



Innovative Medicines Initiative

Remote Assessment of Diseases And Relapse (RADAR)

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efpia

Introduction

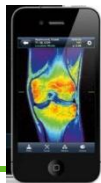


- Remote Assessment for Disease and Relapse (RADAR) is a candidate project as part of the IMI2 joint undertaking
- The EFPIA research directors group have endorsed the RADAR co-ordinators to explore the interest from other companies to participate in this project
- This presentation provides the current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

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**



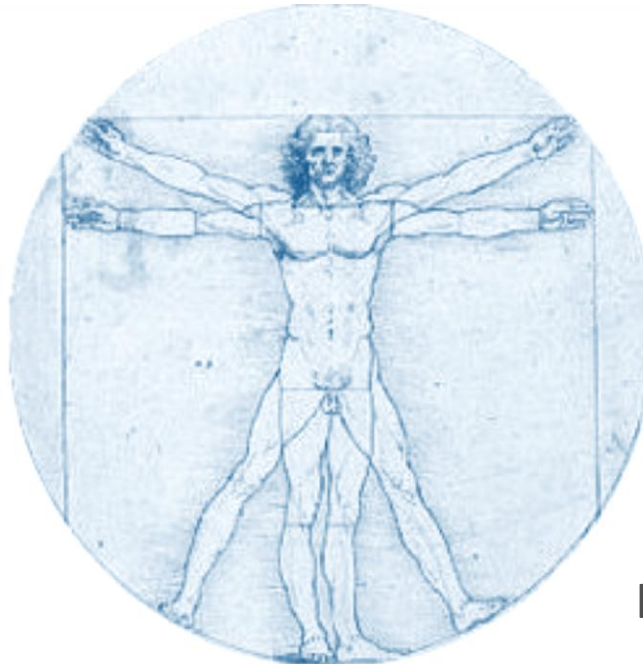
Emerging Technology for Continuous Patient Assessment



Physiology



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



Behavior



- GPS
- Talk patterns
- Text patterns
- Activity/Sleep

Symptoms

- IVR
- Smartphone Symptom assessment



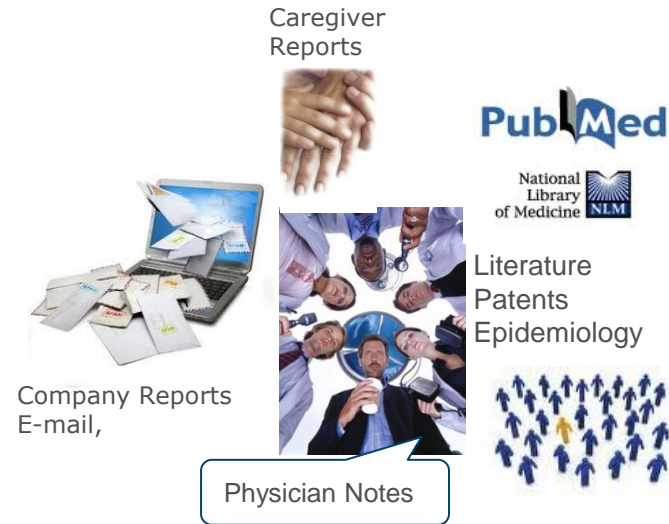
Escalating Data Challenge: From Discrete Information Events To.....



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 Physician Settings

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

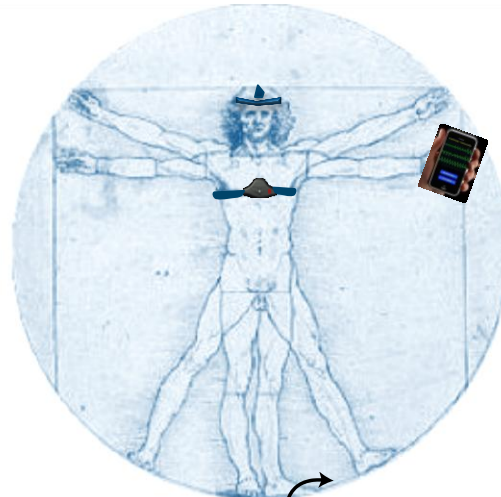
...Continuous Streams of Information 'Quantification of Man'



Mobile Computing Devices



Social Media



Remote Monitoring Sensors

New Data Types, New Tools for: Information Extraction Knowledge Representation

Integration Mining

- | | |
|---|--|
| <p>On-Patient</p> <ul style="list-style-type: none"> - Actigraphy - Speech - Eye movement - EKG, HR, HRV - EEG - Sleep - Galvanic skin response - O2 Sat - Skin temperature | <p>Off-Patient</p> <ul style="list-style-type: none"> - Fixed cameras - Bed embedded sensors - Computer usage - Phone usage - Refrigerator usage - Motion sensors |
|---|--|



Brain Fitness Centers

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?	

Remote Assessment of Diseases And Relapse (RADAR) - AIMS



- **Develop and validate the science of using bio-signatures to characterise disease** and predict changes in disease state **through observational studies** *(basic clin research)*
- Encourage innovation and development of **novel biosensors** and the associated **knowledge management technology** *(basic tech research)*

Remote Assessment of Diseases And Relapse (RADAR) – AIMS (*cn't*)



- Understand the **regulatory and patient pathways** for using remote assessment in healthcare
(MAPPS principle)
- Develop standards for Information Exchange that enable **seamless integration** of sensor, data capture, data management, & analysis technologies
(IT/tech research)

RADAR– Vision



Research and Validation Studies

Neuroscience

Diabetes

Inflammation

Multi Indication

Platform Activities

Analytics Development

Public Datasets

Open Innovation Network

Data Management

Data Capture Standards

Sensor Communication Standards

Biosignatures of Depression Relapse

E.g. Biosignatures for predicting MI/Stroke

E.g. Biosignature of exacerbation in COPD/Asthma

High Risk populations (e.g. aging)

Biosensor Innovation

WP Stakeholder Engagement & Policy Advancement

WP Data Protection, Confidentiality, IP (pnt centric)

WP Project Management & Governance



Topic – CNS

- The aim of **RADAR-CNS** is the characterisation and prediction of changes in disease state in central nervous system (CNS) disorders via non-invasive remote sensing.
 - There is a focus on Multiple Sclerosis and Epilepsy (*possibly Pain too*) all with a common comorbidity in depression.
 - For each disease 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 change in disease state from remote sensing data*
 - Across all three disease areas, a common set of measures and measurements tools is used to track:
 - sleep architecture, physical activity, speech, cognition*
 - social connectivity, memory of subjects*
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Topic – Diabetes

- The goal of **RADAR DIABETES** is to stimulate innovation in technologies that can help patients manage diabetes.

Examples of innovative technologies could be:

- **Bio-sensors** which help to close the loop between patient activities and diabetes control
 - **Algorithms** which help predict short term events such as a hypoglycemic event, or long term events such as a complication
 - **Technologies** helping patients to modify their lifestyle behavior (diet, exercise, medication adherence)
- The project will focus on technology innovation as well as on structural enablers to implement innovative solutions in clinical practice.
 - In particular the regulatory and legal frameworks for the use of bio-sensors, predictive algorithms and engagement technologies will be addressed.
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Possible Future Topic – Respiratory: COPD

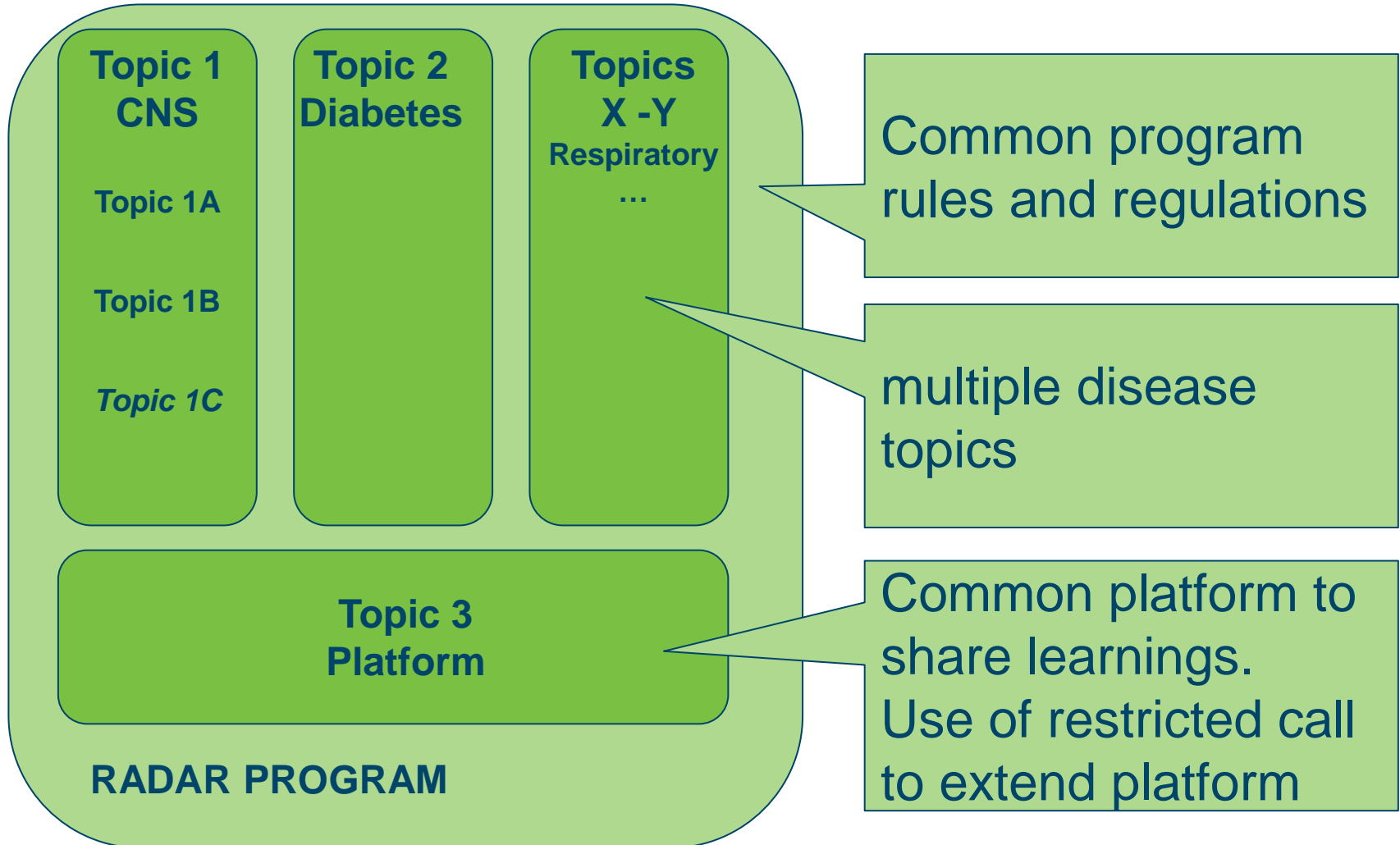


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- Management of patients in a “real world setting”, with an aim of utilising **novel monitoring** (mobile or device centric) **technology** to help patients better manage their condition, including ability to forward predict changes in asthma control or COPD exacerbation risk.
 - A **platform** to securely acquire & perform analytics on **data** in a real world setting and develop measures of real world effectiveness, including **regulatory pathways** for acceptance of the measures in development of new medicines.
 - The development of a **device** (e.g. modified inhaler) that provided measurement and recording of parameters such as lung function, exhaled gases and medication use
 - Capability to measure and monitor key **digital biomarkers**, with a flexible platform for future proofing of the device, such that it is capable of measuring new digital biomarkers as they become appropriate.
 - The objective would be the ability to target the right drugs to the right patient, and to deliver the appropriate amount of drug to control the disease.
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Current Participants

- CNS
 - Janssen, UCB, Biogen Idec, Lundbeck,
- Diabetes
 - GSK, Sanofi, Pfizer, AZ
- *Respiratory*
 - *GSK, Janssen, AZ, BI*
- Technology platform: all
- *Other partners: Reach out to technology companies*

Current Portfolio Organization



Why a Public Private Partnership is needed



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

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

Radar - Summary

- **Develop and validate the science of using biosignatures to characterise disease and predict changes** in disease state
 - Deliverable: a clinical study in the area of depression
 - Encourage innovation and development of **novel biosensors** and the associated **knowledge management** technology
 - Deliverable: novel biosensors for use in future studies
 - Understand the **regulatory pathways** for using remote assessment in healthcare
 - Deliverable: Guidance from regulators about use of remote sensing
 - Develop standards for Information Exchange that enable **seamless integration** of sensor, data capture, data management, & analysis technologies
 - Deliverable: A set of standards for integration of technology in this eco-system
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RADAR
TOPIC 1
CNS

RADAR
TOPIC 2
DIABETES

RADAR TOPIC 1/2
PLATFORM, GOVERNANCE & DATA SHARING

RADAR
TOPIC 1
CNS

RADAR
TOPIC 2
DIABETES

RADAR TOPIC
4 e.g.
RESPIRATORY

RADAR
TOPIC 5
FUTURE
DISEASE
AREA

RADAR TOPIC 3: (expansion)
PLATFORM, GOVERNANCE & DATA SHARING

FUTURE
PLATFORM
EXPANSION