Workshop 3: RADAR Remote Assessment of Diseases And Relapse

Prof T F Meert, PhD., PhD.

Senior Director External Innovation, Discovery Sciences

Universities: KUL, UA, UH, UG, VUB

Nationalen Informationsveranstaltung zur Innovative Medicines Initiative (IMI2)

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Introduction

- Remote Assessment for Disease and Relapse (RADAR) is a candidate project as part of the IMI2 joint undertaking
- The EFPIA research directors group have endorsed the RADAR co-ordinators to explore the interest from other companies to participate in this project
- This presentation provides an straw man proposal for the RADAR project for discussion among (EFPIA) partners

Remote Assessment of Diseases And Relapse (RADAR)

Overall objective

The overall objective of the RADAR project is to develop and validate the science and regulatory approach of using a remote assessment approach to derive biosignatures that characterise disease and predict changes in disease state to support the pre-emption of treatment

To deliver on this objective, we anticipate the following deliverables:

1. The prosecution of a series of observational studies in different therapeutic areas to assess the utility of remote assessment technology in a) characterizing disease and disease fluctuations and b) feasibility and patient compliance

2. The development of novel biosensor technology that both remotely and passively measures physiological and behavioral endpoints

3. An improved understanding of the regulatory pathways for using remote assessment in healthcare

4. The development and publishing of standards for Information Exchange that enable seamless integration of sensor, data capture, data management, & analysis technologies

5. The development of an open source reference platform to enable the collection storage and analysis of remote assessment data

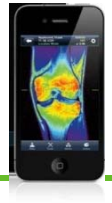
We clearly need to Δ the Paradigm from *Diagnose & Treat* to *Predict & Preempt*: many challenges…….

- Need to be able to **quantitate** physiological/pathophysiological parameters, and **intervene before transitions into more severe disease states**

- Clinic visits are **time-limited evaluations** based on **subjective observations** of both the patient and the HCP

- **Changes in disease state** for each of these diseases can occur on timescales **much shorter than the interval between clinic visits**

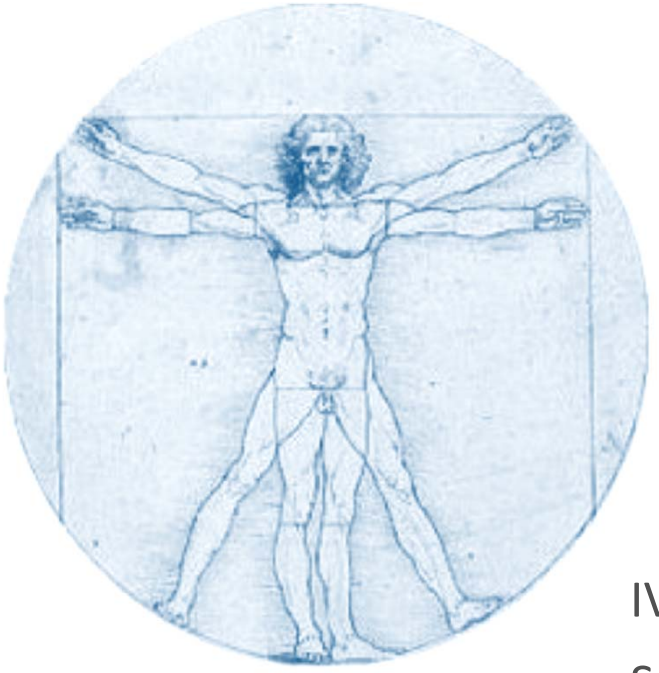
- Through technological advances over the last decade it is now possible to **objectively, remotely, and continuously** measure aspects of patient **physiology, behavior and symptoms**



Emerging Technology for Continuous Patient Assessment

Physiology

ECG
HR/HRV
Respiration
Skin temp
Activity/Sleep
O2 sat



Behavior

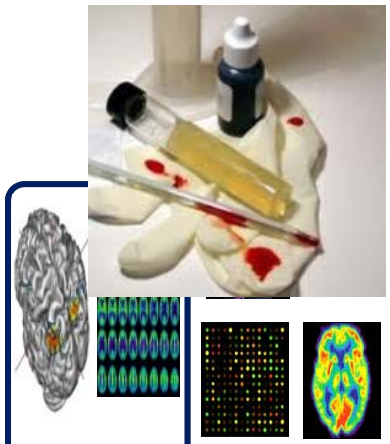
GPS
Talk patterns
Text patterns
Activity/Sleep

Symptoms

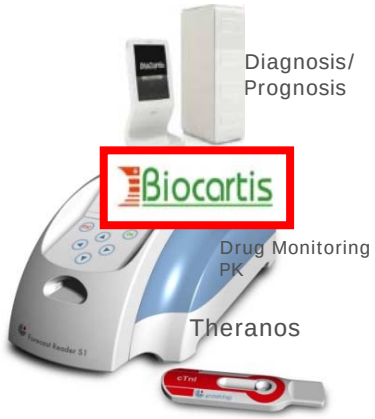
IVR

Smartphone
Symptom
assessment

Escalating Data Challenge:
How the types of data we collect is evolving.....



Discrete Centralized



Discrete Decentralized

Non-Discrete Decentralized

- ‘Point–of-Facility’
- Discrete, Structured, Information Events
- Controlled Populations (clinical trials, longitudinal disease studies)

- ‘Point-of-Need’
- Real-Time Multiplexed Read-Outs (Diagnostic, Prognostic, Drug Monitoring)
- Distributed Populations in Clinic Settings

- Semi-Continuous
- Semi-Structured data
- Multiple sources

....So Data is Evolving to Continuous Streams of Information

'Quantified Self'

Mobile Computing Devices

Remote Monitoring Sensors

flickr SQUIDOO upcoming Google twitter yelp RSS XML YouTube podcast.net TechCrunch facebook Google HubSpot del.icio.us reddit LinkedIn digg dzone

Social Media

Brain Fitness Centers

New DataTypes
New Tools for:
- Information extraction,
- Knowledge representation
- Integration, Data Mining

On-Patient
- Actigraphy
- Speech
- Eye movement
- EKG, HR, HRV
- EEG
- Sleep
- Galvanic skin response
- O2 Sat
- Skin temperature

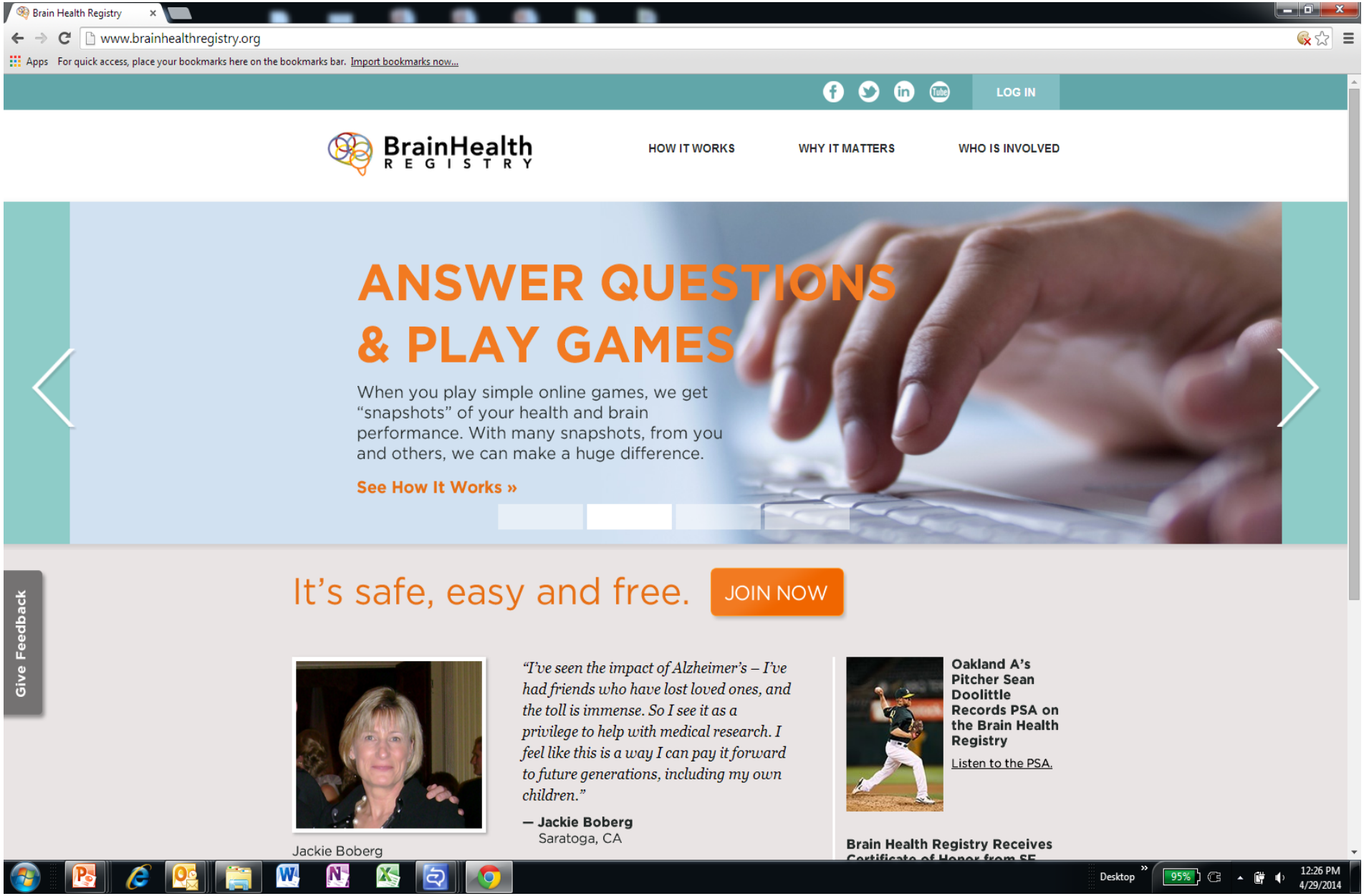
Off-Patient
- Fixed cameras
- Bed embedded sensors
- Computer usage
- Phone usage
- Refrigerator usage
- Motion sensors

As we derive signatures of disease/relapse from the new continuous data types, *we don't have to start from scratch*

EWSQ 10 Patient Version	Potential Technology Correlates
Has your sleep worsened since the last evaluation?	Sleep EEG Actigraphy
Has your appetite decreased since the last evaluation?	
Has your concentration, e.g., ability to read or watch TV, worsened since the last evaluation?	Eye tracking Computer tracking
Have you experienced fear, suspiciousness, or other uneasy feelings while being around people since the last evaluation?	Skin Conductance Heart rate / variability
Have you experienced increased restlessness, agitation, or irritability since the last evaluation?	Actigraphy Galvanic Skin Response Speech Analysis
Have you noticed that something unusual or strange is happening around you since the last evaluation?	
Have you experienced loss of energy or interest since the last evaluation?	Actigraphy Cell phone location
Has your capability to cope with everyday problems worsened since the last evaluation?	
Have you experienced hearing other [illegible] nobody was around since [illegible]	
Have you noticed [illegible] since the last [illegible]	

these technologies use prior clinical knowledge, as well as the *known history* of the patients

Case Study I: Brain Health Registry
Digital, Distributed Longitudinal Assessment of Cognition

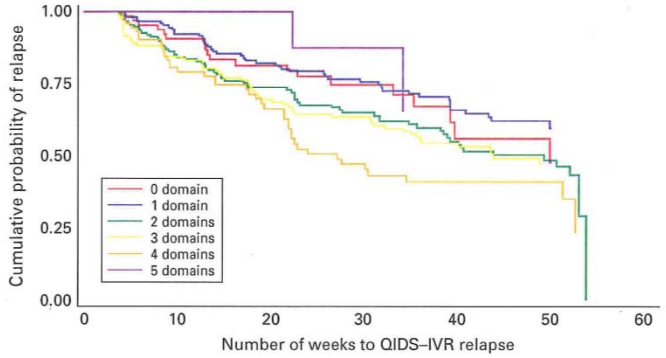


Case Study II: Remote assessment of maintenance of treatment response in MDD patients

a. **Identify patients who may be at increased risk of near term relapse**
b. **Enable measurement-based changes to maintenance regimen**

STAR-D: Subjects w/ greater number of residual symptoms after remission of MDD had a greater probability of relapse

Nierenberg et al., 2010



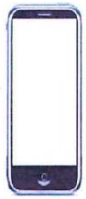
Few studies have addressed predictors of near term relapse or onset of relapse prodrome in MDD

Behavioral assessment

Motor activity, sleep via actigraphy devices

Speech, voice via phone

Track trends



App collects and tracks behavioral data

Assess self-report

Validated questions / scales (e.g., QIDS-SR) administered via smartphone

Transmit information to clinician

Threshold level of decline prompts alert to physician

RADAR Workshop

Kick-starting a coalition on Remote Assessment of Disease and Relapse
Workshop 23-05-2014

efpia
European Federation of Pharmaceutical Industries and Associations

Innovative Medicines Initiative

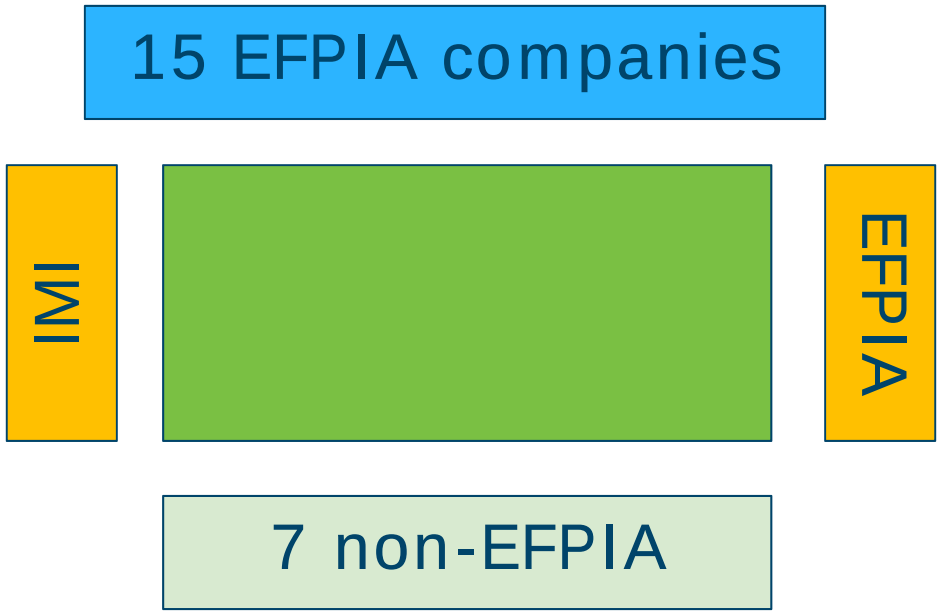
Dear Sir/Madam,

We would like to kindly invite you to join the Innovative Medicines Initiative – RADAR Workshop - Kick-starting a coalition on Remote Assessment for Disease and Relapse - which will be held on 23 May 2014, Brussels.

Venue:
Stanhope Hotel
Rue du Commerce 9
B-1000 Brussels

Radar kick-off meeting

Kick-starting a coalition on Remote Assessment of Disease and Relapse
Workshop 23-05-2014



- RADAR is a candidate project as part of the IMI2 joint undertaking

Remote Assessment of Diseases And Relapse (RADAR) - AIMS

- **Develop and validate the science** of using **biosignatures to characterise disease** and predict changes in disease state **through observational studies**
- Encourage innovation and development of **novel biosensors** and the associated **knowledge management** technology
- Understand the **regulatory pathways** for using remote assessment in healthcare
- Develop standards for Information Exchange that enable **seamless integration** of sensor, data capture, data management, & analysis technologies

Why a Public Private Partnership is needed

AIM	PPP Requirement
Develop and validate the science of using **biosignatures to characterise disease** and predict changes in disease state	Requires input from EFPIA, Academia {Medical Sciences, Engineering, Infomatics}, Patient Groups for success
Encourage innovation and development of **novel biosensors** and the associated **knowledge management** technology	Requires a vibrant eco system of innovative sensor providers from both Academic and SME environment
Understand the **regulatory pathways** for using remote assessment in healthcare	Needs input from EFPIA and Regulators to understand the regulatory requirement of using such technology
Develop standards for Information Exchange that enable **seamless integration** of sensor, data capture, data management, & analysis technologies	Requires participation from Industry, Academia, SME, and Large Technology companies to provide technology that can integrate

Skills and Knowhow

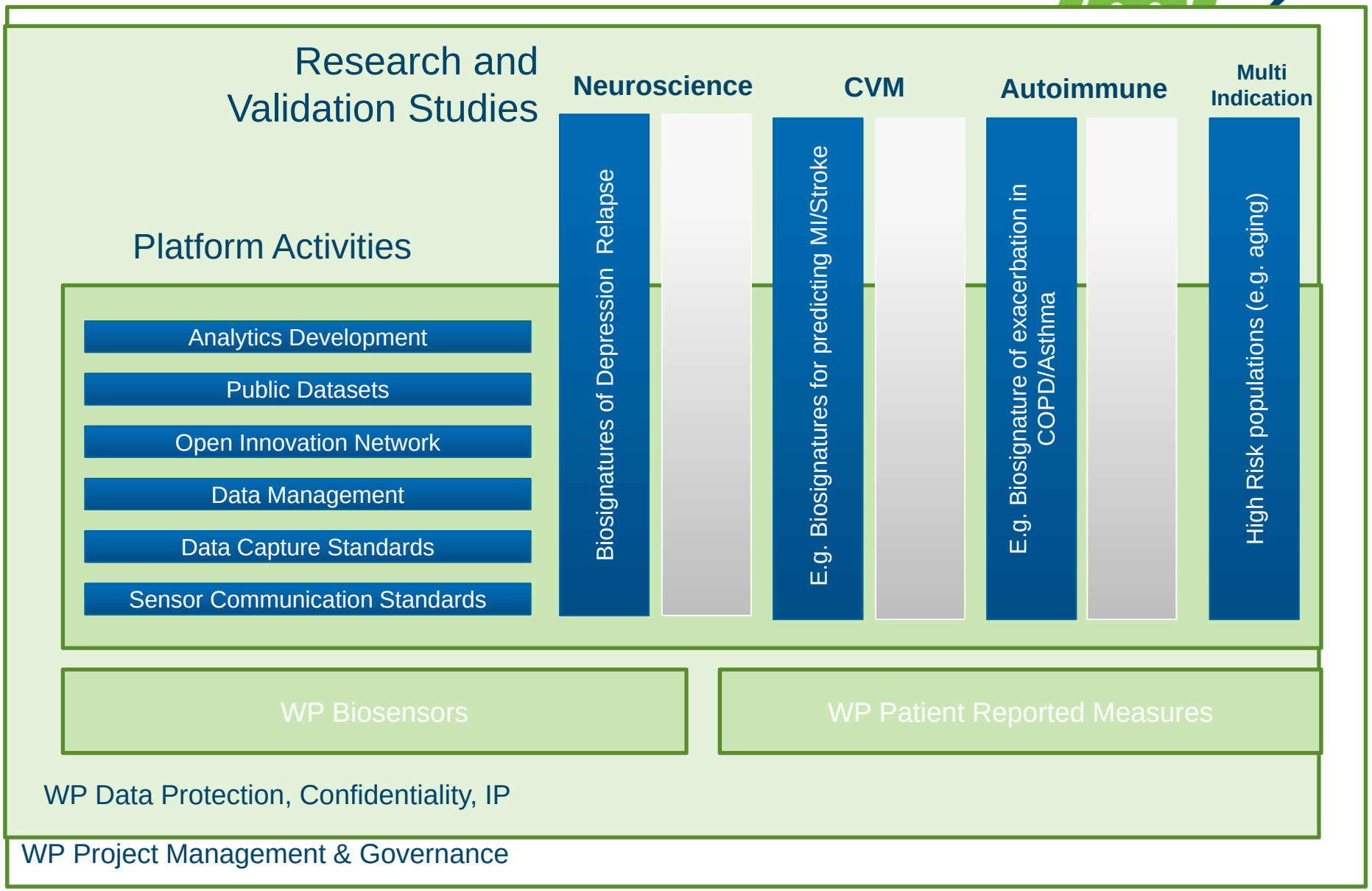
- **Contributions from EFPIA**
  - Clinical Trial Design and Operation
  - Disease Understanding from prior clinical trial
  - Preliminary Know-how about use of remote sensing in clinical trials
  - Data Management and Informatics
- **Contributions from Applicants**
  - Clinical Investigators, Biosensors Data Management and Informatics, Regulators, Patient Groups
- **Opportunities from SME**
  - This project offers a clear role for SMEs in the development in unique biosensor technology

Next Steps RADAR

- 5 Disease-area related follow-up working groups
  - CV/Metabolic
  - Diabetes
  - CNS (mood, pain)
  - Respiratory (Asthma and COPD)
  - Autoimmune (RA, MS)
- One overarching technology working group
- One work stream directed to legal aspects , patient engagement

New workshop planned: September 2nd

RADAR– Vision



Example: Technology Correlates to Clinical Parameters

EWSQ 10 Patient Version	Potential Technology Correlates
Has your sleep worsened since the last evaluation?	Sleep EEG (iVigil) Actigraphy (Hidalgo)
Has your appetite decreased since the last evaluation?	
Has your concentration, e.g., ability to read or watch TV, worsened since the last evaluation?	Eye tracking Computer tracking (Monarca)
Have you experienced fear, suspiciousness, or other uneasy feelings while being around people since the last evaluation?	Skin Conductance (Hidalgo) Heart rate / variability (Hidalgo) Cell phone location (Monarca)
Have you experienced increased restlessness, agitation, or irritability since the last evaluation?	Actigraphy (Hidalgo) Galvanic Skin Response (Hidalgo) Speech Analysis (Hidalgo/IBM)
Have you noticed that something unusual or strange is happening around you since the last evaluation?	
Have you experienced loss of energy or interest since the last evaluation?	Actigraphy (Hidalgo) Computer Tracking (Monarca)
Has your capability to cope with everyday problems worsened since the last evaluation?	Speech Analytics (Hidalgo/IBM)
Have you experienced hearing other people's voices even when nobody was around since the last evaluation?	
Have you noticed any other of your individual early warnings signs since the last evaluation?	