Resource Planning and Management

(Estimating and scheduling timelines)

By Benjamin Watyaba

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Resources and management

Objectives

- Define what constitutes a resource to the clinical trial manager
- Determine which resources will be needed, and how to obtain them
- Estimate how long each resource will be needed for
- How to manage resources effectively
- To ensure that the scope is executed effectively.

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Resources

Sample question

Which of the following resources might you need to consider when starting to plan for your clinical trial?

- ❑A. Access to participants
- ❑B. Investigators
- ❑C. Administrative staff
- ❑D. Computers
- ❑E. Transport
- ❑F. papers on previous trials

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Definition of Resources in Research

- Assets available and anticipated for use in the planning and execution of project operations.

These are:

1. Equipment
2. Facilities
3. Materials and Supplies
4. Information
5. Technology

<u>Thought question</u>

List the resources that you will need when you start your project to serve tea at the first meeting of your trial's management group

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Planning and managing resources

Things to consider

Size of workload

Work estimates

Project estimates are treated as commitments

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Sample question

During which phase of a large multi-center clinical trial project do you believe that you will need the majority of your people, equipment, and other material resources?

- ❑A. During the pre-trial planning phase
- ❑B. During the clinical operations phase
- ❑C. During the data management phase
- ❑D. During the trial closing phase

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Deciding who and what you need

A. **Team**

Research is delivered by a team of people with different personalities, skills, ability, knowledge etc, and the ideal team takes advantage of the complementary skills of the individuals.

"What skills are required in order to complete all of the tasks required in the clinical trial program?

The easiest way to answer this is using the work breakdown structure (WBS).

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Generating the Team

Activities, tasks, and sub-tasks described in the Protocol WBS dictate the sorts of skills required;

- Does the task require specific technical skills?
- Will the task need specific or general experience?
- What type of knowledge or education will be needed?
- What interpersonal skills will be needed?

- How many of each type of skill set will be needed for the completion of each task?
- Which of these skills can be developed through training and development during the trial and how would this development be implemented?
- What levels of supervision will be required for each role?

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Skill inventory

After identifying the skills needed then start a process of matching the right people to the right targets within your team.

Example:

Name	Category	Current Job	Technical Skills	Soft Skills	Experience and/or Degrees
Chris Smith					
Georgie Jones					
Phil Brown					
Ashley King					
Charlie Ellis					
Alex Green					

B. Materials WBS and inventory

Required	Responsible Person or Vendor	Quantity Required	Date Required	Received
Equipment				
Facilities				
Consumables				
Technology				
Information				

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Estimating Timelines

Time estimates are dependent on trial WBS.

For each task, we need to estimate:

A. The effort required to complete the task.

- This is the number of hours of work required to do the task.
- The combined effort for all the tasks determines how much the staffing costs will be for the trial

B. How long the task will take.

- This is the number of days between the task starting and being completed.
- The duration will determine the overall timescale for the trial

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When time can’t be estimated

Optimistic time

Time to complete the task. if everything goes really well, and there are no complications.

Most likely time

This is the time that the activity can usually be completed under normal conditions

Pessimistic time

The time that it will take to complete the activity (produce the first draft of the protocol) in adverse conditions

Sample question

The amount of time needed to complete an ethics proposal is 4 weeks (based on the trial manager spending 25% of their time working on it over the 4 weeks, and no one else needing to be involved).

If the trial manager increased the amount of time he/she spent working on the ethics proposal to 40% of their time how quickly could the ethics proposal be completed?

- ❑ A. 1 week
- ❑ B. 2 weeks
- ❑ C. 2 ½ weeks
- ❑ D. 3 weeks

Example

3.8 Ethics finalized

- 3.8.1 Participant information sheet (12 hours)
- 3.8.2 Informed consent (6 hours)
- 3.8.3 Ethics approvals (32 hours)

In order to work the overall duration of this part of the trial we need to understand how the tasks interrelate. Start-end dates and which tasks are dependent on each other.

Accountability and responsibility

Ensure individuals know their responsibilities and accountabilities for each task in the project.

work and responsibility matrix (RACI matrix) can be used:

- **Responsible** for completing the work.
- **Accountable** for work.
- who needs to be **Consulted** about any given activity?
- who needs to be **Informed** about the activity?

Thank you

sources

- Brown L,T Grundy T. Project Management for the Pharmaceutical Industry, Gower, 2004 pages 54 – 58
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