Presentation Title

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DIA DEVELOP INNOVATE ADVANCE

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The PSUR/PBRER

- PSUR a key element in medicinal product lifecycle by refocussing the PSUR
- Elements that benefit patients and Healthcare management
- Challenges faced in implementation
- Summary

The PSUR/PBRER

- 1992 CIOMS II guideline
- 1996 Step 4 ICH E2C Guideline - provide HAs with update of safety experience at defined intervals
- 2003 Addendum to ICH E2C (R1)
- 2012 ICH E2C(R1) replaced by ICH E2C(R2)
  - the PBRER replaces the PSUR format and content previously described in the ICH-E2C(R1)
  - In at least one ICH region (EU), the legal term PSUR will be retained but the format and content will be that of the PBRER

PSUR as a key element in the medicinal product lifecycle

- balanced evaluation of risk in context of benefit information
- Interdependency of pharmacovigilance documentation
- A new focus on evaluation in the context of pertinent efficacy
- Interval (new) and cumulative data allowing:
  - Comprehensive safety evaluation
  - In context of therapeutic effect
  - providing integrated benefit/risk evaluation consistent with the cumulative knowledge
  - defined point in time.

Elements that benefit patients and Healthcare management

- focus on information from multiple data sources
- Overview of safety signals and signal/risk evaluation
- Improved information on patterns of use/exposure
- Overview of benefits and benefit evaluation
- Integrated benefit-risk evaluation
- Strengthening the link with RM planning
- Stand alone report based on cumulative data - ease of review/assessment
- Supports lifecycle approach to continuous benefit-risk evaluation

Challenges faced in implementation

- Cross functional organisational alignment
- Need for common data base/linkages
- Governance, approval and ownership
- Timely Benefit Risk Assessment working group
- Process to review PBRER quality and improvements

Summary

- Evaluation of cumulative and comprehensive data
- Place risk in the context of benefit
- Align with other safety documentation and Pharmacovigilance planning
- Focus on principle of proportionality
- Supports lifecycle approach to benefit risk evaluation

Is further characterization of Risk Management in the context of Benefit required?

Ask