APACMed
The voice of MedTech

BUILDING A RESEARCH LINKED INCENTIVE (RLI) FRAMEWORK

Making India an Innovation Hub for Medical Devices

KPMG

APACMED INDIA

PARTNER

Indian Medical Parliamentarians' Forum
IMPF

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Foreword

It is with great pride and purpose that we, on behalf of the Indian Medical Parliamentarians Forum (IMPF), present this seminal white paper, **"Building a Research Linked Incentive (RLI) Framework: Making India an Innovation Hub for Medical Devices "**, authored by APACMed and KPMG in India. At a time when India stands at the cusp of redefining its role in the global health ecosystem, this document brings forth a timely, insightful, and actionable roadmap to strengthen our nation's MedTech innovation capabilities.

India's medical devices sector holds immense potential - both to meet our extensive and diverse healthcare needs and to establish itself as a global leader in advanced, inclusive health technologies. Nevertheless, as this white paper clearly explains, this potential is largely underrealised, mainly due to significant gaps in research infrastructure, innovation incentives, and pathways for clinical validation. While notable progress has been achieved in manufacturing through initiatives such as PLI and AatmaNirbhar Bharat, research and development-particularly in high-technology, design-led, and patient-centric medical devices-remains fragmented, underfunded, and disconnected from international innovation networks.

The proposed Research Linked Incentive (RLI) framework addresses this systemic gap head-on. It offers a structured, tiered approach that matches incentives with the maturity and risk levels of innovation, spanning foundational research, prototyping, clinical trials, and regulatory readiness. It underscores the urgent need for India to support not just frugal engineering but also frontier innovation in fields such as AI-driven diagnostics, robotic surgery, implantable bioelectronics, and precision imaging. Most importantly, it integrates fiscal support with ecosystem enablers - such as skill development, testing infrastructure, IP monetisation, and regulatory facilitation - essential to building a truly innovation-ready MedTech environment.

This white paper is more than just a policy proposal; it is a call to action. We encourage industry leaders, startups, academic institutions, clinicians, and global capability centres to engage actively, advocate effectively, and align strategically. The success of the RLI framework relies not only on visionary policymaking but also on informed, united, and persistent stakeholder engagement.

The IMPF reaffirms its dedication to promoting evidence-based, innovation-driven health policy. We fully endorse this white paper and recommend it as essential reading for every policymaker, bureaucrat, investor, and healthcare leader committed to shaping India's future in medical technology.

Dr. Anil Bonde MP
Chairperson-IMPF

Dr. Dharamvira Gandhi MP
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1 Context & Objective

As India marches towards a transformative healthcare system, there is a greater role medical device sector can play. India's medical devices sector, which is projected to grow to USD 30 billion by 2030[1], is strategically important for both public & private health as well as economic growth. Over the last decade, the government has taken steps in the right direction to promote innovation across the sector. The focus has been to transition from a cost & volume-based to a value-based and innovation-based industry. Just like the impetus given to 'Make in India,' there is rising focus on 'Innovate in India,' which could enable India to become a desirable destination for R&D in the medical device domain. The vision can be accomplished by developing a strategy and **a robust, purpose-built & promotive R&D architecture**.

This document outlines a strategy to develop an RLI scheme, on the line of PLI scheme to promote "Make in India", promoting "Innovate In India" as a precursor to "Make In India" for medical devices while drawing from best practices across sectors and countries, and identifying critical research activities and gaps in India's Medtech innovation landscape. The proposed Research Linked Incentive (RLI) framework aims to address some of these gaps by incentivizing R&D in Medtech.

1. Press Release: Press Information Bureau

2 Government of India's R&D Vision for the Medical Devices Sector

भारत सरकार
GOVERNMENT OF INDIA
सत्यमेव जयते

India has set an ambitious vision to become a global hub for medical device innovation and manufacturing, as outlined in the **National Medical Devices Policy 2023**. Furthering this vision, the **National Policy on Research and Development and Innovation in the Pharma-MedTech Sector** emphasizes three strategic pillars[2].

1. **Creating an innovation-conducive regulatory environment**
   By expanding the scope beyond safety and quality to also include support for innovation in product development;

2. **Enabling fiscal and non-fiscal incentives**
   To crowd-in private and public investments by de-risking early-stage and translational research;

3. **Strengthening the innovation ecosystem**
   By promoting public-private-academic partnerships and building institutional mechanisms for sustainable R&D growth.

A significant policy development under this vision is the launch of the **Promotion of Research and Innovation in Pharma-MedTech Sector (PRIP) Scheme**, which outlines a three-tiered support mechanism aligned broadly with stage of research, product-development and market-access. PRIP comprises two components:

- **Component A**
  which is currently being operationalized through the establishment of **Centers of Excellence (CoEs)** at NIPERs and academic institutions, focused on infrastructure and capacity creation for pharmaceutical and MedTech R&D; and

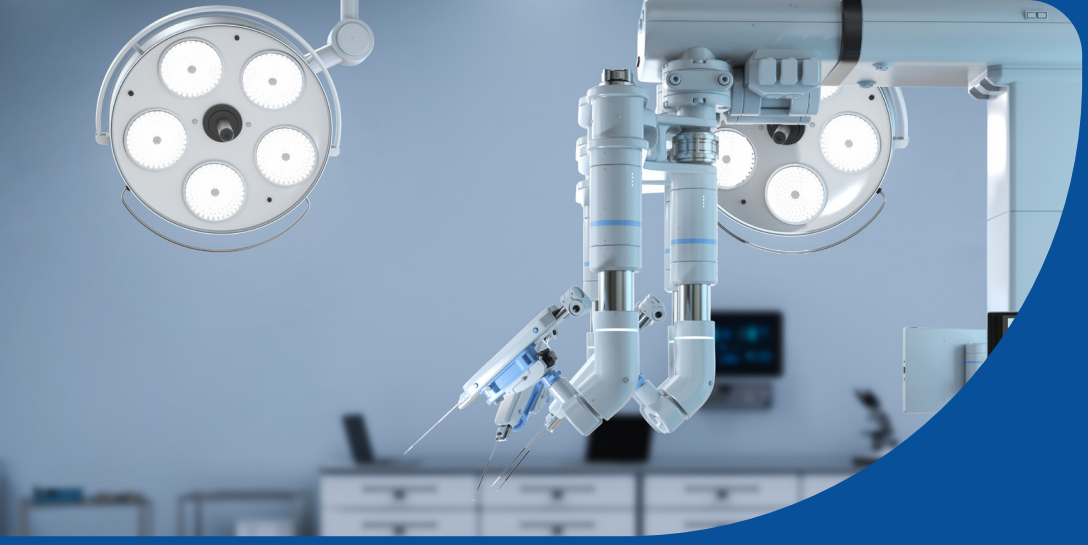
- **Component B**
  which aims to provide direct R&D funding support to private sector industry and MSMEs for innovation projects.

While sectors like **pharmaceuticals and biotechnology** are propelled by targeted interventions by organizations such as **BIRAC, TDB** and emerging **RLI pilots** that aim to de-risk early-stage research, MedTech sector, which is more capital-intensive and complexity-driven, has yet to receive similarly structured R&D support. Particularly in **frontier areas** such as **digital health, AI-enabled imaging, smart implants, precision IVDs**, and **robotic surgery systems**, there is a clear need for a sector-specific, risk-tolerant framework that recognizes the unique characteristics of MedTech innovation

A future-facing **MedTech RLI scheme** should therefore aim to:

- **Recognize and reward** ongoing R&D activities in the country,
- **De-risk high-value innovations** through direct and milestone-based funding,
- **Priority access** to government procurement through R&D component in local content,
- **Foster public–private–academic R&D partnerships**,
- **Support acceleration of clinical trials, regulatory approvals, and IP monetization**, and
- Mobilize R&D investments through India-based stakeholders, including Global Capability Centers (GCCs), which are emerging as critical contributors to knowledge creation and product design for global markets.

2. Notification - R&D Policy.pdf



3 Current Gaps in Research Landscape of of the Medical Devices Sector in India

India has made notable strides in medical devices manufacturing, yet **true self-reliance remains elusive, especially in high-end technology and innovation-driven segments**. The domestic industry fulfills less than 30% of total demand, with most sophisticated equipment (e.g., MRIs, robotic surgery, advanced implants, and molecular diagnostics) being imported. In parallel, Indian innovators (startups, academia, domestic players) face structural barriers to R&D investment – lack of risk capital, inadequate access to prototyping and testing infrastructure, and fragmented translational pathways from lab to market.

In terms of R&D capabilities:

- **Frugal innovation** is active and growing, largely led by startups and academic incubators, but remains limited in scale and commercialization pathways.
- **Frontier innovation**, such as AI-enabled diagnostics, minimally invasive surgical robotics, and implantable bioelectronics, is **still nascent**, with minimal venture and evolving policy support.
- India lacks **integrated R&D clusters, clinical trial infrastructure**, and **regulatory pathways** that support iterative product development for frontier devices.

This R&D gap contributes to India's continued import dependence and weak IP pipeline.

Current policies offer fragmented support with significant focus on downstream activities like manufacturing and compliance. Initiatives are needed to be strengthened to incentivize frontier innovation-especially in areas such as imaging, diagnostics AI, bioelectronic devices, and smart implants. The R&D ecosystem needs scale, continuity, and global connectivity for promising concepts to successfully go through *from lab to market*. Skill-development and academia-industry collaboration are needed to be aligned with national innovation missions for more outcome-linked efforts.

CURRENT POLICY SCHEMES IMPACTING THE MEDTECH SECTOR	KEY SUPPORT AREAS FOR THE MEDTECH VALUE CHAIN				
	MANUFACTURING INCENTIVES	R&D SUPPORT INCENTIVES	REGULATORY FACILITATION	IP FILING/ COMMERCIALIZATION	TALENT UPSKILLING/ TRAINING SUPPORT
PLI Scheme for Medical Devices[3]	●	○	●	○	○
Medical Device Parks Scheme[4]	●	●	●	○	●
National Medical Devices Policy (2023)[5]	●	●	●	●	●
BIRAC (BIG, SPARSH, BioNEST)[6]	○	●	●	●	●
CDSCO Initiatives (Digital Portal)[7]	○	○	●	○	○
Startup India IP Support / BioNEST[8]	○	○	○	●	○
Skill India / PMKVY[9]	○	○	○	○	●
PRIP Scheme (Medtech relevance only)[10]	○	●	○	●	●
		LIMITED TO PILOT GRANTS FOR INFRA, COES		IP FACILITATION GUIDANCE – NO TAX-LINKED INCENTIVES YET	CONCEPTUAL FOCUS ON HR/SKILL BUILDING – STILL EVOLVING

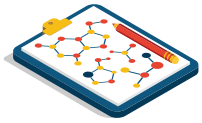
TABLE: GOVERNMENT INITIATIVES FOR MEDICAL DEVICE SECTOR AND THEIR IMPACT ON THE VALUE CHAIN

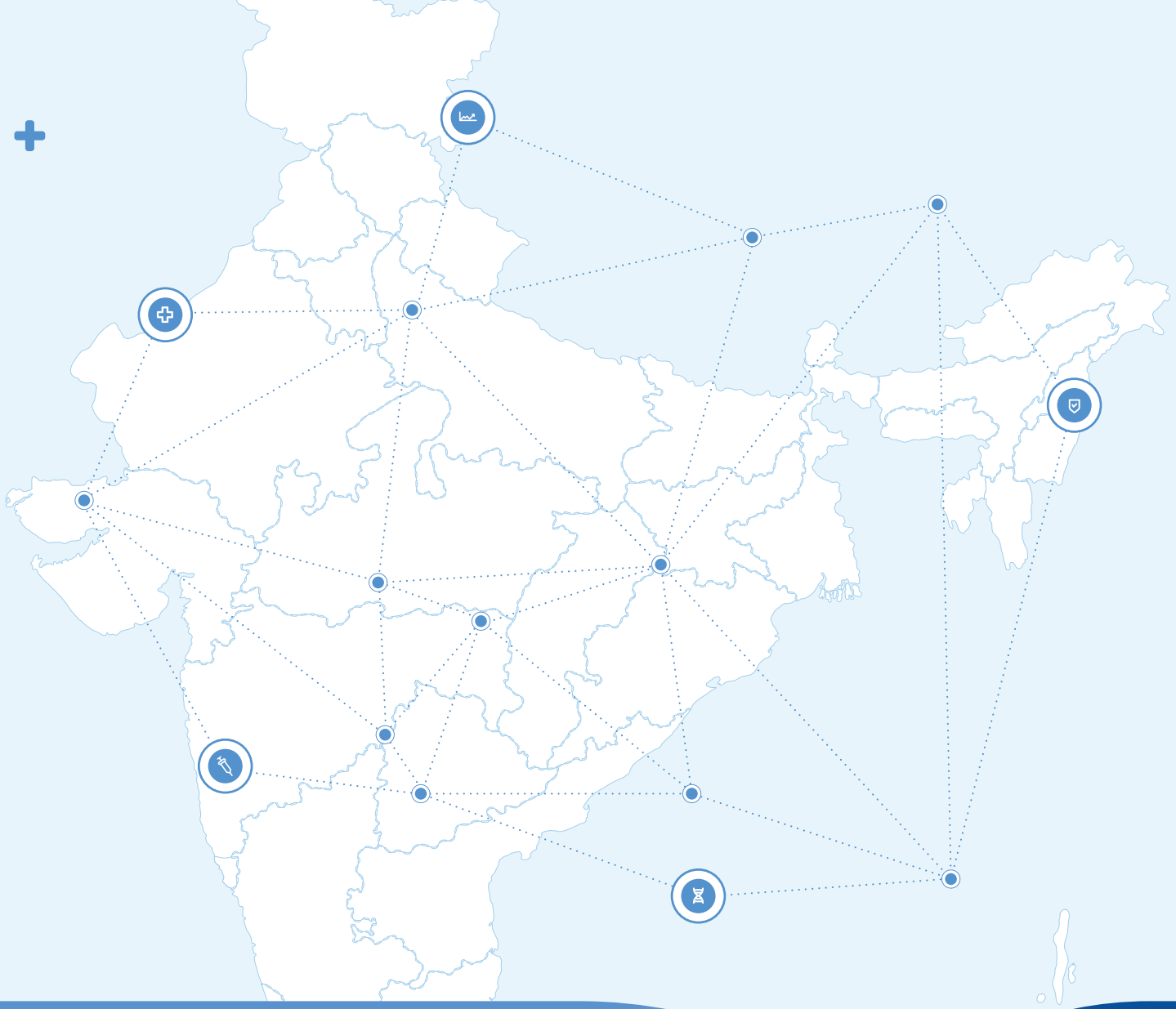
Current Gaps in Policy Support for R&D in the Medtech Sector

- **Most existing schemes (e.g., PLI) focus on manufacturing,** with little to no support for design-led R&D, PoC development, or clinical readiness
- **Lack of targeted fiscal incentives like weighted R&D tax deductions or a Patent Box regime** for MedTech innovators, limiting the ability to monetize Indian-filed IP
- **IP commercialization is supported only at early stages via filing support (e.g., Startup India),** but **there is no downstream support for patent utilization, licensing, or revenue-based incentives**
- **Current skill development programs (e.g., PMKVY) are too generic** and do not sufficiently cater to critical MedTech R&D skills like regulatory science, device engineering, or AI-health integration
- **Medical Device Parks provide infrastructure but lack structured funding or programmatic support** for innovation, testing, validation, or translational research
- **CDSCO initiatives have improved digital regulatory** access; however, there remains an opportunity to complement these efforts with **clinical advisory and capacity-building support, particularly for complex and high-risk medical devices**
- **BIRAC's early-stage support is valuable but limited in scale and continuity,** with no seamless transition to clinical, regulatory, or commercialization stages
- **There is no unified national framework aligning innovation with regulatory facilitation, skilling, and IP monetization** - resulting in fragmented support across the MedTech R&D value chain
- **Absence of a milestone-linked TRL based funding structure tailored to the unique development cycles across MedTech innovation spectrum - The PRIP scheme outlines a 3-tiered funding model,** and the policy mentions alignment with TRLs (Technical Readiness Levels) in principle. However, the scheme is still evolving, especially for MedTech sector as the following are not yet fully defined –
  - **Granular TRL-based milestones across innovation types**
  - **Specific qualifying criteria for device-specific R&D activities,** and
  - **Clear milestone-linked disbursement or co-investment models** tailored to the medical devices innovation lifecycle (which is distinct from pharma / biotech)

The RLI scheme needs to bridge the current implementation gaps, complement PRIP's existing framework and serve as the **catalytic link** that integrates innovation support across this fragmented ecosystem, **spanning idea inception to global market readiness**.

3. Ministry of Chemicals & Fertilizers, DoP Notifications (2020–2024) – https://pharmaceuticals.gov.in
4. DoP Guidelines (2020) – https://pharmaceuticals.gov.in
5. Approved by Union Cabinet, May 2023 – PIB Release: https://pib.gov.in/PressReleasePage.aspx?PRID=1925569
6. BIRAC Official Website – https://birac.nic.in
7. CDSCO Portal – https://cdscoonline.gov.in
8. Startup India Scheme & BIRAC BioNEST Details – https://www.startupindia.gov.in, https://birac.nic.in
9. NSDC, PMKVY 4.0 Guidelines – https://www.skillindia.gov.in
10. MoHFW/DoP Policy Release (2023) – https://pharmaceuticals.gov.in





4

Defining the RLI framework for the Indian Medical Devices sector

The development of an effective **RLI framework demands a granular understanding of the Medtech research value chain**, calibrated incentives aligned with **India's innovation maturity, and smart learning from global and cross-sectoral R&D incentive models.**

4.1

Understanding the Medtech R&D Value Chain

In the context of the RLI scheme, it is critical to clearly define what qualifies as "research" to ensure targeted, high-impact support across the innovation value chain. Unlike traditional sectors, research in the medical devices domain spans interdisciplinary activities which require blending skills across engineering, clinical validation, design and regulatory science. A clear definition enables outcome-linked monitoring, prevents misuse of funds, and aligns with global benchmarks such as BARDA (USA) and EDB (Singapore).

The Medtech R&D Value Chain:
Key Stages, Technology Readiness Levels (TRLs), Activities

STAGE	TRL	KEY R&D ACTIVITIES
Basic & Applied Research	TRL 1-3	Early scientific exploration, hypothesis generation, academic discoveries
Design & Prototyping	TRL 3-5	Functional design, simulation, prototyping, and digital modeling
Pre-Clinical & Clinical Trials	TRL 5-7	Biological testing, in-vitro/in-vivo studies, pilot human clinical trials
Product Validation & Testing	TRL 6-8	Technical performance validation, safety, risk analysis, biocompatibility tests
Regulatory & Market Access	TRL 7-9	Regulatory documentation, product registration (CDSCO, US FDA, EU MDR)
Post-Market Surveillance	TRL 9	Real-world data collection, safety/efficacy tracking, longitudinal outcome data

4.2

Best Practices in R&D Incentive Mechanisms from Global and Cross-Sector Frameworks

The analysis of R&D incentive models from cross-sectoral Indian schemes as well as global frameworks reveals valuable insights for shaping a robust RLI framework for India's Medtech sector – one that balances risk, rewards innovation and catalyzes industry-academia collaboration at scale.

This section presents a cohesive, detailed comparison of R&D incentive frameworks across sectors and geographies. It outlines how research activities are classified, tiered incentives are structured, types and quantum of benefits, key enablers offered, and the mechanisms through which Global Capability Centres (GCCs) are integrated.

Key implications for the Medtech RLI scheme in India based on global and cross-sector learnings:

Global and cross-sector RLI frameworks reveal that a robust incentive structure should:

- **Span the full research value chain**, from ideation to clinical validation to commercialization
- Include **tiered, merit-based funding** and **performance-linked tax incentives**. All effective RLI schemes
  - **Use Technology Readiness Levels (TRLs) to tier incentive** intensity-higher for early-stage innovation.
  - **Balance of One-Time vs Recurring Incentives:**
    - *One-time grants* drive high-risk R&D like PoC and clinical validation.
    - *Recurring incentives* like tax deductions and IP-linked tax breaks support longer-term viability.
- Prioritize **inclusion of GCCs (Global Capability Centers)**: RLI schemes actively incentivize **GCCs to invest in local talent, file IP domestically**, and co-innovate with startups and academia.
- Emphasize on **ecosystem readiness, including regulatory facilitation, infrastructure, and talent pipelines**: Singapore, Ireland, and UK best exemplify how parallel enablers like workforce training, testing centers, and regulatory support create real R&D ecosystems.

A. Examples of India's Policy Precedents and Cross-Sector R&D Incentive Models

SECTOR-SPECIFIC R&D INCENTIVE	CLASSIFICATION & QUALIFICATION OF R&D VALUE CHAIN	TIER-WISE INCENTIVE STRUCTURE	ONE-TIME INCENTIVES	RECURRING/ LINKED INCENTIVES	ECOSYSTEM ENABLERS	GCC INVESTMENT PROVISIONS
INDIA **SEMI-CONDUCTORS** DESIGN LINKED INCENTIVE 11 12 13	**Tier 1 (TRL 3-4)** IP design, EDA tool use **Tier 2 (TRL 5-6)** RTL-GDSII, physical verification **Tier 3 (TRL 7-9)** Post-silicon validation, market-ready chips	**Tier 1:** 60% of eligible R&D costs reimbursed on submission of IP proof and functional design **Tier 2:** 50% on physical prototype and validation report **Tier 3:** 30% post-functional chip tape-out & successful first-pass silicon **Eligible expenses:** design team salaries, EDA licenses, prototype costs	**Up to ₹30 Cr per design/IP**	Post-deployment reimbursements; startup tax incentives	Shared fabless infra, IP support, EDA tool access	Must register IP in India; co-dev with Indian startups encouraged
INDIA **AUTO & EV SECTOR R&D INCENTIVES** DEFINED UNDER PLI SCHEME 14 15 16	**Tier 1 (TRL 4-5)** Battery cells, fuel stacks **Tier 2 (TRL 6-7)** Integrated EV modules **Tier 3 (TRL 8-9)** Market-ready electric drive-train platforms	**All Tiers:** 13-18% incentive on incremental sales after qualifying component certification and commercial sale **Eligible expenses:** R&D CapEx, testing, material cost, manpower	**R&D CapEx included in eligibility criteria**	Linked annual disbursement over 5 years post-revenue	EV testing hubs, validation infra, local sourcing grants	IP linkage to Indian ops required for global OEMs
INDIA **PHARMA/ BIOTECH** DBT/DST 17 18 19 20	**Tier 1 (TRL 2-3)** Molecule screening, early PoC **Tier 2 (TRL 4-6)** Diagnostics, animal studies **Tier 2 (TRL 7-9)** Clinical trials, regulatory dossier	**Tier 1:** Up to ₹1 Cr on PoC success + scientific peer-review **Tier 2:** ₹1-3 Cr on validated pre-clinical results **Tier 3:** ₹3-5 Cr on CDSCO/IND trial application readiness **Eligible expenses:** CRO engagement, trial infra, researchers	**Competitive grants for PoC/ clinical phases**	Tax exemptions for biotech zones; R&D depreciation	Biotech clusters, translational hubs	Indian IP/trial data mandatory for GCC participation
INDIA **PRIP SCHEME** 21 22	**B-I (TRL 1-9)** Early stage R&D for NCEs, biologics, complex generics, medtech ideation **B-II (TRL 5-6)** pre-clinical validation, device prototyping **B-III (TRL 1-4)** clinical trials, regulatory filing, commercial scale-up	**B-I:** Up to 35% of the total cost or Rs 125cr whichever is less on a milestone basis from TRL 1 to reach TRL 9 over a period of five year on benefit sharing principle **B-II:** Up to 35% of the total cost or Rs 100 cr. whichever is less on a milestone basis from TRL 5 to reach TRL 9 over a period of five year on benefit sharing principle **B-III:** Up to Rs. 1 cr. per project for startups/MSMEs working on project in the priority areas	**Competitive milestone-based grants**		Linked with BIRAC, BioNEST, Pharma Parks, Academic-industry consortia, testing infra support	GCCs eligible via Indian legal entities

11. https://itif.org/publications/2024/02/14/india-semiconductor-readiness
12. https://www.meity.gov.in/esdm/design-linked-incentive-dli-scheme
13. https://chipspolicy.gov.in/DLI_Scheme
14. https://www.pib.gov.in/PressReleasePage.aspx?PRID=2085938
15. https://auto.economictimes.indiatimes.com/news/industry/auto-pli-achieves-inr-20715-crore-investment-inr-10472-crore-incremental-sales-centre/116487947
16. https://www.autocarpro.in/news/auto-pli-secures-investment-worth-rs-20715-crore-reports-incremental-sales-of-rs-10472-crore-ians--124036
17. https://www.birac.nic.in/desc_new.php?id=98 (Biotech Ignition Grant - BIG)
18. https://www.birac.nic.in/desc_new.php?id=168 (SPARSH scheme)
19. https://dst.gov.in/programmes/scientific-research-programmes
20. https://dst.gov.in/news/cabinet-approves-prip-promote-rd-industry-academia
21. Approved Operational Guidelines (PRIP).pdf
22. https://www.pib.gov.in/PressReleasePage.aspx?PRID=2019386

B. Examples of Global Models: Structural and Financial Architecture of R&D Incentives

GLOBAL R&D INCENTIVES FOR MEDTECH SECTOR	CLASSIFICATION & QUALIFICATION OF R&D VALUE CHAIN	TIER-WISE INCENTIVE STRUCTURE	ONE-TIME INCENTIVES	RECURRING/ LINKED INCENTIVES	ECOSYSTEM ENABLERS	GCC INVESTMENT PROVISIONS
USA **SBIR / BARDA** 23 24 25 26 27	**Phase I (TRL 2–3)** Concept, feasibility **Phase II (TRL 4–6)** Prototype **Phase III (TRL 7–9)** Clinical validation, regulatory approvals	**Phase I:** $500K after concept + feasibility validation **Phase II:** $2.5M post working prototype + early test data **Phase III (BARDA):** 50% co-funding on IND/NDA submission **Eligible expenses:** PI salaries, clinical trials, IP/legal	**Non-dilutive public R&D grants**	Tax credits; direct govt. contracting	NIH test labs, TTOs, incubators	US IP, operations, and data required for eligibility
SINGAPORE **RIE / EDB** 28 29 30	**Tier 1 (TRL 1–3)** Biomedical discovery **Tier 2 (TRL 4–6)** Biodesign validation **Tier 3 (TRL 7–9)** Regulatory submission, market entry	**Tier 1:** 30%–40% co-funding on validated concept note + plan **Tier 2:** 40%–50% on validated prototype + lab evidence **Tier 3:** 50% on regulatory submission or pilot launch **Eligible expenses:** staff, infra, lab validation	**50% grant for total project costs**	400% R&D tax deduction; 5–10% IP tax (Patent Box)	Biodesign fellowship, clinical validation labs	Local R&D/IP and hiring required for GCCs
UK **INNOVATE UK/ PATENT BOX** 31 32 33 34	**Tier 1 (TRL 2–3)** Device ideation **Tier 2 (TRL 4–6)** Prototype testing **Tier 3 (TRL 7–9)** Regulatory and market scale-up	**Tier 1:** Up to £500K on proof of concept + tech review **Tier 2:** £1M+ upon validated pre-clinical evidence **Tier 3:** £2M after device meets regulatory standards (MHRA/FDA) **Eligible expenses:** R&D labor, trials, validation infra	**Project grants: £500K–£2M**	33% R&D tax relief; 10% IP tax (Patent Box)	NHS test access, regulatory support	IP must be UK-held or licensed; show contribution to economic value
IRELAND **IDA / KDB** 35 36 37 38	**Tier 1 (TRL 2–3)** Early feasibility **Tier 2 (TRL 4–6)** Prototype, trials **Tier 3 (TRL 7–9)** Launch, post-market feedback	**All Tiers:** 25% tax credit on actual qualifying R&D costs (payroll, labs, trial cost) on completion of each R&D phase with proof + audit **Eligible expenses:** trial reports, IP costs, staff time	**Infra funding grants up to €1M**	6.25% tax rate under IP KDB regime	Academic co-dev programs, relocation funds	Must route R&D and IP revenue via Ireland

The learnings from cross-sector RLI models and global frameworks together reflect not only what has worked globally but also what India must adapt selectively for balancing fiscal prudence with strategic ambition. These implications need to be structured into an RLI framework that aligns with India's unique Medtech maturity curve, regulatory ecosystem, infrastructure constraints and innovation landscape.

23. https://www.sbir.gov/about/about-sbir
24. https://www.sbir.gov/sites/default/files/2024-08/SBA_SBIR_STTR_FY21_Annual_Report.pdf
25. https://www.nia.nih.gov/sites/default/files/2019-12/NIA-SBIR-STTR-Overview-Tips-508_0.pdf
26. https://www.nasa.gov/sbir_sttr/post-phase-ii/
27. https://aspr.hhs.gov/BARDA
28. https://www.edb.gov.sg/en/our-industries/biomedical-sciences.html
29. https://www.iras.gov.sg/taxes/corporate-income-tax/claiming-reliefs-deductions/400-tax-deduction-for-r-d-expenses
30. https://www.edb.gov.sg/en/why-singapore/incentives.html
31. https://www.gov.uk/guidance/corporation-tax-the-patent-box
32. https://www.gov.uk/guidance/apply-for-innovation-funding
33. https://committees.parliament.uk/writtenevidence/95267/html/
34. https://www.innovateukedge.ukri.org/
35. https://www.revenue.ie/en/companies-and-charities/reliefs-and-exemptions/research-and-development-rd-tax-credit/index.aspx
36. https://www.revenue.ie/en/companies-and-charities/reliefs-and-exemptions/knowledge-development-box-kdb/index.aspx
37. https://www.idaireland.com/invest-in-ireland/tax
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4.3

Proposed Structure to Strengthen the RLI Framework for Medtech in India

Translating the insights from global and cross-sector R&D frameworks into a workable model for India, this section sets out a structured set of recommendations to shape the RLI framework that is responsive to the unique needs of Medtech in India. The PRIP policy provides an essential foundation on this, however, to achieve executional clarity and outcome-oriented funding, a **dedicated RLI framework is proposed to complement PRIP – targeting support across the innovation maturity spectrum incremental, translational and frontier innovations.** The RLI framework is designed to ensure that public investment is deployed strategically across early-stage discovery, mid-stage validation and late-stage deployment phases. It proposes **alignment to funding tranches to Technology Readiness Levels (TRLs)** and tailoring of eligibility based on **innovation type and entity profile. The goal is to provide a structured, milestone-linked R&D incentivization pathway** - augmenting PRIP's foundational provisions.

The proposed RLI framework is anchored around the following 3 core dimensions:

A. **Tiering structure for the RLI scheme that defines eligible research activities and accommodates the full spectrum of innovation** (across incremental, translational and frontier innovations)

B. **Focused benefit areas** such as tax incentives, project-based grants, clinical trial support, IP-linked rewards, incentives for human capital upskilling and for driving GCC-led R&D investments

C. **Ecosystem and structural enablers** beyond financial support that ensure RLI scheme's uptake, sustainability and long-term impact

Together, these 3 pillars aim to deliver a coherent, scalable and high-impact RLI model tailored to India's Medtech innovation lifecycle.

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INDIA **AUTO & EV SECTOR R&D INCENTIVES** DEFINED UNDER PLI SCHEME 14 15 16	**Tier 1 (TRL 4-5)** Battery cells, fuel stacks **Tier 2 (TRL 6-7)** Integrated EV modules **Tier 3 (TRL 8-9)** Market-ready electric drive-train platforms	**All Tiers:** 13-18% incentive on incremental sales after qualifying component certification and commercial sale **Eligible expenses:** R&D CapEx, testing, material cost, manpower	**R&D CapEx included in eligibility criteria**	Linked annual disbursement over 5 years post-revenue	EV testing hubs, validation infra, local sourcing grants	IP linkage to Indian ops required for global OEMs
INDIA **PHARMA/ BIOTECH** DBT/DST 17 18 19 20	**Tier 1 (TRL 2-3)** Molecule screening, early PoC **Tier 2 (TRL 4-6)** Diagnostics, animal studies **Tier 2 (TRL 7-9)** Clinical trials, regulatory dossier	**Tier 1:** Up to ₹1 Cr on PoC success + scientific peer-review **Tier 2:** ₹1-3 Cr on validated pre-clinical results **Tier 3:** ₹3-5 Cr on CDSCO/IND trial application readiness **Eligible expenses:** CRO engagement, trial infra, researchers	**Competitive grants for PoC/ clinical phases**	Tax exemptions for biotech zones; R&D depreciation	Biotech clusters, translational hubs	Indian IP/trial data mandatory for GCC participation
INDIA **PRIP SCHEME** 21 22	**B-I (TRL 1-9)** Early stage R&D for NCEs, biologics, complex generics, medtech ideation **B-II (TRL 5-6)** pre-clinical validation, device prototyping **B-III (TRL 1-4)** clinical trials, regulatory filing, commercial scale-up	**B-I:** Up to 35% of the total cost or Rs 125cr whichever is less on a milestone basis from TRL 1 to reach TRL 9 over a period of five year on benefit sharing principle **B-II:** Up to 35% of the total cost or Rs 100 cr. whichever is less on a milestone basis from TRL 5 to reach TRL 9 over a period of five year on benefit sharing principle **B-III:** Up to Rs. 1 cr. per project for startups/MSMEs working on project in the priority areas	**Competitive milestone-based grants**		Linked with BIRAC, BioNEST, Pharma Parks, Academic-industry consortia, testing infra support	GCCs eligible via Indian legal entities

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A. Adopting a Tiered R&D Grant Framework Balancing across the Innovation Spectrum

Proposed India MedTech RLI Scheme Grant Framework by Innovation Type

1. Novel / Frontier Innovation

Novel / frontier innovations involve deep-tech and high-risk research aimed at leapfrogging global capabilities in digital health, AI-ML in imaging, robotics, wearable therapeutics, and next-gen implants.

TIER	ILLUSTRATIVE ELIGIBLE R&D ACTIVITIES	SUGGESTED TIER-WISE QUALIFYING MILESTONES	SUGGESTED ELIGIBLE EXPENSES	ILLUSTRATIVE ELIGIBLE ENTITIES
TIER 1	**TRL 1-3** Foundational R&D in materials, bio-simulation, AI/ML diagnostics, novel platforms	Documented PoC; Institutional Ethics Committee clearance; early IP scoping	Salaries of R&D personnel, early PoC development, lab equipment	Indian GCCs, R&D arms of Medtech Companies, spin-offs from academic institutions
TIER 2	**TRL 4-6** Prototyping, usability testing, bench and animal model validation	Validated prototype; pre-clinical results; technology readiness assessment certification	Prototype development, pre-clinical validation, regulatory consulting	
TIER 3	**TRL 7-9** Clinical trials, regulatory approvals (CDSCO/CE/FDA), pre-launch pilots	Proof of dossier submission to regulatory authority; market deployment evidence	Clinical trial costs, CRO services, dossier preparation, tech transfer costs	

2. Translational Innovation

These projects focus on converting academic/lab-level innovation to market-ready products through Indianization, validation / clinical proof of academia-originated tech, localized adaptation.

TIER	ILLUSTRATIVE ELIGIBLE R&D ACTIVITIES	SUGGESTED TIER-WISE QUALIFYING MILESTONES	SUGGESTED ELIGIBLE EXPENSES	ILLUSTRATIVE ELIGIBLE ENTITIES
TIER 1	**TRL 1-3** Feasibility studies, adapting academic innovation for clinical PoC	Tech scoping report, working PoC, 3rd-party validation	Prototyping tools, market scanning costs	Startups, industry-academia consortia, technology transfer offices
TIER 2	**TRL 4-6** Design for manufacturability, usability validation	Usability test report, tech dossier prepared, industrial prototyping	Design services, product trials, pre-certification	
TIER 3	**TRL 7-9** Clinical validation, tech registration, scale-up pilots	Submission to CDSCO or institutional approval for commercial use	CRO fees, clinical data management, usability pilots	

3. Incremental Innovation

Focused on design improvements, cost optimization, form-factor adaptations, import substitution and improving usability of existing / emerging global products for India-specific needs.

TIER	ILLUSTRATIVE ELIGIBLE R&D ACTIVITIES	SUGGESTED TIER-WISE QUALIFYING MILESTONES	SUGGESTED ELIGIBLE EXPENSES	ILLUSTRATIVE ELIGIBLE ENTITIES
TIER 1	**TRL 4-5** Form-factor optimization, usability-focused redesign	Comparative design analysis; Indian PoC documentation	Industrial design costs, basic testing kits, standard certifications	MSMEs, Tier II/III Medtech firms, innovation clusters
TIER 2	**TRL 6-7** Testing for deployment, validation in local settings	Third-party lab reports, usability results	NABL/BIS-certified testing, compliance cost, local trial kits	
TIER 3	**TRL 8-9** Market readiness, limited commercial rollout, CDSCO license	CDSCO license + market entry evidence	Certification costs, field trial support, early production costs	

Key Considerations:

- RLI grants are structured with tiered, milestone-linked eligibility criteria, including third-party validation, technology due diligence, and IP commitment in India
- Disbursement of grants may follow milestone-linked tranches post validation from expert technical panels
- Tie-ups with recognized testing labs, CROs, and incubators to be facilitated via a central nodal implementation body

B. Benefit Areas to Focus on Under the Proposed RLI Scheme

AREAS FOR RLIS

PATENT BOX REGIMES | SUPPORT CLINICAL TRIALS | TAX INCENTIVES | FUND RESEARCH | RESOURCE UPSKILLING

PROPOSED INCENTIVE TYPES	ILLUSTRATIVE BENEFIT UNDER PROPOSED RLI SCHEME	SUGGESTED QUALIFYING MILESTONES / CRITERIA	ILLUSTRATIVE ELIGIBLE EXPENSES
PROJECT-BASED GRANTS	Competitive, time-bound R&D grants across Tier 1 to Tier 3 aligned with TRL maturity and innovation type (Incremental, Translational, Frontier)	**Novel / Frontier:** • Tier-1: Documented PoC; Institutional EthicsCommittee review; early IP scoping • Tier-2: Working prototype, usability results, industry interest • Tier-3: Dossier submission to regulatory authority; market deployment evidence **Translational:** • Tier-1: Tech scoping report, working PoC, 3rd-party validation • Tier-2: Test report, tech dossier completion, industrial prototyping • Tier-3: Dossier submission to regulatory authority; or institutional approval for commercial use **Incremental:** • Tier-1: Comparative design analysis; Indian PoC documentation • Tier-2: Third-party lab reports, usability results • Tier-3: CDSCO license + market entry evidence	**Frontier:** PoC development, researcher salaries, lab setup, pre-clinical validation, Clinical trial costs, CRO services, dossier preparation, tech transfer, IP filing **Translational:** Prototype testing, usability engineering, regulatory prep, CRO fees, usability pilots, certification **Incremental:** Product design improvements, field trials, certification & testing and compliance costs, field trial support, early production costs
R&D TAX INCENTIVES	**Weighted tax deductions** for qualified R&D expenses (especially clinical, pre-regulatory, and testing phases)	• R&D must be carried out in India • Must relate to development or improvement of MedTech product • TRL 4+ activities including clinical validation, biocompatibility testing, regulatory science	Salaries of R&D staff, consumables, software tools (e.g., simulation), clinical trial preparation, testing & certification costs
CLINICAL TRIAL CO-FUNDING	**Priority co-funding** for India-based clinical trials; support for multi-site trials or global regulatory alignment (CDSCO, US FDA, EU MDR)	• Trials registered with CDSCO or ICMR • Linked to market readiness stage (TRL 7+) • Indian sites and investigators involved • Device must have prior PoC or completed validation	Investigator costs, ethics & site approvals, CRO fees, biometrics & monitoring services, participant recruitment, post-trial reporting
PATENT BOX REGIME	**Concessional tax on royalty income** from India-filed and India-commercialized patents	• Patent filed and granted in India • Patent must be commercialized domestically, or license income must be routed through Indian operations	Income arising from licensing, royalties, or product commercialization based on MedTech IP developed in India
HUMAN CAPITAL UPSKILLING GRANTS	**Co-financing of technical/ regulatory trainings** for MedTech professionals – includes clinicians, scientists, engineers, and regulators	• Training must be aligned to MedTech innovation (design, regulatory science, device engineering skilling, validation biostatistics, AI-health tech, etc.) • Delivered by accredited institutions • Linked to project or institutional innovation roadmap	Training course fees, certification costs, institutional capacity building, AI/ML-health tech training modules, international fellowships
INNOVATION INFRA REBATE	**Partial of full reimbursement for use of certified facilities** for device testing, biocompatibility, electromagnetic safety, and regulatory validation	• Facility must be NABL or CDSCO certified • Activities should align with TRL 5–8 stages • Project must have identified commercial/ clinical roadmap	Bench fees for labs, test sample procurement, testing and validation documentation, test result interpretation and certification support
GCC INCENTIVE PREMIUM	Additional bonus on base incentives for GCCs that conduct India-first R&D, co-develop with Indian startups, or file IP in India.		
ONGOING R&D ACTIVITIES	Applicable for Weighted Average Tax Deduction benefit		

C. Ecosystem and Structural Enablers to Maximize RLI Effectiveness

Beyond financial support, a successful RLI scheme must act as a **platform for ecosystem coordination**. Suggested enablers include:

- **MedTech R&D Zones/ Innovation Corridors**
  Shared testing, regulatory, and prototyping infrastructure
- **Regulatory Fast-Track for RLI Projects**
  CDSCO facilitated support on documentation and approvals
- **Digital R&D Hub**
  A national digital database / platform to connect researchers, funders, hospitals, and investors with RLI-backed projects
- **Public Procurement Linkages**
  Mandates or preferences for Indian hospitals to adopt RLI-qualified innovations to scale Indian market access
- **Innovation Sandboxes and Testbed**
  Access to labs, simulation zones, and digital twins for prototyping, especially for startups and MSMEs
- **IP Commercialization Support**
  Advisory and licensing services for converting India-filed patents into revenue

5 Next Steps

As the MedTech Research-Linked Incentive (RLI) framework approaches maturity, the transition from conceptual design to execution demands a deliberate sequence of strategic decisions. These decisions are critical to ensure that the scheme is well-calibrated to India's innovation landscape, operationally viable, and outcome-oriented from the outset.

The following action areas outline the priority focus for all relevant stakeholders:

Defining the Tiered Incentive Architecture

The funding structure linked to Technology Readiness Levels (TRLs) should be finalized-balancing risk-reward dynamics across incremental, translational, and frontier innovations with defined ceilings and co-investment norms.

Codifying Eligibility and Qualification Criteria

Specific guidelines must be issued to define qualifying research activities, clarify IP ownership norms, and establish differentiated pathways for startups, GCCs, academia, and industry consortia.

Aligning with Complementary National Programs

The RLI framework should be mapped alongside existing schemes such as PLI, National Digital Health Mission, and BIRAC to ensure synergy, avoid duplication, and optimize shared infrastructure

Phasing the Rollout Strategy

A targeted, phased launch must be planned - starting with high-potential MedTech segments such as diagnostics, AI-enabled devices, or surgical tools—allowing for controlled scale-up and adaptive learning

Ensuring Ecosystem and Infrastructure Readiness

Mapping and readiness assessment of clinical validation centers, design labs, regulatory support institutions, and testing infrastructure must be conducted to support downstream execution

Global Outreach and Investment Promotion

Strategic communication of India's RLI vision to attract international R&D investment, enable GCC engagement, and foster co-innovation partnerships

Way Forward

For India to emerge as a leading global hub for MedTech R&D, the national focus must now evolve from incremental adaptation to fostering **breakthrough innovation** - driven by a robust **incentivization culture** that rewards risk-taking, long-gestation research, and global market readiness. This transition is essential to make Indian innovation competitive on the global stage.

The path ahead for MedTech RLI lies in **coordinated execution, stakeholder alignment**, and policy agility. Institutional design, implementation capability, and international signaling must now converge to translate this framework into a scalable, high-impact engine for MedTech innovation.

The Government of India has already taken vital steps in this direction. The **recently approved Research, Development and Innovation (RDI) Scheme**, with a focus on scaling up innovation in **strategic and sunrise domains**, is a landmark policy signal in support of deep-tech R&D. Similarly, the establishment of the **Anusandhan National Research Foundation (ANRF)** offers a long-term platform to catalyze academic-industry research collaboration across priority sectors, including medical technology.

As the MedTech RLI framework matures, it must be positioned as a **complementary pillar** to these national initiatives-targeted specifically at India's unique clinical needs, affordability imperatives, and global innovation aspirations. With the right tiered incentives, a transparent execution architecture, and continuous input from industry leaders, academia, startups, and global investors, the RLI scheme can unlock India's next wave of medical technology leadership.

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About Indian Medical Parliamentarians' Forum (IMPF)

IMPF is a distinguished cross-party platform of Parliamentarians committed to advancing healthcare reforms in India. IMPF serves as a vital bridge between lawmakers, industry, and the broader healthcare ecosystem, championing policies that are innovation-friendly, patient-centric, and aligned with national health goals.

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The voice of MedTech

About APACMed

The Asia Pacific Medical Technology Association (APACMed) represents manufacturers and suppliers of medical equipment, devices and in vitro diagnostics, industry associations, and other key stakeholders associated with the medical technology industry in the Asia Pacific region. APACMed's mission is to improve the standards of care for patients through innovative collaborations among stakeholders to jointly shape the future of healthcare in Asia-Pacific. For more information, visit **www.apacmed.org**