# We will start soon…

# Innovative, outcomes-based risk-sharing contracts as a solution within the German AMNOG process?

October 29th, 2020

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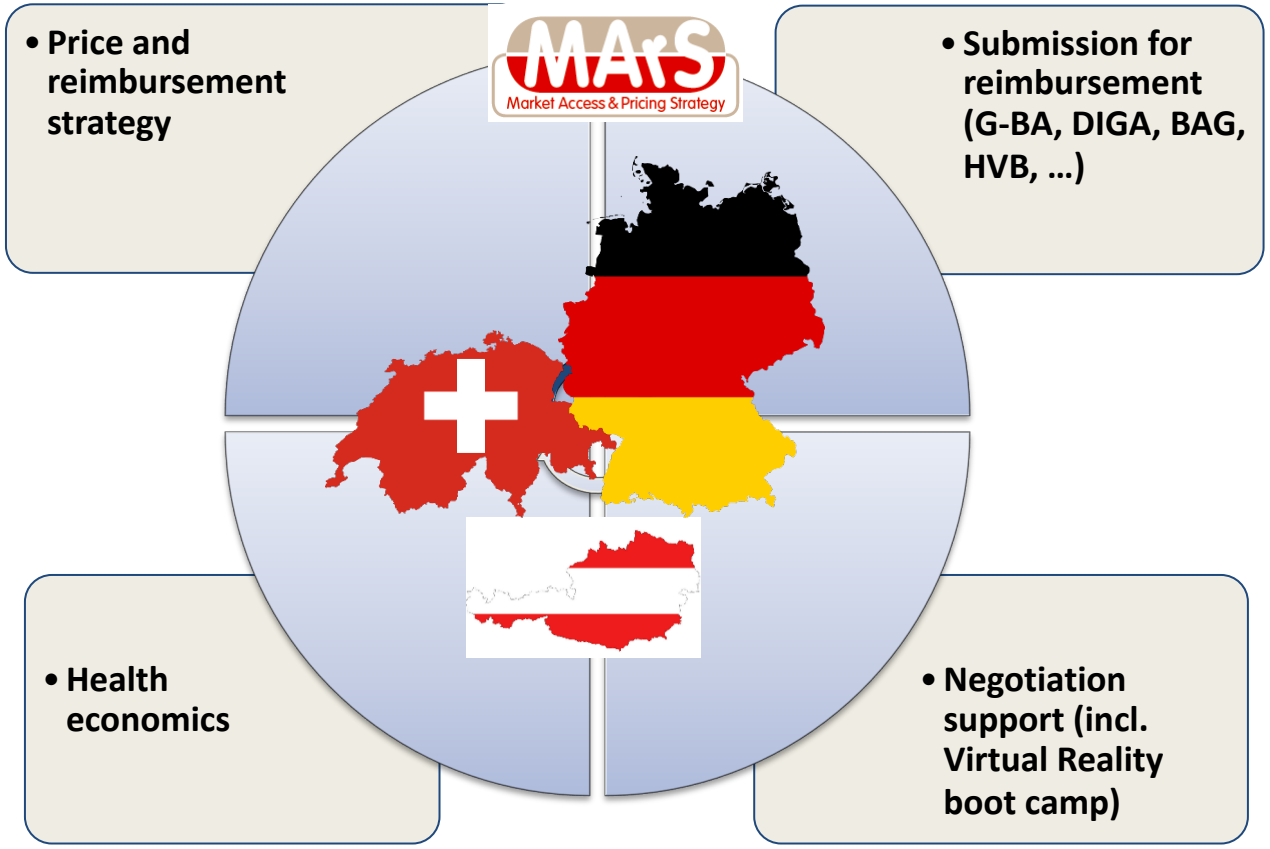
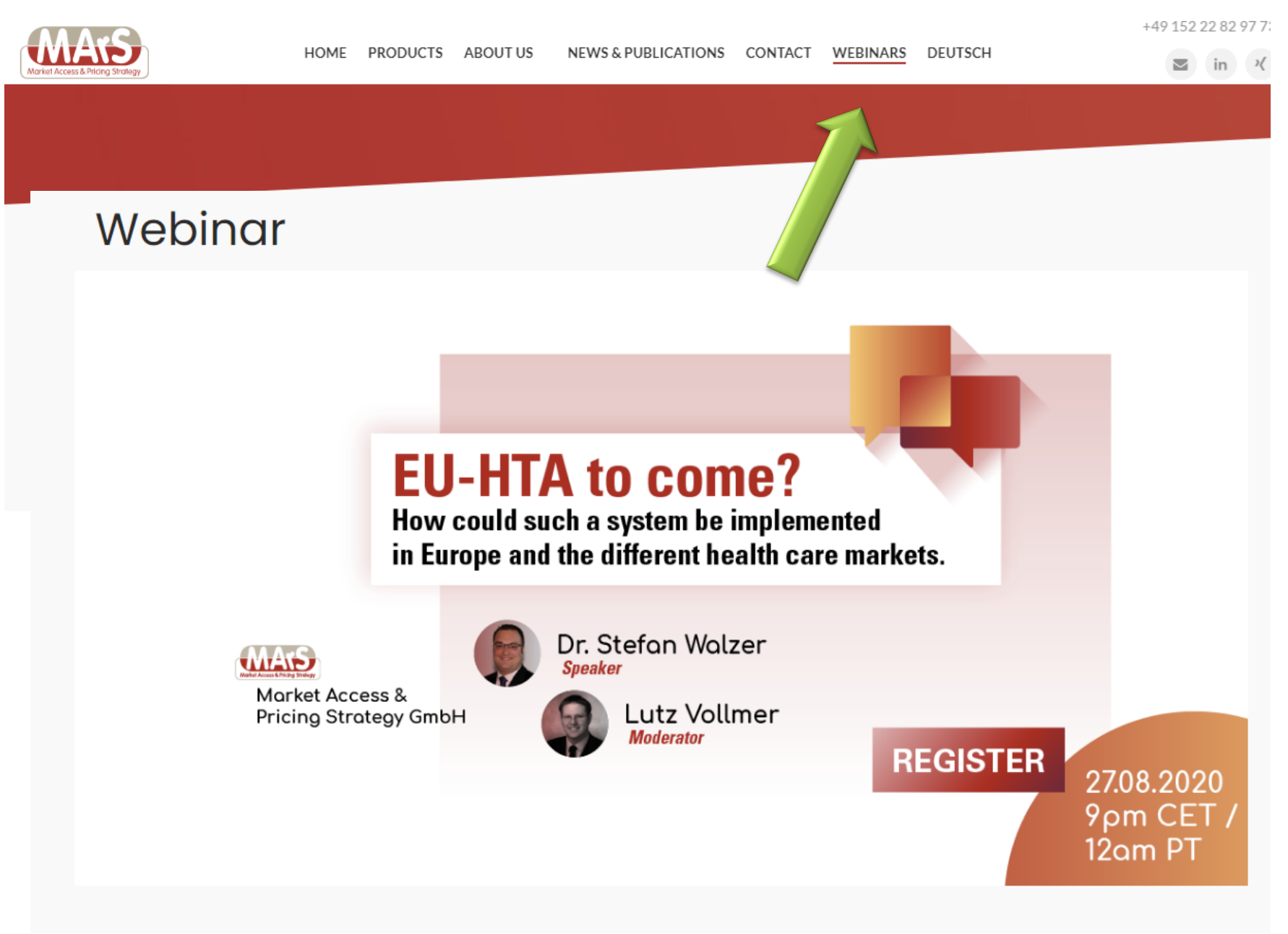
# Your specialist in reimbursement, pricing and health economics in the D-A-CH region



# Questions welcome!

- Feel free to ask questions. After the presentation, we will have time for your questions.
- Use either the Zoom chat function or the Q&A function to raise your questions or comments.
- As always, slides will be provided afterwards, and the video will be published on our website.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Market Access &
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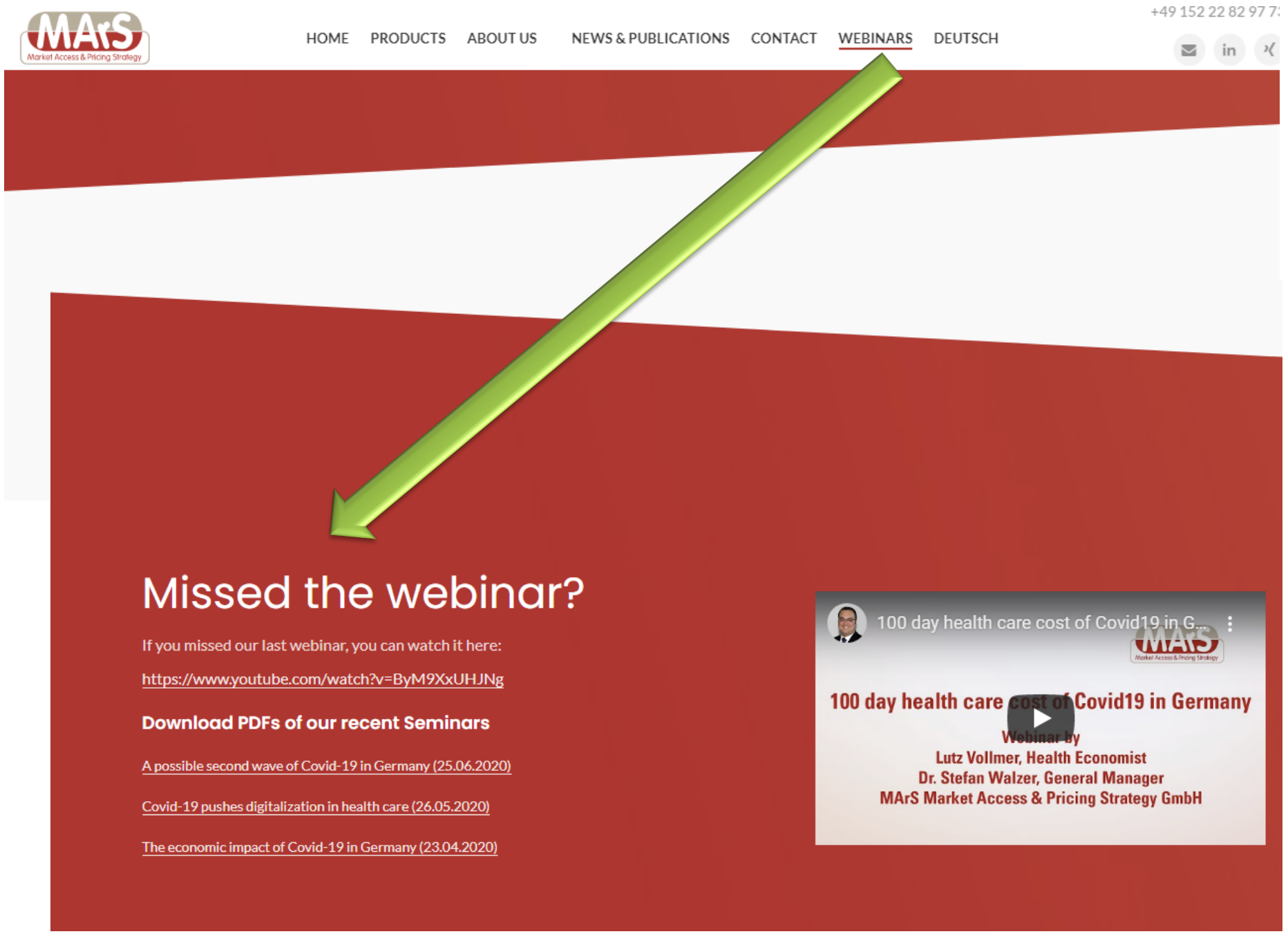
Dr. Stefan Walzer
Speaker
Lutz Vollmer
Moderator
REGISTER
27.08.2020
9pm CET /
12am PT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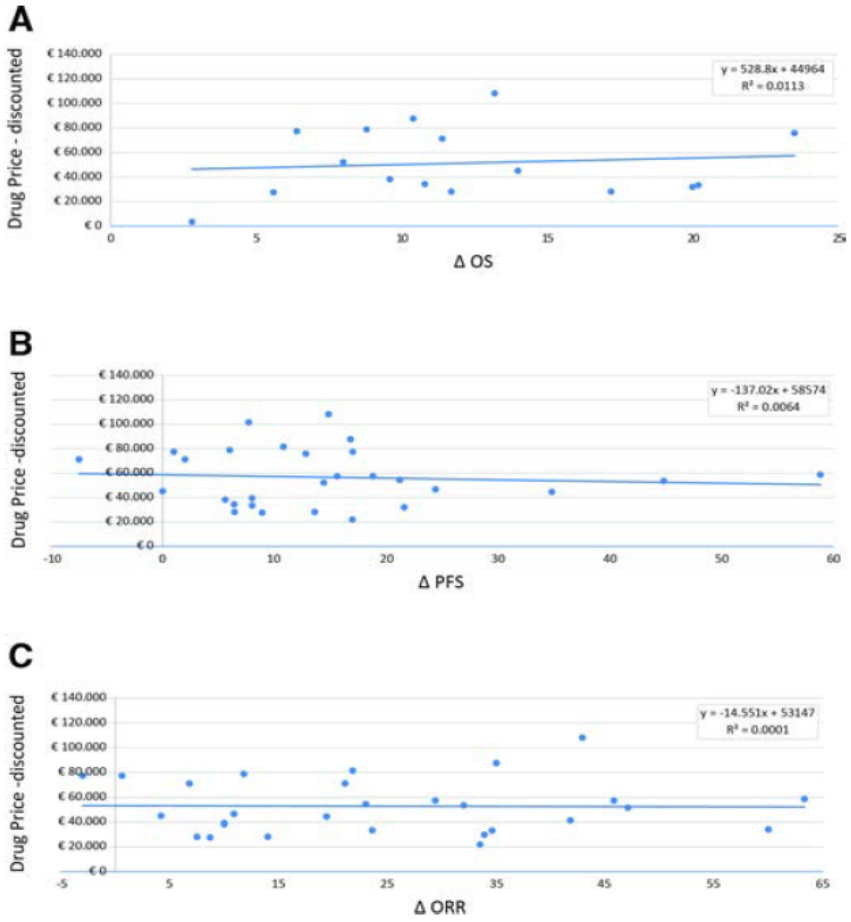
# Why health systems want to share risks

- Most (some) new medicines do not add significant and relevant value **(diminishing marginal benefits)**
- **Not all patients benefit** from expected outcomes of new medicines (targeted therapies and precision medicine is not generalized yet)
- Unconditional use of all new available technology is not (financially) feasible (**healthcare budgets have limits**)

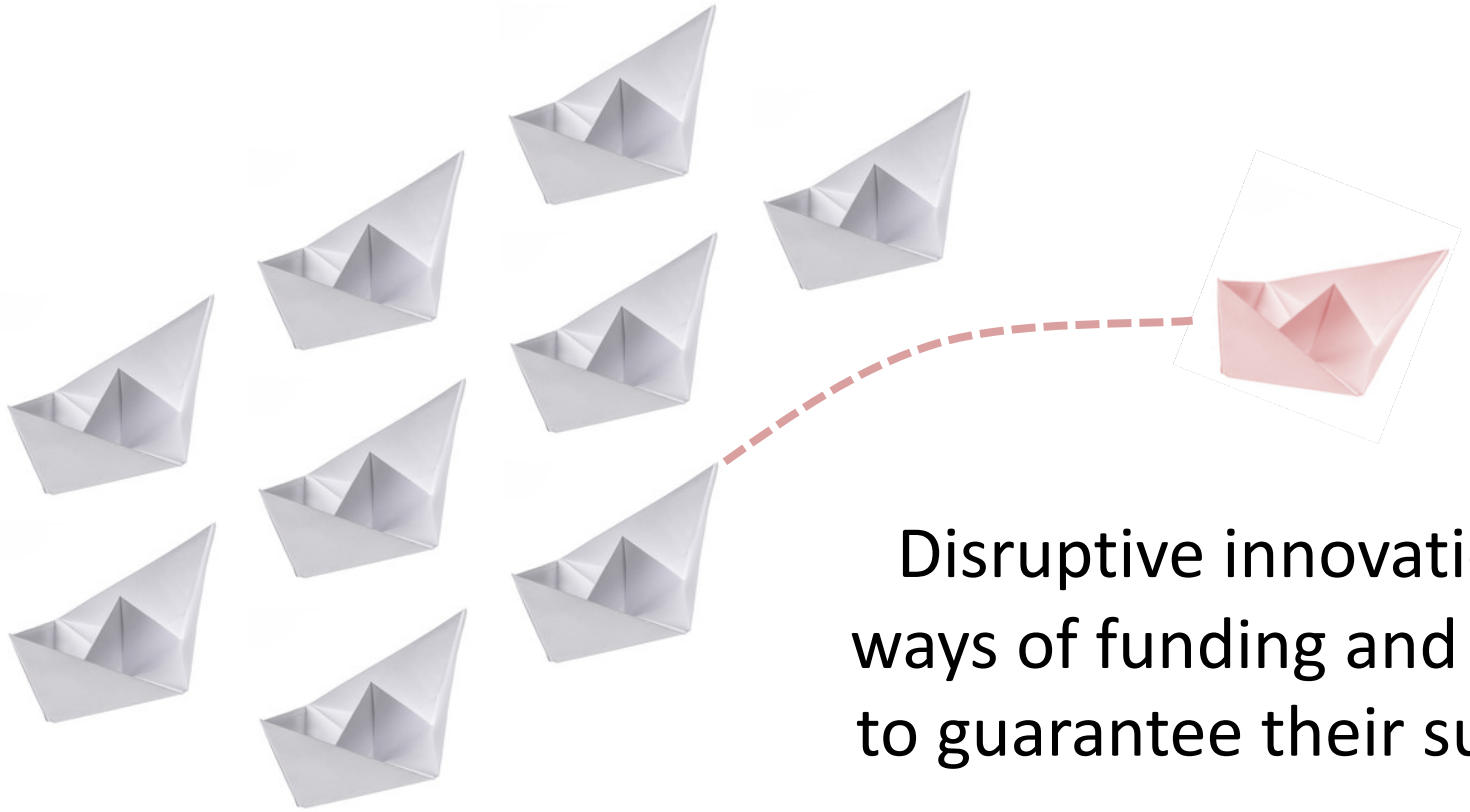



Trotta F et al. 2019 (BMJ Open)



Slide „borrowed“ from Max Brosa 2020 – Medvance Spain

# Disruptive ~~Innovation~~ Success-Story



Disruptive innovations require alternative ways of funding and reimbursement in order to guarantee their successful market access!

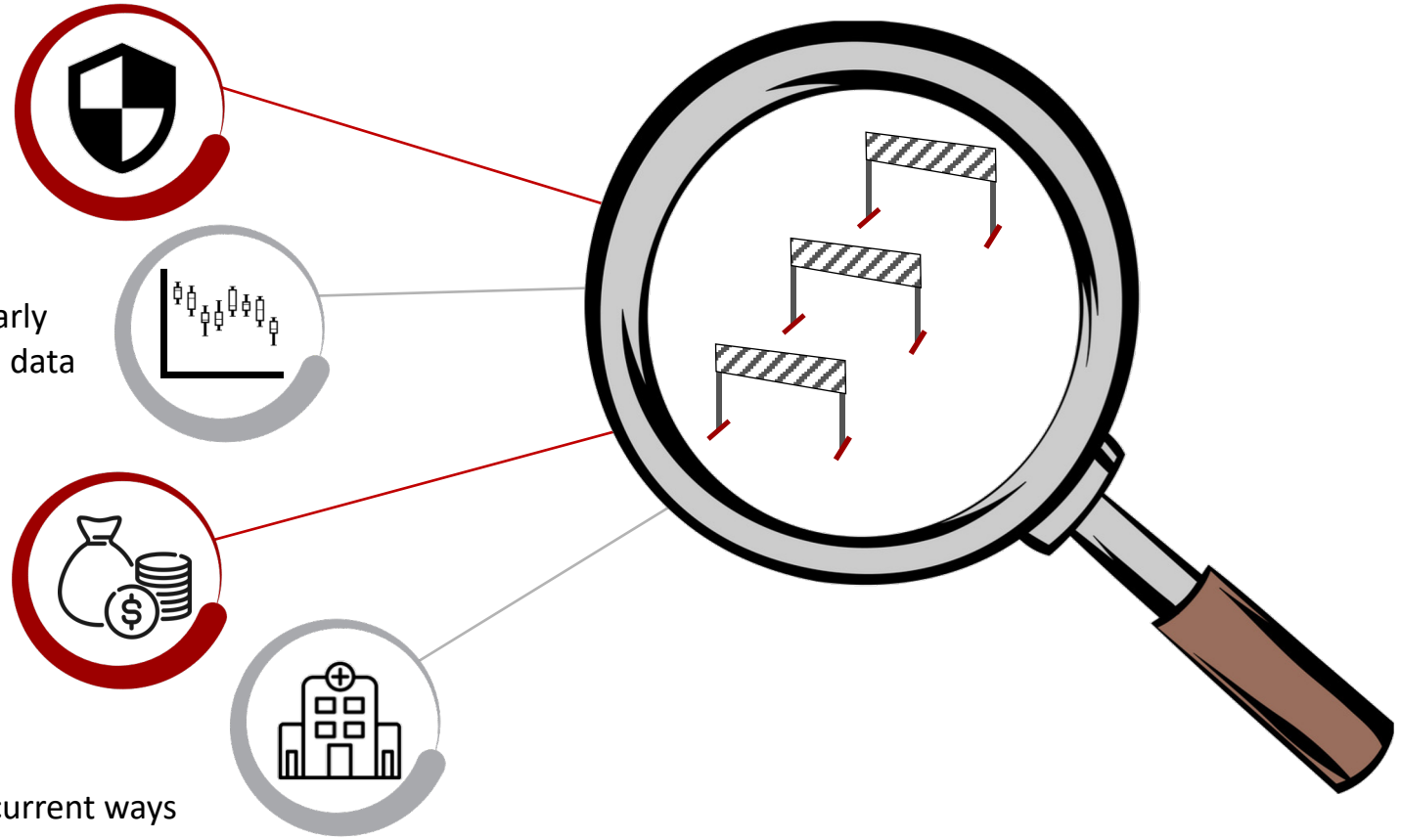
# Challenges of innovative therapies

**Safety:**
Nonetheless innovative therapies receive national or European market authorization, payers are concerned about their long term safety (e.g. for CAR T-cell therapies)

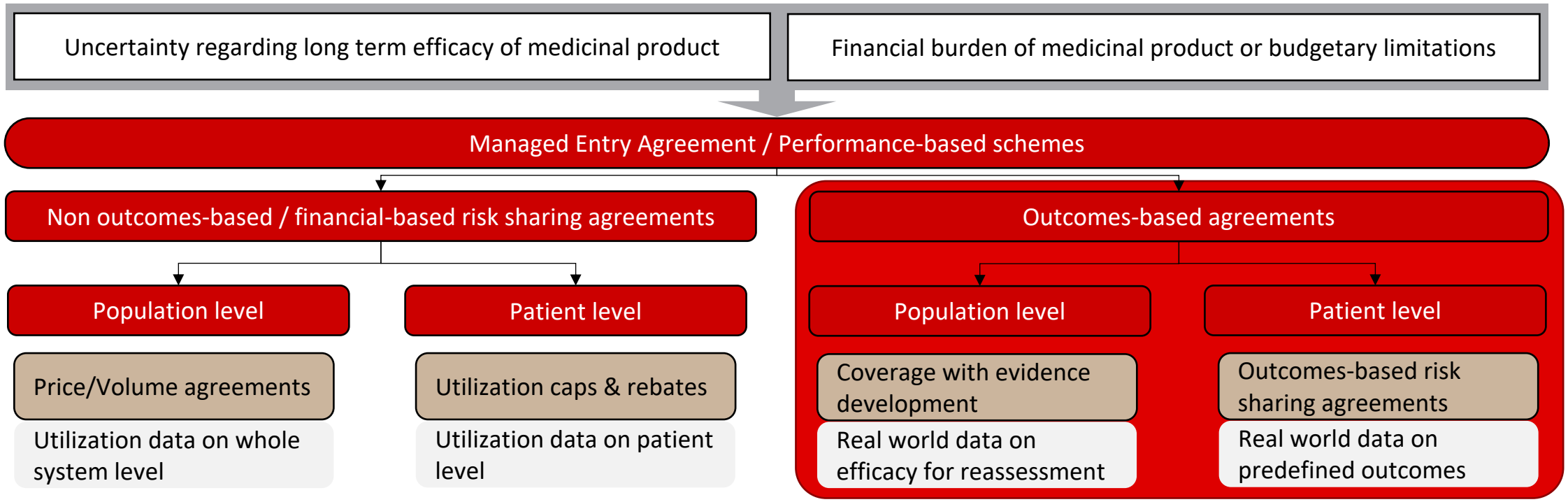
**Efficacy:**
The market authorization already takes place in early stages of the clinical development program, when data on the long term efficacy are limited

**Budget Impact:**
Innovative therapies may lead to considerable budget impacts (e.g. high one time up-front payments for gene therapies)

**Service delivery:**
Some innovative therapies challenge the current ways of service delivery because they require certain competences e.g. to manage their side-effects



# Extract of Managed Entry Agreements




Key:

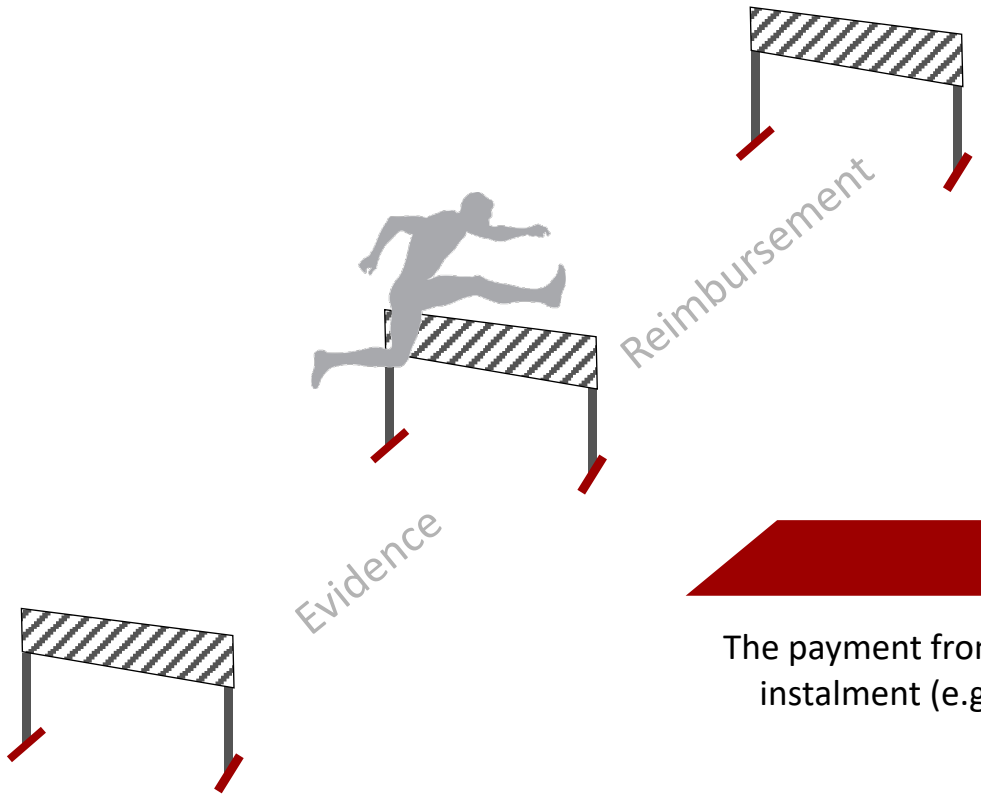
- Challenges for coverage decisions
- Solutions for the coverage challenges
- Example Agreements
- Necessary data

Sources:


- E. Hanna et al. 2018
- A. Navarria et al., 2015
- K. Pauwels et al., 2017
- S. Walzer et al., 2015
- W.C.N. Dunlop et al., 2018
- J.J. Carlson et al., 2010

# Examples of MEAs in the EU5

*MEAs have the potential to address the safety, efficacy and budgetary hurdles of innovative therapies*




## Coverage with Evidence Development

Conditional reimbursement agreement: Marketing authorization holder collects further data on the efficacy and safety.

## Outcomes-based risk-sharing (Pay for Performance)

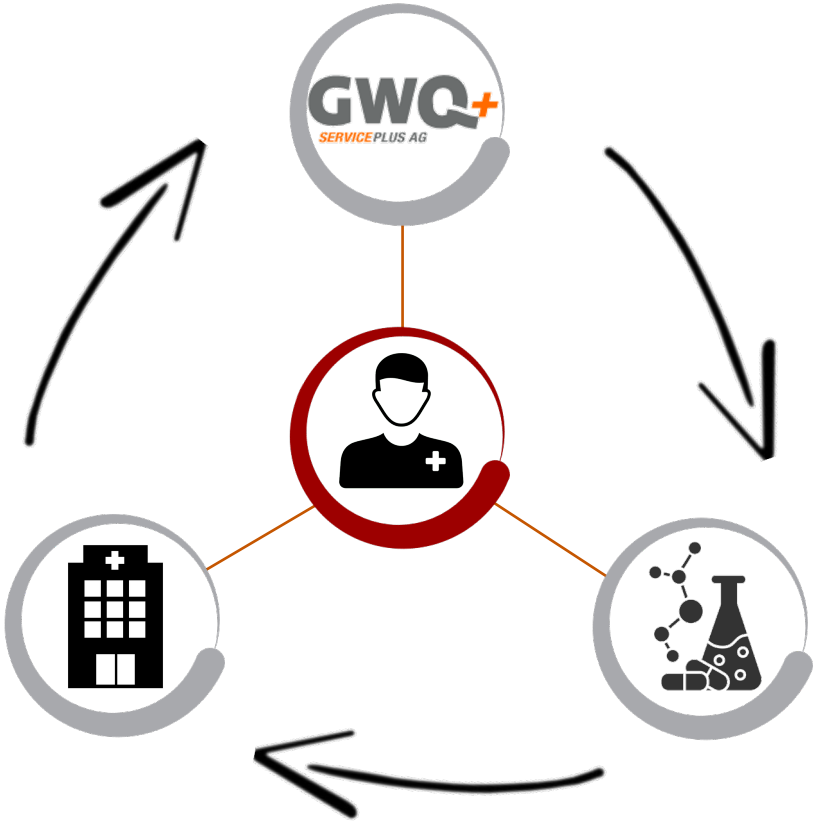
One time payment from the payer to the marketing authorization holder. The marketing authorization pays the full price or part of it back to the payer, if the medicinal product doesn´t result in the anticipated outcomes.

## Outcomes-based staged payments

The payment from the payer to the marketing authorization holder is spilt in several instalments. Each instalment (e.g. at time of application, after one year and after two years) will only initiated if the medicinal product results in the anticipated outcomes.

# MEAs in Germany

- Contracts should take effect from the first day of availability
- Insurance Fund(s) negotiate with MAH based on §130a SGB V
- Contracts in response to public pressure
- MAH hope to support market entry

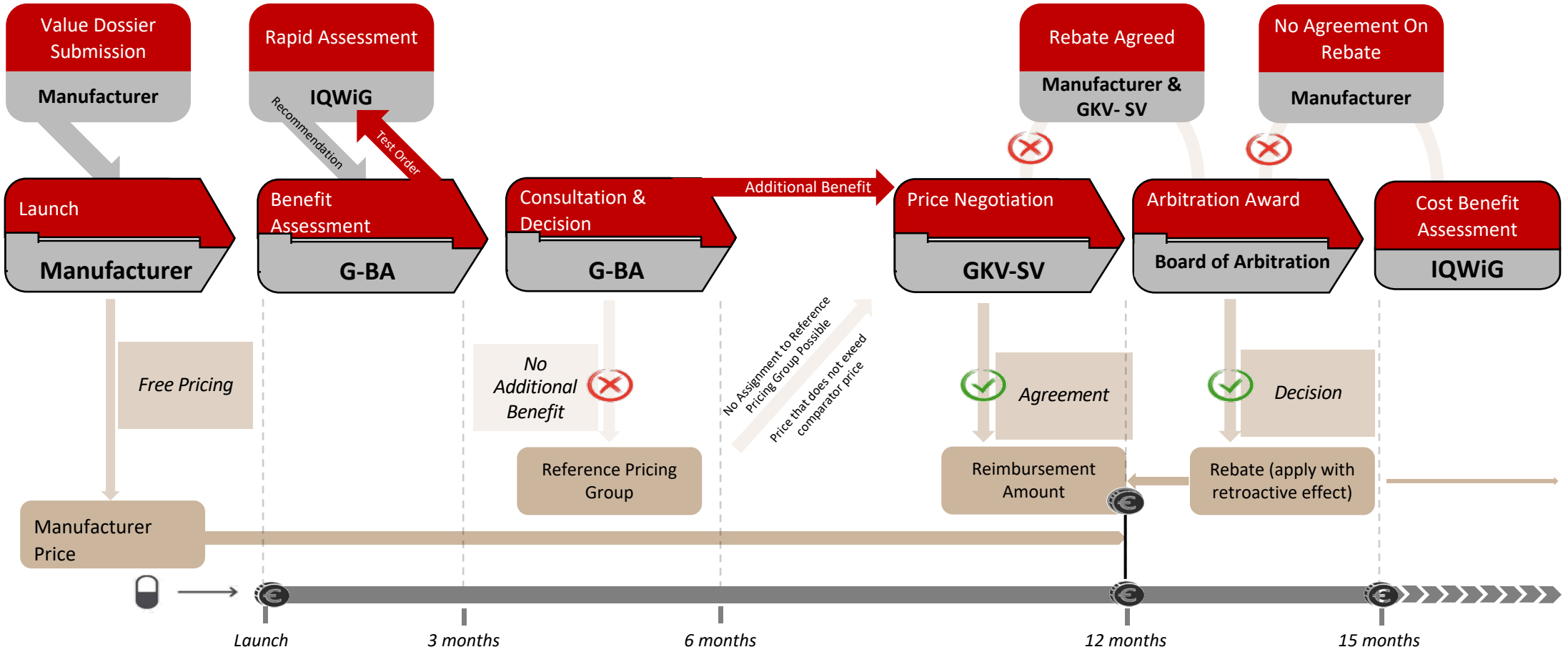





MAH = Marketing Authorization Holder

When

# ~~Where~~ to include MEAs in the AMNOG



# Inpatient Setting

*Payer and marketing authorization holders share the same final goal: Providing the best possible care for patients. However they have divergent intermediate goals*

## Treatment success

Involved parties need to agree on easy measurable treatment outcomes:

What happens if the disease progresses?

## Rebates

Insurance funds always want to have a basic rebate additional to the performance based rebates.


## Time frame

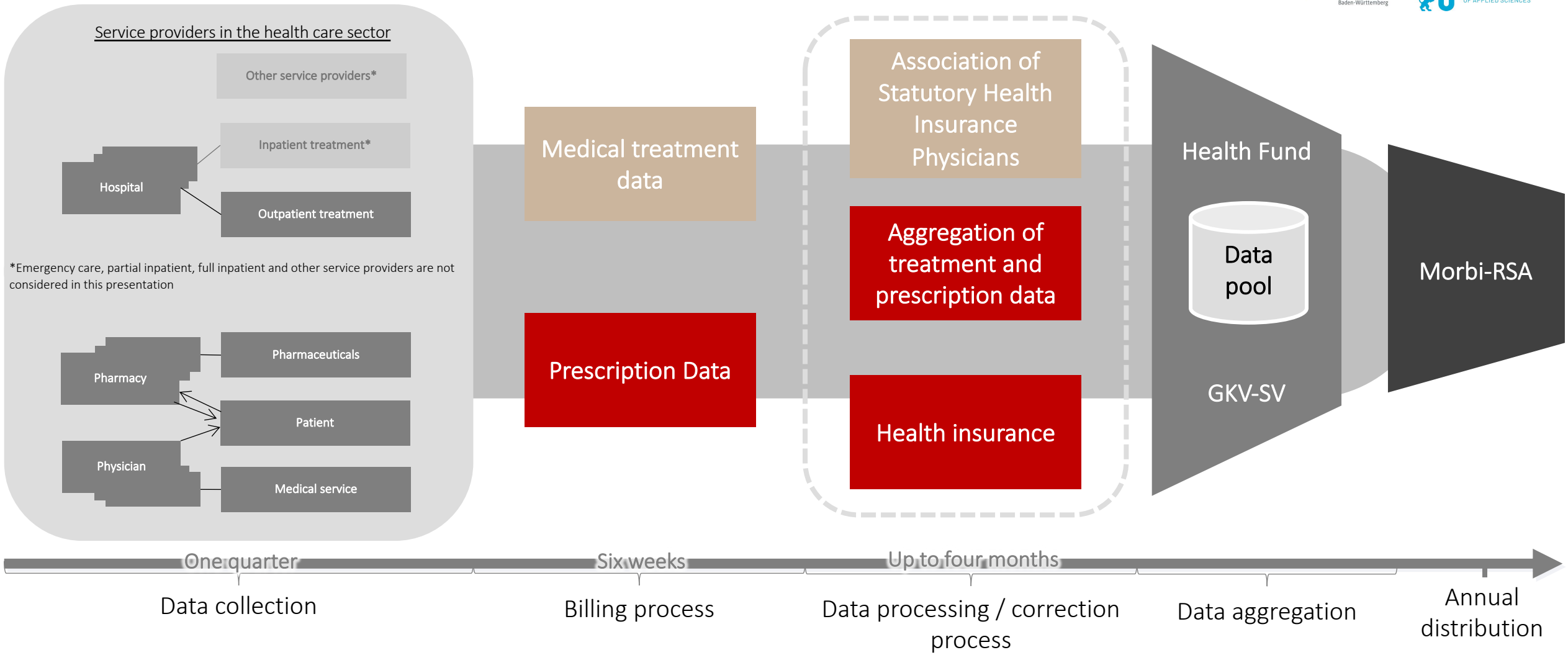
It appears to be a hard discussed topic for how long the agreements should last. This incorporates financial aspects (accruals) as well as medical aspects (time until progression)

## Role in central price negotiation

Marketing authorization holders want the agreements to be considered in the central price negotiations with the GKV-SV.

Insurance funds describe these processes as completely separate negotiations.

# Data Flow in the Outpatient Setting



# How reliable are outpatient data?

| Necessary data | | included | consistency |
|---|---|---|---|
| Medicinal product | Product name | ✓ | ● |
| Demographics | Patient ID | ✓ | ● |
| | Insurance | ✓ | ● |
| | Weight and gender | ✓ | ● |
| Diagnosis | Indication | ✓ | ● |
| | Dosing scheme | ✓ | ● |
| | Actual Dosage | ✓ | ● |
| Therapy | Start date of therapy | ✓ | ● |
| | Duration of therapy | ✓ | ● |
| | Co-medication | ✓ | ● |
| Outcome Measurements | Disease progression through prescription data (e.g. new medication) | ✓ | ● |
| | Disease progression through treatment data (e.g. OPS) | ✓ | ● |
| | Death of patient | ✓ | ● |

**Health Insurances have data on everything they pay for**

- ● Mostly consistent in data set
- ● Consistence is depending on indication
- ● Rather low consistency in data set

# MEAs for Digital Health Applications

| | |
|---|---|
| *Status Quo* | 5 Digital Health Applications in Germany included in the DIGA-directory<br>There are no Information on MEAs for Digital Health Applications available yet |
| *CED* | 3 Digital Health Applications are authorized within the conditional market access framework (comparable to the Coverage with evidence development agreements for pharmaceuticals) |
| *Hurdles* | Budget Impact & Measurement of and payment for Value |
| *Potential Solutions* | MEAs can address the Market Access hurdles of Digital Health Applications |

# MEAs for Digital Health Applications

*MEAs as a toolkit for Digital Health Applications*

**Budget Impact population level:**
Price/Volume agreements with utilization data on whole system level

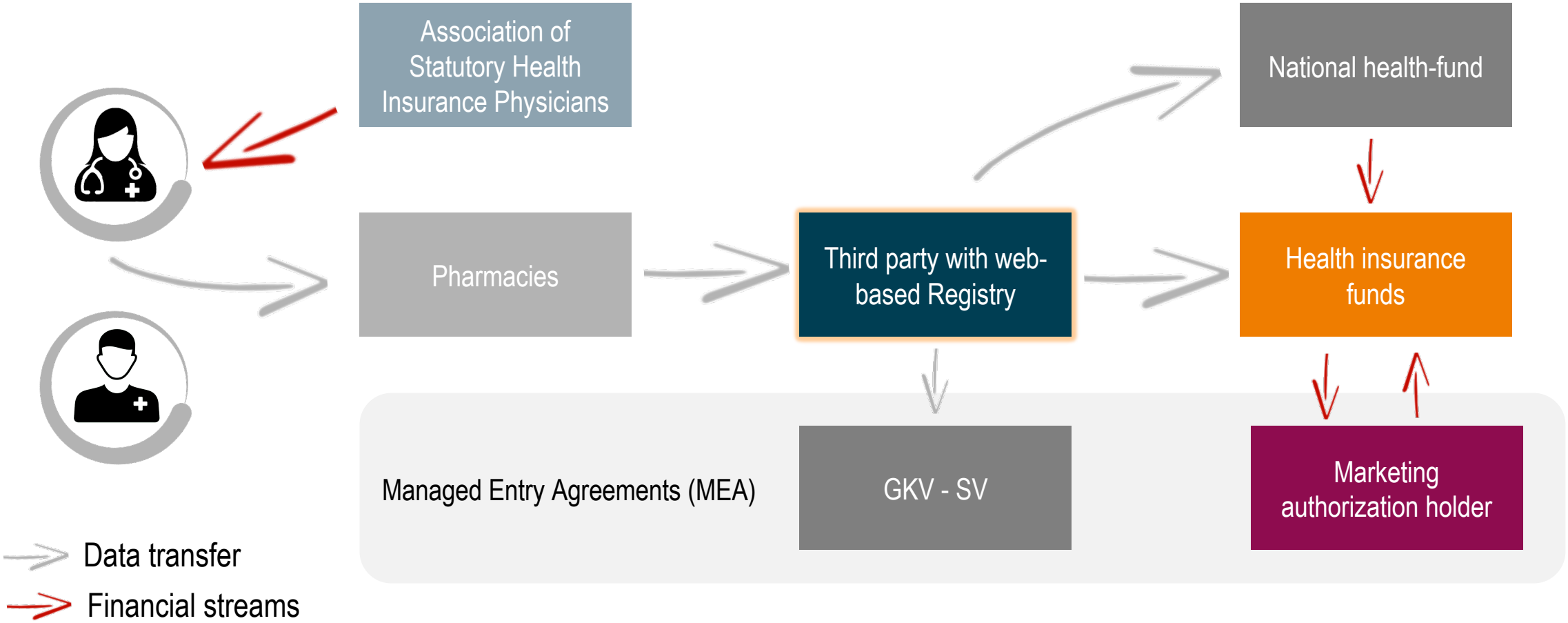
**Financial constrains on patient level:**
Utilization caps & rebates with utilization data on patient level

**Data Uncertainty:**
Coverage with evidence development

**Financial constrains & Data Uncertainty:**
Outcomes-based risk-sharing agreements

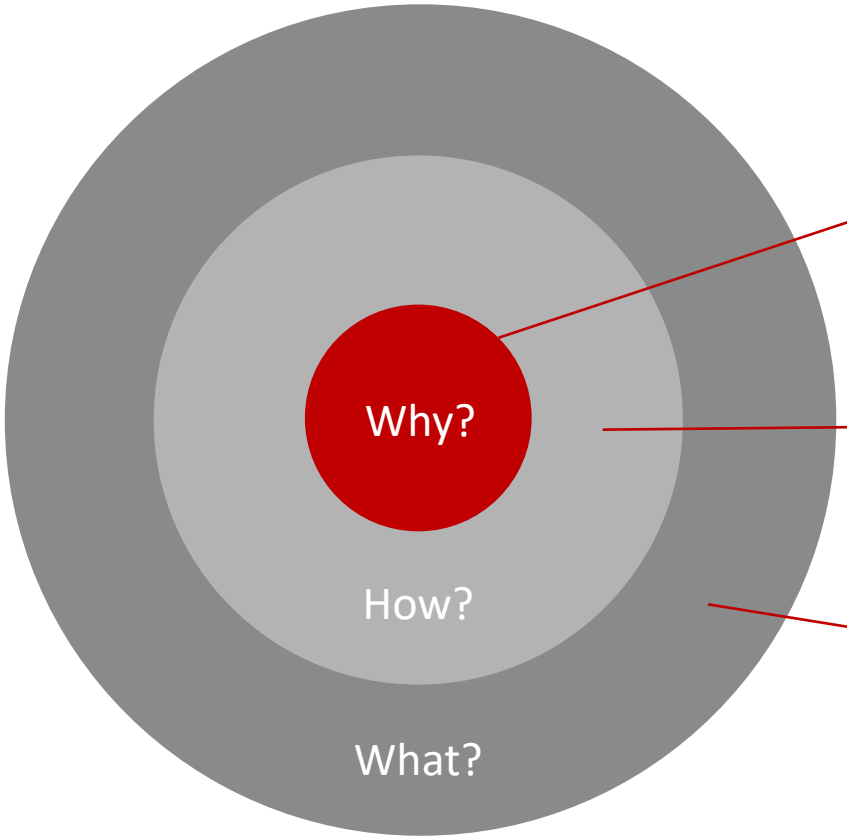
# What if…

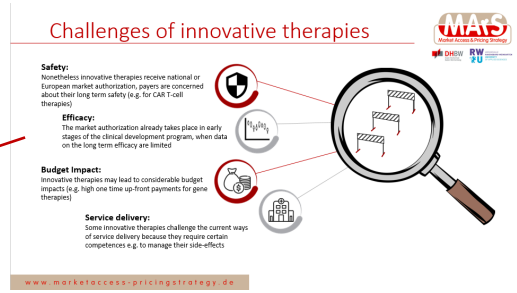
*we would try to implement a centralised system for MEAs*

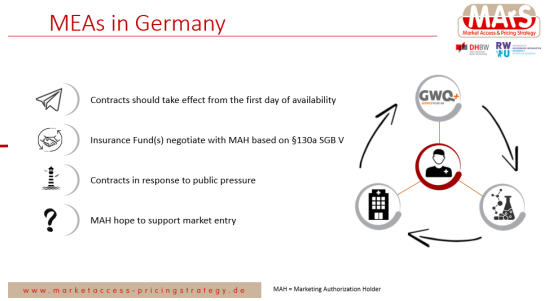


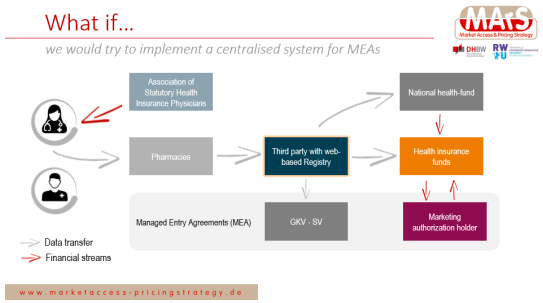
# Conclusions

*MEAs are possible in Germany and a way to share the risk of disruptive innovations*



# Questions?

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https://www.linkedin.com/company/mars-market-access-&-pricing-strategy-ug-h-b-