

Clinical trials in India – the needs of the country and the focus of the sponsors

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Background

- India is a hub of clinical trials and the preferred clinical trials destinations globally
- Compound annual growth rate of $\sim 36\%$ between 2006 -2011
- Revenues worth US\$ 546 million in future
- India suffers a large proportion of disease burden of the world (more than 16.8%)

Background

- ARI -major cause of DALY's loss
- Asia Pacific Region: leading causes of morbidity-respiratory tract infections, childbirth-related conditions, diarrhoea, viral infections, various skin diseases, other respiratory conditions, etc (WHO)

Background

- “10/90 gap”
- Disparities in clinical trials:
 - Biomedical research in public health is less and disproportionately low across major disease conditions
 - Evident from low publications

Research Questions

- What kind of biomedical research is done in India?
- Who are the sponsors/players involved in carrying out these clinical trials?
- What are the real interests of these sponsors?

Methods

- **Source of Data** – CTR-I website, WHO fact sheets on causes of death
- **Universe-** all trials registered in CTR-I as of June 30, 2010. (1,078)
- **Sample size-** 1,078 trials

Methods

- The details of individual trials from the registry were imported to an excel sheet, from which the data was entered into the SPSS software.
- All the variables from CTR-I were taken.
- For this particular study, the information regarding “Diseases” and “Sponsors” were taken.

Methods

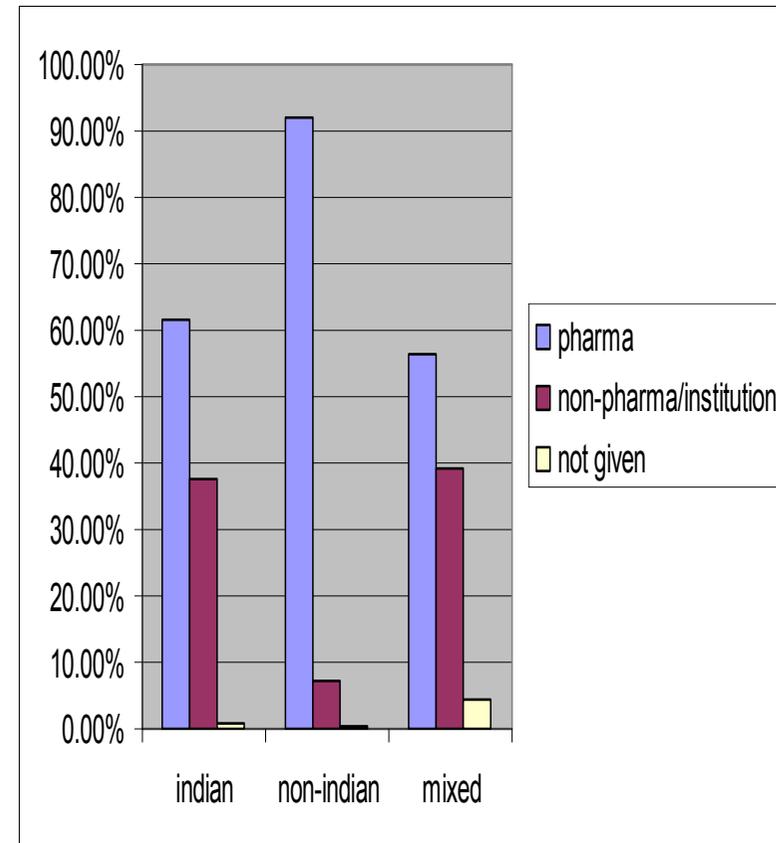
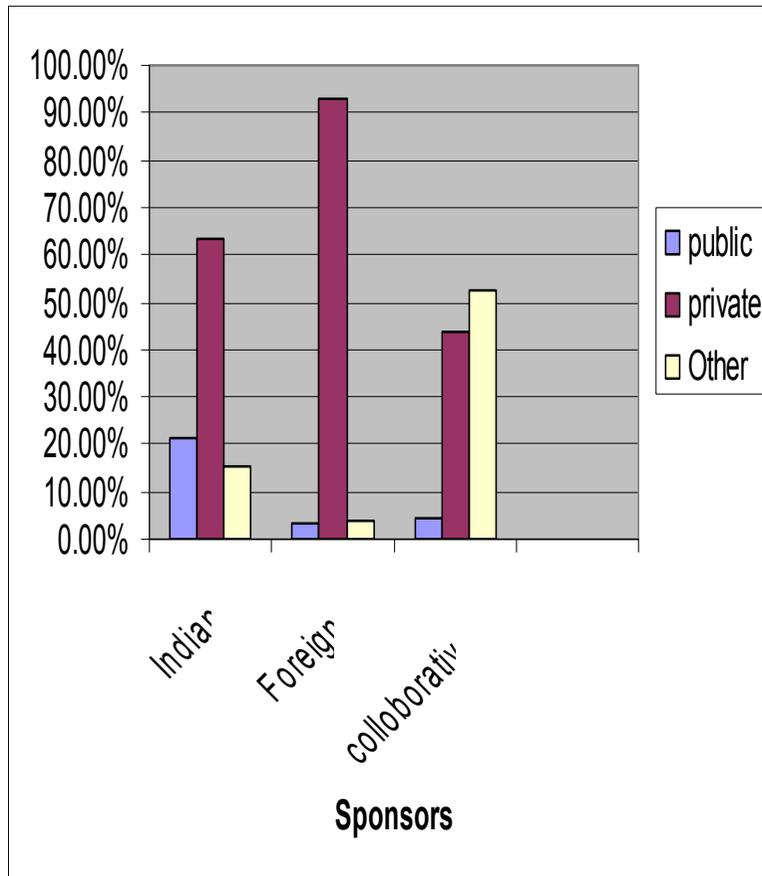
- The WHO's ICD 10 was used to classify the diseases.
- For the sponsors, the individual websites were visited to classify them. These were classified based on nationality, type, and whether pharmaceutical company or not.

As on June 2010, No. of trials registered on CTR-I were 1078

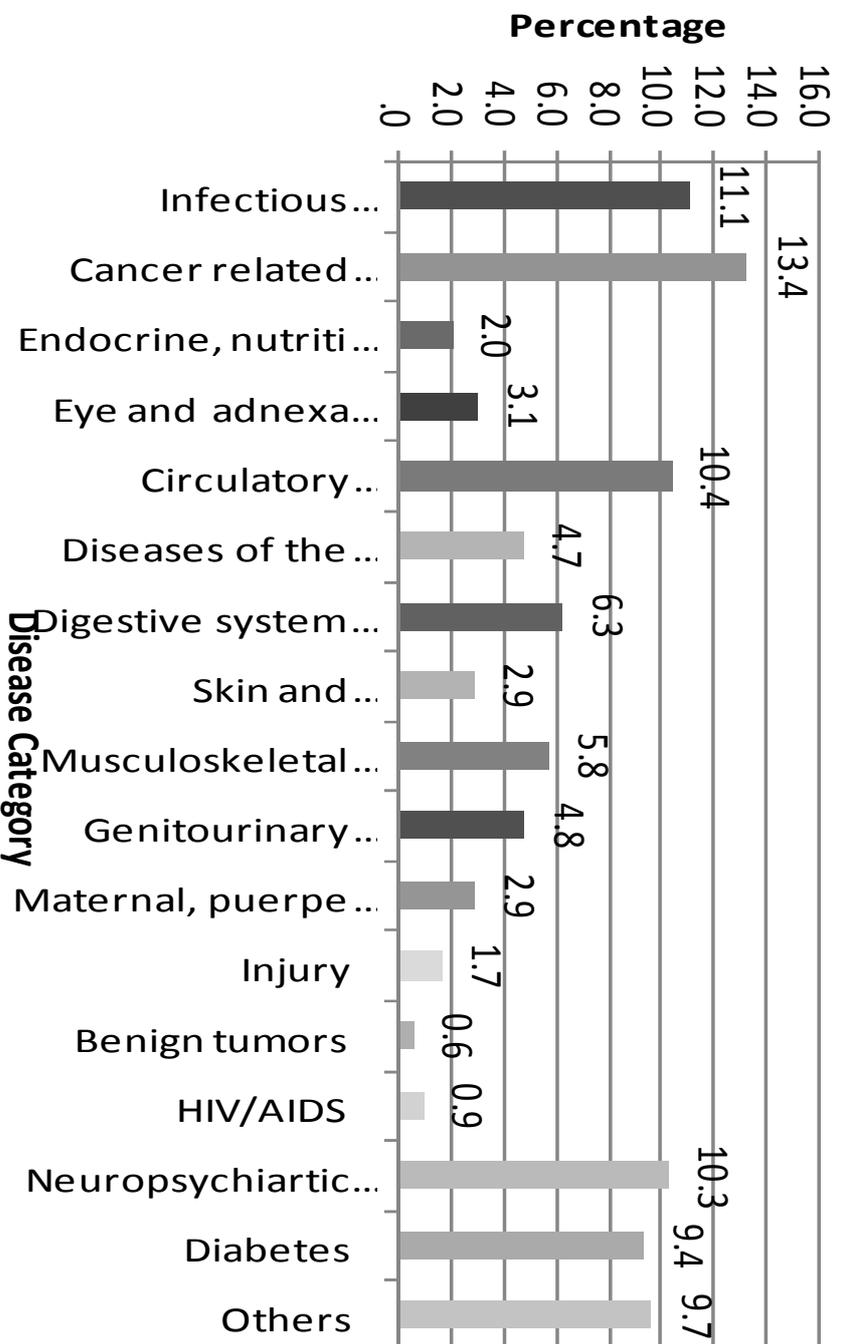
Type of sponsors	%
Public/ Govt. funded	11.9
Private funded	73.2
Other sources	10.4
No information on sponsors	4.5

Origin	%
Indian	45.1
Foreign	47.8
Collaborative	2.0
No information	5.1

Who are these sponsors?



What type of trials are these?



Major causes of death in India

Causes of Death

Top ten causes of death, all ages
India, 2002

Causes	Deaths		Years of Life Lost
	(000)	(%)	(%)
All causes	105	100	100
Ischaemic heart disease	153	15	7
Lower respiratory infections	110	11	13
Cerebrovascular disease	771	7	3
Perinatal conditions	762	7	13
Chronic obstructive pulmonary disease	485	5	2
Diarrhoeal diseases	456	4	8
Tuberculosis	364	4	4
HIV/AIDS	361	3	4
Road traffic accidents	189	2	2
Self-inflicted injuries	182	2	3

Source: Death and DALY estimates by cause, 2002
<http://www.who.int/entity/healthinfo/statistics/bodgbddeathdalyestimates.xls>

Trials in comparison with major causes of death

- Cancer is the most researched upon disease -13.4%
- Infectious disease -11.1%
- Circulatory and neuro-psychiartric illness ~ 10%

Trials in comparison with major causes of death

- Infectious diseases includes lower respiratory infections and tuberculosis – Major causes of death
- 16/1078 (1.48%) on lower respiratory infections
- 7/1078 (0.6%) were on tuberculosis.

Trials in comparison with major causes of death

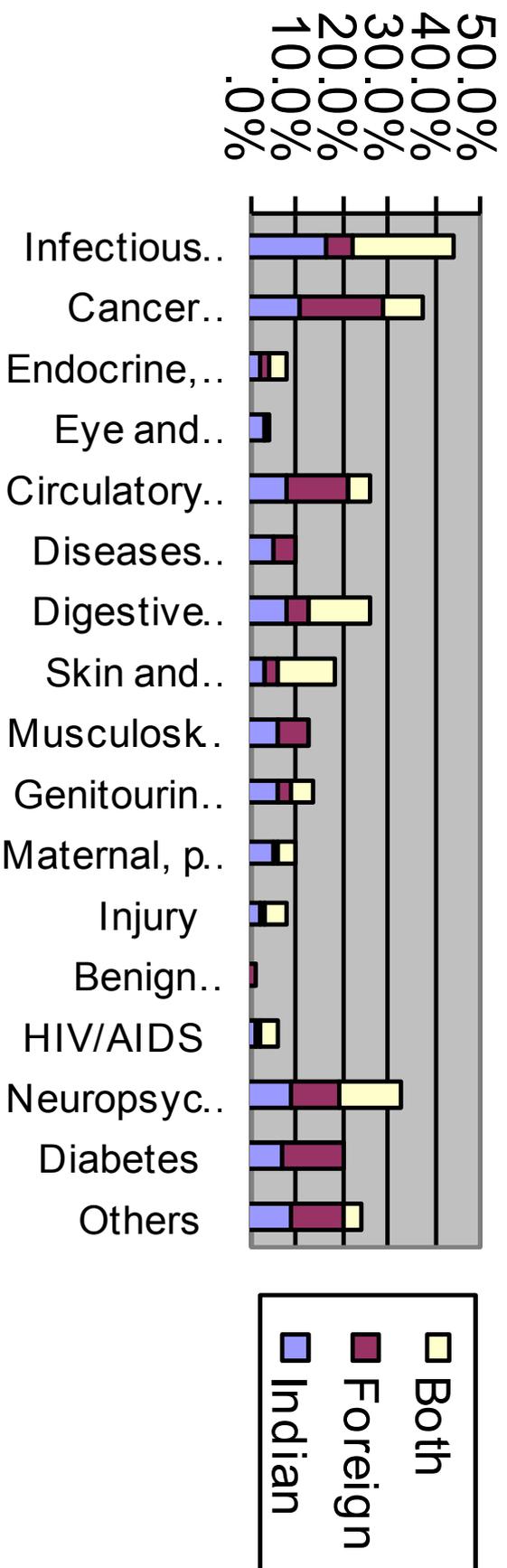
- Trials on HIV (0.9%) and perinatal conditions (2.9%)
- Trials on injury -1.7%

Major causes of death in developed countries

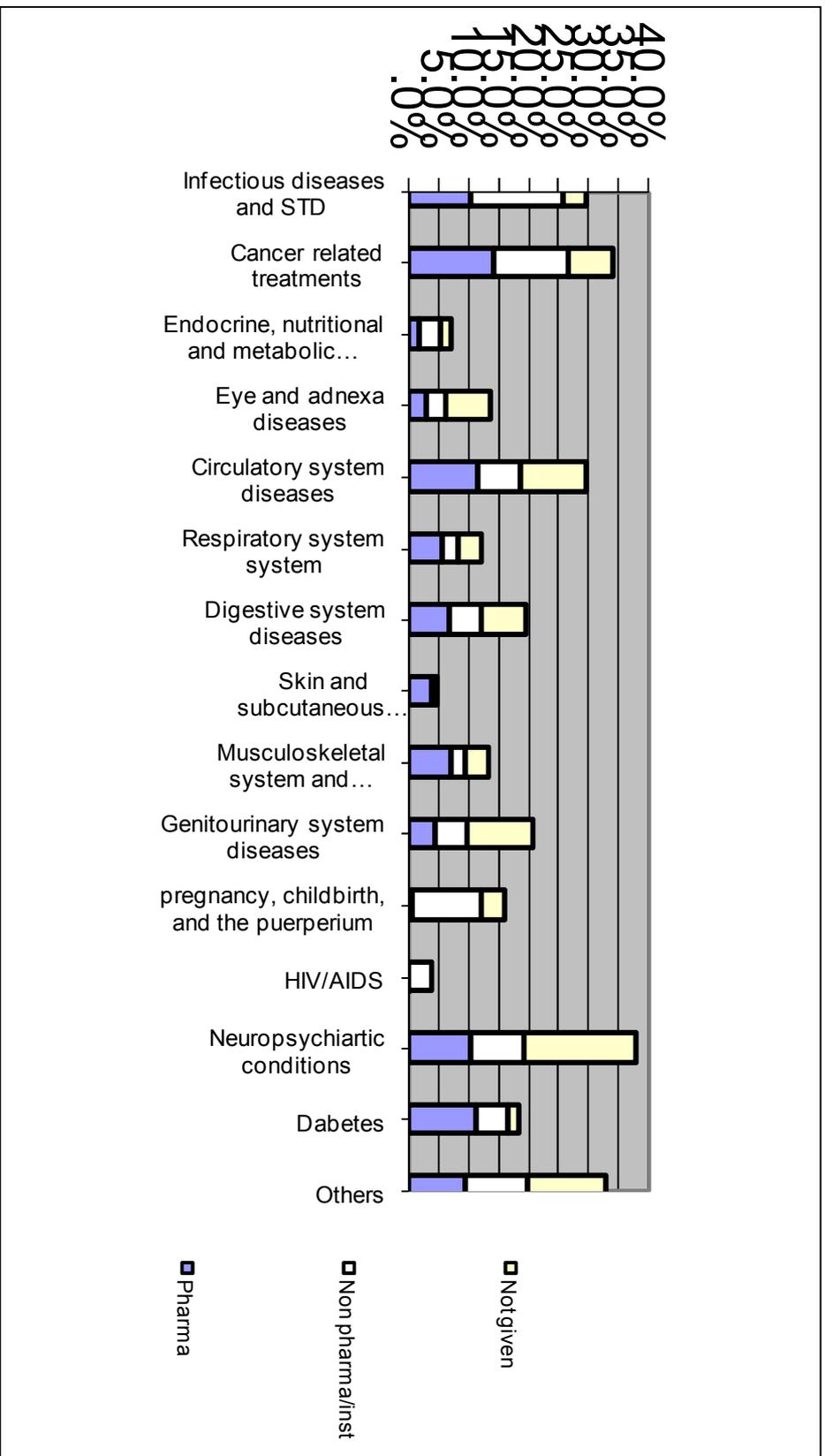
High-income countries	Deaths in millions	% of deaths
Coronary heart disease	1.34	17.1
Stroke and other cerebrovascular diseases	0.77	9.8
Trachea, bronchus, lung cancers	0.46	5.8
Lower respiratory infections	0.34	4.3
Chronic obstructive pulmonary disease	0.30	3.9
Colon and rectal cancers	0.26	3.3
Alzheimer and other dementias	0.22	2.7
Diabetes mellitus	0.22	2.7
Breast cancer	0.15	1.9
Stomach cancer	0.14	1.8

- Source- WHO Fact sheet Top ten causes of death

Sponsors and diseases –origin wise



Sponsors and diseases - Pharma/Institutions



What do foreign sponsors focus on?

- Max. no. of trials that are funded by foreign sponsors and pharmaceutical companies are cancer trials
- Circulatory system related diseases ranks next

Diseases that foreign sponsors focus on

- Diabetes and neuropsychiatric illness
- Few trials on HIV/AIDS (1%), perinatal conditions (0.2%) and injury(1.3%)

What do Indian sponsors focus on ?

- Research on infections are mostly Institute funded (15.3%) and are done by Indian sponsors (15.9%)
- Trials on perinatal condition are usually conducted by Indian sponsors (5.1%) and are also institute funded (8.7%)

Diseases that Indian and foreign collaborations focus on

- Infectious diseases (21.7%)
- Digestive system diseases
- Neuropsychiatric illness
- Skin diseases (13% each)

Limitations

- The data registered on CTR-I can be under represented, as registration was made mandatory only in June 2009.
- Registration of BA/BE studies are not mandatory.

Limitations

- The data are entered by individuals, so when a trial has multiple sites or multiple sponsors, there can be a bias depending on who is entering the data.

Conclusions

- It can be noted that the foreign funding agencies and pharmaceutical companies conduct trials in India on diseases that are more prevalent in developed countries
- The increase in the no. of clinical trials in India by foreign sponsors does not have anything to do with the actual health scenario here

- Do foreign companies come here for the huge pool of patient population?
- Will medicines once approved be made available to the local population