Fifth Annual

COA-CCT Workshop

FDA U.S. FOOD & DRUG ADMINISTRATION
ONCOLOGY CENTER OF EXCELLENCE

ASCO®

SESSION 1 Identifying best methods for item selection to assess tolerability

MODERATOR
Vishal Bhatnagar, MD

Mary (Dicey) Jackson Scroggins

Maxime Sasseville, PhD

Kathryn Mileham, MD

Peter Trask, PhD

Ethan Basch, MD

Arlene Chung, MD

#OCEOutcomes20

Modernizing the Definition of Tolerability

- Tolerability "the degree to which overt adverse effects can be tolerated by the subject" (ICH E9)

- "…the degree to which symptomatic and non-symptomatic adverse events associated with the product's administration affect the ability or desire of the patient to adhere to the dose or intensity of therapy. **A complete understanding of tolerability should include direct measurement from the patient on how they are feeling and functioning while on treatment."** (FOCR White Paper)

https://www.focr.org/tolerability

Core Outcomes and Tolerability

- Overall Survival
- Progression Free Survival
- Overall Response Rate
- Serum Biomarkers

- CTCAE Safety Data
- Dose Modifications

- Hospitalizations
- ED Visits
- Morbid Procedures
- Supportive Care Use

Disease Symptoms

Symptomatic Adverse Events

Overall Side Effect Impact

Physical Function:

Ability to Carry Out Activities that Require Physical Effort

Role Function:

Ability to Work and Perform Leisure Activities

Clinician Reported and Biomarker Data

Patient-Reported and other COA Data

Slide Courtesy of Paul Kluetz, FDA OCE

PRO-CTCAE Instrument & Form Builder

PRO-CTCAE™ Measurement System

Use of PRO-CTCAE is subject to NCI's Terms of Use. Preview the PRO-CTCAE Item Library using the quick guide, download the full instrument using one of the links below, or use our Form Builder to produce a customized 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.

- English (PDF, 560 KB)
- Afrikaans (PDF, 230 KB)
- Chinese (Simplified) (PDF, 350 KB)
- Chinese (Traditional) (PDF, 562 KB)
- Czech (PDF, 257 KB)
- Danish (PDF, 335 KB)
- Dutch (for Belgium and the Netherlands) (PDF, 240 KB)
- Finnish (PDF, 237 KB)

Form Builder

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

There is a need for unbiased, careful item selection of patient-reported symptoms and side effects!

Project Patient Voice

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Project Patient Voice is an online platform for patients and caregivers along with their healthcare providers to look at patient-reported symptom data collected from cancer clinical trials.

- What is the purpose of Project Patient Voice?
- Why is this needed?
- What is the source of this patient-reported symptom information?
- What is the difference between patient-reported symptom information and the safety information in the drug label?
- What is the Pilot Phase of Project Patient Voice?
- How to use Project Patient Voice
- Limitations of Project Patient Voice
- Can my experience with symptoms be added to this information?
- Where can I send comments or questions about Project Patient Voice?

Trial Name	Disease Type	Drug	Study Design	Blinding Status	Comparator Arm	Patient Questionnaire Used to Collect Symptom Data	FDA Label
AURA3	Advanced non-small cell lung cancer with EGFR mutation	TAGRISSO	Randomized	Open label	Platinum-based doublet chemotherapy	PRO-CTCAE	Here

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Ethan Basch, MD

- What strategies can be employed to identify relevant patient-reported symptomatic adverse events in cancer clinical trials?
- What are the advantages of item libraries in selecting patient-reported symptoms and side effects?
- What challenges are encountered in parsimonious item selection? Frequent pitfalls?

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Peter Trask, PhD

- What is the industry perspective on how patient-reported symptoms and side effects are selected?
- How has the broadened definition of tolerability changed assessment of patient-reported symptoms from your perspective?
- How will Project Patient Voice change item selection in future cancer clinical trials?

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Mary (Dicey) Jackson Scroggins

- How much is “too much” when patients are asked about symptoms and side effects?
- Are patients adequately informed on how collected symptom and side effect data will be used?

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Kathryn Mileham, MD

- During a clinical trial, what are practical challenges to rigorous collection of patient-reported symptoms?
- How will Project Patient Voice change your assessment of tolerability of therapy?

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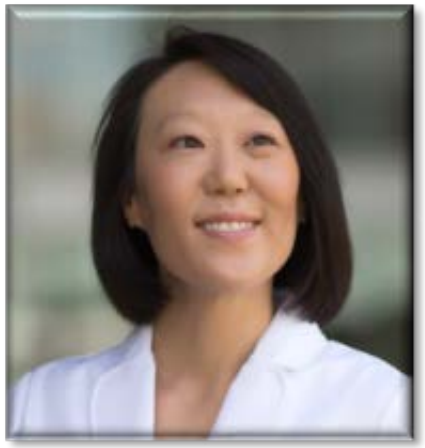

Arlene Chung, MD

- How would a “free-text” item in PRO-CTCAE lead to improved assessment of tolerability?

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Maxime Sasseville, PhD

- What is your regulatory agency's perspective on patient-reported adverse event data?
- How would patient-reported symptoms and side effects impact your assessment of tolerability?

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Ethan Basch, MD

What strategies can be used to ensure thorough collection of patient-reported symptoms and side effects while not over-burdening patients?

Mary (Dicey) Jackson Scroggins

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Maxime Sasseville, PhD

In terms of tolerability and rigorous assessment of patient-reported symptoms and side effects:

What are industry challenges in the context of differing needs from various regulatory bodies?

Peter Trask, PhD

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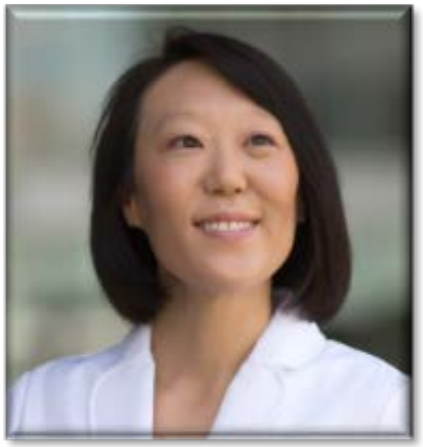

Arlene Chung, MD

Although patient-reported adverse events can inform tolerability in the setting of cancer clinical trials, how can PRO inform tolerability at the point-of-care?

Kathryn Mileham, MD

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