



<http://www.osdd.net>

**Affordable healthcare for All**

## **Framing an Innovation Platform for Neglected Diseases R&D**



**Zakir Thomas**

Project Director, OSDD

Council of Scientific & Industrial Research

New Delhi, India

## A Reminder from History

*“My idea of a better ordered world is one in which medical discoveries would be free of patents and there would be no profiteering from life or death.”*

- Indira Gandhi (1981, World Health Assembly)

# CSIR the Key Player in Indian Generics

## Antiviral

- Abacavir
- Famciclovir
- Nevirapine
- Sustiva

## Antiasthamatic

- Ariflo
- Zafirlucast
- Montelukast

## Antidiabetic

- Miglitol
- Pioglitazone
- Repaglinade

## Antiglucoma

- Dorzolamide
- Latanoprost
- R-Salbutamol

## Antihistaminic

- Cetrizine hydrochloride
- Levocetirizine

## Calcium channel blocker

- S-Amlodipine

## Erectile dysfunction

- Cialis
- Verdenafil

## Proton pump inhibitor

- S-pentaprazole
- Tenatoprazole

## Antibacterial

- Linozolid

## Anticancer

- Irrinotecan
- Amlodipine

## Antidepressant

- Venolofaxine

## Antiemetic

- R-Ondansetron

## Antifungal

- Voriconazole

## Antipsychotic

- Olanzapine

## Cholesterol lowering agent

- Atorvastatin

## Hypnotic

- Zolpidem

## Maternal Health

- Carboprost

**Post WTO Era.....**

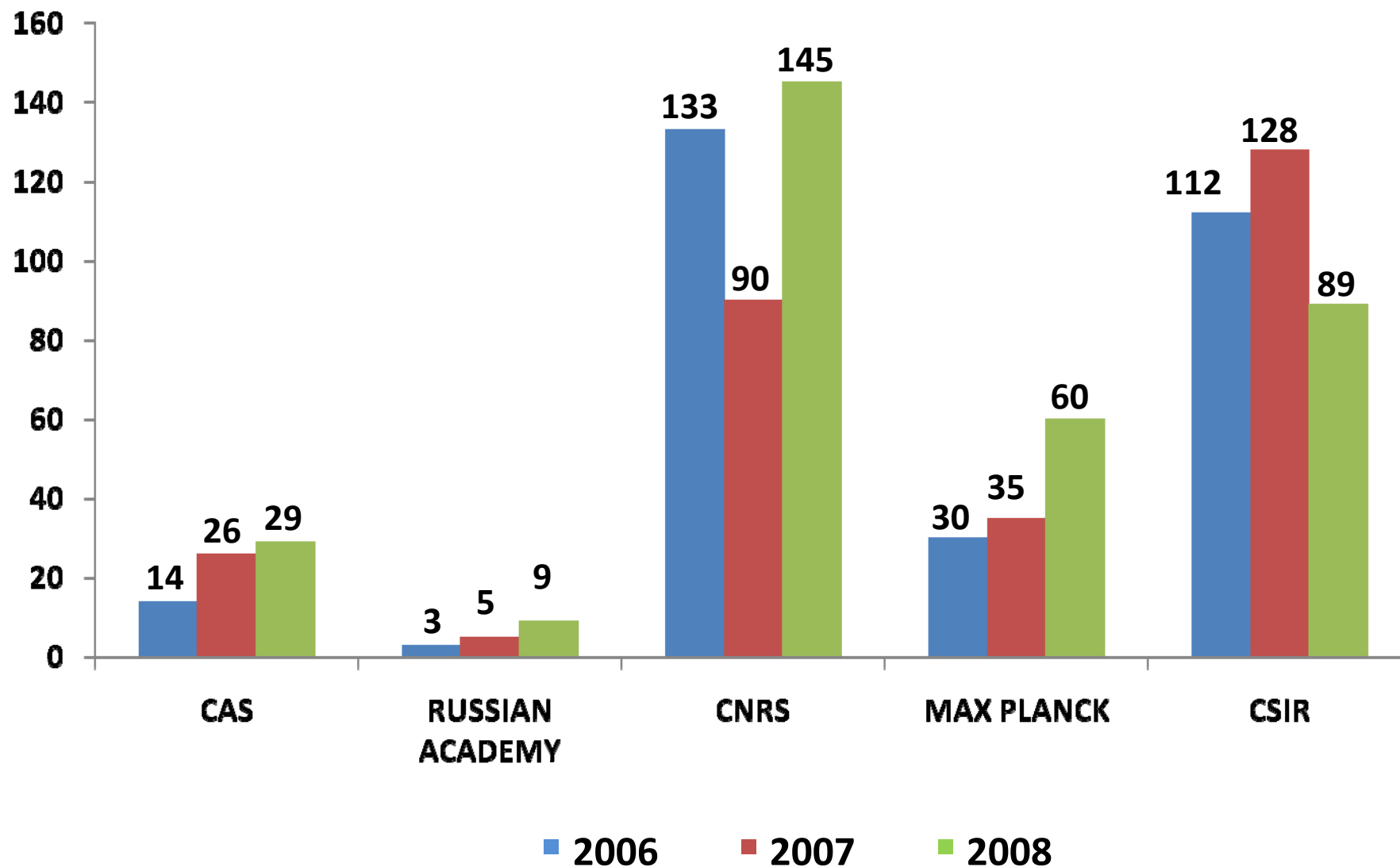
**From Reverse Engineering**

**To**

**IPR Protected Knowledge Partnerships**



# US PTO Patent



# Drugs Launched in 2009 from CSIR

## Recombinant Streptokinase

Developed in collaboration with M/s Shashun marketed by Alembic & Lupin  
Treatment for acute myocardial infarction



## Risorine

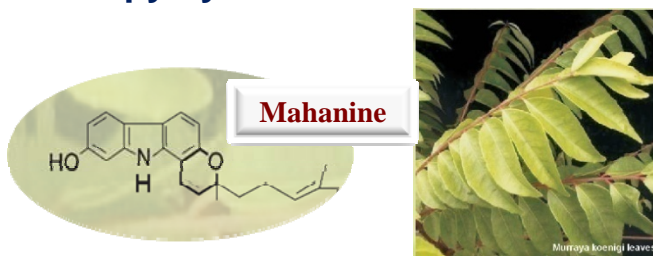
Developed in collaboration  
with M/s Cadila Pharmaceuticals

### Advancement in Tuberculosis Therapy based on Ayurveda lead

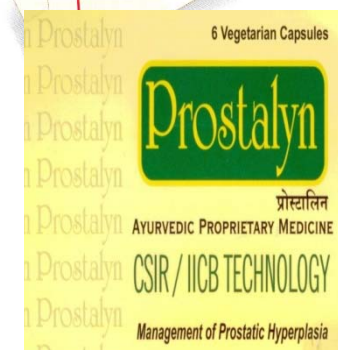
Combination of **Rifampicin** (200 mg), **Isoniazide** (300 mg) and **Piperine** (10 mg)  
Similar therapeutic benefits at less than ½ dose of conventional therapy;  
**Better** safety and tolerability and **Faster** and superior cure rates.  
Risorine will reduce cost of combination therapy by 23%



## Prostalyn



A herbal extract and a molecule for **treatment of prostate cancer** - a pharmaceutical composition useful for the treatment of prostate cancer



# Transfer of Next Generation Molecules

- New Generation Thrombolytic Molecules (Clot Busters) transferred for over US \$ 150 Million in Milestone Payments

live **mint** .com

18 November 2010

THE WALL STREET JOURNAL

## CSIR's molecule success gives a big boost to public research

BY JACOB P. KOSHY  
[jacob.k@livemint.com](mailto:jacob.k@livemint.com)

NEW DELHI

A key molecule to treat heart disease—developed at a government lab and slated for the market in 2012 if human trials are successful—could change the way public research institutes approach drug discovery.

The clot-specific streptokinase has cleared crucial trials on monkeys in the US, according to Girish Sahni, director of Chandigarh-based Institute of Microbial Technology (IMTech), where the drug was developed.

"If the next phase III (human trials) are successful by 2012, it would be a great success," Sahni said.

IMTech, which operates under the Council of Scientific and Industrial Research (CSIR), exclusively licensed the streptokinase molecule to Nostrum Pharmaceuticals LLC, a US-based firm in 2006, in a first-of-its-kind deal involving publicly-funded labs.

Although the licensing fee of ₹25 crore is minuscule compared with the billions a blockbuster drug earns for pharmaceutical firms, it is for the first time that a state-run lab has tried extracting a relatively higher price for a molecule it developed.

"Typically, we've never got more than ₹5-10 crore for licensing molecules," said G.S. Prasad, an IMTech scientist associated with streptokinase's promotional efforts. "So this is a big and encouraging deal that could change the dynamics of molecule development in public labs."

CSIR, India's largest scientific organization, has developed several drugs in its 68 years of existence, but has mostly given them out to local companies on a non-exclusive basis. This meant it rarely earned much money from licensing fees, considered the mainstay of research and development firms.





Wall is not built around a paddy field to protect the property to keep the cost affordable  
While electric fence (strong IP) is put to protect high-value property



**“When it comes to health, we need to have a  
balanced view between *health as a right and  
health as a business*”**

**Prof Samir Brahmachari**

**Chief Mentor, OSDD**

(Ref: Cell (2008) v.133, pp. 201-203)

# **Tuberculosis: Some Bare Facts**

## **Globally:**

**Incidence: 9.4 Million - 1.8 million people died from TB in 2008**

**4500 deaths a day**

**TB claims One life every 20 seconds!**

## **India:**

**Incidence: 2 million new cases annually; 1/5<sup>th</sup> of Global incidence**

**330,000 deaths due to TB each year**

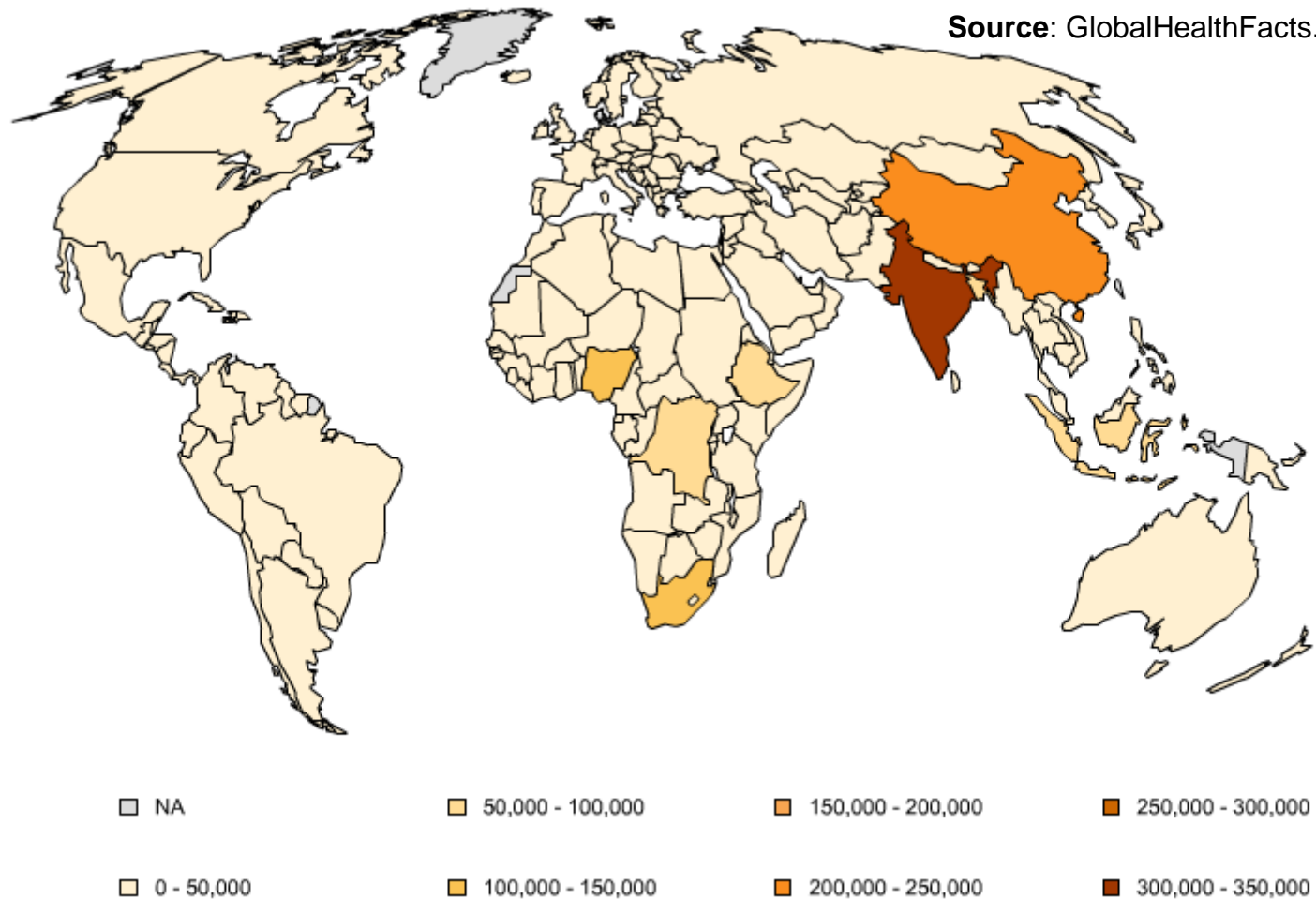
**Over 1000 deaths a day**

**2 deaths every 3 minutes in India alone**

**TB: First Target Disease of OSDD**

## Deaths due to Tuberculosis in 2007

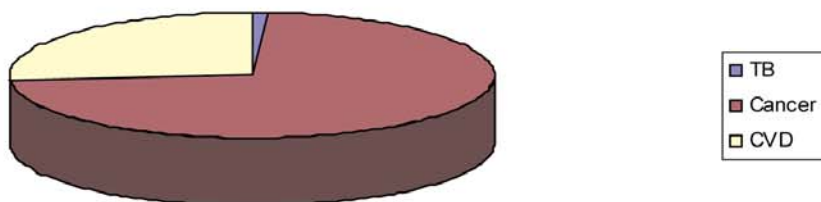
Source: GlobalHealthFacts.org



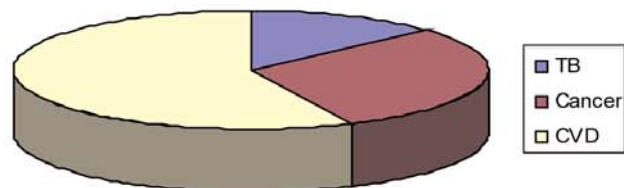
- Can We make the affected communities contribute to the drug research?
- Can we develop competencies in endemic regions?

# Drug pipelines for TB

Number of drugs in clinical stage of development



Number of pharmaceutical and biotech companies involved in drugs development projects

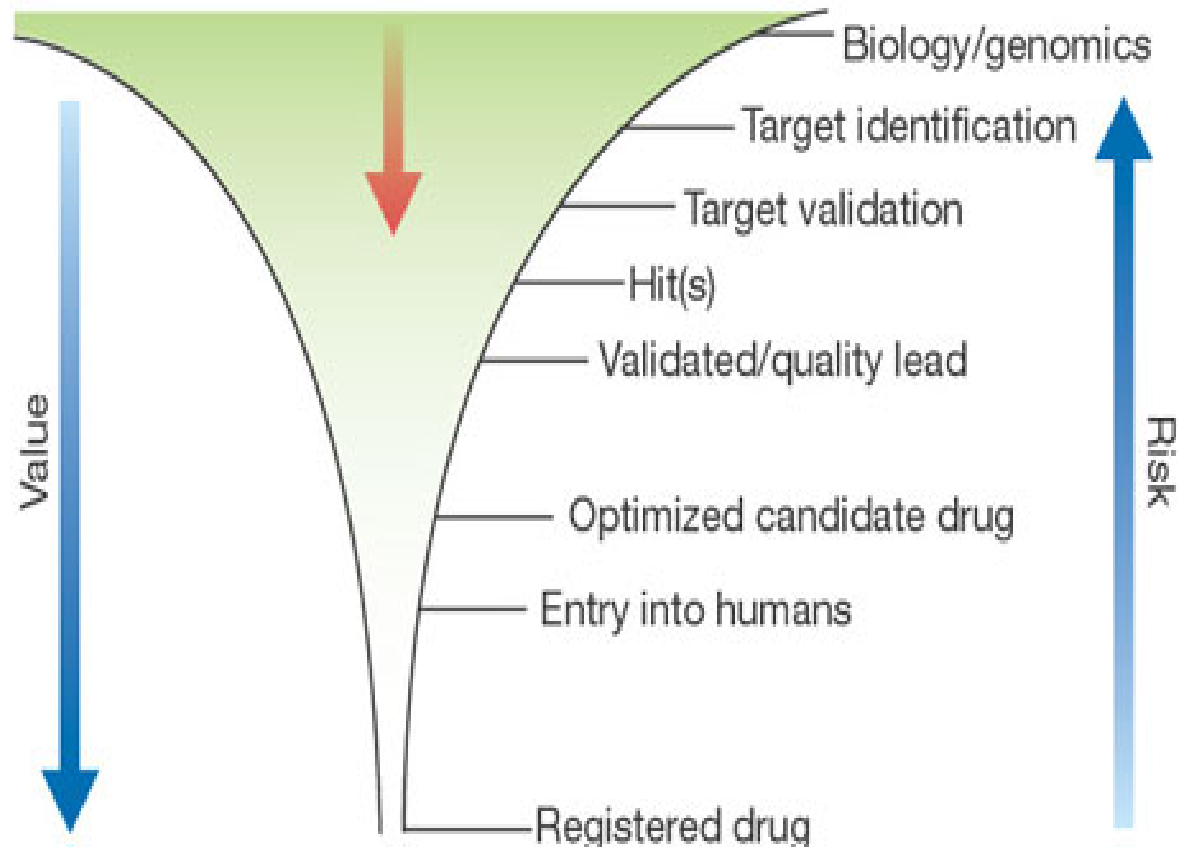


Comparison of worldwide burden of disease in DALY (Disability Adjusted Life Years) for Tuberculosis, cancer and cardiovascular diseases

	TB	Cancer	Cardiovascular diseases
No. of drugs under development	6	399*	146*
No. of pharma companies	12	178*	82*
Burden of disease in DALYs (ooo)§	34,736	77,294	148,190
Compounds/1.000 DALYs	0.17	5.16	0.98
Difference Factor	-	29.88	5.7

**Source:** Casenghi M, DEVELOPMENT OF NEW DRUGS FOR TB CHEMOTHERAPY Analysis of the current drug pipeline

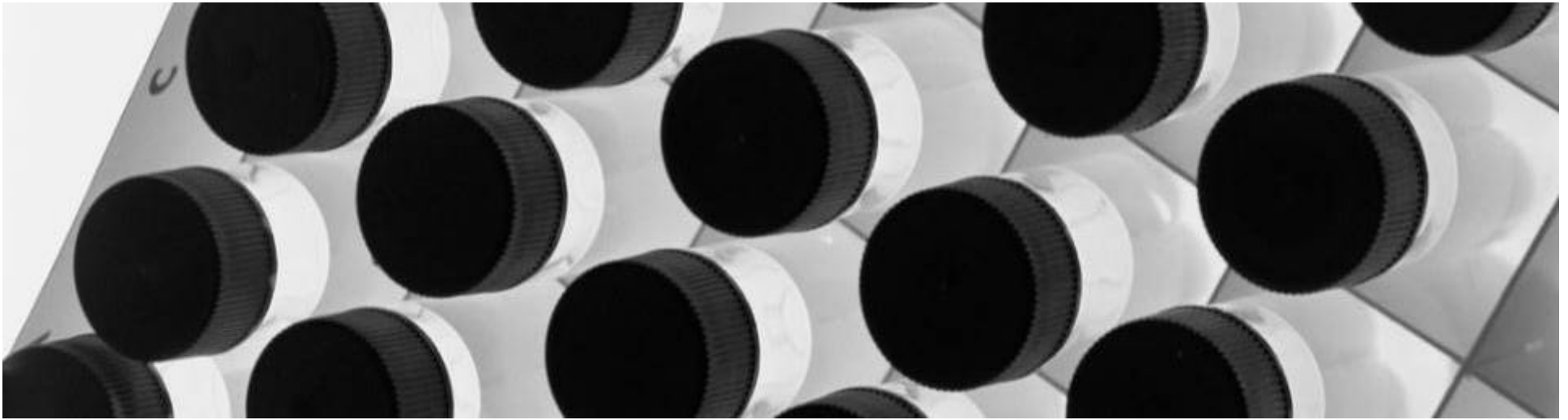
# Neglected Diseases Drug Discovery: Issue with the Funnel



**Estimated Global TB market : \$300-500 Mn only**

**Market does not mitigate the risk**

Robert G. Ridley: Medical need, scientific opportunity and the drive for antimalarial drugs, *Nature* **415**, 686-693

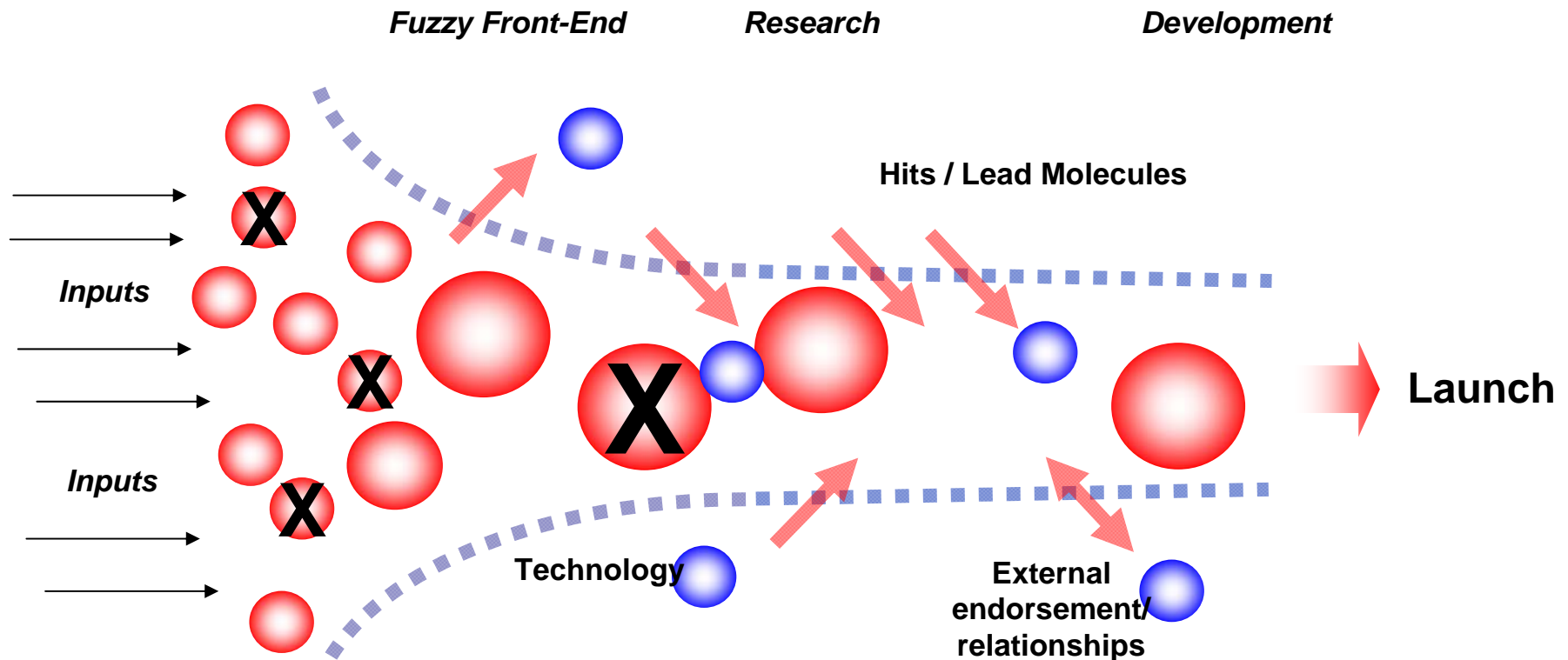


Real Innovation lies in  
“Innovating how we innovate”...

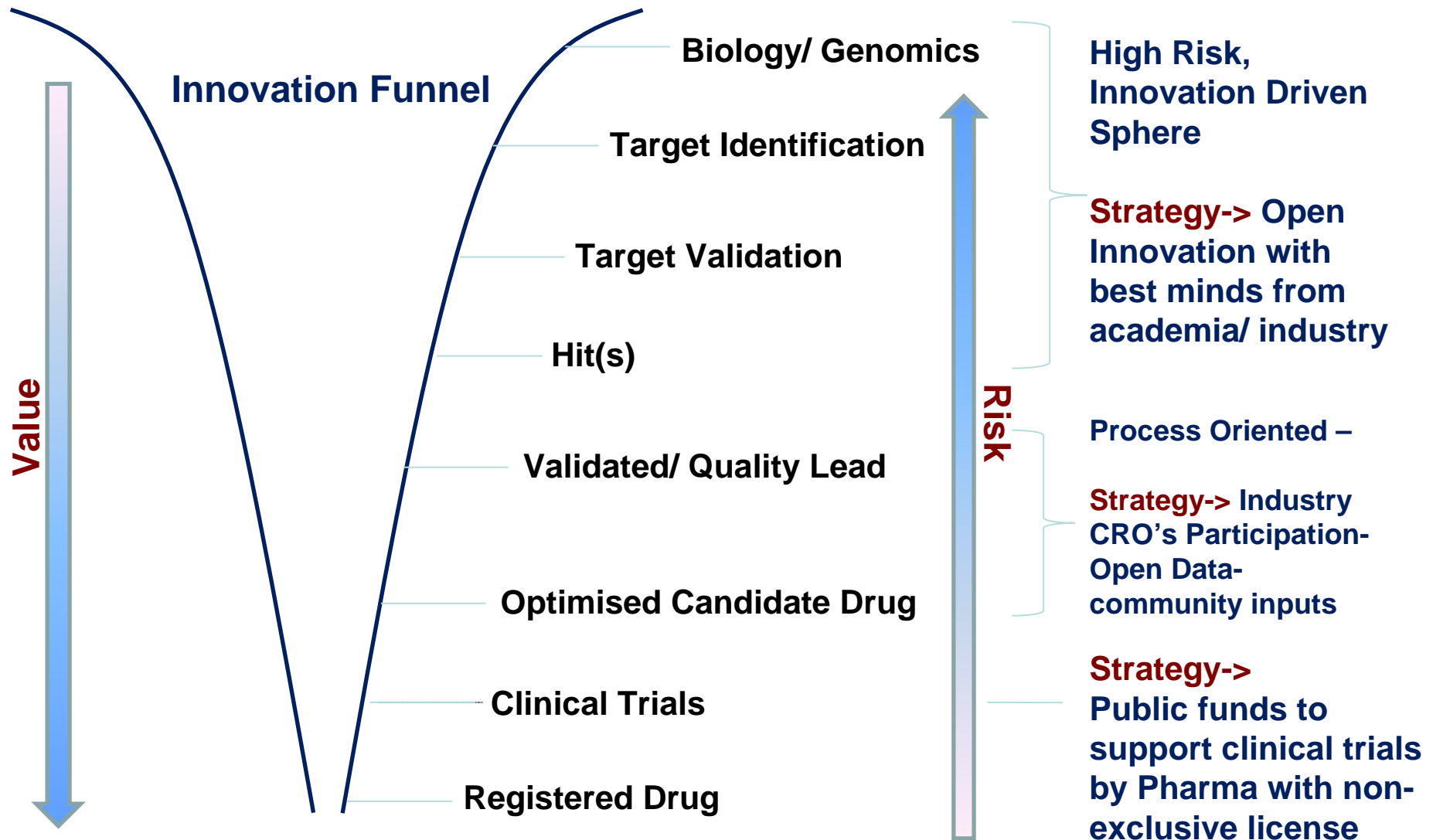


# Open Innovation Model

- Porous-walled funnel facilitates free flow of ideas / projects
- Bring in more eyeballs to look at the inside
- Enables Redundancies and Parallelization

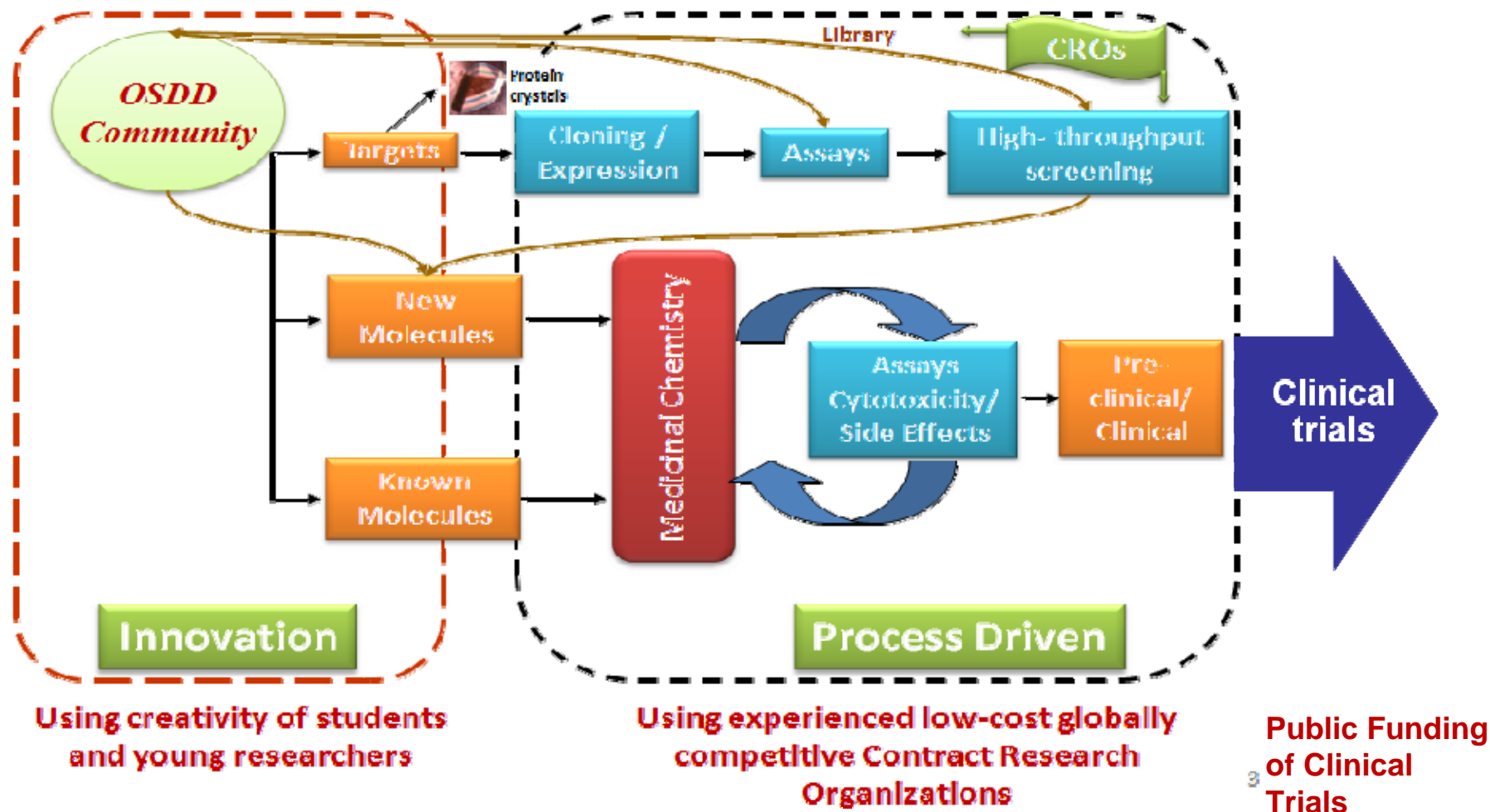


# OSDD Approach to Drug Discovery: A New Paradigm



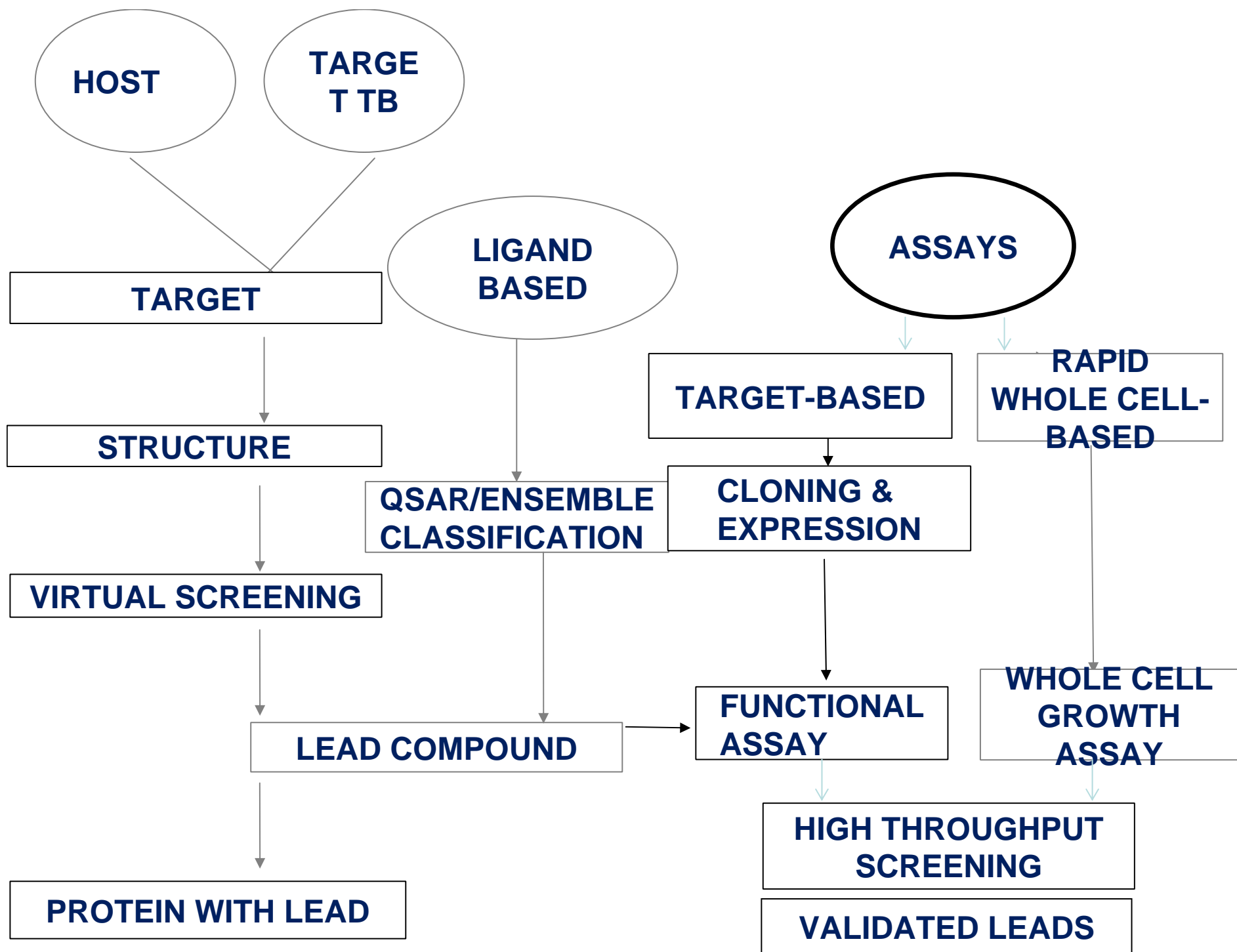
**License the drug on non exclusive basis to ensure access and affordability**

# OSDD: Many Eyeballs make the Bug Shallow



**Funds:**

**Government of India Commitment: ~\$45Mn**



# OSDD Community Effort to further the understanding of the biology of Mtb



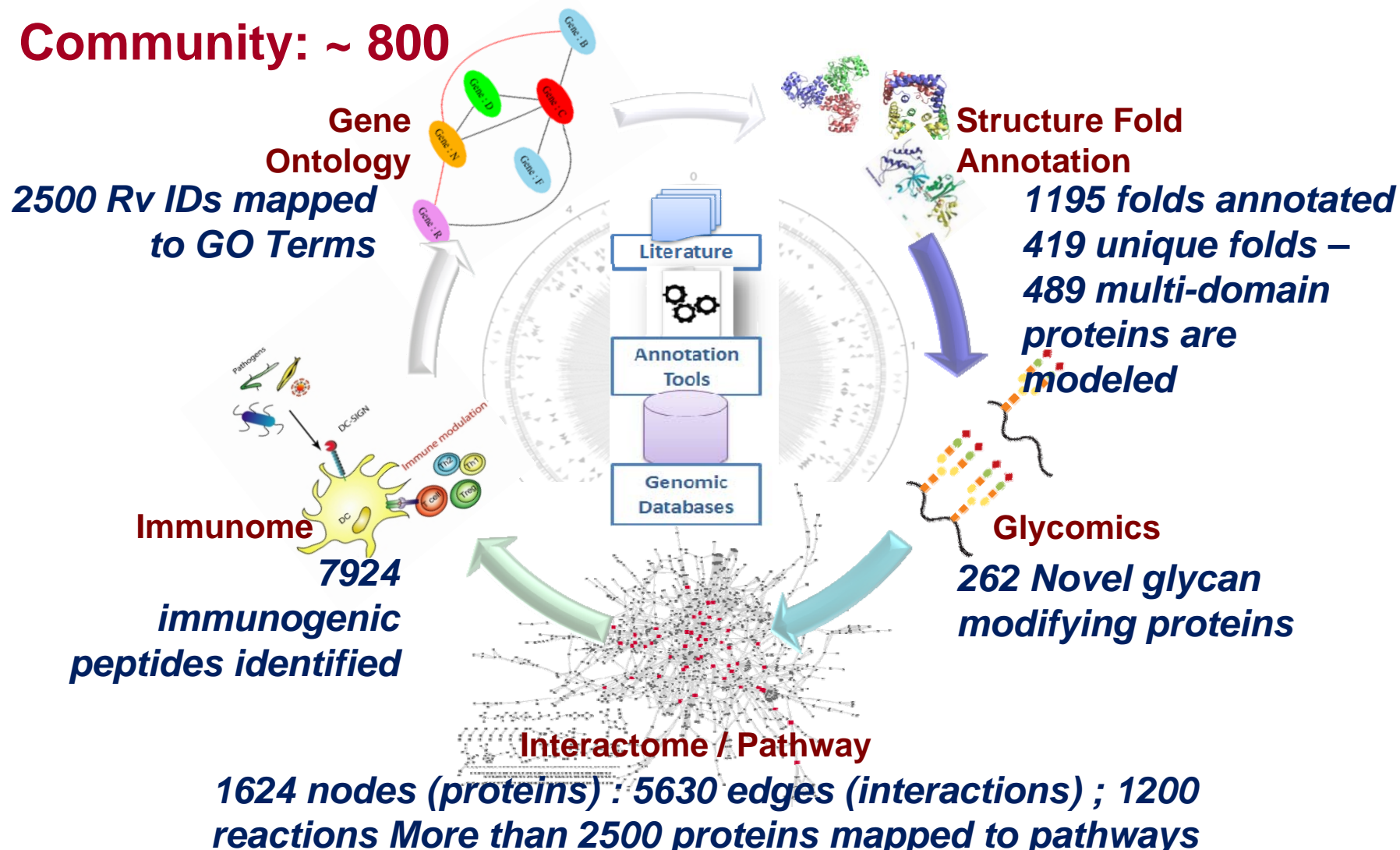
OPEN SOURCE  
DRUG DISCOVERY



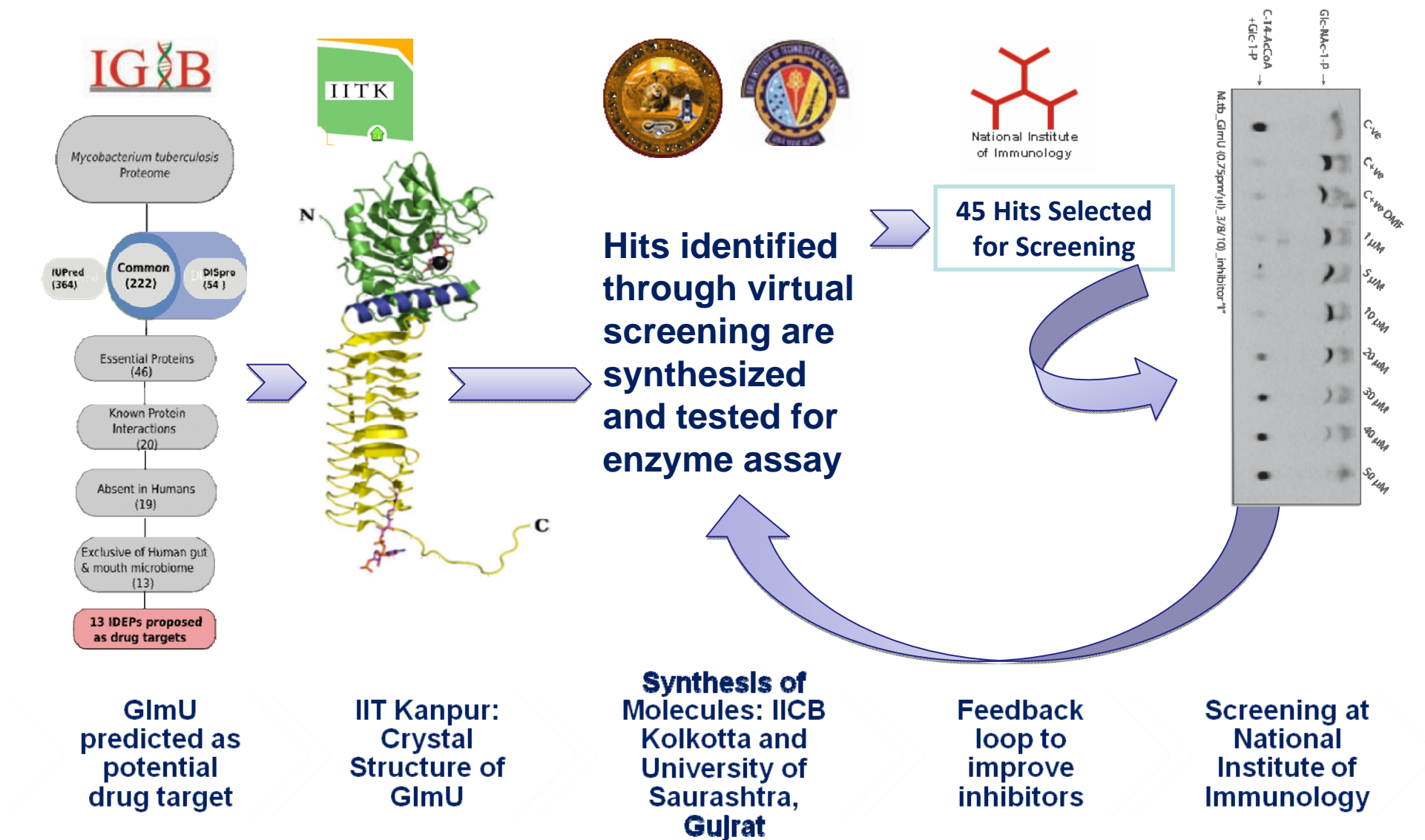
CONNECT to DECODE  
SUMMER RESEARCH PROGRAMME

'10

**Community: ~ 800**



# OSDD - Linking Institutions and Competencies





# OSDD Open Access Resources



**Assembly line for drug discovery**

## **I. Biological Repository**

- i. Open access clinical strains repository
- ii. Open access clone repository
- iii. Open access protein repository

## **II Chemical Repository**

- i. Open access small molecule repository

## **III Open Screening Facility**

**Submit your compounds for anti-tuberculosis screening**

# Status: OSDD Projects



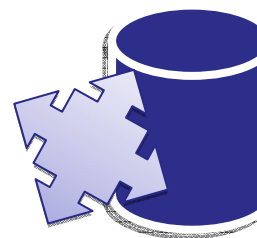
18

19

9

6

2



Other projects aim to develop tools, databases and repositories for the OSDD community

# OSDD: Attribution

- All contributions on the OSDD portal attributed to the authors with date and time stamp
- Authorship: All contributors including virtual collaborators get authorship; OSDD consortium as co author
- Real time data sharing
  - Transparency
  - Collaboration
  - Openness

# Intellectual Property Approach

- Click wrap license agreement – mandates sharing, attribution, contribute back
- Two patent applied molecules in hit to lead phase
- **Patent** only to ensure that:
  - Quality assurance in downstream processes
  - Subsequent innovations remain in open source
  - Affordability : through non exclusive licenses
- All Molecules of OSDD will be non exclusive in the developing world, subject to market competition for affordability

# OSDD : A Global Community - 4511 members from more than 130 countries

Albania	Costa Rica	Iran	Monaco	Sri Lanka
Algeria	Croatia	Iraq	Morocco	Suriname
Andorra	Cuba	Ireland	Mozambique	Sweden
Angola	Cyprus	Israel	Namibia	Switzerland
Argentina	Czech Republic	Italy	Nepal	Syria
Aruba	Denmark	Jamaica	Netherlands	Taiwan
Australia	Dominican Republic	Japan	New Zealand	Tajikistan
Austria	Ecuador	Kazakstan	Nicaragua	Thailand
Azerbaijan	Egypt	Kenya	Nigeria	Trinidad and Tobago
Bahrain	El Salvador	Korea	Norway	Tunisia
Bangladesh	Estonia	Kyrgyz Republic	Oman	Turkey
Belarus	Ethiopia	Laos	Pakistan	Turkmenistan
Belgium	Fiji	Latvia	Panama	Uganda
Belize	Finland	Lebanon	Paraguay	Ukraine
Benin	France	Liberia	Peru	United Arab Emirates
Bhutan	Georgia	Libya	Philippines	United Kingdom
Bosnia and Hercegovina	Germany	Liechtenstein	Poland	United States of America
Brazil	Gibraltar	Lithuania	Portugal	Uruguay
Bulgaria	Greece	Luxembourg	Romania	Uzbekistan
Burundi	Guam	Macao	Russia	Vatican City
Cambodia	Guatemala	Macedonia	Saudi Arabia	Venezuela
Cameroon	Haiti	Malawi	Senegal	Vietnam
Canada	Hong Kong	Malaysia	Singapore	Yemen
Chile	Hungary	Malta	Slovakia	Yugoslavia
China	Iceland	Mauritius	Slovenia	Zaire
Colombia	India	Mexico	South Africa	Zambia
Congo	Indonesia	Moldova	Spain	Zimbabwe

Statistics as of November 2010

# Acknowledgment



Dr. V. M. Katoch  
DG, ICMR

**Mentor**



Dr. S. K. Brahmachari  
DG, CSIR

**Chief Mentor**



Professor M Vijayan  
President, INSA

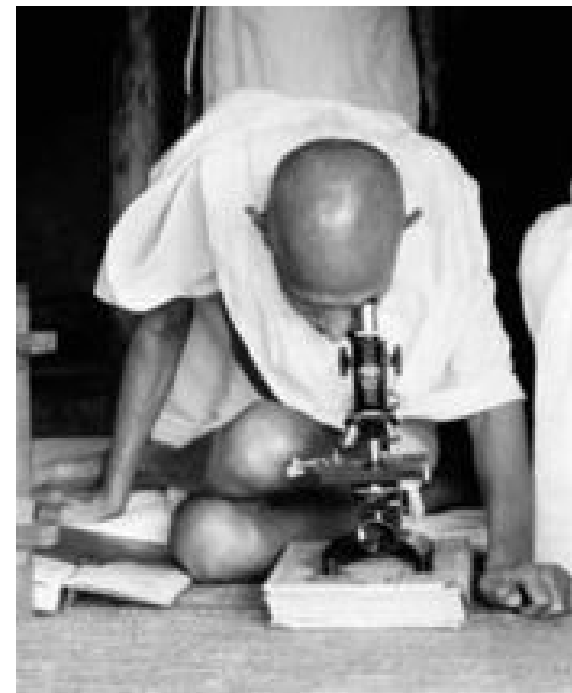
**Mentor**

**...And the OSDD Community**



Be the change you want to see in the world

**Mahathma Gandhi**





***Together we can ...***

***... and we should !***

**Thank You**

**Acknowledgement:  
OSDD Community**

**e-mail: [zthomas@osdd.org](mailto:zthomas@osdd.org)  
Skype: zakir.thomas**