Scientific Conference on Medical Products Regulation in Africa
SCOMRA

AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

REPUBLIC OF KENYA
MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

World Health Organization

AMA
African Medicines Agency

SCOMRA 2025

Digitalization of regulatory business & collaboration to accelerate access to medicines in Africa

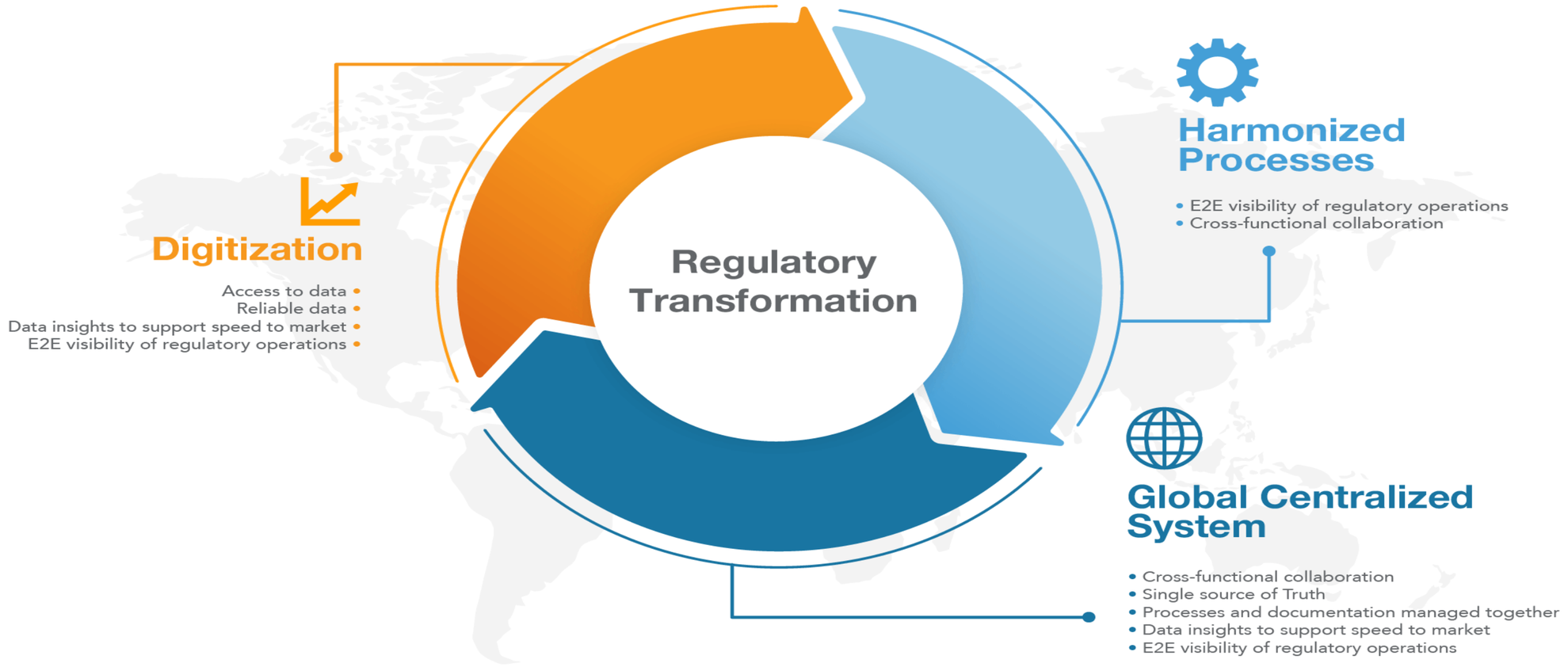
IFPMA

Amira Younes on behalf of IFPMA ARN
Director, Global Regulatory Policy ,Europe, Middle East & Africa, MSD

Unlocking Africa's Health Potential

Africa's moment to innovate

“ Digitalization as a backbone of collaboration and strengthening regulatory frameworks across Africa”



Digital Transformation Vison in Regulatory Ecosystem

Health Authorities Sponsors

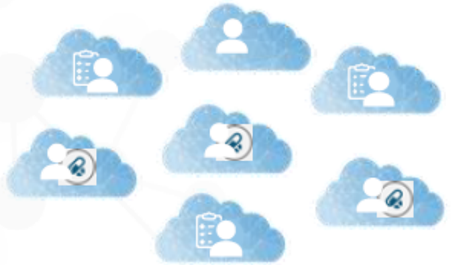
Current/Siloed	Localized/Limited	Regional/Expanded	Global/Comprehensive

1 Point-to-point submissions

- e-paper submission (eCTD)
- Static data shared at pre-defined stages
- Siloed data repositories in industry and jurisdictions

2 Limited data submission in cloud

- Harmonized structured data standards with global accessibility
- Collaboration between sponsors and HA towards cloud submissions
- **Pathway-specific cloud: collaborative review, cloud-based data submission and reliance networks**



3 Regional adoption

- Standardization of cloud services
- Flexible trial models and RWD networks established
- Automated post marketing safety monitoring with Artificial Intelligence
- Clouds un-siloed and high interoperability
- Digital platforms become accessible to all countries

4 Global Cloud Network

- An organised / harmonised global HA network with local branches
- Sponsors self-control therapeutics quality/efficacy/ safety profiles, with continuous AI based analysis
- Full enablement of most use cases (rolling review, CMC data real-time availability, patient-level submissions)
- One global data model with real-time access for all.
- Data-driven information and decisions

DIA

Source: Regulatory Submissions, Information, and Document Management Forum 2025 Feb 3-5 - Rodrigo Palacios

E-CTD Timelines

The late 1990

eCTD format was developed to streamline and standardize electronic submissions in regulatory processes.

2003

The first version of eCTD 3.0 was finalized in 2003

2008

eCTD v3.2 was release and the default version for more than 10 years

2015-2016

eCTD 4.0 was developed to improve robustness, flexibility, long term stability, and a more advanced LCM process

2025

eCTD 4.0 is finally ready for implementation after many years of collaboration with regulatory bodies and industry sponsors

ICH Initiatives Advancing Electronic Submission Standards

- The **International Council for Harmonization (ICH)**
  played a key role in the creation and implementation of the **eCTD format** for **global regulatory standardization**. It provides a comprehensive framework for **electronic Common Technical Document (eCTD)** submissions.

- **Ensuring Consistency**
  These standards help maintain **consistency** in regulatory documentation across various regions, ensuring **uniformity** in submissions.

- **Quality in Documentation**
  The established standards also focus on the **quality** of regulatory documentation, enhancing **compliance** and **review efficiency**.

ICH M2 - Electronic Standards for the Transfer of Regulatory Information (ESTRI)	Global standards for digitization and move to electronic submissions
ICH M4, M4Q, M4E, M4S – Common Technical Document (CTD)	Harmonised organisation of regulatory information
ICH M8 – electronic Common Technical Document (eCTD)	Enabling global regulatory submissions
ISO IDMP - Identification of Medicinal Products	Global standard for product master data
ICH M11 –Clinical Electronic Structured Harmonised Protocol Template	Clinical protocol organization with standardized content with both required and optional components
ICH E2B - Individual Case Safety Report (ICSR) Specification	Global harmonization of adverse event reporting
ICH SPQS (planed) – Structured Product Quality Submission	Harmonized exchange of structured data for CMC information

DIA

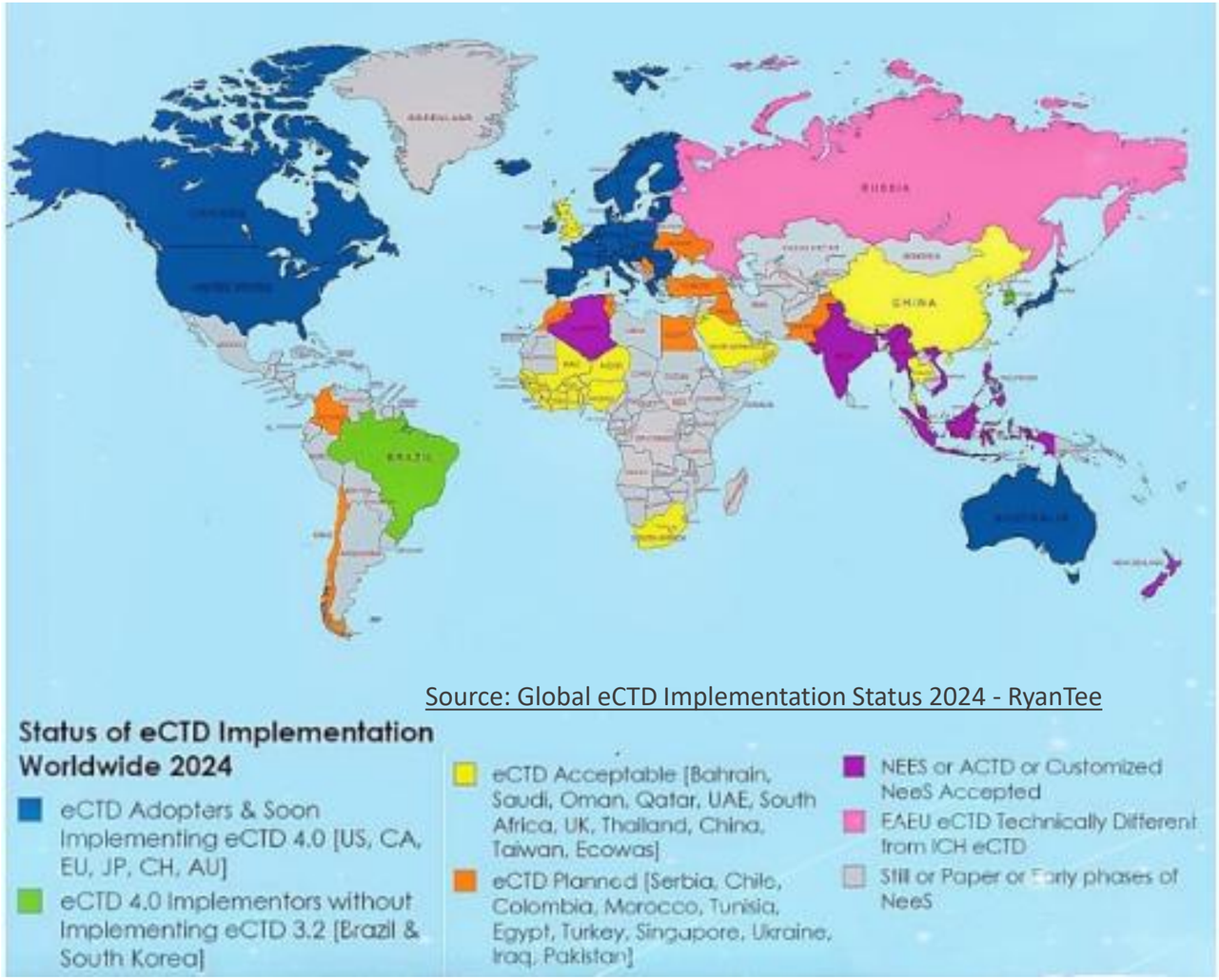
Visual of Global eCTD Adoption

Leading Adopters eCTD 4,0: US, Canada, EU, Japan, Switzerland, Australia.

New Implementers: Brazil & South Korea leap into eCTD 4.0.

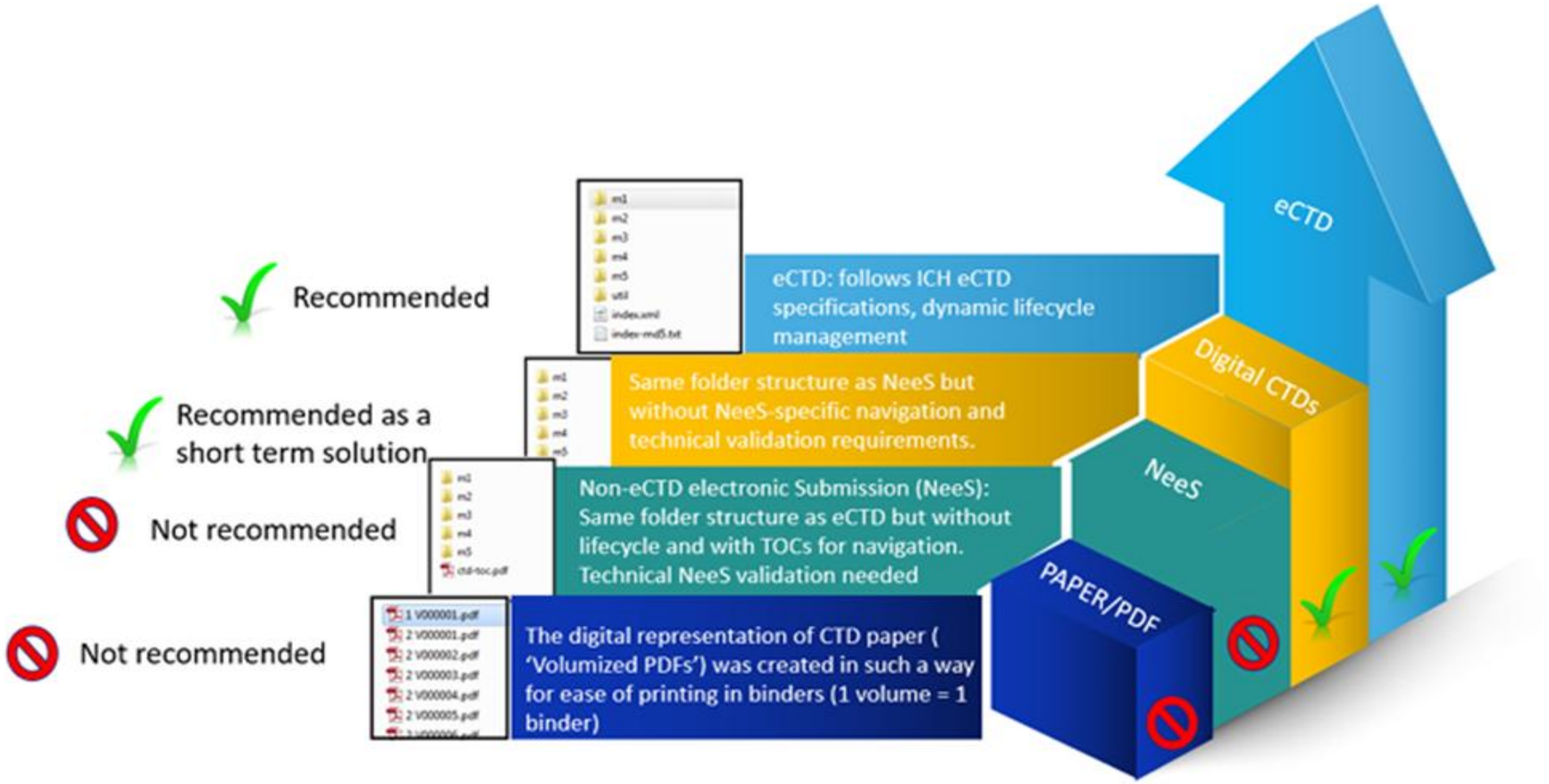
Middle East, Africa, UK, Thailand, China, Taiwan, and ECOWAS embrace eCTD, with ECOWAS **making it mandatory** from **May 1, 2026.**

Varied acceptance formats include: NEES, ACTD, Customized NeeS, EAEU, and Early Phase or Paper Submissions, catering to diverse regional needs.



Source: Global eCTD Implementation Status 2024 - RyanTee

Transitional Format Towards eCTD Adoption



Source: EFPIA Global ICH eCTD Adoption

eCTD v4.0 Adoption

- [1] A Technical pilot includes industry parties who will submit sample/test submissions. Objective determine technical specification.
- [2] A Production pilot includes industry parties who will submit submissions to the regulator for regulatory review. Objective ensure ready for a full release
- Voluntary dates indicate when eCTD v4.0 submissions are accepted into the production environment after all pilots are complete.
- Mandatory dates indicate when all submissions are required to be in the eCTD v4.0 format.
- TBD = Dates and/or materials are not yet known or not ready for public release, respectively.

Region	Technical Pilot[1]	Implementation Dates[2]	Implementation Documents
ANVISA, Brazil	4Q 2025 (Planned)	1Q 2026 (Production Pilot[2]) 2026 (Voluntary)	TBD
EC, Europe	2024 CAPs (Started)	2025 (Voluntary for CAPs[2]) 2026 (Voluntary for MRP/DCP/NP) 2027 (Mandatory for CAPs) TBC (Mandatory for MRP/DCP/NP)	EC, Europe regional implementation page
FDA, United States	2022 - 2Q 2023 (Completed)	2024 (Voluntary) 2029 (Mandatory)	FDA, United States regional implementation page
Health Canada, Canada	2025 (Planned)	2026 (Voluntary) 2028 (Mandatory)	Health Canada, Canada regional implementation page
MFDS, Republic of Korea	TBD	2027 (Voluntary) TBD (Mandatory)	TBD
MHLW/PMDA, Japan	2Q 2021 (Completed)	2022 (Voluntary) 2026 (Mandatory)	MHLW/PMDA, Japan regional implementation page
Swissmedic, Switzerland	2026 (Planned)	2027 (Voluntary) 2030 (Mandatory)	Swissmedic, Switzerland regional implementation page
TGA, Australia	4Q 2025 (Planned)	2026 (Voluntary) TBD (Mandatory)	TGA Implementation of ICH eCTD v4.0 Specification

Source: eCTD 4.0 Implementation - Including Understanding - of Regional Differences and Benefit - SADIA AHMED, Associate Director — Regulatory Technology, IQVIA

The Future - Cloud Based platforms

Real-Time Collaboration
Cloud-based platforms will enable health authorities and industry partners to securely share and access regulatory dossiers and data in real time, driving convergence and collaboration globally.

Empowering Health Authorities
Digital transformation will shift submissions from a ‘push’ to a ‘pull’ model, giving health authorities greater control over information received and enabling ongoing evaluation of clinical and real-world data for adaptive licensing.

Efficiency & Cost Reduction
Pharmaceutical companies are adopting cloud-based Regulatory Information Management systems, which facilitate process convergence, real-time reviews, and cost savings—though full implementation of dynamic dossiers is still several years away.

Source: EFPIA Global ICH eCTD Adoption

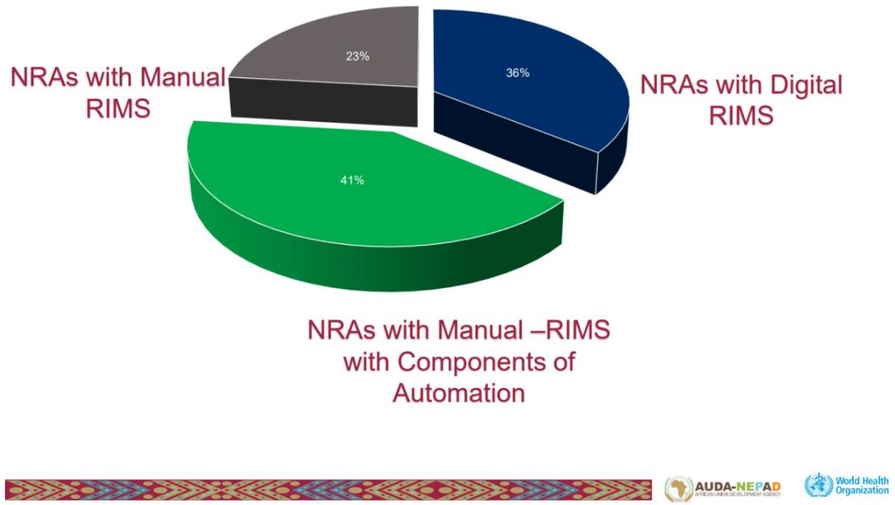
AUDA-NEPAD- leveraging a robust Information management system (IMS)

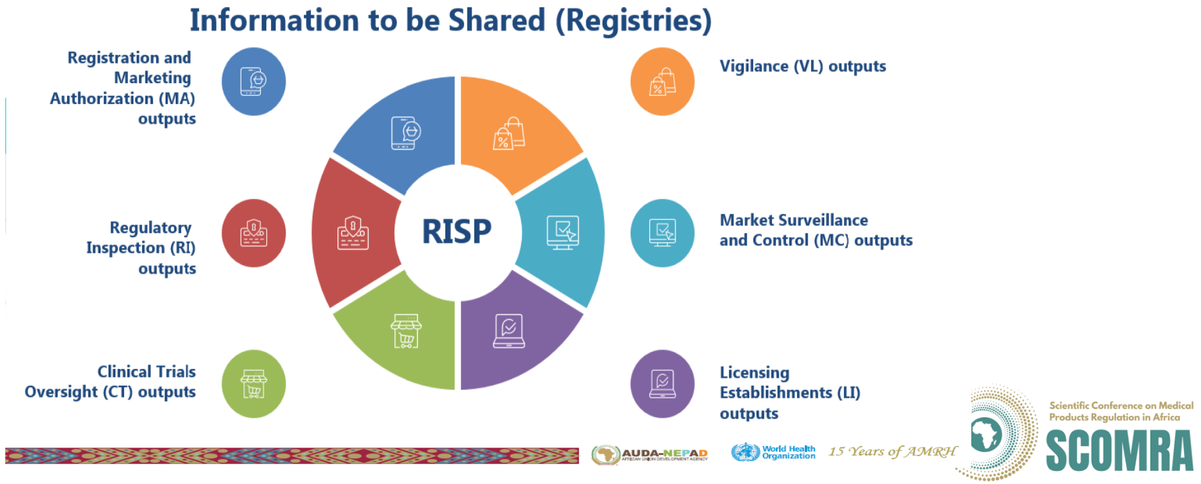
AMA RIMS Strategy

- African IMS Landscape
- Importance of Robust IMS- storing and sharing info, streamlined evaluations, improved communication and coordination and for capacity building
- IMS TC developed RIMS digitalisation strategy
- IMS TC supports continental digitalisation & recommends AU Model RIMS
- Advocacy for continental eCTD common standard (harmonised CTD structure),
- Development of API database
- Electronic DMS development
- Establishment of electronic continental regulatory experts (Ecres)- Hub for experts.

Challenges

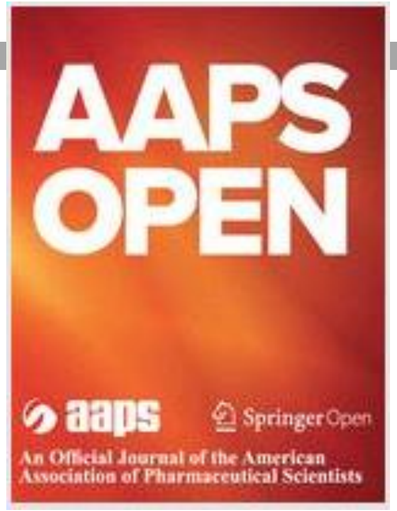
- Lack of data from NRAs
- Interoperability of RIMS
- Cost of digitalisation
- Technical competencies
- Data security
- infrastructure





Resource: CIRS 2025 Workshop Synopsis - Regulatory Collaborative Models.pdf-26-27 February 2025,Johannesburg

2nd APAC Paper accepted for publication by American Association of Pharmaceutical Scientists (AAPS) Open –Published 17 Dec 2014



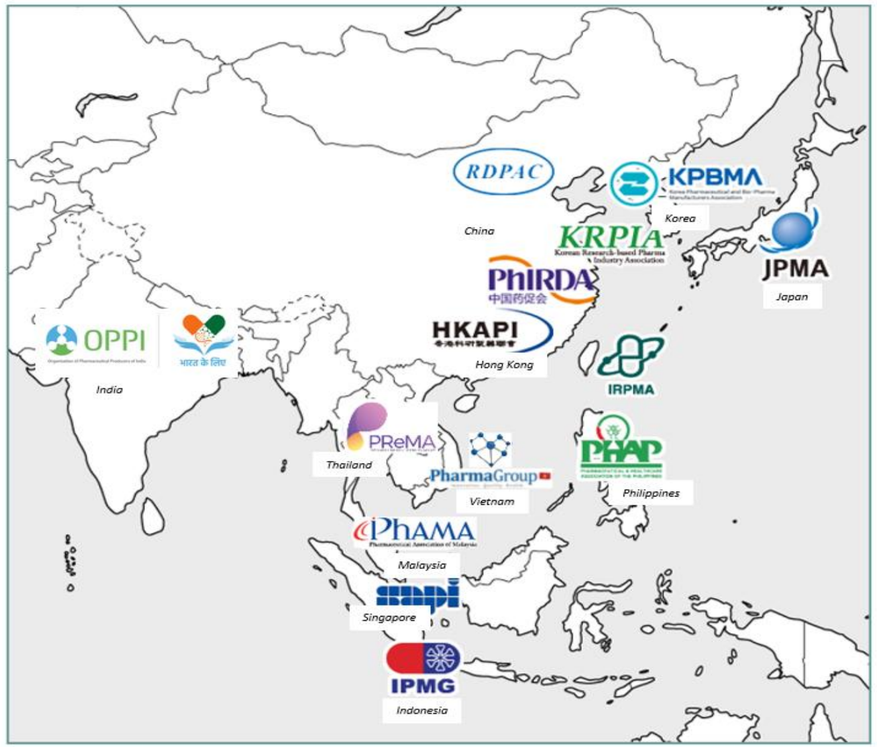
Advancements in Regulatory Agility, Regional Collaboration, and Digital Transformation: Insights from the Asia Partnership Conference of Pharmaceutical Associations (APAC)

Sannie Siaw Foong Chong[1*] · Stephanie Hui Min Ong[2] · Siew Mei Long[3] · Masaaki Kanno[4]. Usanee Harnpramukkul[5] · Kum Cheun Wong[6]· Asawari Sathaye[7] Mamta Singh[8]. Manish Paliwal[9]· Huyen Do[10]· Helene Sou[11]· Richard Simon R. Binos[12]

- The Asia Partnership Conference of Pharmaceutical Associations (APAC) examines recent developments in regulatory practices across Asia, **focusing on regulatory agility, regional collaboration, and digital transformation.**

- The paper identifies key improvements made by national regulatory authorities (NRAs) in adopting regulatory agilities over a two-year span. **It also suggests optimizing regional reliance pathways and recommends best practices for implementing e-submission, real-world evidence (RWE), decentralized clinical trials (DCTs), and paperless e-labelling.**

- **For more details, please refer to:** https://rdcu.be/d3OXr



14 APAC member associations from across Asia

Insights from APAC: #1
58% of NRAs implement entirely paperless e-submission

- ✓ All twelve economies permits e-submissions.
- ✓ In China, India, Indonesia, Japan, the Philippines, Singapore, and Vietnam, e-submissions are entirely paperless.
- ✓ In contrast, the remaining economies still require some form of physical documentation to be submitted.

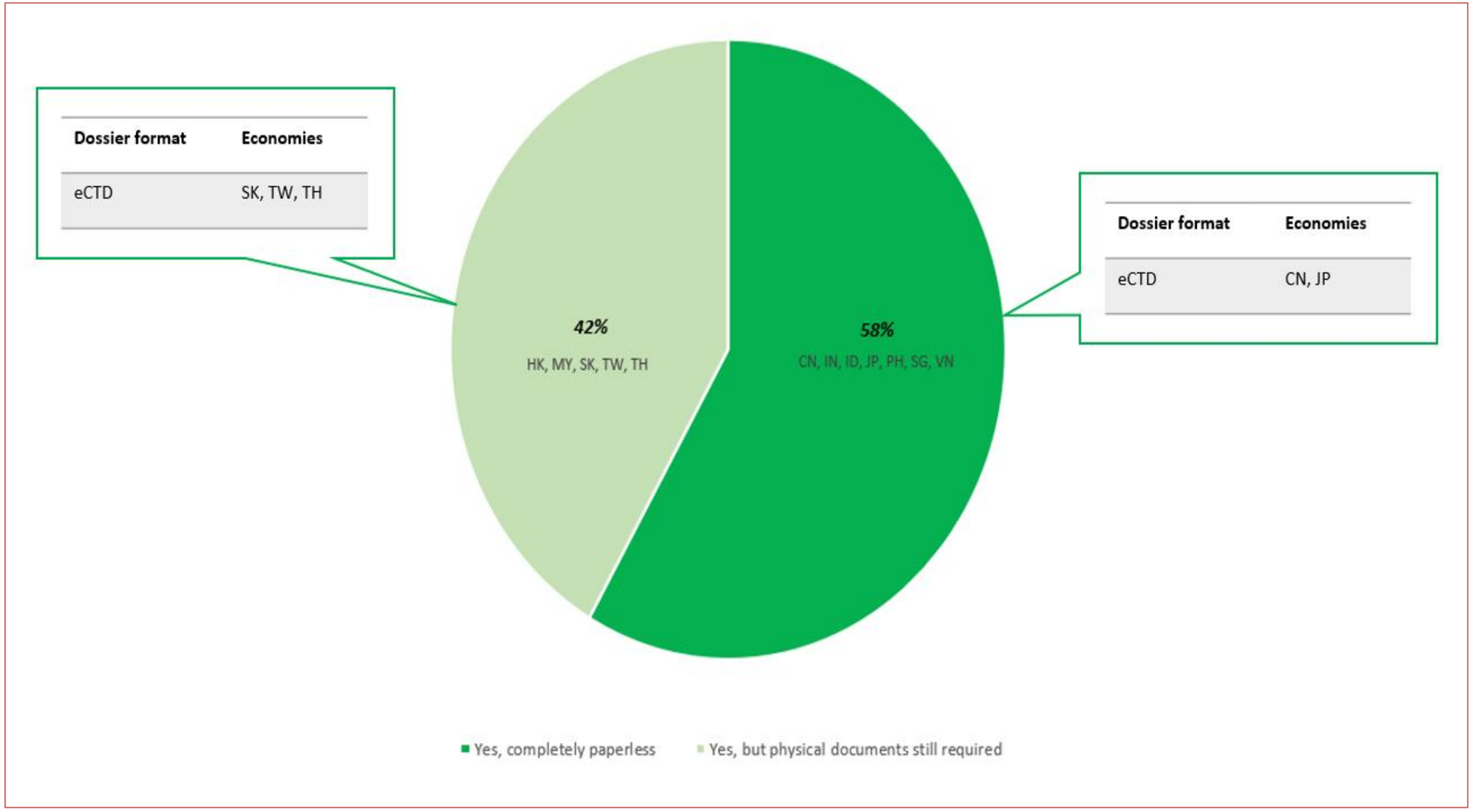


Figure 5: 58% of NRAs implement entirely paperless e-submission.

Insights from APAC: #2
42% of NRAs accept ICH eCTD

- ✓ The ICH eCTD format is implemented in China, Japan, South Korea, Taiwan, and Thailand, which constitutes 42% of NRAs.
- ✓ Hong Kong accepts the ICH CTD format as is, while India mandates country-specific customization of the dossier.
- ✓ The dual system for pharmaceutical registrations, which accepts both ICH and ACTD formats, is implemented in Malaysia, the Philippines, Singapore, Vietnam, and Indonesia.

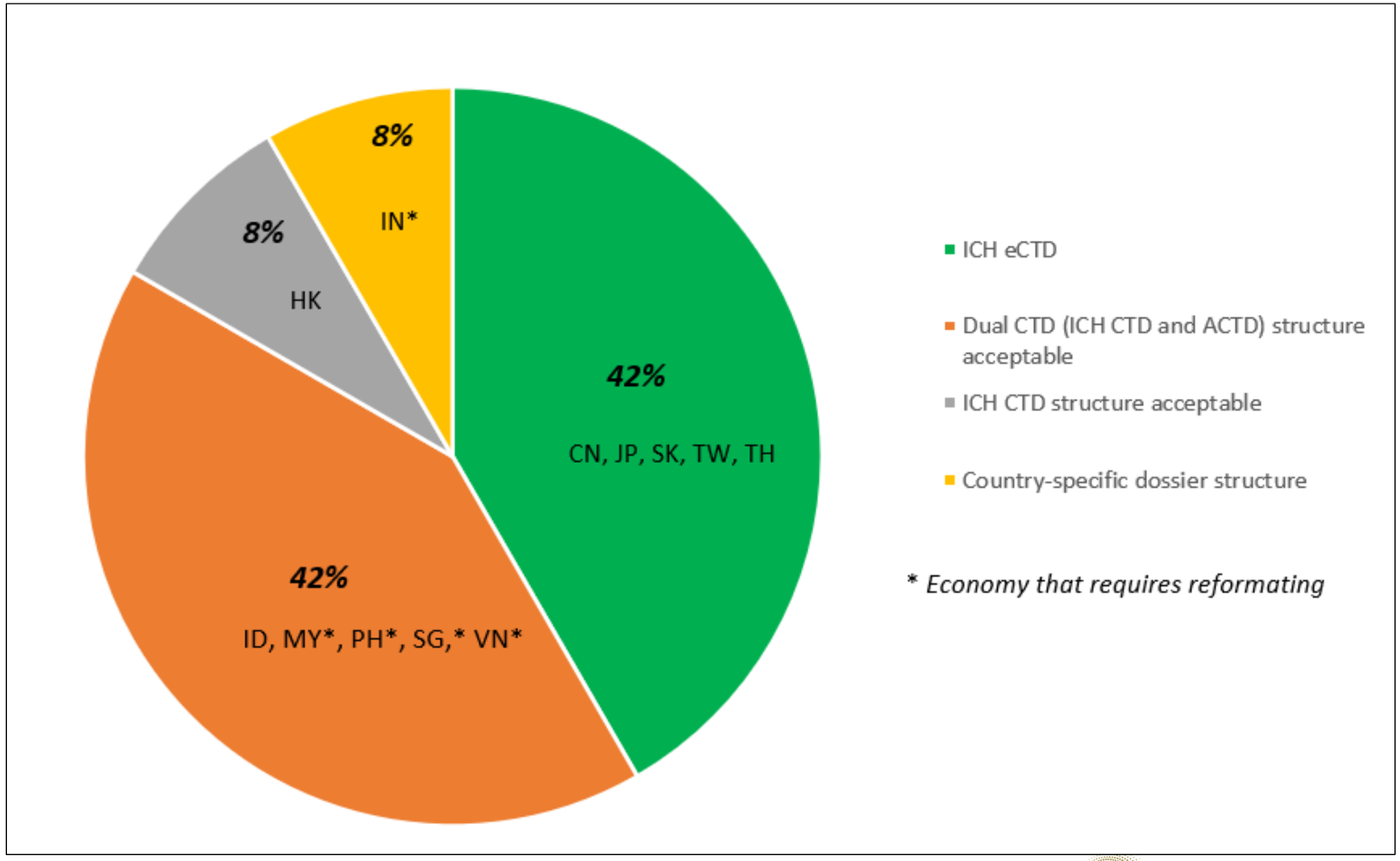


Figure 6: 42% of NRAs accept ICH eCTD.

Scientific Conference on Medical Products Regulation in Africa
SCOMRA

Insights from APAC: #3
Do not mandate baseline requirement

- ✓ ***More than 50% of NRAS do not mandate a baseline requirement for existing products to support the transition to e-submission.***
- ✓ China, Japan, Malaysia, Philippines, Singapore, South Korea, and Taiwan did not mandate baseline requirement when e-submissions were applied retrospectively into existing products

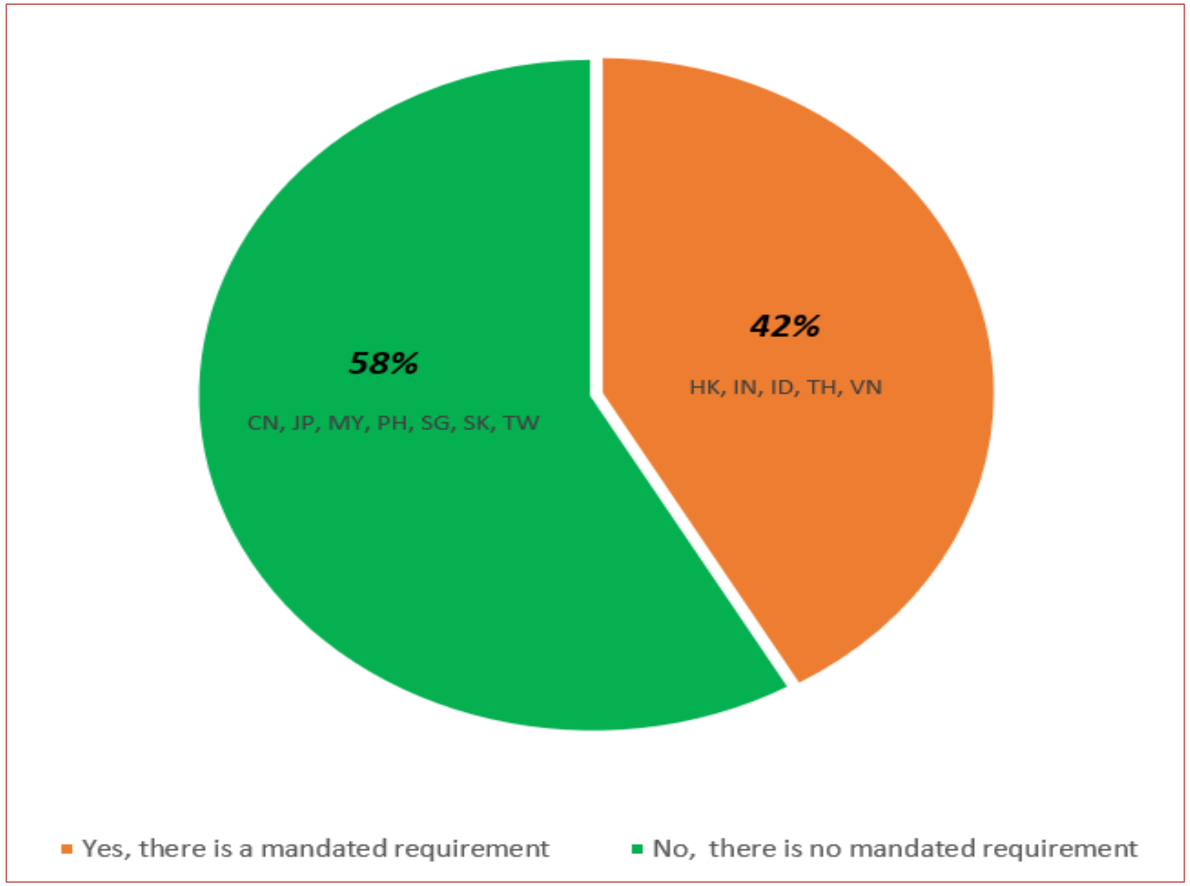
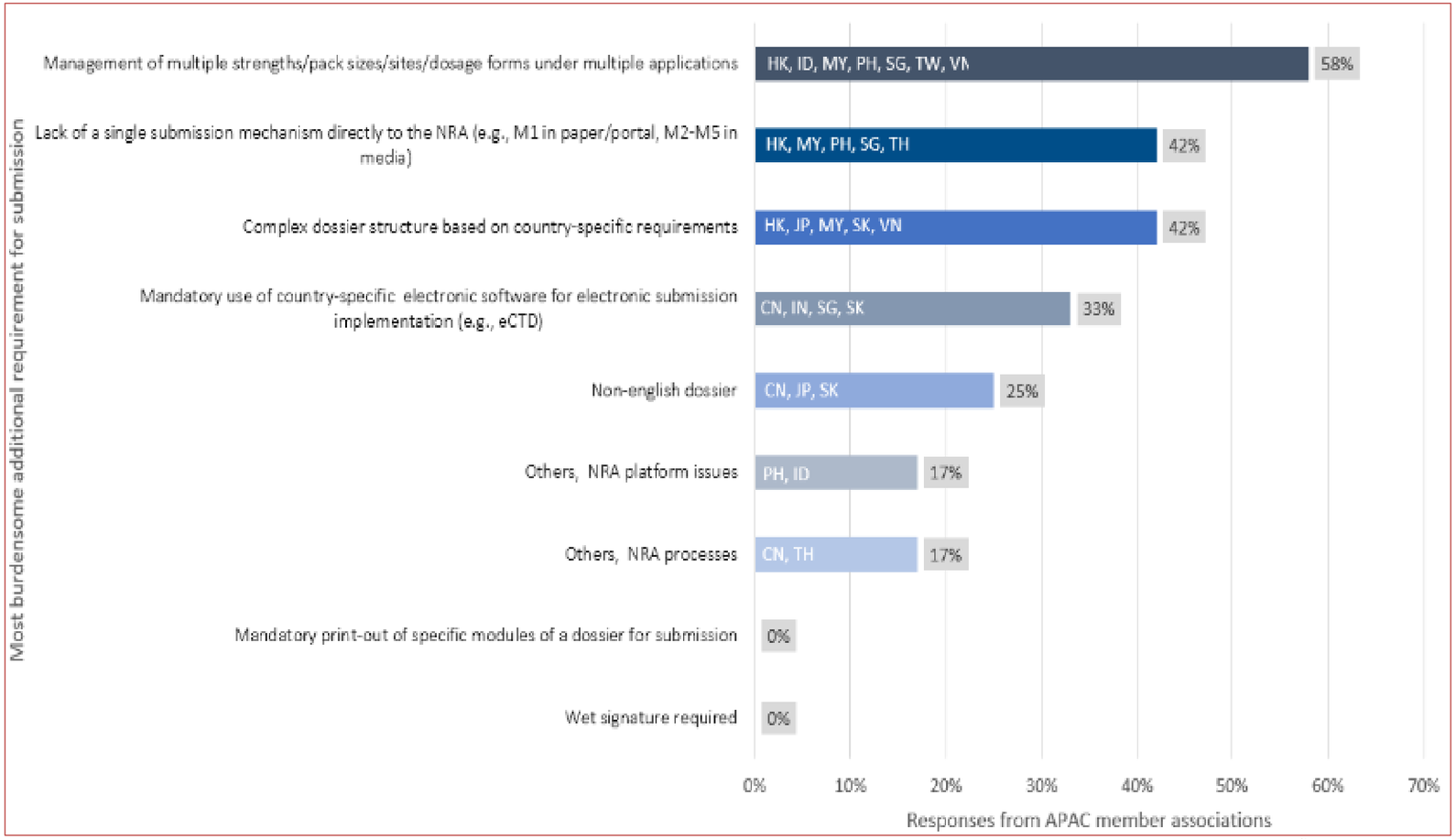


Figure 7: More than 50% of NRAS do not mandate a baseline requirement for existing products to support the transition to e-submission.

Insights from APAC: #4
The most burdensome additional requirements that impact the full benefits of e-submission

<u>The most burdensome additional requirements that limit the benefits of e-submission include, but are not limited to:</u>

- Managing multiple strengths, pack sizes, sites, and dosage forms under multiple applications
- The lack of a unified submission mechanism directly to the NRA from both a management and system perspective
- A complex dossier structure based on country-specific requirements
- Mandatory use of country-specific electronic software, and
- Additional tools such as non-English dossiers



Recommendations for Successful Digital Regulatory Transformation

Collaborative Approach/ Strategic implementation

1) Foster early collaboration among regulators and industry. **2)** Rapidly accept digital CTD formats as an interim solution & maximize technology using electronic submission gateways & online portals. **3)** Leverage shared experience through advice, testing, pilots, and discussion **4)** Allow sufficient time for each stage (Minimum 12 months)

Harmonizing Dossier Formats

Aligning with ICH CTD standards can streamline submissions, reduce reformatting efforts, and support smoother transitions to eCTD while addressing regional needs and capacities

Simplifying and Consolidating Submissions

Consolidating applications—such as multiple strengths, pack sizes, or dosage forms—within eCTD to fully benefit from eCTD's efficiency and effectiveness that is intended for all stakeholders. Avoid mandating baselines requirements to ease transition

Paperless Submissions and Sustainability

Moving toward fully electronic, paperless systems is a shared vision that offers significant efficiency and sustainability benefits.

Some Content provided from
Source: EFPIA Global ICH eCTD Adoption

KEY SUCCESS FACTORS FOR RSS - Conclusion

Strengthening regulatory frameworks and enhancing collaboration through tools, transparency, and digital solutions are crucial for improving the effectiveness of NRAs .

Digitalization

Adopt a digital regulatory strategy (eCTD/electronic submissions, RIMS, cloud solutions and AI) to automate routine assessments, provide predictive insights, and speed reviews for faster, higher-quality regulatory decisions.

Harmonized Processes & Standards

Standardize requirements, standards & workflows across jurisdictions to reduce processing times, improve transparency and traceability, and enable consistent regulatory outcomes.

Interoperable System

Use secure, scalable cloud platforms as centralized hubs for cross-country collaboration and data access to support harmonized practices and accelerate approvals.

Thank you