

**Advancing knowledge-led
development through the
right to science in Africa**

11 November 2019
Addis Ababa University - School of Law

The State of Clinical Trials in Africa

Tsige Gebre-Mariam (Prof.)
School of Pharmacy
College of Health Sciences
tsige.gmariam@aau.edu.et

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Summary

Access to Medicines – a matter of human right

Health



UN Human Rights Symbol

Health is

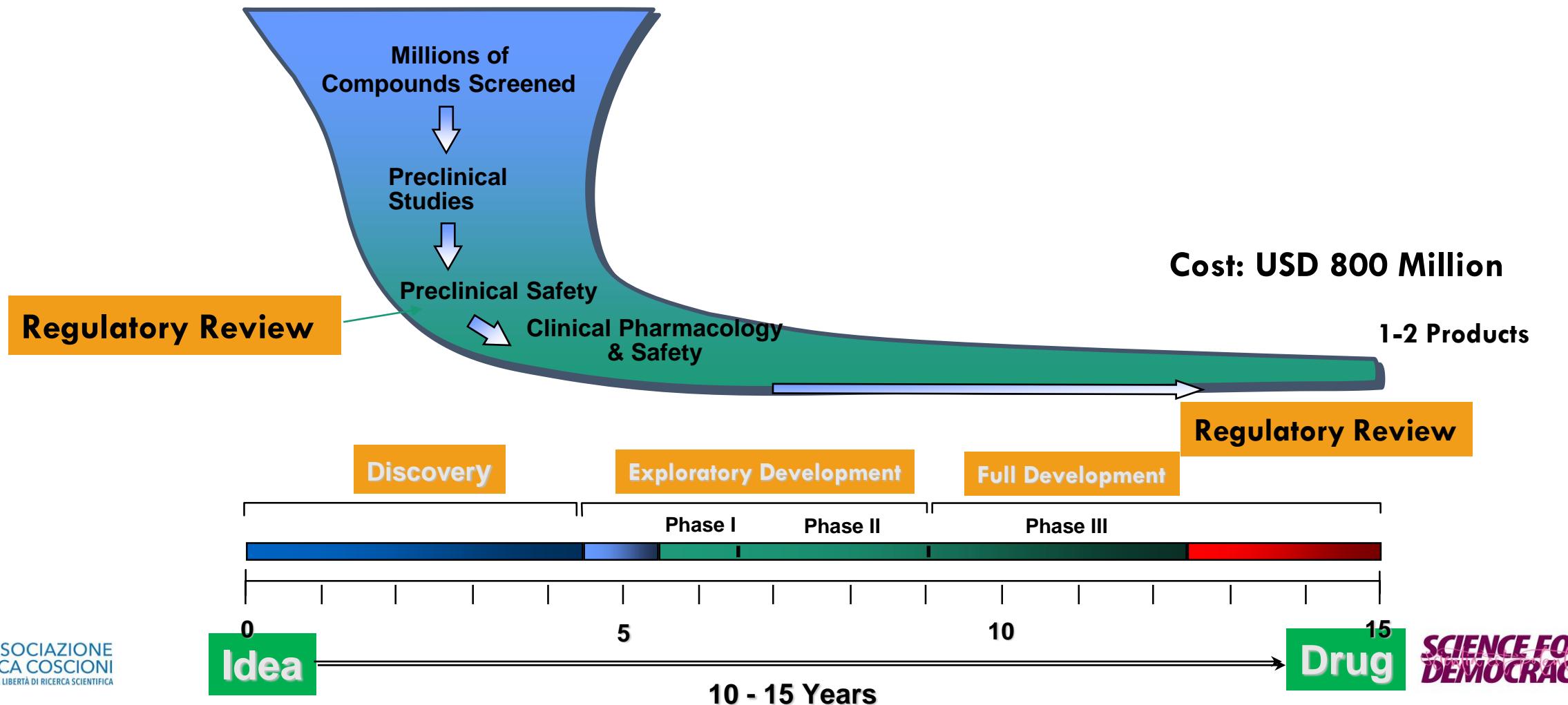
- basic Human Right
- Vital for the use of other rights, particularly the right for development
- indispensable to have life with dignity

Access to safe, effective and quality medicines is the main component of the right to health

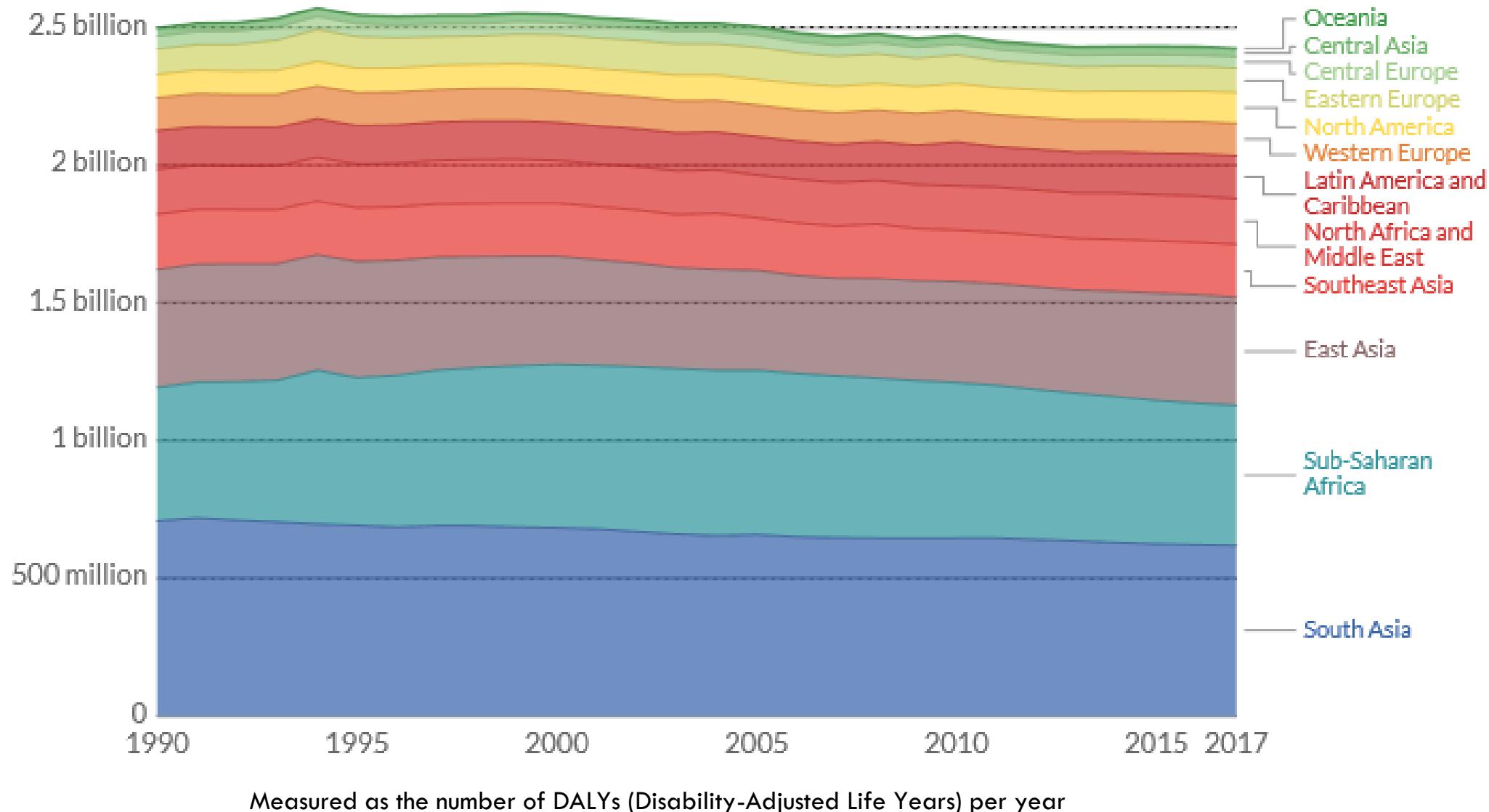
Why Clinical trials?

- Important step in discovering new medicines
- Establish the safety and efficacy of medicines
- Detect, diagnose, and reduce the risk of disease
- Weigh benefits against risks

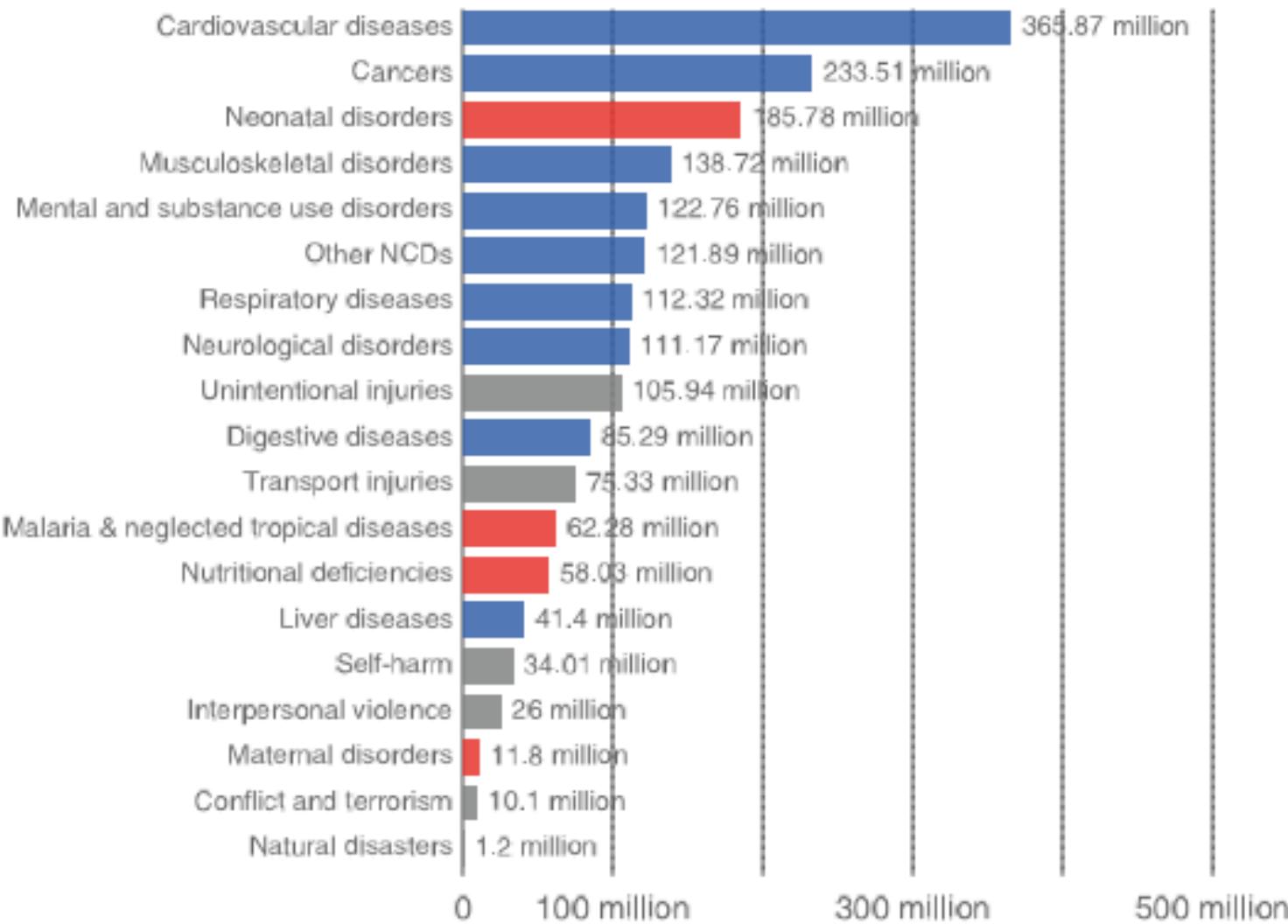
Timelines for standard drug development



Global Disease Burden

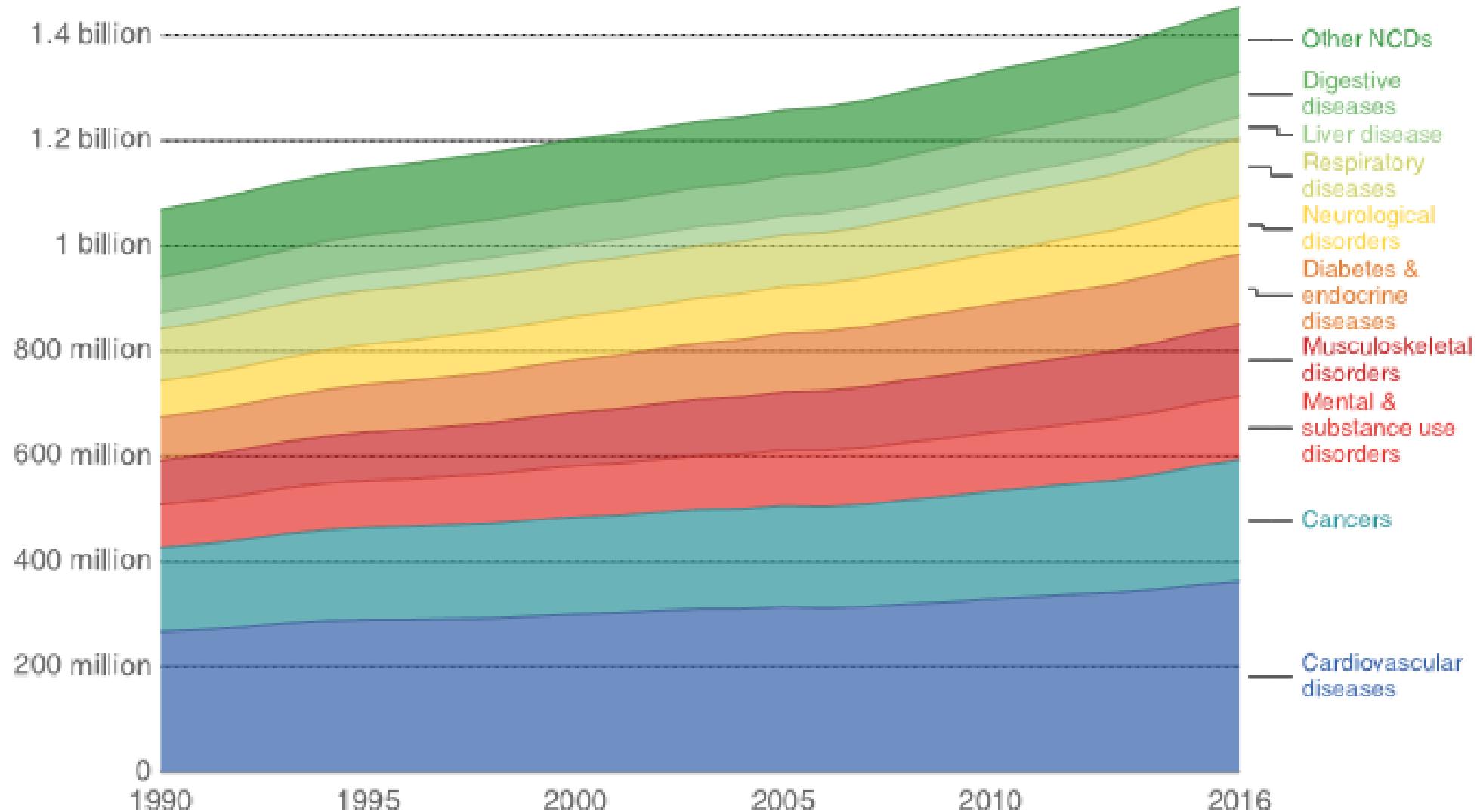


Global Disease Burden by Cause, 2017



Source: *Institute for Health Metrics and Evaluation (IHME), Global disease burden, 2017*

Global disease burden, Non-communicable diseases



Source: Institute for Health Metrics and Evaluation (IHME), Global disease burden, 2017

Africa – The dual burden of disease

Communicable diseases

- HIV/AIDS
- TB
- Malaria
- Diarrhoea
- Hepatitis
- Dengue
- Emerging diseases (Ebola virus, Zika virus), etc.

Non-communicable diseases

- Cancer
- Cardiovascular diseases
- Chronic respiratory diseases
- Diabetes mellitus
- Mental health
- Chronic renal diseases

European & Developing Countries Clinical Trials Partnership (EDCTP)

- Collaborative clinical research between 15 European & 30 SSA countries



- Reduce the individual, social and economic burden of poverty-related infectious diseases in sub-Saharan Africa
- To enhance research capacity / clinical trials and accelerate the development of new or improved medical interventions for the identification, treatment and prevention of poverty-related infectious diseases

Global Participation in Clinical Trials, FDA, 2015/16

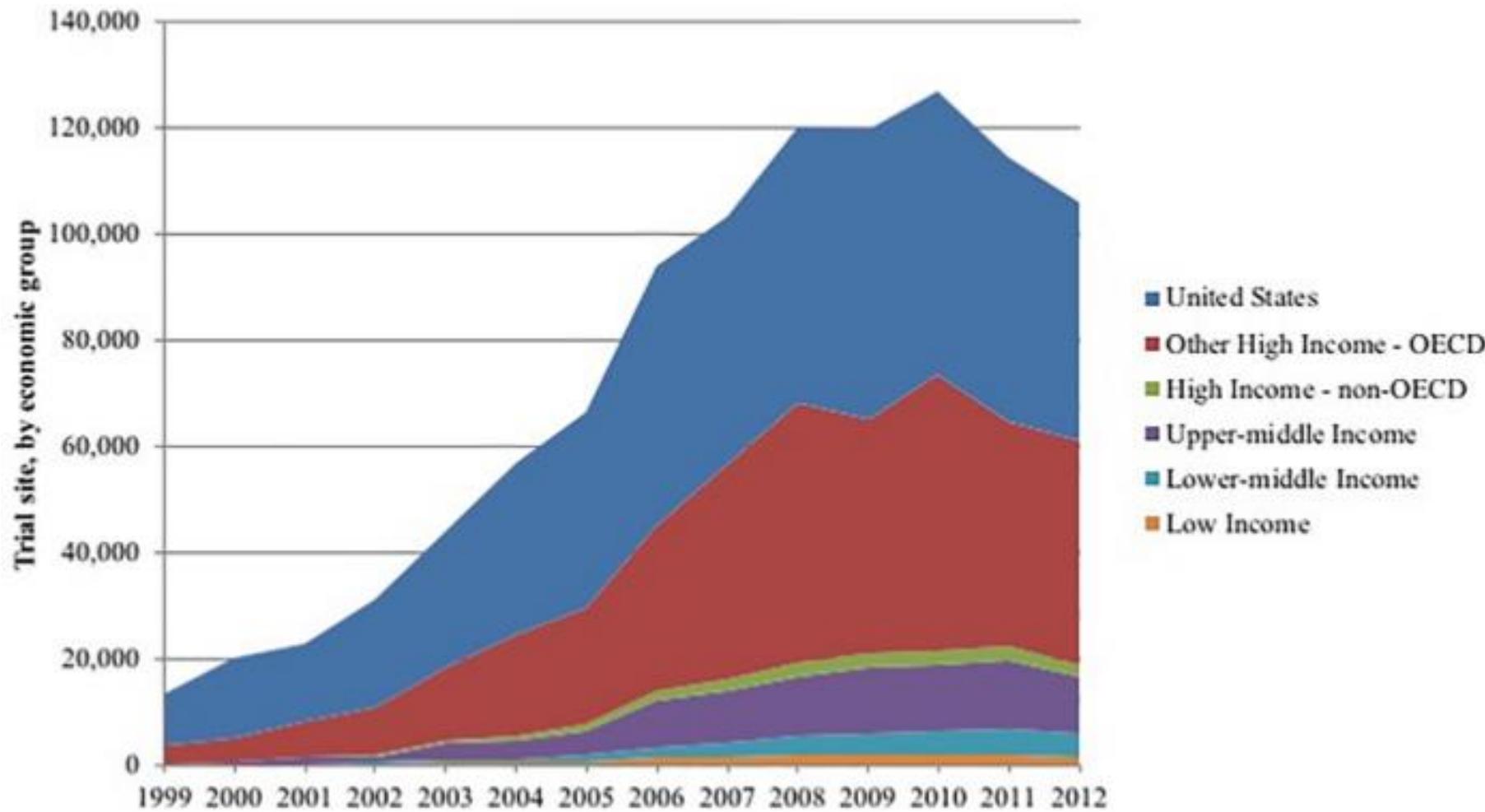
Where are Participants From?

The country contributing the most clinical trial participants was the United States. Compared to the population of the entire world (7.4 Billion), the US (0.35 Billion) makes up a little more than 4% of the world population.

United States
Rest of World

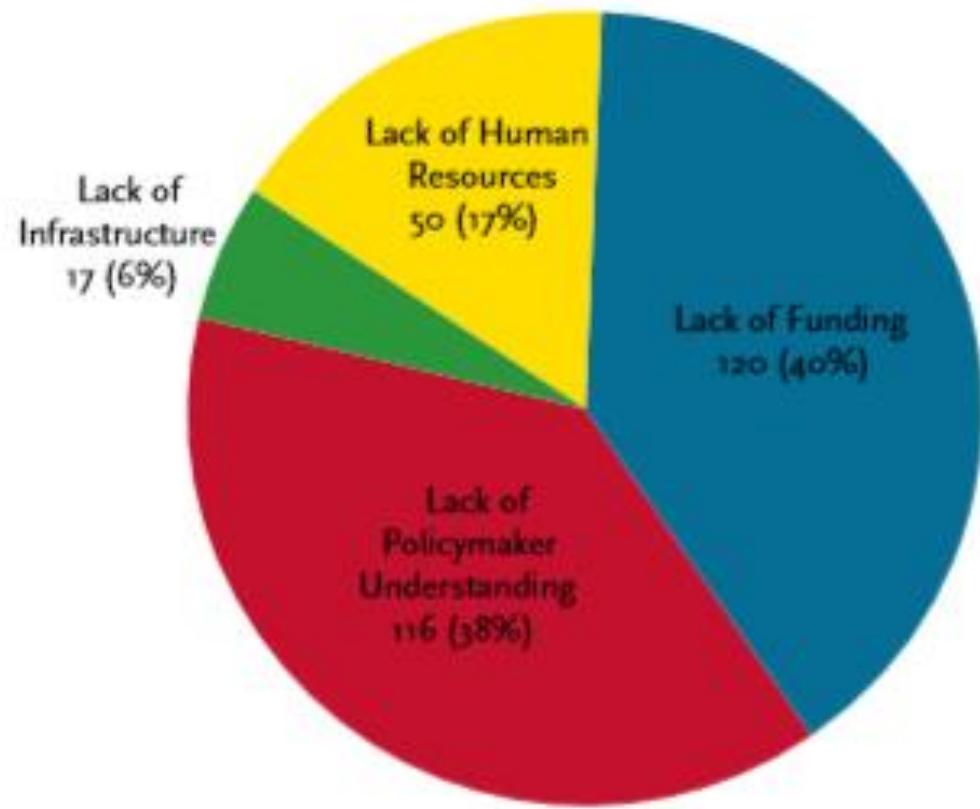


Global Migration of Clinical Trials



Source: Drain et al (2018), PLOS ONE |, February 28, 2018

Barriers for Conducting Clinical Trials in Africa



Source: *Africa Mapping, Current state of health research on poverty-related and neglected infectious diseases in SSA, EDCTB, 2012*

Barriers include:

- Lack of HRs - Few skilled clinical researchers
- Lack of infrastructure, research environment
- Lack of funding
- Ethical and regulatory system obstacles
- Operational barriers and
- Competing demands.

Source: Alemayehu et al. (2018), *Int. J for Equity in Health*, 17:37

Africa Increasingly Attracting Clinical Trials

Africa is increasingly attracting the global pharma industry

Reasons:

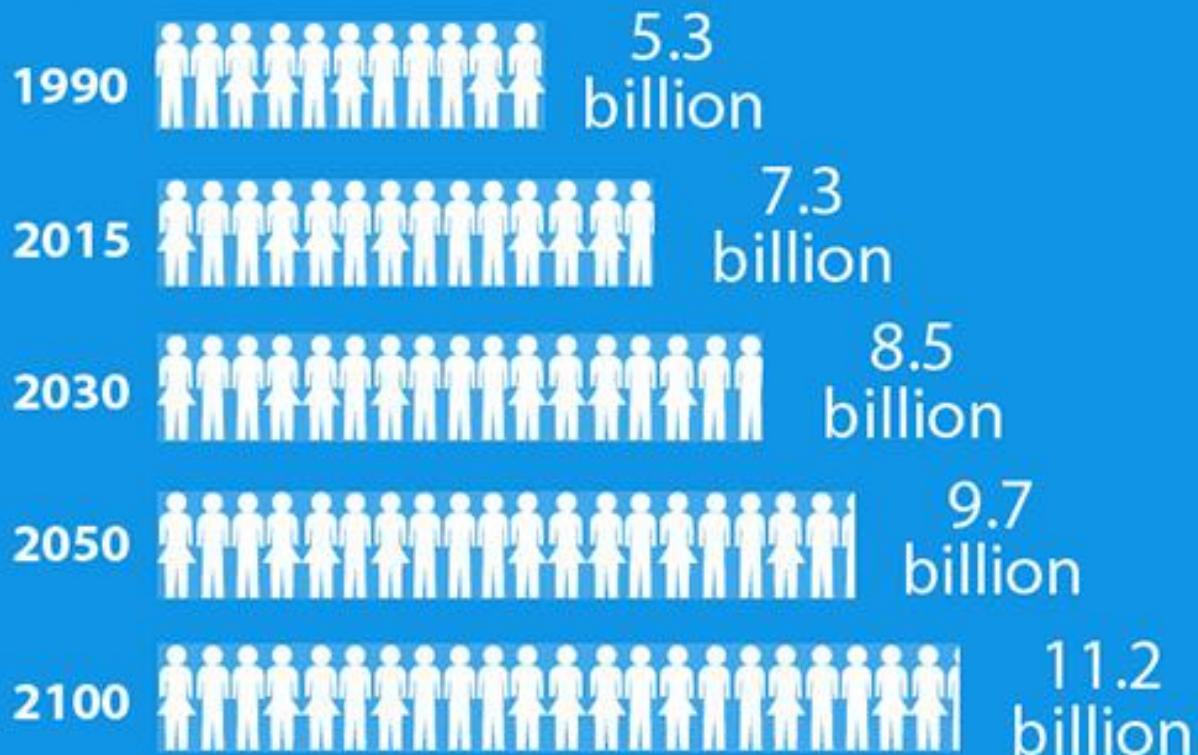
- Faster and cheaper recruitment of clinical trial participants
 - High level of disease burden
 - Limited access to healthcare - ensure steady stream of participants
 - Epidemiological transition
 - Fast-growing population
 - Rapid economic growth
 - A rising middle class

Source: *Clinical trials in Africa- The cases of Egypt, Kenya, Zimbabwe and South Africa*, Wemos Foundation, July 2017

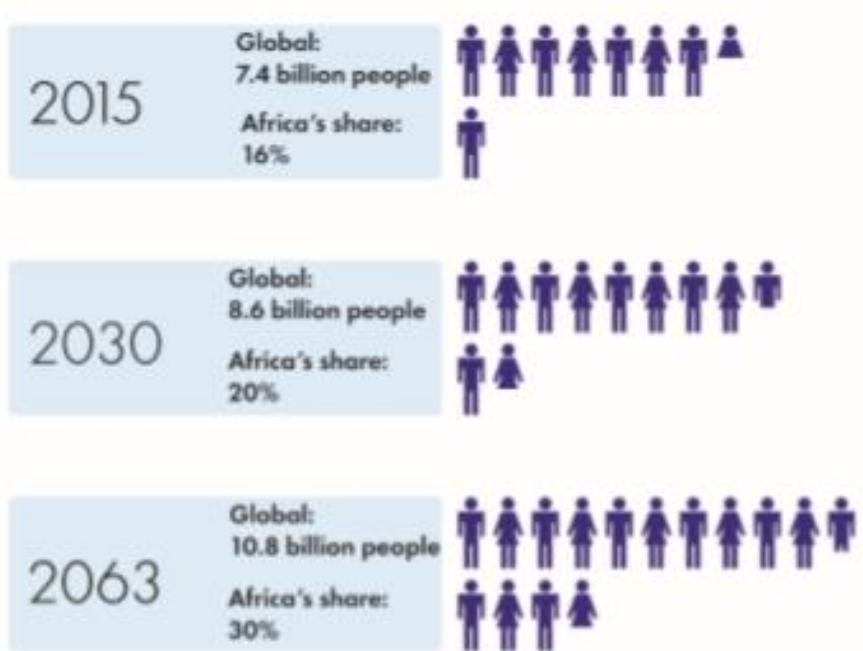
Africa – Population

World Population

Projected world population until 2100



Source: United Nations Department of Economic and Social Affairs,
Population Division, *World Population Prospects: The 2015 Revision*
Produced by: United Nations Department of Public Information



Clinical Trials in Africa: Concern

Case studies in some African countries indicate:

- No unified legislation on clinical trials
- Lack of capacity to monitor clinical trials
- Institutions involved in clinical trials are underfunded and there is no public scrutiny
- Easy to get treatment naïve people who want to access medical care

Source: *Clinical trials in Africa- The cases of Egypt, Kenya, Zimbabwe and South Africa*, Wemos, Health Unlimited, 2017

Development in Clinical trials Regulation

- The African Vaccine Regulatory Forum (AVAREF), a network of National Regulatory Authorities (NRAs) and National Ethics Committees (ECs), was established in Africa in 2006 by the WHO to strengthen the regulation of clinical trials
- However, the assessment of various NRAs led by the WHO with the global benchmarking tool revealed that different NRAs are at different maturity levels.
- The mandate AVAREF was extended beyond clinical trials for vaccines to ALL medical products subject to clinical trials and developed harmonized Tools for Clinical Trial Regulation in Africa which is now in place.

Source: <https://globalforum.diaglobal.org/issue/december-2018/harmonized-tools-for-clinical-trial-regulation-in-africa-are-imminent/>

Summary

- Access to medicine is a matter of human right
- Drug development is time taking and quite expensive
- Local production of quality pharmaceuticals should be strengthened
- Clinical research in Africa should receive due attention
- Africa is increasingly attracting the global pharma industry
- Africa should develop capacity in clinical trials
- Harmonized clinical trials protocols, guidelines and procedures should be in place

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Thank You

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