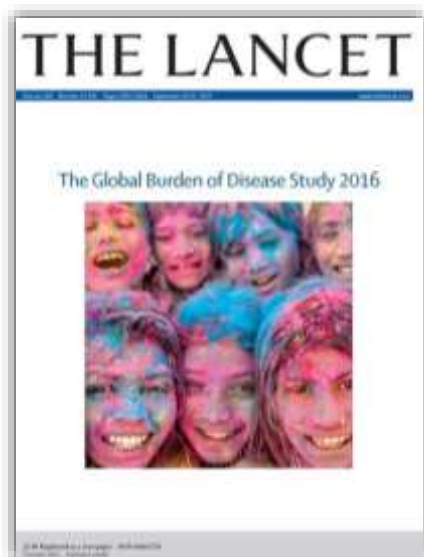


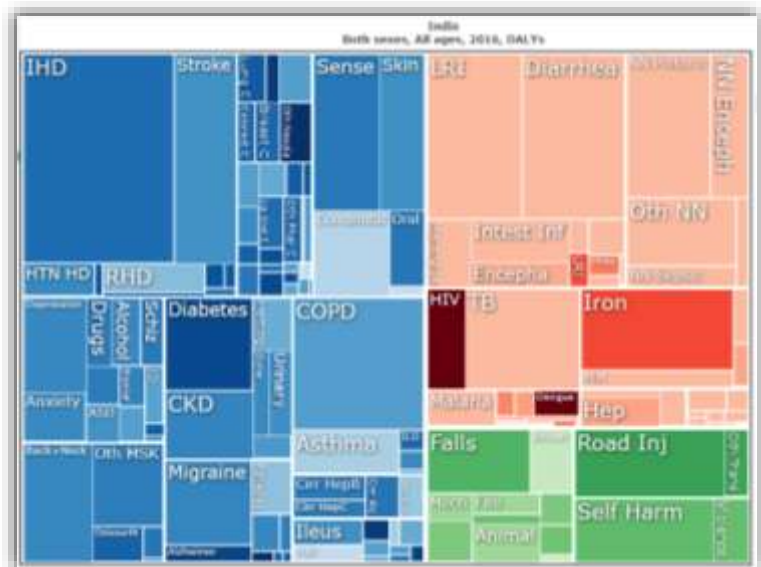
# A Policy Perspective on Real World Evidence & Role of HTA



**Dr. JK Sharma**  
**Managing Director & CEO, AP Med Tech Zone (AMTZ)**  
**Executive Director, Kalam Institute of Health Technology**  
**Chairman, Indian Bio-Medical Skill Consortium**



<https://www.thelancet.com/gbd>



<https://vizhub.healthdata.org/gbd-compare/india>



# DISEASE BURDEN

## Global, regional, and national age-sex specific mortality for 264 causes of death, 1980–2016: a systematic analysis for the Global Burden of Disease Study 2016

GBD 2016 Causes of Death Collaborators\*

### Summary

**Background:** Monitoring levels and trends in premature mortality is crucial to understanding how societies can address preventable causes of early death. The Global Burden of Disease 2016 Study (GBD 2016) provides a comprehensive assessment of cause-specific mortality for 264 causes in 195 locations from 1980 to 2016. This assessment includes evaluation of the expected epidemiological transition with changes in development and where local patterns deviate from these trends.

## Global, regional, and national under-5 mortality, adult mortality, age-specific mortality, and life expectancy, 1970–2016: a systematic analysis for the Global Burden of Disease Study 2016

GBD 2016 Mortality Collaborators\*

### Summary

**Background:** Detailed assessments of mortality patterns, particularly age-specific mortality, represent a crucial input that enables health systems to target interventions to specific populations. Understanding how all-cause mortality has changed with respect to development status can identify opportunities for best practice. To accomplish this, the Global Burden of Diseases, Injuries, and Risk Factors Study 2016 (GBD 2016) estimated age-specific and sex-specific all-cause mortality between 1970 and 2016 for 195 countries and territories and at the subnational level for the five countries with a population greater than 200 million in 2016.

## Measuring progress and projecting attainment on the basis of past trends of the health-related Sustainable Development Goals in 188 countries: an analysis from the Global Burden of Disease Study 2016

GBD 2016 SDG Collaborators\*

### Summary

**Background:** The UN's Sustainable Development Goals (SDGs) are grounded in the global ambition of "leaving no one behind". Understanding today's gains and gaps for the health-related SDGs is essential for decision makers as they aim to improve the health of populations. As part of the Global Burden of Diseases, Injuries, and Risk Factors Study 2016 (GBD 2016), we measured 37 of the 16 health-related SDG indicators over the period 1990–2016 for 188 countries, and then on the basis of these past trends, we projected indicators to 2030.

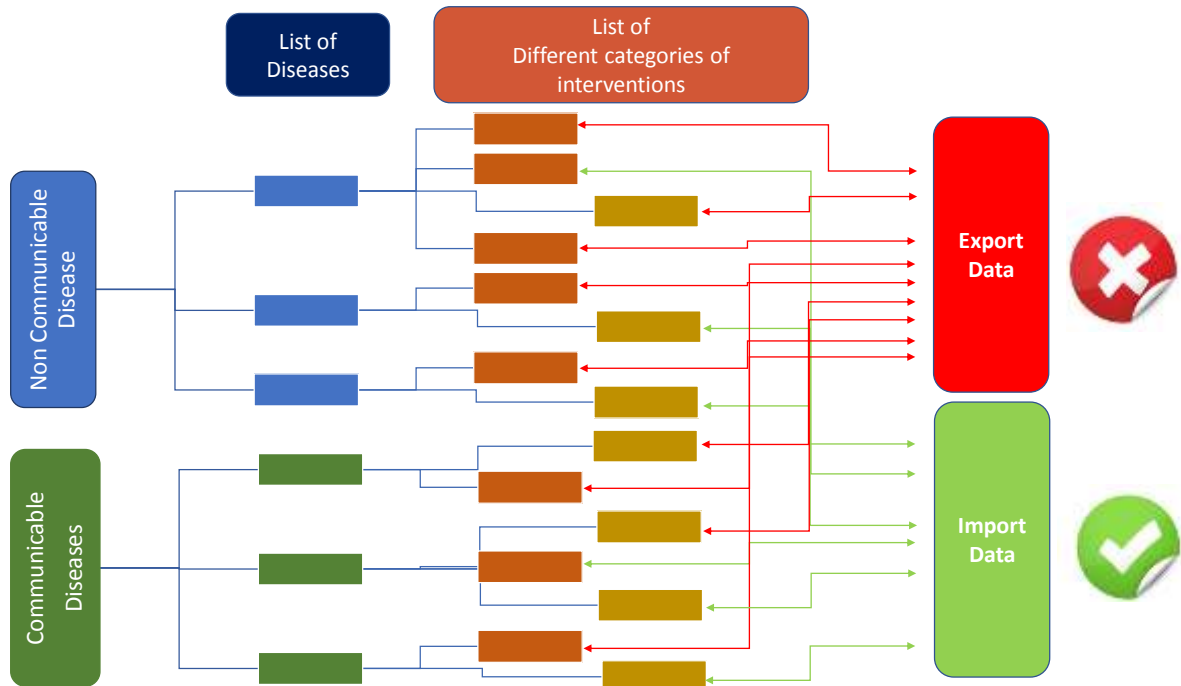
## Causes of death among children aged 5–14 years in the WHO European Region: a systematic analysis for the Global Burden of Disease Study 2016

Stevenson E, Gaudet S, Szeles B, Smith P, Piro S, Robinson S, White T, Sherrin P, Patel J, Anand S, Fildes M, Kelly C, van Riepen S, Goh S, Adams C, Wang C, Wang G, Ffrench-DuResay S, Christopher J, Wang\*, M, Mubarek\*, M, Kumar Nigam\*

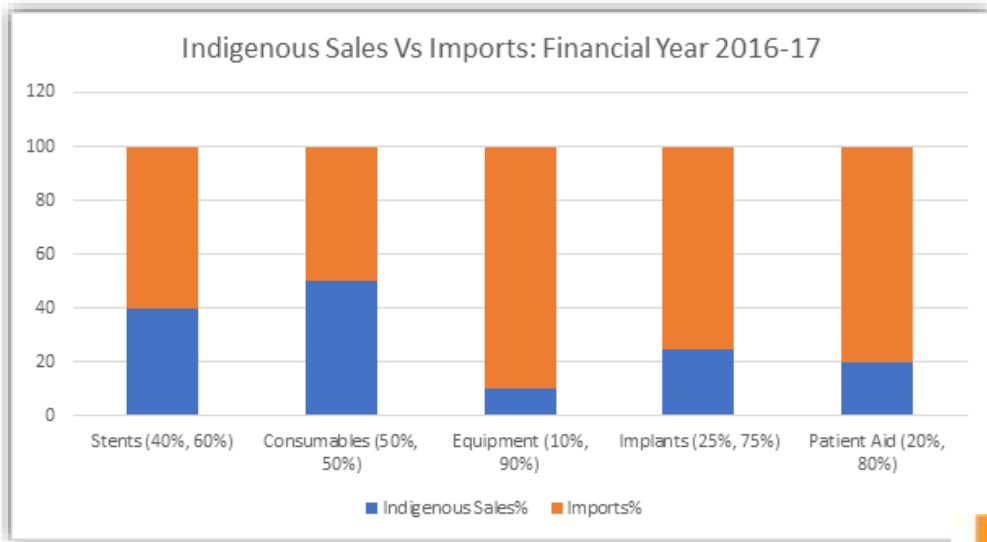
### Summary

**Background:** The mortality burden in children aged 5–14 years in the WHO European Region has not been comprehensively studied. We assessed the distribution and trends of the main causes of death among children aged 5–14 years and 10–14 years from 1990 to 2016, for 51 countries in the WHO European Region.

# Local Evidence Generation Through Global Parameters



# Market Intelligence and Trade



## STAKEHOLDERS CONSULTATION

Formative Industry leaders Research institutes Start-up Partners Technology Meet (FIRST)

Core Technological Links (CTLs)

Core Scientific Facilities (CSFs)



Multi Criteria Decision Analysis (MCDA)



# Government Policy In Research Grant Allotment



**Department of Biotechnology**  
Ministry of Science & Technology  
Government of India

**biac**  
Bioscience Industry Assistance Council  
Public Sector Undertaking of DBT

**National Biopharma Mission**  
INDUSTRY – ACADEMIA COLLABORATIVE MISSION  
FOR  
ACCELERATING EARLY DEVELOPMENT  
FOR BIO-PHARMACEUTICALS  
**Innovate in India (i3)**

Inviting Proposals in the areas of:  
**•Vaccines •Biotherapeutics •Medical Devices & Diagnostics**

Industry – Academia Collaborative Mission of Department of Biotechnology, Ministry of Science & Technology, Government of India for Accelerating Early Development for Biopharmaceuticals; to be implemented by Biotechnology Industry Research Assistance Council (BIRAC) – a Public Sector Undertaking of DBT. The National Biopharma Mission is approved for implementation at a total cost of 2163.2361 million, which is 52% co-funded with World Bank Loan Assistance.

This Request for Proposals (RFP) is to seek technical applications on either of the following:

**FOCUS OF THE CALL**

<p><b>1. Vaccines</b></p> <ul style="list-style-type: none"> <li>Support for accelerating development of:           <ul style="list-style-type: none"> <li>Novel vaccine candidates for HIV, Dengue and Pneumococcal</li> <li>Novel and complex vaccine candidates for other diseases of high burden and priority in India</li> </ul> </li> </ul>	<p><b>2. Biotherapeutics</b></p> <ul style="list-style-type: none"> <li>Support for development of biosimilars (therapeutic protein and monoclonal antibodies) for cancer, rheumatoid arthritis and diabetes</li> <li>Support for establishment of:           <ul style="list-style-type: none"> <li>Process Development Laboratory</li> <li>CMC Facility</li> <li>GLP Validation Facility</li> <li>Cell-Line Repository</li> </ul> </li> </ul>	<p><b>3. Medical Devices &amp; Diagnostics</b></p> <ul style="list-style-type: none"> <li>Support for accelerating development of:           <ul style="list-style-type: none"> <li>Critical medical device technologies for relevant product segments</li> <li>Core technologies as platform technologies for priority products</li> </ul> </li> </ul>
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**How to Apply:**  
Detailed Mission Document and RFPs can be seen at [www.biac.in/nationalbiopharmamission.php](http://www.biac.in/nationalbiopharmamission.php)  
Proposals to be submitted online. Please log on to [www.biac.nic.in](http://www.biac.nic.in).  
Last date for Submission: 15th December, 2017.  
Queries please contact: Head NBM, Email: [technical.biac@gov.in](mailto:technical.biac@gov.in)



**KALAM INSTITUTE OF HEALTH TECHNOLOGY**  
(e-Auction Web Portal)

Home About KIHT About AMTZ Contact Us Auction Free View Bidder Registration  
.....Auction Wizard.....

Organization Motto: Vigyanena Jaataani Jeevanti/ विज्ञानेन जातानि जीवन्ति

**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 shall be achieved through transfer of technical knowledge and bringing strategic and coherent synergy of scientific facilities and institutions to compliment efforts on industrial promotion in the medical devices segment. It lives to bring increased access to affordable health products to citizens and a thriving medical devices manufacturing sector in India

**Solution Provided by**

Antares

Latest circulars/Formats?

Verify PKI Settings

System Requirement

Utilities

Autodesk DWG Viewer

View AutoCaddrawing files.

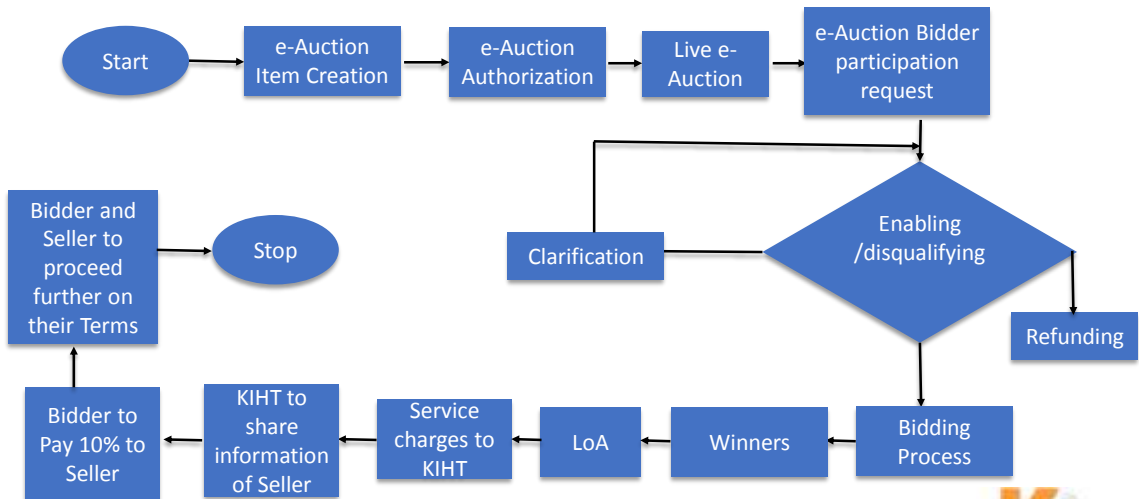
Get Acrobat Reader

To View PDF files

**Certifications**

Digitcert  
STQC

## E-AUCTION PROCESS FLOW



9



## TESTING AND CERTIFICATION

**KALAM INSTITUTE OF HEALTH TECHNOLOGY**

**Non-regulatory Innovation Potential Utility & Novelty Certificate**  
**(NIPUN - निपुण)**

**SERVICES OFFERED**

- Business Plan Reality Check**  
 Scrutinize the plans from every angle to ensure that the product will meet the end-user's needs
- Quality compliance**  
 To complete the design, development, manufacture and certification of medical devices
- Market Access Avenues**
  - Health Technology Assessment
  - Systematic Review/Meta Analysis
  - Program efficiency model
  - Uptake model

**Testing**

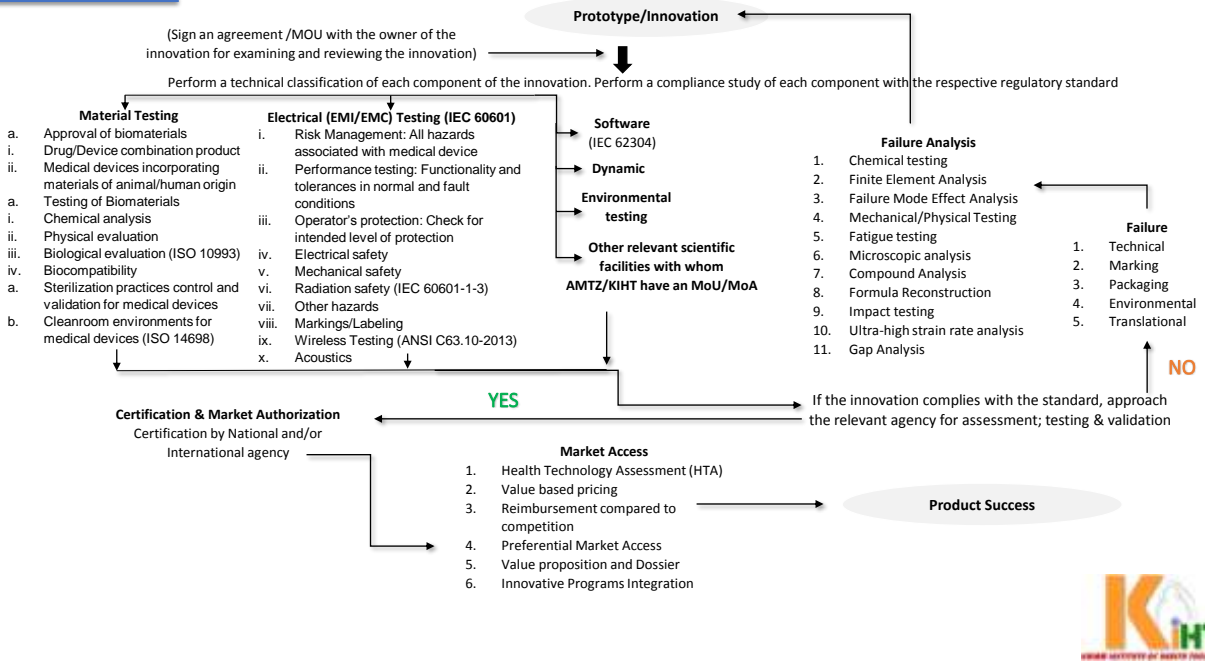
Helps in testing to comply with applicable standards

- ElectroMagnetic Interference (IEC 60601 series)
- ElectroMagnetic Compatibility (IEC 60601-1-2)
- Electrical safety testing
- Biocompatibility (ISO 10993)
- Good Manufacturing Practices (ISO 13485)
- Software testing (IEC 62304)
- Material testing (Relevant ASTM standards)
- Radiation protection (IEC 60601-1-3)

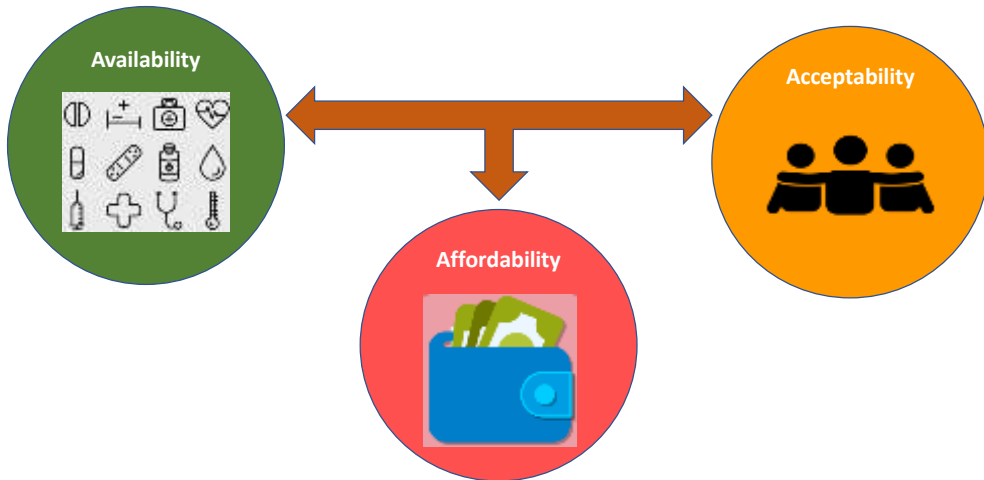
**Rapid Prototyping**

Support the clients in manufacturing

- Low Volume
- High Complexity



## Criteria's adopted to undertake Medical Devices in India through Health Technology Assessment



# Components of HTA



Safety



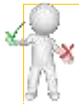
Clinical Effectiveness



Economic evaluation



Budgetary Consideration



Ethics



Legal & Regulatory



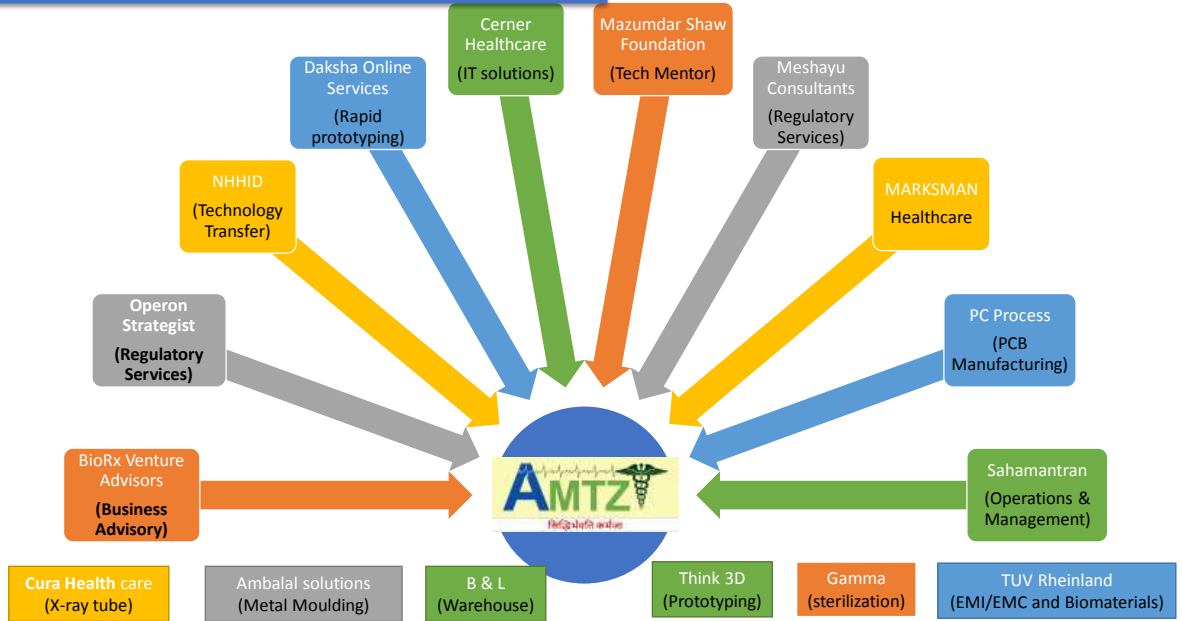
Feasibility



## Research and Development and Manufacturing Support



# State-of-the-art Scientific Facilities



**INNOVATION → MARKET → ACCEPTANCE BY PROVIDERS  
HEALTH TECHNOLOGY ASSESSMENT ACT AS A IMPORTANT  
EVIDENCE BASED TOOL**

