

PARTICIPANTS

Planning for Success

**Effective project
planning and evaluation
in biomedical research**

TRAINING MANUAL

UNICEF/UNDP/World Bank/WHO
Special Programme for Research and
Training in Tropical Diseases (TDR)



Effective project planning and evaluation in biomedical research

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TDR/RCS/PPE/05.1

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Foreword

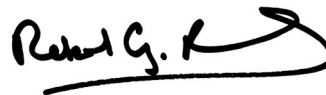
Developing countries continue to be burdened by many diseases that prevent them from making both health and economic improvements. These diseases require a whole range of solutions, from research at the very basic level of science, to developing new medicines, to creating methods of delivering care throughout specific areas and even entire nations.

This integrated approach, which TDR specializes in, is being done through partnerships of governments, private sectors, and academic/research organizations. But foremost, the lead should come from the countries where the diseases are having such an impact.

One of TDR's main missions is to help biomedical researchers from disease endemic countries develop the skills and systems to carry out this leadership and maintain a strong health research community. This capacity building takes many forms, including this manual in *Effective project planning and evaluation in biomedical research*. As part of a skill-building course, participants are taken through all steps of project management while working on their own research projects. The aim is to develop strong research planning, effective implementation and monitoring, clear outputs, accurate reporting, and ultimately, access to more funding and well developed research.

TDR will work to imbed this course in key research and academic institutions in developing countries. Countries and academic and research institutions will play the key role in making this course available. In this context, a train-the-trainer course has been developed to ensure availability of local trainers. The course was successfully pilot tested in South Africa in collaboration with the South African Medical Research Council in early 2005.

We thank all the course participants and advisers who have facilitated the development of this course, and trust that scientists anywhere will find it of value for both day-to-day work and for managing complex projects, programmes and partnerships. And as always, we welcome feedback on the course* so that we can improve our efforts to enhance research and alleviate the burden of disease.



Dr Rob Ridley
Director TDR

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About the training manual

The skill-building course in *Effective project planning and evaluation in biomedical research* has been developed by the UNICEF/UNDP/ World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR) for biomedical researchers in developing countries. Its aim is to strengthen their skills in the organization and management of research projects so as to achieve effective implementation and successful collaboration and in this way increase competitiveness in accessing available funding.

During the four-day course participants work on their own project and go through the various steps of project management. They carefully define and analyse their project, and establish a complete project development plan. They understand how to use the plan first to implement the project on time, under a given budget and within agreed standards, and then to monitor, evaluate and report. The value of teamwork and its processes is highlighted and discussed.

The train-the-trainer course, developed in collaboration with the South African Medical Research Council, Cape Town, South Africa, ensures that competent trainers are available to facilitate the integration of the skill-building course in developing countries.

The support training material for these interactive courses includes the following five handbooks:

- *Training manual for participants*
- *Step-by-step guide for participants*
- *Training manual for trainers*
- *Step-by-step guide for trainers*
- *Train-the-trainer manual.*

The present handbook is the *Training manual for participants*. Its content carefully follows the presentations made at the skill-building course. Starting with an introduction and overview of the course it then gives an overview of good practices in biomedical research; highlights the concept and the value of planning; and presents the various steps of project management: defining the purpose and the scope of a project, establishing a project development plan, and project implementation, monitoring, reporting and evaluation. All the slides to be shown are provided, and each presentation is preceded by the related text. This manual is meant to give participants support during the course, helping them to follow the presentations, to take notes and to be a reference at any time during the training sessions. It may also be used by participants once they are back home as they work on their current project(s) and later, on new projects.

Introduction

BACKGROUND

Biomedical research involves various disciplines and, in the field of tropical diseases, often requires partnerships and collaboration at national and international levels. It includes studies in basic and strategic research (involving pathogenesis and genomics of infectious agent, host and vector), in product research and development (from product discovery with target identification, screening, lead optimization through preclinical development to clinical development) and in field implementation. Projects are becoming more complex, involving an increasing variety and number of experts and partners. They require all collaborators to come together, share their complementary knowledge and work towards the common goal of the completion of the research project on time, within budget, and following agreed quality criteria.

Good coordination and effective project management are essential for the success of a project. The various partners need to work as a team. It is important that all experts and parties involved understand the project in the same way: they should have a common goal, agree on the process to reach it, and understand and trust each other so that their efforts are synergistic. A project has to be carefully planned by all players before it is implemented. Regular monitoring and reporting ensure transparency and enable quick reaction to problems or opportunities.

Planning and evaluation skills are critical in good project management. For a long time these skills were seen as exclusively related to business activities and have therefore often been omitted from academic curricula. Those gaps have been recognized by grant-awarding agencies, donors and also by biomedical researchers in tropical disease-endemic countries that have expressed a need for capacity-building in this area.

To address this need, TDR has developed a skill-building course for scientists in tropical-disease-endemic countries in the area of project planning and evaluation in biomedical research. These

courses give participants the opportunity to enhance their knowledge and awareness of project planning and evaluation, and to understand the value of these activities in their daily work of managing a project and interacting with partners and donors. During the course participants apply this process to their current project. They start by defining what they want to do, why they want to do it and identifying the main steps required to achieve it. For example, in an epidemiological study, participants define the hypothesis they want to demonstrate and the research objectives. They identify the main steps of the development of the study from the preparation of the protocol through data collection to data analysis and reporting. Then participants identify all the activities that need to be completed, organize them in a logical way and present them in a clear and complete development plan including timelines and resources. They anticipate, identify and address potential logistic issues and learn to use the plan to coordinate and monitor development and to ensure good implementation: on time, according to agreed standards, and within budget. They define the project development team, highlighting each member's responsibilities, and establish the teamwork process. They then develop the structure of their reports on the project's progress and ultimate success in meeting its objectives.

TRAINING OBJECTIVES

The course aims to strengthen the skills of biomedical researchers in developing countries in the areas of organization and management of their projects so as to achieve successful implementation and collaboration as well as increased competitiveness in accessing international funding.

The course provides participants with the necessary project planning and evaluation tools and helps scientists to:

- consider and understand the value of planning in improving project implementation, monitoring and evaluation
- strengthen their skills in project planning and evaluation
- apply these skills to everyday work.

SCOPE OF THE TRAINING

The course has been developed for biomedical researchers in tropical-disease-endemic countries who are willing to be involved in partnerships and to work in collaboration with institutions and programmes nationally and internationally.

First, the course focuses on enhancing knowledge and awareness of project planning and evaluation activities, helping participants to understand the process and to realize the value of these activities in their daily work of managing a project and interacting with partners and donors.

Second, the course moves to enhance the practical skills of participants in areas related to project planning and evaluation.

This takes place in three stages:

- defining the project's purpose and scope
- establishing the project's development plan
- implementing, monitoring, evaluating the project and reporting.

TRAINING METHODOLOGY

Participants apply, step by step, the planning evaluation process to their current project and in this way they learn by “doing” and “reflecting”.

Experiential learning cycle

The training methodology is based on the theory of the “experiential learning cycle” developed by Dr David Kolb in 1989. Kolb studied the different phases through which human beings go during the process of learning. He analysed them and developed a training methodology using experience (learning by doing) and reflection as a basis for learning.

The experiential learning cycle integrates:

- concrete experiences
- reflective observations about the experiences
- generalizations about experiences and observations
- active experimentation applying generalizations and observations to new experiences.

Real life case study

The participants work on their own “real life” project. This means that they go through the case studies applying them to their own current project.

Step-by-step learning

The course follows a “step-by-step learning” approach. It is structured in five modules that take the participants through a progressive learning process. Each theoretical section is short and followed by an extensive case study session. During this practical session participants face a concrete experience (their own project) and reflect on it in small groups. They then share, in plenary session, observations with other participants and apply these observations to other projects (other participants' projects). This way, participants apprehend, one by one, the various phases of the process of project planning and evaluation.

“Facilitating” versus “teaching”

There is no single “best” way of planning. The participants, guided by trainers, identify which approaches are most relevant to their project. Interactions of high quality and quantity between the trainers and the participants, and between the participants themselves, are essential to the success of the course. Trust and respect must be developed to allow these interactions to be productive.

TRAINING CONTENT

Following a brief introduction, which provides an overview of the course, the training focuses on a series of five substantive modules leading the participants through a progressive learning process.

Module 1 – Good practices in biomedical research (theory)

Module 1 briefly introduces the main good practices relevant to biomedical research. It gives the rationale for international standards of good practices and the objectives of these good practices. It presents good laboratory practices (GLP), good manufacturing practices (GMP), good agricultural practices (GAP) and good clinical practices (GCP) including an ethics component. It introduces the concept of quality practice in basic biomedical research (QPBR) and generally sites the project planning and evaluation activities in the context of good practices.

Module 2 – Understanding the concept and value of project planning and evaluation (theory)

Through module 2 the process of project planning and evaluation is introduced to the participants. The value of planning and evaluation in managing a project and interacting with partners and donors is highlighted. The module deals with the definition of a project, how it involves teamwork, the objectives of planning activities, and the establishment, use, and value of project development plans.

Module 3 – Phase I: Defining the purpose and scope of a project (theory followed by case studies)

Module 3 leads the participants through the first phase of the process of planning and evaluation. They define what they want to do and why they want to do it. They first establish a statement summarizing the project, then define the goal of the project, its objectives, the indicators, which will be used to evaluate whether objectives have been reached, and finally identify the main steps required to reach the objectives.

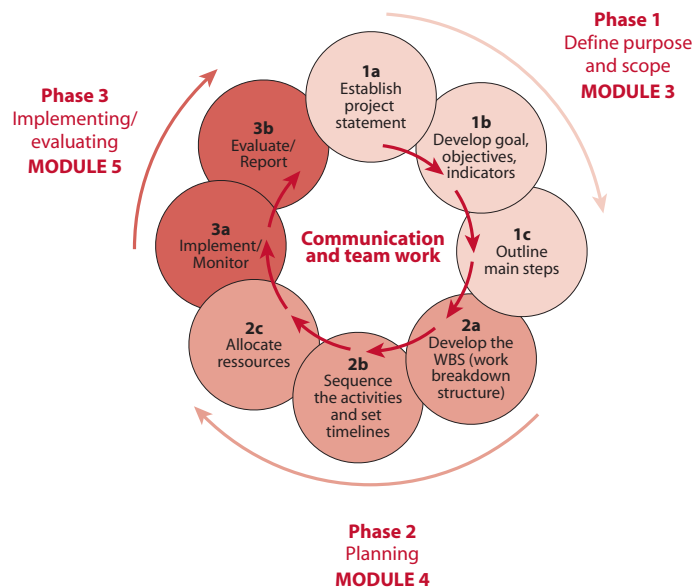
Module 4 – Phase II: Establishing the project development plan (theory followed by case studies)

Module 4 leads the participants through the second phase of the project and evaluation process. They establish a development plan for their project. The module guides them through the development of

the project's work breakdown structure (WBS), the establishment of the sequence of the various activities, the setting of duration time and timelines of activities, the definition of milestones and the allocation of resources. Participants then present their plan using a bar chart (Gantt chart) and a network diagram (PERT chart).

**Module 5 – Phase III: Implementing, monitoring, evaluating and reporting
(theory followed by case studies)**

Module 5 gives an overview of how to use the plan to coordinate the team; to ensure the project implementation on time, according to agreed standards and within budget; and to monitor carefully the project development. The importance is highlighted of regularly updating the plan, reporting on progress, formally closing the project as it ends, and evaluating its success. Participants have the opportunity to establish an appropriate modus operandi for good team coordination and regular monitoring of their project's development. They also establish the project reporting process (types of report, frequency and content).



TRAINING ASSESSMENT

A session on assessment of the course contributes to the improvement of the training and ensures its relevance. It focuses on training output and is based on the participants' receptiveness to the concept and value of the project planning and evaluation process and on their ability, willingness and confidence to apply effective project planning and evaluation skills to their project.

*Effective project planning and evaluation
in biomedical research*

**Introduction
and overview of the
course**



Introduction and overview of the course

1

**Introduction and overview
of the course**

- **Introduction of participants and trainers**
- Rationale for the course
- Objectives of the course
- Framework of the training and course overview



Introduction and overview of the course

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Rationale for the course

- Projects in biomedical research are becoming more and more complex and increasingly involve **networking** and **partnerships**
- Such projects require careful management including **formal planning** activities
- Academic scientific curricula often omit the development of project management skills
- Biomedical researchers and donors are recognizing the need for **capacity-building** in project planning and evaluation in biomedical research
- TDR has developed a **skill-building course on project planning and evaluation in biomedical research** on the lines of the various workshops on **good practices**



Introduction and overview of the course

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Goal of the course

To strengthen the skills of biomedical researchers in developing countries in the areas of :

- Organization and management of projects so as to achieve successful implementation and collaboration
- Ability to compete internationally in making grant proposals

by providing the necessary project planning and evaluation tools.



Introduction and overview of the course

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Training objectives of the course

- Consider and understand the value of planning
- Strengthen skills in project planning and evaluation
- Apply these skills to everyday work



Introduction and overview of the course

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Participants, focus and context

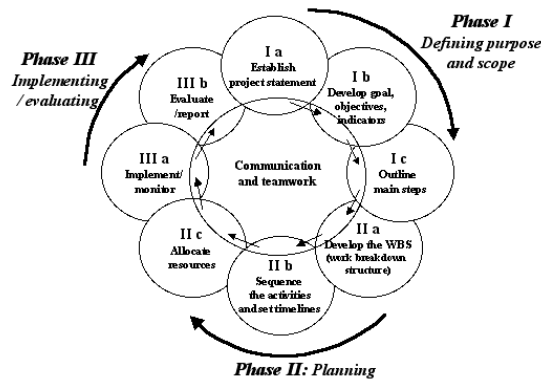
- Who are the participants?
 - Researchers in developing countries working on biomedical research projects involving teamwork
- What is the focus of the training?
 - Knowledge and awareness of project planning and evaluation activities
 - Skills in project planning and evaluation
- What is the context?
 - First step takes place at the course
 - Second step happens once the participant is back home and implements what has been learnt



Introduction and overview of the course

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Project planning and evaluation process: a brief preview



Introduction and overview of the course

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Training approach

Learning by doing:

*“Tell me and I will forget,
show me and I may remember,
involve me and I will understand.”*

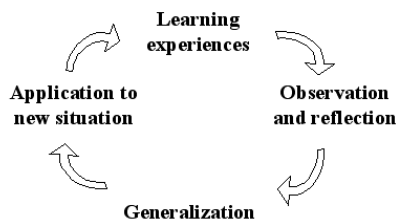
Anonymous



Introduction and overview of the course

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Training methodology: experiential learning cycle



David Kolb 1989



Introduction and overview of the course

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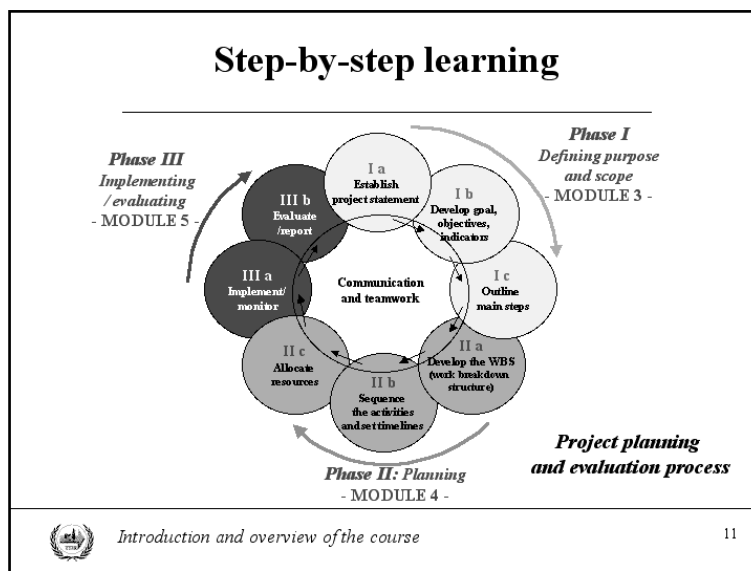
Training methodology: step-by-step learning

- The training is structured into five modules
- The modules take the participants through progressive, step-by-step learning
- Learning is based on the use of examples and “real life” case studies



Introduction and overview of the course

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Training methodology: principles


- There is NO single best way of planning; the trainer helps the participant to identify her/his own best way
- All modules are designed to foster three important interactions
 - Trainer-participant
 - Participant-trainer
 - Participant-participant
- Trust and respect are essential for these interactions to be productive

Introduction and overview of the course

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Course outline


- Introduction and overview
- Substantive training
 - MODULE 1 - good practices in biomedical research
 - MODULE 2 - understanding the concept and value of project planning
 - MODULE 3 - defining the purpose and scope of a project
 - MODULE 4 - establishing the project development plan
 - MODULE 5 - implementing, monitoring, evaluating and reporting
- Training assessment

*Introduction and overview of the course*13

Course agenda

	Day 1	Day 2	Day 3	Day 4	
Am	Introduction & objectives	Case studies (module 3)	Case studies (module 4)	Implementing / monitoring (module 5)	
	Good practices (module 1)	Planning (module 4)		Case studies (module 5)	
	Planning value (module 2)				
Pm	Defining purpose & scope (module 3)	Case studies (module 4)	Case studies (module 4)	Training assessment	
	Case studies (module 3)			Discussion & next steps	

80% of the course time is spent on case studies

*Introduction and overview of the course*14

Module structure

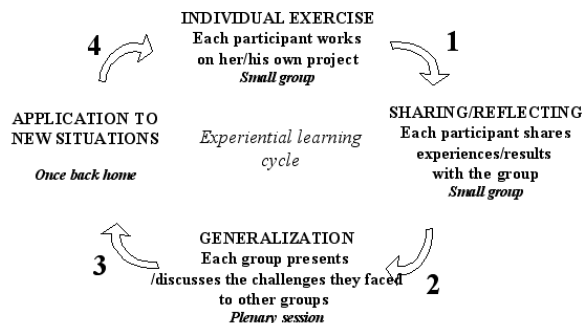
- Raising awareness and providing key information: modules 1 & 2
- Skill-building: modules 3, 4 & 5
 - Introduction and objectives of the module
 - Presentation of the example and initial reflection
 - Statement of the theory
 - Analysis of the example and consideration of the question “does the theory help?”
 - Case studies



Introduction and overview of the course

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Case studies



Introduction and overview of the course

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Training assessment

- Assessment of the training output based on:
 - Participants' receptiveness to the concept and value of the effective project planning and evaluation process
 - Participants' ability, willingness and confidence to apply the effective project planning and evaluation skills to their project



Introduction and overview of the course

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The course in a nutshell...

Participants and trainers work together to:

- Consider and understand the concept and value of project planning and evaluation
- Strengthen project planning and evaluation skills, allowing participants to better manage projects and better communicate with donors, partners and team-members.



Introduction and overview of the course

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MODULE 1

Good practices in biomedical research

LEARNING OBJECTIVES OF THE MODULE

Module 1 introduces the international standards of good practices in biomedical research and intends to enhance participants' awareness of the value of these in their work. It also explains how project planning is an integral part of such practices.

FOCUS OF THE MODULE

The module covers:

- › the rationale for international standards of good practices
- › objectives of good practices
- › good laboratory practices (GLP)
- › good clinical practices-ethics (GCP)
- › good manufacturing practices (GMP)
- › good agricultural practices (GAP)
- › quality practice in basic biomedical research (QPBR)
- › project planning and good practices.

INTRODUCTION

Biomedical research that aims to discover and develop new tools involves many scientific disciplines and types of research. It includes studies in basic and strategic research (in vitro and animal studies, and clinical epidemiology studies), in pharmaceutical product research and development (in vitro and animal product discovery studies, in vitro and animal preclinical studies, clinical studies, and manufacture and production) and in field implementation research (clinical studies).

It was in the field of pharmaceutical product research and development that the concept of international standards of good practices first emerged. In the 1970s, the United States Food and Drug Administration (US FDA) decided to audit laboratories where toxicity studies, used for the completion of a regulatory dossier of drug registration, were conducted. The investigations of the US FDA in about 40 laboratories revealed many cases of badly managed studies, poor training of personnel and some cases of deliberate fraud that demonstrated a lack of data quality. To address these issues and ensure data credibility the US FDA introduced a new regulation to cover non-clinical safety studies: good laboratory practices (GLP) regulations. These regulations were rapidly followed by many nations of the world and, in 1981 the OECD (Organisation for Economic Co-operation and Development) also published the GLP principles that now dominate the international scene. GLP were imposed on the industry by regulatory authorities, followed by good manufacturing practices (GMP) and good clinical practices (GCP).

RATIONALE FOR GOOD PRACTICES IN BIOMEDICAL RESEARCH

If biomedical research is not carried out to internationally agreed standards, then cases such as lack of standardized procedures, raw data not traceable, protocols not followed, inadequate resources, equipment not properly calibrated etc. may occur and prevent mutual recognition of study data across international frontiers.

In addition, a lack of respect for the human rights of trial participants, and poor animal welfare are unacceptable, and should be prevented.

OBJECTIVES OF GOOD PRACTICES

International standards of good practices in biomedical research thus aim to:

- protect human participants and ensure the welfare of animals involved in research
- ensure the quality and credibility of research data.

This allows mutual recognition of study data across international frontiers. It also ensures that the human rights of trial participants are respected and that the welfare of animals used in studies is protected.

WHAT GOOD PRACTICES ARE AND WHAT THEY ARE NOT

Good practices are an attitude translated into a way of working. Good practices are not about what is going to be done but more about how it is going to be done: how it is planned, under which

conditions it is completed, how it is recorded, monitored and reported. It is concerned with the fact that data should be easily verified, and that the process should be transparent and auditable. International standards of good practices define the conditions under which biomedical research studies are planned, performed, recorded, monitored, reported and archived. They create a focus on the quality of the study process, promoting the establishment of a quality system and a sound managerial approach that ensures the quality, traceability, reliability and integrity of data.

Good practices are not directly related to the scientific aspect of the research. They do not evaluate the scientific value of a study.

For example, the implementation of GCP, in the preparation of a clinical trial study, does not affect the relevance of the study, nor its scientific value, but is concentrated on the way the study is planned, the way the protocol is developed, on the presence of appropriate standard operating procedures, informed consent and other required documentation, on the preparation of the site, and whether a quality system has been established etc.

THE VARIOUS GOOD PRACTICE PRINCIPLES

Various principles of good practices, each being specific to a different type of study in biomedical research, have been developed. They include the **GLP** for product safety studies in animals; **GCP** for studies involving human participants; **GMP** for the production of pharmaceutical products; **GAP** for the production of plants used in the manufacture of pharmaceutical product; and lately a draft **QPBR** for basic research and product discovery in animal studies and in vitro.

Although good practices are mandated by regulatory authorities only for studies used in the regulatory dossier of pharmaceutical product registration, they are also relevant and of great benefit to other studies in biomedical research as they ensure quality, traceability, reliability and integrity of data.

Good laboratory practices

GLP are international standards for designing, conducting, reporting, recording and archiving preclinical studies used for the evaluation of the toxicity (in vitro and in animals) of pharmaceutical products. Compliance with these standards provides public assurance of a good level of animal welfare for animals involved in the study. It also provides assurance that the study data are credible, reliable and auditable. The GLP principles developed and revised by OECD are predominant on the

international scene. These principles are mandated by the regulatory authorities for studies used in the regulatory dossier of a pharmaceutical product registration.

<http://www.oecd.org/oecd/pages/home/displaygeneral/0,3380,EN-document-519-14-no-21-6553-0,00.html>

For further information on GLP, contact:

Dr Deborah Kioy, Pre-clinical Coordinator, Product Development and Evaluation, TDR, WHO, 20 Avenue Appia, CH-1211 Geneva 27. kioyd@who.int

Good clinical practices

GCP guidelines provide international ethical and quality standards for designing, conducting, recording, reporting and archiving trials that involve the willing participation of human participants. These guidelines include a strong consideration of ethics and are consistent with the principles that have their origin in the *World Medical Association Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects*. Compliance with these standards provides public assurance that the rights, safety and well-being of trial participants are protected and that the clinical trial data are credible, reliable and auditable.

<http://www.wma.net/e/policy/b3.htm>

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) has developed GCP guidelines that take into account current guidelines on good clinical practices (i.e. guidelines of the European Union, Japan, the United States, WHO etc.). GCP principles are mandated by regulatory authorities for studies that are used for the completion of pharmaceutical product registration dossiers.

<http://www.ich.org/ich5e.html>

The Council for International Organizations of Medical Sciences (CIOMS) has developed *International Ethical Guidelines for Biomedical Research Involving Human Participants*.

<http://www.cioms.ch>

For further information on GCP, contact:

Dr Juntra Karbwang, Clinical Coordinator, TDR, WHO, 20 Avenue Appia CH-1211, Geneva 27. karbwangj@who.int

Good manufacturing practices

GMP guidelines provide international standards for application to the production of pharmaceutical products. They are related to the quality of the production of the bulk material, its formulation into the finished product and the packaging of the final marketed product. Compliance with these standards ensures good quality in the final product including proper characterization, purity of the product and reproducibility of the various production batches.

International GMP guidelines (WHO guidelines, ICH guidelines) have been developed and are mandated by regulatory authorities for the production of pharmaceutical products.

<http://www.ich.org/ich5q.html>

<http://www.who.int/medicines/organization/qsm/activities/qualityassurance/gmp/orggmp.shtml>

For further information on GMP, contact:

Dr Deborah Kioy, Pre-clinical Coordinator, Product Development and Evaluation, TDR, WHO, 20 Avenue Appia CH-1211, Geneva 27. kioyd@who.int

Good agricultural practices

Recently the concept of good agricultural practices has emerged in the manufacture of pharmaceutical products involving plant material. The characterization and purity of plants are greatly dependent on various agricultural factors. The European Agency for Evaluation of Human Medicinal Products (EMA) has released international guidelines in relation to this issue during the course of the year 2002. The guidelines refer to the way the plant is produced and ensure its quality.

<http://www.emea.eu.int/pdfs/human/hmpwp/001899en.pdf>

For further information on GAP, contact:

Dr Deborah Kioy, Pre-clinical Coordinator, Product Development and Evaluation, TDR, WHO, 20 Avenue Appia CH-1211, Geneva 27. kioyd@who.int

Quality practice in basic biomedical research

No good practices guidelines are currently available for in vitro and animal studies in basic and strategic research and in product discovery. It has always been acknowledged that such research needs a lot of flexibility and freedom in order to be creative and productive. This is why the current existing GLP guidelines have been considered inadequate for these types of study. However, it is increasingly felt that an adapted version of GLP could greatly benefit the conduct of these basic and product-discovery research studies. It could, for example, ensure good study planning, the development of standard operating procedures, careful recording and storage of the data, and good resource management. In order to address this need a scientific working group of international experts convened by TDR has prepared a working draft handbook providing standards for quality practice in basic biomedical research (QPBR). This handbook will be finalized by the end of the year 2005.

For further information on QPBR, contact:

Dr Deborah Kioy, Pre-clinical Coordinator, Product Development and Evaluation, TDR, WHO, 20 Avenue Appia CH-1211, Geneva 27. kioyd@who.int

INTERPLAY BETWEEN GOOD PRACTICES AND PLANNING

It is almost impossible to carry out quality work without proper planning; similarly, a project cannot be adequately planned unless the need for good practices is built into the process.

The process of planning and evaluation can be implemented in any biomedical research study, whether it is an in vitro, animal or clinical study. It helps to organize the study carefully, planning all activities in a logical way, including timelines and resources, and identifying and addressing potential issues. Activities should be conducted in a coordinated way, with the progress and the quality of the study monitored. Reporting should be organized and transparent and the success of the study evaluated. By ensuring good organization and management, the process of planning and evaluation of the study contributes to the implementation of the good practices principles.

At a different level, the process of planning and evaluation applied to a whole research project ensures good coordination of the various studies to be conducted for the achievement of the project objectives. This helps to ensure that studies are conducted at an appropriate time and to avoid repetition of studies due to mismanagement.

IN BRIEF...


Good practices do not evaluate the scientific value of research. They aim to protect the rights and safety of the human participants involved and to ensure that study data are credible (reliable, repeatable, auditable, and recognized by scientists worldwide).

The planning of activities is a key element of good practices, helping to ensure quality in the conduct of a study, capturing the data gathered from it, monitoring its progress and reporting its results.

MODULE 1:


Good practices in biomedical research

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graph TD; A[Good practices in biomedical research module 1] --> B[Understanding the value of planning module 2]; B --> C[Defining the project's purpose and scope module 3]; C --> D[Planning module 4]; D --> E[Implementing and evaluating module 5];
```

 *Good practices in biomedical research* 1

Learning objectives of the module

- Be aware of the concept and value of good practices in biomedical research
- Understand how good practices can impact biomedical research
- Position planning activities in relation to good practices
- Use common sense when addressing good practices

 *Good practices in biomedical research* 2

Overview of the module

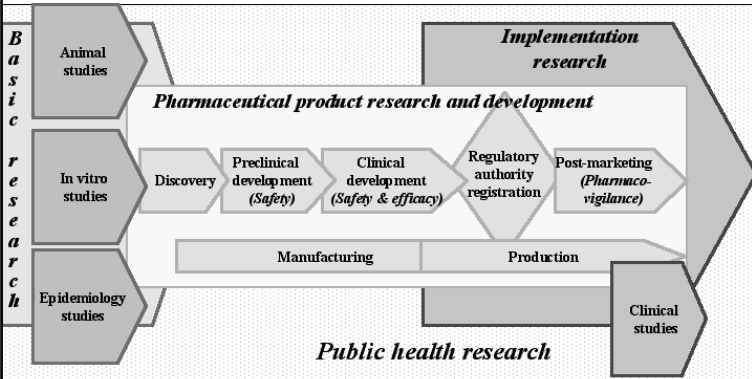
- **Module focus**
 - Rationale for international standards of good practices
 - Objectives of good practices
 - GMP/GAP/ GLP/GCP-Ethics
 - Quality practice in basic biomedical research
 - Project planning
- **Summary**



Good practices in biomedical research

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Biomedical research for the development of new tools



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Rationale for international standards of good practices

*Findings from the United States Food and Drug
Administration audit carried out in the 1970s showed:*

- Lack of standardized procedures
- Raw data not traceable
- Protocols not followed
- Inadequate resources
- Equipment not properly calibrated, etc.

*... these prevent mutual recognition of
study data across international frontiers.*



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Rationale for international standards of good practices (cont'd)

- Human rights of trial participants not being respected
- Poor animal welfare
- Etc...

... these are unacceptable



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Objectives of good practices

- Protection of human participants involved in the research
- Quality/credibility of research data



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Good practices are...

international **quality** standards of ...

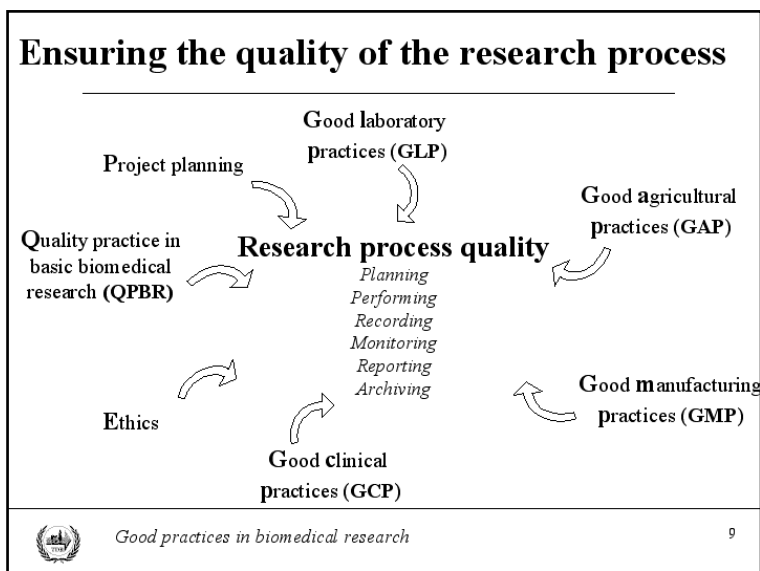
- *Planning*
- *Performing*
- *Recording*
- *Monitoring*
- *Reporting*
- *Archiving*

... biomedical research studies.




Good practices in biomedical research

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Good practices ...

“... do not evaluate the scientific value of a study”.

 *Good practices in biomedical research* 10

Good agricultural practices - GAP

- International standards: EMEA guidelines
- For application to the **production** through agricultural means of plants intended as sources of raw materials for pharmaceutical products
- Should ensure the quality of the plants used (characterization, pharmaceutical raw material content, impurity content, reproducibility)



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Good manufacturing practices - GMP

- International standards: International Conference on Harmonisation (ICH), WHO guidelines
- For application to the **production** of pharmaceutical products (raw materials, bulk syntheses and formulated products)
- Should ensure the quality of pharmaceutical products (proper characterization, purity, reproducibility)



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Good laboratory practices - GLP

- International standards: Organisation for Economic Co-operation and Development (OECD) GLP principles
- For application to **preclinical studies** used to evaluate the **toxicity (in vitro and in animals)** of a product
- Should ensure the quality of the research process (planning, performing, recording, monitoring, reporting, archiving)
- **Do not evaluate the scientific value of the study**



Good practices in biomedical research

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Good clinical practices – GCP and ethics

- International standards: *Declaration of Helsinki*, WHO and ICH guidelines for GCP, Council of International Organizations for Medical Sciences (CIOMS) international ethical guidelines for biomedical research on human participants
- For application to **biomedical research involving human participants**
- Include consideration of ethics
- Should ensure the protection of the human rights, safety and well-being of all human participants included in the study
- Should also ensure the quality of the clinical trial itself (planning, conducting, recording, monitoring, reporting)
- **Do not evaluate the scientific value of the trial**



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Quality practice in basic biomedical research - QPBR

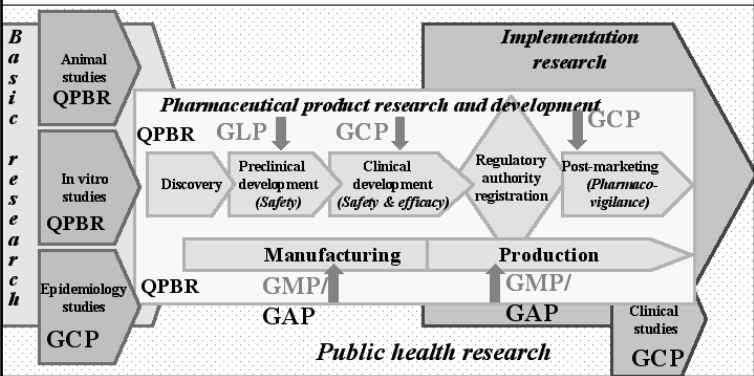
- Working draft developed by a specialized scientific working group convened by TDR, to be revised /finalized in the near future
- Standard: TDR adaptation of good laboratory practices for application to basic biomedical research
- For application in **biomedical basic research in vitro studies and animal studies**
- Address the need for universal acceptability and credibility of data arising from basic research
- **Do not evaluate the scientific value of the study**



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Good practices in biomedical research



Good practices in biomedical research

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Project planning

- Ensures a clear and agreed understanding of the project development strategy and the work needed to bring the project to completion (who does what, under which quality standard, when, at what cost, and who pays)
- Tool to help researchers to structure their work in order to ensure that all activities are done as planned and agreed and to international standards of good practices



Good practices in biomedical research

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Summary

- Good practices do not evaluate the scientific value of a research study
- Good practices aim to protect the rights and safety of involved human participants and to ensure that study data are credible (reliable, repeatable, auditable, recognized by scientists worldwide)
- Planning is a key element of good practices. It helps to ensure quality in carrying out, capturing the data from, monitoring the progress of, and reporting the results of a study



Good practices in biomedical research

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MODULE 2

Understanding the concept and value of project planning and evaluation

LEARNING OBJECTIVES OF THE MODULE

This theoretical session guides participants to:

- › consider and understand the concept and process of project planning and evaluation
- › be aware of the value of planning and the potential influence of this tool on daily work when managing a project and interacting with partners and donors.

FOCUS OF THE MODULE

The module covers:

- › definition of a project
- › teamwork
- › objectives of project planning
- › establishment and use of a project development plan
- › the value of project planning.

WHAT IS A PROJECT?

A project is a series of activities designed to achieve a specific outcome within a set budget and timescale. A project is different from a programme. It has a clear start and a clear end. It has defined objectives that must be met within a specific budget and period of time. It therefore requires an organized plan which includes the sequence of activities to be completed for the development of the project; their relationship, timelines, budget and resources. It involves a team that is created specifically for the project. As it ends the project is formally closed and evaluated.

The main driving forces of a project are quality, cost and time. It is important, when implementing a project, to ensure that all the necessary activities are completed. However, in order to be able to

achieve the project's objectives, it is essential that activities are completed following the agreed standards of quality, on time, and within budget.

HOW PROJECT DEVELOPMENT INVOLVES TEAMWORK

Projects have many facets and usually require several persons to work together in order to achieve the defined objectives. Biomedical research projects always involve various experts, each of them bringing specific and complementary knowledge, such as molecular biology, biochemistry, pharmacology, toxicology, clinical research, or data analysis. These projects require a multidisciplinary approach, which no single individual can provide. In addition, biomedical research projects increasingly involve partnerships and are funded by specific donors. They are therefore complex and require strong coordination and management. The various parties involved need to collaborate to give a complete picture of the project and to allow its effective implementation. They form the project development team.

A biomedical research project development team is often composed of experts/partners/donors from different organizations anywhere in the world. It is seen as a virtual team; a team which is not geographically established. However, members of the project development team need to work together and to work in synergy with each other. They do not implement their part of the work in isolation. They share the goal and objectives of the project and develop ownership of the project. They are therefore concerned with the progress of the project and the impact of their own work on the overall development. They trust each other, interact, and collaborate with each other.

A **project manager** coordinates the team and ensures the development of the project on time, within the agreed standards of quality and within budget, through effective communication. Careful coordination and management are essential for the success of the project. These tasks are time-consuming and the project manager (**who could be, but does not have to be, one of the principal investigators**) needs to dedicate an appropriate amount of time to them.

While the principal investigator's main responsibility is to provide scientific leadership, the key responsibilities of the project manager are:

- to establish the project development team
- to provide overall coordination of the project development team so as to ensure proper planning, effective implementation, monitoring, evaluation and reporting
- to take the lead role in interaction with partners and donors
- to manage the budget and financial matters.

More specifically the project manager should:

- › organize regular project development team meetings, teleconferences and/or any other team communication, in a regular fashion and whenever required
- › ensure that the purpose and scope of the project is defined
- › ensure the establishment, in collaboration with the project development team, of a complete project development plan
- › ensure that the project implementation is on time, keeps within a set budget and meets agreed standards
- › monitor the progress of activities and keep the whole project development team informed about this
- › update the project development plan, in a regular fashion and whenever required, in collaboration with the project development team
- › discuss and solve issues with the project development team and keep them up to date about the project progress, the changes and meeting and teleconference outputs
- › discuss concerns with management and with donors as appropriate
- › keep budget and finance matters up to date and anticipate any issue
- › establish and circulate the project progress reports, to the team members, relevant management and donors
- › formally close the project as it ends and evaluate its success
- › arrange for the establishment of the scientific report and its circulation to the team members, relevant management and donors
- › establish and circulate the final project report to the team members, relevant management and donors.

OBJECTIVES OF PROJECT PLANNING

An effective plan gives a clear vision of the project including what needs to be done, the standards to which it should be carried out, who will do it, when, how much it will cost and who pays for it.

It aims to:

- › ensure the project has a common goal
- › ensure a clear understanding of the development process
- › anticipate, identify and address potential logistic issues
- › enhance communication, coordination and teamwork
- › facilitate systematic project monitoring and reporting
- › facilitate clear project evaluation.

ESTABLISHING AND USING A PROJECT DEVELOPMENT PLAN

The project planning and evaluation process can be divided into three phases covering the establishment of the plan and its use in project management.

Phase I aims to define the purpose and the scope of the project by (1) summarizing in a short statement what is to be done and why; (2) defining the goal, objectives and the indicators used to measure their achievement; and (3) identifying the main steps required to reach the objectives of the project.

Phase II corresponds to the establishment of a complete project development plan: (1) the activities to be completed are listed and organized in a logical way (work breakdown structure); (2) their sequence and timelines are set; and (3) the resources are allocated.

Phase III includes the implementation, monitoring and the evaluation of the project: (1) the agreed and approved plan is implemented and the development is carefully monitored; (2) progress reports are established and circulated for effective communication; and (3) as the project ends it is closed and evaluated (final report).

PRESENTING A DEVELOPMENT PLAN

Project development plans give a clear vision of the project including activities, timelines and resources. They can be presented in various ways, each of them focusing on a different aspect of the project.

Gantt chart

Gantt charts are bar charts, which were developed by Henri Gantt as he was working in the United States army during World War I. The charts represent activities by bars on a calendar. They clearly list activities to be completed, show their sequence and their timelines and allow a quick identification of activities that can be completed in the same timeframe. They can also include details of budgets and human resources.

Gantt charts can be established using either a simple table or specific software, such as Microsoft Project and Power Project, which facilitate the monitoring and updating of the plans.

PERT chart (Programme Evaluation Review Technique)

PERT charts are network diagrams that represent activities by boxes linked to each other in a logical way. They show the flow of activities (from the left to the right of the diagram) and how activities

depend on each other and relate to decision points. They include timelines and can also show resources. The focus of the chart is not on the chronology of the project development (which is better shown in the Gantt chart) but on the relationship and the logic between activities. PERT charts and Gantt charts provide complementary information on the project's development. Although it is possible to establish PERT charts using specific software such as Microsoft Project or Power Project, the use of drawing software like Power Point can be more convenient and allows better customization of the plan.

Other types of plan

Other types of plan are available. From the influence diagram, which simulates various scenarios of project development, to the simple checklist of activities to be completed, the type of plan that is most appropriate to the situation and needs should be selected.

A plan is a tool to support the effective development of a project and should therefore be adapted to each particular need.

THE VALUE OF PLANNING

By defining the purpose and scope of the project and establishing a complete development plan (including activities, their sequence, relationships, timelines and the required resources), the planning process provides a clear vision of the project and facilitates the team's focus on it. The plan, being agreed and approved by all involved parties, ensures consensus and ownership. It enhances teamwork and allows all team members to understand the whole project and to assess the impact of their own work/contribution to the development. It also provides them with the opportunity to anticipate and address potential issues related to the logistics of the project. The plan facilitates the monitoring of activity implementation and therefore supports quick reaction to opportunities or problems. The project's regular updating facilitates the establishment of complete progress reports for good communication within the implementing team and with donors. It also facilitates the evaluation of the project's success at the end of the project.

IN BRIEF...

The process of planning is done, consciously or unconsciously, on a daily basis. The organization of a special meal, weekend, holiday, etc is not always undertaken formally, involving detailed and complete development plans and most of the time events are successful. However, a complex project, which involves a range of expertise, networking and partnership, requires a formal and systematic approach. This allows good project organization, effective communication, timely implementation, and conformity with agreed standards, within the agreed budget.

INTEGRATED EXAMPLE

Through modules 3, 4 and 5, the three phases of the planning and evaluation process are illustrated with an integrated example, the KEP example, which is briefly summarized below.

KEP example – KEP antibodies levels in humans naturally exposed to malaria (*Plasmodium falciparum*)

The 'Key Example Protein' (KEP) of *Plasmodium falciparum* is a prime candidate for inclusion in a vaccine against malaria. Presence of KEP antibodies is associated with naturally acquired protection against malaria attacks in humans. In animal models, vaccination with KEP induces the production of antibodies that provides protection against experimental *Plasmodium falciparum* infection.

In this project (2002-2005) the prevalence of KEP antibodies within populations in malaria-endemic areas will be determined through:

1. a study looking at the levels of KEP antibodies in subjects of different ages (cross-sectional study)
2. a study looking at the levels of KEP antibodies in pregnant women and at the transfer of these antibodies to their infants and their dynamics during the first year of life (longitudinal study)

It is expected that the results of these studies will provide critical information for the development of an effective vaccine against malaria.

This project is based on the collaboration of several partners:

- Department of Molecular Immunology in Gabon (home institution/project management)
- Institute of Child Health in Gabon (management of child health care/field work)
- Department of Community Medicine and Primary Care in Gabon (field study site)
- Medical Research Institution in Europe (training in KEP, immunity in malaria vaccine development, research material)


The project also aims at enhancing malaria research capacity in the involved African institutions: PhD and M.Sc students, and achieving technology transfer from the European partner to Gabon etc.

MODULE 2:

Understanding the concept and value of project planning


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    A[Good practices in biomedical research  
module 1] --> B[Understanding the value of planning  
module 2]
    B --> C[Defining the project's purpose and scope  
module 3]
    C --> D[Planning  
module 4]
    D --> E[Implementing and evaluating  
module 5]
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 *Understanding the concept and value of project planning* 1

Learning objectives of the module

- Consider and understand the process of project planning and evaluation
- Be aware of the value of planning and the potential influence of this tool on daily work

 *Understanding the concept and value of project planning* 2

Overview of the module

- **Example**
- **Module focus**
 - Definition of a project
 - Teamwork
 - Objectives of project planning
 - Establishment and use of project development plans
 - Value of project planning
- **Conclusion**



Understanding the concept and value of project planning

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Example: KEP antibodies levels in humans naturally exposed to malaria (*Plasmodium falciparum*)

- The "Key Example Protein" of *Plasmodium falciparum* (KEP) is a prime candidate for inclusion in malaria vaccine
- The presence of KEP antibodies in humans is associated with acquired protection against malaria attacks
- KEP antibodies provide protection against experimental infection in animal models



Understanding the concept and value of project planning

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Example: KEP antibodies levels in humans naturally exposed to malaria (Plasmodium falciparum) - cont'd

- In this project (2002-2005) the prevalence of KEP antibodies within populations in malaria-endemic areas will be determined through:
 - A study looking at the levels of KEP antibodies in subjects of different ages (cross-sectional study)
 - A study looking at (1) the levels of KEP antibodies in pregnant women and (2) the transfer of these antibodies to their infants and their dynamics during the first year of life (longitudinal study)



Understanding the concept and value of project planning

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Example: KEP antibodies levels in humans naturally exposed to malaria (Plasmodium falciparum) - cont'd

- The project is innovative and requires the collaboration of various experts from different institutions, involving networking, technology transfer and capacity-building:
 - Department of Molecular Immunology in Gabon (home institution/project management)
 - Institute of Child Health in Gabon (management of child health care/field study)
 - Department of Community Medicine and Primary Care in Gabon (field study site)
 - Medical research institution in Europe (training in KEP, immunity in malaria vaccine development, research material)



Understanding the concept and value of project planning

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Definition of a project

A project is a...

“...series of **activities** designed to achieve a **specific outcome** within a set **budget** and **timescale**”.



Understanding the concept and value of project planning

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What makes a project different from a programme?

Key features of a project ...

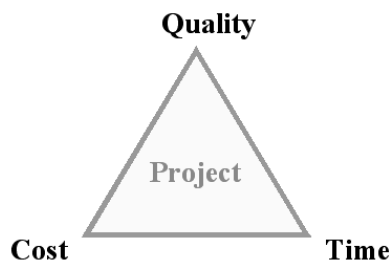
- Established goal / objectives
- Defined start and end
- Organized plan of activities
- Teamwork / team specific to the project
- Allocated resources



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Characteristics of a project

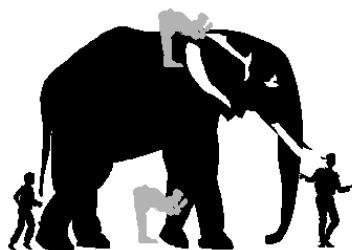


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Multidisciplinary approach

From individualism and disorganization ...



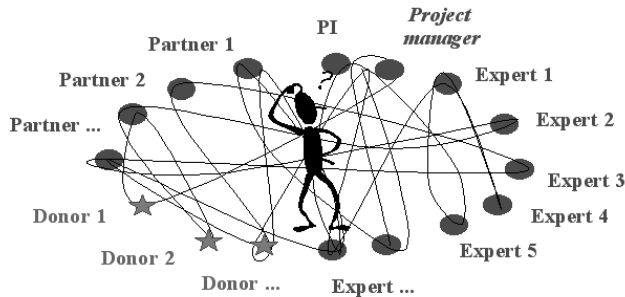
... to the concept of teamwork



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Project development team: a virtual team...



● :Implementing team
★ :Individual funders

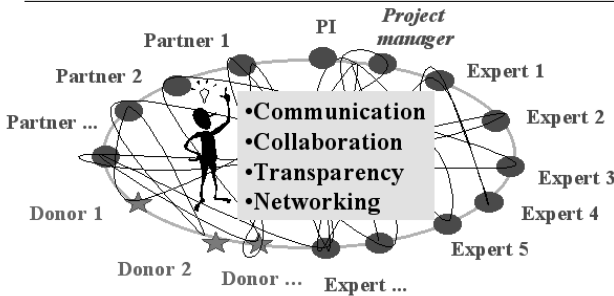
...involved in a complex project



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Project development team: a virtual team ...



● :Implementing team
★ :Individual funders

**... to work together in synergy with each other
to achieve the project's objectives**



Understanding the concept and value of project planning

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Responsibilities of the project manager

Main responsibilities:

- To establish the project development team
- To provide overall coordination of the project development team so as to ensure proper planning, effective implementation, monitoring, evaluation and reporting
- To take the lead role in interaction with partners and donors
- To manage the budget and financial matters



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Responsibilities of the project manager – *cont'd*

More specifically:

- To organize regular project development team meetings, teleconferences, and/or any other team communication in a regular fashion and whenever required
- To ensure the project is defined
- To ensure the establishment, in collaboration with the project development team, of a complete project development plan
- To ensure that the project implementation is on time, keeps within a set budget and meets agreed standards



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Responsibilities of the project manager – *cont'd*

- To monitor the progress of activities and keep the whole project development team informed about this
- To update the project development plan, in a regular fashion and whenever required, in collaboration with the project development team
- To discuss and solve issues with the project development team and keep them up to date about the project progress and changes, and meeting and teleconference outputs
- To discuss concerns with management and with donors if appropriate



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Responsibilities of the project manager – *cont'd*

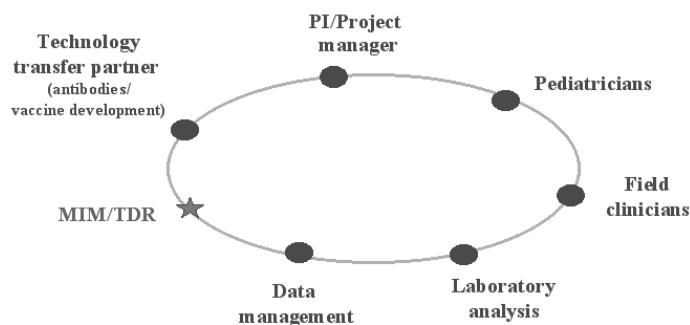
- To keep budget and finance matters up to date and anticipate any issue
- To establish and circulate the project progress reports to the team members, relevant management and donors
- To formally close the project as it ends and evaluate its success
- To arrange for the establishment of the scientific report and its circulation to the team members, relevant management and donors
- To establish and circulate the final report to the team members, relevant management and donors



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Example: KEP antibodies levels in humans naturally exposed to malaria (*Plasmodium falciparum*)



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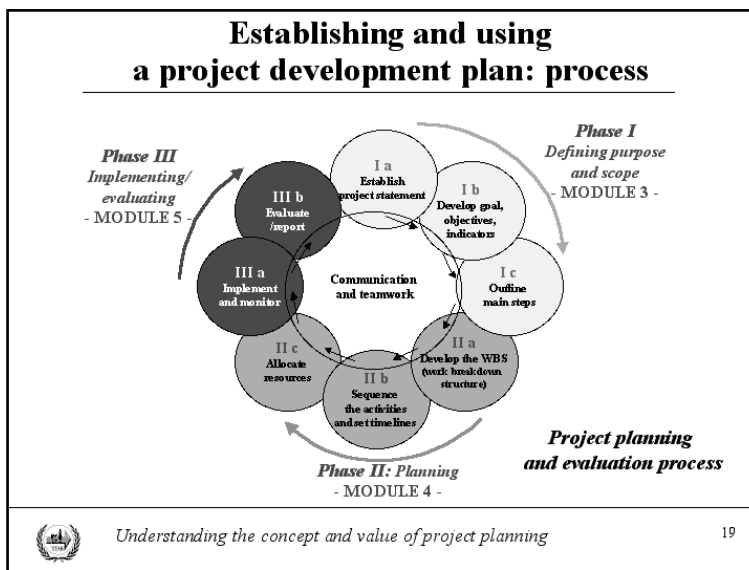
Objectives of project planning

- To ensure that the project has a common goal and a clear definition of the process, including:
 - what needs to be done
 - the standards to which it should be carried out
 - who will do it
 - when will it be done
 - what will it cost
 - who will pay for it
- To identify/anticipate/address potential issues
- To enhance communication, transparency, coordination and teamwork
- To facilitate systematic monitoring and reporting
- To facilitate clear evaluation of the project



Understanding the concept and value of project planning

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Presentation of development plans

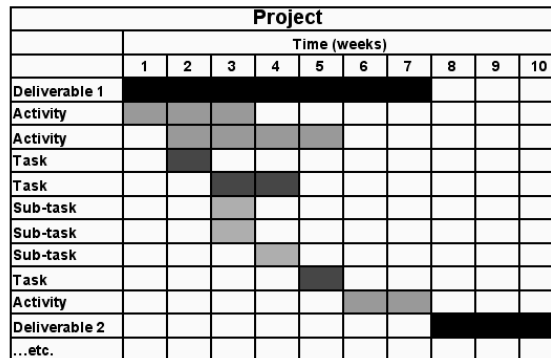
- Several types of plan are available:
 - bar chart (Gantt chart)
 - network diagram (PERT chart)
 - influence diagram
 - check list...
- Choose the most appropriate type of plan for each particular purpose



Understanding the concept and value of project planning

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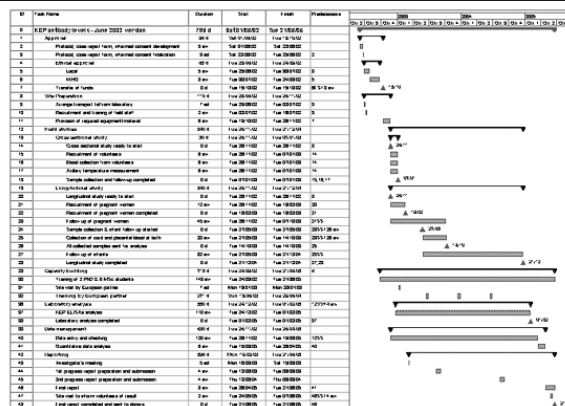
Bar chart (Gantt Chart)



Understanding the concept and value of project planning

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Bar chart (Gantt Chart)



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Value of planning

- Facilitates development of project **focus**
- Ensures **consensus** on project development strategy and project development plan
- Ensures **ownership** of the project
- Ensures **everyone understands** who is doing what, when, and how each action **impacts** the project as a whole
- Enhances **teamwork** and **transparency**
- Facilitates project **monitoring** and **identification of issues**
- Facilitates project **evaluation** and **reporting**
- Provides management/donors with key information for the **review** of the project



Understanding the concept and value of project planning

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Conclusion

- **In our daily life we all plan** our various activities – a special meal, a holiday, a birthday party, etc. , without developing a formal plan, and most times the event is successful !
- However, a complex project involving a range of expertise, networking and partnership requires a more **formal and systematic approach.**

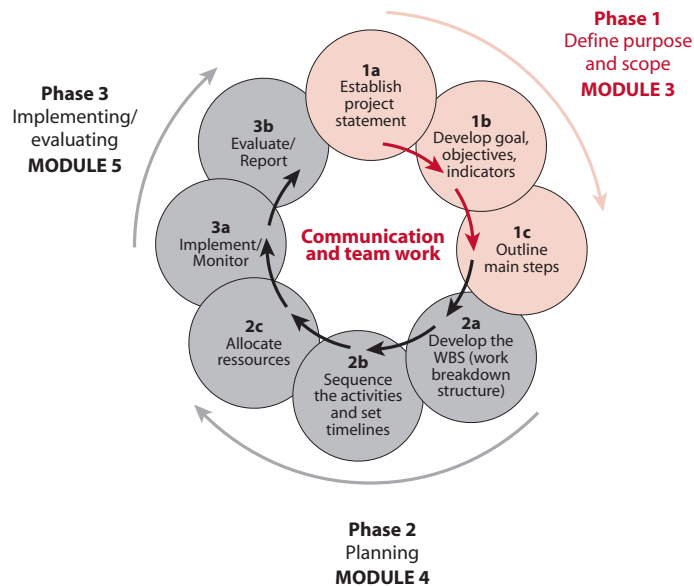


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MODULE 3

Phase I: Defining the purpose and scope of the project



LEARNING OBJECTIVES OF THE MODULE

Module 3 guides participants to:

- › define what they want to achieve
- › highlight why they want to do it
- › set the time by which this should be accomplished
- › identify the main steps that need to be taken.

FOCUS OF THE MODULE

Defining the purpose and scope of the project is the first phase in the process of project planning and evaluation. In module 3 participants are guided through this phase as they:

- establish the project statement
- define the project goal
- define the project objectives
- define key indicators for each objectives
- identify the main steps of the project's development required to reach the objectives.

Module 3 is organized in two sessions. First, a short theoretical session presents the concept of defining the purpose and scope of the project and the various steps this involves. The second session is a case study exercise during which participants have the opportunity to apply these steps to their own current project. This is a "real life" case study where participants learn by working on their own project. They go through each step at a time, first working in small groups and then sharing and discussing their experience, reflection and results with other groups. This allows participants to learn by experiencing their own project and other participants' projects, and reflecting on them.

ESTABLISHING THE PROJECT STATEMENT

The project statement is a short paragraph describing what needs to be done, why it needs to be done and by what date the work must be finished. It is an important step, which defines the project by characterizing it and showing its context and boundaries. It gives the basis of the project and ensures its focus.

For example, in a project aiming to study the development of drug resistance in malaria treatment, the statement would define which aspect of drug resistance the project looks at (epidemiology, mechanism of action, genetics etc.), what it is intended to demonstrate and by when, which type of studies are involved (in vitro, animal, clinical), and the contribution the project will make to public health (e.g. a contribution to the improvement of malaria treatment policy in Nigeria).

KEP example – Project statement

In order to provide critical information for the development of an effective vaccine against malaria, the project aims to determine, by the year 2005, the levels of KEP antibodies in humans naturally exposed to malaria (in relation to age, pregnancy, transfer to newborn infants).

DEFINING THE GOAL OF THE PROJECT

The goal is described in a short sentence that defines the overall aim of the project. It sets the purpose of the project in a larger context and defines its contribution. It is therefore a very general statement. Some examples of goals could be: “improvement of malaria treatment policy in Nigeria”, “malaria vaccine development”, “improvement of the implementation of the national tuberculosis control programme in South Africa” etc.

KEP example – Project goal

To provide critical information on KEP antibodies levels for the development of a vaccine against malaria for children in Africa.

DEFINING THE OBJECTIVES OF THE PROJECT

Objectives are specific project outputs. They describe what will have been achieved by the end of the project and what must be delivered for the project’s success.

They can also describe the requirements which must be met during a project, such as “follow good clinical practices”, “build capacity”, “the cost of the developed tool should not exceed USD X” etc...

Objectives should be **SMART**:

- Specific
- Measurable
- Achievable
- Realistic/Resourceable, and
- Time-specific.

KEP example – Objectives

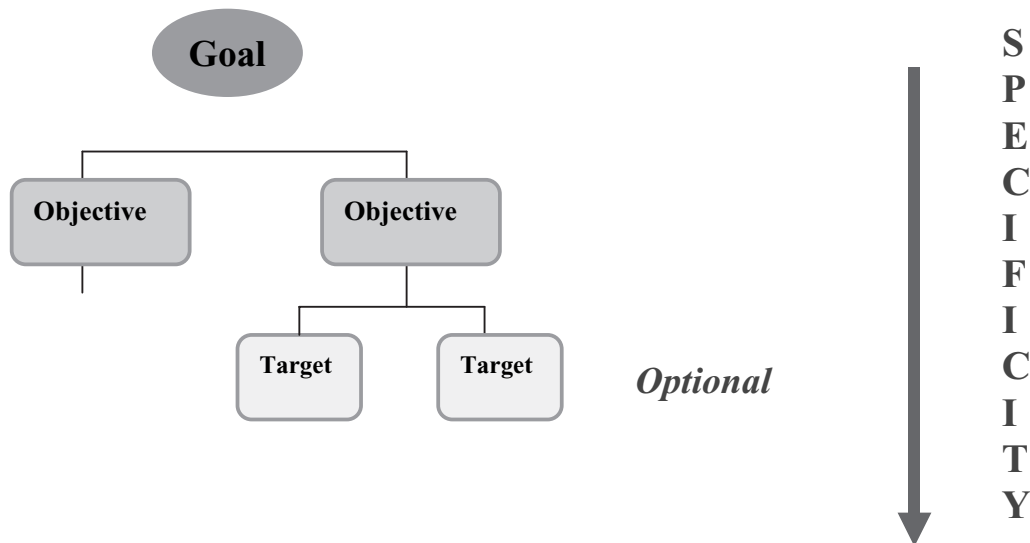
By June 2005:

1. to assess the correlation of the levels of KEP antibodies with age and parasitemia
2. to determine if KEP antibodies are transferred from pregnant mothers to their infants, and to evaluate KEP antibody production from birth through the first year of life
3. to develop human resources and infrastructure to enhance malaria research in Gabon

THE PROJECT HIERARCHY

There is not only a wide range of terms, such as “goal”, “activities”, “objectives”, “main objectives”, “specific objectives”, “target”, “main target”, etc., but the way in which those terms are used can also vary widely, with differing meanings. For example, what one person may call a “main target”, may be what another person would call a “goal”. **It is important, in a project, to define clearly the various terms used and to understand their relationship.** For example, how do the objectives relate to the goal? In some large, long-term projects it may be necessary to break down objectives into more specific deliverables. These may be called “targets” or even “main targets”. These could then be broken down into “specific targets” etc. This breakdown of achievements represents the project hierarchy. The more general aim of the project is placed at the top of the hierarchy pyramid and is broken down into more specific deliverables/outcomes placed a step lower in the pyramid. These specific deliverables/outcomes are themselves further broken down in even more precise deliverables /outcomes placed another step lower in the pyramid.

Project hierarchy:



When establishing a project hierarchy, it is essential to make great use of common sense to define the project clearly and in a logical way. **It is also important to try and keep the whole project hierarchy as simple as possible.**

DEFINING INDICATORS

The project's success is based on the achievement of project objectives. Indicators represent what will be measured at the end of the project in order to show whether the objectives were met. One to three indicators are strategically defined for each objective (or target, if there is one) during the definition of the purpose and scope of the project. These indicators will be measured at the end of the project and will be used to evaluate the project's success.

KEP example – Indicators for each objective

By June 2005:

Objective 1

To assess the correlation of the levels of KEP antibodies with age and parasitemia

Indicator:

Distribution of KEP antibodies according to age and parasitemia described

Objective 2

To determine if KEP antibodies are transferred from pregnant mothers to their infants, and to evaluate KEP antibody production from birth through the first year of life

Indicators:

A. Frequency of KEP antibody transferred to the infants identified at birth

B. Levels of KEP antibodies produced in the first year of life described

Objective 3

To develop human resources and infrastructure to enhance malaria research in Gabon

Indicators:

A. 2 PhD students trained

B. 6 MSc students trained

C. 1 post doctoral scientist trained in special skills/techniques

D. transfer of technology to Gabon laboratory by European partner (malaria vaccine development)

Indicators should also be **SMART** (**S**pecific, **M**easurable, **A**chievable, **R**ealistic/**R**esourceable and **T**ime-specific).

Some examples of indicators: “clinical monitoring report showing compliance with GCP, written by end-2005”; “complete expert report on safety ready by end-2005”; “drug resistance levels in African pregnant women living in malaria-endemic areas measured by end-2005”; “malaria control policy in Tanzania revised by end-2005”; “ability to ...built in institution A by ...”; “drug A available at USD 1 per tablet for the public sector in Gabon by end-2005” etc.

IDENTIFYING THE MAIN STEPS

Once the project objectives (/targets), describing the project outputs, have been defined it is important to identify the main steps to be accomplished in order to meet the project objectives (/targets). The main steps are the key blocks of activities required to achieve the objectives (/targets). They map out the whole development of the project, organizing it in work packages.

IN BRIEF...

The descriptions of purpose and scope of the project present the project in its context and highlight its contribution to public health. The boundaries of the project are clearly defined and the project is focused. The goal, objectives, indicators and main steps of the development are described in a logical way. This allows a succinct and clear presentation of what the project will achieve, which strategy will be followed and how its success will be measured. It gives an organized base for the preparation of a grant proposal and the search for partners.

KEP example – Main steps

1. Seeking approval
2. Study site preparation
3. Field studies
4. Laboratory analysis
5. Data management
6. Reporting
7. Capacity-building

LIFE CASE STUDY

Case-study sessions are based on “real life” cases. This means that participants learn by working on their current project. Small groups of participants involved in the same project are established. The case study is approached in two stages.

1. Exercise and reflection in small groups

Each group discusses and defines the purpose and scope of their project, going through the various steps described above and using the Step-by-step guide. Participants also receive guidance from the trainers as needed.

2. Discussion and generalization in a plenary session


Each group presents and discusses their results and shares their experience and reflections with the other groups. Potential issues are discussed.

MODULE 3:

Defining the purpose and scope of the project


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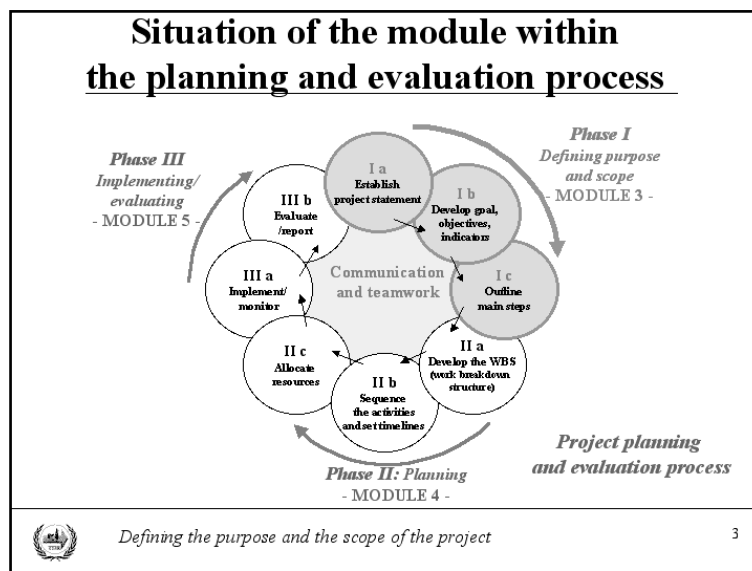
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    D --> E[Implementing and evaluating  
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 *Defining the purpose and the scope of the project* 1

Learning objective of the module

- To define:
 - What we want to achieve
 - Why we want to do this
 - By when should this be accomplished
 - What are the main steps that need to be carried out

 *Defining the purpose and the scope of the project* 2



Overview of the module

- **Module focus**
 - Establishing the project statement
 - Defining the project goal
 - Defining the project objectives
 - Defining key indicators
 - Outlining main steps
- **Summary and conclusion**
- **Case studies**

Defining the purpose and the scope of the project

4

Establishing the project statement

The statement is a short paragraph defining and summarizing ...

- What needs to be done
- Why this needs to be done
- By when the work must be finished

... thereby giving boundaries to the project.



Defining the purpose and the scope of the project

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Example: KEP antibodies levels in humans naturally exposed to malaria (*Plasmodium falciparum*)

Project statement:

In order to provide critical information for the development of an effective malaria vaccine, the project aims to determine, by the year 2005, the levels of KEP antibodies in humans naturally exposed to malaria (in relation to age, pregnancy, transfer to new born infants).



Defining the purpose and the scope of the project

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Defining the goal of the project

The goal is a short and general sentence defining...

- The overall aim of the project
- The contribution of the project in a bigger context

... thereby describing the purpose of the project.



Defining the purpose and the scope of the project

7

Example: KEP antibodies levels in humans naturally exposed to malaria (*Plasmodium falciparum*)

Project goal:

To provide critical information on KEP antibodies levels for the development of a malaria vaccine for children in Africa.



Defining the purpose and the scope of the project

8

Defining the objectives of the project

The objectives are a more specific text which defines...

- What will have been achieved by the end of the project
- Which requirements must be met



Defining the purpose and the scope of the project

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Defining the objectives of the project (cont'd)

Objectives should be SMART ...

- **S**pecific
- **M**easurable
- **A**chievable
- **R**ealistic
- **T**imely



Defining the purpose and the scope of the project

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Example: KEP antibodies levels in humans naturally exposed to malaria (*Plasmodium falciparum*)

Objectives:

By June 2005:

- To assess the correlation of the levels of KEP antibodies with age and parasitemia
- To determine if KEP antibodies are transferred from pregnant mothers to their infants, and to evaluate KEP antibody production from birth through the first year of life
- To develop human resources and infrastructure to enhance malaria research in Gabon



Defining the purpose and the scope of the project

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Terminology ...


“ Goal...objectives... general objectives...specific objectives... targets... specific targets... sub-targets ... etc ”

... are terms not only widely used but used in different ways, so there is a risk of confusion.




Defining the purpose and the scope of the project

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Terminology ...

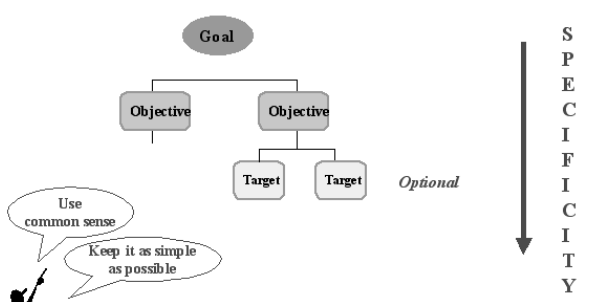
- Define **your** usage of these terms, and their relationship
- Establish the hierarchy of the terms by breaking down each element into its more specific sub-elements:
 - from goal to objectives
 - from objectives to targets (optional)
 - etc...(optional)
- Keep the hierarchy as simple as possible




Defining the purpose and the scope of the project

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Establishing the project hierarchy






Use common sense

Keep it as simple as possible

Targets: “represent what needs to be reached to meet the related objective”



Defining the purpose and the scope of the project

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Defining indicators

- Indicators are what will be measured to show whether or not objectives have been achieved and thus whether or not the project was successful
- One to three indicator(s) should be defined for each SMART objective or for each target (if there are any)



Defining the purpose and the scope of the project

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Example: KEP antibodies levels in humans naturally exposed to malaria (Plasmodium falciparum)

Indicators for each objective:

By June 2005:

Objective 1

To assess the correlation of the levels of KEP antibodies with age and parasitemia

Indicator:

Distribution of KEP antibodies according to age and parasitemia described



Defining the purpose and the scope of the project

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Example: KEP antibodies levels in humans naturally exposed to malaria (*Plasmodium falciparum*)

Indicators for each objective (cont'd):

By June 2005:

Objective 2

To determine if KEP antibodies are transferred from pregnant mothers to their infants, and to evaluate KEP antibody production from birth through the first year of life

Indicators:

- *Frequency of KEP antibody transferred to the infants identified at birth*
- *Levels of KEP antibodies produced in the first year of life described*



Defining the purpose and the scope of the project

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Example: KEP antibodies levels in humans naturally exposed to malaria (*Plasmodium falciparum*)

Indicators for each objective (cont'd):

By June 2005:

Objective 3

To develop human resources and infrastructure to enhance malaria research in Gabon

Indicators:

- *2 PhD students trained*
- *6 MSc students trained*
- *1 post-doctoral scientist trained in special skills/techniques*
- *Transfer of technology to Gabon laboratory by European partner (malaria vaccine development)*

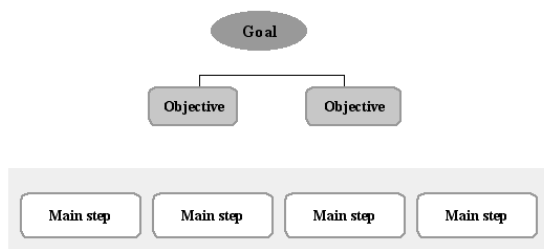


Defining the purpose and the scope of the project

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Outlining the main steps

The main steps are blocks of activities which are required to reach the objectives (or targets if any)



Defining the purpose and the scope of the project

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Example: KEP antibodies levels in humans naturally exposed to malaria (Plasmodium falciparum)

Main steps

- *Seeking approval*
- *Study site preparation*
- *Field studies*
- *Laboratory analysis*
- *Data management*
- *Reporting*
- *Capacity-building*



Defining the purpose and the scope of the project

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Summary and conclusion

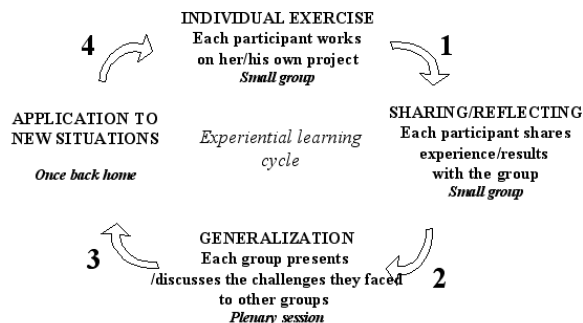
- The description of the purpose and scope of the project puts the project in context, it defines its boundaries and outlines the goal, objectives and indicators in a logical way
- The description lists the main steps required to meet the objectives
- It serves as a basis for presenting the project, writing grant proposals and seeking partners



Defining the purpose and the scope of the project

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Case studies

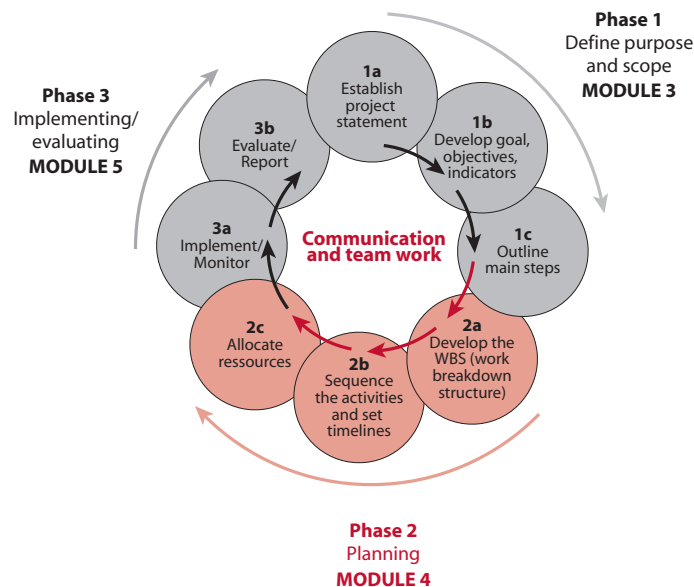


Defining the purpose and the scope of the project

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MODULE 4

Phase II: Establishing the project development plan



LEARNING OBJECTIVES OF THE MODULE

Module 4 guides the participants to:

- apply the planning steps to their current project and thus begin developing a draft development plan for their project to be completed once back home with all team members
- compare the value of the bar chart and the network diagram
- be aware of the range, role and value of software available.

FOCUS OF THE MODULE

Establishing the project development plan is the second phase of the process of project planning and evaluation. Module 4 leads the participants through this phase:

- › developing the work breakdown structure (WBS)
- › defining the sequence of activities
- › setting duration and timelines
- › defining milestones
- › allocating resources
- › presenting the plan using a bar chart
- › presenting the plan using a network diagram
- › reaching agreement on the plan and getting approval.

Module 4 is organized in the same way as module 3, guiding participants through the various steps of the second phase of project planning and evaluation in two sessions. A short theoretical session is followed by a real life case study based on the participants' own projects. Participants work in small groups on the establishment of the development plan of their project and present it in a Gantt chart and in a PERT chart. They then share and discuss their draft charts, their experience and potential issues with the other groups.

DEVELOPING THE WORK BREAKDOWN STRUCTURE (WBS)

The development of the work breakdown structure is a planning tool for identifying, organizing and grouping the project activities to be completed. As the name indicates, the work breakdown structure illustrates the work to be done through breaking down each main step into the various activities that are needed to achieve it. Each of these activities is, in turn, further broken down into the various required tasks. Each of the tasks is broken down into various sub-tasks, and so on. The level of breakdown depends on the required level of planning and monitoring. The last elements of the work breakdown structure are called terminal elements. The sum of all **terminal elements** is equal to the whole project work.

The work breakdown structure can be shown in two basic formats: (1) a graphic representing an organization chart and (2) an outline (see example in box, below). The structure is developed by:

- › listing the main steps of the project
- › listing, for each main step, the various activities required in order to complete it
- › listing, for each activity, the various tasks required in order to complete it
- › breaking down the work until the required level of planning and monitoring is reached
- › testing the work breakdown structure to make sure it will accomplish the project objectives.

KEP example – Work breakdown structure outline

Each main step (approval, site preparation, conduct of field study etc.) has been further broken down into various activities and tasks.

1. SEEKING APPROVAL**1.1. Protocol, case report form, informed consent development****1.2. Protocol, case report form, informed consent finalization****1.3. Ethical approval**

1.3.1. Local

1.3.2. WHO

1.4. Transfer of funds**2. STUDY SITE PREPARATION****2.1. Arrangement of transport****2.2. Recruitment and training of field staff****2.3. Provision of required equipment/material****3. FIELD STUDY****3.1. Cross-sectional study**

3.1.1. Recruitment of volunteers

3.1.2. Blood collection

3.1.3. Axillary temperature measurement

3.2. Longitudinal study

3.2.1. Recruitment of pregnant women

3.2.2. Etc.....

DEFINING THE SEQUENCE OF ACTIVITIES

Once the work breakdown structure outline is established, the sequence is defined. The sequence of activities is the order in which activities will be completed. This order depends on the links established between activities and on how activities depend on each other.

Activity dependencies are identified for each terminal element. They are expressed by terms such as “activity X starts as soon as possible”, “starts in the same time as activity Y”, “finishes at the same time as activity Y”, “starts at the same time as activity Y with a delay of X days”, “starts at the same time as activity Y with an overlap of X days”, “finishes at the same time as activity Y with a delay of X weeks” etc.

KEP example – The sequence and dependencies of each terminal element of the work breakdown structure

1. SEEKING APPROVAL

- 1.1. Protocol, case report form, informed consent development..... start as soon as possible
- 1.2. Protocol, case report form, informed consent development..... starts after 1.1 is finished
- 1.3. Ethical approval
 - 1.3.1. Local..... starts after 1.2 is finished
 - 1.3.2. WHO..... starts after 1.3.1 is finished
- 1.4. Transfer of funds starts after 1.3.2 is finished with 3 weeks of delay

2. STUDY SITE PREPARATION

- 2.1. Arrangement of transport starts after 1.2 is finished
- 2.2. Recruitment and training of field staff..... starts after 2.1 is finished
- 2.3. Provision of required equipment/material..... starts after 1.4 is finished

3. FIELD STUDIES

- 3.1. Cross-sectional study
 - 3.1.1. Recruitment of volunteers..... starts after 2 is finished
 - 3.1.2. Blood collection..... starts at the same time as 3.1.1
 - 3.1.3. Axillary temperature measurement..... starts at the same time as 3.1.1
- 3.2. Longitudinal study
 - 3.2.1. Recruitment of pregnant women..... starts after 2 is finished
 - Etc.....

SETTING DURATION AND TIMELINES

Once the work breakdown structure is outlined and all terminal element dependencies are set, the duration and timelines of activities are estimated. Their start and finish dates depend on the start date of the project, the activities' duration, their links and dependencies and the potential constraints (such as a particular activity having to occur at a particular date). It is important to note that duration and timelines can only be, at this stage, an **estimation** and therefore may/will change during the development of the project as unexpected events occur. However, timelines should be as **realistic** as possible and their estimation should be based on a careful analysis of the work to be done, available resources and other factors that may influence them (such as the malaria transmission season for example). This allows the project team to think through all the required activities, to best organize them and to assess the feasibility of the project. It is also valuable for anticipating, identifying and addressing potential time conflicts and other logistical issues.

Duration and timelines are set by:

- › defining the start date of the project
- › estimating the duration of each terminal element (on which depends the duration of the other elements)
- › setting the start and finish date of activities in accordance with the start date of the project, the activities' duration, their links and dependencies and the potential constraints.

DEFINING MILESTONES

Milestones are key events, achievements or decisions in the development of the project. They are chosen strategically and judiciously in order to provide a means of measuring the progress of the project. They map out the main steps of the development of the project and reflect its progression. They are easily measured and are used for project monitoring. Milestones are defined during the planning phase of the project before the project implementation starts.

Milestones can be:

- › *an achievement* such as "protocol finalized on day X", "database validated and closed on day X", "site visit completed on day X", "training of laboratory staff completed on day X"
- › *the beginning of a key activity* such as "recruitment started on day X", "data analysis started on day X"
- › *a key decision* such as "ethical clearance approved on day X", "decision to start clinical trial on day X"

KEP example – Milestones

1. Ethical approval obtained and transfer of funds made by October '02
2. Cross-sectional study ready to start by November '02
3. Sample collection and follow-up of cross-sectional study completed by January '03
4. Longitudinal study ready to start by November '02
5. Recruitment of pregnant women completed by February '03
6. Sample collection and infant follow-up in longitudinal study started by May '03
7. All collected samples sent for analysis by October '03
8. Longitudinal study completed by December '04
9. Laboratory analysis completed by February '05
10. Final report sent to donors by June '05

ALLOCATING RESOURCES

It is important to identify and allocate, during the planning phase, all required resources related to responsibilities, cost and financial contributors.

The first stage in allocating resources is to define who is doing what. The responsible party may carry out the activity or may choose to contract it out. Once responsibilities are allocated, the cost of activities can be identified or estimated. It is then important to agree on who pays for what (financial contributors).

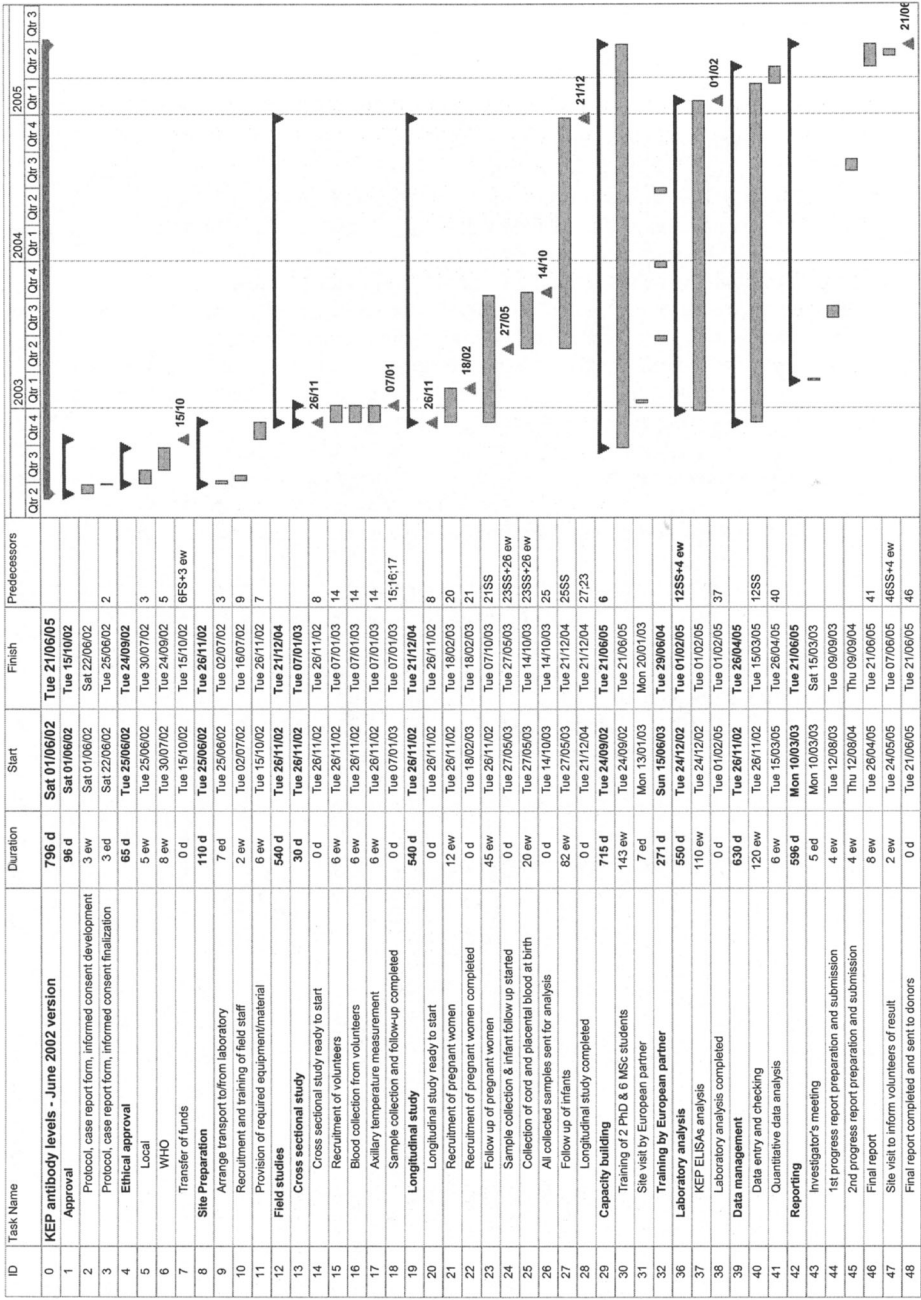
Resource allocation must be established and agreed by all involved parties before the implementation of the project starts.

PRESENTING THE PLAN AS A BAR CHART – GANTT CHART

Activities are represented by a bar on a calendar. The length of each bar corresponds to the duration of the activity and the position of the bar indicates when activity occurs. Duration, start date, finish date, responsibilities, cost and stakeholders can also appear in the chart. Gantt charts give a clear visualization of activities and their timing (chronology, duration). They highlight the possibility of several activities occurring at the same time. They also show milestones and decision points.

Gantt charts can be established using a simple matrix, with activities listed vertically and a calendar set horizontally.

KEP Example – Gantt Chart – KEP antibodies levels in humans naturally exposed to malaria (*Plasmodium falciparum*)



Specific planning software such as Power Project, Microsoft Project are available. Once data such as activities, dependencies, duration, timelines and resources are entered the Gantt chart is automatically designed. These software packages facilitate the updating of the plan and allow a rapid visualization of the impact of changes.

During this module, participants have the opportunity to establish a draft Gantt chart for their project using the basic features of Microsoft Project.

The chart is developed by:

- entering the work breakdown structure
- entering the duration of each terminal element
- entering dependencies and links
- entering start and/or finish constraint dates
- defining milestones
- entering resources
- formatting the chart as appropriate
- assessing the feasibility of the development plan.

PRESENTING THE PLAN AS A NETWORK DIAGRAM – PERT CHART

PERT charts (Programme Evaluation Review Technique) are network diagrams in which activities are represented by boxes linked to each other by arrows. PERT charts show the flow of activities (from the left to the right side of the diagram) and their relationship. Decision points, timelines and resources can be included.

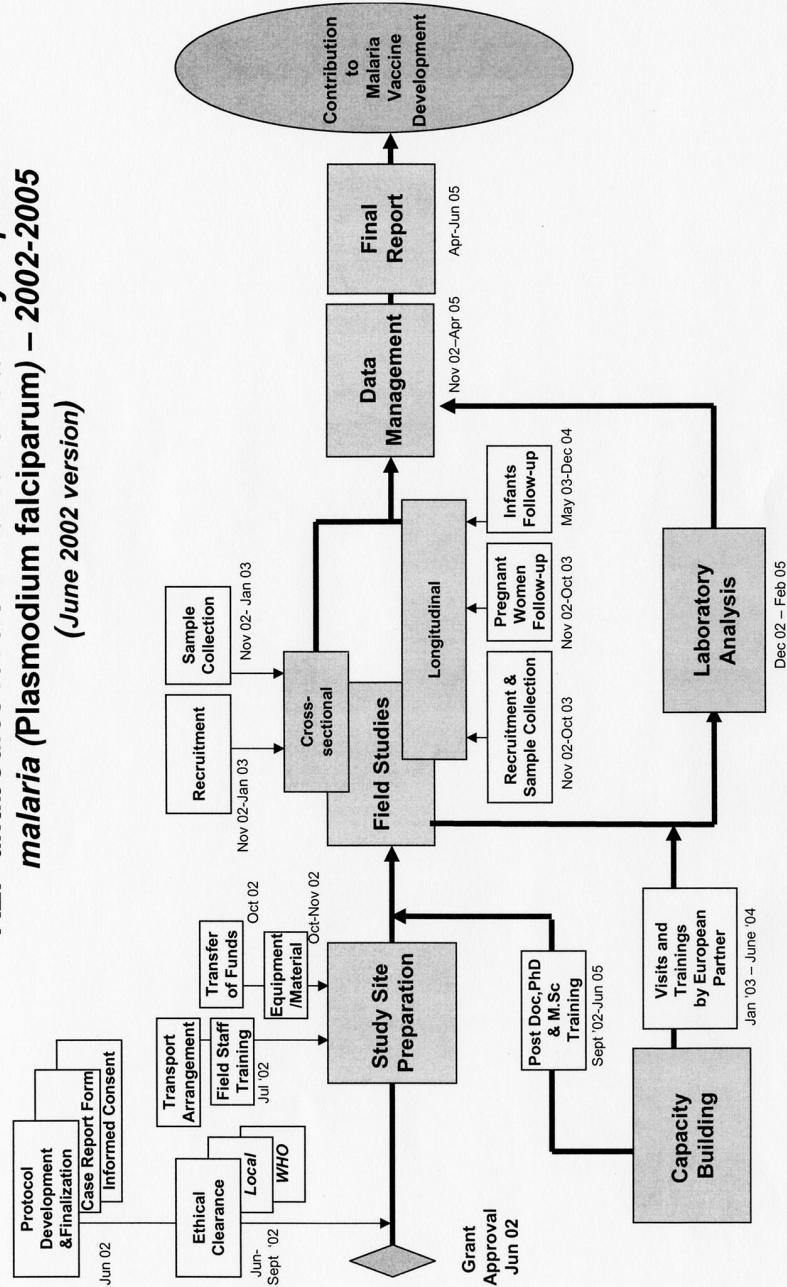
PERT charts give a clear and simple view of the project sequence and activities' dependencies. It also facilitates the identification of the critical path. The **critical path** is the path through the network diagram that determines the shortest time within which the project can be completed. A delay of any activity on the critical path will provoke a delay in the whole project. The information provided in a PERT chart is complementary to the information obtained through Gantt charts. Gantt charts focus on the chronology (the time at which activities happen) as PERT charts highlight the logic (how activities depend on each other).

A PERT chart is developed by:

- drawing a start point on the left of the page and a finish point on the right of the page
- drawing a network of activities represented by boxes linked to each other by arrows and including key decision points represented by a diamond shape
- testing the logic of the network and ensuring that it will accomplish the project objectives
- adding activity timelines under each box, resources (optional), and a legend for the decision points.

KEP Example – PERT chart

Example - PERT chart
KEP antibodies levels in humans naturally exposed to malaria (Plasmodium falciparum) – 2002-2005
 (June 2002 version)



REACHING AGREEMENT ON THE PLAN AND GETTING APPROVAL

Although these tasks cannot be implemented during the course, the importance of this step should be highlighted at this stage. A development plan is only complete when it has been formally agreed by all the parties involved and approved by the relevant management groups. This ensures ownership and commitment that will be crucial for an effective project implementation on time and within agreed standards and budget.

IN BRIEF...

Establishing a project development plan brings together all the information on the project (who does what, when, according to which standards, how much it costs and who pays for it). This is presented in a clear manner (usually by a Gantt chart and/or PERT chart) so that it is understood and agreed by all the parties involved. The development plan is not fixed. It is dynamic and must be adapted to fit new situations. The development plan is a management tool and must be used throughout the whole life of the project. Its regular updating is essential for effective project implementation, monitoring, evaluation and reporting.

REAL LIFE CASE STUDY

Participants continue to work on their own project.

1. Exercise and reflection in small groups

Participants develop a draft Gantt chart and a draft PERT chart for their project following the steps described above and using the Step-by-step guide. They also receive guidance from trainers as needed.

2. Discussion and generalization in a plenary session

Groups present and discuss the drafts they have developed and share their experience and reflection with each other. Potential issues and suggestions are discussed.

MODULE 4:

**Establishing the
project development
plan**

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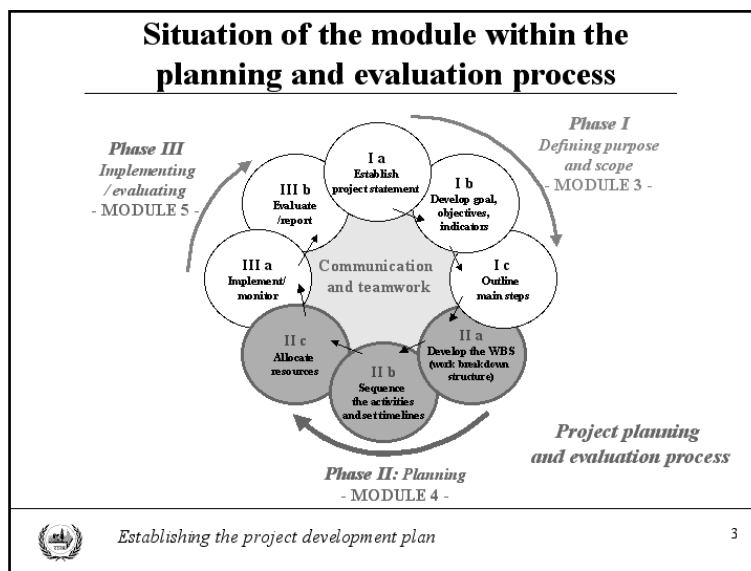
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module 3]
    C --> D[Planning  
module 4]
    D --> E[Implementing and evaluating  
module 5]
  
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Establishing the project development plan 1

Learning objectives of the module

- Apply the planning steps to your own project and thus begin developing a draft plan for your own project (to be completed/endorsed by your team once you are back home)
- Compare the value of the bar chart and a network diagram
- Be aware of the role and value of the software available

Establishing the project development plan 2



Overview of the module

- **Module focus**
 - Developing the work breakdown structure
 - Defining the sequence of activities
 - Setting duration and timelines
 - Defining milestones
 - Allocating resources
 - Presenting the plan using a bar chart
 - Presenting the plan using a network diagram
 - Reaching agreement on the plan and getting approval
- **Summary**
- **Case studies**

Establishing the project development plan

4

Developing the work breakdown structure (WBS)

WBS...

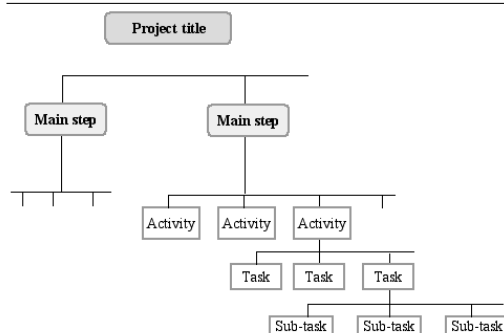
- Can be a graphic or simply an outline
- Shows how main steps relate to activities
- Shows how activities relate to tasks and sub-tasks
- Shows how activities/tasks will help to achieve the main steps



Establishing the project development plan

5

Work breakdown structure: a graphic



Establishing the project development plan

6

Work breakdown structure: an outline

Main steps and activities
1 MAIN STEP
1.1 Activity
1.2 Activity
1.2.1 Task
1.2.2 Task
1.2.2.1 Sub-task
1.2.2.2 Sub-task
1.2.2.3 Sub-task
1.2.3 Task
1.3 Activity
2 MAIN STEP



Establishing the project development plan

7

Example: KEP antibodies levels in humans naturally exposed to malaria (*Plasmodium falciparum*)

- 1. Seeking approval
 - 1.1 Protocol, case report form, informed consent development
 - 1.2 Protocol, case report form, informed consent finalization
 - 1.3 Ethical approval
 - 1.3.1 Local
 - 1.3.2 WHO
 - 1.4 Transfer of funds
- 2. Study site preparation
 - 2.1 Arrangement of transport
 - 2.2 Recruitment and training of field staff
 - 2.3 Provision of required equipment/material
- 3. Field studies
 - 3.1 Cross-sectional study
 - 3.1.1 Recruitment of volunteers
 - 3.1.2 Blood collection from volunteers
 - 3.1.3 Axillary temperature measurement
 - 3.2 Longitudinal study
 - 3.2.1 Recruitment of pregnant women
 - 3.2.2 Etc...



Establishing the project development plan

8

Defining the sequence of activities

- Defining the ordering of activities
 - Which activities start first
 - Which activities need to be completed before moving on to the next
 - Etc...
- Defining activity dependencies/links
 - Start as soon as possible
 - Start in the same time as / finish in the same time as
 - Start in the same time as ...with a delay of “X” days
 - Start in the same time aswith an overlap of “X” days
 - Etc...



Establishing the project development plan

9

Defining the sequence of activities

	Main steps and activities	Dependencies and constraints
1	1 MAIN STEP	
2	1.1 Activity	Start as soon as possible
3	1.2 Activity	Start 1 week after the start of 2
4	1.2.1 Task	Start 1 week after the start of 2
5	1.2.2 Task	Start as soon as 4 is finished
6	1.2.2.1 Sub-task	Start as soon as 4 is finished
7	1.2.2.2 Sub-task	Start at the same time as 6
8	1.2.2.3 Sub-task	Start as soon as 7 is finished
9	1.2.3 Task	Start as soon as 5 is finished
10	1.3 Activity	Start as soon as 3 is finished
11	2 MAIN STEP	Start after 1 is finished



Establishing the project development plan

10

Example: KEP antibodies levels in humans naturally exposed to malaria (*Plasmodium falciparum*)

1. Seeking approval

- 1.1 Protocol, case report form, informed consent development... starts as soon as possible
1.2 Protocol, case report form, informed consent finalization..... starts after 1.1 is finished

1.3 Ethical approval

- 1.3.1 Local starts after 1.2 is finished
1.3.2 WHO starts after 1.3.1 is finished

- 1.4 Transfer of funds..... starts after 1.3.2 is finished
with 3 weeks of delay

2. Study site preparation

- 2.1 Arrangement of transport..... starts after 1.2 is finished

- 2.2 Recruitment and training of field staff..... starts after 2.1 is finished

- 2.3 Provision of required equipment/material..... starts after 1.4 is finished

3. Field studies

3.1 Cross-sectional study

- 3.1.1 Recruitment of volunteers starts after 2 is finished
3.1.2 Blood collection from volunteers starts at the same time as 3.1.1
3.1.3 Axillary temperature measurement starts at the same time as 3.1.1

3.2 Longitudinal study

- 3.2.1 Recruitment of pregnant women starts after 2 is finished

3.2.2 Etc ...



Establishing the project development plan

11

Setting duration and timelines

- Define the starting date of the project
- Estimate the duration of each activity/task
- Establish starting date and finishing date of activities in accordance with:
 - Starting date of the project
 - Dependencies between activities
 - Duration of activities
 - Need to finish projects by a particular date
 - Need to carry out a particular activity by or on a particular date



Establishing the project development plan

12

Defining milestones

- Milestones are key events/accomplishments/ decisions providing a measure of progress
- Milestones can be:
 - The start or end of a key activity
 - The point in the process when a particular decision has to be made
 - The point in the process when a key result will emerge
 - Etc.
- Milestones reflect the main steps of the project and are chosen to allow monitoring of progress at key points



Establishing the project development plan

13

Example: KEP antibodies levels in humans naturally exposed to malaria (Plasmodium falciparum)

Milestones:

- *Ethical approval obtained and transfer of funds made by October '02*
- *Cross-sectional study ready to start by November '02*
- *Sample collection and follow-up of cross sectional study completed by January '03*
- *Longitudinal study ready to start by November '02*
- *Recruitment of pregnant women completed by February '03*



Establishing the project development plan

14

Example: KEP antibodies levels in humans naturally exposed to malaria (Plasmodium falciparum)

Milestones (cont'd):

- *Sample collection and infant follow-up in longitudinal study started by May '03*
- *All collected samples sent for analysis by October '03*
- *Longitudinal study completed by December '04*
- *Laboratory analysis completed by February '05*
- *Final report sent to donors by June '05*



Establishing the project development plan

15

Allocating resources

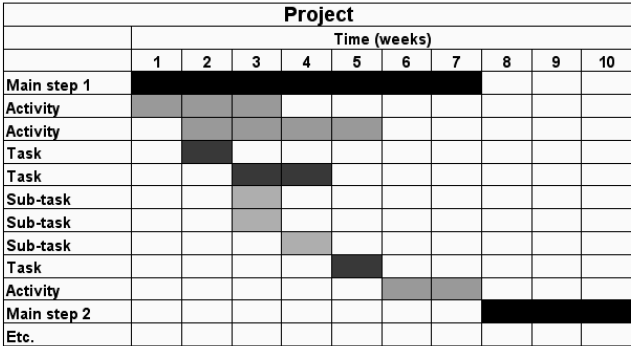
- Responsibility: define who is going to carry out or arrange the contract for each activity
- Cost: estimate the money needed to carry out each activity
- Stakeholder: agree who is going to pay for each activity



Establishing the project development plan

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Presenting the plan as a bar chart: Gantt chart



Establishing the project development plan

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Gantt charts

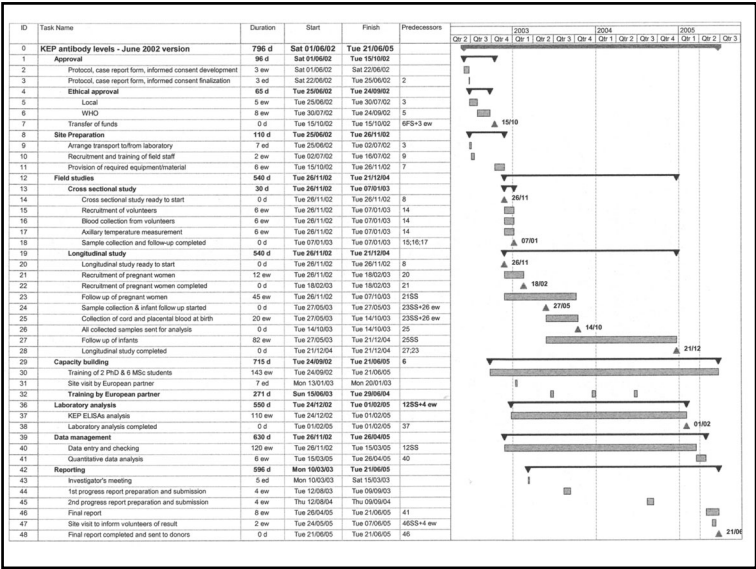
Each activity is represented by bars on a calendar, allowing a clear visualization of:

- The **sequence** of these activities
- Their **duration**
- The milestones
- The responsible person for activity (*optional*)
- The cost of activity (*optional*)

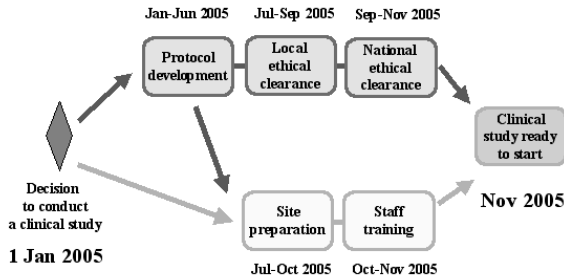


Establishing the project development plan

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Presenting the plan as a network diagram: PERT chart



Establishing the project development plan

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PERT Chart

Programme Evaluation Review Technique

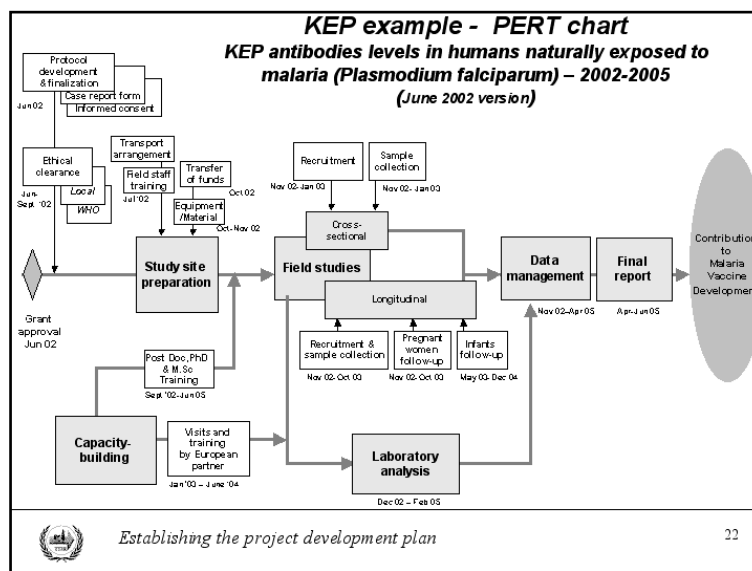
Activities are represented by boxes linked to each other in a logical order allowing a clear visualization of:

- The **relationships and dependencies** between activities
- Which activities are on the **critical path** i.e. their delay would lead to the delay of the whole project (*no buffer*)
- The milestones
- The responsible person (*optional*)
- The cost of activities (*optional*)



Establishing the project development plan

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Agreeing on the plan and getting approval

- Involve as many project team members as possible in the planning phase
- Ensure that all parties directly involved agree with the plan
- Once they are happy with the plan, get formal approval from other relevant parties



Establishing the project development plan

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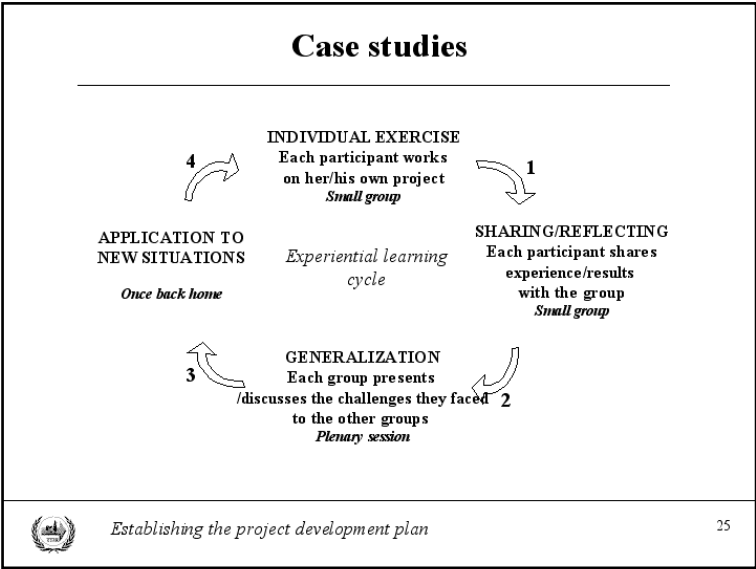
Summary and conclusion

- Establishing a project development plan involves bringing together all the information on the project (who does what, when, how much it costs and who pays for it), and then presenting this in a manner (usually Gantt and/or PERT chart) that is understood and agreed by all the parties involved
- The development plan is not fixed: it must be adapted/revised to reflect the realities of the development process as it proceeds
- The development plan is a dynamic tool and it must be used throughout the whole life of the project



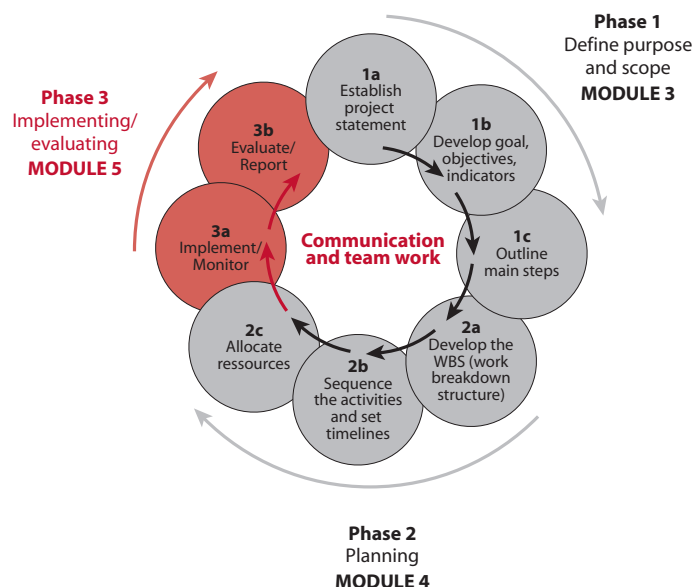
Establishing the project development plan

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MODULE 5

Phase III: Implementing, monitoring, evaluating and reporting



LEARNING OBJECTIVES OF THE MODULE

Module 5 guides participants to use the complete, agreed and approved development plan effectively to:

- implement the project on time, under agreed quality standards and within budget
- monitor the development of the project carefully and regularly and report on its progress

- › adapt to new situations and make arrangements for the changes needed
- › close the project when its development ends
- › evaluate the success of the project and report.

FOCUS OF THE MODULE

The process of implementing, monitoring, evaluating and reporting is the third phase of project planning and evaluation. Module 5 takes the participants through the various steps of this phase focusing on key aspects that participants will have to consider once back home while implementing their project and applying the project planning and evaluation process.

The module covers:

- › starting implementation
- › monitoring
- › updating the plan regularly
- › closing and evaluating the project
- › reporting.

As in the two previous modules, module 5 is structured in two sessions. The first session is short, theoretical, and presents the various steps of phase III. The second session is practical and is based on real life case studies. The case study leads participants (1) to clearly define the project team and its members' responsibilities and to establish a communication strategy to allow effective coordination of the project team and careful and regular monitoring; and (2) to establish the project reporting process (types of report, frequency, content). Participants first work in small groups, as for the previous modules and then share and discuss their results and experiences with the other groups in the plenary session.

IMPLEMENTING, MONITORING AND UPDATING THE PLAN REGULARLY

Starting implementation

When the project development plan is complete, agreed by all involved parties and approved by relevant management groups, the implementation of the project may start. It can be very helpful to use a formal project development team meeting to launch the implementation. The team members review the project statement, objectives, indicators and the complete development plan. They address potential issues and set up a mechanism of communication ensuring teamwork during the implementation phase. Once everything is in place the project manager needs to ensure, using the development plan, that the work starts on time and following the agreed standards of performance.

Monitoring carefully and regularly

Monitoring occurs in three stages: (1) checking and measuring progress; (2) analysing the situation; and (3) reacting to new events, opportunities and issues.

First stage

Monitoring focuses on the project's three main characteristics: quality, time and cost. The project manager coordinates the project team and is always aware of the status of the project. When checking and measuring progress, the project manager communicates with all team members to find out whether planned activities are implemented on time and within the agreed quality standards and budget. The achievement of milestones is measured and reflects the progress of the project.

Second stage

The second stage of monitoring consists of analysing the situation. The status of project development is compared to the original plan, and causes and impact of potential deviation are identified.

Third stage

It is important to anticipate and react quickly to new situations, any new event, opportunity or issue and to identify the necessary actions to be taken. If appropriate, various options are considered and discussed with the project team and a decision is taken on the path to pursue.

Updating the development plan as required

The plan is dynamic and should always reflect reality. Each time that a deviation from the original development plan is identified, whether or not it requires any further action, the development plan is revised accordingly, reflecting the new situation and showing the impact of the deviation on the whole project development. This is crucial for effective implementation and good communication with the project team and with donors. It also facilitates the management of the project budget and finances.

To update the plan:

- involve the whole project team
- revise the development plan (including costs) according to the new situation and to any new decision
- circulate the revised plan highlighting the changes and their impact on the project development to the whole project team for comments and endorsement
- gain approval from other relevant parties as appropriate.

REPORTING AND EVALUATION OF THE PROJECT

Closing and evaluating the project

Each project has an end and should be formally closed. When the development of the project is completed the project team meets and evaluates the project. The project evaluation focuses on the three main characteristics of the project: quality, time and cost. Has the project been developed on time, within the agreed quality standards and budget? The indicators are measured in order to assess whether the project objectives have been met. The financial accounts must be closed. This is also an excellent opportunity to learn from the project's experience and for team members to share the lessons learnt.

The project is closed and evaluated as follows:

- close the project's financial accounts
- ensure all objectives are met by measuring the indicators and by checking if activities were accomplished to the required standards, on time and within budget
- share the lessons learnt.

Project reporting

Project progress and final reports should not be confused with scientific reports. Project progress and final reports contain information on the development of the project whereas scientific reports include the results of the project research.

Project progress and final reports are usually written by the project manager. They are crucial tools not only for effective communication within the project implementing team but also with management, partners and donors. Progress and final reports focus on the three main project characteristics: quality, cost and time. Progress reports describe the progress of the project towards meeting its objectives and the final report describes the project's success in meeting its objectives. Progress and final reports contain (1) a technical section indicating whether activities were accomplished on time and within agreed quality standards of performance and (2) a financial section indicating whether activities were accomplished within budget and including a detailed review of finances.

Progress reports include:

- the purpose and scope of the project
- project progress, looking at the milestones and focusing on the quality, time and cost aspects of the activities
- deviations from original plan and reasons

- › the revised plan
- › the financial report
- › the revised budget, if applicable.

The final report includes:

- › the purpose and scope of the project
- › the project evaluation (quality, time, cost) using indicators
- › deviations from original plan and reasons
- › the financial report
- › a list of publications, if applicable
- › conclusions.

IN BRIEF...

A development plan is a dynamic management tool and needs to be regularly updated to reflect the status of the project development. An agreed, realistic and updated plan is essential if the project is to be completed on time, within required standards and budget, for good communication within the team and with outsiders, and for clear and accurate reporting on and evaluation of the project.

REAL LIFE CASE STUDY

Participants continue to work on their own project.

1. Exercise and reflection in small groups

First participants develop a modus operandi allowing effective coordination of the project team, good communication, and careful and regular monitoring of the development: they define the team, roles and responsibilities; they describe the various ways of communication to be used; and they develop the main items to be discussed during project development team meetings or teleconferences.

After this, they establish the project reporting process (types of report, frequency and content).

2. Discussion and generalization in a plenary session


All groups present and discuss their drafts and share their experience and reflections with each other. Potential issues and suggestions are discussed.

MODULE 5:

Implementing and evaluating

```

graph TD
    A[Good practices in biomedical research  
module 1] --> B[Understanding the value of planning  
module 2]
    B --> C[Defining the project's purpose and scope  
module 3]
    C --> D[Planning  
module 4]
    D --> E[Implementing and evaluating  
module 5]
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Implementing and evaluating

1

Learning objectives of the module

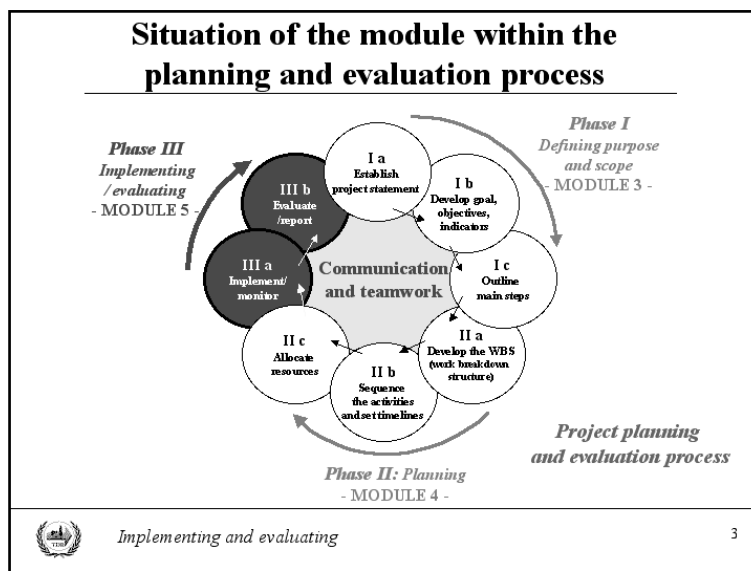
Use the plan to:

- Implement the project on time, under agreed quality standards and within budget
- Monitor the project regularly
- Make required/agreed changes
- Close the project
- Evaluate it and report



Implementing and evaluating

2



Overview of the module

- **Module focus**
 - Starting implementation
 - Monitoring development and addressing new situations
 - Updating the plan regularly
 - Closing the project and evaluating its success
 - Reporting
- **Summary**

Implementing and evaluating 4

Starting implementation

- Once the plan is agreed and approved, the project can start
- Ensure work begins on time and has clear performance standards
 - Organize project team meeting/communication (project implementation launch)
 - Review project statement and objectives
 - Review development plan
 - Address potential issues
 - Set up the teamwork mechanism



Implementing and evaluating

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Monitoring the project

- Regular project monitoring ensures that the team always knows whether or not the project is making progress towards its objectives
- Monitoring should be led by the project manager but is a team activity
- It allows anticipation and quick response to problems or opportunities and helps to ensure successful implementation



Implementing and evaluating

6

Monitoring the project: steps

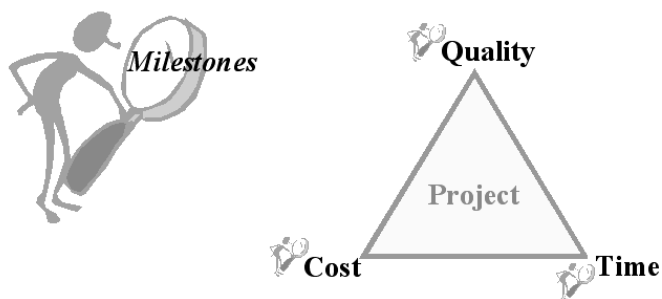
- Measuring progress
 - Communicate with the team
 - Refer to the development plan
 - Review milestones and activity timelines
 - Measure resource use, cost and performance standards
- Analysing the situation
 - Determine causes of deviations
- Determining necessary actions
 - Identify various options to correct significant deviations and adapt to new situations, decide which of these is most appropriate and implement it



Implementing and evaluating

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Monitoring the project



Implementing and evaluating

8

Updating the plan regularly

- The plan should be seen as dynamic and should be adapted to changes in situation and need
- The plan must be realistic and therefore must be updated regularly to reflect any new situation
- Its updating is necessary to ensure effective implementation and monitoring of budget/finance



Implementing and evaluating

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Updating the plan regularly: steps

- Ideally, updating should be done with all team members present
- Revise the development plan (including costs) according to the new situation/decision
- Circulate the revised plan to all team members not present at the meeting for comment/endorsement
- Gain approval from other relevant parties as appropriate



Implementing and evaluating

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Closing and evaluating the project

- Each project has an end and must be formally closed
- Project evaluation allows measurement of the project's success and also analysis of lessons learnt during its life



Implementing and evaluating

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Closing and evaluating the project: steps

- Close the project's financial accounts
- Ensure that all objectives were met by measuring indicators and by checking whether or not activities were accomplished to the required quality, on time and within budget
- Share lessons learnt, not only with team members, but also with colleagues carrying out similar activities



Implementing and evaluating

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Evaluating the project

Lessons learnt !

Implementing and evaluating

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Reporting

- Project progress and final reports are different from scientific reports
- Project progress and final reports contain information on the development of the project
- Scientific reports include information on the results of the project research

Implementing and evaluating

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Project reporting

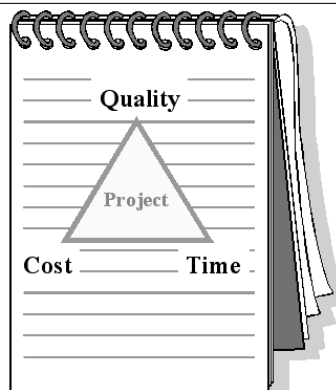
- The report on project progress and the final report are usually written by the project manager
- The reports describe the progress towards the project's objectives (the progress report) or the extent to which it has achieved them (the final report)
- They include a technical section which indicates whether or not all the planned activities were implemented to the required standard, on time and within budget
- They also include a financial section which includes the monitoring/review of finances
- Reports are important tools not only for communication within the project implementing team but also for management, partners and donors



Implementing and evaluating

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Project reporting



Implementing and evaluating

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Progress report: content

- Purpose and scope of the project
- Project progress using milestones and looking at quality, time, cost
- Deviations from original plan and reasons
- Revised plan
- Financial report
- Revised budget, if applicable



Implementing and evaluating

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Final report: content

- Purpose and scope of the project
- Project evaluation (quality, time, cost) using indicators
- Deviations from the original plan and reasons
- Financial report
- List of publications, if applicable
- Conclusion



Implementing and evaluating

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Summary and conclusion

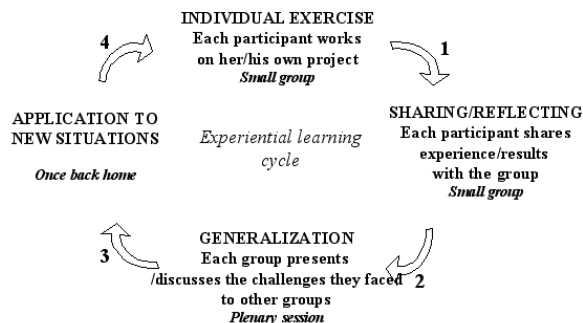
- A development plan is dynamic and needs to be regularly updated
- An agreed and regularly updated plan is essential for the completion of the project on time, to required standards and within budget; for good communication within the team and with outsiders; and for clear reporting and evaluation



Implementing and evaluating

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Case studies



Implementing and evaluating

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Case study

- Teamwork establishment
 - Define the team (names, expertise, roles and responsibilities in the project)
 - Define a communication framework:
 - Communication type
 - Frequency
 - Items to be discussed
- Project reporting
 - Types of report (team, donors/partners, institutions)
 - Frequency
 - Content



Training assessment and the next steps

TRAINING ASSESSMENT

Assessing the training is important. It helps to reflect on the training and to continuously optimize it, thus ensuring that it is always relevant and beneficial. It also provides participants with an opportunity to question and to be aware of what they have been learning, how confident they would be with applying the skills they have learnt once they are back home, and to analyse the way in which they have been learning them.

The training assessment focuses on the training output and it is based on the following criteria:

- › receptiveness to the concept and methodology of effective project planning and evaluation
- › ability, willingness and confidence in applying the skills.

NEXT STEPS

At the end of the course participants have applied phases I and II of the project planning and evaluation process to their own project. They have defined the statement, goal, objective and indicators of the project and drafted a Gantt chart and a PERT chart for the project development. They are aware of the various steps of phase III of the project planning and evaluation process and have developed a modus operandi for monitoring the project, coordinating the project team and enhancing communication within the team and with donors. They also have developed a reporting process.

Once back home, the participants will further implement the process of planning and evaluating their own project:

- › they bring the project team together to discuss, complete and endorse the project planning documents developed during the course

- such meeting is crucial for:
 - setting up formally the project team
 - defining clear roles and responsibilities for each team member
 - ensuring that the project development plan is realistic
 - ensuring good communication within the team and a good understanding of the project development and ownership
- it is important to keep in mind that the planning and coordination of the project are time-consuming. Sufficient time should be reserved for these activities
- once the plans are agreed by the team, participants can then start implementing their project and follow the steps of phase III of the planning and evaluation process.

*Effective project planning and evaluation
in biomedical research*

Training assessment and next steps



Training assessment and next steps

1

Training assessment

- Assessment helps:
 - To continuously optimize the course
 - Participants to reflect on what they have learnt and the potential impact this might have in their daily work
- Assessment focuses on training outputs
- Assessment is based on:
 - Participants' receptiveness of the concept and methodology
 - Participants' ability, willingness and confidence to apply the skills



Training assessment and next steps

2

Next steps

- Once back home participants apply, within their team, the skills for effective project planning and evaluation
 - They organize a project team meeting:
 - To formally set up the team
 - To define clear roles and responsibilities for each team member
 - To review and finalize the project documents and plans developed during the course
 - Once the plan has been approved by the project team and all relevant parties, participants go through the phase III process and use/update the plan to effectively implement, monitor, report and evaluate the project



Training assessment and next steps

3

Thank You



Training assessment and next steps

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Glossary terms and acronyms

CIOMS	Council of International Organizations for Medical Sciences
Critical path	The shortest way through the project plan to complete the project development. The critical path includes all activities which, if delayed, would cause the delay of the whole project.
Main step	The block of activities required to achieve the project objectives. Main steps map out the whole development of the project organizing it in work packages.
Dependence	The link between activities reflecting their relationship.
Elapsed day (or week)	In Microsoft Project, elapsed days (or elapsed weeks) are the number of days (or weeks) to accomplish an activity/ task regardless of whether the days are working days or non- working days. For example, seven <i>elapsed</i> days are one calendar week, so too are five days one calendar week.
EMA	European Agency for Evaluation of Human Medicinal Products (European Medicines Agency)
Experiential learning cycle theory	The training methodology developed by D. Kolb, based on the theory of learning through experience and reflection.
GAP	Good agricultural practices
GCP	Good clinical practices
GLP	Good laboratory practices
GMP	Good manufacturing practices
QPBR	Quality practice in basic and biomedical research

Gantt Chart	A graphic representation of a project development plan where activities are represented by a series of bars displayed on a calendar.
Goal	A short statement defining the overall aim of a project. It sets the purpose of the project and defines its contribution in a larger context.
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
Indicator	A measure of the achievement of the project objectives.
Life case study	A case study based on a participant's current project.
Milestone	Key events, achievements, or decisions in the project development. Milestones map out the main steps of the project and are a means to measure the progress of the project.
Objective	A specific and measurable outcome/deliverable of the project.
OECD	Organisation for Economic Co-operation and Development
PERT chart	Programme Evaluation Review Technique (PERT) A graphic representation of the project development plan where activities are represented by boxes linked to each other by arrows in a network diagram.
Target	A specific and measurable deliverable needed to reach a project objective. Defining targets is optional and might only be needed for complex projects.
Terminal element	The last and most detailed element of the work breakdown structure of a project. Terminal elements depend on the level of detail of the plan.
WBS	Work breakdown structure - a planning tool for identifying, organizing and grouping the project activities to be completed. The main steps of the projects are broken down into the activities needed to complete them. Activities are, in turn, broken further down into the tasks needed to complete them, etc.

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- *WHO temporary advisers*: Dr Fabiana Alves, University of Sao Paulo, Brazil; Dr Romilla Maharaj, Human Sciences Research Council, South Africa; Dr Christine Manyando, Tropical Disease Research Centre, Zambia; Dr Grace Murilla, Trypanosomiasis Research Centre, Kenya; Dr Carol Nonkwelo, Innovation Fund, South Africa; Dr Rosana Norman, South African Medical Research Council, South Africa; Dr Lawrence Yamuah, Armauer Hansen Research Institute, Ethiopia; Dr Dorcas Yole, Institute of Primate Research, Kenya.
- *WHO secretariat*: Dr Béatrice Halpaap, WHO/TDR; Dr Marie Annick Mouries, WHO/TDR.

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Skill building

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