PROJECT MANAGEMENT IN CLINICAL DEVELOPMENT

Clinical research activities are often carried out by external service providers. The interfaces between the internal Project Management Organization of the client and the Project Management Organization of the service organization(s) must satisfy high requirements. A systemic approach to solving complex project situations is acting advantageously on the basis of a recognized process management model.

WHY PROJECT MANAGEMENT?

"The world is getting faster and more complex. The speed in business and private life does not only increase when felt. Technological progress, which is intended to simplify life, creates more complexity. In addition, the digital world offers us an unprecedented variety of choices. Project management brings clarity to this partly opaque world. Because projects provide orientation - and are indispensable for many branches of industry. In the manufacturing industry, the share of project activity already amounts to 42 percent. Projects are the working form of the future.

But in a changing world the question arises: How can projects succeed tomorrow? The answer: By putting people at the center, with their individual competences. People make projects. It's not for nothing that well-trained project managers are in demand like never before. It is they who use their competence to decide on the right and modern methods at the right time."

(Source: https://www.wvib.de/beratung/themen/methoden-sozialkompetenz/3496-projektmanagement-ist-zukunft - own translation of the German text template)

PROJECT MANAGEMENT IN DRUG DEVELOMPMENT AND CLINICAL TRIALS MANAGEMENT

For the planning and provision of the necessary capacities and financial resources, for the continuous analysis of the situation and ensuring the positive course of investigational drug development and clinical trials, the establishment of a comprehensive **Project Management Organization** is of central importance.

The project management team have to master a complex task with the establishment of the project and the ongoing coordination of the project activities: the **internal parties** (e.g. Departments such as Clinical Research, Chemistry, Biotechnology, Regulatory Affairs, Marketing, etc.) and **external parties** (CROs, investigators, central laboratories, regulatory authorities, study sites, potential licensors and licensees, etc.) involved in the project must be coordinated.

Clinical research activities are often carried out by external service providers, the proportion of outsourcing is high. Accordingly, cooperation with outsourcing partners in the clinical development areas of GMP, GLP and GDP (see Figure no. 1) must be given high priority as well. The interfaces between the internal Project Management Organization of the client and the Project Management Organization of the service organization(s) must satisfy high requirements.

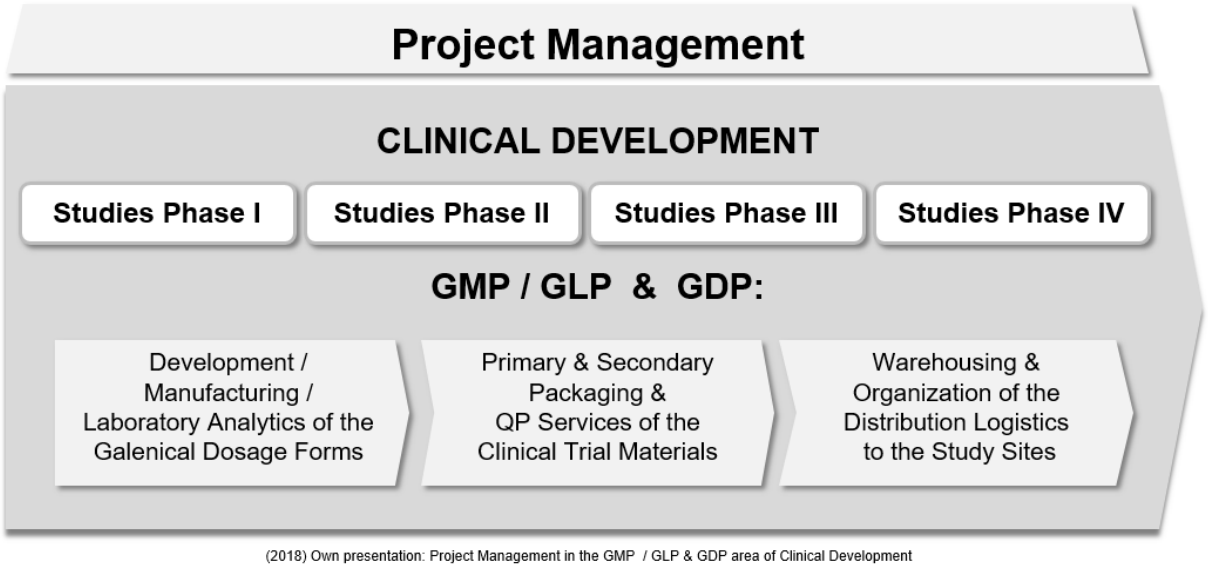


Figure no. 1

A systemic approach to solving complex project situations is acting advantageously on the basis of a recognized process management model. There are several established approaches, one of which will be briefly outlined here: According to the Project Management Institute (PMI), one of the leading international project management associations, founded in 1969 in Pennsylvania (USA) and setting a globally recognized standard which is spread in nearly 200 countries worldwide, the following areas of competence and knowledge should be covered:

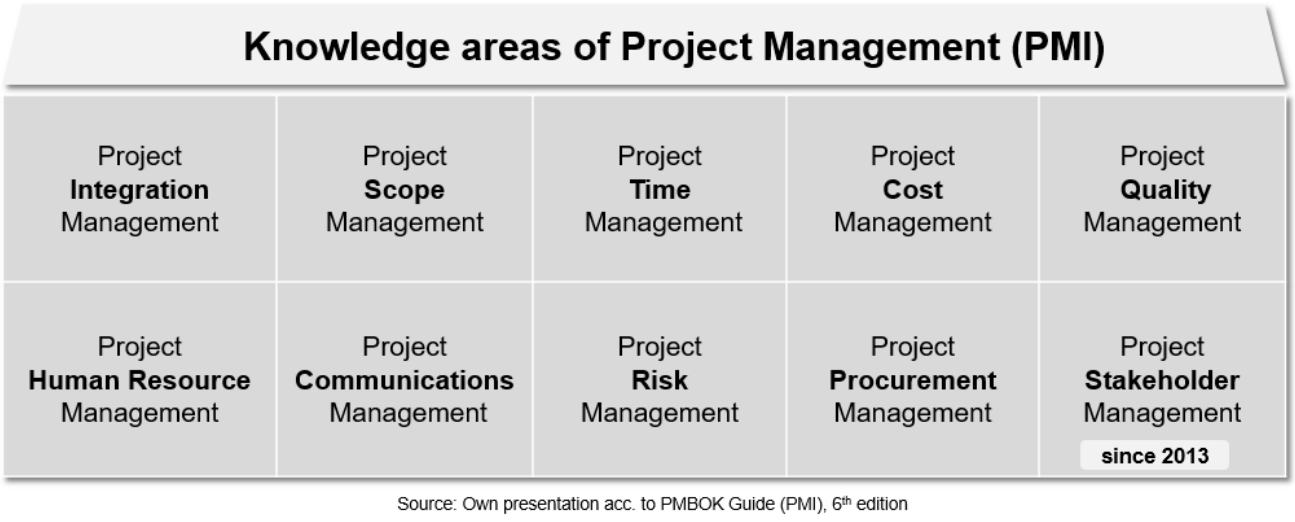


Figure no. 2

The link of the knowledge areas to the process groups **Initiation, Planning, Executing, Monitoring & Controlling** and **Closing** as well finally leads to a landscape of detailed project management processes described

in a structured way. A project management process approach like this provides an excellent basis for establishing a joint project organization between the client's development experts and the outsourcing partner(s), which is necessary to ensure the joint success of the project.

The IPMA/GPM process model, a further recognized standard, which has been also adopted in DIN 69901-2 as well, also leads to the result of a very similar process landscape. PRINCE2, the major project management standard valid in the UK, should also be mentioned in this context.

To avoid misunderstandings, it is not a question of setting up a project management organization that is aligned precisely to model specifications. Each company has its own corporate culture, whether written down or just lived, perhaps even a project culture or defined project rules. However, comparison with a "state-of-the-art" project management standard and the resulting (slight) adaptation of one's own project management methods, might lead, if considered worthwhile and consequently implemented, to a "new" project management culture within the organization.

"AGILE" PROJECT MANAGEMENT

Clinical development requirements often have to be adjusted even after the initial planning has been completed through pre-specified modifications based on interim analysis, so today's evolving clinical development environment requires more and more often a dynamic system using an agile project management approach (just to mention a keyword: "adaptive designs" for clinical trials).

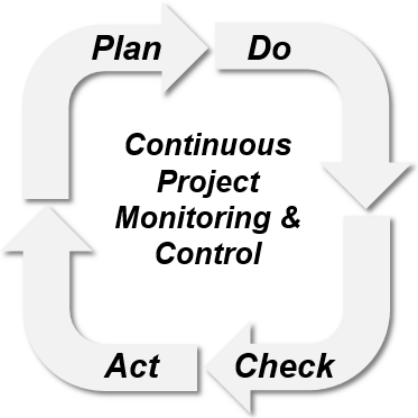
Agile project management in clinical development allows for dynamic response, planning, and execution in response to interim data analyses. Rapid feedback and interaction, continuous adaptation and QA best practices have to be built in to the project management teams committed to schedules, ensuring top-quality output and proven processes … a big challenge for the project team(s), but one that can be met.

Agile development is iterative in the respect that development is completed over several cycles. It is iterative in the sense that the product is not delivered at once, but in smaller dimensioned completed parts maybe based on agreed upon intermediate project results. In the opinion of the author and several other people, agile methods will not totally replace traditional methods in clinical research projects. However, project managers facing continuous changes to requirements throughout the project development process, will have to follow more and more a hybrid project management approach. Traditional methods will have to be "enriched", i.e. supplemented and combined with elements of agile project management methods.

A mandatory prerequisite in any case is a functioning project controlling system that allows appropriate reactions to any occurring changes and deviations (see PDCA below).

PDCA: PLAN → DO → CHECK → ACT

'Plan–do–check–act' or 'plan–do–check–adjust' is an iterative four-step management method used to control projects with an operating principle like a cybernetic circuit loop:



(2018) Own presentation: PDCA cycle

Figure no. 3

Plan: Establish the objectives and processes necessary to deliver results in accordance with the expected / agreed upon outcome of the project.

Do: Implement the plan, execute the process, make the product, work out the performance, continuously monitor the results.

Check: Study the actual results and compare against the expected results to ascertain any differences.
Also check that the project scope has not changed (objectives, extended / additional specifications).

Act: If 'Check' shows differences take the appropriate actions: Initiate/control the change processes, adapt plans and target(s), if necessary.

GLATT PHARMACEUTICAL SERVICES (GPS)

GPS is your reliable outsourcing partner offering the complete range of services in the Clinical Development areas of GMP / GLP & GDP. Project Management is a cross-sectional function in addition that coordinates and controls these service areas.

Project Management

GPS specializes in the execution of clinical development projects. An efficient project management organization forms the cross-sectional function over the entire range of clinical development and ensures that the project goals agreed with the clients are achieved.

A strong, experienced and highly motivated project management team is at the client's disposal in all matters, a "Single-Point-of-Contact" for each client is guaranteed.

The Project Management Office defines the project management standards and controls and monitors the project tasks. Manuals for all development questions and project management tasks form a solid basis for the implementation of all project-related requirements. A comprehensive quality management system (QMS) ensures compliance with GMP / GLP and GDP requirements.

GMP / GLP

GPS develops and produces solid pharmaceutical dosage forms. The focus here is on multiparticulate systems such as pellets and micro pellets as well as granulates. GPS also offers other suitable technical solutions. These include the taste masking of human and veterinary pharmaceuticals, the improvement of bioavailability and the chemical stabilization of drugs.

For clinical studies and market supply, GPS manufactures medicines in bulk and efficiently bring the client's products to market. The technical capabilities of GPS facilitate a seamless scale-up from the lab to commercial

production scale, for which all requisite analytical studies and stability tests can be deducted. For optimal processes and a secure investment.

GDP

GPS offers warehousing / goods storage in all required temperature ranges (15-25°C, 2-8°C; -25°C, -80°C). The (global) distribution tasks in all phases of clinical research are handled in a highly professional manner. Order related picking, packaging and shipping preparation of materials for clinical trials (incl. handling of IVRS triggers) is included as well as the organization of cold chain management solutions. Drug returns and the organization of certified disposal round off the service spectrum here.

The logistics of medicinal products with a marketing approval is supported by a comprehensive “order-to-cash solution”. A bonded warehouse is available and all tasks in connection with an EU import of MPs and IMPs are also offered.

Interested to get additional Information? Please get in touch with us:

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