



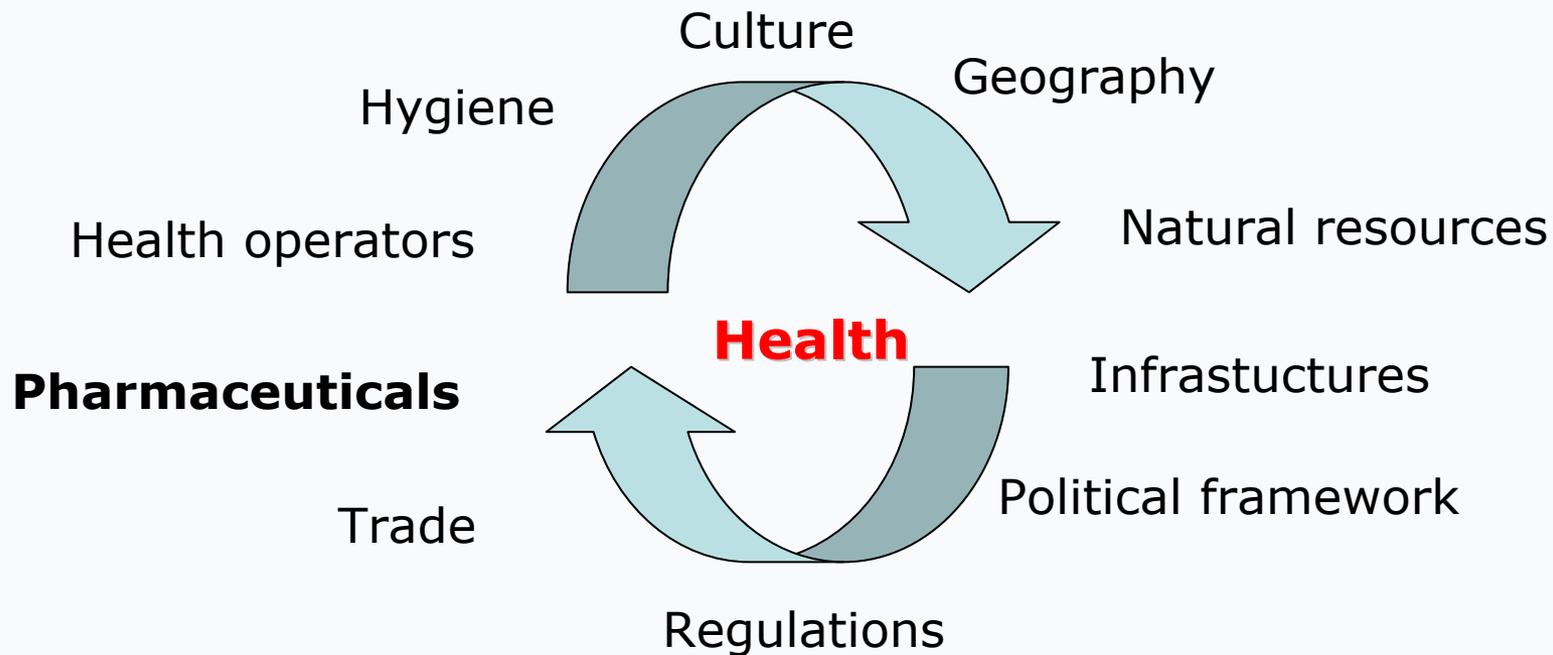
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Biomedical research focused on malaria

Pharmaceutical Industry's commitment

UNICRI- AIFA
Rome, December 16, 2008

Towards a more sustainable world in healthcare: pharmaceuticals, one factor



Work in partnership is the win-win strategy



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Health in Africa: pharma industry's commitment

R&D programs
focused on the
needs of the poorest

Clinical Trials
Good Clinical Practices
Strong ethical principles

Easy access
Efficient distribution
Education of patients
and healthcare
operators

Companies' Corporate Social Responsibility as a tool for progress

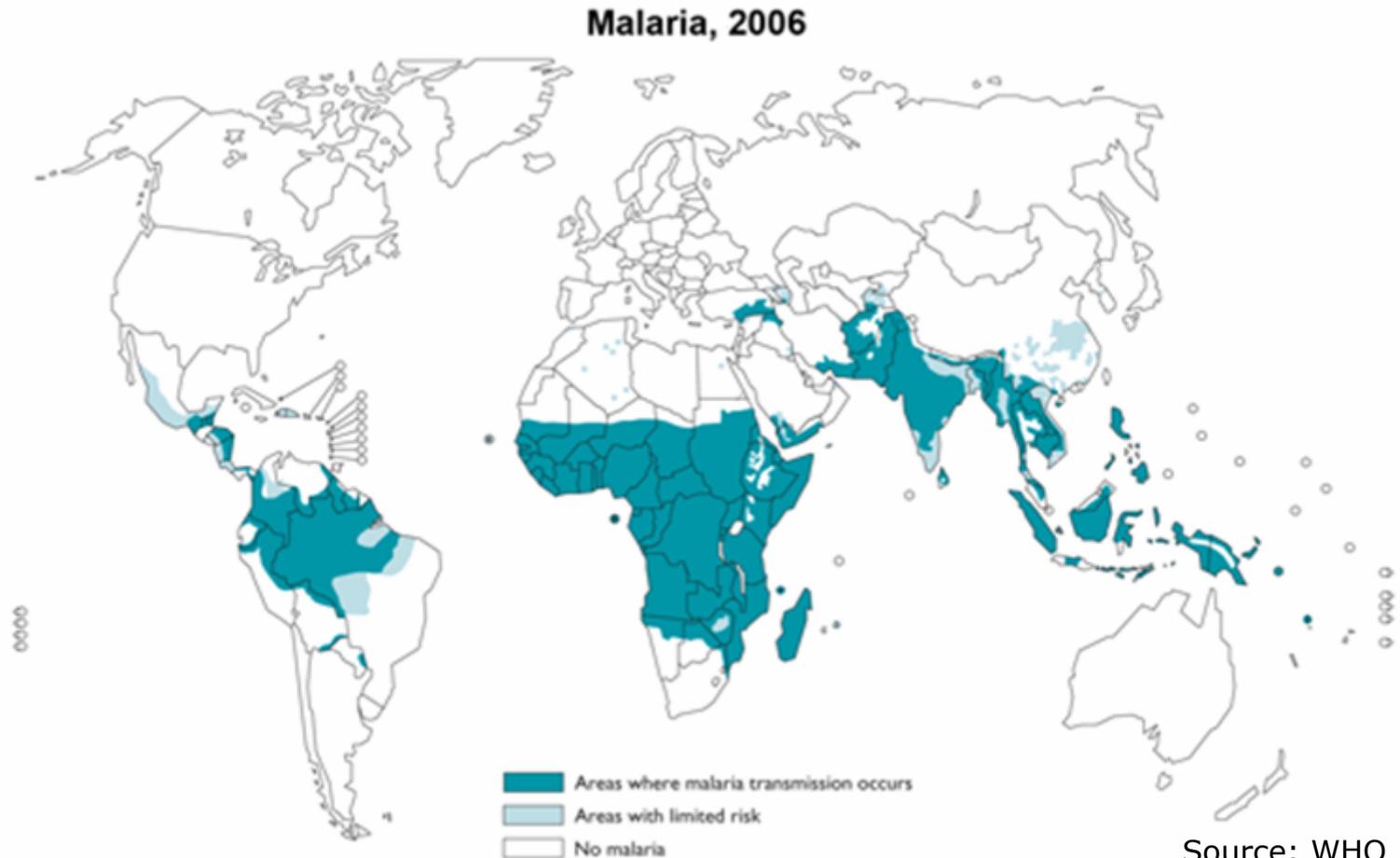
360° commitment;
Ethical behaviours;
Operate transparently;
Creation and sharing of added value;
Not only donations.



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Malaria, more than 500 million cases occur annually worldwide, resulting in 1 million deaths each year, of which 90% occur in Sub-Saharan Africa.



Source: WHO



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Malaria, how pharma industry is involved: fight against malaria and drug-resistance

Some simple treatments or combination treatments available: chloroquine; quinine; doxycycline; primaquine; mefloquine; artemisin derivatives (for instance artesunate, artemether, artemotil, dihydroartemisinin); sulfadoxine-pyrimethamine; atovaquone-proguanil; proguanil-dapsone, chlorproguanil-dapsone and atovaquone-proguanil.

New treatments are under development, for instance dihydroartemisinin + piperazine.

Diseases of the Developing World, Industry R&D– Evolution 2005-2008

	2005	2006	2007	2008
<i>Medicines</i>	32	43	50	58
<i>Vaccines</i>	(not counted)	6	8	9

Malaria, Industry R&D – Status Overview November 2008

<i>Diseases</i>	<i>Ongoing: medicines</i>	<i>Ongoing: vaccines</i>	<i>Approvals since 2005</i>	<i>Stopped since 2005</i>
<i>Malaria</i>	28	4	1	7

Source: IFPMA



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Malaria, clinical trials ongoing

R&D companies' projects carried out on their own or with Product Development Partnerships

Malaria

Company	Partners	Project	Phase
GSK	MMV, WRAIR	Tafenoquine (radical cure of P vivax)	Phase I / II
GSK	Liv, MMV	n-tertbutyl Isoquine (GSK 369796)	Phase I
Pfizer	MMV	Azithromycin & Chloroquine	Phase III
Ranbaxy	<i>company</i>	Arterolane (RBx 11160) & Piperaquine	Phase II
sanofi-aventis	<i>company</i>	Bis-thiazolium (SAR97276A/T3)	Phase II
sanofi-aventis	<i>company</i>	Ferroquine (SSR97193)	Phase II
Sigma-Tau	WRAIR, MMV, EDCTP	Intravenous Artesunate (in children)	Phase III
Sigma-Tau	<i>company</i>	Dihydroartemisinin and piperazine	Phase III
Shin Poong	MMV, Iowa	pyronaridine artesunate / Pyramax®	Phase III
Vaccines			
Amgen	<i>company</i>	MSP1-42 and AMA-1 vaccine	Phase I
GSK	MVI	RTS,S/AS01E vaccine	Phase IIb

Source: IFPMA



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Clinical trials – how pharma industry works:

1) Ethics

The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best current interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.

Medical research is subject to ethical standards that promote respect for all human subjects and protect their health and rights.

*WORLD MEDICAL ASSOCIATION DECLARATION OF
HELSINKI Ethical Principles for Medical Research
Involving Human Subjects*
Introduction



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Clinical trials – how pharma industry works:

2) Partnerships (Product Development Partnership)

Advinus Therapeutics Institute (ATI); Aeras Global TB Vaccine Foundation (Aeras); British Medical Research Council (BMRC); Centers for Disease Control and Prevention (CDC); Centre national de la recherche scientifique (CNRS); Columbia University (Col); Consortium 11 of Grand Challenges in Global Health (GCGH) (GC11); Drugs for Neglected Diseases initiative (DNDi); Epicentre Biotechnologies (Epicentre); **European & Developing Countries Clinical Trials Partnership (EDCTP)**; Global Alliance for TB Drug Development (TB A); Harvard Medicine (Harvard); Institute for OneWorld Health (iOWH); Institut Pasteur (Inst. Pasteur); Intercell AG (Intercell); Johns Hopkins University (JHU); **Liverpool University (Liv)**; **Malaria Vaccine Initiative (MVI)**; **Medicines for Malaria Venture (MMV)**; National Institute of Allergy & Infectious Diseases (NIAID); National Institute of Health (NIH); Oxford University (Oxon); Pediatric Dengue Vaccine Initiative (PDVI); Population Health Research Institute (PHRI); South African TB Vaccine Initiative (SATVI); Southwest Foundation for Biomedical Research (SFBR); Statens Serum Institute (SSI); Swiss Tropical Institute (STI); Texas A&M University (Tex); University College London (UCL); University of California, San Francisco (UCSF); **University of Iowa (Iowa)**; **Walter Reed Army Institute of Research (WRAIR)**; Wellcome Trust (Wellcome); WHO/UNICEF/UNDP/World Bank Special Program for Research & Training in Tropical Diseases (TDR)



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Clinical trials – how pharma industry works:

2) Partnerships (Foundations)

An example: Bill & Melinda Gates Foundation (B&MGF), founded in 2000 and doubled in size by Warren Buffet by donations in 2006, has recently partnered with Rockefeller Foundations and others.

The primary aims of the Foundation are, globally, to enhance healthcare and reduce extreme poverty, and, in the United States, to expand educational opportunities and access to information technology.

Co-operation between research based industry and this Foundation, as well as with other Foundations like this, is essential to build health.



The Italian example: not only donations



Corporate Social Responsibility: it combines innovative research, product success and corporate growth with high social and ethical standards.

R&D: it follows both traditional and innovative approaches, goes beyond improving therapeutic quality and the study of rare diseases to issues that have a strong impact on public health, including **malaria**.

Clinical Trials: focused on **malaria** and carried out in Africa (for instance Phase III Artesunate i.v., Severe Malaria; Phase III Dihydroartemisinin and piperazine),

Capacity Building : Sigma-Tau Sudan Ltd., *"a joint venture Sudanese-Italian company, incorporated January 1982, located in Khartoum north-Sudan. At present... manufacture & distribute pharmaceutical specialties...in the Sudanese markets, both to the private & public sector, ...in the region to Ethiopia, Eritrea, Chad, Iraq and Tanzania"*.

Prevention: vaccinating 3,000 children against the most widespread diseases (tuberculosis, diphtheria, whooping cough, tetanus, poliomyelitis, hepatitis B, Haemophilus influenzae B, measles) in Northern Uganda ("Together for Africa" for AMREF)

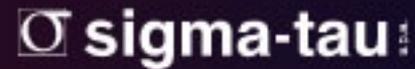
Education: training local health-care operators ("Together for Africa" for AMREF)



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The Italian example: focused on malaria



1) R&D

Medicines for Malaria Venture (39 R&D partners include academic research institutes, biotech firms and pharmaceutical companies. Major pharmaceutical partners: Chong Qing Holley, GlaxoSmithKline, Novartis, Ranbaxy, Sigma-Tau)

Objective: to develop one new antimalarial every 5 years with the first one registered before 2010.

MMV now manages the largest portfolio of malaria medicine research in history, with 19 projects in different developmental stages entering into 2006.



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The Italian example: focused on malaria



2) Clinical trials:

Artesunate i.v., Severe Malaria, Phase III (in collaboration with Walter Reed Army Institute of Research, USA);

Dihydroartemisinin and piperazine (DHA+PQP), two large phase III comparative clinical trials **conducted in Africa (Burkina Faso, Zambia, Kenya, Mozambique and Uganda)** and Asia respectively, which involved a total of about 2,700 patients, of whom 1,600 children under 5, all with uncomplicated malaria caused by *Plasmodium falciparum*.

All trials conducted at the highest international Good Clinical Practice level.

Outcomes (presented at the 57th Annual Meeting of the American Society of Tropical Medicine & Hygiene, New Orleans, Dec. 7-11 2008): combination effective against uncomplicated malaria like other artemisinin-based combination therapies, effective in preventing new infections for about two months, well tolerated with no significant side effects).



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The Italian example: focused on malaria



3) Clinical trials + Access to Medicines

a license and supply partnership agreement has been signed, under which, following applicable regulatory submissions and approvals, the partner companies will market a novel fixed dose artemisinin-based combination therapy (dihydroartemisinin + piperazine) in Africa.

Next step

The hope is that the joint efforts made to develop this new drug and make it available to the greatest possible number of patients will substantially contribute to the achievement of the ambitious goal of the Gates Foundation to eliminate and ultimately fully eradicate malaria.



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Health in Africa: the ultimate goal

Join the efforts of the Developed and Developing Countries for a common goal: build health for all might be the constructive way to go based on human solidarity.

“The extension to all peoples of the benefits of medical, psychological and related knowledge is essential to the fullest attainment of health.”

World Health Organization
Preamble to the Constitution



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