Classificazione delle tossicità secondo CTCAE

Daniele Galanti

C.T.C.A.E.

?

Common
Terminology
Criteria
for
Adverse
Events

C.T.C.A.E. history: before CTCAE

The Evolution and Application of Toxicity Criteria

Andy Trotti

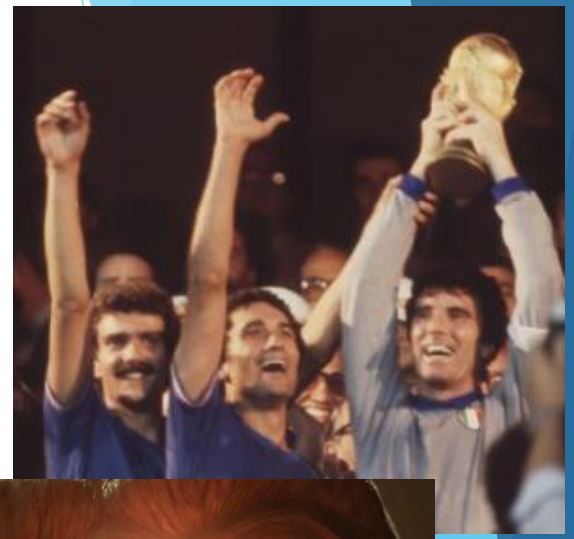
Table 1. The Evolution of Toxicity Grading Systems(1979-1998)

System	*No. of Criteria*	*No. of Organs*	*Modality*	*Phase*
WHO (1979)	28	9	Chemo	Acute
CTC (1983)	18	13	Chemo	Acute
RTOG/EORTC-Acute (1984)	14	13	RT Acute	Acute
RTOG/EORTC-Late (1984)	16	13	RT Late	Late
LENT (1995)	152	22	RT Late	Late

Abbreviation: WHO, World Health Organization.
*Limited pediatric and surgical criteria.

C.T.C.A.E. history

1982: vengono formulati i National Cancer Institute-Common Toxicity Criteria (NCI-CTC)



NCI-CTC nascono come il tentativo di sviluppare un metodo comune di riportare le tossicità durante i trial di fase I, ma successivamente vengono impiegati per descrivere e classificare gli eventi avversi durante nuovi trattamenti oncologici (chemioterapia) in:

- Study summaries
- Investigational New Drugs (IND) reports a FDA
- Pubblicazioni

C.T.C.A.E. history

Perché la necessità per il National Cancer Institute di documentare e riportare accuratamente gli AEs??

- ✓ Federal Regulations
- ✓ FDA1572 Investigator Registration Form
- ✓ Safety
- ✓ Accurata analisi degli effetti avversi degli interventi sperimentali in Oncologia Medica, Radioterapia e Chirurgia Oncologica

C.T.C.A.E. history

Dentro gli obiettivi degli NCI-CTC

- ❑ Definizione degli AEs
- ❑ Definizione della gravità degli AEs

Oltre gli obiettivi degli NCI-CTC

- ❑ Attribuzione degli AEs
- ❑ Interpretazione della gravità degli AEs

C.T.C.A.E. history

1982: format dei NCI-CTC
18 categorie di AEs
49 differenti AEs registrati e classificati secondo il seguente grading:
Grado 1: mild
Grado 2: moderate
Grado 3: severe
Grado 4: life-threatening

C.T.C.A.E. history

1998: CTC v2.0

24 categorie di AEs
~300 differenti AEs (classificazione degli AEs più specifica)

- Allargamento della classificazione degli AEs alla Radioterapia Oncologica e all'Oncologia Pediatrica
- AEs acuti
- 2 appendici

NCI-CTC v2.0 vengono tradotti in numerose lingue e diventano uno standard internazionale di valutazione degli AEs acuti

C.T.C.A.E. history

CTCAE v3.0: Development of a Comprehensive Grading System for the Adverse Effects of Cancer Treatment

Andy Trotti, A. Dimitrios Colevas, Ann Setser, Valerie Rusch, David Jaques, Volker Budach, Corey Langer, Barbara Murphy, Richard Cumberlin, C. Norman Coleman, and Philip Rubin

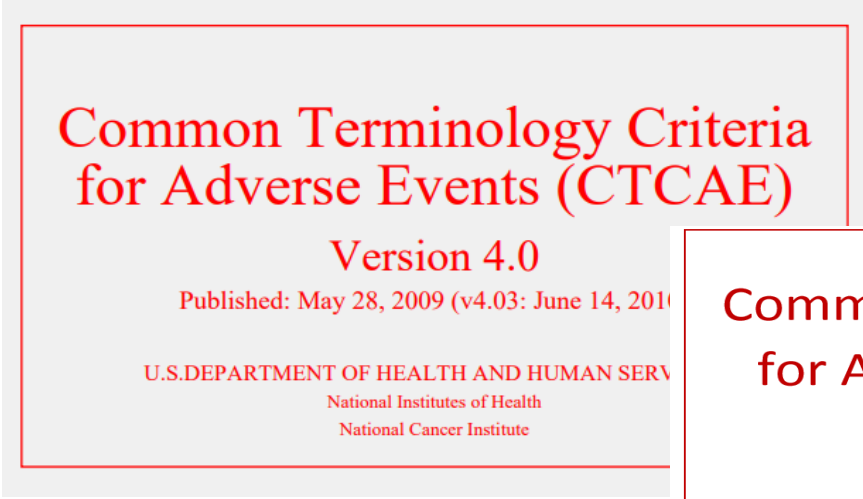
2002: CTC Development Team
(gruppo di esperti oncologi indipendenti e rappresentanti dell'NCI)

nascono i CTCAE v3.0:
- espansione e aggiornamento dei CTC
- inclusione degli AEs tardivi e/o cronici

CTCAE v3.0 rappresenta il primo metodo di classificazione e grading degli AEs sistematico, multimodale, onnicomprensivo (eventi avversi acuti e tardivi), utilizzabile nei trials clinici oncologici e applicabile a tutte le modalità di trattamento

C.T.C.A.E. history

2010: CTCAE v4.0



2017:CTCAE v 5.0

gli ultimi due aggiornamenti dei CTCAE non modificano l'impostazione generale dei CTCAE, ma li aggiornano e li ampliano

What are Adverse Events??

Sinonimi di Adverse Event:

- ✓ side effect
- ✓ acute/late effect
- ✓ complication
- ✓ toxicity
- ✓ morbidity

} Qualsiasi cambiamento indesiderato che può essere causato da un trattamento

Evento avverso (AE):

- segno (es. ipertensione d mab)
- anomalia di labor aminasemia da gefitinib)
- sintomo (es. dolor l'aromatasi)
- malattia (es. tireopatia aut nti-PD1)

sfavorevole e/o indesiderato

What are Adverse Events??

Ogni AE viene definito con un termine proveniente da MedDRA v21.0

AEs possono essere:
- sintomatici o completamente asintomatici;
- clinicamente o radiologicamente rilevabili;
- evidenziabili in test di laboratorio o differenti test diagnostici

AEs possono essere causati e/o favoriti da:
- condizioni pre-esistenti (es. ipertensione, diabete)
- concomitant medications (es. steroidi, anticoagulanti)
- altre cause (es. emotrasfusioni, stravasi)

Which AEs do you have to report??

Obiettivo dei CTCAE:
catturare ogni evento collegato all'intervento che può risultare deleterio per il paziente

Ai clinici viene comunque raccomandato di segnalare solo gli AEs richiesti dal protocollo di studio e/o clinicamente rilevanti per il paziente

I clinici devono classificare l'AE e anche indagarne l'eziologia (AE causato dall'intervento o da altro?)

Which AEs do you have to report??

Attribution Standards

1. Unrelated:
   The Adverse Event is *clearly not related* to the investigational agent(s)
2. Unlikely:
   The Adverse Event is *doubtfully related* to the investigational agent(s)
3. Possible:
   The Adverse Event *may be related* to the investigational agent(s)
4. Probable:
   The Adverse Event is *likely related* to the investigational agent(s)
5. Definite:
   The Adverse Event is *clearly related* to the investigational agent(s)

Which AEs do you have to report??

Information sources for AEs

- Patient diary reports of AEs
- History, Physical Examination and laboratory results documented in patient's notes
- Clinical emergencies

Within CTCAE v5.0

AEs grading

Grade 1: Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated

Grade 2: Moderate; minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADL*

Grade 3: Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization(*) indicated; disabling; limiting self care ADL**

Grade 4: Life-threatening consequences; urgent intervention indicated

Grade 5: Death related to AE

*Instrumental ADL refer to preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc.
**Self care ADL refer to bathing, dressing and undressing, feeding self, using the toilet, taking medications, and not bedridden.
(*)Hospitalisation includes any overnight stay in a healthcare facility

Within CTCAE v5.0

AEs grading

; indica «or» nel grading degli AEs

- indica un grado non applicabile a un AE
(non tutti i gradi possono essere riferiti a un AE; il grado 5 – death - per molti AES non è applicabile)

una breve descrizione accompagna la definizione di ogni AE per chiarirne il significato (- indica che la descrizione non è possibile)

talvolta una nota di navigazione (navigational note) aiuta il clinico nello scegliere l'AE corretto da segnalare

Eye disorders					
CTCAE Term	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**	**Grade 5**
Keratitis	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; moderate decrease in visual acuity (best corrected visual acuity 20/40 and better or 3 lines or less decreased vision from known baseline)	Symptomatic with marked decrease in visual acuity (best corrected visual acuity worse than 20/40 or more than 3 lines of decreased vision from known baseline, up to 20/200); corneal ulcer; limiting self care ADL	Perforation; best corrected visual acuity of 20/200 or worse in the affected eye	-
Definition: A disorder characterized by inflammation to the cornea of the eye.					
Navigational Note: Also consider Eye disorders: Corneal ulcer					

Within CTCAE v5.0

AEs grading

Perché venga assegnato un grado a un AE non è necessario che il paziente sperimenti tutte le caratteristiche dell'AE

In presenza di manifestazioni di un AE riferibili a gradi diversi, l'AE verrà classificato col grado più elevato

Se un AE che si intende segnalare non è menzionato nei CTCAE v5.0 occorre individuare la categoria di appartenenza dell'AE e utilizzare la casella «Other, specify»; l'AE deve essere quindi descritto, utilizzando il più breve numero possibile di parole, e valutato secondo il grading:

- Grade 1 – Mild AE
- Grade 2 – Moderate AE
- Grade 3 – Severe AE
- Grade 4 – Life threatening or disabling AE
- Grade 5 – Death related to AE

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Common Terminology Criteria for Adverse Events (CTCAE)
Version 5.0
Published: November 27, 2017
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
National Cancer Institute

AEs grading

Il grading per ciascun AE è valido sia per gli adulti che per la popolazione pediatrica, a meno che non venga espressamente dichiarato

Vascular disorders					
CTCAE Term	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**	**Grade 5**
Hypertension	**Adult:** Systolic BP 120 - 139 mm Hg or diastolic BP 80 - 89 mm Hg; **Pediatric:** Systolic/diastolic BP >90th percentile but< 95th percentile; **Adolescent:** BP ≥120/80 even if < 95th percentile	**Adult:** Systolic BP 140 - 159 mm Hg or diastolic BP 90 - 99 mm Hg if previously WNL; change in baseline medical intervention indicated; recurrent or persistent (>=24 hrs); symptomatic increase by >20 mm Hg (diastolic) or to >140/90 mm Hg; monotherapy indicated initiated; **Pediatric and adolescent:** Recurrent or persistent (>=24 hrs) BP >ULN; monotherapy indicated; systolic and /or diastolic BP between the 95th percentile and 5 mmHg above the 99th percentile; **Adolescent:** Systolic between 130-139 or diastolic between 80-89 even if < 95th percentile	**Adult:** Systolic BP >=160 mm Hg or diastolic BP >=100 mm Hg; medical intervention indicated; more than one drug or more intensive therapy than previously used indicated; **Pediatric and adolescent:** Systolic and/or diastolic > 5 mmHg above the 99th percentile	**Adult and Pediatric:** Life-threatening consequences (e.g., malignant hypertension, transient or permanent neurologic deficit, hypertensive crisis); urgent intervention indicated	Death

Definition: A disorder characterized by a pathological increase in blood pressure.
Navigational Note: -

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Blood and lymphatic system disorders					
CTCAE Term	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**	**Grade 5**
Anemia	Hemoglobin (Hgb) <LLN - 10.0 g/dL; <LLN - 6.2 mmol/L; <LLN - 100 g/L	Hgb <10.0 - 8.0 g/dL; <6.2 - 4.9 mmol/L; <100 - 80g/L	Hgb <8.0 g/dL; <4.9 mmol/L; <80 g/L; transfusion indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a reduction in the amount of hemoglobin in 100 ml of blood. Signs and symptoms of anemia may include pallor of the skin and mucous membranes, shortness of breath, palpitations of the heart, soft systolic murmurs, lethargy, and fatigability. **Navigational Note:** -					
White blood cell decreased	<LLN - 3000/mm3; <LLN - 3.0 x 10e9 /L	<3000 - 2000/mm3; <3.0 - 2.0 x 10e9 /L	<2000 - 1000/mm3; <2.0 - 1.0 x 10e9 /L	<1000/mm3; <1.0 x 10e9 /L	-
Definition: A finding based on laboratory test results that indicate an decrease in number of white blood cells in a blood specimen. **Navigational Note:** -					
Neutrophil count decreased	<LLN - 1500/mm3; <LLN - 1.5 x 10e9 /L	<1500 - 1000/mm3; <1.5 - 1.0 x 10e9 /L	<1000 - 500/mm3; <1.0 - 0.5 x 10e9 /L	<500/mm3; <0.5 x 10e9 /L	-
Definition: A finding based on laboratory test results that indicate a decrease in number of neutrophils in a blood specimen. **Navigational Note:** -					
Platelet count decreased	<LLN - 75,000/mm3; <LLN - 75.0 x 10e9 /L	<75,000 - 50,000/mm3; <75.0 - 50.0 x 10e9 /L	<50,000 - 25,000/mm3; <50.0 - 25.0 x 10e9 /L	<25,000/mm3; <25.0 x 10e9 /L	-
Definition: A finding based on laboratory test results that indicate a decrease in number of platelets in a blood specimen. **Navigational Note:** -					

Within CTCAE v5.0
non ematological toxicities

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Investigations					
CTCAE Term	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**	**Grade 5**
Alanine aminotransferase increased	>ULN - 3.0 x ULN if baseline was normal; 1.5 - 3.0 x baseline if baseline was abnormal	>3.0 - 5.0 x ULN if baseline was normal; >3.0 - 5.0 x baseline if baseline was abnormal	>5.0 - 20.0 x ULN if baseline was normal; >5.0 - 20.0 x baseline if baseline was abnormal	>20.0 x ULN if baseline was normal; >20.0 x baseline if baseline was abnormal	-
Definition: A finding based on laboratory test results that indicate an increase in the level of alanine aminotransferase (ALT or SGPT) in the blood specimen. **Navigational Note:** Also consider Hepatobiliary disorders: Hepatic failure					
Aspartate aminotransferase increased	>ULN - 3.0 x ULN if baseline was normal; 1.5 - 3.0 x baseline if baseline was abnormal	>3.0 - 5.0 x ULN if baseline was normal; >3.0 - 5.0 x baseline if baseline was abnormal	>5.0 - 20.0 x ULN if baseline was normal; >5.0 - 20.0 x baseline if baseline was abnormal	>20.0 x ULN if baseline was normal; >20.0 x baseline if baseline was abnormal	-
Definition: A finding based on laboratory test results that indicate an increase in the level of aspartate aminotransferase (AST or SGOT) in a blood specimen. **Navigational Note:** Also consider Hepatobiliary disorders: Hepatic failure					
Hypocalcemia	Corrected serum calcium of <LLN - 8.0 mg/dL; <LLN - 2.0 mmol/L; Ionized calcium <LLN - 1.0 mmol/L	Corrected serum calcium of <8.0 - 7.0 mg/dL; <2.0 - 1.75 mmol/L; Ionized calcium <1.0 - 0.9 mmol/L; symptomatic	Corrected serum calcium of <7.0 - 6.0 mg/dL; <1.75 - 1.5 mmol/L; Ionized calcium <0.9 - 0.8 mmol/L; hospitalization indicated	Corrected serum calcium of <6.0 mg/dL; <1.5 mmol/L; Ionized calcium <0.8 mmol/L; life-threatening consequences	Death
Definition: A disorder characterized by laboratory test results that indicate a low concentration of calcium (corrected for albumin) in the blood. **Navigational Note:** -					

Nervous system disorders					
CTCAE Term	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**	**Grade 5**
Peripheral motor neuropathy	Asymptomatic; clinical or diagnostic observations only	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by damage or dysfunction of the peripheral motor nerves. **Navigational Note:** Also consider Nervous system disroders: Peripheral sensory neuropathy					
Peripheral sensory neuropathy	Asymptomatic	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	-
Definition: A disorder characterized by damage or dysfunction of the peripheral sensory nerves. **Navigational Note:** -					

Within CTCAE v5.0
non ematological toxicities

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Gastrointestinal disorders					
CTCAE Term	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**	**Grade 5**
Vomiting	Intervention not indicated	Outpatient IV hydration; medical intervention indicated	Tube feeding, TPN, or hospitalization indicated	Life-threatening consequences	Death
Definition: A disorder characterized by the reflexive act of ejecting the contents of the stomach through the mouth. **Navigational Note:** -					
Nausea	Loss of appetite without alteration in eating habits	Oral intake decreased without significant weight loss, dehydration or malnutrition	Inadequate oral caloric or fluid intake; tube feeding, TPN, or hospitalization indicated	-	-
Definition: A disorder characterized by a queasy sensation and/or the urge to vomit. **Navigational Note:** -					
Diarrhea	Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline	Increase of 4 - 6 stools per day over baseline; moderate increase in ostomy output compared to baseline; limiting instrumental ADL	Increase of >=7 stools per day over baseline; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by an increase in frequency and/or loose or watery bowel movements. **Navigational Note:** -					

Within CTCAE v5.0

«new» toxicities

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Endocrine disorders					
CTCAE Term	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**	**Grade 5**
Hypophysitis	Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by inflammation and cellular infiltration of the pituitary gland. **Navigational Note:** -					
Hypothyroidism	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; thyroid replacement indicated; limiting instrumental ADL	Severe symptoms; limiting self care ADL; hospitalization indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by a decrease in production of thyroid hormone by the thyroid gland. **Navigational Note:** -					
Adrenal insufficiency	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; medical intervention indicated	Severe symptoms; hospitalization indicated	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by the adrenal cortex not producing enough of the hormone cortisol and in some cases, the hormone aldosterone. It may be due to a disorder of the adrenal cortex as in Addison's disease or primary adrenal insufficiency. **Navigational Note:** -					

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«new» toxicities

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Skin and subcutaneous tissue disorders					
CTCAE Term	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**	**Grade 5**
Rash acneiform	Papules and/or pustules covering <10% BSA, which may or may not be associated with symptoms of pruritus or tenderness	Papules and/or pustules covering 10 - 30% BSA, which may or may not be associated with symptoms of pruritus or tenderness; associated with psychosocial impact; limiting instrumental ADL; papules and/or pustules covering > 30% BSA with or without mild symptoms	Papules and/or pustules covering >30% BSA with moderate or severe symptoms; limiting self-care ADL; associated with local superinfection with oral antibiotics indicated	Life-threatening consequences; papules and/or pustules covering any % BSA, which may or may not be associated with symptoms of pruritus or tenderness and are associated with extensive superinfection with IV antibiotics indicated	Death
Definition: A disorder characterized by an eruption of papules and pustules, typically appearing in face, scalp, upper chest and back. **Navigational Note:** -					
Rash maculo-papular	Macules/papules covering <10% BSA with or without symptoms (e.g., pruritus, burning, tightness)	Macules/papules covering 10 - 30% BSA with or without symptoms (e.g., pruritus, burning, tightness); limiting instrumental ADL; rash covering > 30% BSA with or without mild symptoms	Macules/papules covering >30% BSA with moderate or severe symptoms; limiting self care ADL	-	-
Definition: A disorder characterized by the presence of macules (flat) and papules (elevated). Also known as morbillform rash, it is one of the most common cutaneous adverse events, frequently affecting the upper trunk, spreading centripetally and associated with pruritis. **Navigational Note:** -					
Pruritus	Mild or localized; topical intervention indicated	Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL	Widespread and constant; limiting self care ADL or sleep; systemic corticosteroid or immunosuppressive therapy indicated	-	-
Definition: A disorder characterized by an intense itching sensation. **Navigational Note:** -					

And… patients??

P.R.O.-C.T.C.A.E.

P.R.O.- C.T.C.A.E.

patient reported outcomes

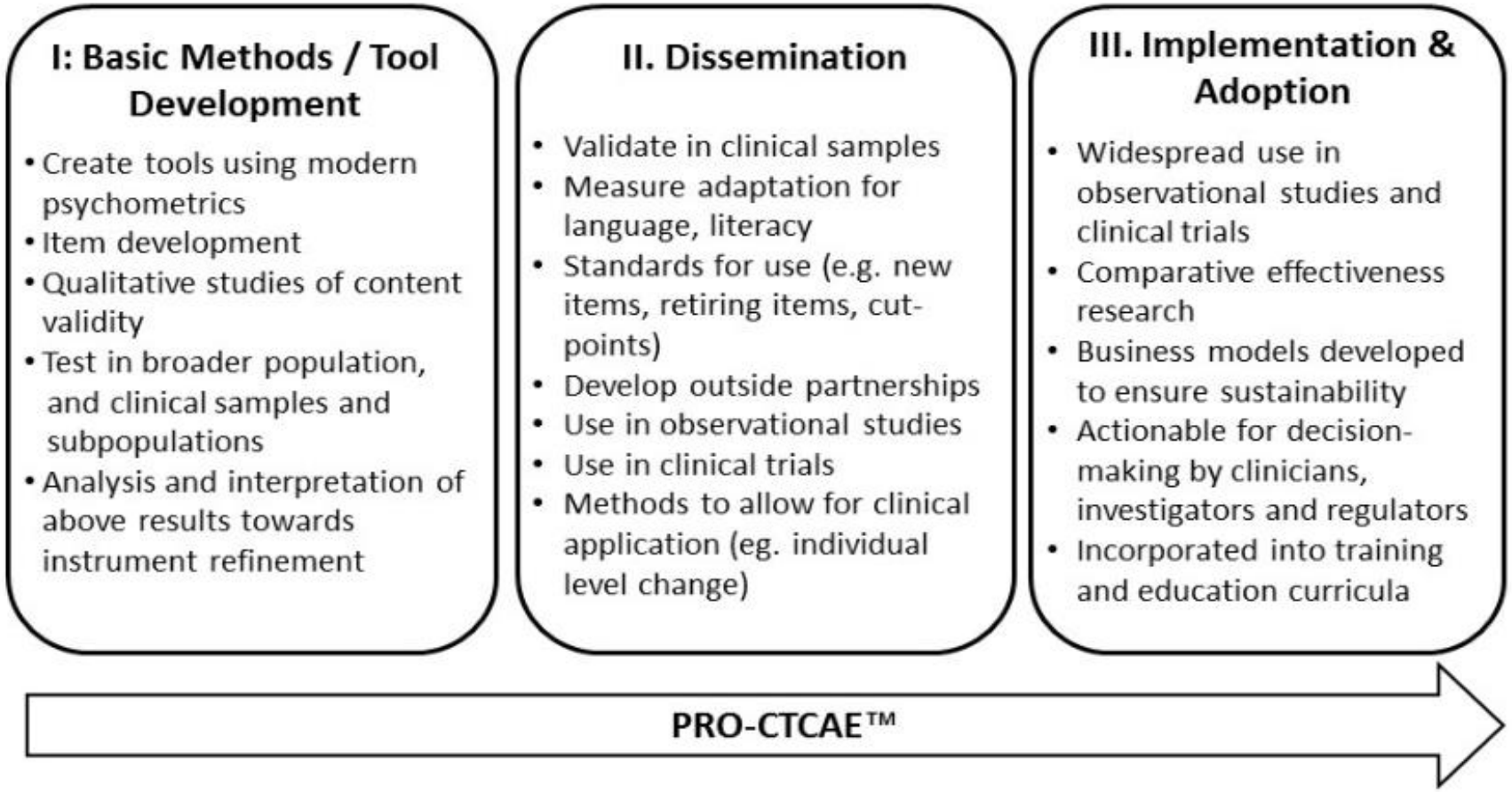
common terminology criteria adverse events

P.R.O.-C.T.C.A.E.

- P.R.O.-C.T.C.A.E. rappresentano un sistema di registrazione e di misurazione degli eventi avversi (AEs) così come vengono riportati dai pazienti
- P.R.O.-C.T.C.A.E. registrano e misurano frequenza, severità e impatto sulla qualità di vita (ADL, IADL) di 78 tossicità sintomatiche dei trattamenti oncologici medici e radianti nei trials clinici attraverso 124 items
- P.R.O.-C.T.C.A.E. non devono essere utilizzati in sostituzione dei C.T.C.A.E. ma in aggiunta ai C.T.C.A.E.
- Frequenza, severità e impatto sulla qualità di vita degli AEs riportati vengono valutati con uno score da 0 a 4 relativamente alla settimana precedente la somministrazione dei questionari di valutazione
- Gli AEs vengono riportati:
  - attraverso sistemi informatici di connessione Internet
  - attraverso sistemi vocali interattivi
  - attraverso questionari cartacei

Sviluppo dei P.R.O.-C.T.C.A.E.

2009 – 2015
by MSKCC & NCI



Source: Smith AW, Mitchell SA, Deaguiar C, Moy C, Riley WT, Wagster M, Werner E. Person-Centered Outcomes Measurement: NIH-Supported Measurement Systems to Evaluate Self-Assessed Health, Function, and Symptomatic Toxicity. *Translational Behavioral Medicine*, 1-5. doi:10.1007/s13142-015-0345-9.

P.R.O.-C.T.C.A.E.

PATIENT-REPORTED OUTCOMES VERSION OF THE COMMON TERMINOLOGY CRITERIA FOR ADVERSE EVENTS (PRO-CTCAE™) ITEM LIBRARY (Version 1.0)

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

Gastrointestinal	
Taste changes	S
Decreased appetite	SI
Nausea	FS
Vomiting	FS
Heartburn	FS
Gas	P
Bloating	FS
Hiccups	FS
Constipation	S
Diarrhea	F
Abdominal pain	FSI
Fecal incontinence	FI

Respiratory	
Shortness of breath	SI
Cough	SI
Wheezing	S

Cardio/Circulatory	
Swelling	FSI
Heart palpitations	FS

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

Neurological	
Numbness & tingling	SI
Dizziness	SI

Visual/Perceptual	
Blurred vision	SI
Flashing lights	P
Visual floaters	P
Watery eyes	SI
Ringing in ears	S

Attention/Memory	
Concentration	SI
Memory	SI

Pain	
General pain	FSI
Headache	FSI
Muscle pain	FSI
Joint pain	FSI

Sleep/Wake	
Insomnia	SI
Fatigue	SI

Mood	
Anxious	FSI
Discouraged	FSI
Sad	FSI

Gynecologic/Urinary	
Irregular periods/vaginal bleeding	P
Missed expected menstrual period	P
Vaginal discharge	P
Vaginal dryness	S
Painful urination	S
Urinary urgency	FI
Urinary frequency	PI
Change in usual urine color	P
Urinary incontinence	FI

Sexual	
Achieve and maintain erection	S
Ejaculation	F
Decreased libido	S
Delayed orgasm	P
Unable to have orgasm	P
Pain w/sexual intercourse	S

Miscellaneous	
Breast swelling and tenderness	S
Bruising	P
Chills	FS
Increased sweating	FS
Decreased sweating	P
Hot flashes	FS
Nosebleed	FS
Pain and swelling at injection site	P
Body odor	S

Attributes	
F: Frequency	I: Interference
S: Severity	P: Presence/Absence /Amount

P.R.O.-C.T.C.A.E.

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Validity and Reliability of the U.S. National Cancer Institute's Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE)

Dueck AC[1], Mendoza TR[2], Mitchell SA[3], Reeve BB[4], Castro KM[3], Rogak LJ[5], Atkinson TM[6], Bennett AV[4], Denicoff AM[7], O'Mara AM[8], Li Y[6], Clauser SB[3], Bryant DM[9], Bearden JD 3rd[10], Gillis TA[11], Harness JK[12], Siegel RD[13], Paul DB[14], Cleeland CS[2], Schrag D[15], Sloan JA[16], Abernethy AP[17], Bruner DW[18], Minasian LM[7], Basch E[19]; National Cancer Institute PRO-CTCAE Study Group.

N=940
pts initiating or undergoing CT, RT or both

- ✓ 122/124 (98%) PRO-CTCAE items were associated in the expected direction with the QLQ-C30 HRQOL summary score
- ✓ 107/124 items demonstrated meaningful correlation (Pearson r≥.1)
- ✓ 124/124 (100%) PRO-CTCAE items were associated in the expected direction with one or more QLQLC30 scales (114/124 demonstrating meaningful correlation; 111/124 coefficients reaching statistical significance)
- ✓ items that were likely to impact physical functioning had the strongest correlations with the QLQ-C30 physical functioning scale
- ✓ items likely to impact cognitive functioning had the strongest correlations with the QLQ-C30 cognitive functioning scale
- ✓ correlation between PRO-CTCAE and PS

P.R.O.-C.T.C.A.E.

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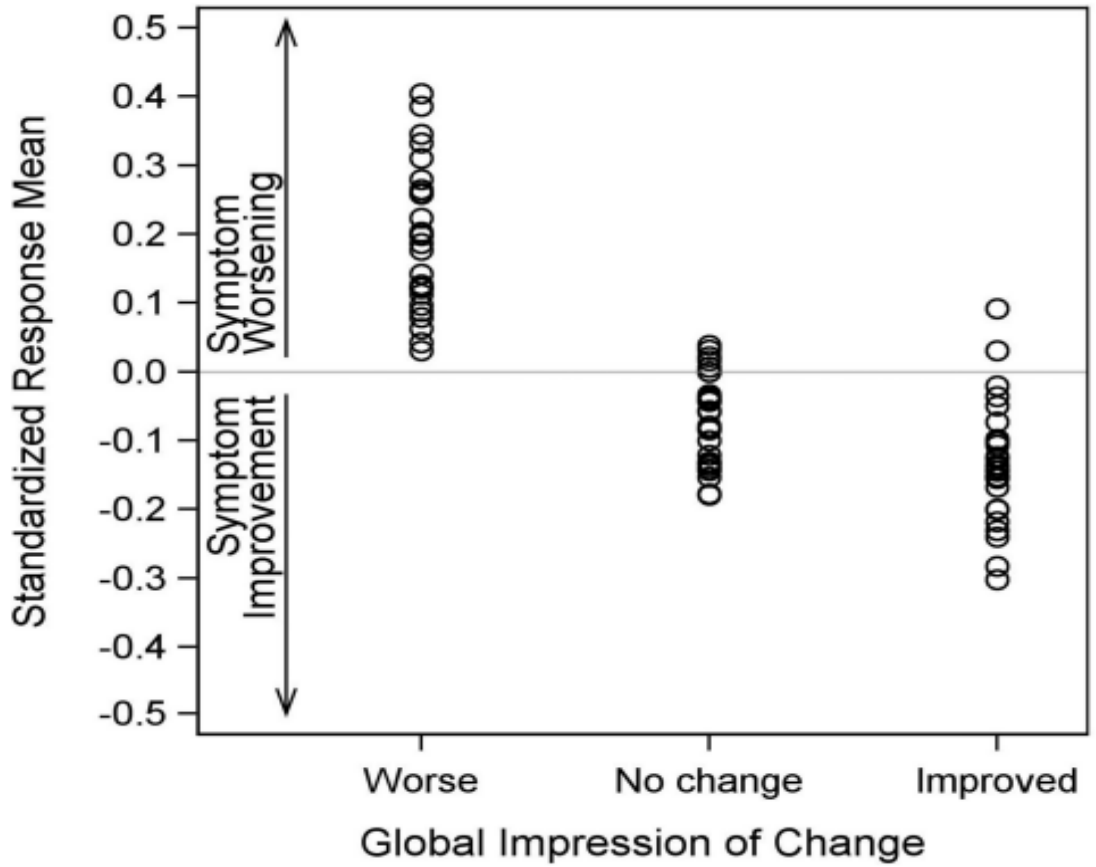
Validity and Reliability of the U.S. National Cancer Institute's Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE)

Dueck AC[1], Mendoza TR[2], Mitchell SA[3], Reeve BB[4], Castro KM[3], Rogak LJ[5], Atkinson TM[6], Bennett AV[4], Denicoff AM[7], O'Mara AM[8], Li Y[6], Clauser SB[3], Bryant DM[9], Bearden JD 3rd[10], Gillis TA[11], Harness JK[12], Siegel RD[13], Paul DB[14], Cleeland CS[2], Schrag D[15], Sloan JA[16], Abernethy AP[17], Bruner DW[18], Minasian LM[7], Basch E[19]; National Cancer Institute PRO-CTCAE Study Group.

N=940
pts initiating or undergoing CT, RT or both



C.T.C.A.E.: future perspectives

- ✓ Aggiornamento dei C.T.C.A.E.
- ✓ Perfezionamento e ampliamento dei P.R.O.-C.T.C.A.E.
- ✓ Sintesi tra P.R.O.-C.T.C.A.E. e C.T.C.A.E.
- ✓ Traduzione e diffusione dei P.R.O.-C.T.C.A.E.

CTCAEs: present and future

Grazie per l'attenzione