

PARTICIPANTS

Planning for

Success

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

STEP-BY-STEP GUIDE

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/05.2

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Design: Lisa Schwarb

Layout: Scantype, Genève

Photos: TDR

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About the step-by-step guide

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 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 *Step-by-step guide for participants*. It is designed to guide the participants through each step of the project planning and evaluation process. It gives step-by-step practical support during the case study sessions at the course (modules 3 to 5). 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.

Objectives and principles

Training objectives

The training programme 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 funding.

The course helps participants to:

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

Objectives of planning and evaluation activities

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.

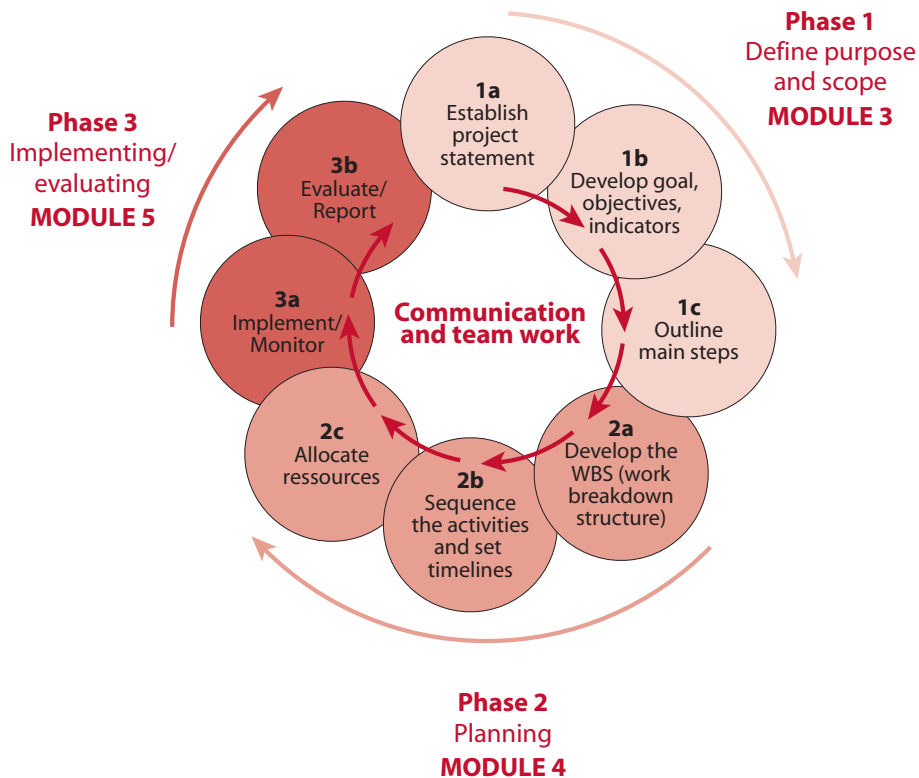
It aims to:

- ensure the project has a common goal
- ensure a clear understanding of the development process
- facilitate the anticipation, identification and addressing of potential logistic issues
- enhance communication, coordination, teamwork and ownership
- facilitate systematic project monitoring and reporting
- facilitate clear project evaluation.

Key principles

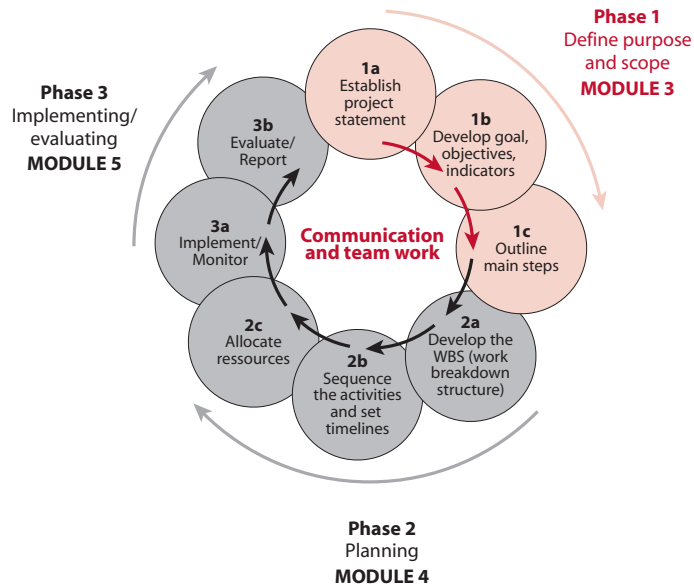
- always use common sense
- stay flexible and adapt to the situation
- keep in mind the objectives of planning and evaluation
- remember that the plan is dynamic and needs to be revised regularly
- keep it simple.

The project planning and evaluation process



PHASE I

Defining the purpose and scope of the project (Module 3)



PHASE I A: ESTABLISH THE PROJECT STATEMENT

- ? Ask yourself:
 - What needs to be done?
 - Why does this need to be done?
 - By what date must the work be finished?
- > Write a short paragraph of two to three sentences answering these questions and thereby giving boundaries to the project.

PHASE I B: DEFINE THE PROJECT'S GOAL, OBJECTIVES AND INDICATORS

- **Define the goal**
- ? Ask yourself:
 - Why is the project carried out?
 - What will be the project's contribution, in a wider context?
- > Write a short and general sentence answering these questions and thereby describing the purpose of the project.
- **Define the objectives**
- ? Ask yourself:
 - What will have been achieved by the end of the project?
 - What requirements must be met?
- > Write a list of objectives, making sure that they are SMART:
 - Specific
 - Measurable
 - Achievable
 - Resourceable/Realistic
 - Time-specific

- **Define the indicators**

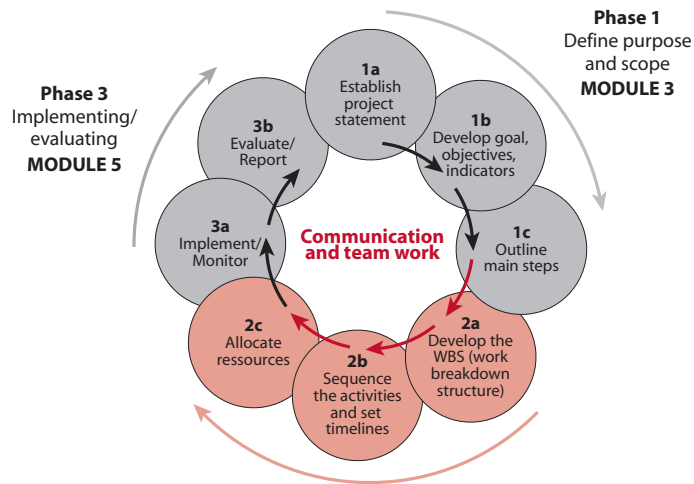
- ? Ask yourself:
 - How will we know when we satisfy each objective?
 - What can be measured to show that the objectives have been met?
- > For each objective, define one to three indicators that will be measured to indicate the achievement of the related objective. Make sure that the indicators are SMART.

PHASE I C: OUTLINE THE MAIN STEPS REQUIRED TO ACHIEVE THE OBJECTIVES

- ? Ask yourself:
 - What are the main steps (blocks of activities) required in the project in order to reach the objectives?
- > List the main steps that allow you to reach the objectives (about three to six main steps).

PHASE II

Establishing the project development plan (Module 4)



You may choose to go through the various steps of phase II using MS Project straightaway. Alternatively, you can first use simple tables and enter the data at the end in MS Project.

PHASE II A: DEVELOP THE WORK BREAKDOWN STRUCTURE

Developing the work breakdown structure (WBS) involves “breaking down” each main step into more specific and detailed elements (activities) to be completed. Each of these activities is, in turn, further broken down into the various required tasks. Each of the tasks is then 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 the terminal elements is equal to the whole project work.

- List the main steps of the project.
- For each main step, list the various activities required in order to complete it.
- For each activity, list the various tasks required in order to complete it.
- Break down the work until you reach the level of detail appropriate to (1) reach the level of monitoring required and (2) assign resources in a realistic way.
- Test the work breakdown structure: go through it and make sure it will accomplish the project objectives.

PHASE II B: SEQUENCE THE ACTIVITIES AND SET TIMELINES

- **Define the order of the various elements (main steps, activities, tasks) and their dependencies and links**
- ? Ask yourself:
 - Which elements start first?
 - Which elements need to be completed before moving to the next one?
 - Which elements can overlap?

- Develop a table and list how each terminal element depends on others, describing logically how those links work, for example, “activity X starts at the same time as activity Y with an overlap of X days;” “activity X finishes at the same time as activity Y”.
- **Set estimated duration and timelines**
 - Set the start date of the project.
 - Estimate the duration of each terminal element. This will determine the duration of the other elements.
 - Estimate the start date and finish date of all elements: most of these will be directed by the elements’ dependencies and their duration time.
 - Include these estimations in the table.
- **Define the milestones**

A **milestone** is a key event/achievement/decision, chosen strategically, to provide a measure of the project’s progress.

- List the key events, achievements and decision points which reflect the various steps of the project.
- Include the milestones and their estimated timelines in the WBS at the appropriate place.
- Make sure you have identified enough (but not too many) milestones in order to map the whole development of the project and so facilitate the monitoring of the progress. You may want to have from one to three milestones for each main step: this is a guideline only; you should apply common sense to your choice.

PHASE II C: ALLOCATE RESOURCES

- **Assign responsibility**
 - ? Ask yourself:
 - Who is responsible for each activity?
 - > Enter responsibilities in a table.
- **Estimate costs**
 - > Estimate the cost of activities.
 - > Enter costs in your table.
- **Define who pays for what and include it in the table/plan**
 - > In order to keep the plan as clear as possible, it might be most convenient to establish, in addition to the Gantt chart and to the PERT chart (see below), a table summarizing the budget, including financial contributors and responsibilities.

PRESENT THE PLAN AS A GANTT CHART (*USING MS PROJECT*)

A **Gantt chart** is a graphic image of the project in which activities are represented by bars on a calendar.

A Gantt chart shows the duration and sequence of activities and the related milestones (in a diamond shape). A Gantt chart can also include resources.

Various planning software are available. *Microsoft Project* is a sophisticated software program providing an extensive tool for project management. This guide does not describe all the features provided by the software. It goes through how to use the basic features of *Microsoft Project* so that you can establish and design a Gantt chart representing the project development plan.

To enter the plan in *MS Project*, carefully follow the steps described below:

- 1) **Open a *MS Project* file.**
- 2) **Close** the “getting started” window on the left of the screen and then the “tasks” window on the left of the screen.
- 3) **Format the calendar:** double click on the timescale and choose the appropriate unit for the “middle tier” timescale and for the “bottom tier” timescale (year, quarter of a year, month, week). Use the middle tier as the major scale of the calendar and the bottom tier as the most detailed scale of the calendar.
- 4) **Save** the file.
- 5) **Enter the project starting date:** go to “project”/“project information”.
- 6) **Enter the elements of the WBS** in the “task name” column (one element per row): follow the steps described in the “Phase II a” section.
- 7) **Indent the elements** according to your WBS by using the “indent” icons in the tool bar (arrows).
- 8) **Enter the estimated duration time** in the “duration” column: use “ed” for days use “ew” for weeks.
- 9) **Enter the links** in the “predecessors” column for each terminal element: see section “phase II b”.
 - a) Enter the number of the task to which the selected element is linked,
 - b) Then next to it, without inserting a space, enter the dependencies (see examples in the box below):
 - “SS” (a task Starts when another one Starts)
 - “FF” (a task Finishes when another Finishes)
 - “FS” (a task Finishes when another Starts)
 - “SF” (a task Starts when another Finishes)
 - c) If needed, next to the dependence enter the overlap (add or subtract an amount of time (“ed” for day and “ew” for weeks) to the date e.g. “+6ew” for “6 weeks later”, “-30ed” for 30 days earlier).

- d) It is possible to enter several links for one element (separate the various links with comas).

Some examples of links and dependencies

Taking task 5 as an example, here are some options for how links can be entered:

“4FS” means that when task 4 finishes task 5 starts

“3SS” means that when task 3 starts task 5 starts

“1SS+3ew” means that task 5 starts when task 1 starts but with a delay of three weeks

“1SS-3ew” means that task 5 starts three weeks before task 1 starts

- 10) Enter the “start date” or “finish date” of tasks in the relevant columns only when absolutely required i.e. certain activities must be accomplished by or on a defined date. These are constraint dates.

Many of the “start” and “finish” dates will be set automatically according to the links, the project start date and the task duration previously entered. These links allow you, as you revise the plan and want to enter a delay for a task, to simply enter the delay in the “duration” column and to have the impact of the delay on the whole project schedule shown automatically.

- 11) **Adapt the time schedule scale:** look at the whole Gantt chart and adapt the format of the time schedule to the timelines of your project.

- 12) **Insert the milestones** defined in the “phase II b” section: select the task which will follow a milestone, go to “insert/new task”, enter the milestone name in the task column and enter “0” in the “duration” column. Ensure that milestones reflect the various steps of the project development and in this way provide a tool for the project monitoring.
- 13) **Insert the name of the responsible person (optional)** in the “resource names” column.
- 14) **Insert activity costs (optional)** in a “cost” column that you can insert by first selecting the whole “resource names” column and then going to the “insert”/ column; in “field name”, choose “cost”.
- 15) **Insert the “project summary task”**: go to “tool/options” and click the “show summary tasks” option (at the bottom of the window). By default the summary task shows the file name. Choose the appropriate wording and add the **version date** next to it.
- 16) **Format the Gantt chart** using the Wizard: go to “format”/Gantt chart wizard and follow the directions (you may not want to choose to see the link lines between dependent tasks as this may look confusing).
- 17) **Review the plan and ensure that it is coherent** and allows the team to meet the project objectives.
- 18) **Save the plan as a picture in a MS World or MS Power Point document** in order to be able to circulate it to all relevant parties who might not have access to *MS Project*.
 - a) Open a *MS World* (or *Power Point*) document, set the paper size as “landscape” and open several blank pages in the document (one page will usually be sufficient for 30 to 45 tasks in *MS Project*).
 - b) In your *MS Project* file, select the 30 to 45 first tasks starting from the top, including the task number column.
 - c) Go to “edit” and select “copy picture”.
 - d) In the “copy picture” window select the “for printer” and “selected rows” options and select the timescale inserting a date one or two months earlier than the “start date” of your project and a second date corresponding to one or two months after the “finish date” of your project (this give the complete picture of the project).
 - e) Go back to the *MS World* (or *Power Point*) document and paste what you just copied by right clicking and choosing the “paste” option.

- f) Adjust the position of the inserted picture by first selecting it (clicking on it), right clicking, (at this stage in *MS Word* choose “format picture/layout/in front of text/ok”) and then selecting it and dragging it.
- g) Adjust the size of the inserted picture by first selecting it, then position the cursor on the small square at the top left of the picture until it becomes a double arrow shape cursor and finally drag the picture diagonally in the opposite corner direction until the required size is reached.
- h) Repeat the above steps, but copying the next 30 to 45 tasks of the project, and paste the picture in the following page of the *MS Word* (or *Power Point*) document.
- i) Continue until the whole project is copied, format the document (title, date, pages etc) and save it.
- j) Make sure the version date is inserted.

PRESENT THE PLAN AS A PERT CHART (USING *MS POWER POINT*)

Activities are represented by boxes linked to each other by lines or arrows.

Decision points are represented by diamond shapes.

A PERT chart describes the various activities to be completed, their relationships and the logical links between them. It shows the flow of the various activities, starting from the left side and finishing at the right side.

It also reflects the plan’s timelines and possibly also its resources.

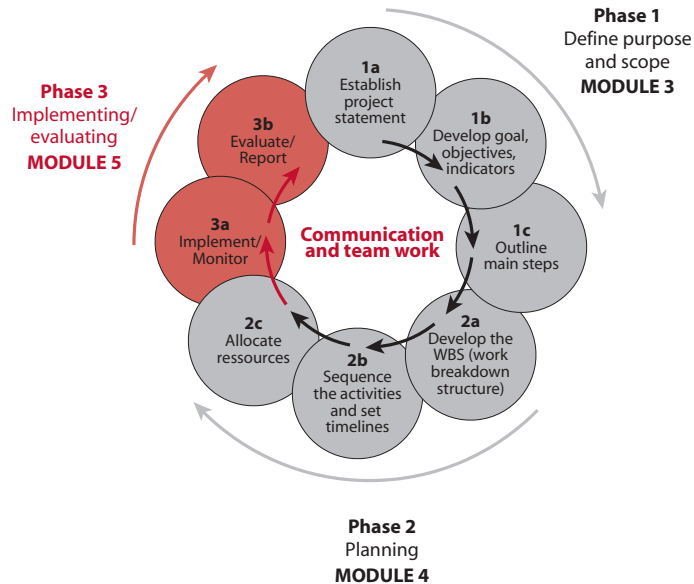
- 1) You may first make a draft diagram on paper.
- 2) **Open a *MS Power Point* file** (blank presentation).
- 3) **Make the drawing toolbar available** on the screen: go to “view / toolbars / drawing toolbar”.
- 4) **Adjust the font size to 10 or 12** (formatting toolbar).

- 5) **Represent the main steps, activities and tasks by boxes:**
 - a) Insert a box on the sheet: click on the rectangle icon (drawing toolbar) once then click on the sheet.
 - b) Change the size and shape of the box by first selecting it (clicking on it) and then clicking on the small square at the low right end of the box and dragging it.
 - c) Format the box by first selecting it (click on it) and then using the different icons on the drawing tool bar (to know what each icon is, place the cursor on it, to select it, click on it, to have access to various choices, click on the little arrow next to it).
 - d) Insert text in the box by selecting the box and typing in the text.
 - e) Format the text by first selecting the box and then using the formatting tool bar and the drawing tool bar for the colour.
 - f) To copy the box, press “Ctrl” while clicking on the box and dragging it on the side (make sure you do not release “Ctrl” before releasing the mouse).
- 6) **Represent decision points** by a diamond shape. Remember, milestones do not need to appear in the chart. In the drawing tool bar go to “auto-shape” / “flow chart” / select the desired shape and click on the sheet. Format it as for the boxes.
- 7) **Organize** the position of the various boxes and the decision points so that the sequence of the elements is described.
 - a) The starting point is placed on the left of the diagram and the finishing point on the right.
 - b) To move a box, click on it and drag it to the selected place.
- 8) **Link the boxes** using lines or arrows thereby describing the sequence and interdependence of the elements.
 - a) Click on the “line” or “arrow” icon of the drawing tool bar.
 - b) Click on the place where the line or arrow should start and drag until the point where the line or arrow stops.
 - c) To format the line or arrow, do as described for the box formatting (size, style, colour).
- 9) When the network diagram is laid out, **insert under each box the start-finish dates using the “text box” icon** (click on it, click on the sheet and type the text then format).

- 10) You may also **insert information on responsible persons and costs (optional)** under each box.
- 11) **Insert the title, the version date and the legend of decision points.**
- 12) **Ensure the diagram is coherent and as simple as possible. Use colours and different shapes only when they have a specific meaning.**
- 13) **Ensure that the plan is feasible and allows the team to meet the project objectives.**

PHASE III

Implementing, monitoring, evaluating and reporting (Module 5)



PHASE III A: IMPLEMENT AND MONITOR THE PROJECT

- Once the development plan is completed, agreed and approved by the project team and all relevant parties, the project's implementation can start.
- The start of the implementation might be **officially** given after the project team has met to review the complete plan and to discuss potential issues.
- The project manager should carefully and regularly monitor the project, reviewing the achievement of the milestones and checking if all activities are completed on time, and are within the agreed quality standards and budget.
- The project team should meet and discuss the progress of the project and any potential issues on a regular basis.
- As deviations from the initial plan are identified, an analysis of the situation should be made and the decision on how to proceed should be taken by the project team. The project development plan should be updated accordingly and circulated to the implementing team and the relevant parties.

PHASE III B: REPORT AND EVALUATE THE PROJECT

- The project manager reports regularly on the progress of the project to all project team members and to relevant management groups.
- Progress reports describe the evolution of the project and its status at the time of the report. They also include a revised plan including any updates and changes. They report on the quality, timelines and finances of the project and on the achievement of the milestones.
- Once the project is completed it is formally closed and evaluated.
- The evaluation focuses on the quality, timelines and budget aspects of the project and confirms whether the objectives were met by measuring the indicators. It is described in the final report.

- During the course, as part of the case study exercise, participants are asked to prepare the following draft documents which will be reviewed and endorsed by the project team after the course:
 - **Draft the modus operandi for an efficient team work within your project development team:**
 - Define the project development team members: names and expertise
 - List respective responsibilities of each member in this project
 - Define the means of communication to be used (type and frequency)
 - Define the main items to be included in the agenda of project development team meetings/teleconferences for discussion.
 - **Draft the project reporting process:**
 - Types of reports
 - Frequency
 - Content.

Integrated example used through the course

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.

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).

KEP example – Project goal

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

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.

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)

KEP example – Main steps

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

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.....

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

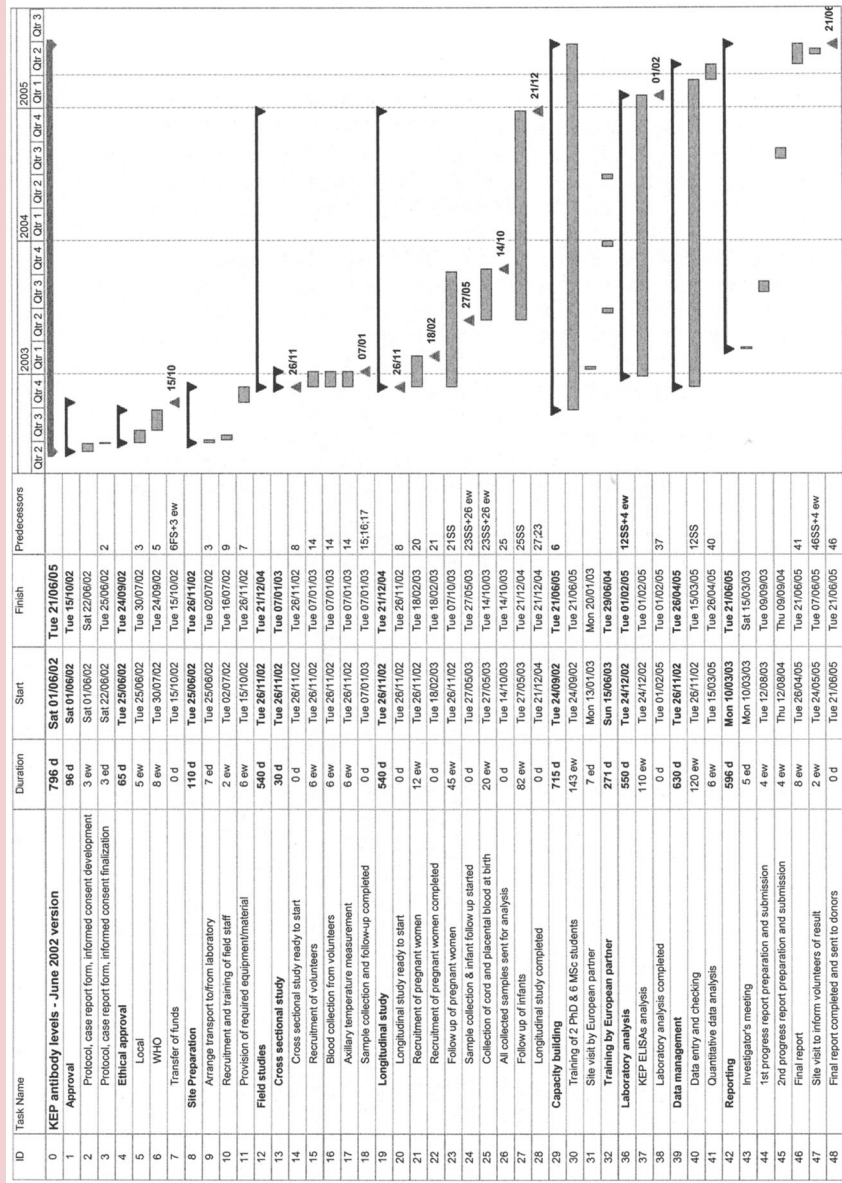
3. FIELD STUDIES

- 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.....

KEP example – Milestones

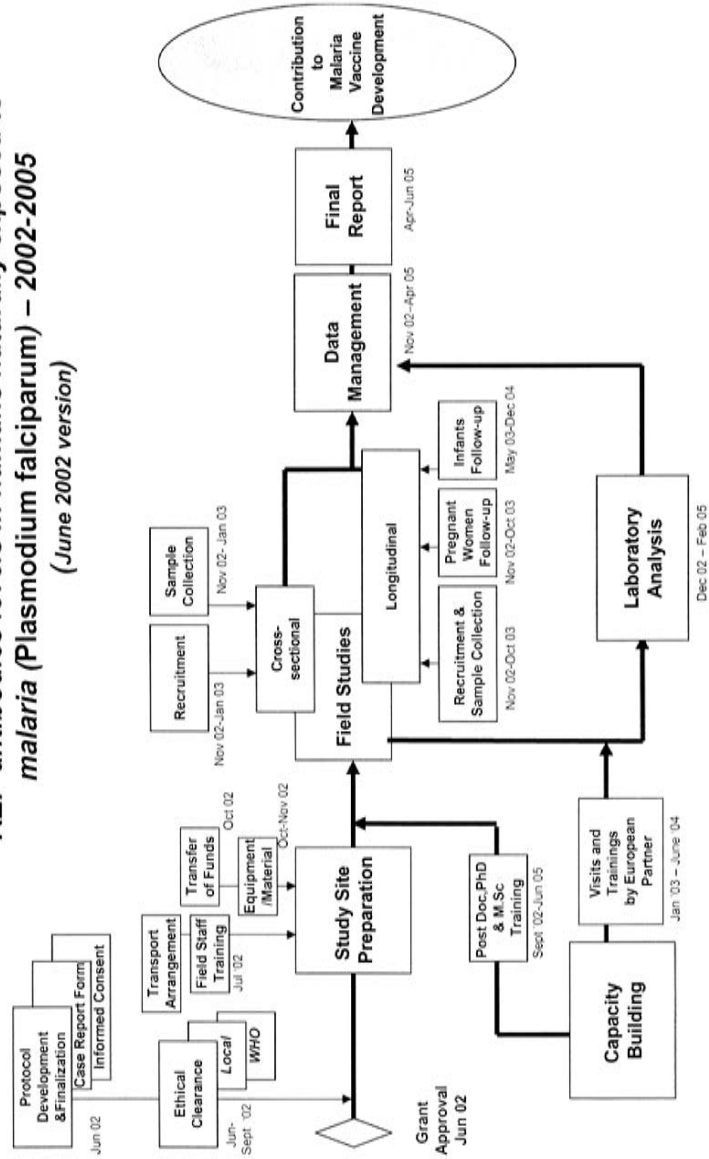
1. Ethical approval obtained and transfer of funds made by October '02
2. Cross-sectional study ready to start by November '02
3. Sample collection and follow-up of cross-sectional study completed by January '03
4. Longitudinal study ready to start by November '02
5. Recruitment of pregnant women completed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

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



KEP Example – PERT chart

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



Skill building

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



WHO/TDR
20, Avenue Appia
1211 Geneva 27
Switzerland
tel +41 22-791-3725
fax +41 22-791-48 54
tdr@who.int
www.who.int/tdr