

EARLY PHASE MODELING (EPM)

Early Phase Modeling in Summary:

- Facilitates the understanding of likely cost-effectiveness of a new treatment
- Assesses impact of different results of planned / ongoing clinical studies
- Reduces time to market

What is Modeling?

A model is a simplified image of reality that describes the relationship between factors (events and consequences) that are important to a decision. The aim of modelling is to make a particular part or feature of the world easier to:

- **Understand**
- **Define**
- **Quantify**
- **Visualize**
- **Simulate**

QUESTIONS ANSWERED BY EARLY-PHASE-MODELING

- What are the key drivers of the cost-effectiveness?
- Can data gaps be filled in clinical trials, or should data be gathered differently?
- What price can be justified for the product?



DID YOU KNOW...

Health Economic Modeling in general

- Links efficacy to effectiveness
- Links intermediate to final endpoints
- Extrapolates available data over the appropriate time horizon

WHAT:

Early-Phase-Models (EPM) give **early feedback** on key drivers for the cost and effectiveness of a product before clinical trial data is available. EPM can assess the impact of different results of planned / ongoing clinical studies, highlight any data gaps, and facilitate development of pricing, market access, and reimbursement strategies.

HOW:

Gathering of available product information and data (clinical effect, cost of healthcare resources, price of new treatment etc.) The model will be constructed based on the **gathered data**, results will be generated and sensitivity analysis will be performed. Model evaluation by clinical expert.

WHEN:

EPM should ideally be performed **as early as possible** in the development process. It can be performed at any stage in the product development phase when there is a need for understanding opportunities and challenges from a health-economic perspective.



YOU CAN USE EPM FOR STRATEGIC DECISIONS

Clinical development program by;

- Identification of data gaps
- Information on parameters / endpoints to be considered in Clinical Trial
- Choice of target patient population, appropriate indication, line in treatment etc.

Market access strategy by;

- Early insights and guidance in pricing potential
- Clarifying the risk / opportunity at both acquisition and divestment
- Facilitate payer perspective communication

HTA/reimbursement by;

- Identification of main factors for increased likelihood for successful reimbursement applications (level of effectiveness required, appropriate comparator)
- Facilitate development of pricing and reimbursement strategies

HOW CAN PHARMALEX HELP?

We develop early-phase models guiding predictions of which price level that may be justified for your product based on available information and the expected outcome of the clinical development program.



INFORMATION SOURCES FOR EPM

- Clinical studies (current treatment)
- Scientific publications
- RWE / databases
- Medical price lists
- Treatment guidelines
- Expert input
- Client estimates of clinical outcomes, new treatment properties, etc.

OUR PROCESS



Gathering of information: Desk research including literature review (scientific journals, healthcare registers, treatment guidelines, cases from HTA etc), clinical expert input, input from client.

Development of EPM: based on the findings, a model will be constructed, filled with appropriate data, results will be generated and sensitivity analysis will be performed. Model evaluation by clinical expert.

Report and presentation: description of available information and rationale for selection of input data, description of the EPM, results, key drivers of results based on the sensitivity analysis, strengths and limitations with the EPM, identified data gaps, etc.



EPM WILL PROVIDE

Early insights in realistic pricing of a new treatment.

- Appropriate material for health technology assessment (HTA) / reimbursement prepared

Description of the value and likelihood of market access for a product in divestment processes.

- It clarifies the risk/opportunity at both acquisition and divestment and is useful for strategic decisions.

DID YOU KNOW...

EPM can help reduce time to market and reduced time to patient access

ABOUT PHARMALEX



25+ YEARS
OF INDUSTRY EXPERIENCE



OVER 50%
OF OUR PROJECTS ARE GLOBAL



100% COVERAGE
OF ALL PRODUCT CATEGORIES INCLUDING MEDICINAL PRODUCTS, MEDICAL DEVICES, CONSUMER HEALTH AND VETERINARY



40+ HEALTH AUTHORITY MEETINGS PER YEAR WITH EMA/FDA/PMDA



95% OF OUR PROJECTS PASSED SUCCESSFULLY THROUGH DEVELOPMENT PHASE WITHOUT MAJOR FINDINGS