ICH　M2：医薬品規制情報の伝送に関する電子的標準

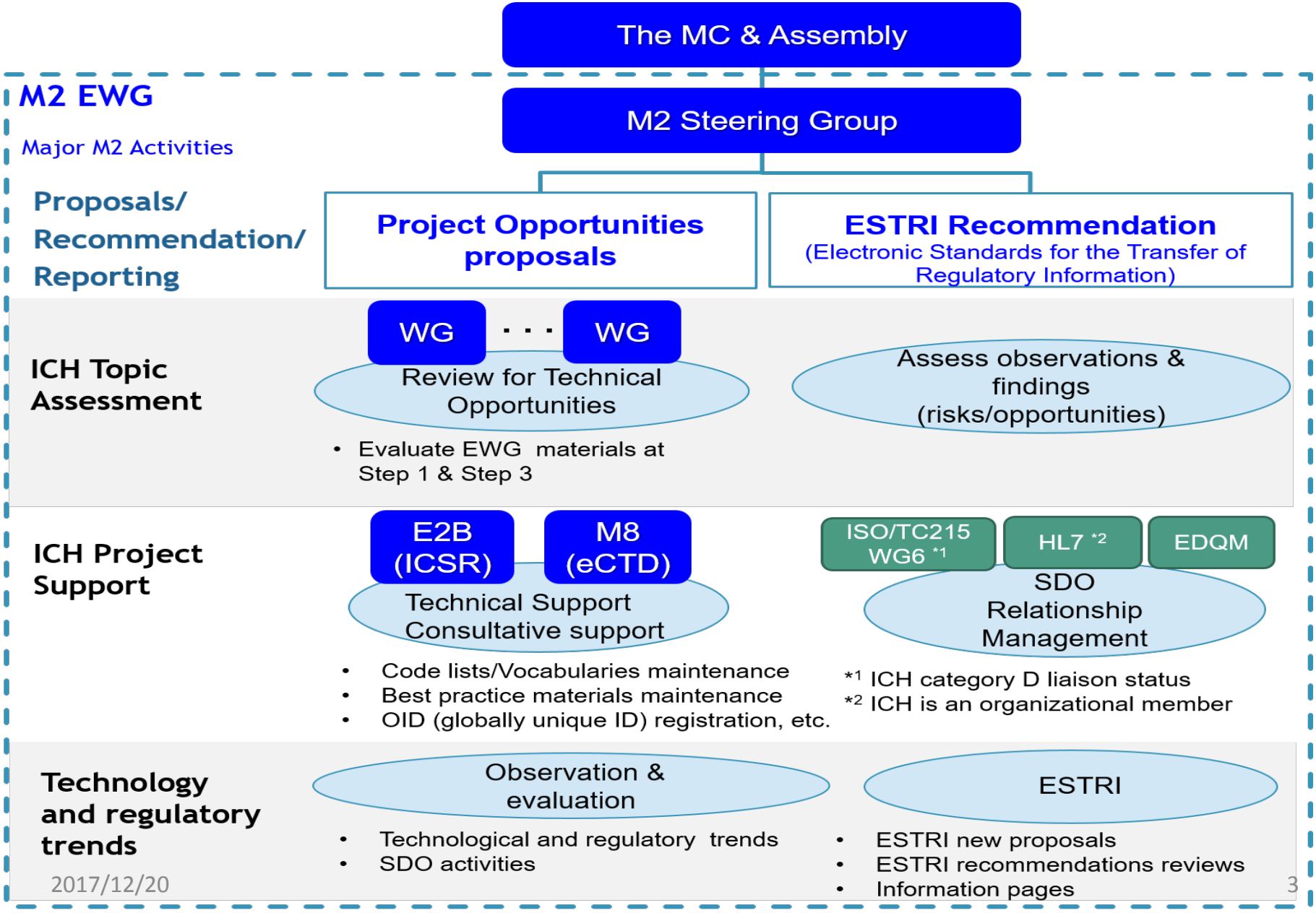
in Geneva, November 2017

第37回ICH即時報告会

Topics Outline

1. M2 Overview
2. Strategic Project Opportunities
   - Common Protocol Template
   - Electronic Clinical Trial Application/Notification
   - Emerging Project Opportunities
3. ICH Project Support
   - Terminologies maintenance
   - Data Integrity Monitoring
4. ESTRI – Electronic Standards for the Transfer of Regulatory Information
5. Proposed Work Plan

M2 Overview


The MC & Assembly
M2 EWG
M2 Steering Group
Major M2 Activities
Proposals/ Recommendation/ Reporting
Project Opportunities proposals
ESTRI Recommendation
(Electronic Standards for the Transfer of Regulatory Information)
ICH Topic Assessment
WG
WG
Review for Technical Opportunities
Assess observations & findings (risks/opportunities)
• Evaluate EWG materials at Step 1 & Step 3
ICH Project Support
E2B (ICSR)
M8 (eCTD)
Technical Support Consultative support
ISO/TC215 WG6 *1
HL7 *2
EDQM
SDO Relationship Management
• Code lists/Vocabularies maintenance
• Best practice materials maintenance
• OID (globally unique ID) registration, etc.
*1 ICH category D liaison status
*2 ICH is an organizational member
Technology and regulatory trends
Observation & evaluation
ESTRI
• Technological and regulatory trends
• SDO activities
• ESTRI new proposals
• ESTRI recommendations reviews
• Information pages

Strategic Project Opportunities

Common Protocol Template (CPT) opportunity

- The Situation Today -
  - Clinical Trial Protocols are created today with no standard table of contents and no structured content. This lack of consistency and the missing ability to easily find specific content results in very inefficient, labor-intensive protocol development and review in an environment of increasingly complex clinical trials.
- Opportunity - If a standardized and structured common protocol template existed, then:
  - For regulators, this could mean reduced review complexity; easier data interpretation; ability to easily compare protocols and provide better scientific advice; easier searching, answering information requests…
  - For sponsors, this could mean improved trial design efficiency; clinical trials management; process automation and data re-use; improved study quality and execution…
- Of potential interest and relevance to E3, E6, E8, E9 and E17

After Engaging with Topic Experts

- Review of benefits:
  - Previously identified benefits to regulators and industry were validated by SME (Subject Matter Expert) feedback
  - Additional benefits also identified
- Interest expressed by all parties
  - A detailed spreadsheet of comments and cross-references was developed
- Potential intersection or relevance to E3, E6, E8, E9 and E17 has been confirmed
- A concept proposal was developed
  - The proposal and comments spreadsheet provide rich input to a new topic EWG
  - Recommend a single EWG comprised of topic and technical experts working together
  - ***Name : CeSHarP - Clinical electronic Structured Harmonized Protocol***

EWG Recommendation

Single EWG

- Mix of topic and technical experts working together to:
  - First, confirm scope and then agree on harmonized content and format
  - Second, identify and adopt or develop an electronic means to create and exchange this structured information

- This model has worked well for E2B
- A technical EWG liaison with M2 will help ICH to maintain an overall consistency across ICH technical projects and ESTRI recommendations

Next Steps

- M2 work on this proposal is complete
- PhRMA will submit a new topic proposal and the M2 pre-concept work for ICH consideration in the upcoming topic nomination and review cycle (submission deadline 15DEC2017)

Electronic Clinical Trial Application (eCTA) Opportunity

- Clinical Trials (CT) need an application or notification/registration in most countries.
- The structure and required contents of a clinical trial submission are not harmonized. For example:
  - Content: extent of information on Safety, Quality and Efficacy varies by country.
  - Structure also varies by country.
- Different submission must be created for each country. Industry maintains multiple clinical trial management systems to support the differing country requirements
- Existing structural and technical solutions may exist, such as (1) Japan's current practice and (2) implementation of new supporting structure within eCTD

Accomplishments

- An initial draft of the concept proposal has been created; this will change based on further SME input
- This is a progress report rather than a final proposal for a new topic
- Further discussion is ongoing, getting input from various parties
- ***Name change: eCCTS – electronic Common Clinical Trial Submission***

Next steps

- Perform a survey on regional processes for Clinical Trial Submissions identifying similarities and differences across parties
- Engage SME for further input with survey results as background
- M2 will complete the pre-concept paper including an overview on potential benefits and risks for regulators and industry based on expert input

Emerging Project Opportunities

Review of Emerging Project Opportunities

- Several emerging project opportunities have been identified by M2 members
  - e-Trial Master File (eTMF)
  - Notification – Administrative
  - Electronic standard for transfer of Regulatory label information (ESTReLI)
- M2 is reviewing internally for:
  - Significant interest across parties
  - Perceived benefit
  - Feasibility
- Those with broader interest and benefit will be presented to MC and Assembly for their consideration
  - Any new project opportunities will be presented after this meeting

e-Trial Master File (eTMF)

- Informal conversation with subject matter experts, to confirm benefits to regulators
- There must a compelling business case
- information gathering exercise of eTMF e.g. DIA, OASIS, EMA Reflection Paper
- facilitate a discussion with OASIS, has to task to bring their experts to facilitated discussion with M2 and SME’s.

Electronic standard for transfer of Regulatory label information (ESTReLI)

- regulators benefit of electronic labels; publication; health care system.
- Any proposal should ONLY include Structure and NOT content
- US FDA uses Structured Product Labeling(SPL), Canada is planning for SPL, and PMDA implements SGML, for their package insert e-standard;

Next Step

- prepare a one pager describing the opportunity for discussion by M2.

ICH Project Support

Terminologies Maintenance

- Joint Meetings with M8 & E2B
  - Reviewed the Terminologies Maintenance process including comments from M8 & E2B
  - Identified action items and next steps with both groups
- Next steps
  - M2 will revise the Terminologies Maintenance process and review with M8 & E2B
    - M2 will act on specific needs of each group
  - M2 will formalize agreements with M8 & E2B to implement the Terminologies Maintenance process

Revised PDF Specification

- The challenge: All parties publish regional differences in how to submit files in PDF
- The effort: jointly with M8, reduce the differences as much as possible across regions, but still allow regional differences where needed
- A revision to the existing recommendation was completed
- The recommendation will be published on the ESTRI web page

Planned Activities

- ESTRI Activities:
  - Work on ESTRI Web migration
  - Perform ESTRI Standards maintenance
- Project Opportunities Proposals:
  - Review ICH work products reaching Steps 3 or 4
  - Continue individual discussions with EWG Experts for topics at Step 1
  - Take actions on eCCTS Project Opportunity Proposal
  - Prioritize and develop emerging Project Opportunity Proposals
- ICH Project Support:
  - Adjust Terminology Maintenance Process based on joint meeting outcomes
  - Share Plain-Language outreach material on M2's Role and aids for EWGs/IWGs
  - Determine actions needed for Data Integrity Guidance Monitoring
  - Update M2 description on ICH website

Thank You for Your Time and Attention