PRO CTCAEs

Where are we ?

PROs: context

- Clinicians Focus on Safety or Toxicities Requiring Action

- Patients Focus on Day to Day Effects of Therapies

PROs: context

- Usual description of adverse events with the 790-items CTCAE (Common Terminology of Adverse Events) criteria under-detects symptomatic, though significant events

- Patients' reports better reflect their underlying health status than doctors do w/CTCAE, and most of patients are capable and willing to report their symptoms

- Direct patients' reporting bypasses the multistep process to research database where information is lost

PROs: context

- PRO-based AE reporting must comply with several rules:
  - AEs must include « classic » and non-classic items (unanticipated symptoms)
  - Reporting must catch the worst magnitude of any AE
  - AEs must be assessed at sufficiently frequent intervals
  - AEs to be scored independently

NCI developed PRO-CTCAE

- A consortium was established
    - AEs must include « classic » and non-classic items (unanticipated symptoms)
    - Reporting must catch the worst magnitude of any AE
    - AEs must be assessed at sufficiently frequent intervals
    - AEs to be scored independently
    - Terms adapted to non-medical users

Where are we now with PRO-CTCAE ?

- Paper = IVRS = iPad
- Validated in foreign languages: English, Spanish
- On the way: German, Swedish, Danish, Chinese, Japanese, Korean, Italian
- Desperately missing: French