

10 YEARS OF
BREAKTHROUGHS
A HEALTHIER
FUTURE



RADAR-CNS

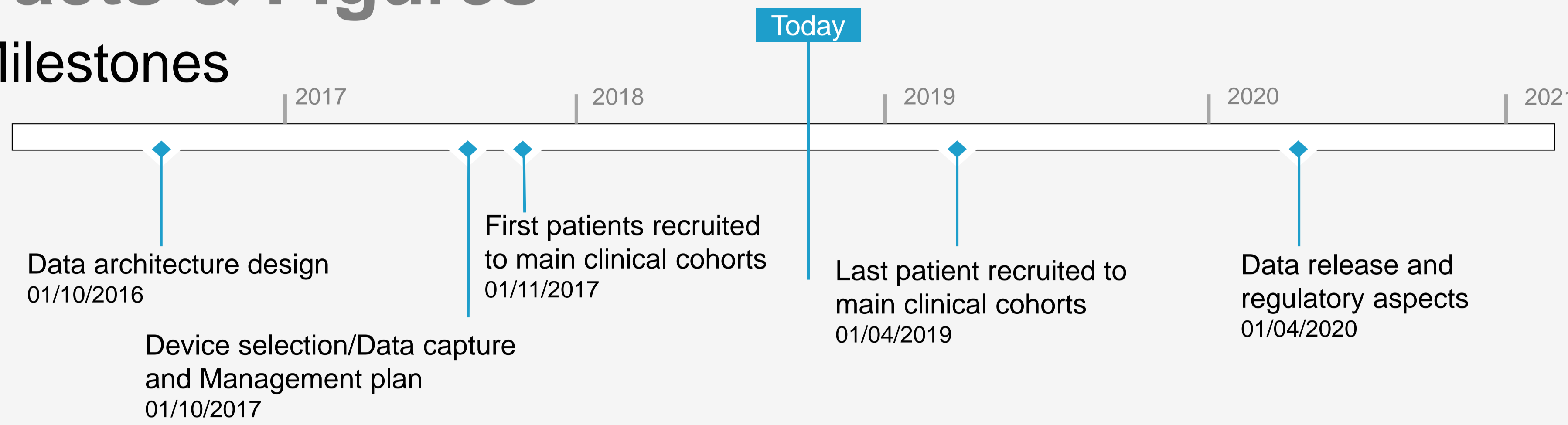
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A NEW WAY TO MONITOR MULTIPLE SCLEROSIS

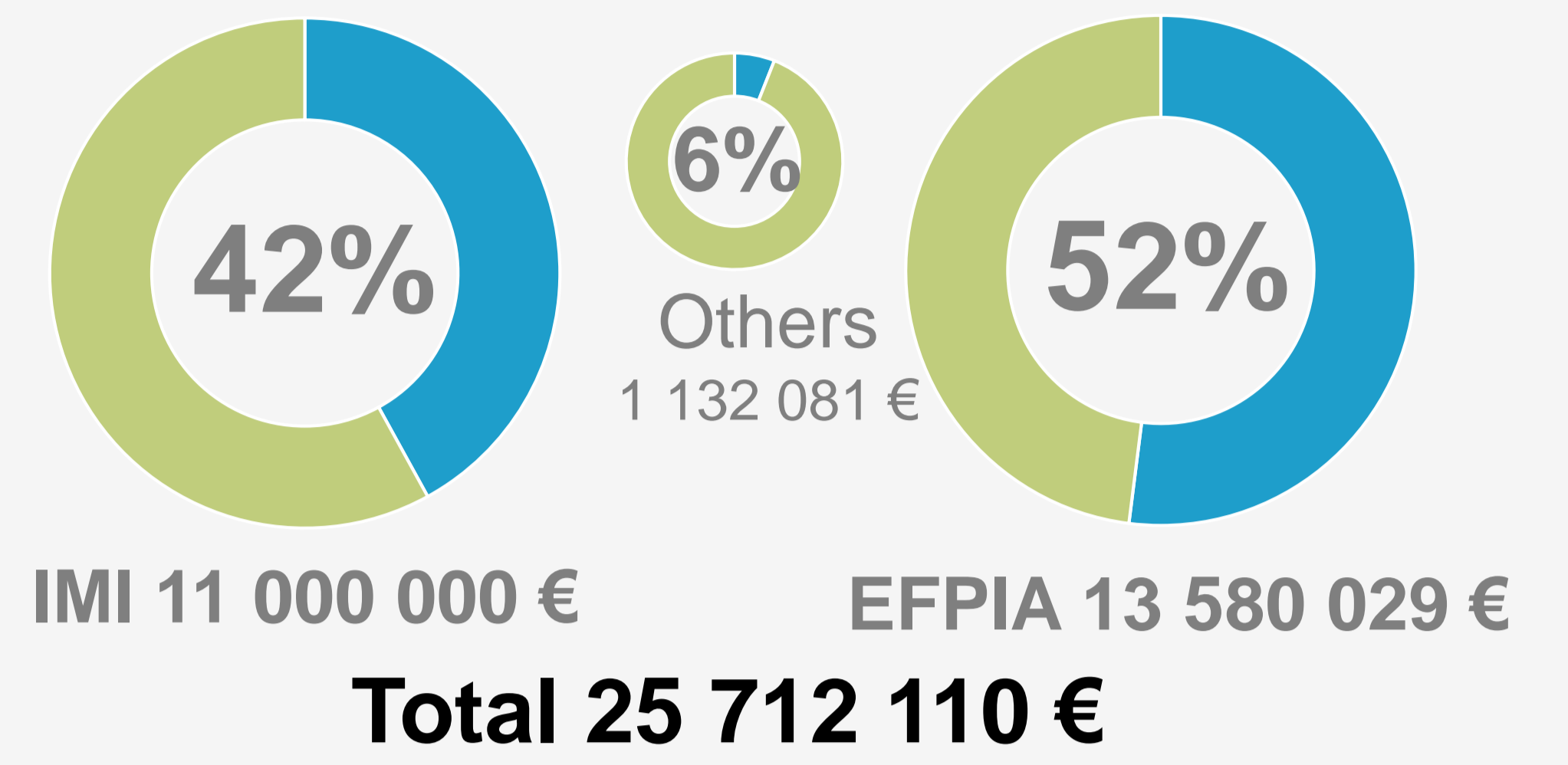
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Facts & Figures

Milestones



Contributions



Challenge

Remote Assessment of Disease and Relapse in Central Nervous System Disorders (RADAR-CNS) is an international research project, which aims to improve healthcare provision and to develop new ways of monitoring major depressive disorder, epilepsy and multiple sclerosis (MS) using wearable devices and smartphone technology. The RADAR-CNS ambition is to transform patient care through remote assessment. It is an international consortium of academic and EFPIA members who are leaders in the fields of depression, multiple sclerosis and epilepsy, with clinical expertise and access to patient cohorts in each disease area, combined with leading technical and methodological experts in the disciplines required for RMT development and implementation (Fig1).

MS Depression and MS Disability and Fatigue studies are two observational, non-randomized, non-interventional studies, using commercially available wearable technology and smartphone sensors. Both MS studies are multicenter, international trials involving 3 MS centres: San Raffaele Hospital in Milan, Fundacio Hospital Universitari Vall D'Hebron in Barcelona and Region Hovedstaden in Copenhagen.

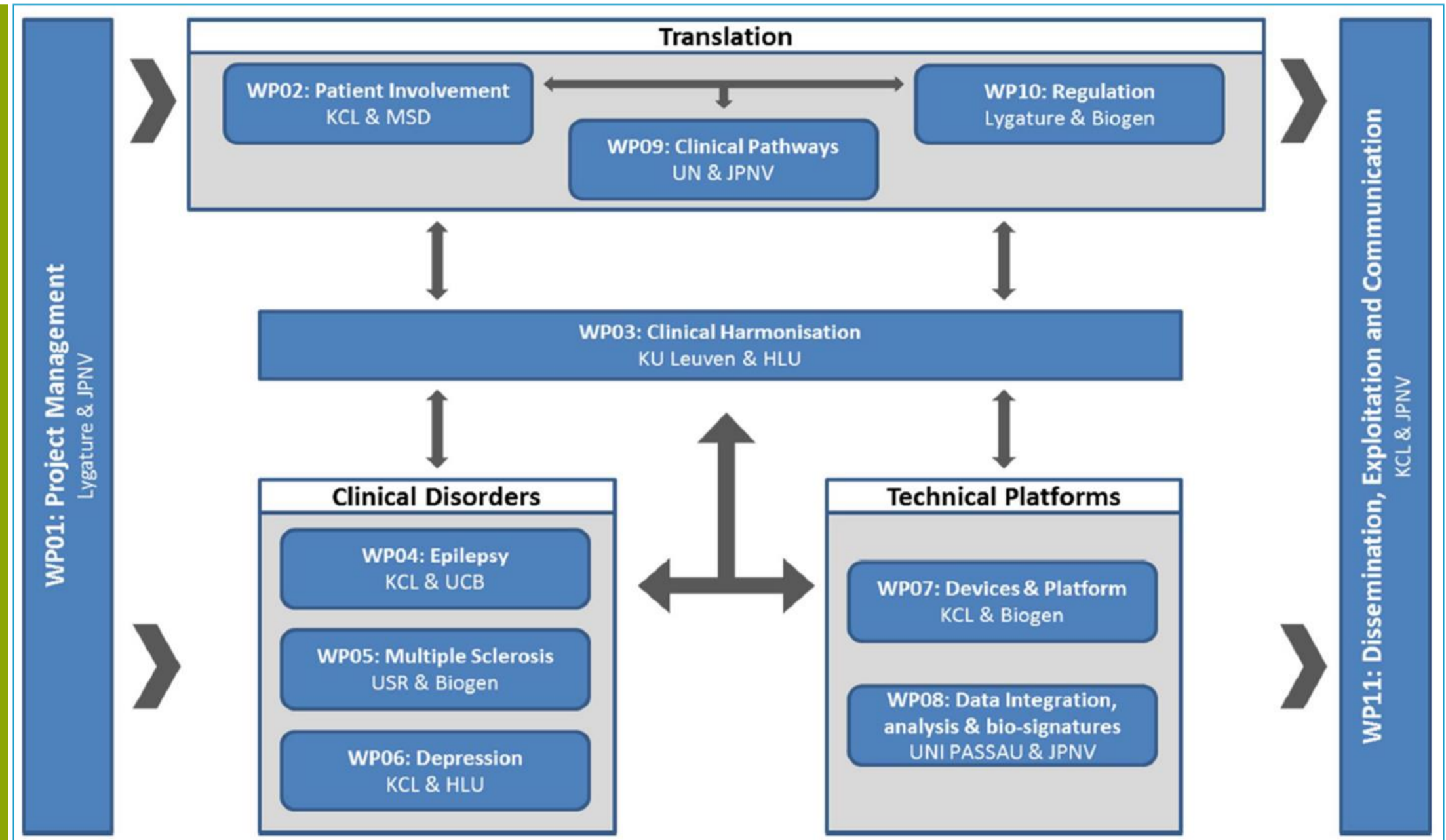
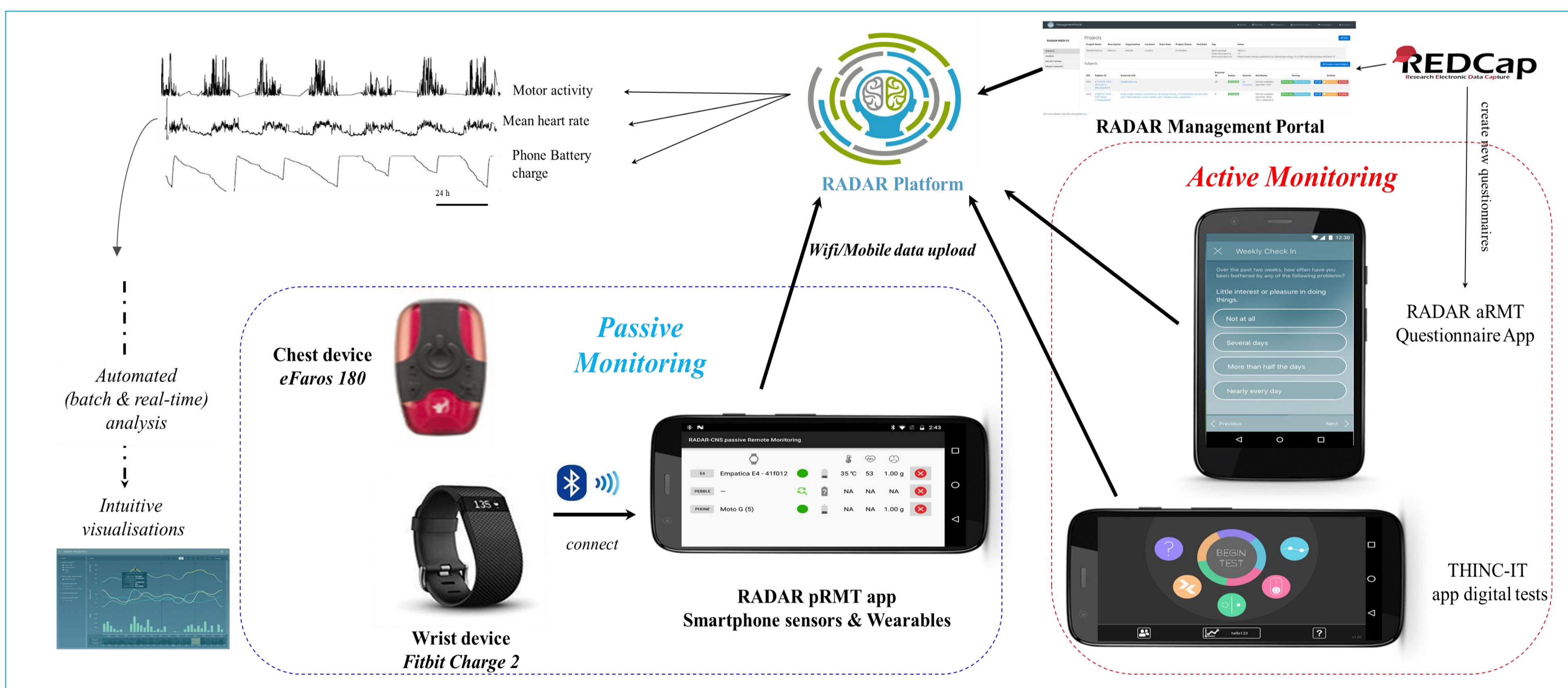


Figure 1: Project structure



Results

Through the RMT we will prospectively collect data, both passively (pRMT) and actively (aRMT), to provide information on potential predictors of outcome assessments. Moreover, to assess if RMT is a reliable instrument to characterize mood changes, cognition and disability, patients will also undergo to clinical visits at baseline and every 3 months to collect data about disability, cognition and emotional status using standard evaluations.

Passive Remote assessment (pRMT)

For pRMT we will use a wearable devices and smartphone sensors to collect multisensory data in order to investigate what type of features derived from the smartphone-biosensors correlates to the traditional clinical diagnosis based on the standard evaluation. Data will be collected through the RADAR-CNS passive app developed by WP7.

- Wrist worn device (Fitbit Charge 2):** Movement, daytime activity, sleep characteristics
- Smartphone sensors:** Collect data on ambient noise, light, GPS location, length and duration of calls, number of text messages.....
- Chest worn device (eFaros180):** Standing balance, gait variability, steps count, falls, ECG...

Active Remote assessment (aRMT)

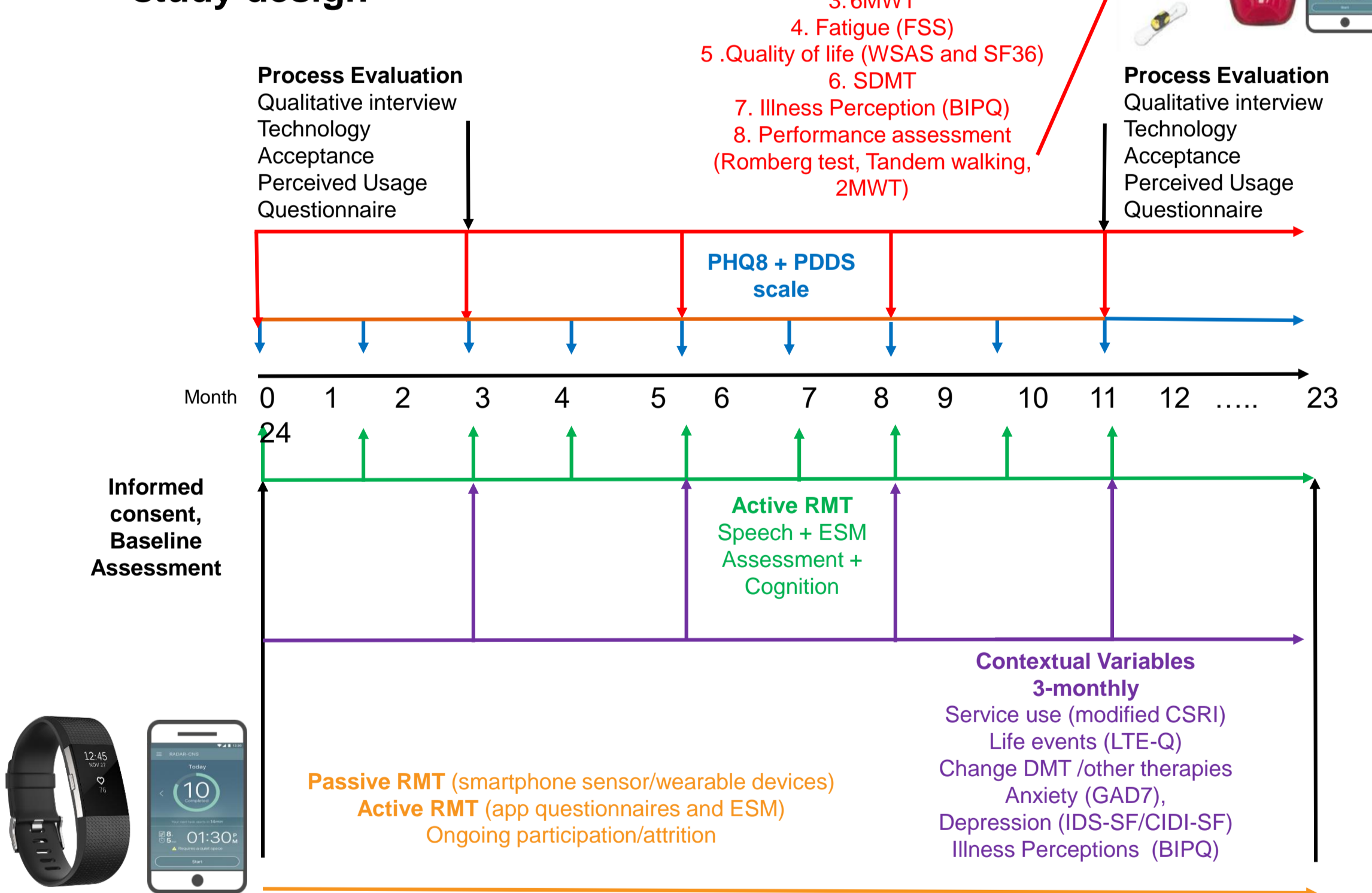
The aRMT consists of self-reported questionnaires and brief tests to evaluate different aspects of mood changes, disability, fatigue, and cognition. Questionnaires and tests will be delivered through the smartphone app (RADAR-CNS active app) and through the web-based platform (REDCap) at fixed time points.

MS disability and fatigue study

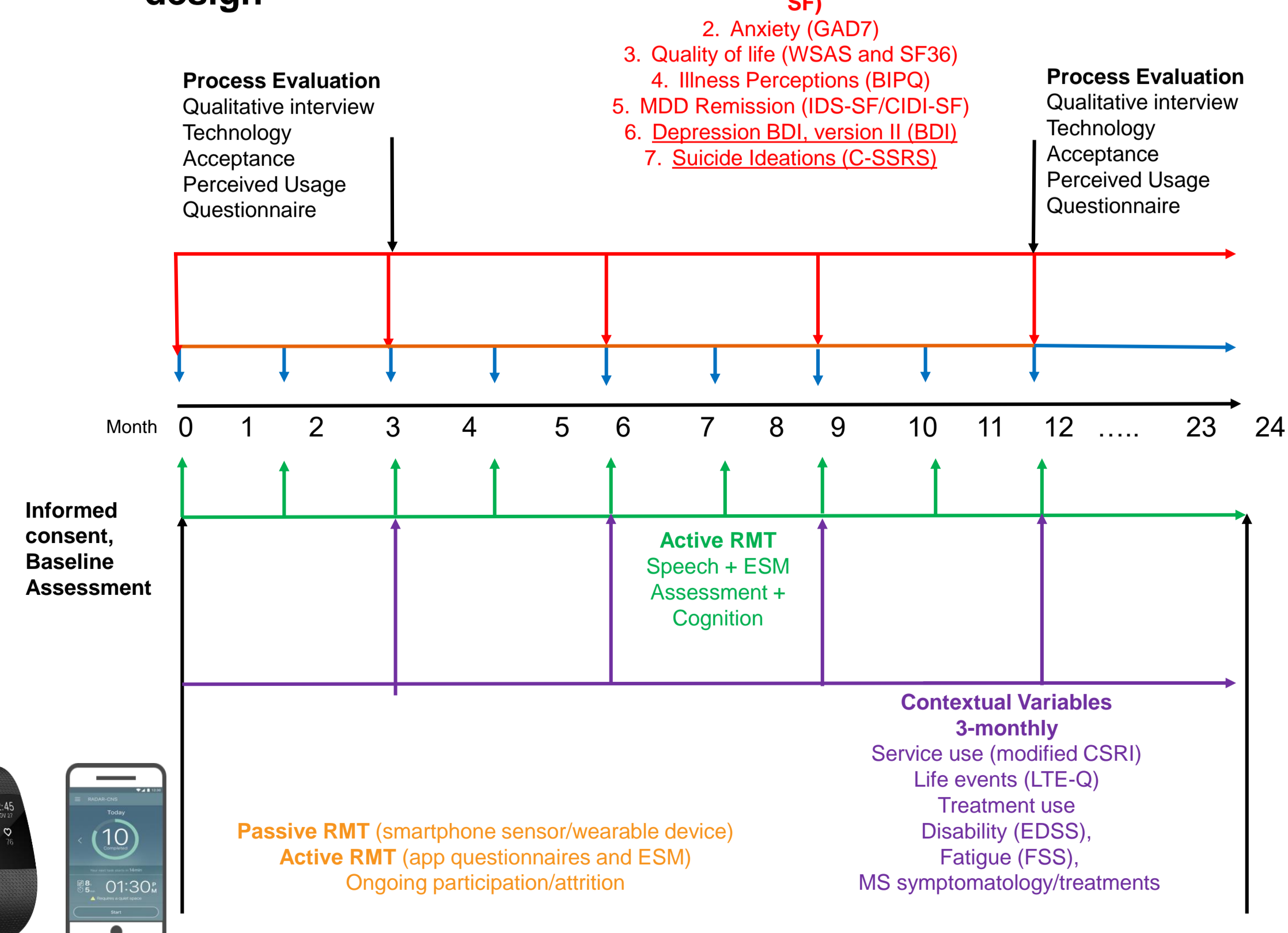
STUDY DURATION: 24 months
SAMPLE SIZE: 300 with a RR MS and 100 with a Secondary Progressive SM (SPMS)

AIM: The major aim is to evaluate if RMT represent a reliable and feasible instrument to better characterize the disability status of person with MS. Its objectives are to determine the usefulness of RMT as a possible tool to qualify the disability level of patients and locomotor function and to detect longitudinal changes over time and to determine the usefulness of RMT to detect fatigue and its possible predisposing factors compared with standard evaluations.

MS Disability and Fatigue study design



MS Depression study design



MS Depression study

STUDY DURATION: adaptive design, all patients will be followed for at least six months and for a maximum of 24 months.
SAMPLE SIZE: 240 newly diagnosed patients

AIM: It aims at evaluating if the remote monitoring technology (RMT) represent a reliable and feasible instrument to better identify and characterize mood changes in newly diagnosed MS patients. Its objectives are to determine the utility of RMT in improving the detection of mood changes, to determine whether multi-parametric RMT can provide information predictive of depression and to determine the incidence of depression in this specific MS population.

CONCLUSIONS

We believe that remote monitoring of persons with MS in ecological condition will give us a full picture of a person's condition at a level of detail that was previously impossible.

This offers the opportunity to detect changes in disability, fatigue and mood before the individual themselves is aware of it. This could help to predict – or even avoid – relapse and disease progression

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innovative medicines initiative

