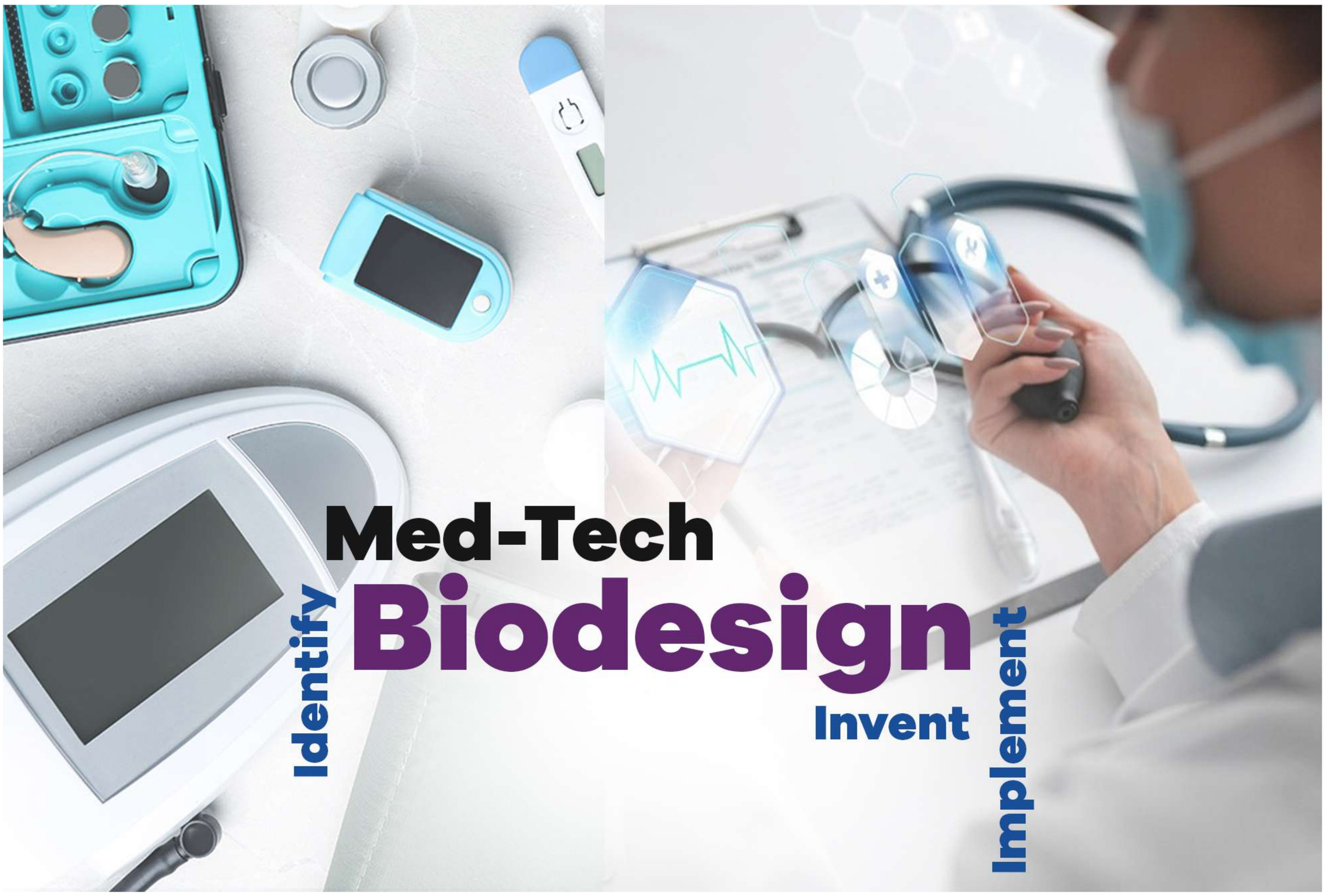

DBT-Handbook on Biodesign for Med-Tech Innovations

(A guidance for aspiring Med-tech entrepreneurs)

DEPARTMENT OF BIOTECHNOLOGY
MINISTRY OF SCIENCE & TECHNOLOGY
GOVERNMENT OF INDIA

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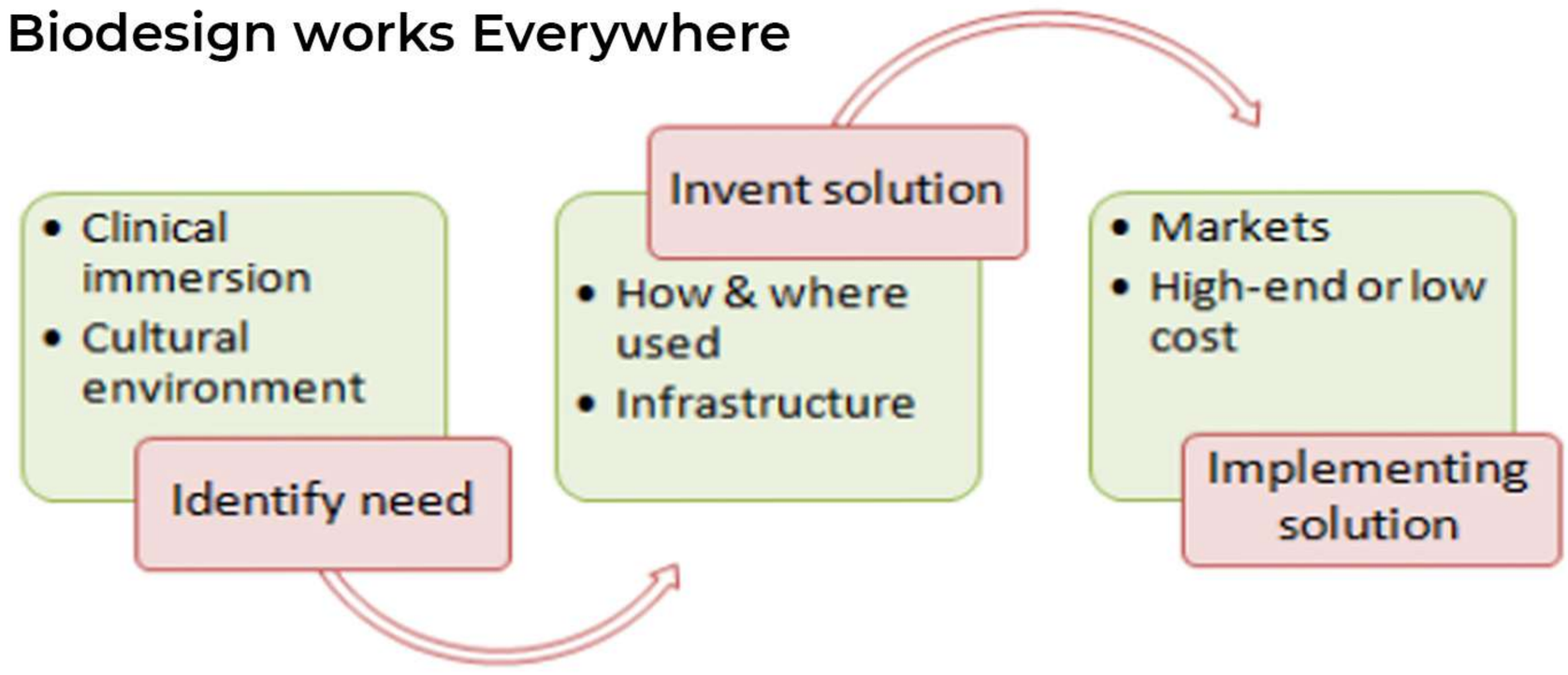
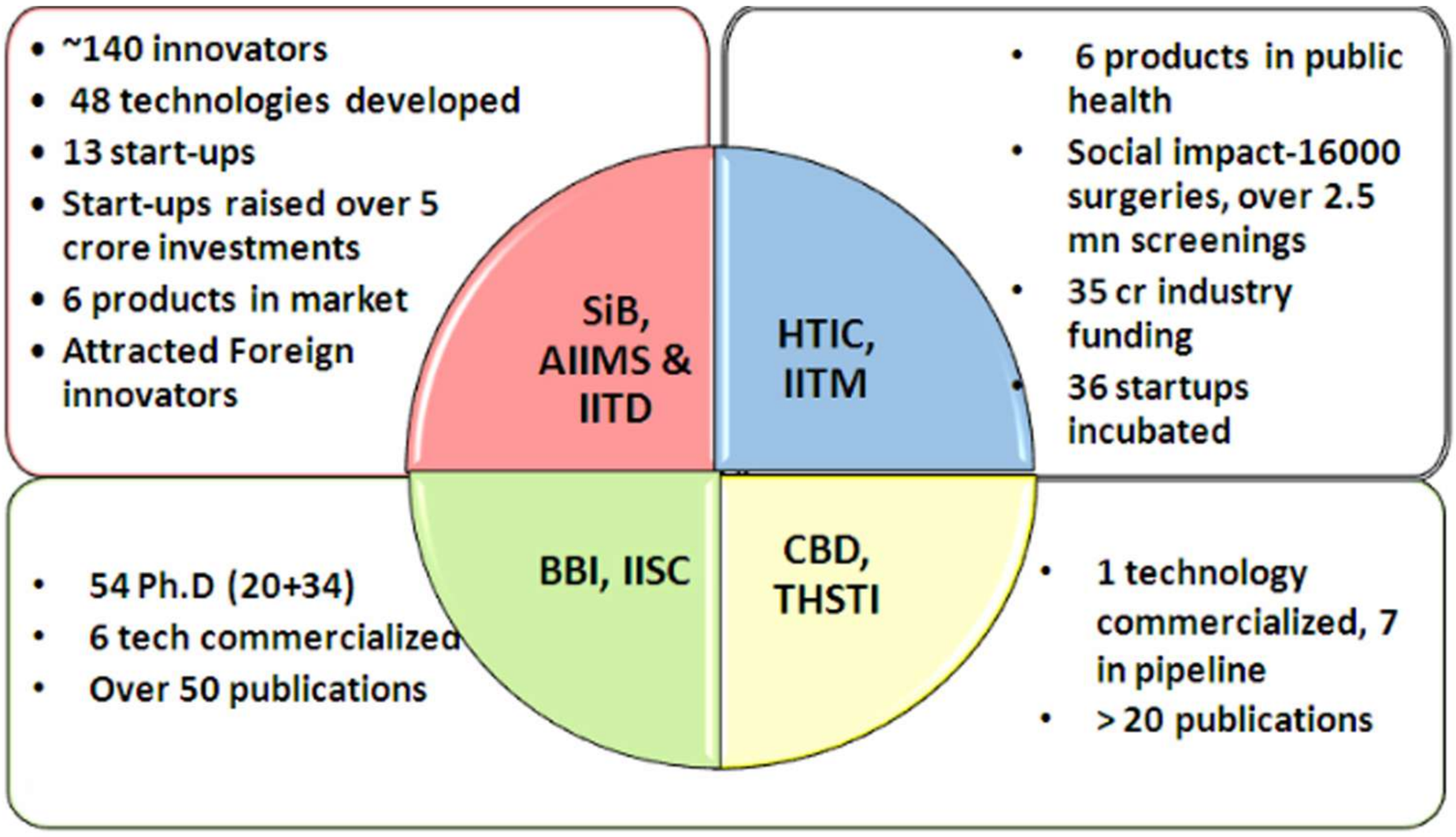
CHAPTER 1: INTRODUCTION

1.1 DBT BIODESIGN PROGRAM

The Biodesign program of the Department of Biotechnology (DBT) was pioneered by the visionary former DBT secretary late Dr M.K. Bhan in the Year 2008 to ignite the then nascent med-tech ecosystem in the country. Biodesign is a global phenomenon and works everywhere.

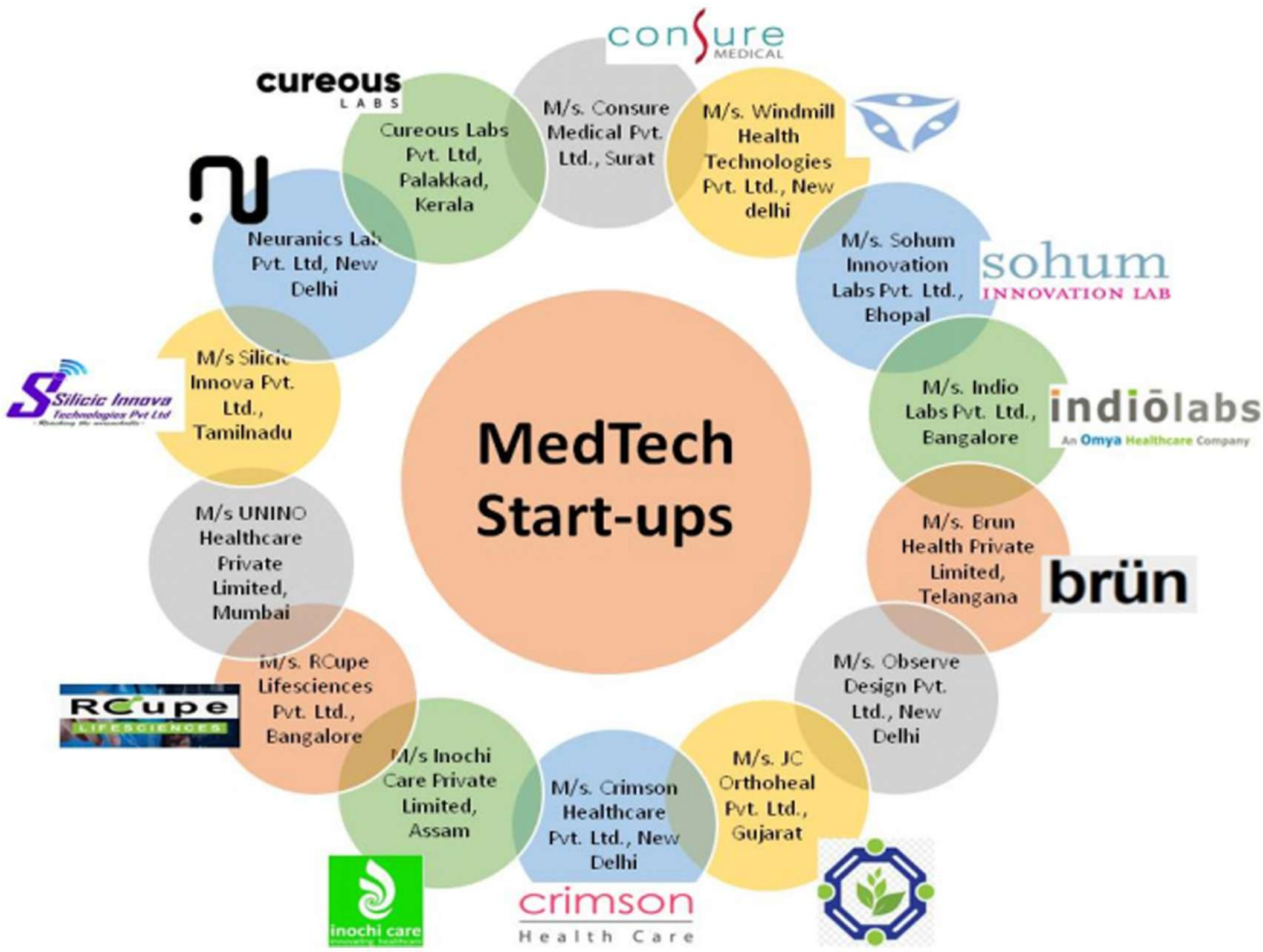


DBT established four different models of Biodesign-centers across the country.

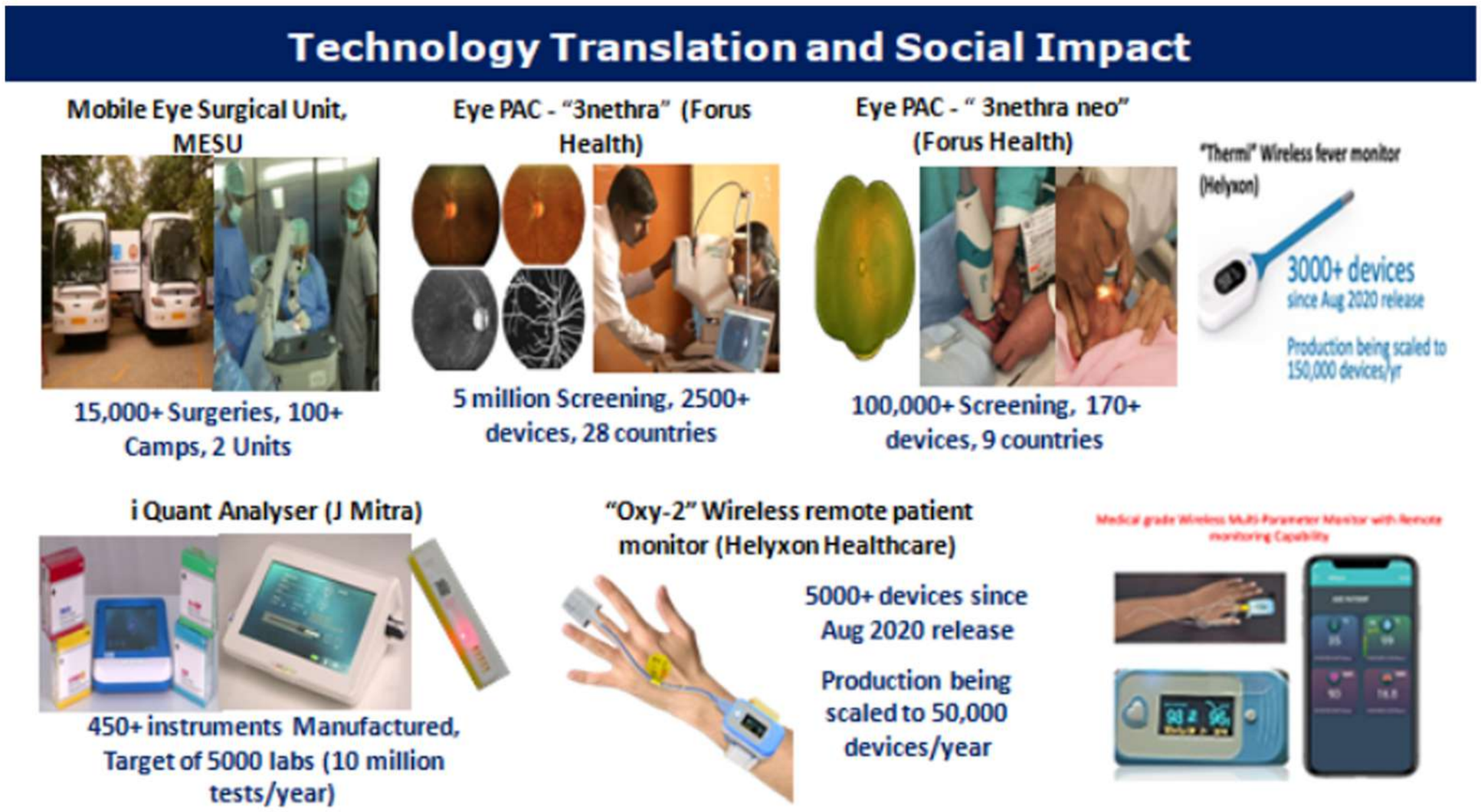


*SiB – School of International Biodesign; HTIC – Health Technology Innovation Center; BBI – Bengaluru Bioengineering Initiative; CBD – Center for Biodesign.

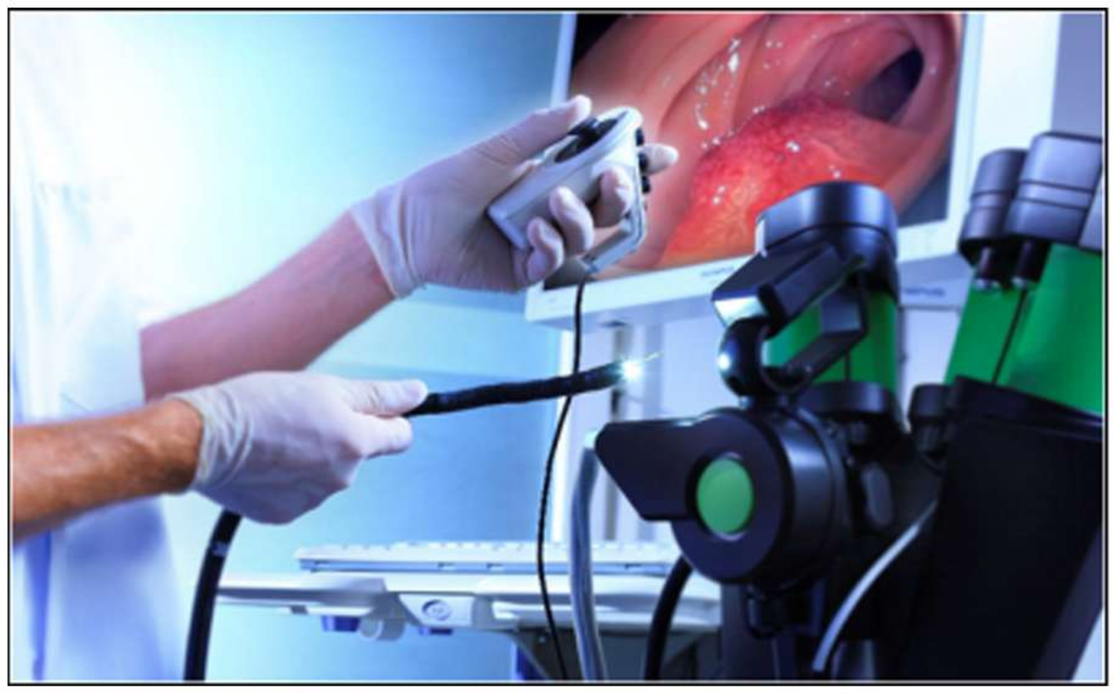
- DBT initiated this as a fellowship program jointly at AIIMS and IITD with clinical immersion in India and biomedical training in Standford. The program has become self-sustainable in terms of the biomedical training since 2014 as the training is indigenously provided and fellows from other countries like Australia, Japan are visiting India for this program. 140 fellows and interns have been trained, 147 Patent filed: 61 Indian Patent, 32 PCT and 54 National Phase applications filed, 33 Patents granted (8 Indian, 25 Foreign). 11 Industrial Design Applications filed and 7 were granted; 23 Trademark Applications filed, and 19 were registered. 52 technologies developed, 23 Technology licensed, 14 start-ups formed in the area of work & 3 more in related domains, 7 products have been commercially launched. More importantly, when we tracked the career paths of the trained fellows, 90% of them continued their career paths in the med-tech ecosystem.



- The second center was at IIT Madras (IIT-M) Research Park with IIT-M faculty participating with clinicians in and around the region. This followed a Harvard Model wherein the clinical need is identified by the physician and the IIT-M faculty with expertise in systems engineering designed and built products. The salient achievement has been deploying these products into public-health and patient care delivery channels and attracting huge industry funding. Six products were launched for public health care and have enabled the impacting lives of millions in performing on-site surgeries and assessments. The center has grown from 4000 sq.ft to 12,000 sq.ft space with dedicated med-tech incubation.



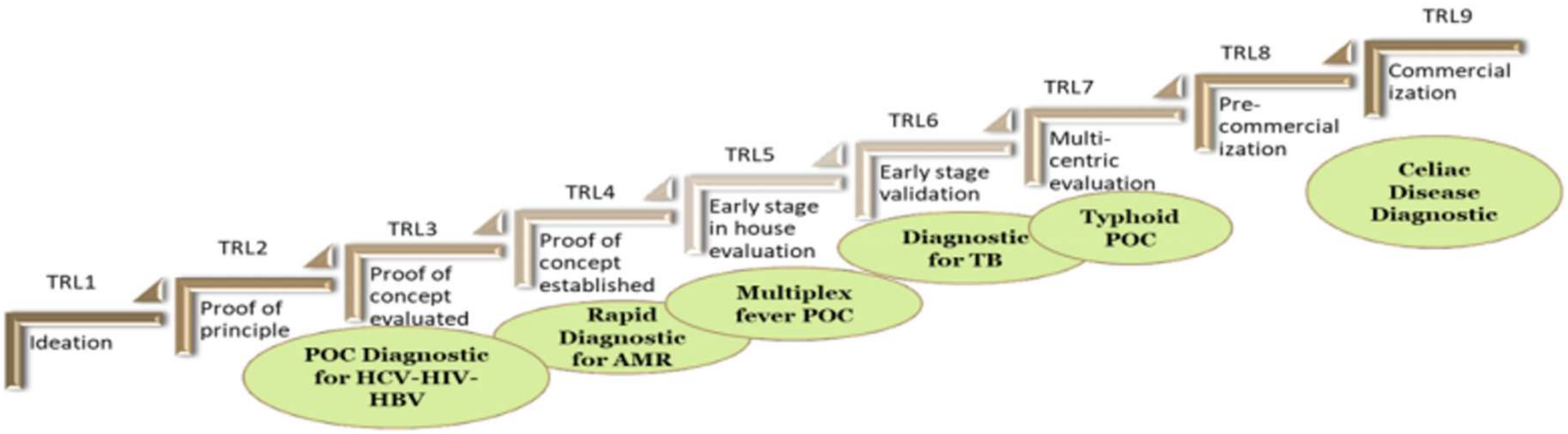
- The third center at IISC Bengaluru in collaboration with hospitals around Bengaluru has helped in championing the new generation leadership in this interdisciplinary domain with about 30 research students pursuing Ph.D. Products developed have been licensed to start-ups for further development. What was initiated as a project by DBT has now emerged as a new, key research center of the institute. Many faculty members from IITs have joined the center. Along with CMC, Vellore, jointly supervised MD-PhD program, is being implemented. In addition to capacity-building, a number of publications and significant research leads have emerged from this initiative.



Endoscopy simulator – EndoMimyk

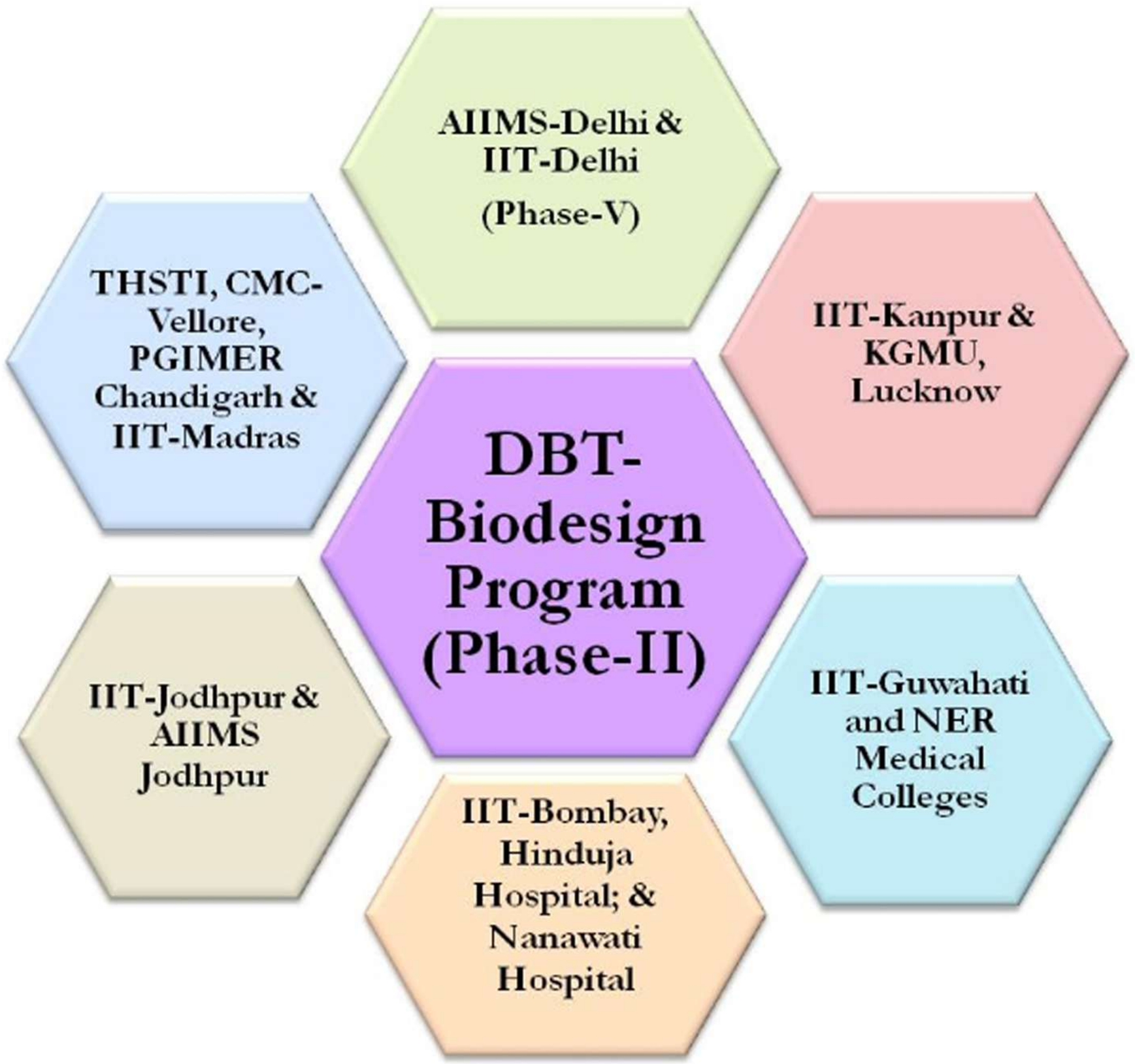
ELISA Diagnostic Kit for Celiac Disease

- The fourth center at Translational Health Science and Technology Institute (THSTI), Faridabad adopted biodesign for translational biomedical research with a thrust focus on in-vitro diagnostics. Numerous national and international collaborations have been forged and a state-of-art support infrastructure has been created. All these have helped in expanding capacity-building for healthcare innovation in India. The “mission critical centre” of the institute has a pipeline of diagnostic products at different stages of development with a number of research articles and patents on these.



1.2 NEW INITIATIVES

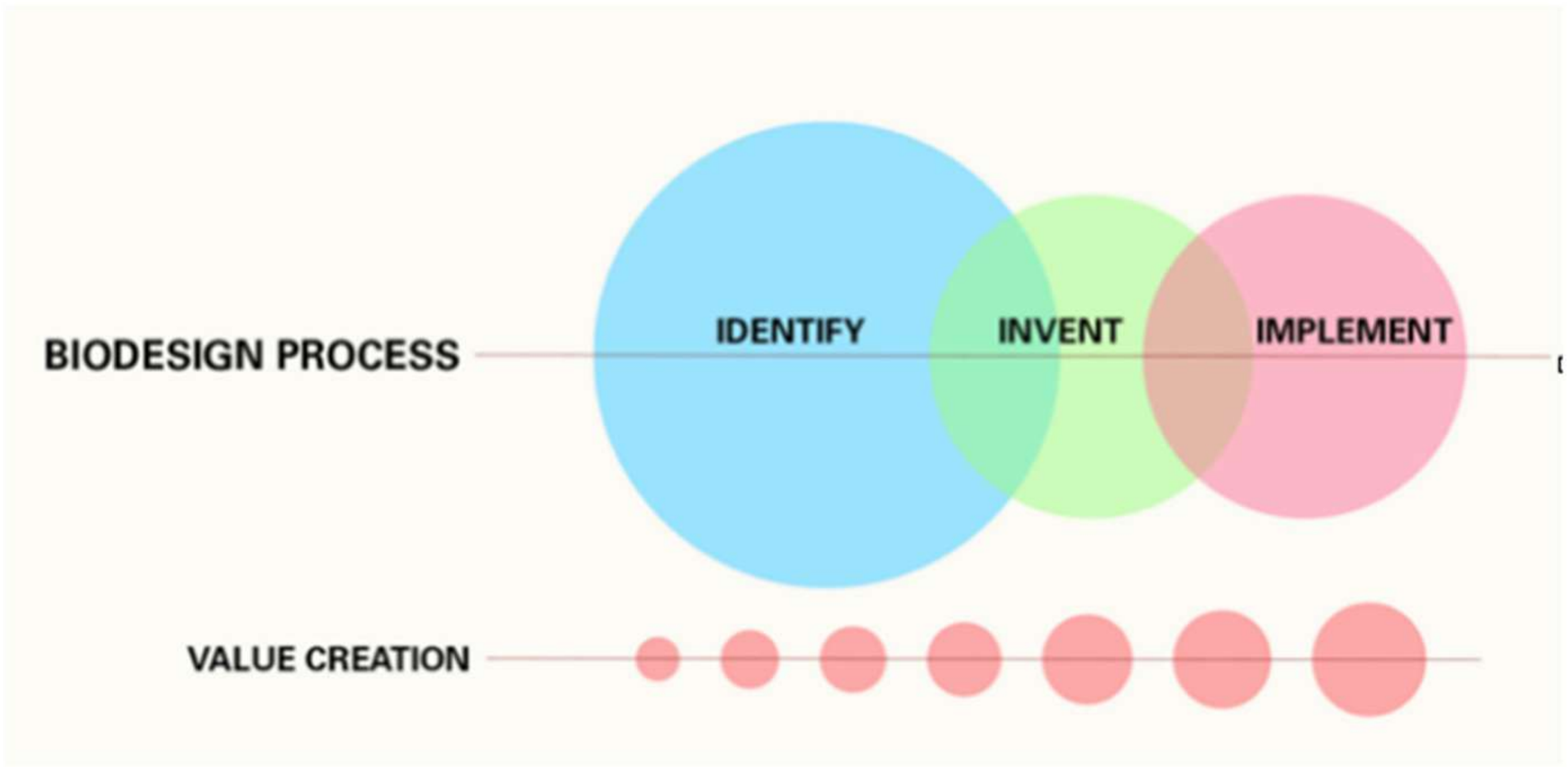
To promote successful med-tech entrepreneurship in the country, DBT has initiated more Schools of Innovation in Biodesign (SiB). Five new centres have been established @ IIT Kanpur, KGMU; IIT Guwahati and medical colleges from NER; IIT Bombay, Hinduja Hospital and Nanawati Hospital; IIT Jodhpur & AIIMS Jodhpur; THSTI, CMC-Vellore, PGIMER Chandigarh, IIT Madras along with continuing support for the AIIMS-IIT D center.



CHAPTER 2: BIODESIGN PROCESS

2.1 BACKGROUND:

The roots of the Biodesign program are based on the Biodesign process - Identify, Invent, and Implement. The process lays special emphasis on: the first hand observation of healthcare delivery to IDENTIFY unmet clinical needs, a design thinking-led multi-disciplinary INVENTION process and an effective IMPLEMENTATION process that rationally takes into account the multiple complex realities of business in the real world of health-tech. This requires radical cross-disciplinary collaboration between leaders from the fields of medicine, design, engineering and business, a bold, innovative approach and focus on real-world clinical and social impact.



The Biodesign process is a 2-year fellowship program in Biomedical device innovation to a multidisciplinary team of fellows consisting of doctor/s, engineer/s, and design professionals. Bringing forth impactful novel medical devices and training med-tech innovators to solve unmet clinical needs of the developing world is the key goal of the program.

2.2 SALIENT FEATURES OF THE BIODESIGN PROGRAM ARE:

a. The philosophy is facilitated self-directed learning based on real-world projects. This approach offers maximal scope for minimally supervised self-driven professional evolution.

b. It is based on the concept of finding several unmet clinical needs and filtering them using the filters of clinical impact, market impact, and IP potential. This critical process helps fellows to reach a few promising and potential needs to solve. This stage of the program is focused on ‘what to solve’ and less emphasis on ‘how to solve’.

c. The program focuses on novel ways and approaches to solve unmet clinical needs. It suggests quick prototyping of the selected ideas to validate the scientific principle and take feedback from the stakeholders. This is according to the concept of ‘fail early, fail fast’ - to understand what works and what doesn't.

d. It provides support to fellows to develop fully functional prototype during the span of the fellowship. Fellows would learn to recruit any additional staff, procure resources required for the project & take critical feedback from the real-world professionals while prototyping and making a complete product.

e. Biodesign program is a true entrepreneurship development program in the med-tech domain. Fellows ensure that all feedback around developing the product is used in the successful implementation of their product in the real-world setting.

f. It equips fellows to understand the principles of validating medical devices, pilot and pivotal trial designs, drawing scientific evidence & its statistical analysis to establish the effectiveness and efficacy of the solution.

2.3 BIODESIGN PROCESS:

Implementation of the Biodesign process consists of the following steps:

a) Selection of Fellows:

The fellows are normally selected from a pool of applicants who come from medicine, design, engineering and business backgrounds. Fellows could be selected based on a track record of innovation (patents, inventive research projects etc). Preference could be given to those who have licensed technologies/products or have the experience of establishing and operating a start-up company. Mid-level executives from the Industry who have gained professional experience may also be considered. Fellows must possess attributes such as flexibility to learn, adapt in new environment, team work, interest in the field of clinical- social impact i.e., interest in creating value for the society.

b) Team Formation:

Selected fellows go through an orientation on the program framework. The selected fellows could be grouped into teams (3-4 fellows each). Teams need to be formed out of the selected fellows with composite backgrounds. Teams need to understand strength- weakness of each of the team member and team dynamics to innovate and get success in the complex med-tech environment. To define the fellowship requirements, the selected fellows can be bound by a fellowship agreement, clearly defining their roles, responsibilities, and obligations during their fellowship tenure. The fellowship agreement also binds the fellows to a package of practices essential for protecting their innovations and smooth implementation of the program including maintenance of confidentiality, maintenance of lab note books, terms for hiring external service providers/consultants etc.

c) Selection of strategic clinical area for clinical immersion:

Mentors of the Biodesign program should provide a strategic clinical area to the fellows based on the potential of unmet needs in the focus area. There is a possibility of more than one strategic area for clinical immersion for each of the Biodesign team. Mentors of the Biodesign program need to ensure less bureaucratic and enabling clinical immersion experience for the fellows.

d) Documentation of observations/ unmet clinical needs:

Documentation of observations or unmet clinical need is an essential part of the Biodesign process. Fellows need to observe needs, while shadowing physician consultants, residents, nurses in different settings (OPD, ICU, aftercare). They need to understand the emotional burden of the diseases and the clinical condition. Many key insights of the clinical need would come out during immersion. Fellows need to be curious, have empathy, and understand the current care cycle to identify priority unmet clinical needs in the ecosystem.

e) Formation of need statements:

Creation of need statements is an important part of the Biodesign process. Mentors of the Biodesign program have to ensure that the fellows learn how to create clear, comprehensive need statements. Fellows should understand that the need statements will change when seen from different perspectives.

f) Needs Filtering:

Needs filtering is critical step in the Biodesign process to select high impact needs. Fellows need to be taught- selection of filters, prioritization and team competence.

g) Need Selection and need specification:

Once the top 2-3 needs are selected; fellows need to spend effective time forming the need specification. The detailed need specification would consist of description of the disease, burden, priority unmet clinical need, stakeholder analysis, current solution landscape with advantages and challenges, market statistics and futuristic solutions.

h) Brainstorming and selection of ideas to prototype:

Fellows are provided the right environment to conduct brainstorming session around the need. They will follow the core principles of brainstorming and generate as many ideas as possible and document them. This is creative part of the process and has to be enabled with basic prototyping material for visualization and detailing.

i) Proof of concept (POC) & IP search:

As the team gains confidence in the idea that they want to pursue, they need to plan for proof of concept and must conduct preliminary IP scoping to understand the novelty, non-obviousness and clinical and market utility of their concept.

j) Business model and implementation model:

Business and implementation model is essential component of the Biodesign process. Fellows need to evolve these in parallel to product development so as to add the essential features for enhancing the commercial potential of their product.

2.4 FELLOWSHIP SCHEDULE:

All innovators to the programs are selected through a competitive process keeping in view the aptitude, competence and entrepreneurial spirit. A batch generally does not contain more than 3 teams, each team consisting of not more than four fellows/innovators.

The teams are multidisciplinary with each member from different backgrounds- clinical/engineering/business/sciences etc.

Each fellow will receive a fellowship for duration of two years. The fellowship at present is Rs. 60,000/- per month during I year, which is reduced to Rs. 50,000/- per month during II year, to encourage the fellows to move out of the fellowship and to keep up with their pace of establishing their enterprise.

The expected activities are summarized in table below:

Year	Activities
First year	Clinical Immersion (3-6 months), Needs identification, Needs filtering, Brainstorming, Ideation, Prototyping, Product Development
Second year	Product refinement, Product finalization, Grant writing, Patent search, IP filing, Company formation, Licensing of technology

First year:

In the first year of fellowship program, the fellows would undergo the process of Clinical Immersion for three to six months in the hospitals and clinical settings in the selected strategic focus area. The team is expected to examine clinical needs within the Indian settings for identifying opportunities for medical technology innovation that is clinical problems potentially addressable by a technology solution. The identified clinical needs are filtered by the team to select top 15-20 needs, with advisory from faculty and mentors within the next two months. Subsequently over the next few months, the selected needs are further shortlisted by the team to explore top 3-5 needs based on market demand and potential nationally and globally and are taken forward through a process of inventing, prototyping, product development, IP protection etc. in association with faculty member(s) who are selected in consultation with Executive Directors of the program. The faculty members could be associated in the program as inventors and/ or mentors. At least one faculty member should be included in each project to facilitate the continuity of the project and to ensure that the project is taken to its logical conclusion.

Second year:

In the second year of the fellowship program, the teams are expected to be involved in fund raising, refinement of prototypes, bench validation, clinical validation, preparing business plan, transition to startup formation etc.

2.5 GLOBAL CONTEXT TO BIODESIGN FELLOWSHIP:

a) International Partnerships:

The program also fosters international partnerships with foreign Universities having an active Biodesign ecosystem with a view to collaborate for training of foreign students in the Biodesign process including need identification and development of affordable medical devices as per unmet needs of India. All centers are encouraged to forge international collaboration and attract international innovators into their respective centers as well as send their innovators in exchange visits. Umbrella agreements may be signed by the institutes with various interested countries. The partnerships could be mutually executed and each side may sponsor their respective fellows and hospitality may be extended through partnerships.

The partnership also provides the Indian fellows an opportunity to do a short-term observership/visiting in these foreign Universities/ Institutes that will provide them quality exposure for enhancing technical, innovation and business skills and bolster motivation catalyzing the learning curve.

b) Learning from established Med-tech Startups in India & other countries:

Fellows need to learn from other med-tech startups within India and other countries. From time to time, medical startup companies should be invited and fellows will learn from the success- failure from the decisions that the companies have taken in the past. Medical technology ecosystem is a global ecosystem and one needs to be aware of the global markets and other solutions conceptualized in other geographies.

2.6 VALUE MANAGEMENT:

a) IP management:

The program fellows need to be provided hand holding support throughout the fellowship in identifying promising novel inventions and securing it through appropriate means such as Patents, Industrial Designs, Trademarks, Copyright etc. It will be the responsibility of the host institute/s to apply and maintain the patent as per **DBT-IP guidelines 2023.**

b) Technology commercialization:

The fellows are eligible to license the technologies they developed after establishing a startup within one year of completion of the fellowship tenure. If not, licensing of technologies to other startups/industries must be pursued. Piling of protected technologies without further transfer for commercialization must be avoided by the Biodesign centers. The program also has a provision for the assignment of technologies to the startups established by the fellows upon achievement of certain pre-determined milestones, including the commercial launch of the technologies in India for the benefit of Indian society.

Meticulous post-transfer monitoring is a pre-requisite for ascertaining adherence to agreed milestones in accordance with the License Agreement. Such monitoring efforts may involve providing handholding support during the technology validation stages, prosecution of the patent filings, adherence to the license terms and collection of royalties from the Licensee, once the product is placed in the market.

CHAPTER 3: MEDICAL DEVICES IP AND ITS PROTECTION

The program aims to encourage institutions and individuals to innovate and develop medical devices; Institutional filing of patents for their inventions, and subsequently out-licensing such technologies for commercialization by inventor-founded entities.

3.1 IP GENERATED THROUGH BIODESIGN PROJECTS:

► All Institutes that are a part of the DBT- Biodesign program shall be encouraged to seek the protection of Intellectual Property Rights (IPR) for novel inventions generated by such development projects.

► The filing of patents must be in the name of the institute(s). The primary and secondary inventor(s) shall be designated as the inventors of the product/innovation. All the inventors, in compliance to the conditions stipulated in fellowship grants, and the associated Faculty are required to assign to the institution all rights, title and interest in their inventions and related property rights that result from activity conducted in the course of their Fellowship tenure and/or in the use of institutional resources. If there has been no legal binding agreement in this regard while inducting the Fellows, all inventors will execute a letter of assignment for the IP in favour of their institution before the filing of the patent application. This will also apply to faculty engaged in mentoring the fellows.

► If there is more than one institution involved in the IP generated, the institutions, being joint holders of the patent, must enter into a multiparty agreement regarding the protection of the Intellectual Property, management of intellectual property, execution of licensing transaction and the revenue sharing formula. Where two or more institutes with separate IPR policies are involved, a standard framework/ policy for sharing IP generated through the Biodesign project should be in place before commencing the project.

Also, in such a case, one of the institutes should lead asset management and IPR protection. The lead institute shall file the patent on behalf of the institutes and be a nodal point for all activities related to that IP.

► There should be a redressal mechanism/committee at each institute for solving disputes arising during the generation of IP. Where two or more institutes are involved, this mechanism/committee should have members from all involved institutes.

► Since the filing of IP and post-filing activities requires the help of experts, the institute(s) is advised to engage professional bodies dealing with Patent filing and prosecution as needed.

► It shall be the responsibility of the Executive Director of Biodesign Center to ensure that support of DBT is suitably acknowledged in the publications (papers, reports, etc.), products, technologies and the catalogues arising out of the project.

3.2 PROTECTION AND MANAGEMENT OF IP

The Biodesign program should develop a mechanism such as setting up / associating an IP Management Cell (IPMC) for IP management, technology transfer, post-transfer monitoring, techno-legal activities, revenue collection and disbursement etc. The Biodesign program should follow the following steps for effective management and protection of IP.

Identification of Project Team

To start with, the Biodesign fellows would identify the colleagues and faculty members (as team members) who would be associated with generation of IP both in the capacity of inventors and mentors in consultation with the Executive Directors of the Biodesign Program. At least one faculty member would be included in each project to facilitate the continuity of the project and to ensure that the project reaches the final stages. The team members would identify one team representative and execute a legal undertaking to this effect on the stamp paper.

The team representative shall be responsible for steering all activities of IP protection, tracking relative contribution of each member towards the technology development, and coordinating with IPMC for all IP-related matters, including executing documents related to IP matters.

The fellows shall provide the team information to the IPMC for the records and necessary action before the commencement of the research work. In the event a team member leaves, and/ or a new member joins the team, the team representative, in consultation with the Executive Directors, shall submit the changes in team composition to IPMC.

Maintenance of Strict Confidentiality

The team members shall maintain complete confidentiality of all information in any form, written or oral. No presentations/poster/prototype displays in workshops and conferences and publications would be made until the patent application is filed. In exceptional situations, where non-confidential disclosure can be justified, the team representative shall take prior approval from Executive Directors through IPMC.

Maintenance of Lab Notebooks

The team members shall keep and maintain written records of all inventions (solely or jointly with others) during the term of his/her association with the project. The records will be in notes, sketches, drawings and any other format. These records will help document each member's relative contribution to technology development. Each member shall get their records signed every week by the Executive Directors/mentors.

Lab notebooks shall be property of the Biodesign Center, and if any team member leaves in between, the notebooks shall be submitted to the E.D. of the Biodesign Center. After project completion, the records shall be maintained at the Biodesign Center.

Hiring External Service Providers/Consultants

Where it becomes essential to hire the services of the external service provider (s)/Consultants (s), the project team will submit a justification to IPMC as to why the specific work cannot be undertaken by their team or by other fellows.

If such justification is found in order, the teams will be required to seek approval for hiring an external service provider, from Executive Directors. IPMC shall facilitate hiring external service providers considering the techno legal requirement for such hiring. Each of such service providers will enter into non-Disclosure agreements as needed and shall not have any claims on the invention disclosures with explicit covenant stipulated in service agreements.

Protection of IP

All inventions made by Fellows must be disclosed promptly in writing to designated authority within the institution. The inventors will submit details of the invention with the prior art, if any deployed in the invention and market relevance by submitting the prescribed invention disclosure form. The IPMC will review the disclosure and propose an invention protection strategy after carrying out triage of the invention disclosure to ensure novelty, inventiveness, and market relevance. The IPMC will also review internally or with the help of external professionals, background IP if any, deployed by inventing team in the development of the product, which would require third-party IP to be in-licensed before filing the patent. Such third-party background IP may relate to design elements, algorithms, adjuvants etc., deployed in the product, having prior IP ownership with third parties. The IPMC, may authorize the filing of IP in the name of the institution/institutions, duly ensuring the assignment of rights by the inventors in favor of the institution/ institutions. The institution may avail the services of IP attorneys empanelled by the Biodesign Program as needed.

Efforts should be made to file a provisional patent application even when the IP is in its initial stages of development to secure the novelty of the IP as soon as possible. This would provide the team one year of lead time to further work on the IP and confirm the novel features, following which a complete patent application may be filed. For seeking protection

in foreign countries, filing through the PCT route may be adopted by IPMC, based on the evaluation of the commercial potential and after due approval from Executive Directors.

Suppose the Biodesign program determines that any IP should be retained as a trade secret. In that case, IPMC shall recommend necessary measures to delineate the boundaries of a trade secret to secure and protect the same and commercialise the same, where appropriate by licensing to the spin-out entity founded by the inventors.

Third-party disclosure where service providers are retained

For third-party disclosures to hire the services of external service providers, an NDA shall be executed for which approval shall be sought from the Executive Directors of the participating institutes.

3.3 POST-FILING MANAGEMENT OF IP

As mentioned above, a patent application is usually filed as a provisional application to establish the priority of the invention in case the disclosed invention is only at an early stage. Within 12 months from the date of the Provisional application, a complete specification must be filed, and decisions also need to be taken on foreign filings. A PCT (Patent Cooperation Treaty) can be filed within 12 months of filing the provisional specification. After the expiry of 18 months from the filing date or priority date, the patent application gets published. IPMC can fast-track the overall patent publication process, for which a request for early publication can be filed at any time after applying with the Patent Office. Subsequently, a Request for Examination (RFE) is to be filed within the stipulated time of the date of filing of the complete specification, which leads to the issuance of First Examination Reports (FER). IPMC must ensure a timely written response to FER by an IP attorney (legal representative of the Program) within the stipulated time, including amending the claims and/or making changes to satisfy the queries raised in FER in consultation with the inventor(s). If the examiner is satisfied with the amendments, the Patent Office issues a patent certificate.

3.4 INDUSTRIAL DESIGN:

After filing the design application with the prescribed fee, the design application is accorded a date and a serial number. The serial number eventually becomes the registration number of the design post-registration. Once the design application is filed, it is taken up for examination. In the examination report, the examiner highlights the defects or objections in the application, if any, noticed during the examination of the application.

The IPMC must ensure and correct the defects notified by the examiner within the stipulated time, from the official date of the examination report. If the IPMC, through its IP attorney, fails to respond to the objections or does not comply with the objections raised, then the design shall be deemed to have been abandoned. In case the IPMC contests the objections through an IP attorney, the Patent office provides a hearing. The hearing is appointed within 1-2 months. The IP Attorney shall communicate the Controller's decision after the hearing in writing (stating reasons) to the IPMC. The application is registered once all the requirements are fulfilled by the IPMC, after which it is published in the Patent Office Journal. Once the design is registered and details are entered in the Register, a certificate of design registration is issued, valid for ten years from the date of registration, after which an extension can be filed for another five years.

3.5 TRADEMARK:

Once the Trademark application is filed, a number gets allotted/generated. In an intermediate stage, prior to the proper examination phase, the Registrar examines the application for any formality errors like incorrect class, incorrect category, improper documents, incorrect goods & service description, or any improper information. The IPMC must ensure to reply to the report within thirty days from the date of receipt or else the application will be abandoned.

The application examination is mainly conducted to check and ascertain whether the applicant's mark is distinctive, whether it conflicts with any of the already existing registered trademarks or the pending ones or whether there exists any possibility of deceptiveness etc. The Registrar then issues an Examination Report citing the objections against the mark (if any). The IPMC, through its IP Attorney, must ensure a written response or reply to the Examination Report with the requisite evidence of distinctiveness within the stipulated time, from receipt of the examination report to overcome the objections cited in the report.

If the trademark application, after clearing the examination phase, gets allowed/accepted, then the trademark is advertised/published in the Trademark Journal to invite the public to file the opposition (if any) against the registration of the said mark. If no opposition is filed or the opposition filed is decided in favour of the applicant, then the Registrar registers the trademark. Thereby a Certificate of Registration gets issued in favour of the trademark applicant, and the ® symbol can be affixed next to the logo or trademark of the applicant.

IPMC shall inform the fellows any change in process/law for registration of IP/process/trademark, etc.

IP arising out of public-funded research is a huge asset and must be appropriately harnessed for maximizing socio-economic impact and achieving public good. Public interest should be protected with clauses on availability of the final product in Indian markets at affordable rates, especially for products with potential for mass deployment. Timelines on commercialization should be clearly defined in licensing agreement.

All institutes should mandatorily report the details of their scientific outcomes - published articles, patents granted, and technologies commercialized to DBT. The outcomes are to be reported at the following links -

https://dashboard.dbtindia.gov.in/sbt/publication/

& https://dashboard.dbtindia.gov.in/sbt/patents/

CHAPTER 4: COMMERCIALIZING IP- LICENSING & ASSIGNMENTS

4.1. CURRENT LICENSING AND ASSIGNMENT FRAMEWORK OF BIODESIGN PROGRAM

As per the existing licensing framework of Biodesign program, each team has an exclusive option to request a worldwide exclusive license of the Intellectual Property (one or more) in which the fellows (team members) have contributed as inventors within one year from the completion of fellowship tenure. IPMC shall license the Program IP to the start-up constituted by the team as a private limited company with a reasonable paid up capital (presently 1.5 lakhs). The Start-up may be established by one or more members (fellows) of the team. In case all team members are not interested in associating with the Start-up for taking forward the technology, the fellows who are promoters of the Start-up would need to submit a “No Objection” from the other team members. Start-up pays a nominal lump sum amount (presently Rs. 50,000/-exclusive of taxes) and a royalty (presently 5%) on gross sales of product as the License fees, at present to DBT, which may henceforth, in view of DBT-IP guidelines, be taken up by the institution, as per rates decided by institutional IPMC. The Start-up can also avail the option of IP assignment only upon achievement of the Milestone stipulated in the license agreement, i.e. commercial launch of the product in India and receipt of regulatory approval from CDSCO under Medical Device Rule, 2017. The licensee is entitled to exercise an option to purchase the licensed patents, its improvements and associated intellectual property upon payment of all expenses incurred by the institution towards protecting the licensed patents, its improvements and associated IP up to that point of time and the value of the licensed patents, its improvements and associated Intellectual Property mutually agreed to by Licensor and Licensee and as ascertained by a technology valuation process. However, all such IP assignments must be referred to DBT for approval, prior to assignment.

4.2. PROPOSED LICENSING STRATEGY

The strategy aims to:

► List the potential modes of IP licensing with their advantages and disadvantages

► Outline potential methods for harmonizing institutional procedures for IP licensing.

Licensing options will vary from exclusive royalty-bearing licenses to non-exclusive royalty-bearing and non-exclusive royalty-free licenses. However, several factors impact the procedure/strategy of IP commercialization as detailed in this document.

Modes of IP Licensing and their impact on different stakeholders

Following are broad principles that may be considered in deciding on IP commercialization modalities.

a. The mechanism of licensing is to be decided on a case-to-case basis by the host institute through the institutional IP committees. Transparent mechanisms should be built-in by the institutes to ensure that IP is transferred to the right licensee with potential capability and competence to scale-up the innovation especially for exclusive licensing.

b. Following licensing, the host institution should report details to DBT.

c. In exclusive licensing, for products/technologies that are intended for large scale public deployment, agreements should include a clause of affordability in Indian markets.

d. The public-interest issues in exclusive licensing will be protected appropriately and all Indian patents are secured by the GoI through March-in Rights including the option of compulsory license under our patent law, if there will be any exigency arising for that technology/patent.

e. IP Assignment requests, if any, needs to be referred to DBT by the host institutions and will be taken up separately on a case to case basis with approval of Secretary, DBT.

4.3 NON-EXCLUSIVE LICENSING

a. For research leads in higher TRLs, non-exclusive licensing may be the preferred modality with licensing fees decided on a case to case basis.
b. Competition to be encouraged so as to bring out high-quality, affordable products in the market.
c. Timelines on commercialization should be clearly defined in licensing agreements.
d. Preference to Biotech SMEs and for manufacturing in India.

4.4 EXCLUSIVE LICENSING

a. For research leads in lower TRLs, exclusive licensing may be considered.
b. Public interest should be protected with clauses on availability of the final product in Indian markets at affordable rates, especially for products with potential for mass deployment.
c. Timelines on commercialization should be clearly defined in licensing agreement.
d. Preference to Biotech SMEs and manufacturing in India.
e. Preferred purchase arrangements for start-ups for products developed under Government funded programs.
f. A standard licensing agreement framework may be developed by the public institution that would ensure a share of the revenue earned by the licensee to be given to the partnering public institutions for a limited timeframe.
g. The license shall be subject to the irrevocable, royalty-free right of the Government of India to practice or to require the licensee to grant sublicenses to responsible applicants, on reasonable terms, when necessary to fulfill health or safety or security needs of the country.

4.5 FACTORS TO CONSIDER FOR DECIDING THE MODE OF LICENSING

Institutions may opt to license the IP on an exclusive or non-exclusive basis, duly factoring variables such as the nature of the technology, Technology Readiness Level (TRL), available market size, risk assessment and investment requirement (i.e. how much further development a technology requires by the industry to take it to the market). The choice of licensing type typically depends upon the following factors:

► **Market potential:** if the technology developed has significant market potential beyond the ability of the single licensee to exploit the potential, the licensor may contemplate exclusive licensing with a clear stipulation for sub-licensing rights that not just the licensee but the licensor can exercise to ensure more comprehensive delivery of the products in needy markets.

►**Technology readiness level (TRL) of the innovation:** The technologies that are close to being commercialised and at the higher side of TRL (i.e., ≥ TRL-7) require less significant investments to take them to market and may not involve significant risk-related investment for their commercialisation. The institution has borne the investments needed to mitigate the technology risk in such inventions. Therefore, these technologies may be considered for non-exclusive licensing by the institution. Whereas the technologies at the lower side of TRL (i.e., ≤TRL-6), would require the licensee to commit significant risk-related investments to advance the product to market readiness. Therefore, the institution may consider them to license on an exclusive basis to reward the licensee for meeting the risk-related investment in the pre-market stage.

►All exclusive licensing rights granted will be subject to the stipulation of milestones for the licensee to accomplish with a reasonable grace period for the fulfillment of milestones. In effect, all exclusive licensing agreements will be limited exclusive agreements, duly stipulating the withdrawal of exclusive status in case of prolonged dormancy of efforts on the part of the licensee to accomplish stipulated milestones.

► **IP Assignments:** Assignments are considered for technologies in which the licensor is not willing to invest in further development or wait for future royalty flows due to its limited commercial value perceived by the institution. However, the potential licensee may foresee commercial value and want to pursue commercialization by securing rights to the inventions. In such circumstances, if the request for assignment emanates from the inventor(s), then the Institution will assign the ownership rights back to the inventors for commercialization. Even though the institution has not filed for IP, since the ownership of the invention vests with the institution, the grant of assignment is must for the inventors to possess the commercialization rights. In such circumstances, there will be no stipulation of royalties or any form of benefit sharing for the rights assigned back to the inventors.

► However, if the institution has filed for IP and the inventor licensee seeks assignment instead of licensing with royalty benefit flows, such requests may be considered if the assignee can meet the commensurate assignment fee stipulated by the institution, computed based on the technology readiness level and the market potential assessed.

► All licensing must be duly reported to DBT.

4.6 ROYALTY-FREE LICENSE

If the inventors perceive establishment of social enterprises as non-profit entities, royalty-free (pro-bono) license may be considered, keeping in view the societal gains from such licensing. However, the license agreement should include unambiguous covenants to the licensee to meet royalty obligations, should the enterprise opt to commercialise inventions for profit, irrespective of the legal status of the entity. A clear description will be articulated in the licensing agreement as to what constitutes cost and profit.

Note: The above mentioned modes of licensing and factors are suggestive and the IPMC may decide on mode of licensing and rates of royalty as per institutional guidelines or incase of multi-institute IP, as per prior agreed terms between the parties. The same should be reported to DBT. For details refer to DBT-IP Guidelines 2023.

CHAPTER 5: REVENUE/ROYALTY- SHARING

5.1 ETHOS

The developers, i.e. primary and secondary inventors of the program devoting efforts to develop the products must be the primary beneficiary of the returns. The clinical and academic mentors (also called secondary inventors, henceforth) along with other stakeholders such as institutions involved in the program should also be considered. Institutional IP guidelines may also be considered. An equity-based mechanism may be also opted for payment to the mentor(s) and affiliated institutions once the product is commercialized, instead of conventional royalty mechanism.

5.2 BENEFICIARIES

Towards commercialization of an IP, following categories are involved:

i.Primary inventor(s): The group of people who contributed towards the development of the commercialisable product. Sometimes, the share of IP among the inventors are defined, sometimes it is shared equally by all inventors. Example- Principal investigator(s) / Investigators / Research associates / fellows / ideators / innovators/ any other main leads working on execution of the project.

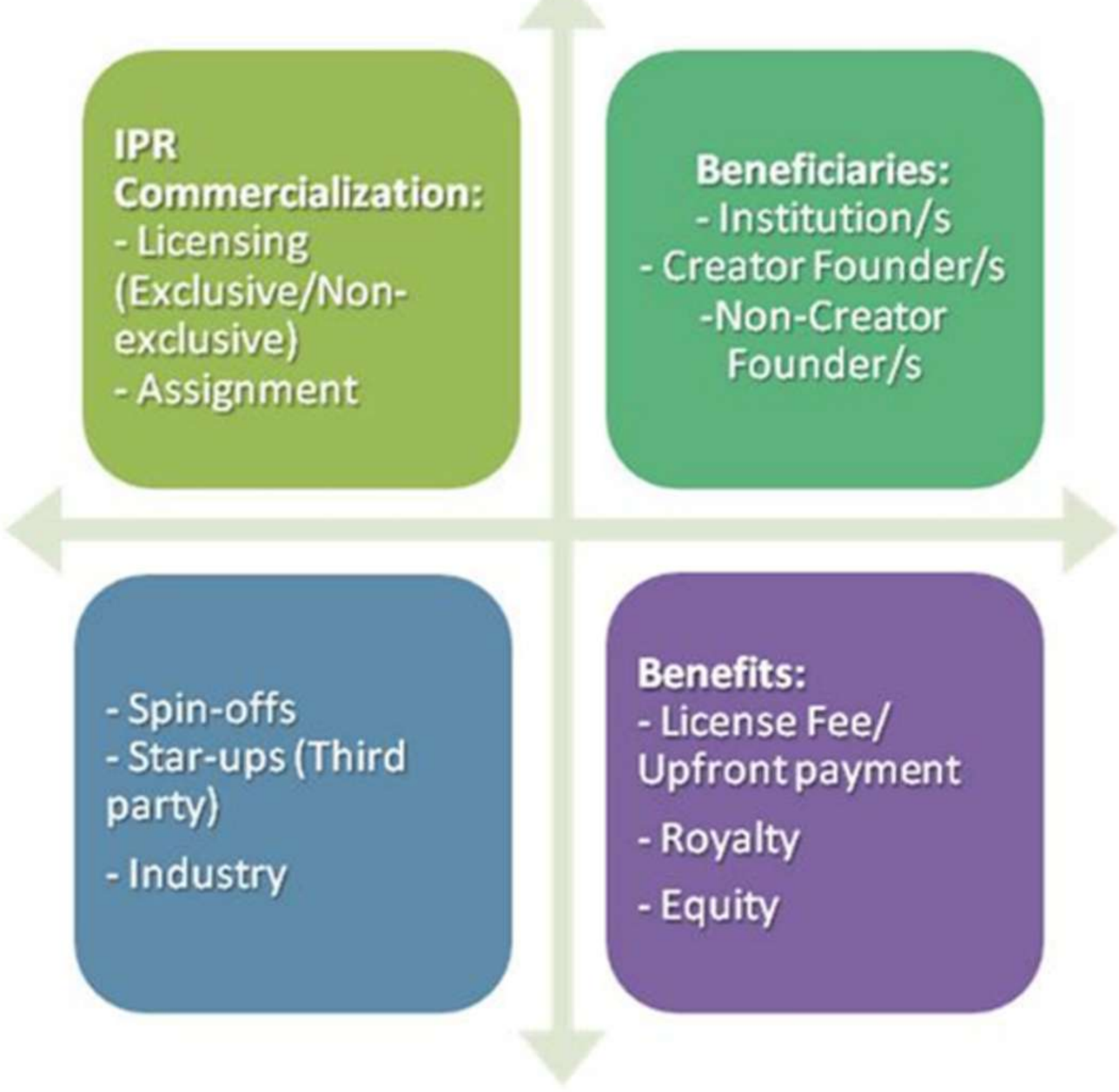
ii.Secondary inventor(s): The clinical or academic mentor or team of mentor(s) who guided the primary inventors in execution of the project and develop the commercialisable product. Example – medical mentor / lead / team of mentors; engineering mentor / lead/ team of mentors in case of SIB program.

iii.Institutions: DBT-Biodesign centers and its other collaborating institutions

iv.Sponsoring organization /DBT

v.Others – to be defined by respective centers based on their other engagements.

It is to be recognised that IP by itself has no commercial value unless some entity is willing to pay for deploying it, which will happen only when commercialization is a distinct possibility. The owner legal entity (here it is one or more of the institutes owning the IP) must not have any discretionary power vis-à-vis transferring the technology to an entity so long as the intended licensee fulfills its obligations.



Each Biodesign center partners may decide on the mode of IPR commercialization i.e., licensing or assignment. Preference may be given to Spin-offs having innovators as creator founders.

5.3 SPIN-OFF CREATION AND BENEFIT SHARING MODEL

Spin-offs are formed when the innovators in the institution establish a start-up entity to transform technological inventions developed with their institutional affiliation. The institution is provided equity holding by the start-up entity, in partial or complete substitution of upfront cash compensation for licensing the technology to the spin-off company.

We address hereunder potential for spin-off creation and the institutional rights in case of licensing of technology to spin-outs:

Transfer of technology by the lead institution managing the IP to a spin-off entity with equity stake taken by the institution, will always involve a license of technology from the institution, similar to the license provided to inventor entities where no equity stake is taken. The element of exclusivity and non-exclusivity described in this policy will apply in case of spin-off too. The exclusive license to spin-off will be for specific fields of use and for a specific period, linked to milestones.

License terms for Spin-off

The following terms are intended to encourage inventors to pursue the path of entrepreneurship with support from institutions that can provide wider window of external resource mobilization and lower burn of cash due to lower up-front payments by the licensee.

Conditions for institutional investment in spin-offs:

The primary condition for institutional investment in spin-off will be the participation of at least one of the Fellows of the Institute as creator-founder in the spin-out venture.

Participation of creator-Founders in spin-off:

► One or more of the creators do not wish to become creator-founders and to negotiate their own financial arrangements with the spin-off, the arrangements defined under “Special Situations” will apply.

► The creator-founder(s) must submit an acceptable business plan to the institutional Biodesign Committee.

Institutional Equity Ownership in the spin-off:

► The Institutional equity ownership in the spin-off at the time of formation of the spin-off company will be a pre-determined fixed percentage, determined by IPMC, broadly keeping in view the institutional guidelines as well as scope and mandate of the Biodesign Programme.

Tentative holding may be as follows:

- ◈ Up to 6% of equity with voting rights if the license is non-exclusive.
- ◈ Up to 10% of equity with voting rights if the license is exclusive.

► If all the creators take the role of creator-founders, the institutional equity ownership will be reduced as under:

- ◈ Up to 4% of equity with voting rights if the license is non-exclusive
- ◈ Up to 6% of equity with voting rights if the license is exclusive.

► The shares will be allotted on the effective date of license agreement. The allotment of stocks to the institutional partners will be in the same proportion determined and agreed upon for royalty distribution. Out of shares allotted for institutions, 15% of the stocks may be earmarked for the lead institution designated to manage the IP in the spin-out and the balance 85% may be distributed to the institutions in the proportion agreed upon inter-se institution including the lead institution. Among the institutions, the equity distribution to the institution/ department/ inventors/ faculty/ mentors etc., will be in the proportion agreed upon by the institution as per their distribution policy. Each of the institution will convey to the lead institution the distribution formula for the issuance of equity shares accordingly by the spin-off entity.

► The creator-founders will not be eligible for any share of the equity from the block of equity earmarked for the institutions, as they gain their holding in their venture directly.

► The securities owned by the institution will rank pari passu in rights to the securities owned by the creator – founders and shall be no less favourable. The institutions will have rights to contribute to future shareholding to maintain the percentage of holding. The institution(s) will also have co-sale rights, the right to participate in any proposed sale of the company's stock to third parties, should the creator-founder engage in partial or total sale of the entity.

Royalty Payments

Terms of Royalty payable to the lead institution are stipulated in recognition of the cash shortage during the initial phases of the spin-off. Royalties to the institution shall be payable as per agreement between the parties.

Sharing of Royalty receivables:

► 15% of the royalty received may be retained by the lead institution managing the license transaction. The balance 85% royalty received by the lead institution may be distributed to all participating institution in the agreed proportion, including the lead institution. Each participating institution will distribute royalty to the institution, department, and inventors who are not creator-founders as per their institutional policy.

► Royalties will not be shared with creator-founders, whom the Spin-off company compensates through their holding and compensation benefits.

Compensation to inventors who do not wish to become creator-founders:

► If one or more of the creators do not wish to become creator-founders, such a case will require lead institution to provide for eligible allocation of equity. The amount of royalties payable by the spin-off will also accrue to them.

► The methodology for calculating appropriate financial participation by such non-founder-creators is depicted below. The model presumes 5 creators, out of which two opt to be creator-founders and the rest opt to be not engaged with the venture as creator-founders.

The equity percentage to be assigned by the spin-off to non-founder creators will be proportionate to the split percentages of the non-founder creators, eligible as per the institutional policy. If the non-founder creators come from more than one institution, the equity allotment will be as per the proportion of entitlement for the non-founder creator within the total share of allotment for the institution. The amount of royalties payable by the spin-off will be similarly adjusted.

An illustrative example is depicted below:

Assumptions: Exclusive license, Institutional equity participation=10%.

The overall entitlement of creators shares of benefit: 50%.

Retaining 15% for management of IP, the overall share of the creators will be 50% of 85% - i.e., 42.5%.

With 10% stipulation for exclusive license, the total accrual of share of the creators will be 4.25% shares.

Now, let us reflect the split inter-se creators, with the assumption of five creators.

Creator's entitlement splits as per the institutional policy from the total earmarked share for creators (presuming all the creators are from the same institution)

Creator1	40.00%
Creator2	25.00%
Creator3	20.00%
Creator4	10.00%
Creator5	5.00%
Total	100.00%

Presuming creator 1 and creator 2 become creator – founders (with entitlement of 65% of the benefit share earmarked for all creators) of the Venture and creators 3 to 5 opt to be non-founder creators (with entitlement of 65% of the benefit share earmarked for all creators); then the creator – founders 1 and 2 will get no share of equity from the institutional allotment and no share of royalties.

The allocation of equity to the non-founder creators will be as under:

Equity Participation:

►Equity participation to be assigned to non-founder creator by the Institution will be: 35% of 4.25% = 1.48%

►Equity split to be attributed by institution to individual non-founder creators: Creator 3: 20% of 1.48% = 0.3%

►Royalty Participation: Royalty participation with related split will be arrived in the same manner as equity allotment for non-founder creators

Board Representation:

Though the institutional subscriber may have a right to appoint a board member, such rights will be exercised only in exceptional cases, where the institutional holding exceeds 10% in case of high value technologies providing institutions with higher stake at the time of creation of spin-offs.

Use of institutional services:

If the spin-off, prefers to avail any services from the institution(s), then a separate contract research agreement will be entered into by the spin-off with due negotiation of the terms of such contract services.

Deferral of Reimbursement of Patenting Expenses:

Patenting expenses incurred by institution for the patenting of the technology(ies) related to the spin-off: The institution may agree to the deferral of such patenting expenses (i) for up to 3 years from the start date of the license agreement or (ii) until the closing date of a change of control event or (iii) for international patents, until the start of expenses for the “national phase” of patenting - whichever may occur sooner. After such a date the spin-off will be responsible for promptly reimbursing institution for all deferred and ongoing expenses.

5.4 GRIEVANCE REDRESSAL AND ARBITRATION

► It is conceivable that in certain cases there will be dispute among inventors regarding the recipient of the license. In such cases a time bound dispute resolution process must be put in place.

► It is proposed that a standing committee possibly – advisory committee/ overview committee/ highest committee of the program will oversee all such dispute resolution process.

► The committee must opine based on competence of a given inventor or a group of inventors to commercialize the product. In other words, only an entity that has the competence for commercialization will be eligible to receive the license.

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