



Post-Market Safety Reporting Challenges for Devices Referencing Drugs (DRD)

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Disclaimer

Speaker's personal opinion and interpretation and does not reflect any company or organizational position

Devices Proposed for a New Use With an Approved, Marketed Drug

DRDs may be proposed:

- ▶ (1) Improve / enhance the safety or effectiveness of the marketed drug for its already approved indication;
- ▶ (2) Expand use - with the approved drug for an indication for which the drug is not approved; or
- ▶ (3) Additional benefit, such as increasing user comfort or convenience.

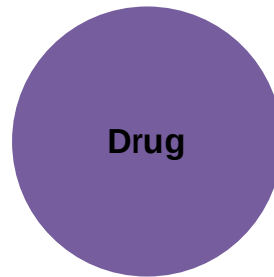
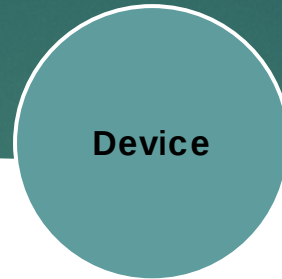
Change in Dose, Route, or Delivery (Rate of administration)

Changes the safety profile

Postmarket Safety

- ▶ Postmarket Safety: Plan to adequately address adverse events (AE), including medication errors
 - ▶ Identify
 - ▶ Capture
 - ▶ Report and
 - ▶ Respond appropriately to AEs associated with the new drug use per the DRD labeling

Safety information



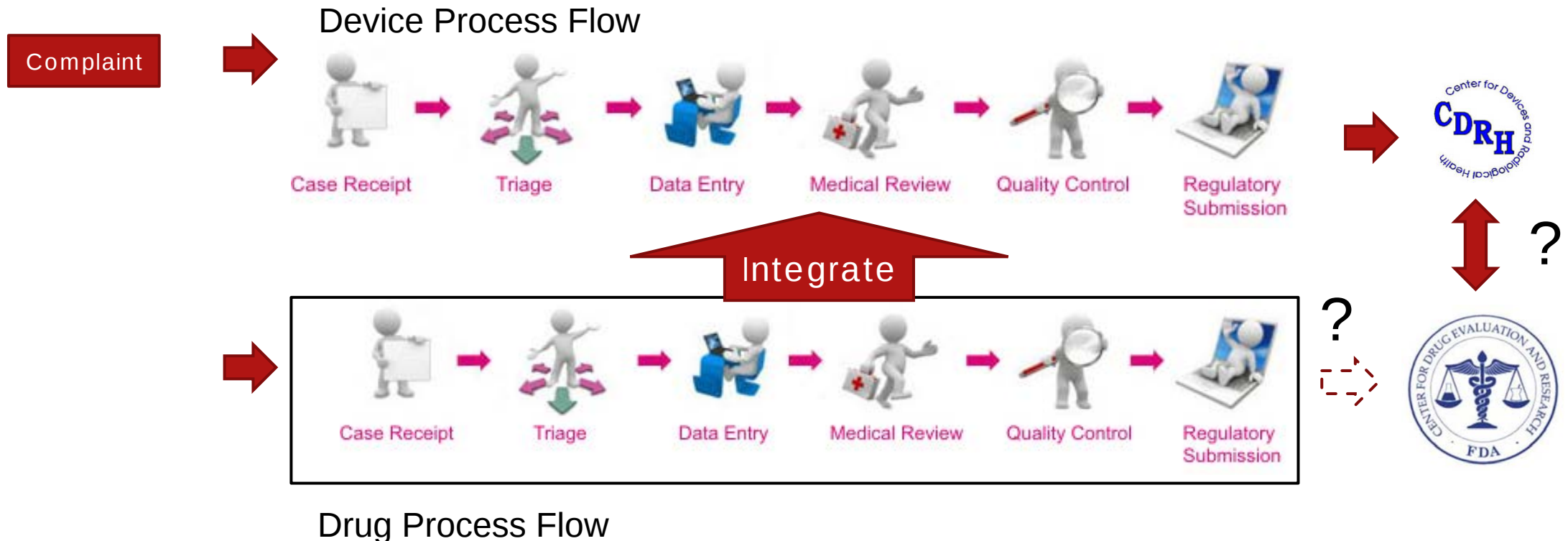
PMSR for DRDs – How?

Most Appropriate Reporting Approach for Drug Related Events?

- ▶ Follow the Device Approach?
 - ▶ **30-day Malfunction report (initial & supplemental)**
 - ▶ 5-day report (initial & supplemental)
 - ▶ Correction or removal report/record
- ▶ Utilize the Drug/Biologic Approach?
 - ▶ **15-day Report (initial & follow up)**
 - ▶ Field Alert Report (drug)/Biologic Product Deviation Report (biologic)
 - ▶ Periodic Reports
- ▶ Device-Drug Combination Product Approach? (similar to 2016 PMSR rule)
 - ▶ **15-day expedited and malfunction reports within 30 days**
 - ▶ 5-day report
 - ▶ Correction or removal report/record
 - ▶ Periodic report

Challenges for DRD Manufacturers – Who?

- Organizational
 - Create and integrate a new Pharmacovigilance (PV) group
 - Cross-training PV and Device Complaint Handling group

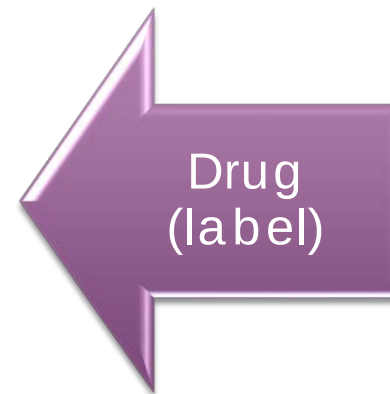
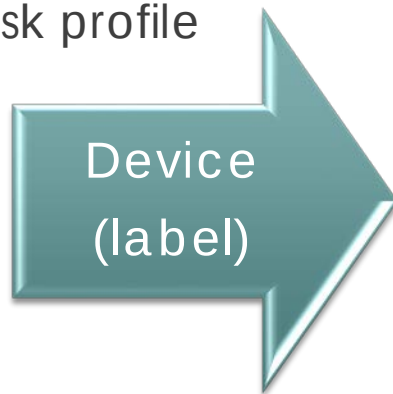


Challenges for DRD Manufacturers

- ▶ Missing Safety History - Expectedness
- ▶ Infrastructure and Training
- ▶ Data Architecture
- ▶ Processes unique to Drugs – Causality / relatedness / attribution
- ▶ Definitions
- ▶ Coding
- ▶ Periodic Safety Reporting
- ▶ Corrections & Removals / Field actions

Challenges for Reference Drug Manufacturers

- ▶ How to handle new adverse events reported by the DRD manufacturer?
 - ▶ Update labeling based on general pharmacovigilance principles?
 - ▶ Off-label use? Use error?
 - ▶ Patient / HCP information
 - ▶ Field actions / corrections
 - ▶ Product Risk profile



Other Challenges

- ▶ Global product profile? DRD or Drug manufacturer responsibility
- ▶ Drug cause vs Device caused vs Combination caused events
- ▶ Investigate / evaluate / assess – lots & batches used
- ▶ Discontinuation of the drug product
- ▶ Duplicate (Multiple) reports with similar or differing information
- ▶ Analysis
- ▶ Clinical trial

Safety is what matters

