Current Landscape of Clinical Research in India

Dr. Chirag Trivedi

President, Indian Society for Clinical Research (ISCR)
Director & Head of Clinical Study Unit, Sanofi

Presentation Agenda

- India's position in the global clinical research map
- Evolution of Indian Clinical research environment
- About ISCR
- Future for Indian Clinical Research
- Continuing to work together

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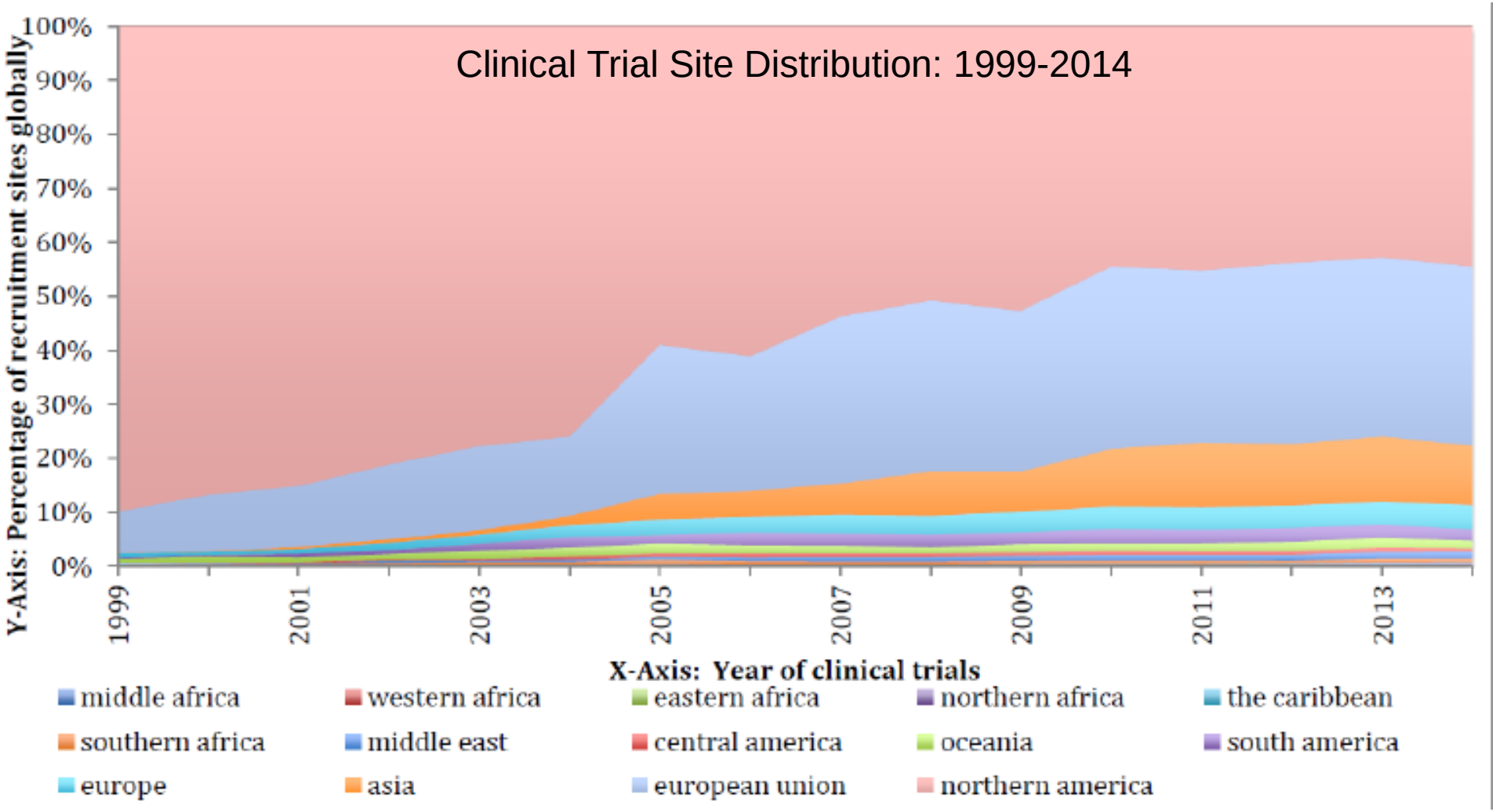
India's position in global clinical research

Increased # trial sites in Developing countries



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Italy	8502	48373	2.54	10.30	5.69
Spain	8137	47114	2.48	14.05	5.79
Russian Federation	3449	27599	1.45	25.91	8.00
Poland	4559	27512	1.45	17.49	6.03
China	6891	26612	1.40	36.19	3.86
Belgium	6566	24644	1.29	6.77	3.75
Australia	5218	24143	1.27	2.77	4.63
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Brazil	4960	17784	0.93	16.20	3.59
Czech Republic	3155	17009	0.89	22.49	5.39
Hungary	2911	15693	0.82	22.49	5.39
India	2949	15494	0.81	22.59	5.25
Israel	5591	13409	0.70	14.71	2.40
Sweden	4367	12885	0.68	13.50	2.95
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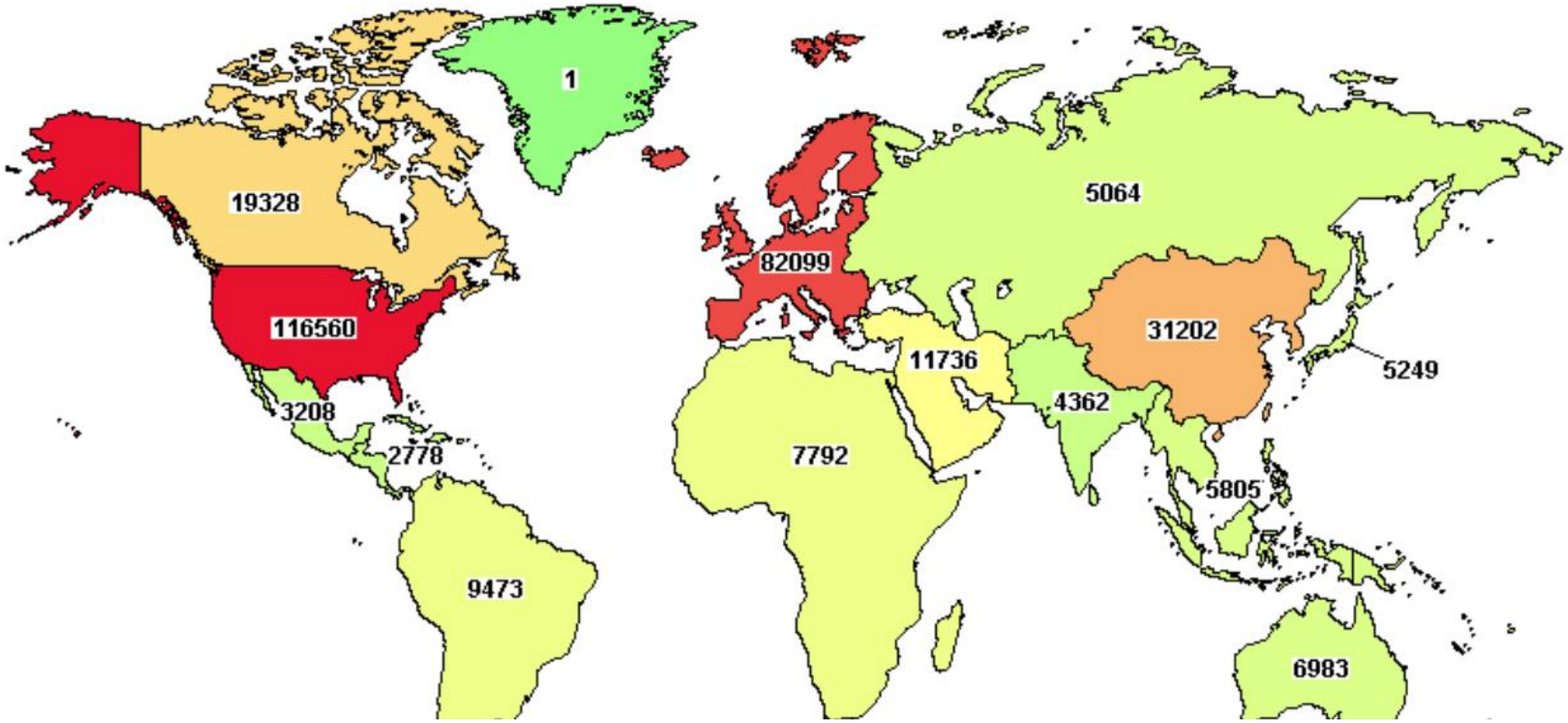
With >1.3 bn population and 1/5th of global disease burden India conducts ~1.2% of the global clinical studies



Current # of registered clinical studies globally – 290,291

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Source: www.clinicatrials.gov Accessed on: 22 Nov 2018

Evolution of clinical research in India

Indian Clinical Research

In 2013-2014…

Clinical trial evolution in last few years….

2013-2014

2015 onwards

Balanced, Predictable, Stable Environment

Complex, Uncertain, Ambiguous environment

Then

- Public Interest Litigation
- Rules on medical management and compensation for adverse events
- Ethics Committee (EC) registration
- Audio-Visual recording of informed consent process
- 3 trials per investigator
- Decreased number of clinical trials
- Low motivation for Investigators and site teams
- Impact on academic trials

Now

- Balanced medical management and compensation rule
- Rule amended for Audio-Visual recording of consent
- Significant improvement in the approval timelines
- EC to decide # of trials per investigator
- Investigator, Site and EC accreditation proposed
- Ease of conducting academic trials


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through clinical research

About ISCR

Indian Society for Clinical Research (ISCR)

Launched in June 2005	• A professional association of all stakeholder groups involved in Clinical Research
Registered society	• With a charter to represent interests of the Clinical Research community

Members	• 36 AMOs
	  • Multinational and Indian Pharma and CROs
	  • Academia and Hospitals
	• 520 Individual Life Members
	  • Doctors, Site staff, Ethics Committee members, clinical research professionals

Councils and Chapters	• 7 councils covering different aspects of clinical research • 3 regional chapters

ISCR Vision

- Promote a compelling scientific disposition and widespread awareness of clinical research for the advancement of healthcare

ISCR Mission

- Inspire and align diverse stakeholders to shape and foster an environment facilitating ethical and responsible clinical research for better patient outcomes

Some of ISCR's significant achievements…

Helped build a strong foundation for clinical research

- Capacity building for various organizations, hospitals and ethics committees
- Conferences / Training / workshops by the councils and chapters

Instrumental in shaping the clinical research environment

- As an impleader for the PIL filed in Supreme Court of India
  - provided factual data that was quoted by regulators
- Worked with the regulators for making things easier for e.g., amendments to
  - Rule 122DAB to make the regulations more balanced
  - Rule of NMT 3 trials per investigators
  - Requirements for A-V recording of informed consent process
- Simplification of the regulatory review and approval processes leading to a significant reduction in the timelines

Became an important, value adding partner to all stakeholders

- Providing inputs to government policies and regulations
- Support for Ethics Committee registration and accreditation

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The future for Indian Clinical Research

Significant tailwinds now…

- Balanced regulatory environment
- Strong thrust from Govt and Regulators to promote innovation in India through clinical trials
- New Clinical Trial Regulations to be introduced soon…
  - simplify processes
  - reduce approval timelines
- Increasing importance of real world evidence

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ISCR's roadmap

Our Pillars

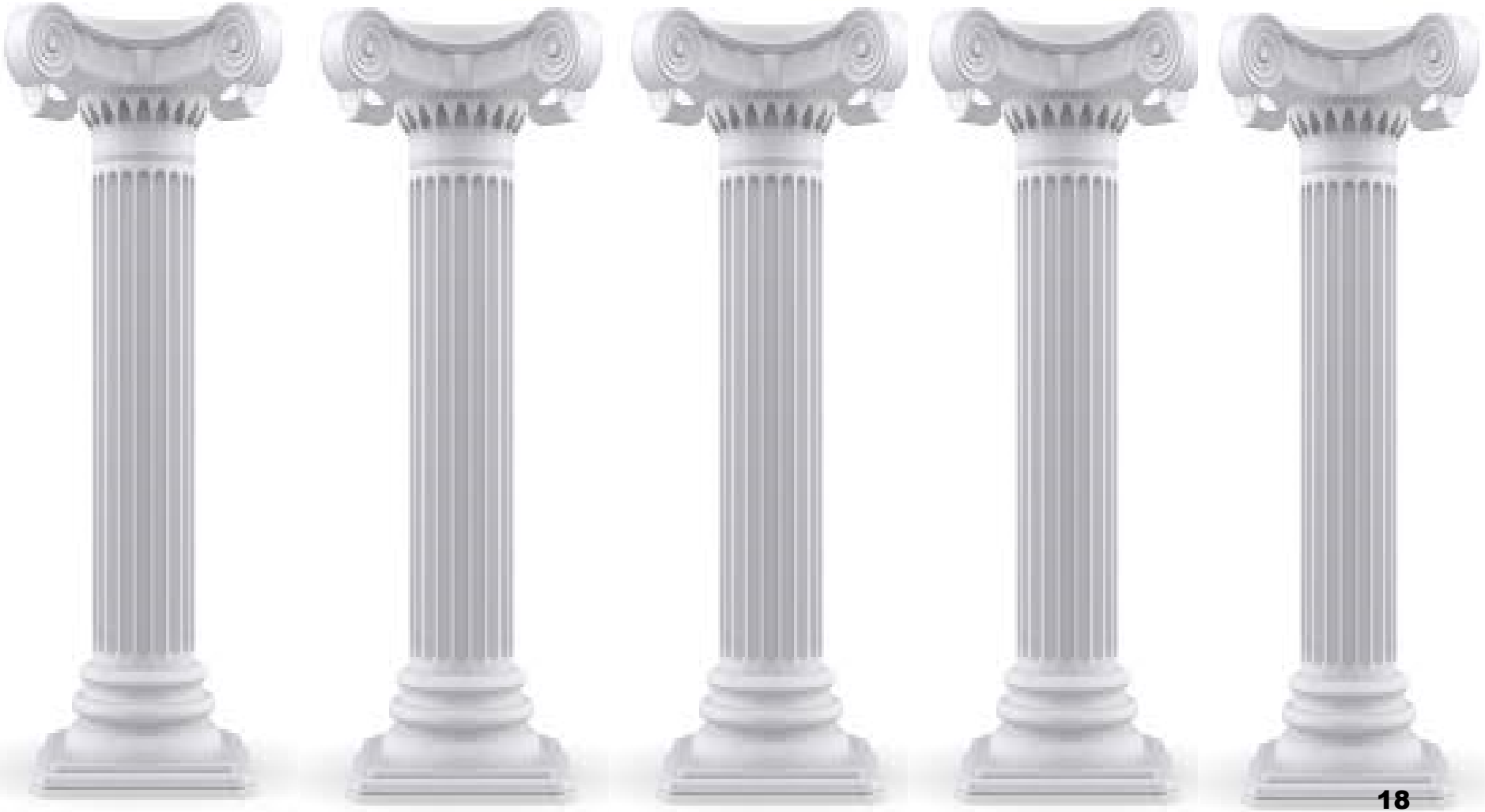
Capacity Building

Advocacy efforts

Confidence Building

Increasing Awareness

Data Generation



ISCR Plans…

Short term (1-2 yrs)

- Confidence building measures
- Advocacy efforts
- Increasing Patient Awareness
- Increasing outreach
- White papers / publications
- Awareness / training programs

Mid-term (3-5 yrs)

- Expanding from Clinical Trials to Clinical Research
- Increasing working with academic institutes
- Increased Capacity building
- Working with Physician and Industry associations
- Indian Physicians / scientists to be a part of global committees

Long term (>5 yrs)

- Increasing the digital adoption quotient
- India leading global drug development

Our strong partnership for fighting the unmet medical needs

Investigators

ISCR

Continue working together (1)

Joint advocacy efforts

- Key stakeholders, for e.g.,
  - MoH, Regulators, NITI Aayog, Associations, Academic Institutes, Ethics Committees, PAGs, etc.

Environment shaping activities

- Inputs to Regulatory policies and framework
- Increasing awareness
  - Doctors, Patients, Media
- Capacity building
  - Hospitals, Doctors, Trained Professionals
  - Infrastructure

Continue working together (2)

For our common pursuit to fight the unmet medical needs…

- What are your expectations from ISCR?
- What more should we do to continue working together?

ISCR's 12th Annual Conference

13-16 Feb 2019

Delhi

Announcement: 12th Annual ISCR Conference 2019, Delhi

- **13-16 February 2019**
- **Venue: Hotel Eros, Delhi**
- 5 Pre-conference Workshops
- 2 Track Main Conference (15-16 Feb)
- 1 Workshop at Medanta Hospital, Gurgaon
- **Registrations are open**, please visit www.iscr.org for details

- **On behalf of Local Organizing Committee and the Scientific Committee, I welcome you all to participate**

For any queries: info@iscr.org

THANK YOU

OPPORTUNITIES & CHALLENGES FOR DRUG AND VACCINE DISCOVERY IN INDIA

Dr. Chirag Trivedi
Director & Head of Clinical Study Unit, Sanofi
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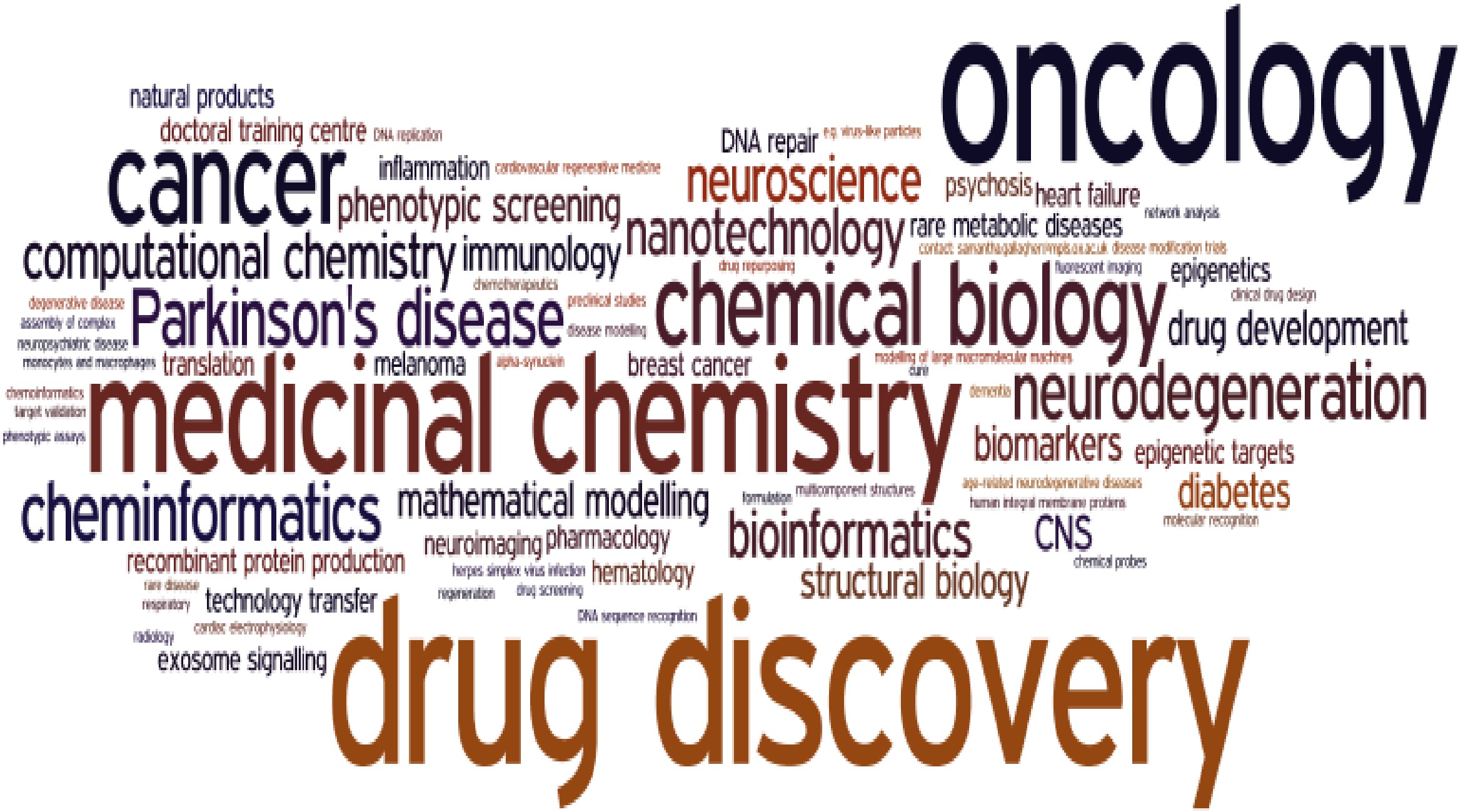
Disclaimer

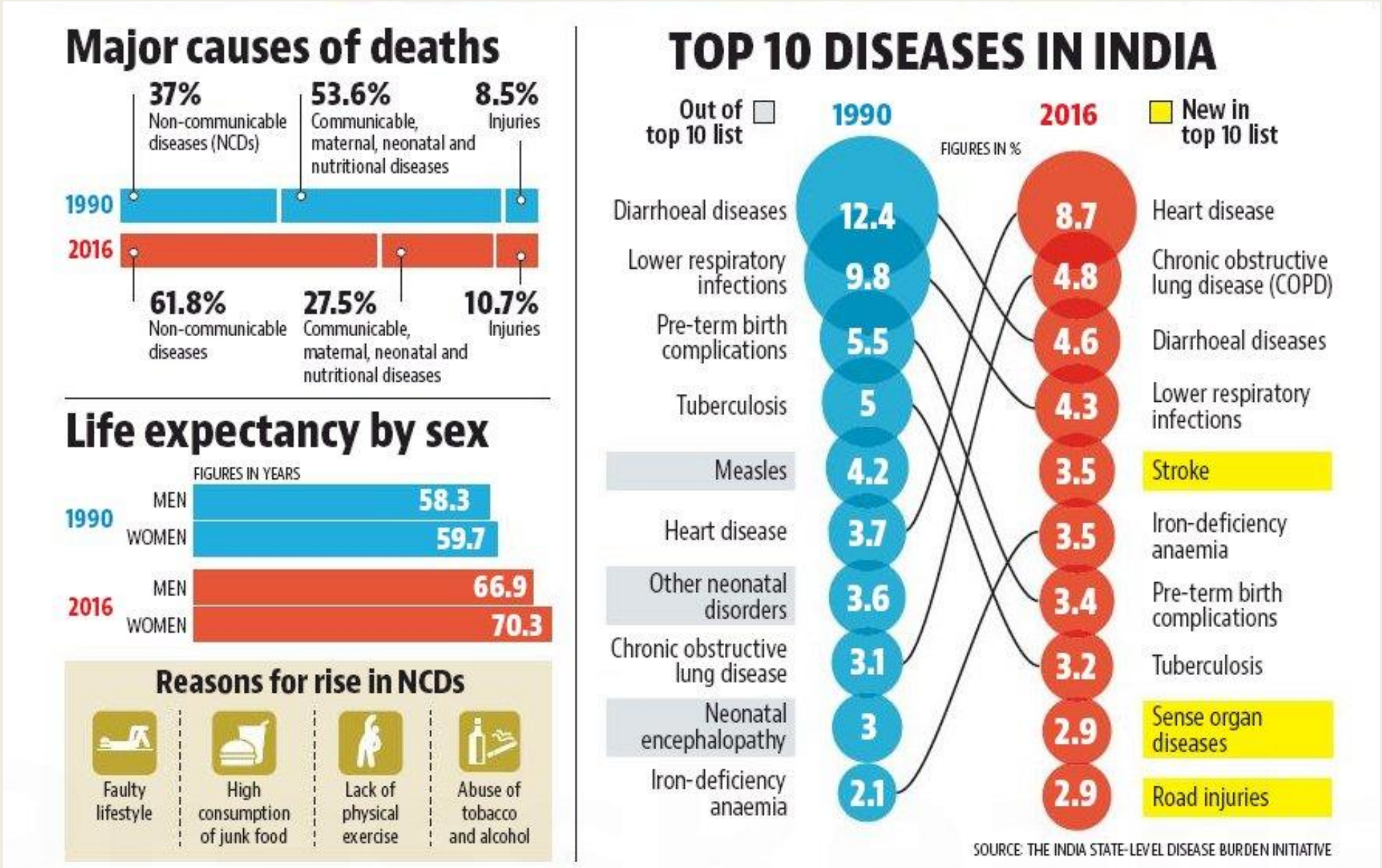
- The views expressed in this presentation are of the Speaker and does not necessarily reflect that of Sanofi
- Relevant references are cited
- Freely available images are taken from internet

Outline

- Importance of Drug discovery
- India’s disease burden
- Current clinical research landscape in India
- Way forward
- Developing vaccines
- Large sample size

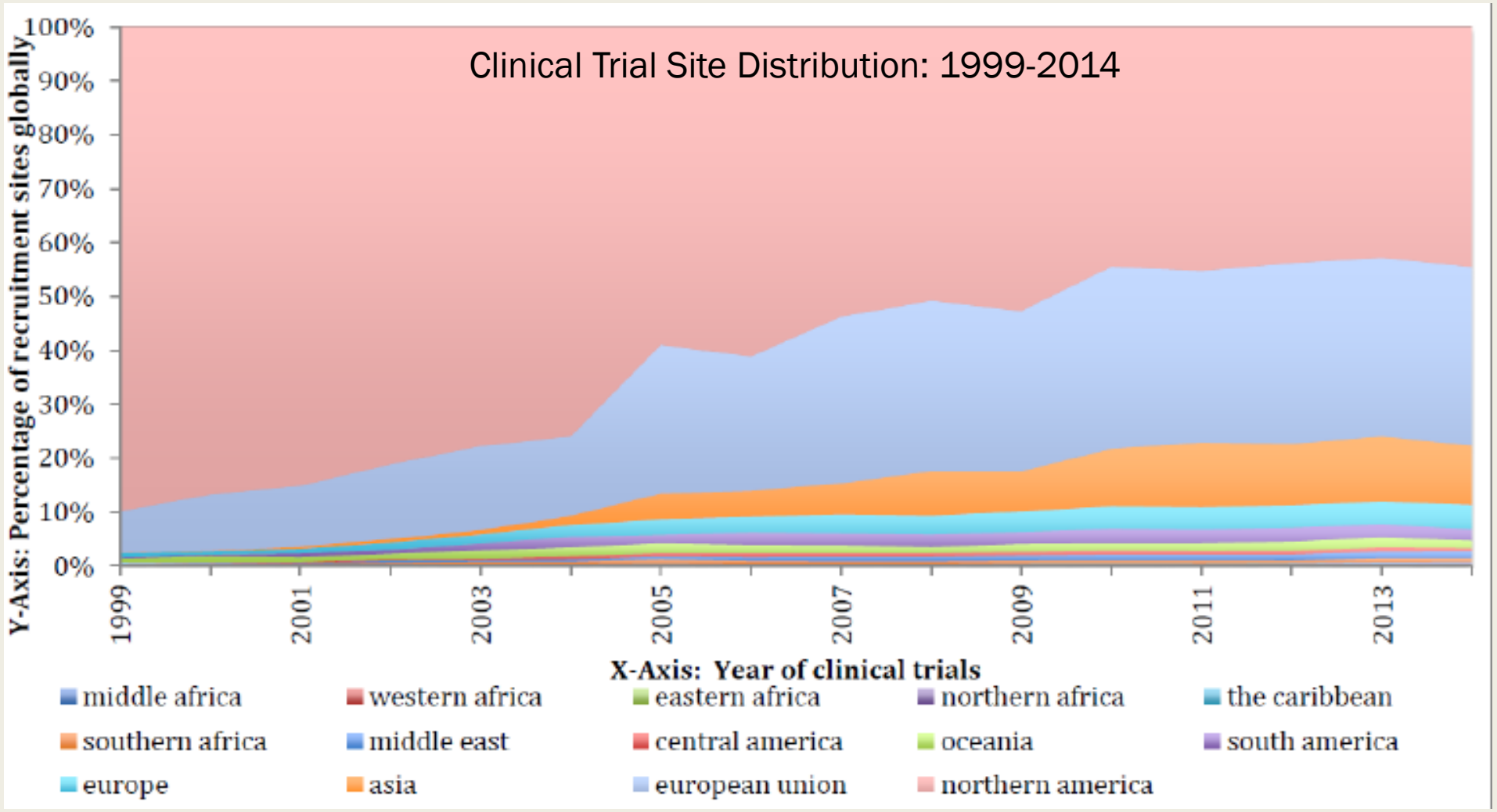

oncology
natural products
doctoral training centre
DNA replication
DNA repair
e.g. virus-like particles
cancer
inflammation
cardiovascular regenerative medicine
neuroscience
psychosis
heart failure
phenotypic screening
nanotechnology
rare metabolic diseases
network analysis
computational chemistry
immunology
drug repurposing
fluorescent imaging
epigenetics
chemotherapeutics
chemical biology
clinical drug design
degenerative disease
assembly of complex
Parkinson's disease
preclinical studies
drug development
disease modelling
neuropsychiatric disease
translation
melanoma
alpha-synuclein
breast cancer
modelling of large macromolecular machines
monocytes and macrophages
medicinal chemistry
dementia
neurodegeneration
chemoinformatics
target validation
biomarkers
epigenetic targets
phenotypic assays
cheminformatics
mathematical modelling
formulation
multicomponent structures
age-related neurodegenerative diseases
diabetes
human integral membrane proteins
molecular recognition
neuroimaging
pharmacology
bioinformatics
CNS
recombinant protein production
herpes simplex virus infection
hematology
chemical probes
rare disease
regeneration
drug screening
structural biology
respiratory
technology transfer
DNA sequence recognition
cardiac electrophysiology
radiology
exosome signalling
drug discovery

Large unmet medical need for our patients




Welcome
to India for Global Clinical Research
Hope & Hype

Increased # trial sites in Developing countries



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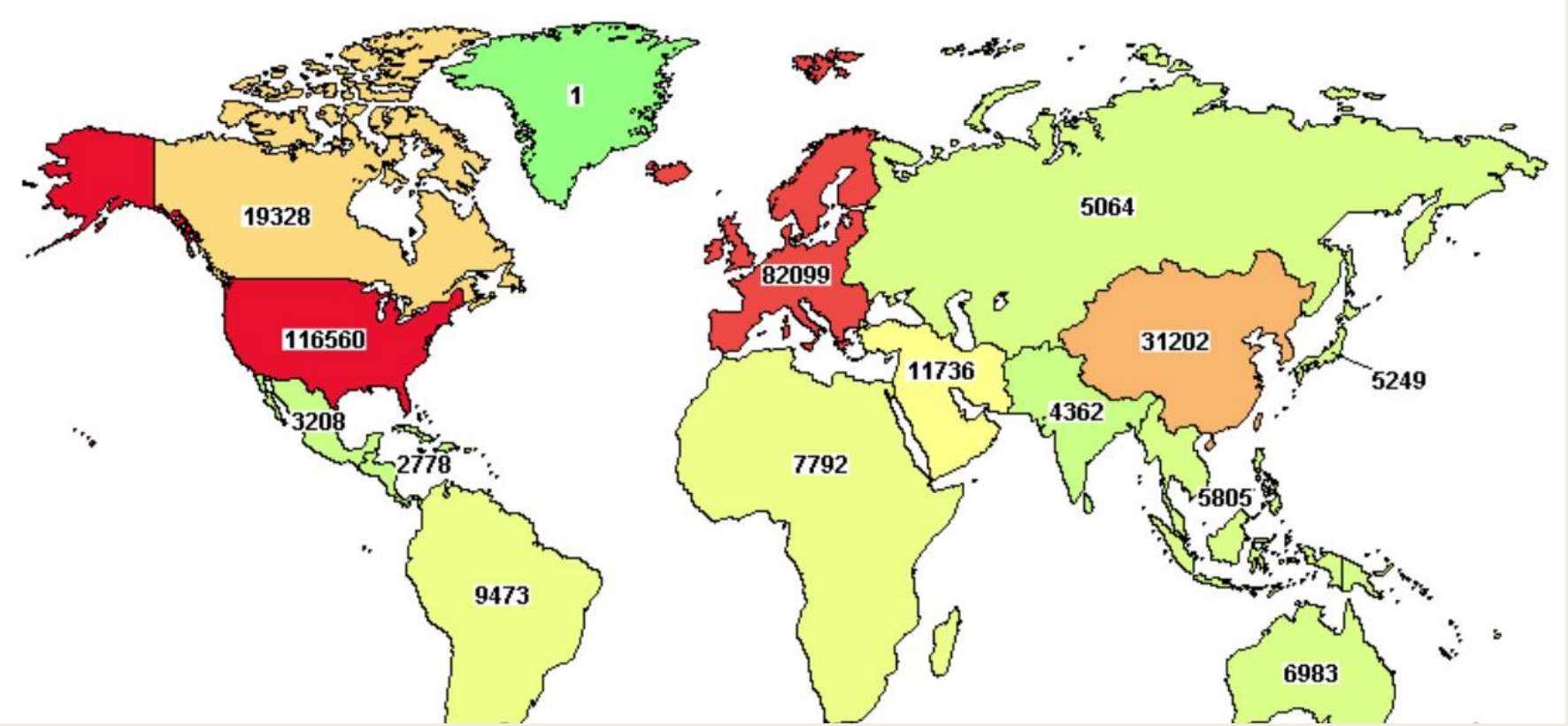

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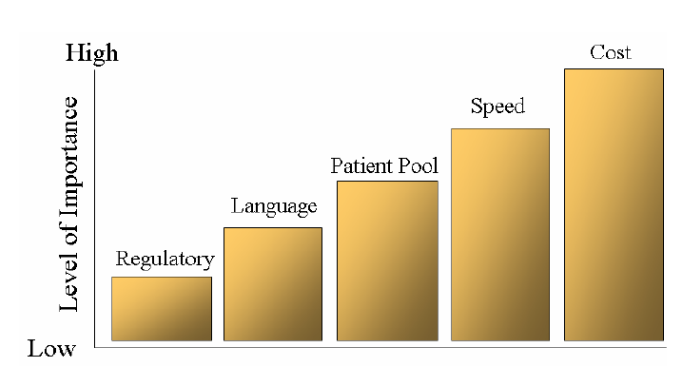
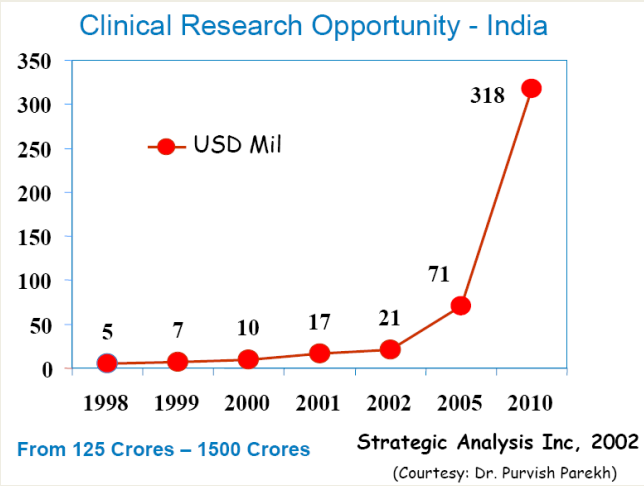
The Two Faces of Indian Clinical Research....



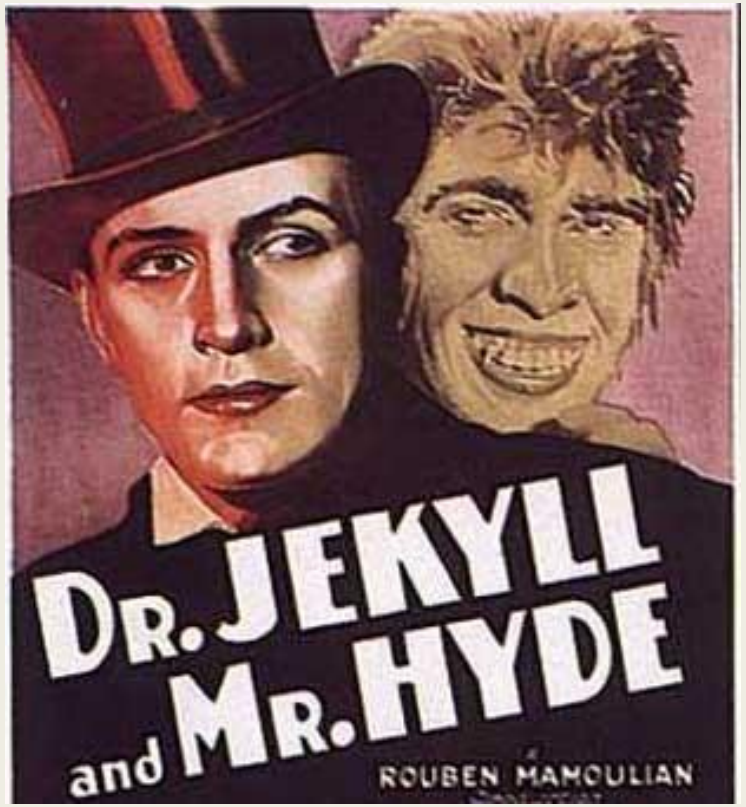


A New Colonialism? — Conducting Clinical Trials in India

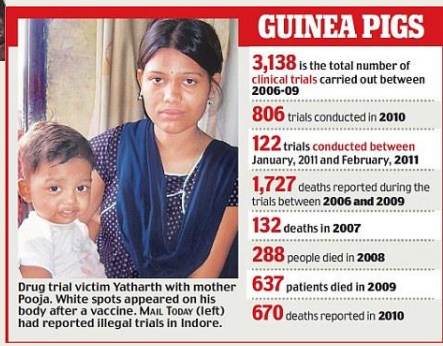
Samiran Nundy, M.Chir., and Chandra M. Gulhati, M.D., D.T.M.&H.

The NEW ENGLAND JOURNAL of MEDICINE

"Dark Side of Clinical Trials" – discovered in India??



Parliament questions & PIL in Supreme Court




Evolution of the Regulatory scenario in last 5 years

Significant tailwinds now…

- Balanced regulatory environment
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- New Clinical Trial Regulations to be introduced soon…
  - *simplify processes*
  - *reduce approval timelines*
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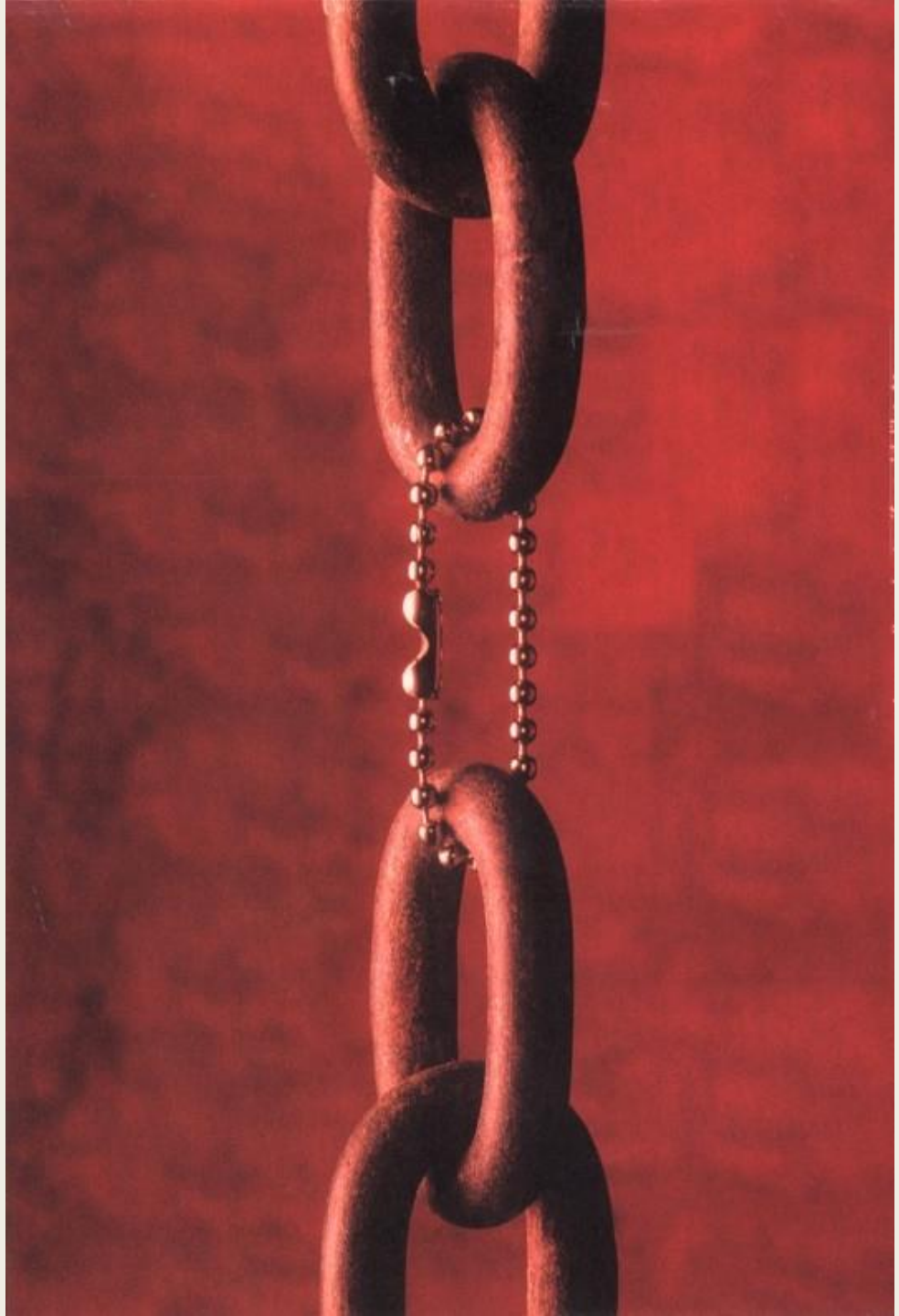


Importance of Strengthening All Stake holders

- We are as good as our weakest link
- Strengthening the stake holders and their Quality standards is of paramount importance
- Promoting discovery and development in India
- Need to further strengthen capacity all over the country


Regulations
Transparency
Policies
Requirements
COMPLIANCE
Rules
Standards
Law


HPV
healthcare
healthcare
measles
prevent
malaria
physician
virus
symptom
yellow fever
injection
antibodies
protection
pharmaceuticals
virus
healthcare
pathogen
infection
infection
public health
risk
protection
polio
antibodies
tropical disease
measles
immunity
infectious disease
immune system
travelling
infection
quarantine
pathogen
measles
flu shot
antibodies
tropical disease
physician
quarantine
health
pandemic
flu
flu
protection
prevent
tropical disease bacteria
vaccination
HPV
risk vaccination
immunity
safety
health
risk
infectious disease
virus
pandemic
yellow fever
chicken pox
immune system
public health
malaria
hepatitis
flu shot
health
travelling
prevent
HPV
flu
pandemic
injection
bacteria
immune system
flu shot
travelling
pathogen
bacteria
polio
pharmaceuticals
malaria
public health
injection
symptom
immunity
pharmaceuticals
yellow fever
quarantine
infectious disease
vaccination
physician
chicken pox
chicken pox
safety
safety
hepatitis
polio
symptom
hepatitis

hindustantimes

Make in India: Country emerges as the new hub of vaccine research

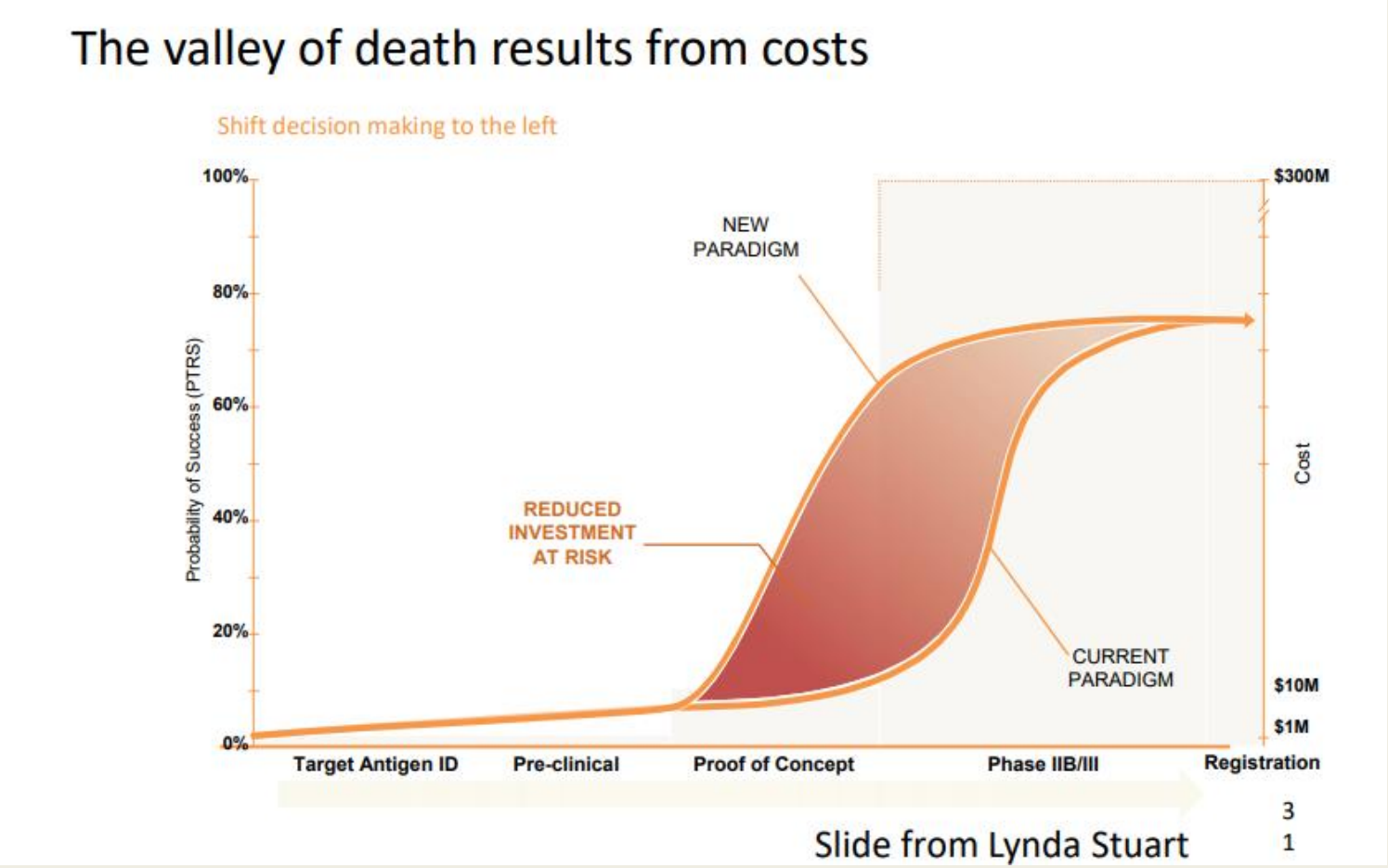
More than 60% of the world's vaccines are made here and India is a member of the International Vaccine Institute's governing council, committing US $500,000 each year.

INDIA Updated: Oct 16, 2017 10:08 IST

Malavika Vyawahare
Hindustan Times

India has marched from being one of the world's top vaccine-manufacturing hubs to become an emerging player in research and development, a feat that gives the densely-populated tropical country a shot in the arm.

Stages of vaccine development



Newer strategies for vaccine development

- Strategy
  - Live recombinant
  - Recombinant proteins
  - Replicative defect/virus like particles
  - Alpha virus replicons
  - Naked DNA plasmid
  - Recombinant vectors
  - Prime boost using DNA
  - Reverse genetics
  - Peptides
  - T cell receptor
- Examples
  - Dengue, parainfluenza
  - Hep B, Pertussis toxin
  - HPV, HSV
  - HIV, haemorrhagic fevers
  - Hepatitis B
  - CMV, HIV
  - HIV, malaria
  - Influenza, RSV
  - Cancer
  - Multiple sclerosis

Slide of Dr. Gagandeep Kang, THSTI

Some challenges in Vaccine Development

- Identify an antigen
- For efficacy – need good immunomarkers
- Large sample size
- In future, focus may be more on newer technology

OUR MOTTO

Nobody should die of a vaccine preventable disease

Thank You