COntinuous Multi-parametric and Multi-layered analysis Of DIabetes TYpe 1 & 2

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Clustering Event Ambient Intelligence Advanced Technologies in Support of Healthcare and Assisted Living
Heraklion, Crete, Greece, on 26-27th September, 2013

The Commodity12 project is partially founded by the Eu.
Collaborative Project
7th Framework Programme
Priority FP7-ICT-2011-7
Information Society Technologies
Proposal No 287841

http: //www.commodity12.eu/

COMMODITY12 - Facts

- **7th Framework Programme** – Priority 2 "Information Society Technologies"
- **Call identifier:** F P 7 - I C T - 2 0 1 1 - 7
- **Strategic objective:** ICT-2011.5.1.b: Personal Health Systems (PHS)
- **Contract No.:** 287841 – COMMODITY12
- *Enlarged project: COMMODITY12-enlarged*
- **Instrument Type:** Small or medium-scale focused research project (STREP)
- **Duration:** 01.10.2011 – 30.09.2014 *(enlarged: 31.12.2014)*
- **Community financial contribution:** 3.722.000 € (max.) *(enlarged: 4.051.000 (max))*
- **Project Management:** German Research Centre for Artificial Intelligence (DFKI)
- **9 Partners** *(enlarged: +1 partner)*

COMMODITY12 - Consortium

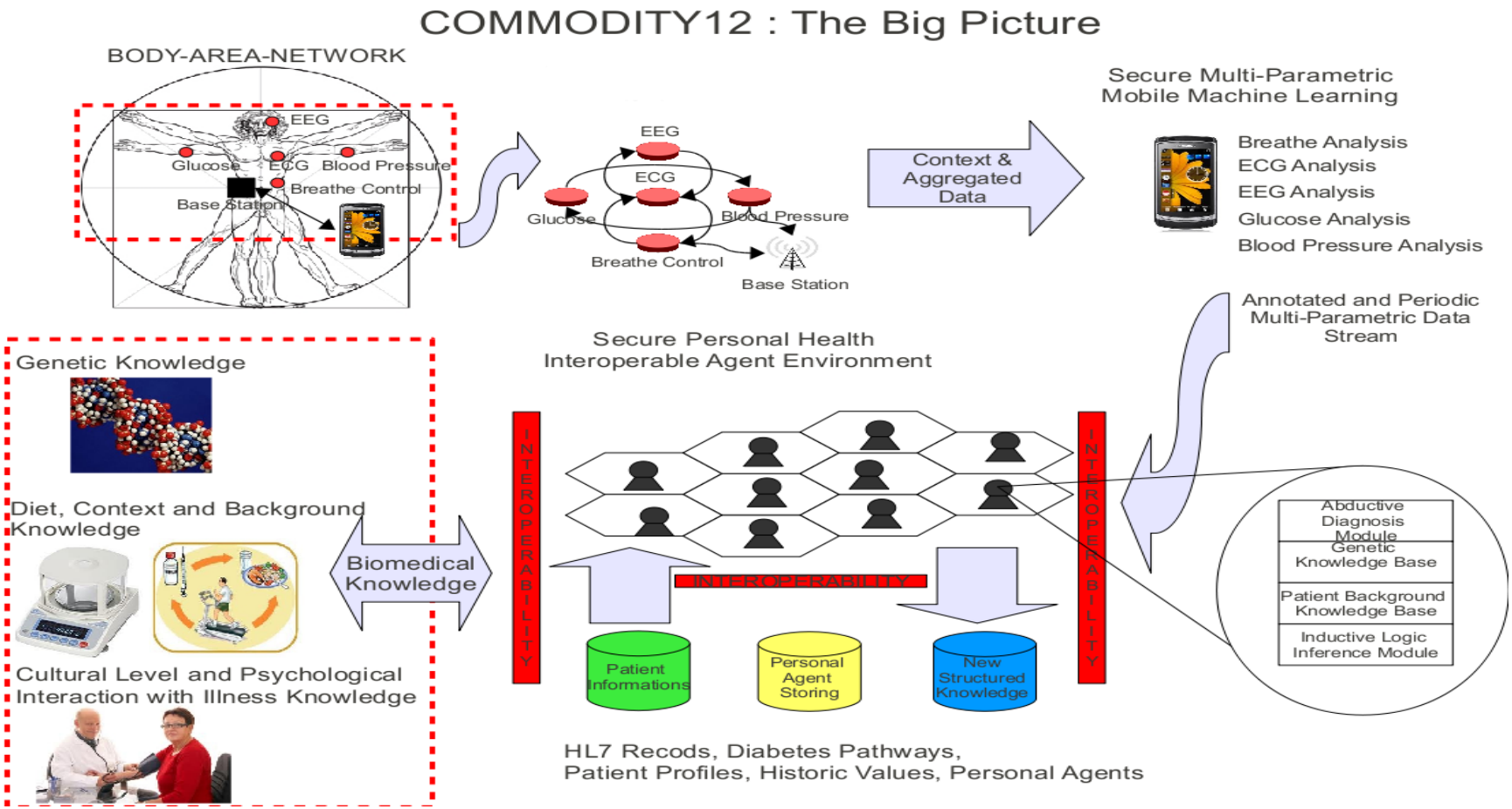
- German Research Center for Artificial Intelligence - DFKI (Germany) (Co-ordinator)
- Haute Ecole Spécialisée de Suisse Occidentale (Switzerland)
- Imperial College of Science, Technology and Medicine (United Kingdom)
- Royal Holloway and Bedford New College (United Kingdom)
- Universytet Medyczny W Lodzi (Poland)
- BodyTel Europe (Germany)
- Hospices Cantonaux CHUV (Switzerland)
- Centre National de la Recherche Scientifique (France)
- Portavita BV (The Netherlands)
- *JOŽEF STEFAN INSTITUTE (Slovenia) –enlarged project*

COMMODITY12 - Vision

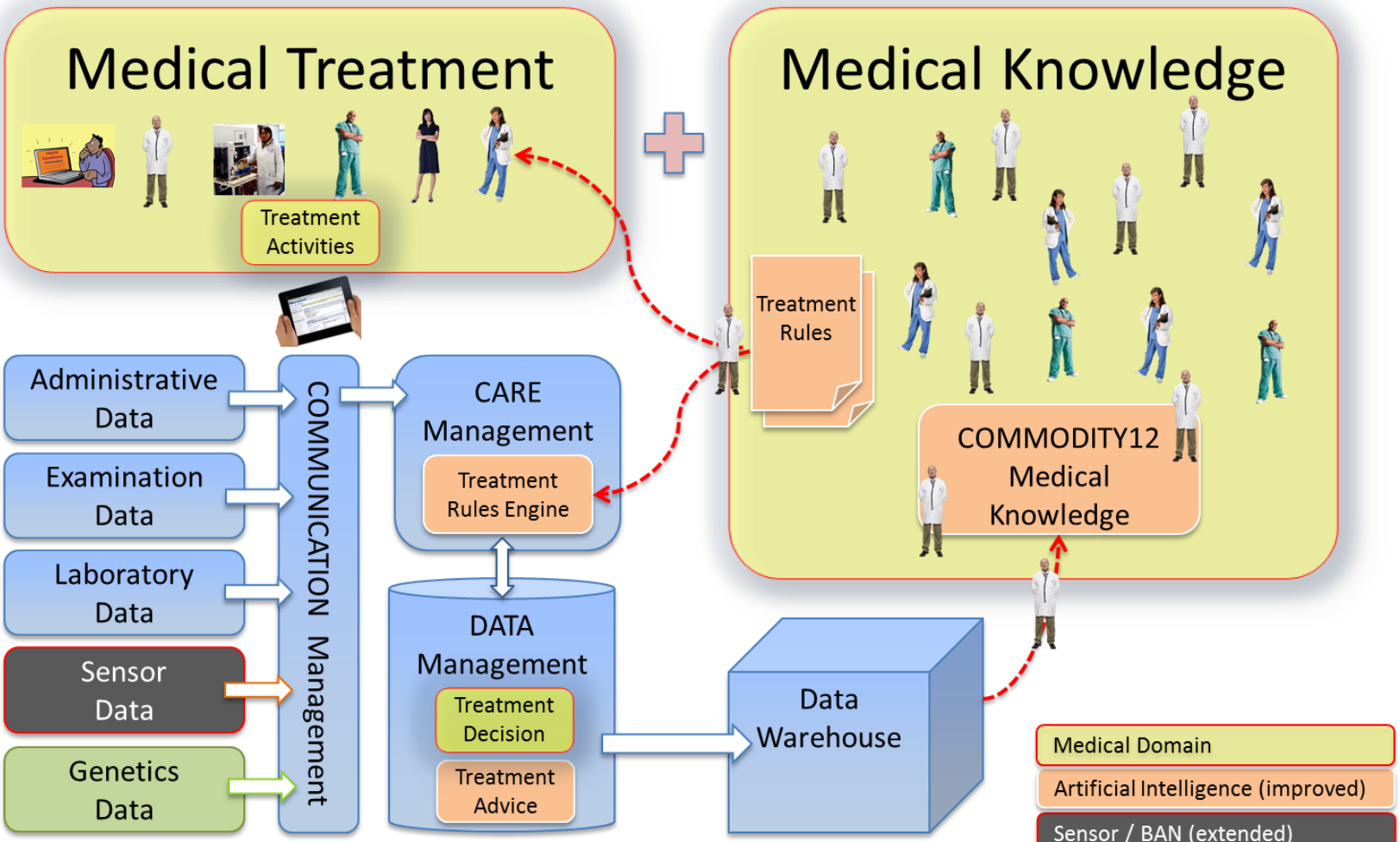
COMMODITY12 aims to design, build, and validate an **intelligent system** for the **analysis** of **multi-parametric medical data**. It will uptake the existing cutting-edge technologies and extend these technologies by combining state-of-the-art networks, software interoperation, and artificial intelligence techniques in order to realize the concept of **translational medicine** by means of a Personal Health System.

Moreover, the COMMODITY12 system will build a new level in **patient empowerment**, providing the tools for self-management support. Indirectly, this system will also help wider implementation of Personal Health Systems, reinforcing leadership and innovation capability of the European industry in that area.

COMMODITY12 – Big Picture

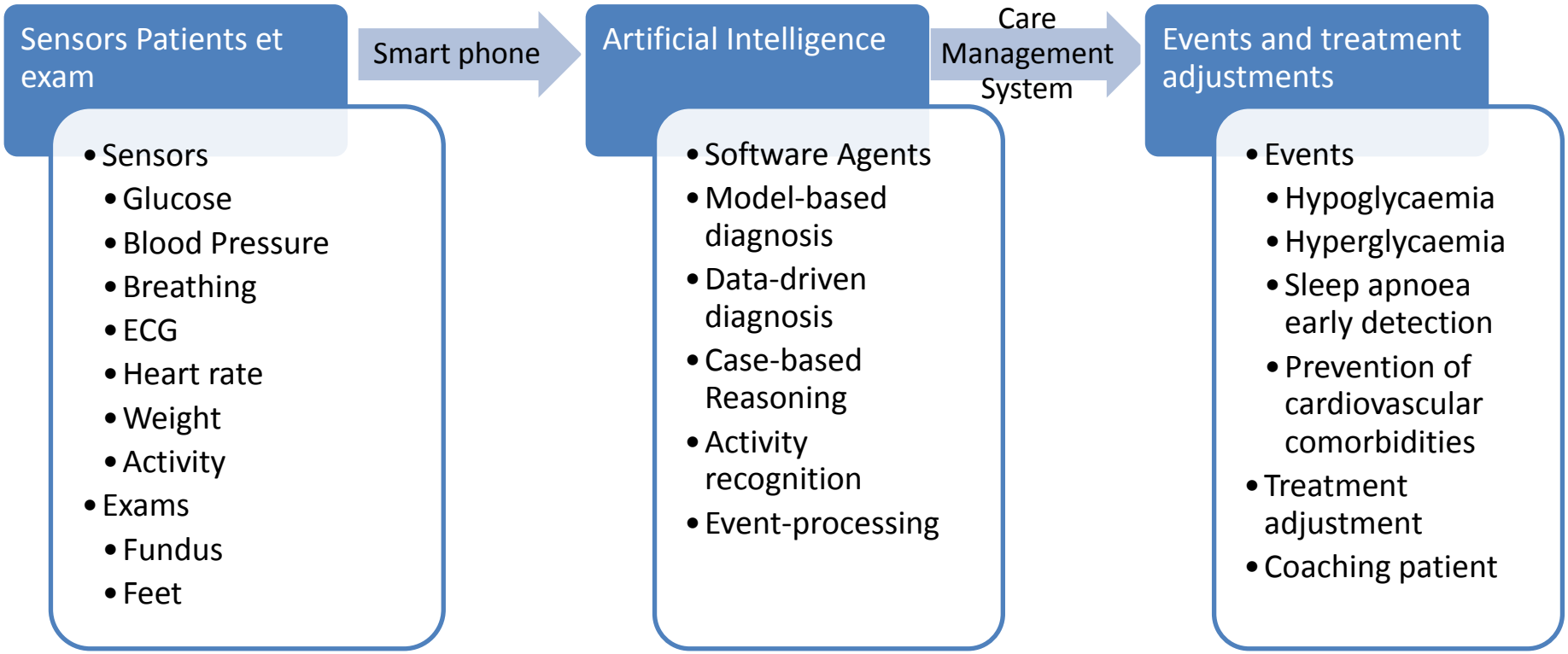


Architecture Commodity12

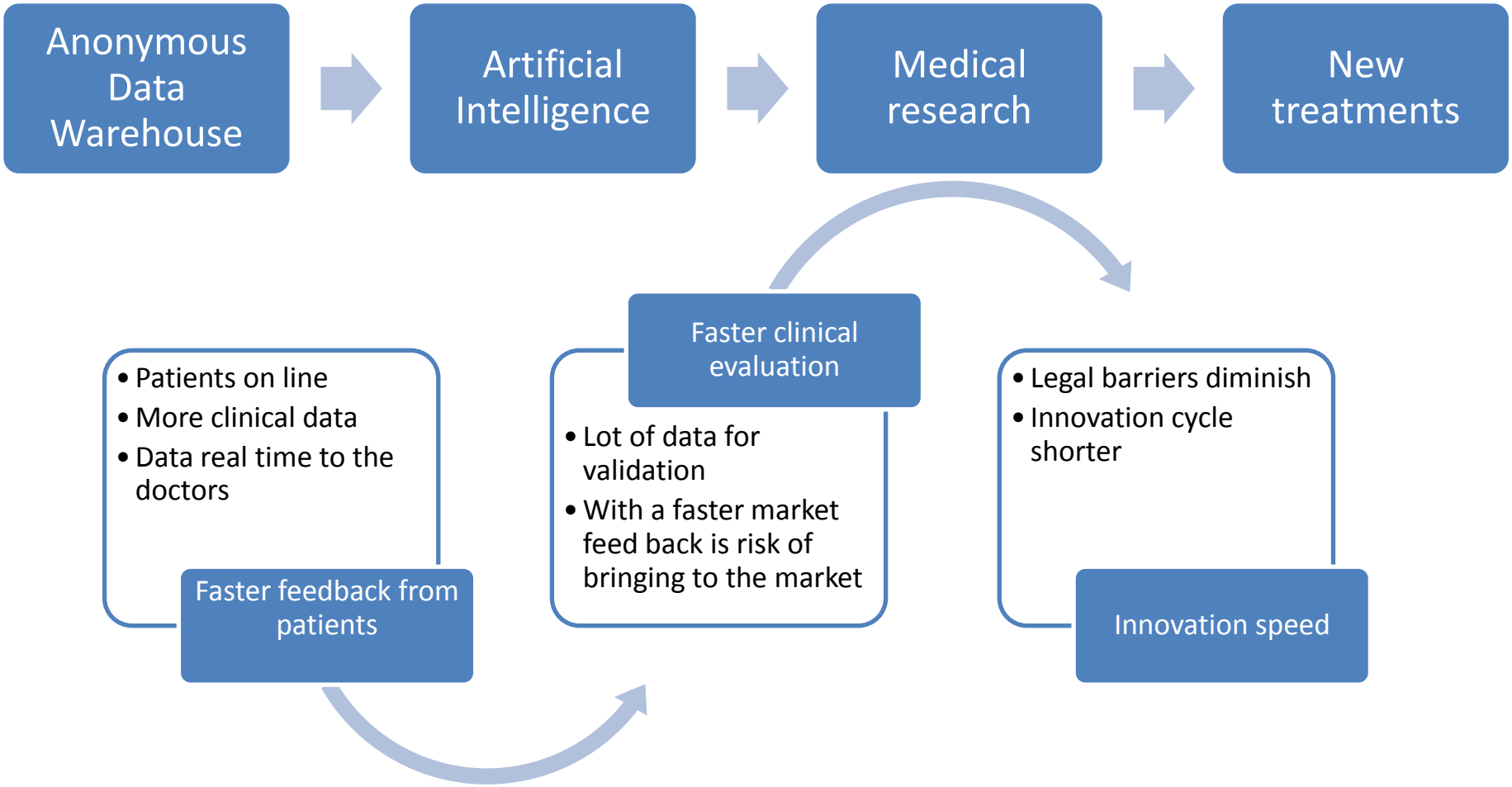


Logical Structure for Dissemination Version 1.0

Impact on the treatment chain



Impact on medical innovation



Challenges Commodity12

- Patient acceptance of the body sensors
- Validation and acceptation by the users of Artificial Intelligence
- Compliance of the platform with European laws (Medical Devices Directive)
- Usability of the different modules
- Internal compatibility and external interoperability of the platform
- Sustainability of the platform

Medical characteristics of COMMODITY12 system

- Helps healthcare professionals in analysing medical data
- Empowers the patients in self-management of their disease
- Designed for DM1 and DM2 patients
- Takes care of cardiovascular comorbidities

COMMODITY12 system algorithm

Medical knowledge based on:

- Current guidelines
- Results of the focus studies
- Analysis of large databanks

Along the system use, new knowledge will be accumulated!

- Analysis of clinical outcomes
- Lifestyle & patient history
- Genetic factors

Clinical scenarios for C12 system

- A new DM1 patient visiting for the first time an endocrinologist
- DM1 patient with nocturnal hypoglycemia which requires an insulin pump
- DM1 patient with a Dawn phenomenon
- Overweight DM2 patient with hypertension
- Very obese DM2 patient with high cholesterol

Parameters to be used by COMMODITY12 system

Parameters of the glycemic control:

- fasting glucose – mean, % of time within target range
- HbA1c
- hypoglycemic events

Parameters allowing for detailed calculation of CV risk:

- physiological parameters
- lifestyle & patient history
- genetic factors

Other parameters

- Patient adherence

Aims of COMMODITY12 clinical trials

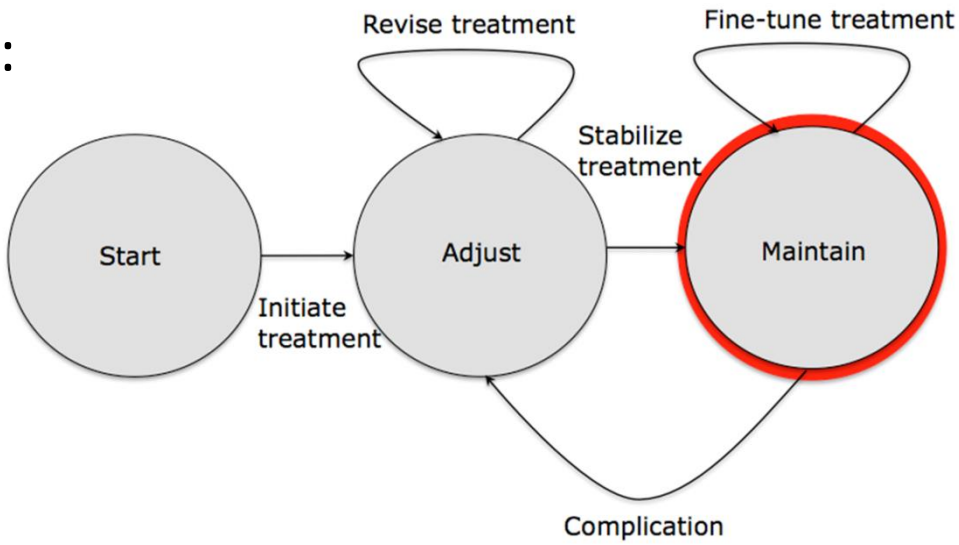
- To assess the concept and performance of C12 system in real life conditions by comparison of e-health and conventional methods of diabetes-related data management
- To test the results of the COMMODITY12 Project by performing rigorous prototype validation of C12 system with real patients.
- To lay a foundation for future commercialization of C12 system

Research questions for C12 trials:

- Is COMMODITY12 system able to provide DM patients with more effective and easier way of daily management of DM
- Is COMMODITY12 system able to provide DM patients with more effective and easier way of prevention of CV comorbidities
- Is COMMODITY12 system able to provide healthcare workers with more effective and easier way of daily management of their DM patients

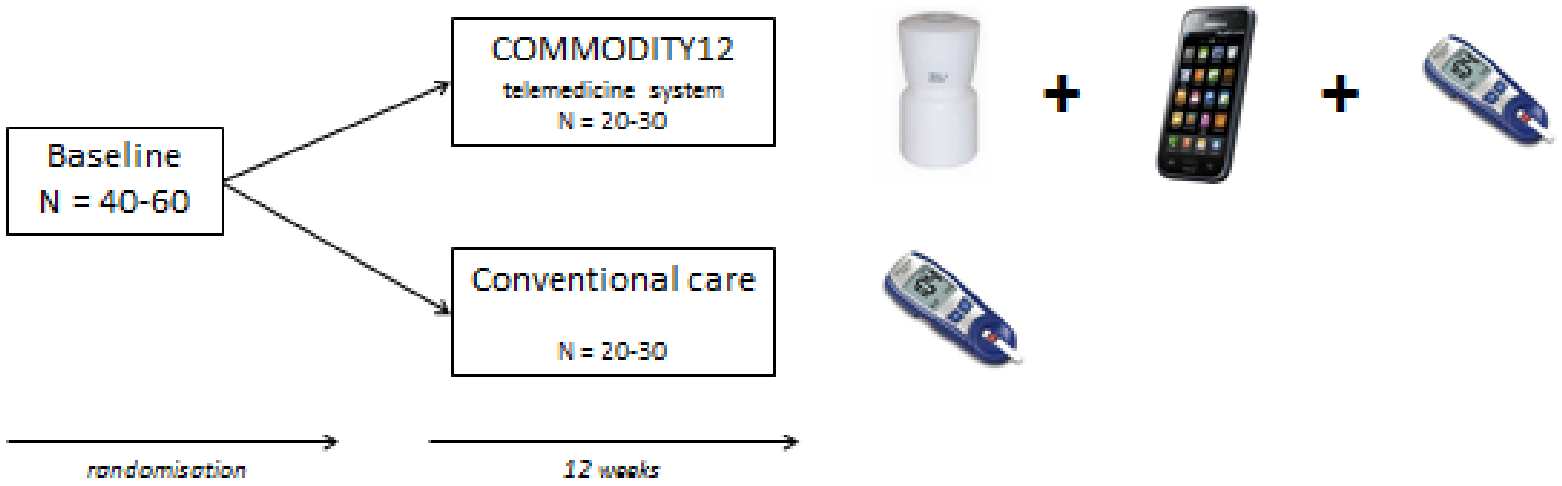
Inclusion criteria (selected)

- Diagnosis: DM1, DM2
- Phase of the treatment: maintenance therapy
- Age: 18-65
- Ability to use the cell phone and the sensors



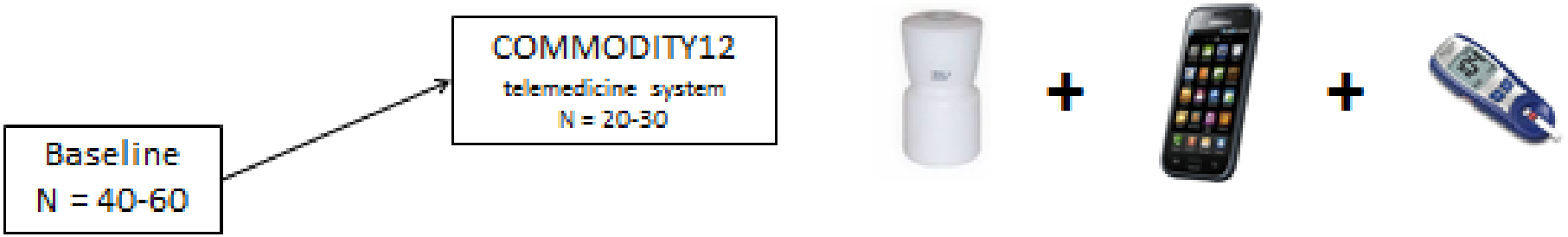
General design of the C12 trials

Trial design: randomized controlled minifeasibility trials



- DM1- 40 patients
- DM2- 60 patients

Parameters assessed in C12 trials (1)

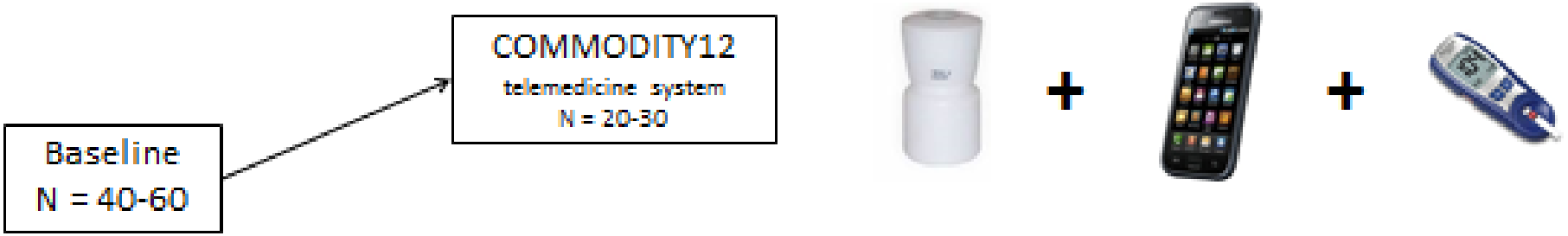


randomisation

- physiological parameters
- genetic factors
- patient history

- glycemic control parameters (incl. CGM)
- ECG, mobility, breathing
- weight
- RR
- patient adherence
- lifestyle & patient history

Parameters assessed in C12 trials (2)



- quality of life
- resources utilisation
- patients' assessment of COMMODITY12 system use (subjective & objective)
- doctors' assessment of COMMODITY12 system use (subjective & objective)

Thank you!

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