Remote Assessment of Disease and Relapse (RADAR)

Topic 1 - RADAR:CNS

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Challenges in Managing Chronic Disease Today

- Physician visits are **time-limited evaluations** based on **subjective observations** of both the patient and the physician or psychiatrist

- **Changes in disease state** for each of these diseases can occur on timescales **much shorter than the interval between physician 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**
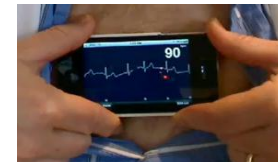
Vision of Tomorrow: Next Generation Patient Centric Data
MOVE FROM DIAGNOSE AND TREAT TO PREDICT AND PREEMPT

Multi-Platform Biomarker Data from Controlled Studies

Caregiver Reports

PubMed
National Library of Medicine NLM
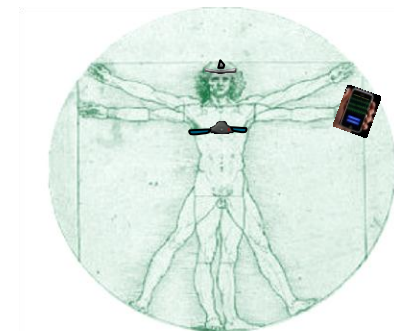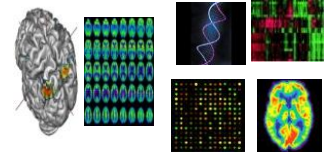
Literature
Patents
Epidemiology

Physician Notes

Patient Hospital Records Data

Predict and Preempt:

➤ relapse in depression

➤ exacerbation in MS

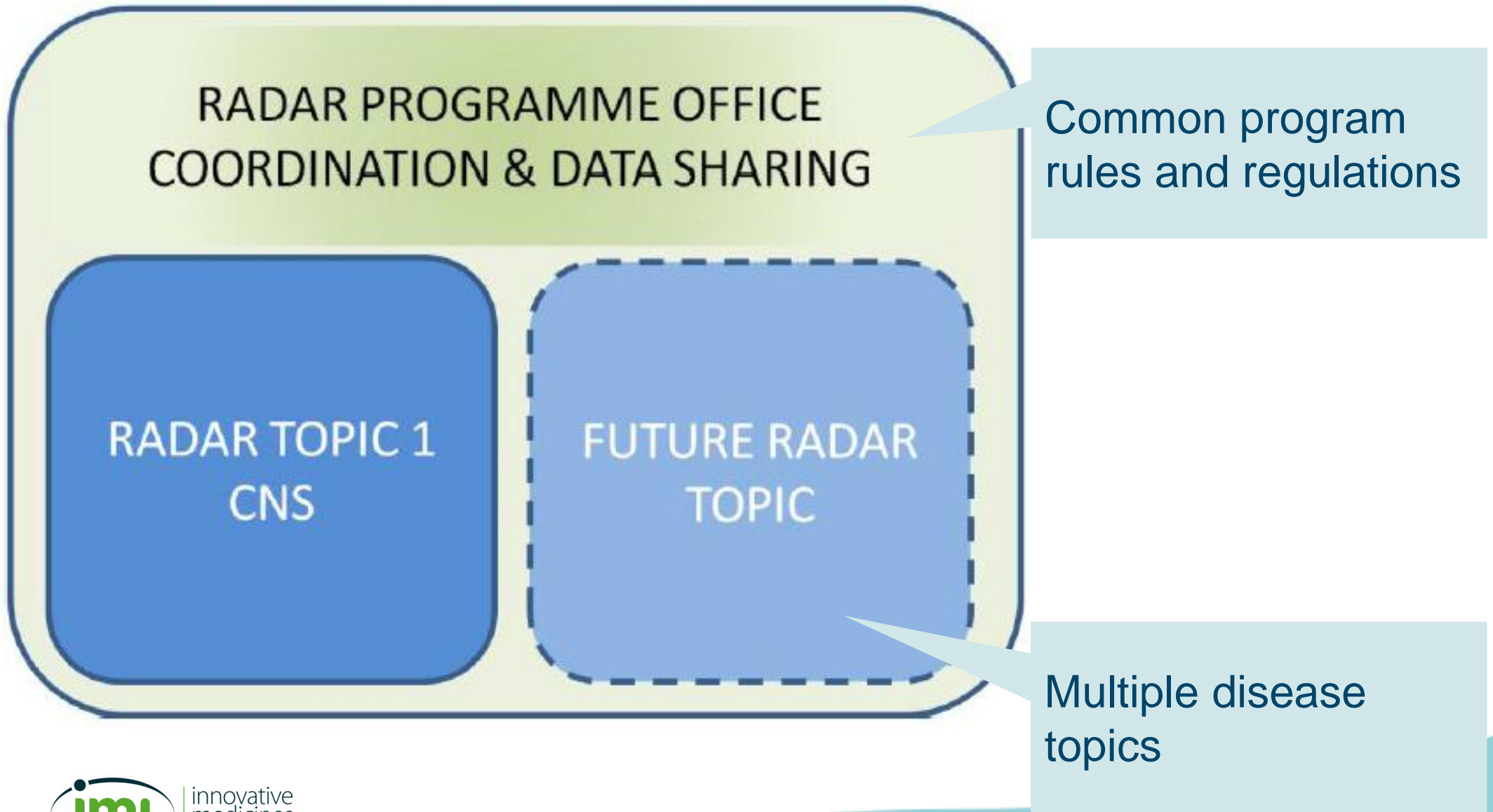➤ epileptic fit

➤ Onset of mania

➤ Psychotic break etc.

Continuous Real-Time Patient Data Home Monitoring. Remote Sensing. (Actigraphy, Physiological)

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Planned RADAR Program

Objectives of the RADAR:CNS Topic

- The aim of RADAR:CNS topic is the characterisation and prediction of changes in disease state in central nervous system (CNS) disorders via non-invasive remote sensing.

- This topic is planned to be focused on the three diseases of unipolar depression, multiple sclerosis and epilepsy. For each disease it is proposed that a non-interventional/observational study of subjects is undertaken with three objectives:
  - Characterisation of changes in disease state
  - Characterisation of changes in disease state due to drug effects
  - Prediction of change in disease state from remote sensing data

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Need for public-private collaboration

- Development and validation of remotely sensed biosignatures does not fit traditional business models of pharma or technology companies. Requires pre-competitive collaborations.

- Requires innovation and development across multiple disciplines such as: biosensors, streaming analytics, data science, clinical trial designs etc. This requires a vibrant eco system across academic and industry partners.

- Launch, clinical adoption and patient acceptance will require alignment with heathcare authorities, physician groups, regulators and patient advocacy groups.

Suggested architecture of the project

Cohort 1
Depression

Cohort 2
Epilepsy

Cohort 3
Multiple Sclerosis

RADAR:CNS Remote Assessment Tools
- Sleep architecture
- Physical Activity
- Speech
- Cognition
- Social Connectivity
- Memory

Of subjects of all of the target diseases

Regulatory & Policy:

How can biosignatures impact patients and care

Data Management and Modelling

Project Management

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Expected contributions of the applicants

- **Academic, clinical and disease area experts**: patient cohorts, design and conduct of clinical studies (end-points, inclusion criteria etc.). Interpretation of results for clinical significance.

- **Device and sensor companies:** latest remote assessment technologies that could be further developed or modified for use as intended in CNS diseases.

- **IT/Analytics partners:** data management architecture, state-of-the-art algorithms to derive bio-signatures of symptoms and relapse from collected streaming data.

- **Regulatory and health-care systems experts**: definition of regulatory and clinical-care pathways respectively for the remote assessment solutions.

- All consortia partners are expected to actively participate in publications to raise awareness and gather further input from the larger scientific community.

Expected (in kind) contributions of EFPIA members

- **Clinical/Regulatory expertise**: Janssen, Lundbeck, BiogenIdec, Merck and UCB have years of experience developing therapeutics in CNS disease areas, and will bring expertise related to clinical study design execution and regulatory approval pathways
- **Clinical Data:** Industry members will bring bio-sensor, clinical and patient self-report data collected in observational studies in relevant patient populations
- **Data Capture/ Data Management/Analytics/Data mining**: Industry consortia members will bring expertise in data management and data-mining through their internal IT and Informatics groups
- **Devices:** Industry partners will bring available devices to measure actigraphy, stress (galvanic skin response), cognition and other relevant parameters.

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Key "points to consider" for applicants

- How will you demonstrate that you can design and initiate the appropriate clinical studies to evaluate remote assessment real world cohorts?

- How will you ensure that sufficient patients will be recruited across all three patient cohorts?

- How will you enable the entire consortium to work with regulatory agencies ? How can discoveries made be translated into new models of care ?

- How can you provide a common technology tool kit for all three cohorts ?

Key deliverables of the full project

➤ Development of candidate bio-signatures that predict relapse and track disease state changes using parameters such as: sleep architecture, physical activity, speech, cognition, social connectivity, memory

➤ Development of algorithms and analytic infrastructure suitable for collecting and analysing data from RADAR-CNS studies

➤ Actionable privacy and usability parameters that would drive eventual uptake of and adherence

➤ Delineation of regulatory pathways necessary for approval of remote sensing solutions in real-world patients.

➤ Delineation of clinical care pathways and use cases of remote-sensing solutions, i.e. how they impact and interface with stake-holders such as patients, care-givers, case-managers, physicians etc.

What's in it for you?

- Academic researchers: novel ways to characterize disease and patients (digital biomarkers). Access to new types of data.

- SMEs: advance sensor technologies and IT infrastructure to fulfil unmet clinical leads in collaboration with experts, access to patients

- Patients' organisations: ability to harness and control the use of their own data and revolutionary advances in sensor and mobile computing technologies towards advancement of their health and well-being

- Pharma and tech companies: new ways to engage and understand patients. Move to a predictive and preemptive paradigm

Questions?

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