SREE CHITRA TIRUNAL INSTITUTE
FOR MEDICAL SCIENCES & TECHNOLOGY

BRINGING LIFE TO INNOVATION AND INNOVATION TO LIFE

VISION 2030
A PERSPECTIVE PLAN
for Biomedical Technology Development

EXECUTIVE SUMMARY

The Vision 2030 - A Perspective Plan envisages the vision and deliverables of Sree Chitra Tirunal Institute for Medical Sciences & Technology, Trivandrum, in the area of Biomedical Technology development during the decade 2021-2030.

This plan identifies the following themes for the Biomedical Technology initiatives of the Institute:

- Applied Research
- Technology Development
- Medical Device Evaluation and Regulatory Support
- Skill Upgradation
- Technology Translation
- Green Initiatives

Under each theme, 10 year goals and deliverables are identified, keeping in view of the present capabilities and the potential for capacity augmentation. In addition, prior to technology development, active efforts will be made to carryout health technology assessment and intensify market analysis. Similar efforts will be made in marketing these technologies.

Among the themes, Applied Research and Technology Development, the products are grouped into nine broad areas such as:

- Cardiovascular devices
- Neuro-prostheses
- Orthotics and rehabilitation
- *In vitro* diagnostics (IVD)
- Hard tissue devices
- Biologics
- Regenerative technology
- Point of care devices
- Connected health

The goals, infrastructure, resource requirements and other capabilities that need to be developed or augmented, are detailed in this plan. It is envisaged that about 50-60 technologies will be transferred or ready for transfer during this period. An addition of 42 Scientists/Engineers and another 58 Scientific/Technical & Administrative staff are envisaged. The additional expenses for implementation of this plan will be ₹ 350 Crores for the 10 year period starting from 2020-21.

PROLOGUE BY DIRECTOR

Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST), Trivandrum, is an Institute of National Importance with a unique mission to develop biomedical technologies, provide and demonstrate high standards of patient care and develop post graduate training programs of the highest quality. The Biomedical Technology Wing of the Institute, through the successful development and commercialisation of its technologies, has done justice to its primary mandate and played a pivotal role in establishing a medical device industry base in India.

The Institute envisions to become a global leader in developing and translating affordable and innovative healthcare technologies and today it is well poised, than ever before, to actualize this ambitious goal. The Perspective Plan 2030 aims to harness the collective efforts and skills available in the three wings of the Institute to realise this vision. The key pillars that will help SCTIMST build this vision are Applied research, Technology development, Tie ups with the medical devices industry, Entrepreneurial activity and Networking with agencies within and outside the Nation.

SCTIMST undertook a comprehensive planning exercise during the current year which led to the Perspective Plan 2030. Several working groups within the Institute developed the Plan with the assistance of experts from outside. This was also an enlightening exercise of envisioning the future of the Institute and has helped bring the clarity and focus needed for translating our plans into tangible results.

The broad objectives for the next decade are now clearly laid out before us. These include the creation of the requisite infrastructure, enhancing team strength and encompassing new and diverse skill sets and increasing the technology development outputs. These goals are formulated in a manner that adheres to the mandate of the Biomedical Technology Wing, builds on the strengths of the multi-domain teams of engineers, scientists, clinicians, public health experts and technical staff available in the Institute, taps the technological advancement in the field of medicine, fulfils the aspirations of the new generation and sparks their tremendous energy. The enhanced thrust on technology development provided by the Technical Research Centre (TRC) for Biomedical Devices under the Department of Science & Technology, the incubation ecosystem provided by the Technology Incubator, TIMed and the strong linkages with the Indian Medical Device industry are also leveraged.

I wish to thank the members of the team who took up this task of developing the Perspective Plan 2030 with great enthusiasm and for their untiring efforts. I also wish to thank the esteemed members of the Institute Body, Governing Body, President's Committee, Research Council and Technology Development Committee, distinguished Industrial partners, faculty and staff for their valuable inputs. The future we envision is fuelled by the strong support provided by the Department of Science and Technology led by Prof. Ashutosh Sharma, the directions provided by none other than Prof. M.S. Valiathan and Shri. K.M. Chandrasekhar, Hon'ble President of the Institute and the lessons shared by the experienced well wishers of the Institute.

The Perspective Plan 2030 document will serve the purpose of aligning all the stakeholders of the Institute towards a set of common goals so that the sum total of our efforts and achievements is far more than our individual contributions. I have strong belief and faith in the fact that the Biomedical Technology Wing will be the Nation's pride and will seize the opportunities before it, to own its rightful place among the best in the world.

Prof. Asha Kishore, M.D, D.M
Director

PROLOGUE BY HEAD, BMT WING

The Biomedical Technology Wing (BMT Wing) of Sree Chitra Tirunal Institute for Medical Sciences & Technology has been in the area of technology development for biomedical devices since early 1980s. We have been following a frugal, yet a state-of-the-art bench-to-bed methodology. The successful stories of Chitra Heart Valve, Blood bag, Hydrocephalus shunt to name a few, bear huge testimony to the in-house capabilities. The Wing largely owes the success to its well trained and committed team of engineers, scientists, clinicians, public health experts and technicians as well as its unique research, development as well as testing facilities – all under one roof, working towards a common vision.

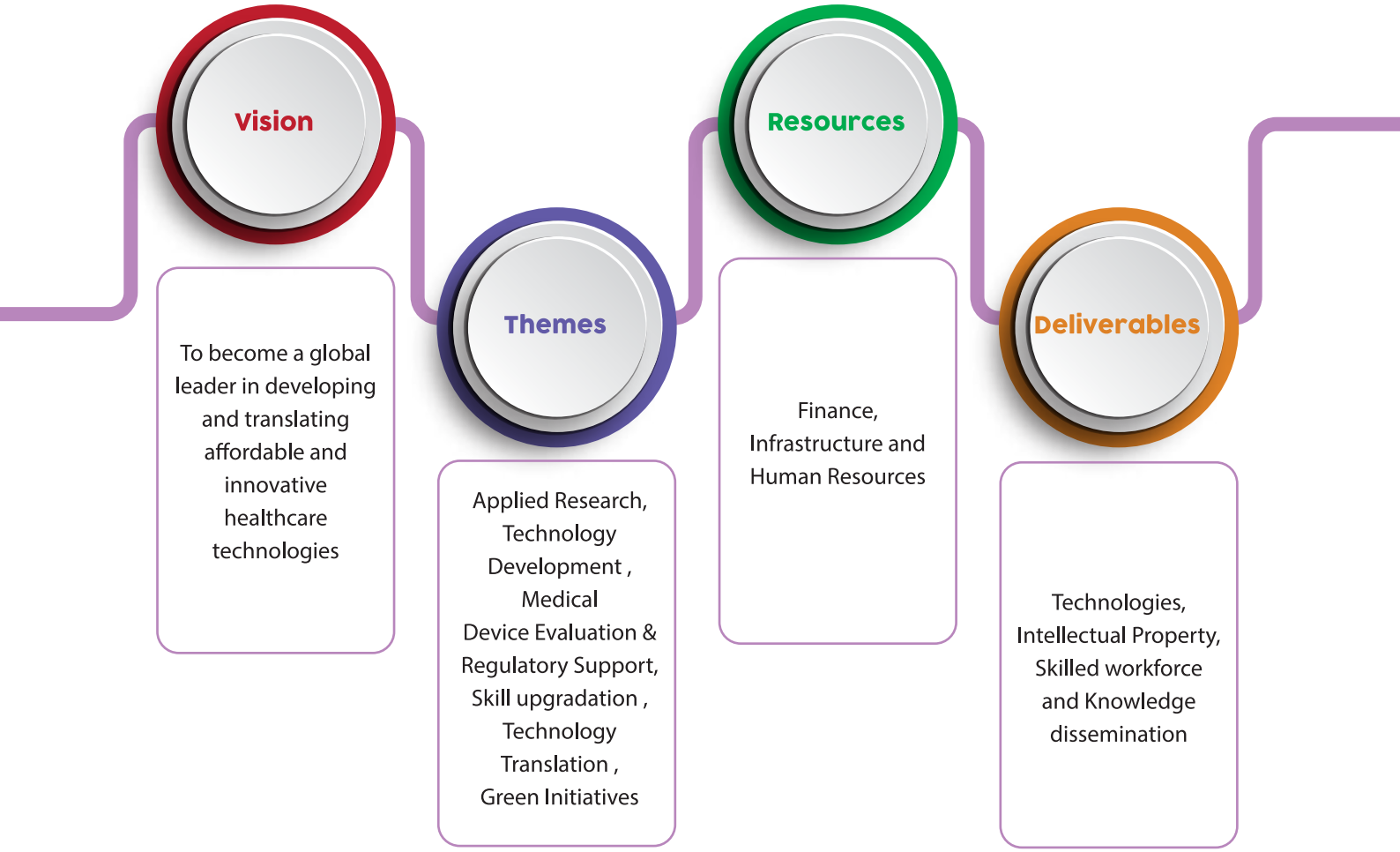
Futuristic, personalised medicare is closely linked to technologies that are on the anvil in the field of biomaterials and biomedical devices. It is estimated that presently, nearly 75% of medical devices available in India are imported. There is a clear need to indigenize the development and manufacture within the country. With the large knowledge base, a well – equipped R&D infrastructure and an emerging new industry culture, it is immensely possible for India to make this happen.

Keeping in view the vast progress in the field of medicine, technology and sciences, it is imperative that BMT Wing does a rediscovery of its strengths vis-a vis the changes that are taking place in the outside world. While speed of innovation and rapid commercialization holds the key to success, utmost care has to be given while translating any technology that relates to human health. This Perspective Plan 2030 has been developed as a tool to achieve these twin objectives. It is envisaged that the above approach together with the "**Make in India**" Plan leading imports substitution will provide necessary impetus to growth in this field. The plan covers future development in infrastructure, human resources and technical facilities to drive biomedical innovation and product realisation. To be at the forefront of market viable biomedical products that are suited to our unique demands requires particular skill and strategies. The BMT wing aims to improve access to healthcare devices and services by addressing the above needs.

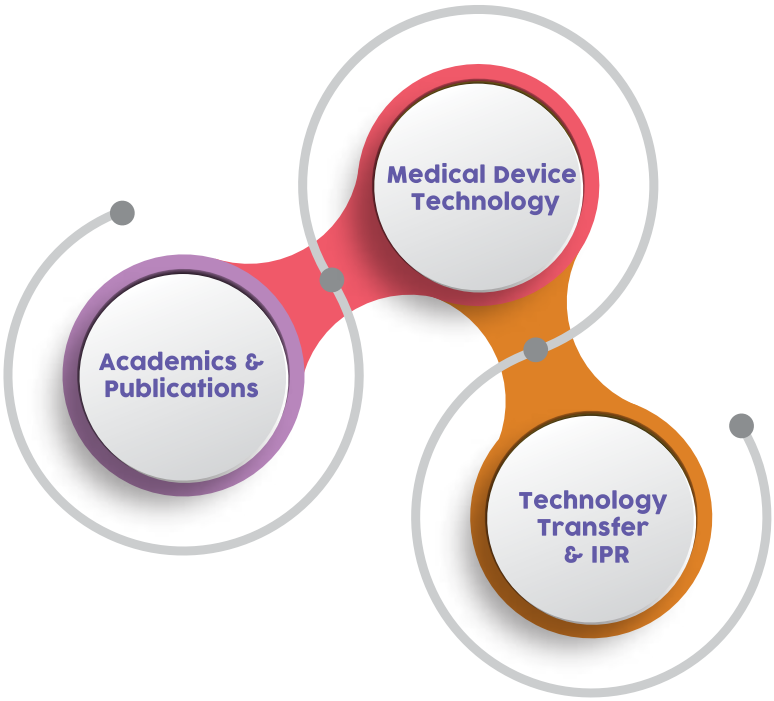
The Perspective Plan outlines a collective effort by clinicians, technologists and scientists at SCTIMST to maintain our creative impetus together with a series of product development programs. The concerted effort of multiple disciplines is addressed to facilitate ideation, research, development and testing to conform to regulatory requirements and market demand. The working culture, inherent strength and logical assessment of technology development at Chitra will serve as a source to build upon. Partnerships at international and national level will offer us an opportunity to tap in to the accumulated expertise and collaborate on mutually beneficial opportunities. Such networks will also help in the development of a trained workforce to supplement our core objectives.

It is hopeful that as we march forward, the Perspective Plan will help us to address the diverse needs of the biomedical device market to a greater extent.

Dr. Harikrishna Varma P.R, Ph.D
Head, BMT Wing


Vision
To become a global leader in developing and translating affordable and innovative healthcare technologies
Themes
Applied Research, Technology Development , Medical Device Evaluation & Regulatory Support, Skill upgradation , Technology Translation , Green Initiatives
Resources
Finance, Infrastructure and Human Resources
Deliverables
Technologies, Intellectual Property, Skilled workforce and Knowledge dissemination

CONTENTS


Medical Device Technology
Academics & Publications
Technology Transfer & IPR

VISION STATEMENT OF SCTIMST ON BIOMEDICAL TECHNOLOGY

Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST), Trivandrum was established as an Institute of National Importance with a unique mandate that combines development of biomedical technologies, advanced specialty patient care, higher education, clinical, basic & applied research and public health, under a single Institutional framework. The institute is instrumental in establishing an efficient medical device industry-base in India, by successfully developing and commercializing technologies of high societal impact.

The vision statement of the Institute on Biomedical Technology is envisaged as:

> *"To become a global leader in developing and translating affordable and innovative healthcare technologies"*

Flagship products- Commercialised

TTK-Chitra Heart Valve

Mechanical heart valve prosthesis – TTK-Chitra heart valve licensed to TTK Healthcare Ltd., crossed over 100,000 implantations in more than 400 centres (in India and abroad) in the last 25 years.

Disposable blood bags

Disposable blood bags introduced for the first time in India, way back in 1980s that changed the blood transfusion practice in the country – which was commercialised by M/s. Terumo Penpol Ltd. and HLL Lifecare Ltd. - now crosses an annual production of over 50 million and are exported to around 80 countries.

EMILY

India's first (and world's second) hormone releasing Intrauterine System (IUS) for contraception and abnormal uterine bleeding; was jointly developed with HLL Lifecare Ltd. and launched under the brand name EMILY.

Other products transferred to the industry

- First and second generation vascular grafts
- Second generation TTK-Chitra heart valve
- Bubble oxygenator and the second generation Membrane oxygenator
- Hemoconcentrator
- Hydrocephalus shunt
- Products for dental and orthopedic applications

PREAMBLE

Background

Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST), Trivandrum was established by an Act of Indian Parliament in 1980 as an Institute of National Importance under the Department of Science & Technology (DST), Government of India. The Institute has a unique mandate that combines development of biomedical technologies, advanced specialty patient care and health science studies under a single Institutional framework. The Institute has the status of a University and consists of the Biomedical Technology Wing (BMT Wing), a tertiary super specialty Hospital Wing and the Achutha Menon Centre for Health Science Studies (AMCHSS).

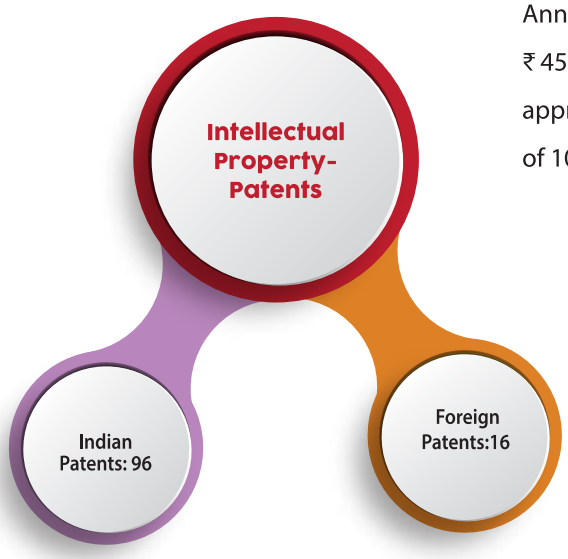
The Biomedical Technology Wing located at the Satelmond Palace at Poojappura, Trivandrum consists of a culturally diverse and pluralistic team committed to applied research and medical device development & evaluation. The Hospital Wing has 253 beds and serves as tertiary referral center for cardiovascular, thoracic and neurologic diseases. The Achutha Menon Centre for Health Science Studies (AMCHSS) is recognised as a Centre of Excellence for Public Health. The Centre focuses on research in the areas of non-communicable diseases, gender and health, health policy and management.

SCTIMST has a strong foundation in the integration of clinicians, scientists, engineers and healthcare professionals to cater to the unmet clinical needs of the society and to transfer the technologies to the industry.

Biomedical Technology Wing

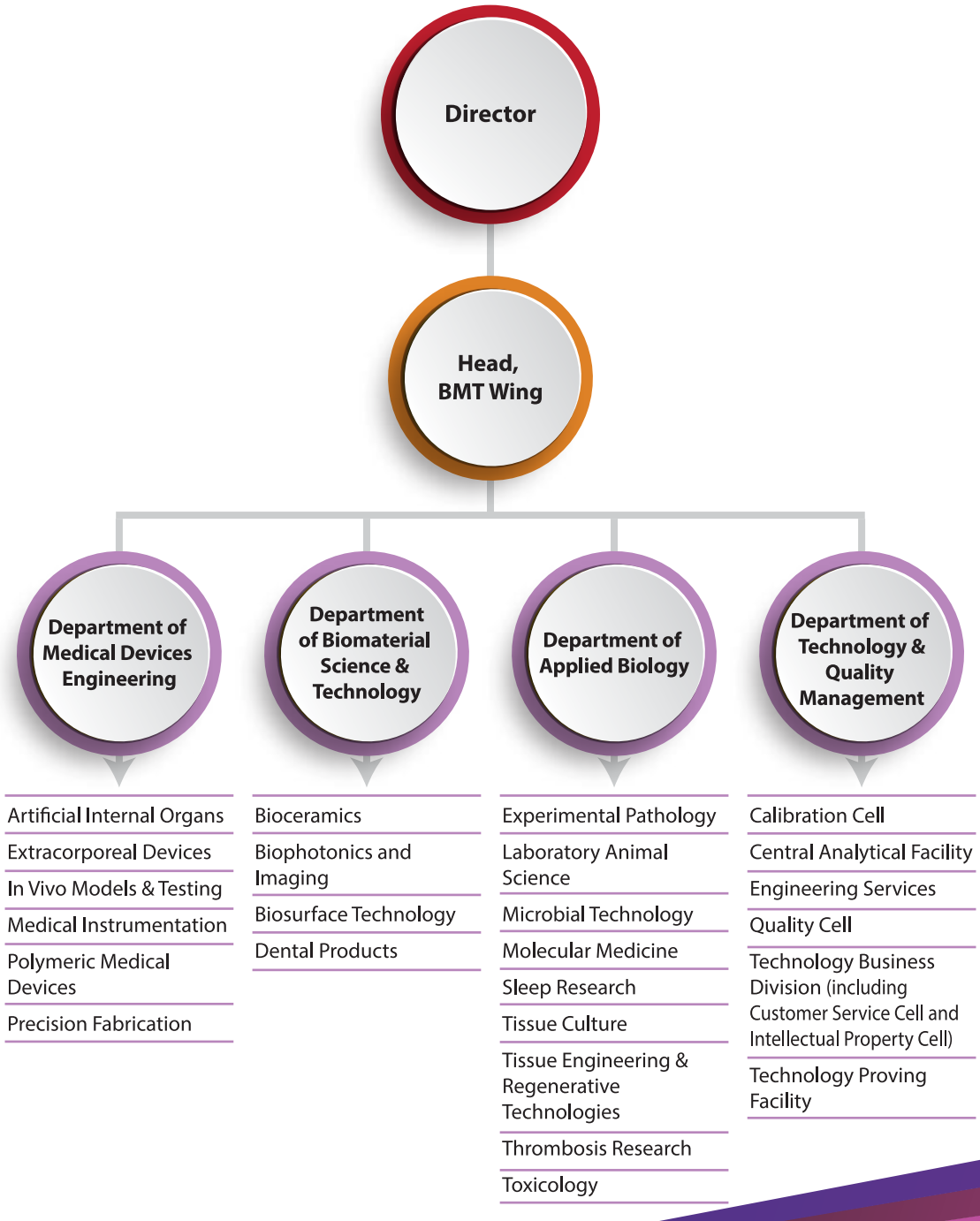
Biomedical Technology Wing, of SCTIMST right from its inception was pioneering in the development of biomedical products and transferring them to industries. So far, 49 technologies have been transferred to 24 industries all over India. The institute holds 16 foreign, 96 Indian granted patents and 12 design registrations to its credit and another 114 patents are in various stages of processing.

Annual turnover based on SCTIMST's technologies is about ₹ 450 crores with a direct employment generation of approximately 2,000 and an indirect employment generation of 10,000.



Organisational Structure

The Biomedical Technology Wing houses multidisciplinary research laboratories and product development facilities organised into four Departments. These four Departments collaborate with other Departments and Divisions of the Institute and external organisations to achieve the vision.



Highlights of Current Status

Biomedical technology development activities were accelerated during the past three years, with the strong support of Department of Science & Technology, Govt. of India. A fully-functional infrastructure facility for medical device engineering - M.S. Valiathan Medical Devices Engineering Block - was dedicated to the Nation on 16th March 2015. Nine technologies were transferred to healthcare industries spread over different parts of India through the technology conclaves on 19th November 2016 and 15th May 2017. The first medical device technology incubation centre in India, SCTIMST-TIMed, started functioning in the BMT Wing campus from 16th March 2015.

Technical Research Centre (TRC)

BMT Wing is identified as a Technical Research Centre (TRC), the nodal research centre for development of biomedical devices in the country by the Department of Science & Technology, Government of India. The Centre is proposed with a mandate of developing about 33 medical device technologies in 5 identified segments viz. cardiovascular, neuroprosthetics, hard tissue devices, biologics and *in vitro* diagnostics (IVD). At present, 26 technology development activities have been initiated under TRC and 7 more are planned. A Medical Device Regulatory Compliance Facility (MDRCF) for supporting the Indian medical device industry and an Industry-Institute Partnership Cell (IIPC) for training human resources are also functional as part of TRC.

Accredited Testing & Evaluation Facility

The BMT Wing is accredited for its testing services based on the quality management system as per the international standard ISO/IEC 17025, by COFRAC, France (Comité Français d'Accréditation) since 2003. The facility is the first and the only one in the country which is being utilised by a large number of medical device manufacturers from India and abroad. The thermal and volumetric calibration services are accredited by the National Accreditation Board for Laboratories (NABL), India.

SCTIMST-TIMed

SCTIMST has led its way by commercialising medical technologies in India and has supported industries to set-up manufacturing facilities by providing Technology Proving Facility. However, these were limited to the industrial partners who have acquired technologies from the Institute. Considering the recent scenarios in the technology development and commercialisation, a technology business incubation centre, with all essential facilities for manufacturing was found essential. SCTIMST-TIMed, a not-for-profit registered society was established within the BMT Wing campus to provide incubation support to innovators, start-ups and industry. Currently, there are six incubatees with SCTIMST-TIMed.

TIMed is financially supported by the Department of Science & Technology (DST), Govt. of India and the Kerala State Industrial Development Corporation (KSIDC).

Technology Development

In the year 2016-17, five technologies were transferred to industries and another 12 technologies in the final stages of development are ready to transfer. From the various technologies under development, 11 Intellectual Property Rights have been filed. During this period, there are 85 publications in peer reviewed journals and 99 conference publications.

Revenue Generation

Revenue generation of BMT Wing is mainly from extramural research funding and technology transfer in the form of royalty and license fee. Other sources of income are from testing, calibration and device evaluation studies for both internal and external stakeholders. In the year 2016-17, ₹ 5.6 crores was received as extramural fund. An amount of ₹ 74.3 lakhs was received from technology transfer and testing services.

CHALLENGES AND OPPORTUNITIES

Indian population is expected to be about 1.5 billion by the 2030s. Exponential increase can be expected in the number of people suffering from lifestyle disorders such as diabetes, cardiovascular diseases, cancers, geriatric problems, bone and musculoskeletal disorders, etc. National requirement of providing healthcare for such a huge population is a challenging responsibility. Hence availability of affordable medical devices technology is crucial in the prevention, diagnosis and treatment of diseases, as well as patient rehabilitation.

The current market for biomedical devices in India is estimated to be ₹ 24,000 crores. Approximately 75% of this demand is met by imports with the Indian industry playing a very limited role. Various factors that restrict the growth of Indian medical device development industry are identified as lack of availability in skill development avenues, less knowledge about market-appropriate products, poor medical device regulations, non-availability of accredited device evaluation facilities, very little collaboration between research organisations with industry, regulatory agencies, healthcare providers and end users. Also, Indian medical device industry needs to compete with quality products from multinational companies developed through stringent international regulations, standards and evaluation criteria.

Rising income levels, ageing population, increased prevalence of lifestyle-related diseases and the Government's commitment to provide healthcare services at a reasonable cost and the introduction of new **Medical Devices Rules 2017,** make the biomedical technology segment one of the most attractive segments for growth in India for the next few decades. The following are the key drivers to the growth of biomedical technology in the country:

Market Factors

Growing population, ageing, increasing income and associated disposable income, increasing socio-economic inclusion of rural and deprived in the mainstream economy, heightened manufacturing innovation to create customised products to meet the needs of all income segments, changing disease prevalence pattern (e.g. early onset of diabetes and heart diseases) and growing awareness among the middle class to focus on early detection and disease prevention.

Non-market Factors

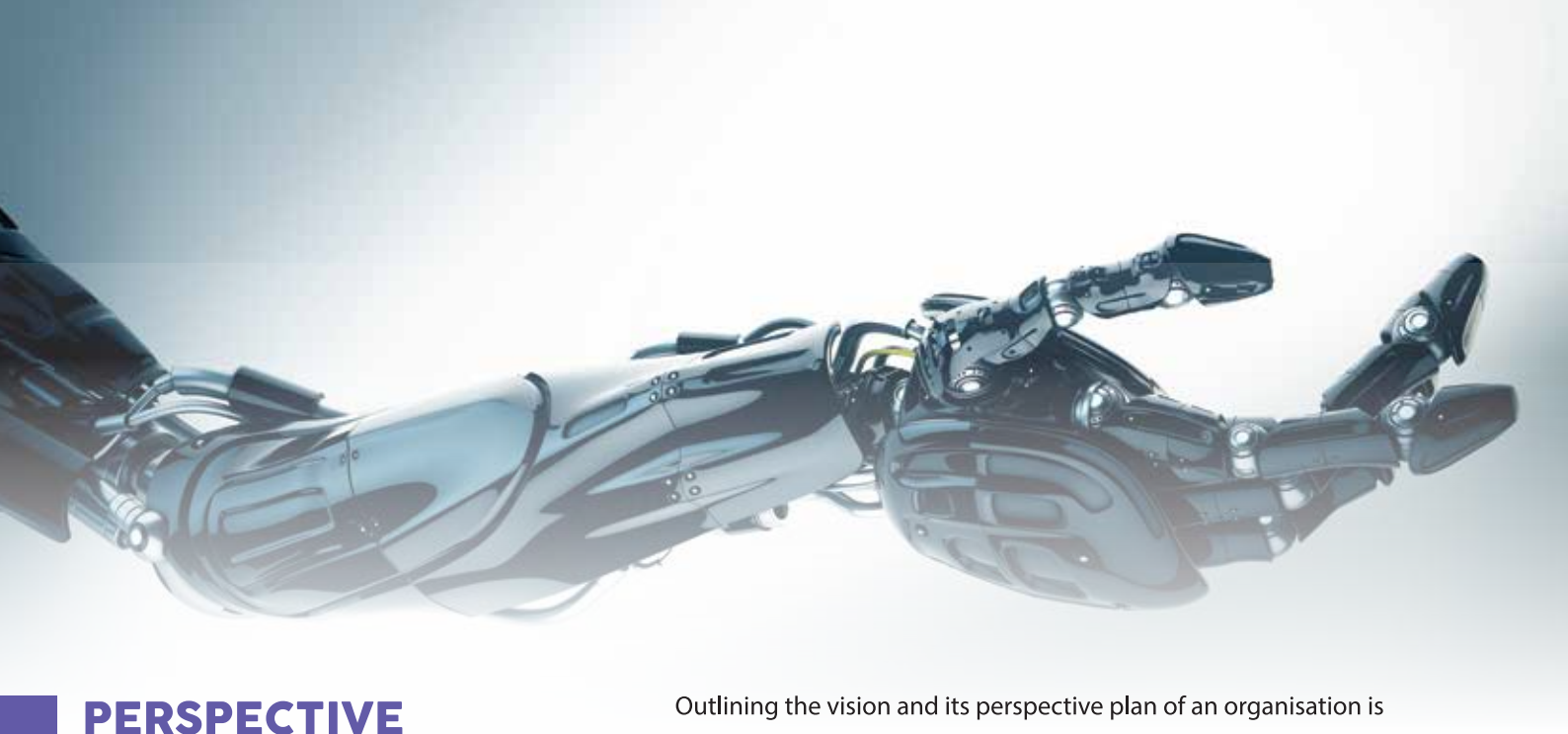
Development of infrastructure, favorable regulatory systems getting implemented, foreign direct inflow (FDI), outsourcing of manufacturing and R & D activities to India, Government initiatives to improve healthcare access through insurance schemes such as RSBY (Rashtriya Swasthya Bima Yojana), Aarogyasri, etc.

Opportunity for SCTIMST

In this scenario, the institute can play an important role with its vast experience in medical device development and evaluation for making India to be a global leader in medical technology. Institute can foster the indigenous development of advanced biomedical products and technologies to achieve self-reliance and make healthcare technologies accessible and affordable to the public. SCTIMST has a unique strength of having a hospital and a technology research center within the Institute. This enables clinical participation in each of the programmes being carried out, by clinicians from both internal and external collaborations through the alumni. This clinical collaboration, right from the beginning of the product development can ensure better acceptance of the product in the market.

Institute can also explore new avenues such as to function as a medical device testing laboratory, a notified body for auditing the medical device manufacturers and support other organisations to establish evaluation laboratories in the country. Also, the systematic medical device evaluation strategies followed will enable the Institute to adapt easily to the changing regulatory environment and to commercialise the future products competitively.

One important pre-requisite of the medical technology marketing is the assessment of societal impact and economic aspects. The Achutha Menon Center for Health Science Studies is the right platform to conduct health technology assessments for future programmes.



PERSPECTIVE PLAN 2021-2030

Outlining the vision and its perspective plan of an organisation is challenging since it requires to be specific, while being non-restrictive. Aligning vision in biomedical technology of the Institute with the national vision is even more challenging because of an added constraint vis-à-vis avoiding duplication of the works that others with a larger knowledge base could do better.

Keeping in perspective the current strengths of the Institute, in this plan, we found it appropriate to limit the focus into the following six themes.

I. Applied Research

Conducting basic research in various areas of biomedical sciences and technology; translating the research output to processes enabling technology development.

II. Technology Development

Diffusing the knowledge developed as medical device products at a level which industry can absorb.

III. Medical Device Evaluation & Regulatory Support

Augmenting testing & evaluation services by Public Private Partnership (PPP) model to support the industry as well as the regulatory system.

IV. Skill Upgradation

Strengthening the skill in design, tissue engineering, sensors & instrumentation, *in-silico* modeling, prototyping, testing & evaluation, Good Manufacturing Practices (GMP), etc.

V. Technology Translation

Attracting more industries towards healthcare products, foster, support and mentor start-ups, state-of-the-art self-contained manufacturing facility, etc.

VI. Green Initiatives

Campus and its terrain is gifted with potential for conservation of natural resources like rain water, solar and wind energy. A green campus self-sufficient in both water and energy can be made a reality with the support of concerned agencies.

Perspective plan for the themes and their deliverables

The themes 'Applied Research' and 'Technology Development' are considered as most important and are grouped as a single entity due to their interdependency, resources requirements and deliverables.

Theme I & II

Applied Research and Technology Development

Under Applied Research and Technology Development themes, the products are further segregated into four sub themes namely: **diagnosis/monitoring, curative/assistive, substitutive and regenerative.**

There are enormous possible areas to operate in each sub theme; however, considering the present capabilities and the potential for capacity augmentation, the following nine focus areas are identified.

- Cardiovascular devices
- Neuroprostheses
- Orthotics & rehabilitation
- *In vitro* diagnostics (IVD)
- Hard tissue devices
- Biologics
- Regenerative technology
- Point of care devices
- Connected health

The objective is to develop and commercialise healthcare technologies of societal impact and undertake applied research in the frontier areas of biomedical science & engineering.

SCTIMST has a proven track record of technology development in the cardiovascular, neuroprosthetics and hard tissue devices. The Institute also has vast research experience in the development and evaluation of biomaterials, animal studies, tissue engineering, biologics, etc. Extending this expertise and knowledge-base to other areas to cater to our country's current healthcare needs is an important concern for the Institute. For this purpose, new focus areas such as Regenerative Technologies for the substitution of physiological functions, *In vitro* Diagnostics, Point of care devices, Connected health, Orthotics and rehabilitation are identified.

Additional areas of expertise are required for accomplishing the goals set under the new focus areas. This can be achieved by collaborating with academic institutes and industrial partners.

The goal is to transfer 40 technologies during the decade 2021-2030 and another 20 technology leads in the advanced stages of development. From these activities, about 100 intellectual properties and 500 publications are expected.

I. List of products in themes I & II

Ten-year goals and deliverables for each of the focus areas are depicted in the following tables and charts.

Sub themes : Curative and Assistive Devices			
Areas	**Medical Device**	**Timeline**	
		Start	**End**
Cardiovascular	Pediatric membrane oxygenator	2014	2021
	Centrifugal blood pump and flow meter	2016	2023
	Embolisation devices	2016	2022
	Paracorporeal left ventricular assist device	2016	2024
	Flow diverter stent	2017	2023
	Leukodepletion filter	2017	2022
	Annuloplasty ring	2017	2023
	Hollow fiber membranes	2018	2025
	Defibrillator	2018	2024
	PDA and ventricular septal defect occluder	2018	2024
	Coronary & peripheral stents	2018	2025
	ECMO system	2020	2027
	Implantable left ventricular assist device	2021	2029
	Vascular closure device	2021	2025
	Clot retriever device	2022	2028
	Organ transportation system	2023	2030
	Cardiac mini pacing device	2023	2030
Point of Care	Pneumatic compression device for DVT	2015	2019
Hard Tissue	Inter - vertebral spacer system	2016	2022
	Ceramic cement systems	2016	2022
	Bioactive material platform for drug delivery in bone	2016	2022
	Radiopaque injectable hydrogels for meniscal repair	2021	2028
Neuroprostheses and neurology	Deep brain stimulator	2016	2022
	Optical peripheral nerve stimulator	2017	2022
	Programmable hydrocephalous shunt	2018	2025
	Functional electrical stimulators	2021	2027
	Biomaterials for axon repair	2026	2030
	Brain computer interfaces	2026	2035

Sub themes : Curative and Assistive Devices (contd.)			
Areas	**Medical Device**	**Timeline**	
		Start	**End**
Biologics	A wound healing matrix from porcine cholecystic – extracellular matrix	2016	2022
	Alginate scaffold with recombinant growth factors for wound healing	2016	2022
	Biodegradable PLGC – fibrin graft for skin regeneration	2016	2022
	Chitosan /Alginate based antioxidant polymeric wound dressings for controlled antibiotic delivery	2017	2022
	Standardization of albumin and factor VIII production IVIG purification method from "small pool" human plasma	2017	2022
	Characterisation of *Bacillus* species producing the antimicrobial molecule against methicillin resistant *s aureus* (MRSA)	2017	2023
	Gel dressing for internal wound application	2022	2028
	Micro and nano controlled drug delivery vehicles	2025	2030
Regenerative Technology	Lint free absorbent dressing for wounds	2016	2022
	Bioactive drug delivery system	2018	2025
	Fabrication and evaluation of microneedles for drug delivery	2018	2026
	Implantable drug delivery systems	2019	2025
	3D printed drug loaded microneedles	2025	2030
Connected Health	Proactive technology driven model for healthcare	2017	2022
	Intelligent health information infrastructure	2025	2030
Orthotics and Rehabilitation	Geriatric assist devices	2020	2025
	Spinal fixation device	2021	2026
	Knee support devices	2021	2026
	Robotic exo-skeleton	2023	2032

Sub themes : Regenerative Devices			
		Timeline	
Areas	**Medical Device**	**Start**	**End**
Hard Tissue	Tissue engineered bone	2010	2020
	Osteochondral constructs	2018	2022
Regenerative Technology	Cartilage repair products	2016	2020
	Tissue engineered organs - liver, cornea, skin, cartilage, blood vessel	2016	2030
	3D Bioprinting of hard and soft tissues	2018	2022
	Advanced wound care devices	2019	2025
Biologics	Bioinks for 3D bioprinting	2025	2030

Sub themes : Diagnosis and Monitoring Devices			
Areas	**Medical Device**	**Timeline**	
		Start	**End**
Cardiovascular	Cardiovascular imaging and diagnostics	2022	2028
***In vitro* Diagnostics**	PT/INR Test System	2016	2022
	Point of care diagnosis of infectious diseases	2017	2022
	Ketonuria assessment in newborns	2018	2023
	Rapid diagnostic for bacterial infections	2021	2030
Neuroprostheses and neurology	Intracranial electrodes	2016	2020
	Cerebral micro dialysis catheter	2018	2024
	Telemetric polysomnography	2021	2026
Point of Care	Vein Viewer	2016	2020
	Biosensors for wound analysis	2018	2022
	Anemia detection device	2018	2023
	NIR Oximetry	2021	2028
	Feto-placental health monitor	2021	2026
Connected health	Networked medical devices	2019	2024
	Machine learning of multimodal imaging data	2024	2030

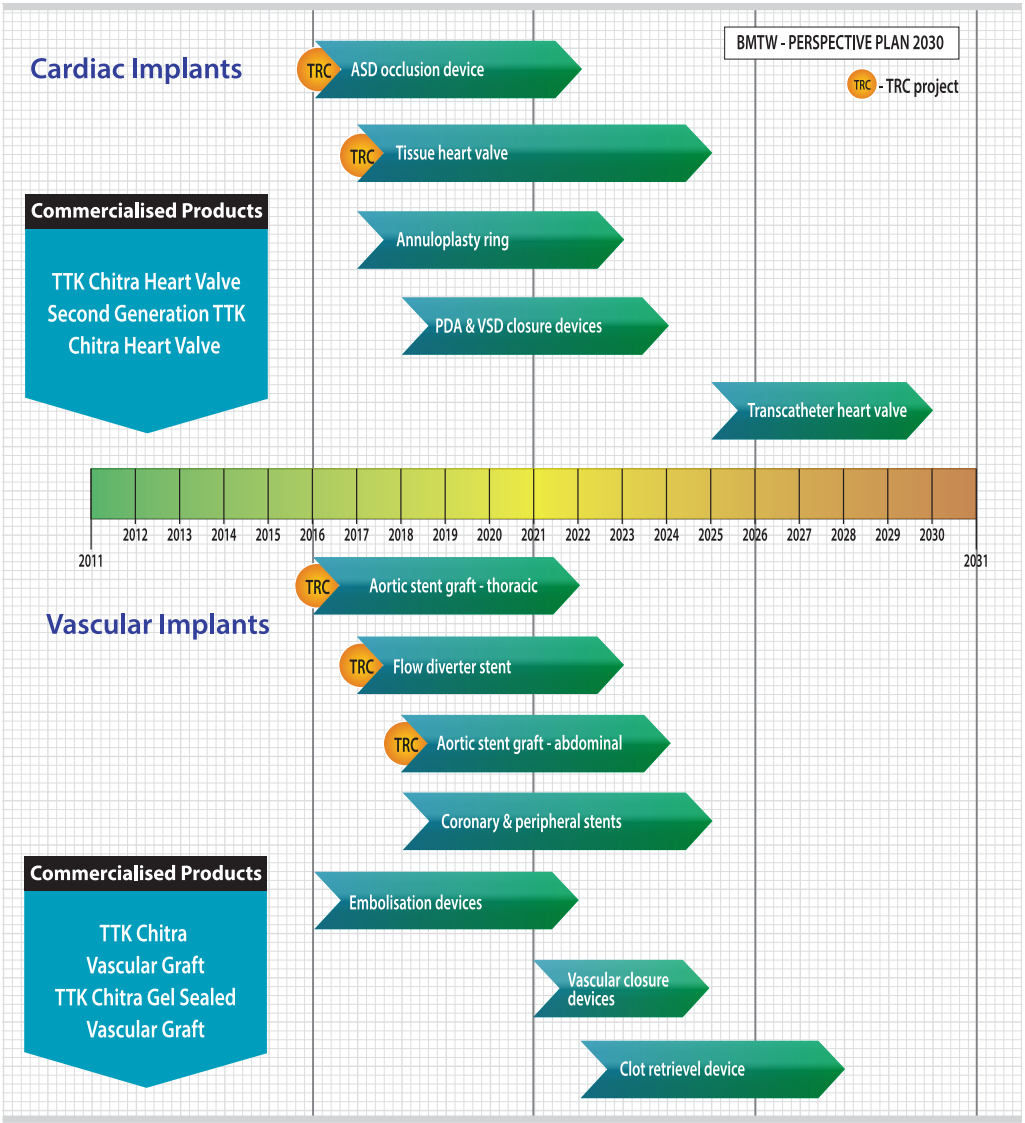
Sub themes : Substitutive Devices			
Areas	**Medical Device**	**Timeline**	
		Start	**End**
Cardiovascular	Atrial septal defect occluder	2016	2022
	Aortic stent graft - thoracic	2016	2022
	Bioprosthetic (tissue) heart valve	2017	2025
	Total artificial heart	2023	2035
	Trans catheter heart valves	2025	2030
	Aortic stent graft – abdominal	2018	2024
Hard Tissue	Artificial joints	2018	2026
	Surface functionalised and coated Implants	2020	2026
	Customized implants	2022	2028
Orthotics and Rehabilitation	Voice prosthesis	2017	2025

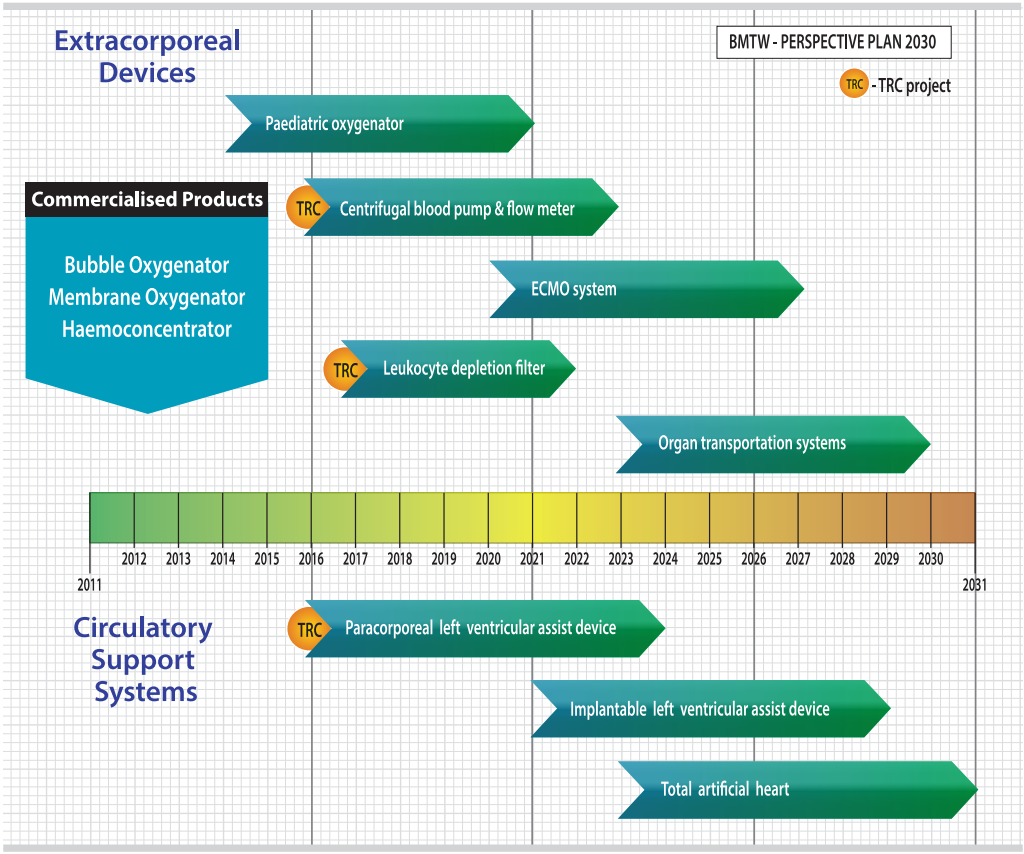
II. New areas of expertise to be developed

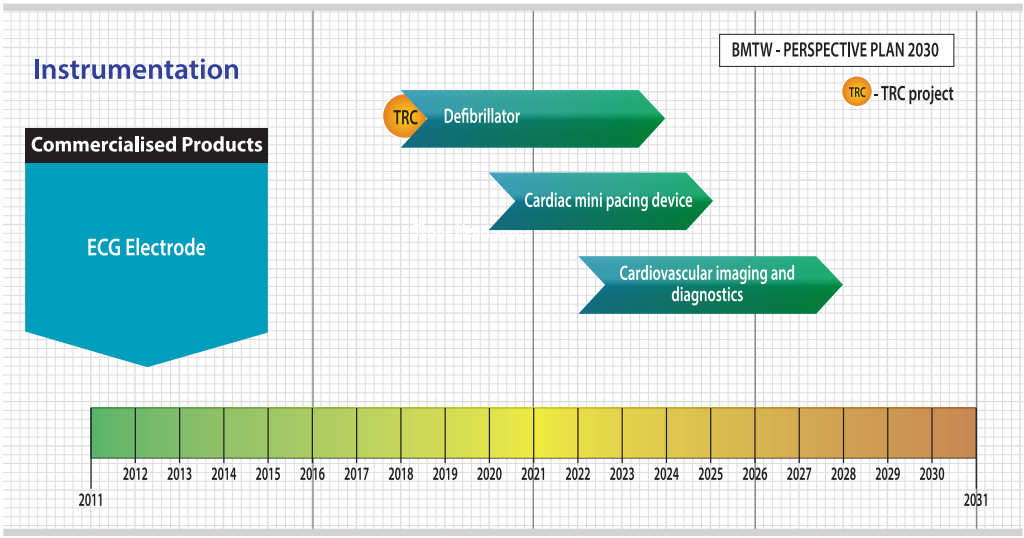
- Biomechanics
- Biomimetic surface technology
- Clinical data analysis
- Computational fluid dynamics (CFD)
- Finite element analysis (FEM)
- Flow visualisation
- Human factors engineering
- Implantable batteries
- Internet of Things (IoT)
- Industrial design
- Metallurgy
- Microelectromechanical systems (MEMS)
- Reliability analysis
- Virtual reality

III. Execution Timeline for Theme I & II

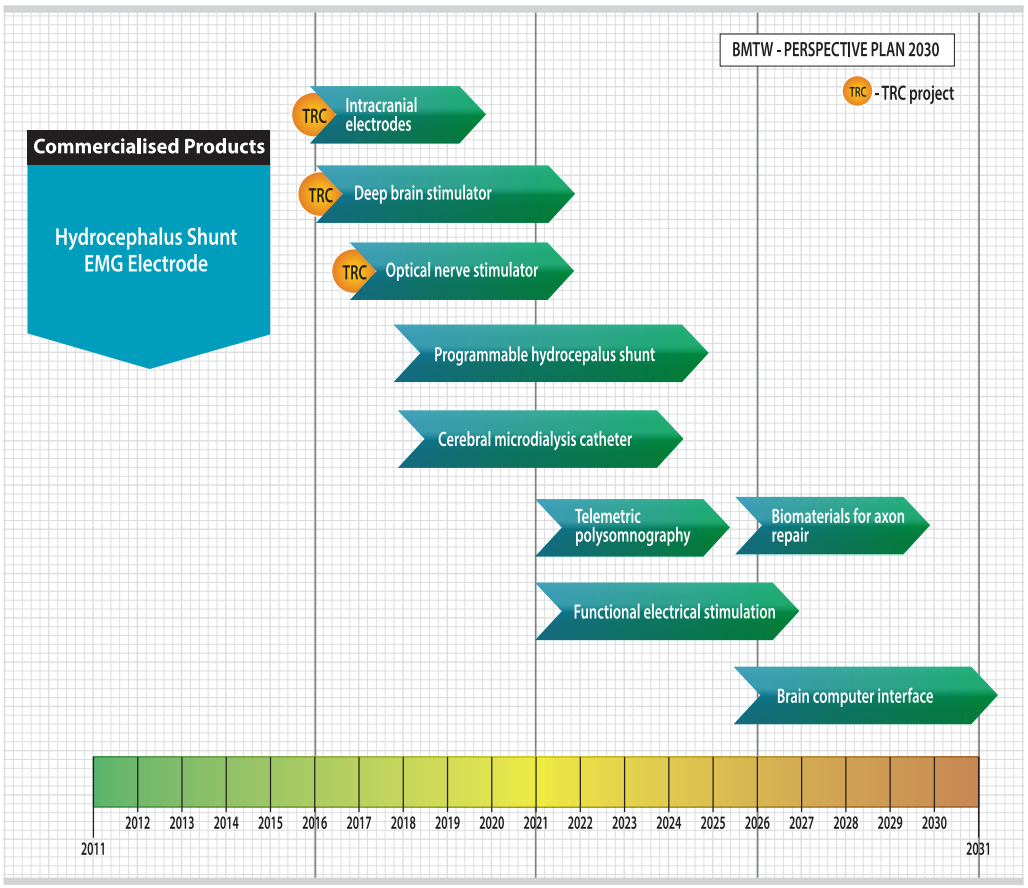
Cardiovascular devices



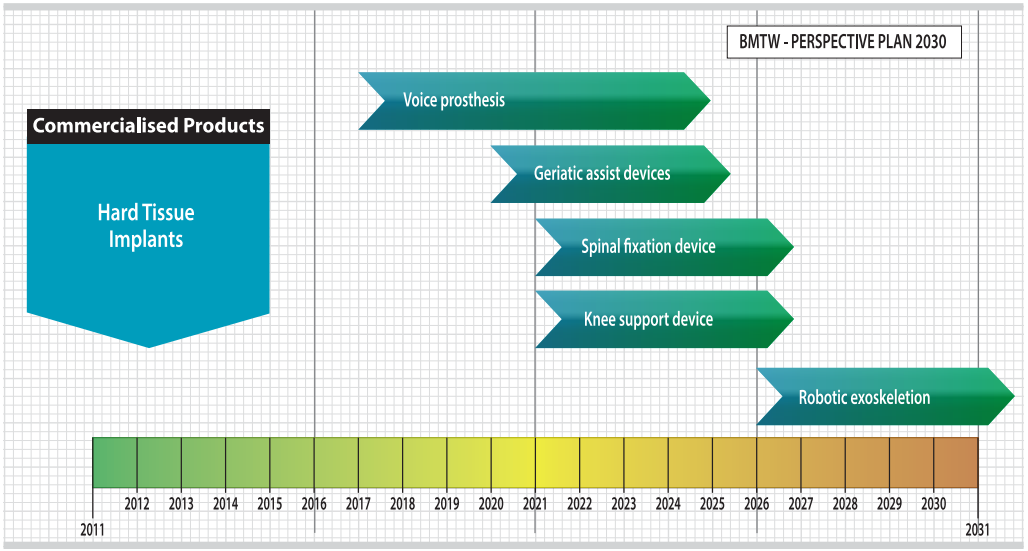

Extracorporeal Devices
BMTW - PERSPECTIVE PLAN 2030
TRC - TRC project
Paediatric oxygenator
Commercialised Products
Bubble Oxygenator
Membrane Oxygenator
Haemoconcentrator
TRC Centrifugal blood pump & flow meter
ECMO system
TRC Leukocyte depletion filter
Organ transportation systems
2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023 2024 2025 2026 2027 2028 2029 2030 2031
Circulatory Support Systems
TRC Paracorporeal left ventricular assist device
Implantable left ventricular assist device
Total artificial heart


Instrumentation
BMTW - PERSPECTIVE PLAN 2030
TRC - TRC project
Commercialised Products
ECG Electrode
TRC Defibrillator
Cardiac mini pacing device
Cardiovascular imaging and diagnostics
2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023 2024 2025 2026 2027 2028 2029 2030 2031

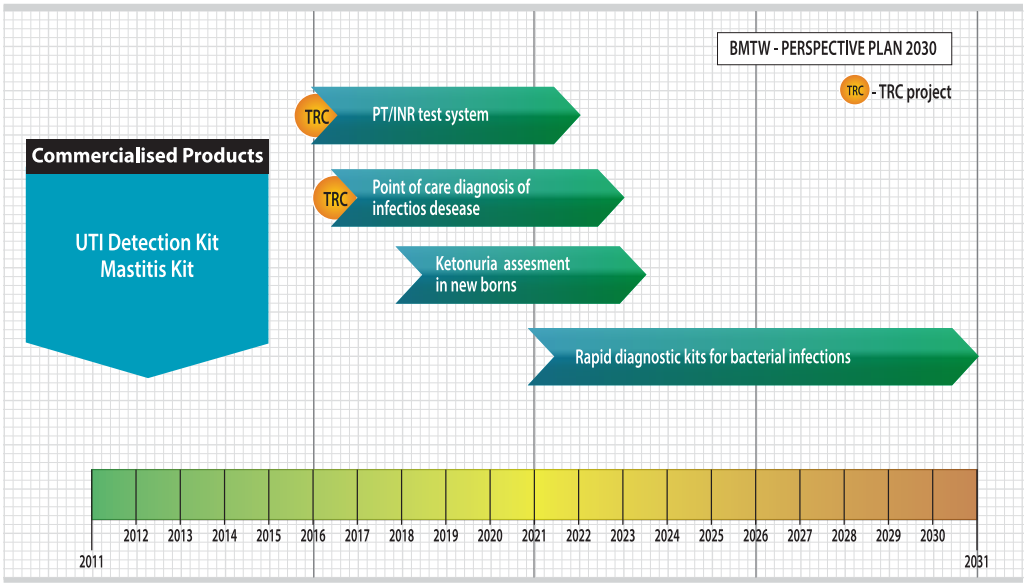
Neuroprosthetics and Neurology



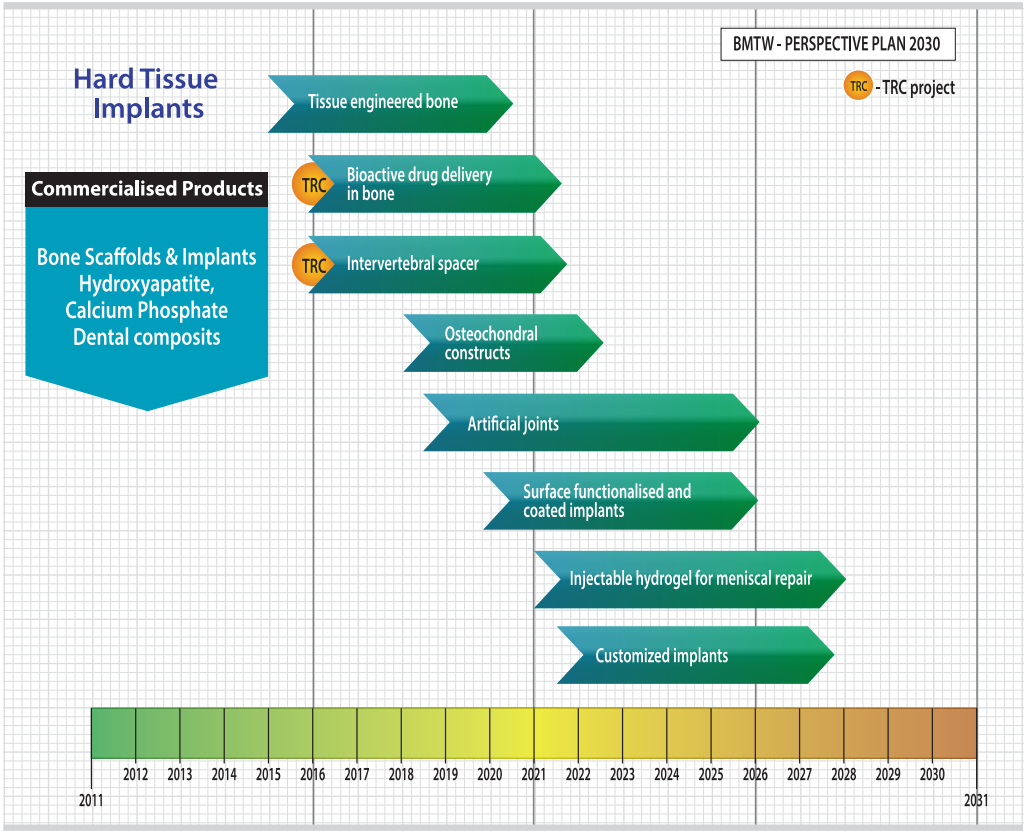
Orthotics and Rehabilitation



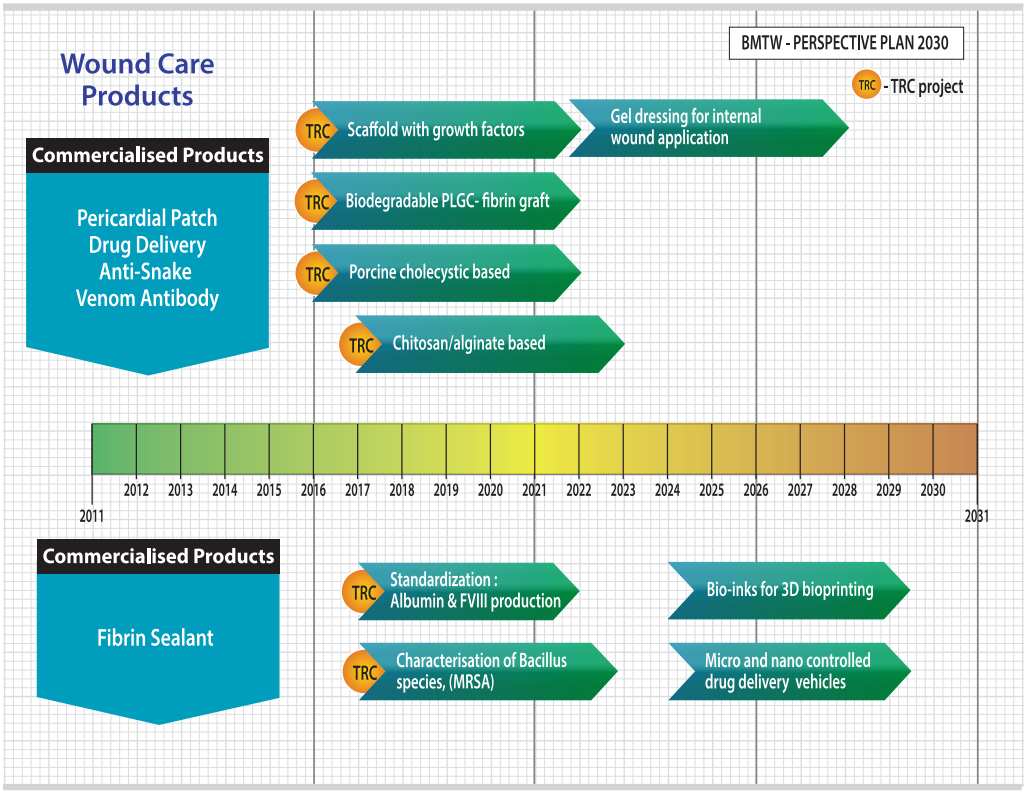
In Vitro Diagnostics (IVD)



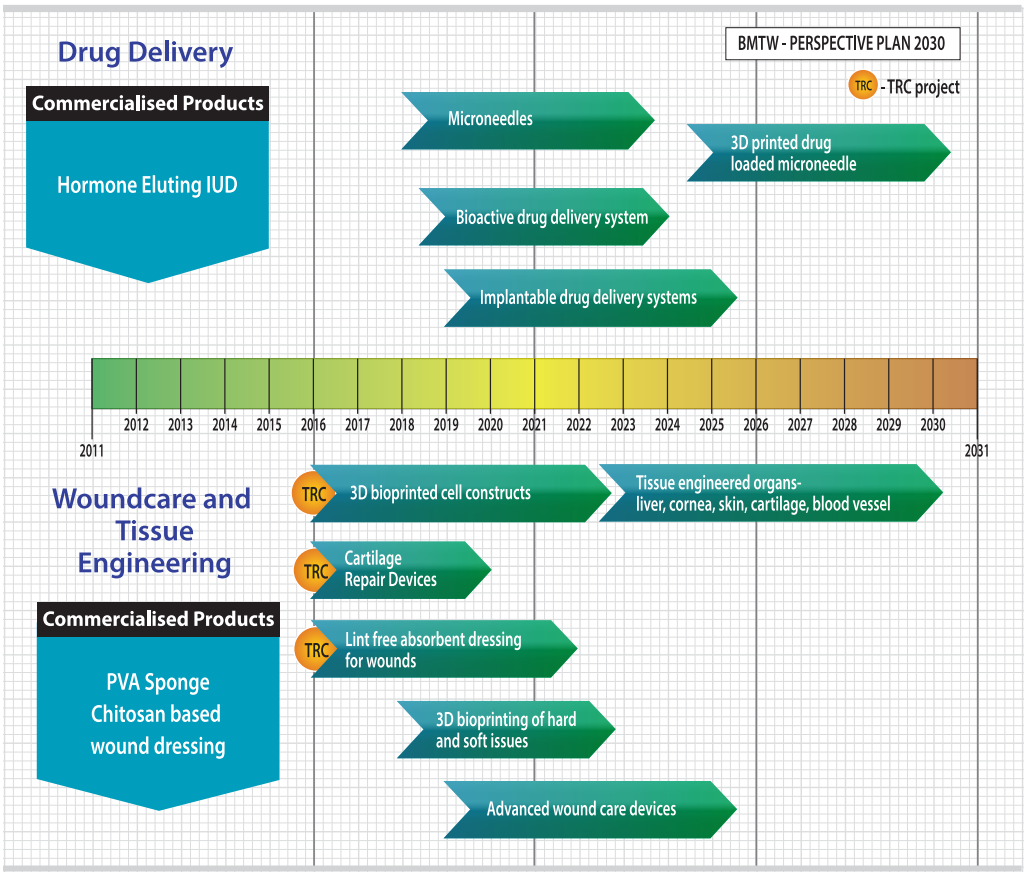
Hard Tissue Devices



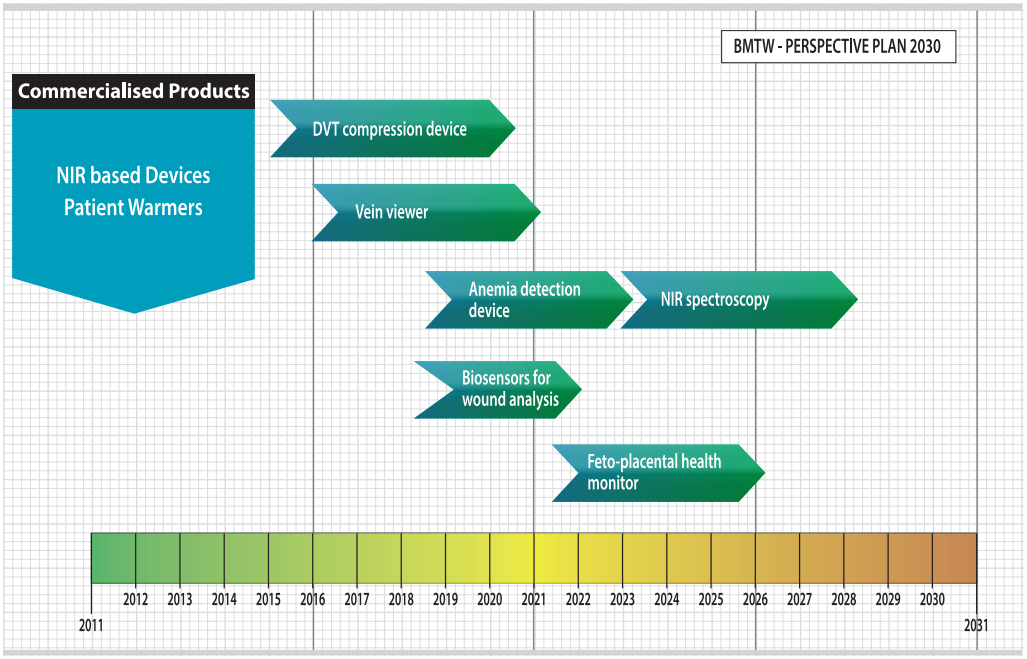
Biologics



Regenerative Technology

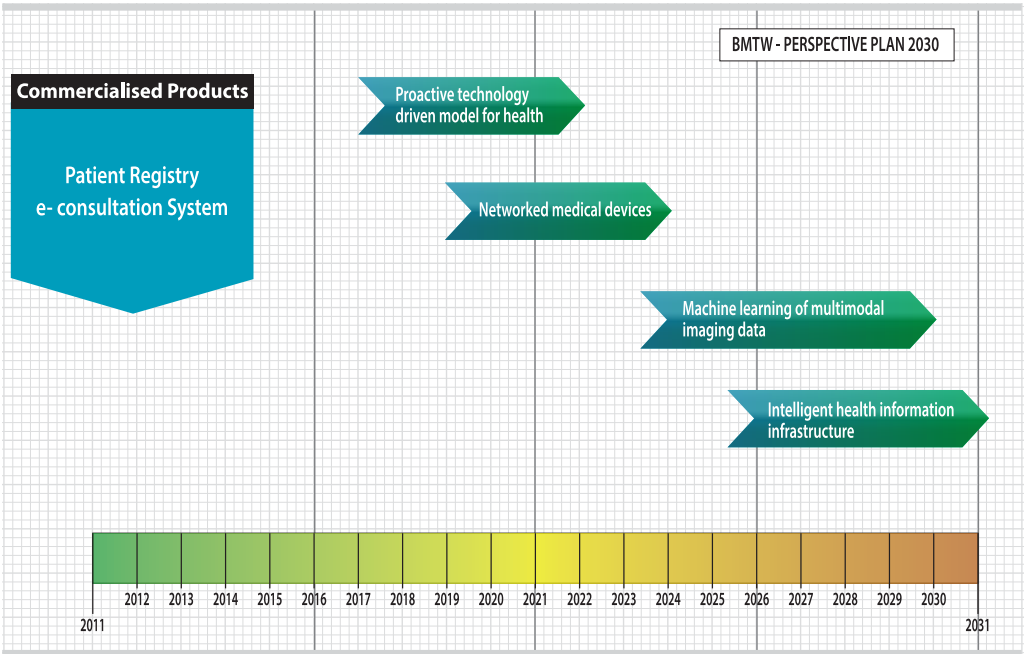


Point of Care Devices



Connected health

Connected health is a new modality of healthcare delivery and social care with the optimum use of health technology, digital media and mobile telecommunications. The objective is to increase the reach and affordability of healthcare to the entire classes of population. More collaborative efforts using technology-enabled care strategy are planned for the purpose.



IV. Development Strategy

The proposed programmes are planned to develop in a time-bound manner with a clear understanding of its market needs and analysing its impacts. In this regard, it is proposed to carry out health technology assessment jointly with the AMCHSS to systematically evaluate the properties, effects and the impacts of the identified programmes.

Collaboration of the technology development team and clinicians, who are the end users of these technologies, will increase the acceptability of the product in the market. For development of products in its thrust areas such as cardiovascular and neurology, SCTIMST had always ensured internal and external clinical collaboration. Currently, more programs are identified in new focus areas and hence suitable clinical partners will be identified and their participation will be ensured throughout the development lifecycle.

Intensified marketing strategies with a strong market research team are also envisaged for assessment of market needs and financial aspects of the project. The team shall implement innovative strategies and identify suitable industry partners for the successful commercialisation of the product.

With a proper need analysis and improved marketing strategies, products will have high success in the market.

Theme III

Medical Device Evaluation & Regulatory Support

The Institute has a strong foundation in the development and evaluation of biomaterials and medical devices. Being an Institute of national importance, we are obliged to support the Indian medical device industry through biomaterial evaluation, functional evaluation of the devices and support for regulatory approval. Medical device regulatory compliance facility was established as part of this in the BMT Wing. In view of the recent implementation of Indian **Medical Devices Rules 2017**, a national testing facility is also envisaged in addition to the above facility.

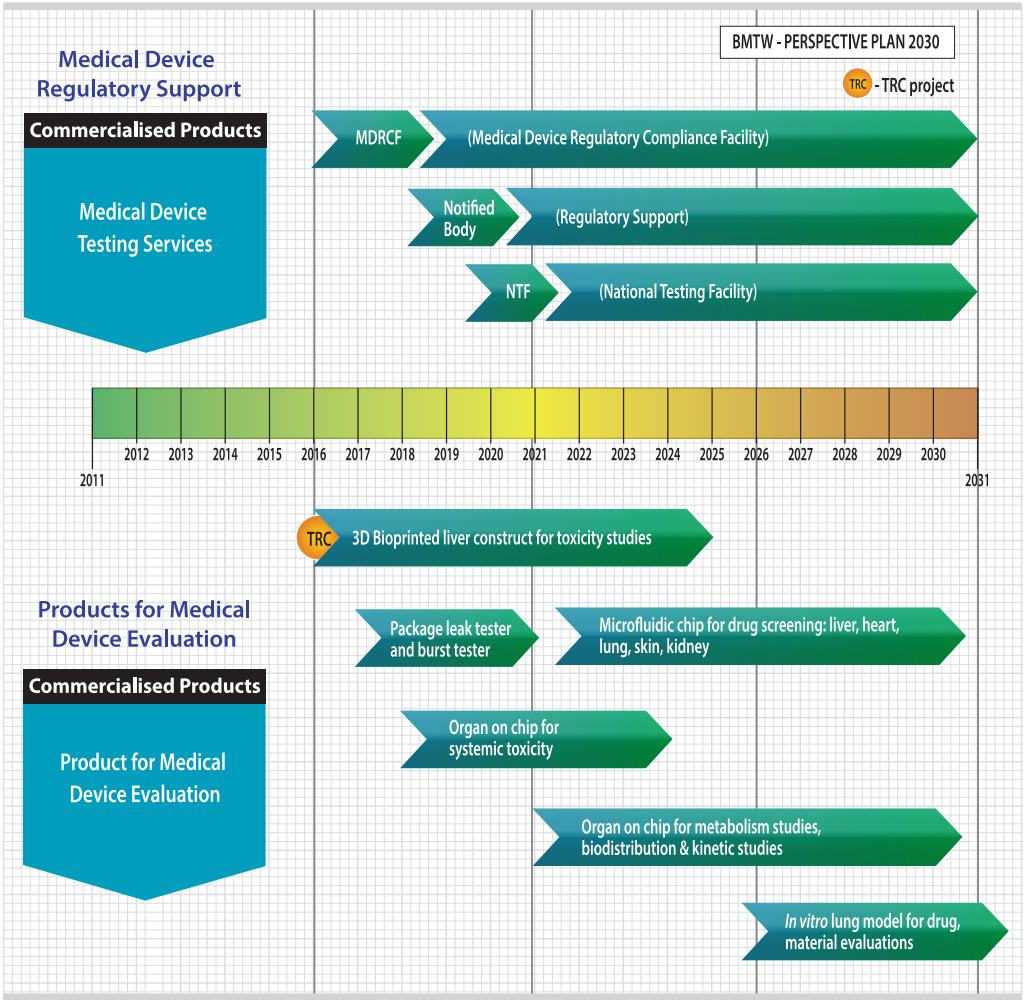
Tissue Engineered 3D constructs for the toxicology evaluation of biomaterials and medical devices are also being planned as a substitute for animal evaluation.

Sub themes
Biomaterial evaluation (analytical and biological)
Functionality evaluation of Medical device
Regulatory compliance facility
Notified Body for Indian Medical Device Regulatory system
Facility for accreditation assistance

Deliverables for Theme III

Devices and Tissue Engineered 3D constructs for Biomaterial and Medical Device evaluation		
	Timeline	
	Start	End
3D Bioprinted Liver construct for *in vitro* toxicity and drug screening	2016	2025
Package leak tester and burst tester	2017	2022
Organ on chip for systemic toxicity	2018	2024
3D construct for toxicity studies	2018	2024
Microfluidic chip for drug screening – liver, heart, lung, skin, kidney	2021	2030
Organ on chip for metabolism studies, bio-distribution and kinetic studies	2021	2030
In vitro lung model for drug and biomaterial evaluations.	2026	2033

Timeline for Theme III



Theme IV

Skill Upgradation

Availability of trained manpower is essential for the growth of any industry; and the Institute is instrumental in delivering a significant number of professionals to various medical devices industries and academic institutions.

Various types of skill upgradation programs including apprenticeship trainings and training for industry professionals are conducted to cater to the requirement of trained manpower in medical device industries. The Institute also conducts academic programmes like M.Tech, M.Phil and Ph.D in Clinical Engineering and Biomedical Sciences & Technology and the students are well-accepted by the industry and academic institutions.

The Institute is planning to develop innovative educational tools using virtual reality and augmented reality, so that the students and trainees can experience the human anatomy and physiology without physically using human and animal models. These will be excellent tools for healthcare professionals to practice latest medical devices being developed and also to evaluate the devices to a great extent thereby reducing the actual number of clinical and pre-clinical evaluations.

Sub themes
Virtual and augmented reality for training
Postgraduate training programs
Finishing schools for scientific/technical personnel
Skill upgradation programs for the industry personnel
School of Medical Device Technology
R & D outreach programmes

R & D Outreach program

Building up of a strong population with active participation and genuine interest in research and technology development is a national requirement. In this regard, motivating younger generation at their grooming period is critical.

SCTIMST is planning various **outreach programmes** in schools and colleges for encouraging students and teachers in generating original ideas and use of technology to solve problems.

Theme V

Technology Translation

The impact of research and technology developments will be fruitful only when it reaches society at affordable costs. Technology commercialisation activities at various levels have to be encouraged to attain the national goal of self sufficiency in medical device requirement. SCTIMST has a long history of translating its research outputs into products available in the market. Hence, the Institute can play a major role in the effective translation of research outputs of both external and internal parties. The technology incubator, SCTIMST-TIMed was already established to cater to the above needs.

TIMed has the right ecosystem for any entrepreneur venturing into the medical device manufacturing with appropriate infrastructure and utilities like office space, laboratory, and clean work space within the Biomedical Technology Wing campus. They can also utilise the testing facilities of BMT Wing for evaluation of the devices.

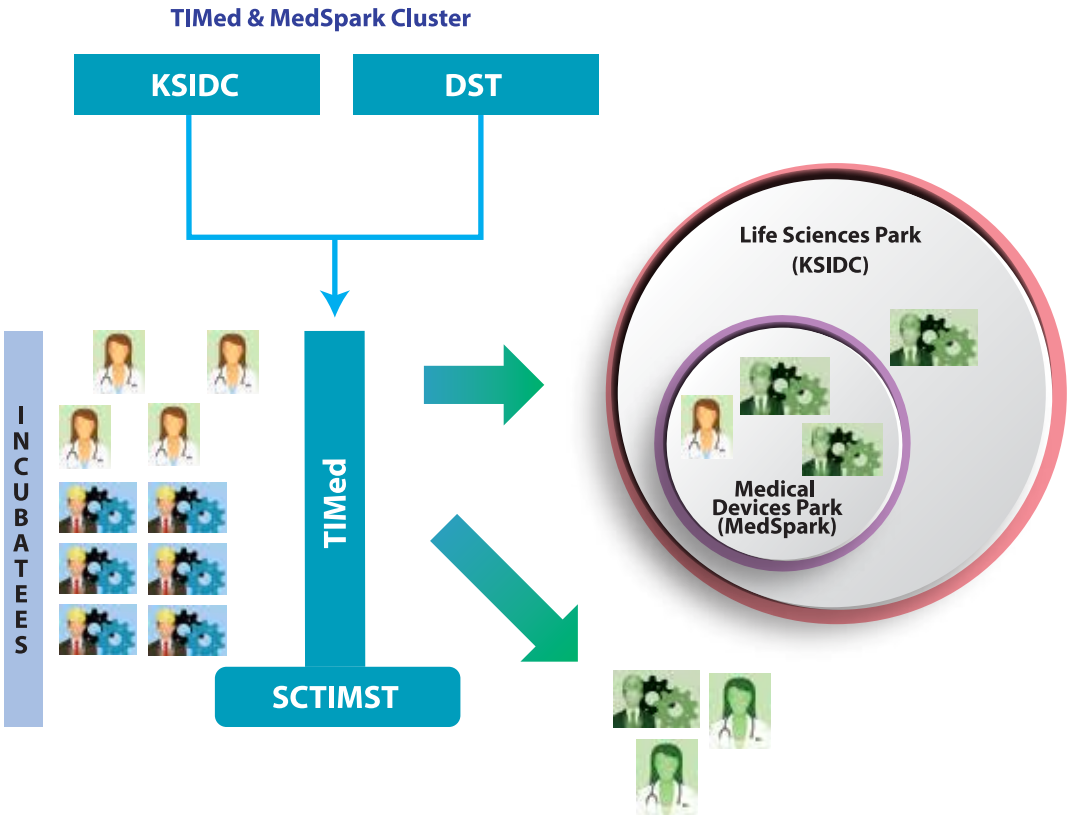
A joint initiative with Kerala State Industrial Development Corporation (KSIDC) is proposed for further extension of this, through a manufacturing and R & D ecosystem, medical devices park (**MedSpark**) with support from the Central and the State Governments.

Deliverables for Theme V

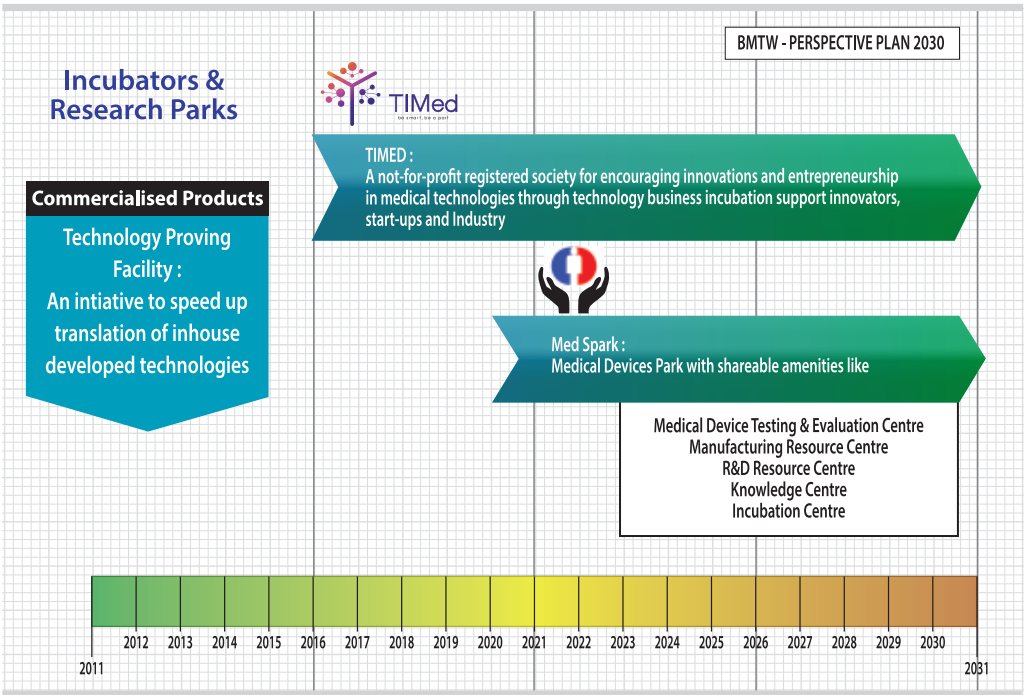
MedSpark

The proposed Medical Devices Park is envisioned to enable the Indian Medical Device Industry to exploit new and emerging technologies, by closing the gap between research findings and their development into commercial propositions through the provision of a business-focused capability that bridges research and technology commercialisation.

The overall mission of MedSpark will be to develop knowledge and capability in technology development, technology incubation, business incubation, medical device evaluation and manufacturing, by closely working with the leading universities and research institutions. This, combined with an open access technology infrastructure and the provision of contract research, will enable the industry to share the cost of their R & D, access skills and infrastructure and avail testing and evaluation support which might not otherwise be within their reach. This will reduce risk, shorten time to market and exploit synergies of knowhow across the value chain.



Time Line for Theme V



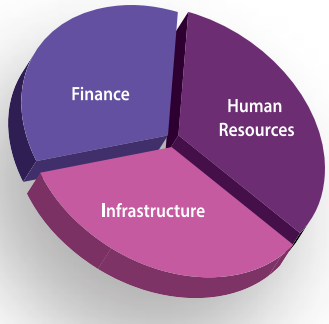
Theme VI

Green Initiatives

Campus and its terrain is gifted with potential for conservation of natural resources like rain water harvesting, solar and wind energy tapping. A green campus self-sufficient in both water and energy can be made into a reality with the concerned agencies working on this.

Sub themes
Self-sufficient water resources
Effective utilisation of renewable energy sources
Getting ISO 14000 certification for the campus
Green Campus campaign for Satelmond Campus (BMT Wing)

Resources



Resources in the form of workforce/human resources, necessary infrastructure and most importantly the finance required are essential for realising any project. To attain the vision envisaged for 2030, additional resources are required to achieve the stated objectives.

I. Infrastructure and utilities

One prerequisite for meeting the goals is the availability of good quality infrastructure in the form of laboratory space, equipment, seminar halls, technology information center etc. Additional infrastructure like seminar halls, student hostel, faculty hostel, amphitheatre and augmentation of utility services including electricity, water and networking are also envisaged to be implemented to improve the overall functionality of the technology development activities.

Equipment

The Institute is currently in the process of expanding the laboratory space as part of the combinational devices block. Considering the additional areas of expertise planned, upgradation of facilities and equipment in line with the state-of-the-art is essential. Optimisation of the use of existing infrastructure can improve the utilization better; however, equipment reaching their service life needs to be replaced and additional equipment to be added in order to meet the requirement of planned activities.

Networking and collaboration

Only essential core facilities required for these projects will be setup in-house; all other facilities required will be shared in collaboration with other national and international organsation.

Details of new Facilities proposed to be setup are provided in Annexure I.

II. Human Resources

BMT Wing consists of Scientists and Engineers with varied interdisciplinary backgrounds, complementing each other to cater to the needs of various stages of medical device development and evaluation. To satisfy the increasing market demands and proposed scope of expansion, additional expertise needs to be acquired and existing areas need to be enhanced wherever the critical mass is lacking. Additional areas of expertise identified include orthotics, combinational products, *in vitro* diagnostics, wearable medical devices, optical medical devices, connected health, medical robotics etc.

Since the Indian '**Medical Device Rules-2017**' are in force, every product reaching the market needs to satisfy the regulatory requirements. This includes testing and evaluation of devices at various stages of development with proper documentation. Additional human resources will be essential in various streams for fulfilling these requirements of the medical devices which are planned to be developed in-house and for the proposed activities in regulatory support and skill upgradation for the external stakeholders like Indian medical device industries.

Human Resources requirements in core areas		
Specialisation	**Scientists/ Engineers**	**Scientific/Technical**
Product Development	20	15
Product Evaluation	7	10
Technology Management	5	5
Applied Research	8	10
Quality Management System	2	3
Total	**42**	**43**

Human Resources requirements in Administration		
Specialisation	**Officer**	**Assistants**
Material Management	1	2
HR Management	1	2
Finance	1	2
Engineering Services	1	3
Estate Management	1	1
Total	**5**	**10**

III. Financial Resources

At present, about 15% of the funding in the BMT Wing is from internal revenue streams and extramural projects. Efforts will be made to increase this further and avenues like social responsibility funding options also will be explored; commercialisation of the technologies being developed is expected to improve the internal revenue significantly.

Internal Revenue generation

Apart from the revenue from license fee, royalty and test charges, enhancement of the following can strengthen the funding requirements.

- Encourage industry-sponsored product development programmes.
- Income from organising custom-made expertise development programmes like on-bench trainings, workshops, etc.
- Funding from CSR (Corporate Social Responsibility).
- Adapt PPP model for providing facilities in testing, prototyping (pilot productions) and device manufacturing.
- Regulatory support for industries.
- Provide support for implementing quality system for device development programmes.

Additional Fund flow requirement for the perspective plan in ₹ Crore.

Category	2020-21	2021-22	2022-23	2023-24	2024-25	2025-26	2026-27	2027-28	2028-29	2029-30	₹ Crore.
Capital expenses											
Equipment	20.00	35.00	5.00	5.00	5.00	10.00	10.00	10.00	5.00	5.00	110.00
Building :											
Civil construction	8.00	10.00	2.00	---	---	---	---	---	---	---	20.00
Building utilities	---	5.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	21.00
Augmentation of Existing infrastructure	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	20.00
									Subtotal, Capital expenses :		**171.00**
Recurring Expenses											
Manpower	3.00	6.00	7.50	9.50	10.45	11.50	12.64	13.91	15.30	16.83	106.63
Revenue expenditure	3.00	4.00	4.00	6.50	7.15	7.87	8.65	9.52	10.47	11.52	72.67
									Subtotal, Recurring Expenses :		**179.30**
Year wise Total	**36.00**	**62.00**	**22.50**	**25.00**	**26.60**	**33.36**	**35.30**	**37.43**	**34.77**	**37.34**	
										Grand Total ₹ Crore	**350.30**

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ANNEXURE I

New facilities proposed

- Biocompatible coating
- Confocal Raman microscope
- Electrical safety analysis
- GMP facility
- High performance computing
- Laser welding
- Medical device modelling and simulation
- Metallic implant fabrication (Foundry)
- Micro electronic fabrication
- Microfluidic device development
- Powder free manufacturing
- Precision machining center
- Rapid prototyping with metallic materials
- Soft lithography work station
- Virology laboratory

NOTES

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