



UiO • Faculty of Medicine

RESPONSIVENESS AND POST-TRIAL ACCESS OF CLINICAL TRIALS IN THE PHILIPPINES

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Health equity

“Equity is the absence of avoidable or remediable differences among groups of people, whether those groups are defined socially, economically, demographically, or geographically.

Health inequities therefore involve more than inequality with respect to health determinants, access to the resources needed to improve and maintain health or health outcomes. They also entail a failure to avoid or overcome inequalities that infringe on fairness and human rights norms.”

Amartya Sen on health equity

“The reduction of health inequality has not advanced health equity, since the latter requires us to consider further the possibility of making different arrangements for resource allocation, or social institutions or policies. To concentrate on health inequality only in assessing health equity is exactly similar to approaching the problem of world hunger (which is not unknown) by eating less food, overlooking the fact that any general resource can be used to feed the hungry better.”

Public Health, Equity, and Ethics, 2004

Health equity has many aspects, and is best seen as a multidimensional concept. It includes:

1. Concerns about achievement of health and the capability to achieve good health, not just the distribution of health care.
2. The fairness of processes and thus must attach importance to nondiscrimination in the delivery of health care.
3. Requires that the considerations of health be integrated with broader issues of social justice and overall equity, paying adequate attention to the versatility of resources and the diverse reach and impact of different social arrangements.

Applied to research:

Distributive justice, i.e., the fair distribution of benefits and risks, cannot be seen in isolation. Rather, the just distribution of research goods must take cognizance of the following:

1. Concerns about achievement of health and the capability to achieve good health;
2. The fairness of processes;
3. Considerations of health research be integrated with broader issues of social justice and overall equity.

Helsinki 2013

20. Medical research with a vulnerable group is only justified if the research is [responsive to the health needs or priorities of this group](#) and the research cannot be carried out in a non-vulnerable group. In addition, [this group should stand to benefit from the knowledge, practices or interventions that result from the research.](#)

Unesco declaration on bioethics and human rights

Article 15 – Sharing of benefits

1. Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, [in particular with developing countries](#).

CIOMS 2016

Guideline 2:

Before instituting a plan to undertake research in a population or community in low-resource settings, the sponsor, researchers, and relevant public health authority must ensure that the research is **responsive to the health needs or priorities** of the communities or populations where the research will be conducted. As part of their obligation, sponsors, and researchers must also:

- **make every effort, in cooperation with government and other relevant stakeholders, to make available as soon as possible any intervention or product developed, and knowledge generated, for the population or community in which the research is carried out, and to assist in building local research capacity.** In some cases, in order to ensure an overall fair distribution of the benefits and burdens of the research, additional benefits such as investments in the local health infrastructure should be provided to the population or community; and
- **consult with and engage communities** in making plans for any intervention or product developed available, including the responsibilities of all relevant stakeholders.

UN General assembly (2008): human rights guidelines for pharmaceutical companies in relation to access to medicines

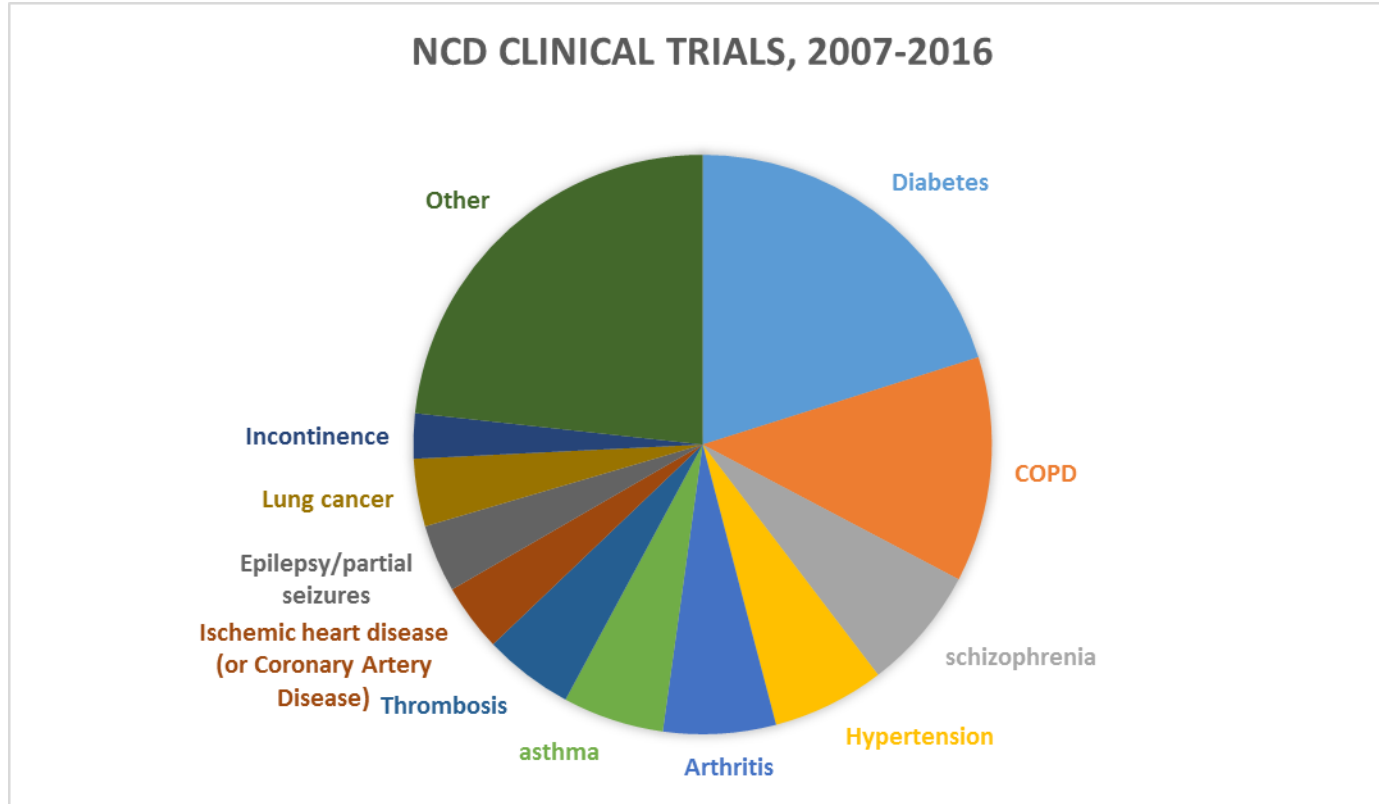
Preamble:

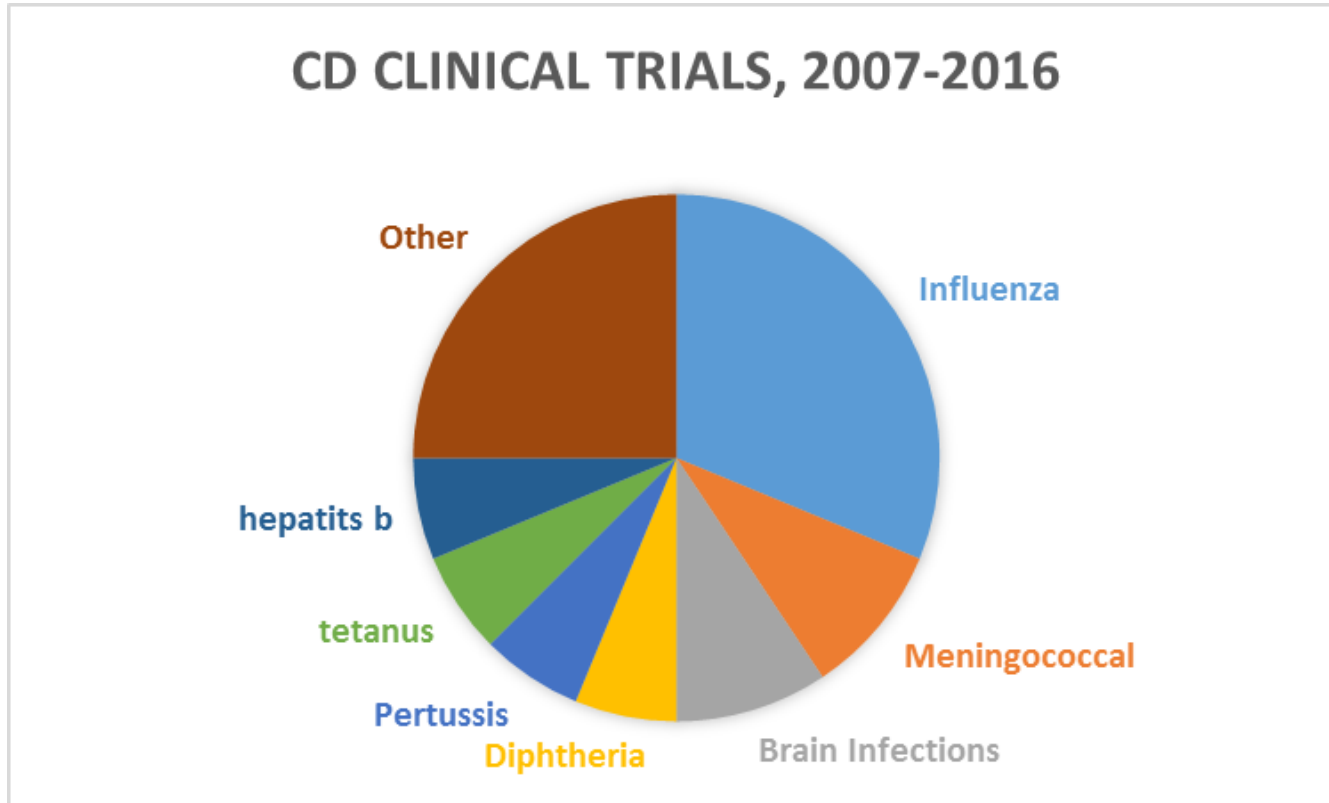
- States have the primary responsibility for realizing the right to the highest attainable standard of health and increasing access to medicines.
- In addition to states, numerous national and international actors share a responsibility to increase access to medicines.
- Pharmaceutical companies including innovator, generic, and biotechnology companies, have human rights responsibilities in relation to access to medicines.
- Pharmaceutical companies contribute in various ways to the realization of the right to the highest attainable standard of health...Enhancing access to medicines, however, has the central place in the societal mission of pharmaceutical companies.

Article 1: The company should adopt a human rights policy statement which expressly recognizes the importance of human rights generally, and the right to the highest attainable standard of health in particular, in relation to the strategies, programmes, projects, and activities of the company.

RESPONSIVENESS

- 2007-2016
- [Clinicaltrials.gov](https://clinicaltrials.gov/) – clinical trials in the Philippines
- [Healthdata.org](https://healthdata.org/) – causes of death and DALY (YLL and YLD) for the Philippines and the US





Philippines, 2007-2016

Causes of death	n of clinical trials
Tuberculosis	0
Chronic kidney disease	0
Lower respiratory infections	1
Alzheimer disease and other dementias	1
Cerebrovascular disease	3
Tracheal, bronchus, and lung cancer	6
Ischemic heart disease	6
Asthma	9
Hypertensive heart disease	10
Chronic obstructive pulmonary disease	20
Diabetes mellitus	32

YLL	n of clinical trials
Congenital birth defects	0
Neonatal preterm birth complications	0
Tuberculosis	0
Neonatal sepsis and other neonatal infections	0
Chronic kidney disease	0
Diarrheal diseases	0
Neonatal encephalopathy due to birth asphyxia and trauma	0
Lower respiratory infections	1
Cerebrovascular disease	3
Ischemic heart disease	6

YLD	n of clinical trials
Low back and neck pain	0
Sense organ diseases	0
Migraine	0
Anxiety disorders	0
Depressive disorders	1
Skin and subcutaneous diseases	2
Asthma	9
Other musculoskeletal disorders (arthritis)	10
Chronic obstructive pulmonary disease	20
Diabetes mellitus	32

United States, 2007-2016

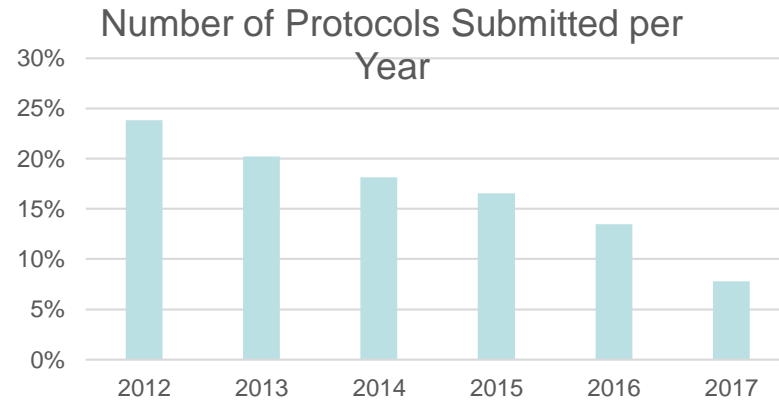
Causes of death	n of clinical trials
Chronic kidney disease	0
Alzheimer disease and other dementias	1
Lower respiratory infections	1
Colon and rectum cancer	2
Cerebrovascular disease	3
Breast cancer	3
Ischemic heart disease	6
Tracheal, bronchus, and lung cancer	6
Chronic obstructive pulmonary disease	20
Diabetes mellitus	32

YLL	n of clinical trials
Drug use disorders	0
Chronic kidney disease	0
Alzheimer disease and other dementias	1
Lower respiratory infections	1
Colon and rectum cancer	2
Cerebrovascular disease	3
Ischemic heart disease	6
Tracheal, bronchus, and lung cancer	6
Chronic obstructive pulmonary disease	20
Diabetes mellitus	32

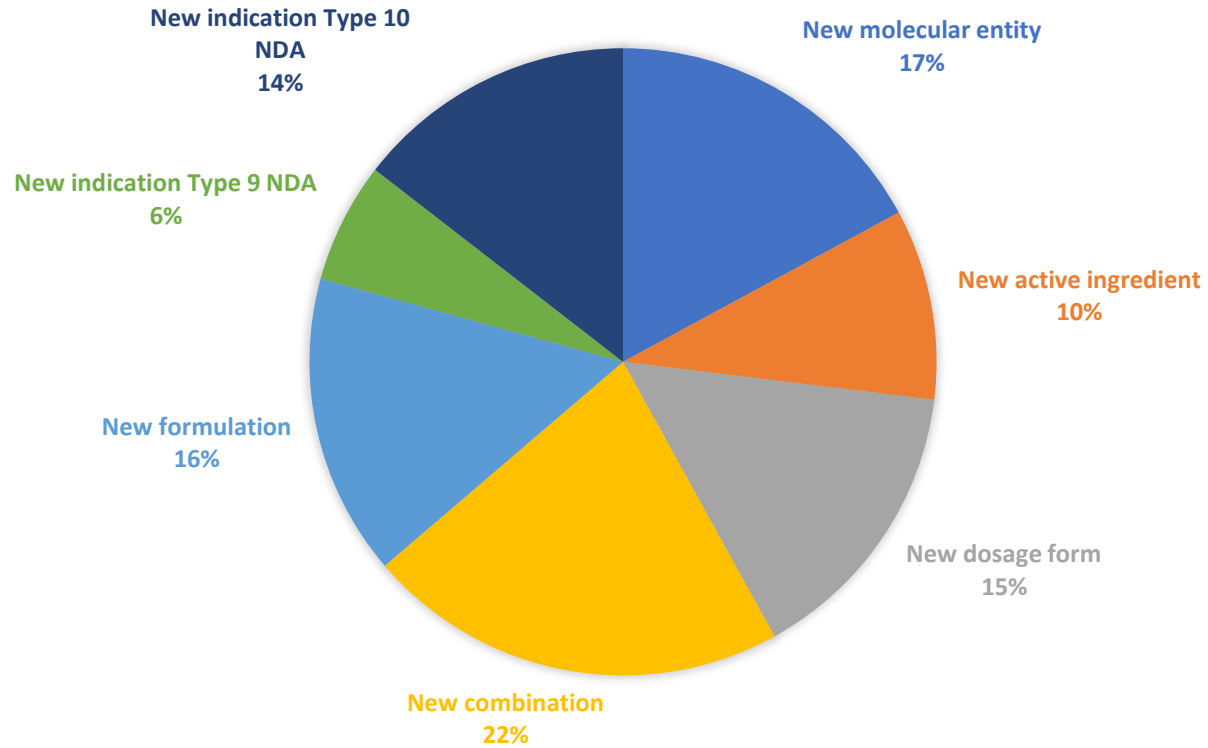
YLD	n of clinical trials
Low back and neck pain	0
Drug use disorders	0
Sense organ diseases	0
Migraine	0
Anxiety disorders	0
Depressive disorders	1
Skin and subcutaneous diseases	2
Other musculoskeletal disorders	10
Chronic obstructive pulmonary disease	20
Diabetes mellitus	32

POST-TRIAL ACCESS

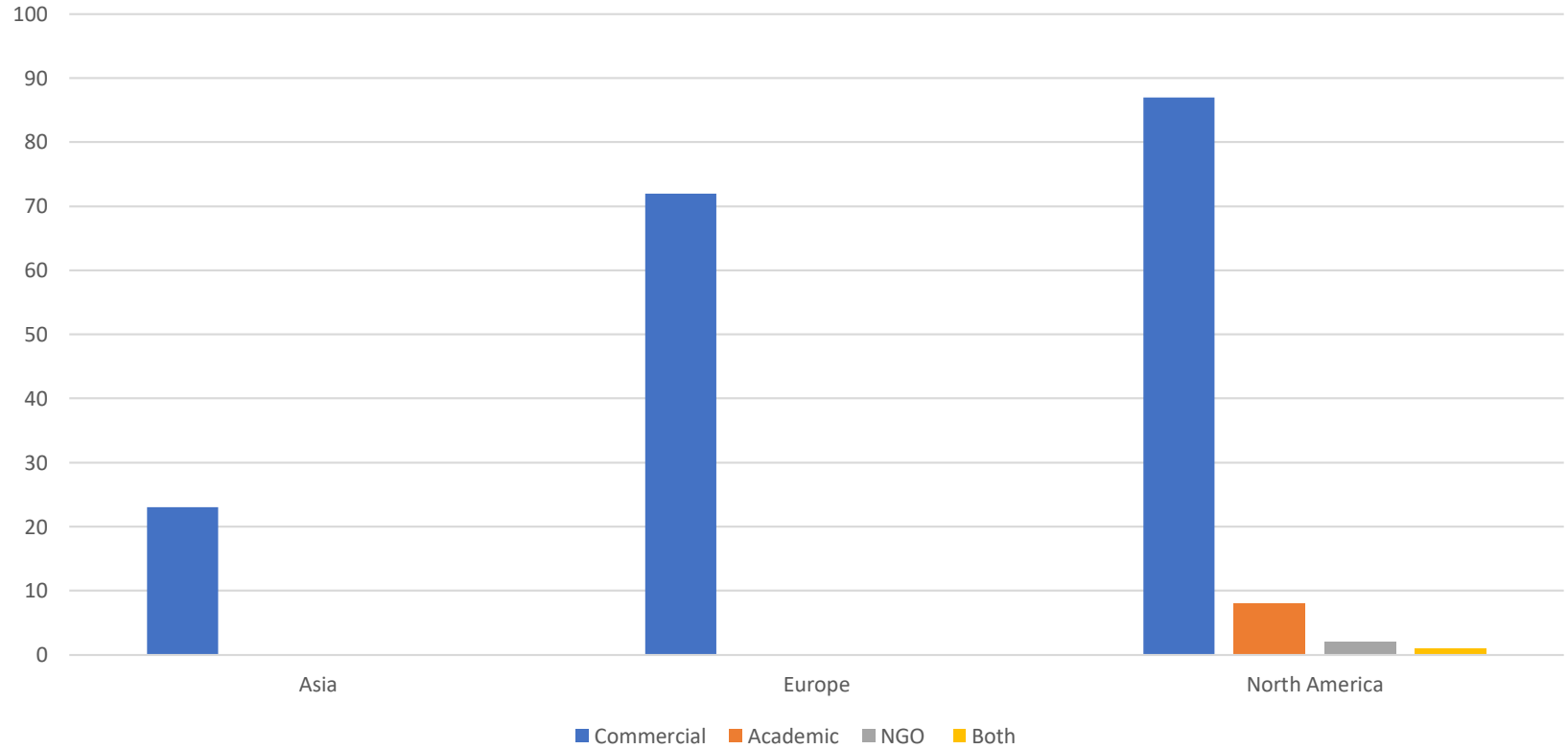
- 2012-2017
- UP-NIH IRB
- 193 protocols

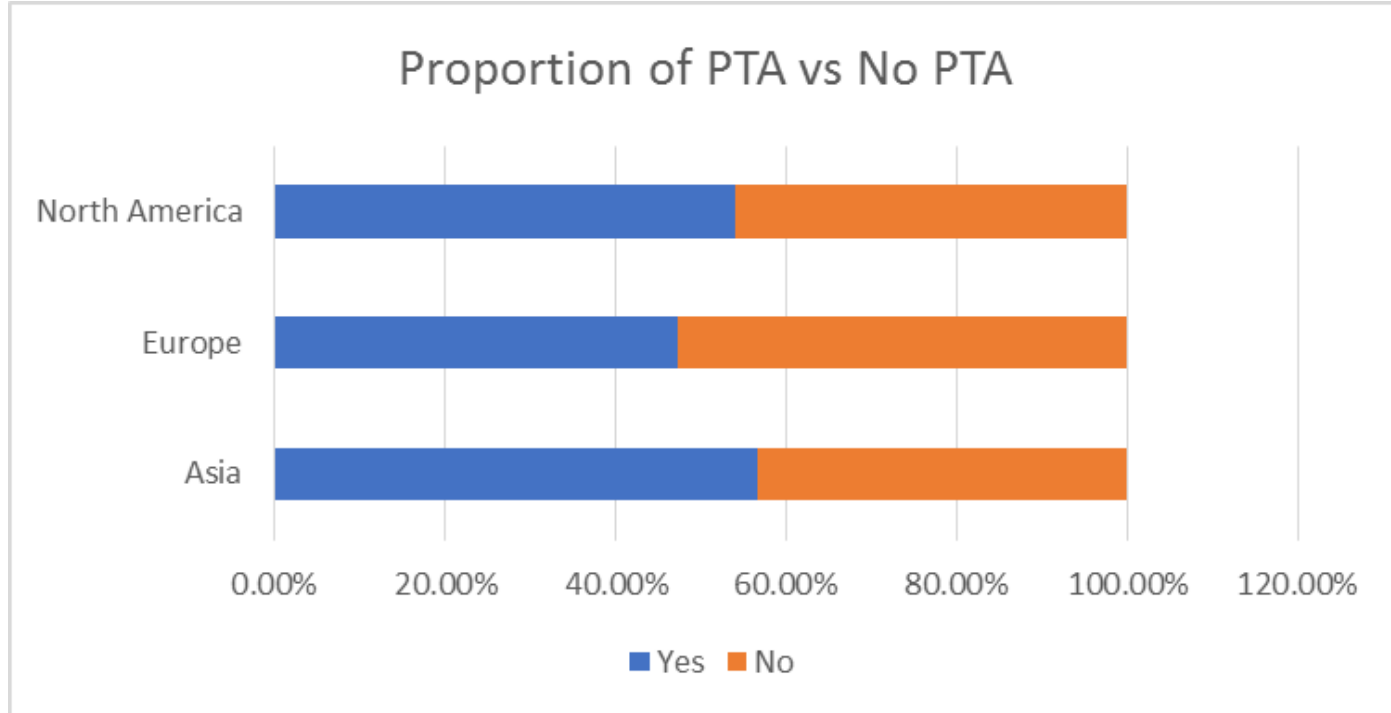


TYPES OF STUDY DRUGS (ALL)



Regional Origin of Clinical Trials





Provisions by Year Submitted

