

TRANSLATIONAL RESEARCH ECOSYSTEM IN INDIA: CURRENT STATUS, CHALLENGES, AND WAY FORWARD



Translation Research (TR) is the process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public — from diagnostics and therapeutics to medical procedures.

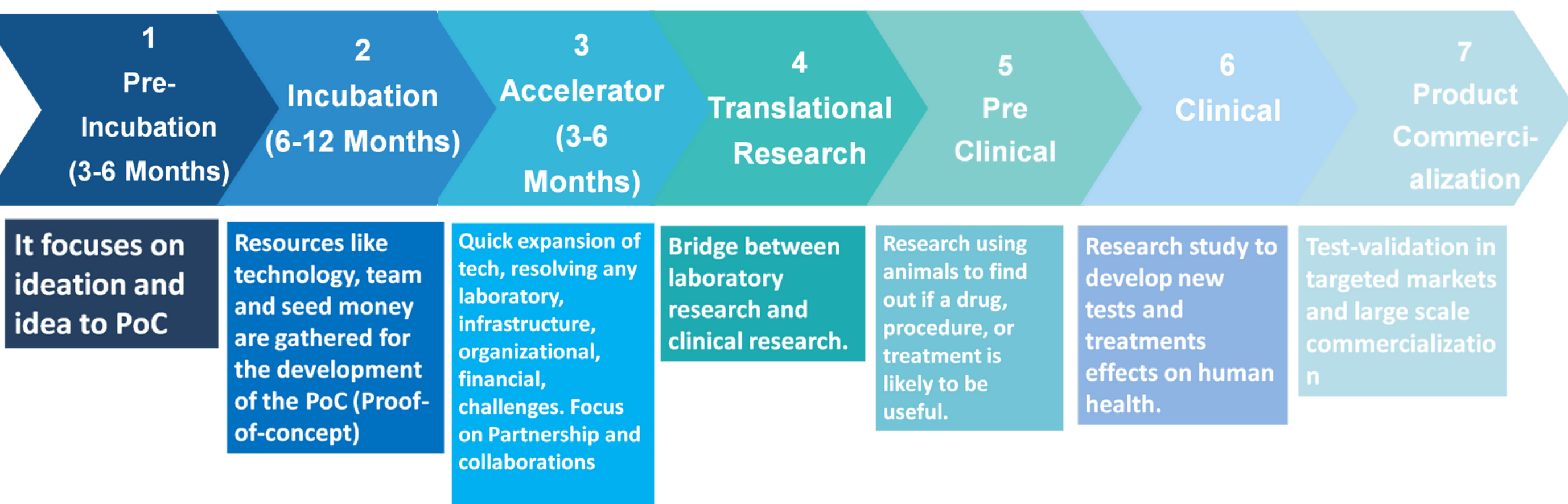
'Translating' Findings

Knowledge/ Understanding
(from basic research)
Bench/ Laboratory
Science (Knowledge Phase)

**T
R**

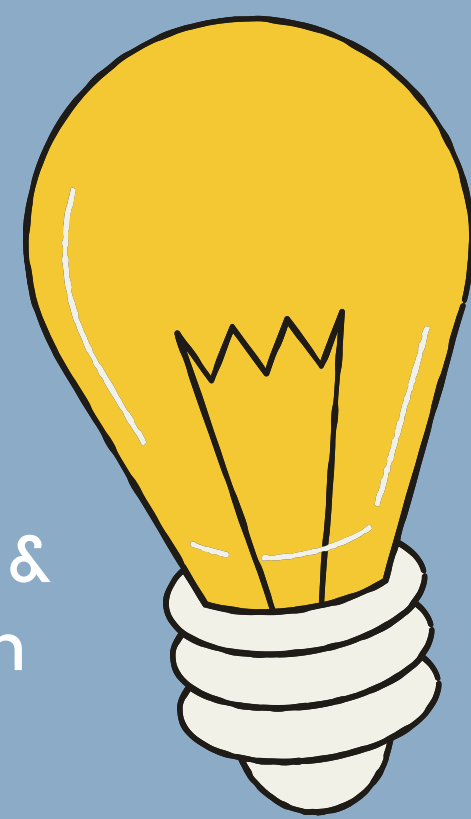
Action/ Intervention
Bedside/ Clinic Intervention
Medecine (Action Phase)

PHASES OF TRE



MAJOR POLICIES

- Make in India for R&D
- National Biotechnology Development Strategy
- Policy To Catalyze Research & Development And Innovation In The Pharma- Medtech Sector In India
- National Medical Device Policy 2023



Brief History

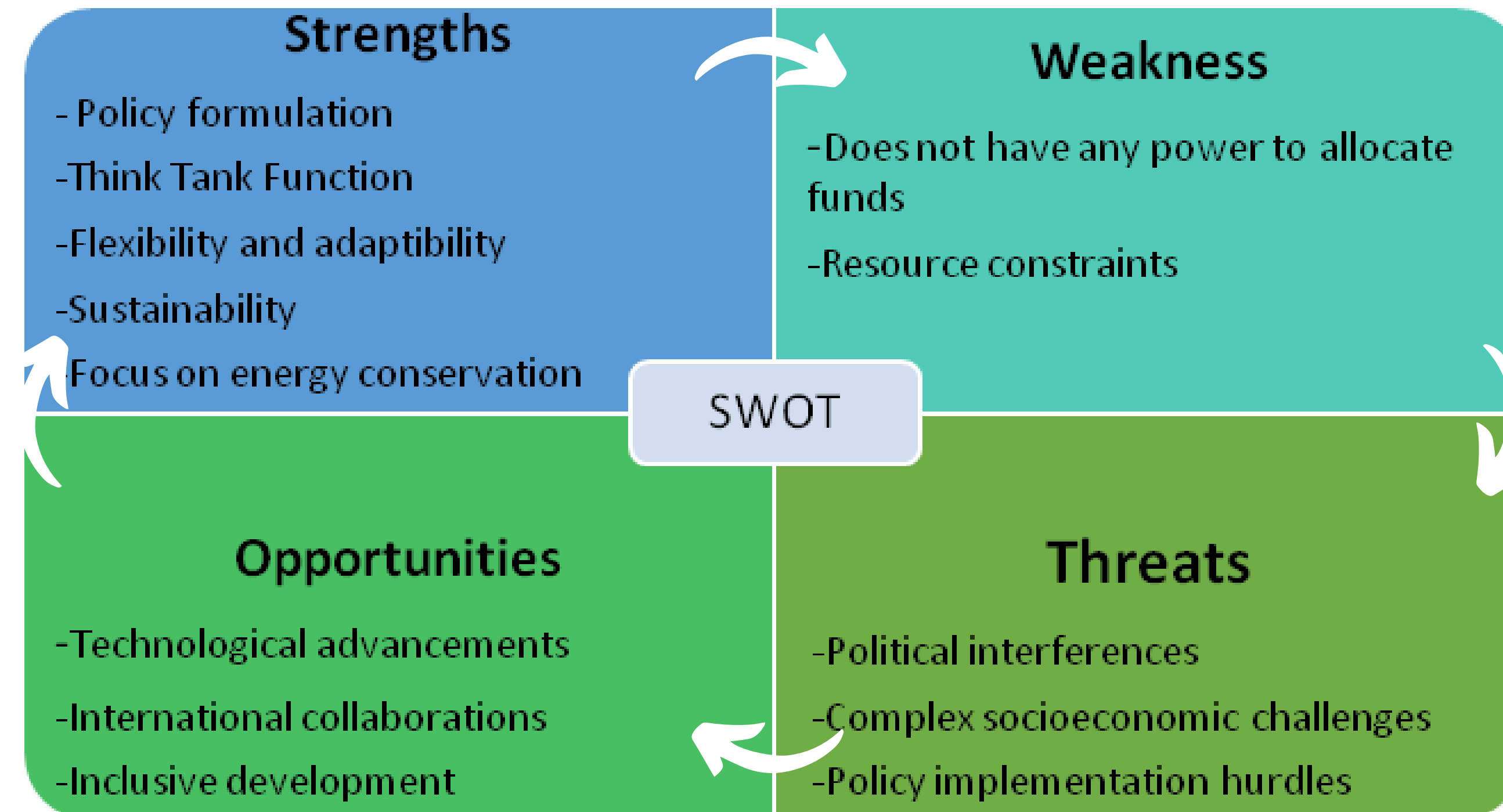
NITI Aayog also known as National Institution for Transforming India Aayog was formed on 1st January 2005. After the dissolution of the Planning Commission, it was replaced by the NITI Aayog, the country's premier policy-making think tank of the Government of India

Mission

To provide data-based policy inputs for making India the 3rd largest economy by 2047 while achieving Sustainable Development Goals including employment for all by 2030.

Vision

For achieving this vision, NITI Aayog would provide specialized inputs – strategic, functional and technical to Prime Minister and the Government at all levels (Centre as well as States).



WAY-FORWARD

- Scientists and researcher education, training and education and orientation should be done
- Provision of data sharing platform
- Separate law for Medical devices and clear regulation mechanisms for all the medical devices class A, B, C, and D which makes export easy
- Sufficient financing should be provided all at once, no subsidies
- The industry should step forward and provide funding for the translational research initiative.
- Reduction in the cost of manufacturing and product design
- Raw materials should be available in the proper quantities.
- The manufacturer's major goal should be to practice responsible manufacturing.
- Industry and academics should have constant communication
- Testing facilities should be expanded

CHALLENGES

Pre- Incubation, Incubation and Accelerator Phases

- Less experienced & untrained clinicians and researchers
- Lack of mentoring & coaching
- Lack of government-linked company support
- Insufficient funding

Translational Research Phase

- Wastage of time and energy due failure of research
- Lack of previous research data transparency and availability
- Lack of repetitive interactive feedback between different disciplines

Pre-Clinical and Clinical Phase

- Delays in approval from regulatory agencies
- Non availability testing facility
- Understaffed research teams
- Limited understanding of patients/ participant
- Failure of studies in human trials after successful animal trail methods

Product Commercialization Phase

- Lack of a stable pricing and policy environment
- huge malpractice among drug sellers
- foreign companies do not introduce new drugs in the Indian market, discouraging innovation and drug discovery

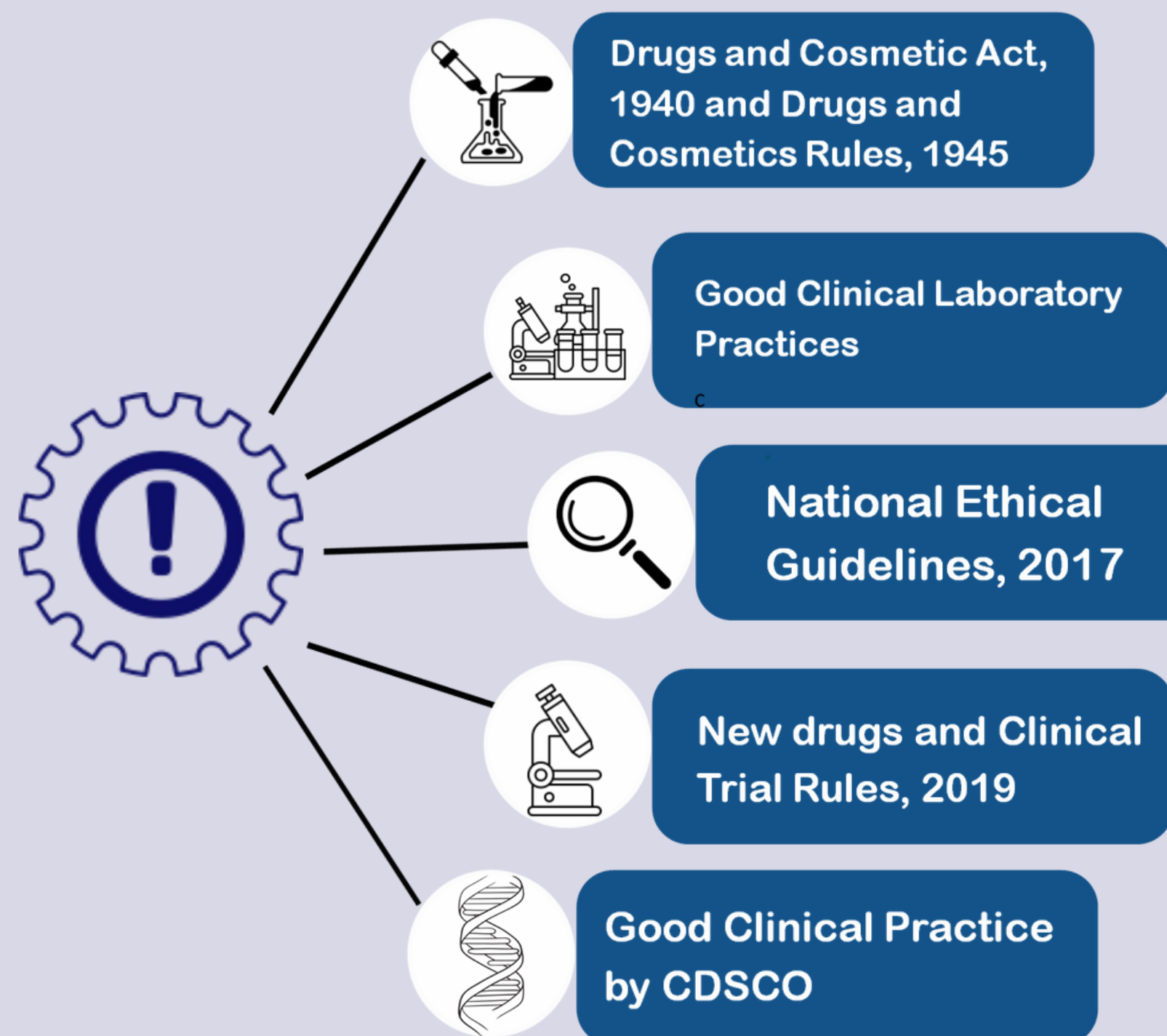
LEARNINGS

Policy formulation, Research Analysis, Proposal Writing, Policy Writing, Literature Review, Data collection and analysis, Conducting meetings and minutes preparation

GALLERY



LEGAL FRAMEWORK OF TRE



THE REGULATORY BODIES ARE–

Central and State Drugs Standard Control Organization (CDSCO) and State Licensing Authorities (SLA)

MAJOR TR INSTITUTES & INITIATIVE IN INDIA

- THSTI- TRANSLATIONAL HEALTH SCIENCE AND TECHNOLOGY INSTITUTE, INDIA
- CLINICAL DEVELOPMENT SERVICES AGENCY (CDSA)
- ANDRA PRADESH MEDTECH ZONE LTD (AMTZ)
- STANFORD BIODESIGN IN INDIA

PHASE AND ITS SCHEME

Pre- Incubation Phase

- BIG- Biotechnology Ignition Grant
- E-Yuva

Incubation Phase

- BioNEST
- Atal Incubation Centres
- Medi Valley Incubator

Accelerator Phase

- SBIRI- Small Business Innovation Research Initiative
- BIPP -Biotechnology Industry Partnership Programme

Translational Research

- ETA- Early Translation Accelerator
- Accelerated Translational Grant For Commercialization (ATGC)
- (DST-BDTD) Biomedical Device And Technology Development Programme
- Ind-CEPI Mission
- PACE- Promoting Academic Research Conversion To Enterprise

Pre-Clinical and Clinical Trial Phase

- INTENT (ICMR)
- DPRP - Drugs And Pharmaceuticals Research Programme (DST)

Product Commercialization Phase

- medtech -Product Ignition and Development Enabler (mPRIDE) Programme
- (PCP-FUND) Product Commercialization Programme Fund