Expectation to International Harmonization from Pharmaceutical Industry

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JPMA ICH Project Committee
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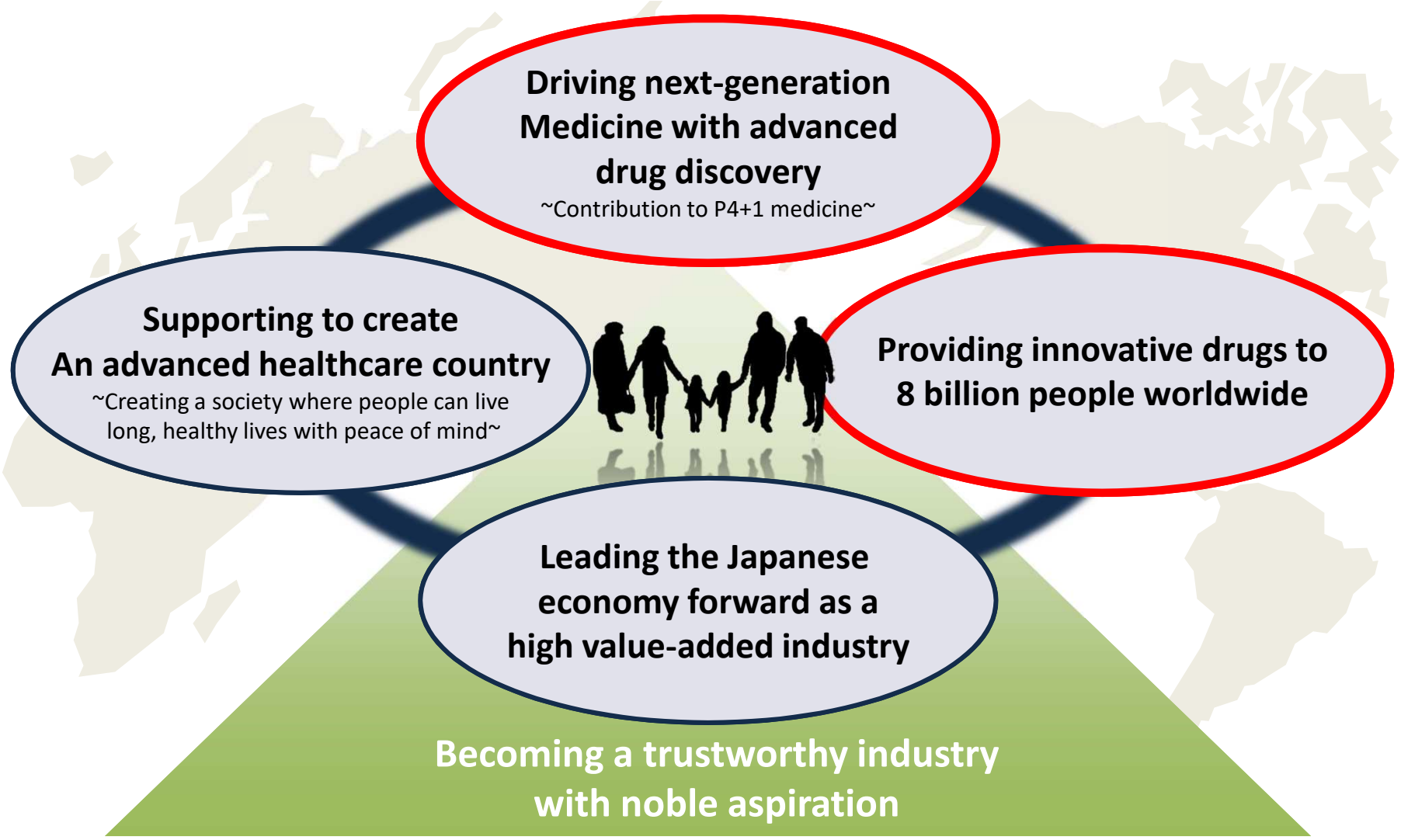
Outline

1. JPMA Industry Vision 2025
2. Challenges in Regulatory Harmonization
3. Dialogue between Regulator and Industry
4. Expectation to Further Harmonization

JPMA's Industry Vision 2025

- The vision represents JPMA' aspiration in ICH activities as well.



JPMA's Business Plan in FY2018

- In FY2018, JPMA is working on 4 major activities, aiming for the 2025 vision.

I. **Improve quality of medical care with fostering innovation, Contribute to economic growth with the value of medicines**
   1. Promote innovation which leads the next-gen medicine
   2. Strengthen cooperation with AMED
   3. Deal with new regulatory framework for early access

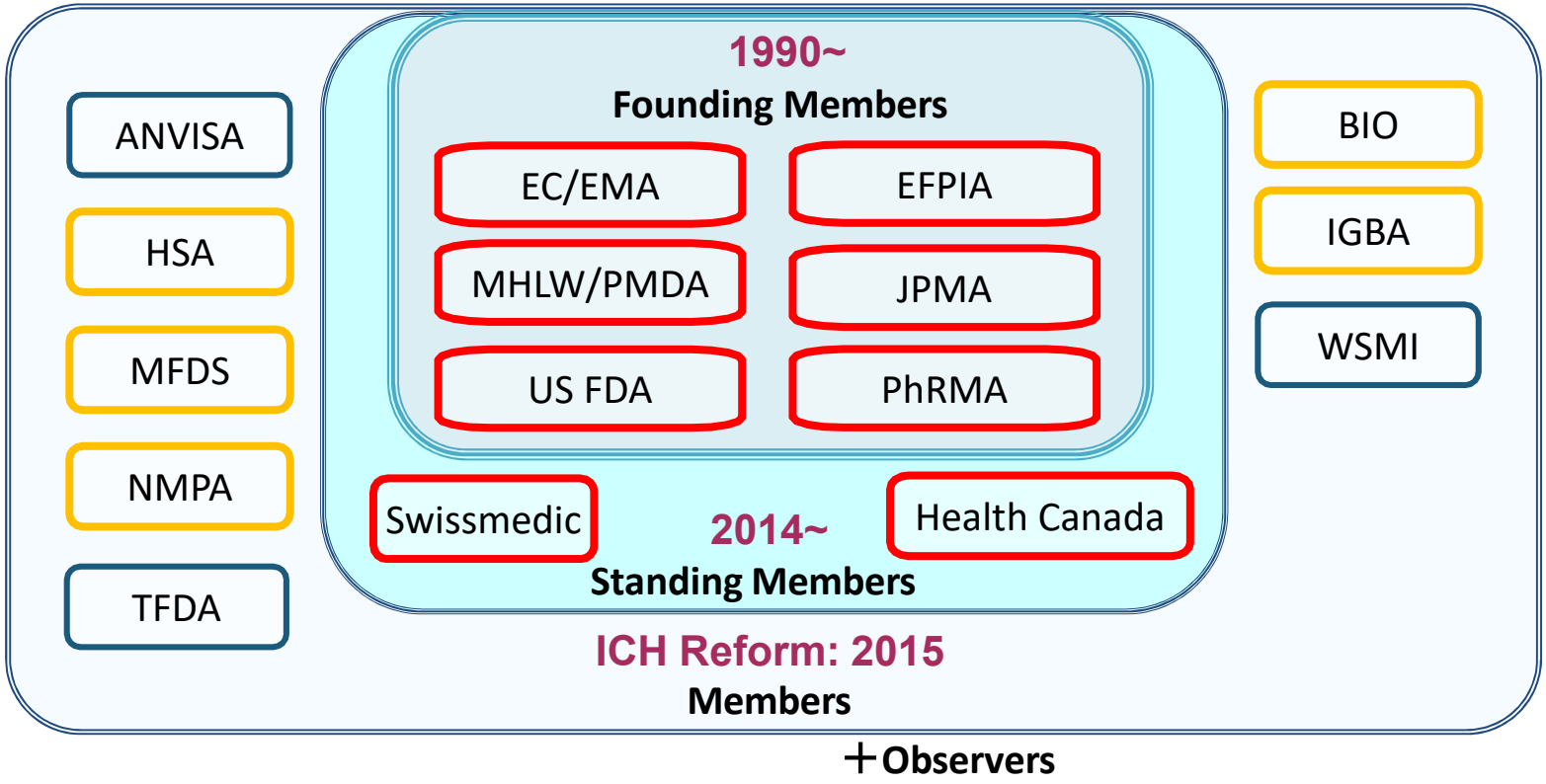
II. **Drive international activities and cooperation, Contribute to global health**

III. Further through compliance, Build further trust with the public

IV. Foster further understanding of the pharmaceutical industry

ICH – Unique Venue for Reg Harmonization

- ICH is an unique harmonization project, involving the Regulators and Industries across the globe.



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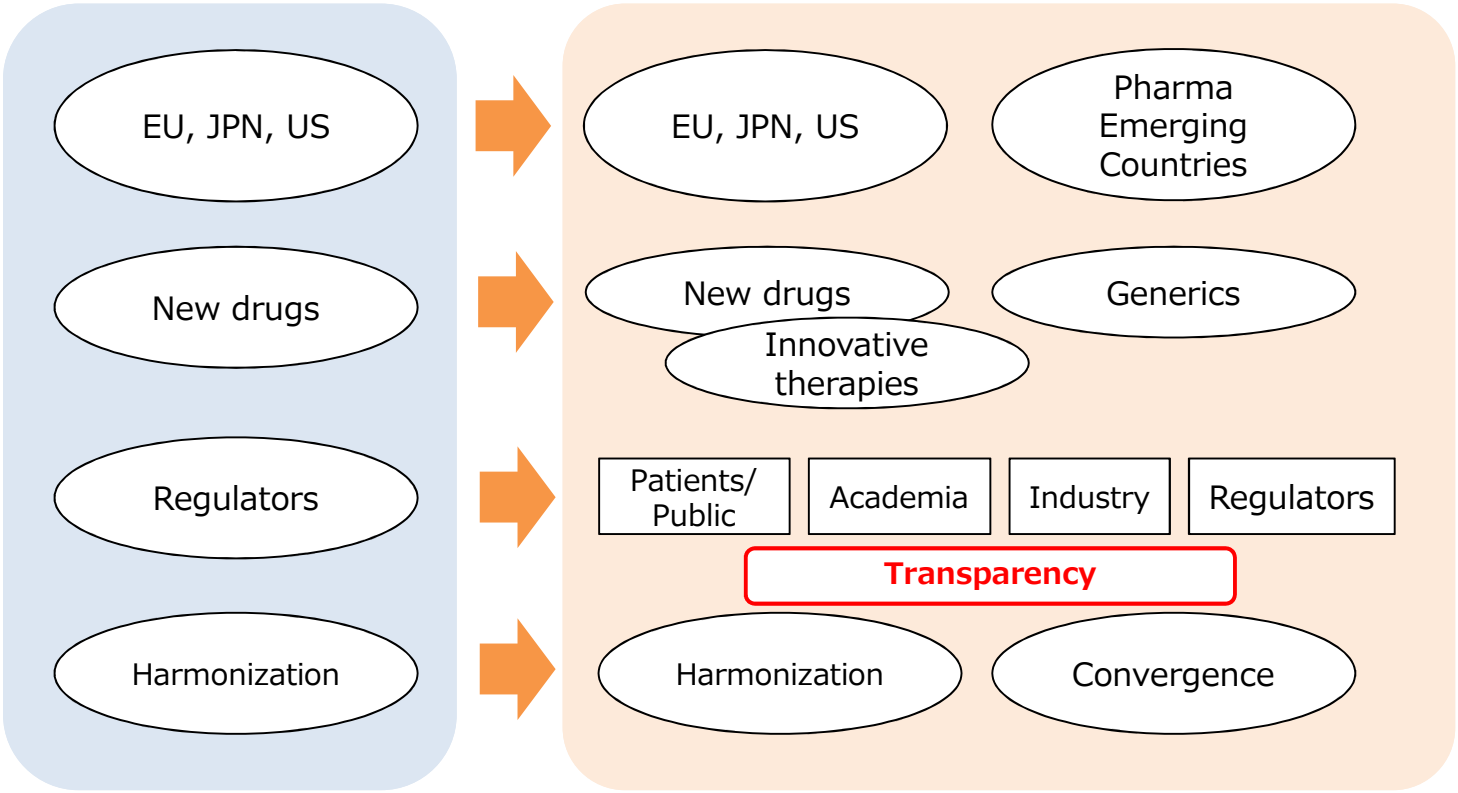
Environmental Change surrounding ICH

- With the momentum of the ICH reform in 2015, ICH is evolving to adapt to the paradigm shift in the pharmaceutical regulatory field.

<Paradigm Shift in Pharmaceutical Regulatory Field>



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Drug Reg. Authority as Member/Observer

- As the eligibility criteria to become a New ICH Member of Regulators, the prioritized three ICH GLs (Tier 1 GLs) need to be implemented.

	Member	Observer
Eligibility Criteria	• Regular Attend (past) • Experts in WGs (past) • **Q1, Q7, E6 implemented**	None
Right	• Attend ICH meetings • Experts in EWG • Vote in Assembly	• Attend ICH Assembly without voting right • Experts in EWG if allowed
Duty	Implementation of ICH GLs	None
Annual Fee	20,000 CHF (Reg Member)	

2

Challenges in Reg Harmonization in ICH

- In addition to Tier 1 GLs, ICH is now working on visualizing the GL implementation status (esp for Tier 2 GLs), which facilitates further GL implementation.

Tier	ICH Guideline	Rules on Implementation
1	**Q1** - Stability **Q7** - GMP for API **E6** - GCP	• **Implemented** as eligibility criteria to become ICH Member
2	**E2A** - Clinical Safety Data Management: Definitions and Standards for Expedited Reporting **E2B** - Data Elements for Transmission of Individual Case Safety Reports **E2D** - Post-approval Safety Data Management: Definitions and Standards for Expedited Reporting **M4** - CTD **M1** - MedDRA	• Implement as a priority • Submit specific plans (including milestones and timeframes) for implementation **within the next 5 years**
3	Other all ICH GLs	• Implement as gradually

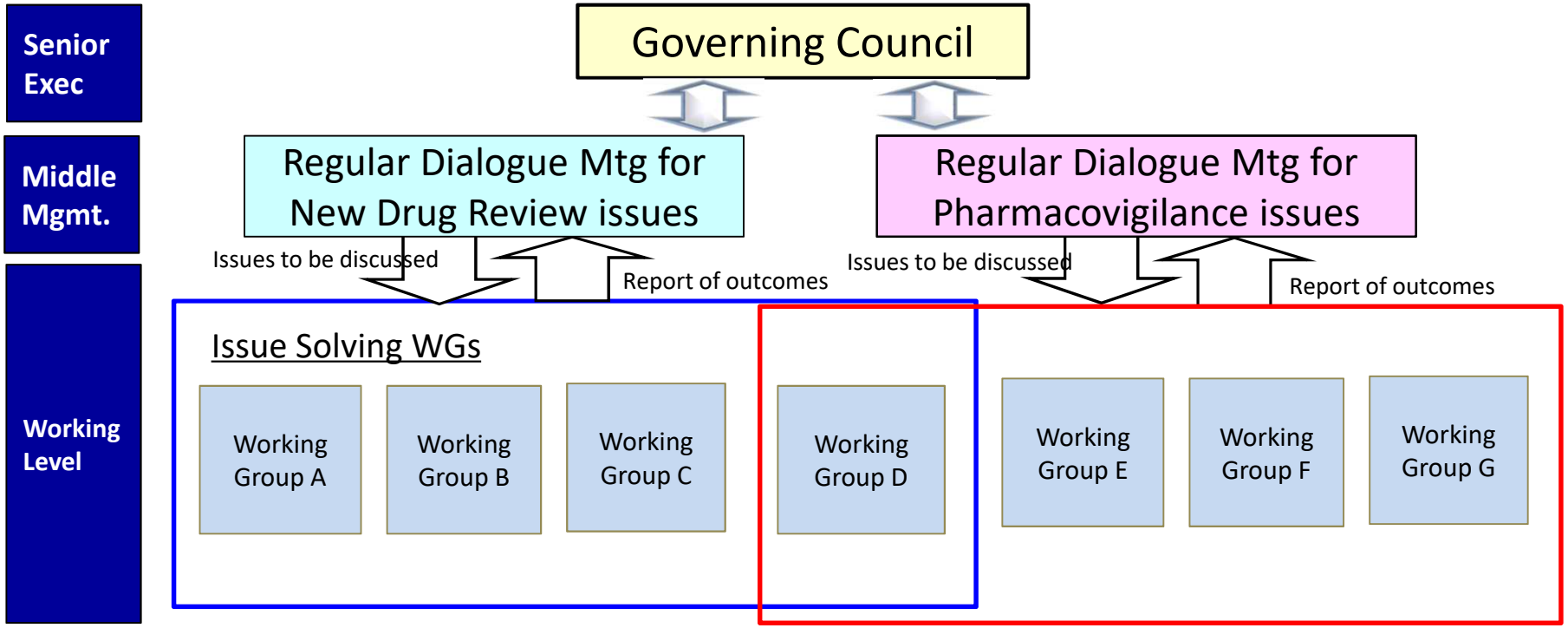
ICH-driven 3rd party survey is targeted for completion mid-2019: outcomes to be utilized for further training activities.

3

Dialogue btw Regulator and Industry

- In Japan, clear dialogue schemes across the organization levels have been established between Regulator and Industry. Based on these dialogues, the ICH GL implementation is also supported by Industry.

<Overview of Dialogue Scheme btw Regulator and Industry>



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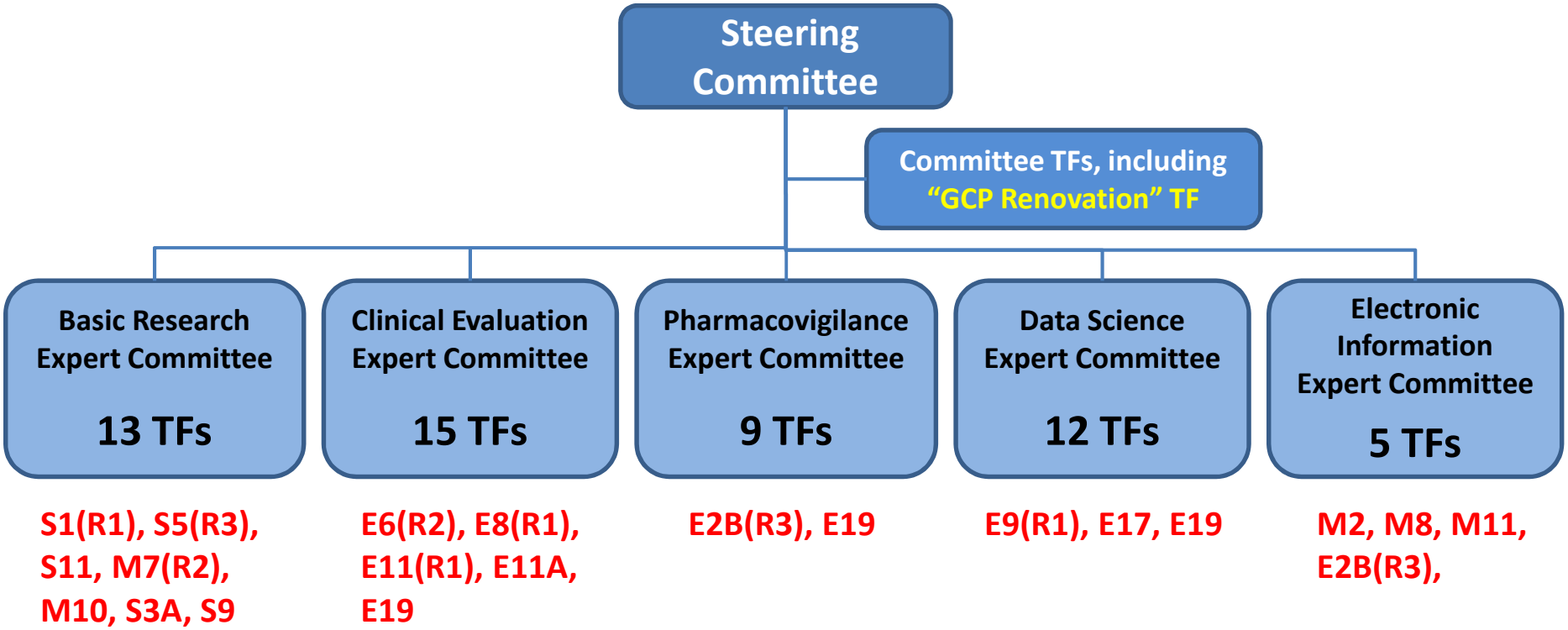
Cooperation in ICH GL Implementation

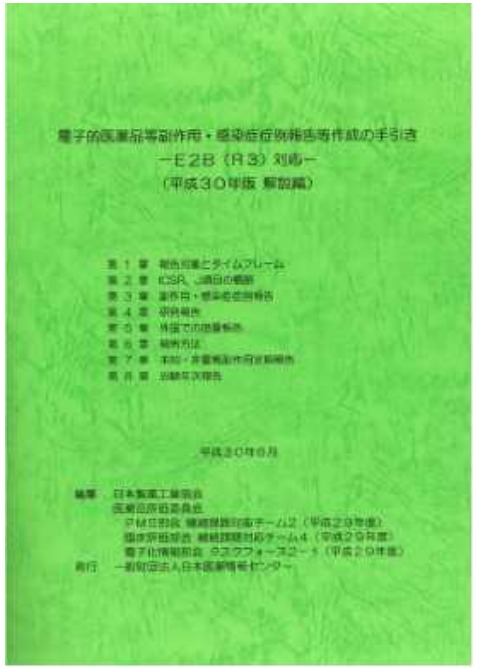
- In JPMA, each Functional Committee has set up multiple Task Forces to support ICH activities including follow-up and outreach activities to ensure adequate implementation / adherence of the ICH GLs.

<Example - Drug Evaluation Committee of JPMA>



Example - Cooperation in Implementation

- To implement E2B GL in Japan, JPMA issued the local handbook for safety reporting (“Green Book,” also reviewed by PMDA), which supported smooth implementation across various size of the companies.



<Features of E2B Green Book>

- Green book covers not only E2B but also E2A & E2D which are basis for E2B safety reporting.
  e.g., when a company conducts E2B reporting
  - ✓ which part of E2D GL should be referred
  - ✓ why a company should follow the procedure
- Green Book has been timely updated and issued according to the revisions of E2B GL
  → Number of pages for the latest version of the E2B(R3) Green Book: ***more than 450 pages***

→ Deliverable from close collaboration btw MHLW/PMDA and JPMA

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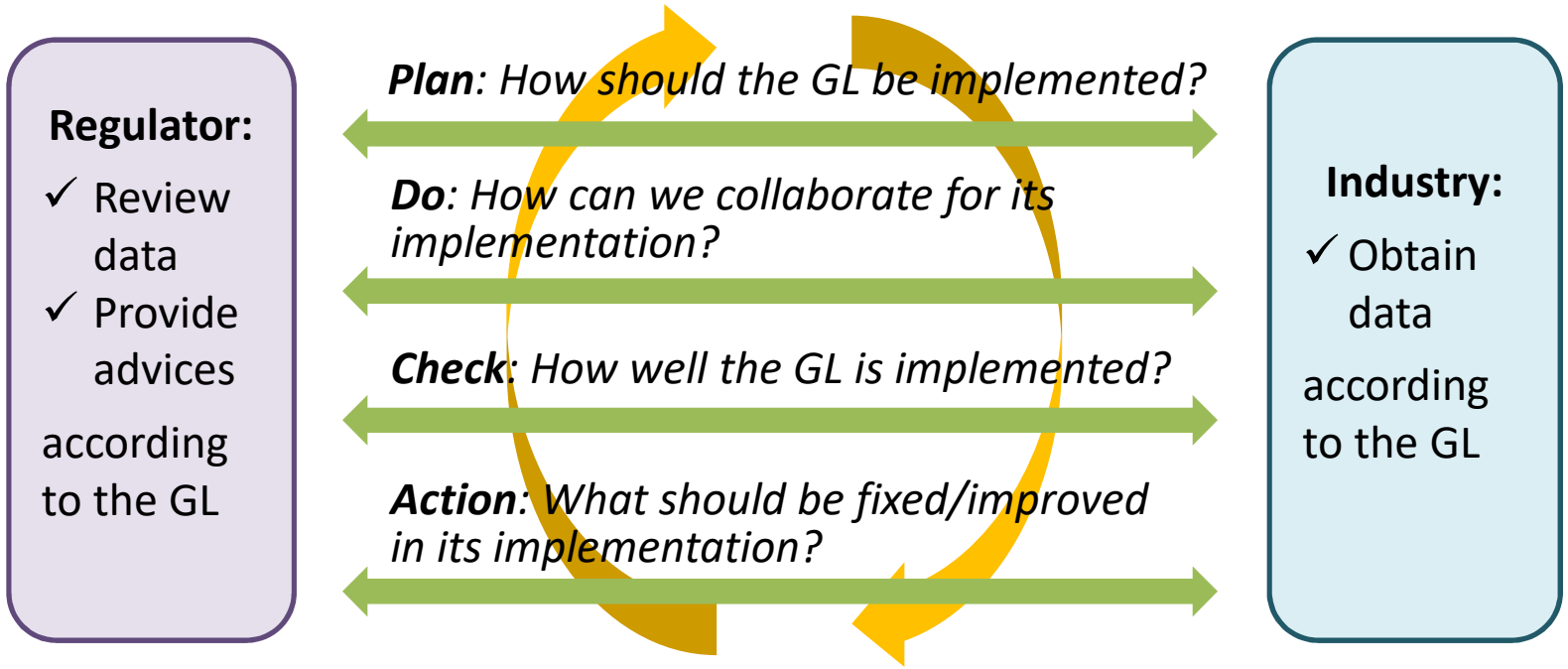
Expectation to Further Harmonization - 1

JPMA

- Productive dialogue between Regulator and Industry is a key:



More dialogues between Regulator and Industry are welcomed and expected in Brazil as well.

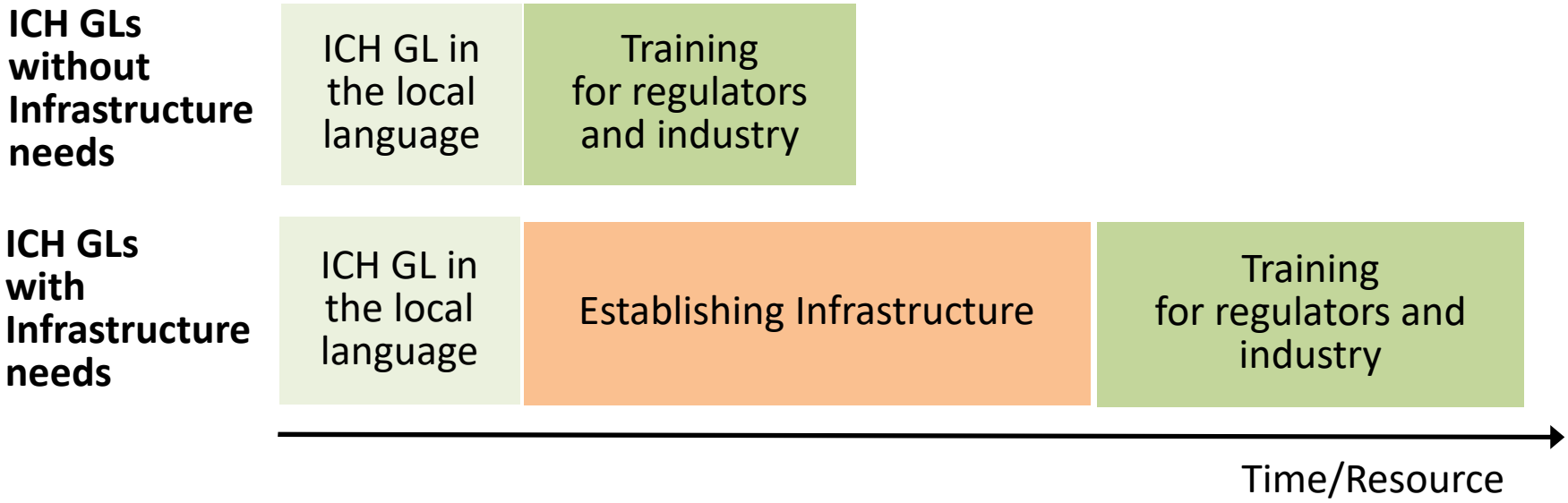
Expectation to Further Harmonization - 2

- Prioritized GLs (Tier1/Tier2) are highly influential guidelines for pharmaceutical industry, thus systematic implementation and consistent operation per GLs would be critical.

  Tier 1 GLs (Q1・Q7): the local regulations to be aligned with the ICH GLs

  Tier 2 GLs: infrastructure to be established to support/enhance its implementation

<Image of 2 types of GL implementation>



Expectation to Further Harmonization - 3

- Further leveraging harmonized GLs is expected to enhance early access of Japan-origin new drugs to patients in Brazil.

E17

Simultaneous access for new drugs under development

E5

Early access for approved drugs in Japan

Summary - Key Take Away

- At the evolving and expanding ICH, implementation and training of the ICH GLs are being more focused than ever before; both challenges and opportunities exist.

- In Japan, one of key factors for the successful GL implementation was productive dialogue and collaboration between the regulator and the industry.

- More dialogue between the two would enhance more robust GL implementation in Brazil as well, which would lead to further regulatory harmonization between Brazil and Japan.

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Bringing Innovation in Drug Discovery to the World

JPMA