

ICH REGIONAL PUBLIC MEETING

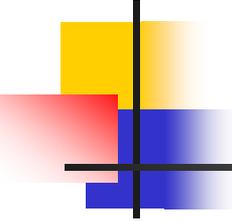
Tuesday, October 21, 2008

ICH M2 Activities

Mary Ann Slack

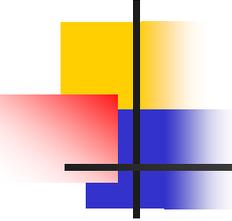
*Director, Office of Business Process
Support*

*FDA Center for Drug Evaluation and
Research*



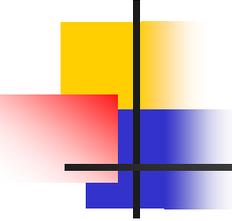
M2 Activities

- eCTD
- SDO Collaboration & Involvement
- ICSR Standard
- MPID Standards



Electronic Common Technical Document (eCTD)

- eCTD Next Major Version (eCTD NMV)
 - Requirements Under Development
 - Anticipated: Extend HL7 RPS to meet eCTD requirements
 - HL7 Project to Develop RPS2 Currently Underway
 - Broad Scope – includes human pharmaceuticals and biologics
as well as other products such as devices, vet meds, food additives
 - Iterative & Phased Approach allows for new requirements to be incorporated at different times in the project
 - Includes participation by several ICH Parties
- Planned for November ICH Meeting
 - Finalize eCTD NMV Requirements

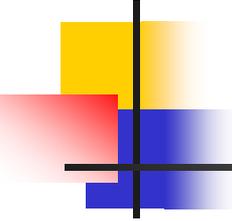


Standards Development Organizations (SDOs) Collaboration & Involvement

- M2 SDO Subgroup established
 - Establish/Manage Relationships with SDOs
 - Facilitate ICH Projects Through SDO Processes
 - Address Process Needs & Issues
 - Inform M2 and Other EWGs as Necessary

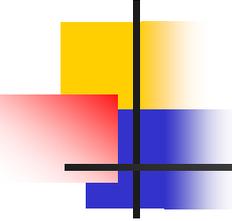
- Current Standards Development Initiatives:
 - Individual Case Safety Report Standard
 - Identification of Medicinal Products Standards

- Recently Agreed
 - Propose Joint Initiative (ISO, CEN & HL7) Project to Develop RPS to Meet eCTD NMV Requirements
 - Transition Into or With Current HL7 Project (Recognizing Current Scope/Schedule) to Develop ISO/CEN/HL7 International Standard that ICH can Adopt as the Next Major Version of eCTD



Individual Case Safety Report (ICSR)

- ICSR Draft International Standard (DIS) submitted to ISO TC215 for review
 - Several issues currently being addressed
- ICSR Implementation Working Group Activity
 - Joint M2/E2B(R3) Development of ICSR Implementation Guide
 - Joint M2/E2B(R3) Development of ICSR Acceptance Test Plan
 - Mapping of Requirements to Draft Standard
- Planned For November ICH Meeting
 - Near Final Implementation Guide (pending changes to DIS)
 - Near Final Test Plan (pending changes to DIS)
 - Discussion of Business Rules



Identification of Medicinal Products (IDMP)

- Committee Drafts submitted for review to ISO TC215
 - 11238 – Ingredients (substances)
 - 11615 – Medicinal Product Identification
 - 11616 – Pharmaceutical Product Identification
 - 11239 – Routes of Administration, Dosage Forms, Units of Presentation
 - 11240 – Units of Measurement
 - 11595 – Laboratory Test Units
- Modeling of the draft standards is progressing, to be included in draft standards documents
- Planned for November ICH Meeting
 - IDMP implementation activities planning