

PRO CTCAEs

The 2017 update

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
 - Built a library (where you pick the items of your choice)
 - Terms adapted to non-medical users
 - PRO-CTCAE responses are scored from 0 to 4
 - Up to three questions per AE Item (Frequency, Severity, Interference)

Where were we last year with PRO-CTCAE ?

- Paper = IVRS = iPad
- Validated in foreign languages: English, Spanish
- On the way: German, Swedish, Danish, Chinese, Japanese, Korean, Italian
- Desperately missing: many including French (GINECO willing to help)



Where are we now with PRO-CTCAE ?

Healthcare Delivery Research Program

Home

Data, Tools, and Initiatives

Funding Opportunities

Research Portfolio

Events and Media

About

Measurement Tools

Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE™)

The PRO-CTCAE Measurement System

Background

Development, Testing, and Implementation

Language Translation: Methods and Certificates



Data, Tools, and Initiatives

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Language Translation: Methods and Certificates

Language Translation: Methods and Certificates

- ▶ Methods used to translate and linguistically validate PRO-CTCAE follow the Principles of Good Translation and Cultural Adaptation Practice as articulated by ISPOR in 2005.
- ▶ These methods include:
 - ▶ development of item definitions;
 - ▶ dual forward translation with reconciliation, dual back translation, back translation review and harmonization;
 - ▶ review by a bilingual oncology clinician (physician or nurse) to verify terminology;
 - ▶ final proofing by another independent bilingual oncology clinician, including diacritics; and
 - ▶ cognitive testing with a diverse sample of cancer patients who are receiving active cancer treatment or who have recently completed active treatment.
- ▶ This approach is designed to yield translated versions of PRO-CTCAE that are conceptually equivalent to the English version, and readily understood by the target population.
- ▶ The [PRO-CTCAE Instrument](#) is currently available in English, Danish, German, Japanese, and Spanish. Additional translations are in development (including Chinese, Czech, Dutch-Flemish, French, Greek, Hungarian, Italian, Korean, Polish, Portuguese, Russian, and Swedish), and will be posted upon completion.

Though, GINECO will still not FREXIT

- Done: English, Danish, German, Japanese, and Spanish
- In development: Chinese, Czech, Dutch-Flemish, French, Greek, Hungarian, Italian, Korean, Polish, Portuguese, Russian, and Swedish)
- Will be posted upon completion, but no ETA
- GINECO offered to help to speed this a little bit. Didn't work

Can we anticipate ?

- Incorporate PRO CTC AE 's in the next GCIIG studies
- Mandatory because
- OS is increasing
- Innovative, maintenance therapies are underway
- QoL to be a major endpoint
- Has to be appropriately monitored

United we stand

