

Product Development Management (PDM)

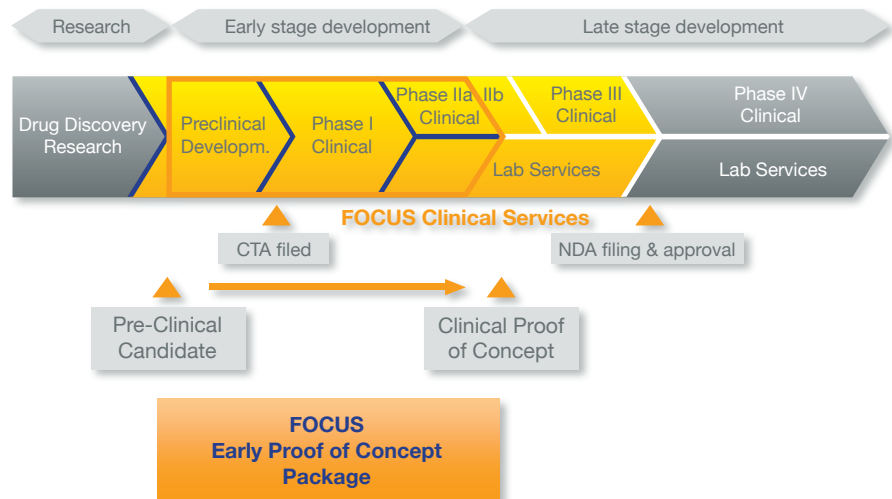
Using our **in-depth knowledge and experience in early drug development** as well as our **own operational capabilities**, FOCUS is well set to support your company to achieve the decisive clinical Proof of Concept milestone for your pre-clinical candidates in the most timely and economical fashion.

What is it?

A **Comprehensive, Tailor-made, One-stop Shopping Service Package** based on FOCUS drug development know-how comprising of

- strategic
 - conceptual
 - operational modules
- combined with
- strong scientific & operational project management

to progress your development candidate **to clinical Proof of Concept (PoC)** in the most **timely** and **economical** fashion.



FOCUS has special expertise in both Consulting & Performing Early Drug Development Programs for the biopharmaceutical industry, fully understanding the mind-set and needs of such companies.

Product Development Management at Work

To get started

We listen to you and learn about your goals and the current status of the project. Then we ask questions, discuss and digest the information to translate it into a **preliminary development outline** based on our industry know-how. This **free-of-charge service** forms the basis for your decision to enter into collaboration with us.

How do we operate this in detail?

- **Familiarization** meeting with FOCUS presenting PDM Concept & Sponsor presenting preliminary compound information
- **Confidentiality** Agreement
- **Brainstorm Meeting** to understand the science and current development status of the compound
- Preparation of preliminary **Development Road-Map** incl. time lines and budget free of charge

→ **Go/NoGo** decision by Sponsor

Our **transparent contractual frame-work** using **individual work orders for each operational module** offers **full flexibility as to scope and timing** of the respective services.

Development Plan

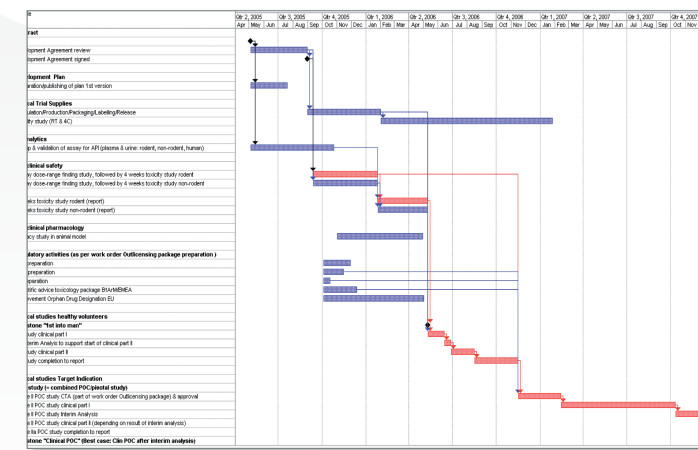
The preliminary road map is transformed into a **fully-fledged development plan** identifying the

- contents
- time lines
- sequence
- budgets

of **all operational modules** including **critical path analysis**.

We offer a **seamless work flow** from **planning** through **execution** to **reporting**.

Hence, we understand our task to be your **responsible partner throughout the whole project** and offer you access to the combined experience & know-how of the FOCUS group & strategic partners.



Deliverables are

- Development Plan
- All Study Reports
- Investigator Brochure
- Project Management Documentation File
- Regulatory Affairs Documentation File
- Respective Parts of Common Technical Document (CTD)

The FOCUS PDM development plan and final documentation package is the **solid basis** for

- regulatory purposes
- further global development studies
- the conclusion of high value licence deals

Track Record

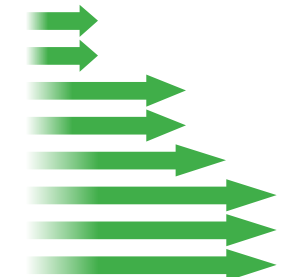
Several integrated **Early Proof of Concept packages** have been initiated comprising of both NCEs and NBEs in a broad range of therapeutic areas.

Ongoing

- NCE as Topical Formulation in various Viral Diseases
- MAb in Cancer Metastasis
- Protein-based Immune Modulator in Autoimmune Diseases
- DNA-based Immune Modulator in Cancer
- NCE with novel Mode of Action in Chronic Heart Failure
- NCE as Inhalative Liposomal Formulation in Lung Infection
- Biosimilar in Cancer
- Herbal-based Immune Modulator in Cancer

Terminated

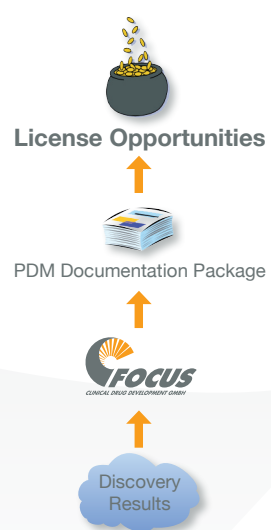
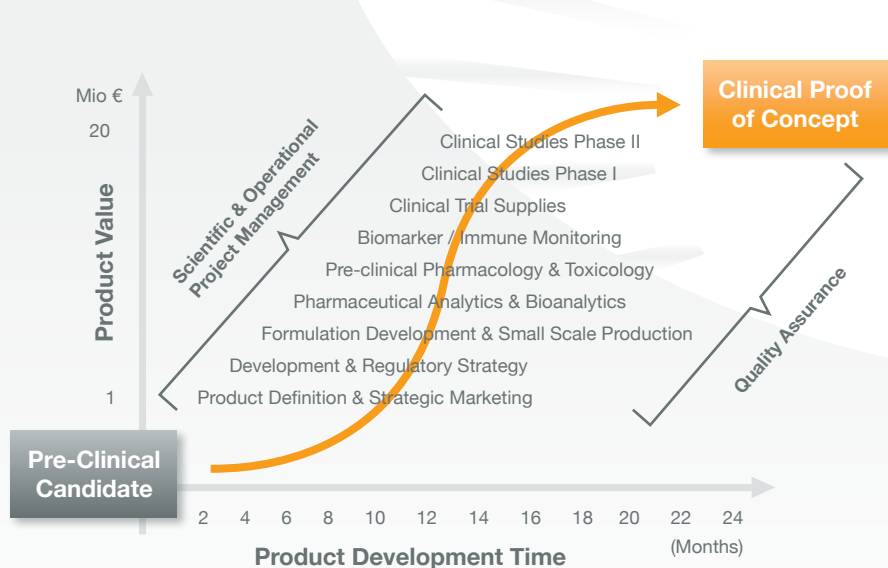
- Peptide-based Immune Modulator in Autoimmune Diseases: toxicology studies completed
- Enzyme-inhibiting NCE in Cancer: on hold at preclinical stage
- NCE in Psychiatry: Ph I volunteer studies completed



Early Proof of Concept Package

Includes all strategic and operational modules, e.g.:

- Regulatory Strategy and Development Plan
- Formulation Development
- Pre-clinical Safety and Efficacy Testing
- Analytics and Biomarker
- Phase I and II Studies in Healthy Volunteers and Patients including adaptive trial designs
- Interaction with Authorities
- Scientific and Operational Project Management



With this integrated service package, FOCUS strives to optimally support both virtual biotech and midsize biopharmaceutical companies to rapidly move their pre-clinical candidates to clinical Proof of Concept.

Product Development Management for Early Proof of Concept

The unique combination of

drug development and clinical pharmacology know-how,

together with an

in-house infrastructure

to support every aspect of the program including the conduct of work according to

GMP, GLP and ICH-GCP

international standards, ensures

high quality fast results.

The FOCUS PDM program will help you to make a **quantum leap in the exploratory development of your new medicinal products.**

Product Development Management means progressing discovery results to Licence Opportunities

For more information please contact us and visit our website www.focus-cdd.de

Product Development Management for Early Proof of Concept



The creative, tailor-made, cost and time effective way to add value to your development pipeline