03-06 December 2024

ARC 2024

ASIA REGULATORY CONFERENCE

EVOLVING LANDSCAPES

Asia's role in driving a more efficient, innovative and patient-centric regulatory environment

CONFERENCE REPORT

Organized by IFPMA

In partnership with Medicines Australia

Introduction to the

12th Asia Regulatory Conference

For over a decade, the Asia Regulatory Conference has served as a platform for meaningful and solutions-oriented exchanges among regulatory authorities, academia and experts from the pharmaceutical industry on timely topics to evolve the regulatory landscape in the region.

In the 12th edition of this conference, held on 3-6 December 2024, stakeholders explored how regulatory reliance and work-sharing between national regulatory authorities can support pharmaceutical innovation and address regional health challenges.

This document serves as compilation of the key insights coming from each session.
To view the full program, speakers and rewatch the recordings, please go to www.arc.ifpma.org.

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12th Asia Regulatory Conference in figures

- **4 days** of keynote speeches, panel discussions and interactive Q&As
- Over **40 speakers** representing voices from patient organizations, national regulatory authorities, and industry experts in pharmaceuticals
- **1030 registered participants**, from **46 countries**

List of participating international or national regulatory authorities as speakers:

- Egypt Drug Authority
- Health Science Authority, Singapore
- Medicines and Healthcare Products Regulatory Agency, United Kingdom
- Ministry of Food and Drug Safety (MFDS), Republic of Korea
- National Medical Products Administration, China
- National Pharmaceutical Regulatory Agency, Malaysia
- Pharmaceuticals and Medical Devices Agency, Japan
- Philippines FDA
- Swissmedic
- Thailand FDA
- Therapeutic Goods Australia
- World Health Organization

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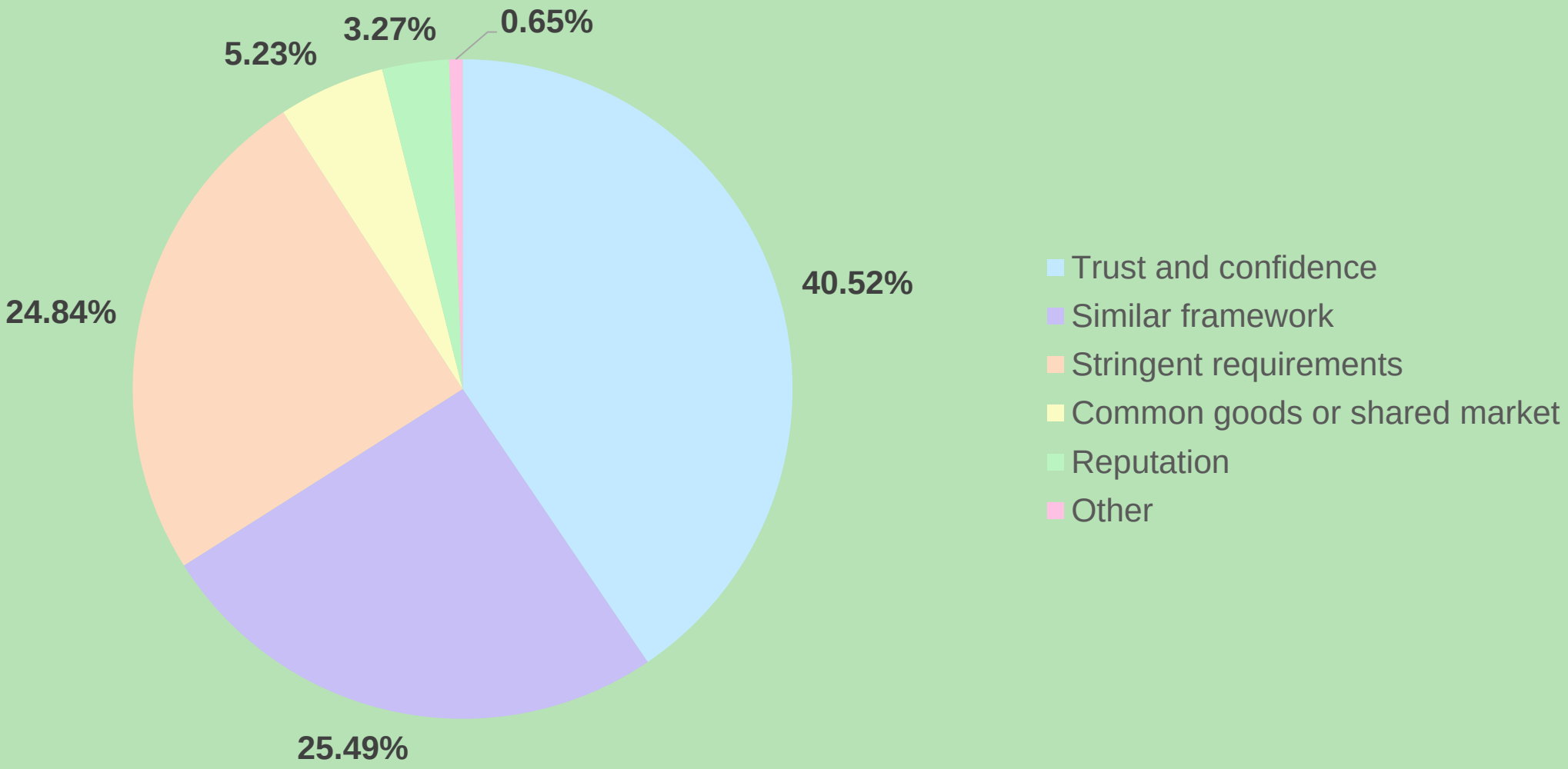
DAY 1: Key takeaways and insights
Session: Collaboration and worksharing to bring innovation to patients

- **Australia's Regulatory Strengthening Program (RSP):** Launched in 2018, the RSP aims at strengthening capability and enhancing stakeholder collaboration in the Indo-Pacific region to increase the availability of safe and effective medicines and medical devices through improved regulatory practice and regional coordination. With three targeted areas of activity focusing on quality, safety & efficacy and risk communication, the RSP includes opportunities to engage in regulatory reliance and collaboration. The RSP also supports individual countries to conduct Global Benchmarking activities.

- **World Health Organization:** For the World Health Organization (WHO), regulatory reliance exists in various forms (worksharing, unilateral/mutual recognition, abridged pathway using reliance, etc.) and can help to address the access gap for patients. The principles underpinning regulatory reliance include more efficient use of resources, promote increased trust and collaboration while decreasing duplication of activities. Throughout the implementation of regulatory reliance, the sovereignty and decision-making of the National Regulatory Authority (NRA) is preserved. The WHO implements regulatory reliance in several of its processes, including prequalification and collaborative registration procedures.

- **The ACCESS Consortium:** Comprised of five NRAs from Australia, Canada, Singapore, Switzerland and the United Kingdom, the ACCESS Consortium is designed to maximize international co-operation and reduce regulatory duplication while providing access to medicines and vaccines across a collective population base of around 160 million. The objectives of the ACCESS Consortium focus on strengthening worksharing initiatives, expanding the lifecycle approach and including regulatory innovation that targets a healthcare systems approach. The ACCESS Consortium currently includes working groups targeting generics, biosimilars, new active substances, complimentary health products, information technology management, clinical trials and advanced medical products.

- Following the panel discussion on collaboration and worksharing to bring innovation to patients participants were asked to respond to a poll: **“How should a regulator decide who to rely on?”**
- The results show that trust and confidence, the presence of a similar framework or stringent requirements are the main criteria.



DAY 2: Key takeaways and insights
Session: Reliance case studies & lessons learned

- **Strengthen regional cooperation to facilitate sharing and acceptance of key documents:** Ensure key documents that enable reliance (assessment reports, approval letters and GMP certificates) can be used by relying NRAS. Such documents should be explicitly listed and readily available when they are public. For non-public information, appropriate legal and technical frameworks should be developed or adapted to enable sharing of information. Leverage lessons learned ACCESS, ORBIS, ICMRA pilots and OPEN experiences in regulatory cooperation to create efficient, mutually beneficial frameworks that are adaptable to each country's unique context.
- **Integrate reliance as a strategic tool with consistent training programs:** Embed reliance as a core element of the regulatory toolkit to enable risk-based decision-making and optimize resource use. Reliance should not be limited to specific pathways but integrated across the full life cycle. Support regular training programs for regulators and industry stakeholders on applying reliance models, sharing best practices and lessons learned). WHO's regional reliance workshops are a valuable example of collaborative training approaches, while also raising awareness about reliance, its advantages, and its implementation status globally.
- **Establish best practices for documentation formats and Use:** Develop global best practices for regulatory documentation aligned with risk-based principles and WHO good reliance practices. This includes fostering a better understanding of documents provided by reference agencies—such as approval letters, assessment reports, GMP certificates, and their respective roles in supporting reliance. By clarifying what information each document offers and how it can be leveraged effectively, regulatory authorities can streamline and implement informed reliance, adapting sources to fit specific needs.

DAY 2: Key takeaways and insights
Session: Reliance across the product lifecycle

- **Standardize variation categories for PACs:** Harmonize post-approval change (PAC) categories to align with internationally recognized frameworks such as ICH Q12 and WHO guidelines. Adopt clear classification categories, such as prior approval (major changes), notification (moderate or low-risk changes), and not reportable (changes managed within the pharmaceutical quality system) as well as clear requirements and predictable timelines. This alignment facilitates reliance as well as worldwide implementation of changes when using standard pathways.
- **Adapt documentation requirements for PACs reliance process:** For reliance-based evaluations of PACs, ensure documentation requirements are adjusted to risk categorization and purpose-specific (e.g Assessment report and approval letters can be used when available for major changes). Companies may add declarations of differences between the reference variation package and the one submitted to the relying NRA, when applicable. “Informed” reliance process with streamlined documentation requirements will incentivize use of reliance across the full product life cycle, ensuring patients have continued access to high quality, safe and efficacious products.
- **Foster practical GMP inspection reliance through global frameworks:** Build trust in shared GMP inspection outcomes based on similar information available in inspection reports, GMP certificates, and other key documentation. NRAs should leverage collaboration frameworks like PIC/S to enable unilateral reliance or mutual recognition, reducing duplication and / or length of inspections to improve resource efficiency and sustainability. Practical implementation should focus on ensuring processes for verifying inspection outcomes align with different terminologies used in domestic legal frameworks while maintaining global inspection standards.

DAY 3: Key takeaways and insights
Session: E-labelling as a pathway to a future Universal Label

- Dynamic progress for e-labeling initiatives such as issuance of e-labeling guidance in Asian region has been made for the last few years.
- The implementation of FHIR e-labeling should be advocated as the international electronic common standard across Asia.
- The availability of patient centric labeling is only around 30 % of the markets in Asian region. The important introduction of patient centric e-labeling should be encouraged.

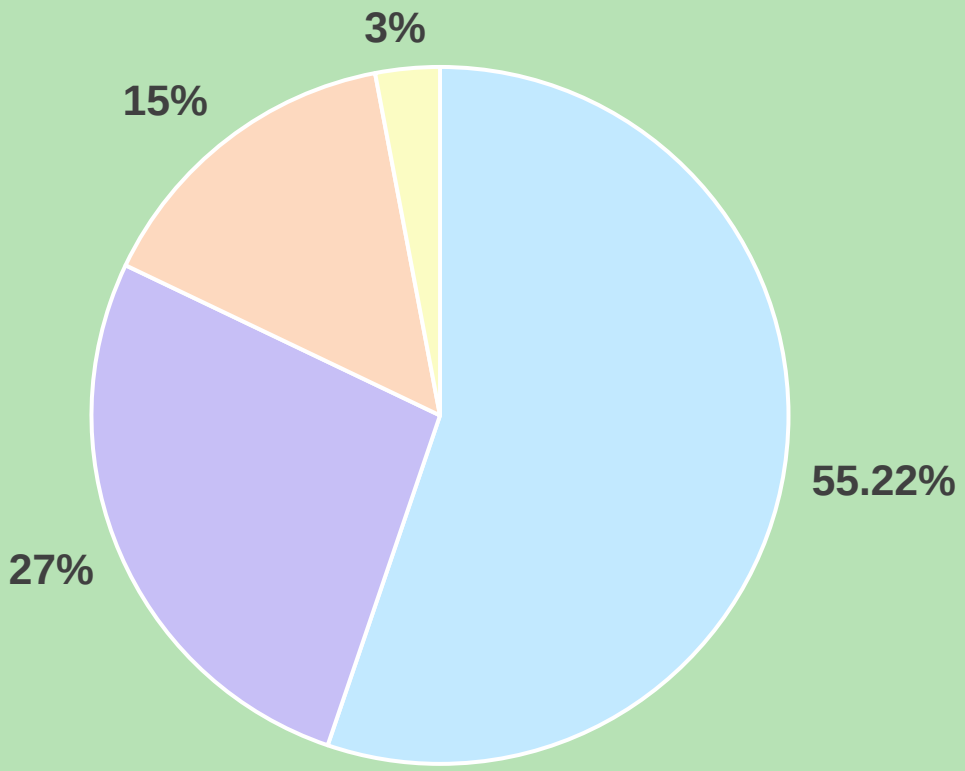
DAY 3: Key takeaways and insights
Session: Universal Labelling Opportunities & Challenges

- **Technological advances are occurring at a fast and furious pace**
  - Other industry sectors such as banking and home appliances have rapidly accelerated their digital approach during/post COVID with widespread use of QR codes
  - Medicines are becoming more complex making health literacy a critical factor for safe use to achieve optimal clinical outcomes with new technologies potentially providing more options
- **Medicines labelling regulations in most countries remain reflective of a pre-digital era where printed packaging was the only option**
  - ICH has harmonized many aspects of the requirements for quality, safety and efficacy data but medicines labelling has not been addressed
  - For prescription medicines a printed dispensing label is often the key information accessed by patients
  - When administered in hospital setting patients may not receive the original medicines pack
- **Changing medicines legislation to achieve harmonization can be time consuming and complex, but brings benefits for all stakeholders by enabling better use of resources to drive innovation**
  - Globalization and harmonization are a key focus for both industry and regulators
  - Reviewing the purpose and role of printed information in a rapidly evolving digital ecosystem is essential to optimize patient care

DAY 3: Key takeaways and insights
Session: Preparing regulatory systems for combination products for advanced therapies and biologics

- For both Advanced Therapeutics and Medicinal Products (ATMPs) and drug device combination products (DDCPs), **regulatory frameworks are still developing** worldwide.
- **For ATMPs**: There are ongoing global regulatory harmonization and convergence efforts (WHO, ICH, APEC) to manage the differences in the maturity of frameworks among countries. There are opportunities for i**dentifying best practices and developing harmonized guidelines and standards**.
- **For DDCPs**: Lack of common terminology, potential difficulties to classify and navigate different requirements, e.g. for complex devices and drugs.
- **Combined ATMPs** are complex DDCPs with specific scientific and regulatory challenges (e.g. impact assessment of device to drug effect, biocompatibility, GMP considerations, and others).
- There is a **need for more global convergence, flexible regulatory pathways based on risk-based approaches and regulatory reliance**.
- Importance of **early scientific interactions** between sponsors/manufacturers and regulators.
- **Sharing expertise and best practices** among regulators and all stakeholders.

- Following the panel discussion on preparing regulatory systems for combination products for advanced therapies and biologics, participants were asked to respond to a poll: **“How would you value a roadmap for the development of regulatory practice and capabilities for combined medical products, including cell & gene therapy combined products”?**
- The results indicated that **82% of participants would find this roadmap valuable** or an essential initiative for the regulatory community in Asia Pacific.



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DAY 4: Key takeaways and insights
Session: Driving Global Harmonization to Advance Global Health

- **Regulatory alignment**: The adoption of ICH guidelines promotes harmonized regulatory standards, reducing inefficiencies, enhancing predictability, and ensuring that medicines meet consistent quality, safety, and efficacy requirements across markets.

- **Mutual benefits for regulators and industry**: ICH membership strengthens regulatory systems by providing clear, harmonized frameworks, reducing duplication, and fostering global collaboration. For both regulators and industry, this translates into streamlined processes, better resource utilization, and faster patient access to medicines.

- **Collaborative implementation drives success**: The effective implementation of ICH guidelines depends on robust engagement between regulators and industry, ensuring shared understanding of expectations and enabling the seamless adoption of new standards within national regulatory frameworks.

- **Capacity building and global health impact:** ICH plays a critical role in enhancing regulatory capacity through training, knowledge sharing, and the adoption of harmonized guidelines. This strengthens regulatory systems worldwide, ensuring better health outcomes by improving access to safe, effective, and high-quality medicines.

DAY 4: Key takeaways and insights
Session: eCTD Harmonization in Asia: Unlocking the Benefits of Standardized Submissions

- **Paperless submissions and sustainability:** Moving toward fully electronic, paperless systems is a shared vision that offers significant efficiency and sustainability benefits.

- **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 it intended for all stakeholders.

- **Collaboration with pragmatic approach is key:** Early conversation and pragmatic approach during the transition to eCTD—such as not mandating baseline submissions—can ease challenges for all stakeholders. **Collaboration** - Enable full benefits of eCTD digital efficiency and standardization that facilitates work-sharing/reliance across multiple regulators, thereby expediting the launch of innovative medicines for people in Asia.

DAY 4: Key takeaways and insights
Session: Advancing Clinical Trials: The Impact of E6(R3) Guideline

- **Consistent understanding of E6(R3):** A unified understanding of the revisions is essential for implementing this Tier 1 guideline. It is critical to understand the “why” behind the changes, as outlined in the ICH Reflection Paper and Concept Paper.

- **Fit-for-Purpose, risk-proportionate approach with unchanged core principles:** E6(R3) introduces a fit-for-purpose, risk-proportionate framework focusing on the factors critical to quality - what matters most for participant protection and trial reliability. While the guideline introduces flexibility, the fundamental principles of ensuring participant safety and the reliability of trial results remain unchanged.

- **Stakeholder mindset and behavior shift:** A shift in mindset and behavior among all stakeholders is essential for successful implementation. **Training, education, and proactive communication** will help drive this cultural change and ensure alignment with E6(R3).

- **Real-World Data (RWD) integration:** It's crucial to ensure that RWD is fit for purpose by managing control over data collection, securing access agreements, ensuring accurate data linkage, and prioritizing cybersecurity and privacy in remote trials.

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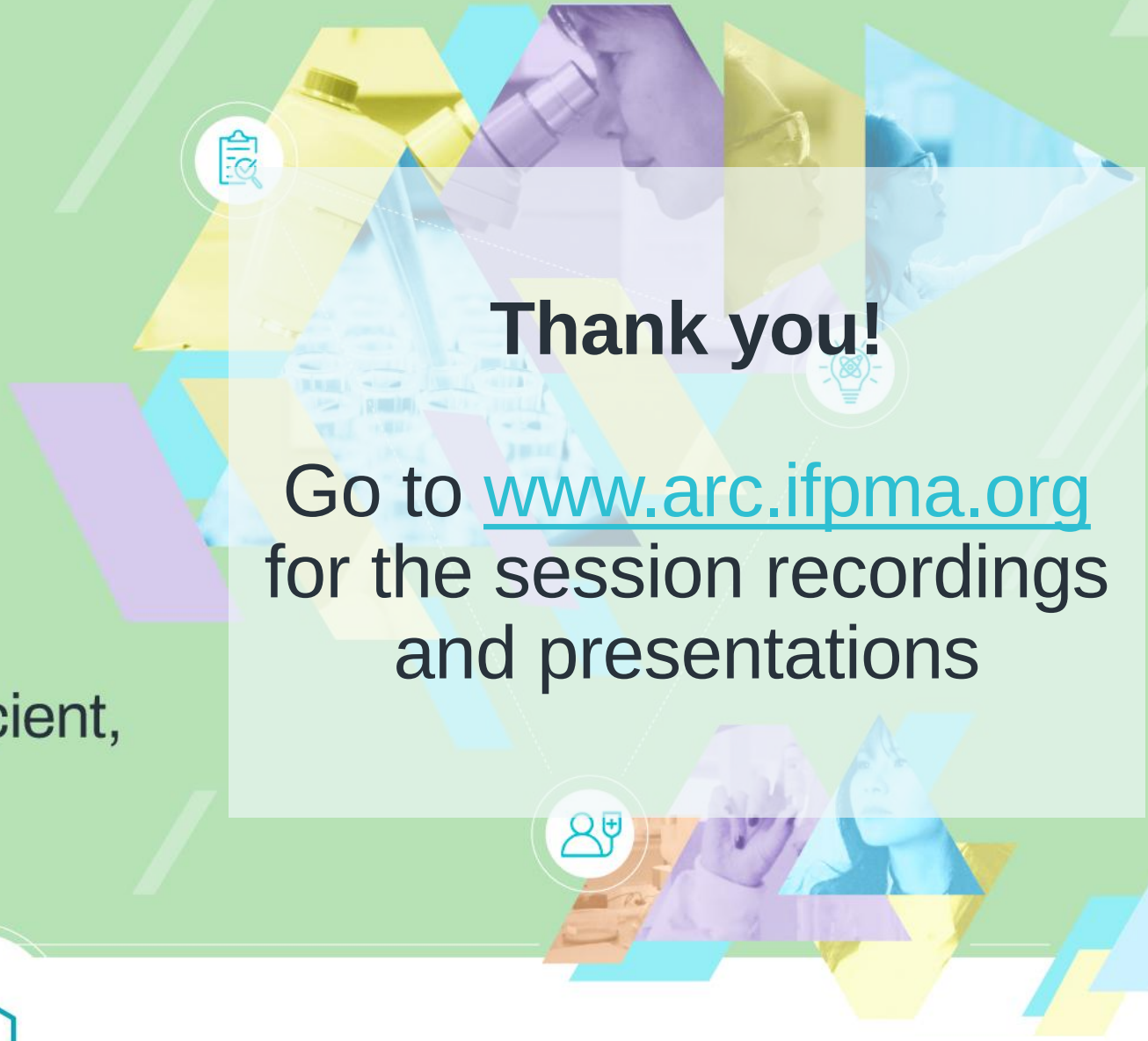

Thank you!

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