eHealth
Better Healthcare for Europe

Information Society Technologies

SEVENTH FRAMEWORK PROGRAMME

European Commission
Information Society and Media

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

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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/

ATTD
Advanced Technologies & Treatments for Diabetes
7TH INTERNATIONAL CONFERENCE ON ADVANCED TECHNOLOGIES & TREATMENTS FOR DIABETES
FEBRUARY 5-8, 2014
VIENNA, AUSTRIA

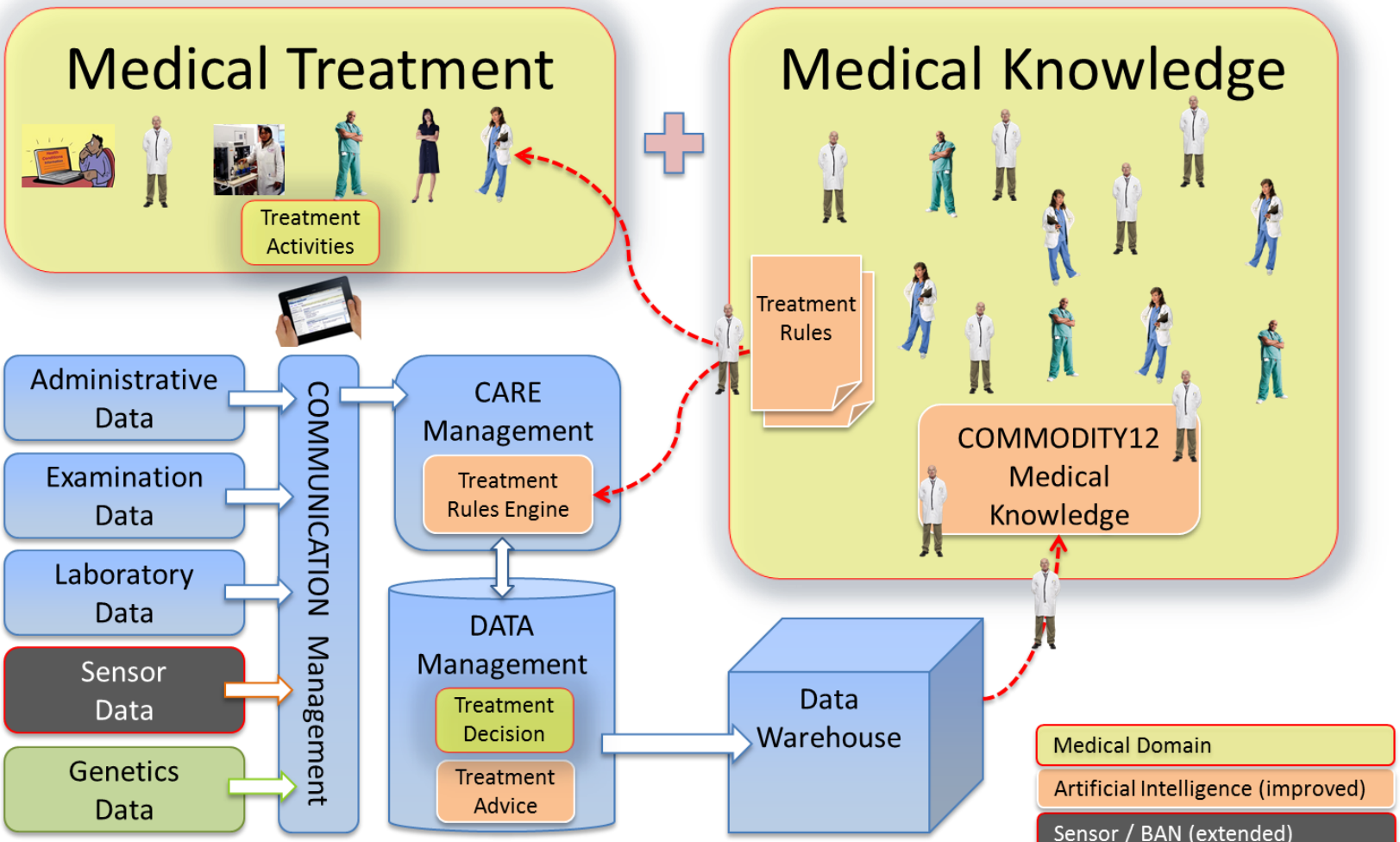
Workshop
"7th Framework Program–funded eHealth systems for diabetes"

ATTD 2014, Vienna, February 5, 2014

Plan of the presentation

- Ecosystem Commodity12
- The impact on the treatment chain
- The impact on the medical innovation chain
- Technical challenges of Commodity12
- Medical characteristics of the Commodity12
- Commodity12 validation in clinical trials

Ecosystem Commodity12



Logical Structure for Dissemination Version 1.0

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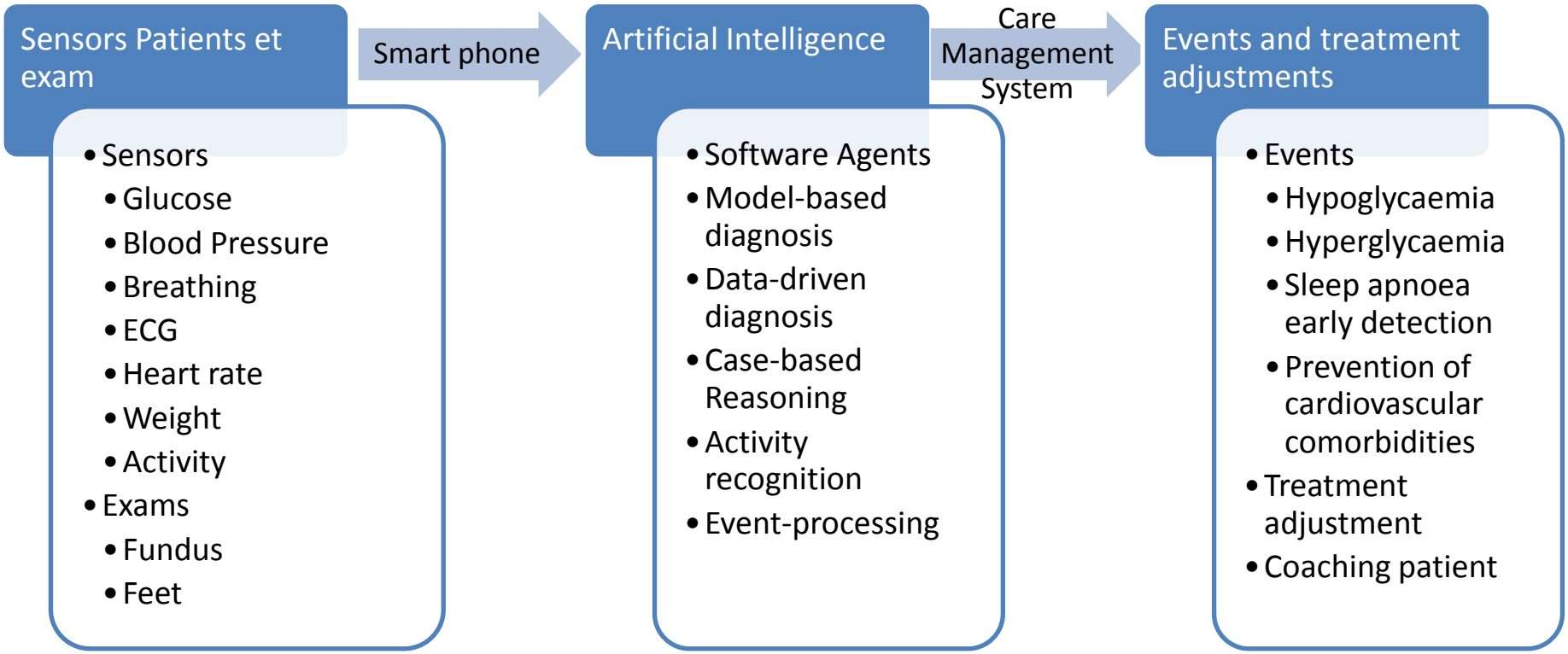
Impact on the treatment chain



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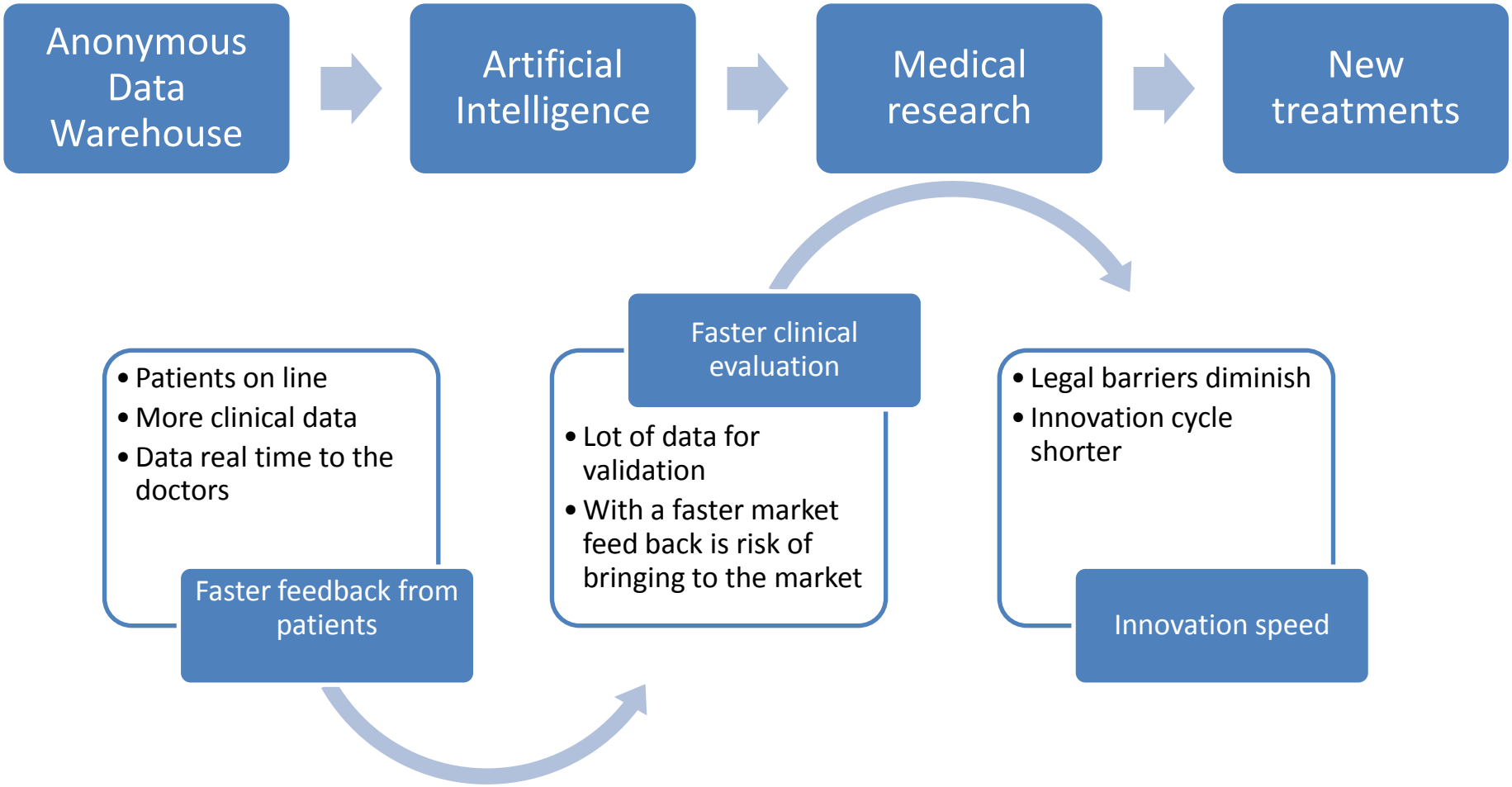
Impact on medical innovation



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Challenges Commodity12

- **Patient acceptation** 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

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Medical characteristics of COMMODITY12 system

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

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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

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Parameters to be used by COMMODITY12 system

Parameters of the **glycemic control:**

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

Parameters allowing for **calculation of CV risk:**

- physiological parameters
- lifestyle & patient history
- genetic factors

Other parameters

- Patient adherence

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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

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Telemedical outpatient monitoring and management by COntinuous Multi-parametric and Multi-layered analysis Of TYpe 1 diabetes mellitus (COMMODITY 1): An open randomized controlled pilot study on behalf of the COMMODITY 12 Investigators

Dr. med. Serban-George Puricel

ATTD 2014

Vienna

Patient with a diagnosis of Diabetes Mellitus Type 1

COMMODITY 1

>18 years
Speaks French
Written informed consent
Willing to participate in follow-up
No major psychosocial impairment
Pregnancy

Single center, parallel group, open label, randomized controlled trial

1:1 Randomization per sealed envelope

Standard Care N=20

3 months follow-up

PHS Care N=20

PHS = Personal Health System

1° end point: Whole trial feasibility and system operability

2° end points: HbA1c, plasma glucose, hypo- and hyperglycemic episodes, arterial blood pressure, weight, number of clinic visits, health care costs

PHS Care

Clinic visit 1

Baseline

Height, weight, blood pressure, pulse, abdominal girth, HbA1c, total cholesterol, LDL, HDL, triglycerides, creatinine, urea, sodium, potassium, urinary albumins

6x/day plasma glucose

2x/week: blood pressure

2x/week: Weight

CGM during 4 days 1x/month

2x/week (1x at day and 1x at night): heart and respiratory rate

1 Month

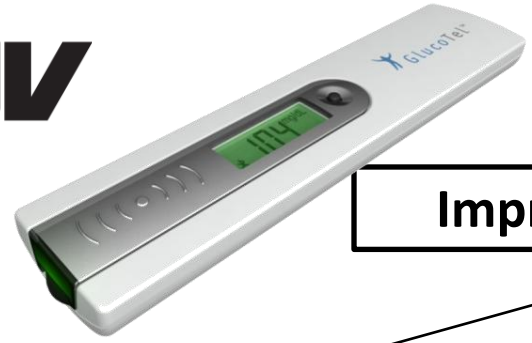
2 Months

Height, weight, blood pressure, pulse, abdominal girth, HbA1c, total cholesterol, LDL, HDL, triglycerides, creatinine, urea, sodium, potassium, urinary albumins, genetic analysis

Clinic visit 2

3 Months

Study completion



Improve Glycemic control

Alerts for Hypoglycemia | **Alerts for Hyperglycemia** | **Alerts for HbA1c target**

Alerts based on the 2014 ADA Position Statement – Standards of Medical Care in Diabetes

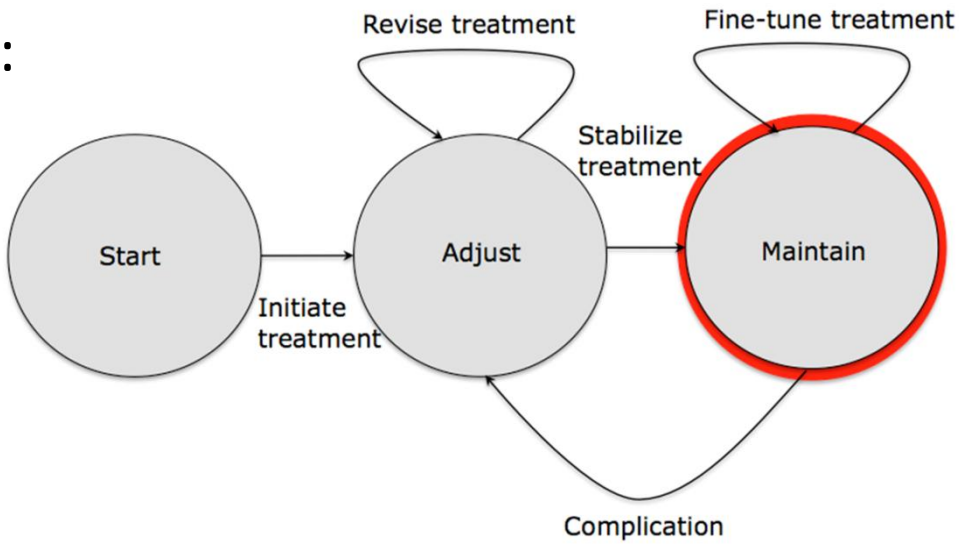
Retrospective Analysis of CGM Data

Improve Prediction of Hypo-/Hyperglycemia in individual patients

Improve understanding of Hypo-/Hyperglycemia

COMMODITY2 trial in DM2 patients Inclusion criteria (selected)

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



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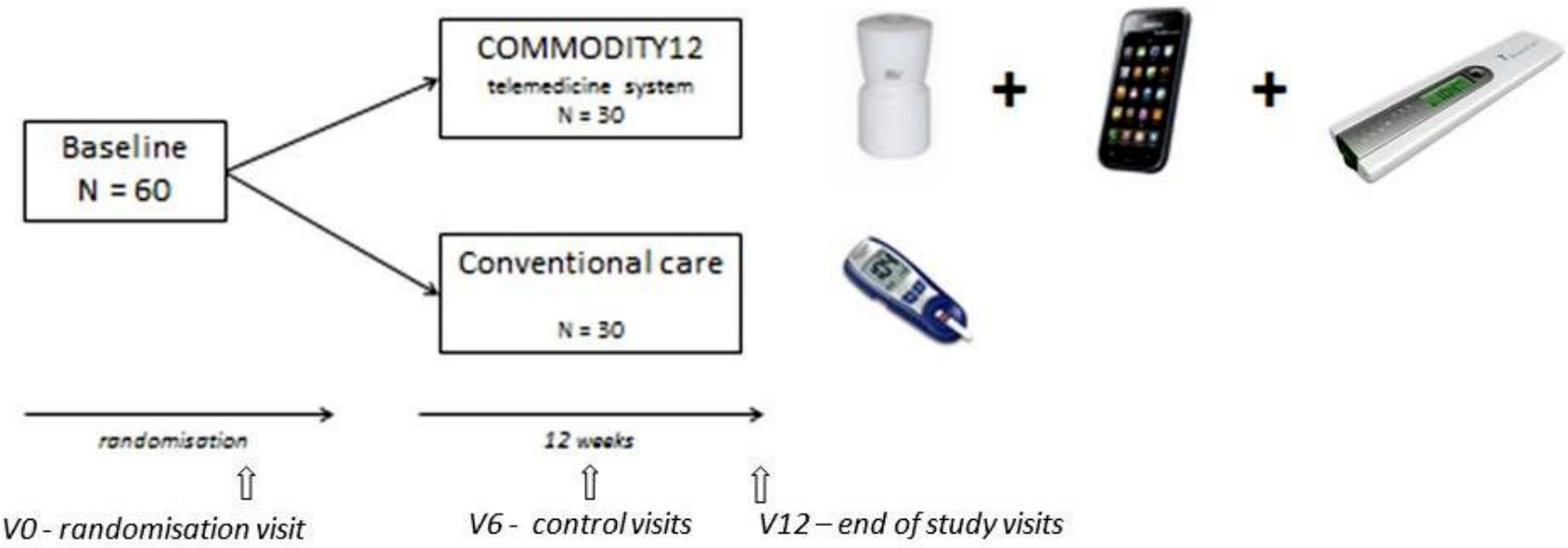
COMMODITY2 trial in DM2 patients
General design

Trial design: randomized controlled minifeasibility trial



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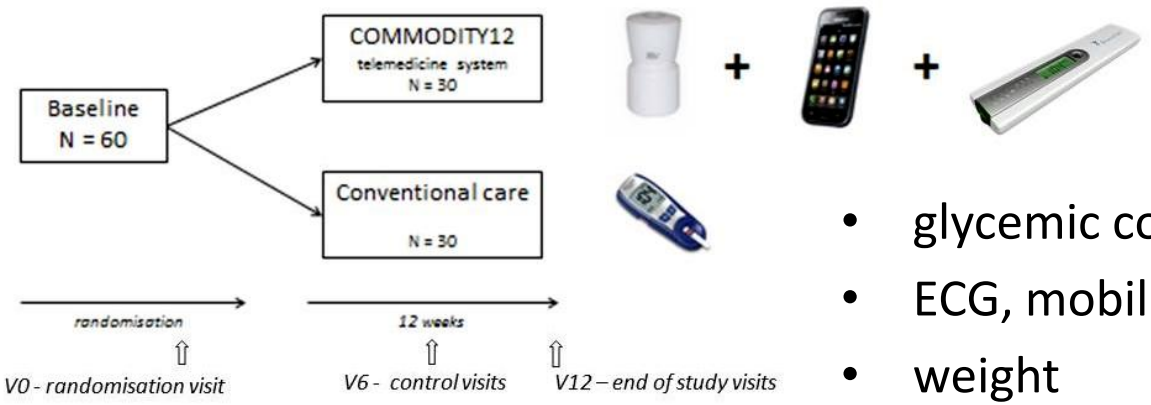
COMMODITY2 trial in DM2 patients Parameters assessed



- physiological parameters
- genetic factors
- patient history

- glycemic control parameters
- ECG, mobility, breathing
- weight
- RR
- patient adherence
- lifestyle & patient history
- quality of life
- resources utilisation
- patients' assessment of C12 system use
- doctors' assessment of C12 system use

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Thank you!

visit us at **www.Commodity12.eu**