

## Project Background

The Value of Treatment for brain disorders (VOT) is a health economics and outcomes research initiative coordinated by the European Brain Council (EBC). The Value of Treatment (VOT) initiative aims to examine health gains and socio-economic impacts resulting from optimized healthcare interventions in comparison with current care or inadequate treatment and converge data evidence to policy recommendations on how to improve the care pathway(s). Convinced that a complex issue such as chronic pain would benefit from the VOT methodology, a case study on this transversal topic was launched by EBC in December 2020.

## Types of Chronic Pain Disorders

The WHO ICD-11 classification<sup>1</sup> was used to select three types of chronic pain disorders.

1. fibromyalgia (as an example of primary chronic pain)
2. painful diabetic neuropathy (as an example of chronic secondary neuropathic pain)
3. non-specific low-back pain (as an example of musculoskeletal pain considered as a common type somewhere in the continuum between chronic secondary and chronic primary pain).

## Objectives of the Chronic Pain study:

In line with the VOT research methodology (figure 1), the objectives of the study are:

1. To explore the patient pathway of adults of working age in the three selected diseases: fibromyalgia, painful diabetic neuropathy, non-specific low-back pain.

The study will focus on the **following gaps**:

- a. Long waiting times to access primary care (GPs)
- b. Lack of referrals to secondary care between primary care – secondary care & tertiary care (fibromyalgia and non-specific low back pain).

2. To compare **best practice healthcare intervention**:

Interdisciplinary Multimodal Chronic Pain Management with current care: monomodal therapy (drug or physiotherapy or psychotherapy alone) in adults of working age

For the definition of 'Interdisciplinary Multimodal Chronic Pain Management', the working group refers to the components of [interdisciplinary chronic pain management as defined by IASP](#) and the [2017 article published in Pain Journal](#). In dialogue with the patients, the working group considers that Interdisciplinary Multimodal Chronic Pain Management must combine the following modalities/therapies according to a plan: Medication, Physiotherapy, Psychotherapy/mental health interventions, Complementary medicines, Self-management.

Self-management is used as a broader term that includes self-medication as well as patients actively involved in treatment and care decision-making. It may also include other aspects such as diet or exercise.

## Countries:

Initially: Germany. Another two countries to be selected among these four: Sweden, Portugal, Italy, Slovenia depending on data availability.

## Funding:

The study is supported with grants from Grünenthal and Pfizer.

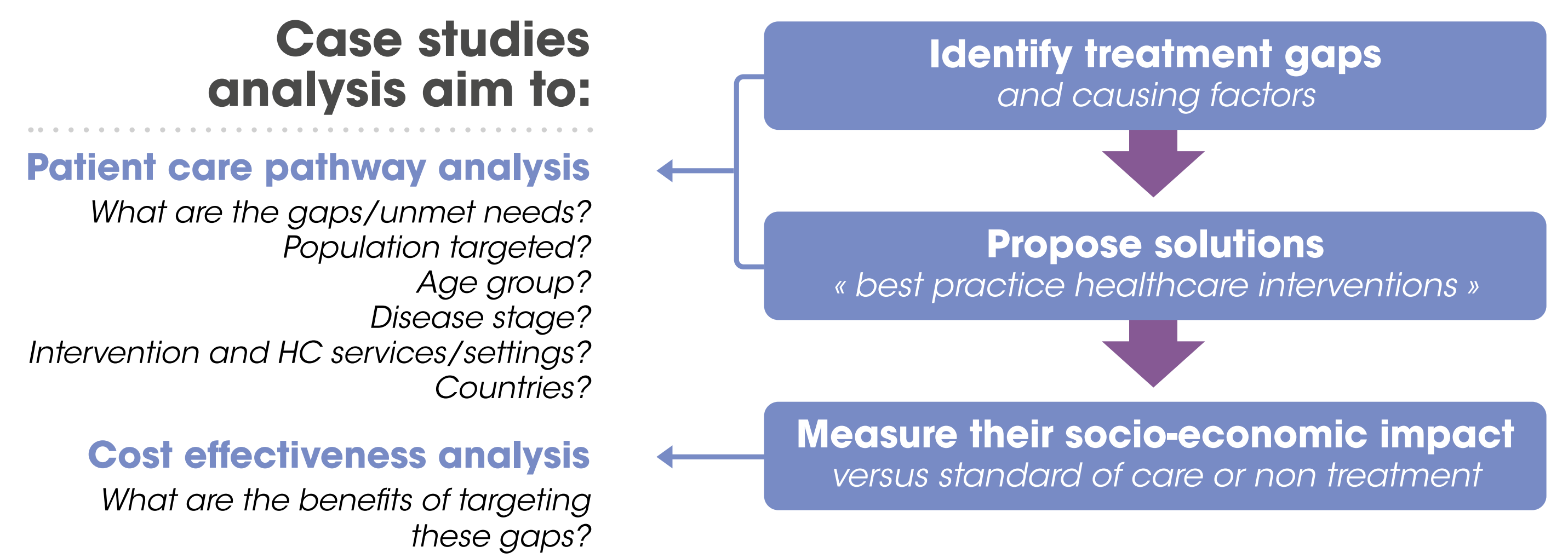
## Research Collaboration

Collaboration between scientists, clinicians, health economist and patient association. Representatives of:

- The European Pain Federation (EFIC)
- Pain Alliance Europe (PAE)
- The European Academy of Neurology (EAN)
- The European Psychiatric Association (EPA)
- Health economist, A2 Minerva

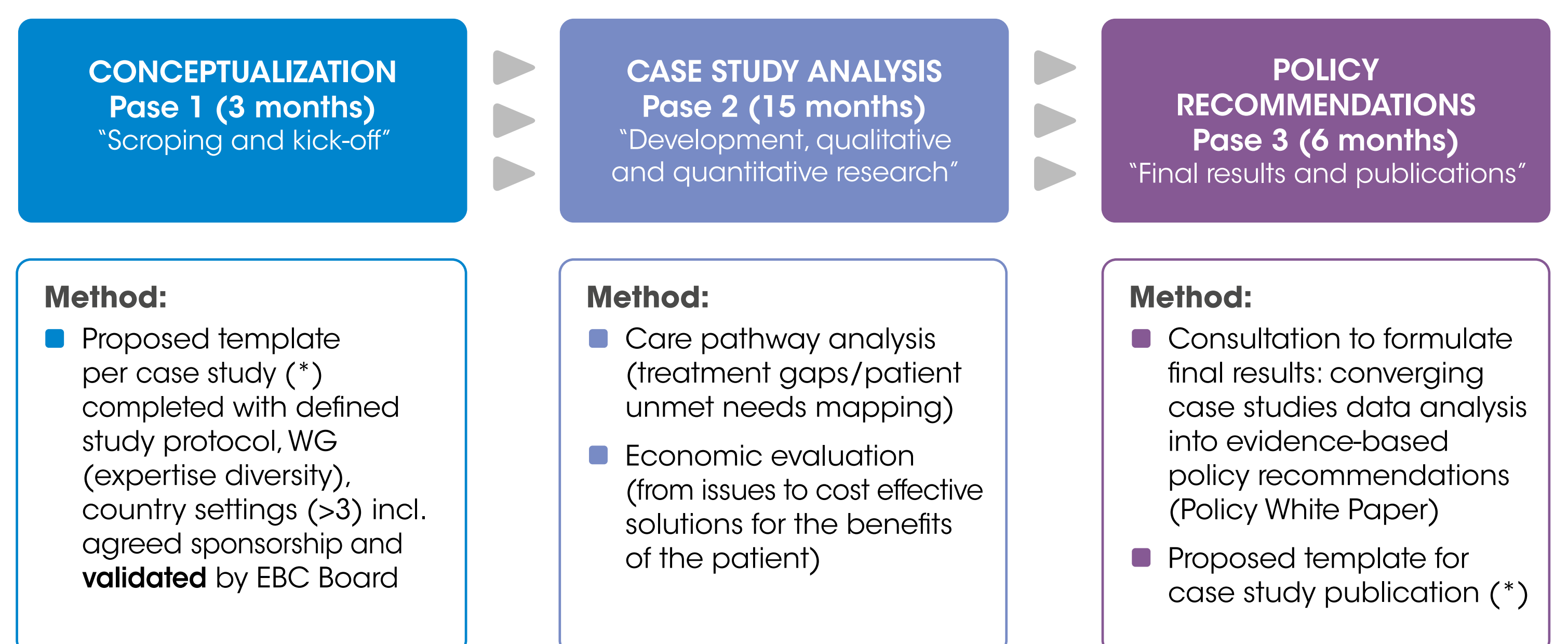


## VOT Research Methodology - Figure 1



## Three Research phases - Figure 2: Research 3 phases

The VOT initiative consists of three phases: conceptualisation, development and research, final results and publication (cf figure 2).



## Phase 2 - Case study analysis method: care pathway analysis and economic modelling

The care pathway analysis will be followed by an economic evaluation. The economic modelling will be a care pathway model with different variables: optimizing monotherapy to combination multimodal therapies, optimizing referral patterns and diagnostic times.

### Selected indicators: costs & effectiveness

#### Cost indicators:

- **healthcare** (direct medical and non-medical costs)
- **societal** (indirect costs)
- **costs for patients**

#### Effectiveness indicators:

- **Pain severity** with indicators of pain intensity, stress and functional impairment (in daily life and at the workplace) = quality of life.
- **Co-morbidities**: Depression & anxiety, medication overuse (benzodiazepines, gabapentinoids, opioids and NSAIDs), sleep disturbances. Suicide will be included in the discussion part according to international data available on mortality rates related to depression and medication overuse.

## Project timeline: December 2020 – February 2023

| VOT  | Phase 1   | Phase 2  | Phase 3  |
|--|---|--|--|
| Chronic Pain New case study<br>Planned Timeline:<br>24 months starting in Dec 2020             | «Scoping and kick-off»<br>Dec 2020 - May 2021<br>(6 months) | «Development, qualitative and quantitative research»<br>June 2021 - August 2022<br>(15 months) | «Final results, reports and publications»<br>Sept 2022 - February 2023<br>(6 months) |
| Month  | M1 - M2 - M3 - M4 - M5 - M6                                 | M7 - M8 - M9 - M10 - M11 - M12 - M13 - M14 - M15 - M16 - M17 - M18 - M19 - M20 - M21           | M22 - M23 - M24 - M25 - M26 - M27  |
| A1. Scoping meeting (5)  | Start   | End  |  |
| A2. define scope, research questions and methodology including WG                              | Start   | End  |  |
| Financing  | Pfizer / Grünenthal   |  |  |
| A3. «Data collection, analysis and interpretation» via literature review, situation assessment |   | Start  | End  |
| A4. Care pathway analysis  |   | Start  | End  |
| A5. Economic evaluation based on care pathway analysis + scientific report                     |   | Start  | End  |
| A6. Final report and policy recommendations  |   |  | Start  |
| A7. Publication / posters  |   |  | Start  |
| Financing  |   | Pfizer   | Grünenthal   |
| Projections - Total financing  |   |  |  |

A \*Activities\*:  
 • Phase 1 defined under A1, A2  
 • Phase 2 defined under A3, A4, A5  
 • Phase 3 defined under A6, A7