ICH E6 Revision 3 Update

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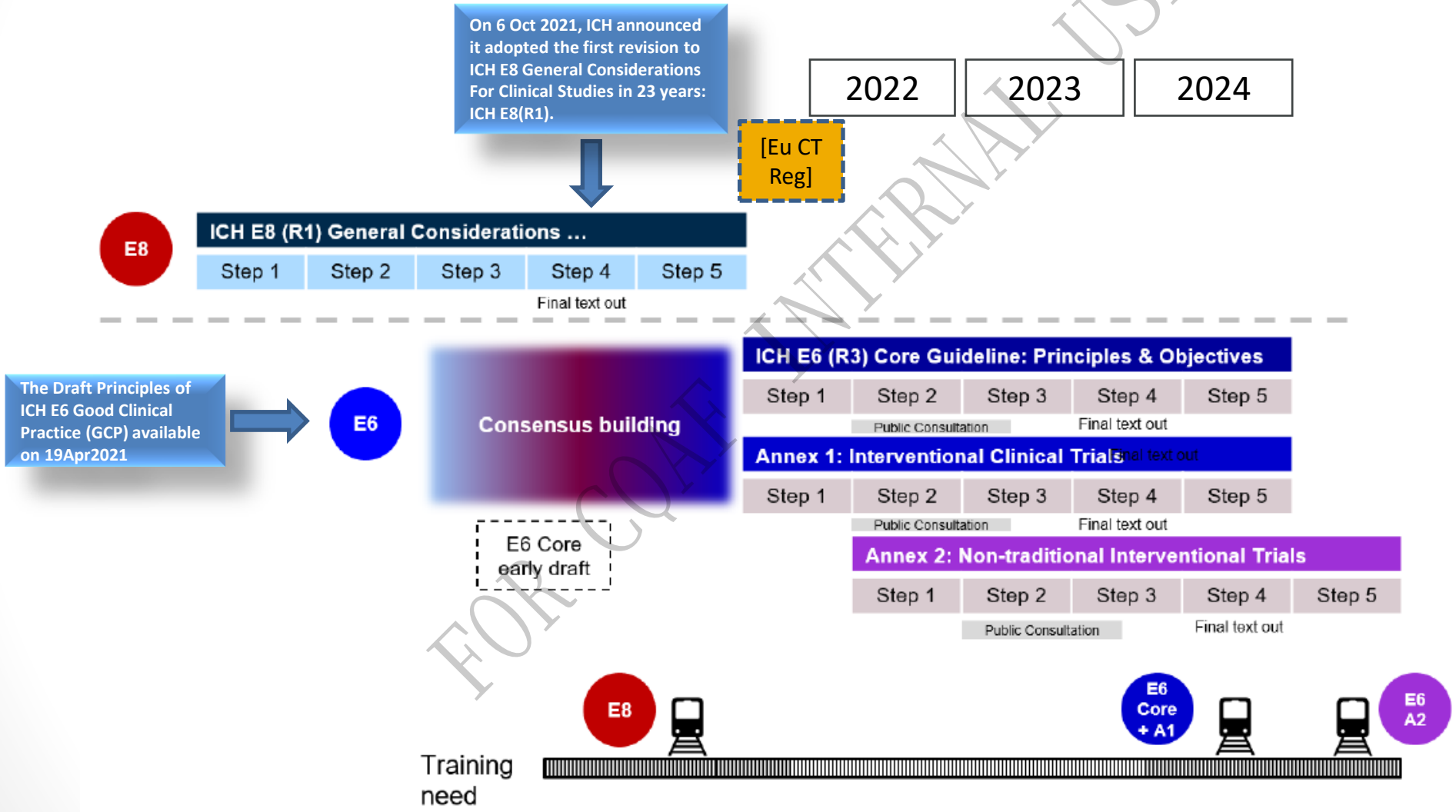
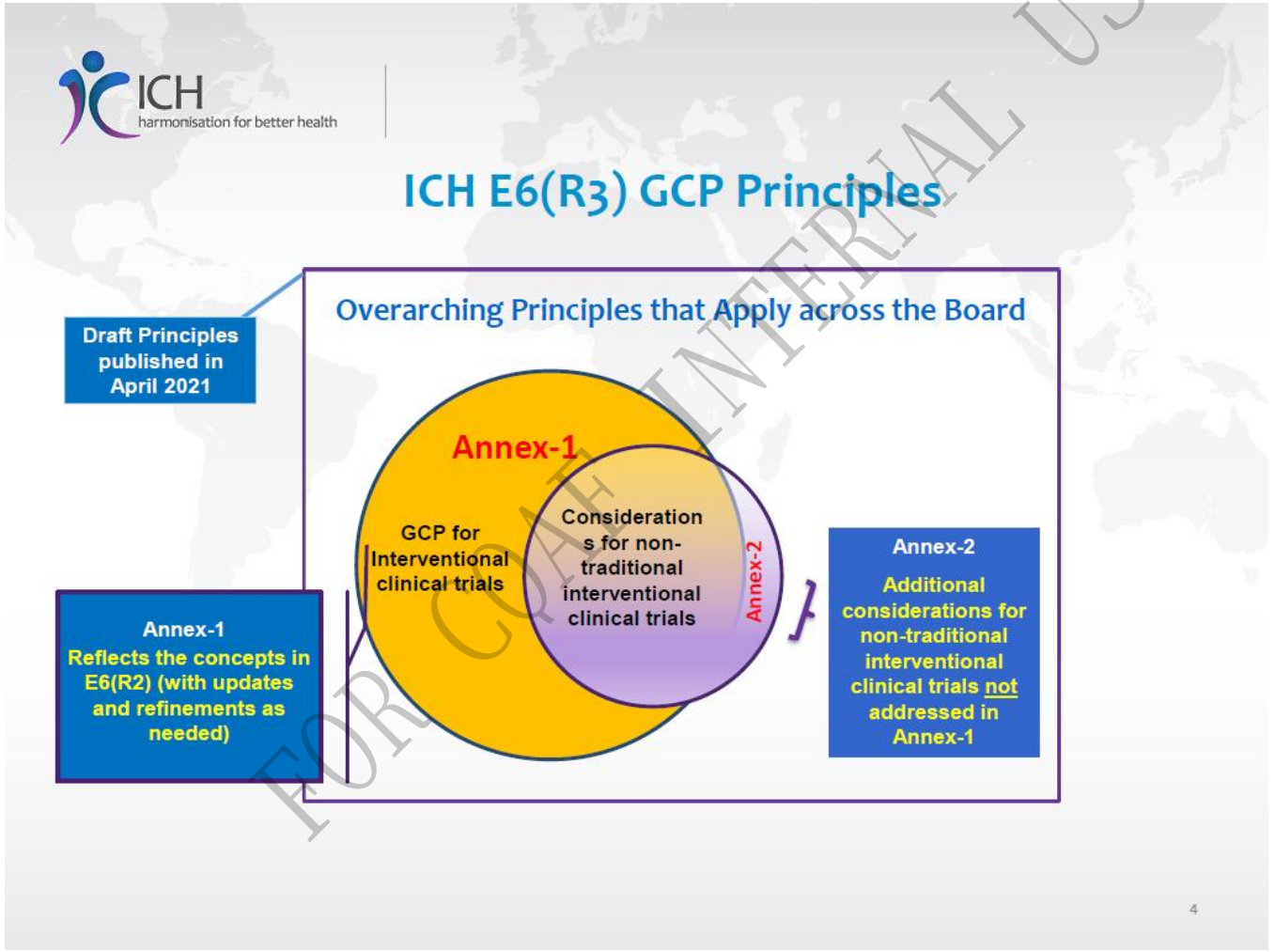
Outline

- Recap Roadmap and Timelines for E8 (R1) and E6 (R3)
- Approach of E6 (R3) Development and Revision Trends
- Updates on Stakeholder Engagement and Input Analysis
- Opening Discussion

Recap Roadmap and Timelines for E8 (R1) and E6 (R3)

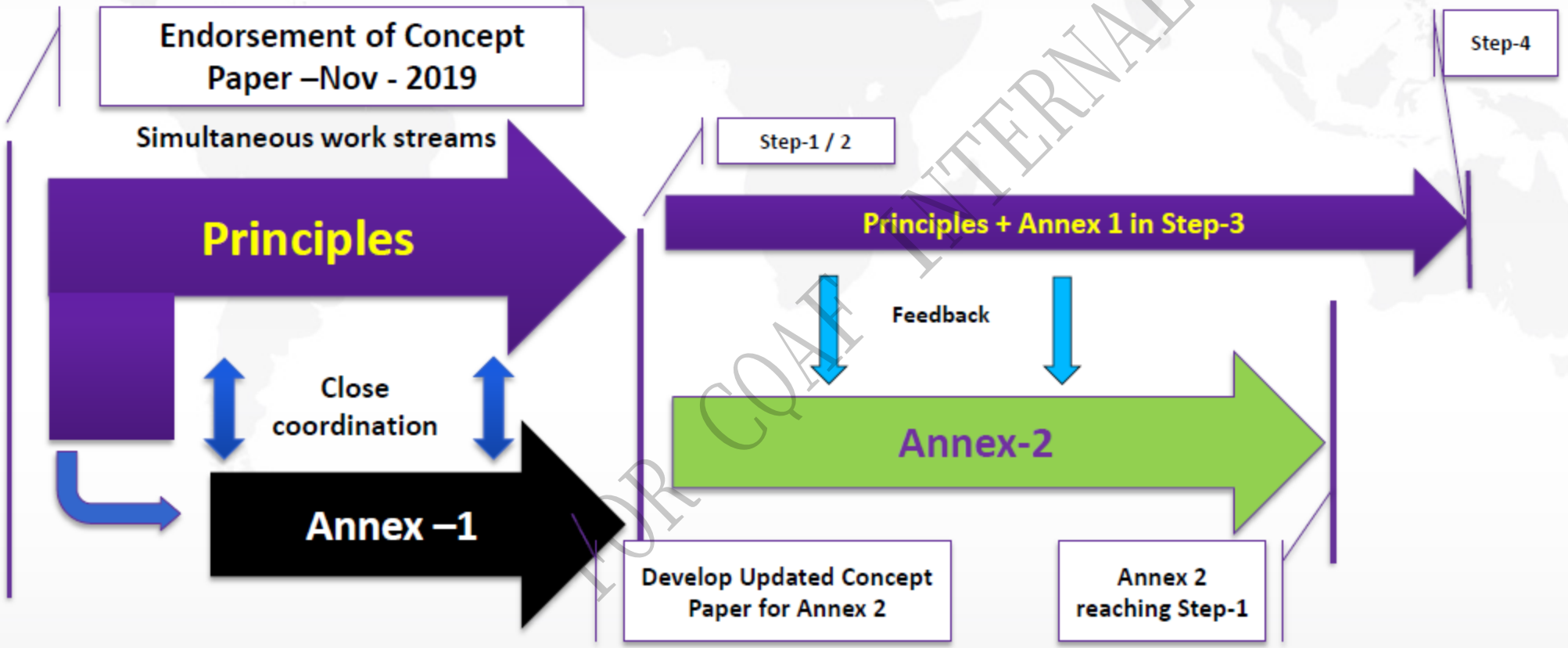


Approach to E6(R3) Development



Approach to E6(R3) Development

Simultaneous work on the principles & Annex-1



The Draft Principles of ICH E6 Good Clinical Practice (GCP)

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19 April 2021

ICH-E6 Good Clinical Practice (GCP)

Explanatory Note

The International Council for Harmonisation (ICH) is committed to developing timely technical requirements for pharmaceuticals for human use in a manner that is responsive to the needs of the global community. ICH is committed to stakeholder engagement and transparency in the development of its guidelines.

ICH E6 Principles

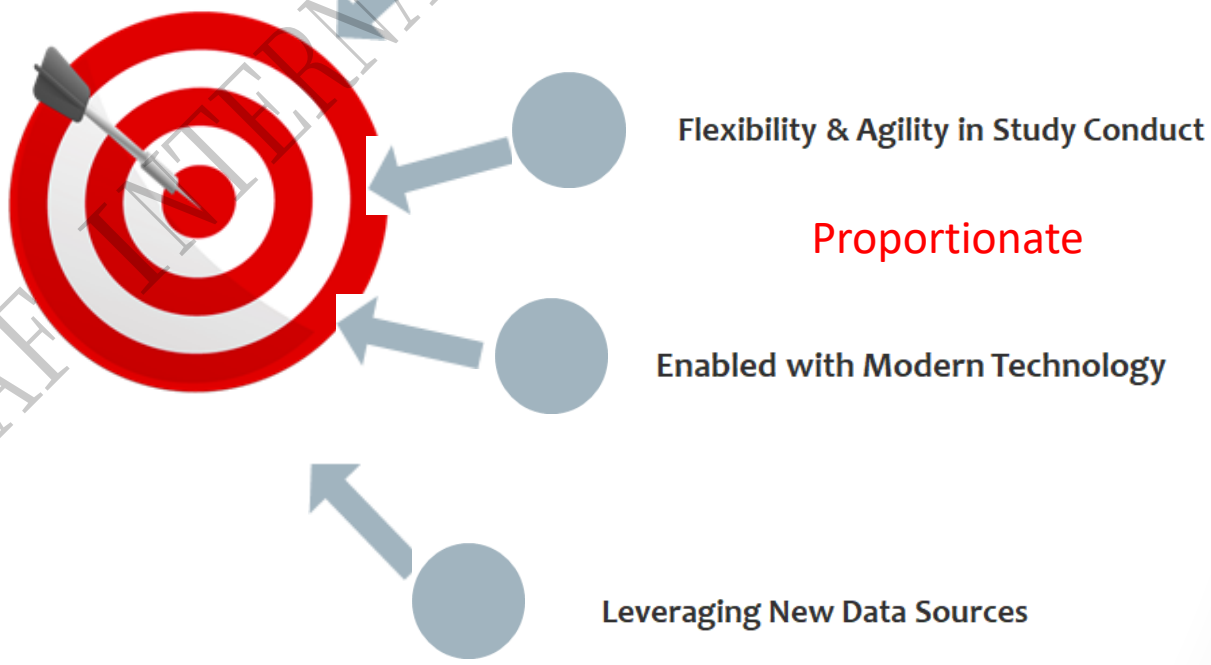
(Draft Version: March 2021)

Clinical trials are a fundamental part of clinical research that support the development of new medicines or uses of existing medicines. Well designed and conducted clinical trials help answer key questions in health care and drug development. Their results are essential for evidence-based healthcare decisions. Trials with inadequate design and/or poorly conducted trials may place participant safety at risk and yield inadequate or unreliable evidence. They waste resources and the efforts and time of investigators and participants.

Date: 2021-Dec-17

Why Revise ICH E6(R2) and What will be the revision trend

- Research landscape is evolving
  - Trial designs are increasingly innovative – E.g., decentralized trials
  - Technology is evolving on all fronts
- Need to maximize efficiencies to facilitate innovations and clinical trials
- Digitization of research and healthcare
- Real-world data sources Use of Electronic Health Records
  - Patient-generated data
  - Data gathered from digital health tools
  - Telemedicine/remote assessments of patients for safety & physician reported outcomes



Summary of Changes of R3 Principles

- Avoid unnecessary excluded study populations; expend the scope of medical care decision maker
- The informed consent should be based on thorough understanding of information provided. The information to be provided and the informed consent process depends on the study.
- Trial should be based on current reliable science and method and should be reviewed periodically.
- The qualification requirement for study personnel expand to the upper and down steams.
- “quality by design” throughout the entire trial
- from “risk-based” to “proportionate with risk” throughout the entire course of the trial
- Protocol and relevant document being clear, concise, and practical
- Specify the requirements for trail information related system and process; the clinical trial registry should be public and transparent.
- Add new principles for role and responsibilities
- Risk-based approach in IP management

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Engagement

- Many stakeholders are impacted by ICH-E6 GCP guidelines
- E6 stakeholder outreach approaches are approved by ICH and are ongoing.
- The knowledge gained by learning from stakeholder experiences and viewpoints will further enrich EWG discussions

Source: https://www.jpma.or.jp/english/ich/list/ich210707.html

E6(R3) EWG Analysis

Process for Analyzing Stakeholder Input

- **Goals of this analysis**
  - Identify opportunities for improvement in E6(R3)
  - Provide potential options on how and where to apply the modifications

Source: https://www.jpma.or.jp/english/ich/list/ich210707.html

Initial Prioritized Sections

- Data Management / Data Governance
- Responsibilities
- Monitoring
- Informed Consent
- Safety
- Protocol
- Essential Documents

Source: https://www.jpma.or.jp/english/ich/list/ich210707.html

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First Topics for Drafting

- **Data Management / Data Governance**
  - 233 stakeholder comments
  - E.g., digital data flow
- **Responsibilities**
  - 170 stakeholder comments
  - E.g., responsibilities of the concerned parties in relation to new technology
- **Monitoring**
  - 69 stakeholder comments
  - E.g., different types of monitoring, on-site, central, and remote

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Source: https://www.jpma.or.jp/english/ich/list/ich210707.html

E6(R3) EWG Analysis

Establishing Small Group (Drafting Groups)

- **Small Groups**
  - Subset of full EWG
  - Divided into drafting groups to facilitate topic discussion with full EWG and leads drafting a specific topic / section
  - Regularly meet to ensure that cross-section topics are addressed and considerations applicable throughout the guidelines are aligned

Source: https://www.jpma.or.jp/english/ich/list/ich210707.html

E6(R3) EWG Analysis

EWG Review and Stakeholder Engagement

- **EWG Review and Stakeholder Engagement**
  - Small group will regularly consult the full EWG
  - EWG will provide stakeholder representatives with updates on progress of drafting groups
  - EWG will prioritize opportunities to engage stakeholder representatives
  - EWG will agree on the proposed concepts and draft text

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Source: https://www.jpma.or.jp/english/ich/list/ich210707.html

中国质量保证论坛(CQAF),成立于2010年的非赢利组织，是医药行业质量专业人士的交流平台。在这里大家分享GxP领域的知识和最佳实践，了解可能影响行业发展的国内和国际法规监管动态；探讨行业的热点问题，并于其他行业协会合作，增进与法规部门沟通，共同打造优良的医药研发生态。

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http://www.cqaf.org/index/membership