

# GInAS

## (Global Database for ISO11238)

### Pharma and Software Industries Perspectives

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# IRISS - Background

- IRISS = Implementation of Regulatory Information Submission Standards
- Global, open, multidisciplinary, non-profit organisation dedicated to robust implementation of regulatory submission standards around the world
- 250+ members representing ~100 pharma, software and consultancy companies regulators
  - Predominantly North American/European membership
- Active groups for
  - Advertising and Promotional materials
  - Labelling
  - E-submissions
  - CMC
  - IDMP (including XEVMPD)

# Current Understanding (1)

- Independent databases exist in multiple agencies with differing scopes and levels of details
- GlnAS intends to create an database that is compliant with ISO11238 (Substances) but which may also include data that is beyond the scope of the ISO standard to accommodate historic information held by some regulators
- Where pre-existing data is available this will be used by regulators to populate the GlnAS via a suitable process of reconciliation of the various data sources

# Current Understanding (2)

- Ultimately the scope of GInAS will cover
  - All substance (active ingredients, adjuvants, excipients) used in authorised and investigational medicinal products in participating regions
  - Specified substances (Groups 1, 2, 3 and 4) for both authorised and investigational medicinal products
    - Group 1: Constituents
      - Including material containing multiple substances (e.g. Colorants, growth media)
      - Physical form and physical properties
    - Group 2: Limited manufacturing information
      - E.g. Synthetic, extractive, recombinant
      - E.g. Manufacturer
    - Group 3: Grade and source of grade
      - E.g. Grade and source (pharmacopoeial)
    - Group 4: Detailed manufacturing information, constituents and specifications
      - Akin to CTD Module 3 level of information
- The plan to implement the various aspects of the scope is unknown to industry at present
  - Impacts on systems and processes are yet to be identified
  - Multiple potentials sources and outputs of data during any transition period will have to be supported

# Key areas of concern

- Vision and commitment from Regulators
- Responsibility and timelines for population
- Completeness and accuracy of data
- Commercial confidentiality
- Unique and unambiguous identification across countries/regions
- Availability of key data for use in vendor and in-house software

# Vision and commitment from Regulators

- Uncertain which regulators are fully committed to the program for GInAS
  - Whether it will replace existing systems and identifiers
  - Over what timeframe will it be implemented and populated
    - And data utilised in business processes
- A clearly articulated vision for how the database will be populated and used is necessary
- Clarification is sought specifically regarding the vision and intended use for Investigational substances

# Responsibility and timelines for population

- Data held by regulators is unlikely to cover all substances in all products
  - Who will be responsible for population of missing active, adjuvants and excipients?
    - Regulator(s) or industry?
- How will any conflicts of data be identified and resolved?
- Who will be responsible for provision of specified substance information?
  - API manufacturers?
  - Innovative company?
  - Multi-constituent excipient manufacturers?
  - Etc...
- Any differences in procedure between authorised and investigational products?
- Service level agreements and timelines for population should be established so that no delays for submission or pharmacovigilance processes occur due to delays in populating GInAS or the issuing of Substance/Specified Substance codes

# Completeness and Accuracy of Information

- Will issuing/availability of Substance IDs/Specified Substance IDs be dependent upon complete set of validated data?
  - Impact on regulatory processes that might require IDs?
  - Or content of dossier to include required set of data
  - Must be clear on what data are mandatory/optional
- Reduced set of level of detail for investigational substances must be supported
- Mechanism for industry to challenge/check data brought into GlnAS and added in future
  - Particularly for innovative substances

# Commercial Confidentiality

- No concern regarding public availability of data for substances in authorised medicinal products
- Significant concern with need to ensure commercial confidentiality for
  - Investigational substances
  - Detailed manufacturing processes
  - Use of specific manufacturers of actives and/or excipients
  - Formulas of multi-constituent substances e.g. flavours, in-house culture media etc.

# Unique and unambiguous identification

- A single globally unique substance identifier should be available to use in all regulatory processes, in all participating countries/regions
- Should not have to use regional codes as well
  - E.g. if Global ID is to be the UNII then this should be able to be used in European processes and not to also have an EV Code that must be used
    - Historical codes can be retained for cross-referencing purposes

# Availability of key data

- Corporate systems will need access to key data fields for the purposes of
  - Medicinal product identification processes
  - ICSR creation and reporting
  - Internal inventory systems
- Data downloads should be easy
  - Including for bulk downloads
- Real-time availability to both non-commercially confidential and commercially confidential data should be provided (secure web-services)
  - Confidential information should only be available to those authorised to access it
  - Should not have radically different ways for provision of IDs for authorised and investigation substances
  - Internal systems need to be able to combine these sources