Meaningful engagement of sites and investigators in under-represented regions

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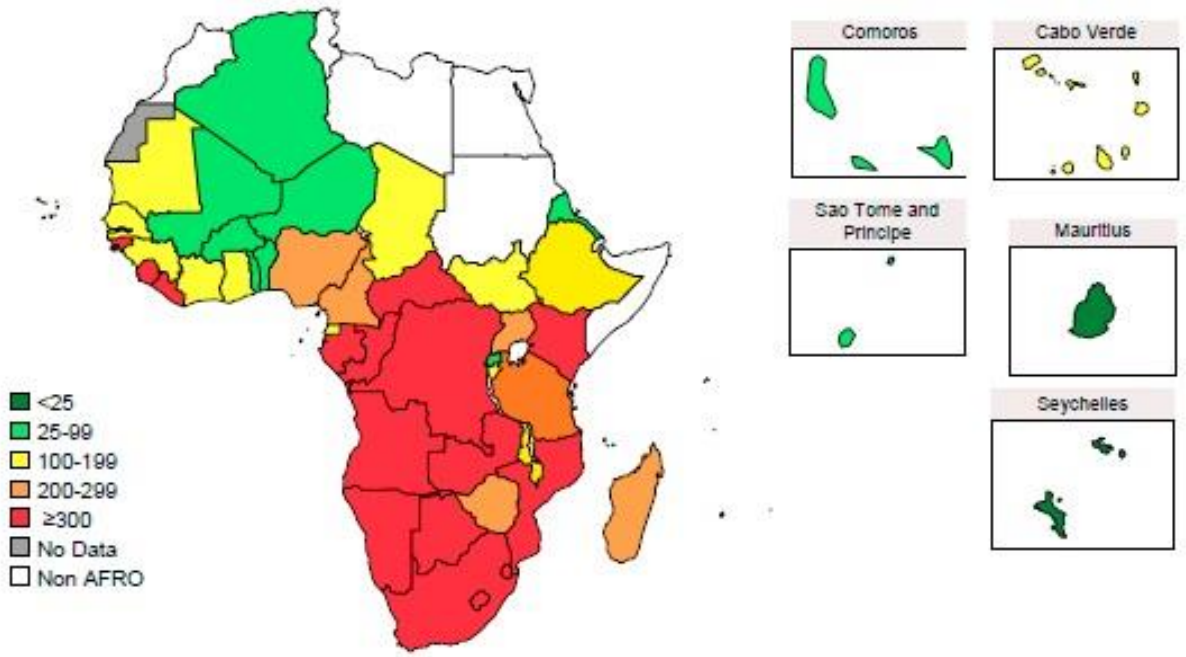
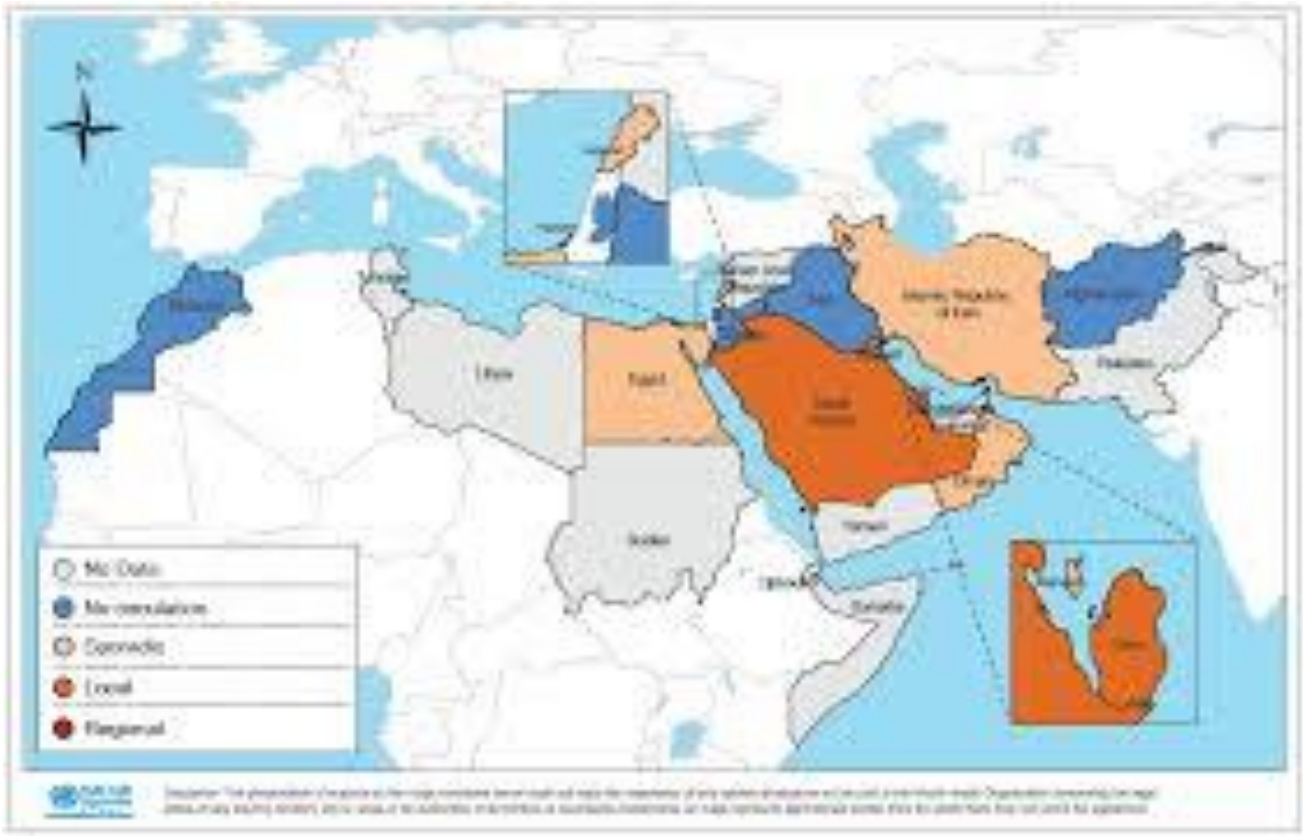
The “EMRO” (East Mediterranean Region) : one of the six geographical areas created by the WHO. Stretching from Morocco to Pakistan, and if we add Algeria, it covers **22 countries** and represents a **population of nearly 630 million.**

The Middle East, Mediterranean, Africa (MEMA) region, with the WHO AFRO (left panel) and EMRO (right panel) countries.



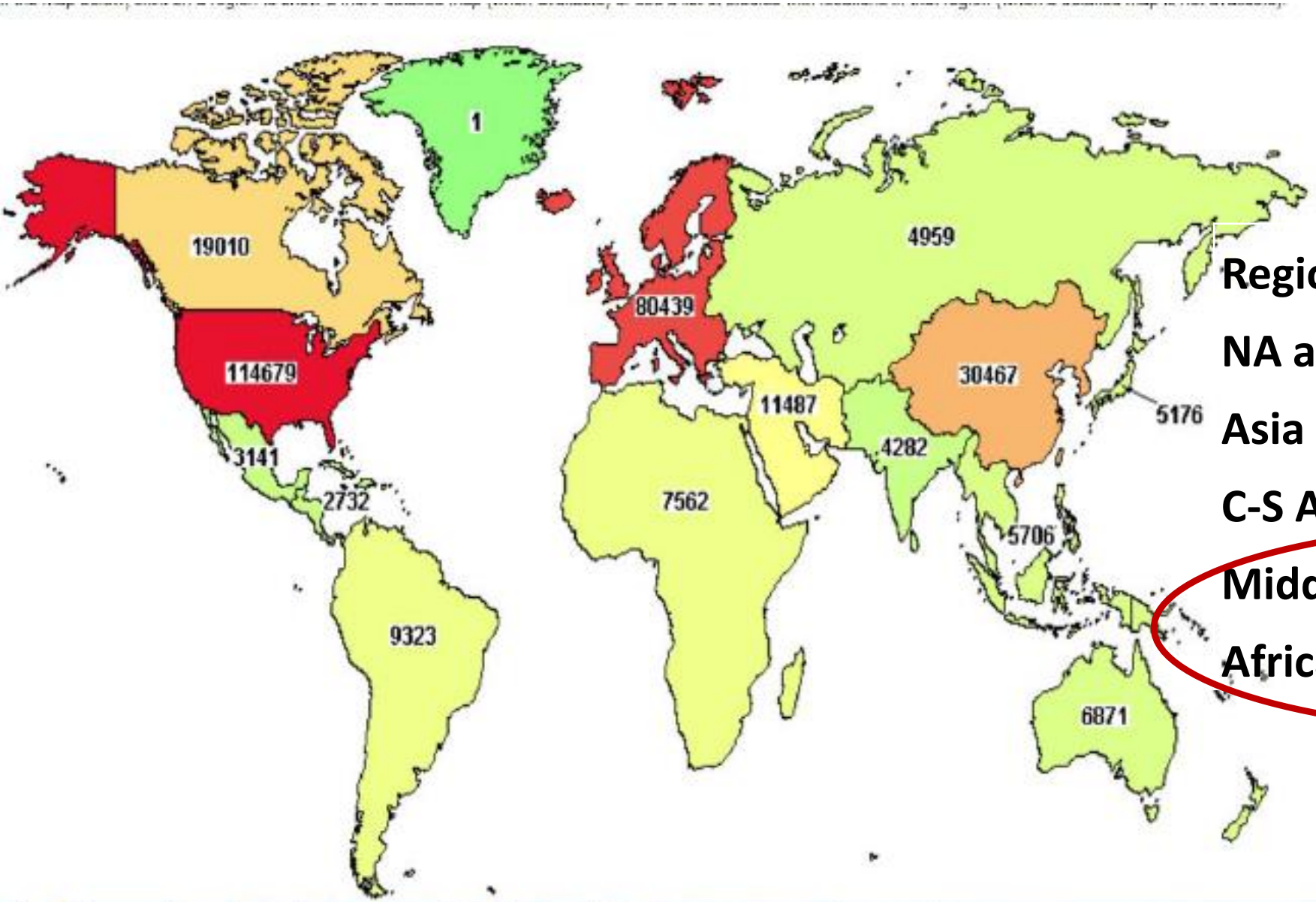


68 countries, totalling a population of over 1.6 billion i.e 20% of the world.

Current situation of Clinical Trials in MENA

- Small contribution from the Region to the international effort of knowledge production
- The region rather a consumer of knowledge, not much a producer
- International collaborations are built on one way benefit
- Healthcare policy lacks good quality local genuine health data

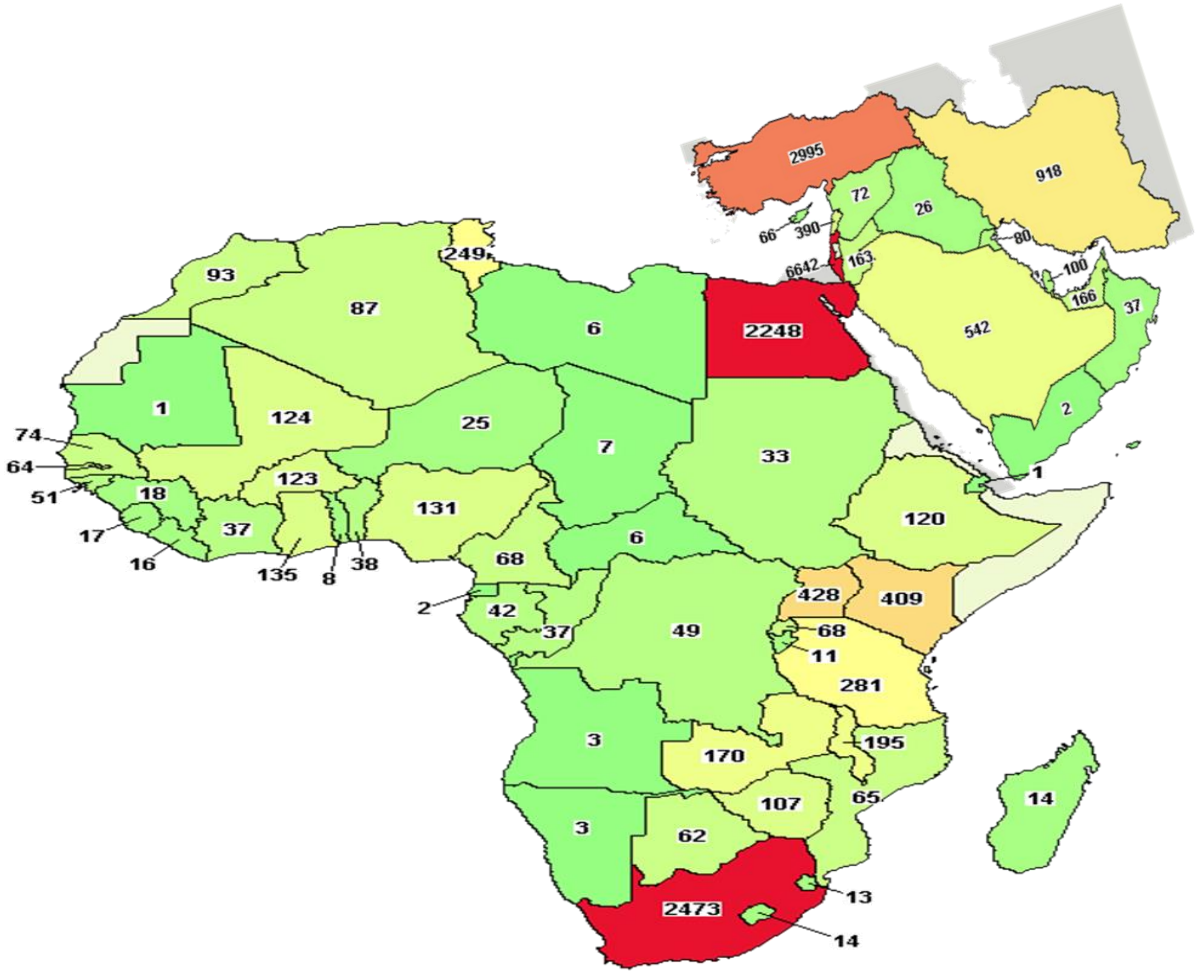
Global distribution of clinical trials



Region	N of CT	%
NA and EU	214128	**70%**
Asia	57460	**18.7%**
C-S America	15196	**4.96%**
Middle East	11487	**3.75%**
Africa	7562	**2.5%**

Source: Clinicaltrials,gov

Clinical Trials in Africa – Middle East



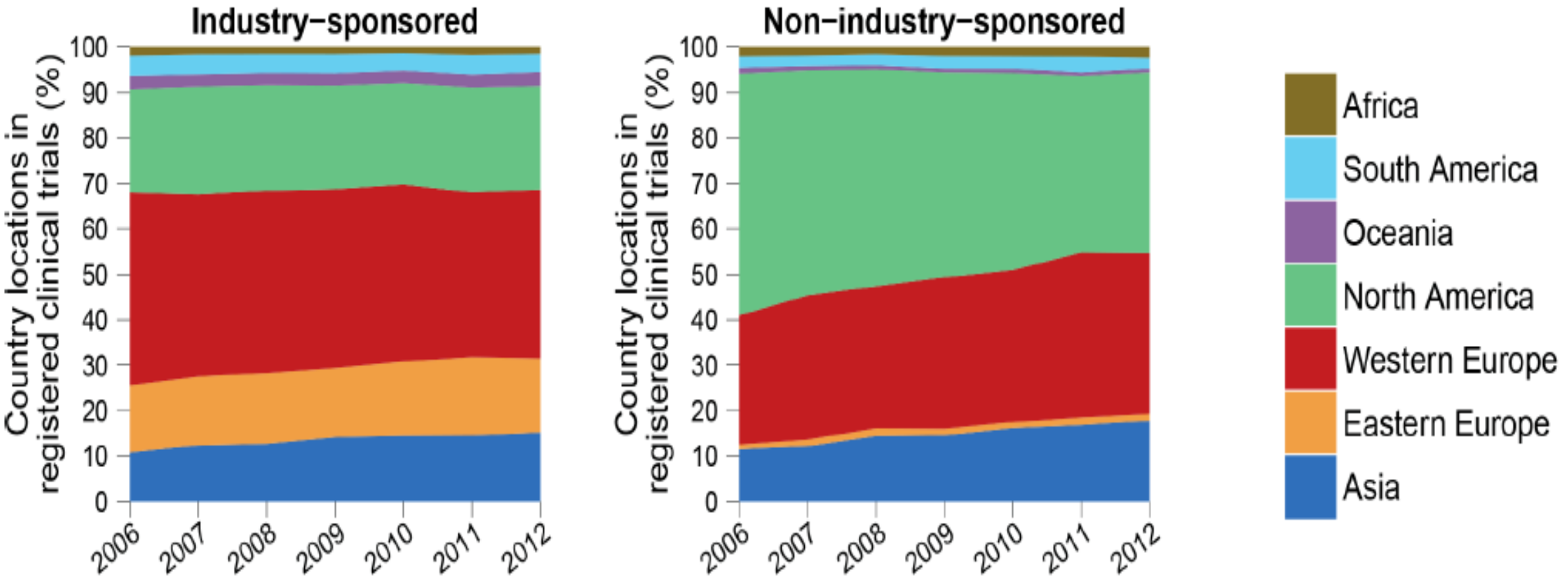
Africa and MENA

20% of world population

involved in **6.5%** of Clinical trials

Source: Clinicaltrials,gov

The annual distribution of country trial locations (Clinical trials initiated between 2006 and 2012)



20% of the world → **6% of the worldwide registered trials**

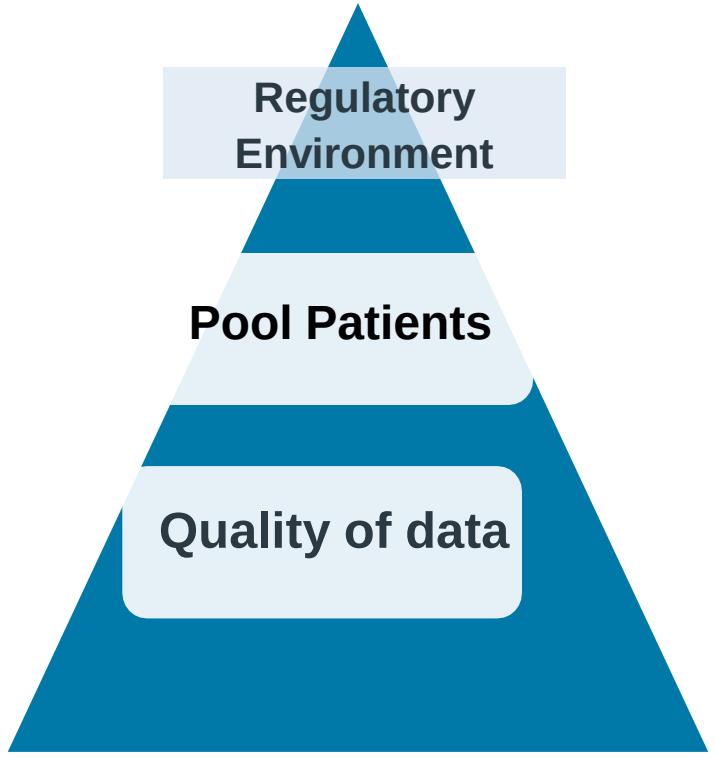
The Paradox …

Low and Middle Income countries:

80% of disease burden in LMIC but < 10% of research conducted in these settings

Attractive Factors for Conducting CTs in a Country

- Efficient administrative and regulatory system
- Short delay of validation
- Experienced centers
- Adequate/ Rapid enrollment
- Adequate research infrastructure
- High quality follow-up
- Smooth import /export procedures
- Favorable political environment



Weaknesses

- Cultural gaps (“Why do we need research”?)
- Low access to tech, including to ICTs
- Unequal distribution of health research professionals
- Few research networks
- Lack of rigorous evaluation
- Lack of HQP (Physicians, other scientists, statisticians…)
- Challenging political environment

Challenges

- Collaborations with international research institutions and physicians is:

  more frequently based on exploitation of Africa – Middle East scientists (brain drain), cohorts and valuable biobanks,

- Industry view the Region as the next frontier in global health business, but not necessarily in global health research

Challenges

- ***National*** and ***regulatory*** barriers
- ***Structural***: Lack of career and job opportunities for those wanting a career that is largely research
- ***Institutional***: No protected time, Large teaching and clinical loads, lack of credit for research productivity, Need new and special career tracks for researchers.
- ***Local and national***: Lack of support / infrastructure to initiate small projects

How should be the collaboration with LMIC ?

- A ***real commitment*** to long term training and mentoring and building local capacity
- Addressing questions of local interest and importance
- PI or co-PI from LMIC (with close support from HIC)/DSMB
- Work together every step of the way, to learn of local challenges and find context specific solutions.
- Share leadership on key publications
- Help develop new studies
- Avoid “brain drain”
- Establish long friendships and collaborations

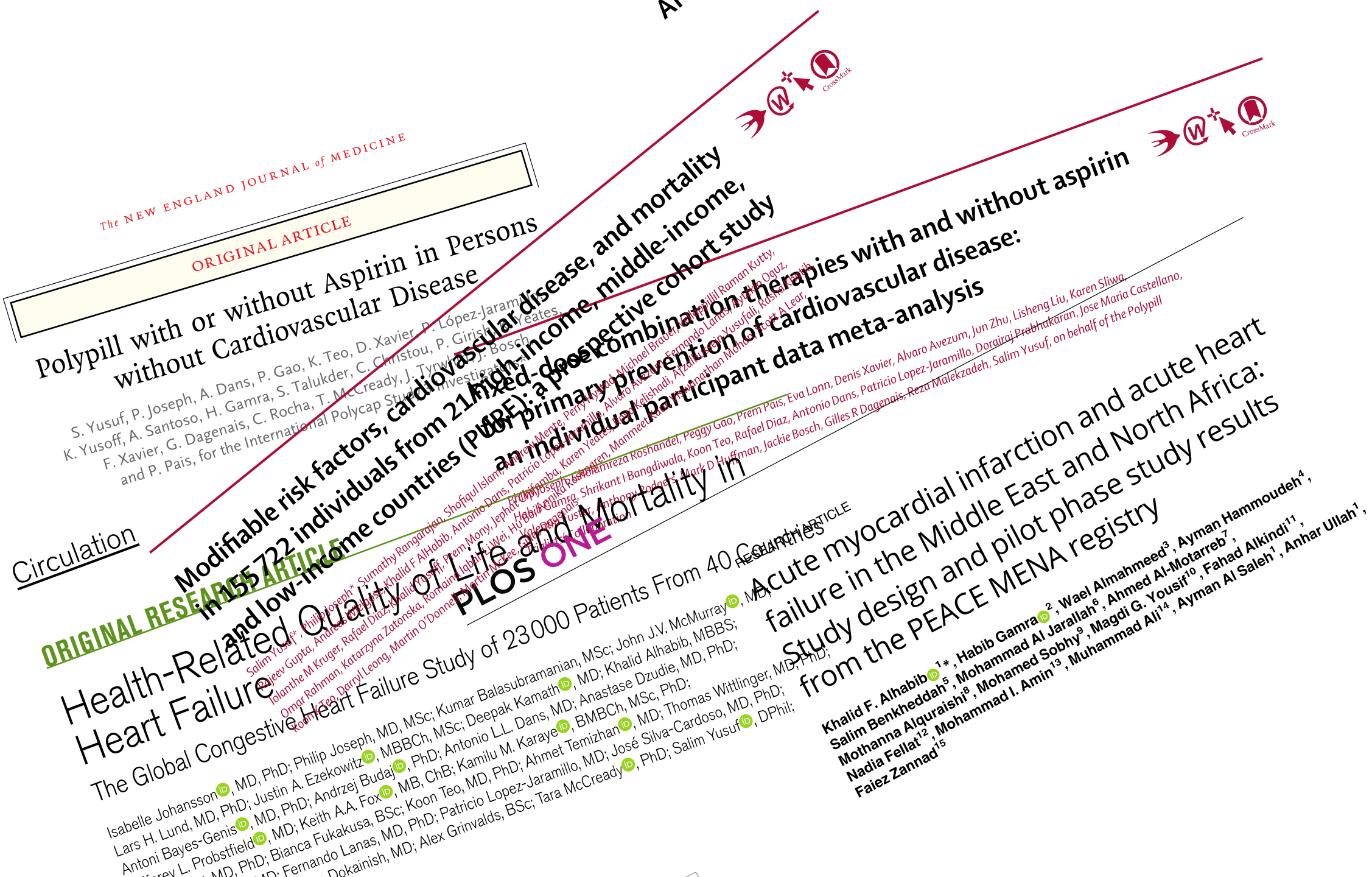
PHRI
Some trials done solely in LMIC

- ***BENEFIT*** : Benznidazole Chagas disease in 60 centers in S America(n=2700)
- ***IMPI*** : Steroids and a vaccine in TB(n=1200) Pericarditis in 12 countries in Africa
- ***INVICTUS***: Anticoagulants in Rheum V Heart Dis (RCT: of 4500, Registry of 3000/ 11,000)
- ***OSCAIL*** : Rehab after a stroke (200 in 3 countries-Rwanda, Zimbabwe and India)
- ***CREATE*** Trial and Registry

PHRI:
Observational and Epi studies

- **INTERHEART**: 28,000, case control study in 52 countries
- **INTERSTROKE:** 26,000 , case control study in 33 countries
- **PURE:** 200,000 cohort study in 27 countries , 12 years FU
- **Genetics** of Rheum HD: 2000 RHD in Africa
- **INTER CHF** (n= 5000) , **G-CHF** (25,000 from 40 countries with 4 year follow up) registries
- **Registries: VISION** (n= 50,000) in noncardiac surgery , **OASIS** in ACS (n=15,000 in 12 countries), **CREATE** (n=20,000) in AMI in 100 centers in India, **INSPIRE** stroke (10,000 India) *

  All 30 d to one year F/U .



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Working with investigators from LMIC or underprivileged settings

- Need a real, deep and sustained commitment
- Sustained research programs and funding
- Development of researchers from these settings and mentoring.
- Recognizing the researchers from LMIC.
- Exploitative and extractive relationships to be avoided

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Research Article

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Clinical research in Africa And Middle East: roadmap for reform and harmonisation of the regulatory framework and sustainable capacity development

Faiez Zannad, Mohamed Sobhy, Wael Almahmeed, Mohamed Balghith, Javed Butler, Souad Dziri, Sahar Ebrahim, Ashraf El Fiky, Ahmed Elshal, Ines Fradi, Ziyad Ghazzal, Chokri Jeribi, Zainab Samad, Maciej Kostrubiec, Manal Milhem, Mossad Morsi, Ali Oto, Hany Ragy, Georges Saade, Rana Malkawi, Azza Saleh, Dina Shokri, Karen Sliwa, Habib Gamra, for the CVCT Regulatory summit Think Tank

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Summary of the Report

- Only 7% of African countries have moderately developed capacity for research.
- Lack of a robust, international standards, regulatory framework
- Uncertain public confidence and poor awareness of the importance and the objectives of clinical research
- However, there are promising regulatory initiatives in few countries in the region
  - Egypt, Tunisia, Saudi Arabia, Lebanon and South Africa
- Clinical research centres in some countries, mostly affiliated with academia.
- **Progress** is being made towards:
  - higher standards of human subjects' protection,
  - adequate functioning of ethics review systems,
  - streamlined authorisation timelines, and contained bureaucracy.

Offline: Global health has forgotten the Arab World

Richard Horton
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www.thelancet.com **Vol 393 April 6, 2019**

- What can be done?
- Instead of waiting for governments to act, the health and medical research communities could do more to encourage collaborations.
- By forging bilateral educational, clinical, and research partnerships, possibilities for a transformational shift in opportunities for a new Arab generation are palpable.
- Arab countries are an illuminatingly rich arena for health action.

A progress has been made recently in Clinical research in some Emerging countries

- **Egypt** MOH has adopted important enhancements on the clinical research front.
- **Turkey** has initiated many reforms to localize clinical as a part of its transformation program.
- **Saudi Arabia** has set up the Saudi Food & Drug Authority (SFDA) to increase transparency and regulate clinical trials– research-but still areas for improvement
- **Lebanese** Ministry of Public Health (MoPH) has taken steps to be active participant encouraging more clinical trials
- **Jordan** has passed Clinical Studies Law and established the Jordanian Food & Drug Administration to facilitate clinical trials
- **Tunisian** Ministry of Public Health (DPM) has taken active steps in 2016 to regulate the conduct of clinical trials in Tunisia.

CONCLUSIONS

- Improving representation in clinical research as a global perspective is urgent

- Improving representation in clinical research requires investment (Training, Capacity building..)

- Improving representation in clinical research is the responsibility of everyone involved in the clinical research enterprise. participants, communities, investigators, IRBs, industry sponsors, institutions, funders, regulators, journals, and policy makers.

CONCLUSIONS

- Previous experiences have shown that it is possible to conduct good quality research in under-represented regions (LMICs), so let us capitalize on those achievements and expand clinical research to those countries


Thank You