SHORT ARTICLE

# Developing a New Assistive Technology: Parameters, Standards and Compliance Frameworks

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**CITATION**
Sharma HK. Developing a New Assistive Technology: Parameters, Standards and Compliance Frameworks. Journal of the Epidemiology Foundation of India. 2025;3(1Suppl):66-70.
DOI: https://doi.org/10.56450//JEFI.2025.v3i1Suppl.009
**ARTICLE CYCLE**
Received: 10/11/2025; Accepted: 15/12/2025; Published: 31/12/2025


## ABSTRACT

**Background:** Assistive Technology (AT) development in India lacks a unified compliance and regulatory framework. **Objective:** To provide a framework that guides innovators in developing ATs aligned with regulatory, ethical, and quality standards. **Methods:** A comprehensive synthesis of national (ICMR, CDSCO, BIS, MoHFW, MeitY, MoSJE) and international (ISO, IEC, FDA, WHO, CE) standards was undertaken to frame a multi-tier compliance pathway. **Results:** A structured compliance process integrating user-centric design, safety testing, ethical, clinical validation, and digital interoperability was developed. **Conclusion:** The proposed framework enables developers to design, test, and commercialize ATs safely, ensuring compliance, accessibility, and sustainability across India's regulatory ecosystem.

## KEYWORDS

Assistive Technology; Compliance Framework; Standards; Accessibility

## INTRODUCTION

Assistive Technology transforms independence and well-being for individuals with functional impairments(1,2). However, AT innovation in India faces fragmented compliance pathways, inconsistent validation standards, and limited end-user integration particularly in low-resource settings(2). The absence of a unified framework encompassing technical, clinical, ethical, and digital standards has restricted scalable AT development(2). This paper presents a structured, multi-dimensional compliance roadmap integrating Indian (ICMR, CDSCO, BIS, MoHFW, MeitY, MoSJE) and global (WHO, ISO, IEC, FDA, CE) frameworks as a practical guide for innovators from concept to deployment, ensuring safety, inclusivity, and accessibility.

**Core Parameters for Assistive Technology Development:** AT development begins with understanding core parameters determining design, validation, usability and acceptability. The proposed ten-parameter framework outlines essential technical, regulatory, and ethical dimensions (Table 1)(2,3). These include user-centered co-design, biocompatibility, durability, affordability, interoperability, and sustainability. Alignment with ISO 9241 (usability), IEC 60601 (safety),

and ISO 10993 (biocompatibility) ensures reliability(4–6). Cultural and environmental adaptability are equally important ATs must use locally manufacturable components, support multilingual use, and adhere to RoHS and E-Waste Management Rules (2022)(7).

**Table 1: Core parameters for Assistive Technology development.**

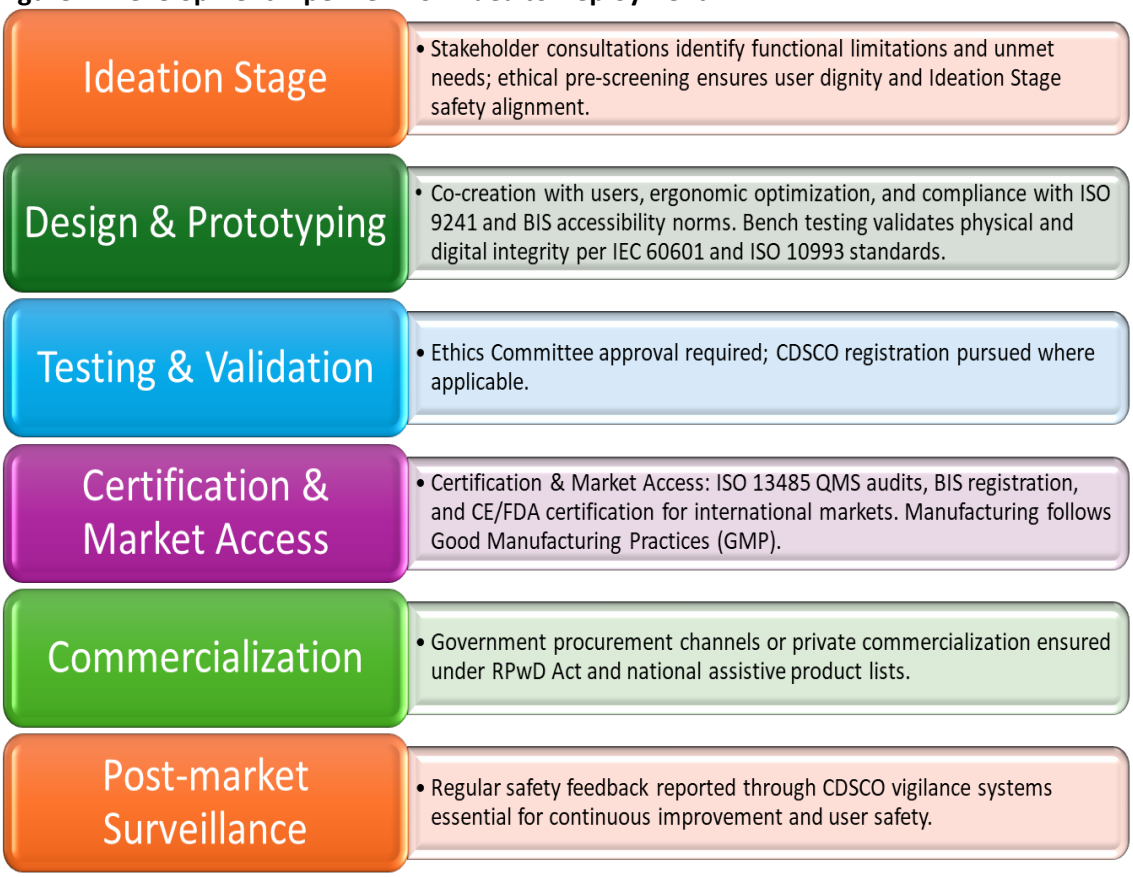
| Parameter | Description / Focus | Key Considerations |
|---|---|---|
| **User-Centric Design** | Developed in consultation with intended users (functionally impaired, elderly, caregivers). | Participatory design workshops, user trials, ergonomics, human–machine interface optimization. |
| **Functional Efficacy** | Device must perform its intended assistive function reliably. | Task performance tests, response accuracy, speed, adaptability to individual differences. |
| **Safety and Biocompatibility** | Avoid any physiological or electrical harm. | IEC 60601 (medical electrical safety), ISO 10993 (biocompatibility for wearables). |
| **Reliability & Durability** | Long-term mechanical, electrical, and environmental stability. | Temperature, vibration, and stress testing; IP ratings for dust/water resistance. |
| **Affordability & Scalability** | Cost-effective, locally manufacturable, maintainable. | Modular design, indigenous components, 3D-printing feasibility, repair ecosystem. |
| **Accessibility & Usability** | Easy to learn, intuitive, compatible with diverse user abilities. | ISO 9241 (ergonomics of human–system interaction), WCAG (for software interfaces). |
| **Interoperability & Data Security** | Especially relevant for digital/IoT-enabled ATs. | ABDM compliance, HL7-FHIR standards, data encryption, GDPR/Digital India Act adherence. |
| **Sustainability** | Circular design, energy efficiency, eco-friendly materials. | Lifecycle analysis, recyclable materials, RoHS compliance. |
| **Cultural & Contextual Relevance** | Adapted to India's local needs, environment, and cultural diversity. | Language localization, usability in rural and urban settings. |
| **Ethical Considerations** | Ensuring respect, dignity, and informed consent of users. | Ethics committee approvals, inclusivity principles, data privacy safeguards. |

**Regulatory and Compliance Frameworks (India and Global):** While the development pipeline (Figure 1) outlines the sequential stages for AT development, each stage is governed by specific regulatory and compliance requirements. Understanding these frameworks is essential for developers to navigate the pathway successfully and ensure their device meets all mandatory standards.

In India, ATs are governed by CDSCO under the Medical Device Rules, 2017, categorizing products from Class A (low-risk) to Class D (high-risk). Compliance mandates ISO 13485 for quality management and IEC 60601 for safety in all electronic and medical devices. Software-based Ats, particularly AI-enabled or digital applications require CDSCO, BIS, and MeitY approvals under the Software as a Medical Device (SaMD) category(8,9).

India's accessibility standards (GIGW 3.0, BIS IS 17802:2021, RPwD Act 2016) ensure "accessibility by design"(10). Global market entry requires CE, FDA, and ISO 9999 compliance(10). Data security must align with ISO/IEC 27001 and the Digital Personal Data Protection Act (2023). Clinical validation follows IEC 62304 and ISO 14155, with ethics approval obtained under ICMR National Ethical Guidelines (2017; 2023 Addendum) before human trials. Environmental compliance includes RoHS and E-Waste Management Rules (2022). For example, a developer creating an AI-powered mobility aid would classify it as Class C/D (high-risk), requiring full CDSCO approval, biocompatibility testing, clinical trials, ABDM integration, and data security audits before market entry(4–11).

**Figure 1: Development Pipeline: From Idea to Deployment**




**Institutional Alignment in India:** India's AT development ecosystem comprises interconnected institutions: ICMR (biomedical R&D and ethical oversight), MoHFW/CDSCO/DGHS (device clearance and post-market safety), DST/DBT/MeitY (innovation funding and technical standards), MSME/SIDBI (indigenous production and start-up incubation), MoSJE/DEPwD (inclusion policies), and BIS (safety benchmarks). National hubs (AMTZ, KIHT, SCTIMST) provide testing, validation, and certification support. For digital ATs, interoperability alignment with Ayushman Bharat Digital Mission (ABDM) ensures national health data system integration(9,10).

Developers utilizing this ecosystem reduce liability risks, gain faster market access, receive government support, achieve cost-effectiveness through shared infrastructure, and ensure long-term sustainability through standardized pathways.

**Ethical, Societal, and Innovation Considerations:** Informed consent, data safeguarding (Digital Personal Data Protection Act 2023), equity across socio-economic groups including rural areas, dignity, and empowerment rather than dependency. Gender- and age-sensitive design ensures inclusivity(9).

Integrate AI for adaptive personalization, enhance indigenous content, maintain affordability within ten percent of comparable global devices, and ensure ABDM interoperability. Performance targets: 85% user acceptance, low-carbon/recyclable materials for environmental sustainability.

**Compliance Checklist Template:** The compliance checklist (Table 2) provides a ready-to-use reference for developers, policymakers, and evaluators to track the readiness of an AT product through each regulatory, ethical, and quality milestone(2,3). This structured tool enables uniform documentation, transparency, and regulatory preparedness fostering standardization across institutions, start-ups, and R&D centers.

**Table 2: Assistive technology development compliance checklist template**

| Section | Parameter / Compliance | Description / Key Requirement | Responsible Agency / Reference |
|---|---|---|---|
| **Regulatory & Legal** | Medical Device Classification | Determine if the AT qualifies as a medical device under MDR 2017 | CDSCO / MoHFW |
| | BIS / ISO Standards Compliance | Check applicable BIS or ISO standards (e.g., ISO 9999 for AT classification) | BIS / ISO |
| | Ethical Clearance | Obtain IEC/IRB approval if user testing is involved | ICMR / Institutional Ethics Committee |
| | Intellectual Property (IPR) | File for patent/trademark/design registration | DPIIT / IP India |
| **Design & Accessibility Standards** | Universal Design Principles | Follow accessibility guidelines (e.g., ISO 9241, GIGW 3.0 for digital) | MoSJE / BIS / NCPEDP |
| | Human-Centred Design Validation | Include end-user feedback and usability testing | ICMR / WHO / User Groups |
| | Assistive Product Classification | Align with WHO APL or ISO 9999 | WHO / BIS |
| **Safety & Quality Testing** | Electrical & Mechanical Safety | Meet BIS/IEC standards for safety | NABL-accredited labs / CDSCO |
| | Biocompatibility / Material Testing | For devices with human contact | NABL / NIB / BIS |
| | Clinical Performance Evaluation | Validate clinical safety and effectiveness | ICMR / MoHFW |
| **Digital Health & Data Compliance** | ABDM Integration | Ensure Health ID, HPR, HFR, and data exchange compliance | NHA / ABDM |
| | Data Privacy & Security | Follow IT Act, 2000 and DPDP Act, 2023 provisions | MeitY |
| | Interoperability Standards | Use HL7 FHIR, SNOMED-CT, LOINC where applicable | NHA / MoHFW |
| **Manufacturing & Scale-up** | GMP / QMS Certification | Obtain ISO 13485 / QMS certification | CDSCO / BIS |
| | Environmental & Waste Compliance | Meet e-waste, RoHS, and eco-design requirements | CPCB / MoEFCC |
| | Indigenous Manufacturing Alignment | Ensure 'Make in India' and Atmanirbhar compliance | DPIIT / MeitY |
| **Market & Post-market Activities** | Pricing & Affordability Assessment | Evaluate cost-effectiveness and inclusion in public procurement | NPPA / MoHFW |
| | User Training & Capacity Building | Develop manuals and training modules | ICMR / RCI / NGOs |
| | Post-market Surveillance | Monitor adverse events and device performance | CDSCO / ICMR |
| **Ethical & Societal Impact** | Inclusion & Accessibility Impact | Assess social inclusion, disability equity | MoSJE / NITI Aayog |
| | Gender & Diversity Considerations | Evaluate design inclusivity | WHO / MoWCD |
| | Environmental Sustainability | Evaluate life-cycle sustainability of materials | MoEFCC |

## RECOMMENDATION

This framework provides a practical roadmap for compliant AT development in India. Innovators should follow the integrated CDSCO, BIS, ICMR, and global standards pathway ensuring regulatory approval, ethical

validation, and product safety. The compliance checklist facilitates uniform progress tracking from design to deployment, fostering transparency and local manufacturing. This unified approach supports safe, affordable, inclusive AT innovation aligned with Industry 5.0 and ABDM, positioning India as a leader in global assistive technology development.

## Authors Contribution

All authors have contributed equally.


## Financial Support and Sponsorship

Nil


## Conflict of Interest

There are no conflicts of interest.


## Acknowledgement

The authors acknowledge the Indian Council of Medical Research (ICMR), New Delhi, for providing institutional support and guidance for this work.


## Declaration Of Generative AI And AI Assisted Technologies In The Writing Process

The authors haven't used any generative AI/AI assisted technologies in the writing process.

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