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トピックリーダー

橋本 勝弘

M2の役割・責務（１）

M2の役割・責務の変更（2014年6月ミネアポリス会議）

- 過去：ICSR(E2B)、eCTD(M8)等、個別・具体的なテーマに係るIT技術検討・支援
- 現在：Technical Bigger Picture
  ICH全体における電子的標準に関する技術的整合性の構築・維持・調和、先進的IT技術の積極的な導入の推進　等を追加

  → 電子的標準やIT技術を広くWatching、積極的な紹介

M2 Recommendation定義変更（2014年11月リスボン会議）

- 過去：強制力のある勧告（実装義務）
- 現在：利用可能技術としての勧告（技術カタログ）

M2の役割・責務（２）

電子的標準　作成プロセスの変化

- 過去
  - ICHの中で電子的標準の作成（開発から公開まで）
- 現在
  - ICHからSDO（Standard Development Organization、ISOやHL7等の国際的な標準開発団体）に作成依頼
  - SDOが電子的標準（国際規格）、実装ガイド等の作成
  - ICHとして実装ガイド等を勧告・公開

→　SDO Management/Monitoringの重要性増大

大きく変わったM2の役割・責務

M2's Charge（現在）

M2 maintains technical 'bigger picture', ensures ICH awareness, enables technical harmonization

- **Coordination of ICH Projects with Information Technology Requirements**
  - Inventory of ICH Projects with Defined Technical Components
  - Assessment of ICH Concept Papers
  - Review of Technical Outputs from EWGs
  - Maintenance Procedures
  - Standards Development Organisations (SDO) Relationship Management
  - Inventory of SDO projects
  - Review of SDO activities in context of ICH scope and activities
- **Assessment and Recommendation of Technology and Information Standards**
  - Overview of Evolving Technology and Information Standards
  - Propose new technical recommendations for ICH adoption

Topics
（ICH福岡会議結果を中心に）

1. Technology Watch
   （各種電子的標準や先進的IT技術の動向Watching）
2. SDO Monitoring Activities
   （国際的標準開発団体の活動のMonitoring）
3. M2 Management Activities
   （他のEWG/IWGとのCollaboration等）
4. ESTRI Activities
   （ICHにおける電子的標準／IT技術の勧告等）
5. Major Activities: Now to Jacksonville
   （12月のジャクソンビル会議に向けた活動・課題）

1. Technology Watch

（各種電子的標準や先進的IT技術の動向Watching）

Technology Watch

- **Key Regulatory & IT Trends**
  - Regulatory drivers can serve to identify or prioritize M2 efforts where no Technology Project or ESTRI Recommendation exists
    - May need additional process to formalize identification and prioritization of Key Drivers
- **SDO Monitoring**
  - Supports ICH Technical Projects
  - Supports ESTRI Recommendations
  - Provides a framework in which to view & discuss “technical standards” of relevance across ICH
  - Provides forum to discuss opportunities to leverage SDO activities that intersect ICH members / common interests
- **Internal Review & Consultation**
  - Providing long-term, cross-ICH support to technology project “early adoptions”
  - Concept Paper reviews against external activity

Technology Watch: Regulatory Business Trends

Regulatory Business Trend	Description
Globalization	Globalization of the health products supply chain has fundamentally altered the economic, security and health product safety landscape and demands a major change in the way Regulatory Agencies fulfil their mission.
Big Data	Regulatory agencies are challenged to handle the growing data sets from healthcare practitioners, product manufacturers/ sponsors, patients, regulatory groups and other organizations. There is a need to mine, model, simulate, hypothesize and predict much faster which is difficult with current solid structured data platforms.
Transparency & Openness	Help Citizens to better understand how and why our decisions are made. They can use this information to make well-informed decisions on their health and the health of their families. Assist industry to be better positioned to comply with current regulatory requirements and plan for upcoming regulatory changes.
Compatibility and Interoperability with Healthcare	Regulators and the healthcare community need to be “interoperable” in order to leverage information in a manner that provides for timely access related to patient safety and benefits

- Common trends impacting the regulators
- We used this to help focus our technology watch

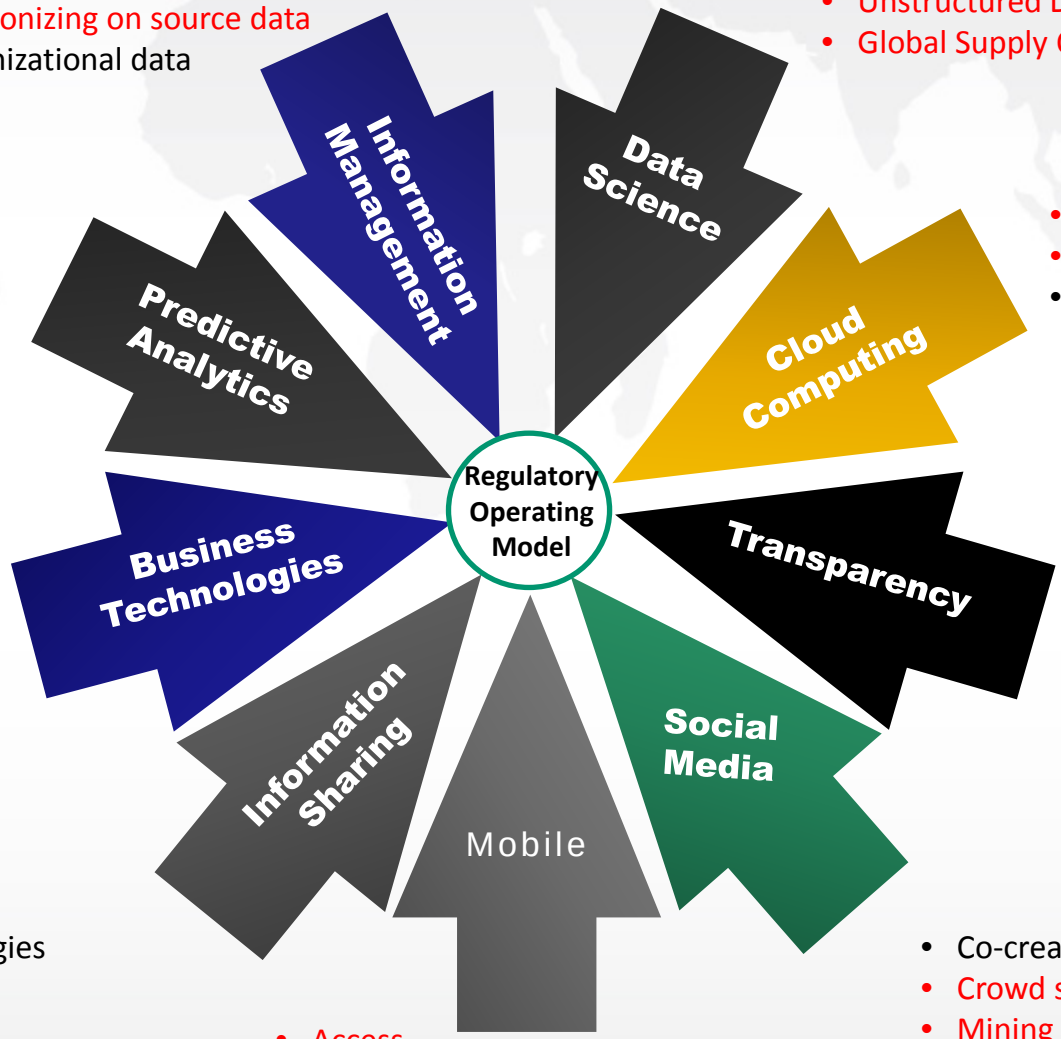
Technology Watch: Information Technology Trends

- Master Data Management
- Referential data integrity
- Harmonizing on source data
- Organizational data

- Geo-location data
- Structured Product Data
- Unstructured Data
- Global Supply Chain Management

- Machine Learning
- Machine Intelligence
- Natural Language Processing

- Security
- Privacy
- Data location



- Automation
- Social enabled Business processes

- Redaction
- Web publishing
- Privacy
- Confidentiality

- Collaborative technologies
- Security data and information exchange
- Meta data

- Access
- Wearable medical sensors
- Medical test devices
- Rapid data dissemination

- Co-creation
- Crowd sourcing
- Mining social media
- Tools & Apps
- Events monitoring

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Technology Watch - Opportunity (Use Case)

- Example: Identification & Role of Facility in Supply Chain to address safety & quality issues
  - **Business Trend: Globalization & increasing complexity of supply chain**
  - **IT Trend: structured data**
  - **ICH Stakeholder Need: Globally unique facility identification**
  - **Enabler (from SDO monitoring): ISO IDMP / HL7 CPM / Globally unique facility identifier**
  - **Advice to SC: identify a project to use structured data for this purpose**
- **Benefits**
  - **Proactively share information in "real time" (e.g., inspections, compliance, managing drug shortages)**

Note: Demonstration of Technology Watch "line of reasoning"

2. SDO Monitoring Activities

（国際的標準開発団体の活動のMonitoring）

30 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	8-Jun-2015	No/Minimal Impact
A2	W3C	XML	M2 ESTRI	8-Jun-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	8-Jun-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	8-Jun-2015	No/Minimal Impact
A8	ISO TC171 SC2	ISO 19005 (PDF/A)	M2 ESTRI	8-Jun-2015	No/Minimal Impact
A20	CDISC	Study Data Exchange Standards	TBD (E17?)	8-Jun-2015	No/Minimal Impact
A21	CDISC	Dataset-XML	TBD	8-Jun-2015	No/Minimal Impact
A28	HL7-FMG	FHIR (Fast Healthcare Information Resources)	E2B/IDEX/M8	8-Jun-2015	No/Minimal Impact
A29	HL7-M&M	HL7 RIM (Reference Information Model)	E2B/IDEX/M8	8-Jun-2015	Impact/Managed
A30	HL7-RCRIM	Safety Report / ICSR	E2B	8-Jun-2015	No/Minimal Impact
A31	ISO TC215	27953 ICSR	E2B	8-Jun-2015	No/Minimal Impact
A35	ISO TC215 WG6	ISO DTS 19844 (Substances) IG	IDEX/E2B/M2 ESTRI	8-Jun-2015	Impact/Managed
A36	ISO TC215 WG6	ISO DTR 14872 (ISO IDMP Maintenance Guidelines)	IDEX/E2B/M2 ESTRI	8-Jun-2015	Impact/Managed
A37	ISO TC215 WG6	ISO DTS 20451 (Pharmaceutical Product ID) IG	IDEX/E2B/M2 ESTRI	8-Jun-2015	Impact/Managed
A38	ISO TC215 WG6	ISO DTS 20440 (Dose Forms/Routes of Admin) IG	IDEX/E2B/M2 ESTRI	8-Jun-2015	Impact/Managed
A39	ISO TC215 WG6	ISO DTS 20443 (Medicinal Product Identification) IG	IDEX/E2B/M2 ESTRI	8-Jun-2015	Impact/Managed
A40	ISO TC215 WG6	ISO IDMP 11238 (Substances) 3yr Review/Revision	IDEX/E2B/M2 ESTRI	8-Jun-2015	Impact/Managed
A41	HL7-RCRIM	SPL/CPM for IDMP	IDEX/E2B	8-Jun-2015	Impact/Managed
A42	HL7-RCRIM	SPL for Content of Labeling	TBD	8-Jun-2015	No/Minimal Impact
A43	HL7-RCRIM	SPL for Facility/Organization Information	TBD (Q12?)	8-Jun-2015	Impact/Managed
A44	HL7-RCRIM	SPL for Lot Distribution Reporting	TBD	8-Jun-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	8-Jun-2015	No/Minimal Impact
A54	HL7-RCRIM	eStability	TBD	8-Jun-2015	No/Minimal Impact
A60	ISO TC215 WG6 & WG3	DTS19256 (Med. Prod. Dictionary Sys. for Health Care)	E2B	8-Jun-2015	Impact/Managed

SDO Activity Monitoring - Summary

- **Monitoring "intelligence" is obtained via ICH member involvement in SDOs between meetings (e.g., mailing lists, teleconferences, in-person meetings, etc.)**
- **ICH risks managed through SDO monitoring & involvement**
  - Formalized review serves as a "check-point" for impact considerations
  - Workbook maintains historical review record and thus "organizational memory"
  - Note: activities not assigned to topic groups are being evaluated for potential broad ICH impacts

Workbook v2.4[1]

- **27 Items in Workbook**
  - **17 active updates by 7+ reviewers**
  - **3 "Review Complete"**
  - **7 deemed relevant (w/o Topic Group)**
- **Topic Association**
  - **12 E topics (6 E2x & 6 IDEX)**
  - **7 M2 ESTRI**
  - **1 M8**
- **Impact Risk Management**
  - **9 no/minimal impact**
  - **9 potential impact but managed**
  - **1 potential impact and not managed**
  - **1 unknown impact**

Workbook v3.1 in Fukuoka[2]

- **30 Items in Workbook**
  - **Discussed in M2**
  - **3 additions**
  - **7 "Review Complete"**
  - **Applicable to information exchange within human pharmaceuticals & generally used by 1 or more ICH regions**
- **Topic Association[3]**
  - **13 E topic (5 E2x & 7 IDEX)**
  - **8 M2 ESTRI**
  - **2 M8**
  - **8 TBD**
- **Impact Risk Management**
  - **20 with no/minimal impact**
  - **10 with impact but managed**

[1]reviews compiled by 03JUN; [2]current & new items reviewed by full M2; [3]some affiliated with multiple topics

3. M2 Management Activities

（他のEWG/IWGとのCollaboration等）

M2 Management Activities: Joint Meetings

E6 EWG

- Jointly reviewed and discussed comments to E6 Addendum

M8 EWG

- Jointly reviewed and discussed several technical areas
  - Controlled Vocabulary Maintenance
  - Comments on Submission Format Document : Methods for Creating PDF Documents and Images
- M2 took several actions that have been taken up in the workplan

  - Use of embedded fonts: further review to determine if subset of embedded fonts is acceptable
  - Investigate allowing use of Jbig2 compression algorithm as defined in the ISO 32000-1:2008 for PDF 1.7

4. ESTRI Activities

（ICHにおける電子的標準／IT技術の勧告等）

New Recommendations (1)

Endorsement

File Format: DOCX

- **DOCX was confirmed as an additional file format standard that may be accepted by all regions**
- **DOCX Recommendation ready for SC sign-off**

This recommendation is for the following 2 versions of the ISO 29500 standard as follows:

- **ISO/IEC 29500:2008 (Transitional)**
- **ISO/IEC 29500:2012 (Strict)**

It is the intention of the EWG to standardize on ISO/IEC 29500:2012 (Strict) at some point in the future.

This recommendation is for an additional file format and is not intended as a replacement for ISO-32000 (PDF) or PDF/A.

New Recommendations (2)

Endorsement

File Integrity: SHA-256

- **SHA-256 was confirmed as a standard for file integrity that may be accepted by all regions**
- **SHA-256 Recommendation ready for SC sign-off**

Information transfer: genericode

- **genericode was confirmed as a standard for enumerating code lists that may be accepted by all regions**
- **genericode Recommendation ready for SC sign-off**

Recommendation Revisions

Endorsement

General: ESTRI Gateway

- Implementation status of each region was reviewed
- ESTRI Gateway Recommendation was reviewed and revised to reflect the current state
- Revised ESTRI Gateway Recommendation ready for SC sign-off

General: Procedure

- Procedure Recommendation was reviewed and revised to reflect the current state
- Revised Procedure Recommendation ready for SC sign-off

Structured Content

Endorsement

- Confirmed utility of structured content per previous evaluation and SC endorsement
- M2 will identify/develop a list of topics to leverage structured content
  - ICH concept paper evaluation
  - Evaluate candidates for structured content for existing ICH topics and possibly other topics
  - Evaluate work in SDOs (SDO Monitoring and Tech Watch) for overlaps with topic content
  - Develop a list of candidates and prioritize for SC consideration
  - Develop draft concept papers for SC consideration
  - Next step to be determined based on SC input
- Concept papers will all follow a common template -Focused specifically on structuring content and identifying enabling standards

Redaction

1. **Reviewed regional redaction processes and guidelines**
2. **Developed a list of regional requirements**
3. **Next Steps:**
   - **Confirm the matrix of requirements vs regulators needs**
   - **Check requirements against existing formats and tools**
   - **Develop an information paper indicating how the requirements might be met to enable electronic redaction**

5. Major activities: *Now to Jacksonville*

（12月のジャクソンビル会議に向けた活動・課題）

Major activities: Now to Jacksonville Dec 7th to 10th

Endorsement

- Execute Structured content proposal based on SC feedback
- Update Best Practice Maintenance document to address code list maintenance in support of EWGs
- Address actions from joint M2-M8 meeting
- Provide final updates to ESTRI site
- Develop an Information Paper indicating how the requirements might be met to enable electronic redaction
- Advance ESTRI activities for PDF creation, evaluate support for AS3/AS4 in EDIINT, redaction evaluation, structured content approaches across ICH regions

Request face-to-face meeting in Jacksonville - 4 days

ICH
harmonisation for better health

ご清聴

ありがとうございました