

Pharmaceutical Innovation and Meeting the Needs for Global Access



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How the R&D Pharmaceutical Industry Helps to Improve Health in the Developing World

- Innovation
- Access
- Corporate Good Governance

Principal Focus and Actions
of the Research-Based
Pharmaceutical Industry in
Contributing to Global Health

R&D Pharmaceutical Innovation to Treat HIV/AIDS

- 1981 - HIV/AIDS identified
- 1987 - 1st antiretroviral (ARV) approved
 - Industry norm is ~10 years to approval
- today - 26 antiretrovirals approved (4 different classes)
 - ~ 1 per year since disease identified
 - BUT: 14 approved for children ≤ 16 years & 6 approved for ≤ 3 years
- today – 92 candidate therapies in clinical trials for HIV/AIDS
 - 46 candidate antiretrovirals (at least 2 new classes)
 - 20 candidate vaccines
 - (~ 15% chance of approval once a candidate starts clinical trials...)



Pediatric Trials Search

Join myPortal

The IFPMA Clinical Trials Portal is now easier to use! Create your own profile and enjoy access to these new features:

- Create and save up to six search queries.
- Repeat these queries whenever you wish.
- Receive an e-mail alert when a new matching trial is posted.

[Join now >>](#)

Search Ongoing Pediatric Trials

Terms to search for:

antiretroviral



Terms to exclude:



Trials conducted in:



Search

Clear

use synonyms



Pediatric Trials Search

Pediatric clinical trials are research studies designed to answer specific questions about a new medical treatment, or new ways of using known treatments in children under 16-18 years of age, depending on region.

[Read more...](#)

IMPORTANT: Your search will be restricted to clinical trials containing the terms juvenile, child, pediatric, infant and other like terms. If you do not wish to restrict your search, please use the general search pages.

Search Ongoing Pediatric Trials:

Antiretroviral

623 found

Print

Total results returned: 500 of total results found: 623

1 2 3 4 5 6 7 8 9 10 ...

Title: A Pilot Study of the Immunologic Reconstitution in HIV-1 Infected Children Receiving Highly Active Antiretroviral Therapy With Combination Ritonavir, Nevirapine and Stavudine - Full Text View - ClinicalTrials.gov

Infobox

Search score: 92%
No location info

Description: A Pilot Study of the Immunologic Reconstitution in HIV-1 Infected Children Receiving Highly Active Antiretroviral Therapy With Combination Ritonavir Nevirapine ...This is a pilot study to evaluate the ability of highly active antiretroviral therapy administered to

Title: Comparison of New Anti-HIV Drug Combinations in HIV-Infected Children Who Have Taken Anti-HIV Drugs - Full Text View - ClinicalTrials.gov

Infobox

Description: ...AMENDMENT 7/17/98 48 weeks in stable HIV-infected children with 16 weeks

Industry R&D Projects for Diseases of the Developing World (DDW)

- Updated Annually
- 10 DDW prioritized by TDR:
 - Sleeping Sickness, Dengue, Leishmaniasis, Malaria, Schistosomiasis, Tuberculosis, Chagas, Leprosy, Lymphatic Filariasis & Onchocerciasis
- Programs by:
 - Companies + Product Development Partnerships
 - Companies Alone
- 15 R&D pharma/vaccine companies
 - 3 have a dedicated DDW R&D centre
 - 1 has 2 dedicated DDW R&D centers (1 for medicines + 1 for vaccines, opened 2008)



International Federation of Pharmaceutical Manufacturers & Associations
Fédération Internationale de l'Industrie du Médicament
Federación Internacional de la Industria del Medicamento

Status Report

Pharmaceutical Industry R&D for Diseases of the Developing World

This document lists research-based pharmaceutical company⁽¹⁾ projects⁽²⁾ to develop new medicines and vaccines for the ten diseases of the developing world (DDW) prioritized by the WHO/UNICEF/UNDP/World Bank Special Program for Research & Training in Tropical Diseases (TDR):

- Priority 1: African trypanosomiasis, Dengue & Leishmaniasis,
- Priority 2: Malaria, Schistosomiasis & Tuberculosis,
- Priority 3: Chagas Disease, Leprosy, Lymphatic Filariasis & Onchocerciasis.

Data on research projects underway for these diseases published in 2005 by the Pharmaceutical R&D Policy Project⁽³⁾ under Dr. Mary Moran and subsequently by the IFPMA show the evolution and status of industry R&D for DDW.

Industry DDW R&D – Evolution, 2005-2007			
	2005	2006	2007
Medicines	32	43	50
Vaccines	(not counted)	6	8

Industry DDW R&D – Status Overview as of 30 October 2007				
Diseases	Ongoing: Medicines	Ongoing: Vaccines	Approvals since 2005	Stopped since 2005
Tuberculosis	20	2	-	1
Malaria	24	4	-	4
Other TDR Diseases	6	2	1	1
Totals	50	8	1	6

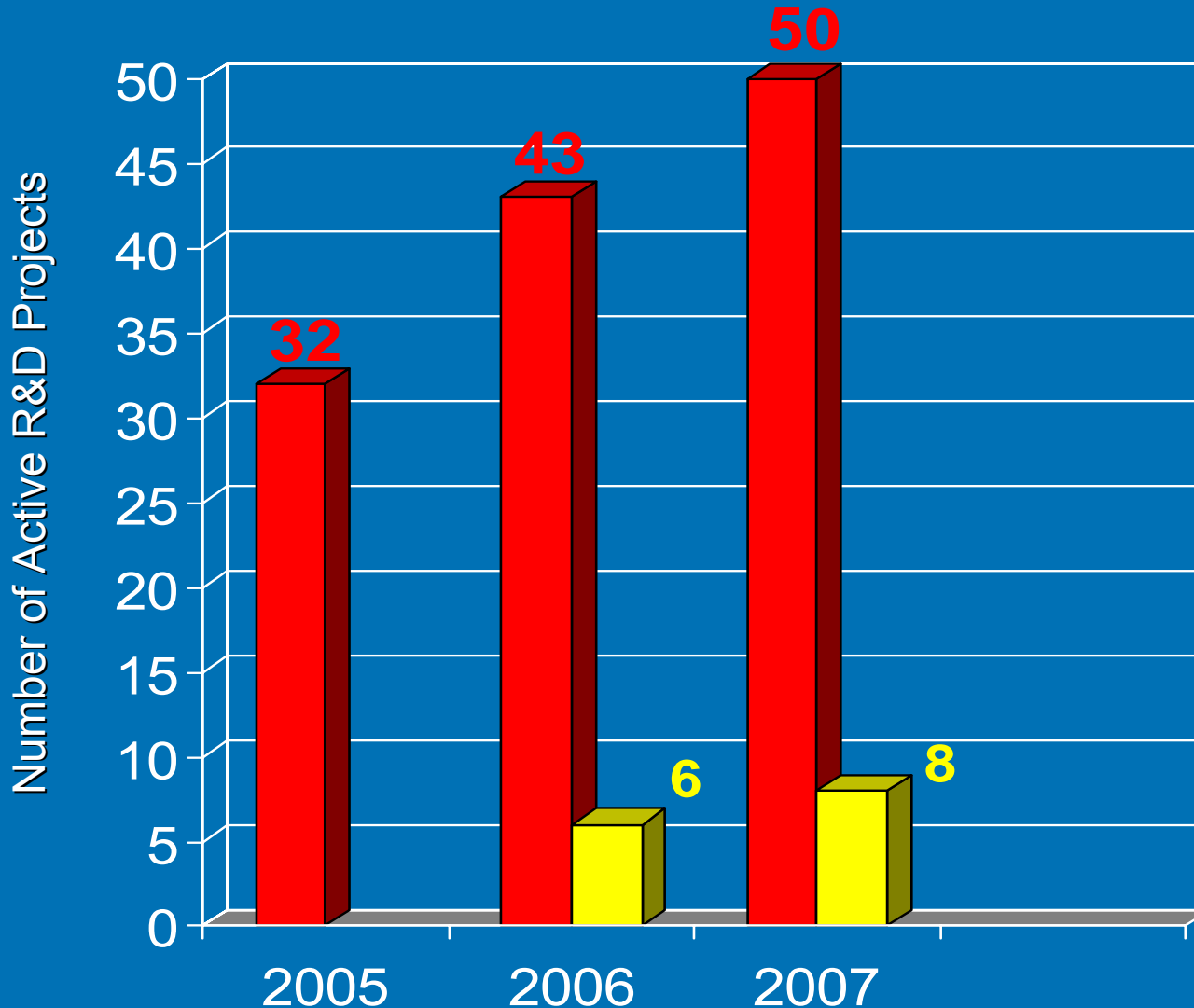
Slightly more than half of these R&D programs are being undertaken by companies working with Product Development Partnerships⁽⁴⁾, while the rest are by companies on their own. The industry's efforts to help improve global health are supported by four company R&D centers which are dedicated solely to research and development for diseases of the developing world.

Industry Dedicated DDW R&D Centers				
Company	Center	Location	Disease(s)	Started
AstraZeneca	Bangalore Research Institute	Bangalore, India	Tuberculosis	2003
Eli Lilly	TB Drug Discovery Partnership	Seattle, USA	Tuberculosis	2007
GlaxoSmithKline	DDW Drug Discovery Center	Tres Cantos, Spain	Malaria Tuberculosis	2002
Novartis	Novartis Institute for Tropical Diseases	Singapore	Dengue Fever Malaria Tuberculosis	2002

This document does not cover R&D for HIV/AIDS, which is a health issue in both developed and developing countries, but it should be noted pharmaceutical companies have developed 22 antiretroviral (ARV) medicines, of which 11 are available in pediatric formulations and, in 2006, were developing a further 35 new ARVs, at least 6 additional pediatric formulations for ARVs and 19 HIV vaccines.⁽⁵⁾

2 November 2007

Industry DDW R&D is Growing



■ Medicine R&D Projects
■ Vaccine R&D Projects

R&D Projects undertaken By IFPMA Member Companies, alone or with Product Development Partnerships

1 project = 1 compound in development OR 1 screening program for 1 disease

BUT:
44 out of the 50 medicines are for TB or Malaria...




Industry Partnerships to Improve Health in Developing World



Partnerships to Build
Healthier Societies
in the Developing World

- Updated Annually
- Long-Term Health Development Partnerships
- Low & Middle Income Countries
- Main Activities
 - Access (31%)
 - Capacity-Building (42%)
 - Education for patients (28%)
 - R&D for DDW (23%)
 - Many programs > 1 area of activity

Industry Partnerships for Developing Countries

Section	 2006	 2007	 2008
HIV/AIDS	24	52	54
Tuberculosis	12	13	14
Malaria	11	13	14
Tropical Diseases	8	19	18
Vaccine Preventable	9	10	12
Child & Maternal		17	23
Chronic Diseases		11	20
TOTALS	64	135	155

Biggest increase:
HIV / AIDS

Biggest increase:
Chronic Diseases



International
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www.ifpma.org/healthpartnerships

IFPMA Partnerships: Table of Contents & Search - Windows Internet Explorer

Browser navigation bar showing address bar (http://www.ifpma.org/Healthpartnerships), search bar (Google), and menu items (File, Edit, View, Favorites, Tools, Help).

IFPMA logo and navigation menu: Home, Issues, Health Partnerships, News & Publications, Influenza Vaccines, About Us.

Health Partnerships for the Developing World - 2008
The R&D Pharmaceutical Industry's Contribution to the health-related UN Millennium Development Goals

- Table of Contents & Search
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- HIV/AIDS
 - ARV Access
 - Mother & Child Programs
 - Capacity Building
 - R & D
- TUBERCULOSIS
 - Access & Capacity Building
 - R & D
- MALARIA
 - Access & Capacity Building
 - R & D
- TROPICAL DISEASES
 - Access & Capacity Building
 - R & D
- PREVENTABLE DISEASES
 - Access & Capacity Building
 - R & D
- CHILD & MATERNAL HEALTH
 - Access & Capacity Building
- CHRONIC DISEASES

Search interface showing search results for Kenya. The search bar contains 'Kenya' and the results list 36 items found. Red boxes highlight the search term and the total count.

Health Partnerships Book (pdf) [English](#) | [printer-friendly copy](#) | [mail a link to this page](#)

Search for: All partners... Remember?

36 items found

- HIV/AIDS - ARV Access (3)
 - [Boehringer Ingelheim Access](#)
 - [GlaxoSmithKline Access to ARVs](#)
 - [Technology Transfer & ARV Licensing in Developing Countries](#)
- HIV/AIDS - Mother & Child Programs (4)
 - [PMTCT: Abbott Rapid HIV Test Donation Program](#)
 - [PMTCT: Viamune® Donation Program](#)
 - [Regional Psychosocial Support Initiative](#)
 - [Secure The Future® Children's Clinics & PMTCT](#)
- HIV/AIDS - Capacity Building (9)
 - [CARE Program](#)
 - [GlaxoSmithKline's Positive Action on HIV/AIDS](#)
 - [GSK - Other HIV/AIDS Capacity-Building Initiatives](#)
 - [J&J - UCLA Management Development Institute](#)
 - [Medical Mission Sisters](#)
 - [Merck & Co., Inc. HIV/AIDS programs - Africa](#)
 - [Mildmay International & GlaxoSmithKline Partnership](#)

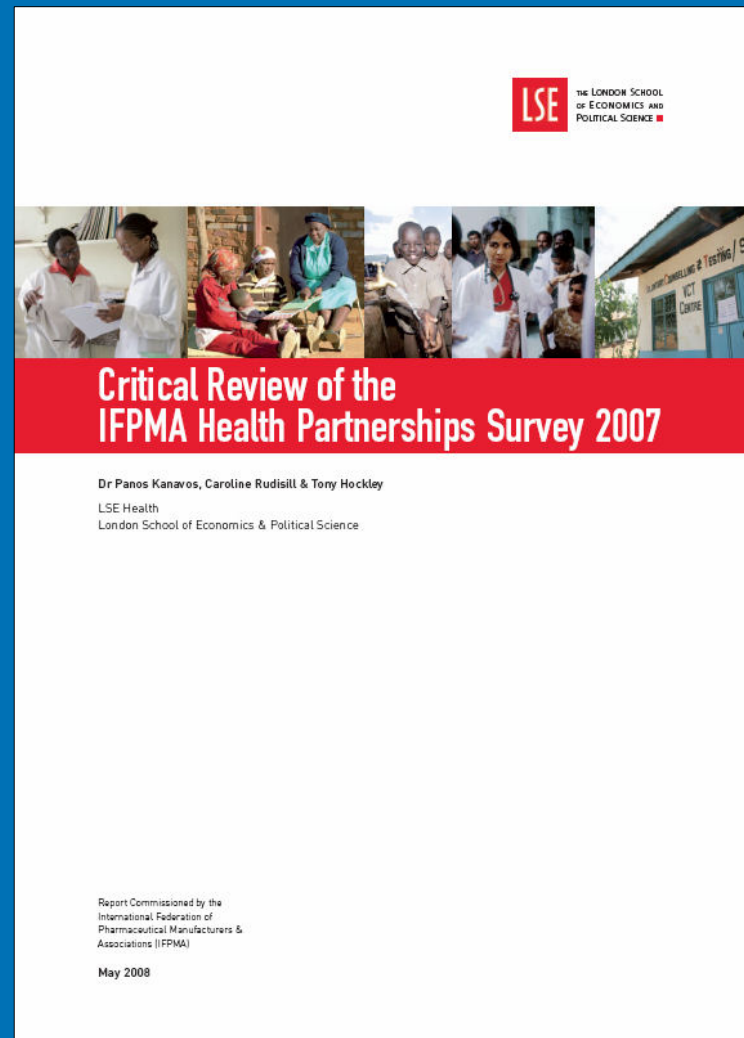
**Search by
Developing Country:
Kenya**

36 programs found

HIV/AIDS	17
Tuberculosis	3
Malaria	6
Other Tropical	4
Preventable	1
Child & Maternal	1
Chronic	4

Measures Industry's Philanthropic Contribution to Improving Developing World Health

- Since 2000
- Low & Middle Income Countries
- Long-Term Health Programs
 - Excludes Emergency Aid
 - Excludes R&D for DDW
- Measures:
 - Positive Health Interventions (PHIs)
 - Value of Aid (USD)
- Reviewed by LSE Health
- Results 2000-2007 (2000-2006)
 - 1.3 billion PHIs (1 billion PHIs)
 - USD 6.7 billion (USD 4.8 billion)



- National Regulations & Standards
- Ethical Clinical Trials
 - IFPMA Clinical Trials Portal (www.ifpma.org/clinicaltrials)
- Ethical Promotion
 - IFPMA Code of Marketing Practices (www.ifpma.org/EthicalPromotion)
- Ensuring Product Quality
- Fighting Counterfeits
- Fighting Corruption
- Pandemic Influenza Preparedness
 - IFPMA Influenza Vaccines Resource (www.ifpma.org/Influenza)



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Influenza Task Force

Business Continuity

Pandemic Influenza Preparedness: Business Continuity Planning for the Global Healthcare Industry

Pharmaceutical manufacturers, and the wider global healthcare industry, play an important role in maintaining and improving the health of society through the production and delivery of medicines and medical services. However, like other organizations, the industry is vulnerable to external crises that can interrupt business operations and consequently impact its capacity to deliver healthcare services and medicines.

One such potential crisis is the threat of pandemic influenza, which the World Health Organization (WHO) believes may be imminent. While the severity and impact of such an event remains uncertain, a pandemic has the potential to massively affect society, leading to widespread illness and death and interruptions in critical business and governmental operations. Therefore, given the likelihood of a pandemic, pharmaceutical manufacturers and the wider healthcare industry would be wise to adapt their business continuity plans to include a response to this potential crisis.

While many organizations already have business continuity plans in place, it is important that they are reviewed and updated to address the specific case of an influenza pandemic. Unlike other crises, an influenza pandemic could result in a peak employee absenteeism rate of 30% - 50% and may last for an extended period of time. Therefore, pharmaceutical manufacturers' continuity plans must focus on maintaining the manufacture and supply of essential medicines to patients and communities around the world during an influenza pandemic.

To assist the industry in its planning, the IFPMA has developed [detailed guidance](#) outlining the key areas that pandemic influenza business continuity plans should address. The IFPMA recommends that members develop detailed plans to address the issues covered in this document, and publish a non-confidential overview on their websites to enhance confidence and demonstrate their preparedness to key stakeholders, including employees, governments, suppliers, customers, health care professionals and local communities.

Good Corporate
Governance

IFPMA Guidelines

“Pandemic Influenza
Preparedness:
Business Continuity
Planning
for the Global
Healthcare Industry”



Print Email

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Conclusion

The R&D Pharmaceutical Industry commits to:

- Continue to act responsibly in its sphere of activity
- Work collaboratively to make new medicines & vaccines
 - Available
 - Accessible

to the Global Patient Community

Lessons Learned

Improved Access to Health Care in Developing Countries Requires:

- A Concerted, Partnership-based Strategy
- Supported Globally with:
 - Financial Resources
 - Know-how about Good Practices

and...

- National and Community Efforts to increase Poor People's Access to Essential Health Services