
Sanofi and DNDi an innovative public-private partnership

The case of Human African trypanosomiasis and Fexinidazole

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May 12, 2021

DNDi
Drugs for Neglected Diseases *initiative*



Photo: Neil Brandvold - DNDi

DNDi ORIGINS

Born on the frontlines of medical action



“

When we received the Nobel Peace Prize in 1999, MSF did not have the medicines we needed to carry out our lifesaving work. So, we decided to dedicate a portion of the funds received to launch a brand-new model of R&D.

Four years later, DNDi was born.”

DR. BERNARD PÉCOUL

Founding Executive Director, DNDi. Former General Director of MSF, Doctors Without Borders/ Médecins Sans Frontières

15 YEARS, 8 TREATMENTS, MILLIONS OF LIVES SAVED

Treatments delivered



8 field-adapted and affordable treatments for 5 diseases (some of them deadly)

R&D pipeline replenished



- 20+ NCEs
- 4 million+ compounds screened
- 13 projects in Phase III and registration

Clinical trials conducted



An average of 20 active clinical studies

Research networks established

- 4 clinical research networks
- COVID-19 Clinical Research Coalition with 350+ members

Global partnerships forged



200+ partner institutions in 40+ countries

Diverse global team mobilized



A diverse global team of 250+ staff

Policies influenced

DNDi's model, experience, and lessons learned documented and disseminated

New organization to fight drug-resistant infections

DNDi joined forces with the World Health Organization (WHO) in 2016 to create the Global Antibiotic R&D Partnership (GARDP)

SLEEPING SICKNESS

Public Health Challenge



8.5 MILLION people live in areas at moderate to very high risk



67.5% of the world's sleeping sickness cases in 2018 were reported in the Democratic Republic of Congo

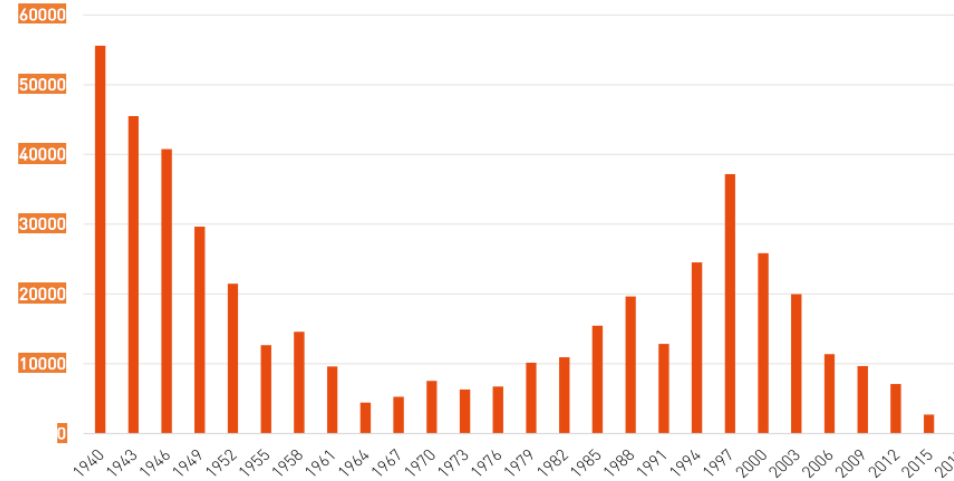


24 COUNTRIES in West & Central Africa are endemic for the *T.b. gambiense* strain



13 COUNTRIES in East & Southern Africa are endemic for the *T.b. rhodesiense* strain.

THE HISTORY OF SLEEPING SICKNESS



The history of sleeping sickness is one marked by the appearance of deadly epidemics interspersed by decades where the disease seems largely under control.

Until 2009, treatments were very complex or highly toxic to the point they killed 5% of patients.

Patients needed to be hospitalized to receive intravenous infusions

AND

To undergo a painful lumbar puncture to stage the disease



Sleeping sickness is usually fatal if left untreated.

Sanofi – DNDi an innovative public-private partnership

A collaboration of more than 15 years for sleeping sickness



2005
DNDi began compound mining in Hoechst (now Sanofi)'s libraries

2009
DNDi and Sanofi sign a collaboration agreement on development and manufacture

2017
Sanofi, submitted in December 2017 a dossier for review by the EMA (art 58)

2019
WHO publishes new guidelines for the treatment of HAT including fexinidazole

2007
Pre-clinical studies begin Sanofi provides initial samples, data, and advice based on the previous Hoechst development programme

2011
DNDi and Sanofi request joint scientific advice to USFDA and EMA on clinical plan development. Ph II/III studies start in 2012 in DRC and CAR

2018
EMA gave a positive opinion on fexinidazole which was subsequently approved in DRC the same year

Innovative management of intellectual property in the interest of public health

Fexinidazole donated to WHO



“Most people affected by sleeping sickness live in remote rural areas. Providing a 'last mile' treatment is a challenge if we want to reach sustainable elimination of the disease.”

Luc Kuykens
Senior Vice President Sanofi Global Health Programs



15 years ago MELARSOPROL

Toxic treatment, 'fire in the veins', killed 1 in 20 patients



2009 NECT

Effective & improved therapy but hospital-based and bulky – complex logistics.



2018 FEXINIDAZOLE

A patient-centered, easy-to-use medicine, once a day for 10 days



Recommended in November 2018 by the European Medicines Agency, developed in partnership with:



Year 2023 ACOZIBOROLE – ONE DOSE FOR A CURE?

The first DNDi new chemical entity resulting from its own lead optimization programme to enter clinical development.



SLEEPING SICKNESS

Product & Impact

A **REVOLUTION** in the treatment administration : from a vertical approach with long treatment hospitalization and experienced healthcare workers to **an all oral cure which can be taken at home**

- In **DRC** only, end of 2020 :
- > **45 %** of new HAT cases treated with fexinidazole
 - > Close to **500** healthcare professionals trained to deliver Fexinidazole
 - > Close to **200** primary healthcare facilities ready to treat diagnosed patients



Efficacious for **both stages** of the disease for **adults AND children**



Fexinidazole will contribute to the elimination of the disease as a **public health problem**. Together with Acoziborole, we believe that the ultimate goal of **elimination of disease transmission** by 2030 has never been closer to realization

Ending the neglect to attain the Sustainable Development Goals

A road map for neglected tropical diseases 2021–2030
Overview



As of April 2021, in DRC, **100% of eligible patients** received fexinidazole and for the first time some patients were treated on an outpatient basis