46TH MEETING OF THE CTAC MEMBERS (VIRTUAL)

CLINICAL TRIALS AND TRANSLATIONAL RESEARCH ADVISORY COMMITTEE (CTAC) NATIONAL CANCER INSTITUTE NATIONAL INSTITUTES OF HEALTH DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEETING AGENDA

WEDNESDAY, NOVEMBER 10, 2021 – OPEN 11:00 A.M. – 3:00 P.M. (EASTERN) JOIN MEETING <u>HTTPS://VIDEOCAST.NIH.GOV/</u>

11:00 a.m. – 11:05 a.m.	١.	CALL TO ORDER & OPENING REMARKS	Dr. Meropol
11:05 a.m. – 11:35 a.m.	II.	NCI DIRECTOR'S UPDATE	Dr. Sharpless
11:35 a.m. – 11:50 a.m.	III.	LEGISLATIVE UPDATE	Ms. Holohan
11:50 p.m. – 12:30 p.m.	IV.	CLINICIAN SCIENTIST AWARDS	
		EARLY-STAGE SURGEON SCIENTIST PROGRAM	Dr. Zahir
		• R50 CLINICIAN SCIENTIST RESEARCH AWARD	Dr. Doroshow
		• DISCUSSION: REIMAGINING THE CANCER CLINICAL INVESTIGATOR TEAM LEADERSHIP AWARD (CCITLA)	All Participants
12:30 p.m. – 1:20 p.m.	v.	CTAC STRATEGIC PLANNING WORKING GROUP	
		• OVERVIEW OF THE PROGRESS TOWARD IMPLEMENTATION OF THE RECOMMENDATIONS	Dr. Doroshow
		• CTEP ANALYSIS OF IMPLEMENTING ASCO-FRIENDS BROADENED ELIGIBILITY CRITERIA IN CTEP-SPONSORED TRIALS	Ms. Denicoff
		DISCUSSION	All Participants

1:20 p.m. – 1:35 p.m.	BREAK	
1:35 p.m. – 2:50 p.m.	VI. FDA DRAFT GUIDANCE ON THE INCLUSION OF PATIENT REPORTED OUTCOMES (PROs) IN CANCER CLINICAL TRIALS	Dr. Minasian
	FDA DRAFT GUIDANCE ON PROs	Dr. Bhatnagar Dr. Kluetz
	INCLUSION OF PROs IN NCI CLINICAL TRIALS	Dr. Minasian
	• THE VALUE OF & CHALLENGES IN IMPLEMENTING PROS IN CANCER CLINICAL TRIALS	Dr. Dueck
	DISCUSSION	All Participants
2:50 p.m. – 3:00 p.m.	VII. ONGOING & NEW BUSINESS	Dr. Meropol Dr. Doroshow
	RETIRING MEMBER RECOGNITION	Di. Dorosnow
	WORKING GROUP UPDATES	
3:00 p.m.	ADJOURN	
	<u>Confirmed Future Meeting Dates</u> Wednesday, March 16, 2022 Wednesday, July 13, 2022 Wednesday, November 9, 2022	

Wednesday, March 15, 2023 Wednesday, July 19, 2023 Wednesday, November 8, 2023