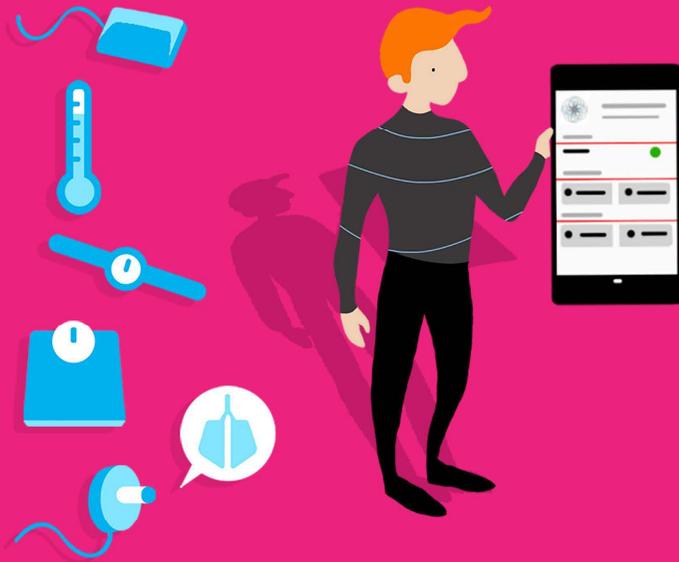
- Bluetooth connection established inside CHDR MORE application
- Measurements are done directly inside of the CHDR MORE application
- Data sent directly to CHDR
- Subjects can view the results



Welke meetmethoden worden gebruikt:

Meetinstrumenten voor thuisgebruik

App



Waarom:

Ons doel is een methode te ontwikkelen om het effect van nieuwe medicijnen te meten. Want meten is weten!

Wie:

Proefpersonen van 18 jaar en ouder

Wat wordt er gemeten via de app:

Sociale Activiteit

Beweging en Locatie



Gesprekken

Oproepen

Berichten

App gebruik

Beweging

GPS / Locatie

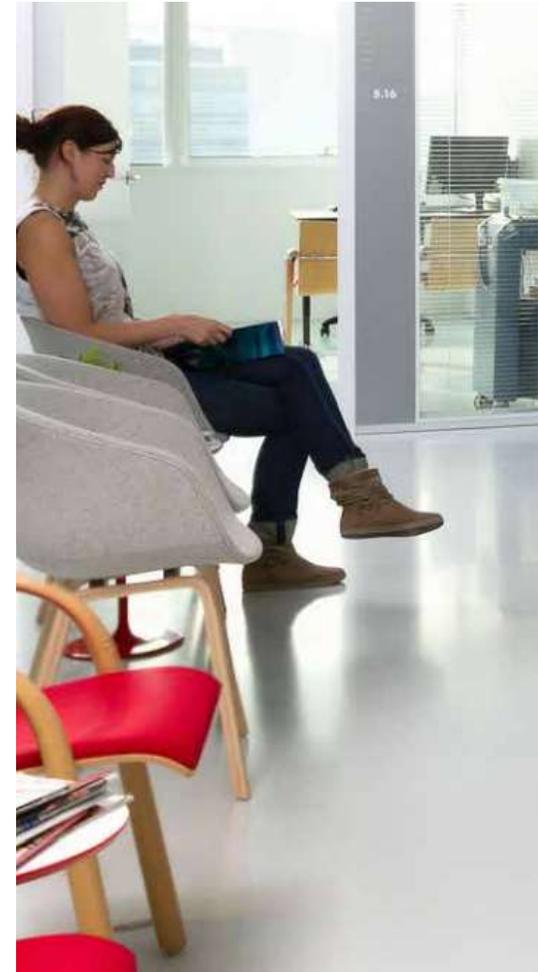


De inhoud van gesprekken wordt niet opgenomen, er wordt alleen gekeken naar hoe vaak gesprekken plaatsvinden.

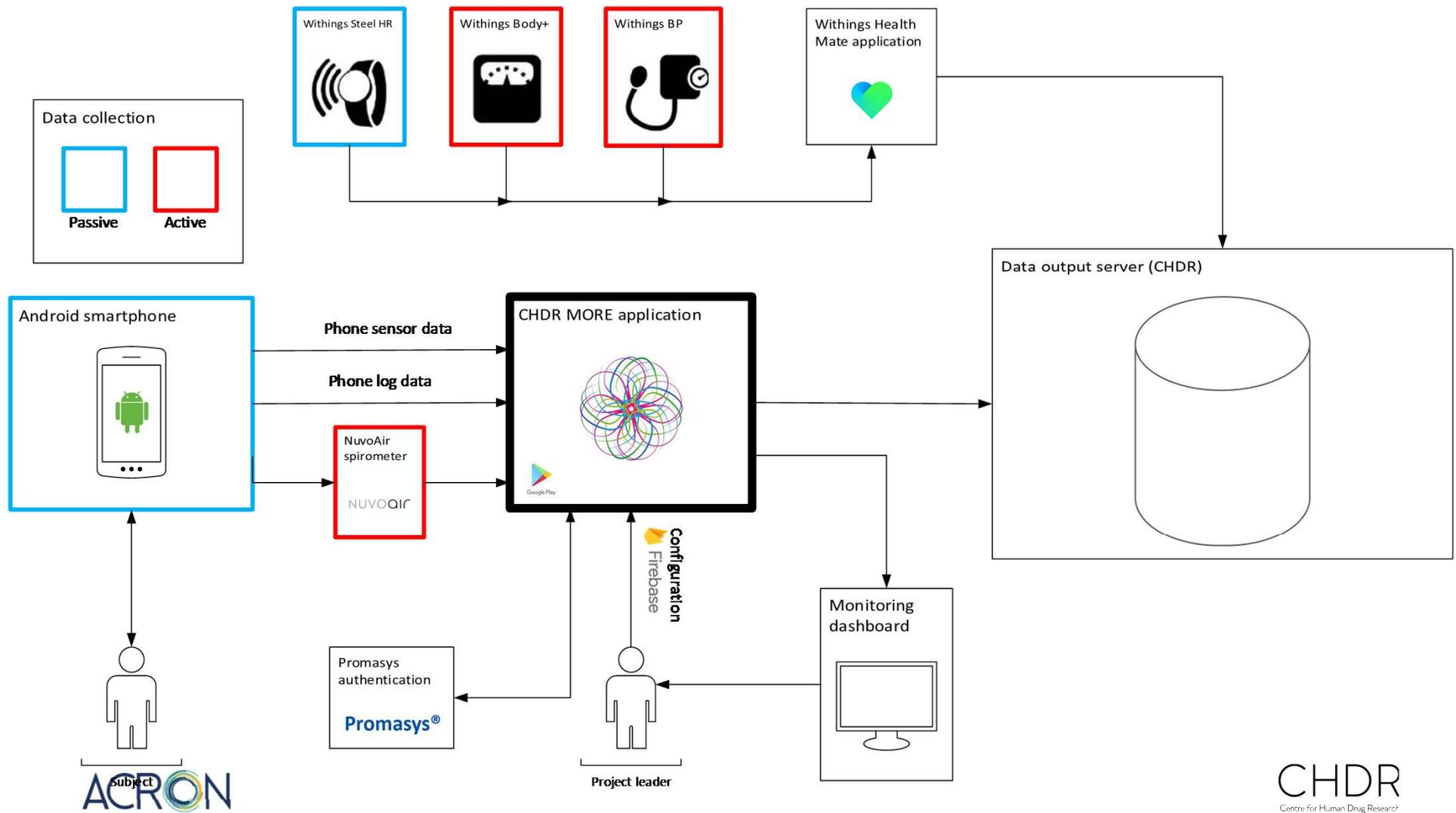
De app is ontwikkeld door en voor het CHDR. Verzamelde gegevens blijven dan ook binnen het CHDR en worden niet gedeeld met anderen.

Motivation

- High cost of trials
- Duration of clinical visits is limited
- No solution for monitoring subjects at home
- Majority of people carry a smartphone with them at all times



Data flow



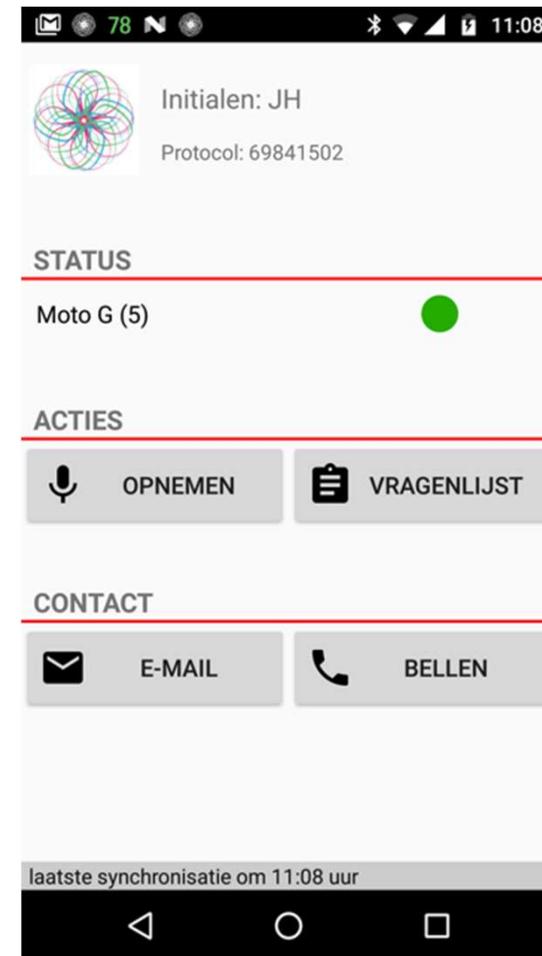
User Interface – Start screen

- Subject information is pulled from Promasys (QR code)
- All parameters are configurable for different studies
- Multiple studies at the same time

- Troubleshooting indicator

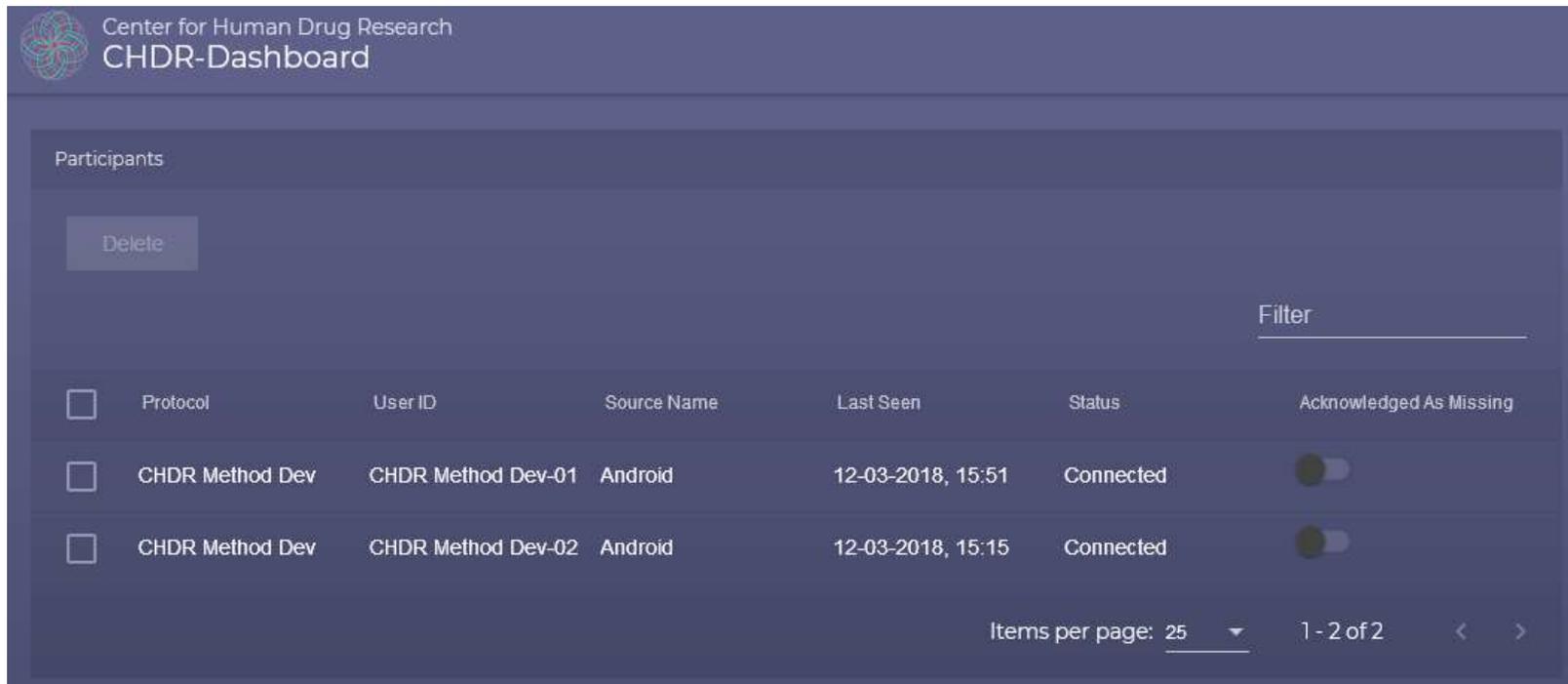
- Voice recordings (a notification is sent as a reminder)
- Open a questionnaire app (can be set to any app)

- Contact information of the CHDR project leader in case of problems



Data loss prevention

- Notification shown at all times
- Troubleshoot indicator in-app
- Dashboard



The screenshot shows the CHDR-Dashboard interface. At the top left is the logo and text 'Center for Human Drug Research CHDR-Dashboard'. Below this is a 'Participants' section with a 'Delete' button. A 'Filter' input field is on the right. A table lists participants with columns for checkboxes, Protocol, User ID, Source Name, Last Seen, Status, and Acknowledged As Missing. At the bottom right, there is a pagination control showing 'Items per page: 25' and '1 - 2 of 2'.

<input type="checkbox"/>	Protocol	User ID	Source Name	Last Seen	Status	Acknowledged As Missing
<input type="checkbox"/>	CHDR Method Dev	CHDR Method Dev-01	Android	12-03-2018, 15:51	Connected	<input type="checkbox"/>
<input type="checkbox"/>	CHDR Method Dev	CHDR Method Dev-02	Android	12-03-2018, 15:15	Connected	<input type="checkbox"/>

Future work

- Adding more (wearable) devices and monitoring of keystrokes
- Being able to detect crying, coughing, snoring, etc. using openSMILE

