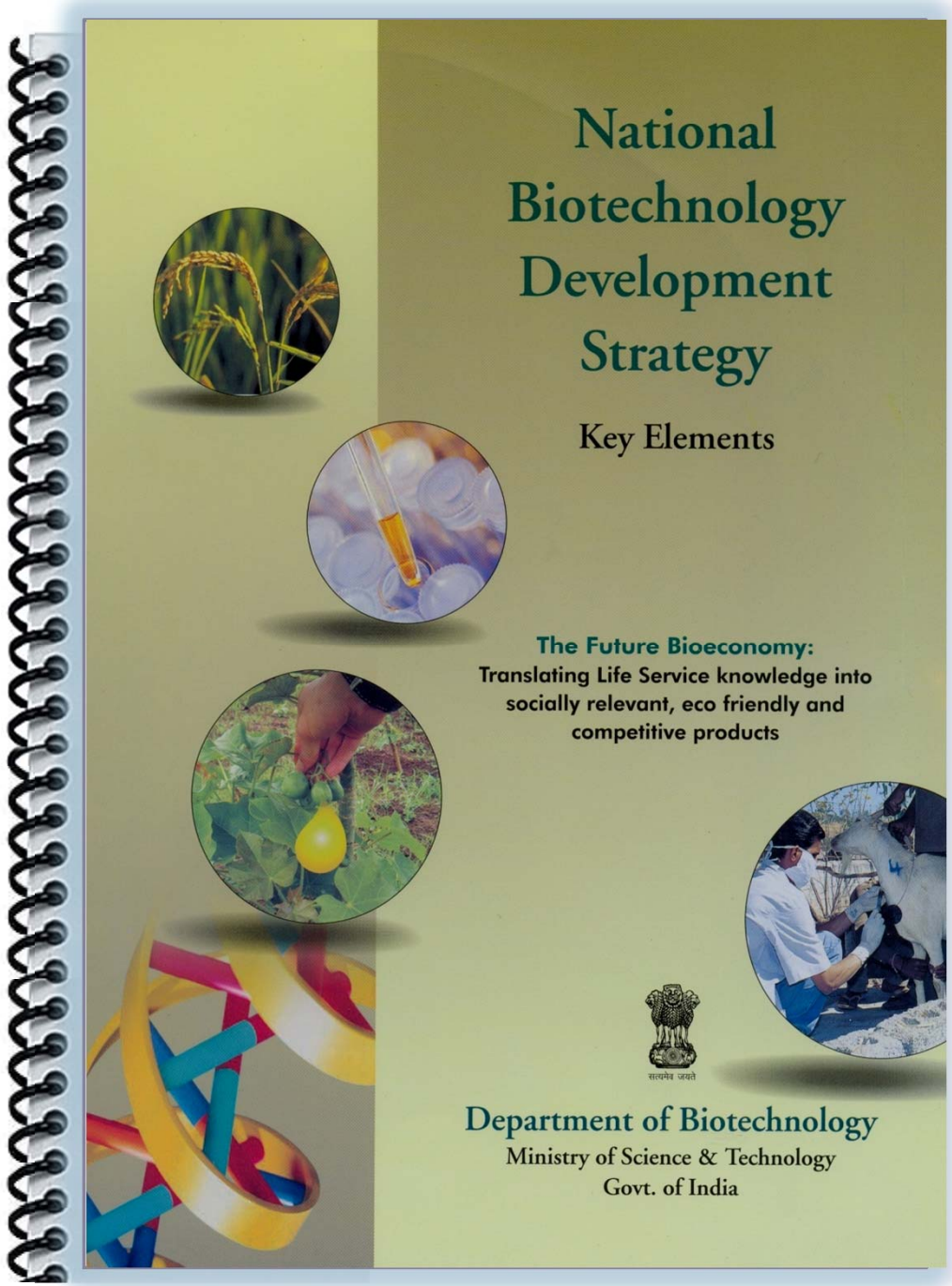
Empowering and Enabling the Biotech Innovation Ecosystem

Dr. Renu Swarup, Adviser, Department of Biotechnology

&

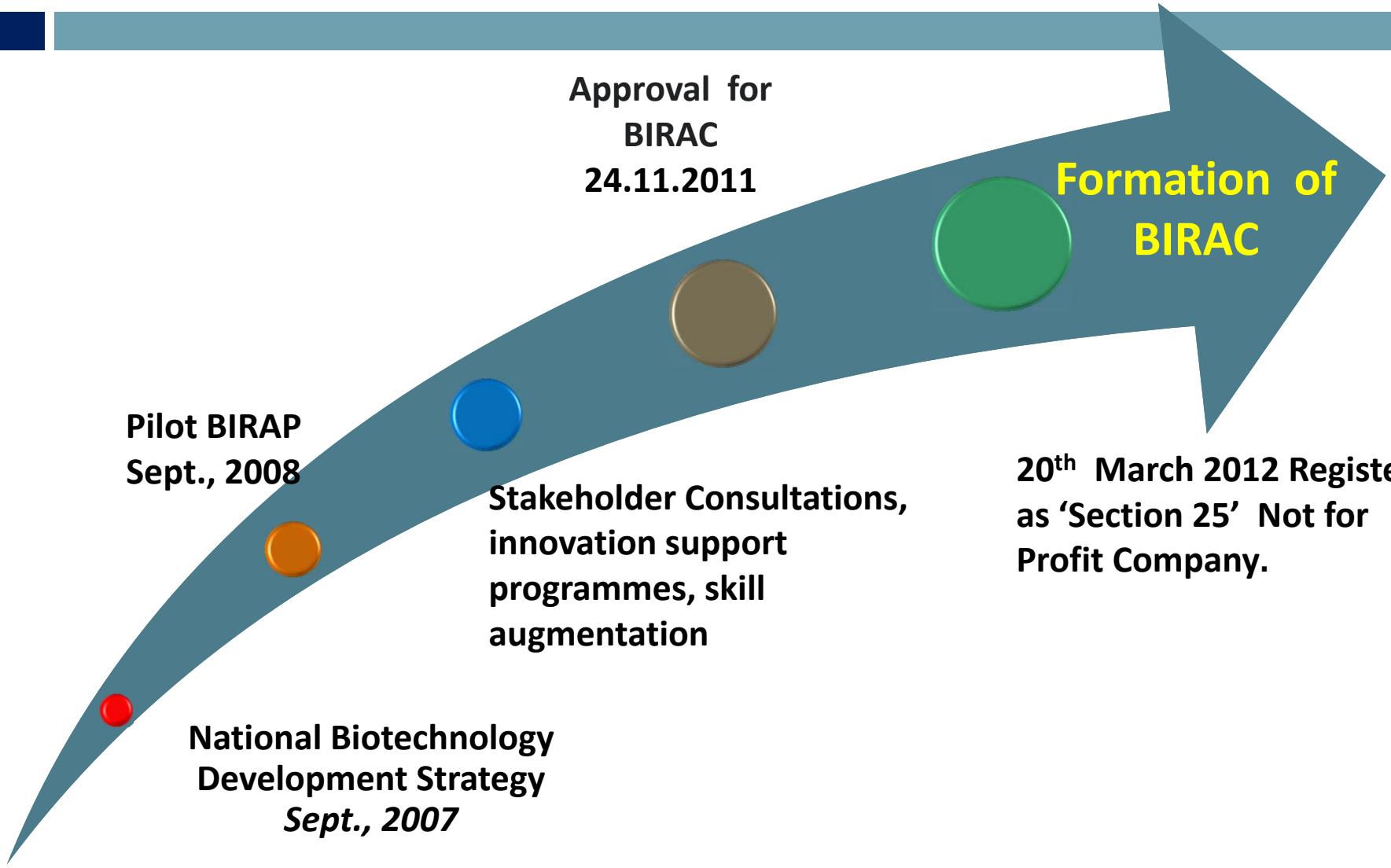
Managing Director, BIRAC



BIRAC to Nurture Industry R&D

30% budget to be spent on PPP

How we moved…..


Approval for BIRAC 24.11.2011
Formation of BIRAC
Pilot BIRAP Sept., 2008
Stakeholder Consultations, innovation support programmes, skill augmentation
20th March 2012 Register as 'Section 25' Not for Profit Company.
National Biotechnology Development Strategy Sept., 2007

Our Focus-

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

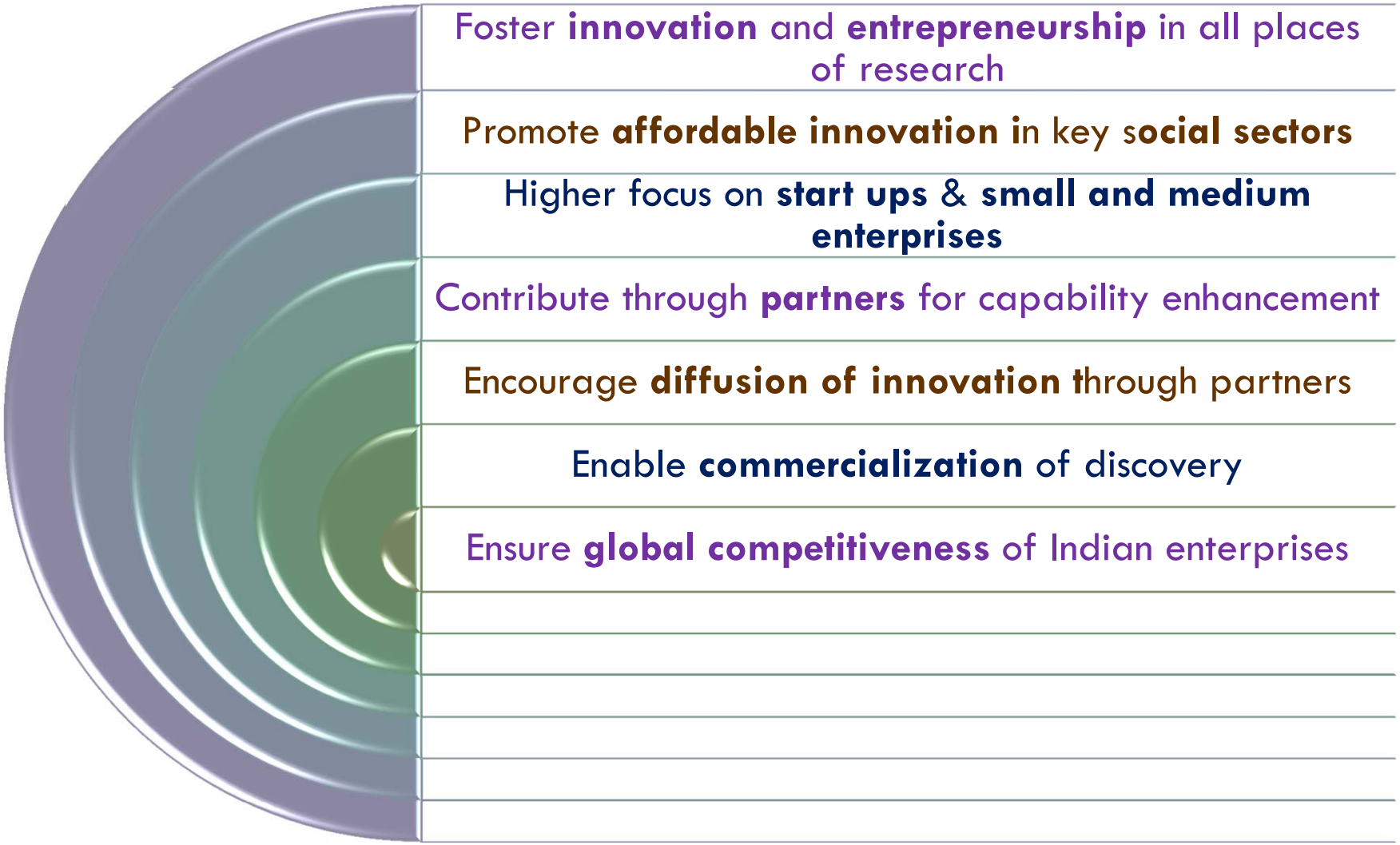
BIRAC Vision-

"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 Strategies



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**

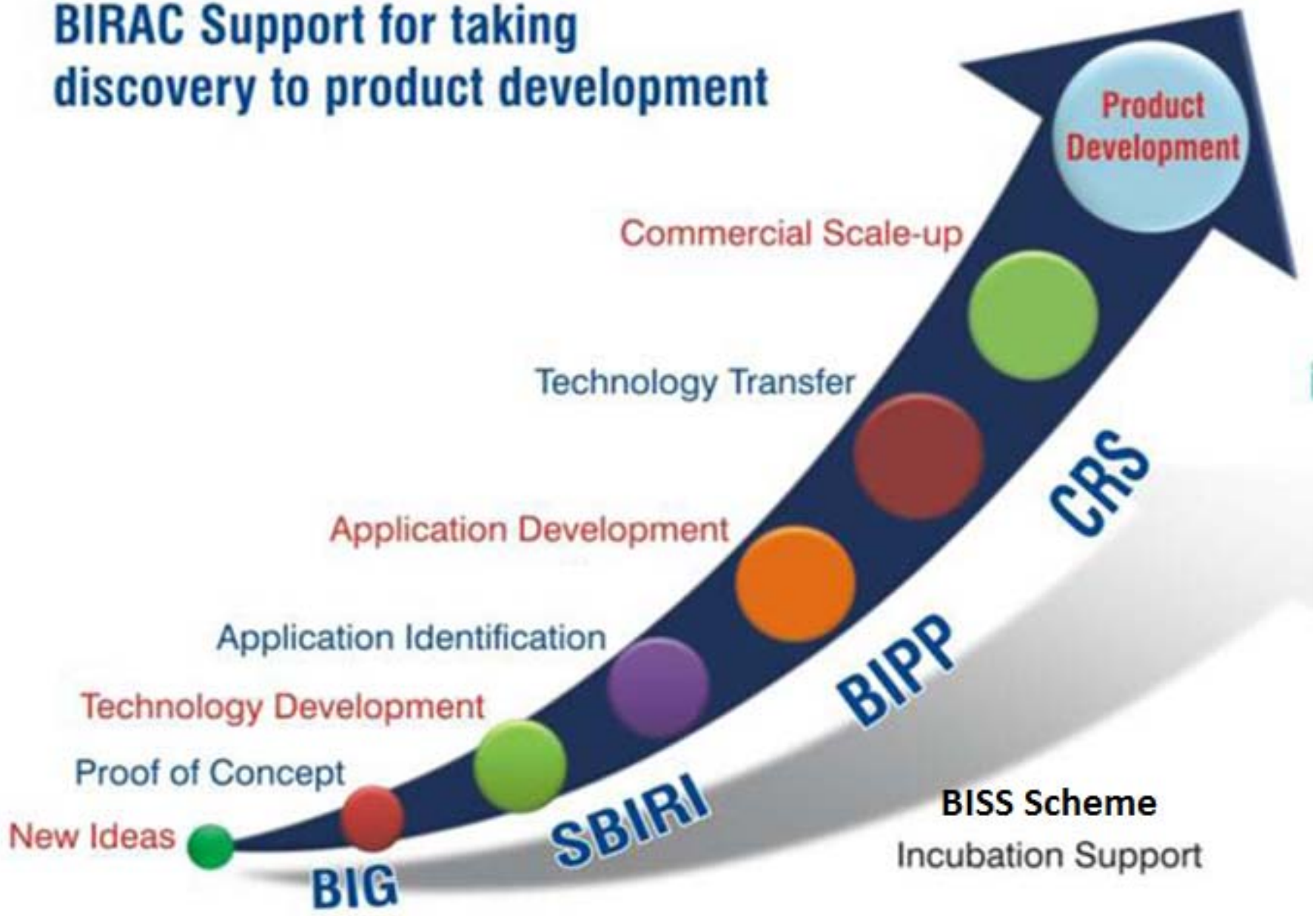
How does BIRAC accomplish its Mission

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
Product Development
Commercial Scale-up
Technology Transfer
Application Development
Application Identification
Technology Development
Proof of Concept
New Ideas
BIG
SBIRI
BIPP
CRS
BISS Scheme
Incubation Support

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.

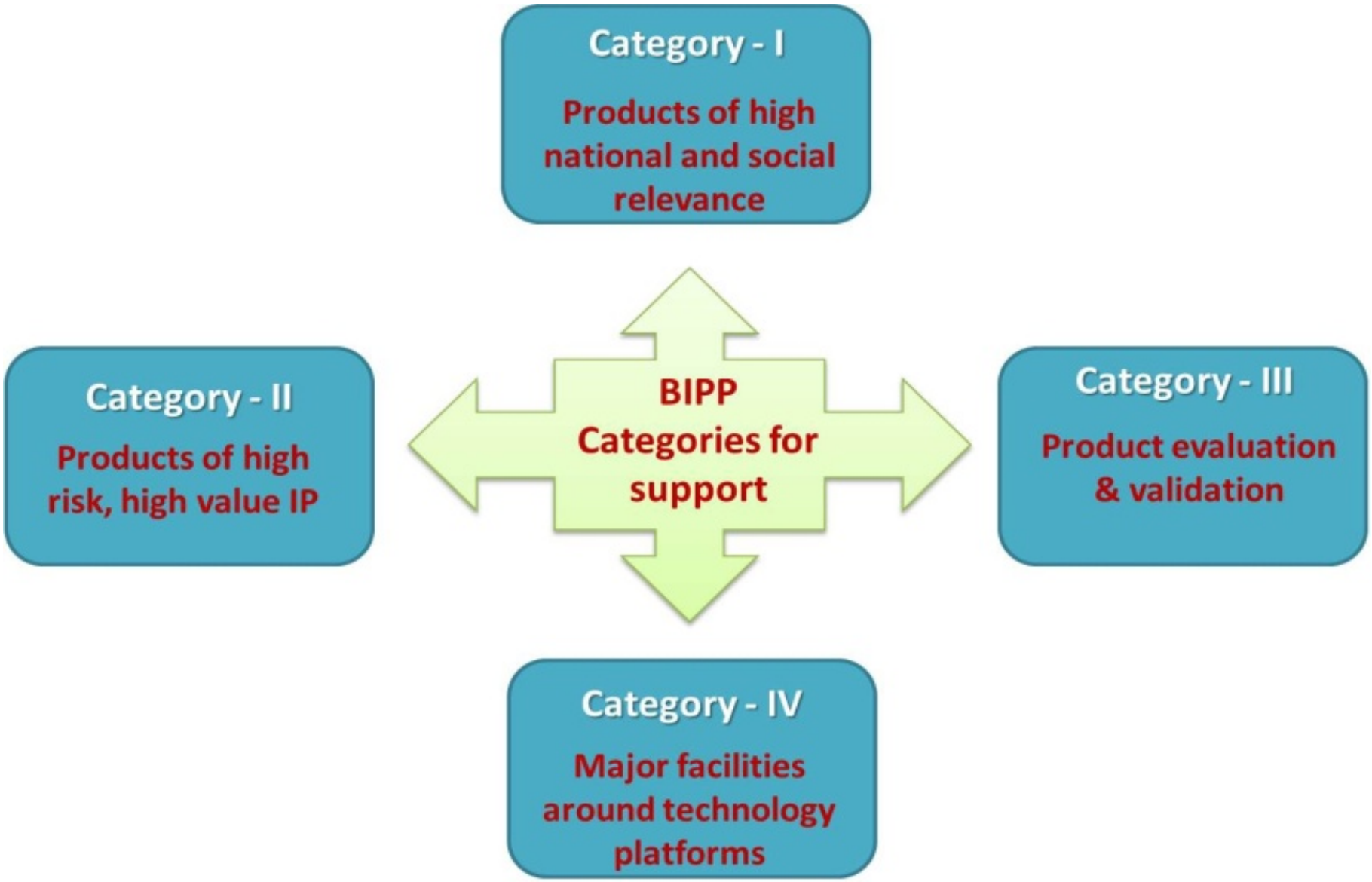
• Supporting research project for novel IP generation.

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


Category - I
Products of high national and social relevance
Category - II
Products of high risk, high value IP
BIPP
Categories for support
Category - III
Product evaluation & validation
Category - IV
Major facilities around technology platforms

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

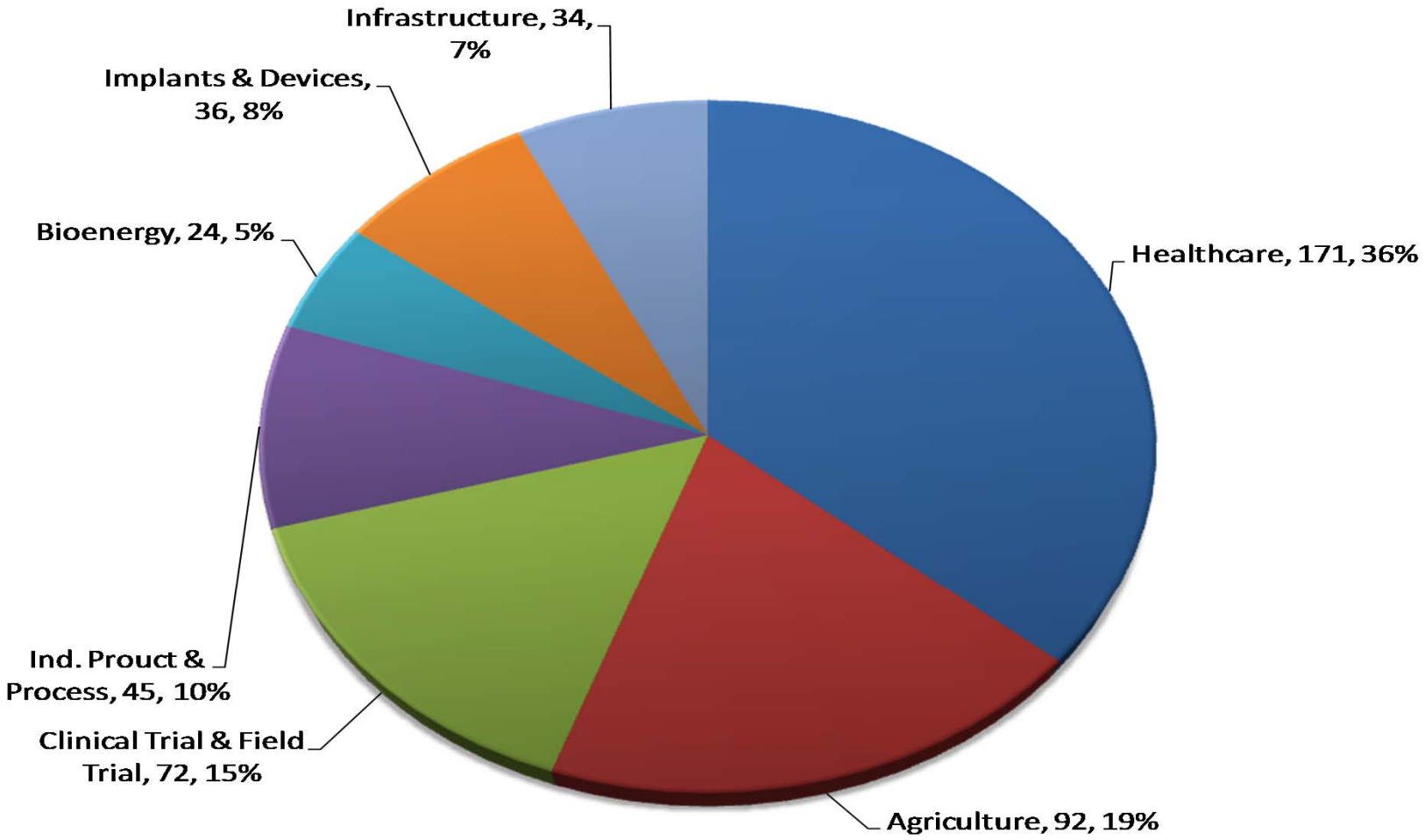
Dr. Purnima Sharma
Managing Director
Biotech Consortium India Limited
New Delhi

An Overview

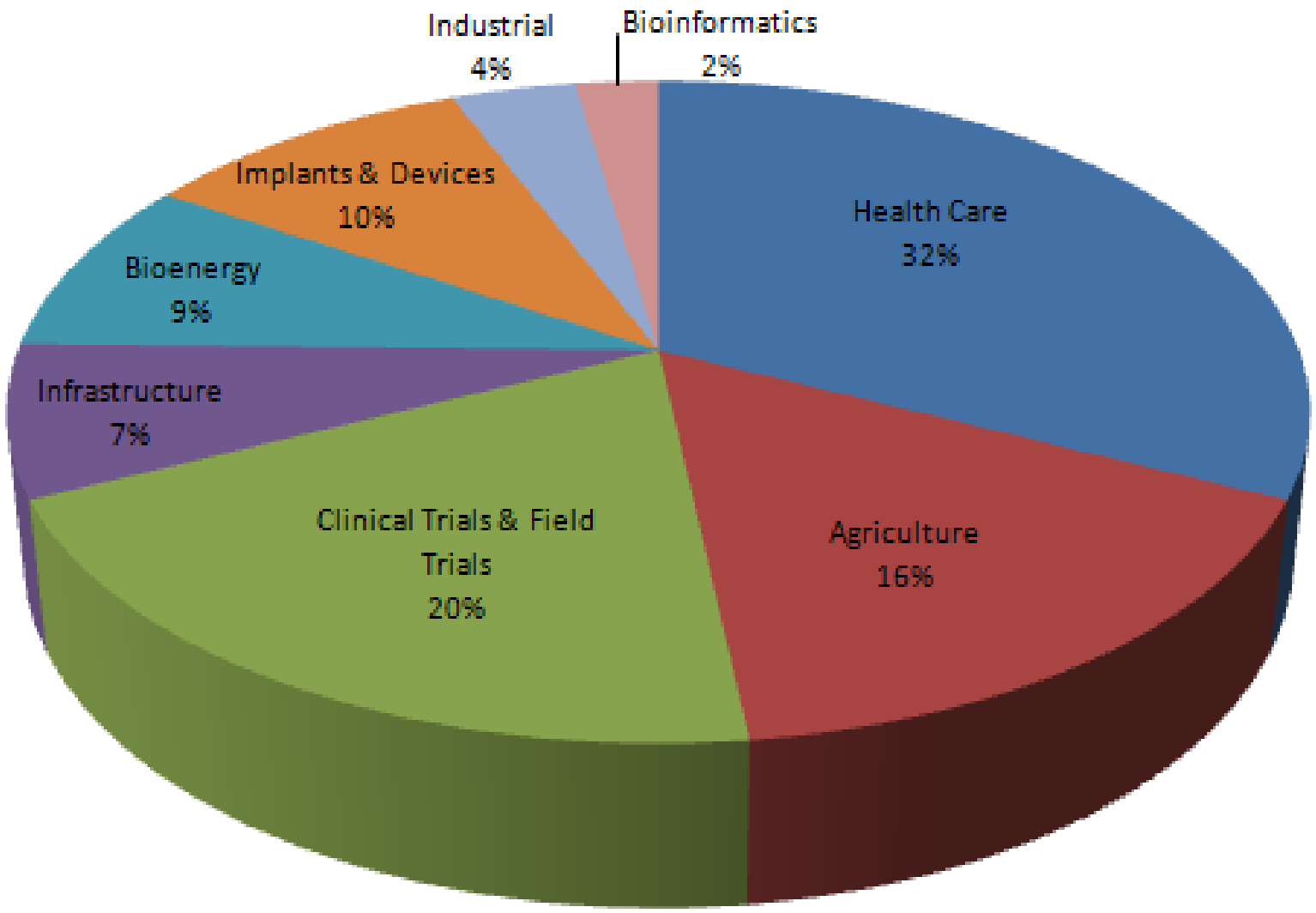
- Scheme Launched ---- **December 2008**
- Total Number of Calls--- **21 (till March 2012)**
  - Regular--- **10**
  - Special--- **11**
- Number of Projects Received --- **551**
- Number of Projects Approved --- **> 90**
- Total Budget Committed –-- **Approx Rs. 650 Crore**
  - Company Contribution–--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

BCIL

Total Proposals Received: 551

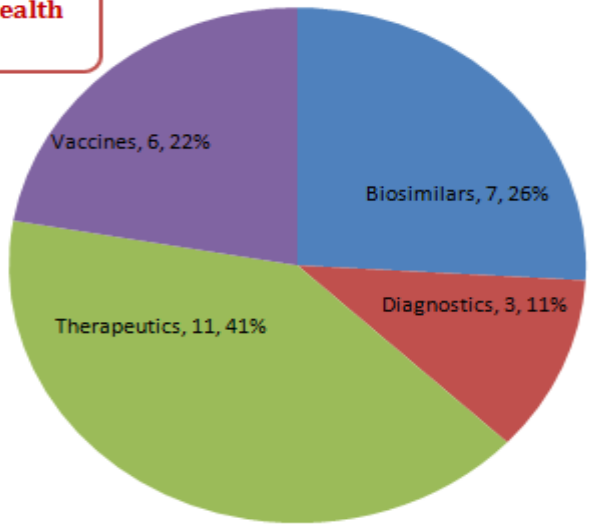


Area Wise Sanction of Projects Under BIPP



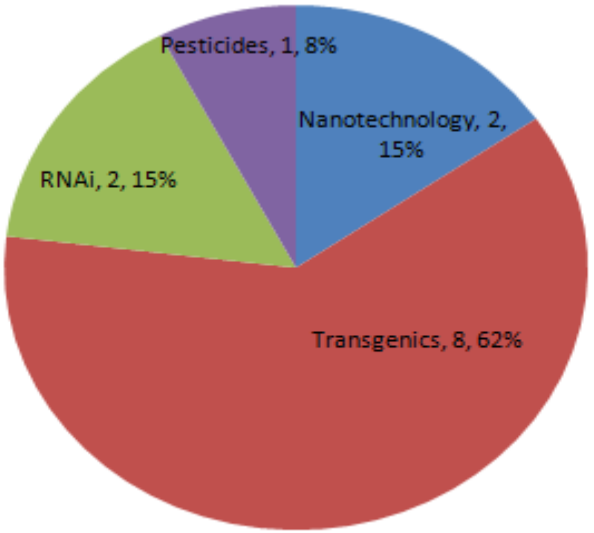
BCIL

Projects Sanctioned Under Health Care Category



Total 27 Projects

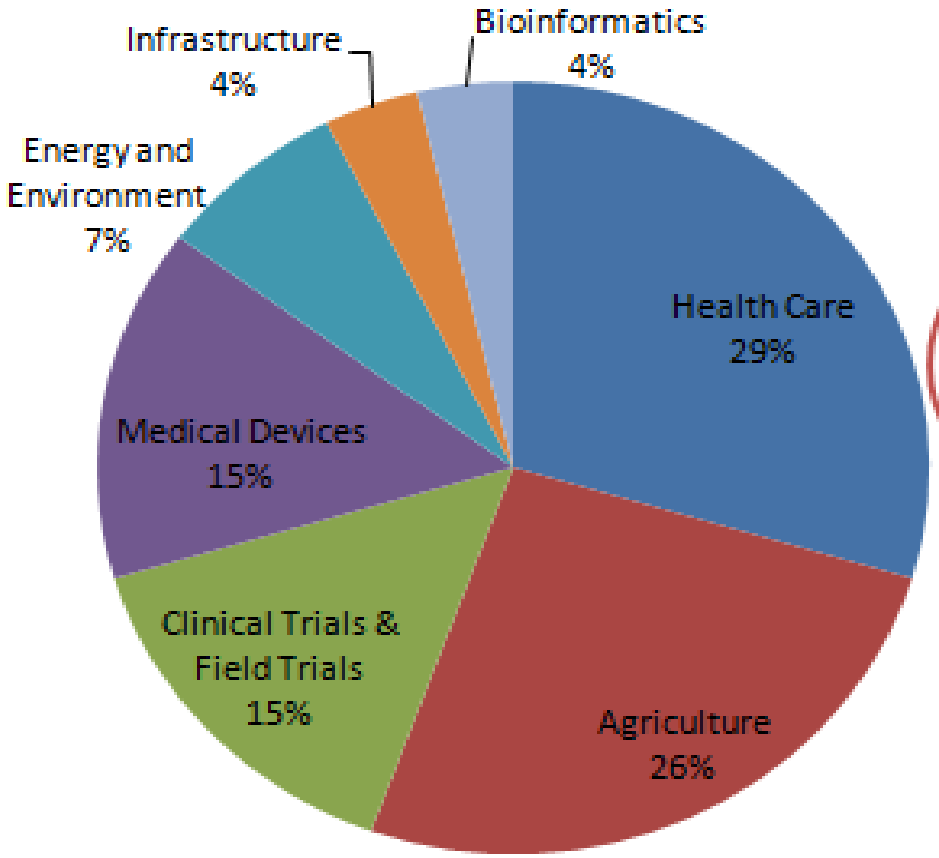
Projects Sanctioned Under Agriculture Category



Total 13 Projects

BCIL

Area Wise Percentage of Collaborative Projects



Total 27 Collaborative out of 80 Sanctioned Projects

BCIL

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


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

- ***H.armigera*** **(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:

Bollworm

Sucking pest

Weeds

- Reduce yield loss
- ↓ Cost of cultivation

Insect resistant plant

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 noval / 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 igra 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***

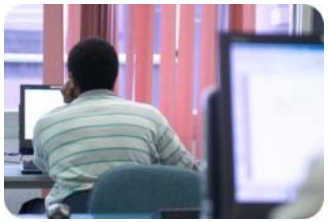
b) **Approach for transforming the multigene construct**

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 bioeffecacy

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

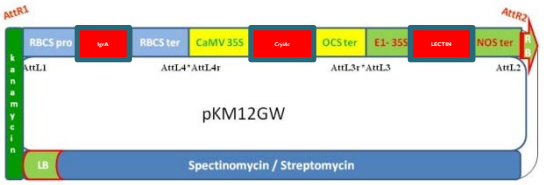
Conceptual frame work

Genes

AGTCAAGGCACATACAC
TTCAGTCCGGTACTACTGT
TGTTAGAGGACCCGGATT
CACGGGAGGAGACATT
CTTCGTCGTACAAGTGGA
GGACCCTTTGCTTACACT
ATCGTTAACATCAATG

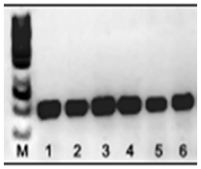
Transformation

Characterization



Gene construct

Transformants



Characterization

Events

Field evaluation

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 trasngenics

- **Molecular characteristion**
- **Insect infestation / exposer**

Objective: evaluation of the Bio-effecacy 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

Academic institute

Sharing expertise

by collaboration

Private R & D

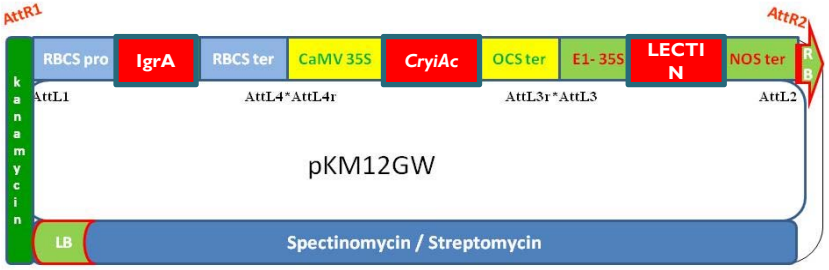
Private industry

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 !

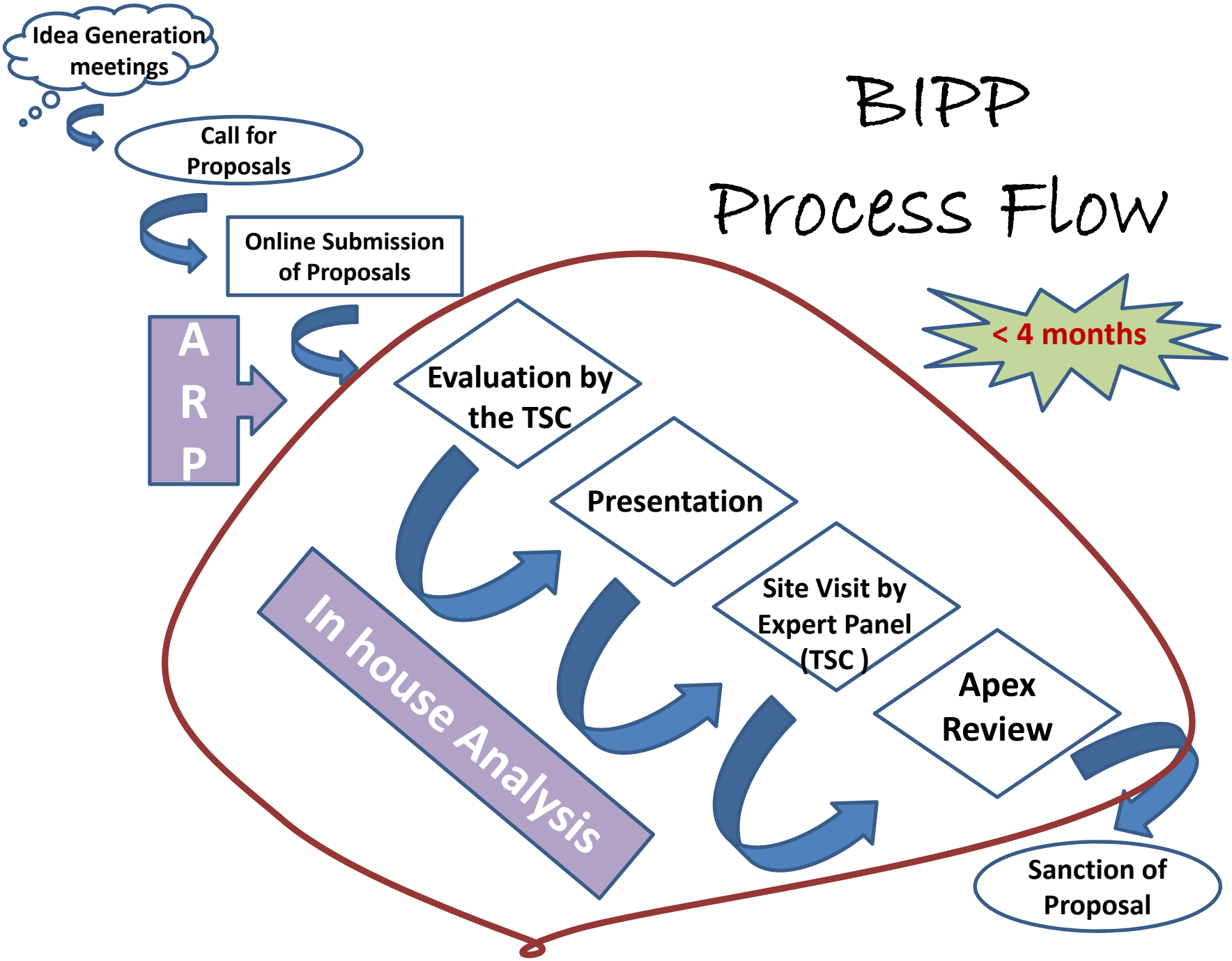
Mechanics of BIPP

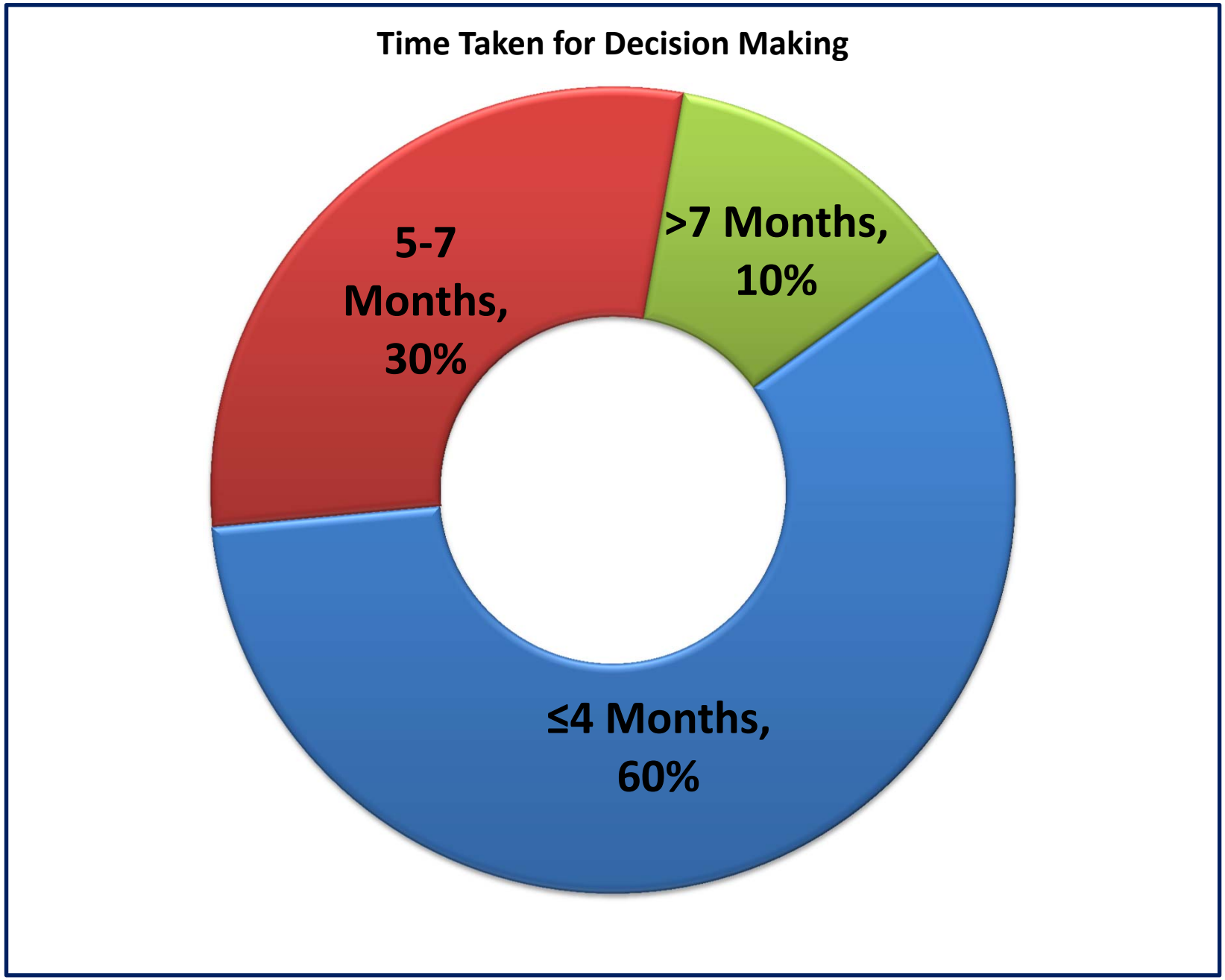
Ms. Shilpy Kochhar

Deputy Manager

Biotech Consortium India Limited (BCIL)

BIPP Process Flow




Time Taken for Decision Making
5-7 Months, 30%
>7 Months, 10%
≤4 Months, 60%

Expert Committee Meetings on priority areas

In house discussions

Discussions sessions chaired by Secretary, DBT

Idea Generation Meetings

Priority Agri Areas

H1N1 vaccine develop-ment

Secondary Agriculture

Biosimilars

Genesis of Special Calls

Antivirals

Affordable Health Care Technologies & Products

Call for Proposals

Regular Calls

thrice a year

- February
- June
- October

Special Calls

need based

21 Batches processed till date

10-Regular

11-Special

Regular Call is Currently Open Till 31st July, 2012

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

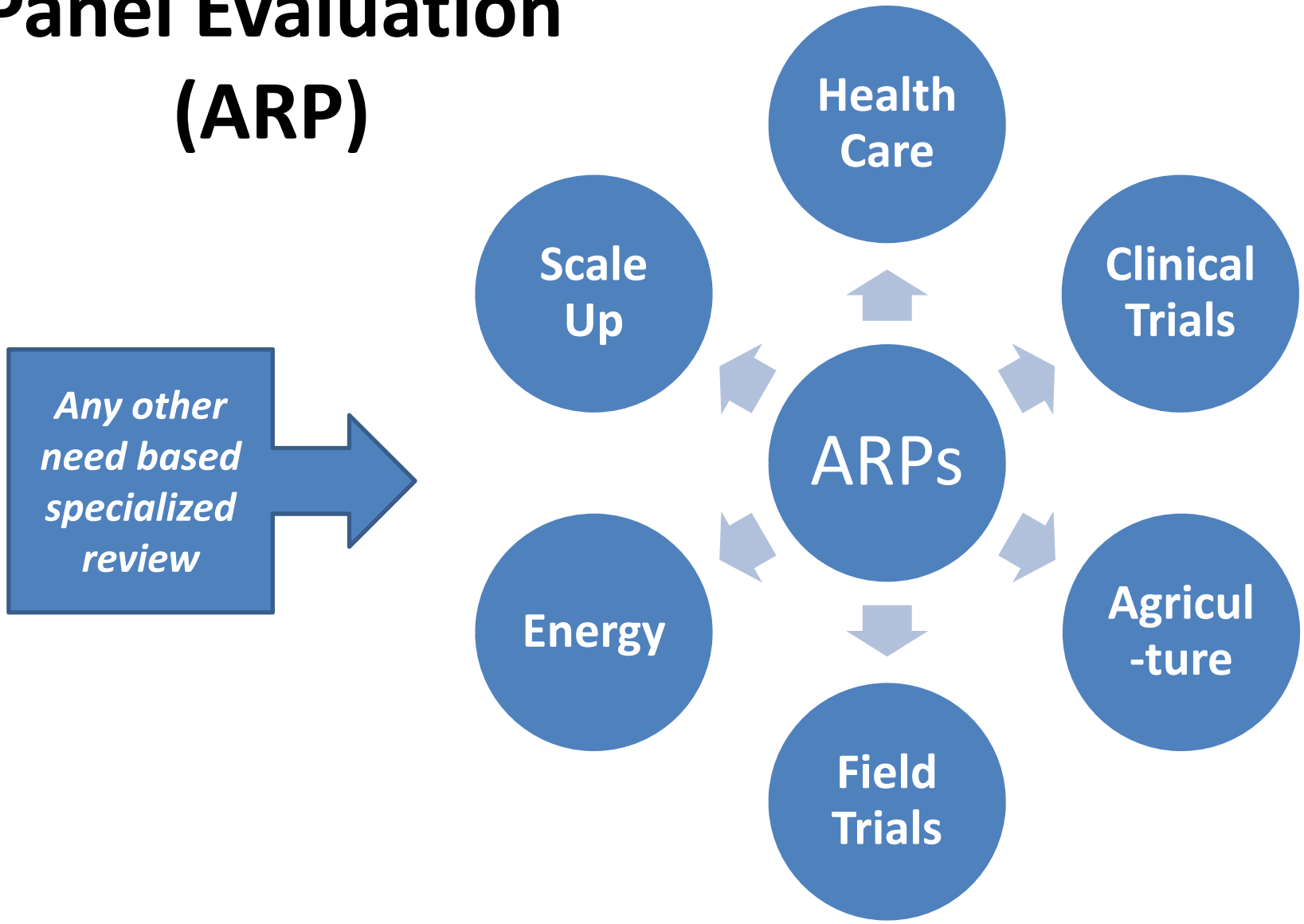
DSIR Requirements

- 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

- Acceptance of Offer
- Finance Approval

Sanction Order Issuance

- Necessary Resolutions to be passed by the Board
- Signing by all parties

Agree-ment Signing

- No Lien Account
- Collateral in favor of DBT

Release of Install-ment

Standard templates can be downloaded from BIRAP website

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 Constitution

Submission of MCR by the Company
(including detailed technical report, financial documents, Statement of Expenditure)

Examination of Technical Report by the PMC and Financial Docs (incl. Bank statements, invoices etc.) by Financial Experts

In case of delays, interim report is obtained from company, examined by the PMC and extension order issued

Clarifications on the queries raised by PMC Members/FE

Release of Installment due upon satisfactory report from the PMC and FE

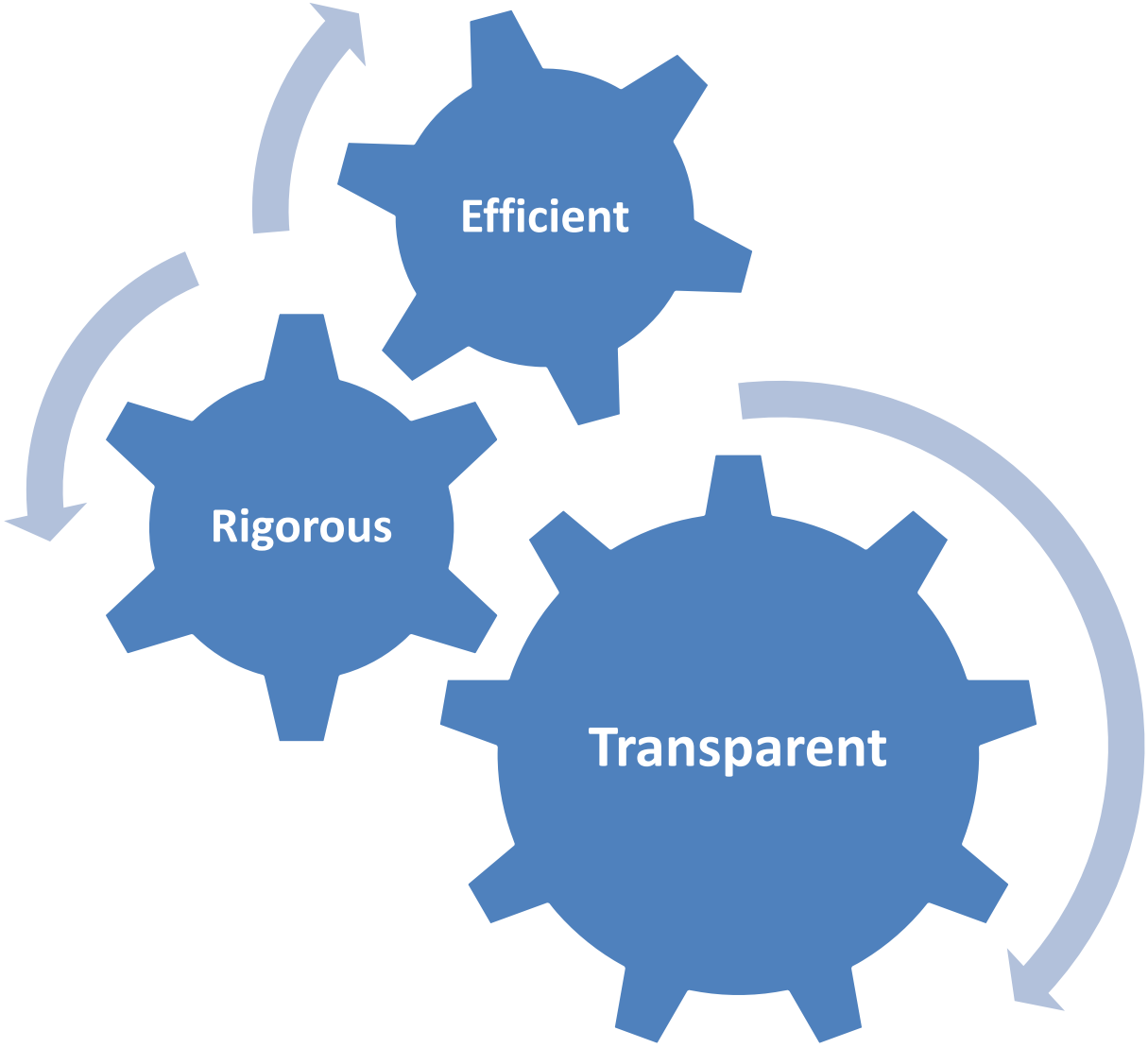
In case of short term projects, at least one site visit is ensured.

Site Visit prior to 3rd and Final Installment

Presentation before TSC sometime between 3rd and Final installment

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

To Conclude: BIPP is



THANK YOU

QUERIES, IF ANY ?????

DBT and BIRAC awareness workshop

How to write an effective grant proposal

to enhance the level of response from the private sector and their public partners

Rita Mulherkar
ACTREC, Navi Mumbai

Biotechnology Industry Research Assistance Council (BIRAC)

With an aim to increase and motivate the innovation capabilities and strategic research of biotech industry in India.

BIRAC, a unique initiative of government will provide financial support to mid-level, quality innovation targeted at development of product and competitive solutions.

Furthermore, BIRAC will be an autonomous, independent and dynamic company under Companies Act to promote the high risk assignments with unique methodologies that have potential for commercialisation.

BIRAC Mandate

•To trigger, transform and tend, biotech start-ups to convert innovative research in public and private sector into viable and competitive products and enterprises.

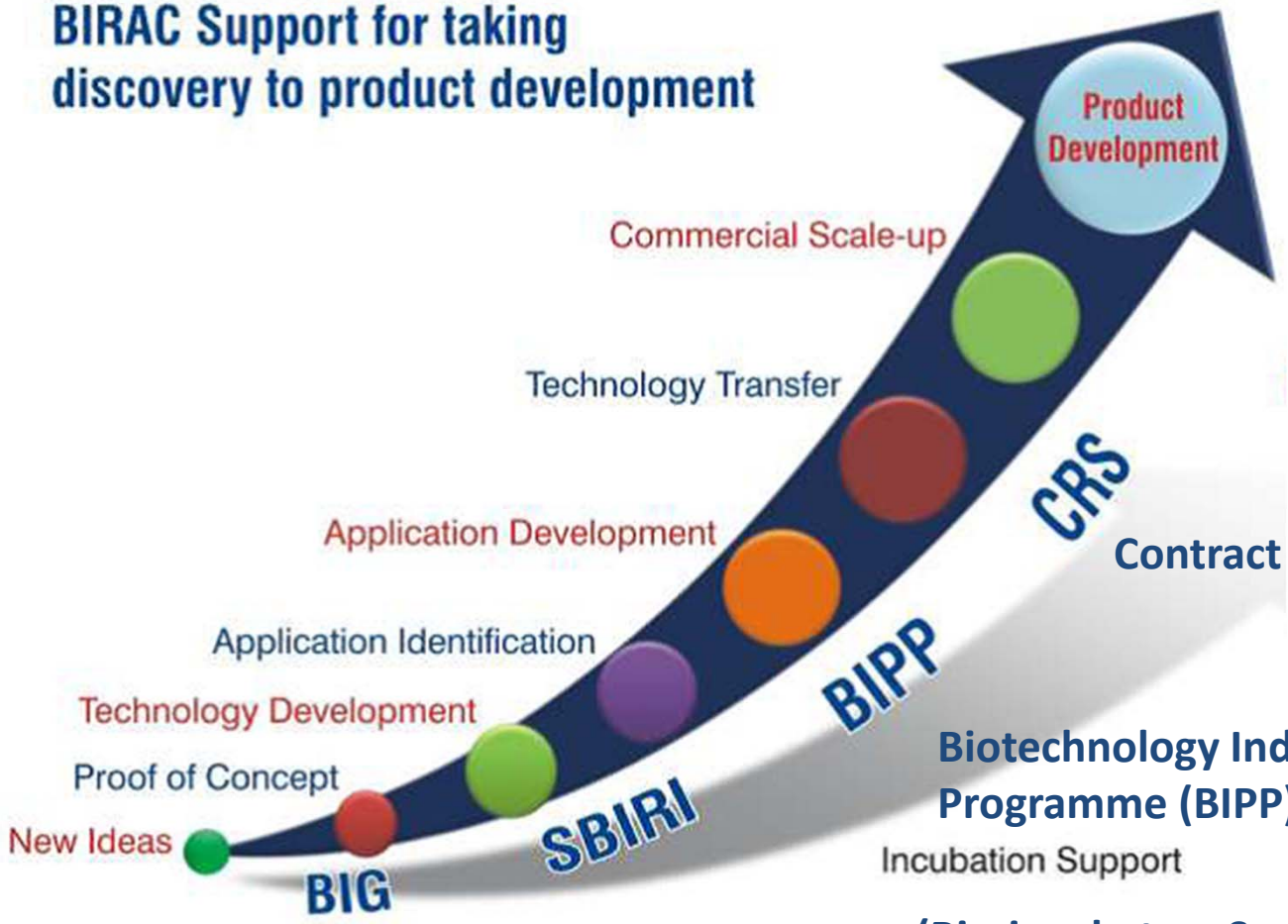
•Conceptualize and support development of affordable, novel, deployable products and technologies in Healthcare, Agriculture, Environment, Bio-energy, and other industrial products and processes involved in manufacturing through public private partnership

•To support and strengthen small scale and medium enterprises through gap filling interventions that facilitate high risk research, innovation and product development.

•To provide financial, infrastructural, institutional and mentoring support so that barriers to entry are reduced for the budding entrepreneurs.

•To encourage knowledge networking among biotech entrepreneurs at national and international level to maintain the technological advantages and scientific edge.

•To provide all other policy and institutional support for all stakeholders involved in converting biotechnological innovations into an enterprise.



Contract Research Scheme (CRS)

Biotechnology Industry Partnership Programme (BIPP)

(Bio-incubators Support Scheme - BISS)

Biotech Ignition Grant schemes (BIG)

Small Business Innovation Research Initiative (SBIRI)

New ideas – Proof of Concept – Technology development – Commercial scale-up – Market development

The Indian industry has to speed-up its efforts to gain competitive advantage as a nation to capture the global market and generate wealth.

The commercialization of new technologies and high tech projects in various biotech industries need to be accelerated to meet the future challenges and realize full potential of biotechnology.

Biotechnology research has vast potential for commercialization in the areas of agriculture, human and animal health, environment, diagnostics, immunobiologicals and various industrial products like antibiotics, industrial enzymes, vitamins etc. The global biotechnology has been undergoing dynamic changes in terms of perspective and priorities.

While we may capitalize on our strength in bio generics, innovation is needed for development of new products and processes.

There is a need to create a critical mass of small business units that have the potential to drive the innovation.

UNIQUE FEATURES OF SBIRI

•Supports start-up units, small and medium enterprises, as well any other private industry with not more than 500 employees in R&D.

•Offers Phase I funding for showing proof-of-concept of innovations based on valid hypothesis, R&D aimed at product development (and not for academic purpose), development of lab-scale technology, refinement & validation of a technology at small scale etc.

•Offers Phase II funding for process/ product development, scale-up of technology, validation & trials, demonstration, commercialization of innovative R&D, etc.

Biotechnology Industry Partnership Programme (BIPP) is a government partnership with Industries for public support on a cost sharing basis for:

(i) Path-breaking research in frontier futuristic technology areas having major economic potential and making Indian industry globally competitive and focused on IP creation with ownerships by Indian industry and where relevant, collaborating scientists.

(ii) The development of appropriate technologies in the context of recognized national priorities in the area of agriculture, health, bioenergy, green manufacturing, when the scale of the problem has serious consequences for social and economic development.

BIPP is an Advanced Technology Scheme only for high risk, transformational technology/process development. No incremental development is supported under BIPP.

Indicative priority areas for consideration under BIPP

(A) Agriculture Technologies
(B) Public Health Technologies - Vaccines and Biologicals
(C) Energy Bioscience

ELIGIBILITY

•Can be submitted solely by a private entity or jointly with other private or public partner (Universities or National Institutes).

•At least 51% of the shares of the company are to be held by Indian Citizens.

•Industry should have DSIR* recognized in-house R&D unit *or have IP ownership (including copyrights* etc.), developed or acquired, and that will be used for the proposed project. *(The companies who are in the process of obtaining DSIR recognition or intend to do so can also apply. However final decisions on their applications will be subject to fulfillment of eligibility criteria.)*

Broad Outline on Developing a Proposal

• Start with an original idea not published or patented with Freedom To Operate

•Carry out proper literature search to strengthen your idea

• Ensure some preliminary work is done on this Idea

• Devise a plan with clarity along with other members of the company or collaborators

• Set objectives and milestones that are achievable

• Work on a realistic & appropriate budget for the proposal

Writing a grant proposal:

The Title

- 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 Project

TITLE OF PROPOSAL

X To develop novel immunoassay format using flash type chemi-luminiscence and magnetic particles as matrix for HPV

✓ Development of immunoassay based high throughput diagnostic kit for HPV using magnetic particles

X An ABC company proposal to develop novel immunoassay format

X Diagnostic kits for detection of Human Papilloma Virus

X Immunodiagnostic kit using magnetic particles

Title should be appropriate with clear expression of concept

PROPOSAL SUMMARY

1. Essence Of The Proposal Highlighting The Following

1.1 Novelty Does the project generate novel concept? From the existing scientific knowledge / inventions develop a product What is new in your project?

1.2 Inventive Step Is it planned to develop a new approach / process to exploit the existing scientific knowledge?

1.3 Scope Of Industrial Application What is the scope for industrial development?

1.4 National Importance/ Social Relevance Importance of the unmet national need; Relevance to humans / animal needs / Addresses issues of mortality / morbidity etc.; will there be economic benefits to the society?

1.5 Market Potential Demand supply gap / Edge over competitors / Cost effectiveness / Improved specifications

1.6 Risk Factors What are the potential risks/bottlenecks – both scientific and commercial, and alternative strategies/approaches in case of roadblocks

NOVELTY (Prior art search report to be enclosed)

The assay reduces the window period of detection

- ✓ The **novelty of the project** is to design a universal assay methodology amenable for automation in clinical settings for HPV

The assay can be automated for high throughput screening

- ✓ The **novel part of technology** is to use universal assay protocol and universal core reagents to detect different analytes using specific antibodies/antigens in an automated setting.

Should clearly state how the core element of proposal can address the existing gap

INVENTIVE STEP

The innovative step here is the combination and specific binding of XYZ magnetic particle, reporter and linkers

- ✓ The inventive step is to utilize the XYZ particles as matrix, chemi-luminiscent reporter molecule and A and B as the linkers in developing universal reagents, harmonized assay protocols in different assay formats such as competitive, indirect, sandwich. The assays will utilize flash type chemi-luminiscence for faster turnaround time and higher throughput

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Innovative process or product should be set apart from the usual approach

PRELIMINARY WORK DONE

(BACKGROUND INFORMATION)

The company has submitted PoC data of antigen/antibody binding with XYZ coated magnetic particle. The complex then forms the matrix-tracer complex which binds to the analyte.

- Detailed preliminary background data showing working hypothesis should be provided.
- Even for discovery projects some scientific basis or some experimental data should be provided
- Collaborator's and Company's role in the proposal should be clearly stated
- Wherever possible, proof of concept data in the form of tables, pictures and graphs should be submitted

NATIONAL IMPORTANCE and RELEVANCE

In developing countries, up to 23 per cent of malignancies are caused by infectious agents, including hepatitis B and C virus (liver cancer), human papilloma viruses (cervical and ano-genital cancers), and Helicobacter pylori (stomach cancer). In developed countries, cancers caused by chronic infections only amount to approximately 8 per cent of all malignancies.

Human Papilloma Virus (HPV) plays a major role in the etiology of Cervical cancer. Early detection of the high risk HPV types has been shown to reduce the cervical cancer burden. There is no indigenous technology available for performing the assays for HPV detection in an automated manner. This endeavour will make the technology available to the masses and will reduce the dependence on expensive foreign suppliers and allow public institutions to provide more healthcare support for the same amount of money.

Describe the ways through which the present proposal can deal with unmet needs of the Society

OBJECTIVES

Objectives should be “SHARP“& “QUANTIFIABLE”

- ✖ Design
- ✖ Feasibility
- ✖ Optimization
- ✖ Validation

- ✓ Development of XYZ labelled magnetic particles as a universal matrix for different assay formats for different analytes.
- ✓ Flash type chemiluminiscence reporting for enhanced sensitivity and improved signal to noise ratio.

Clearly state the strategy with probable outputs

MILESTONES WITH TIMELINES

MILESTONES – "SMART", "ACHIEVABLE", "REALISTIC"

- Initial risk report with alternatives to the strategy/approach
  - The binding between XYZ particle, reporter and linkers will not work
  - Automation of assay will not produce high specificity and sensitivity
- Development of prototype assays
- Pilot lot manufacturing
- Submission Of Report

ESTIMATED TIME PERIOD SHOULD BE RELEVANT TO MILESTONE

Should be monitorable, time bound and specific

BUDGET supported with proper quotes

Equipment: should be as per the need of the proposal

- High end equipment specific to the proposal

Manpower: salaries should be as per Govt. standards

Consumables: should be asked only for the proposed work

Outsourcing: should be minimized to extent possible

Travel and contingency: should be properly justified

Should not be highly inflated or underestimated

Offer a moderate, realistic budget within which you can deliver the promised outputs in the promised time, and thereby contribute to some stated desirable impact.

2. What Does The Present Proposal Aim At?

Establishing proof-of-concept , Discovery linked innovation, validation of existing R&D hypothesis?
Reason

3. Is This Proposal Based On IP Owned The Company/Collaborator/Licensed From Abroad? Technology not in public domain, including own technology, Prior Art Search for Novelty Assessment, Possibility of generating foreground IP, Freedom To Operate

4. Anticipated Outcome/Deliverables The outputs of a project are what you expect to be in place at the conclusion of the project. Outputs are intangible (e.g., decisions, policies) or tangible (e.g., new buildings)

TECHNICAL DETAILS

1. Significance of the proposal

2. Ratioanale Of The Study Supported By Cited Literature

2.1 Relevant References

3. Current Status Of Research And Development In The Subject Area (Both International And National Status)

4. In Case The Technology Is Licensed From Abroad, Status Of Independent Validation In The Country Is Too Be Provided Clearly

TECHNICAL DETAILS

Approach and methodology:

- 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

PROPOSAL OBJECTIVES & WORK PLAN

Objectives should clearly state what you want to achieve and the work plan should give experimental details of how the objectives will be achieved.

Sl.No.	Objective	Methodology/Experimental Design To Accomplish The Stated Objective	Alternate Strategies

TIME LINES (Should be for each objective above)

Activities	Month Of Start Of Activity	Month Of End Of Activity	Indicators Of Progress	Role Of Collaborators
OBJECTIVE :				

Financial Input Required (Rs. Lakhs):

Broad Parameters for Evaluation

Category I&II

A.	**Significance / Scientific Merit**	/15
i	National importance/societal relevance of the problem being addressed by the present proposal	
ii	Contribution to advancement in the existing scientific knowledge	
iii	Level of advancement of technology	
B.	**Approach and Methodology**	/20
i	Is the conceptual framework, design, methodology, and analysis adequately developed, well-integrated, well-reasoned, and appropriate to the aims of the project?	
ii	Is the research plan, research objective and proposed scheduled clearly presented and realistic?	
iii	Does the applicant acknowledge potential problem areas and consider alternative strategies?	
iv	The proposal aims at: a. Discovery Linked Innovation b. Establishing proof-of-concept c. Validation of existing R&D hypothesis	
v	Level of Risk* * High scores are allotted for high risk projects	

C.	**Innovativeness**	/15
i	Level of innovation	
ii	Does the project generate novel concept, approach, methodology, tools, or technologies	
iii	Does the project challenge existing paradigms?	
iv	Does it address an innovative hypothesis or critical barrier to progress in the field?	
D.	**Intellectual Property**	/20
i	Relevance of the background IP for the proposed project	
ii	Possibility of generating foreground IP	
iii	Does the applicant have freedom to operate in the proposed area?	
iv	Does the applicant acknowledge potential restrictions towards freedom to operate?	

E. Commercial Potential / Societal Relevance /10

1. Unmet national needs - Relevance to human / animal needs
2. Level of commercial potential

F. Investigators credentials /10

i. Is the work proposed appropriate to the experience level and training of the PI(s) and other researchers?
ii. Do the PI (s) and investigative team bring complementary and integrated expertise to the project, if applicable?

G. Adequacy of Research Infrastructure /10

i. Are the research facilities available for the proposed work adequate
ii. Extent to which high end equipments proposed to be used are already existing in the company
iii. Extent of support available from other ongoing similar projects/scheme?

Potential Causes for Rejection

- Poorly written
- No evidence of Innovation or Uniqueness
- Insufficient technical details
- No originality in Idea
- Unclear about potential pitfalls or risks or solutions
- Lack of credible PI or team
- Noncompliance with regulatory requirements
- Unrealistic timelines or objectives
- Unconvincing case of commercial potential / societal impact
- Unfamiliar with relevant published data

THANK YOU

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Effective Public Private Partnership *for* Successful Research Proposal : An experience

Dr. G. K. Garg

Director (ITR)
Krishidhan Research Foundation Pvt. Ltd.
Jalna
MAHARASHTRA

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Personal Success Rate in Project / Program Proposal:

Value (Lacs)	Applied	Approved	Rejected	Total Funds (Lacs).	Reason for rejection
1-10	7	5	2	31.00	1. Too ambitious 2. Lacked expertise
10-100	13	12	1	324.00	Hypothesis too speculative
100-1000	12 +(6)+ 4	9 +(3)+2.5	3 +(3)+ 1	4670	Biodiversity Partnership lacking infrastructure
>1000	4	4	0	45,000	
Total=	46	35.5	10	50,025	

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Comparative strength and limitations

Strength	**Public Sector**	**Private Sector**
	Scientific Resources	**Focus**
	Discovery	**Magnitude of operation.**
	Information	
	Intellectual pool with job security	
	Long Learning Mode.	
Limitation	**Restricted administrative & financial freedom.** **Delayed decisions often cause failure or sub optimal performance.**	**Limited Economic risk need reasonable assurance for success.** **Have to fight the public perception of profit only image**

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Projects need to have:

- **Partnerships with Complementary skill.**
- **Deliverables Product**
- **Purpose: Can not be to get a grant alone**
- **Benefit to Society :**
  - **Economic Benefit**
  - **Safe to health and Environment**
- **Competitive edge**
  - **Unique**
  - **Solves an intractable problem**

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Feasibility Planning

A. Scientific

- Prior Knowledge
- Analogy
- Corollary
- Competence

- Sequence in implementation
  - Gene/ Marker
  - Transformation / MAS
  - Expression /Phenotype
  - Economic Evaluation.

- In-house/ Professional
  - * FTO
  - * Biosafety :
  - Intuitive & knowledge based Assessment of marketability of the product.

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B. Commercial

- Regulatory
- Market Identification
- Ease in Production & Quality Assurance

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How to write a Project:

Prerequisite.

- Perceive a product with Unique advantage.
- Have an idea how can this be achieved.
- Find an academic partner that has experience, competence & trust.
- Have multiple discussion session
- Difficult if only one partner has academic competence.
- Devise a plan with clarity who will do what.
- Divide the responsibility.
- Decide on IP Ownership & benefit sharing.

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Actual Proposal writing Sequence:-

Title :- It should be summary of an abstract. Define product, procedure and purpose in 10-15 words –Industry

Project Summary:-

- What do you wish to achieve.
- Why do you wish to achieve.
- How it is proposed to be achieved.
- If successful how will it benefit society & the Company.
- What additional support is needed?.

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Technical Status : Academic Partner.

- Status.
- Analogies
- Corollaries
- **Experience** & Competence.

Deliverables : To be identified jointly.

- **Gene, vector, transformation event, identification of event, evaluation, bio-safety, etc.**
- **Actual plan for each deliverable.**
- **Who will do what : Alone/ Jointly**
- **What is to be out sourced.**

Plan for evaluation: Industry

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Budget

- **How much Support for each:**
  Base it on strength.

Priority: **Dot it yourself.**
Jointly.
Out source

FTO/IP: **Who should get it done.**
From Whom.

MOU's: **Legal vetting by both the partners.**

Finally

- **Partnerships are built on trust- have faith in your partner**
- **Blame Game for failure is suicidal – Fight with situation not with partner**
- **Enjoy working together for science – fruit will follow**

THANKS