What is GInAS, What can it be, How will it be sustained, How will it be governed.

June 11, 2014

Substances In Regulatory Practice

- Substances form the essence or basis of every product
- Interactions between substances are responsible for nearly all pharmacological activity.
- Substances are a lynchpin on which to organize regulatory information but many regulatory agencies only identify them by names or codes
- Names and codes are not sufficient to fully define or relate substances to one another, products or adverse events.
- Regulatory agencies need to be able to define substances in an unambiguous manner
  - Mislabeling of substances or ingredients in a product allows regulatory action
- ISO 11238 (IDMP) provides a framework for defining all substances and related regulatory information

Need for a Global Database

- Global marketplace for ingredients requires a global system to monitor the global supply chain
- Global database means better data, less redundacy, more data, less mapping
- ISO 11238 has recently been developed to describe substances/specified substances in medicinal products
- Complex, expensive to implement a system based on 11238 on a individual basis may prevent adoption of standard
- Pharmacovigilance based on substances with global data
- Better coordination of regulatory activity and clinical trials (inspections, specifications, drug shortages)
- Standards/Specifications can converge more rapidly

GInAS Goals

- To develop and deploy an information system that can serve as a global repository for definitional, regulatory and scientific information on substances Establish a consortium of regulators and other international organizations to manage and govern the repository;
- To develop and distribute a global identifier for every substance in medicinal products and clinical trials;
- To distribute an information system for both regulators, companies and other interested parties to facilitate registration into the global repository;

GInAS History

- Grew Out of a Meeting Hosted by USP and NCATs (NIH) in February 2013
- 2nd meeting hosted in the Netherlands (September 2012
- Uses Software Developed by NCATs
- Prototype hosted at Health Canada
- Canadian, Dutch, German, Japan, Swiss, and US regulators, EDQM and USP have involved in the development of the system and standard
- Software can be deployed locally (Each regulator/company can have their own independent system using NCATS software and public data)
- System will be distributed by NCATs with a large set of public domain data and updated periodically

GInAS Data Integration

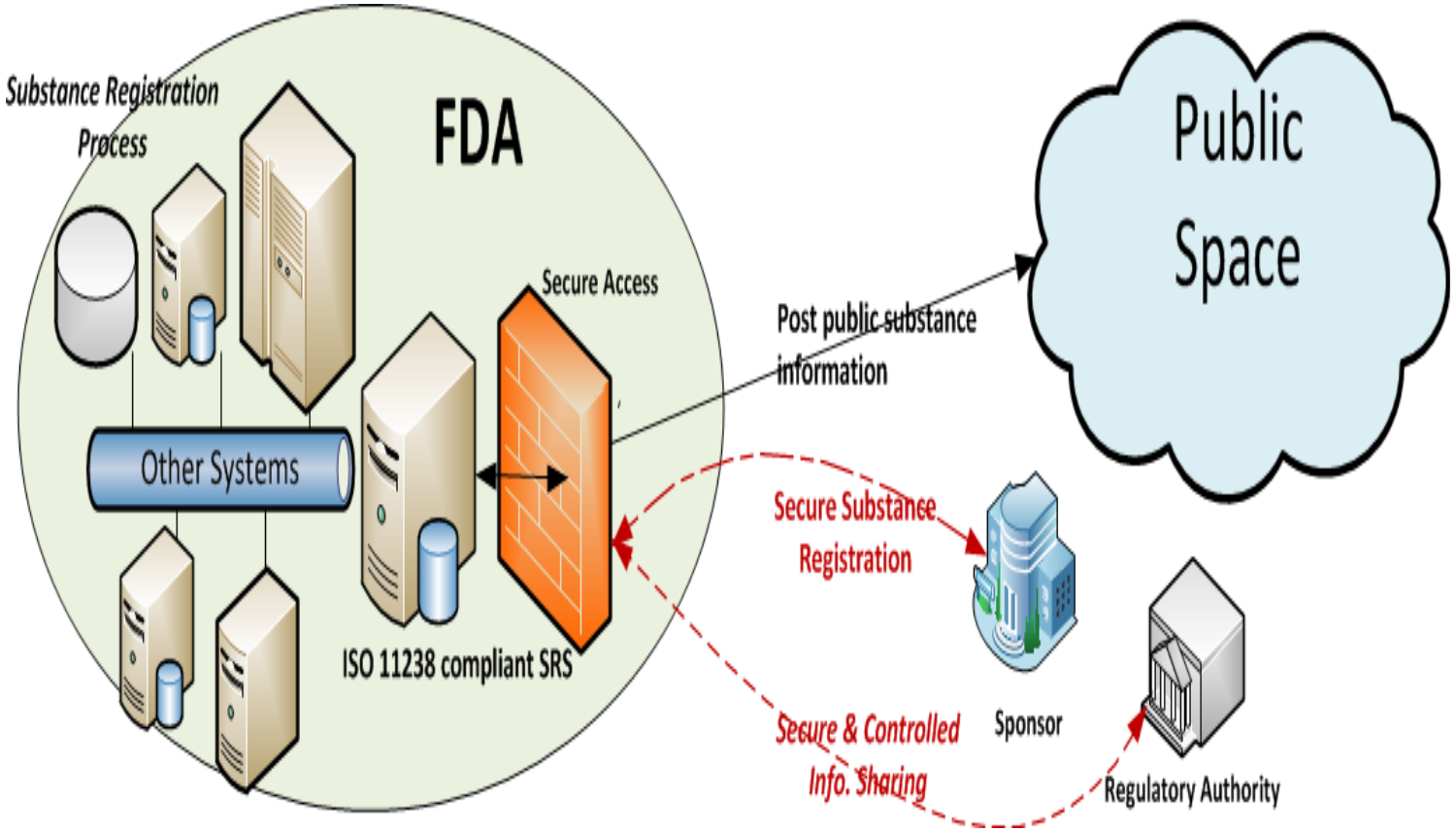
- Data That Should be Linked Substances
  - INDs, NDAs, BLAs, CFR's; Orphan Drug Applications
  - Products that Contain Each Substance
  - Pharmacological Classification
  - Active Moieties, Related Moieties and Salts
  - LADMER
    - Metabolites
    - Metabolic Enzymes, Transporters, and Effects
    - Drug target (therapeutic and other), type of interaction
    - Solubility and Permeability (BCS)
    - Protein Binding
  - Impurities and Related Substances

GInAS Data Integration

- Data That Should be Linked Substances
  - Constituents of Complex Materials
  - Specifications
  - Physical and Biological Properties
  - Environmental Fate
  - Uses
  - Toxicological, Animal, and Clinical Studies
  - ICSRs
  - Manufacturers, Sites, and Manufacturing Data
- Data should always be a click away
- Both Internal and External Links

How Can GInAS Work

– **GINAS and FDA**



Progress so Far

- Prototype system deployed at Health Canada
  - http://ginas.hc.ircan-rican.org/ginas/
  - User: tester
  - Password: ginastest
- First Version of Modules for all five types of substances, mixtures and group 1 specified substance completed.
- System ready to be deployed within FDA Environment
- NCATS will provide a distributable system at June meeting at USP.
- Migration of some public data has already occured

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