

# Globally Validating a Serious Adverse Event Tracking System

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## ◆ SAE Reporting & Tracking Applications

- Many Vendors Market AE Tracking Applications
- Most follow their own SDLC
- Should you still *Validate*?
  - ▼ Yes
  - ▼ Why?
  - ▼ How Much?




◆ Validation in this country is a Best Practice

– Few Regulations but many Guidelines

▼ Following ICH, FDA and other agencies are moving to require electronic submission of AEs

▼ Companies must decide what their goal is:

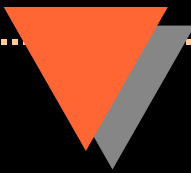
– Good Business Practice - Provide Quality Data

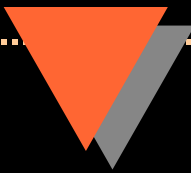
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- ◆ What does Validation mean?
    - Vendor Purchased Applications
      - ▼ Accept what you've purchased?
      - ▼ Audit the vendor, et fini?
      - ▼ Validate it?
    - Home-Grown Systems
      - ▼ SDLC
      - ▼ SOPs



◆ Validation is ...

- Confirming the SW meets your requirements
- Confirming the SW works according to the documentation
- Confirming SOPs describe using the SW appropriately
- Confirming your data are *Accurate* and *Safe*

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- ◆ For SAE systems Validation also is ...
    - Confirming the SW generates reports according to regulations and guidelines
      - ▼ Electronic submission of Individual Safety Reports (ISRs)
      - ▼ FDAs future plans for electronic submission of MedWatch 3500A

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- ◆ For Worldwide Validation certain ground rules need to be defined
    - Worldwide Team
    - Worldwide Plan
    - Control



## ◆ Planning

- Members of the Validation Team
- Requirements for FDA and other international regulatory agencies
- International Validation Policy
- Project Plan
- Validation Plan



◆ Know the Software Vendor

- Does the software run on all platforms
- Does vendor incorporate FDA changes in software in a timely manner.
- Does vendor provide world wide support
- Does vendor have a knowledgeable support staff.



◆ International Agreement

- Definition of Validation Terminology
- Dictionaries
- Reports
- Customizations



## ◆ Distribution

- What data will be distributed
- To whom will the data be distributed
- What times of the day will the data be distributed
- Contingency plan for errors and down system



## ◆ Control

- Decide which country will control distributing software, perform customizations, installs and updates