ENCePP Registry of PASS Studies

Nick Halsey, EMEA

Current Activities

- System specifications
  - Storyboards/Use cases
  - Data fields
- EudraCT data
  - Rationale for use
- Harmonisation

System Specifications

- Storyboards
  - A written set of stories describing someone using the system to either search or input the data in the registry
  - Useful tool in creating specifications for how the system should work from a user perspective

Data Fields

- Review list of fields required for the ENCePP database
- Define the required vocabularies/look-ups
  - Avoid free text fields to allow searching functions
- For each field a decision will be required:
  - Will it be publicly available or hidden
  - Can it be used as a search criteria
  - Mandatory or optional for data entry

Rationale for accessing EudraCT Data

- An ENCePP study may also be Clinical Trial e.g. studying new patient population such as paediatrics
  - In such instances the Clinical Trial must be registered to obtain regulatory approval
  - A large number of fields must be completed by the Sponsor of the Trial (up to 800 fields)

- Therefore asking the Sponsor to re-enter the same data for the ENCePP registry is an unnecessary burden

Rationale for accessing EudraCT Data

- The data entered in the EudraCT database is saved as XML. Therefore it is technically feasible to use this file to upload the relevant parts of Clinical Trial into the ENCePP registry
  - It should be noted that the ENCePP registry can not be linked directly to the EudraCT database due to security and data confidentiality issues

EudraCT data

- The fields in the EudraCT database were examined to see their relevance to the ENCePP registry and the relevant ones have been highlighted for potential inclusion
  - From the 800 data fields 160 have been selected for further review by the drafting group

Open issues

- Discuss how to capture drug information,
  - Brand or Substance level?
  - Use the EudraVigilance Medical Product Dictionary as source of look-ups?
  - How to handle clinical trial drugs

Future Work

- Future work
  - User guides, how to enter the information, how to search
  - International harmonisation, any additional requirements to the current to ISO/HL7 standards development work for the registration of studies