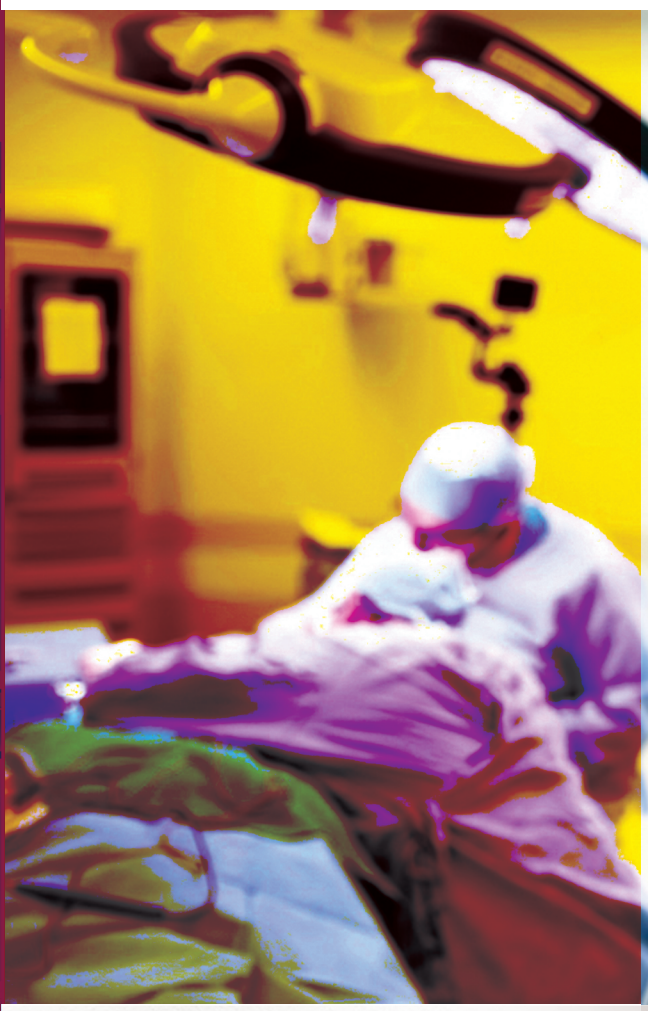
KALAM INSTITUTE OF HEALTH TECHNOLOGY

ANNUAL REPORT 2017-2018



ADDRESS

C/o AMTZ Campus, Pragati Maidan,
VM Steel Project S.O,
Visakhapatnam: 530031.

KIHT

विज्ञानेन जातानि जीवन्ति

(PROJECT UNDER DEPT. OF BIO TECHNOLOGY, GOVT. OF INDIA SUPPORT)

विज्ञानेन जातानि जीवन्ति

KALAM INSTITUTE OF HEALTH TECHNOLOGY ®

Kalam Institute of Health Technology

(Science is the sustainer of Life)

Annual Report 2017-18

AMTZ Campus, Pragati Maidan, VM Steel Project S.O,

Visakhapatnam – 530031, Andhra Pradesh, India

Governing Council 2017-18

Prof. K. Vijay Raghavan — **President**

Principal Scientific Advisor, Govt. of India

Dr. Renu Swarup — **Chairperson**

Secretary, Dept. of Bio-Technology, Govt. of India

Dr. Poonam Malakondaiah — **Member**

Special Chief Secretary (HM&FW), Govt. of Andhra Pradesh

Sri Rajiv Agarwal — **Member**

Joint Secretary, Dept. of Industrial Policy & Promotion (DIPP), Govt. of India

Dr. Mohd. Aslam — **Member**

Senior Advisor, Dept. of Bio-technology, & MD, Biotechnology

Industry Research Assistance Council (BIRAC)

Sri Rajiv Nath — **Member**

Forum Coordinator, Association of Indian Medical

Device Manufacturers (AIMED), New Delhi

Dr. B. Ravi — **Member**

Institute Chair Professor, Mechanical Engineering,

IIT Bombay, Mumbai

Prof. Balram Bhargava — **Member**

Executive Director, School of International Bio-Design,

AIIMS, New Delhi

Dr. Swati Basu — **Member**

Scientific Secretary, Office of Principal Scientific

Adviser to the Govt. of India

Dr. V. G. Somani — **Member**

(wef February 19, 2018)

Joint Drugs Controller (I), CDSCO

Dr. Jitendar Sharma — **Member**

Secretary & Executive Director, Managing Director & CEO, AMTZ

Executive Body 2017-18

Dr. Mohd. Aslam — **Chairperson**

Scientist 'G', Senior Advisor,
Dept. of Bio-technology, & Managing Director,
Biotechnology Industry Research Assistance Council

Dr. Jitendar Sharma — **Co-Chairperson**

Executive Director, KIHT

Dr. Rakesh Kumar — **Member**

Head – Strategy & Deputy Country Director, UNDP

Dr. Balram Bhargava — **Member**

Executive Director, School of International Bio-Design,
AIIMS & DG, ICMR

Dr. Alka Sharma — **Member**

Advisor & Scientist 'G', Dept. of Biotechnology

Dr. Suresh Kumar — **Member**

Scientist 'F', Office of Principal Scientific Advisor to
Govt. of India

Dr. R. K. Srivastava **Member**

WISH Foundation and ex-DGHS

Mr. Rajiv Nath **Member**

Forum Coordinator, Association of Indian Medical Device Manufacturers (AIMED)

Prof. B. Ravi **Member**

Institute Chair Professor, Mechanical Engineering, IIT Bombay

Dr. Madhur Gupta **Member**

Head, Pharmaceuticals & Technologies, WHO India

Dr. Meenakshi Sharma **Member**

Scientist 'F', Indian Council of Medical Research

Mr. Nitin Bharadwaj **Member**

Vice President (Administration), KIHT

Assistant Director, KIHT – Member Secretary

Introduction

Medical devices can be considered the most complex commodity in the world given its relevance to the healthcare sector and the application for addressing for healthcare solutions. Awareness of a common man towards prevention measures rather than curing, has globally stimulated scientists and innovators to work out solutionsto increasing needs of healthcare.The development of technology over the years has led innovators to fork out more and more precise and user-friendly devices which aids the healthcare professionals to support the growing awareness of healthcare needs. The gamut of product range based on various products (right from a tongue depressor to high-end electronics), the sensitivity of application of such products on human beings, the need for cost effectiveness to ensure reach of the poorest of the poor, make this sector highly complex.

World over, developed countries have mastered the art of innovation on all spheres of life and medical devices is no exception. It required the genius of Indian minds to break into generics manufacturing of pharmaceutical products which the country presently boasts of, as India has penetrated the markets in nearly 250 countries in the world with its cost-effective medicines. Kalam Institute of Health Technology is such a pioneer initiative promoted by the Department of Bio Technology to enable India to break into the sphere of medical devices industrydominated by afew countries in the world. KIHT was created out of the vision of the former Principal Scientific Advisor to Government of India, Dr. P.Chidambaram, who felt that India, which has become a leader in satellites and space research, cannot be found wanting to address the solutions sought by the medical devices sector, keeping in view the abundance of talent, commitment and innovative minds to find solutions with an Indian touch, apart from the huge size of the Indian population whose primary healthcare needs still remains unaddressed in remote areas. Dr Chidambaram felt that India has the competence and facilities to match global products and it only required a facilitating environment to achieve the objective of having a robust manufacturing ecosystem, which would make India move away from over dependence on imported technology and products.

The Andhra Pradesh Government came forward in 2017 to support the mission of DBT to create an institutionlike KIHT, which blended well with the objective of Andhra Pradesh MedTech Zone, the industrial park for the sector. KIHT set forth in its mission with a handful of dedicated scientists and in the first year of its operations has established itself as the focal point of the country in the medical technology field.

KIHT provides the much-needed back end support of the Make-in-India initiative for manufacturing medical devices in the country. In the current scenario, there is an immense need to use medical devices effectively to address the huge gap between demand and supply of healthcare services in India. Most of the medical devices are imported and indigenous manufacturing is largely restricted to medical consumables and some low-end technology products. Even though India is having large pool of diverse researchers, there is a felt need of having a centralised team for focusing the strengths of the country to drive India towards an outcome oriented approach in the medical devices sector.

Mission

Kalam Institute of Health Technology (KIHT) aims to facilitate focused research on critical components pertaining to medical devices by supporting institutions involved with R&D, industry, policy makers and knowledge repositories. This is sought to achieved through transfer of technical knowledge and bringing together the strategic and coherent synergy of scientific facilities and institutions to compliment efforts on industrial promotion.The outcome remains the single motto of bringing increased access to affordable health products to citizens and aid a thriving medical devices manufacturing sector in India.

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2017-18 by the Numbers

CHAPTER 1

Genesis of KIHT

While many projects on medical technology are funded in the country by the country, involving several ministries and departments involving multiple stakeholders need continuous technical inputs in the process to improve medical devices cost, quality and scale. The need to support all the stakeholders in various ministries and departments led to the formation of a society under the aegis of Dept. of Bio-Technology, Govt. of India and Andhra Pradesh MedTech Zone, a public-sector enterprise of the Govt. of Andhra Pradesh. Named in the memory of the 11th President of India, Bharat Ratna Late Dr. Avul Pakir Jainulabdeen Abdul Kalam - a world renowned scientist, pioneer in technology and a 'People's President", the Kalam Institute of Health Technology (KIHT) was formed on February 23, 2017.

The main objective of KIHT is:

a) Identification of key technology gaps which could be identified for supporting Department of Bio-Technology to provide support for R&D for focused development of medical technologies; and
b) Undertaking technology transfer of available technologies with from academia and research institutes to the industry.

The Principal Scientific Advisor to the Govt. of India acts as the President of the Society and Governing Council is headed by Secretary, Dept. of Bio-Technology, Govt. of India. The Governing Body has a mix of representatives from the Government, technical experts, academicians and medical device industry.

The Governing Body had its first meeting on November 10, 2017 at New Delhi under the Chairmanship of Prof. K. VijayRaghavan, then Secretary, Dept. of Bio-Technology, Govt. of India. The Governing Body,among other administrative decisions, provided the direction of efforts in prioritising and improving the liaising mechanism in the medical technology sphere.

KIHT in its first year of formation moved into top gear connecting with various research institutions in the country for taking forward its mandate of doing focused research facilitation on critical components. It has also wings for providing guidance on market access and policy interventions required for the growth of the medical technology sector.

KIHT was notified by the office of the PSA in June 2018 as the Project Analysis Unit for all Health Technology Projects in the country. This was preceded by a meeting convened by the PSA on April 30, 2018 at the KIHT campus with a host of country's leading R&D institutions working on medical technology for taking stock of the status of projects which received government funding in the health technology domain.

Governing Body Meeting Highlights:

KIHT's First Governing Body meeting was held on 10th November 2017 at CSIR Science Centre, New Delhi. Seven Governing Body members including Dr. Vijaya Raghavan, Dr. Poonam Malakondaiah, Dr. Renu Swarup, Dr. Balaram Bhargava, Dr. B. Ravi, Mr. Lalit Mahajan, and Dr. Jitendar Sharma along with other special invitees have attended.

The following are the key decisions undertaken by Governing Body after deliberations and discussions:

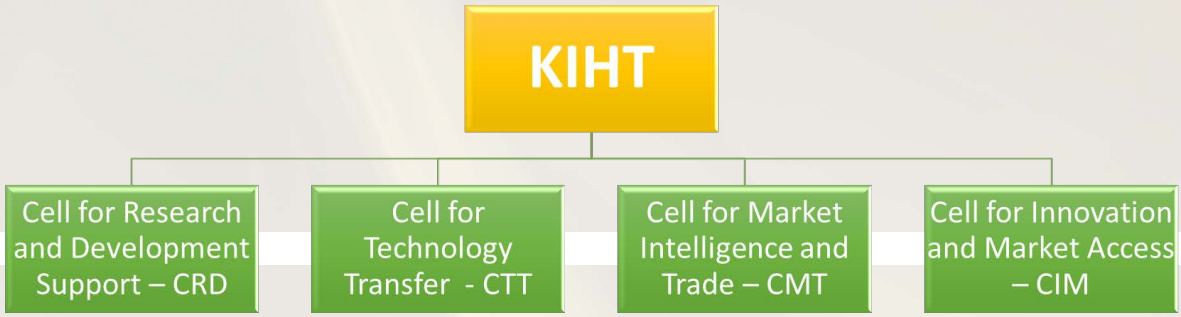
1. e-auction method for rapid technology transfer.
    a. The Governing Body also accorded approval for registration of industry partners for the auctioning process as per RBI rules while keeping it free for research institutions and individual innovator who would sell their Intellectual Property (IP) and/or Manufacturing Rights.
    b. Charging a modest processing fee of 2% for each technology that is transferred.

2. KIHT was permitted to enter in an agreement with Indian Angel Network (IAN), for the purpose of co-funding innovations and incubating start-ups in the medical technology space.

    a. IAN have agreed to co-invest in start-ups along with KIHT (KIHT-20%, IAN-80%).
    b. It was proposed that KIHT's 20% support for rapid R&D would be interest free loan which would be recoverable in full within four years, thereby presuming its corpus funding.

3. Formation of an Executive Body to guide the periodic funding of the organization.
    a. Dr. (Smt.) Renu Swaroop, Senior Advisor, Dept. of Bio-technology & MD, BIRAC, Chairperson
    b. Dr. Jitendar Sharma, Executive Director, KIHT & CEO, AMTZ, Co-Chairperson
    c. Dr Rakesh Kumar, Head- Strategy & Deputy Country Director- UNDP
    d. Dr Suresh Kumar, Scientist, Office of PSA to Government of India, Member
    e. Dr. (Smt.) Alka Sharma, Director & Scientist F, DBT, Member
    f. Dr. R. K. Srivastava WISH Foundation and ex-DGHS, Member
    g. Mr. Rajiv Nath, Forum Coordinator, Association of India Medical Device Manufacturers, Member
    h. Mr. Nitin Bhardwaj, Vice-President (Admin), KIHT, Member
    i. Dr. Balram Bhargava, Executive Director, School of International Bio-design, Member
    j. Dr. Madhur Gupta, Head, Pharmaceuticals and Technologies, Member
    k. Prof. B. Ravi, Institute Chair Professor, IIT Bombay, Member
    l. Assistant Director, KIHT, Member Secretary

4. Permitted KIHT to form national and international partnerships with certification and testing agencies and to charge a service fee of 2% on the testing and certification charges.



Cell for Research & Certification (CRC)

Cell for Research & Certification(CRC) supports government to do focused spending of research grants on prioritized medical devices (based on communicable and non-communicable disease burden) and their critical components which arehighlyimported. CRC maintains a unique repository of product specific dossiers which provides end-end information like its technicality, EXIM analysis, potential market, demand etc pertaining to the product.In addition, the cell also facilitates all stakeholders to undertake development of medical devices in the country tapping the ecosystem available in AMTZ.

Responsibilities:

- Provide critical component knowledge to institutions for focused research & development
- Facilitate core scientific facilities available in AMTZ in development of core medical device technologies
- Facilitate focused and target-oriented R&D by institutions that specialize in respective domains
- Identify knowledge groups that specialize in key and strategic medical devices segments
- To develop cost effective channels for technology intensive programs

Cell for Technology Transfer (CTT)

Cell for Technology Transfer facilitates technology transfer of innovations from academia, research institutes, innovators and start-ups, etc. to manufacturing industry. Such Technology Transfer process involves liaising of healthcare innovations to manufacturers through a unique e-Auction web portal, exclusively designed and customized for healthcare technologies.

To ensure that Government investments in Research & Development related to healthcare technology do not end up as mere reports / patents / shelf prototype, Technology Transfer as a tool is aimed at benefiting the society by converting the research findings into commercial projects. CTT also guides the manufacturers with all possible supports in testing, validation, regulatory process, health technology assessments and other certification process in streamlining the entire manufacturing process.

Responsibilities:

- Support MedTech transfers and facilitate rapid industrial promotion
- Promote setting up of scientific facilities for developing and Pre-market approvals
- Connect with knowledge networks viz. National & International Organizations, Industry Associations, Business councils, Regulatory agencies, Trade departments, Quality promotion etc.
- Facilitate scientific cooperation, coordination of activities, information exchange, exchange of expertise and implementation of joint projects
- Implement specific projects funded by Government, bilateral, multi-lateral, and other funding agencies for growth in health technology
- Improve access towards affordable health technologies

Cell for Innovation & Market Access (CIM)

Manufacturing coupled with high throughput research and development has driven the medical devices to a higher dimension globally. Concomitantly, the dynamic nature of standards and regulations worldwide has picked up pace in recent years. The CIMacts as a nodal point to address such needs of the industry and aims at imparting expertise to the Indian manufacturers in consonance to the regulations worldwide.

CIM has incorporated strong framework to dispense tangible output of thematic concepts conceived by the innovators in a comprehensive manner. This is achieved by imparting guidance to the manufacturers and innovators to the extent regulations and quality compliance requirements, technology design and development as also applying Health Technology Assessment (HTA) tools. HTA aims to accelerate the performance of health systems by using robust evidence-based approaches to make clear, consistent recommendations about which health technologies to be applied in a given situation with a focus on patient-care. Policy makers are more concerned about benefits accruing to populations in general rather than individual patients. HTA imparts societal benefits in terms of therapeutic value, health system value, ethical treatment, etc.

The CIM cell supports quality improvement and efficiency of the system by furnishing equitable and fair access to healthcare by speeding the processes and comprehensive evaluations at a functional level. This helps mitigate the burden of diseases that leads to loss of lives and targets universal health coverage to ever increasing Indian population.

CIM provides turnkey development services or alternatively focuses on critical subsystem and works towards the social benefits.

Responsibilities:

- Identifies and suggests measures to stakeholders with respect to Trade, Technical barriers, Operational requirements that retard manufacturing
- Undertakes research and analysis about concerns, Rapid action requirement, and long-term strategy in MedTech industry and research
- Undertakes economic evaluation and systematic review of medical technologies
- Support repository of medical device specific best practices, technology upgrades, skill building programs, knowledge sharing platforms, and quality promotion of Medical devices
- Promote general awareness on medical device safety, standards, and facilitate information to all health technology stakeholders

Cell for Market Intelligence & Trade (CMT)

CMT Cell does analysis of data related to international trade, ForeignDirect Investments (FDI) and Mergers and Acquisitions (M&A) in medical devicessector. The Cell analyses data to decipher current trends in imports, exportsand flow of investments, which are convertedinto reports at periodic intervals. Such reports are meant for stakeholders including start-ups, corporates and corporate financiers. Thedata collected is at a HS (Harmonised System) code level which is extrapolated to sectorallevel on a regular basis and trends assessed.

The knowledge base thus createdforms the foundation for all tax suggestions on tariffs to government agencies, forchanges in customs duties for raw materials and finished goods. CMTplays a key role as an advisor to Govt. on critical policy and process interventions.

CMT offers suggestions to Indian manufacturers on specific queries related to duties on specific components for medicaldevice manufacturing with a view to support the domestic market.Workshops are conducted for dissemination of information to all stakeholders.

Responsibilities:

- Act as knowledge repository for export and import data on medical devices
- Act as advisory board on all matters relating to medical device sector
- Act as an advisory board on policy matters pertaining to medical devices
- Act as bridge between Start-ups and Corporates, and analysing Investments and advising accordingly

CHAPTER 2

Activities

e-Auction of Healthcare Technologies:

Launch of e-Auction web portal on 15th February 2018, by Union Minister for Chemicals & Fertilizers

KIHT has a unique e-Auction platform for accumulating innovative healthcare technologies across the country and creating a repository technology bank and facilitate transfer of such technologies/ prototype/ intellectual property to interested manufacturers/ researchers. It is first of its kind platform in the world for healthcare technology. The e-Auction web portal will unlock the innovative healthcare technologies developed in R&D institutes/ start-ups/ incubation centres in the country by increasing visibility there by licensing them to local industrythat increases indigenous manufacturing and decreasing dependency on imports. Licensing of innovative healthcare technologies to indigenous manufacturers is expected to significantly reduce the cost of medical devices. As most of these innovations are for improving accuracy or efficiency of diagnosis and treatment of various health conditions, this will enable doctors to serve more patients and provide better outcomes at affordable cost. This will benefit the majority of patients, especially those in the shorter sections of society.

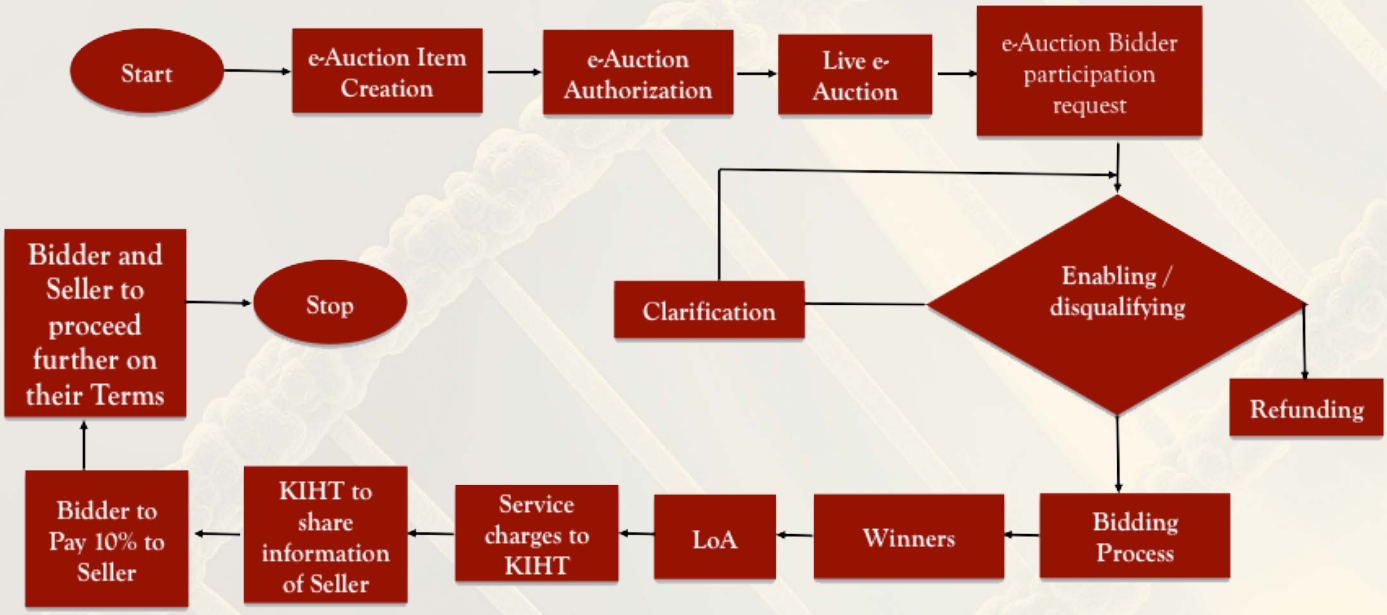
The main objectives of KIHT's technology transfer process is to bring down the treatment cost of the patients by;

(i) Liaising of Technologies to the Industry through this unique e-Auction web portal platform;

(ii) Encouraging the local manufacturers to focus on indigenous products commercialization;

(iii) Reducing the dependency on imports and by using indigenous products and improve the access towards affordable health technology.

The e-Auction web portal was launched on 15th February 2018, by Shri Ananth Kumar, Union Minister for Chemicals & Fertilizers on India Medical Devices Summit 2018, the largest exhibition and conference on the Indian Medical Devices Sector Organized by Dept. of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Govt. of India in partnership with Federation of Indian Chambers of Commerce & Industry (FICCI).

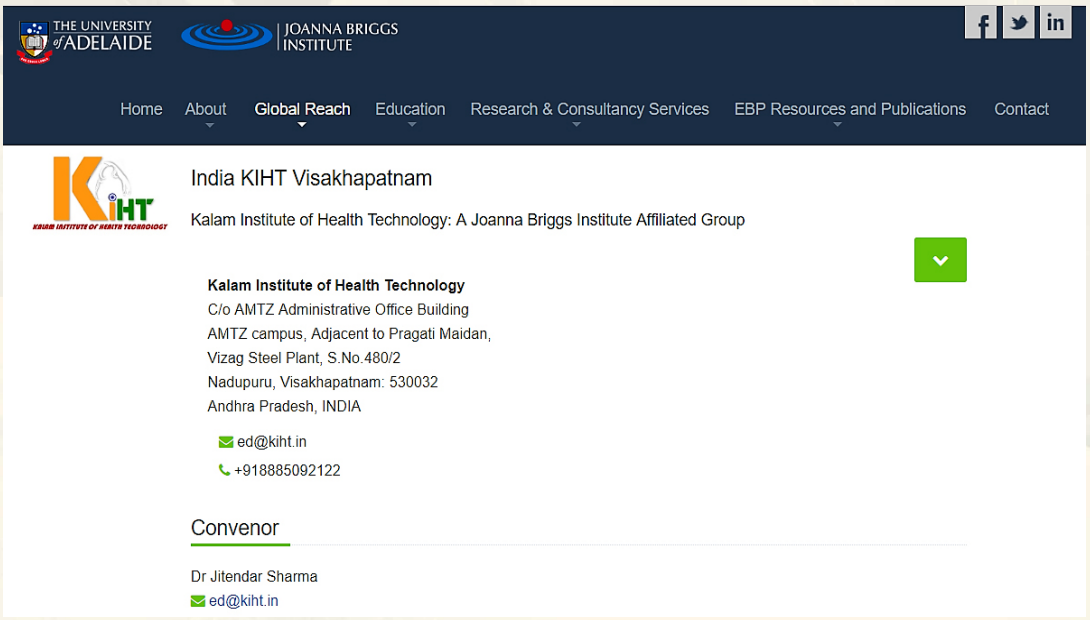


Health Technology Assessment:

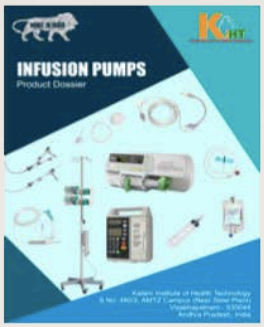
Health technology assessment (HTA) refers to the systemic evaluation of properties, effects and impact of health technology. It is a multidisciplinary process to evaluate the social, economic, organizational and ethical issues of a health intervention or health technology. The main purpose of conducting an assessment is to have informed policy decision making process. HTA division also aids technology transfer and scaling of medical technology by rendering comparative overview of clinical and economic effectiveness of the innovation in a systematic, transparent approach.

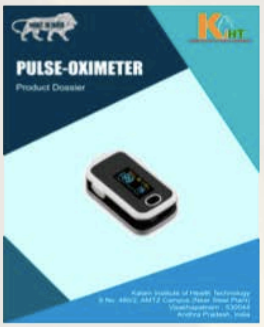
KIHT is recognized as a regional hub by the Department of Health Research, Ministry of Health and Family Welfare, Govt of India for technical support and executing HTA for medical technologies, devices and diagnostics.

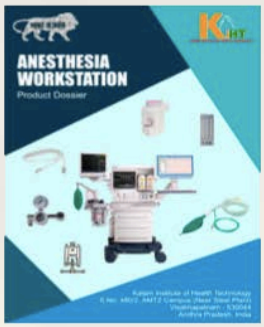
HTA team fromKIHT is trained and certified from the Joanna Briggs Institute, University of Adelaide for systematic review/ meta-analysis.With the mutual collaboration, KIHT is also hosting a nodal centre for handling JBI projects which would conglomerate JBI standards to the health technology landscape of India. Systematic Reviewas per JBI standards would strengthen the HTA programme in the country and open up avenues for government, academia as well as private partners in having more validated health access avenues.

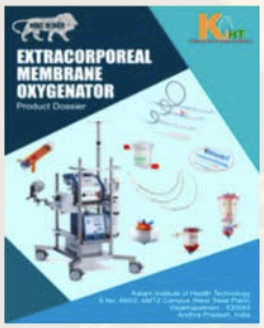


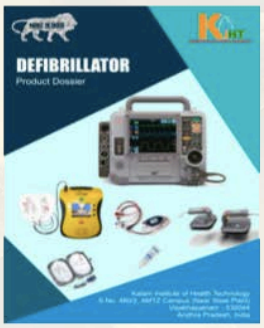
Product Dossiers:

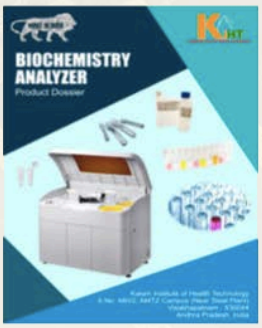












As part of its constant endeavour to cater to the needs of the medical devices industry, KIHT has come out with unique product-wise dossiersto disseminate information specific to devices in healthcare which are complex in technology and import dependent. These user-friendly dossiers capture key features of a product like design, technology, market share, patent status, etc. and facilitates users like start-ups, researchers, academicians, manufacturers and other stakeholders in taking decisions on R&D, investment, potential market, innovations etc.

Policy Reports

The following policy reports were prepared in 2017-18 by KIHT:

i) Disease Burden of India

The Disease burden of India report prepared by KIHT documented need-based research funding in medical technology sector. Medical technologies relevant to the Indian burden of disease were mapped to their export and import data to arrive at the first ever national priority list of essential medical technologies relevant to the Indian context. This report served as the main backbone for the medical devices segment in the national biopharma mission grant call from BIRAC which promulgated need-based research funding.

ii) Pre-owned and Refurbished Medical Device Market in India

Healthcare is an essentiality which can at times be expensive for a large proportion of Indian population where the per capita health expenditure is only 1.41% of GDP (accounting to barely USD 132) much behind the world average of 5.99% of GDP. This meagre margin puts India at 145th place among World

Health Organization (WHO) nations. One possible avenue for a limited healthcare access country like India in providing quality and affordable healthcare is the option of reusing medical devices. Reusing or refurbishing is an effective cost-efficient strategy to protect the product's functional attributes while allowing patient access to safe and economical medical equipment.

Medical equipment put into service essentially meets safety standards and effective usage as defined by the manufacturer. Those devices which have been refurbished or reengineered are hence recommended to be considered as remanufactured and should meet the same set of parameters as the Original Equipment Manufacturer (OEM). This report gives an overview of pre-owned medical device market in India, guidelines and regulations followed by different countries and preface on the phased reduction of imported refurbished products and anti-dumping policies in India per se.

iii) Synoptic view on greenfield & brownfield investments in medical devices sector in India

Foreign Direct Investment (FDI) has mainly two kinds of investments, Greenfield and Brownfield. In Greenfield investment, a parent company builds its operations in a foreign country from the scratch which also includes establishment of new distribution hubs and offices.

Whilst, in brownfield investment, a company or government entity purchases or leases existing production facilities to launch a new production activity in the foreign country, as the structure already stands.

A company may prefer a greenfield or brownfield investment that depends on various factors which includes as follows:

- Global strategy of the company
- Opportunities for their product portfolio
- Access to capital and human resources
- Outsourcing of manufacturing facility to save cost

This report highlighted that India will become the global market for medical devices manufacturing and export by allowing both Greenfield and Brownfield investments and investments can be boosted up by taking suitable action for filling the gaps that are prevalent in the sector:

1. Greenfield investments be allowed up to 100% and Brownfield investments be capped to 49%. In addition, 10% of the Brown field investment could be invested in Research & Development.

2. Export processing zones be established for the purpose of encouraging the exports of the indigenously manufactured medical technology products.

3. Tax exemptions be provided such that the companies reinvest their profits earned in the previous financial year for the company's expansion.

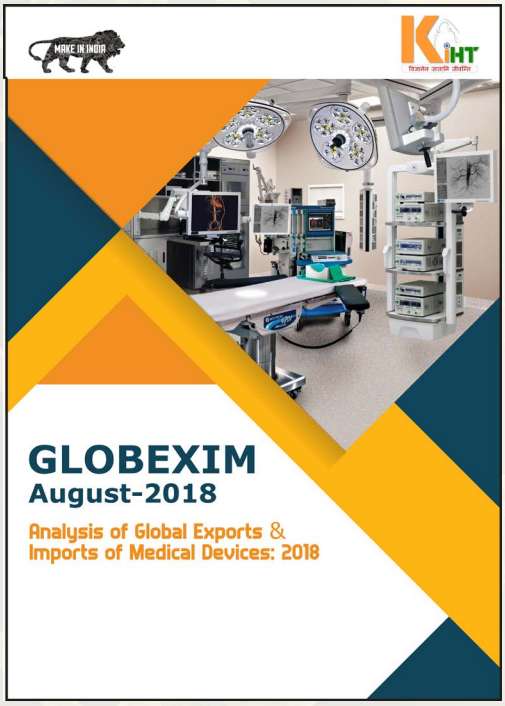
4. Interest free loans be made available so that the companies will establish their state of art infrastructure in India.

iv) Endoscope Reprocessing

Healthcare is expensive for a large proportion of the population, in spite of high per capita income and good health insurance penetration. Reprocessed devices reduce cost of the procedure, there is a potential risk of compromising patient safety due to cross contamination due to inadequate sterilization. There is also risk of performance alteration of reprocessed devices during sterilization/disinfection processing. Therefore, there is a need for formulating proper guidelines to decide methods of reprocessing for endoscopy equipment. This report highlights recommendations on the guidelines to be followed by clinical settings for the safety of patients during the re-use.

v) Medical Devices EXIM Report

The 2018 Medical Devices EXIM Report is an insightful compilation of information about EXIM analysis of medical devices. With ageing population worldwide and sustained demand for better health, the health care sector is poised to grow significantly. Medical devices industry is a growing field and the potential for growth is the highest among all sectors in the healthcare market. The EXIM report provides the reader a perspective about the gamut of medical devices industry, its development and the available market opportunities.



KIHT Contributions:

- Back-end support for policy decisions in pricing by Govt. of India (price capping of stents and total knee replacements)
- Preliminary review of BIRAC shortlisted projects under National Biopharma Mission I3 programme
- CIM released the tender for empanelment with various testing, inspection and certification agencies to certify the germinating innovations in healthcare sector under NIPUN scheme

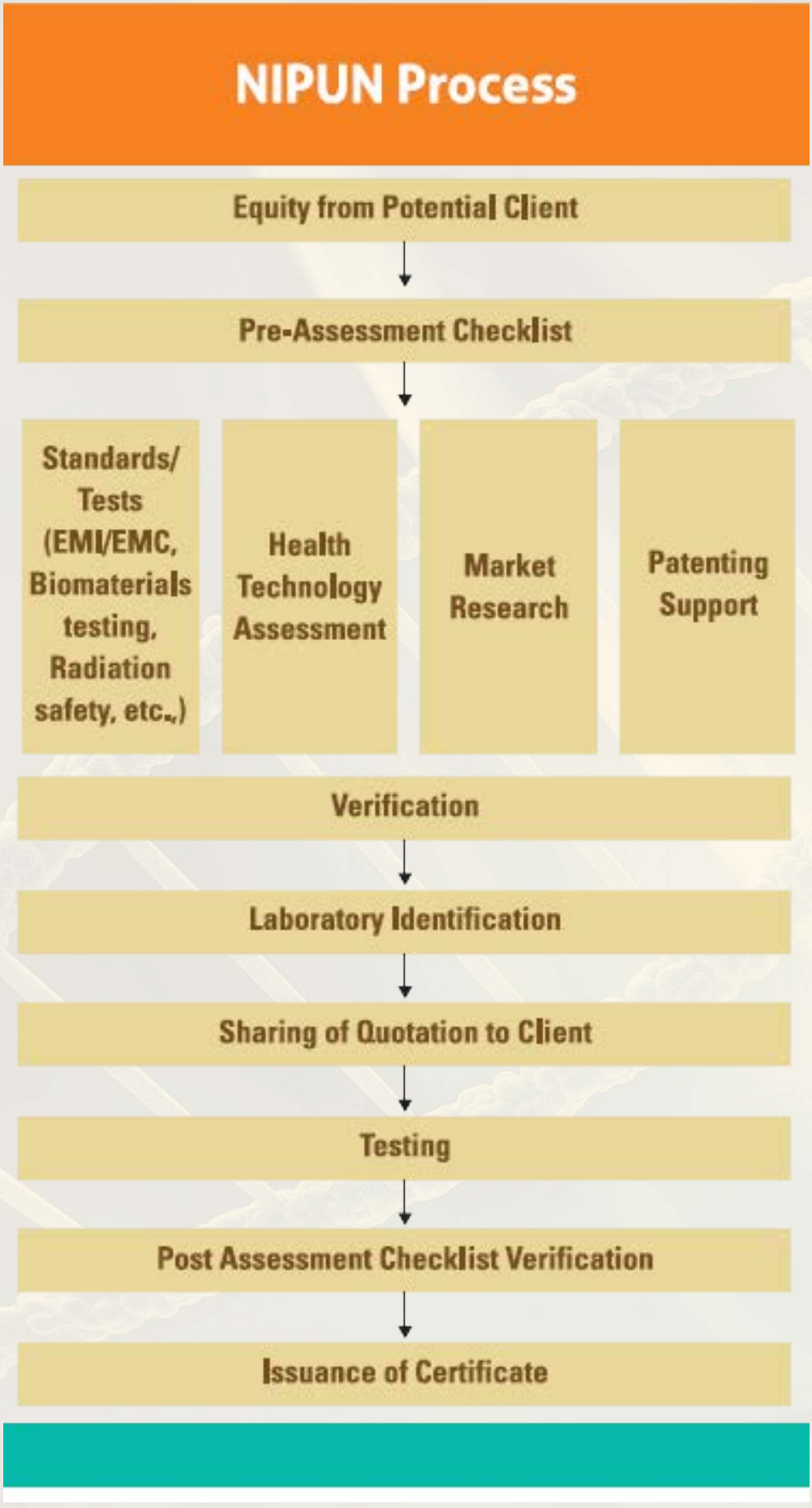
Non-Regulatory Innovation Potential-Utility-Novelty (NIPUN) Certification

The regulatory and non-regulatory process involved in the highly complex medical technology sector is a huge dissuading factor for innovators / manufacturers to commercially exploit their innovations / product initiative. There are globally accepted practices defining standards, quality of the product, efficacy, safety aspects, etc. which needs to be imbibed by Indian stakeholders in a systematic way.

To address the concerns of such stakeholders and act as a single point window for all non-regulatory requirements of the medical technology sector, as also provide a simplified approach to the current process in the commercialization of product, KIHT has launched this initiative of NIPUN (Non-regulatory innovation Potential Utility Novel Certificate). This pioneer initiative takes care of all the process relating to having a certified product in hand for gaining market access.

NIPUN - launch by Principal Scientific Advisor to Govt. of India, Prof. K. Vijayraghavan

NIPUN covers all aspects relating to mapping of suitable standards, confirmatory assessment in empanelled labs, product testing, comprehensive Health Technology Assessment, and all other associated steps required to move for regulatory filing in various markets as also seek market authorisation within the country. The certificate issued by KIHT is accompanied by all outcomes, research studies and certifications required for the product and the data provided could be used for regulatory filing in India and abroad.


NIPUN Process
Equity from Potential Client
Pre-Assessment Checklist
Standards/ Tests (EMI/EMC, Biomaterials testing, Radiation safety, etc.,)
Health Technology Assessment
Market Research
Patenting Support
Verification
Laboratory Identification
Sharing of Quotation to Client
Testing
Post Assessment Checklist Verification
Issuance of Certificate

CHAPTER 3

Events

KIHT extensively participated in most major medical devices and allied technology meets, conferences, conclaves, forums across the country. This included major events hosted by institutions like IISc, IITs, institutions of excellence and research centres as also those hosted by industry organisations like CII, FICCI, PHD Chamber of Commerce etc. There were also invitation from Embassies of Foreign countries which showed interest in Indian R&D in the medtech sector.

In its first year of inception itself, KIHT became a noted institution in the academic and industry circles pan India, as representatives actively participated in delivering talks, lecture series and speeches on evolving modalities of medical technology, the relevance of government policies in academic research and promotion and facilitation offered by KIHT in various disciplines.

Formative Industry leaders Research institutesStart-up partners Technology Meet

KIHT organized the Formative Industry leaders Research institutes Start-up partners Technology (FIRST) Meet on 21-22 August 2017. The main objective of this meeting was to discuss the core technologies involved in manufacturing of medical devices, to identify the critical components and explore the opportunities of doing relevant research and development to ensure that manufacturing can be done in India in future related to the prioritized medical devices.

The outcome of this meeting lead to the National Biopharma Mission call for funding proposals in selected technologies which the nation decided to prioritize on. This was the first instant where funding opportunities for MedTech innovation were mediated through need-based approach, an endeavour incepted and carried out by KIHT through BIRAC under Department of Biotechnology.

8th International HTA fellowship

The 8th International Fellowship Program on HTA was organized from March 05-09, 2018 and successfully trained 35 participants on HTA process and benefits. Eminent facultyrepresenting national and international organizations included:

- Dr. Jitendar Sharma, Executive Director, KIHT; MD & CEO, AMTZ
- Prof. Prakesh Shah, Director, Canadian Neonatal Network; Professor, Dept of Pediatrics and HPME, Univ. of Toronto.
- Dr. Anirban Basu, Professor & Director, Pharmaceutical Outcomes Research and Policy program, University of Washington.
- Dr. Roli Mathur, Scientist'D', Division of BMS, Indian Council of Medical Research

HTA Fellowship Program

LEARN – Product Specific Workshop Series

KIHT conducted its first unique workshop in the series titled 'LEARN' which imparts knowledge on five major dimensions of a specific medical device namely Live product teardown, Explore funding opportunities, Analysis of market potential, R&D strategizing, and Next level upgradation. The main objective of this unique program is to promote and accelerate indigenous manufacturing of medical devices, which is achieved by encouraging start-ups and innovators by providing them with a common platform. In this two-day workshop, three products viz. Anaesthesia Machine, Biochemistry Analyzer and Infusion pumps were covered and total of 31 biomedical professionals from all corners of India have participated.

Review on Government Funded Research Projects in the area of Medical Technology by Principal Scientific Advisor:

KIHT hosted the first round of meeting as part of comprehensive review of research projects in the medical technology space funded by several ministries / departments which was held on 30th April 2018. 29 people from various IITs and research organisations have attended the meeting and presented the status of ongoing projects and the issues that are facing currently. Principal Scientific Advisor to Government of India along with Dr. Jitendar Sharma ED, KIHT suggested various services offered by KIHT including technology transfer and NIPUN certification which helps in achieving the respective project's objectives.

CHAPTER 4

Collaborations/MoUs

In process of capacity building in the country on HTA, KIHT has also signed MOU with Tata Institute of Social Sciences and developing a Post Graduate Certification programme on Health Technology Policy and Research Outcome.

For facilitating transfer of healthcare innovations from academia and research institutions to manufacturers, KIHT is making MoUs with educational institutions and research organizations. Since the inception, KIHT has made around 13 MoUs exclusively for Technology transfer including:

18 Jan 2018	IIT Bombay
04 Feb 2018	IIT Guwahati
10 Feb 2018	CSIR-CSIO, Chandigarh
10 Feb 2018	DST-Centre for Policy Research (DST-CPR) at Panjab University
25 Feb 2018	Mavom Labs, Bangalore
25 Feb 2018	Nextec Lifesciences Pvt. Ltd., Lucknow
25 Feb 2018	PSPR 3D Tech, Hyderabad
25 Feb 2018	National Research Development Corporation
28 Feb 2018	College of Engineering, Pune
28 Feb 2018	Periwinkle Technologies Pvt. Ltd, Pune
28 Feb 2018	Adiuvo Diagnostics Pvt Ltd, Nellore
28 Feb 2018	Dr Vijay Panchanadikar, Pune
29 Mar 2018	Muse Diagnostics Private Limited, Karnataka

MoU signing with various parties

As part of initiating various projects related to healthcare and medical technology, KIHT also made MoUs with diverse stakeholders for different objectives including (Madhuri)

- CSIR-CGCRI
- Biotechnology Corporation of India Limited
- IIPHG
- M.S. Ramayya Institute of Technology, Bangaluru
- LOYOLA COLLEGE
- CSIR-Central Scientific Instruments Organisation

Collaborations

Indian Angel Network (IAN)

Leveraging Innovative & Germinating Health Technologies for Indigenous Capacity Building (LIGHT) is a novel funding platform which is coined by the Kalam Institute of Health Technology (KIHT) and collaboratively organised by Indian Angel Network (IAN) and Andhra Pradesh MedTech Zone (AMTZ). This unique program aims to enhance funding probability and market access for the start-ups/ manufacturers/ innovators etc. in medical technology field which will in turn boost the indigenous manufacturing.

IAN have agreed to co-invest in start-ups in a 1:4 ratio along with KIHT (KIHT-20%, IAN-80%). It was proposed that KIHT's 20% support for rapid R&D would be interest free loan which would be recoverable in full within four years, thereby presuming its corpus funding.

Diaserve Project

Chronic kidney diseases are ever increasing in India along with exceeding higher prices for dialysis. The major component of the haemodialysis process, the dialyzer was till date entirely imported. KIHT CIM team took initiatives to first ever 30 pieces of dialyzer indigenously prepared units with due diligence testing and compliance. The project is in process, possibility of manufacturing indigenous for over 30 lakh units also in realisation stages.

BIS Membership

Bureau of Indian Standards is the National Standards Body engaged in the formulation of Indian Standards in various areas of Science and Technology. Indian Standards on Medical Devices and related subjects are developed by 19 Sectional Committees under Medical Equipment and Hospital and Planning Division Council. These 19 Sectional Committees have developed more than 1100 Indian Standards. Dr. Jitendar Sharma, Executive Director and Mr. Kingshuk Poddar, Assistant Director are nominated for 15 technical committees of Medical Equipment and Hospital Planning Department of BIS to contribute in the formulation of National Standards on relevant subjects. The Indian Pharmacopoeia Commission had a detailed meeting with KIHT-AMTZ on avenues of standards specification on MedTech and nutraceuticals and have agreed to endow KIHT with the task of consolidating appropriate standards in this purport. CIM will be carrying out this responsibility along with subject matter experts from AMTZ.

Plasma Fractionation Facility

The consumption rates for two important plasma proteins- Albumin and IVIG, far surpass the rates of production, thereby making establishment of a plasma products company not just a scientific necessity but also an indispensable socio-economic obligation.For contract manufacturing of plasma derived medicines within AMTZ, tender document for is prepared by CIM and stakeholder consultation is in progress.

Wolbachia Project

Taking into account the growing menace of dengue fever arising from mosquitoes, Department of Health, Govt. of Andhra Pradesh has initiated Wolbachia mediated dengue prevention program which is initiated and monitored by KIHT. Government issued the above mentioned work order to Dr H P Puttaraju, (Bangalore University) and Rev. Dr S. Ignacimuthu,S.J. (Director, Entomology Research Institute, Loyola College, Chennai) as service providers and the allotment of fund and scientific monitoring of the project were carried out by the CIM team.

MedikaBazaar for e-auctioning technologies

KIHT has strategically partnered with MedikaBazaar, for increasing the visibility of healthcare innovations present in the e-Auction portal. MedikaBazaar is the leading online portal (India's Medical Device Flipkart), selling finished medical devices. It liaisons with manufacturers and the end-users who wants to buy medical devices. As MedikaBazaar has approximately 8500 medical device manufacturers, distributors, importers etc., every e-auction item KIHT approves for auctioning, MedikaBazaar automatically receives the details thereby it updates its database sends email and message to all its stakeholders on the details of auctioning technology. Partnering with MedikaBazaar has increased the visibility of healthcare technologies that are being auctioned in e-auction portal.

First Governing Body Meeting November 10, 2017

First Executive Body Meeting January 18, 2018

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