



# Investigators and MedDRA

MedDRA User Group Meeting

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# What is meant by good quality data?

- Complete
- Accurate
- Diagnosis supported by appropriate investigations
- Causality assessment



# Coding of Clinical Trial Data

- Most data entered on Case Report Forms is coded in some form
- Facilitates storage, retrieval, analysis and presentation of data
- Some coding is performed by investigators at point of data entry
  - e.g. numeric codes for severity of adverse event: 1= mild, 2= moderate etc.
- Other coding of text data is performed by the sponsor company after data collection
- Accuracy of initial coding determines accuracy of analysis



# Making the Most of MedDRA

- To take advantage of MedDRA's richness and specificity, the source data should be
  - clear
  - concise
  - complete
  - accurate
- General principles apply to all clinical data



# Problems with coding data

- Appropriate coding requires clear initial data
- A meaning that is clear to the investigator at the point of data entry may be unclear to the sponsor at the point of data coding
- Example: Ambiguous information
  - Congestion (nasal, liver, sinus, pulmonary?)
  - Cramp (muscle, menstrual, abdominal?)
  - Pain (pain where?)



# Miscellaneous verbatims

- Recurrent fatal stroke
- LK RTCTL UNSP XTRNDL ORG
- Scary encounter
- Funk exacerbated
- Normally normal after drinking coffee
- Went to hell
- Patient is intermittently tiresome
- Infection in first finger of the right foot
- Fireballs in uterus
- Blast (menopause)
- Too many yellow shirts



# Benefits of Quality Data

- Fewer queries for investigator and sponsor
- Accurate & timely information on issues that affect conduct of clinical trial and affect patient safety
- Improved communication among sponsors, investigators and regulatory agencies about medicinal products
  - Aids in safety signal detection and evaluation
  - Ensures accuracy of information about the product including investigators' brochures & prescribing information
  - Benefits medical professionals
  - Benefits patients



# Discussion points

- What kinds of strategies are being used to obtain best quality data from source?
- Are those strategies working?
- What about EDC?
- What is the appropriate level of MedDRA knowledge for investigators/CRAs?