COMED
PUSHING THE BOUNDARIES
OF COST AND OUTCOME ANALYSIS
OF MEDICAL TECHNOLOGIES

How Early Dialogues in Medical Devices Contribute to Faster Reimbursement Decisions: A Stakeholder Analysis

Organized Session: Pushing the Boundaries of Existing Methods for Cost and Outcome Analysis of Medical Technologies: First Results from H2020 EU Project COMED

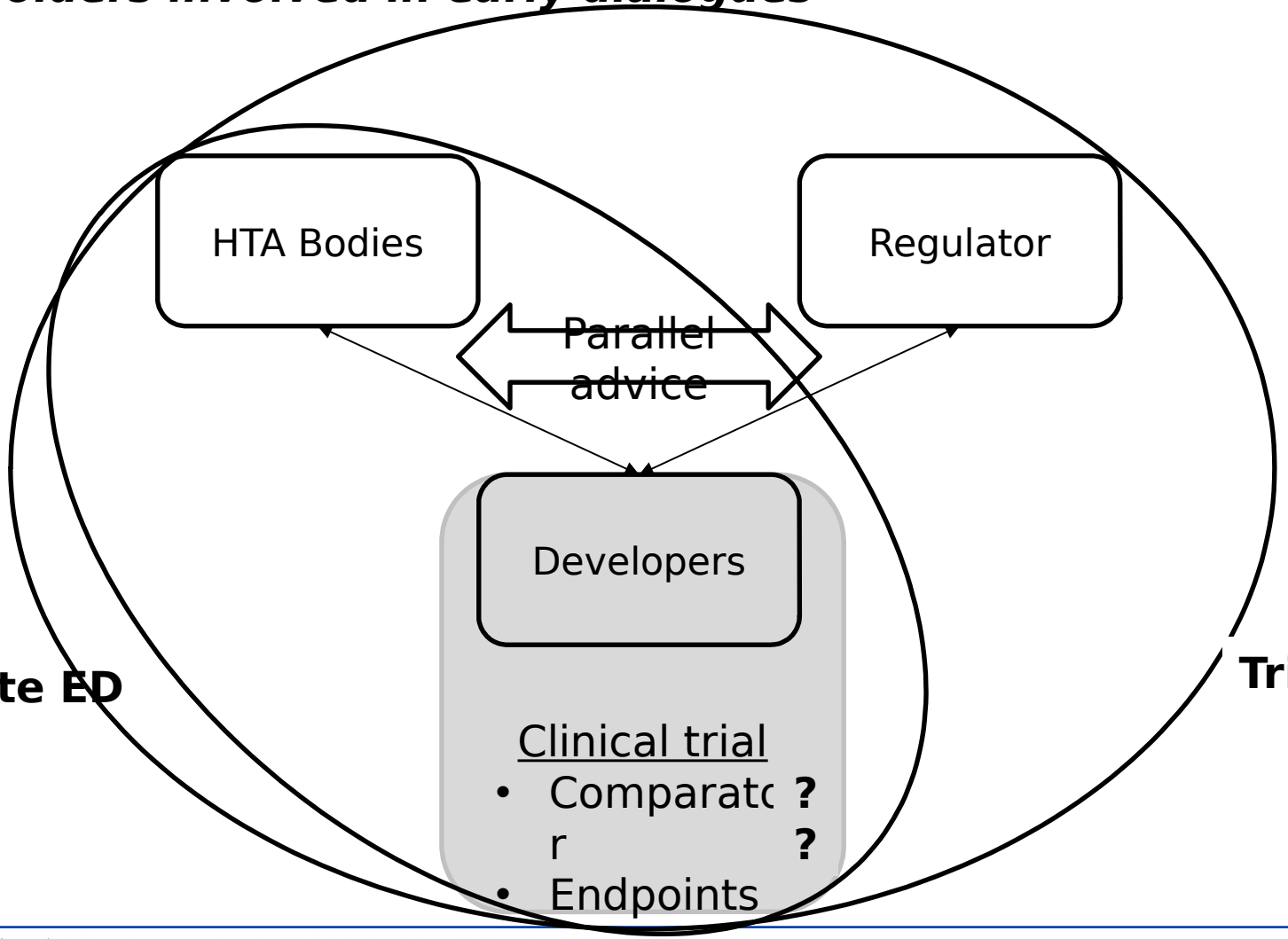
Basel, July 15, 2019

Florian Dams

Early dialogues aim to improve the data produced by developers in view of future HTA assessments

UNIVERSITÄT BERN
KPM KOMPETENZZENTRUM PUBLIC MANAGEMENT

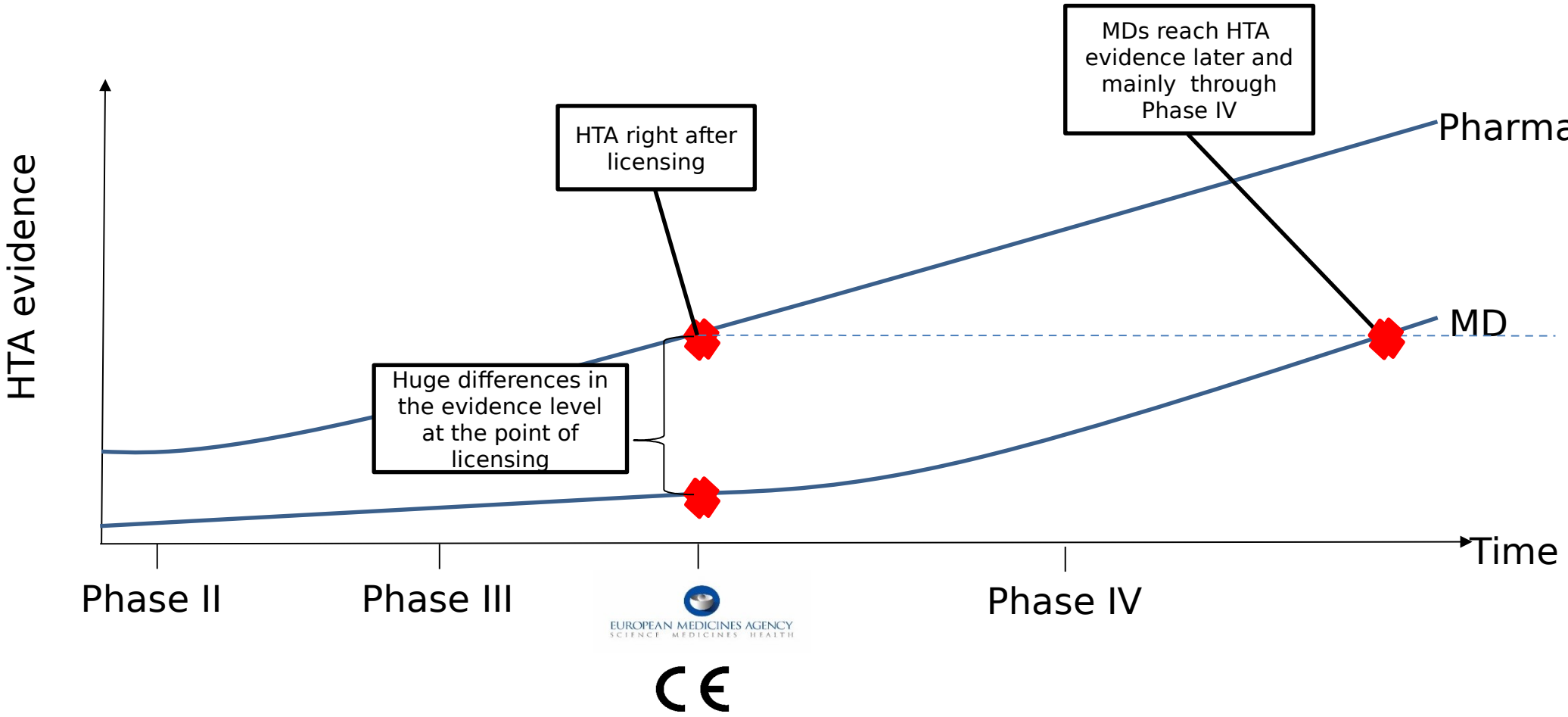
Stakeholders involved in early dialogues



Medical devices lack HTA relevant evidence at market launch

Level of HTA evidence for medical devices and pharmaceuticals

UNIVERSITÄT BERN
KPM KOMPETENZZENTRUM PUBLIC MANAGEMENT



HULSTAERT, F., NEYT, M., VINCK, I., STORDEUR, S., HUIĆ, M., SAUERLAND, S., . . . VAN BRABANDT, H. (2012). PRE-MARKET CLINICAL EVALUATIONS OF INNOVATIVE HIGH-RISK MEDICAL DEVICES IN EUROPE. *INTERNATIONAL JOURNAL OF TECHNOLOGY ASSESSMENT IN HEALTH CARE*, *28*(3), 278–284.

Little is known about early dialogues in medical devices when compared to pharmaceuticals

UNIVERSITÄT BERN
KPM KOMPETENZZENTRUM PUBLIC MANAGEMENT

Reasons to investigate

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on health technology assessment and amending Directive 2011/24/EU

- **Joint clinical assessments**
- **Joint scientific consultation**

eunethta
EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

Joint action 2
- **EUnetHTA: 2 MD EDs, 11 Drugs**
- **SEED: 3 MDs, 8 Drugs**

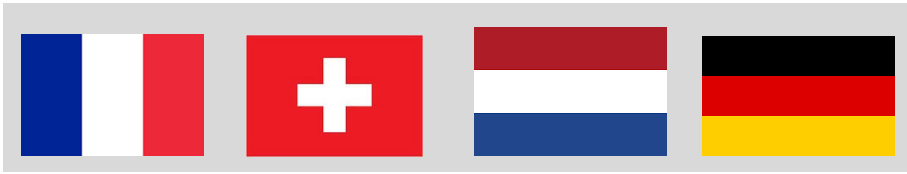
Joint action 3
- **multi-HTA Early Dialogues for MDs**
- **1 completed, 1 in progress, 1 withdraw**
- **workshop Task force on HTA and MDs**

We survey Developers, Regulators (competent authorities) and HTA Bodies about their knowledge and preferences in Early Dialogues

Focus countries

UNIVERSITÄT BERN
KPM KOMPETENZZENTRUM PUBLIC MANAGEMENT

Social Health Insurance (SHI):



National Health Systems (NHS):

Central and Eastern Europe (CEE):

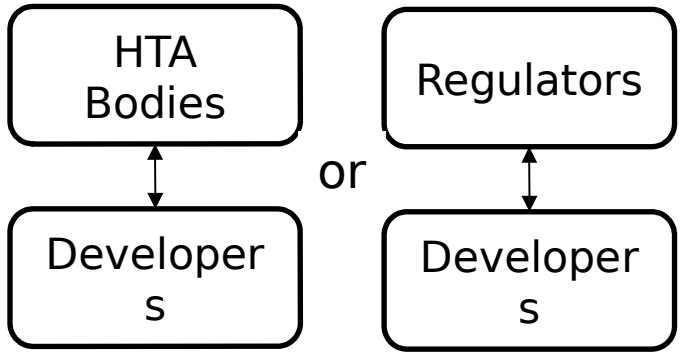
The first part of the survey asks stakeholders about bipartite EDs, whereas the second asks about tripartite EDs that involve regulators

UNIVERSITÄT BERN
KPM KOMPETENZZENTRUM PUBLIC MANAGEMENT

Structure of the questionnaire

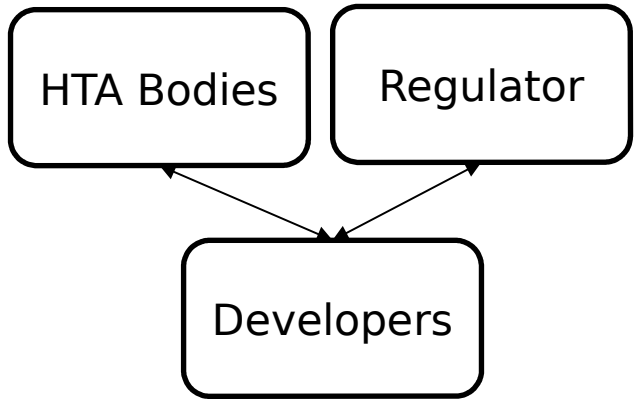
Bipartite (current situation)

Do HTA bodies and Competent Authorities offer EDs?
Are manufacturers aware of it?
What are challenges and opportunities?



Tripartite (future scenario)

- Do HTA bodies and Competent Authorities cooperate?
- Do stakeholders see potential for tripartite EDs for MDs?
- What are challenges and opportunities?



Medical devices are licensed by private for profit companies, which has implications for tripartite EDs

Regulating bodies of pharmaceuticals and medical devices in Europe

	Pharmaceuticals	**Medical devices**
EU level	European Medicines Agency • EU wide MA	Medical Device Coordination Group • Advising/harmonizing role
Member State level	MS Medicines Agency • National MA	Competent Authorities/ Designating Authorities • Supervising, authorizing role
Corporate level	/	Notified Bodies • Certification: EU, EEA, CH, TR

The piloting revealed several challenges for bipartite but in particular for tripartite EDs involving regulators

UNIVERSITÄT BERN
KPM KOMPETENZZENTRUM PUBLIC MANAGEMENT

Piloting feedback

Developers

- HTA does not seem to play a huge role yet
- Many SMEs, with fewer resources
- Currently challenged by MDR

Regulator

- Notified bodies are not allowed to consult
- HTA requirements should not interfere with the regulation

HTA Bodies

- HTA is most advanced and used in pharmaceuticals

Contacts

UNIVERSITÄT BERN

KPM KOMPETENZZENTRUM PUBLIC MANAGEMENT

Florian Dams
Prof. Dr. Rudolf Blankart
Carlo Federici

Universität Bern
Kompetenzzentrum für Public Management
Schanzeneckstrasse 1
3012 Bern
Schweiz

florian.dams@kpm.unibe.ch
T +41 31 664 63 21

rudolf.blankart@kpm.unibe.ch
T +41 031 664 63 10

carlo.federici@unibocconi.it

www.kpm.unibe.ch