April 13th, 2023 - Geneva

Rising Pharmaceutical Innovation in the Global South: Painting with New Colors

OSUN Research Collaboration on Technology, Equity and Right to Health - Medicines

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Rising Pharmaceutical Innovation in the Global South: Painting with New Colors

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Introduction

Context:

Scarce information on existing activities, capacities, and outcomes of pharmaceutical innovation in low- and middle-income countries (LMICs)

Objectives:

1. To provide a baseline picture of pharmaceutical innovation in LMICs.

2. To identify possible alternative R&D models being implemented in LMICs.

Methodology:

- Literature review
- Scoping interviews
- Database analysis
- Innovative proposals of R&D

Literature review and Scoping interviews

Most active LMICs

- Growing activity in pharmaceutical innovation in developing countries
- Mostly only a few LMICs - China, India, Brazil, South Africa, and Cuba

Innovation pathways

- "Imitation to innovation"
- Funding and cumulative capacity for R&D from production and sale of generics & research services
- Reduced policy space due to international agreements restricting access to information, knowledge, and technology

Government role and R&D funding

- Limited private capital
- Significant government funding and support
- Philanthropic funding and development assistance

R&D policies

- Policies linking R&D capacity, technological and industrial development, and public health needs
- Mandatory local manufacturing policies
- Clinical trials to be conducted domestically
- Low political priority, especially beyond UMICs

Literature review and Scoping interviews

Actors involved in pharmaceutical R&D

- Role of academic institutions and SMEs
- Gaps in translational research
- International collaboration

R&D priorities

- Addressing local needs and improving ease of use
- Risk of private sector not addressing diseases mostly affecting “poor market segments”

Challenges and barriers

- Lack of financial and human resources
- Research infrastructure
- Targeted policies
- Regulatory issues
- Limited pharmacovigilance

Literature review and Scoping interviews

Outputs

Table 1. Examples of pharmaceutical products developed in LMICs

Outputs

- 23 products, from 7 LMICs - Brazil, China, Cuba, Egypt/Malaysia, India, Russia
- Drugs, biologics and vaccines, plant-based medicines, diagnostics platforms, monoclonal antibodies, and gene therapies
- To treat several diseases, including NTDs, infectious diseases, HIV, tuberculosis, meningitis, viral hepatitis, diabetes, antibiotics, and cancer.
- Developed by private companies, public and private universities, public research centers, and state-owned institutions, as well as in collaboration with global initiatives

Database analysis

Data

WHO Global Observatory on Health Research and Development

- World RePORT
- G-FINDER
- WHO International Clinical Trials Registry Platform (ICTRP)

Indicators

- Funding flows
- Health research capacity
- Clinical trials

*Two files with supplementary data used for the analysis of clinical trials are available online.

Database analysis:
Funding flows and R&D capacities

Data: WHO Global Observatory on Health Research and Development

Highest percentage of GDP invested in health GERD:

UMICs: South Africa 

LoMICs: Kenya 

LICs: Mozambique 

Highest number of health researchers per million inhabitants:

UMICs: Bulgaria 

LoMICs: Egypt 

No LICs in top 10 countries

Database analysis:
Funding flows and R&D capacities

Data: World RePORT by NIH

LMICs with the highest number of research grants for biomedical research:

South Africa 

China 

Kenya 

LMICs with the highest number of research organizations receiving grants:

UMICs: China, South Africa, Brazil 

LoMICs: India, Kenya 

LICs: Uganda, Malawi 

Database analysis:
Funding flows and R&D capacities

Data: G-FINDER, R&D funding for diseases “that disproportionately affect the world’s most disadvantaged populations”

From 2010 to 2020, there was **an increase of more than 450%** in the total amount funded by **MICs**.

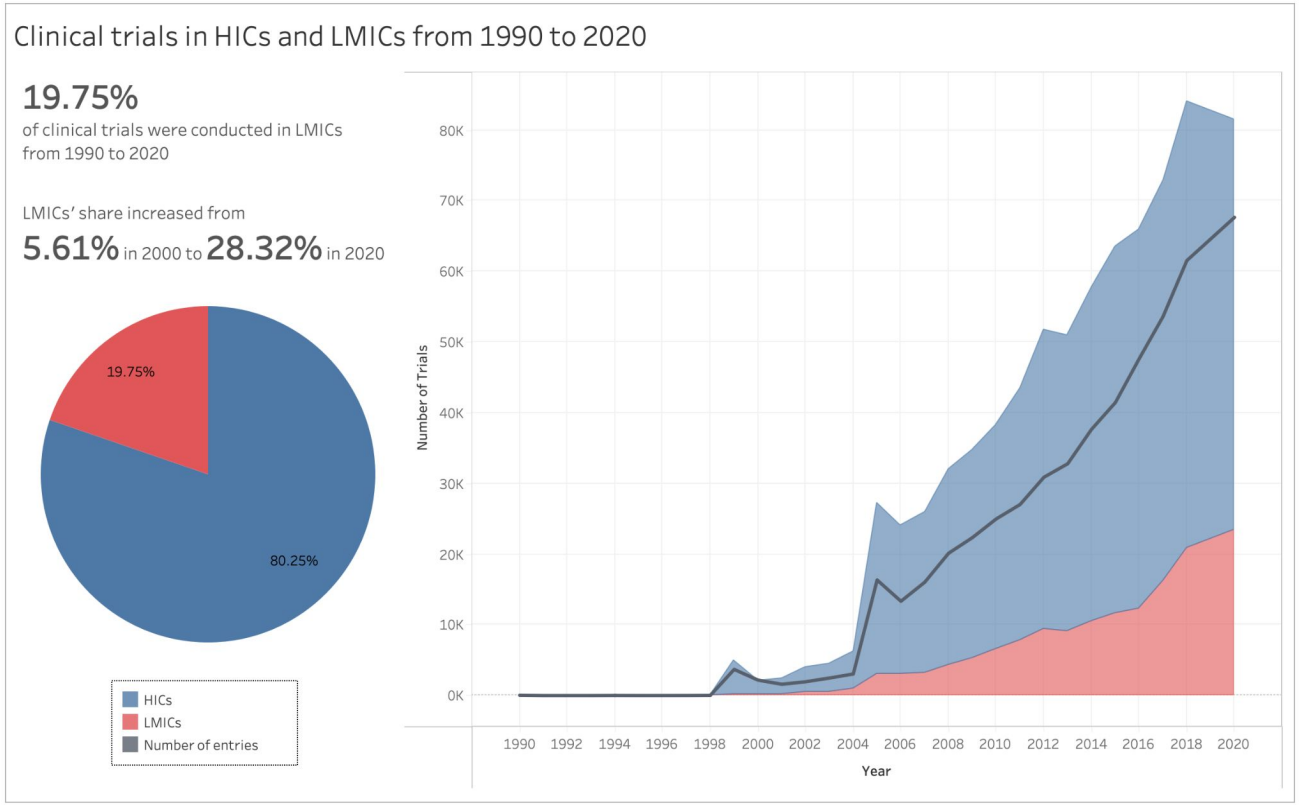
Funding from **LICs** remained roughly the same.

Among LMICs:

The most significant public funder: **India** 

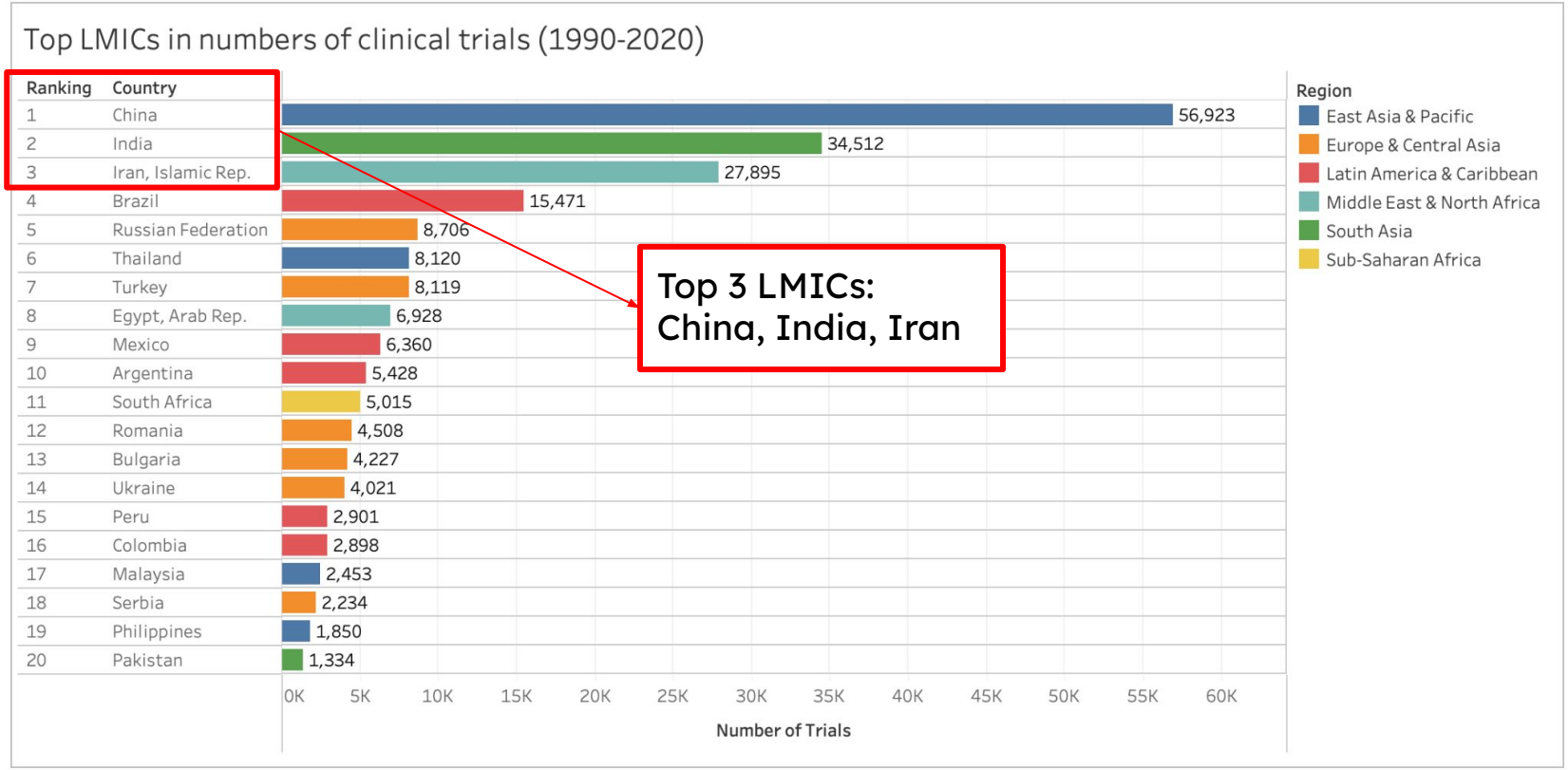
The top receiving countries: **India and South Africa** 

Database analysis:
Clinical Trials - Number of Trials



From 2010 to 2020, the number of trials in LMICs increased by **375%.**

Database analysis:
Clinical Trials - Number of Trials



Database analysis:
Clinical Trials - Phases

The largest numbers of trials were in **phase 3** in both HICs and LMICs.

Most of the top 20 LMICs had a relatively larger number of **phase 2 and phase 3 trials**.

China had a significant share of **phase 0 and phase 1** trials;

India had a significant share of **phase 1** trials.

A significant **increase in phase 0 trials** in LMICs from 2010 to 2020.

Egypt and **Thailand** showed significant growth in earlier stages R&D.

Indicating growing capacity in the riskier, more innovative, earlier stages of R&D in LMICs

Database analysis:
Clinical Trials - Type of Diseases

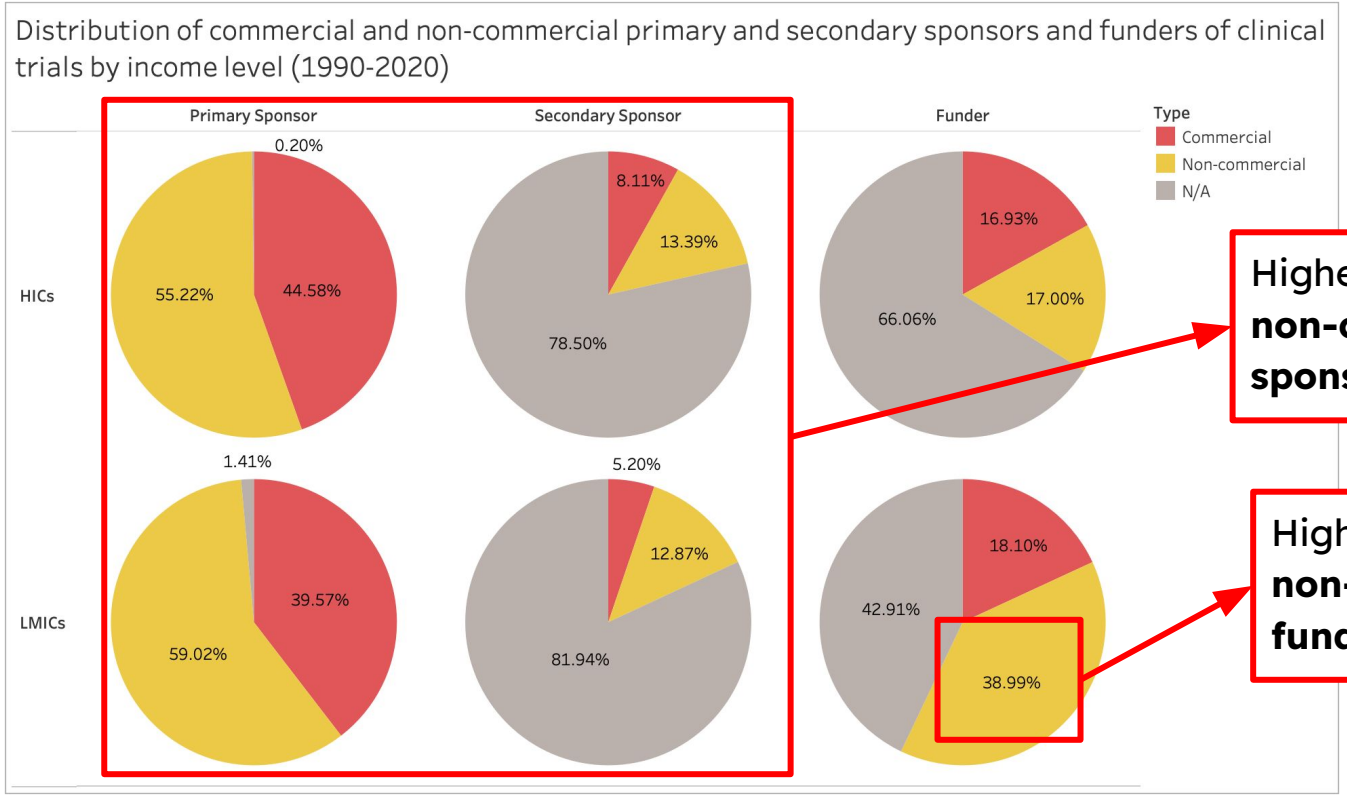
The largest numbers of trials were for **malignant neoplasms** in both HICs and LMICs.

Infectious and parasitic diseases represented only about 5% of trials in HICs, and **9% in LMICs.**

A significant **increase** in trials for:

- **Respiratory diseases** (all countries)
- **Non-communicable diseases** (LMICs)
- **Congenital anomalies** (LMICs)

Database analysis:
Clinical Trials - Type of Sponsors / Funders



Higher number of **non-commercial sponsors**

Higher number of **non-commercial funders** in LMICs

Database analysis:
Clinical Trials - Type of Sponsors / Funders

Roles of **non-commercial** actors:

- **Increasing involvement** of non-commercial sponsors and funders over the past years, particularly in the **early R&D phases.**

- Non-commercial actors played a markedly dominant role in some areas, such as **maternal conditions**, **sexual health**, **perinatal conditions**, and **nutritional deficiency**

Innovative proposals of R&D

WHO/CEWG - 2013

- 52 of the 106 project proposals
- Submitted by governments, public research institutes, and universities
- 34 proposals from 23 LMICs

- Important role of non-commercial actors
- Willingness to take alternative approaches to R&D in LMICs

Table 9. List of LMICs with organizations that submitted proposals of projects of innovative R&D to the WHO

African Region	Asian Region	Latin American Region
Ethiopia	Bangladesh	Bolivia
Kenya	India	Brazil
South Africa	Indonesia	Colombia
Sudan	Malaysia	Costa Rica
Tanzania	Sri Lanka	Cuba
Zimbabwe	Thailand	El Salvador
		Ecuador
		Guatemala
		Peru
		Venezuela

See also Appendix 5.3. List of proposals submitted by organizations based in LMICs

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Discussion and conclusions

- Broad picture of who was involved in pharmaceutical R&D in LMICs, in which countries, for which diseases, in which R&D phases, and with what results – and changes over time
- Growing investment in R&D, particularly from MICs
- Growing capacity - increase in the number of research organizations and the amount of funding received
- Growing number of clinical trials, including in the earlier, more innovative and riskier phases
- Very significant and growing role of non-commercial funders and sponsors
- High number of non-commercial actors suggests fertile soil for alternative R&D models in LMICs that are not driven primarily by market incentives

Top 16 LMICs involved in pharmaceutical R&D			
Brazil	Cuba	Iran	Russia
Bulgaria	Egypt	Kenya	Serbia
China	Georgia	Malaysia	South Africa
Colombia	India	Mozambique	Uganda

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