ISO IDMP Overview

Vada Perkins
US FDA

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prEN ISO/DTS Implementation Guides for the ISO IDMP Standard

- The International community identified the need for the implementation guides for the ISO IDMP as ISO *Technical Specifications*
- The ISO IDMP Implementation Guides are under development with the aim of defining how to generate and maintain ISO IDMP **Globally**
- The **Standards** provide definitions and conceptual models for the unique identification of medicinal products throughout the product lifecycle;

- The **Implementation Guides** will provide instructions on how to apply and use the ISO IDMP standards (e.g. mandatory/ optional fields/ business rules/ data types; Use of normative messaging standards e.g. HL7 standard

Discussion Topics

- Latest activities since ISO-Berlin
  - DTS 19844 (Substances)
  - DTS 20443 (MPID)
  - DTS 20451 (PhPID)
  - DTS 20440 (DF/RoA)
  - DTR 14872 (IDMP Maintenance)

- External Related Activities
  - Maintenance
    - Global Substance Information System (GSIS) (Substances)
      - Core of GInAS
    - EDQM (DF/RoA)
    - Algorithm (PhPID)
      - Based on HL7 V3 content
- Key Decisions for Next Steps
  - All draft documents submitted to ISO Secretariat post-ballot (March 2015)

Key Decisions for Next Steps

- Final draft versions submitted to ISO Secretariat (March 2015)
  - DTS 19844 revised per the comments received during the 2nd ballot cycle
  - ISO Ballot: 7 Nov 2014 -7 Jan 2015
  - Comment disposition: 2 Feb 2015-28 Feb 2015
  - ISO TC215/WG6 Meeting: San Francisco (April 2015)
    - Comment disposition
    - Revisions to ISO IDMP DTS documents
    - Publication/additional ballot cycle preparations

ISO DTS 19844

- Weekly meetings with ISO substance experts since ISO-Japan (June 2014-Sep 2014)
  - Resolution of comments from 1st ballot cycle
  - 22 Aug 2014 deadline for submission to ISO Secretariat for WG 6 review and preparations for a 2nd ISO ballot cycle (submitted Oct 31, 2014)
  - 2nd Ballot closed 7 Jan 2015
    - Comment resolution 2-28 Feb 2015
  - ISO-SF (April): Prep for official publication of 1st edition/release or 3rd ballot cycle of 19844

ISO DTS 19844 Identified Experts

Canada (SCC): Mary J. Raphael

Great Britain (BSI): Julie James, Andrew Marr, Barry Hammond

Germany (DIN): Thomas Balzer

Italy (UNI): Paolo Alcini, Ilaria Del Seppia

Japan (JISC): Takashi Misu and Izumi Oba

Netherlands (NEN): Herman Diederik **(Editor)**

Switzerland (SNV): Phillipp Weyermann

United States (ANSI): Vada Perkins (Project Lead), , Lawrence Callahan **(Editor)**

ISO DTS 19844: 1st Edition (for ballot)

- Addition of Annexes
  - Chemicals
  - Proteins
  - Nucleic Acids
  - Herbals

- 2nd Edition (May 2015 ballot cycle)
  - Polymers
  - Structurally Diverse Substances (e.g., biologics)

ISO DTS 20443 (Medicinal Products)

- 1st cycle ballot closed 7 Jan 2015
  - Comment resolution 2-28 Feb 2015
- ISO-SF (April): Prep for official publication (TS) or 2nd ballot cycle of 20443

ISO DTS 20443 Proposed Experts

Canada (SCC): Mary J. Raphael

Great Britain (BSI): Julie James, Andrew Marr, Barry Hammond

Germany (DIN):

Italy (UNI): Paolo Alcini, Ilaria Del Seppia

Japan (JISC): Takashi Misu and Izumi Oba

Netherlands (NEN):

Switzerland (SNV): Phillipp Weyermann

United States (ANSI): Vada Perkins (Project Lead/Editor)

ISO DTS 20451 (Pharmaceutical Product Identification)

- 1st cycle ballot closed 7 Jan 2015
  - Comment resolution 2-28 Feb 2015
- ISO-SF (April): Prep for official publication or 2nd ballot cycle of 20451

ISO DTS 20451 (PhPID) Proposed Experts

Canada (SCC): Mary J. Raphael

Great Britain (BSI): Julie James, Andrew Marr, Barry Hammond

Germany (DIN):

Italy (UNI): Paolo Alcini, Ilaria Del Seppia

Japan (JISC): Takashi Misu

Netherlands (NEN): Leonora Grandia

Switzerland (SNV): Phillipp Weyermann

United States (ANSI): Vada Perkins (Project Lead/Editor)

ISO DTS 20440 (DF/RoA/UofP)

- 1st cycle ballot closed 7 Jan 2015
  - Comment resolution 2-28 Feb 2015
- ISO-SF (April): Prep for official publication or 2nd ballot cycle of 20440

ISO DTS 20440 Proposed Experts

Canada (SCC): Mary J. Raphael

Great Britain (BSI): Christopher Jarvis (Project Lead/Editor), Julie James, Andrew Marr, Barry Hammond

Germany (DIN):

Italy (UNI): Paolo Alcini, Ilaria Del Seppia

Japan (JISC): Takashi Misu and Izumi Oba

Netherlands (NEN):

Switzerland (SNV): Phillipp Weyermann

United States (ANSI): Vada Perkins, Bill Hess

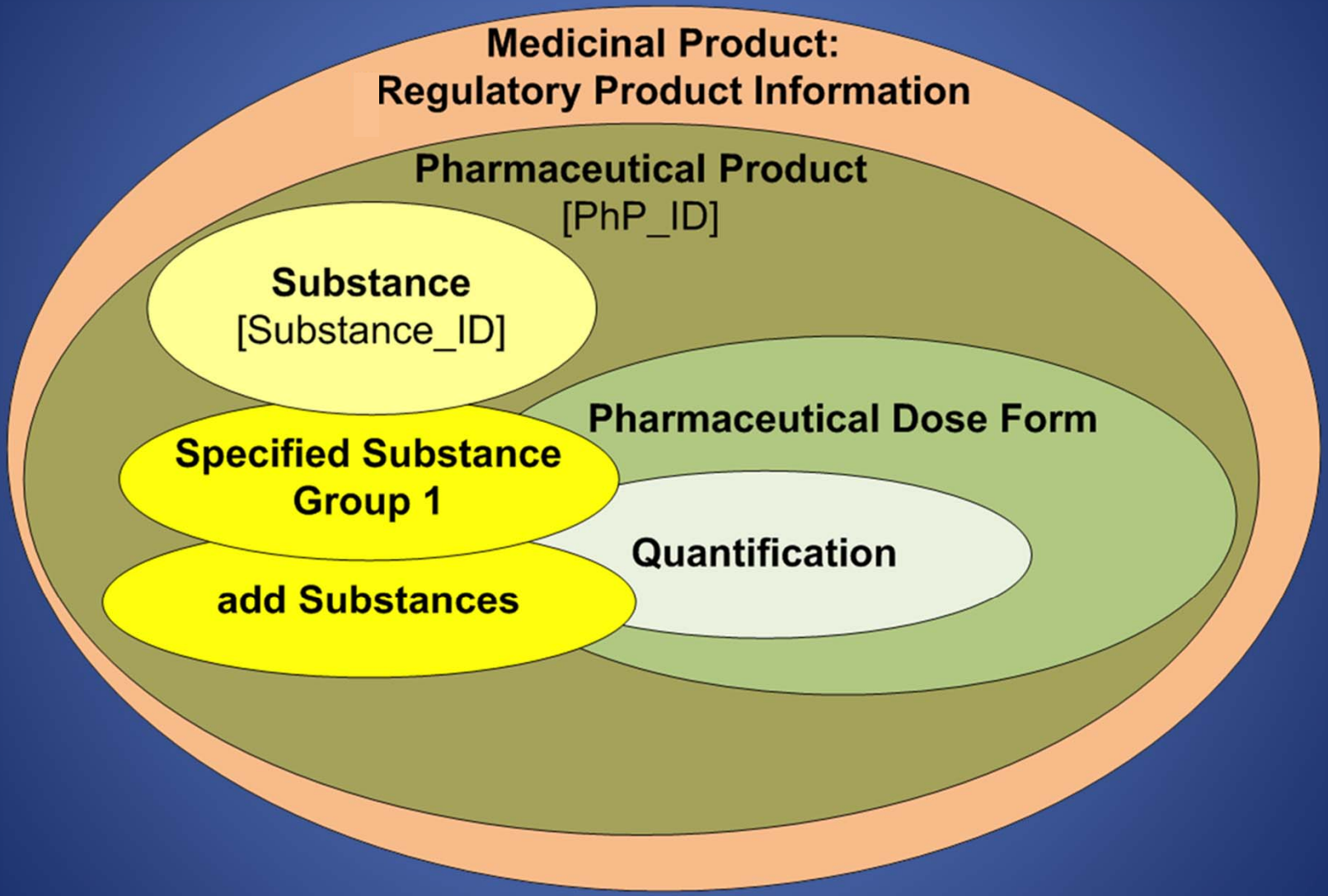
Maintenance

- Substances-ISO 11238
  - DTS 19844
- DF/RoA/UofP-ISO 11239
  - DTS 20440
- Pharmaceutical Product-ISO 11616
  - DTS 20451
- Medicinal Product-ISO 11615
  - DTS 20443
- Units of Measure (ISO 11240)
  - No DTS necessary

Substances: Global Substance Information System (GSIS)

- Open source substances software
  - Core of GInAS, FDA-SRS, others…
- Universal substances identification
  - Compliant with ISO 11238 and ISO DTS 19844
  - Compatible with regional requirements/considerations
- Ongoing discussions with various stakeholders

ISO-IDMP SUBSTANCE DATABASE APPROACH



Requirements for Substance ID Maintenance *(consistent with 2010 Task Force conclusions)*

- Must Maintain Substance ID For Pre And Post Market Substances and include the translations in all EU languages

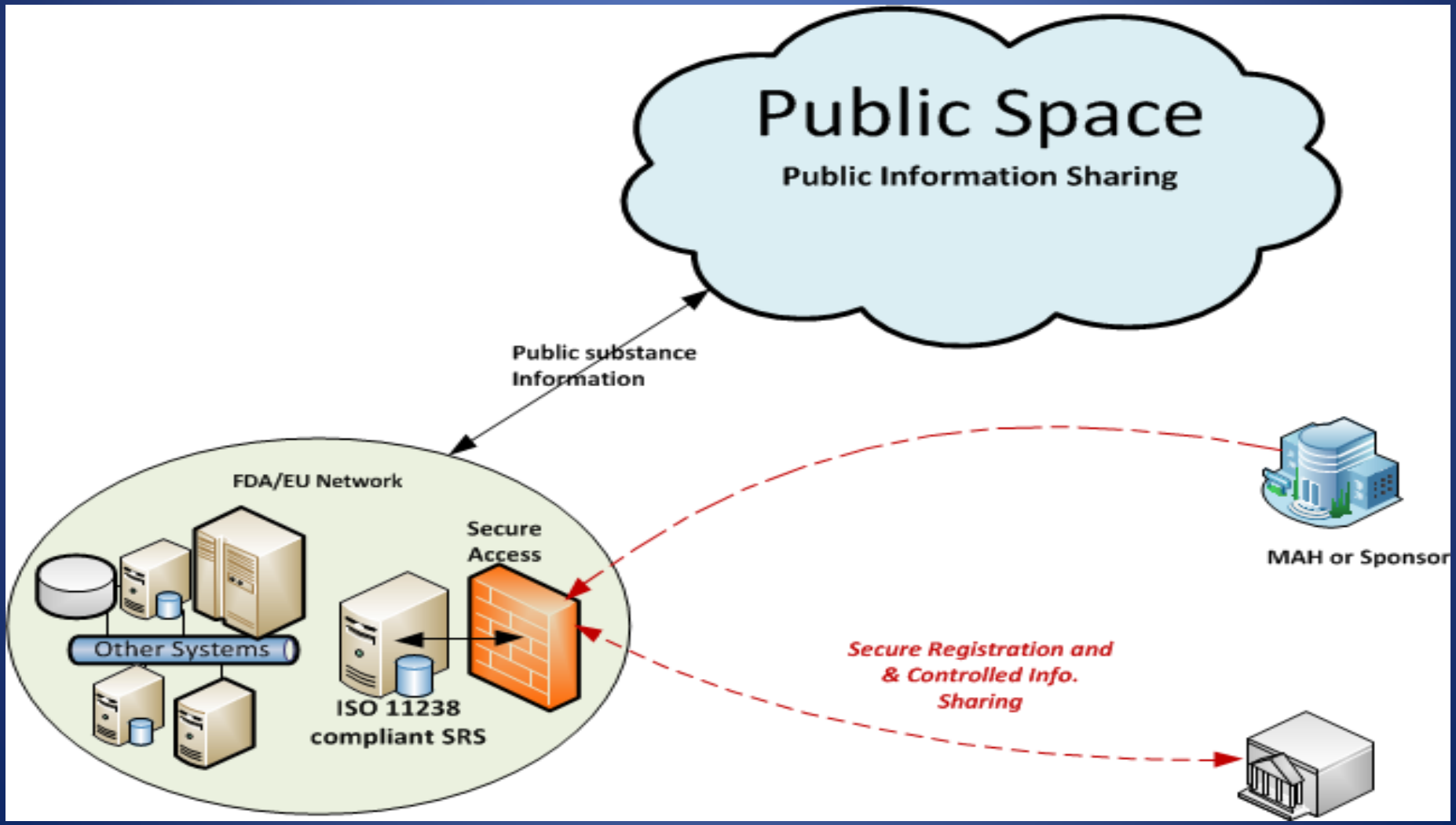
- Must Protect ***Confidential/Trade Secret*** Information
  - Safeguard against unauthorized access
  - Post online only after information is publicly available
  - Not ALL defining elements that describe a substance may be in the Public Domain

Requirements for Substance ID Maintenance *(consistent with 2010 Task Force conclusions)*

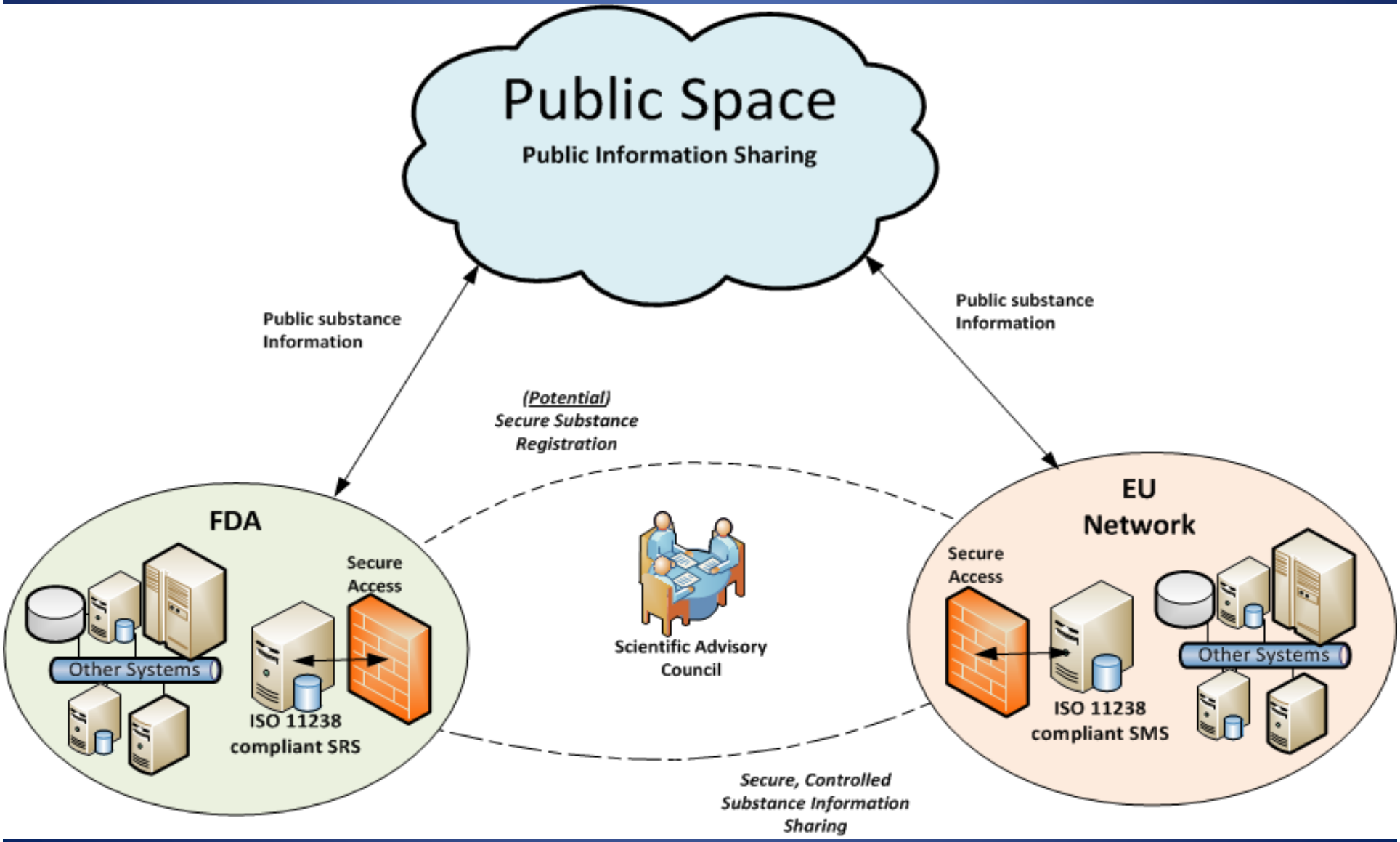
- Must Maintain ***Reliable Authoritative Source***
  - Safeguard data integrity
  - Safeguard against improper/inappropriate data
    - No automatic acceptance of substance information
    - Information must be verified and validated before acceptance
- Must Follow ***Consistent Change Control Practices***
- Must Provide an ***Arbitration Process*** for Disagreements

FDA's Position on Substance Registration

- Register and maintain substances centrally with EU
- Share information with EU regulatory authorities



Envisioned EU-FDA
Substance Registration and Data Sharing



ISO 11239/DTS 20440: European Directorate for the Quality of Medicines and Healthcare (EDQM)

- Mapping of DF/RoA terms
  - EU, US, Japan, Health Canada
- Database (beta) with a list of centralized terms mapped/linked to regional terms/IDs
- Stakeholders can access terms/IDs from EDQM free of charge

ISO 11616: Algorithm

- Based on ISO IDMP standards and HL7 Common Product Model (CPM)
  - Content and Message
- Algorithm made available to all members of the IDMP External Group (IDEX)
  - Testing (beta)
    - US, EU, JP, HC, others

The PhPID Algorithm Requirements (not all inclusive)

- To ensure that the same combination of input data will always generate the same ID
- To ensure that a different combination of input data will always generate a different ID
- To ensure that PhPIDs are generated by using only open technologies

ISO IDMP Work Streams

- ISO TC 215, WG 6
- Health Level Seven (HL7) RCRIM
- IDEX (IDMP External Group)
  - Periodic meetings (approx. q 1-2 months)
- International Pharmaceutical Regulators Forum (IPRF)
  - TBD (request to be submitted by Feb 2015)

Questions

vada.perkins@fda.hhs.gov