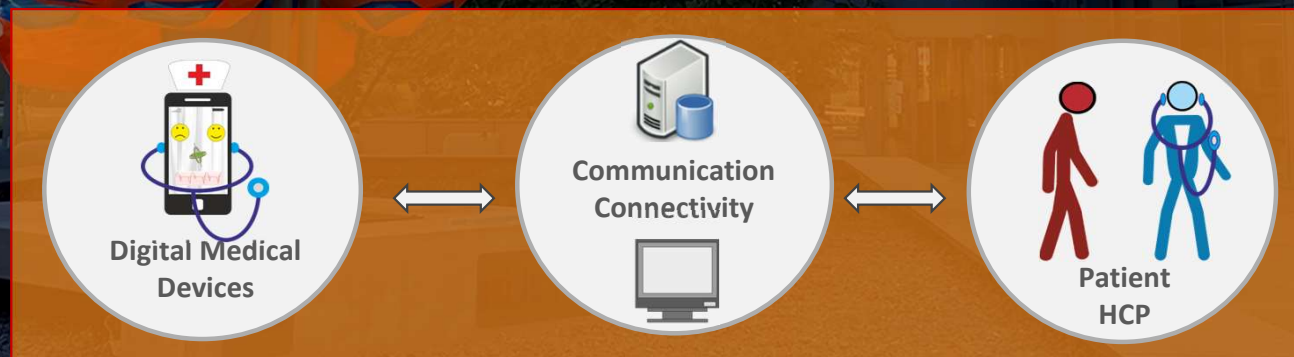
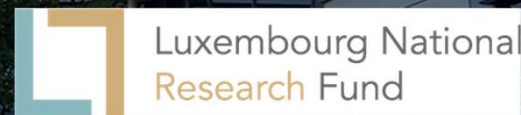


Patient centred societal benefit lessons from the German DiGA

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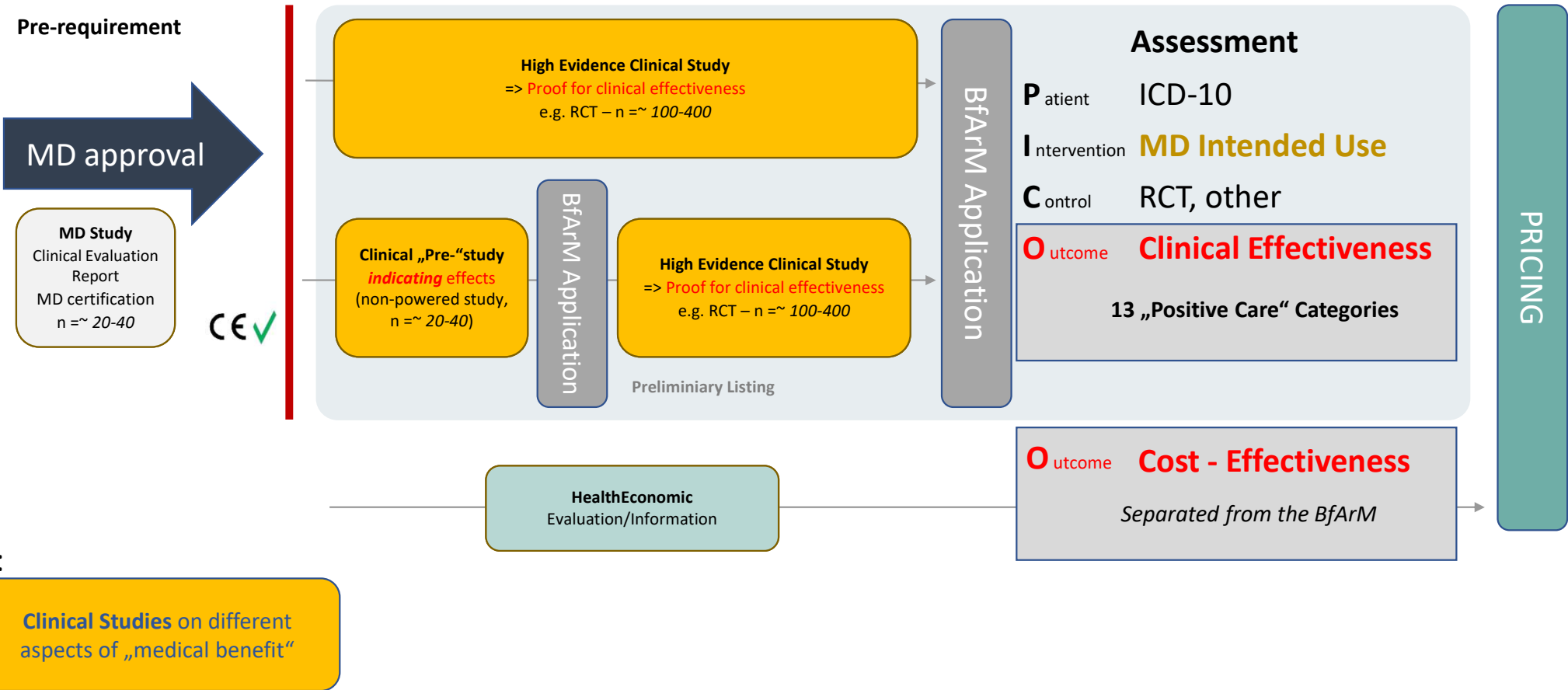
„Societal benefits“ for each patients (*not for society as a whole*)

Patient-centered values generated by digital support



Regulatory procedure for DiGAs: „Fast Track“

Evidence based Digital Medicine – different clinical studies and outcomes



„Positive Care Effects“ – Outcome categories of the German DiGA

Patient-centered outcomes – new terminology needed?

Clinical outcomes (primary endpoints)

- Medical benefits (*for each patient*)
- Structural&Procedural benefits (*for each patient*)



Organizational outcomes - benefit/costs (appraisal considerations)

- *For patients*
- *For healthcare provider*
- *For payer*

New Definition of „Positive Care Effects“ (- Endpoints)

Medical Benefits

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



New Definition of „Positive Care Effects“(- Endpoints)

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



New Endpoints used by DiGAs

Patient-relevant improvement of structure and processes



Bundesministerium
für Gesundheit

§: DVG

Patient-centered structural/procedural Outcomes	Final listed DiGAs (28)	Preliminary listed DiGAs (21)
1. coordination of treatment procedures		
2. alignment of treatment with guidelines and recognized standards		1
3. adherence		
4. facilitating access to care		
5. patient safety		
6. health literacy	1	2
7. patient autonomy – shared decision making	3	
8. coping with illness-related difficulties in everyday life	1	1
9. reduction of therapy-related efforts and strains for patients and their relatives	1	

BfArM Verzeichnis, 49 DiGAs listed, Nov. 2023

