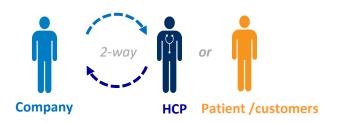
# Safety Reporting from Company Sponsored Marketing Programs

#### **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.

#### **Marketing Programs In Scope of this Poster**





### 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

#### **Safety Information Refers To**

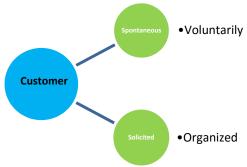
Adverse Event Product Complaint

Safety
Information

Other Reportable Info
(\*OLU, EDP, etc.)

Unexpected Therapeutic
Effects

#### Types of Safety Reports from Marketing Programs



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**

• Potential operational risks rassessed early

Potential operational risks related to safety reporting are assessed early

• Take into account safety reporting considerations

 Review program design and the planned process for identifying and reporting product safety information to the company

 Collaborate with safety groups who make recommendations to address any identified risks related to safety reporting

## Safety Information May Derived From Marketing Programs That NOT on Purpose



## Approval

Conduct

Review

- Evaluate potential resource impacts from the programs with large volume of Safety Information to be reported
- Be vigilant to program safety monitoring procedures
- Add additional risk mitigation procedures to reduce the risk of missing safety information
- Add safety reporting requirements in the vendor contract for clarify
- Complete vendor AE report training
- Ensure vendor has safety reporting procedures
- Monitor vendor performance on f AE reporting
- Periodic audits

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