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Clinical trials as part of reimbursement strategy

Gerd Gottschalk, October, 26th 2017

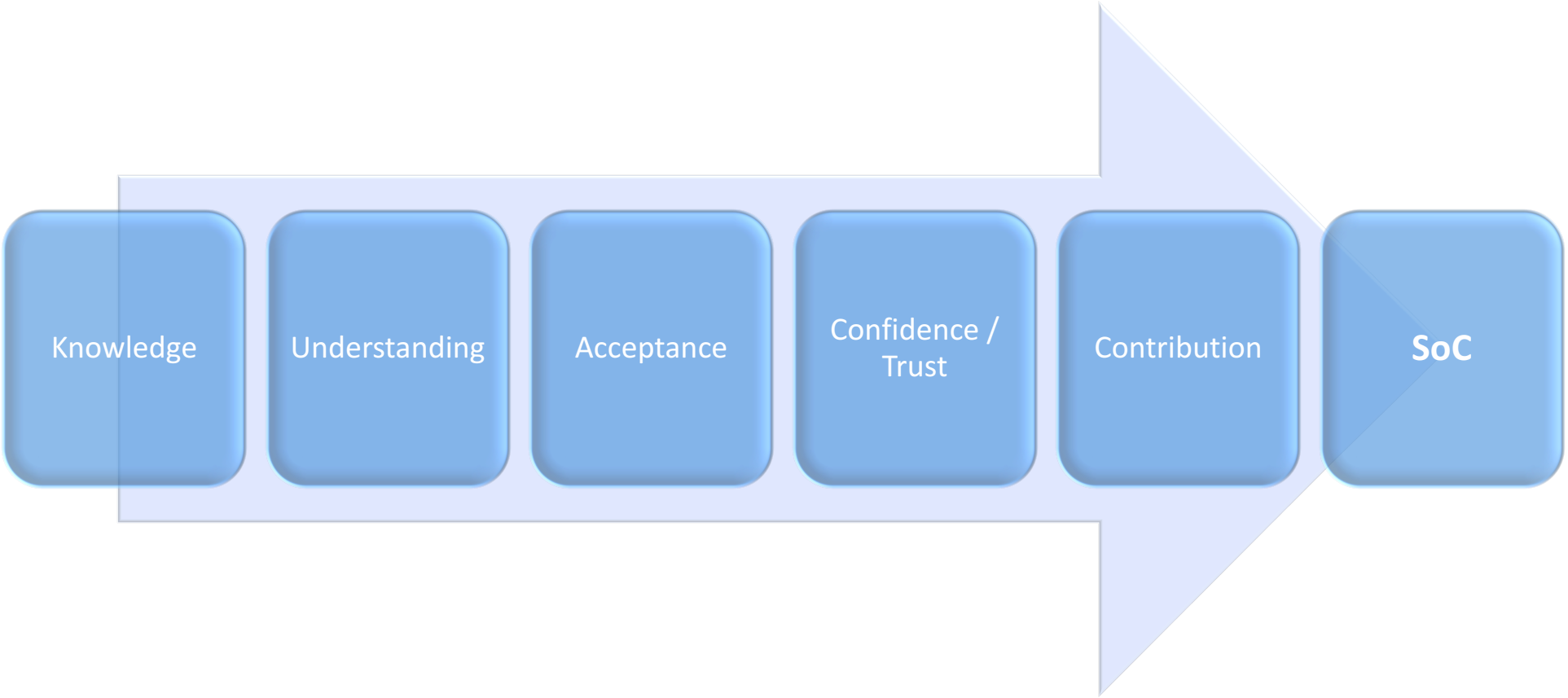
Work Experiences:

- Health Insurance Funds
  18 years
- MedTech Industry
  13 years
- Innovations:
  Continuous Glucose Monitoring (Type 1 Diabetes)
  EndoBarrier® (Type 2 Diabetes & Obesity)
  Pulsante® Microstimulator (Cluster Headache)

Outline

- **Objectives of Reimbursement**
- Clinical Strategy
- Evidence Assessment Germany

Objective of Reimbursement



- Achievement of Standard of Care (SoC)
  - NO Reimbursement = NO Market

Cost-Benefit-Ratio

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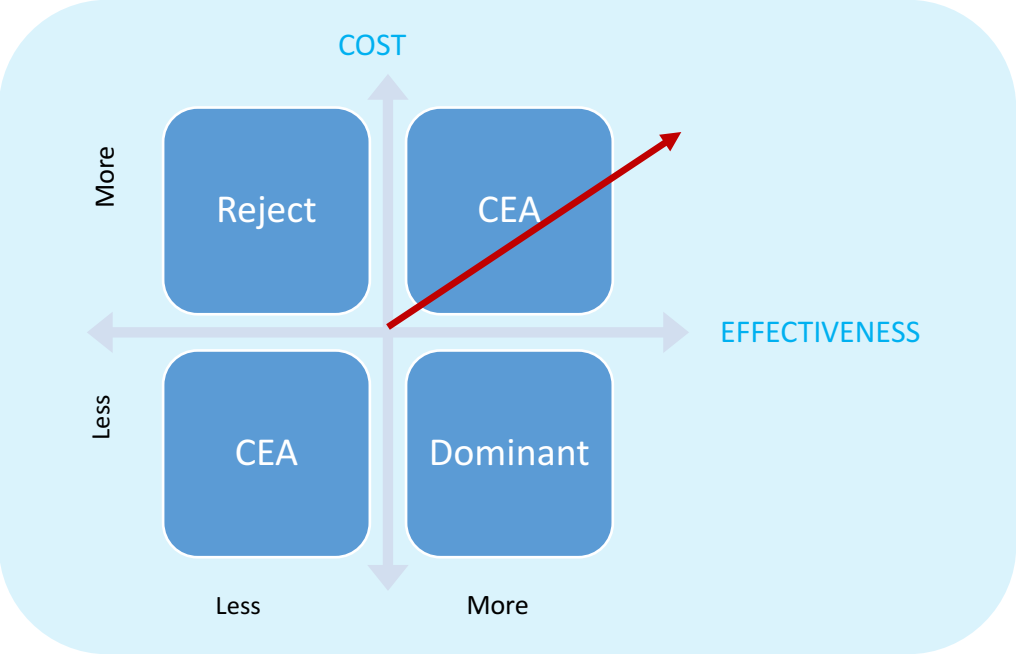
Evaluates and compares costs and effectiveness of alternative interventions



- **QALY**
  Quality adjusted life years
- **ICER**
  Incremental Cost-Effectiveness Ratio
- **Efficacy Border →**
  (prefered in Germany)

If the payer/society is willing to pay (WTP) XYZ$ or more per Life Year Gained, then Treatment A is Preferred and Considered "Good Value for Money"

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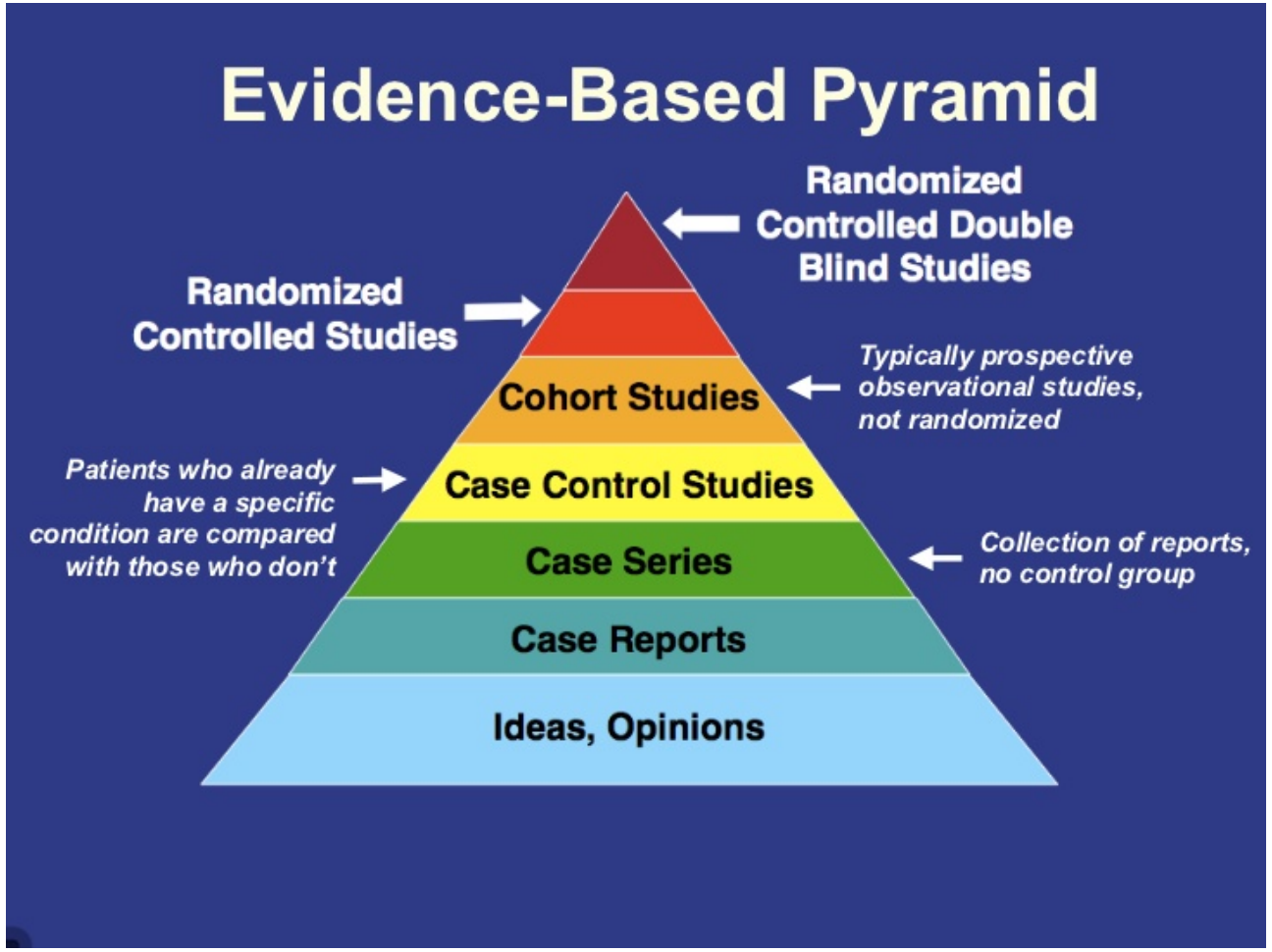
Evidence Ranking



Clinical strategy required

- Type of study
- Questions to be answered?
- Patient population / indication
- Number of patients (power analysis)
- Intervention and comparator (SoC)
- Primary and secondary outcome parameters (PRO)
- Period of observation
- Quality management
- Timing

Excursion: Clinical strategy

Study Characteristic	Study 06-6	Study 07-1	Study 07-1 (X-over)	Study 08-2	Study 08-1	Study 09-3 (Re-implant)	Study 10-1
Indication	T2D	T2D	T2D	T2D	Obese	Obese	T2D
Country	Brazil	NL – 3 sites	NL – 3 sites	Brazil	Chile	Chile	UK
PI	Moura	Greve	Greve	Cohen	Escalona	Escalona	Teare
# of implant	22	39	28	20	43	19	45
# of controls	NA	38	NA	NA	NA	NA	NA
Design	Single Arm	RCT-diet control	OLE	Single Arm	Single Arm	Single Arm	Single Arm
BMI (kg/m^2)	40-60 w/o co-mo; 35-60 w/co-mo	30-50	NA	26-50	40-60 w/o co-mo. 35-60 w/co-mo	NA	30-50
A1C (%)	Not defined	7.5 – 10	NA	7.5 – 10	NA	NA	7.5 – 10
Duration	12 mo	6 mo	6-12 mo	12 mo	12 mo	12 mo	12 mo
Post follow-up	6 mo	6 mo	6 mo	12 mo	6 mo	6 mo	6 mo
Endpoint	% EWL	A1C	A1C	A1C	%EWL	%EWL	%EWL
Status	Complete	Complete	Complete	Complete	Complete	Complete	Complete

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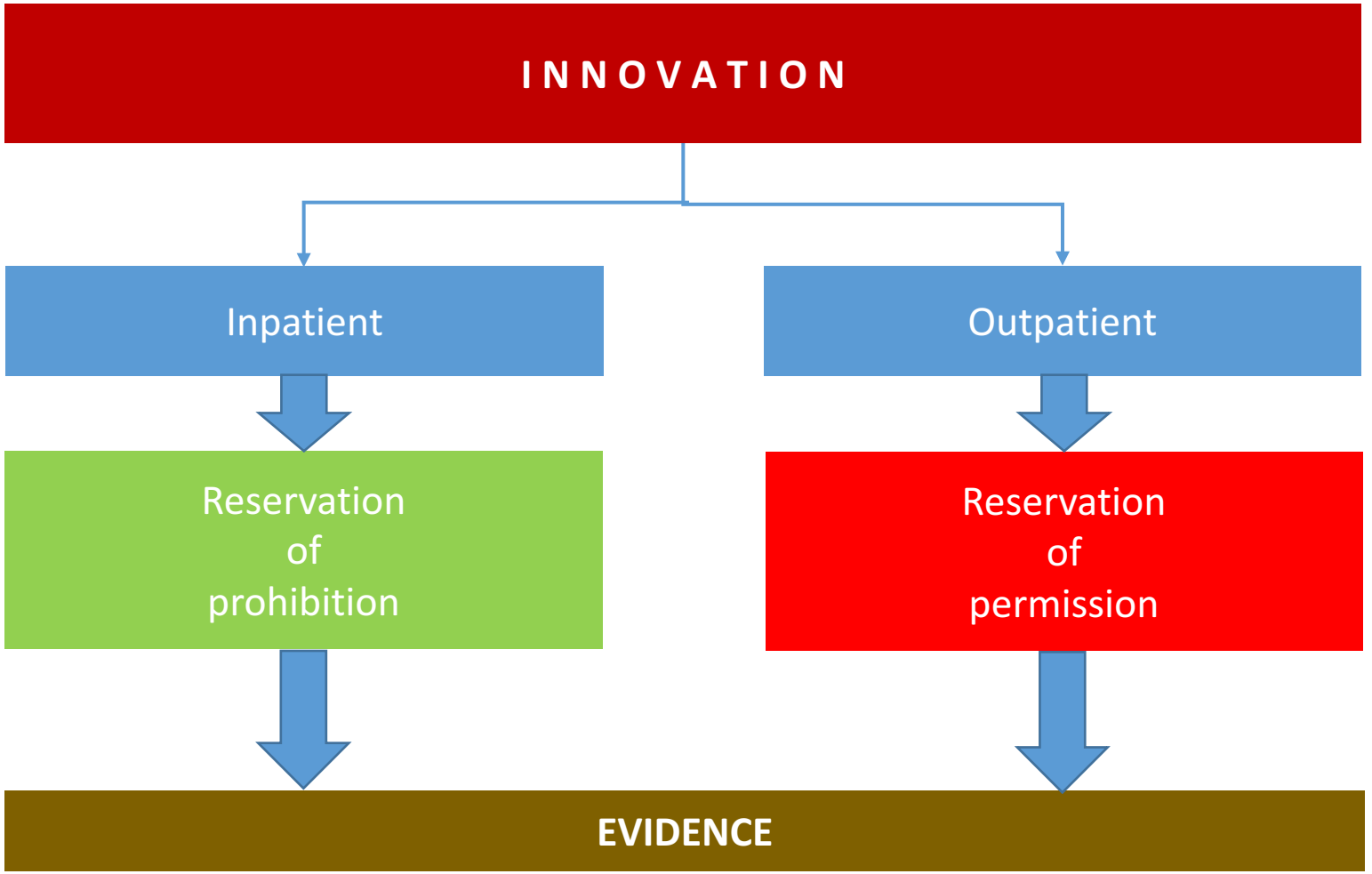
Germany: Two Pathways



Germany: Outpatient

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INNOVATION

Acceptance	Trial (CED)	Skip counsel	Exclusion
meet criteria proven evidence	not enough evidence, but proven potential	not enough evidence & proven potential, but ongoing studies	no benefit no potential harmful, ineffective

- **Potential: potential of a required treatment alternative**
- **CED: coverage by evidence development**
- **Timing: 8– 15 years (very formal process)**

Impact of CED programs:
- Procedures paid by HIFs
- Overhead paid by manufacturer

Germany: Inpatient (NUB)

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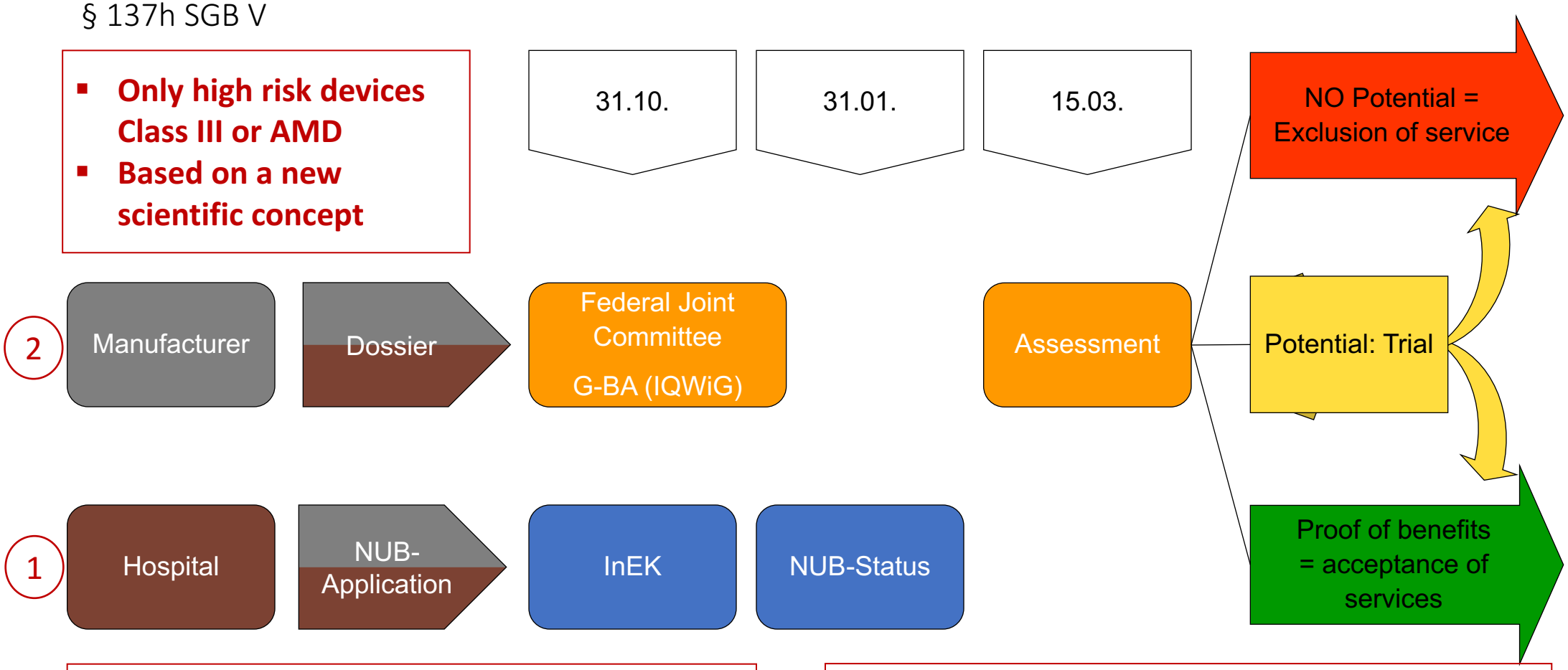
- **Only high risk devices Class III or AMD**
- **Based on a new scientific concept**



Two applications:

- **NUB: closing financial gap**
- **Dossier: early evidence assessment**

- **NO Potential = Exclusion**
- **Fast track closing financial gap**
  Timing: 3-5 years (depending on trail)

Take Away

- RCT – RCT – RCT / Control – Control – Control
- Clinical STRATEGY essential - REIMBURSEMENT strategy before CE-mark
- Support of MEDICAL SOCIETIES required (KOL management)
- Use PUBLIC CONSULTATION opportunities (e.g. GER / UK / F / N)
- COUNTRY FOCUS with European / International prospective

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