GLOBAL DISPARITIES IN NON INVASIVE BRAIN STIMULATION REGULATION : COMPARATIVE INSIGHTS FROM FOUR LMICs

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Introduction

Non-invasive brain stimulation (NIBS) techniques such as transcranial magnetic stimulation (TMS) and transcranial direct current stimulation (tDCS) are rapidly advancing in neuroscience and psychiatry.

Governance and research activity, however, remain concentrated in high-income countries (HICs), while low- and middle-income countries (LMICs) are expanding their contributions but often under general rather than modality-specific regulatory frameworks. This global imbalance highlights important equity, ethics, and access challenges — while also underscoring the need to recognize existing strengths in LMIC ethics oversight and research ecosystems.

Our Aim

- Map global NIBS research output (HIC vs LMIC).
- Review regulatory/ethical coverage in 4 LMICs (India, Brazil, South Africa, Nigeria).
- Compare LMIC frameworks to HIC benchmarks (USA, EU).
- Propose policy roadmaps for inclusive governance.

Methodology

Step 1: Bibliometrics
- Data: Scopus (2015–25)
- Cleaning: DOI de-dup → Title+Year fallback
- Country: 1st affiliation → WB FY26 HIC/LMIC
- Analyses: Trends, LMIC share, Top 10, Regions

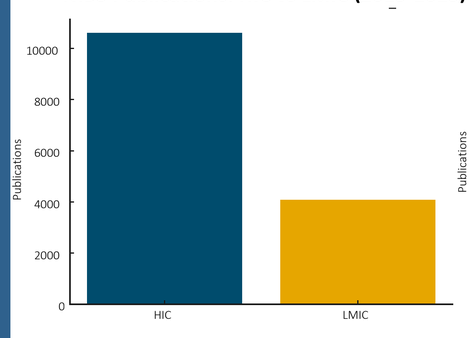
Step 2: Policy/Regulation
- Reviewed regulators (ANVISA, CDSCO, SAHPRA, NAFDAC) & ethics codes
- Extracted rules on device classification, licensing, ethics, and safety

Step 3: Case studies
- Countries: India, Brazil, South Africa, Nigeria
- Compared clinical use, regulations, ethics frameworks, and gaps

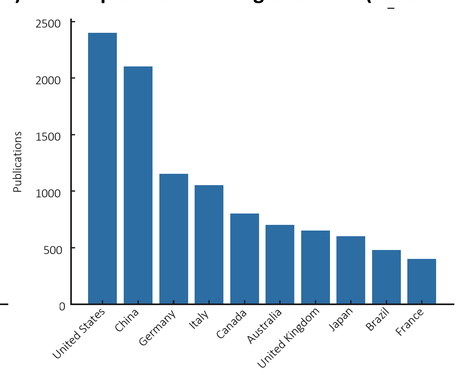
Step 4: Synthesis
- Benchmarked LMIC findings against FDA and EU MDR frameworks.
- Drafted a policy action matrix highlighting priority reforms

Results

NIBS Publications: HIC vs LMIC (2015-2025)

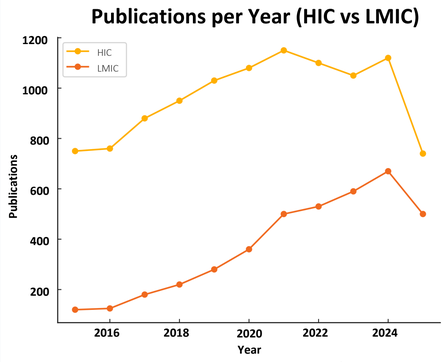


Top 10 Contributing Countries (2015-2025)



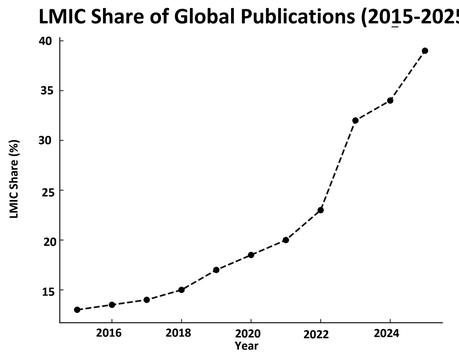
- 13,995 publications analyzed (2015–2025).
- HICs: 10,360 (74%); LMICs: 3,635 (26%).

Publications per Year (HIC vs LMIC)

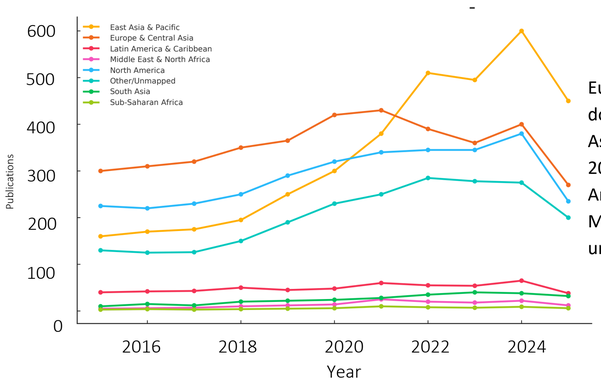


- LMICs grew: 116 → 495 papers (CAGR ~15.6%).
- HIC stable output: 764 → 749
- Top LMICs: China (2,108), Brazil (458), India (rapid growth)

LMIC Share of Global Publications (2015-2025)



Share rose from 13% (2015) → ~40% (2025).



Europe, East Asia, and North America dominate NIBS research, with East Asia showing the fastest growth after 2021. Contributions from Latin America, South Asia, Africa, and the Middle East remain limited, underscoring global imbalances.

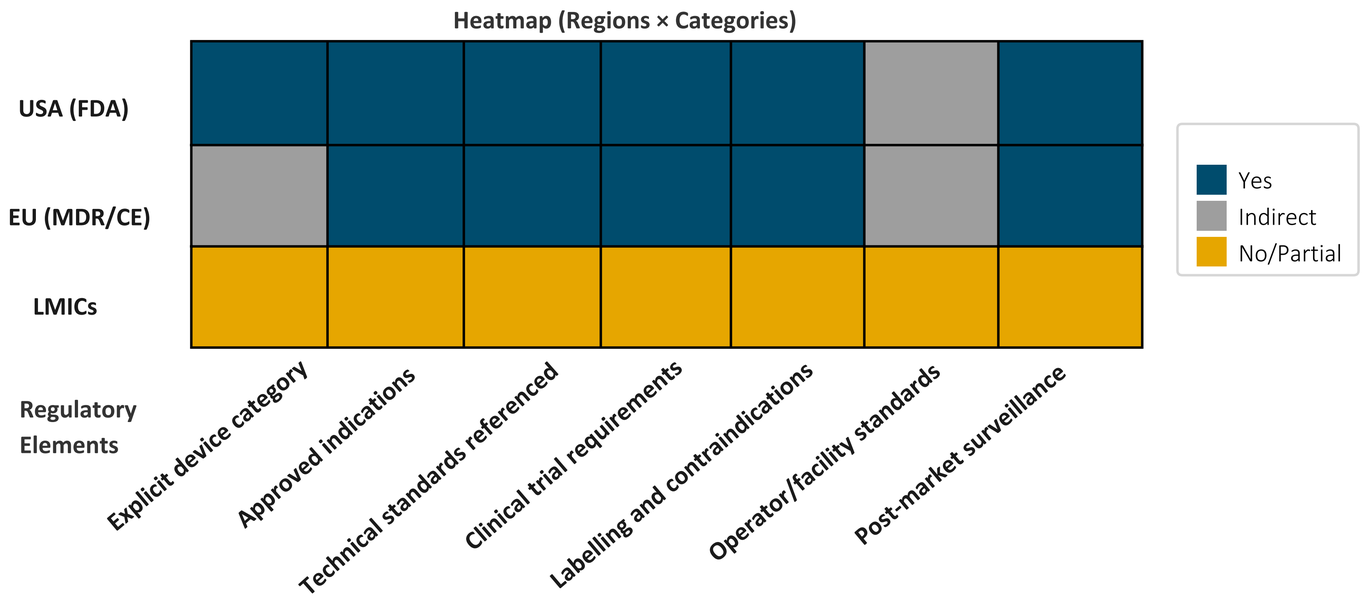
Displaying the contribution of HICs and LMICs in publications done on NIBS region wise (2015-2025)

Note: 2025 data shown only up to August — final year totals expected to align with previous trend

References

- CDSCO. Medical Devices Rules, 2017. Ministry of Health, India.
- ANVISA. RDC 751/2022: Medical Device Regulation. Brazil.
- SAHPRA. Guideline for Classification of Medical Devices & IVDs, 2025. South Africa.
- NAFDAC. Guidelines for Registration of Medical Devices, 2024–25. Nigeria.
- ICMR. National Ethical Guidelines, 2017. India.
- CNS. Resolution 466/2012 & updates. Brazil.
- NHREC. National Code of Health Research Ethics. Nigeria.
- South African Dept. of Health. Ethics in Health Research, 3rd ed., 2024.
- FDA. Class II Special Controls Guidance: rTMS Systems, 2011. USA.
- EU. Medical Device Regulation (MDR 2017/745).

Results: Regulatory and Oversight Gaps in NIBS



Case Studies: LMIC Snapshots

Comparative insights from Brazil, India, Nigeria & South Africa

Regulatory Pathways

Across all four countries, NIBS (TMS/tDCS) devices are regulated under general medical device laws, not NIBS-specific rules.

- **India**: CDSCO under MDR 2017, with clinical investigation pathways defined.
- **Brazil**: ANVISA RDC 751/2022 provides risk-based classification but no TMS/tDCS note.
- **Nigeria**: NAFDAC has updated registration, renewal, and reliance mechanisms; draft 2025 regulations underway.
- **South Africa**: SAHPRA's 2025 classification guideline is modern, yet generic.

➡ Coverage is strong but lacks TMS/tDCS-specific clarity (similar to FDA/CE)

Ethics Oversight

All four countries have national ethics frameworks with robust committee structures.

- **Brazil**: CEP/CONEP system, one of the strongest in LMICs.
- **India**: ICMR guidelines + NDCTR 2019 ensure EC registration and governance.
- **Nigeria**: NHREC centralizes EC oversight and training.
- **South Africa**: NHREC + 2024 "Ethics in Health Research" guideline updates national processes.

➡ Ethics is a relative strength, though efficiency varies.

Clinical & Research Ecosystem

Capacity is uneven:

- **Brazil**: A global leader, USP and Hospital das Clínicas publish extensively.
- **India**: NIMHANS, AIIMS, and multiple hospitals provide strong clinical and research hubs.
- **Nigeria**: Emerging practice, concentrated in tertiary centers; publications limited.
- **South Africa**: Local services exist (e.g., Stellenbosch University rTMS), but output is modest.

➡ Brazil & India: mature hubs. Nigeria & South Africa: emerging capacity.

Policy & Practice Gaps

Common themes include:

- No NIBS-specific device classification or technical notes.
- Lack of standardized operator/facility competency requirements and reliance on general adverse event systems.
- Reimbursement and public-sector integration remain limited. These practice-level challenges mirror global patterns, since even in HICs reimbursement and integration are inconsistent.

➡ Closing these gaps is key for safe and equitable expansion.

Policy Recommendations

Tier 1 (6–12 months): Quick Wins

- Issue a short technical note: clarify how TMS/tDCS fit into existing device rules.
- Add NIBS-specific fields in adverse event reporting (device ID, dose, outcomes).
- Provide ethics committees with a NIBS checklist for consistent reviews.
- Launch pilot Centers of Excellence for training and safe rollout.

Tier 2 (12–24 months): System Enablers

- Develop national training and facility standards (roles, protocols, safety checks).
- Use reliance on FDA/CE/WHO approvals to shorten device access times.
- Introduce pilot reimbursement codes in public systems for proven uses.
- Strengthen equity in research: require local sites, capacity building, and fair data use.

Tier 3 (24+ months): Longer-Term Architecture

- Create a national registry to track treatments, outcomes, and safety.
- Run regular reviews (every 2 years) to update guidance and cover new methods.
- Build regional partnerships: shared reviewer tools, pooled procurement, and training exchanges.

Conclusion

LMICs now generate ~40% of NIBS research, yet regulator-issued guidance is remains general rather than NIBS-specific. Unlike HICs, oversight in many LMICs does not clearly define device categories, dosing protocols, or safety reporting. Without stronger vigilance, equity and patient safety remain at risk.

Urgent steps include:

- Publishing clear technical notes to guide device use
- Adding NIBS-specific fields in adverse event reporting
- Building regional capacity through training, ethics primers, and registries