Como garantizar acceso equitativo a tecnologías de salud para COVID-19 desde la investigación y desarrollo

Francisco Viegas

Policy Advocacy Adviser

fviegas@dndi.org

DNDi

Drugs for Neglected Diseases *initiative*

Leading institutions as founding partners

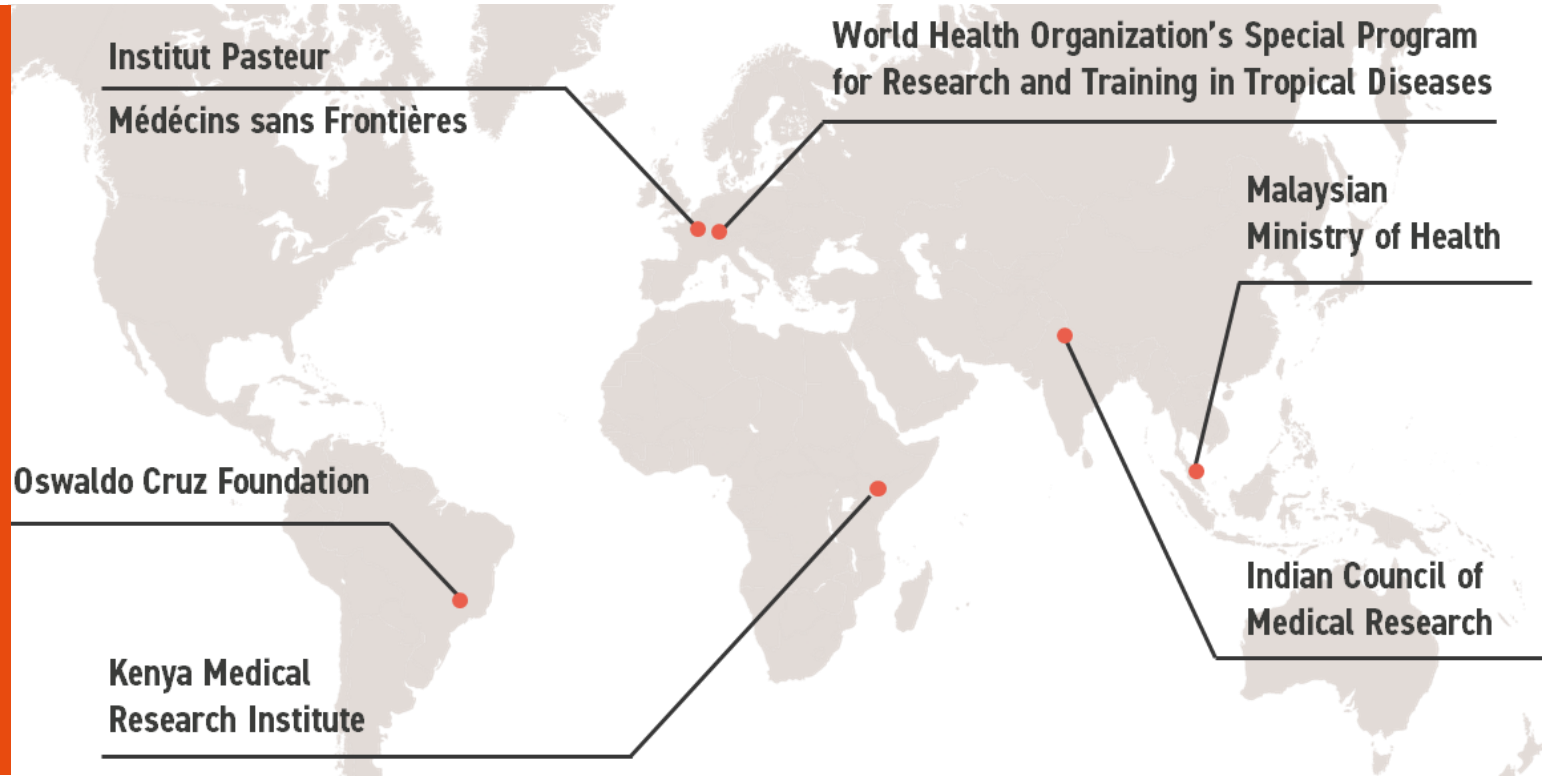
1999

- JAMA article: ***'Access to essential drugs in poor countries - A Lost Battle?'***
- **MSF commits Nobel Peace Prize** funds to the Drugs for Neglected Diseases Working Group

2003

Creation of DNDi as non-profit drug research & development (R&D) organization by

6 leading research institutions



PUBLIC HEALTH-DRIVEN R&D

DND*i* was created to address the needs of neglected patients…


SLEEPING SICKNESS


CHAGAS DISEASE


MYCETOMA


FILARIAL DISEASES


LEISHAMANIASIS


HIV


HEPATITIS C


ANTIMICROBIAL RESISTANCE

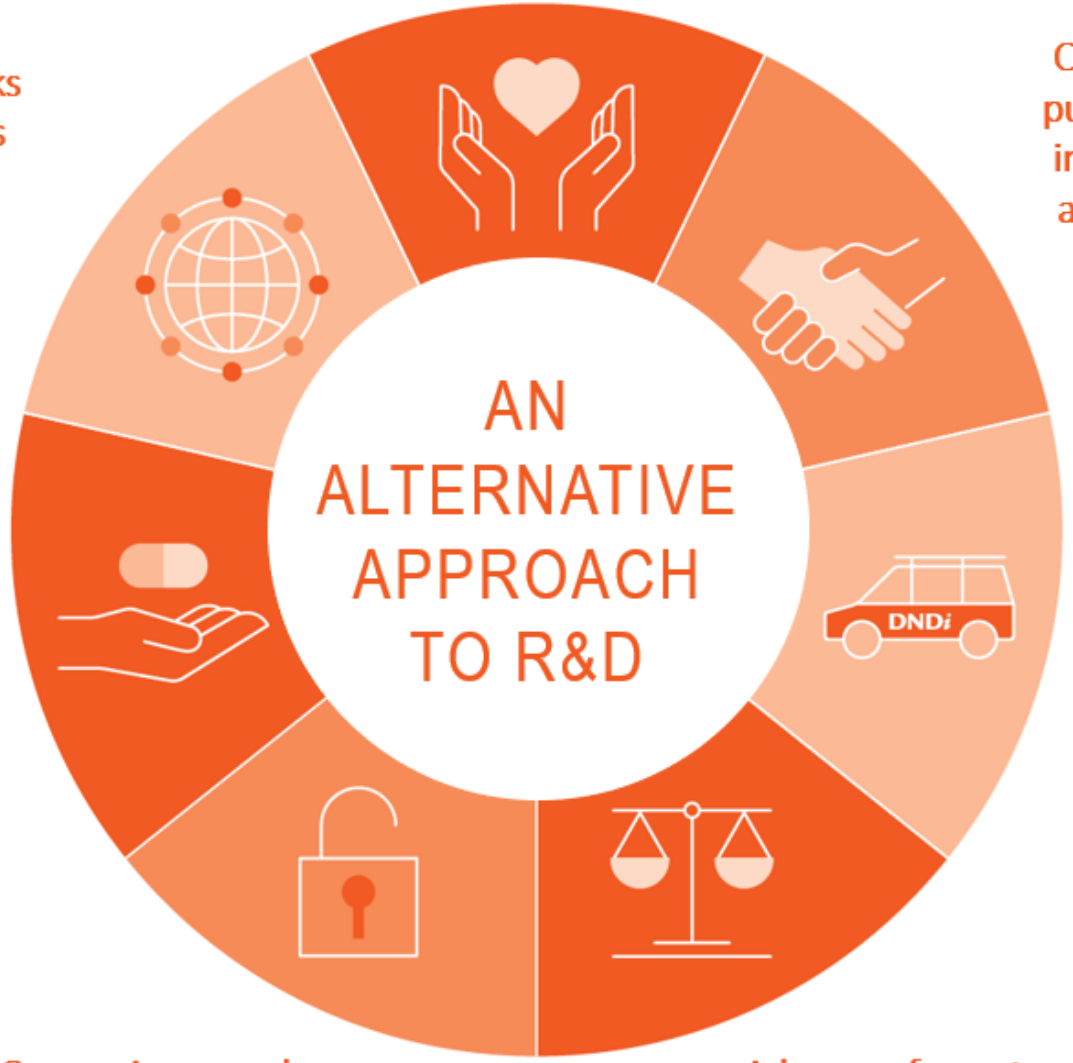

MALARIA (UNTIL 2015)

…from the laboratory bench to the bedside.

Patients – not profits – at the heart of R&D

Diverse scientific leadership with networks across endemic regions of Africa, Asia, and Latin America

Collaborations with public sector, private industry, academia, and patient groups



An R&D organization that thinks of access from end to end

Affordable and accessible treatments

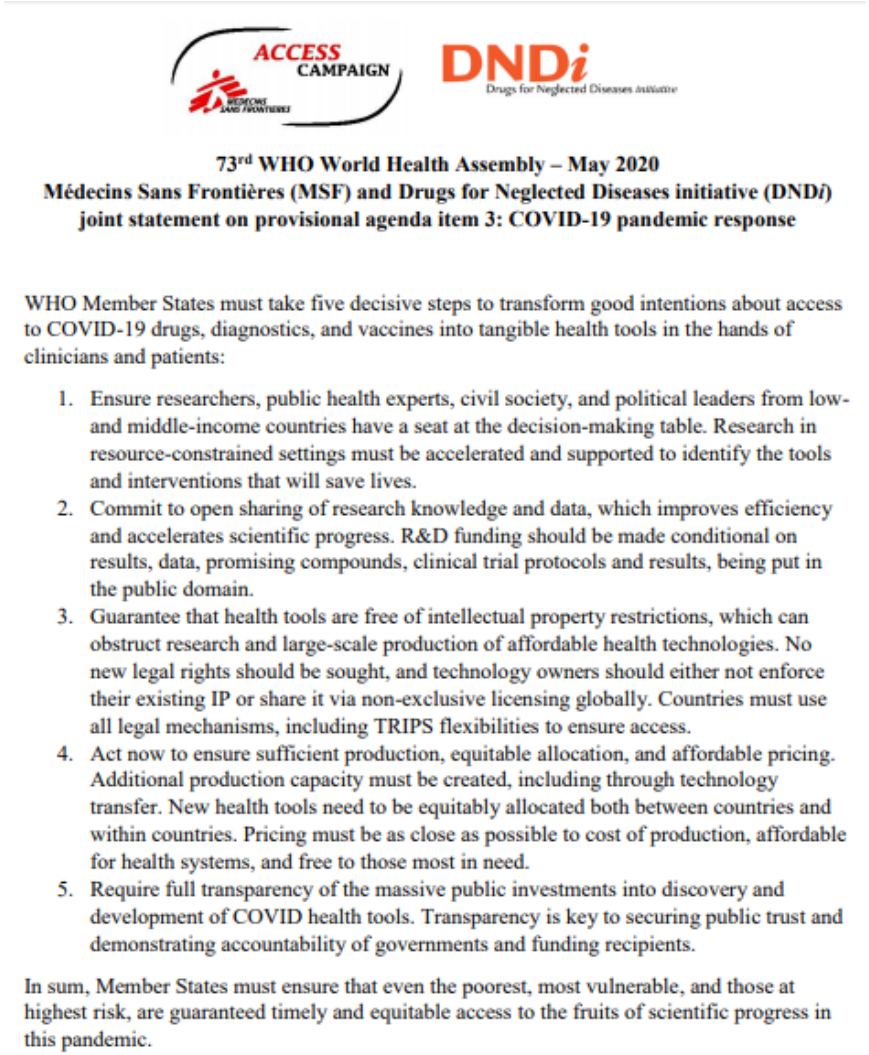
Financial and scientific independence

Open science and transparency

Advocacy for systems change in global R&D

COVID-19 main points needed for equitable access in the global response

1. Include all countries in processes
2. Sharing of knowledge, data and open innovation approaches
3. Health Technologies free of intellectual property
4. Ensure that production, distribution and allocation is sufficiently available, especially for vulnerable populations
5. Transparency of R&D costs and public investments
    1. Public resources in R&D
    2. Our populations are volunteers in most clinical trials



ACCESS CAMPAIGN — MEDECINS SANS FRONTIERES

DNDi — Drugs for Neglected Diseases initiative

73rd WHO World Health Assembly – May 2020
Médecins Sans Frontières (MSF) and Drugs for Neglected Diseases initiative (DNDi) joint statement on provisional agenda item 3: COVID-19 pandemic response

WHO Member States must take five decisive steps to transform good intentions about access to COVID-19 drugs, diagnostics, and vaccines into tangible health tools in the hands of clinicians and patients:

1. Ensure researchers, public health experts, civil society, and political leaders from low- and middle-income countries have a seat at the decision-making table. Research in resource-constrained settings must be accelerated and supported to identify the tools and interventions that will save lives.
2. Commit to open sharing of research knowledge and data, which improves efficiency and accelerates scientific progress. R&D funding should be made conditional on results, data, promising compounds, clinical trial protocols and results, being put in the public domain.
3. Guarantee that health tools are free of intellectual property restrictions, which can obstruct research and large-scale production of affordable health technologies. No new legal rights should be sought, and technology owners should either not enforce their existing IP or share it via non-exclusive licensing globally. Countries must use all legal mechanisms, including TRIPS flexibilities to ensure access.
4. Act now to ensure sufficient production, equitable allocation, and affordable pricing. Additional production capacity must be created, including through technology transfer. New health tools need to be equitably allocated both between countries and within countries. Pricing must be as close as possible to cost of production, affordable for health systems, and free to those most in need.
5. Require full transparency of the massive public investments into discovery and development of COVID health tools. Transparency is key to securing public trust and demonstrating accountability of governments and funding recipients.

In sum, Member States must ensure that even the poorest, most vulnerable, and those at highest risk, are guaranteed timely and equitable access to the fruits of scientific progress in this pandemic.

Identifying and addressing gaps in the drug development process

DEVELOPMENT STAGE		DNDi ADDRESSING GAPS	COVID-19
 RESEARCH	Curiosity-driven basic science to increase understanding of a disease, including the identification of candidate drug targets and the generation of lead compounds	▪ Target Product Profiles: needs, acceptability, quality, end-price ▪ Stakeholder involvement and public leadership from the beginning ▪ **Open, collaborative, drug discovery**	▪ TPPs public health driven? (i.e price, cold chain, etc) ▪ Public leadership? ▪ Sharing of knowledge and Clinical trials results? ▪ Open innovation?
 TRANSLATION/ Pre-clinical research	Applied research to validate candidate drugs, including lead-optimization, synthesis, dosage and stability studies, and toxicology- safety studies	▪ **Licensing terms that reduce bottlenecks, and allow access to knowledge and medicines** ▪ Multisectoral stakeholder platforms ▪ Clinical capacity-building in public and private sector	▪ Licensing for access? ▪ Research Collaboration? ▪ Transparency of protocols and results?
 DEVELOPMENT	Phase I-II-III clinical studies, bioavailability, scaling up production, regulatory review	▪ **Innovative regulatory approaches** ▪ Enable access and scale-up through working with treatment providers and communities ▪ Updated evidence-based guidance ▪ **Technology transfer (+ than one)**	▪ Sufficient tech transfer and scaling up? ▪ Allocation prioritizing vulnerable populations? ▪ Collaboration? ▪ Transparency of R&D costs and public investment?
 Regulatory approval/IMPL EMENTATION	Surveillance, reporting adverse events, production and distribution, etc.		

COVID-19 CLINICAL RESEARCH COALITION

Facilitating and accelerating research in resource-limited settings

COVID-19 Clinical Research Coalition

DND*i* initiated the
COVID-19 CLINICAL RESEARCH COALITION
in April 2020 to fast-track research on prevention, diagnosis, and case management specifically in resource-limited settings.

DNDi R&D costs

Minimum and maximum costs from discovery to registration for projects in DND*i*'s portfolio, given as out-of-pocket costs and adjusted for standard attrition (in millions of euros, minimum and maximum costs per phase)

Transparency and accountability

	Discovery & pre-clinical	Clinical development & registration		Total	Range of costs, with attrition
		Phase I	Phases II & III and registration		
Existing drugs without new formulation*	Not applicable		€4-10	**€4-10**	**€4-12**
Existing drugs with new formulation*	€1-2	€1-4	€3-7	**€4-13**	**€5-32**
New chemical entity	€10-20	€4-6	€30-45	**€44-71**	**€60-190**

*Combinations (as loose or fixed-dose combinations) or repurposing of existing drugs

Final remarks

- Equitable access can and must be prioritized from the outset of any R&D project, particularly in a pandemic
- More open innovation, collaboration and sharing of clinical trial data, both positive and negative
- All countries should engage in global discussion to enable equitable access
- Allocation of Public funds and contracts should be transparent, and strings attached for public interest, including transparency of R&D costs
- Tech transfer and removal of IP barriers should be the norm, particularly in a pandemic, to ensure sufficient production

Thank you!

fviegas@dndi.org

Twitter: @franciscoA2M

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