Why are guidelines important to the pharmaceutical industry?

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Universal Guidelines - Benefits

- Save time and money
- Insure copyright
- Provide valid adaptations -- translations acquired by some one other than self

Standard Approach Would . . .

- Provides uniform basis for evaluation
- PRO results more likely to be accepted by regulatory agencies
- Allows for conventional data analysis and interpretation
- Establishes reliability and validity of PRO instrument
- Reduces variability

Guidelines may differ by type of measure

- Multi-item, multi-domain PRO instruments usually require detailed methods
- Diaries and event logs may require less rigid translation procedures
- Clinical measures, e.g., Global Impression of Change, may need separate guidelines

Where do we go from here?

- **Does it matter to industry if there is more than one set of guidelines?**
- **What type of measures should the guidelines include? e.g., PRO, caregiver/proxy response measures, clinician measures?**