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Clinical Evidence for Digital Medical Devices

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Digital transformation of Medicine

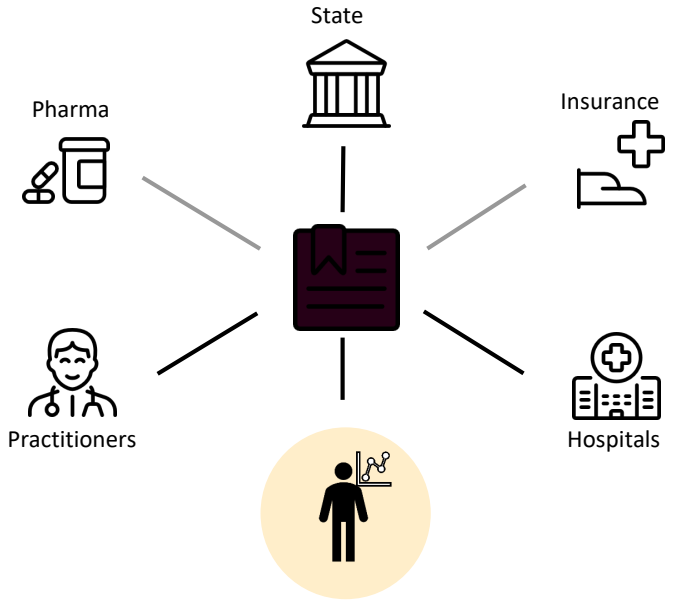
Driver towards patient-centric, data-driven, and evidence-based healthcare

Medical information technology

Connected health

- Availability
- Interoperability
- Security&Safety

DATA
HealthTech Product



Digital Medicine

Healthcare Application
(Digital Medical Devices – DMDs)

- Functionality
- Healthcare Services
- Evidence for Effectiveness

TRUST

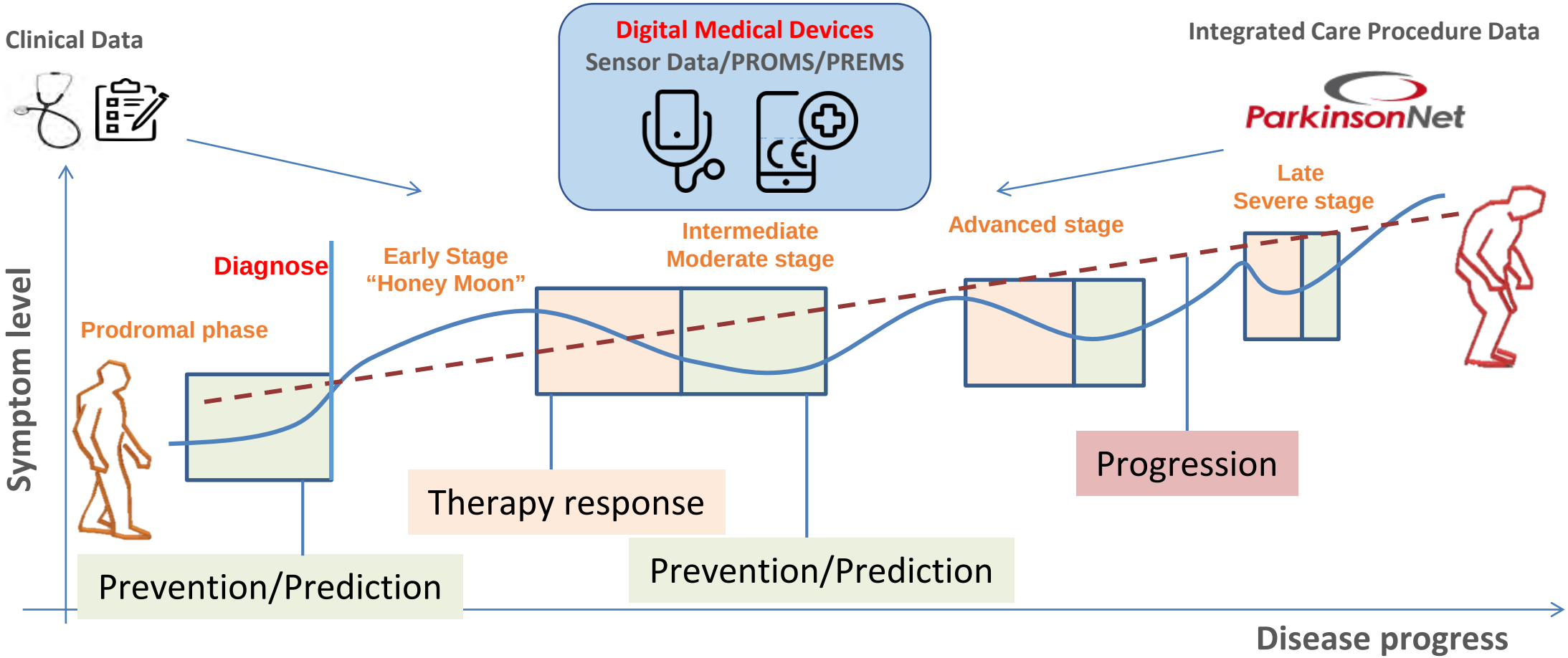
Patient

VALUE

Data-driven chronic disease management

Care Pathways for real-world evidence based digital medicine

Management of Parkinson's Disease 20 Years from Now:
Towards Digital Health Pathways
Klucken, Krüger, Bloem, Park Rel Disord 2018



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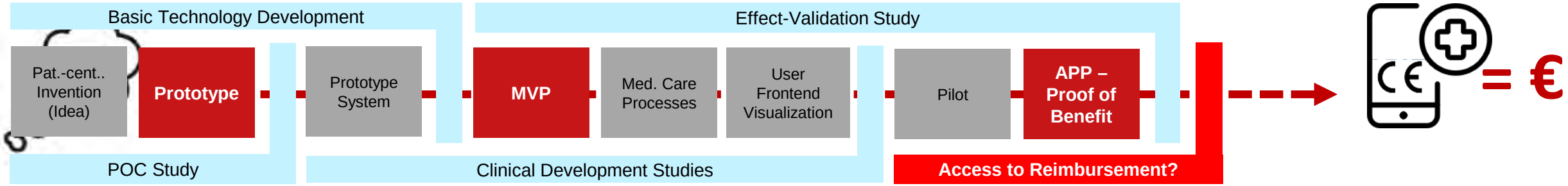
Translational Research in Digital Medicine

From Innovation to Valorisation



Dr. Sensor | Algorithms | Data Management | Clinical Study Center | Care Team | Tele Nurse

Engineering/Data Science | **Medical Science** | **Population Health Science**

Technology Readiness

Health Functionality/Performance/Safety

DMD Development Model - Idea to Product

Rampp et al. TBME 2014
Kanzler et al. EMBC 2015
S. Schülein et al., JNER2017

Sensor-based gait analysis in Parkinson Disease

Basic Technology Development

- Pat.-cent.. Invention (Idea)
- **Prototype**
- Prototype System

Approval Study

- **MVP**
- Med. Care Processes
- **User** Frontend Visualizatio n
- Pilot
- **APP – Proof of Benefit**

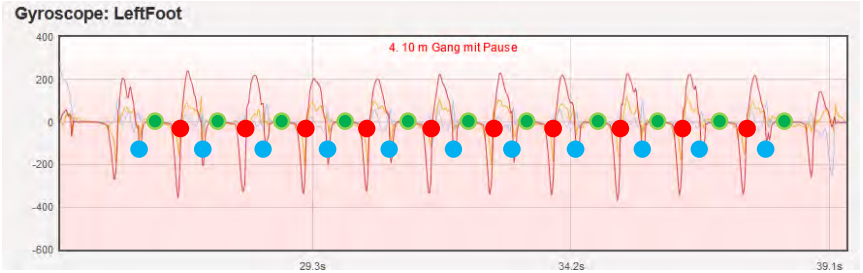
Market Survey Study

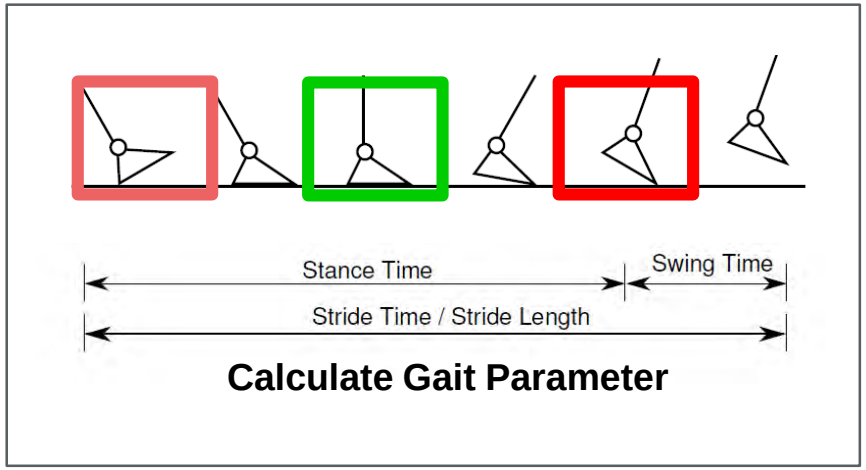
- **Product/ Service**
- Marketing & Sales

POC Study | Clinical Studies

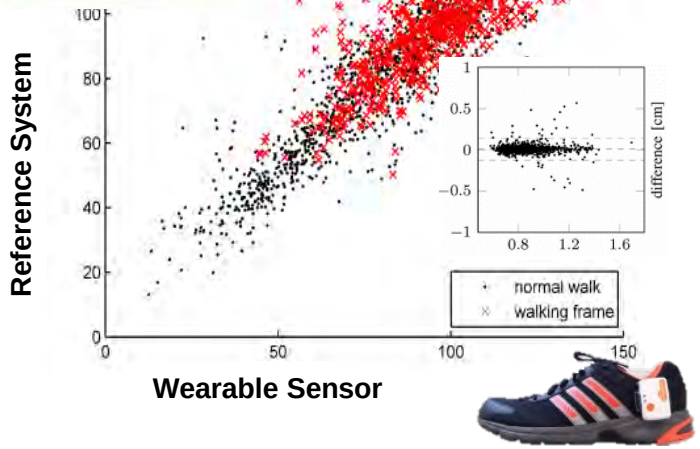
Impact: **Performance/accuracy** **Safety** Health Effects Usability Clinical effect Efficiency Adoption

Research:





Stride Length validation



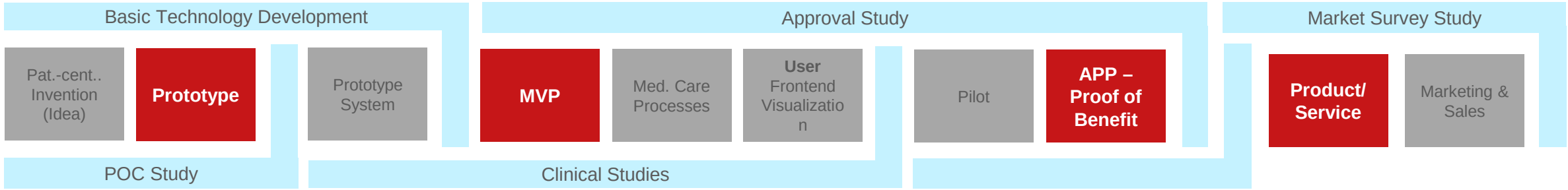
Outcome Validity:

Technical / Criterion Validity

Schlachetzki et al. 2019
Sapienza et al. - in preparation

DMD Development Model - Idea to Product

Correlation to clinical symptom + Application in different clinical test paradigms

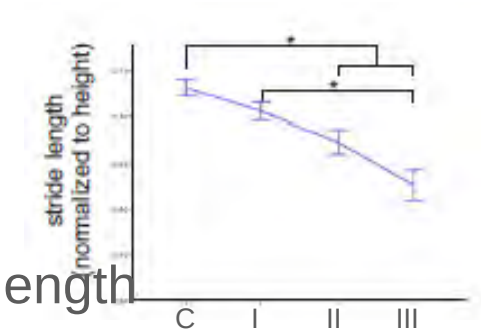


Impact: Performance/accuracy | Safety | **Health Effects** | **Usability** | Clinical effect | Efficiency | Adoption

Research:

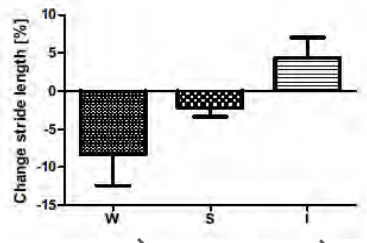
„Short Steps“

Correlation to Disease stage



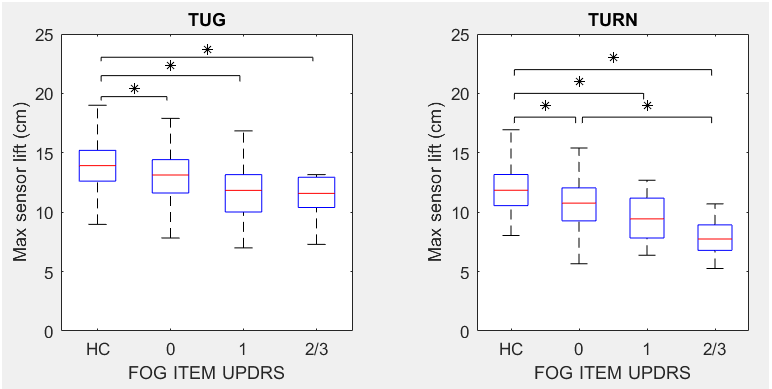
Stride length

Sensitivity to change

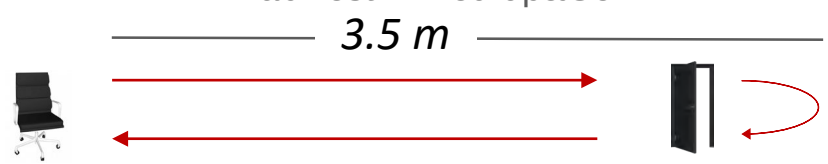


worsened stable improved

Test Paradigm - Application



Lab Test: Timed-up&Go



Outcome Validity:

Technical / Criterion Validity

Clinical / Construct Validity

Application Validity Usability

PDnetGo – Managed Care and Self-Management

Funded by
eit Health
Co-funded by the European Union

PARKINSON GO


Gait assessment

\+

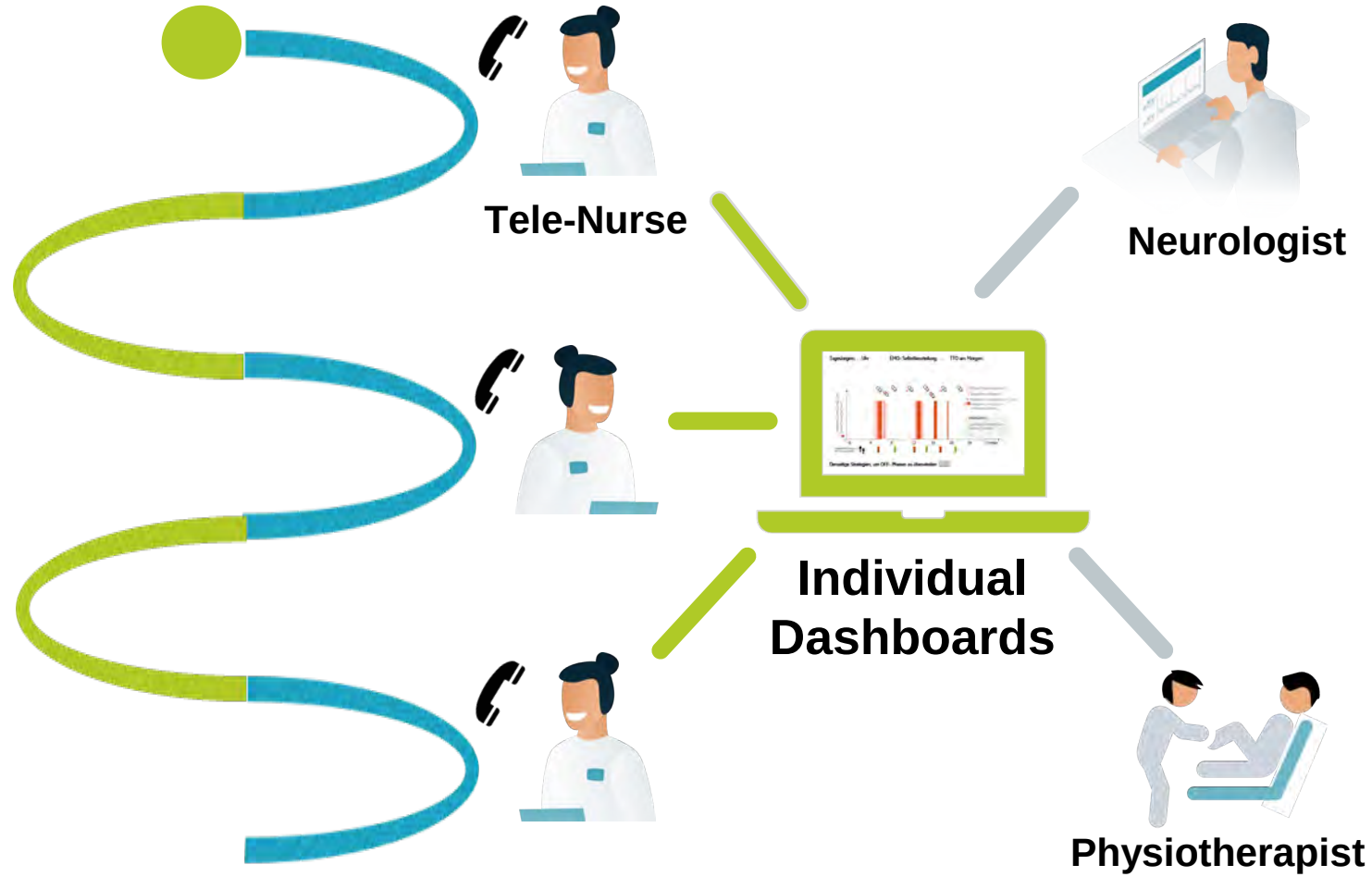

PROM/PREM

\+


Exercises

Patient involvement

Care pathway



Continuum of care

Digital Medical Service for Parkinson Patients and HCPs

Functional Components of the App – User Dashboards – Integrated Care Pathways

Patient

HCP

Self management

Medical history
Health status and biggest issues

Diary
Mobility, Gait safety, General condition

Adaptive communication
Individualized feedback depending on symptom pattern/ gait parameters

Continuous gait parameters, activity, mobility

Short gait tests
Gait parameter

Coaching & Education

Training videos
Specific gait and movement instructions

Individual hints
Recommended actions

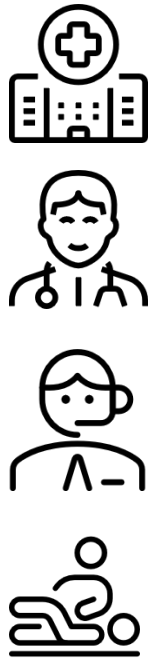
Knowledge library
Information and recommendations
Symptom, Treatment
Behavior

Diagnostics, Monitoring & Clinical Decision Support

Parameter Visualization
Gait Parameter, Activity Profiles, PROMS/PRESM

AI-based Prediction
Diagnose, Progression, Treatment selection

Care Management
Patient
Communication
Notification
Tele-Nurse Service
Support



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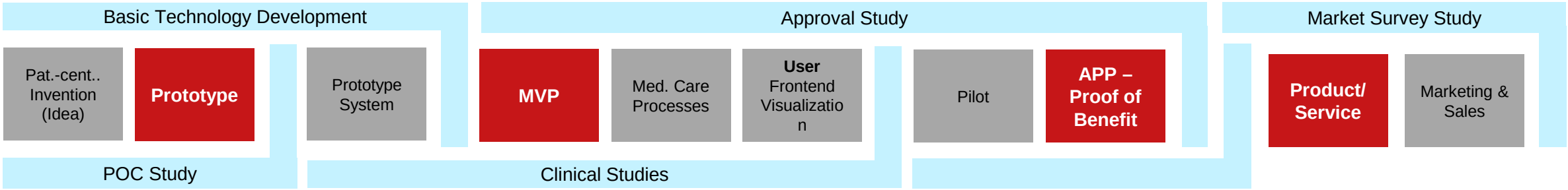
DMD Development model - idea to product

life-cycle related research & evidence validity



Impact: **Performance/accuracy** **Safety** **Health Effects** **Usability** **Clinical effect** **Efficiency** **Adoption**

Research:

10 years development cycle
Over 150 Publications
Over 30 different Endpoints/outcomes

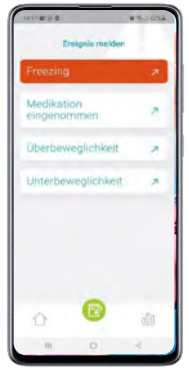
CE

Portabiles
HealthCare Technologies

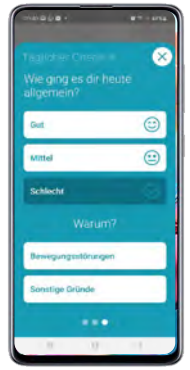
Continuous gait monitoring

Standardized gait tests

Medication & symptoms



Patient diary



Clinical studies for
=>DIGA

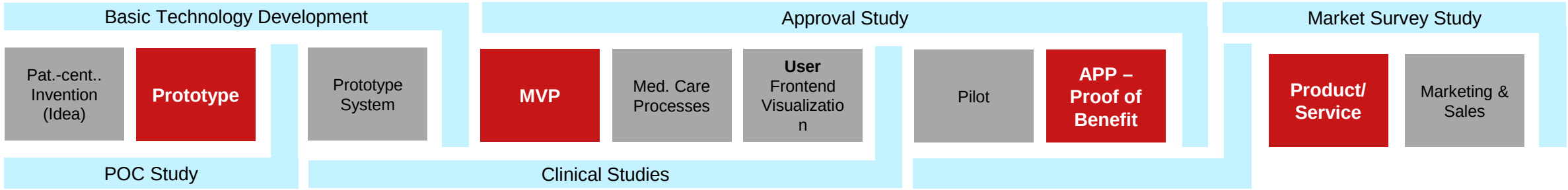
=>Telemonitoring

=> Care Service

S. v. Schagen PhD-Project

From Ideation to HealthTech Product

Development phases of DMDs – life-cycle related research & evidence validity



Impact: **Performance/accuracy** **Safety** **Health Effects** **Usability** **Clinical effect** **Efficiency** **Adoption**

Research:

Engineering/ Data Science

Medical Science

Socio-economic Science

Technology R&D

Medical correlation

Medical applicability

Intervention

Acceptance&costs

Outcome Validity:

Technical / Criterion Validity

Clinical / Construct Validity

Application Validity Usability

Clinical effectiveness

Cost effectiveness

Application types of digital medical devices (DMDs)

Digital = smart (not just a technical measurement device)

Category	Examples – Application Purpose	Beneficiary (direct)	Value/Service
Digital Diagnostics CE ✓	Wearable sensors / objective outcomes / PROMS Home-/Telemonitoring devices, imaging, multi-*omics*-parameter pattern Diagnostic/prognostic algorithms („AI“)	**Healthcare Provider**	Better information Clinical Decision Support *Precision/Accuracy*
Digital Therapeutics CE ✓	Interventional Functionality Digitale Gesundheitsanwendung (DiGA)	**Patient** *(caregiver)*	Medical benefit Treatment support Positive Healthcare Effects *Effectiveness*
Digital Management	Smart data-management platforms / component Patient-centered Personal Health Records (PHRs) interoperable to EHR from HCPs/3rd parties Data-exchange spaces. (Telemedical platforms)	**HCP + Patients**	Communication improvement Data availability *Efficiency*
Digital Analytics	Registries data-driven research – big data, AI Dashboards (Corona-Dashboard)	**Patients + HCP** **Society** (public&private)	KnowHow, *Innovation* *Acceptance* *Quality, Benchmarking*

Klucken et al. – in preparation

DiGA: New „Positive Care Effects“ (Endpoints)

Medical Benefits

Bundesministerium für Gesundheit

§: DVG

1. the improvement of the state of health
2. the reduction of the duration of a disease
3. the prolongation of survival
4. an improvement in the quality of life

Methodology
Endpoints
Trial Design

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DiGA: New definition of „Positive Care Effects“(Endpoints)

Bundesministerium für Gesundheit

§: DVG

Patient-relevant improvement of structure and processes

1. coordination of treatment procedures
2. alignment of treatment with guidelines and recognized standards
3. adherence
4. facilitating access to care
5. patient safety
6. health literacy
7. patient autonomy – shared decision making
8. coping with illness-related difficulties in everyday life
9. reduction of therapy-related efforts and strains for patients and their relatives

Challenge:
Methodology
Endpoints
Trial Design

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DMD National Regulatory & Assessment Frameworks

DIGA
Fast track
RMB

Pecan
Fast Track
RMB

Mhealth
Pyramide
RMB

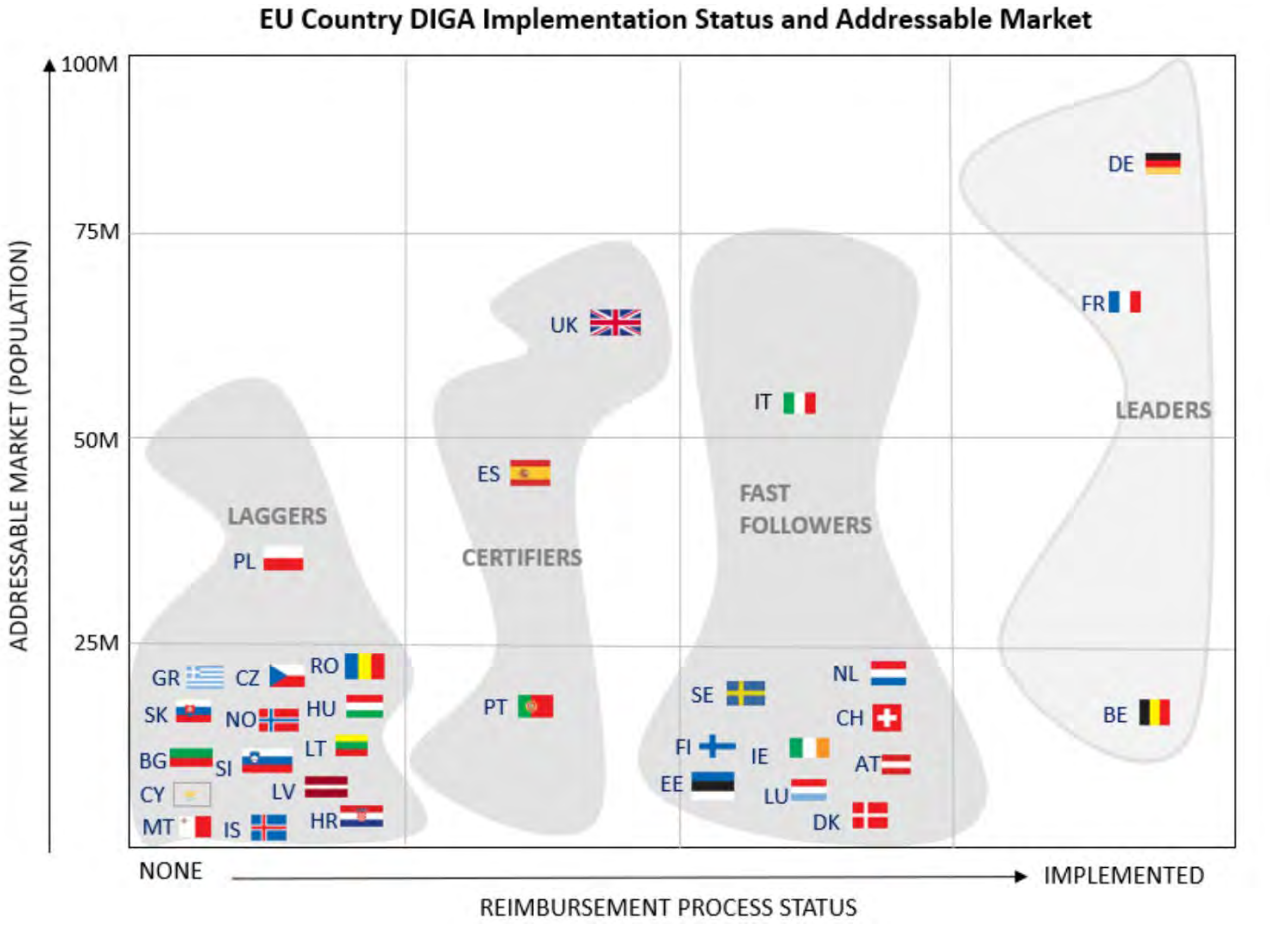
Mixed public/ private approach
RMB

Helsenorge.no
RMB

Digi-HTA
No RMB

SaMD
510k, pre-CERT

NICE TIER-based
Approach
No RMB



Differences in

- Taxonomy, Nomenclature, Classification
- Assessment pathways&scope
- Reimbursement pathways
- Risk assessment schemes
- Evidence requirements
- Evaluation timelines
- …

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Co-funded by the European Union

European Taskforce for Harmonised Evaluation of Digital Medical Devices (DMDs)

DMD Evaluation Taskforce (EvalEUDMD)

European Taskforce for Harmonised Evaluation of Digital Medical Devices (DMDs)

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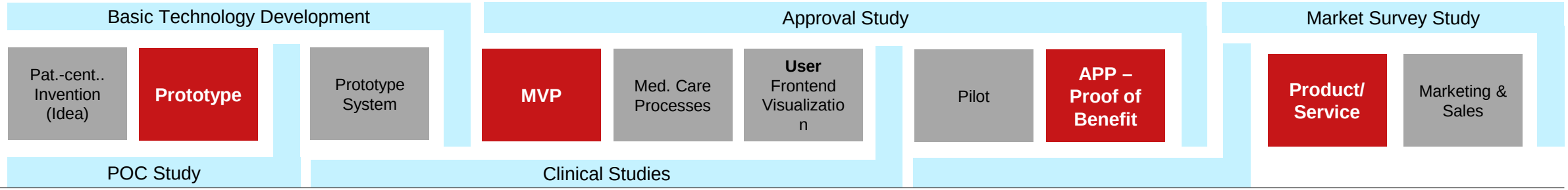
Sijmen v Schagen
Petra Wilson

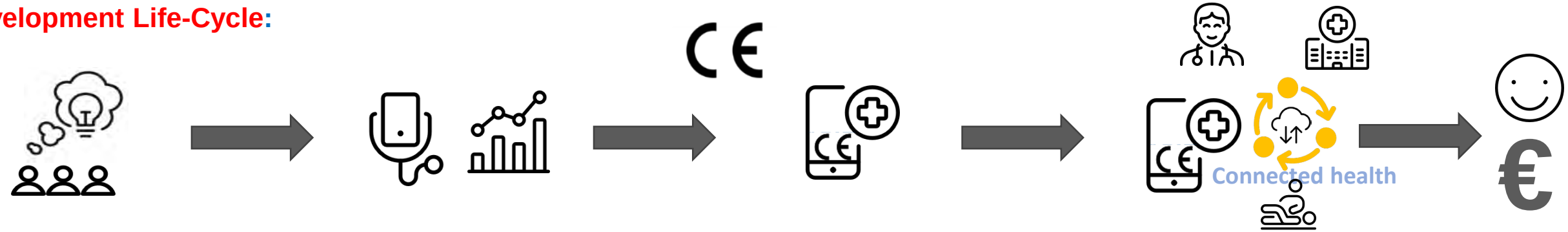
Evidence based Digital Medicine

Different type of evidence throughout the development life cycle of healthtech



Impact: **Performance/accuracy** **Safety** **Health Effects** **Usability** **Clinical effect** **Efficiency** **Adoption**

Development Life-Cycle:



Existing Outcomes	Accuracy	Safety	Clinical effect	Economic effect
	Usability	Literacy	Organization aspects	HCP acceptance
New Outcomes	organization	structur/ proced. improve	patient autonomy	shared decision

Digital Medicine Group

ParkinsonNet Luxembourg

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Luxembourg National Research Fund

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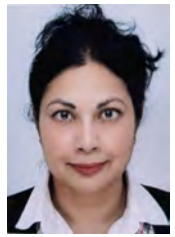

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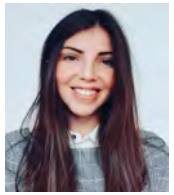

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