

# Regulating PDTs: The German experience

**Jonas Albert**

Managing Consultant, Digital Health Unit – fbeta GmbH

Director Health Reality Lab Network – HLaN e.V.

# Disclosures / Disclaimers


- **Working on Digital Health Projects for the BfArM (Bundesinstitut für Arzneimittel und Medizinprodukte) and the German Federal Ministry of Health**
- **Consulted Selfapy GmbH, Newsenselab GmbH, Perfood GmbH**

The BFARMs Perspective on Evidence for PDTs (DiGAs)


# Evidence-Requirements and Examples




P - Population



I - Intervention



C - Control

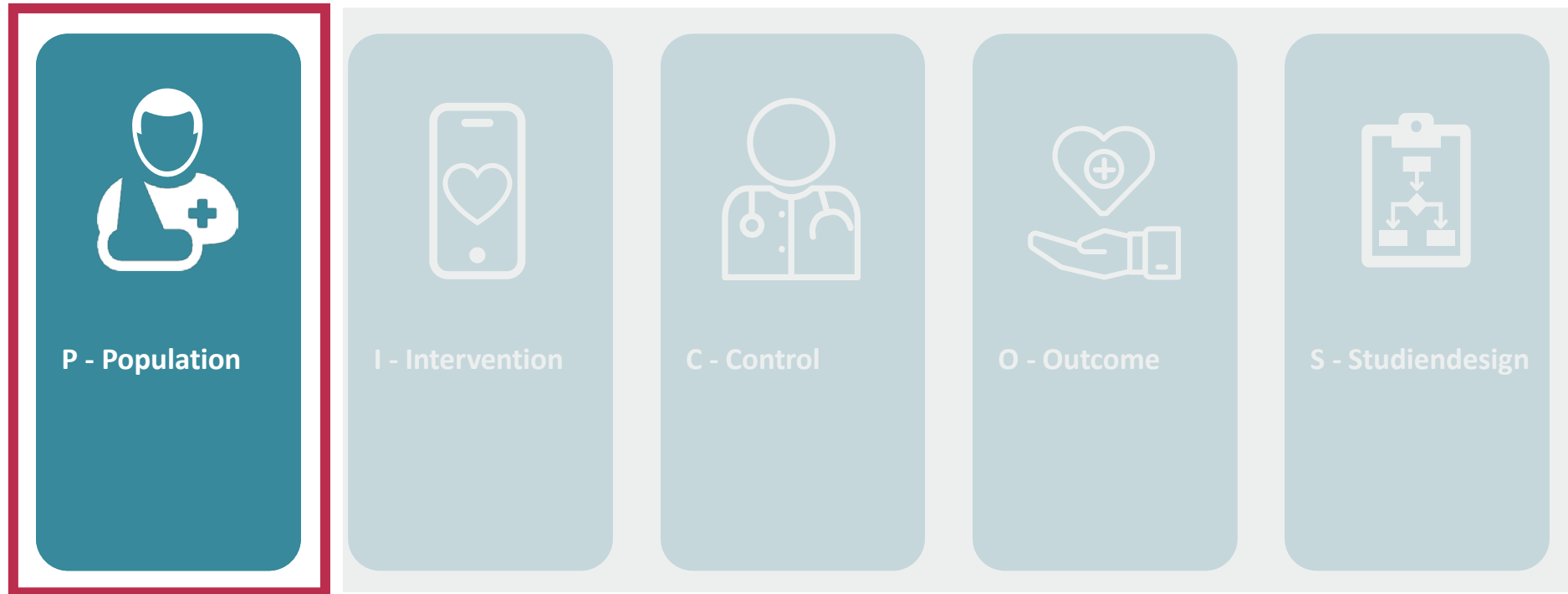


O - Outcome



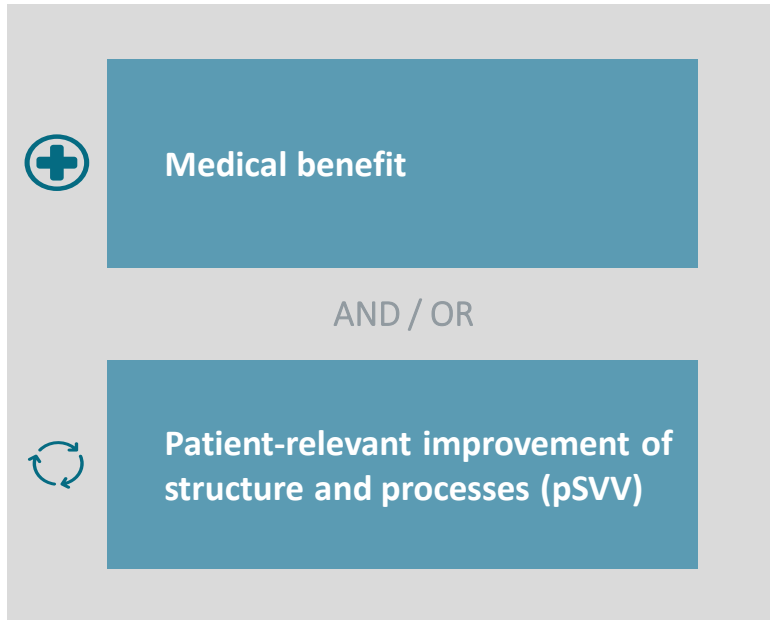
S - Study design

# Population



# Definition of the patient group based on ICD-10 Codes

## Positive healthcare effects

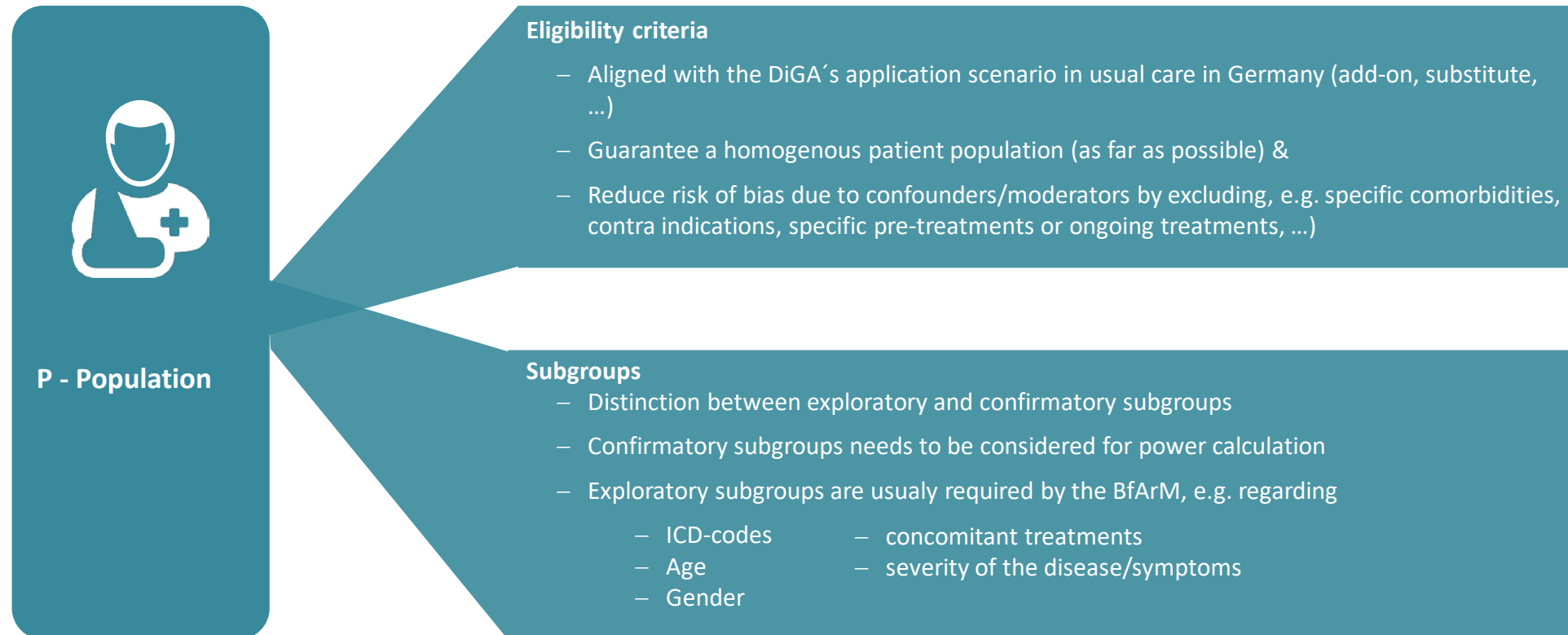


## Definition of the patient population

- **Specification** of the positive healthcare effects (pVE) with associated **patient group**
- **Listing** only for stated and **proven** indications
- Definition and delimitation of the patient group must be based on **ICD-10 codes**
- **Individual proof** for each indication
- In the case of several indications, **collective proof** possible if comparability with regard to pVE is ensured
- **Specific justification** required why a collective proof is applicable

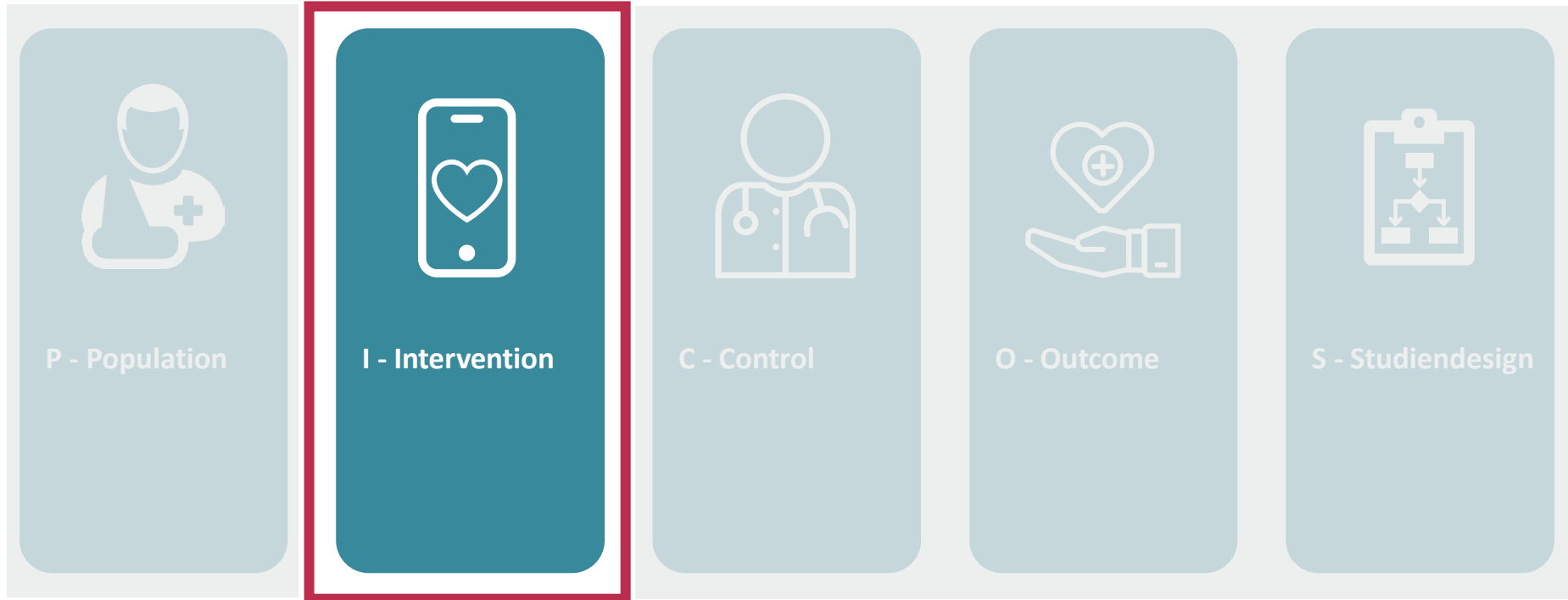
- Identification and selection of relevant ICD-10 Codes
- Rational for a collective proof required
- Decision regarding exploratory/confirmatory subgroup analyses

# PICO(S) framework: P - Population



The BFArMs Perspective on Evidence for PDTs (DiGAs)

## PICO(S) framework: I - Intervention



# PICO(S) framework: I - Intervention



## Interventional period

- Time period of usage (short-term intervention vs. long-term support)
- Duration within study (3-6 month due to limited duration of 12 month)
- Time to results within study (minimal time of app usage to achieve improvements, time of app usage to achieve best results, ...)
- Follow-up (yes/no and duration of follow-up)

## Usage of the app within usual care

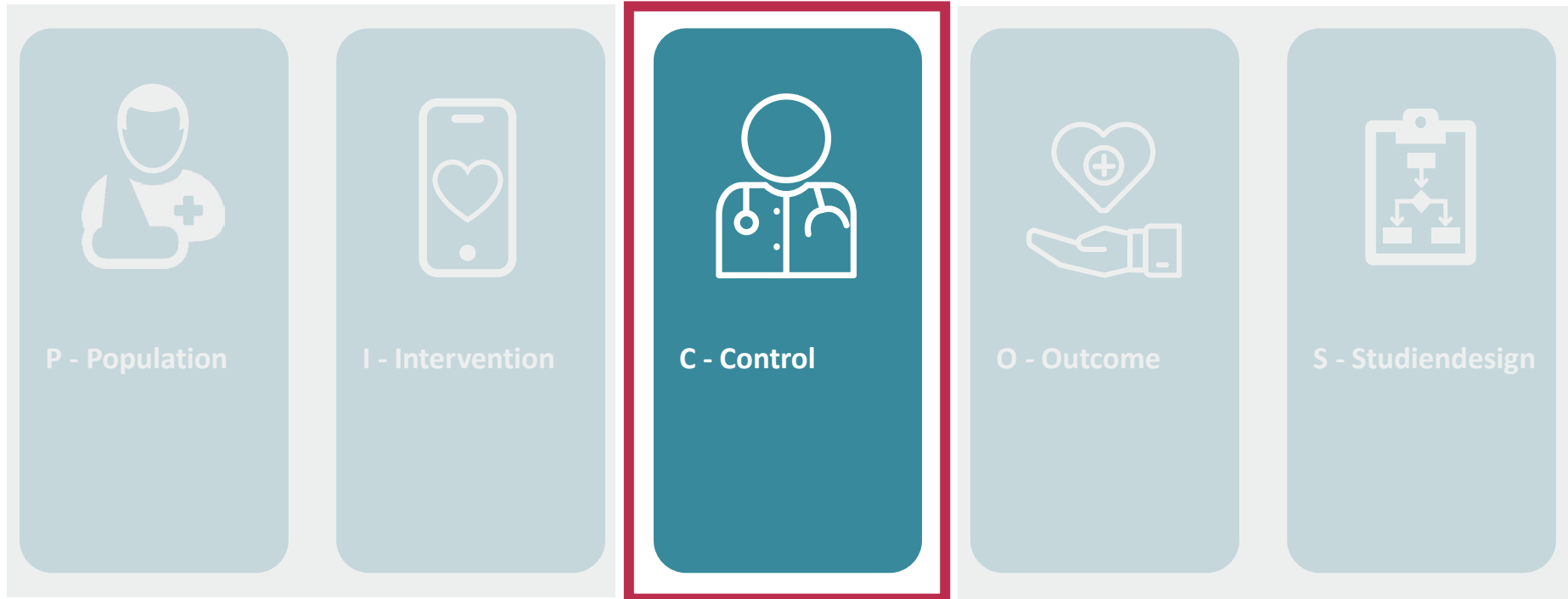
- Time period of usage (short-term vs. long-term)
- Line of therapy (first line, second line, etc.)
- Interaction with other services
  - Add-on to existing services (add-on)
  - Substitution of existing services (substitute)
  - Stabilization of results from primary treatment / tertiary prevention
  - Closing treatment gaps (bridge)

## Definition of usual care / care-as-usual (= „Versorgungsrealität“)

- Guidelines: How should patients be treated?
- Usual care: How are patients treated in Germany?
- Which healthcare professionals are participating?
- How many physician-patients contacts do patients have within usual care?



# PICO(S) framework: C - Control



## PICO(S) framework: C - Control



### Definition of usual care / care-as-usual (=Versorgungsrealität)

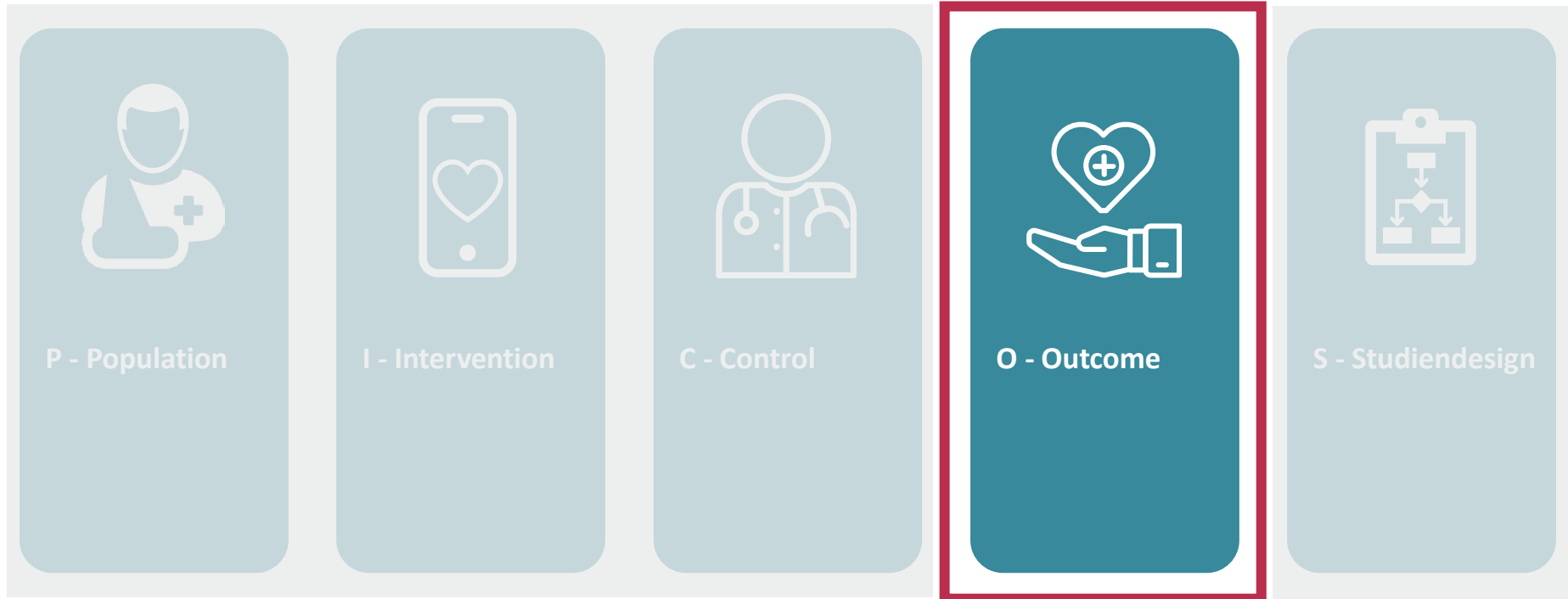
- Guidelines: How should patients be treated?
- Usual care: How are patients treated in Germany?
- Which healthcare professionals are participating?
- How many physician-patient contacts do patients have within usual care?

### Usage of the app within usual care

- Time period of usage (short-term vs. long-term)
- Line of therapy (first line, second line, etc.)
- Interaction with other services
  - Add-on to existing services (add-on)
  - Substitution of existing services (substitute)
  - Stabilization of results after primary treatment /tertiary prevention or closing treatment gaps (bridge)

The BFArMs Perspective on Evidence for PDTs (DiGAs)

# PICO(S) framework: O - Outcome



# Positive healthcare effects according to DiGA-Ordinance

Proof of

**positive healthcare effects**

is the prerequisite for listing



## Medical benefit

- Improvement of the state of health
- Reduction the duration of the disease
- Prolongation of survival
- Improvement in the health-related quality of life
- ...

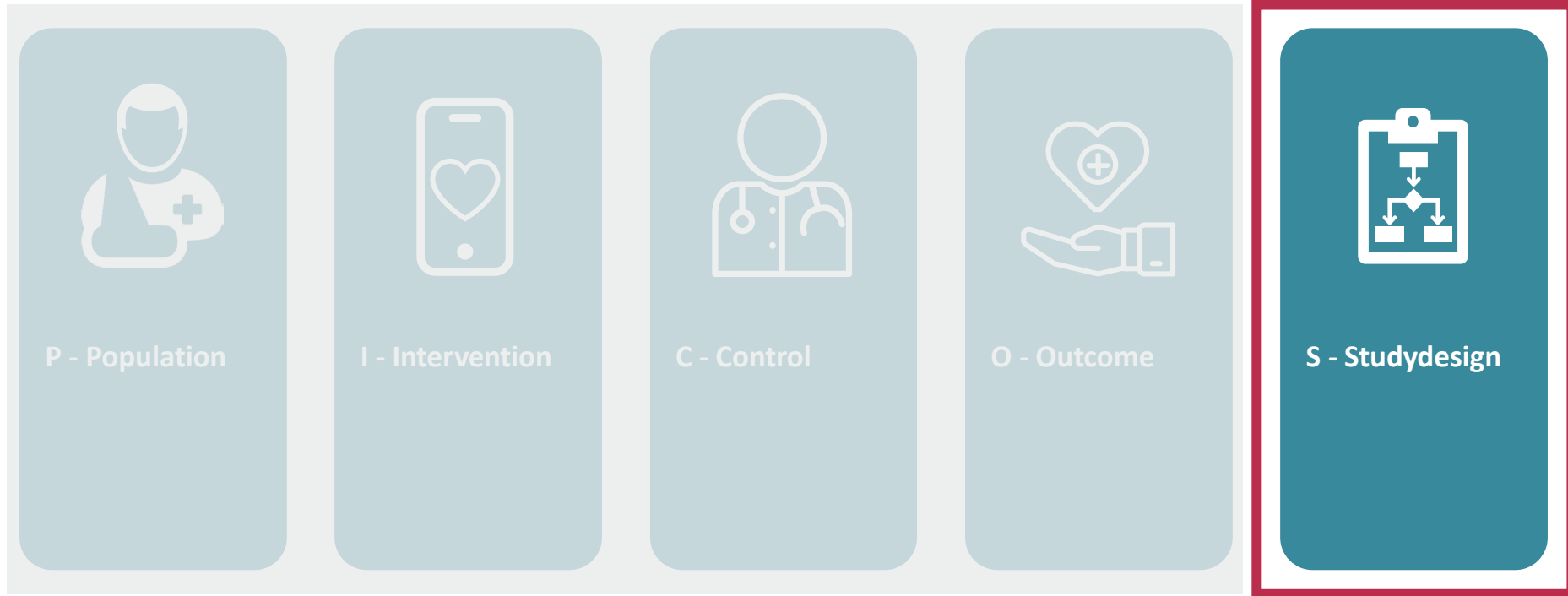


## Patient-relevant improvement of structure and processes

- Coordination of treatment processes
- Alignment of treatment with guidelines and accepted standards
- Adherence
- Facilitating access to care
- Patient safety
- Health literacy
- Patient autonomy
- Coping with illness-related difficulties in everyday life
- Reducing therapy-related expenses and strains for patients and their relatives
- ...

The BFARMs Perspective on Evidence for PDTs (DiGAs)

# PICO(S) framework: S - study design



## The BFArMs Perspective on Evidence for PDTs (DiGAs)

### Examples for Evidence-Studies for Depression-DiGA (final listing)

Name	Indication(s)	Number of Participants	Intervention-Type	Control-Conditions	PvE-relevant Outcome	Study-type	Other interesting Info
Deprexis (Gaia AG)	F32.0, F32.1, F32.2, F33.0 F33.1, F33.2	1013 plus 163	App-guided cognitive behavioural therapy	Care as usual including Psychotherapie and anti-depressant medication	PHQ-9 after 12 weeks	2-armed, randomised, controlled prospective study	Impact of psychotherapy and relevant pharmaceutical therapy Therapie was assessed
Selfapys Online-Kurs bei Depression (Selfapy GmbH)	F32.0 F32.1 F33.0 F33.1	400	App-guided cognitive behavioural therapie with and without psycho-therapeutic support	Care as usual including psychotherapy and anti-depressant medication	BDI-II after 12 weeks	3-armed, randomised, controlled prospective study	Impact of psychotherapy and relevant pharmaceutical therapy Therapie was assessed

## The BFArMs Perspective on Evidence for PDTs (DiGAs)

# Examples for Evidence-Studies for Migraine-DiGA (preliminary and de-listed)

Name	Indication(s)	Number of Participants	Intervention-Type	Control-Conditions	PvE-relevant Outcome	Study-type	Other interesting Info
SinCephala (Perfood GmbH)	G43.0 G43.1	71	Nutrition-based behavioural intervention, support by a CGM-Monitor	No control (assumed stable condition due to chronic migraine)	Migraine-Days after 12 weeks	Uncontrolled, intraindividual study.	BfArM accepted no control, as no spontaneous improvement of patients was expected
Msense (Newsenselab GmbH)	G43 (all sub-indications)	346	App-guided behavioural intervention to identify and alleviate migraine-triggers	Care as usual plus „Sham-DiGA“ (App with a migraine-diary)	Migraine-Days after 12 weeks	2-armed, randomised, controlled prospective study	The active control-group created so much participation-bias that the effects of the app became non-significant for the number of participants