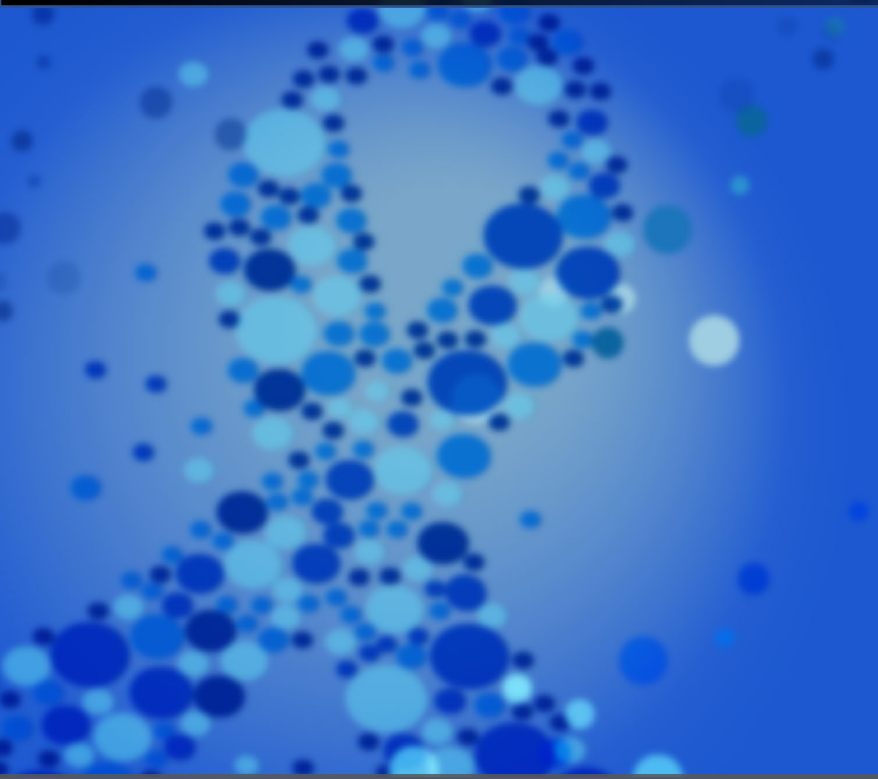
Clinical Outcome Assessment in Cancer Clinical Trials 2024

Modernizing Tolerability Assessment in Cancer Clinical Trials

9th Annual
Virtual Public Workshop

June 25, 2024
11:00 AM – 2:30 PM ET



WELCOME

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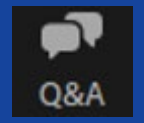
Webcast Guide

- To ask a question or make a comment, click the 

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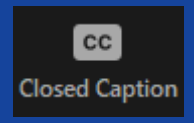
- To show captioning, click the 

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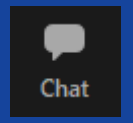
- Links to reference materials may be shared periodically through the 

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Clinical Outcome Assessment in Cancer Clinical Trials 2024

Agenda

June 25, 2024 (11:00 AM – 2:30 PM ET)	
11:00 AM – 11:10 AM	Welcome and Opening Remarks
11:10 AM – 12:25 PM	Session 1: Revisiting Core Item Sets in Oncology Trials – Where are we and where do we want to go?
12:25 PM – 12:40 PM	Break
12:40 PM – 1:55PM	Session 2: Revisiting Core Item Sets in Oncology Trials – How do we get there?
1:55 PM – 2:25 PM	Panel Discussion Q & A
2:25 PM – 2:30 PM	Workshop Conclusion and Adjournment

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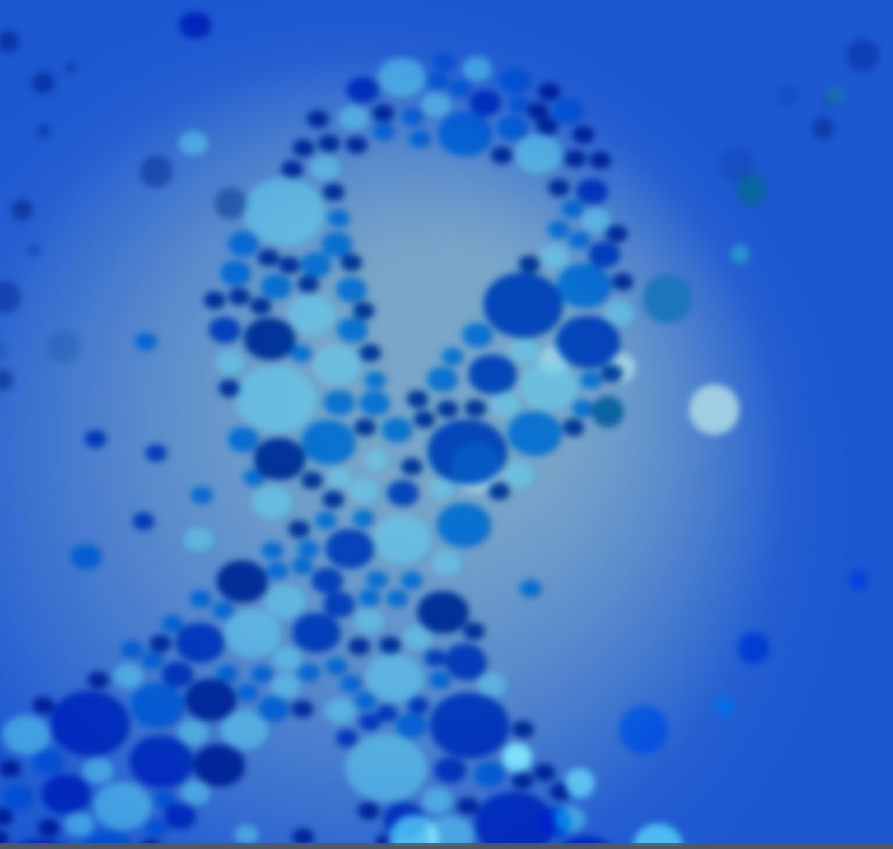

Opening Remarks

11:00 AM – 11:10 AM ET

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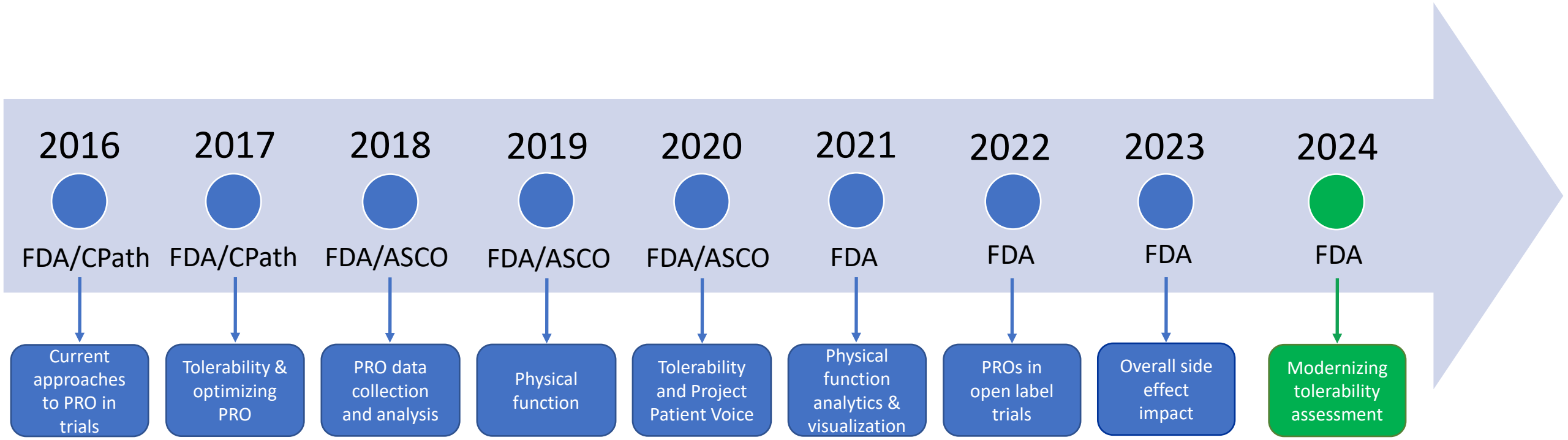
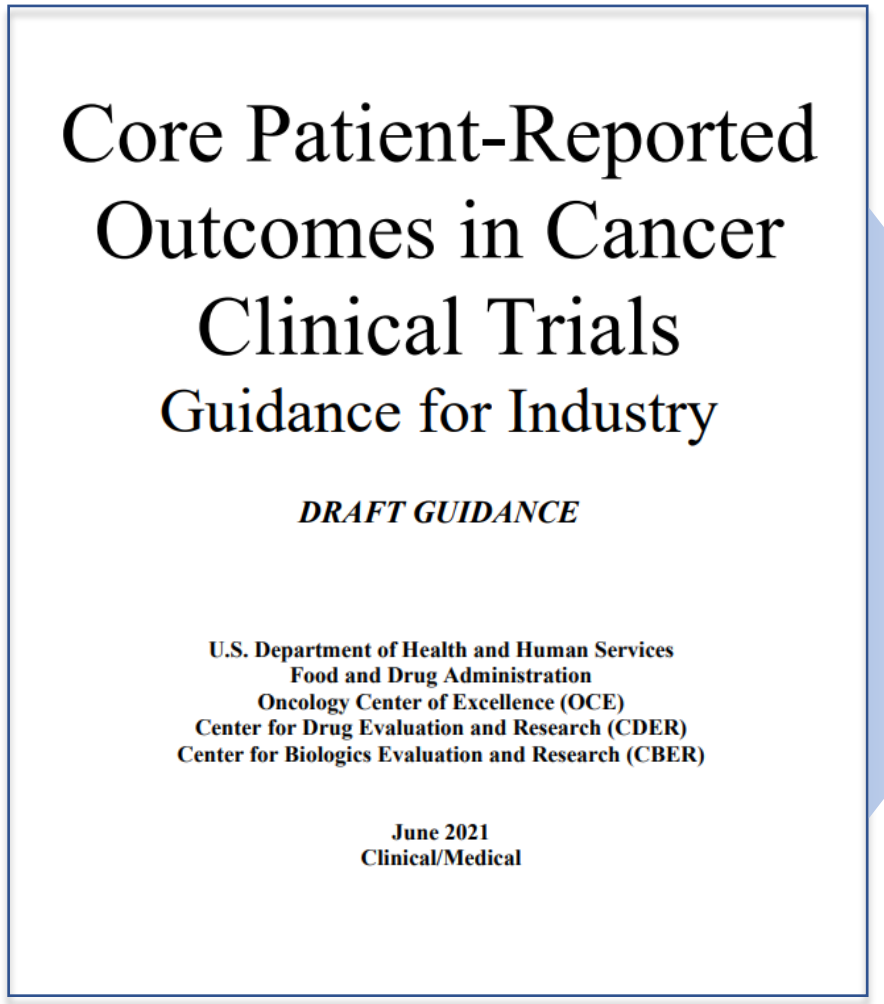
Workshop Over the Years



FDA OCE PFDD Program ("Past and Upcoming Events"): https://www.fda.gov/about-fda/oncology-center-excellence/patient-focused-drug-development

Clinical Outcome Assessment in Cancer Clinical Trials 2024

Context for Today's Workshop



Generate PRO data that is:
Relevant, Usable, Interpretable

- Disease-related symptoms
- **Symptomatic adverse events**
- Physical function
- Role function
- Overall side effect impact

Clinical Outcome Assessment in Cancer Clinical Trials 2024

Context for Today's Workshop

- Definition of "tolerability" has evolved
- Novel treatments for cancer - mechanisms of action are diverse
- Item libraries are robust and translated into many languages
- Patients are more familiar with PRO assessment
- FDA OCE uses well-collected PRO to evaluate new therapies
- Methods to communicate this data have been established

Vision for the Future

- **Modernize Tolerability assessment:**
  - Select symptoms from item libraries based on MOA
  - High frequency assessment when symptoms likely to occur
- **Optimize use of patient-generated data:**
  - Integrate PRO assessment into early phase trials
  - Encourage use of Project Patient Voice
  - Continue research into novel technology (e.g., wearables)

Core Outcomes

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 Generated Data

Core Outcomes

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

Physical Function:

Role

Symptomatic Adverse Events

Overall Side Effect Impact

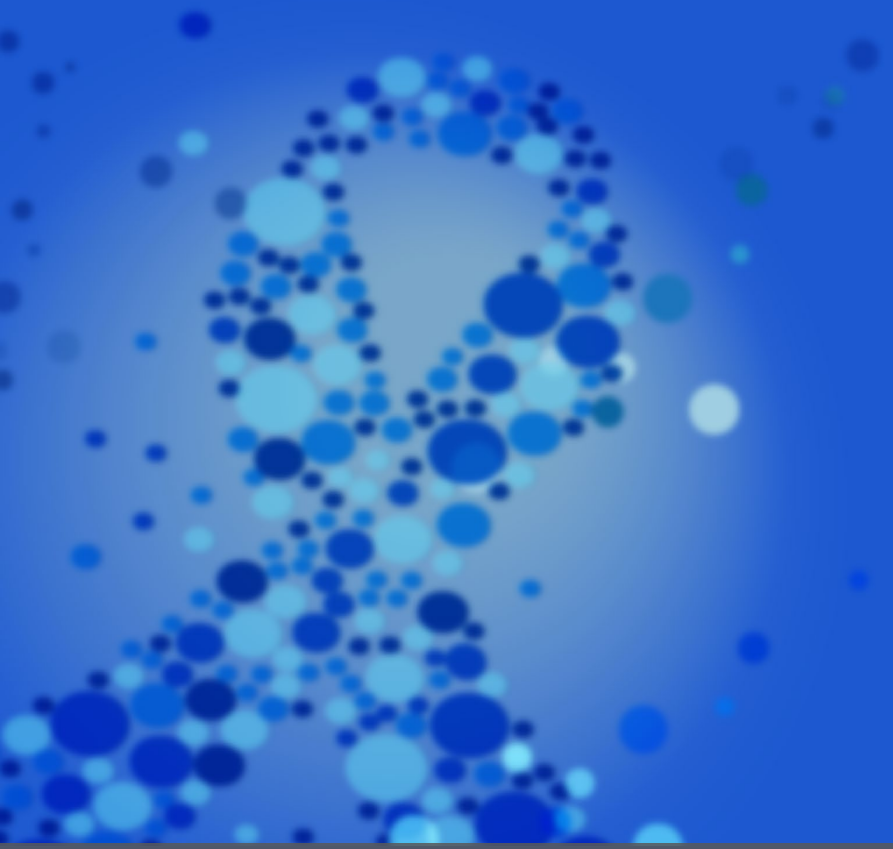
Effort

How to select the most relevant patient-reported symptomatic AEs?

Clinician Reported and Biomarker Data

Patient Generated Data

Clinical Outcome Assessment in Cancer Clinical Trials 2024



Session 1:

Revisiting Core Item Sets in Oncology Trials – Where are we and where do we want to go?

11:10 AM – 12:25 PM ET

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Session 1: Revisiting Core Item Sets in Oncology Trials –
Where are we and where do we want to go?

Moderator

Terri Armstrong

NCI

Panelists

Yelak Biru

Patient Advocate

Erica Horodniceanu

FDA

Tito Mendoza

NCI

Bryce Reeve

Duke

Gita Thanarajasingam

Mayo Clinic

Lynne Wagner

UNC

Session 1 Introduction

Terri Armstrong, PhD

Senior Investigator

Associate Director, Patient-Centered Outcomes

CCR, NCI, NIH

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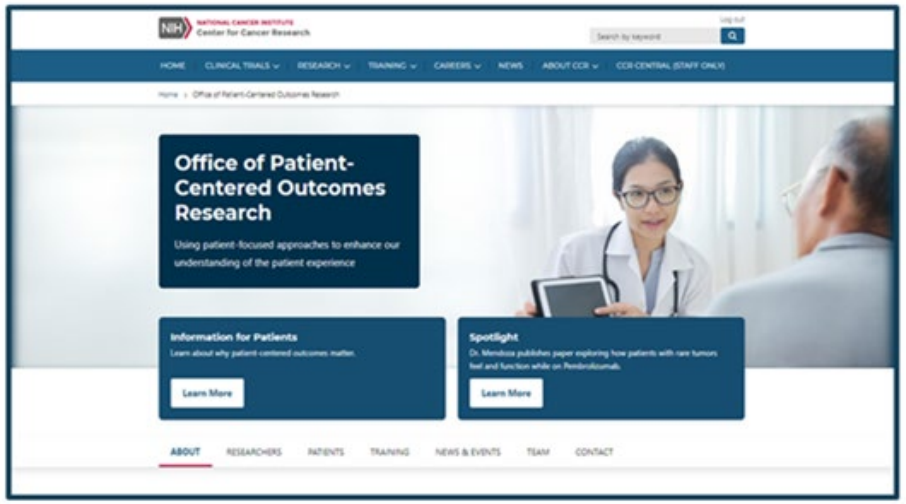
Center for Cancer Research

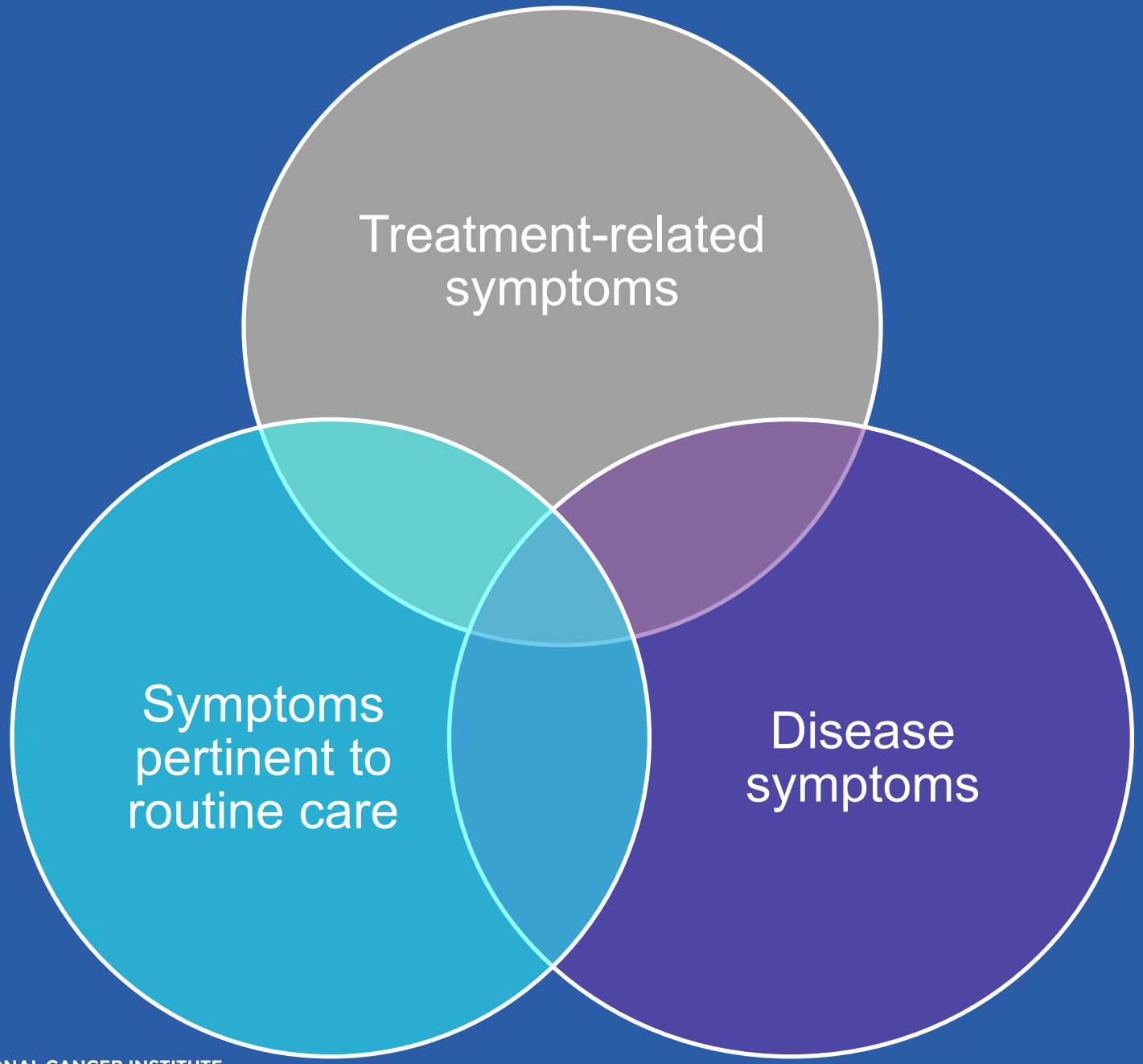
6.25.24

Office of Patient-Centered Outcomes Research (OPCORe)
Center for Cancer Research, NCI, NIH

- The **goal** of the Office of Patient-Centered Outcomes Research (OPCORe) is to integrate the voice of the patient, and in particular, the use of patient-centered outcomes into early-phase clinical trials.
- **Mission:** To advance understanding of the clinical benefit and tolerability of cancer therapies by integrating patient-centered approaches into CCR clinical trials and by fostering inclusive education and collaboration with stakeholders.
- Hosted an Early Phase Trial Working Group Meeting in 2023, as a precursor to today's workshop



Intersection and differences in symptom occurrence



All important and dependent on target goal of measurement

Why are we here?

- Patient-reported symptom and functional assessment are critical to **inform tolerability**
- Today's workshop focus is on **oncology clinical trials**
- PRO assessment is relevant to early and late phase trials
- Existing symptom lists may not capture side effects from wide ranging and novel classes of anti-cancer drugs

Session 1 Objectives

1. Provide contextual background for patient-reported symptom assessment – an overview of existing “core” symptom sets.

2. Review how current clinical trials require novel methods to select symptoms, including use of PRO item libraries.

3. Emphasize how early phase trials, pediatric trials, and use of novel agents require parsimonious symptom assessment.

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Session 1: Revisiting Core Item Sets in Oncology Trials –
Where are we and where do we want to go?

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Recommended Patient-Reported Core Set of Symptoms to Measure in Adult Cancer Treatment Trials

	Literature reviews						Data sources									
	2001-2011 Reilly et al.†				1990-2007 Kim et al.‡		CDUS/ AdEERS§ 2004-2008		1992-2006 EORTC‖		2006-2008 SOAPP¶		2011 PRO-CTCAE#		2011 FACT**	
	Prevalence		Severity		Prevalence		Prevalence		Prevalence		Prevalence		Prevalence		Importance	
Symptom	%	rank	mean	rank	%	rank	%	rank	%	rank	%	rank	%	rank	%	rank
Fatigue	60	1	4.6	1	62	1	6.2	2	32	2	34	1	58	1	48	1
Insomnia	49	2	4.2	2	41	4	0.6	17	25	4	27	2	35	3	16	5
Pain	48	3	3.4	5	40	5	7.7	1	25	3	19	5	42	2	11	6
Anorexia	45	5	3.9	3	32	9	2.2	5	18	6	17	9	34	4	6	7
Dyspnea	44	6	2.8	8	26	12	1.8	7	15	7			19	15	4	8
Cognitive problems	44	7	3.1	7	25	13			14	10	17	9	21	13	3	11
Anxiety	41	9			54	2			32	1	19	5	31	6	26	3
Nausea	40	10	2.5	10	21	15	3.3	3	9	12			22	12	21	4
Depression			2.7	9	39	6			19	5	17	9	26	10	27	2
Neuropathy					29	10	1.9	6			19	5	19	16		
Constipation					27	11	1.4	11	14	9			30	7	4	9
Diarrhea					16	17	3.1	4	6	13			25	11	4	10
Dry mouth	48	4	3.5	4	42	3					19	5	32	5		
Irritability					37	7			15	8						
Drowsiness					36	8					22	3				
Coughing					26	12	1.0	13								
Taste alteration					23	14	0.6	19					28	9		
Itching					23	14										
Dizziness					20	16	0.5	20								
Vomiting					13	18	1.7	8		14			8	19		
Alopecia							1.5	9			20	4	30	7		
Headache													20	14		

*Citation: Reeve BB, Mitchell SA, Dueck AC, Basch E, Cella D, Reilly CM, Minasian LM, Denicoff AM, O'Mara AM, Fisch MJ, Chauhan C, Aaronson NK, Coens C, Watkins-Bruner D. Recommended patient-reported core set of symptoms to measure in adult cancer treatment trials. JNCI: Journal of the National Cancer Institute. 2014 Jul 8;106(7):dju129.

FDA OCE PFDD Research Initiative

Most common symptomatic adverse reactions of selected solid tumors and hematologic cancers based on US drug labels (2015 – 2021)

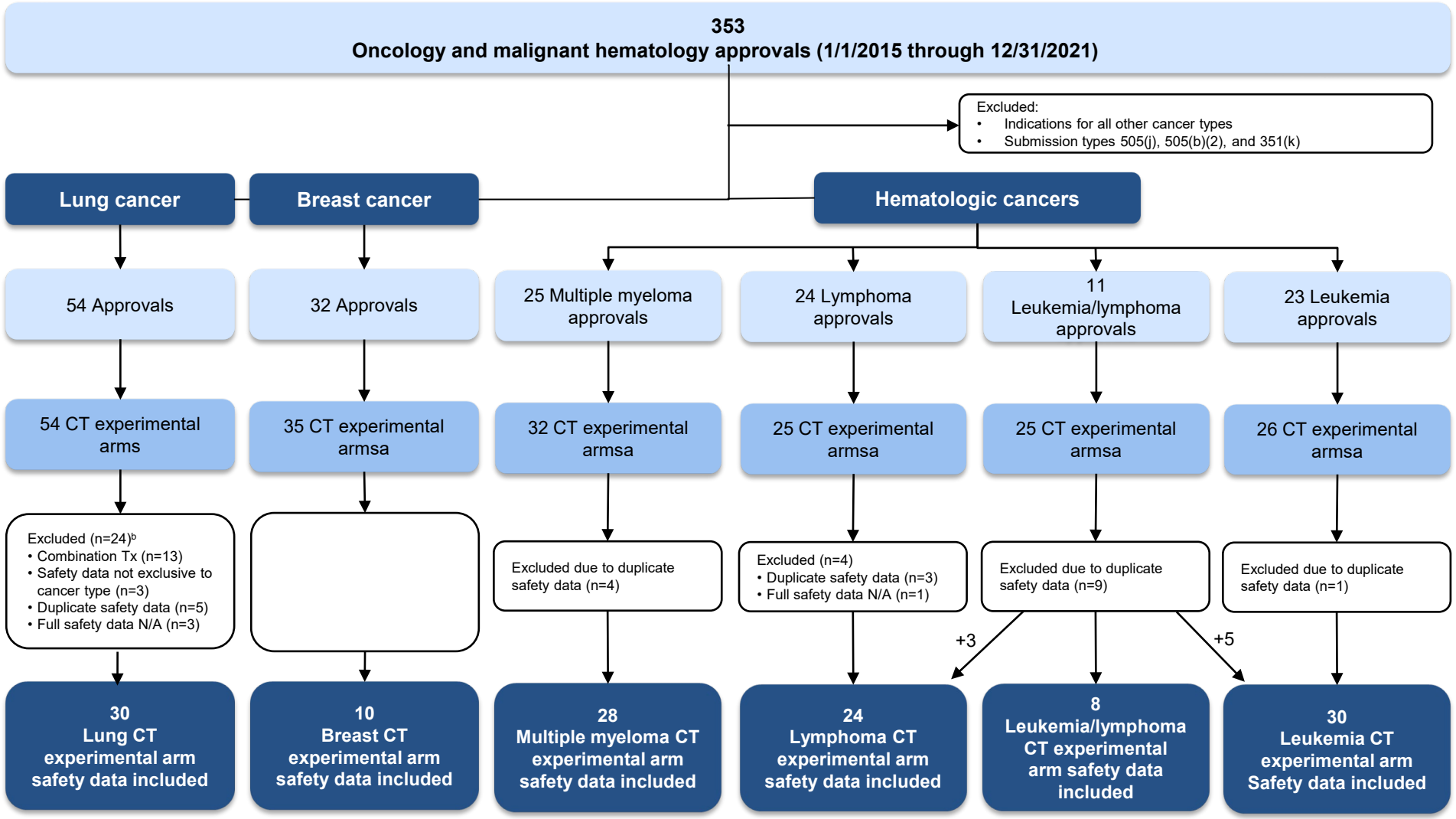
June 25, 2024

Objective and Methods

To determine the most common symptomatic adverse reactions for recently approved oncology drug products for selected solid tumors and hematologic cancers

- Data source:
  - Cancer drug approvals from 2015 through 2021
  - Drug USPI* - Section 6 for safety data; Section 14 for clinical trial information
- Data extraction:
  - Drug and trial information: drug MOA, confirmed indication for associated approval, trial name, NCT number, trial design, monotherapy/combination for treatment arm
  - Safety data for experimental arm(s): Sample size for trial safety data, and all-grade symptomatic adverse reactions reported in ≥ 20% of patients within experimental arm of the trial
- Data Analysis:
  - Number (%) of clinical trial experimental arms reporting each symptomatic adverse reaction in ≥ 20% of patients

*Accessed via Drugs@FDA: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm



(a) Some approvals were supported by more than one clinical trial and/or trials with more than one experimental arm with safety data.
(b) Initial reason for exclusion represented; some experimental arms had more than one reason for exclusion.
Abbreviations: CT, clinical trial; N/A, not available; Tx, treatment.

Results

Most common symptomatic adverse reactions (reported in ≥20% of patients) in ≥50% of clinical trial experimental arms from FDA-approved drugs from 2015 to 2021, by n (%) of trial arms[a]

Symptomatic AR	All (N=130)	Lung (n=30)	Breast (n=10)	Leuk (n=30)	Lym (n=24)	Leuk/Lym (n=8)	MM (n=28)
Fatigue	92 (71%)	22 (73%)	8 (80%)	17 (57%)	19 (79%)	5 (63%)	21 (75%)
Diarrhea	91 (70%)	17 (57%)	9 (90%)	17 (57%)	18 (75%)	7 (88%)	23 (82%)
Nausea	73 (56%)	13 (43%)	8 (80%)	20 (67%)	12 (50%)	6 (75%)	14 (50%)
Cough	49 (38%)	13 (43%)	2 (20%)	4 (13%)	11 (46%)	5 (63%)	14 (50%)
Rash	45 (35%)	13 (43%)	2 (20%)	10 (33%)	9 (38%)	7 (88%)	4 (14%)
Vomiting	34 (26%)	7 (43%)	8 (80%)	8 (27%)	5 (21%)	0 (0%)	6 (21%)
Musculoskeletal pain	33 (25%)	9 (30%)	0 (0%)	7 (23%)	10 (42%)	7 (88%)	0 (0%)
Decreased appetite	30 (23%)	10 (33%)	5 (50%)	4 (13%)	4 (17%)	1 (13%)	6 (21%)
Alopecia	7 (5%)	1 (3%)	5 (50%)	0 (0%)	1 (4%)	0 (0%)	0 (0%)

(a) Bold/Grey shading displays AEs in ≥50% of arms.
Abbreviations: AR, adverse reaction; Leu, leukemia; Lym, lymphoma; MM, multiple myeloma.

Considerations and Conclusions

Across all selected cancer types, fatigue, diarrhea, and nausea are among the most common symptomatic adverse reactions within the CT experimental arms included

- However, analysis does not differentiate between higher percent of patients with an adverse reaction within a trial, duration, or severity
  - Example: Vision disorders in clinical trial of drug to treat NSCLC

- Consider a narrow core set of symptomatic adverse events to serve as a minimum list, supplemented with additional expected symptomatic adverse events depending on context, and free text item to be measured as patient-reported outcomes in cancer trials

Acknowledgements

- Paul Kluetz
- Vishal Bhatnagar
- Tejaswi Datla (ORISE Fellow)
- Meena Murugappan

Prevalence of Symptomatic Adverse Events and Other Toxicities Associated with Newer Cancer Therapies: *A Scoping Review*

Tito Mendoza, PhD
Amanda L. King, PhD, APNP-BC
Tamara Vasilj, MD

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Center for Cancer Research

August 28th, 2023

Overview

1. Scope of Review & Methods
2. Immunotherapy Symptomatic AEs
3. Targeted Therapy Symptomatic AEs
4. T-Cell AEs
5. Summary

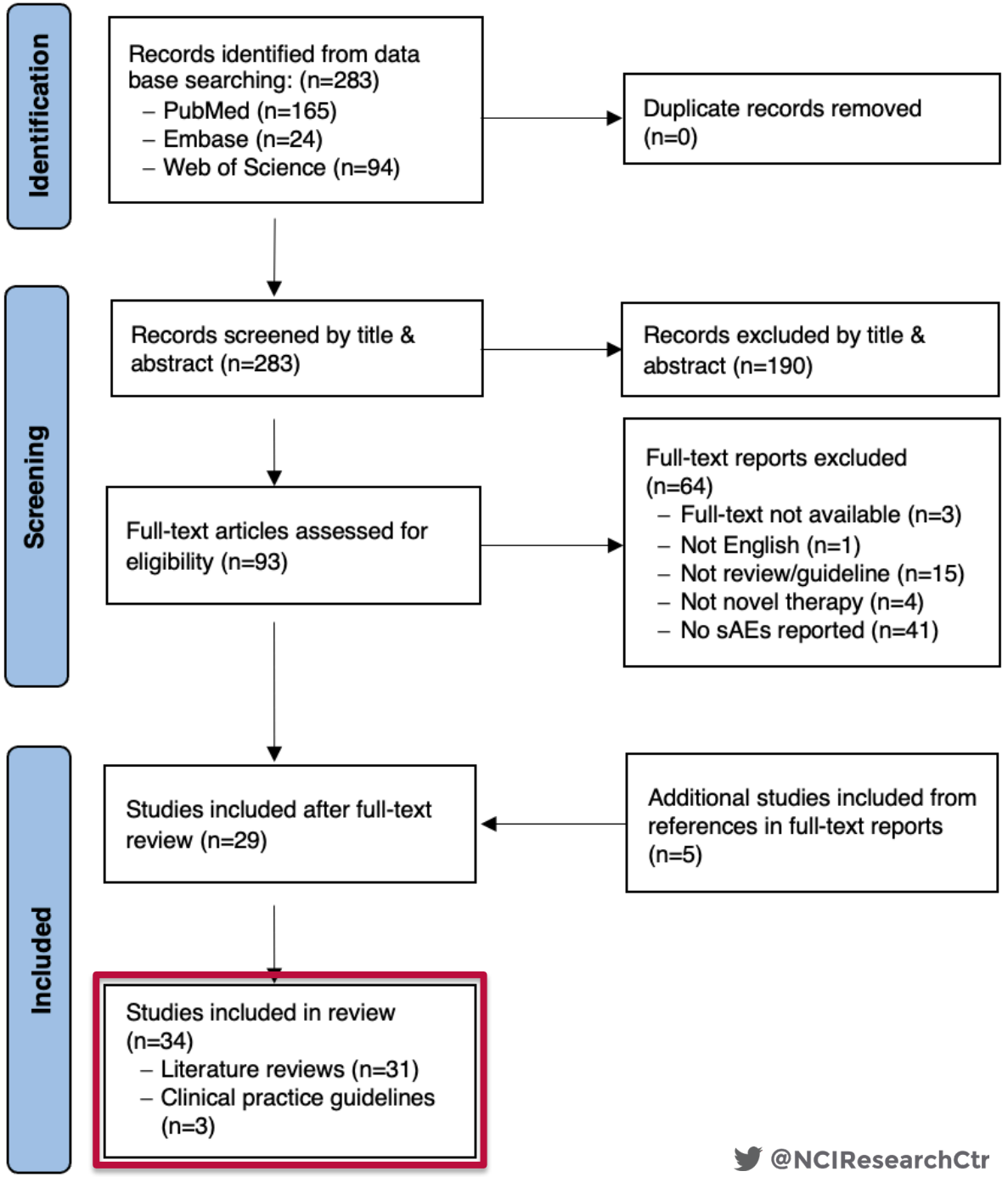
Scope of Review & Search Strategy

Research question: *For adult patients with cancer on novel therapies, what are the most important (common & severe) symptomatic adverse events that are reported?*

- Scoping review of published literature related to sAEs associated with newer cancer therapies
- **Search strategy:** guided by research librarian
  - Limit to English, 2014 to present, reviews of clinical trials/clinical practice guidelines
  - *Search terms:* [immunotherapy/AE OR molecular targeted therapy/AE OR precision medicine/AE] AND neoplasms

PRISMA Consort Diagram

- Novel therapies in final sample:
  - **IMMUNOTHERAPY**
    - Checkpoint inhibitors: *16 papers*
    - T-cell therapies: *11 papers*
    - Immunomodulators: *4 papers*
    - Vaccines: *1 paper*
  - **TARGETED THERAPY**
    - Small molecule therapies: *10 papers*
    - Monoclonal antibodies: *7 papers*



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

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

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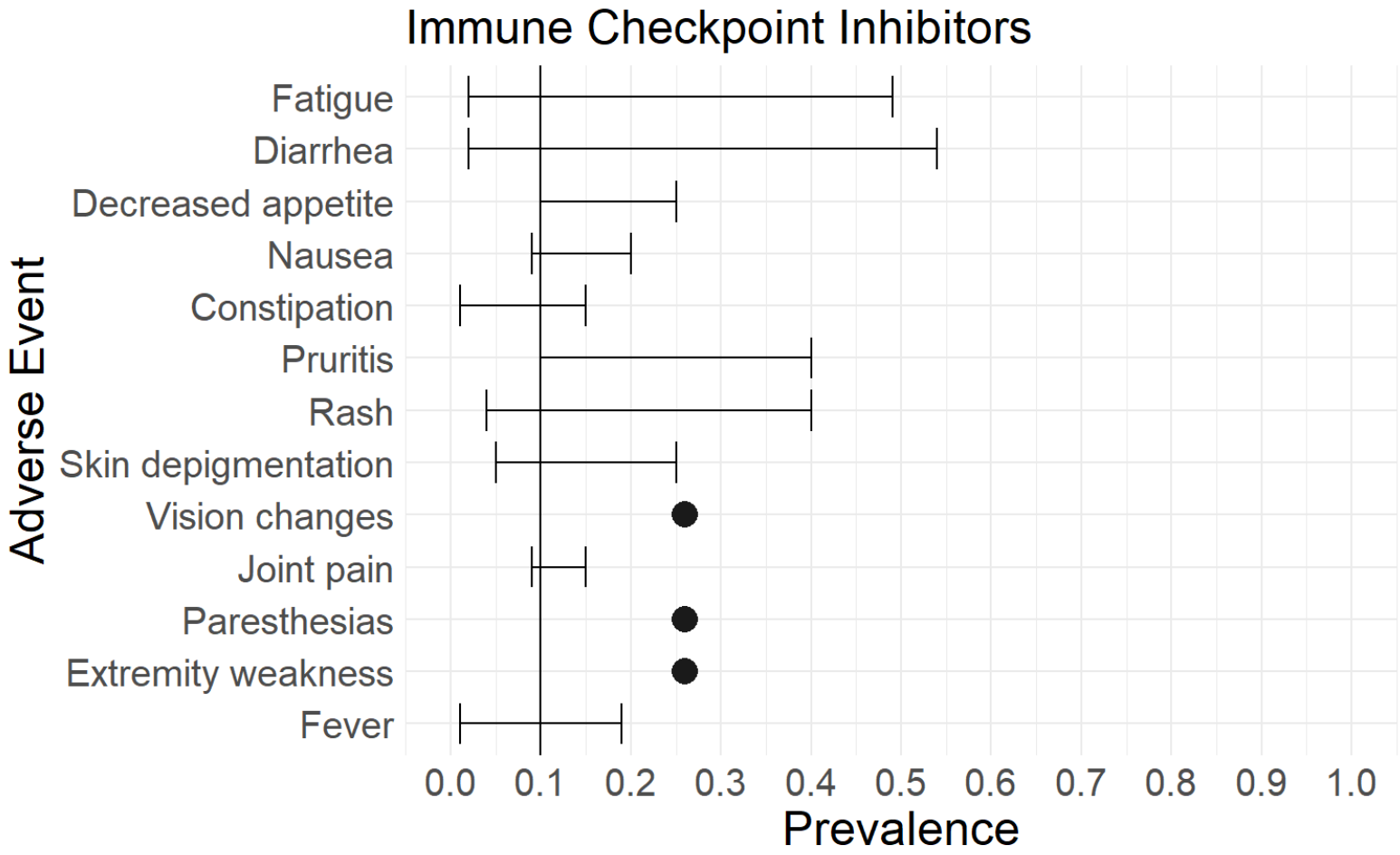
Most prevalent symptomatic AEs (all grades)



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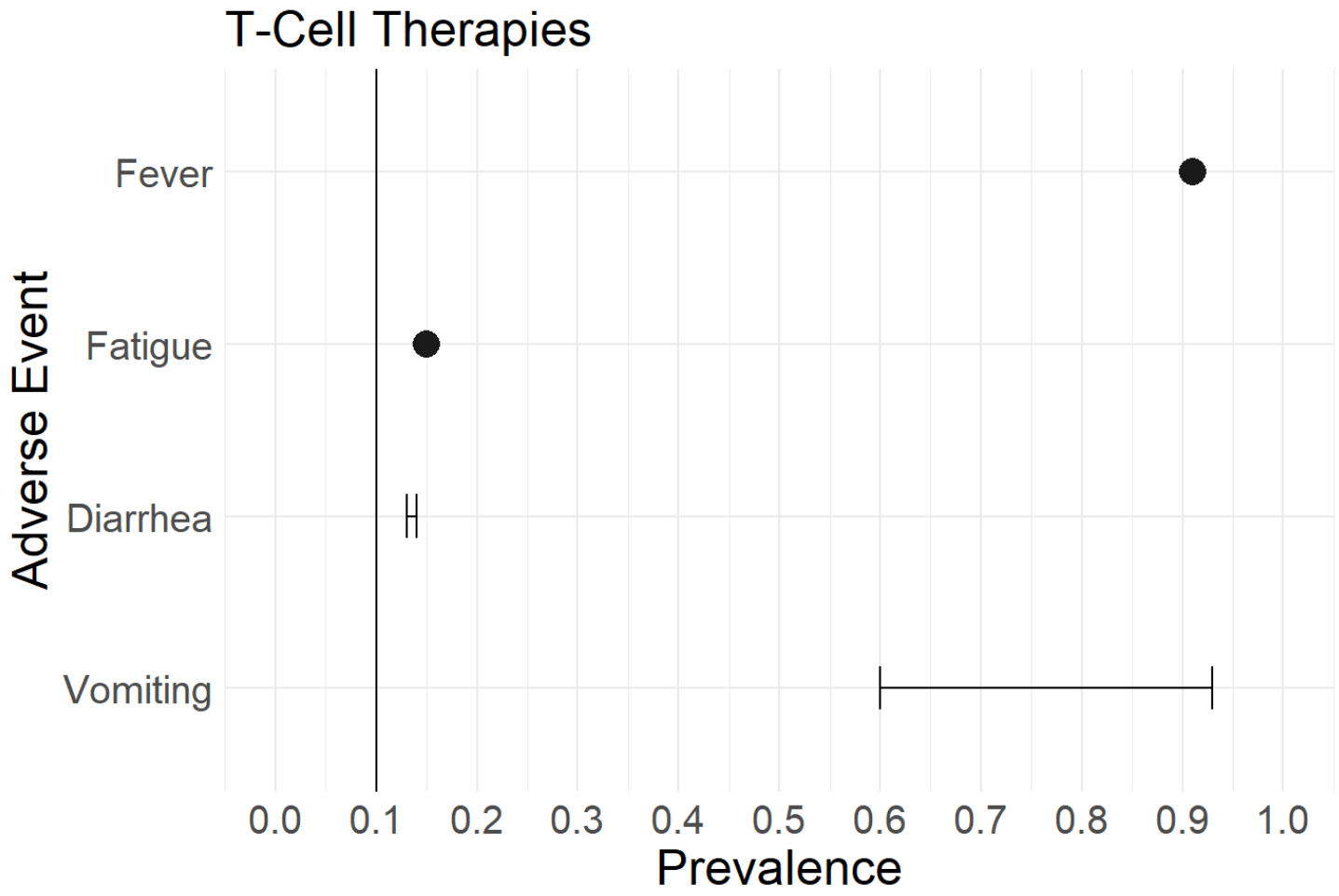
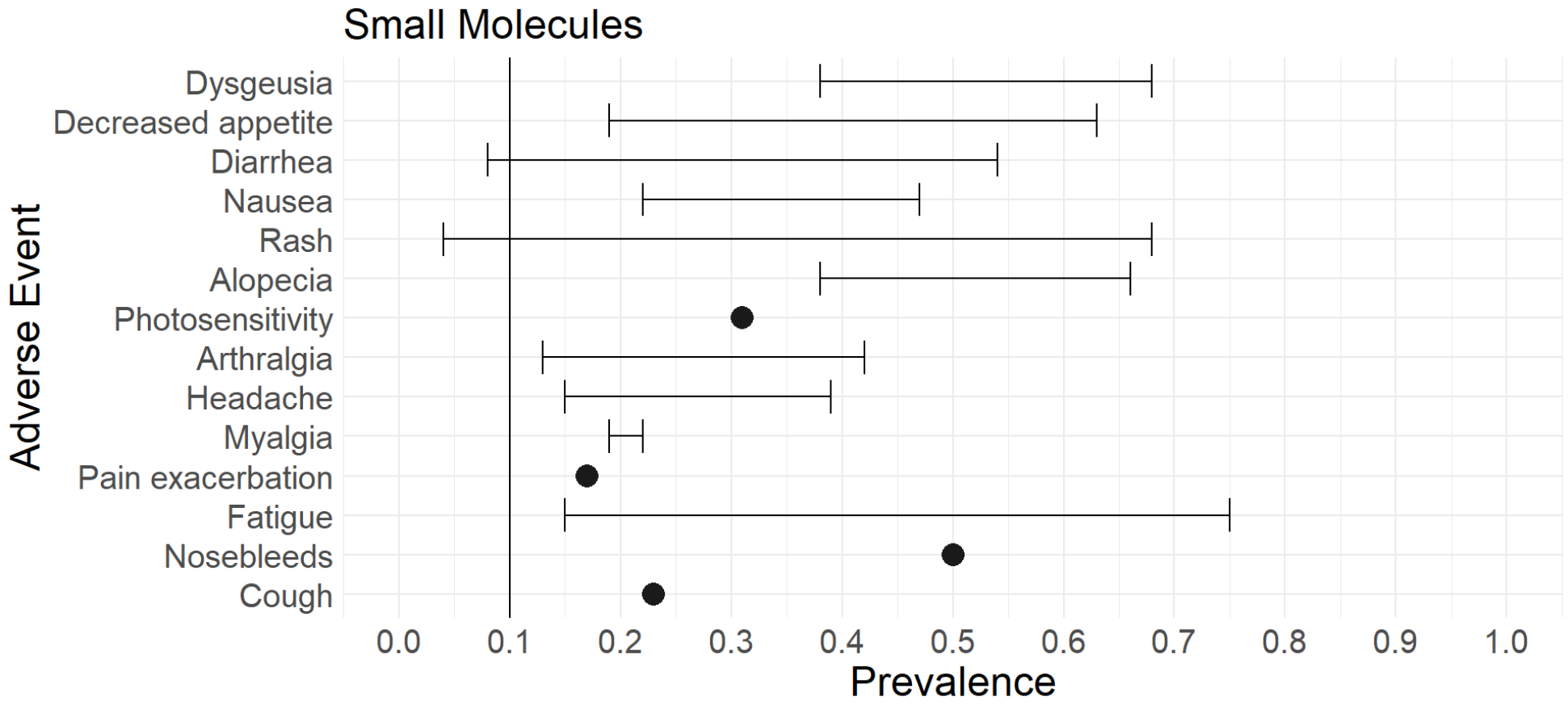


Most prevalent symptomatic AEs (all grades)



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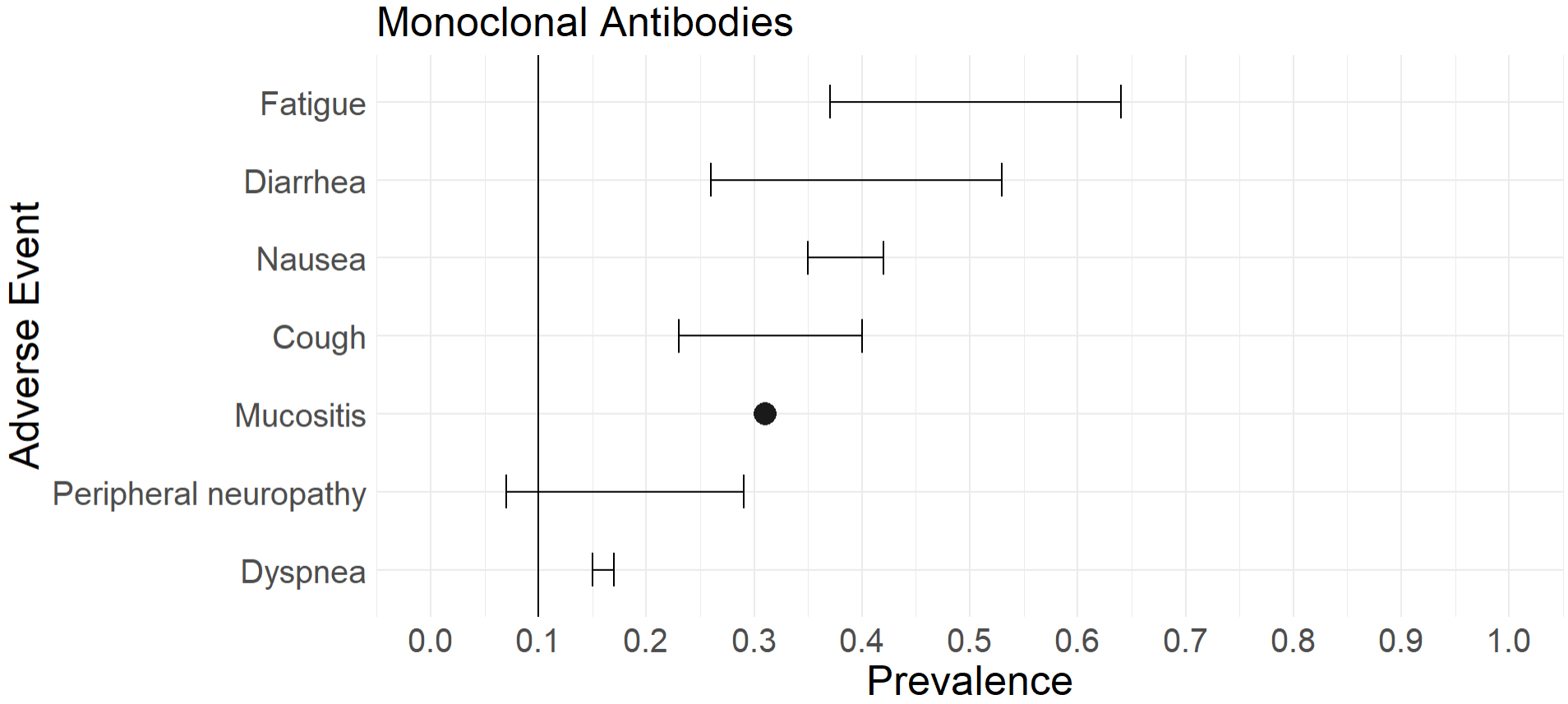


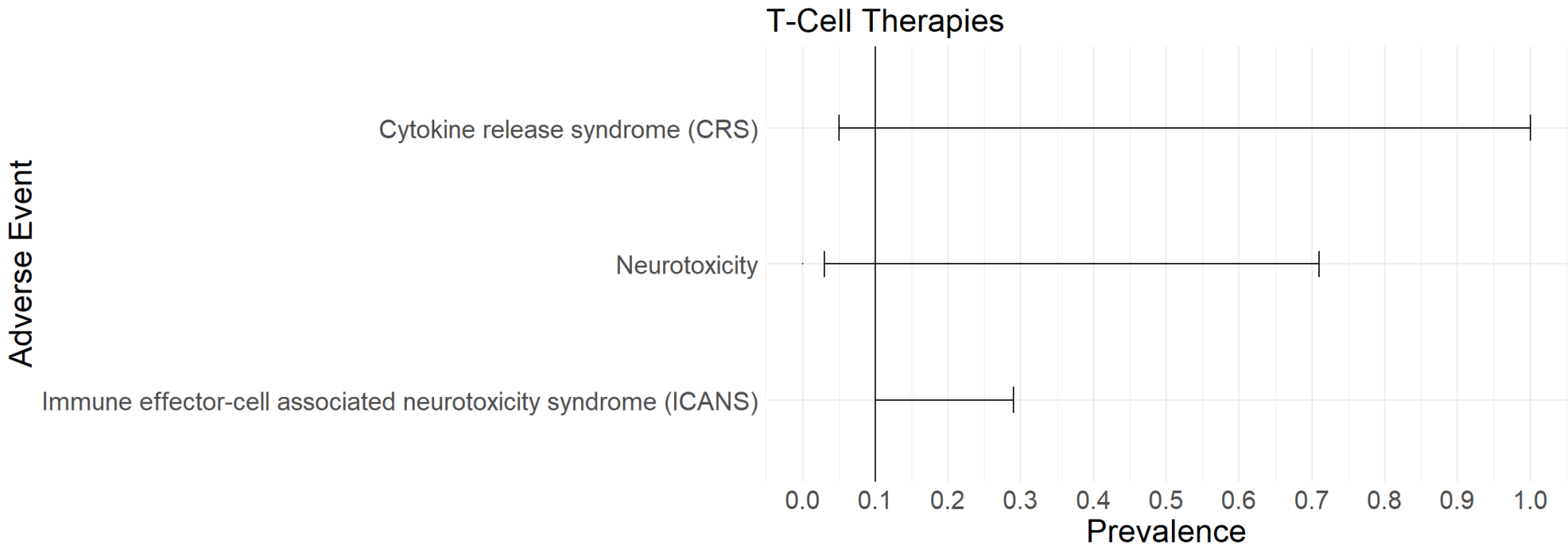
Immunotherapy Symptomatic AEs	Range (%)
Rash	17-70
Diarrhea	19-54
Nausea	19-54
Vomiting	19-54
Constipation	19-54
Abdominal pain, cramping	19-54
Dyspnea	53
Joint pain	15-40
Muscle pain	2-40
Cough	35
Chest pain	7
Headache	3-6
Ocular toxicity Dry, itchy or watery eyes, pain & changes in vision, blurry or double vision, floaters, flashing lights, changes in color vision, eye redness	0-1

Most Prevalent Symptomatic AEs (all grades) based on ASCO (2019), ESMO (2022) and Toxicity Management Working Group (2017) guidelines

ICI targets:
CTLA-4 inhibitors
PD-1/PD-L1 inhibitors

ICI drugs:
ipilimumab
pembrolizumab
nivolumab
atezolizumab
durvalumab
avelumab

Most prevalent AEs (all grades)



Reeve Core	Immunotherapy	Targeted Agents	Guidelines (Immunotherapy)
Fatigue	Fatigue	Fatigue	Fatigue (no prevalence data but listed as a common symptom for numerous AE syndromes)
Pain	*Joint pain		*Joint pain
Anorexia (appetite loss)		*Decreased appetite	
Dyspnea	Dyspnea		Dyspnea
Cognitive problems			
Anxiety (includes worry)			
Nausea		*Nausea and vomiting	Nausea and vomiting
Depression (includes sadness)			
Sensory neuropathy			
Constipation			Constipation
Diarrhea	Diarrhea	Diarrhea	Diarrhea
	Rash	Rash	Rash
		Alopecia	
	Cough		Cough
	Vision changes	Vision changes	

Summary

- Fatigue, diarrhea and rash are reported as top common symptoms in patients being treated with either immunotherapy or targeted therapy
- Vomiting, fever, diarrhea, fatigue, itchiness and rash are the top 6 symptomatic AEs seen in at least 40% of patients being treated with immunotherapy (immune checkpoint inhibitors, T-cell therapies, immunomodulators, vaccines)
- Fatigue, diarrhea, taste changes, decreased appetite, rash and alopecia are the top 6 symptomatic AEs seen in at least 50% of patients being treated with targeted therapy (small molecules and monoclonal antibodies)
- There is lack of symptomatic AEs data in patients being treated with T-cell
- For patients being treated with T-cell, many AEs are reported as syndromes (e.g. ICANS, CRS)

Acknowledgments

- Terri S. Armstrong, PhD, ANP-BC
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- OPCORe/NOB trainees:
  - Sefanit Berhanu, BS
  - Ciara Locke, BS
  - Morgan Johnson, BS
  - Bennett McIver, BS

Clinical Outcome Assessment in Cancer Clinical Trials 2024

Session 1: Objectives

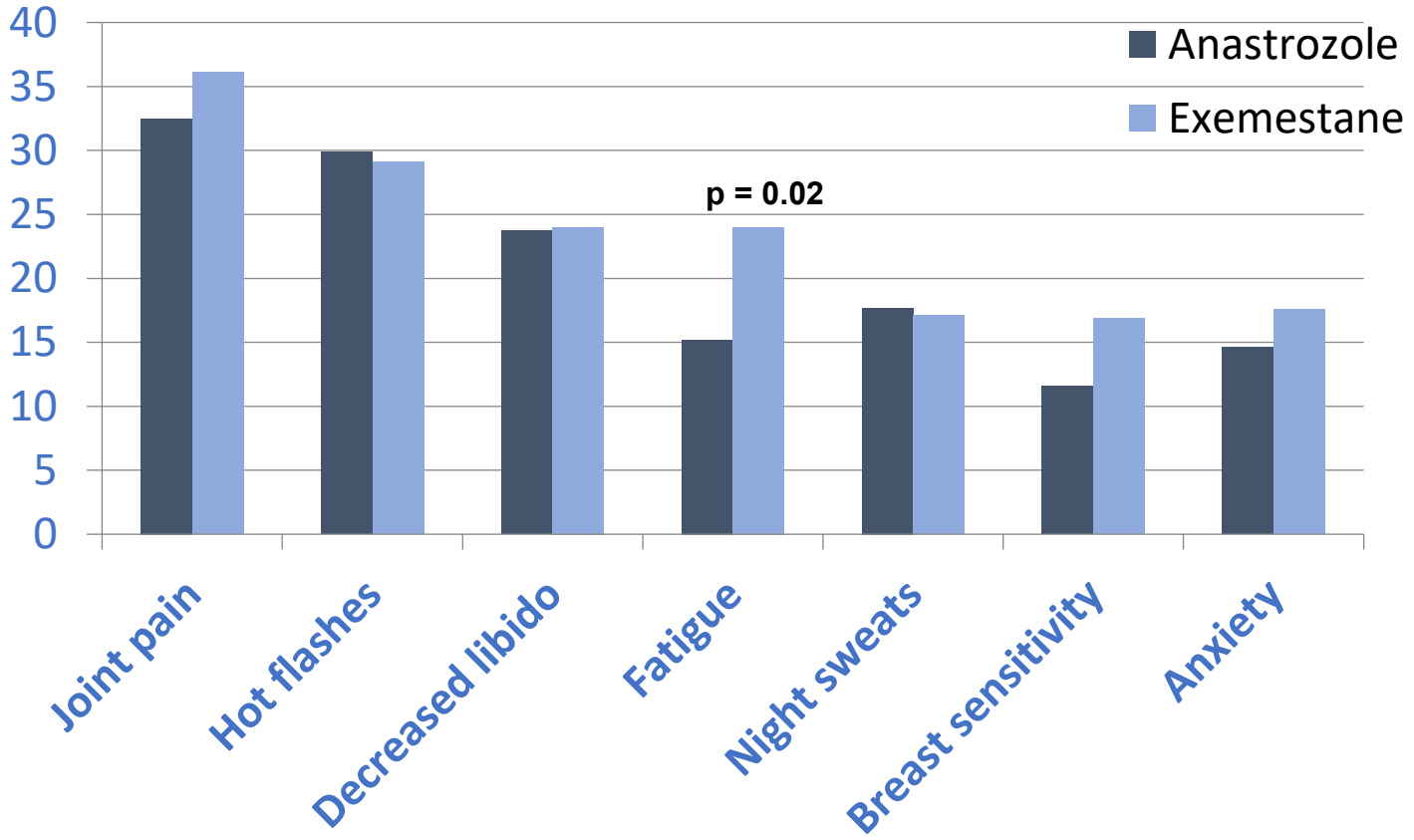
- Yelak Biru
- Erica Horodniceanu
- Tito Mendoza
- Bryce Reeve
- Gita Thanarajasingam
- Lynne Wagner

1. Provide contextual background for patient-reported symptom assessment – an overview of existing “core” symptom sets.
2. Review how current clinical trials require novel methods to select symptoms, including use of PRO item libraries.
3. Emphasize how early phase trials, pediatric trials, and use of novel agents require parsimonious symptom assessment

E1Z03: Post-menopausal ER+ Breast Cancer

Most Common Moderate or Severe Symptoms at Month 3

% Pts rating sx "Quite a bit" or "Very much'



N = 686

12/04 – 12/05

Individual FACT-ES items

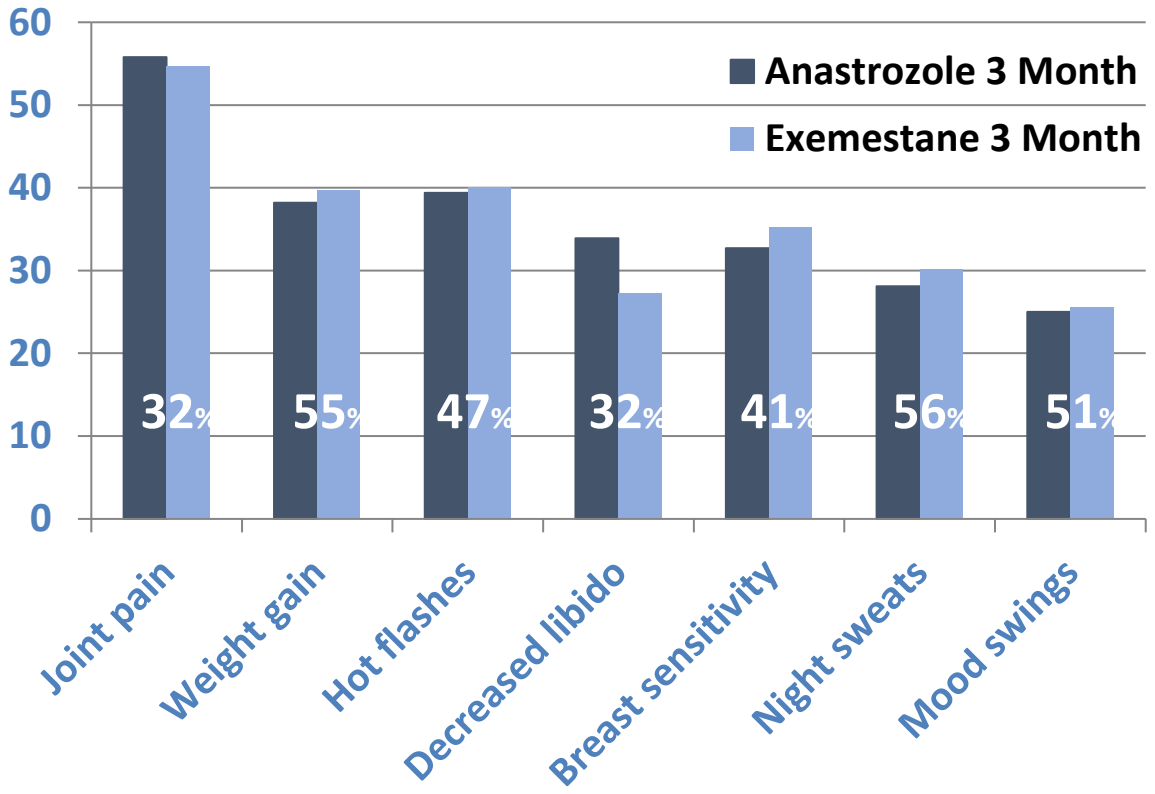
Arm A = Arm E, p = n.s. except fatigue

Wagner et al. Breast CA Res Treat 2018

E1Z03: Post-menopausal ER+ Breast Cancer

Most Common New Symptoms at Month 3

% of patients with NEW symptom



% of sample reporting no symptom at baseline

Individual FACT-ES items
Arm A = Arm E, p = n.s.

Wagner et al. Breast CA Res Treat 2018

UNC LINEBERGER COMPREHENSIVE CANCER CENTER

Learning Clinical Trials System

- Nimble trial design to facilitate measurement of emerging and unexpected toxicities
- Open-ended PRO-CTCAE to inform PRO items

Session 1: Revisiting Core Item Sets in Oncology Trials –
Where are we and where do we want to go?

Moderator

Terri Armstrong

NCI

Panelists

Yelak Biru

Patient Advocate

Erica Horodniceanu

FDA

Tito Mendoza

NCI

Bryce Reeve

Duke

Gita Thanarajasingam

Mayo Clinic

Lynne Wagner

UNC

Core Outcomes

Overall Survival
Progression Free Survival
Overall Response Rate
Serum Biomarkers

CTCAE Safety Data
Dose Modifications

Hospitalizations
ED Visits
Morbid Procedures
Supportive Care Use

Clinician Reported and Biomarker Data

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

Patient Generated Data

Core Outcomes

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Progression Free Survival
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ED Visits
Morbid Procedures
Supportive Care Use

Disease Symptoms

Physical Function:

Role

Symptomatic Adverse Events

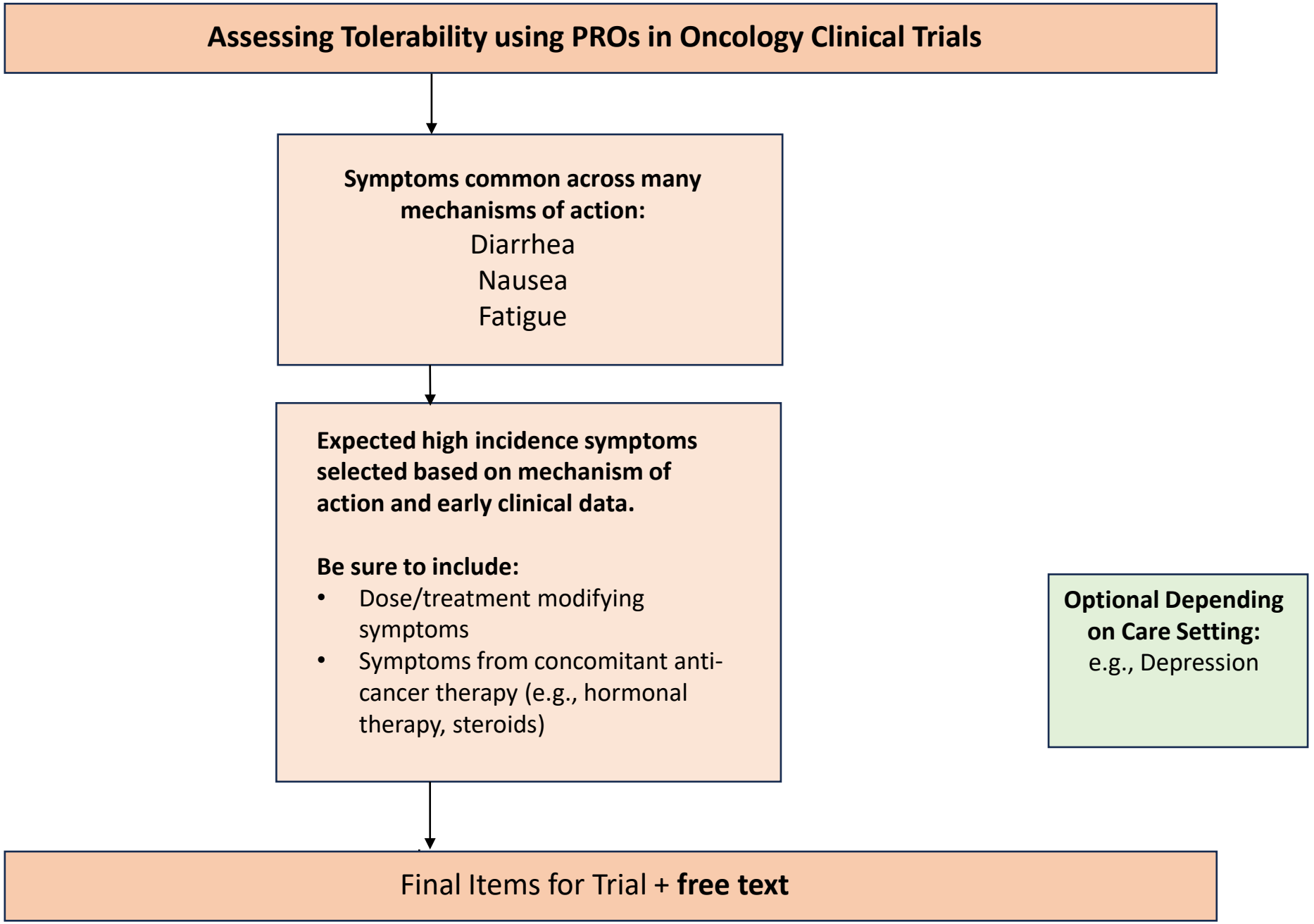
Overall Side Effect Impact

Effort

How to select the most relevant patient-reported symptomatic AEs?

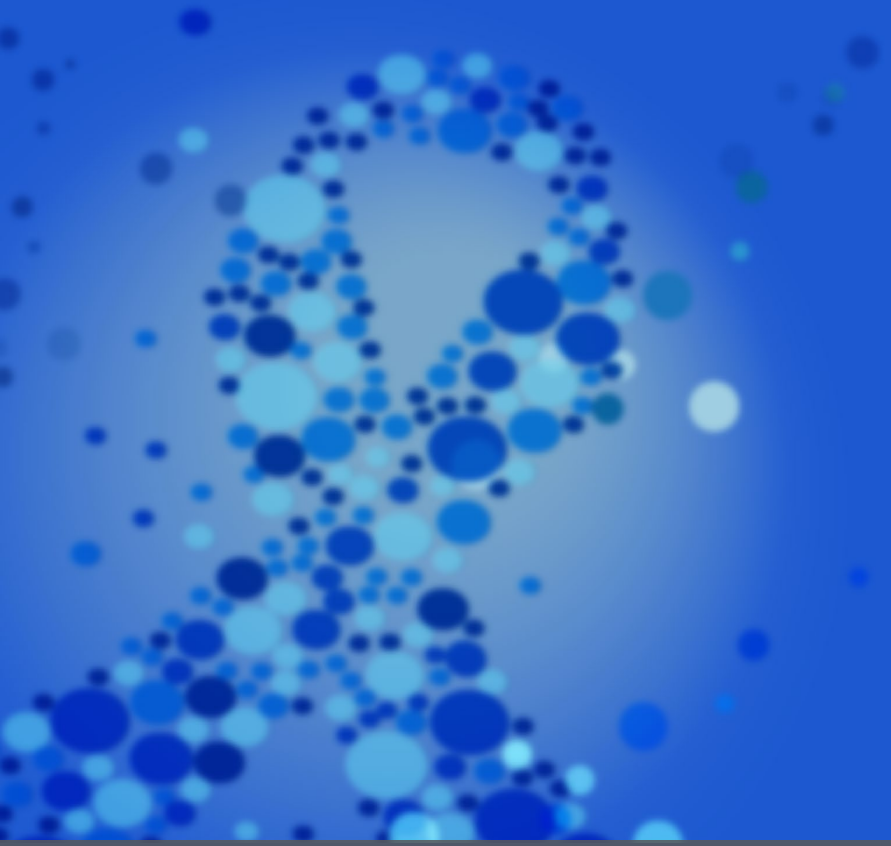
Clinician Reported and Biomarker Data

Patient Generated Data



manuscript pending

Clinical Outcome Assessment in Cancer Clinical Trials 2024

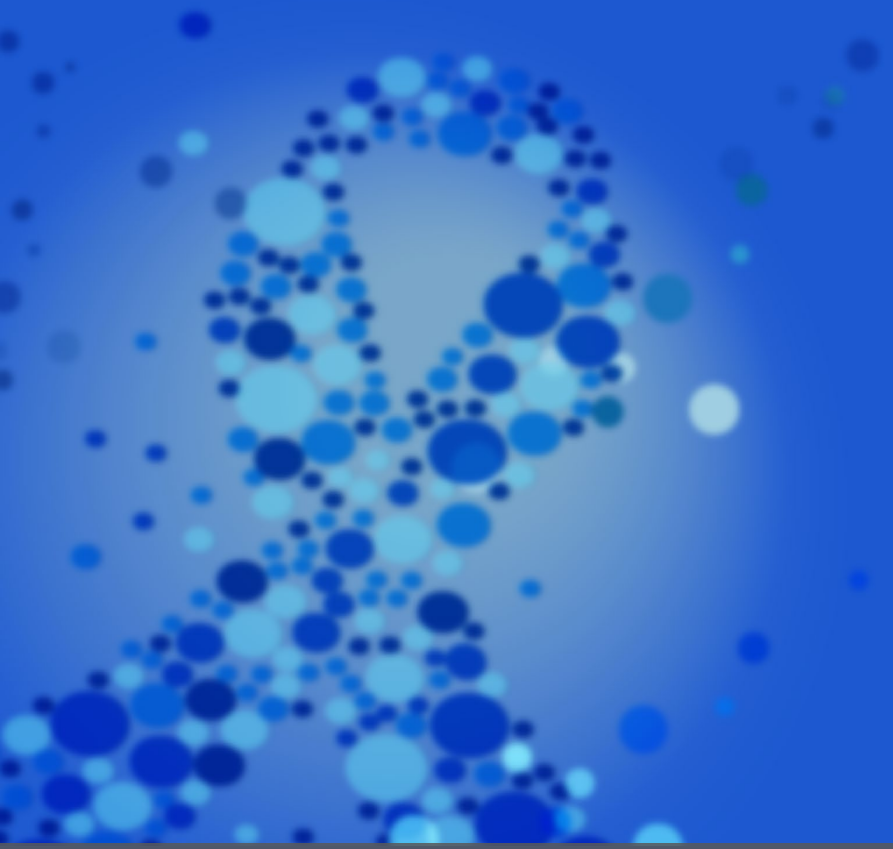


BREAK

Up Next: Session 2 at 12:40 PM ET

Hosted by the
FDA ONCOLOGY CENTER OF EXCELLENCE

Clinical Outcome Assessment in Cancer Clinical Trials 2024



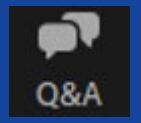
Session 2:

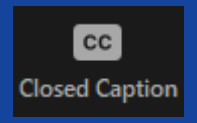
Revisiting Core Item Sets in Oncology Trials – How do we get there?

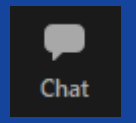
12:40 PM – 1:55 PM ET

Hosted by the
FDA ONCOLOGY CENTER OF EXCELLENCE

Webcast Guide

- To ask a question or make a comment, click the 

button below!
- To show captioning, click the 

button below.
- Links to reference materials may be shared periodically through the 

button below.

FDA

Hosted by the
FDA ONCOLOGY CENTER OF EXCELLENCE

Assessing Tolerability using PROs in Oncology Clinical Trials

Symptoms common across many mechanisms of action:

Diarrhea

Nausea

Fatigue

Expected high incidence symptoms selected based on mechanism of action and early clinical data.

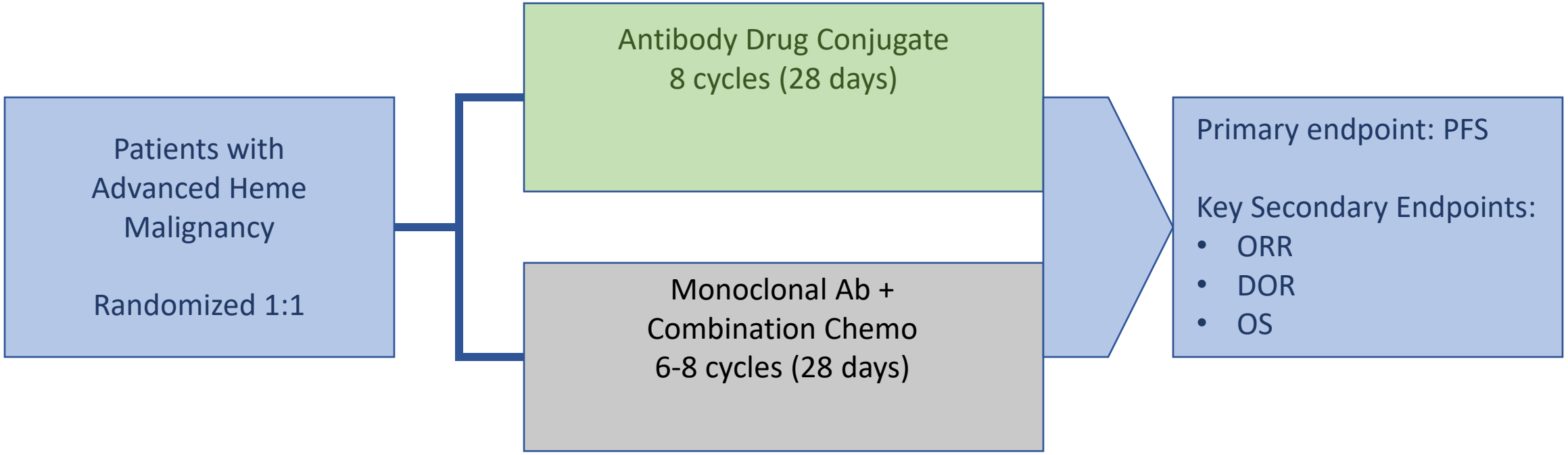
Be sure to include:

- Dose/treatment modifying symptoms
- Symptoms from concomitant anti-cancer therapy (e.g., hormonal therapy, steroids)

Optional Depending on Care Setting:
e.g., Depression

Final Items for Trial + **free text**

Hypothetical Late Phase Trial



How to select the most appropriate patient-reported symptoms to assess tolerability?

Core Outcomes

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 Generated Data

Hypothetical Symptoms from Trial Agents

Antibody Drug Conjugate

- Fatigue (60%)
- Neuropathy (50%)
- Decreased Appetite (40%)
- Nausea (40%)
- Stomatitis (30%)
- Pruritis/Rash (12%)
- Vision changes (12%)
- Dyspnea (10%)

Monoclonal Ab + Combination Chemo

- Nausea (80%)
- Fatigue (60%)
- Vomiting (40%)
- Diarrhea (40%)
- Alopecia (40%)
- Constipation (15%)
- Back pain (10%)
- Insomnia (10%)

Assessing Tolerability using PROs in Oncology Clinical Trials

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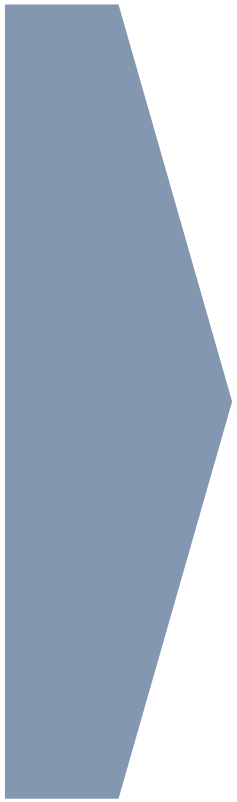
- Insomnia (10%)

Hypothetical Trial Symptom List

List of symptoms to assess using an item library:

1. Fatigue
2. Neuropathy
3. Decreased Appetite
4. Nausea
5. Stomatitis
6. Vision changes
7. Vomiting
8. Diarrhea
9. Alopecia
10. Free-text



"...symptomatic AEs expected to occur from both treatment regimens should be assessed for all patients in both arms."

"Assessment frequency should be higher within the first few treatment cycles and depending on the trial may be less frequent in later cycles."

Core Patient-Reported Outcomes in Cancer Clinical Trials: Draft Guidance for Industry

Core Outcomes

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Progression Free Survival
Overall Response Rate
Serum Biomarkers

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Session 2: Revisiting Core Item Sets in Oncology Trials – How do we get there?

Moderator

Vishal Bhatnagar

FDA

Panelists

Ethan Basch

UNC

Cheryl Coon

Critical Path Institute

Amylou Dueck

Mayo Clinic

Megan Fitter

FDA

Jan Geissler

Patient Advocate

Madeline Pe

EORTC

Ashley Wilder Smith

NCI

Clinical Outcome Assessment in Cancer Clinical Trials 2024

Session 2: Objectives

- Ethan Basch
- Cheryl Coon
- Amylou Dueck
- Megan Fitter
- Jan Geissler
- Madeline Pe
- Ashley Wilder Smith

1. Consider actionable methods to modernize existing PRO item libraries/measures.
2. Provide a framework for a potential symptom core item set applicable across therapeutic areas and contexts.
3. Review analysis and visualization techniques for core symptoms assessed during cancer trials.

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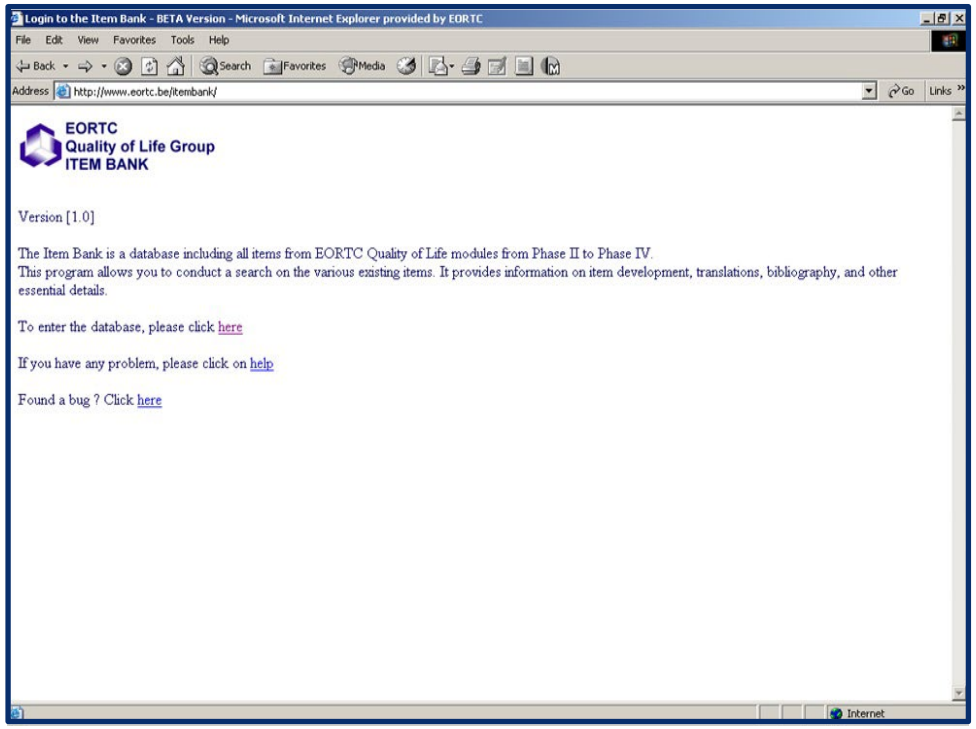
European Organisation for Research and Treatment of Cancer

Getting to know the EORTC Item Library

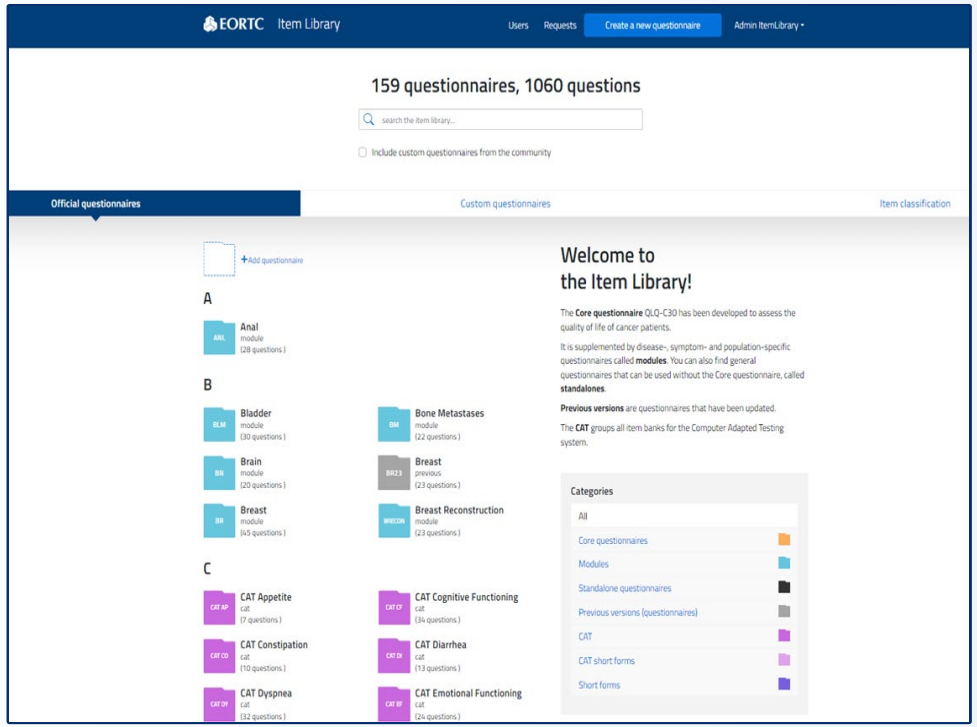
FDA COA-CTT Workshop, June 25 2024

Madeline Pe, PhD
Head of Quality of Life Department
European Organisation for Research and Treatment of Cancer (EORTC)
Brussels, Belgium

Where did we come from?



Where are we now?



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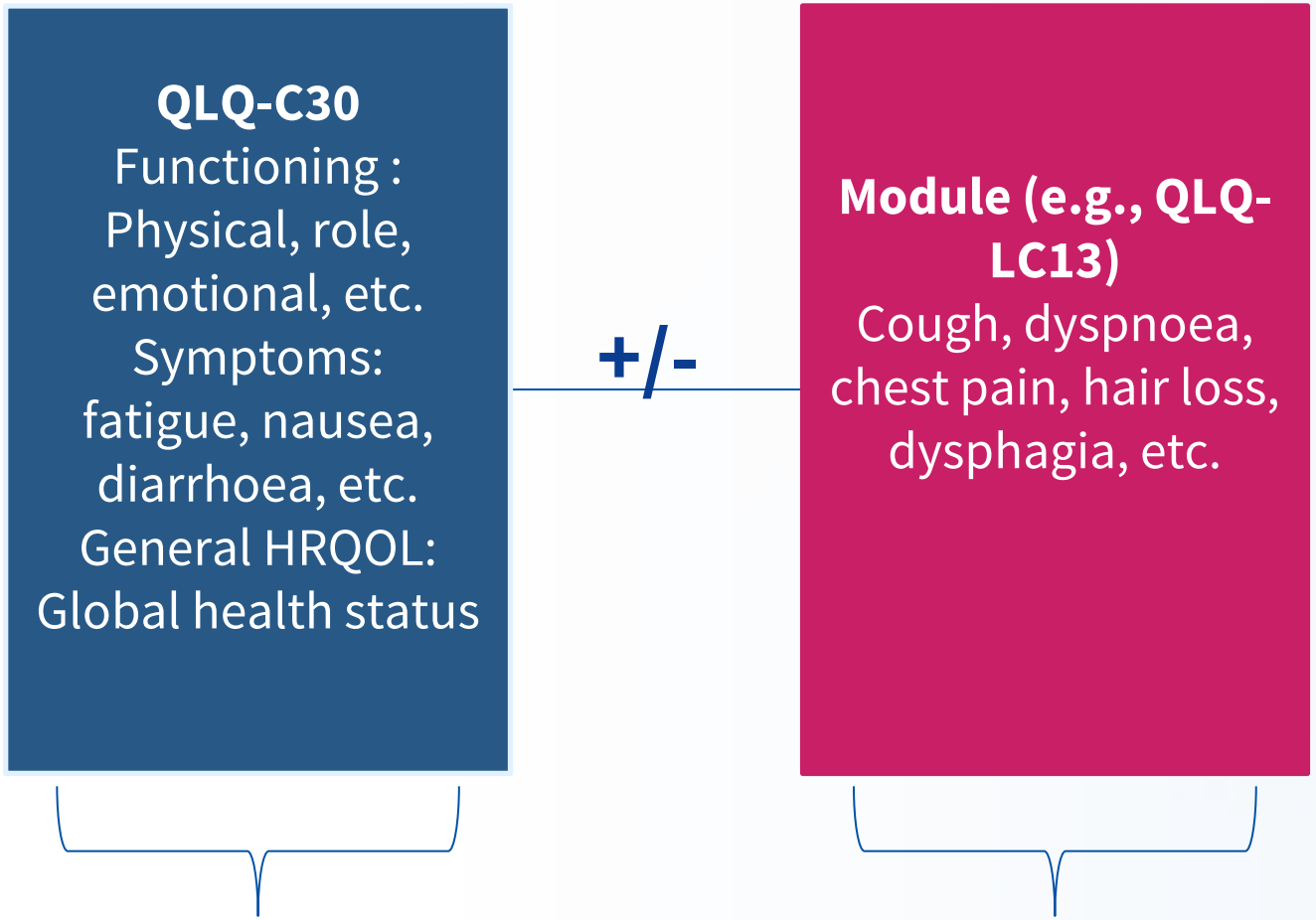
How did we get here?



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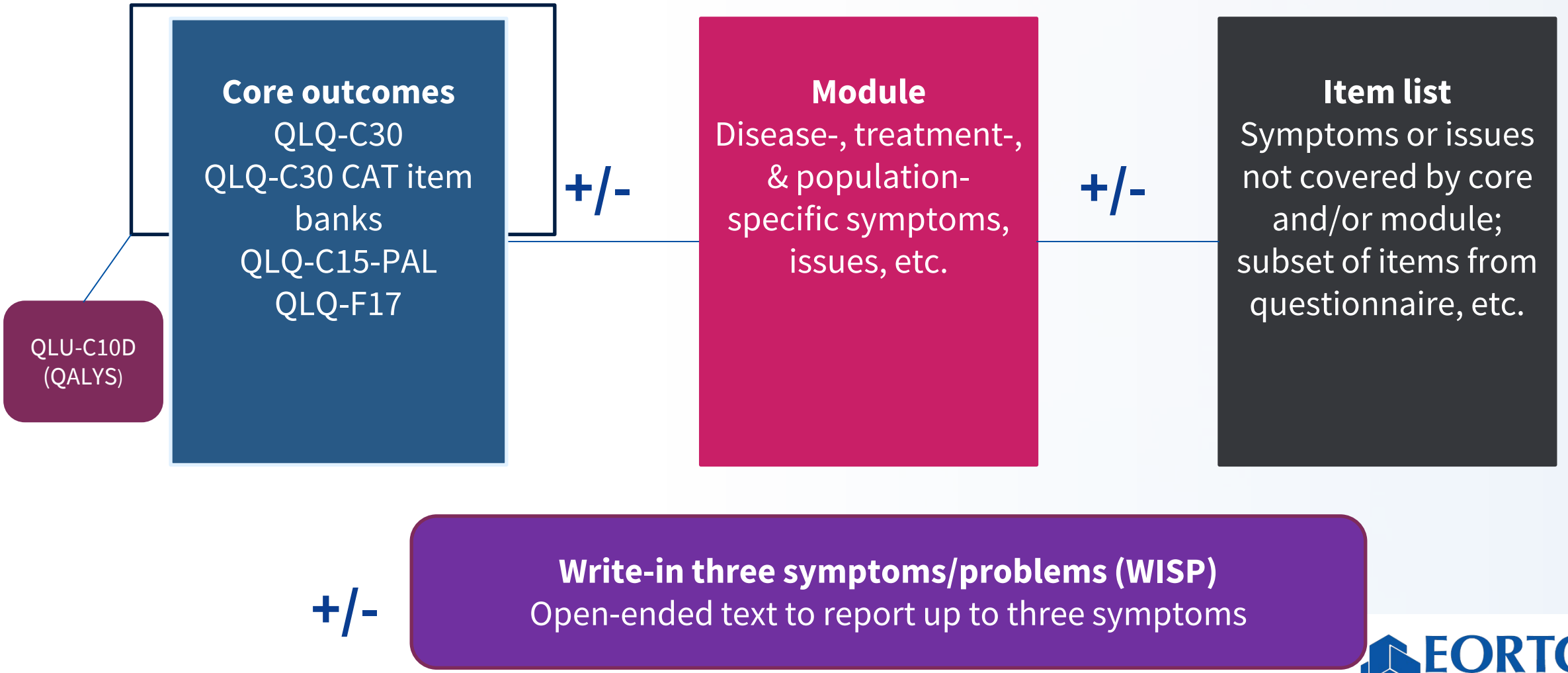
Towards a more flexible (& pragmatic) PRO measurement strategy



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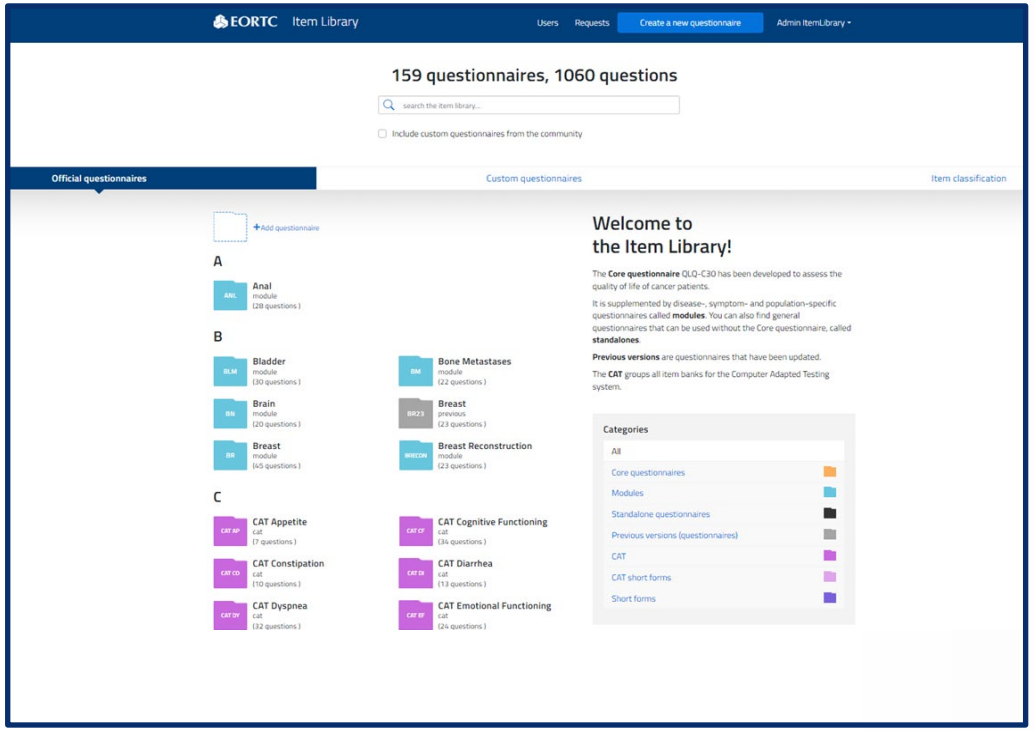
How is the EORTC Item Library used?



To support the development and validation of new (static) questionnaires and questionnaire updates

As a reference tool to search for items, translations, references, questionnaires, etc.

To create **new item lists** for use in different research and clinical settings

https://itemlibrary.eortc.org/

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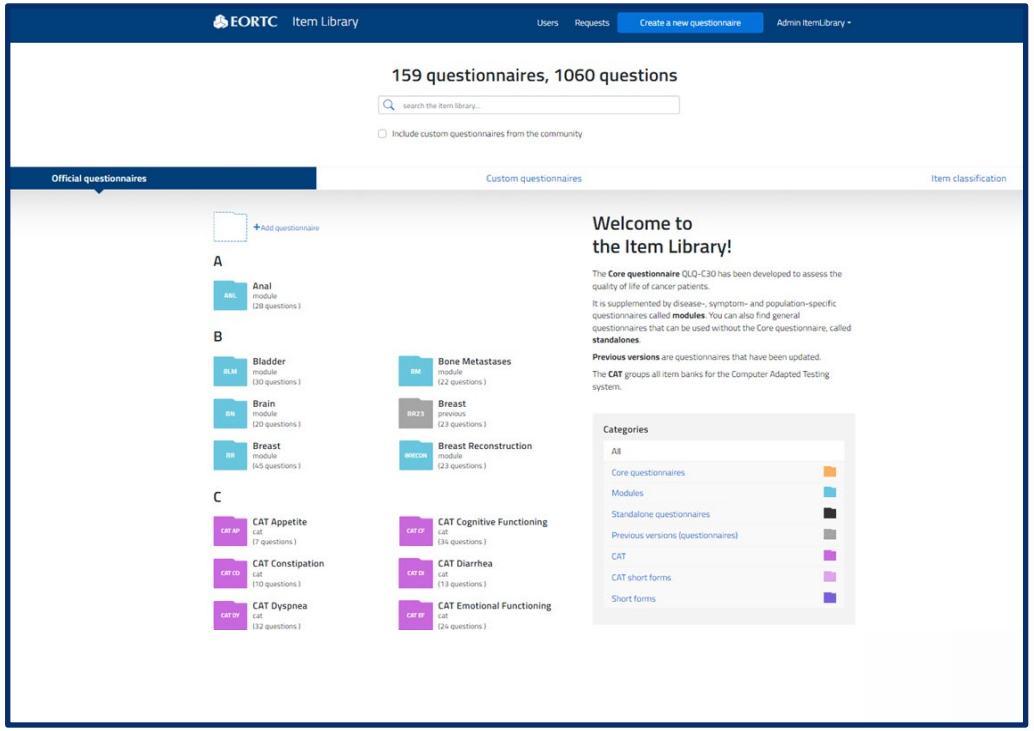
How is the EORTC Item Library used?



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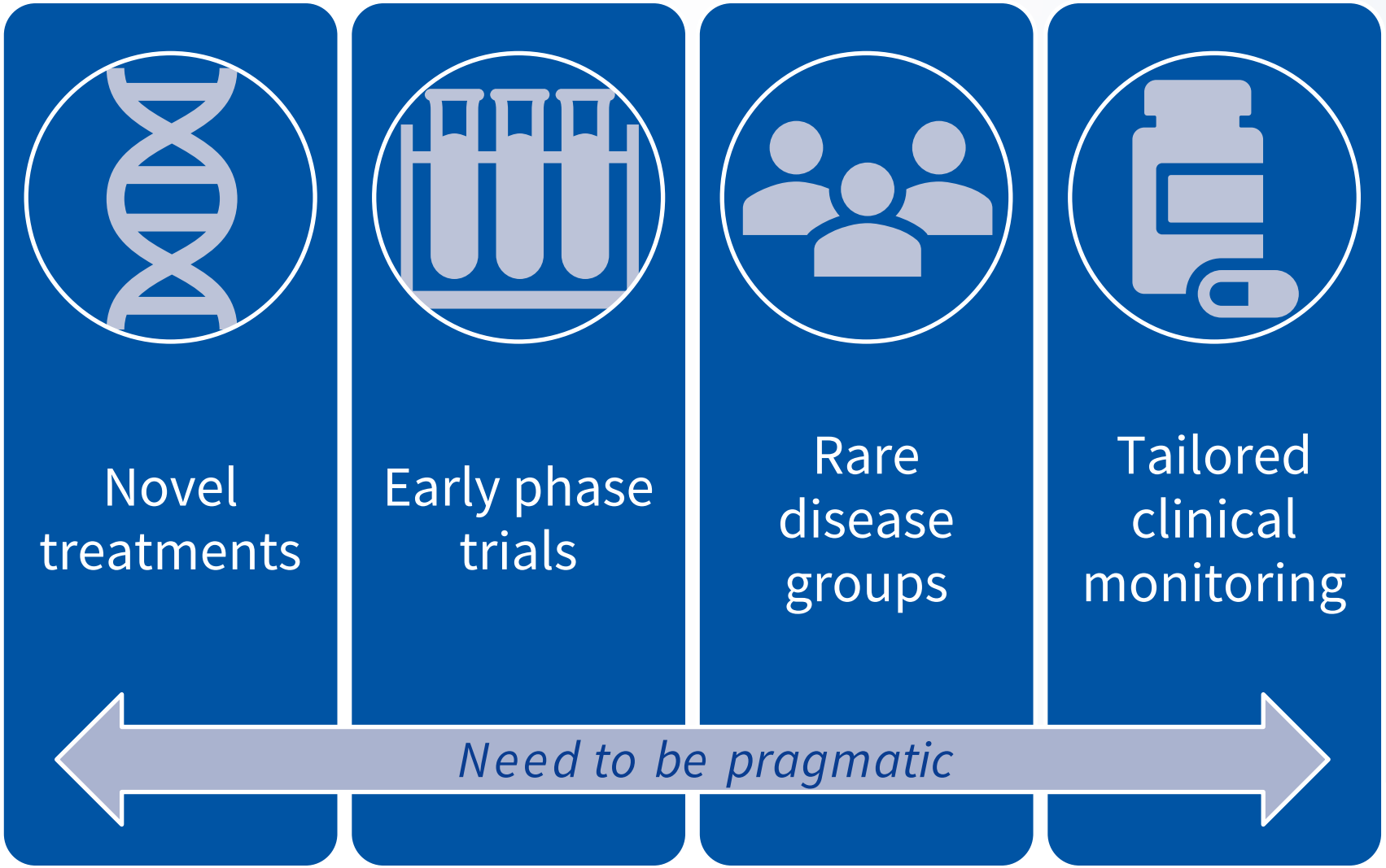
European Organisation for Research and Treatment of Cancer

Example settings for item list use



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Content classification - CTCAE

- Previous work linking 950 EORTC items to CTCAE framework found considerable coverage of Aes
- 208 different CTCAEs linked to EORTC items
- Findings integrated into Item Library to facilitate identification of items based on symptomatic AE

SOCs	Total AEs covered by EORTC items N (%*)
Cardiac disorders	2 (1.0)
Ear and labyrinth disorders	3 (1.4)
Endocrine disorders	2 (0.1)
Eye disorders	14 (6.7)
Gastrointestinal disorders	37 (17.8)
General disorders and administration site conditions	15 (7.2)
Immune system disorders	1 (0.5)
Infections and infestations	5 (2.4)
Injury, poisoning and procedural complications	7 (3.4)
Investigations	3 (1.4)
Metabolism and nutrition disorders	1 (0.5)
Musculoskeletal and connective tissue disorders	17 (8.2)
Nervous system disorders	23 (11.1)
Psychiatric disorders	12 (5.8)
Renal and urinary disorders	9 (4.3)
Reproductive system and breast disorders	21 (10.1)
Respiratory, thoracic and mediastinal disorders	16 (7.7)
Skin and subcutaneous tissue disorders	16 (7.7)
Surgical and medical procedures	1 (0.5)
Vascular disorders	3 (1.4)
Total SOCs (N=20)	*Total AEs (N=208)

Gilbert A*, Piccinin C*, Velikova G, Groenvold M, Kuliś D, Blazeby JM, Bottomley A. Linking the European Organisation for Research and Treatment of Cancer Item Library to the Common Terminology Criteria for Adverse Events. Journal of Clinical Oncology. 2022;40(32):3770–80. https://doi.org/10.1200/JCO.21.02017

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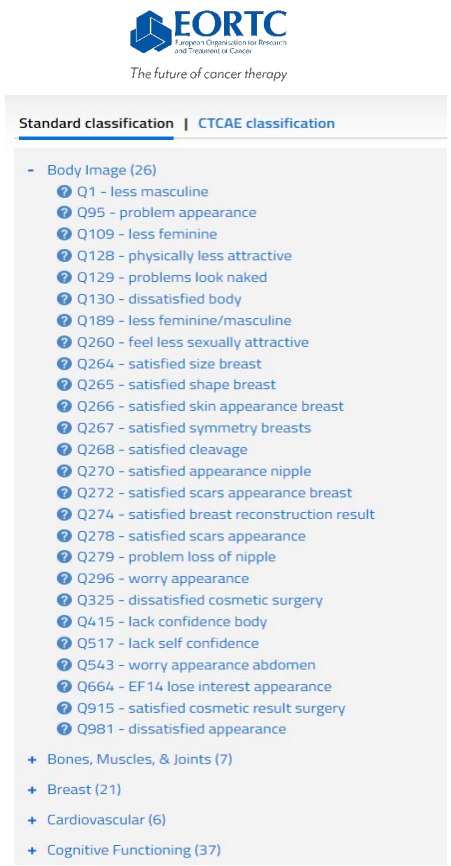
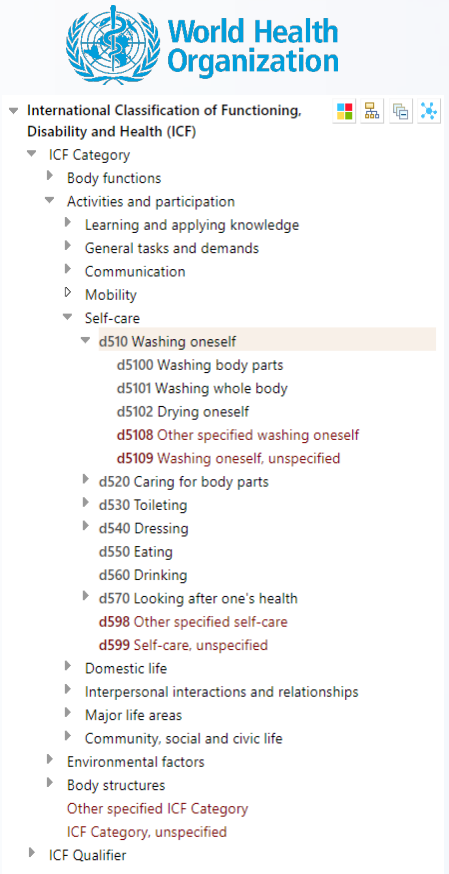
Content classification – WHO-ICF



- Developed using bottom-up approach
- Available in Item Library within “Item classification” view
- Currently being updated



- Applied to EORTC items using a top-down approach, following specific WHO-ICF linking rules
- Coding underway & will eventually be implemented in Item Library

https://itemlibrary.eortc.org/
https://apps.who.int/classifications/icfbrowser/

Cieza A et al. Refinements of the ICF Linking Rules to strengthen their potential for establishing comparability of health information. Disabil Rehabil. 2019;41(5):574–83. https://doi.org/10.3109/09638288.2016.1145258
Schurr T et al. Patient-reported outcome measures for physical function in cancer patients: content comparison of the EORTC CAT Core, EORTC QLQ-C30, SF-36, FACT-G, and PROMIS measures using the International Classification of Functioning, Disability and Health. BMC Medical Research Methodology. 2023;23(1).1: 21. https://doi.org/10.1186/s12874-022-01826-z

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What sorts of item lists are frequently requested by industry users?

Concept(s)	Core outcomes (functioning & symptoms)	Treatment and/or disease-related side effects	Global impression of side effect burden
Approach(es)	• Subset of QLQ-C30 domains	• Select treatment- and/or disease-specific items	• Single item measure of side effect burden (*Q168 To what extent have you been troubled with side-effects from your treatment?*)
PRO measurement strategy to fit FDA scope	• QLQ-C30 (physical functioning, role functioning, **diarrhoea, nausea and fatigue**)	• Disease-specific module (e.g, BR23) • Item list from Item Library (e.g., breast and arm **symptom scales** from BR23)	• Item List 46 / Item Q168

Reflects current scope of US regulatory guidance

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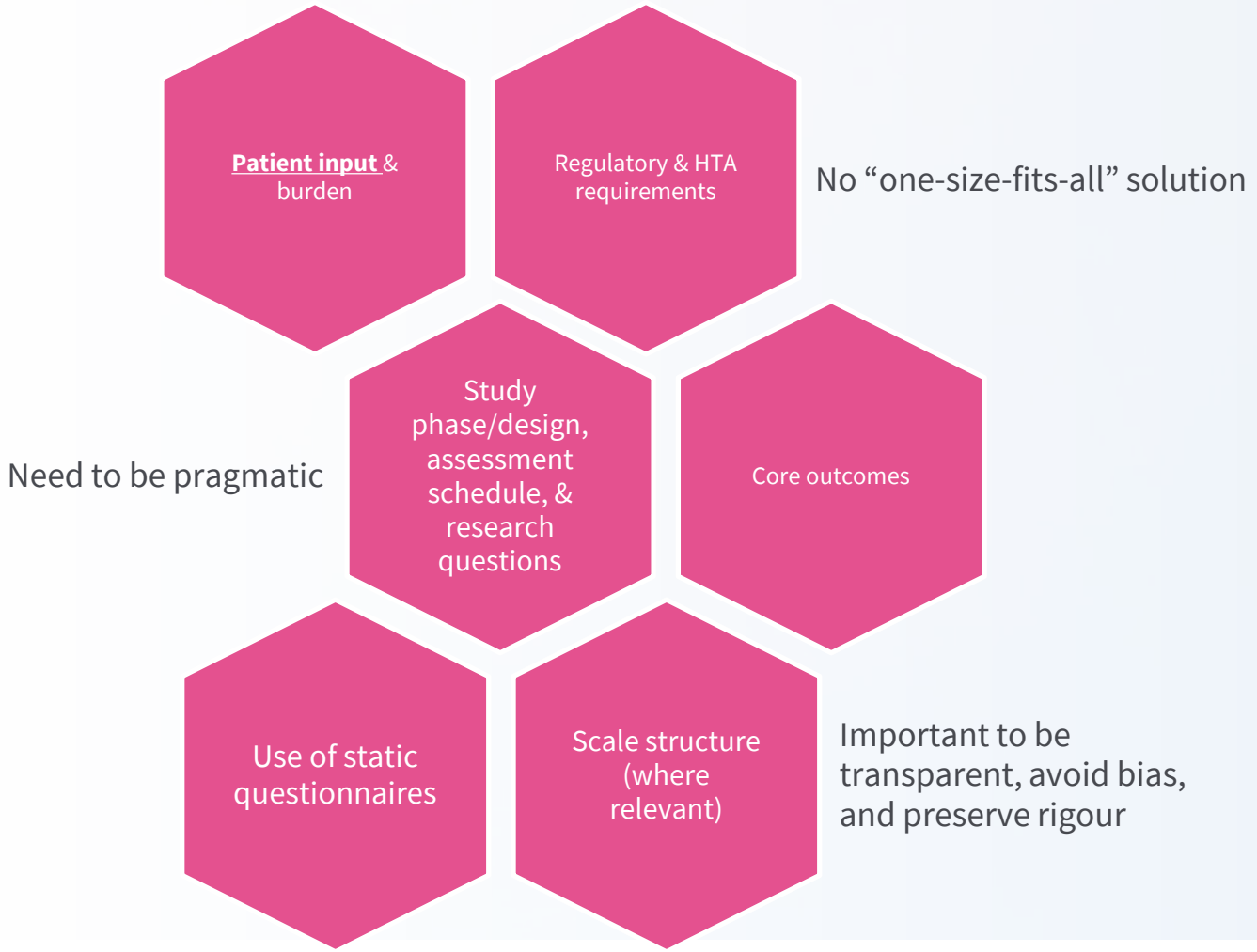
Encouraging best practices for use of item libraries

- With added flexibility comes important need to minimize bias and avoid cherry-picking of items
- Investigators should account for design of item list in a transparent and comprehensive way
- Important to consider different factors when using a flexible measurement approach, including need to **ensure comparability and generalizability and measure core outcomes**



https://www.eortc.org/app/uploads/sites/2/2018/09/IL-manual-20180305.pdf
https://www.eortc.org/app/uploads/sites/2/2022/10/EORTC-Item-Library-User-Guidelines.pdf

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Acknowledgements

- Christopher Bedding, Leeds Institute of Medical Research, University of Leeds, Leeds, UK
- Corneel Coens, EORTC HQ, Brussels, BE
- Alexandra Gilbert, Leeds Institute of Medical Research, University of Leeds, Leeds, UK
- Johannes Giesinger, Medical University of Innsbruck, Innsbruck, AT
- Mogens Groenvold, University of Copenhagen and Bispebjerg/Frederiksberg Hospital, Copenhagen, Denmark
- Hayat Hamzeh, Leeds Institute of Medical Research, University of Leeds, Leeds, UK
- Dagmara Kuliś, EORTC HQ, Brussels, BE
- Bonnie Pacheco, EORTC HQ, Brussels, BE
- Claire Piccinin, EORTC HQ, Brussels, BE
- Rosemary Peacock, Leeds Institute of Medical Research, University of Leeds, Leeds, UK

itemlibrary@eortc.org

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Measuring Symptomatic Adverse Events with PRO-CTCAE

Ashley Wilder Smith, PhD, MPH
Outcomes Research Branch
Healthcare Delivery Research Program
Division of Cancer Control and Population Sciences

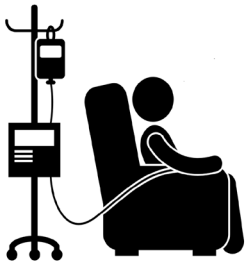
NIH NATIONAL CANCER INSTITUTE

FDA COA-CCT Workshop
June 25, 2024

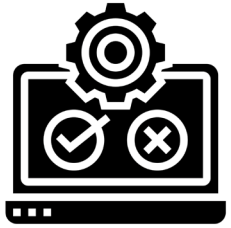
Goals

- Using PROs to assess Symptomatic Adverse Events
- PRO-CTCAE purpose and availability
- Study Design and Interpretation Considerations
- Current Use of PRO-CTCAE
- Strengthening PRO-CTCAE for Widespread Adoption

Understanding Safety and Tolerability in Cancer Clinical Trials

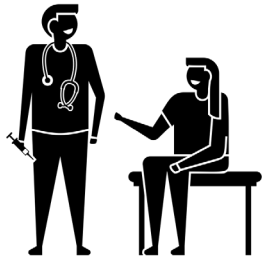


Safety and tolerability are fundamental to conclusions about the effectiveness of cancer therapies, including comparative effectiveness



In cancer clinical trials, adverse events (AEs) are graded and reported using the *Common Terminology Criteria for Adverse Events* (*CTCAE, v5*)

10% of the 800 adverse events listed in CTCAE are symptoms and are amenable to self-reporting



Validity of symptom reports erode when filtered through research staff and clinicians[1]

Staff-based AE reporting occurs at clinic visits; AEs occurring between visits may be missed

Having patients report symptomatic AEs can improve precision and reproducibility of adverse event reporting

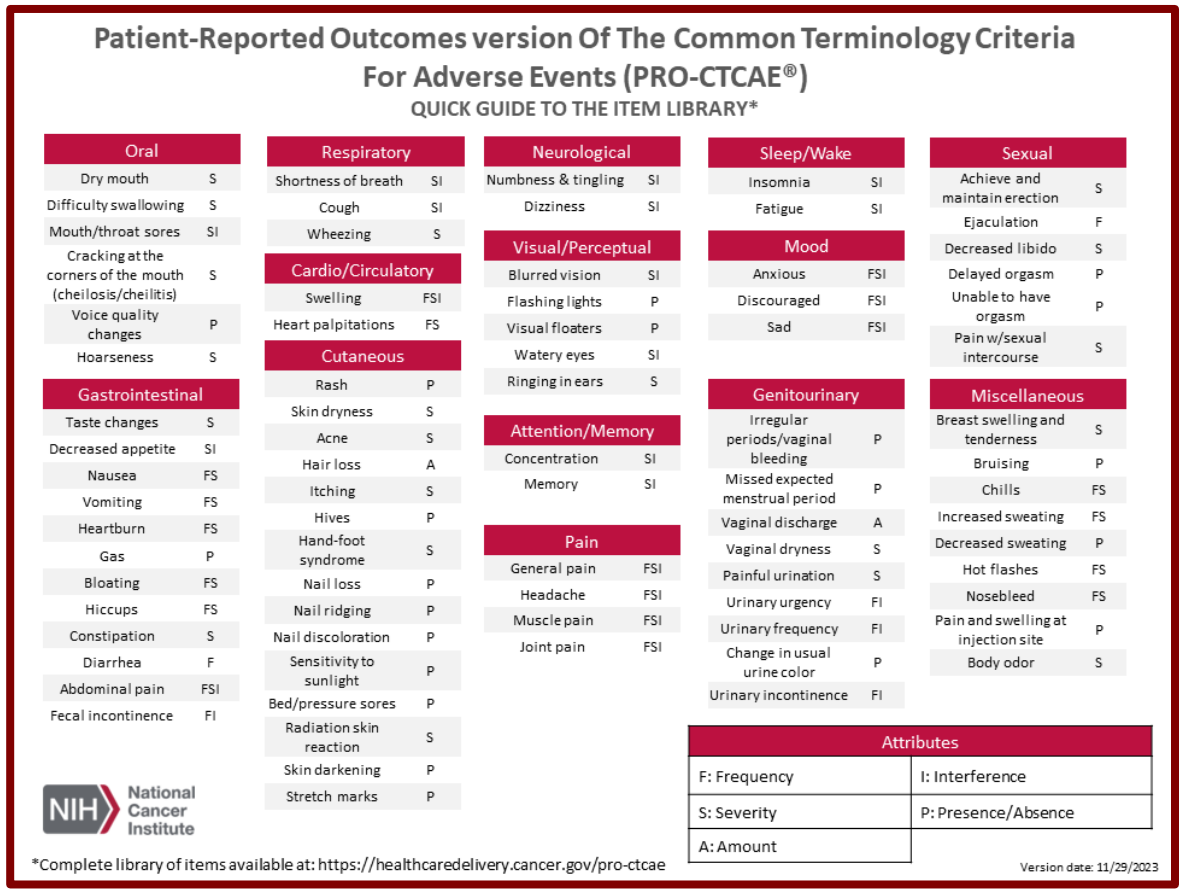
[1]Xiao et al. (2013). *Cancer Nurs.*,36(6):E1-E16. doi: 10.1097/NCC.0b013e318269040f

NCI's Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE®) Measurement System

- Designed as part of an Adverse Event reporting Paradigm; different from PROs identified under a Health-related Quality of Life conceptual framework
  - PRO measurement system allows patient self-reporting of 78 symptomatic adverse events
  - Designed to be used as a companion to the CTCAE to capture the patient's experience of symptomatic toxicities in cancer clinical trials
  - Investigators prospectively select PRO-CTCAE items that reflect anticipated symptomatic toxicities based on earlier phase trials and pre-clinical data
- PRO-CTCAE items evaluate symptom frequency, severity, interference, amount, presence/absence; standard recall period is the '*last 7 days*'
- Conditional branching logic can be implemented with electronic data capture, thereby reducing respondent burden

PRO-CTCAE® Measurement System Item Libraries

- Investigators select items from Adult or Pediatric PRO-CTCAE Item Libraries
- Open-ended “free text” item available to collect unsolicited patient-reported adverse events



Patient-Reported Outcomes version Of The Common Terminology Criteria For Adverse Events (PRO-CTCAE®)

QUICK GUIDE TO THE ITEM LIBRARY*

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	A
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

Genitourinary	
Irregular periods/vaginal bleeding	P
Missed expected menstrual period	P
Vaginal discharge	A
Vaginal dryness	S
Painful urination	S
Urinary urgency	FI
Urinary frequency	FI
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

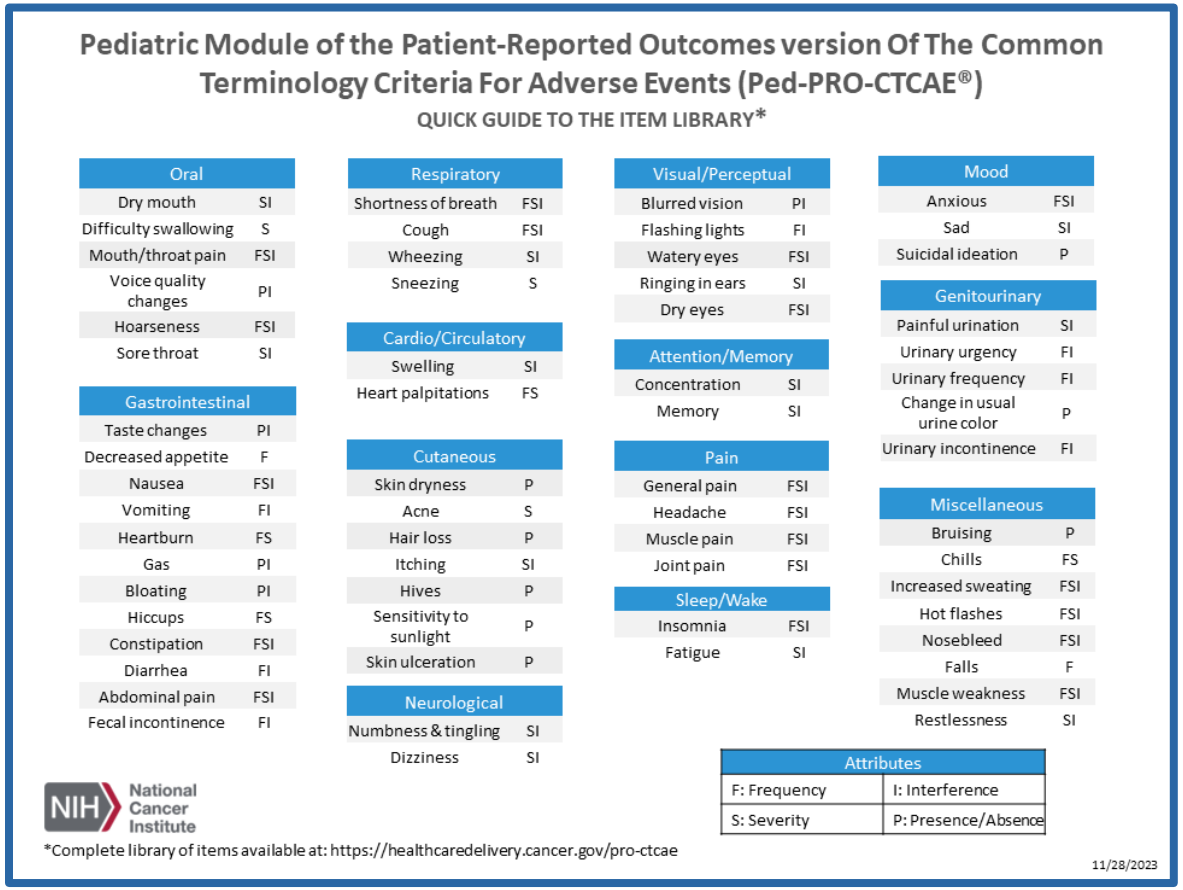
Miscellaneous	
Breast swelling and tenderness	S
Bruising	P
Chills	FS
Increased sweating	FS
Decreased sweating	P
Hot flashes	FS
Nosebleed	FS
Pain and swelling at injection site	P
Body odor	S

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

National Cancer Institute

*Complete library of items available at: https://healthcaredelivery.cancer.gov/pro-ctcae

Version date: 11/29/2023



Pediatric Module of the Patient-Reported Outcomes version Of The Common Terminology Criteria For Adverse Events (Ped-PRO-CTCAE®)

QUICK GUIDE TO THE ITEM LIBRARY*

Oral	
Dry mouth	SI
Difficulty swallowing	S
Mouth/throat pain	FSI
Voice quality changes	PI
Hoarseness	FSI
Sore throat	SI

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

Respiratory	
Shortness of breath	FSI
Cough	FSI
Wheezing	SI
Sneezing	S

Cardio/Circulatory	
Swelling	SI
Heart palpitations	FS

Cutaneous	
Skin dryness	P
Acne	S
Hair loss	P
Itching	SI
Hives	P
Sensitivity to sunlight	P
Skin ulceration	P

Neurological	
Numbness & tingling	SI
Dizziness	SI

Visual/Perceptual	
Blurred vision	PI
Flashing lights	FI
Watery eyes	FSI
Ringing in ears	SI
Dry eyes	FSI

Attention/Memory	
Concentration	SI
Memory	SI

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

Sleep/Wake	
Insomnia	FSI
Fatigue	SI

Mood	
Anxious	FSI
Sad	SI
Suicidal ideation	P

Genitourinary	
Painful urination	SI
Urinary urgency	FI
Urinary frequency	FI
Change in usual urine color	P
Urinary incontinence	FI

Miscellaneous	
Bruising	P
Chills	FS
Increased sweating	FSI
Hot flashes	FSI
Nosebleed	FSI
Falls	F
Muscle weakness	FSI
Restlessness	SI

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

National Cancer Institute

*Complete library of items available at: https://healthcaredelivery.cancer.gov/pro-ctcae

11/28/2023

Design Considerations: PRO-CTCAE® and CTCAE

- PRO-CTCAE is designed as a companion to the CTCAE
  - Provides complementary information
  - Timing of assessments should be comparable, and data reported in parallel
- Study design and analysis plan should consider published guidelines for protocol development and statistical analysis of studies that include a PRO[1,2]
- PRO-CTCAE is used to describe safety and tolerability of a regimen;
- CTCAE grades are used for decisions about trial eligibility, dose delays, dose reductions or treatment discontinuation

[1]Calvert et al. (2018). JAMA. 2018 Feb 6;319(5):483-494. doi: 10.1001/jama.2017.21903.
[2]Coens et al. (2020). Lancet Oncol. 21(2):e83-e96. doi: 10.1016/S1470-2045(19)30790-9.

Design Considerations: Choosing PRO-CTCAE® Items

- Judicious item selection to minimize patient burden
- Need for parsimony: PRO-CTCAE is efficient, flexible, and targeted, to accurately determine the unique toxicity profile of each regimen based on prior data
- Select items based on CTCAE-graded toxicities observed in earlier phase studies of agent, knowledge of drug class and anticipated on- and off-target effects; qualitative work in the population (if it exists); expert opinion of study chair and investigators
- Symptomatic toxicities should match the Comprehensive Adverse Event and Potential Risks (CAEPR)
- In a multi-arm trial with different agents and regimens, all participants should report on the same AE items across the different trial arms to reduce reporting bias

PRO-CTCAE® Interpretation

- **Scoring**:
  - PRO-CTCAE Score ≠ Clinician CTCAE Grade

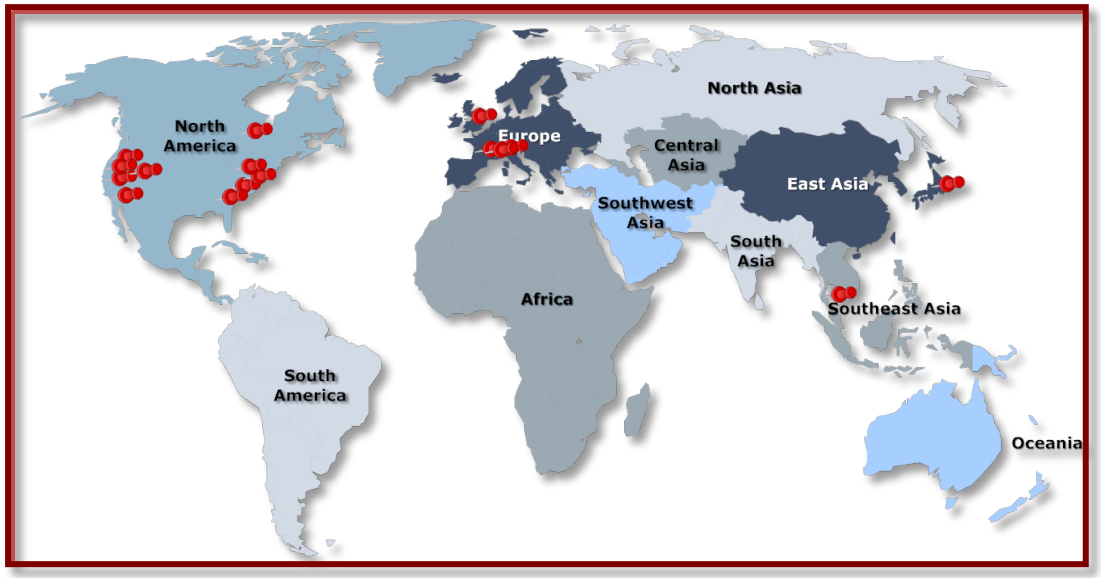
Frequency	Severity	Interference	Presence/Absence
In the past 7 days, how often did you have _____?	In the past 7 days, what was the severity of your _____ at its worst?	In the past 7 days, how much did _____ interfere with your usual or daily activities?	In the past 7 days, did you have any _____?
• Never • Rarely • Occasionally • Frequently • Almost constantly	• None • Mild • Moderate • Severe • Very severe	• Not at all • A little bit • Somewhat • Quite a bit • Very much	• No • Yes

- **Mode Equivalence[1]:** for electronic (web), interactive voice response; and paper
- **Recall Period:** 7-days
  - 24-hour recall has acceptable measurement properties when assessed daily[2]
  - Weekly assessment using 24-hour recall results in under detection of symptomatic AEs[3]

[1]Bennett et al. (2016). *Health and Quality of Life Outcomes*.,19;14:24.doi: 10.1186/s12955-016-0426-6
[2]Lee et al. (2023). Quality of Life Research, 32, 2047-2058 [3]Paudel et al. (2024). JNCI, https://doi.org/10.1093/jnci/djae049

Expanding Adoption and Implementation

- Collaborations with national and international organizations to enhance uptake and adoption in clinical trials
  - NCI National Clinical Trials Network (NCTN) and Early Therapeutics Clinical Trials Network (ETCTN)
  - Regulatory: US Food and Drug Administration, NHS in UK, EMA
  - International: Adopters: Italian NCI, Japanese NCI, Danish Cancer Society, German Society of Hematology and Medical Oncology



- PRO-CTCAE translated and linguistically validated in > 60 languages; 15 additional languages in development
- Pediatric module validated in 3 languages; 8 additional languages in development and scheduled for release by early 2025

Inclusion of PRO-CTCAE® in Cancer Clinical Trials and Clinical Research

- PRO-CTCAE is being used across the world in industry-sponsored trials, academic trials, and government funded trials
- Requests for PRO-CTCAE internationally have increased substantially with the translation and validation into over 60 languages
- In the NIH grant portfolio, from 2011-2023, there have been more than 100 funded grants that use PRO-CTCAE
- There have been 330 studies registered in ClinicalTrials.gov from 2010 to present, with over 40 in 2024 alone

For more information about PRO-CTCAE® visit:

https://healthcaredelivery.cancer.gov/pro-ctcae

Session 2: Revisiting Core Item Sets in Oncology Trials – How do we get there?

Moderator

Vishal Bhatnagar

FDA

Panelists

Ethan Basch

UNC

Cheryl Coon

Critical Path Institute

Amylou Dueck

Mayo Clinic

Megan Fitter

FDA

Jan Geissler

Patient Advocate

Madeline Pe

EORTC

Ashley Wilder Smith

NCI

Assessment of Tolerability with Patient-Reported Outcomes:
Current State and Future Directions

Ethan Basch, MD, MSc

9th Annual FDA COA-CCT Workshop

June 25, 2024

Assessment of Patient-Reported AEs is No Longer Optional in Product Development

- Essential for understanding the patient experience of cancer treatment
- Necessary to fully characterize tolerability

- *In the future, tolerability assessment without patient-reported AEs will be considered incomplete*

Tools and Methods Exist Today

- Validated item libraries are well established
  - E.g., PRO-CTCAE, EORTC, PROMIS
- Item selection approach has been provided
  - Core (cross-cutting) symptomatic AEs
  - Context-specific AEs
  - Free text
- Prior trials have shown high patient completion rates and meaningfulness of patient-reported data

Future Directions

- Update/refine item libraries to meet AEs experienced by contemporary treatments and populations
- Define systematic approaches to step 2 in item selection (rationalizing context-specific AEs)
- Develop methods to map free text responses to structured data
- Establish recommendations for practical elements of data collection
  - Frequency of assessments, recall period, duration of assessments
  - How/whether to share PRO-CTCAE data with site investigators in real-time
- Characterize role of PRO AEs in dose-finding trials

Clinical Outcome Assessment in Cancer Clinical Trials 2024

Session 2: Objectives

- Ethan Basch
- Cheryl Coon
- Amylou Dueck
- Megan Fitter
- Jan Geissler
- Madeline Pe
- Ashley Wilder Smith

1. Consider actionable methods to modernize existing PRO item libraries/measures.
2. Provide a framework for a potential symptom core item set applicable across therapeutic areas and contexts.
3. Review analysis and visualization techniques for core symptoms assessed during cancer trials.

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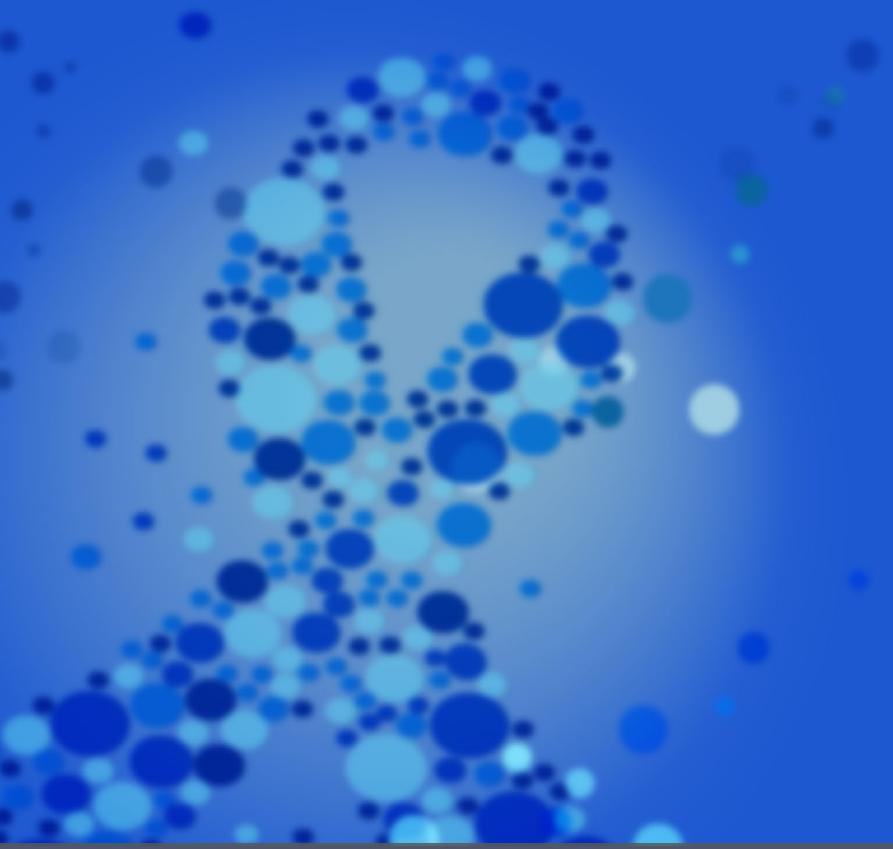
Clinical Outcome Assessment in Cancer Clinical Trials 2024



Panel Discussion Q&A

1:55 PM – 2:25 PM ET

Hosted by the
FDA ONCOLOGY CENTER OF EXCELLENCE

Clinical Outcome Assessment in Cancer Clinical Trials 2024

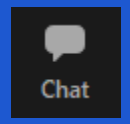
Modernizing Tolerability Assessment in Cancer Clinical Trials

9th Annual
Virtual Public Workshop

June 25, 2024
11:00 AM – 2:30 PM ET

Conclusion

2:25 PM – 2:30 PM ET

Workshop recordings will be posted within three weeks on the Workshop event page (click the "Chat" 

button below to access Workshop links).

Hosted by the
FDA ONCOLOGY CENTER OF EXCELLENCE

Clinical Outcome Assessment in Cancer Clinical Trials 2024

Modernizing Tolerability Assessment in Cancer Clinical Trials

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Thank you

Acknowledgements:

- Caitlin Drew
- Erica Horodniceanu
- Kirsten Goldberg
- Richard Krzysztofik
- Syed Shah
- Joan Todd
- Erin Villanueva
- All Session Panelists
- OCE leadership and staff

See you next year!

Hosted by the
FDA ONCOLOGY CENTER OF EXCELLENCE