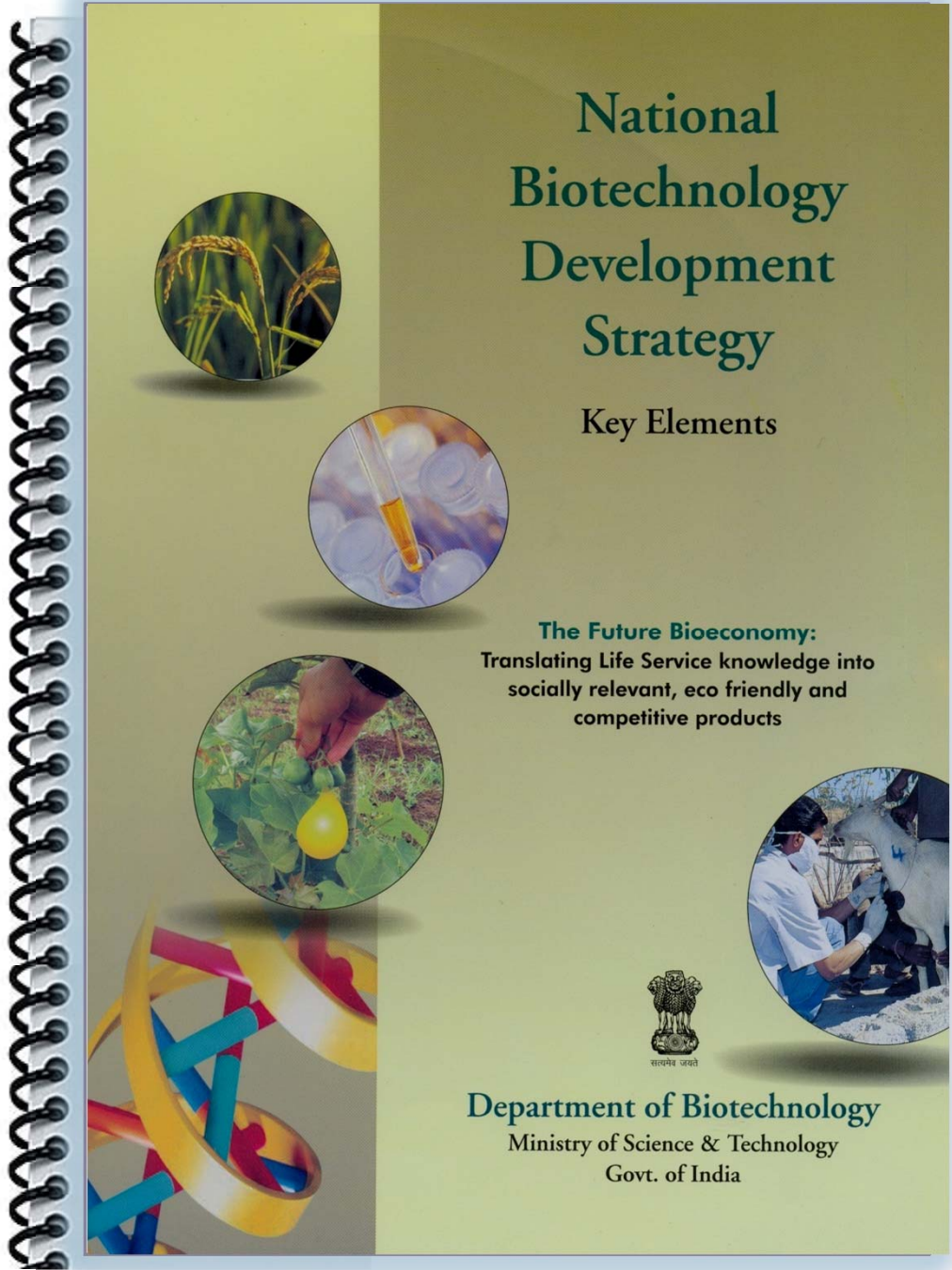


Empowering and Enabling the Biotech Innovation Ecosystem



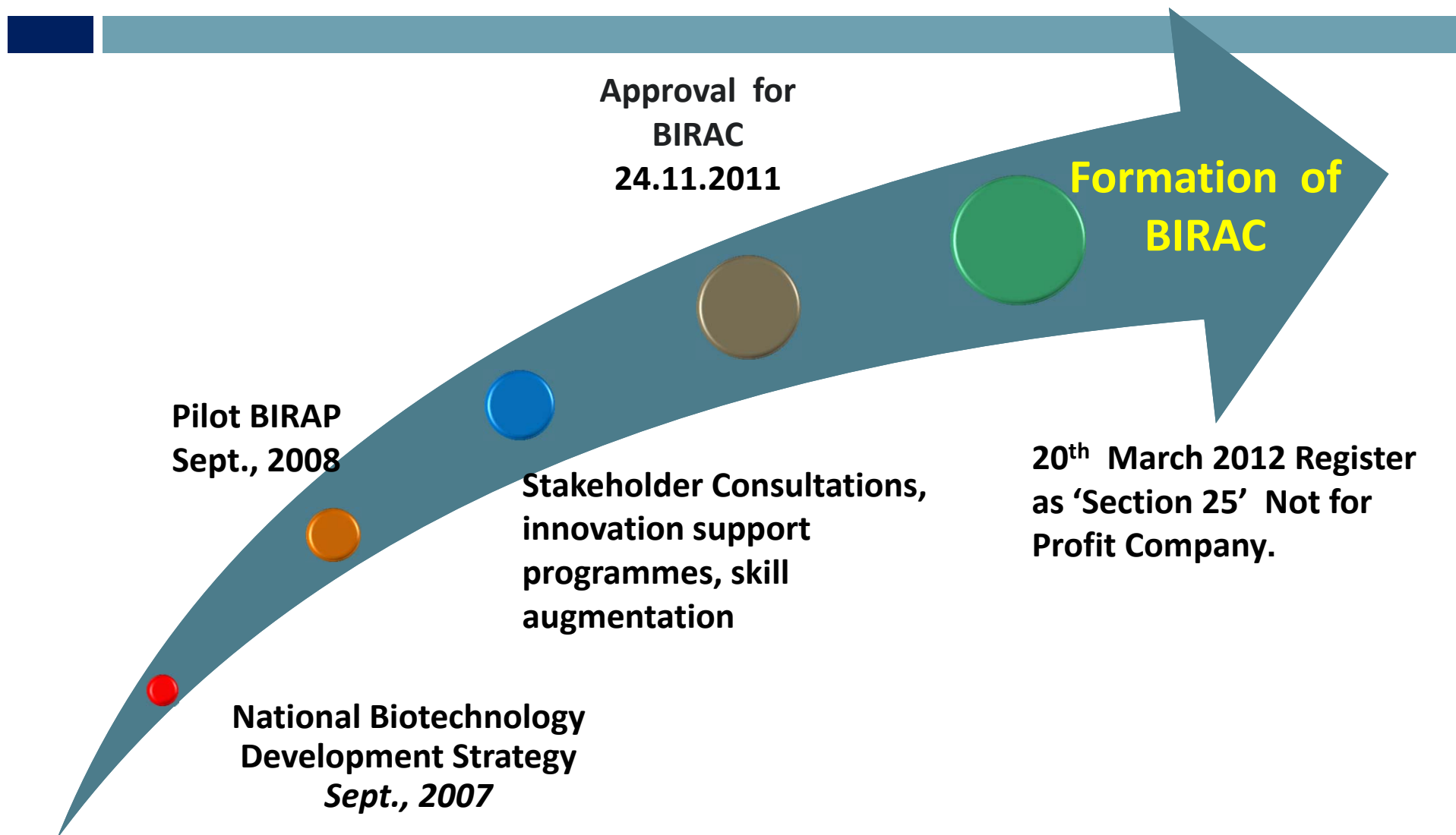
**Dr. Renu Swarup, Adviser, Department of Biotechnology
&
Managing Director, BIRAC**



BIRAC to Nurture Industry R&D

30% budget to be spent on PPP

How we moved.....





Our Focus-

To strengthen and empower the emerging Biotech enterprise to undertake strategic research and innovation, addressing nationally relevant product development needs.



BIRAC Vision-

“To Stimulate, foster and enhance the strategic research and innovation capabilities of the Indian biotech industry particularly SME’s, to make India globally competitive in biotech innovation and entrepreneurship, for creation of affordable products addressing the needs of the largest section of society.”

BIRAC Mission-

“Facilitate and mentor the generation and translation of innovative ideas into biotech products and services by the industry, promote academia – industry collaboration, international linkages and encourage techno entrepreneurship and enable creation and sustainability of viable bio-enterprises.”



BIRAC Verticals

- **Fostering innovation and Enterprise Building:**
 - **Fostering Innovation**
 - **Knowledge, Technology Mapping and Management**
 - **Technology Transfer, Licensing and Acquisition**

- **Provide enabling services for promoting the innovation ecosystem**

- **Build Strategic Alliances – National & International**

How does BIRAC accomplish its Mission

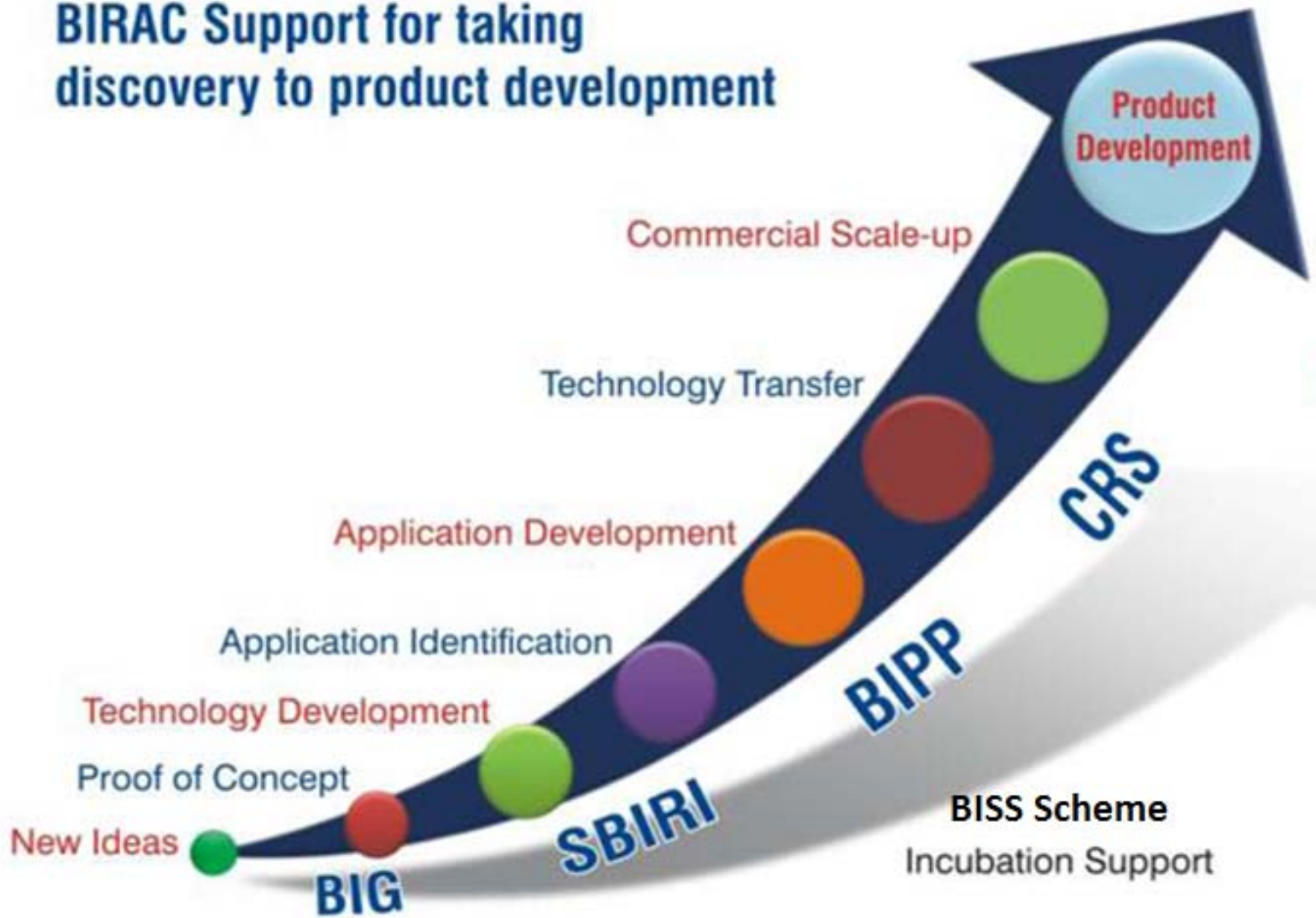
Ensuring Entitlements

- **Ignite new Ideas- Biotech Ignition Grant Scheme (BIG)**
- **Support early stage research for proof of concept validation – Small Business Innovation Research Initiative (SBIRI)**
- **Partnership with industry for high risk discovery led innovation research – Biotechnology Industry Partnership Programme (BIPP)**
- **Facilitating technology validation and development – Contract Research Scheme (CRS)**

Empowering for Achieving Excellence

- **Create world class quality Incubation space (Bio-incubators) for entrepreneurs and star-ups.**
- **Create common service facilities in public and private sector to serve the needs of Start Ups.**
- **Create Schemes that facilitate the acquisition or license of innovative technology and technology mapping for identifying patentable technology at national or international level.**
- **Create capacity in various fields required for successful Bio enterprises.**

BIRAC Support for taking discovery to product development



Biotechnology Ignition Grant (BIG) Scheme

Purpose:

Establish and validate of Proof of Concept

Encourage researchers to take technology closer to market through a Start Up

Target Groups:

Entrepreneurs from Academia or an Incubatee

(PhDs, Medical degree holders or Biomedical Engg. Graduates)

Support:

Grant-in-Aid limited up-to INR 50 Lakh
Mentoring and hand-holding

Supports up-to Proof-of-Concept stage

Small Business Innovation Research Initiative - SBIRI

- **Objectives**

- To support early stage, proof-of-concept research

- **Mission**

- Nurture innovative and emerging technologies/
entrepreneurs

Biotechnology Industry Partnership Programme- BIPP

Purpose:

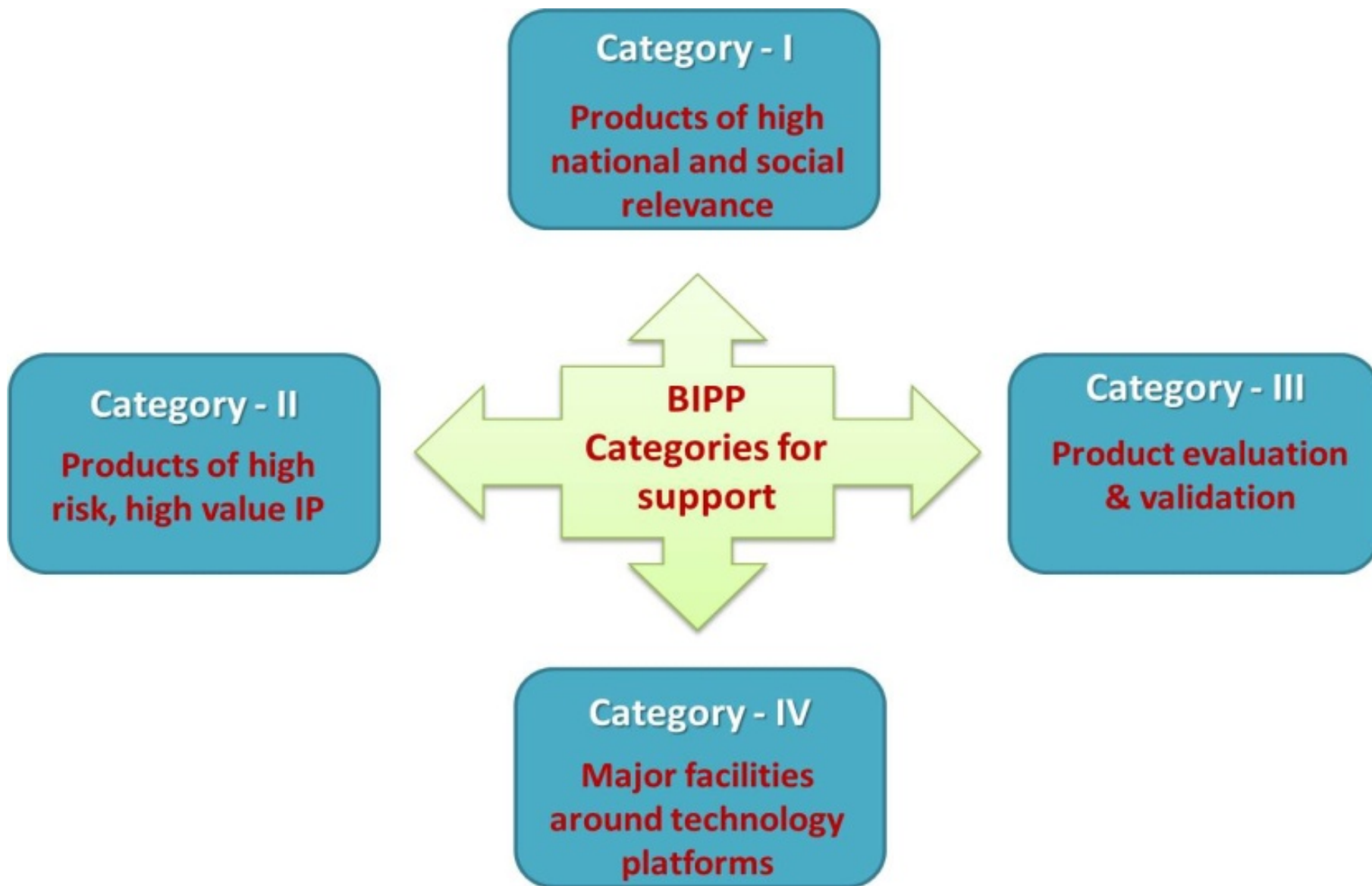
- Govt. partnership with Industries
- *Cost sharing basis*
- For path-breaking research in frontier futuristic technology areas having major economic potential.
- Focused on IP creation
- IP ownership retained by Indian industry/collaborating scientists.

Support:

- For high risk, highly innovative accelerated technology
- For nationally and socially relevant areas, with no assured market. \
- Provides for product evaluation and validation through support for field trial for agriculture products and clinical trials (Phase I, II, III) for health care products.
- Supporting research project for novel IP generation.

Target:

- Indian Biotech companies registered under Indian Company Act 1956
- 51% Indian shareholding (including NRI's)
- DSIR recognized R&D
- Apply independently or in collaboration with companies, not for Profit organisation or academics partners



Contract Research Scheme- CRS

Purpose:

Academia-industry interaction

Industry to validate process or partner for specific research

Leads should be at a level which provides sufficient data for Scale up/Validation:

- Exploratory validation of technology
- Small scale contract research resulting in generating several batches of process or multiple prototypes
- Large scale validation of prototype to commercial design

Target Groups-

Research institutes, Universities, Public funded research

Laboratories, Governmental organizations, Research foundations
AND

Companies / industries

Company partner should have DSIR recognized R&D/Service unit(s)

Support:

- Funds for validation of PoC
- IP Services and Management
- Legal support: MTA, NDA, IP protection contracts, Licensing agreements

Bio-incubator Support Scheme- BISS

Purpose:

Strengthening and Up-gradation of the existing Bio-incubators and also to establish New World Class Bio-incubators in certain strategic locations.

Target Groups:

- Existing Bio-incubators across the country
- New Bioincubators

Support:

- Provide incubator space to Start-ups and Entrepreneurs.
- Provide access to a pool of special equipments in the Central Equipment Facility.
- Connect and facilitate Industry - Academia Interaction
- Provide enabling services and required mentorship for IP and Technology Management, Legal and Contract, resource mobilization and networking platform.
- Governance models would be cooperative or autonomous.

Further details at :

<http://www.birac.nic.in>

<http://www.dbtindia.nic.in>



BIPP Overview and Key Elements of Effective Grant Writing

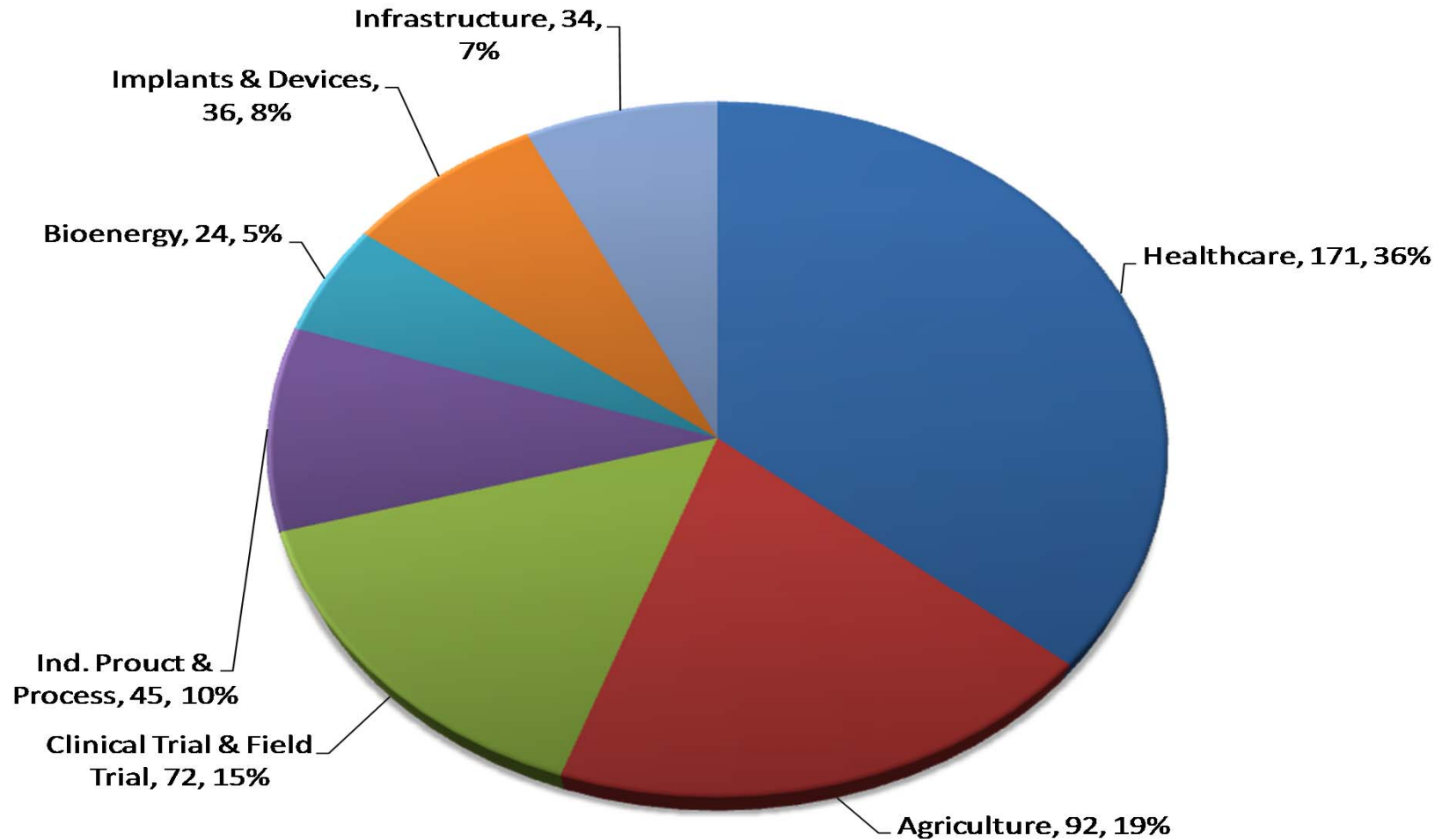
Dr. Purnima Sharma
Managing Director
Biotech Consortium India Limited
New Delhi

An Overview

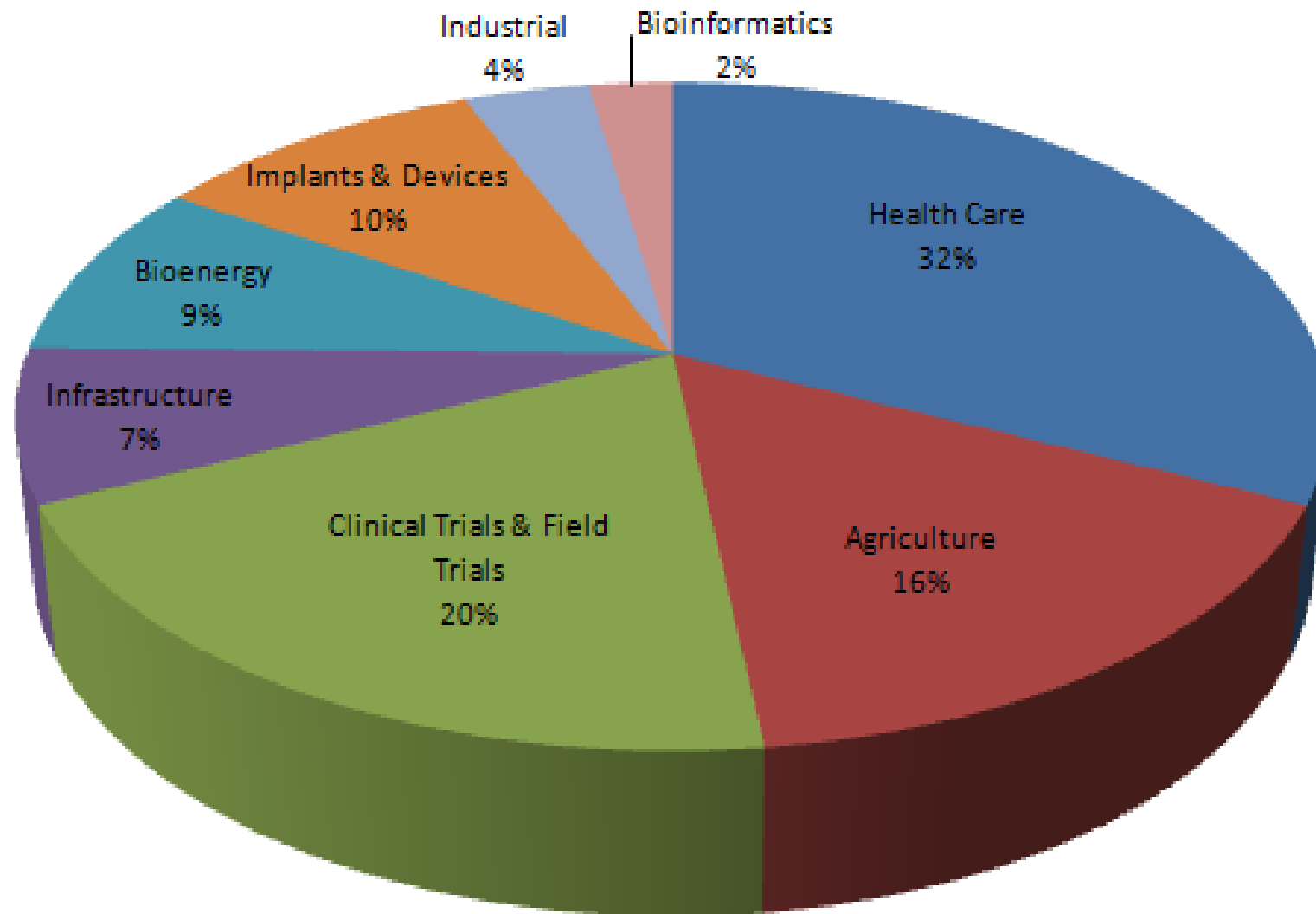
- ❖ Scheme Launched ---- **December 2008**
- ❖ Total Number of Calls--- **21 (till March 2012)**
 - ❖ Regular--- **10**
 - ❖ Special--- **11**
- ❖ Number of Projects Received --- **551**
- ❖ Number of Projects Approved --- **> 90**
- ❖ Total Budget Committed --- **Approx Rs. 650 Crore**
 - ❖ Company Contribution--- **Rs. 430 Crore**
 - ❖ BIPP Contribution--- **Rs. 220 Crore**



Total Proposals Received: 551

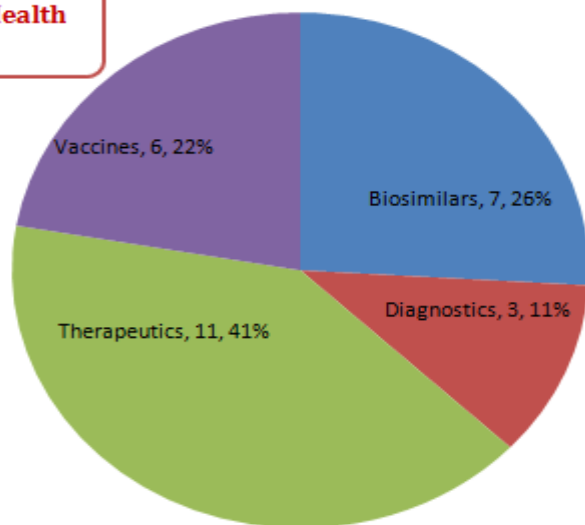


Area Wise Sanction of Projects Under BIPP



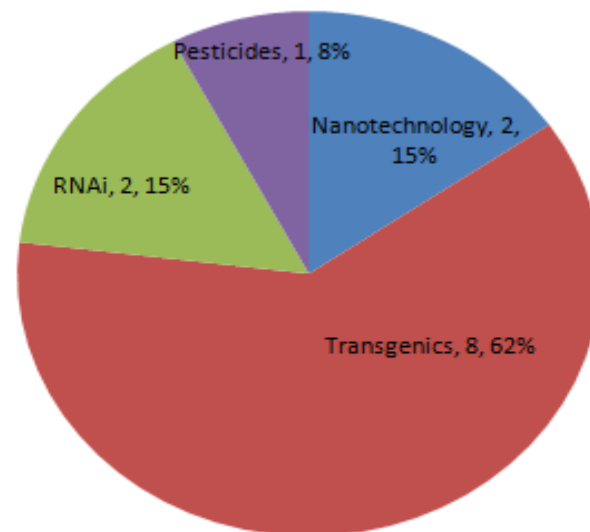
Projects Sanctioned Under Health Care Category

Total 27 Projects

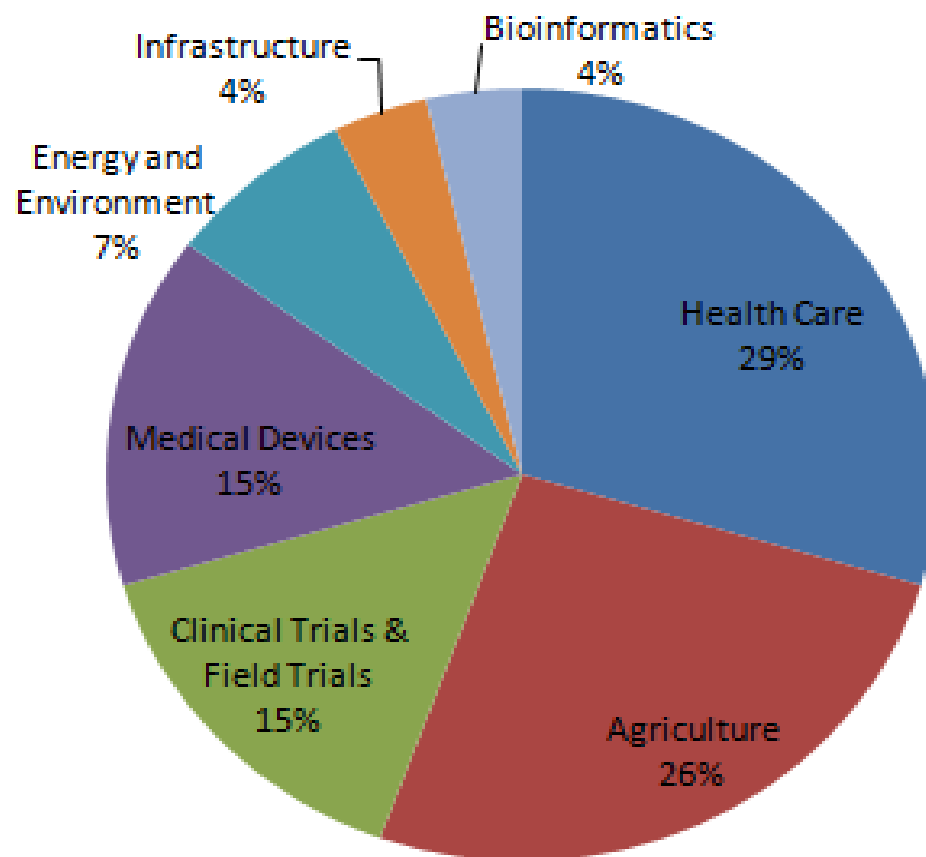


Projects Sanctioned Under Agriculture Category

Total 13 Projects



Area Wise Percentage of Collaborative Projects



Total 27 Collaborative out of 80 Sanctioned Projects





Key Elements of Effective Grant Writing

Play According To The Rules

- ✓ Read the Guidelines
- ✓ Understand the Guidelines
- ✓ Follow the Guidelines

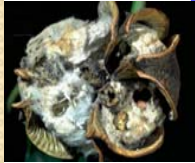
Following the Guidelines

- Make sure that you are eligible
- Read the instructions carefully
- Respond to all sections
- Cover all the topics
- Keep all preliminary & support data ready
- Use headings that correspond to guidelines

Next Step After Reading the Guidelines



7/20/2012



Developing the Proposal : Points to be addressed

-Problem addressed
Aim of the proposal

Relevance and importance of the proposed project

Status – Review

Scientific strategy & approach

Objectives

Plan of work

Expertise & infrastructure

Time lines

Outcome / deleverables



Identification of the problem

- It should be relevant
- There must be innovative approach to address the problem

Case study:

Major constraints to realize the potential yields of cotton

Yield losses due to

- | | |
|---------------------|-------------|
| - <i>H.armigera</i> | (20 – 60%) |
| - sucking pest | (22 -35 %) |
| - weeds | (15 – 30%) |

Improving Bt-cotton

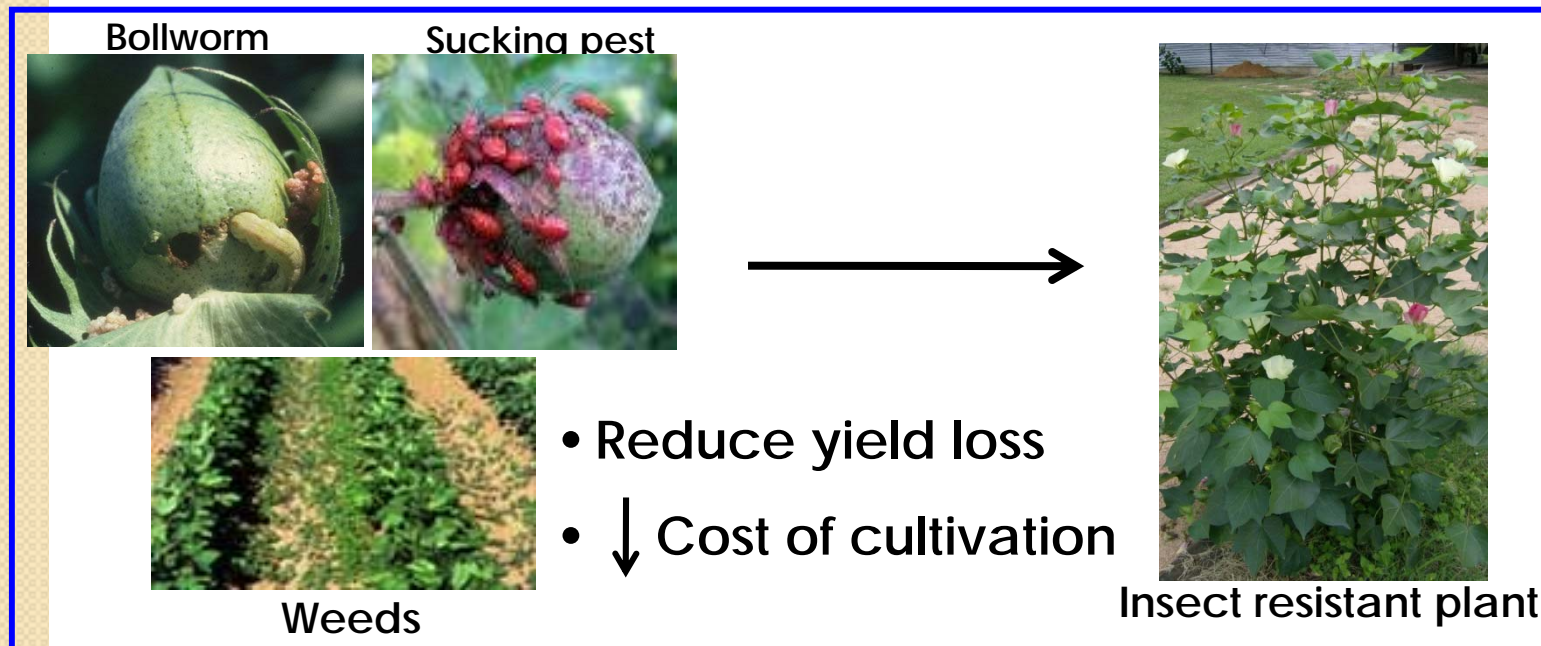
for sucking pests and effective control of weeds is useful

Criteria - Significance

Relevance and significance of the proposed project

- The problem is of great concern
- Addressing the problem will provide economic benefits to the society
- out come of the project solve the problem

Case study:



Improving insect tolerance and effective control of weeds has phenomenal significance

Criteria – commercial potential / societal relevance

How to address the problem
review the status/options
justify the approach proposed

Case study:

What are the options to improve the tolerance ? ...

- **Identifying resistant genotypes**
- **Integrated pest management (IPM)**
- **Genetic improvement**
 - **Transgenics**
 - **Molecular breeding**

What is the status in the literature on these aspects

- a) **Present status of IPM**
- b) **relevant resistant sources/ constraints**
- c) **Are there validated insecticidal proteins / genes**
- d) **Which is the effective herbicide – do we have options to improve resistance to herbicide**

Scientific strategy

What is the scientific strategy to address the problem

- Based on the existing scientific options
- Should be novel / innovative
- Implementable in time lines

Case study:

- There is no known sources of resistance
- Improving insect and herbicide resistance by transgenic approach is relevant
- Identify/relevant genes coding for insecticidal proteins
- (*Cry1Ac* & Garlic Lectin) and
- herbicide tolerant genes (*igrA*)
- co expressing by multigene constructs

Criteria –scientific merit

Two options

- ✓ Stack the genes by crossing
by developing individual transgenics
 - Bt cotton
 - lectin cotton
 - herbicide tolerance cotton
- ✓ Transfer a cotton genotype
 - with multigene cassette with all the three genes

Multigene Construct is advantages
because
"one locus" no segregation

- ✓ Background IP
- ✓ Possibility of generating foreground IP
- ✓ Freedom To Operate to use genes, constructs

Criteria –innovativeness

TITLE of PROPOSAL

- The project title should be short, concise, and preferably refer to a certain key project result or the project activity
- Project titles that are too long or too general fail to give the reader an effective snapshot of what is inside
- It should be explanatory and define the essence of the
- It facilitates in assigning appropriate review groups

Example:



Multi technological interventions to develop various biotic stress tolerant cotton for International markets" - Title is **diffused**



"co-expression of insecticidal protein cry1Ac, lectin and herbicide resistance gene iga to improve multiple biotic stress tolerance" - Title is **more specific**

It is clear from the title that simultaneous expression of specific genes is the focus to improve biotic stress tolerance in cotton. And thus, to address important constraint from insect and weeds.

Novelty of the scientific strategy

New approaches to achieve the goal using already validated approach

What is the novelty....?

- Simultaneously developing resistance to both *H.armigera* and sucking pests
- Value addition by managing the weeds
- Avoid antibiotic marker for selection
- All the genes is in single locus
- Cost effective / time saving

Criteria –innovativeness

What is the inventive step in the project

Develop a new approach / process to exploit the existing scientific knowledge

Case study:

The function of *cry1Ac*, Lectin and *igrA* is known

- a) Developing a strategy for developing multigene construct for co expression of *cry1Ac*, Garlic lectin and *igrA*
- b) Approach for transforming the multigene construct
- c) Suitable protocols for characterization of transgenics

Preliminary work done

Scientific data to support the proposed concept / scientific strategy

✓ It could be from the literature



✓ In-house - Experiments



Case study:

- **Proof to support abilities to develop multigene constructs**
- **Proof to demonstrate the availability and ability to study bioefficacy**

Goal & objectives

Goal – To develop a product/process by addressing a constraint

Case study:

Goal - “ Improving resistance to insect pest and herbicide”

Objectives:

What is proposed to achieve adapting a well defined plan of work or methodology

Case study:

- Development of multigene construct with *Cry1AC*, *GL* (*Garlic lectin*) and *IgrA*
- Development of transgenics with multigene construct and characterization of putative transformants
- Evaluation of transgenics for better performance based on bio-efficacy

Criteria –approach

Approach & Methodology

Should be

- ✓ Adequately developed
- ✓ Well-Integrated
- ✓ Well-reasoned
- ✓ Appropriate to the aims of the project
- ✓ Realistic research plan with specific milestones
- ✓ Clarity on regulatory pathway
- ✓ Potential Problems and alternative strategies

Plan of work should address

- a. Conceptual frame work
- b. Design of the experiments
- c. Methodologies
 - a) To generate product/ process
 - b) Test the product process
- d. Components to be outsourced

Conceptual frame work

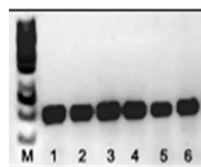
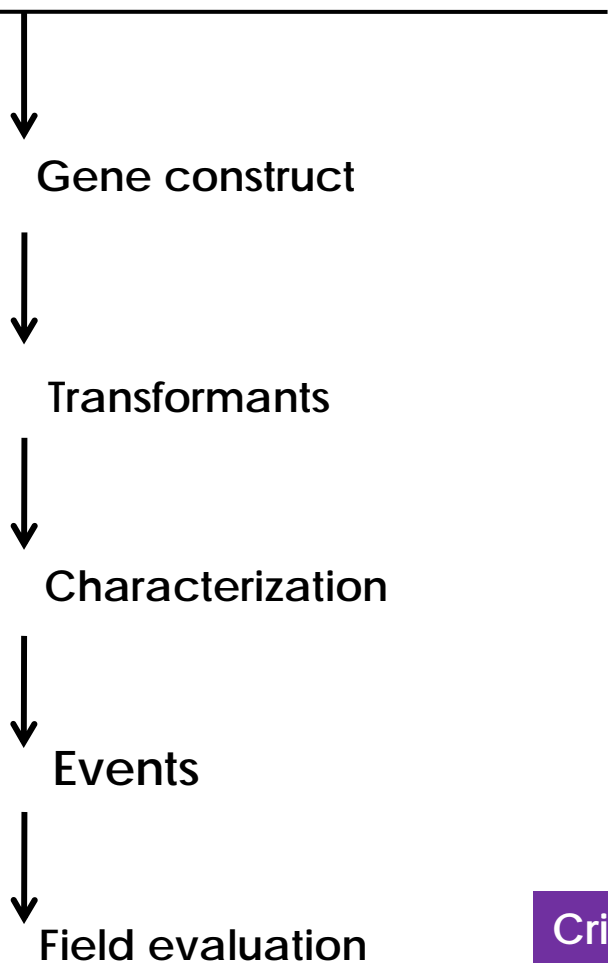
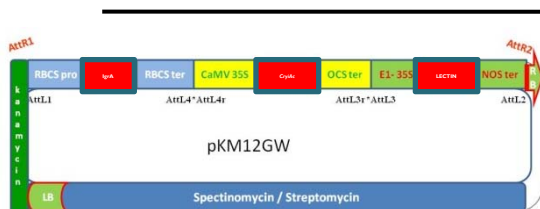
Genes

```
AGTCAAGGCACATACAC  
TTCAGTCCGGTACTACTGT  
TGTTAGAGGACCCGGATT  
CACGGGAGGAGACATT  
CTTCGTCGTACAAGTGGG  
GGACCCITTGCTTACACT  
ATCGTTAACATCAATG
```

Transformation



Characterization



Criteria -approach

Work plan

Elements of work to be implemented as per the proposed objectives

It is desirable to plan for work elements as objective wise

transgenic development and evaluation

Objective: multigene construct

- Method and steps to develop construct

Objective: development of transgenics and their characterization

- Protocols to be adapted and proposed selection
- number of events to be generated
- Evaluation of transgenics
 - Molecular characterization
 - Insect infestation / exposure

Objective: evaluation of the Bio-efficacy of transgenics

- Bioassays against insects
- Bioassay against herbicide

Criteria –approach & methodology

Expertise and infrastructure

Crucial to implement the objectives



- Critical assessment
- To bring in expertise by hiring
- Develop required infrastructure as the essential component of the project budget
- likely collaborators



Collaboration and public private partnership

In-spite of focused objectives and approaches
often projects are not considered



Because of lack of expertise and infrastructure
in proposed / specified area

We need to find collaborators for facilities and expertise



- we should work together

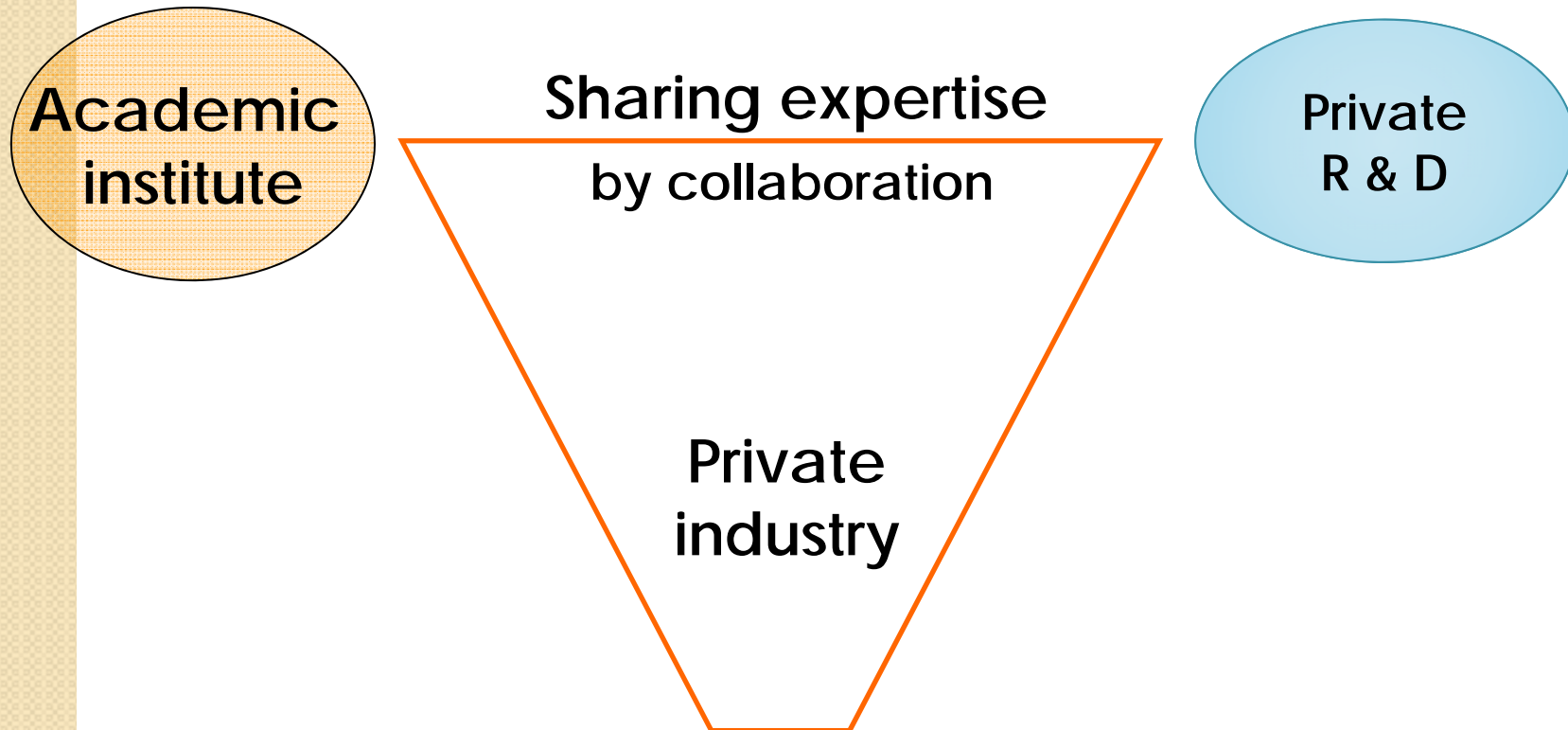
Diverse expertise is needed
to address the research programmes

collaboration is the key



Recent concept is

Knowledge economy partnership



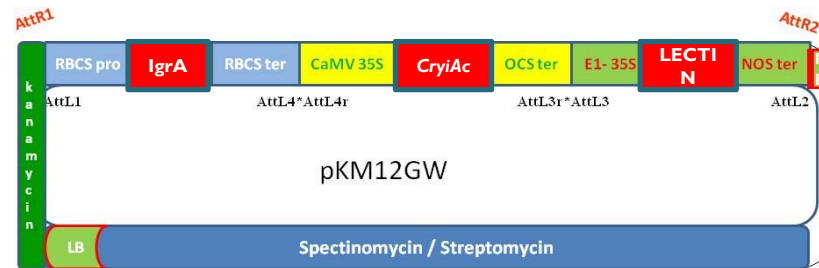
Time lines



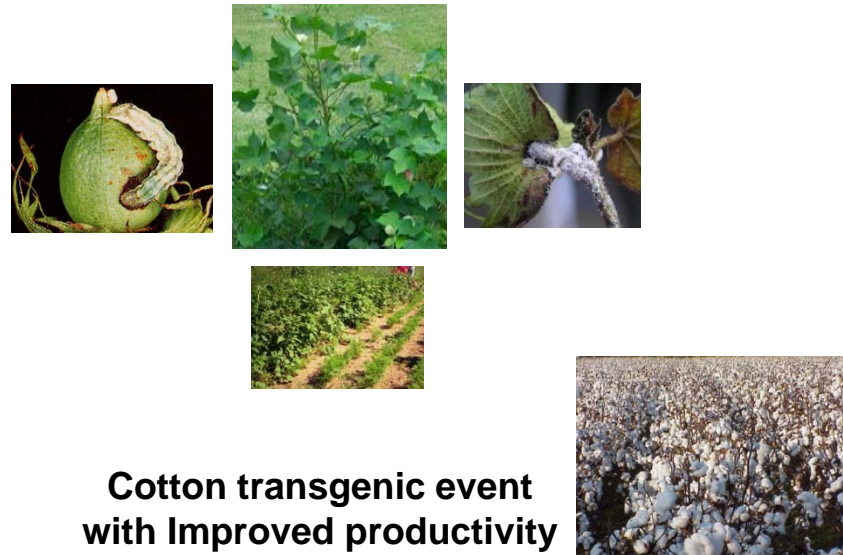
- It is crucial to be realistic
- Transformation and development of transformants is species specific
- Bio-efficacy tests involves raising the plant material
- Number of transformants/events that needs to be evaluated in confinement facility

Out come/ deliverables

- ✓ **Multigene expressing cassettes with specific genes**



- ✓ **Transgenic events with multiple stress tolerant**



Cotton transgenic event with Improved productivity

Other aspects

Budget

Man power



Should match

the work elements

Equipments

Infrastructure

Required for the project experiments

Consumables

contingency

Justify based on the planned programme



Budget

Should

- Be realistic and justifiable for the proposed work.
- Not be over/under budgeted
- Use same unit throughout the proposal
- Mention clearly Recurring and Non Recurring

Regulatory Issues

- ❑ Clear understanding and conformity with regulatory requirements

- ❑ Approval from regulatory authorities
 - ✓ rDNA work
 - ✓ Clinical trials/ Field trials

Technology Ownership

□ License to the Technology

- ✓ License to the main technology if in-licensed
- ✓ License to components required for practicing technology
- ✓ Clarity on terms of license
 - Use, Produce, Sell
 - Territory
 - IP ownership on improvements/ modifications

Ownership of IP for Technology

- ❑ With applicant company and not with employees
- ❑ Clarity on IP sharing among collaborators

Supporting Data

Should Have

- Collaborators details & relevant documents like
(NDA/ MoU/ MTA/ License Agreements etc)
- Resumes of PI's & Scientific Team
- Patents Status (FTO reports / Prior art search)
- Financial Statements of the company

Abstract / summary

Most important component

Should be concise

Should be one page

It should cover

- **Need / relevance / importance**
- **Brief description of strategy / approaches/Novelty**
- **Goals & objectives**
- **Source of IP**
- **Expected out come and also success indicators**

THANK YOU !



Mechanics of BIPP

Ms. Shilpy Kochhar

Deputy Manager

Biotech Consortium India Limited (BCIL)

Idea Generation meetings

Call for Proposals

Online Submission of Proposals

ARP

Evaluation by the TSC

Presentation

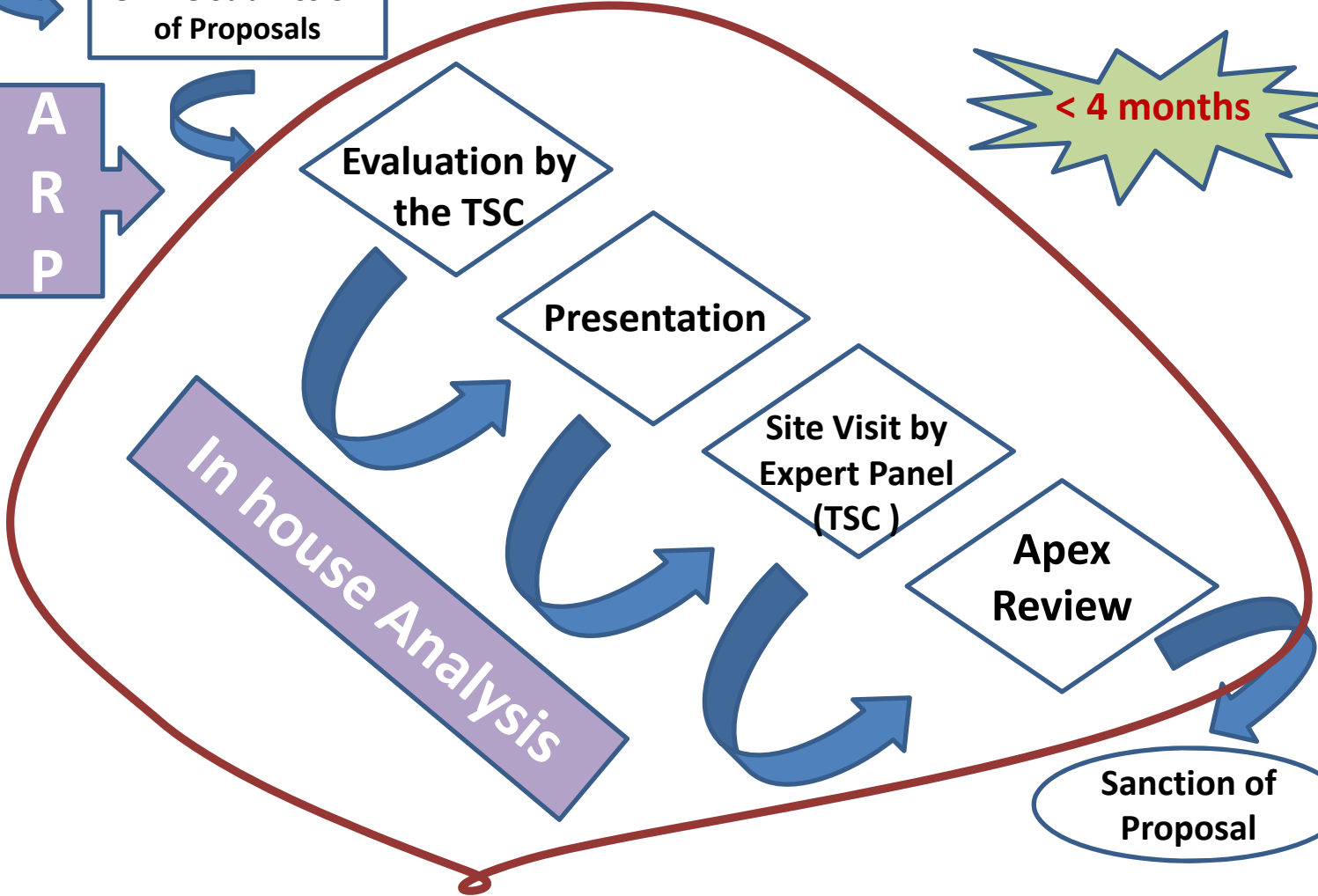
Site Visit by Expert Panel (TSC)

Apex Review

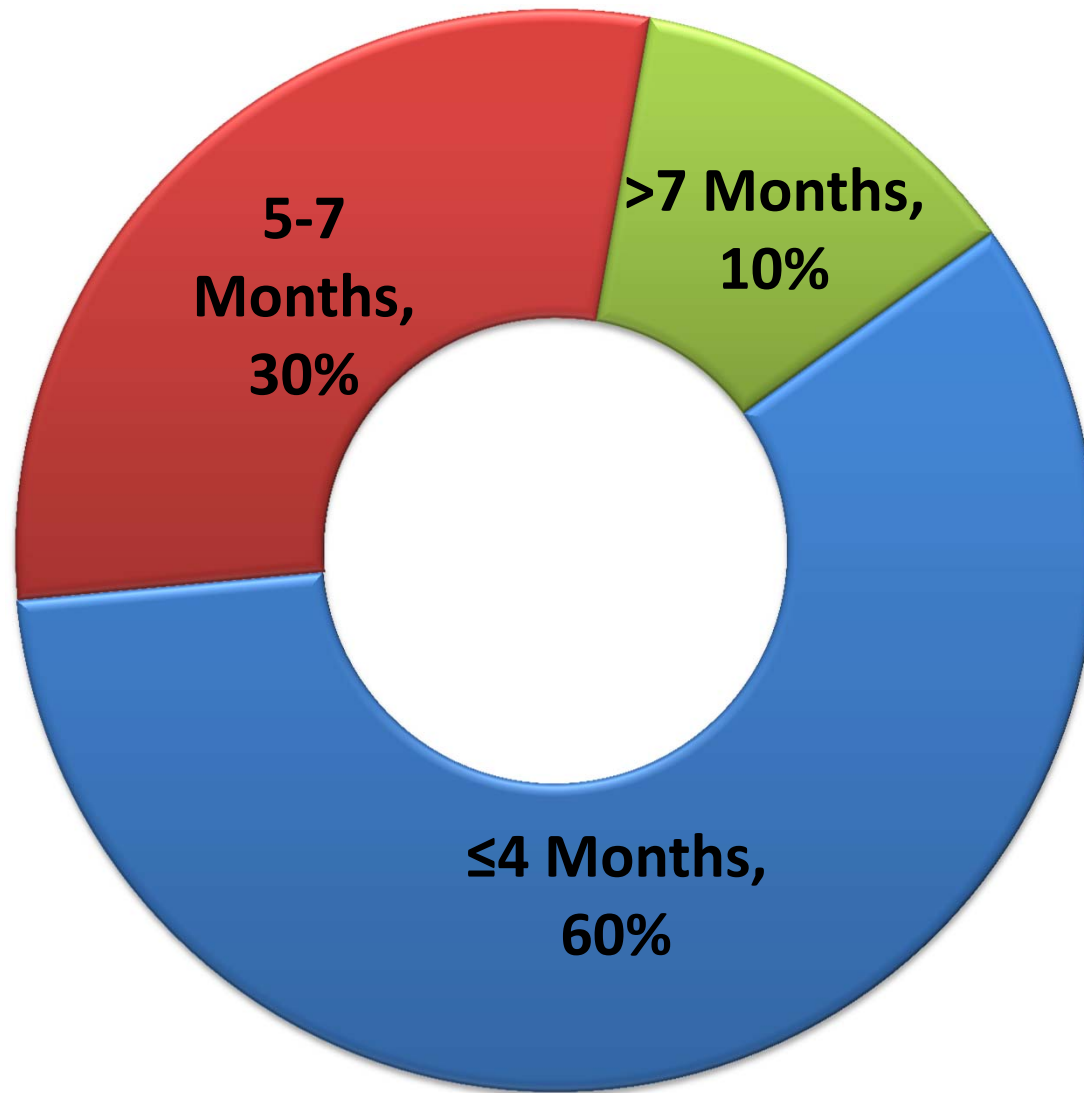
Sanction of Proposal

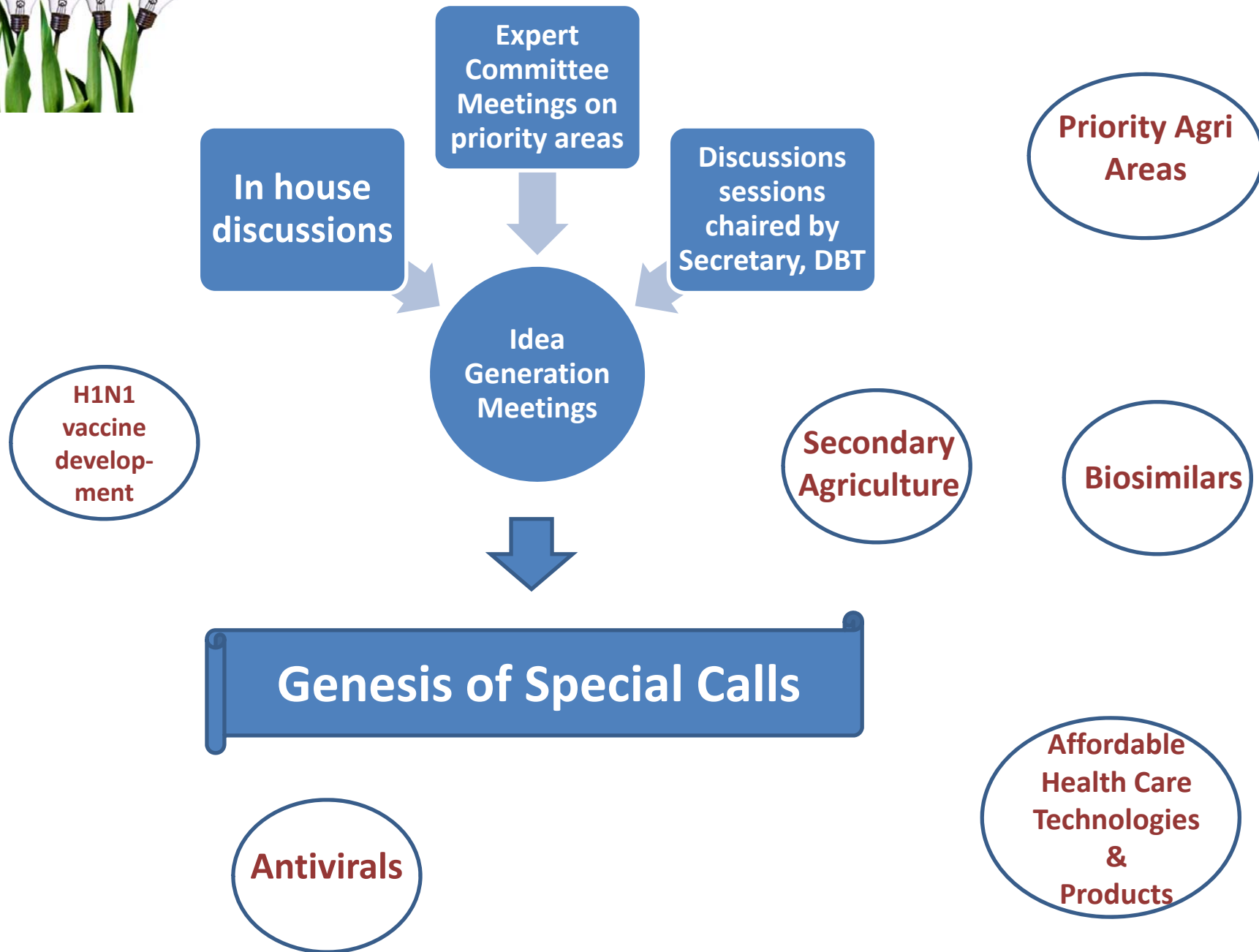
< 4 months

BIPP Process Flow



Time Taken for Decision Making





Call for Proposals

Regular
Calls
*thrice a
year*

- February
- June
- October



21 Batches
processed
till date
10-Regular
11-Special

Regular Call is
Currently Open
Till 31st July, 2012

Special
Calls
need
based

Duration of Call:
30 - 45 days

- Information about an active call***
- ***Published in all national dailies***
 - ***Biotech magazines***
 - ***Can be accessed at any point of time from
DBT/BIRAC /BCIL websites***

Submission of Proposals

Online only

www.birapdbt.nic.in



Register your
company with
BIRAP

- Requires only minimum details
- No upper limit to the number of users with one company

Choose the
Relevant
Call

- In case of multiple active calls, relevant call needs to be chosen
- Begin proposal submission by filling in the *Basic Information Page*.

Final
Submit

- Submit all the Forms (*some forms follow a hierarchy and need to be submitted in a sequential manner only*)
- Be careful about the information provided (*in particular for the milestones and financial data*)

Eligibility Issues



Primary Applicant

Eligible

- For Profit Company registered under **Indian Companies Act 1956**
- Minimum of **51%** shareholding with Indians and/or NRIs

Ineligibles

- Any entities other than registered company:
Proprietorship, Partnership, NPOs, NGOs, Trust, Society, Educational Institutes/ Universities, Any other

Collaborating Organizations:

- Another registered company
- Institute/University
- Trust/Society/NGO

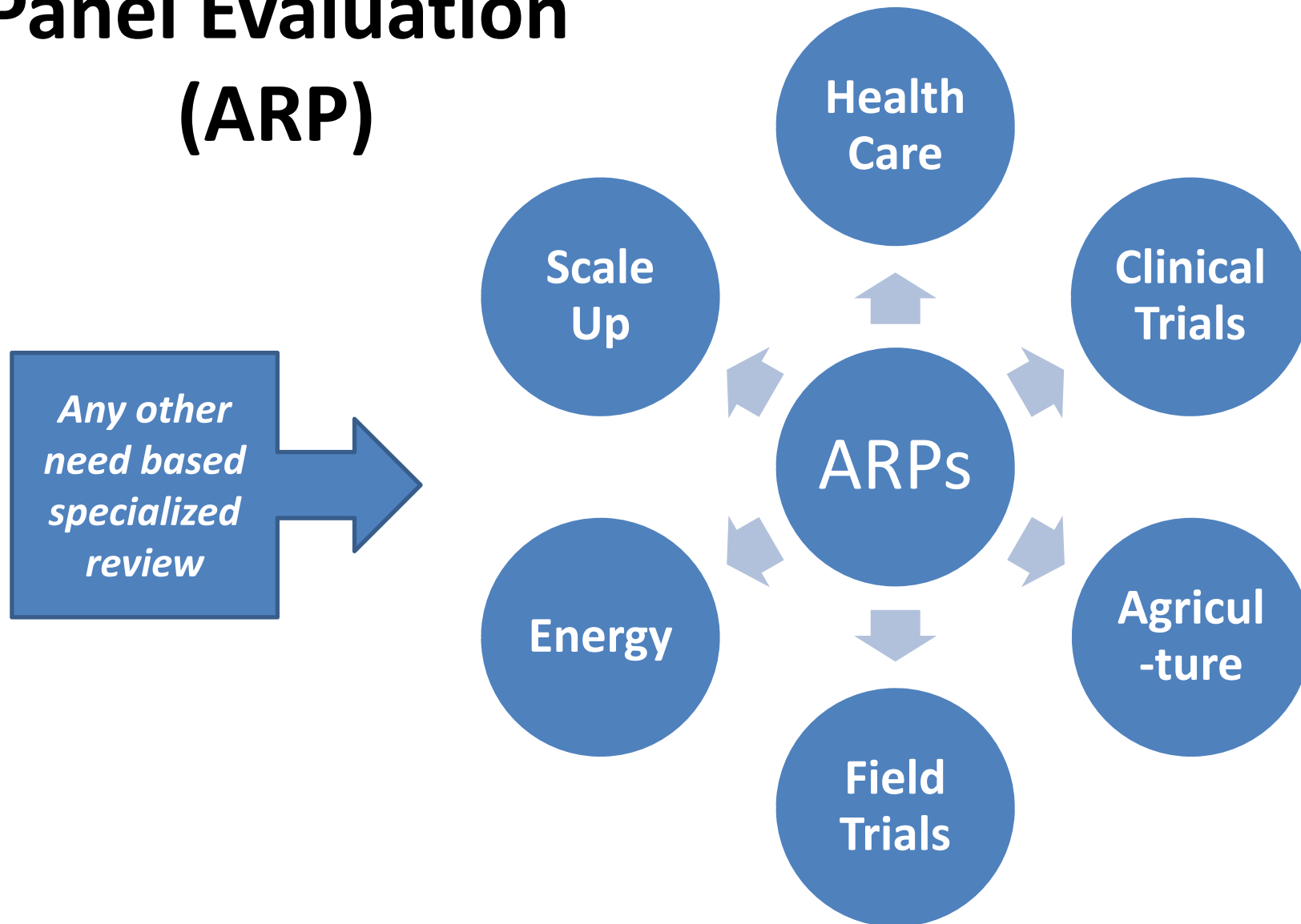
DSIR Requirements

- DSIR recognition for the in-house R&D lab **mandatory** for the primary applicant as well as for all company type collaborators
- In case, DSIR is unavailable, it is mandatory to have **applied to DSIR** before proposal submission
- **For incubatees:**
 - DSIR recognition of the incubator is considered as sufficient
 - Tenure of Incubatee with the incubator should be more than the proposal duration

Submission of necessary documents is the key.

Area Review Panel Evaluation (ARP)

- *ARP evaluation is completely online*
- *First level of filtering based on scientific merit*



In house Expertise

- **Technical:**
 - A pool of scientists who prepare in-depth analysis reports/ SWOT Analysis for proposals
- **IP Issues:**
 - BIRAP-BCIL IP cell examines each and every proposal to identify the potential hiccups in the path of research/ commercialization

Due care of regulatory issues is taken and no project is sanctioned till regulatory requirements are met with

Technical Screening Committee (TSC)

TSC: Decision Making Body

TSC Review covers the following:

- Final decision on ARP Evaluation
- Review of Presentation by shortlisted ones
- Consideration of site visit reports
- Review of clarifications (as and when required)

TSC comprises eminent scientists from academic institutes and universities across the country

Site Visit:

Critical due diligence of the facts and figures



Technical

Team of subject specific experts in the area

Examination of facilities, manpower, budget, timelines, expertise.....

Financial

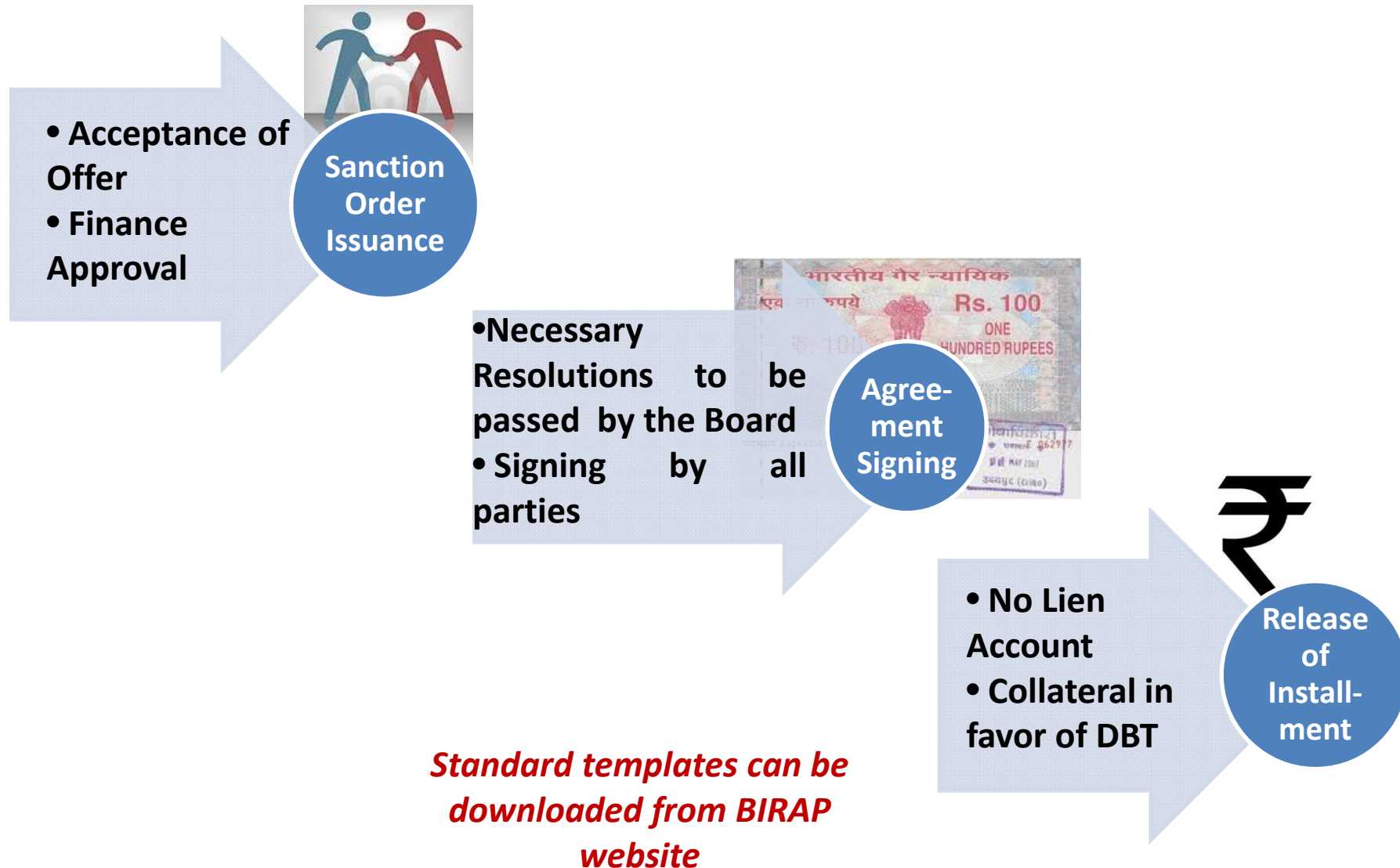
An audit of the financial status of the company by a Chartered Accountant

**Examination of the key aspects:
Liquidity, Profitability, Debts, Assets.....**

Apex Committee: Constitution and Review

- Final approving authority which recommends processing of a proposal for sanction by the DBT
- High level expert committee chaired by the Secretary, DBT
- Comprises members from different Ministries
- Consideration of Proposals recommended by TSC after exhaustive review process

Sanction and related processing

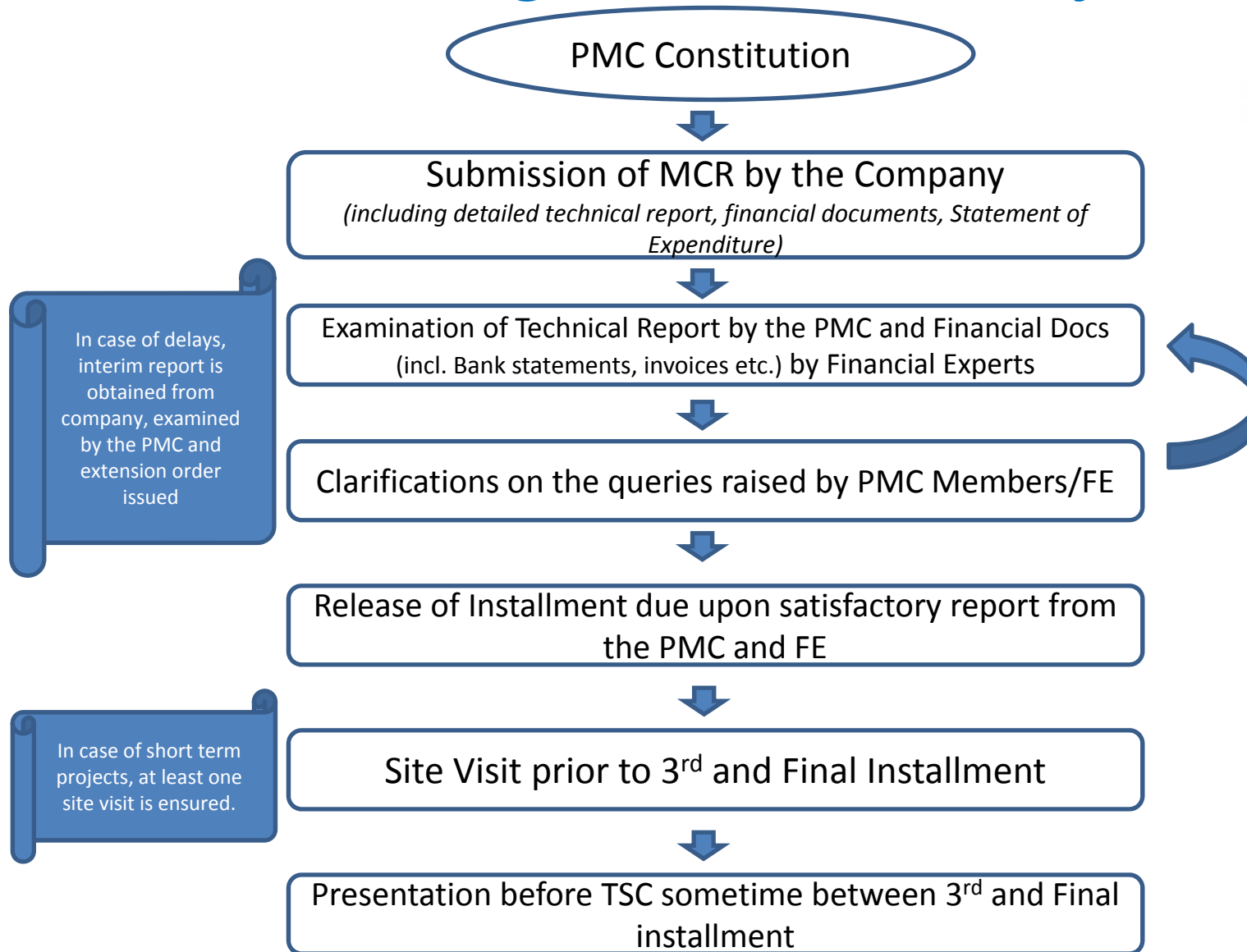


Schedule for Release of Installments

Milestone based:

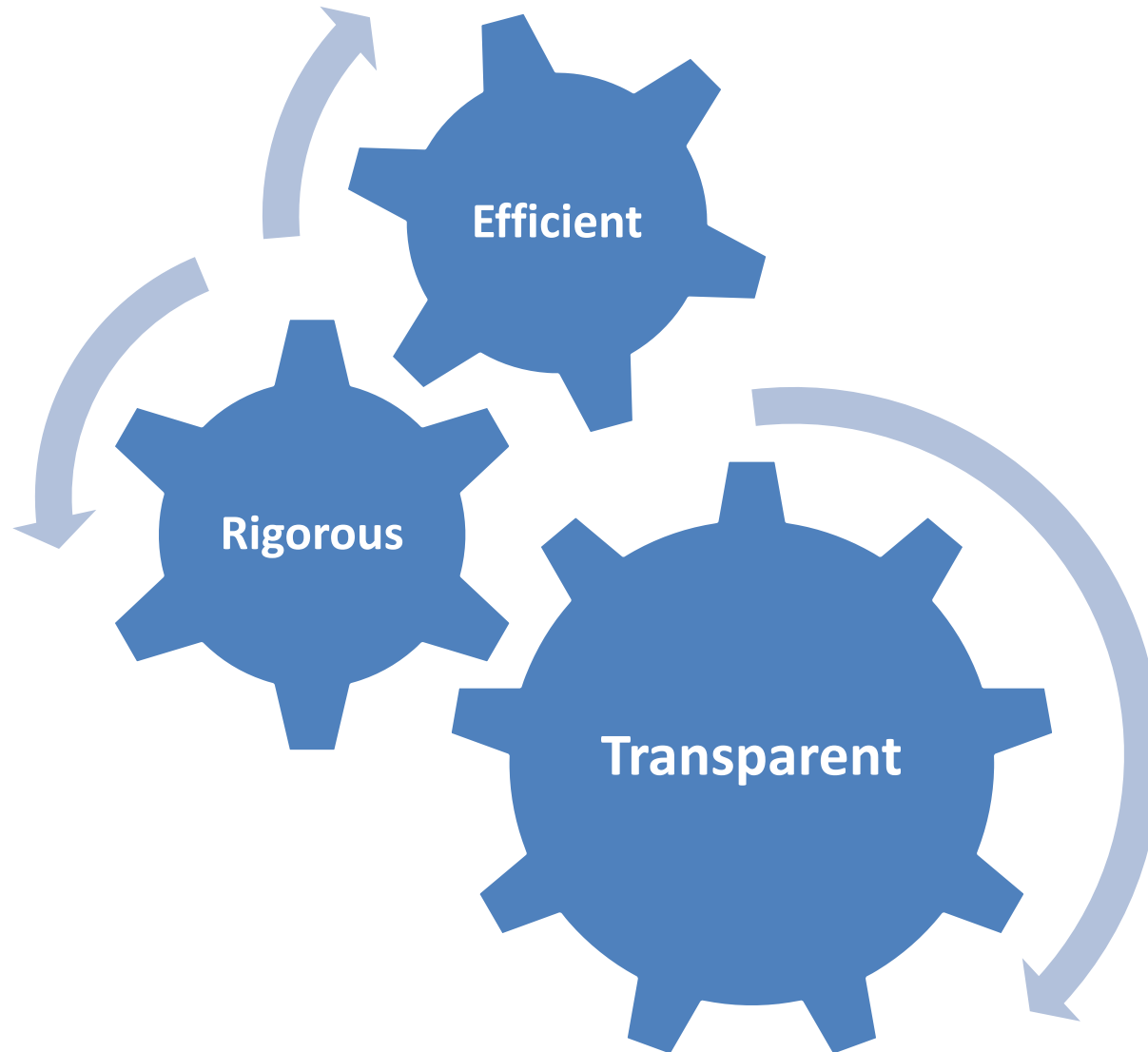
- 1st 30% (Signing of Agreement)
- 2nd 20%
- 3rd 20%
- 4th 20%
- 5th 10% (Completion of the Project)

Monitoring of Sanctioned Projects



PMC members are also assigned the role of mentors, wherever felt necessary

To Conclude: BIPP is



THANK YOU

QUERIES, IF ANY ??????