ICH M2 EWG
動向報告

M2：Electronic Standards for the Transfer of Regulatory Information (ESTRI)
医薬品規制情報の伝送に関する電子的標準

日本製薬工業協会
ICHプロジェクト委員会
M2 EWGトピックリーダー
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M2's Charge

- **(WHAT) Coordination of ICH Projects with Information Technology Requirements**
  - ***(WHY) To help ICH WGs and ensure technical outputs are effective and consistent, to be the ICH "watchdog" for technological impacts and opportunities***
    - **(HOW) Technical support for WGs**
    - **(HOW) Evaluating existing ICH topics for technical impacts and opportunities; "connecting the dots" across topics**
- **(WHAT) Assessment and Recommendation of Technology and Information Standards**
  - ***(WHY) To stay current with advancing technology, and to take advantage of technological solutions to solve regulatory business problems***
    - **Always starts with a business problem**

Activities in Jacksonville (TOC)

1. ESTRI Activities
2. M2 Management Activities
3. Technology Watch Activities
4. SDO Monitoring Activities
5. Structured Content
6. M2 Operating Model
7. M2 Work Plan

ESTRI Activities

- Updated regional uptake of all ESTRI recommendations
- Agreed to address the interest expressed by the EU in AS-4 (new or revised EDIINT recommendation)
- M2 to research acceptability of PDF/A-3 and whether it should become an ESTRI recommendation in response to comment received by M8 during eCTD 4.0 Step 3 Review
- Removed ESTRI website references and links to the "Recommendation Notebook" (retired Nov-2005) and agreed to archive all retired recommendations to the M2 archive on the ICH Collaboration Website
- Updated, signed-off and uploaded the ESTRI Glossary (v2.0) on the ESTRI Website
- Reviewed and discussed Approaches to Redaction
  - Reviewed regional redaction processes, guidelines and tools
  - Finalized a matrix of common requirements for electronic redaction in the ICH regions
  - Developed a draft information paper that covers:
    - Business opportunities and objectives of electronic redaction
    - Recommendations with regard to tools and the handling of documents to enable the electronic redaction of documents in an efficient manner

M2 Management Activities

a. Question from E2B re: UTF-8

- Assessed and developed feedback to E2B re: how to respond to Q&A question concerning character field length values

b. Assess RoA Controlled Vocabulary

- M2 followed-up with M8 to identify and evaluate the use of their terminology set, specifically Routes of Administration. M2 will formally establish a process (with content experts), for identification of well-defined controlled vocabularies.

Technology Watch Activities

- Review and discussed Regulatory Trends and their sources; discussed the approach to develop the next version of the Technology Watch Report (v2.0)

- Scheduled dedicated meeting (10-March-2016) for M2 members to provide input on current Regulatory Trends.

Technology Watch Report

ICH活動に関連／影響しうるIT動向等を2年毎に
（従来は） Steering Committeeに報告
（次回は2016年6月に予定）

SDO Monitoring Activities

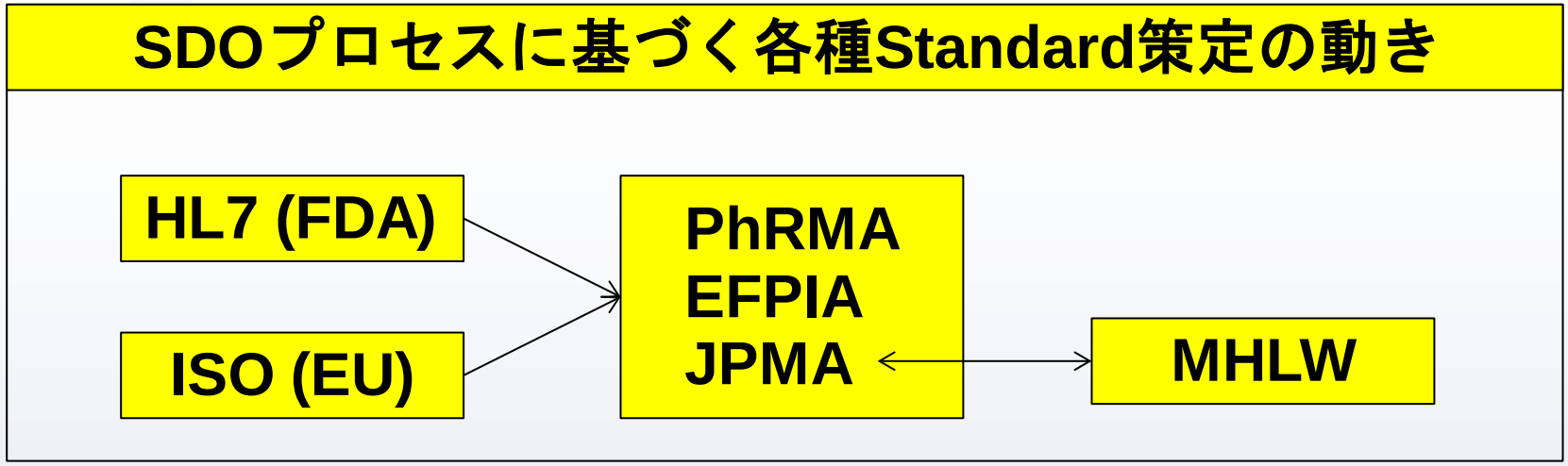
- EWG review of SDO Monitoring activities collected between meetings via ICH member involvement in SDOs (e.g., mailing lists, teleconferences, in-person meetings, etc.)
- Identified three potential opportunities for ICH harmonization where at least two ICH parties are already adopting a common standard
  - Establishment / Organization Identification
    - HL7 standard in use by FDA
    - Health Canada and EU reviewing for use
  - Content of Labeling
    - HL7 standard in use by FDA
    - Adoption beginning in Health Canada
    - Consideration being given in EU
  - Structured Clinical Study Data Standard
    - CDISC standards used by FDA
    - MHLW use begins in 2016

31 SDO Monitoring Activities

ID	SDO	SDO Activity for Monitoring	Relevant ICH Topic(s)	Latest Review Date	Latest Impact Risk Summary
A1	ISO TC171 SC2	ISO 32000 (PDF)	M2 ESTRI	3-Dec-2015	No/Minimal Impact
A2	W3C	XML	M2 ESTRI	3-Dec-2015	No/Minimal Impact
A3	IETF	ediint	M2 ESTRI	12-Nov-2013	No/Minimal Impact
A4	IETF	RFC1321 (MD5)	M2 ESTRI	12-Nov-2013	No/Minimal Impact
A5	ISO JTC1/SC 34	ISO 29500 (OOXML)	M2 ESTRI	7-Dec-2015	No/Minimal Impact
A6	OASIS Code List TC	Genericode	M2 ESTRI	2-Jun-2014	No/Minimal Impact
A7	NSA	SHA-2 (256)	M2 ESTRI	6-Dec-2015	No/Minimal Impact
A8	ISO TC171 SC2	ISO 19005 (PDF/A)	M2 ESTRI	3-Dec-2015	No/Minimal Impact
A20	CDISC	Study Data Exchange Standards	TBD (E17?)	8-Dec-2015	No/Minimal Impact
A21	CDISC	Dataset-XML	TBD	8-Jun-2015	No/Minimal Impact
A28	HL7-FMG	FHIR (Fast Healthcare Information Resources)	TBD	7-Dec-2015	No/Minimal Impact
A29	HL7-M&M	HL7 RIM (Reference Information Model)	E2B/IDEX/M8	6-Dec-2015	Impact/Managed
A30	HL7-RCRIM	Safety Report / ICSR	E2B	7-Dec-2015	No/Minimal Impact
A31	ISO TC215	27953 ICSR	E2B	7-Dec-2015	No/Minimal Impact
A32	HL7-RCRIM	AE FHIR Resource	E2B	7-Dec-2015	Unknown
A35	ISO TC215 WG6	ISO DTS 19844 (Substances) IG	IDEX/E2B/M2 ESTRI	7-Dec-2015	Impact/Managed
A36	ISO TC215 WG6	ISO DTR 14872 (ISO IDMP Maintenance Guidelines)	IDEX/E2B/M2 ESTRI	7-Dec-2015	Impact/Managed
A37	ISO TC215 WG6	ISO DTS 20451 (Pharmaceutical Product ID) IG	IDEX/E2B/M2 ESTRI	7-Dec-2015	Impact/Managed
A38	ISO TC215 WG6	ISO DTS 20440 (Dose Forms/Routes of Admin) IG	IDEX/E2B/M2 ESTRI	7-Dec-2015	Impact/Managed
A39	ISO TC215 WG6	ISO DTS 20443 (Medicinal Product Identification) IG	IDEX/E2B/M2 ESTRI	7-Dec-2015	Impact/Managed
A40	ISO TC215 WG6	ISO IDMP 11238 (Substances) 3yr Review/Revision	IDEX/E2B/M2 ESTRI	7-Dec-2015	Impact/Managed
A41	HL7-RCRIM	SPL/CPM for IDMP	IDEX/E2B	7-Dec-2015	Impact/Managed
A42	HL7-RCRIM	SPL for Content of Labeling	TBD	7-Dec-2015	No/Minimal Impact
A43	HL7-RCRIM	SPL for Facility/Organization Information	TBD (Q12?)	7-Dec-2015	Impact/Managed
A44	HL7-RCRIM	SPL for Lot Distribution Reporting	TBD	7-Dec-2015	No/Minimal Impact
A45	HL7-RCRIM	SPL for REMS	TBD	8-Jun-2015	No/Minimal Impact
A48	HL7-RCRIM	ePSUR	E2C	8-Jun-2015	No/Minimal Impact
A49	HL7-RCRIM	Risk Management Plans	E2E	8-Jun-2015	No/Minimal Impact
A50	HL7-RCRIM	RPS	M8	6-Dec-2015	No/Minimal Impact
A54	HL7-RCRIM	eStability	TBD	7-Dec-2015	No/Minimal Impact
A60	ISO TC215 WG6 & WG3	DTS19256 (Med. Prod. Dictionary Sys. for Health Care)	E2B	2-Dec-2015	No/Minimal Impact

Structured Content

- M2 revisited the scope and intent of the structured content topic
- M2 concluded there are multiple potential use cases but no specific candidate could be agreed
- M2 proposed to the ICH Assembly this activity is completed and concept proposals for potential candidates should come through the traditional channel
- The proposal was agreed by the ICH Assembly



M2 Operating Model

- Discussed with the Management Committee (MC) the need to change current way of working
- MC requested M2 provide input on a new operating model by March-2016

Next face-to-face meeting
M2 would like to defer the decision to meet face-to-face at the June 2016 Lisbon ICH meeting at this time.

M2 EWG 業務の特徴

- **継続的業務が多い**
  - ✓ **SDO Monitoring**
  - ✓ **Technology Watch**
- **Feasibility Study的要素（新規技術適用可否）**
- **Speedの要求**

M2 Work Plan
from December 2015 to June 2016

	Milestones	Deadline
SDO Monitoring	Update status	May 2016 (every 6 months)
Technology Watch Report 2016	Report to the MC	June 2016 (every 2 years)
Coordination of ICH use of Controlled Vocabularies	Continuous	
Harmonization of PDF specification	PDF Specification update	June 2016
Information paper on Redaction	Finalized Information Paper	June 2016
Survey on M8 SDO project	Questionnaire to M8 Report to the MC	June 2016
Supporting activities for EWGs	Continuous	
Advance ESTRI activities	Continuous	

ICH
harmonisation for better health

Thank You