

Challenges for Registries from the Viewpoint of a Pharmaceutical Manufacturer

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Topics

- **Registries – Setting the goal**
- **Managing quality**
- **Dealing with stakeholders**

Registries – Setting the goal

The term 'registry' for a plentitude of disease-related information has muddied the water.

Registry can be defined as, e.g.,

- '... list of patients presenting with the same characteristics. This characteristics can be a disease, or a specific exposure. Both types of registries, which only differ by the type of patient data of interest, can collect a battery of information using standardised questionnaires in a prospective fashion.'
(ICH Tripartite Guideline Pharmacovigilance Planning E2E, 18. Nov 2004, and Guideline on Risk Management Systems for Medicinal Products for Human Use, EMEA/CHMP/96268/2005, as well as EUDRALEX Vol 9A: Guidelines on Pharmacovigilance for Medicinal Products for Human Use).

Registries – Setting the goal

... or:

- ‘... an organised system for the collection, storage, retrieval, analysis and dissemination of information on individual persons exposed to a specific medical intervention who have either a particular disease, a condition (e.g., a risk factor) that predisposes to the occurrence of a health-related event, or prior exposure to substances (or circumstances) known or suspected to cause adverse health effects (i.e., individuals with a disease or risk factor who are not treated or exposed to medical interventions other than the intervention of interest).’
(Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiological Assessment, US Department of Health and Human Services, CBER/CDER, March 2005).

Registries – Setting the goal

... but also:

- ‘... prospective, observational cohort studies of patients who have a particular disease and/or are receiving a particular treatment or intervention. They can be used for understanding the natural history, assessing or monitoring real-world safety and effectiveness, assessing quality of care and provider performance, and assessing cost-effectiveness.

Registries involve prospective data collection of clinical, economic, and PRO information, and are increasingly relying on real-time data capture. they better reflect real-world patients, management practices, and outcomes. ... Disease registries enable providers and payers to gain insight into the most cost-effective treatment approaches.’

(Garrison Jr. LP, Neumann PJ, Erickson P, et al. Using real-world data for coverage and payment decisions: The ISPOR real-world data task force report. Value Health 2007;10:326-35).

Registries – Setting the goal

Registries are designed for a variety of purposes, which can be divided into 3 main categories:

- Clinical outcomes (e.g., natural history of disease, morbidity/burden of illness, treatment pattern, safety surveillance data, quality of care, provider performance)
- Economic data (e.g., resource utilisation, medical utility)
- Patient-reported outcomes (e.g., health-related Quality-of-Life, treatment preference, or satisfaction)

Defining registries – Points to consider

Goal setting:

- It is crucial to have a clear definition of the purpose of a registry
- A registry should principally be designed for its primary objective, and target audience
- ‘value-of-information-analysis’
- If a registry includes data on drug utilisation, it should entail reporting of suspected adverse drug reactions, and ideally have an interface with the manufacturer

Managing quality

Robust design of data collection format:

- Users are unlikely to spend much time on database training
 - Familiar 'touch-and-feel'
 - Questionnaire should be self-explanatory
 - Built-in annotations, and edit checks
- Choice of parameters that are clear-cut, reduce ambiguity

Managing quality – Points to consider

Validation of data:

- Data need to be reviewed regularly by a (medically) qualified person
 - Completeness and consistency
 - Periodic safety review, if drug treatment information is collected
 - Issue queries
- Develop interface with drug manufacturers

Dealing with stakeholders

Patients:

- Consult with patients in order to
 - make objective(s) relevant
 - design under practical aspects
 - obtain endorsement
- Respect their right to privacy

Dealing with stakeholders

Healthcare professionals (HCP's):

- Registries are usually perceived as extra burden
- Each registry has different design, features ...
 - Will appreciate degree of standardisation
- Consider primary motivators for HCP's
 - What is the benefit to my practice ?

Dealing with stakeholders

Industry:

- Interest in safety surveillance data, and economic aspects
- Mostly open to provide funds
 - Expect delivery on milestones
 - Expect certain standards on quality
 - Limited by annual budget cycles
- Obligation to report safety data to regulatory authorities

Dealing with stakeholders – Points to consider

Multi-stakeholder relationship:

- Registries are joint ventures between different stakeholders, with potentially different interest
- Develop communication plan around registry
 - Open dialogue from the early planning phase on
 - Consensus on objectives
 - Manage expectations