



Commission Strategy for Research on Poverty-related Diseases

- ❁ **Global agreement to combat the poverty related diseases HIV/AIDS, malaria and TB as a priority**
 - ☞ improving health is one of the most effective investments to reduce poverty
- ❁ **The Council has endorsed the Commission's proposal for a comprehensive, global, multisectoral approach:**
 - " Programme for action "**
 - ☞ improving impact of existing interventions
 - ☞ increasing affordability of key pharmaceuticals
 - ☞ developing new more effective interventions
- ❁ **In this context DG Research proposes in its next Framework Programme major initiatives on Poverty-related Diseases**
 - ☞ strong focus on clinical trials of new interventions for use in developing countries (EDCTP)
 - ☞ basic fundamental research for development of new candidates



Why microbicides are a priority in the new Commission's strategy

- ❁ **The number of individuals infected with HIV and other sexually transmitted diseases is increasing dramatically**
- ❁ **~1.8 million women infected with HIV in 2001**
- ❁ **Heterosexual transmission may account for as much as 85-90% of new cases of HIV infection**
- ❁ **Female-controlled methods to prevent HIV infection offer an opportunity to have impact on the epidemic**

Urgent need to develop safe and potent topical microbicides under the control of women

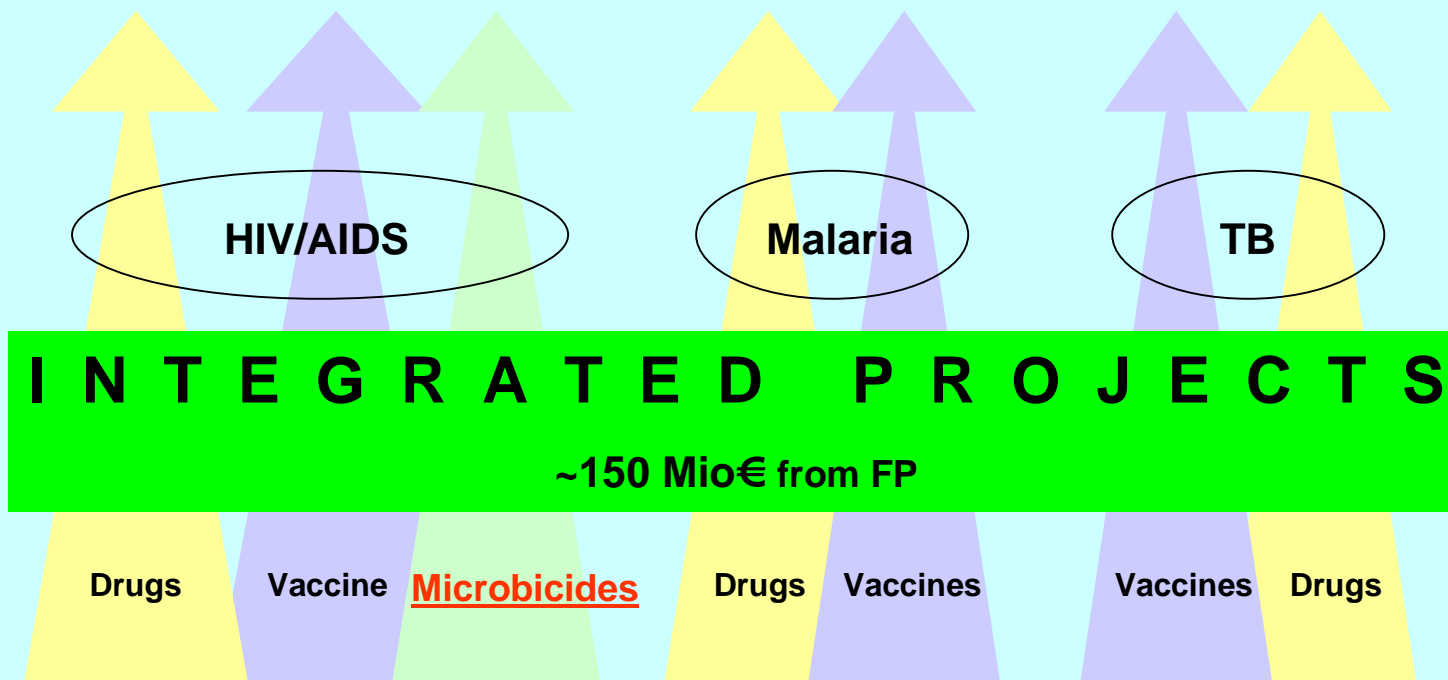
CONFRONTING THE MAJOR COMMUNICABLE DISEASES LINKED TO POVERTY (*Priority 1.1.1.ii.c*)

European Commission - Directorate-General for Research

EUROPEAN DEVELOPING COUNTRIES CLINICAL TRIALS PROGRAMME

(ART. 169)

~200 Mio€ from FP



Clinical
inputs from
national
programme

Pre-clinical

Discovery

Genomics



Integrated projects

- 🌀 **Designed to generate the knowledge required to implement the priority themes**
 - 👉 by integrating the critical mass of activities and resources needed
 - 👉 to achieve ambitious clearly defined scientific and technological objectives
- 🌀 **Selected by public calls for proposals and peer review**
- 🌀 **Financed up to €several tens of millions as a “grant to the budget”**
 - 👉 paid as a contribution to actual costs
 - 👉 duration of typically three to five years, or more depending on need

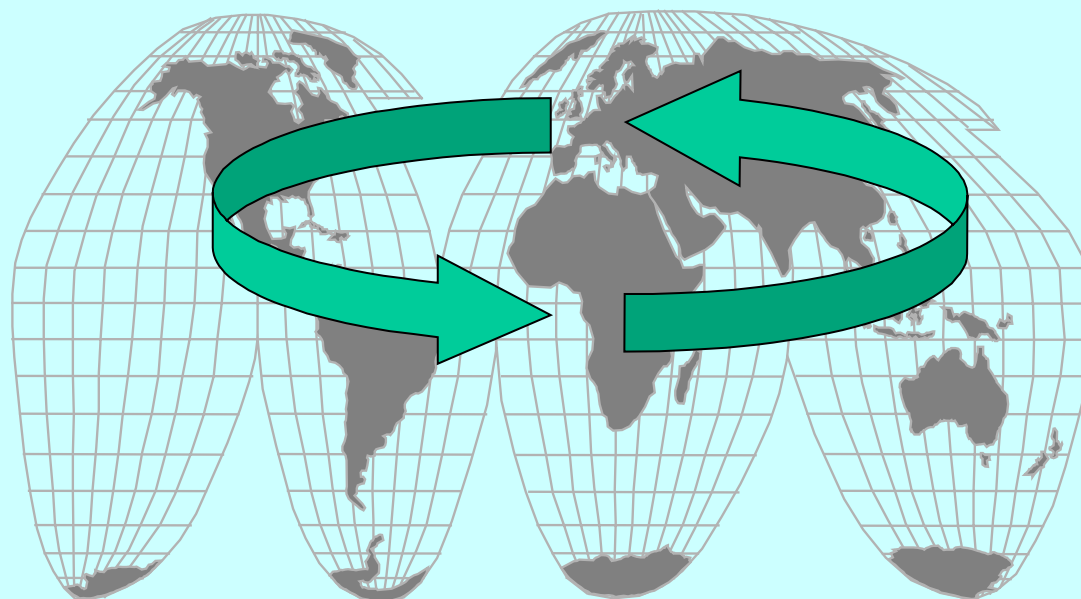


Expression of Interest

- ❁ **Opening call March 2002, deadline 7 June**
- ❁ **Consult the research community on its readiness to prepare research actions using *Integrated Projects* or *Networks of excellence* within the Thematic Priority Areas of Research**
- ❁ **Assist the Commission in preparing the Work Programmes and defining the scope of the first call for proposals of FP6**
- ❁ **Short document (5 pages max) containing**
 - ➡ **rational for proposing the research action**
 - ➡ **objectives**
 - ➡ **the general approach foreseen to reach the objectives**
 - ➡ **possible composition of the consortium**
- ❁ **Evaluation by the Commission with the assistance of external experts**
- ❁ **No direct feedback to applicant, general feedback on priority**



**EUROPEAN and DEVELOPING countries CLINICAL TRIALS
PROGRAMME (EDCTP)**
**NORTH and SOUTH PARTNERSHIP FOR CLINICAL TRIALS
ON POVERTY-RELATED DISEASES**





Aims of the EDCTP

- ✓ Increase EU effectiveness in RCTs
- ✓ Attract more resources for these interventions
- ✓ Accelerate candidate products
- ✓ Develop DCs capacity for doing RCTs
- ✓ Strengthen DCs decision making process

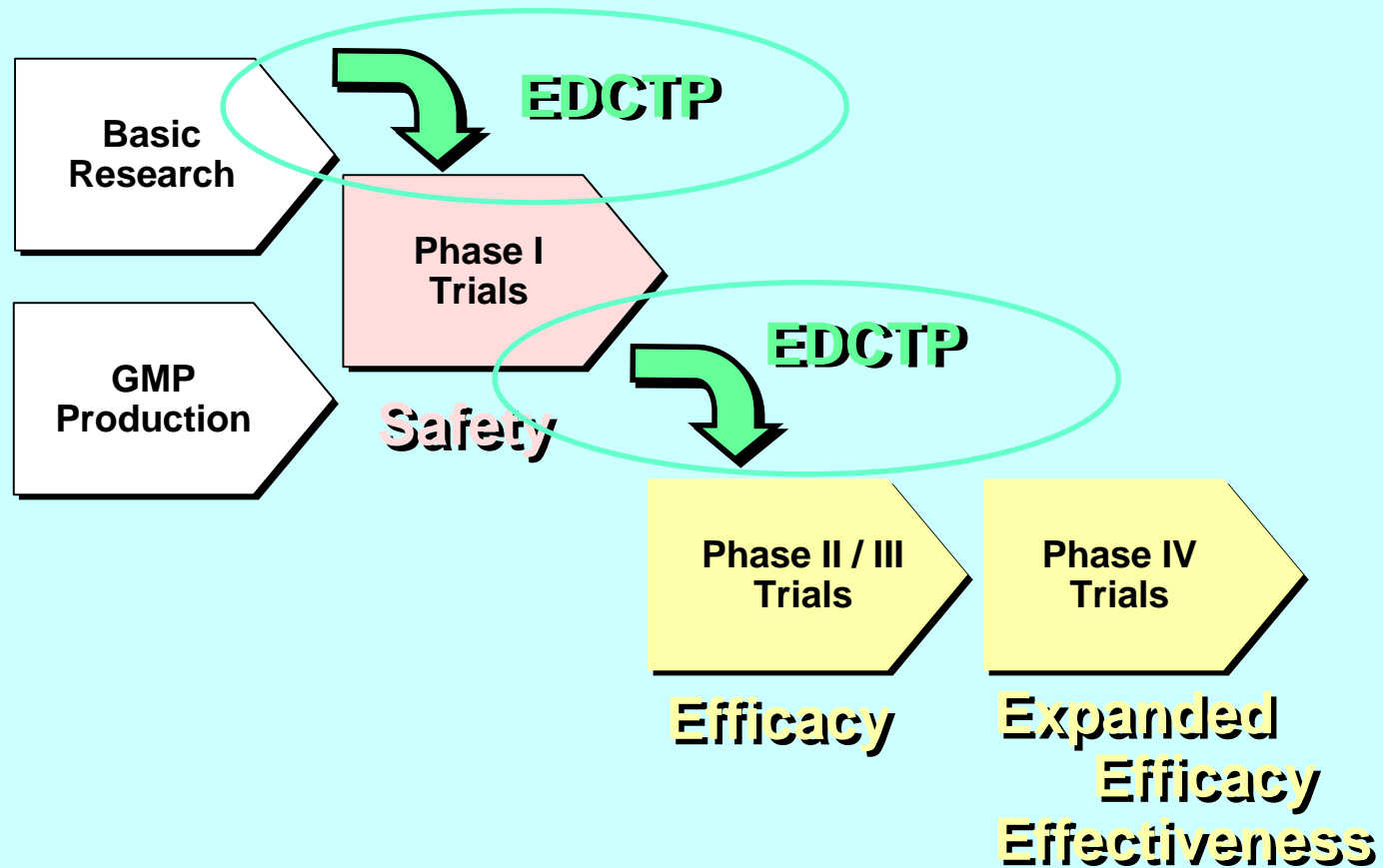


EDCTP Functions

- **Networking EU National Programmes**
- **Networking DCs R&D activities (sites & programmes)**
- **Capacity building and training in DCs**
- **Sponsoring: putting together financial packages, external sources of co-financing and building partnerships with industry**
- **Develop a reliable and powerful presence in global R&D arena**



The Clinical Trials Pathway:





European and Developing Countries Clinical Trials Programme

Accompanying Measure (1.25 M €)
DCs + 15 European Countries

Co-Decision by EU Parliament & Council

