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

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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.

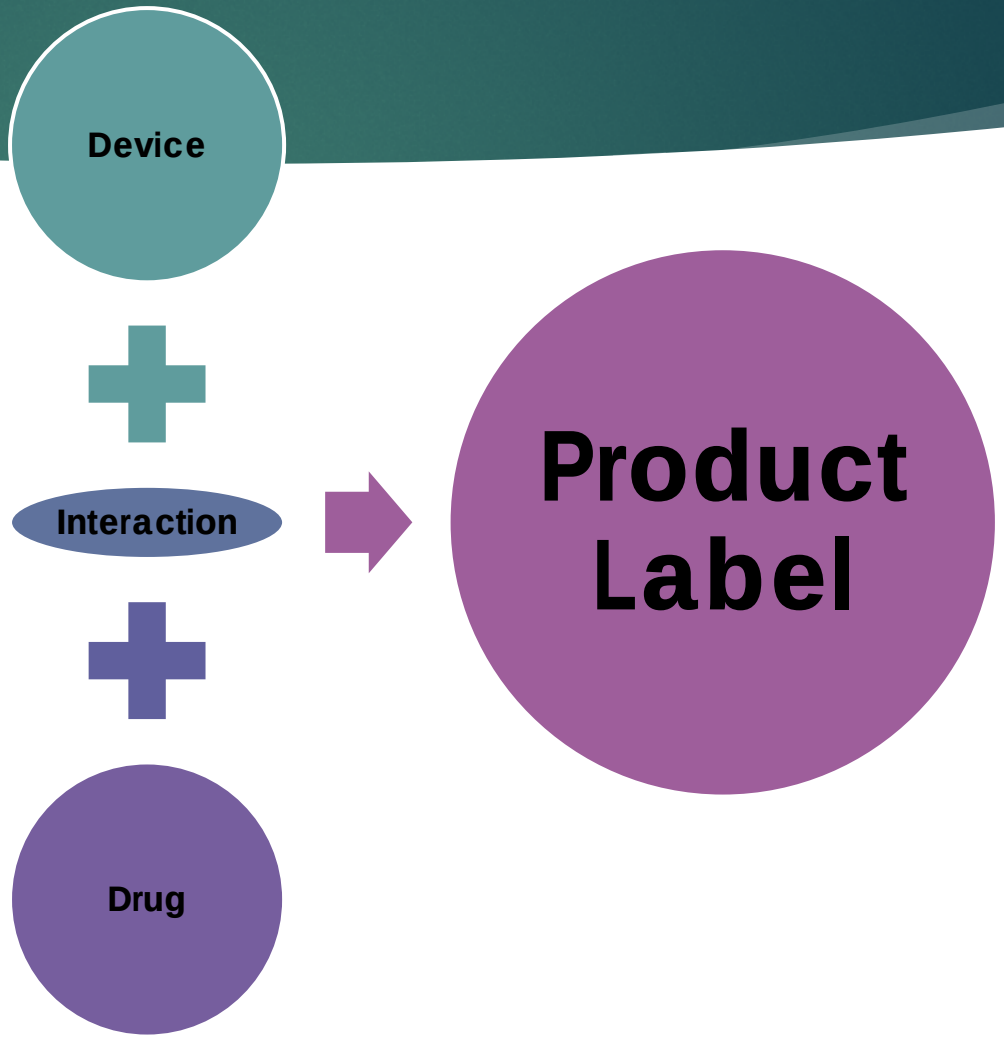
Change in Dose, Route, or Delivery (Rate of administration)

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



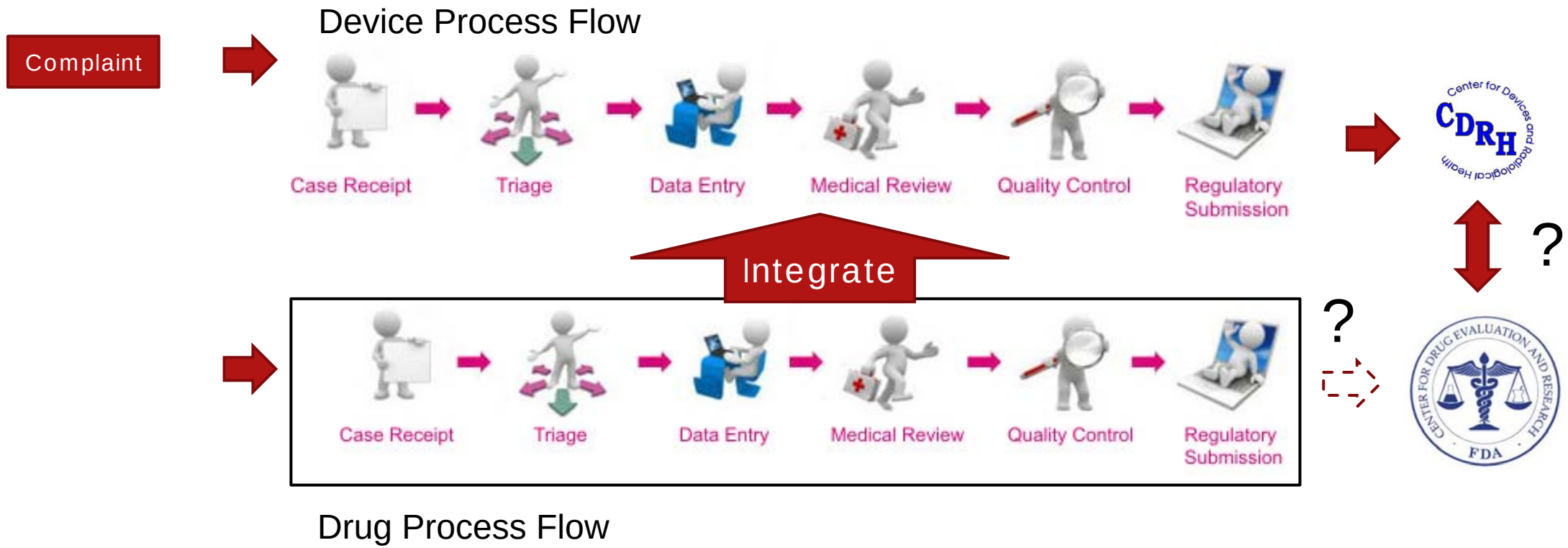
PMSR for DRDs – How?

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