

# PRO CTCAEs

5 minutes on the 2018 fall 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 are we now with PRO-  
CTCAE ?

## Measurement Tools

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

**The PRO-CTCAE Measurement System**

**Language Translation: Methods and Certificates**

**Certified Translations**

[Data, Tools, and Initiatives](#)[Measurement Tools](#)[Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events \(PRO-CTCAE™\)](#)[The PRO-CTCAE Measurement System](#)[Language Translation: Methods and Certificates](#)[Certified Translations](#)

## PRO-CTCAE Certified Translations

### PRO-CTCAE Certified Translations as of June 2018

Languages	Countries Tested <sup>1</sup>
Chinese (Traditional)	USA, Taiwan
Czech	Czech Republic
Danish	Denmark
Dutch	Belgium, The Netherlands
English (Universal)	USA, Australia, Canada, UK
French (Canadian)	Canada
French (for France, Belgium, Switzerland)	France, Belgium, Switzerland
German	Germany, Austria, Switzerland
Greek	Greece
Hungarian	Hungary
Italian	Italy
Japanese	Japan
Korean	Korea
Polish	Poland
Portuguese (for Portugal)	Portugal
Portuguese (for Brazil)	Brazil
Russian	Russia
Spanish (Universal)	USA <sup>2</sup> , Spain, Chile

1: Cognitive interviews.

2: Tested in native Spanish-speakers residing in the US for whom Spanish remains their primary language, from the following countries of origin: Argentina, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, El Salvador, Honduras, Mexico, Nicaragua, Peru, Puerto Rico, Uruguay, Venezuela.

# GINECO has just started

- The Niqole study
- A real-life study evaluating niraparib in a french patient cohort
- Mostly focusing on quality of life
- Incorporation of (besides other scales) the NCI-CTC PRO AE scoring
- First lesson: very easy to build using the NCI tool
- Second lesson: Handling the data is more tricky

# Using the NCI tool

## PRO-CTCAE Instrument & Form Builder

Use of the PRO-CTCAE is subject to NCI's [Terms of Use](#). Download the full instrument below, or use our Form Builder to produce a custom PRO-CTCAE form in any available language for your study. Form Builder is quick, easy to use, and eliminates the potential for cutting and pasting errors.

- ▶ [Item Library \(PDF, 138 KB\) \(English only\)](#)
- ▶ [English \(PDF, 311 KB\)](#)
- ▶ [Chinese \(Traditional\) \(PDF, 354 KB\)](#)
- ▶ [Czech \(PDF, 792 KB\)](#)
- ▶ [Danish \(PDF, 879 KB\)](#)
- ▶ [Dutch \(for Belgium and the Netherlands\) \(PDF, 261 KB\)](#)
- ▶ [French \(Canada\) \(PDF, 721 KB\)](#)
- ▶ [French \(Belgium, France, and Switzerland\) \(PDF, 350 KB\)](#)
- ▶ [German \(PDF, 707 KB\)](#)
- ▶ [Greek \(PDF, 721 KB\)](#)
- ▶ [Hungarian \(PDF, 303 KB\)](#)
- ▶ [Italian \(PDF, 1.2 MB\)](#)
- ▶ [Japanese \(PDF, 609 KB\)](#)
- ▶ [Korean \(PDF, 1.5 MB\)](#)
- ▶ [Polish \(PDF, 310 KB\)](#)
- ▶ [Portuguese \(Brazil\) \(PDF, 200 KB\)](#)
- ▶ [Portuguese \(Portugal\) \(PDF, 202 KB\)](#)
- ▶ [Russian \(PDF, 1.0 MB\)](#)
- ▶ [Spanish \(PDF, 271 KB\)](#)
- ▶ [In development and testing: Simplified Chinese, Malay, Romanian, and Turkish.](#)

### Form Builder



Use Form Builder to generate a custom built form for your study.

Easy  
User-friendly



# Pretty easy

## PRO-CTCAE items needed

You will have the opportunity to revise these choices on the next page.

### Oral

- Dry mouth
- Difficulty swallowing
- Mouth/throat sores
- Cracking at the corners of the mouth (cheilosis/cheilitis)
- Voice quality changes
- Hoarseness

### Gastrointestinal

- Taste changes
- Decreased appetite
- Nausea
- Vomiting
- Heartburn
- Gas
- Bloating
- Hiccups
- Constipation
- Diarrhea

### Cutaneous

- Rash
- Skin dryness
- Acne
- Hair loss
- Itching
- Hives
- Hand-foot syndrome
- Nail loss
- Nail ridging
- Nail discoloration
- Sensitivity to sunlight
- Bed/pressure sores
- Radiation skin reaction
- Skin darkening
- Stretch marks

### Neurological

- Numbness & tingling
- Dizziness

### Sleep/Wake

- Insomnia
- Fatigue

### Mood

- Anxious
- Discouraged
- Sad

### Gynecologic/Urinary

- Irregular periods/vaginal bleeding
- Missed expected menstrual period
- Change in usual urine color
- Urinary incontinence

Pick your favorite ones

# And we're done !

## NCI PRO-CTCAE™ ITEMS

Item Library Version 1.0

French (Belgium, France, and Switzerland)

Form created on 3 October 2018

Lorsqu'elles prennent leur traitement anticancéreux, il arrive que les personnes manifestent différents symptômes et effets secondaires. Pour chaque question, veuillez cocher la case ou inscrire un ☒ dans la case qui décrit le mieux vos expériences au cours des 7 derniers jours...

1.	Au cours des 7 derniers jours, quelle a été la SÉVÉRITÉ de votre SÉCHERESSE DE LA BOUCHE à son PIRE DEGRÉ ?				
	<input type="radio"/> Aucune	<input type="radio"/> Légère	<input type="radio"/> Modérée	<input type="radio"/> Sévère	<input type="radio"/> Très sévère

3.	Au cours des 7 derniers jours, à quelle FRÉQUENCE avez-vous été atteint(e) par les symptômes suivants ?				
	<input type="radio"/> Jamais	<input type="radio"/> Rarement	<input type="radio"/> Occasionnelle ment	<input type="radio"/> Fréquemment	<input type="radio"/> Très fréquemment
	Au cours des 7 derniers jours, quelle a été la SÉVÉRITÉ de vos VOMISSEMENTS à son PIRE DEGRÉ ?				
	<input type="radio"/> Aucune	<input type="radio"/> Légère	<input type="radio"/> Modérée	<input type="radio"/> Sévère	<input type="radio"/> Très sévère

Patients tick the boxes

# Can we anticipate ?

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