

Safety Reporting from Company Sponsored Marketing Programs

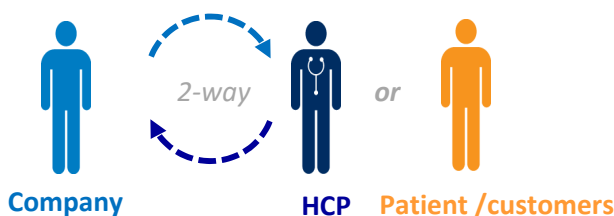
Background

Companies conduct marketing programs on their marketed products to gain insight from, or provide information or support to, its customers (including healthcare professionals, patients and customers). Some of these programs allow for two-way communication between the company and its customers. Although the primary purpose of these programs is generally not to collect safety information, product safety information may become evident to the company's employees, contingent workers, or vendors working on the company's behalf during the conduct of these programs. This poster is aim to introduce how to manage the safety reporting of these programs.

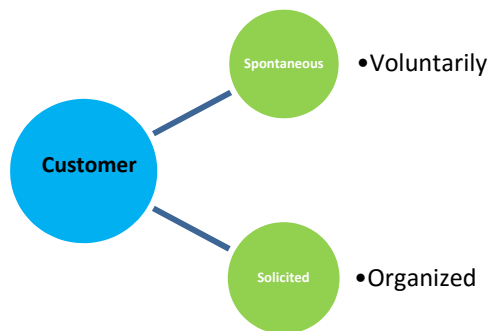
Safety Information Refers To



Marketing Programs In Scope of this Poster



Types of Safety Reports from Marketing Programs



Programs in Scope

Company sponsored programs including:

- Digital Media
 - Mobile Apps
 - Interactive Internet Sites
 - Social Media (e.g., WeChat)
- Interactive Webcast
- Patient Support Programs
- Disease Awareness / Screening
- Market Research
- Email or Texting Programs with Customers
- Business Reply Cards/Mails

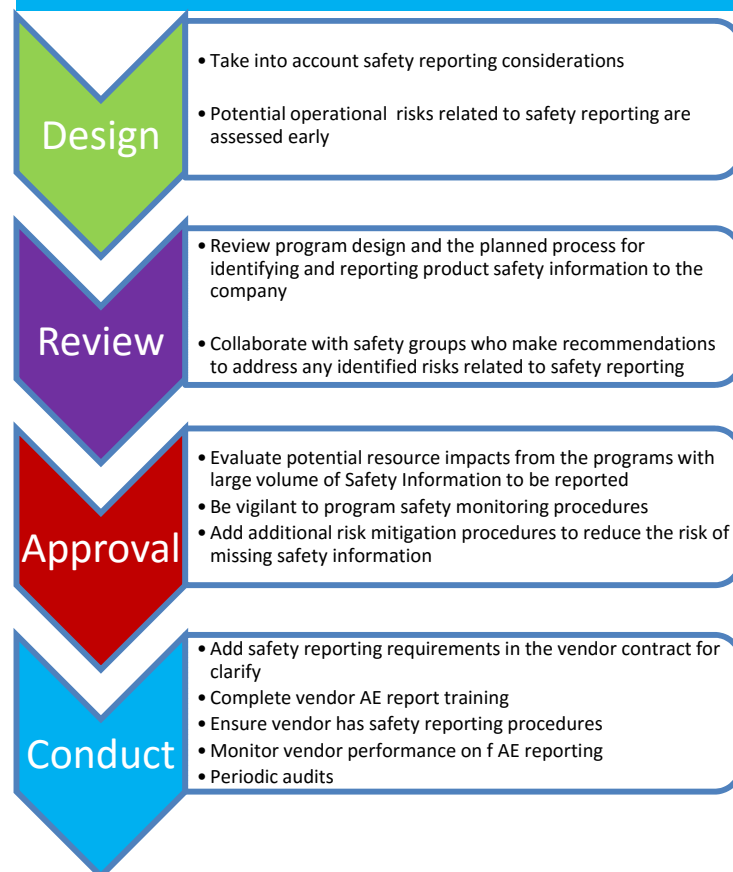
Programs Out of Scope

Company activities including:

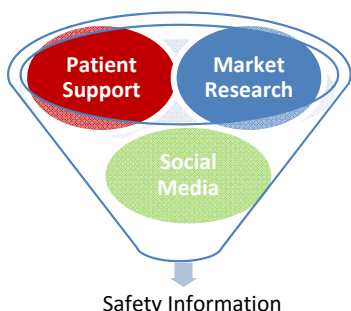
- Sales calls
- Non-Interventional Studies
- Clinical Trials/Compassionate Use
- Advertising & Promotional Materials
- Advisory Boards
- Speaker Training Programs
- HCP / Consultancy Engagements
- Company Medical Information Exhibits, Congress Participation
- Webcasts
- Investigator Initiated Studies

The design of the marketing programs (i.e., organized safety data collection versus volunteer reporting) determines the type of safety reports.

Considerations During Different Phases of the Programs



Safety Information May Derived From Marketing Programs That NOT on Purpose



* OLU=Off Label Use; EDP= Exposure During Pregnancy