Safety reporting – Sponsor responsibilities

To consider before study start:

- Are all safety aspects and reporting procedures properly described in the **Clinical Trial Protocol**?
- Need for a **Data Monitoring Committee**?
- Who will act as **Medical Monitor**?
- Who will take care of **SUSAR reporting**?
- What are the **safety reporting requirements** in each participating country?
- What is the **Reference Safety Information**?

During study:

- SAE processing – SUSAR reporting
- SUSAR line listings to investigators
- Urgent safety measures
- DSUR
- IB updates (if IB is in use for the clinical trial)

Time frames for reporting SUSARs to authorities:

- Fatal or life threatening SUSARs:
  - Within 7 days of becoming aware
  - Follow-up information within 8 days thereafter
- Other SUSARs
  - Within 15 days of becoming aware