

# Remote Digital Biomarker Monitoring

Bringing a smartphone-based diagnostic test for Parkinson's disease progression into an interventional trial

**pRED Informatics**

Pharma Research & Early Development

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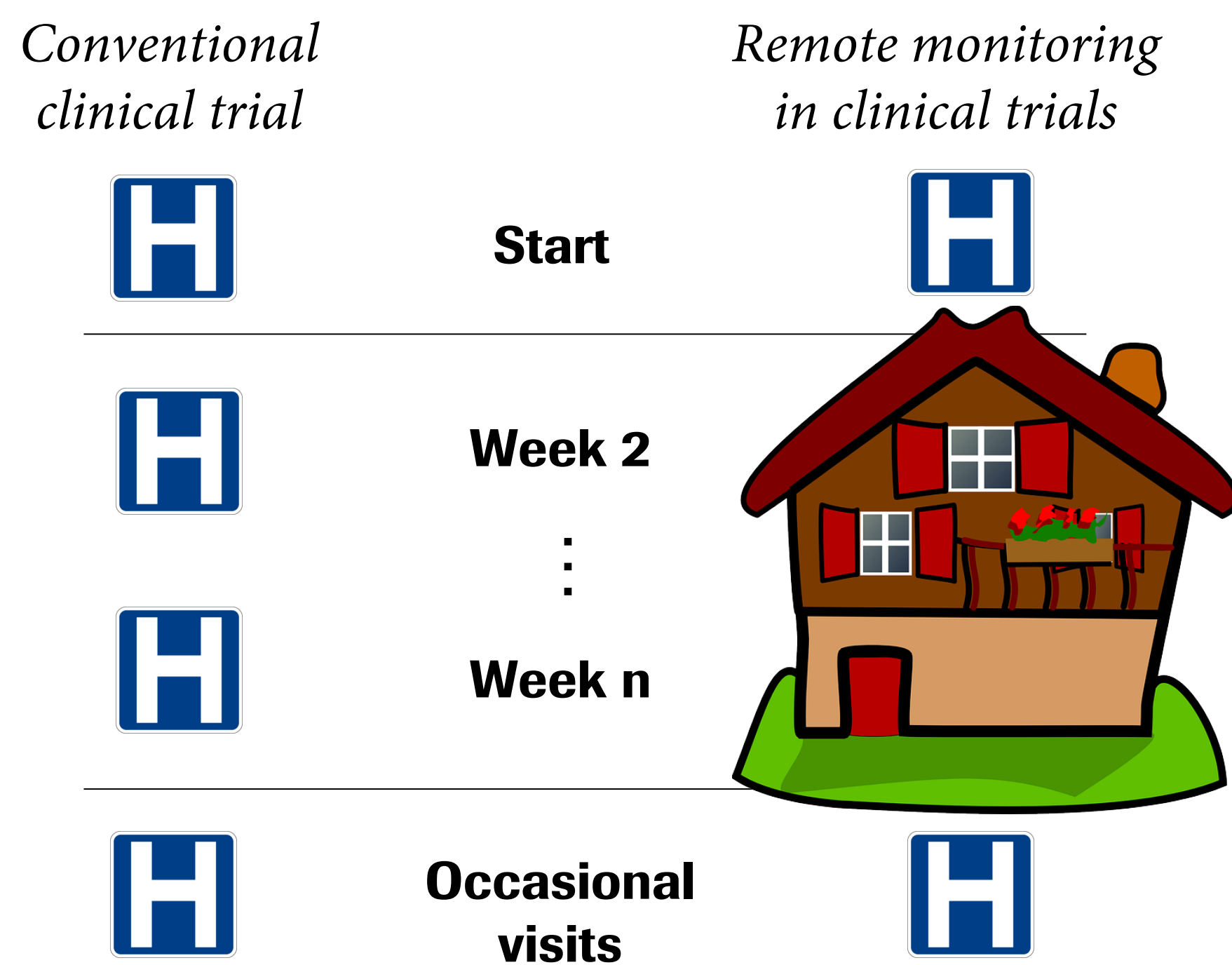
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## 1 – Introduction to remote monitoring in clinical trials

- Improve on subjective rater scales with objective sensor-based test results
- Enable continuous (24/7) data collection
- Reduce # of site visits for patients
- Gain insight into patient behaviour



## 2 – Remote monitoring for Parkinson's Disease (PD)

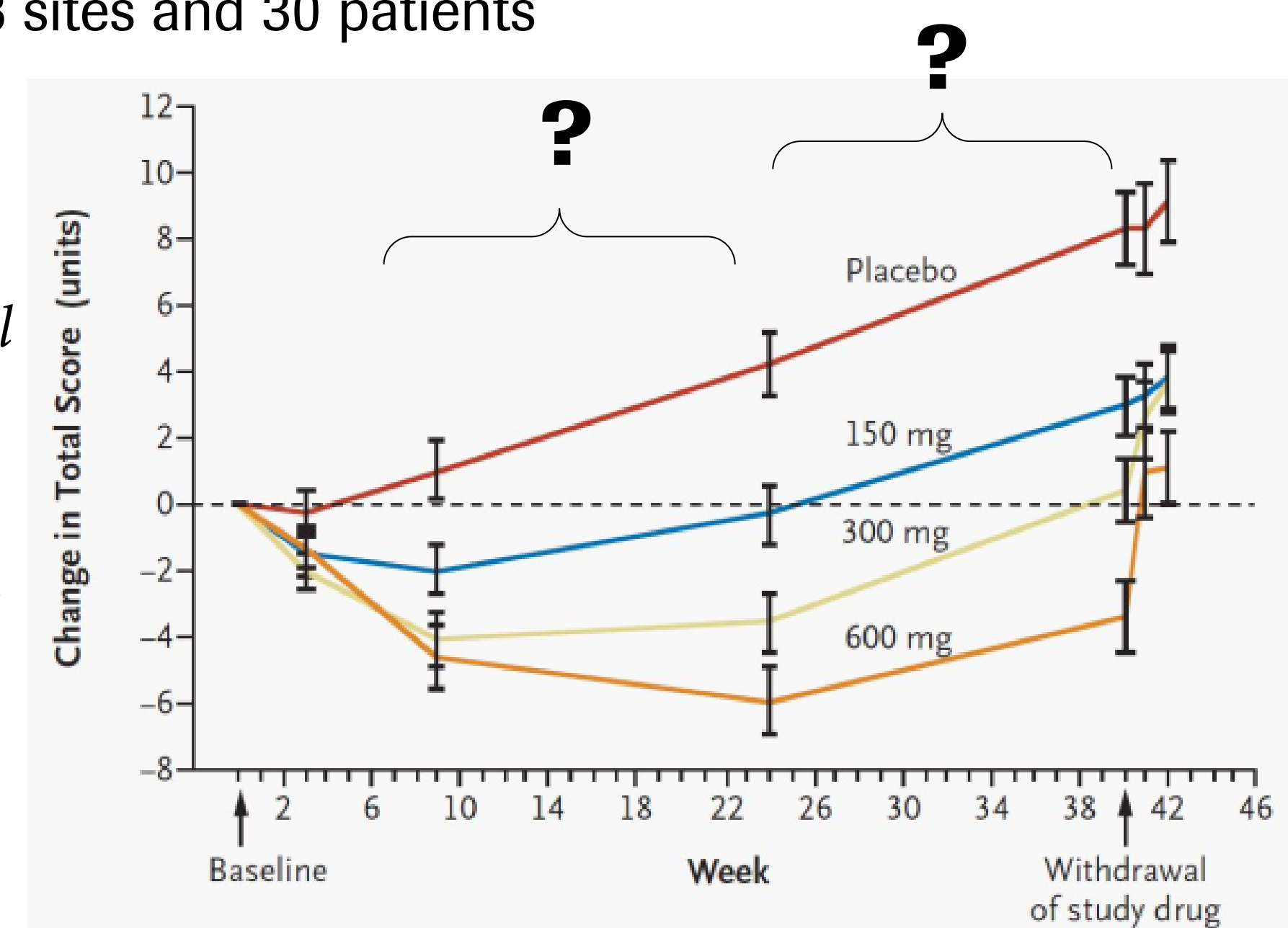
### Scientific rationale

- UPDRS\* → smartphone-based test
- First Pharma to bring objective PD sensor data analysis to an interventional trial
- Supporting an interventional PD study with 8 sites and 30 patients

### Operational rationale

- Develop professional workflow
- Maintain workflow during the trial
- Explore patient engagement

A typical Clinical trial with Ldopa today: what happens between UPDRS tests?



Source: N Engl J Med. 2004 Dec 9;351(24):2498-508. Fahn SJ, et al

\*UPDRS: Unified Parkinson's Disease Rating Scale

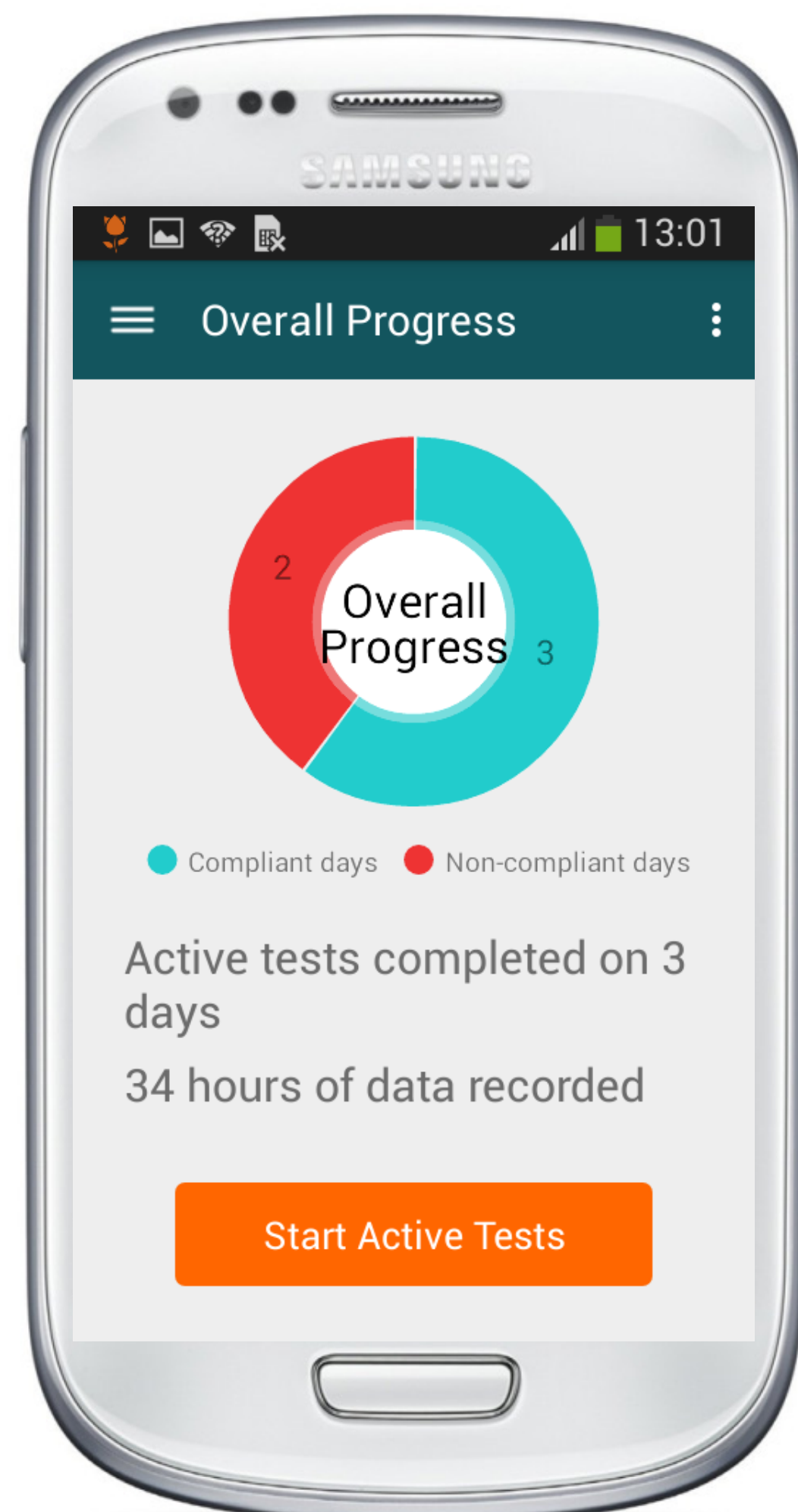
## 3 – Internal technology implementation

### Managing soft- and hardware

- Requirements and architecture
- Design and user experience
- Testing

### What we have implemented

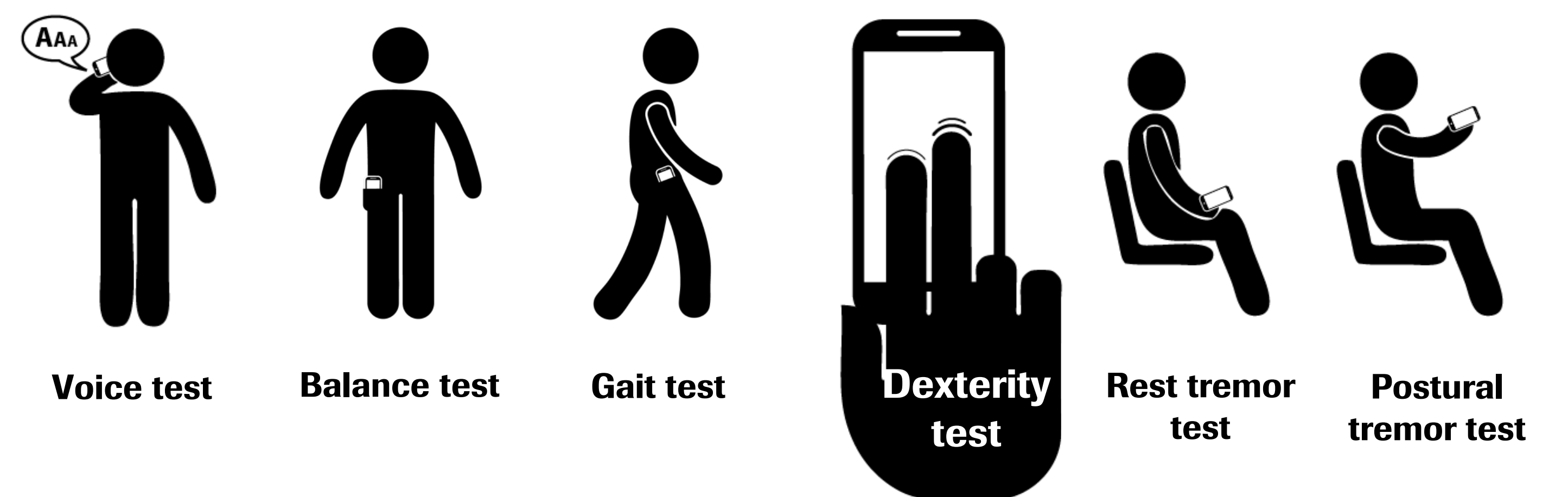
- Smartphone app with
  - Six "Active tests"
  - Continuous "Passive Monitoring"



## 4 – The patient's daily remote monitoring routine

### Active tests

Patients complete six tests on the App at the same time each day



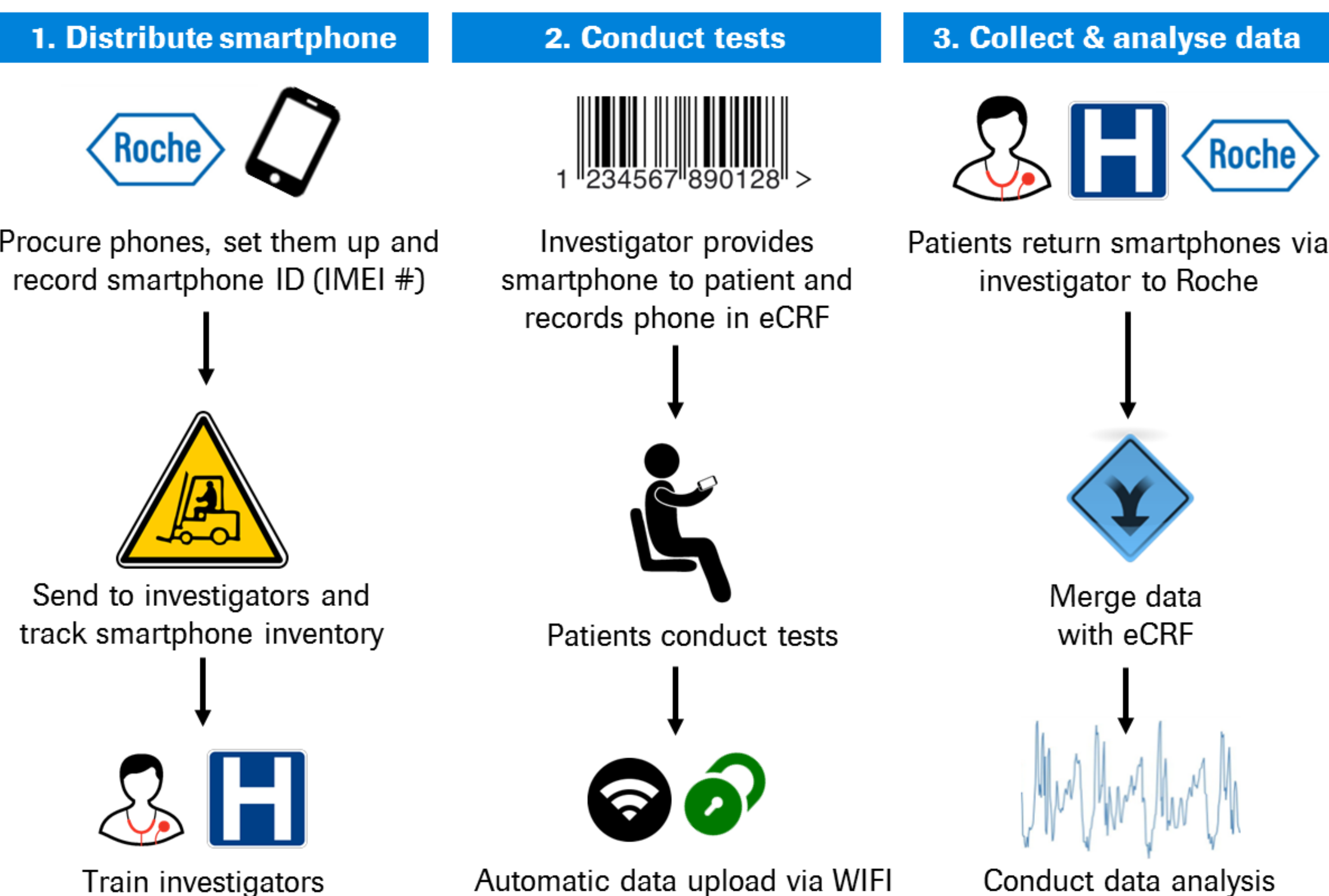
### Passive monitoring

Patients carry the phone around all day as they go about their daily activities



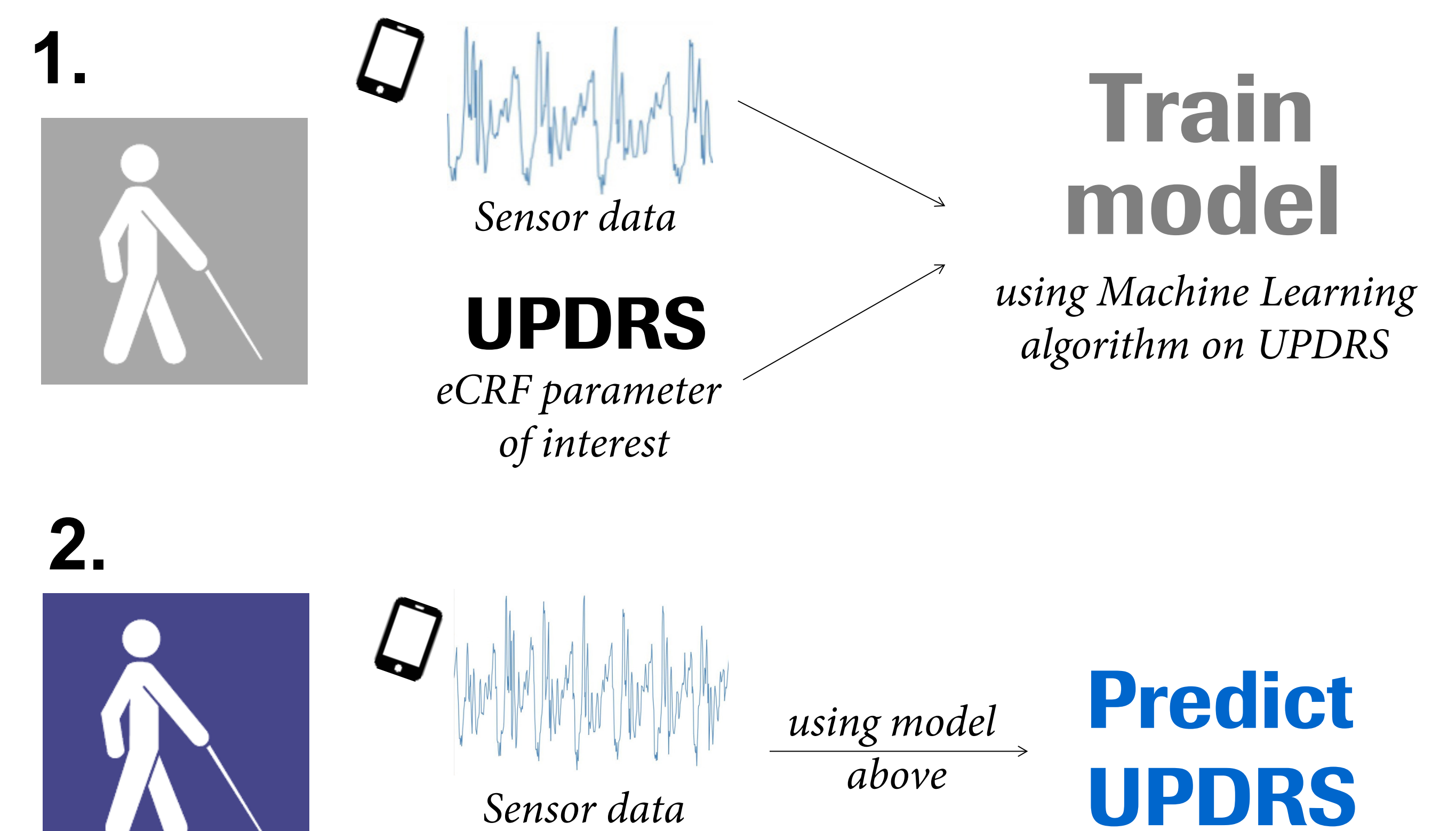
Passive monitoring

## 5 – Deploy end-to-end workflow to trial



## 6 – Data analysis with supervised machine learning

Objective: Train a computer to recognize and quantify levels of Parkinson's disease from smartphone sensor data



...and complement the UPDRS score.