Principles of Clinical Trial Project Management

EUPATI
European Patients' Academy on Therapeutic Innovation

Principles of Clinical Trial Project Management

1. Clinical trial project management
2. Clinical trial planning:
    - Role of the patient in clinical study planning
    - Project manager complex role and technique
    - Sequencing and scheduling
    - Building the study team
    - Study team resource planning
    - Communication
    - Clinical trial budget
3. Performance management
4. Risk management

Clinical Trial Project Management

A clinical trial is complex because:

- it consists of many processes
- it involves many functions in different organisations
- it involves collaboration of many people
- it needs to follow strict regulations
- it requires top quality performance of all involved
- it needs to adhere to strict timelines
- it needs to respect restricted budgets
- it needs intensive planning and risk management

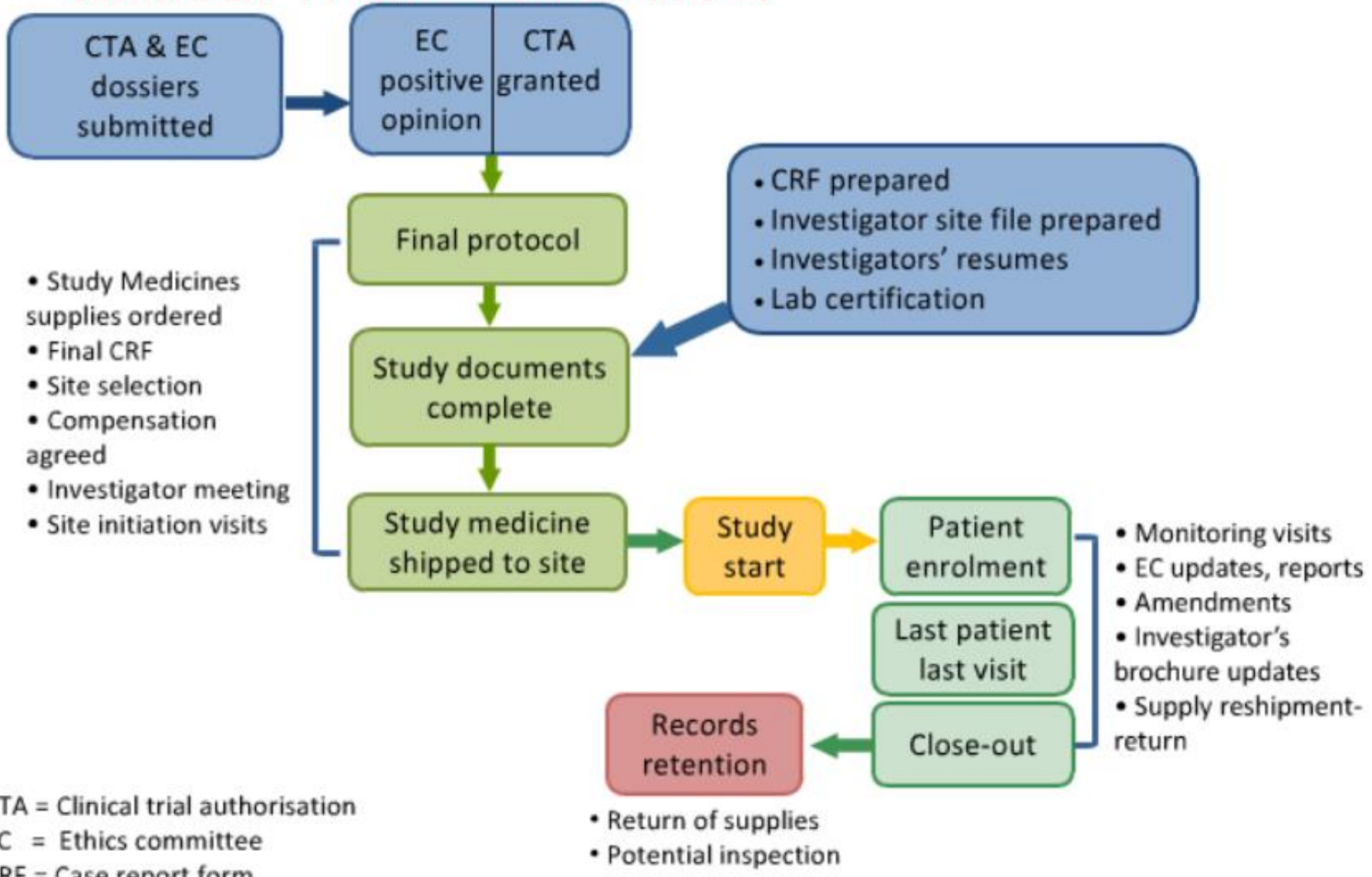
…while ensuring the integrity and safety of the patients involved

Objective of a good clinical trial project management:

Conduct the study and report the results:

- in reliable quality
- on time
- within budget
- in compliance with applicable laws, regulations and guidelines

Clinical Trial - Overview



CTA = Clinical trial authorisation
EC = Ethics committee
CRF = Case report form

Clinical Trial Planning

Extensive planning of all aspects of the study is crucial!

'A 6-Month Process for Planning Multinational Clinical Trials'*

List of 100 Points to Consider in Effective Study Preparation

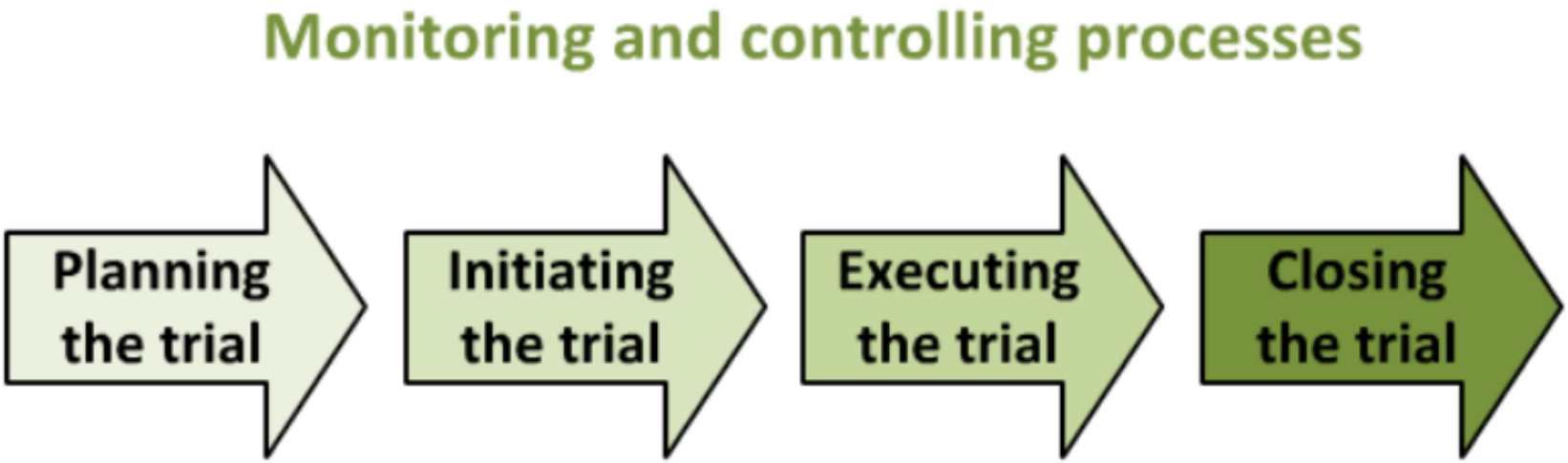
This list provides a comprehensive understanding of the different aspects that need to be considered, decided and prepared to be able to start a clinical trial with the enrolment of the first patient.

*Source: http://www.appliedclinicaltrialsonline.com/node/244284?rel=canonical

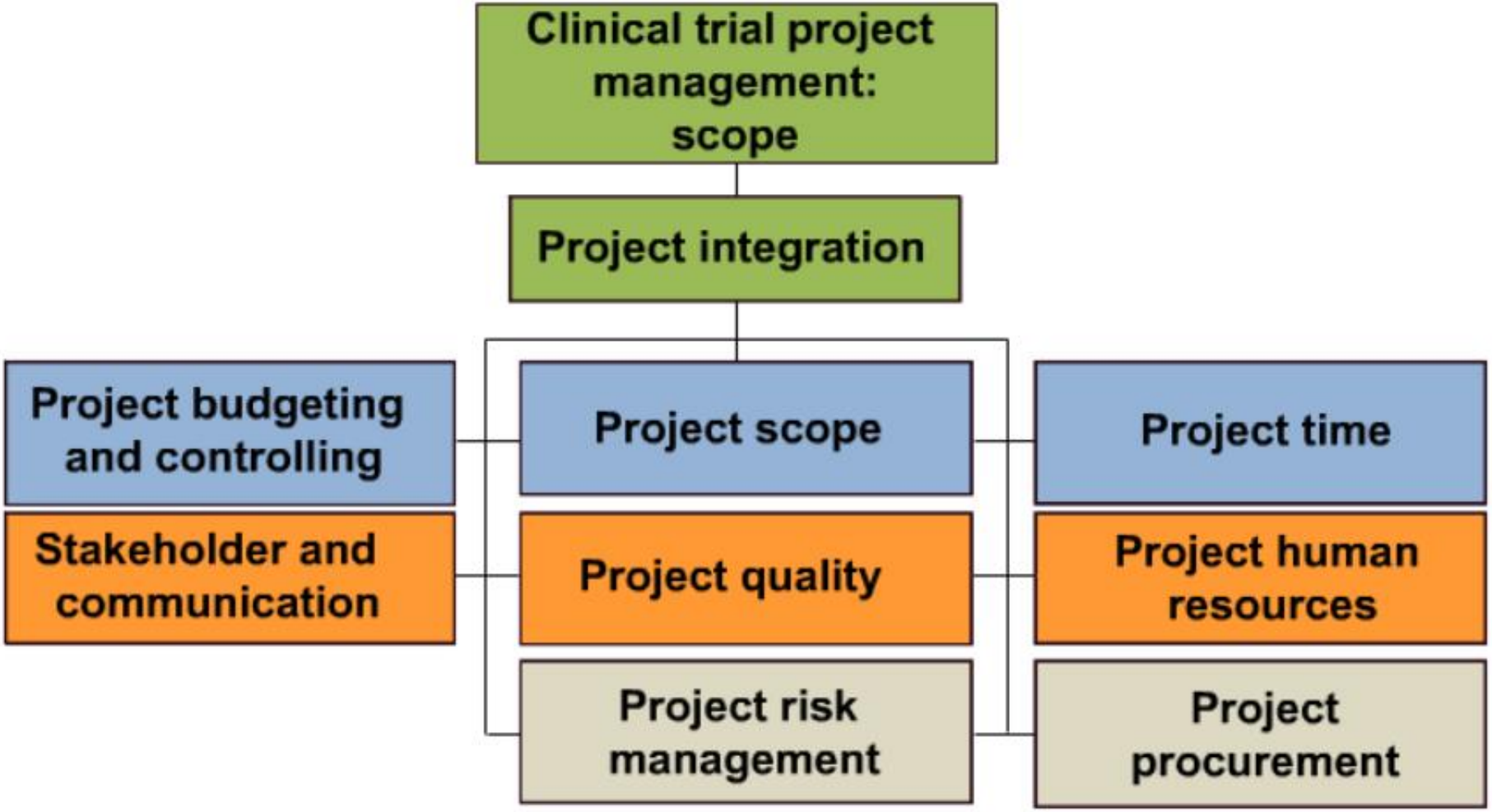
Planning: Role of the Patient

- Input to protocol development concerning
  - Patient-relevant trial endpoints
  - Acceptable study design and comparator treatment (placebo or control treatment)
  - Acceptable visit scheme and activities during these visits
- Input to selection of investigators (which types of investigators are treating patients with this disease in a particular location)
- Input to collaboration with patient organisations:
  - Where to find them?
  - How to collaborate with them?
- Input to patient information and informed consent process
- Advice on most suitable approach to diaries and other means of patient-reported data

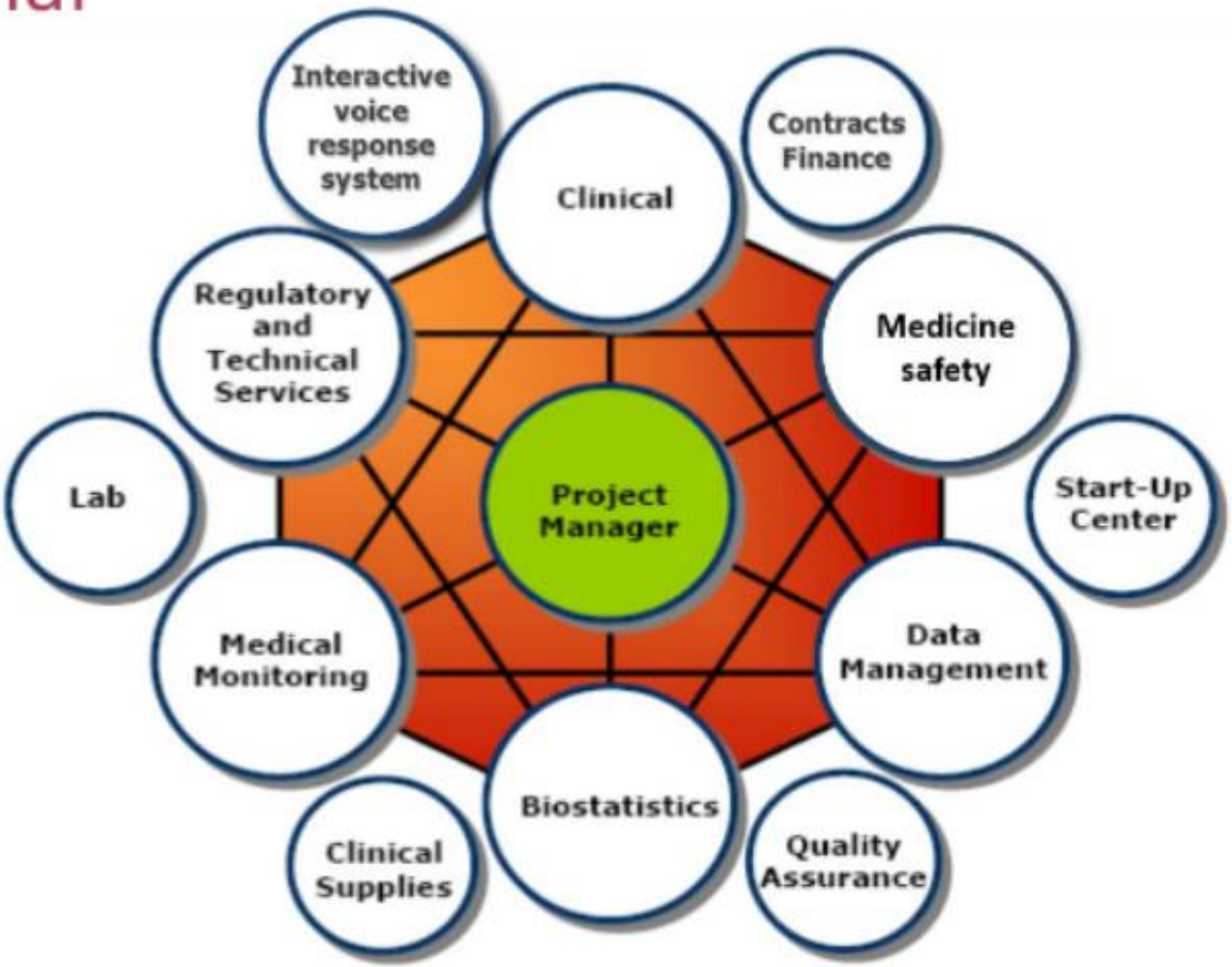
But clinical project management is not only about planning.
It also covers the entire trial performance:



Project Management Knowledge Areas



Planning: Project manager complex role in a trial



The project manager liaises with disciplines:

- Financial management and accounting
- Purchasing and procurement
- Sales and marketing
- Contracts and commercial law
- Legal and regulatory
- Manufacturing and distribution
- Organisation and supply chain
- Goals planning, how-to planning, timing and progress measurement planning
- Human resources
- Health and safety practices
- Information technology (IT)
- Pharmacovigilance

Resource Management – gaps

Develop creative ideas to decrease a resource gap:

- Reduction of task units (e.g. number of patients to be enrolled)
- Extension of time frames (e.g. enrolment period)
- Delegation to other team members
- Utilisation of staff with capacity in other departments
- Hiring part-time staff or students
- Hiring new fulltime staff
- **Insourcing** - staff contracted from an interim staff provider for a certain period of time.
- **Outsourcing** - work contracted to an external service provider who performs this task on behalf and under supervision of the sponsor

Communication Plan

A communication plan will:

- Minimise / avoid misunderstandings
- Motivate internal and external team members
- Clearly outline expectations, tasks and responsibilities of all parties
- Document what was done
- Make sound business sense
- Include the patients' perspective

Communication management

Examples of stakeholders

- Patients
- Healthcare providers
- Regulators
- Investigators
- Partners/potential licensees
- CROs (contract research organisations)
- Payers
- Insurers
- Senior management
- Patient advocacy groups
- NGOs (non-governmental organisation)
- Academic research groups
- Media
- Financiers (investors)
- Lobbyists
- Governments
- Shareholders
- Sponsors

Planning: Clinical trial budget planning

Cost factors in clinical trials

Different cost factors in a clinical trial budget:

- In-house costs of performing the trial (staff + overheads)
- Investigator and hospital costs
- CRO and other vendors costs
- Study medicine production, labelling and packaging
- Study approval, regulatory review, ethics committee fees
- Insurance
- Shipments
- Training
- Investigator meeting
- Other:_____

Factors affecting the trial budget

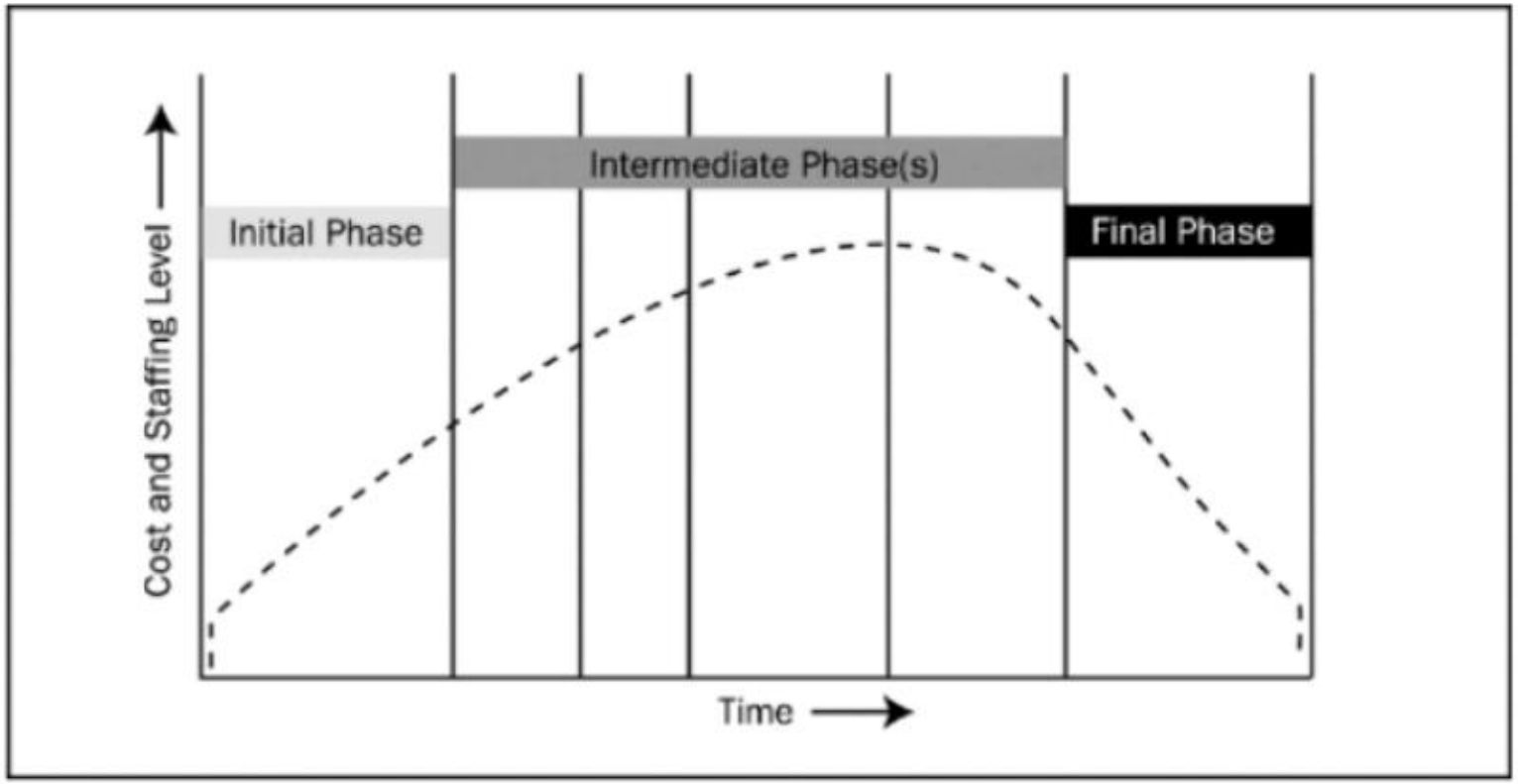
- Type and frequency of tasks to be performed and complexity of the trial
- Staff levels included and their responsibility for tasks
- 'Hourly rates' of staff levels involved
- Level of outsourcing
- Trial duration
- Number of sites and countries involved
- Study medication costs
- Intensity of trial supervision (e.g. frequency of monitoring)

Starting phase

- Rough assumptions on:
  - Number of study sites involved in which countries
  - Number of patients to be enrolled
  - Investigator and hospital fees per patient
  - Study medicine production, labelling and packaging costs
  - In-house costs
  - CROs and other vendors costs
  - Laboratory and other external clinical assessment costs
  - Overhead costs
  - Pass-through costs
- With increasing knowledge about the trial protocol and organisation the budget items get refined

Trial cost cycle

Common trial cost characteristics



Performance management

Regular review of the status of critical trial elements in comparison to plan:

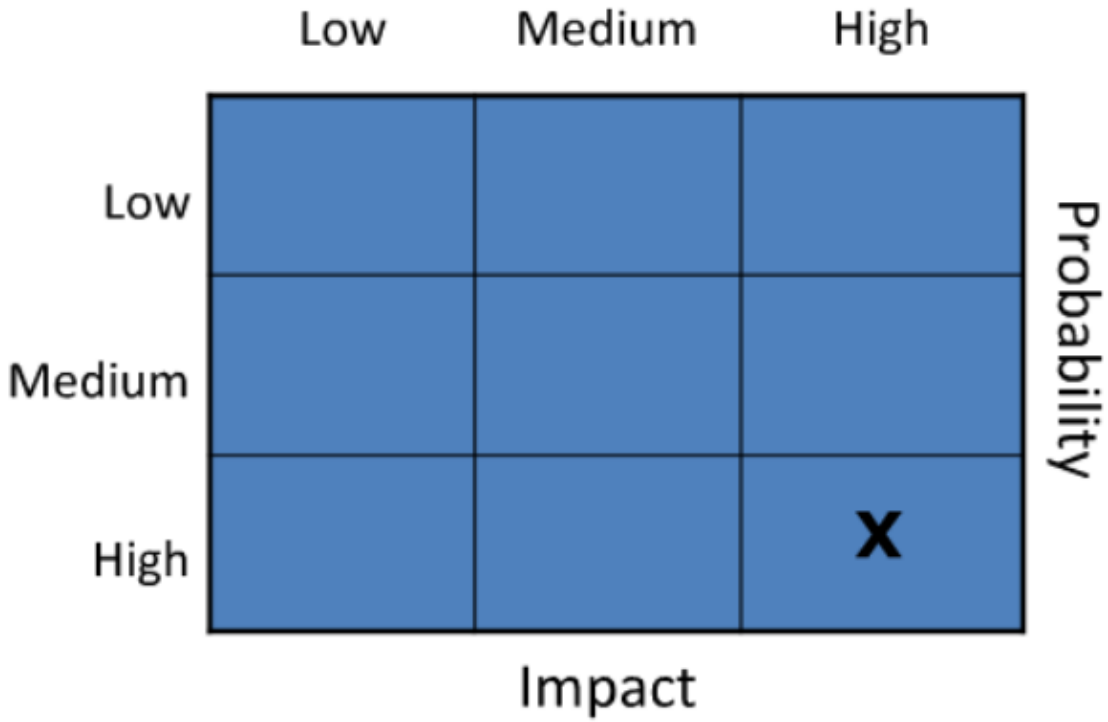
- Study approval
- Site initiation
- Patient recruitment
- Safety of treatment and reporting to authorities and ethics committees
- Study medication supply
- CRF completion
- Monitoring
- Data cleaning status
- Statistical evaluation
- Final report
- Budget and cash-flow situation

Risk management: Risks in clinical trials

Risk assessment

Example: If enrolment is slower than expected (happens often), there is a real risk of not finishing on time – enormous impact on the trial

Risk: Patient enrolment slower than expected.



Risk management. Summary

Benefits of risk management are:

1. Proactive study management
- more prevention - less correction
- increased risk transparency and awareness
- increased trust in study management

2. Less efforts to compensate deviations

3. Less individual and subjective risk handling
- clear definitions, standardised processes and tools
- more reasonable risk decisions

Better study progress and higher success rate!