

DNDi is an initiative founded by the Indian Council of Medical Research, Institut Pasteur, Kenya Medical Research Institute, Ministry of Health Malaysia, Médecins Sans Frontières, Oswaldo Cruz Foundation and WHO/TDR

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Overview

The portfolio-building process is going full steam ahead: The Scientific Advisory Committee met on 6-7 May to evaluate responses received to the second call for letters. The LEAP (Leishmaniasis East Africa Platform) meeting in Addis Ababa took the registration of paromomycin a step forward. And FACT (Fixed-dose Artesunate Combination Therapy) is preparing for the launch of clinical trials in July.

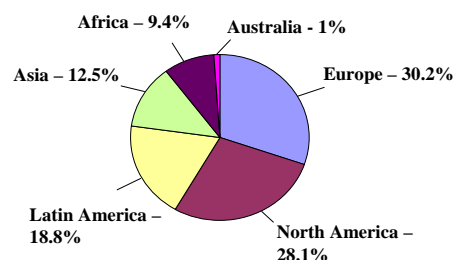
The DNDi team has been putting the final touches to the Human Resources Policy and the Intellectual Property Policy before submitting to the Board of Directors. Fundraising efforts have begun to support our projects, with an initial focus on developing opportunities with the US, the European Commission, and Italy. The hunt is drawing to a close for a Fundraising and Advocacy Director. Filming is underway for three short DNDi films.

And just in case you hadn't noticed, we are trying out a new design for the DNDi Newsletter! We hope you like it.

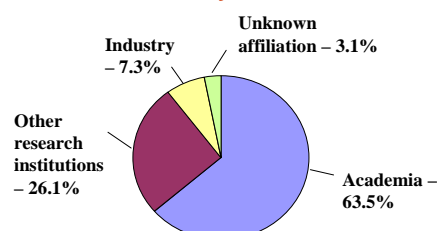
Portfolio Progress

Promising projects evaluated: The second call for letters resulted in 96 submissions of project ideas. Almost 40% of these came from developing countries and over 66% targeted leishmaniasis. Ten investigators have been asked to submit full proposals before 30 July, and an additional 4 will be asked to complement existing DNDi projects. We hope that 4-6 will be selected for the portfolio.

96 letters of interest (2004)
Distribution by location



96 letters of interest (2004)
Distribution by affiliation



Interesting Links

www.globalforumhealth.org

The 10/90 Report on Health Research 2003-2004

www.plos.org

A new open access medical journal PLoS Medicine will be launched in Autumn 2004

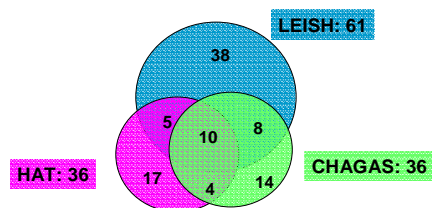
Latest figures from the Global Forum:

It has been estimated that global spending on health research has risen from \$30 billion in 1987 to \$100 billion in 2001. The public sector accounted for 50% of this funding...

"Health is not a consequence of development but a key factor in achieving development."

Stephen Matlin, Director, Global Forum for Health Research, quoted in the BMJ, 22 May 2004; 328:1220

96 letters of interest (2004) Distribution by disease



Malaria clinical trials begin in July 2004: The Fixed-dose Artesunate Combination Therapy (FACT) project is making headway in the two projects on artemisinin-based fixed-dose combinations for chloroquine-resistant malaria. Despite some minor delays in accessing drug substance data, all activities for the preparation of clinical supplies of artesunate-amodiaquine (AS/AQ) and artesunate-mefloquine (AS/MQ) will be pursued and drug products/supplies will be delivered to the trial sites in July 2004. Finalization of the clinical protocols is underway; consequently, clinical trials will start in July 2004 for AS/AQ in Burkina Faso and for AS/MQ in Thailand.

Preparing a clinical trial with paromomycin in Africa. DNDi, in partnership with TDR and IOWH, aims to register paromomycin as a new treatment for visceral leishmaniasis in Africa using the Leishmaniasis East Africa Platform (LEAP). This group held a meeting in Addis Ababa on 12-13 May on the design of the clinical trial of paromomycin (PM). A 700-patient study over 12 months will be conducted during 2004-05 to compare 17-day sodium stibogluconate (SSG)-PM combination, SSG 28 days, and PM 21 days at 5 trial sites: one in Kenya at KEMRI; two in Ethiopia, at Gondar in the north and Arba Minch in the south, and two in Sudan, both in Gedaref state where 75% of the VL occurs at Kassab and Um El Kher (MSF).

LEAP is a network of scientists formed to explore promising treatment options for kala-azar, to estimate needs in terms of capacity strengthening for clinical studies, to design and implement training programmes to improve capabilities, and to develop treatment protocols. In addition, LEAP will build collaborative relationships with the health and drug registration bodies in each country to facilitate the process of making new treatments readily accessible to patients.

Assessing the clinical utility of nifurtimox for stage 2 sleeping sickness: a DNDi-TDR collaboration. An expert meeting was organised at DNDi on 22 April, to review available data on the use of nifurtimox in African trypanosomiasis and agree on a common action plan to reinforce the evidence base on the efficacy and safety of this drug with the aim of ultimately obtaining a WHO recommendation for its use in HAT treatment. Based on limited past information and ongoing studies, the combination of nifurtimox and eflornithine shows promise for the treatment of HAT. A DNDi-TDR call for Letters of Intent has been launched to invite investigators, particularly from developing countries, to participate in clinical research that will further document the utility of this drug in sleeping sickness. This research will be jointly coordinated by DNDi and TDR, and selected investigators will be offered training to strengthen their clinical research expertise in conducting clinical trials and improve their institutional research capacity. The call text is available on http://www.who.int/tdr/grants/grants/afri_c_tryps.htm and the deadline is 15 July 2004.

DNDi fellowships. In keeping with its aims to use and strengthen existing capability in disease endemic countries, DNDi has awarded fellowships to three post-doctoral fellows, one each from India, Brazil and Kenya. The fellowships will be for a period of 4 months each, attached to DNDi discovery projects in Dundee University, Washington University, and Harvard University. The fellowships start in the fall.

Concerning sleeping sickness:

"Our challenge is to find a successor for melarsoprol."

Bernard Pecoul, Executive Director, DNDi

DNDi in Brazil

Bernard Pecoul's visit to Brazil reaffirmed DNDi's relationship with the Oswaldo Cruz Foundation (Fiocruz).

- Ana Rabello, leishmaniasis expert at Fiocruz, is gathering information on leishmaniasis in Latin America. This will help to promote DNDi's goals and develop a strategy to proactively identify promising projects.
- The help of an expert on Chagas disease will be needed soon, as the drug pipeline for this disease is empty. Fiocruz could help DNDi build a strategy to develop drugs for Chagas disease.
- The DNDi-Brazil website will be created in June. Meanwhile, the Fiocruz website will help promote a photo exhibition on Neglected Diseases (Access Campaign exhibition that could become a Fiocruz + DNDi co-sponsored exhibition) and advocate for DNDi activities.

Recruitment Update

- **Fundraising & Advocacy Director.** The finalists from 75 applicants are being interviewed.
- **Finance & Administration Director.** Recruitment for this position will begin in the third week of June.
- **Assistant, R&D.** Applications are coming in for this post which has been advertised locally.
- **China expert.** CNRS (Centre Nationale de Recherche Scientifique, France) has seconded Bernard Mely to DNDi for a year to help explore needs and opportunities in China.

Policy Documents

The following draft policy documents will be discussed at the Board of Directors meeting, 24-25 June 2004.

- **DNDi's IP Policy**, written in collaboration with a small group of lawyers: Christopher Garrison, Sisule Musungu, Frederick Abbott, Warren Kaplan
- **DNDi's Human Resources Policy**, written in consultation with Derrick Wong.

Fundraising Begins

The groundwork for fundraising has begun in the form of relationship building. In April-May, Europe and the US were targeted for preliminary awareness-raising visits.

- DNDi was presented to the European Commission DG Research, the European Parliament, the Vatican Pontifical Councils on Health and Justice & Peace, the Region of Tuscany (proposal on LEAP to be developed), and MSF Italy.
- DNDi's proposal to the European and Developing Countries Clinical Trials Partnership (EDCTP) to conduct FACT clinical trials in five additional sites in Africa was turned down.
- Jana Armstrong, Bernard Pecoul, and Yves Champey visited current and potential donor institutions and foundations in the US – MSF, Doris Duke, NIH (NIAID, Fogarty, Office of Technology Transfer), UN Foundation, HHMI, and USAID. In July they will visit British funding agencies (Wellcome Trust, DFID, MRC etc.).

More Links

www.emea.eu.int

The EMEA is a decentralized drug evaluation body of the European Union

www.ippph.org

IPPPH aims "to increase the effectiveness of public-private collaboration particularly by helping those seeking to develop health products... needed to fight neglected diseases ..."

www.barcelona2004.org

"a new forum for reflection and experimentation in relation to the main cultural and social conflicts that humanity is faced with at the outset of the 21st century"

www.latinpharma.net/expo2004

an event focusing on the pharmaceutical industry, research institutes, and universities.

<http://www.who.int/lep/ND/>

for a report of the WHO Workshop on intensified control of neglected diseases, Berlin

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Communications & Advocacy

Ingrid Cox has joined on a part time temporary basis to assist with DNDi's publication strategy.

Publications. *DNDi's R&D portfolio*, a document describing our portfolio building strategy and current projects is available at jbanerji@dndi.org or www.dndi.org.

A revised version of *An Innovative Solution* is in print and on www.dndi.org.

DNDi film. Members of the Scientific Advisory Committee were interviewed for the DNDi film in production. Board Members will be interviewed during the June Board meeting. The film crew has filmed two case studies of leishmaniasis in Bihar, India.

Profile of new R&D Director. Read about Simon Croft in *The Lancet*: http://www.thelancet.com/journal/vol363/iss9424/full/llan.363.9424.dissecting_room.29777.1

Meetings Attended: Mar-Jun 2004

DNDi attended numerous meetings between March and June, notably:

15 March: Yves Champey presented DNDi to the **European Agency for the Evaluation of Medicinal Products (EMA) in London**. The EMA's main responsibility is the protection and promotion of public and animal health, through the evaluation of medicines for human and veterinary use.

15-16 April: Bruce Mahin, interim Finance Director, attended a workshop in London convened by the **Initiative on Public-Private Partnerships for Health (IPPPH)** on "Combating Diseases Associated with Poverty: Financing Strategies for Product Development and the Potential Role of Public-Private Partnerships".

27 April: Yves Champey, Els Torreele, and Grace Murilla of KETRI, Kenya, were present at a public hearing on lack of R&D for neglected diseases at the **European Parliament in Brussels**.

8 June: Bernard Pecoul gave a presentation on "Confronting New Health Challenges in Developing Countries: Access to Essential Medicines" at the **Forum Barcelona 2004**.

10-11 June: Michel Lotrowska and Eloan dos Santos Pinheiro made presentations at the **LatinPharma 2004 conference in Sao Paulo, Brazil**. In addition, a virtual forum from 2-7 May on R&D, drugs and neglected diseases was extremely well attended. LatinPharma contributes to the development of the industry by presenting new concepts and exchanging new information.

11 June: Bernard Pecoul and Simon Croft made presentations at the 600th anniversary celebrations of **Turin University**.

14 June: Els Torreele was invited to participate at a roundtable discussion on 'Accords multilatéraux de commerce et santé publique', at the **University of Lausanne**.

21 June: Els Torreele attended the follow up session of WHO's meeting on **Intensified Control of Neglected Diseases in Rome**. The first session held in Berlin, 10-12 December 2003 sought to: assess the impact and cost of neglected diseases, assess available tools and strategies, determine priorities for future research, and identify the most cost- and resource-effective ways of planning, supporting and implementing intensified disease control.