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Overview of Clinical Trials for the APP
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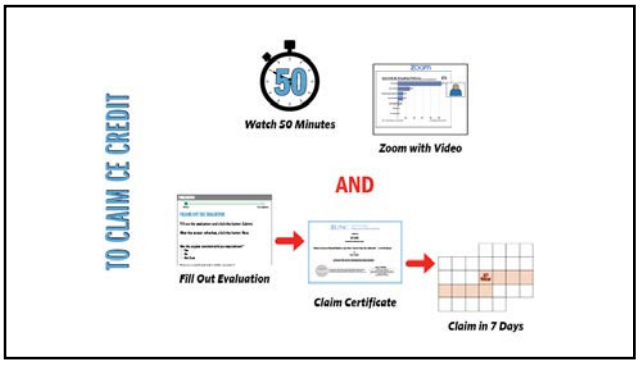
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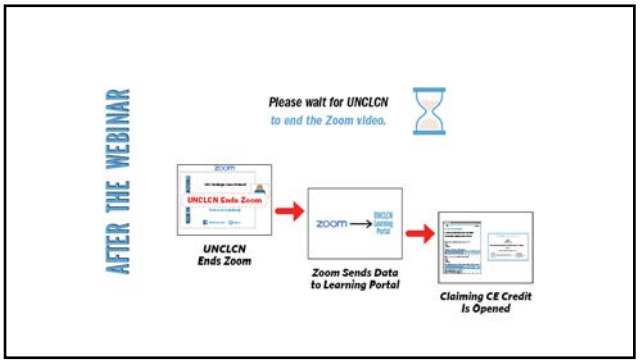
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Live Webinar
Clarissa Dillon, PA-C
Overview of Clinical Trials for the APP
July 19

6

OUR PRESENTER

Clarissa Urban, PA-C

Clarissa Urban, MMSc, PA-C, is a physician assistant in the oncology division of the UNC Cancer Center in Chapel Hill.

She graduated from Emory University Physician Assistant Program in 2014 and worked for five years in adult hematology and oncology at a community private practice in Cary, North Carolina.

She joined the UNC Healthcare team in 2019 and works with the gastrointestinal oncology and breast oncology and has a primary focus on early-phase clinical trials looking at novel treatments for cancers in adults.

She is certified as a Physician Assistant by the NCCPA and licensed by the North Carolina Medical Board.

7

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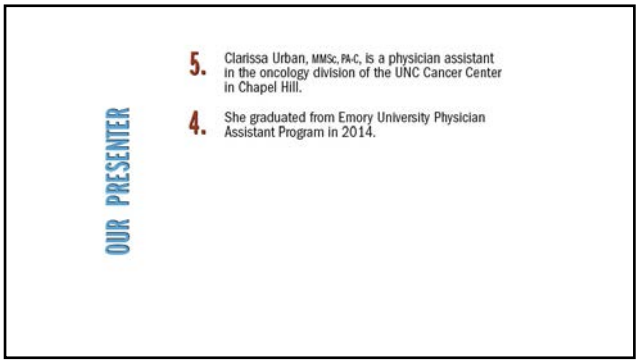
9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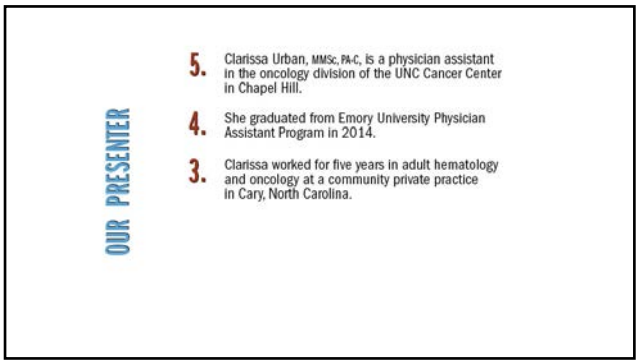
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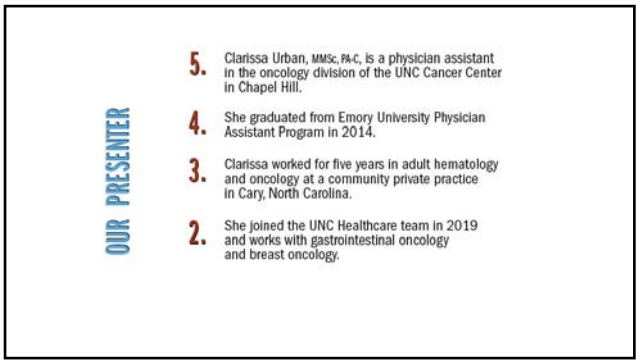
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12

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1. Clarissa has a primary focus on early-phase clinical trials looking at novel treatments for cancers in adults.

13

14

DISCLOSURES

This activity has been planned and implemented under the sole supervision of the Course Director, William A. Wood, MD, MPH, in association with the UNC Office of Continuing Professional Development (CPD). The course director and CPD staff have no relevant financial relationships with ineligible companies as defined by the ACCME.

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15

16

Overview of Clinical Trials for the APP

with a special focus on Oncology

Claire Urban, PA-C
July 2023
APP Grand Rounds

17

Disclosures

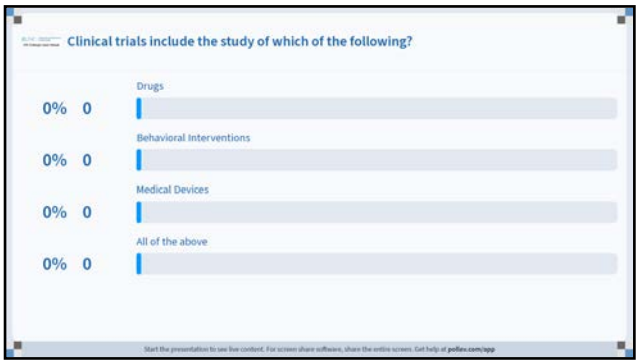
- None

18

Outline

- Define clinical trials
- Detail different phases of clinical trials
- Discuss documents and resources pertaining to clinical trials
- Review the grading of adverse events
- Describe clinical trial team
- Discuss diversity in clinical trials
- Expand on phase 1 studies

19



20

Clinical Trials – NIH definition

- A prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (new drugs, treatments, devices, or new ways of using known drugs, treatments, or devices)
- Clinical trials are used to determine whether new biomedical or behavioral interventions are safe and effective
- Through clinical trials, we can find new ways to improve treatments and the quality of life for people with disease.

21

Phases of Clinical Trials

Phase 1

- Often a drug is being studied for the first time in humans
- Purpose:
  - To find a safe dose
  - To decide how the new treatment should be given (by mouth, in a vein, etc.)
  - To see how the new treatment affects the human body and addresses disease
- Number of people taking part: 15-30
- A Phase I Dose Escalation Study of the Safety, Pharmacokinetics and Pharmacodynamics of MRX-2843 in Adult Subjects with Relapsed/Refractory Advanced and/or Metastatic Solid Tumors

22

22

Phases of Clinical Trials

- **Phase 2**
  - Purpose:
    - To see how the new treatment affects the body
    - To determine if the new treatment has positive effect
  - Number of people taking part: Less than 100
  - Example: Phase II Trial of ERK Inhibition Alone and in Combination with Autophagy Inhibition in Patients with Metastatic Pancreatic Cancer

23

23

Phases of Clinical Trials

- **Phase 3**
  - Purpose:
    - To compare the new treatment (or new use of a treatment) with the current standard treatment
    - Expanded # of sites, can be international
    - Next step is FDA authorization
    - Can include placebo
  - Number of people taking part could be > 100- 1000s
  - Example: A Phase III Study of Apixaban in Patients With Atrial Fibrillation (AVERROES)

24

24

Phases of Clinical Trials

- **Phase 4**
  - Purpose:
    - Post marketing studies
    - Determine long term effects
  - Example: Phase 4 Study of Effect of Aspirin on Flushing in DMF-Treated Subjects with Relapsing-Remitting MS

25

Question: You have approached a patient about participating in a phase 1 clinical trial studying a new drug developed to reduce neuropathy from diabetes.

The patient asks
"Well does it work? How strong is the dose?"
You say:

26

27

Different types of trial sponsors

- Investigator initiated trials (IIT or IST)
  - Could be funded by grants or pharmaceuticals
- Pharmaceutical sponsored trials
- Cooperative group trials – in oncology includes national cancer institute (NCI) sponsored cooperative groups like ALLIANCE, ECOG, NRG, ETCTN

28

Clinical Trial Documents/Resources

- Protocol
  - Includes eligibility criteria
  - Schedule of Events
- Informed consent
- Assessment of adverse events (CTCAE)
- Investigator brochure

29

What is a Protocol?

- Document that provides road map to your study
- The reason for doing the trial
- How many people are needed for the trial
- Any drugs or other treatments that will be given, how they will be given, the dose, and how often
- What medical tests will be done and how often
- What types of information will be collected about the people taking part (blood, tissue, questionnaires)
- Specifics on concomitant medications
- Ensures study is conducted appropriately and consistently across team members and sites
- Ensures safety of study subjects and integrity of data generated

30

Schedule of Events

Table 7-2 Multiple Dose/Dose Escalation Treatment Time and Events Schedule Cycle 1

	Dose-Escalation Phase								
	Multiple-Dose Treatment (28-day Cycle) Visit Day (window)								Follow-up EOS/ Early Withdrawal[2]
Study Procedure	1[1]	2	4 (± 2 days)	10 (± 2 days)	16 (± 2 days)	17 (± 2 days)	24 (± 2 days)	28 (± 2 days)	Variable
Assess vital signs[3,4]	X	X	X	X	X	X	X	X	X
Abbreviated physical examination[5]	X				X			X	X
Clinical laboratory sample collection[6]	X	X	X	X	X		X	X	X
Obtain 12-lead (supine) electrocardiogram[7]	X								X
Ophthalmologic Evaluation[8]	X								X
Urine pregnancy test	X								X
Collect peripheral blood pharmacodynamic samples[9]	X								X
Review concomitant medications and adverse events	X	X	X	X	X	X	X	X	X
Administer [redacted] in clinic[10]	X				X	X			
Collect blood pharmacokinetic samples[11]	X	X			X	X			
Collect blood samples for metabolic profiling	X	X			X	X			
Drug accountability[12]	X				X			X	X
Urinalysis									X

Abbreviations: EOS = End-of-Study; PK = pharmacokinetic;

[1] Subjects will be leave after the 8 hour PK blood sample is taken. Subjects will return the following day for the 24 hour PK blood sample.

[2] The Follow-Up Period will consist of an EOS/Early Withdrawal visit to occur within ~2 weeks after the last dose of study drug or as soon as possible after early withdrawal for those subjects who discontinue.

[3] Approximately 10 mL of blood will be collected for safety laboratory tests. Hematology: white blood cell count with differential, hemoglobin, hematocrit, platelet count, red blood cell count, mean corpuscular volume, mean corpuscular hemoglobin, and mean corpuscular hemoglobin concentration; Serum Chemistry: albumin, alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase, blood urea nitrogen, bicarbonate, calcium (albumin corrected), chloride, creatinine, glucose, lactate dehydrogenase, phosphorus, potassium, sodium, total bilirubin, magnesium, uric acid, and total protein.

[4] Study drug will be administered by study site staff after predose procedures have been completed.

Schedule of Events

Eligibility Criteria

- Outlined in protocol
- Disease type
- Number of allowed prior treatments
- ECOG performance status / Karnofsky status
- Allowed comorbidities
- Laboratory requirements
- Allowed concomitant medications or therapies

ECOG Performance Status / Karnofsky status

34

Informed Consent

- Signed by the patient prior to any study procedures
- Patient is provided a copy & has time to review it prior to signing
- Details purpose/goal of study, study treatment/alternatives to study treatment, tests/procedures involved, potential risks/benefits, how long study follow-up will be, any tissue/blood samples that will be collected
- Written in approachable language
- Written in patient's primary language

35

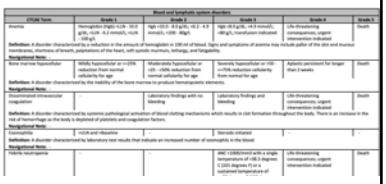
Adverse Events

- Definition: any change in patient's condition from the day protocol treatment began, regardless of cause
- Protocol includes specifics on dose modifications based on specific adverse events and how severe the adverse events are
- Use CTCAE (Common Terminology Criteria for Adverse Events) as standard to grade severity of side effects.
- CTCAE is organized by organ system.
- Determine relationship to study treatment (unrelated, unlikely, possible, probably, definitely) and clinical significance (did you have to take action?)

36

CTCAE

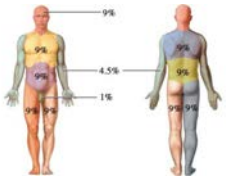
- Grade 1 Mild
- Grade 2 Moderate
- Grade 3 Severe or medically significant but not immediately life-threatening
- Grade 4 Life-threatening consequences
- Grade 5 Death related to AE



37

37

Using CTCAE - Example



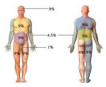
- Patient AB is participating in a clinical trial studying a new drug to prevent diabetes related neuropathy.
- AB presents on the first day of the next cycle with labs for evaluation per protocol.
- They report since starting the drug they have a new rash.
- What to do?

"Determining Total Body Surface Area." https://www.health.state.mn.us/communities/ep/surge/burn/tbsa.html. 18 May 2023

38

38

Using CTCAE - Example



- Rash covers chest. It is an erythematous papular rash.
- AB reports that the rash is not bothersome and they have not tried anything on it.

Infections and infestations					
CTCAE Term	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Papulopustular rash	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; IV antibiotics indicated	Life-threatening consequences	Death

Definition: A disorder characterized by an eruption consisting of papules (a small, raised pimple) and pustules (a small pus filled blister), typically appearing in face, scalp, and upper chest and back. Unlike acne, this rash does not present with whiteheads or blackheads, and can be symptomatic, with itchy or tender lesions.
Navigational Note: -

39

Using CTCAE

- Based on CTCAE, grade 1 rash.
- Next steps, is it related to study drug?
- Management?

Infections and infestations

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Navigational Note: -

40

Investigator Brochure

- Document that outlines information about investigational agent
- Results of previous studies in which the investigational agent was used
- Often includes studies in humans, animals, and cell lines
- Has information on previously identified adverse events
- Great resource to reference when determining causality of adverse event

41

42

Regulatory and Administrative Details

- Multiple Levels of Review
  - PRC (Scientific Review Committee)
  - NC TRACS/ GCRC (General Clinical Research Center)
  - IRB (Institutional Review Board)
  - NIH Office of Extramural Research
  - FDA - IND
  - Institutional Administrative Review
    - Financial, legal, logistical

43

Clinical Trial Team – Principal Investigator

- Principal Investigator (PI) has ultimate responsibility for the team's performance on the:
  - Science
  - Integrity of the research
  - Business operations
- Understands and follows the protocol as approved by the IRB
- Follows all applicable federal, state and institutional regulation
- PI responsibilities are stated in the FDA regulations
- PI can delegate responsibilities to clinical trials study team
  - Study team does day-to-day functions involved in a clinical trial
  - PI ultimately is responsible for the research and actions of the study team

44

Who are the other players?

- ***Sponsor:*** An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial.
- ***Investigator:*** A person responsible for the conduct of the clinical trial at a trial site.
- ***Sponsor-investigator:*** An individual who both initiates and conducts, alone or with others, a clinical trial.
- ***Clinical Research Nurse***
- ***Study Coordinator***
- ***Data manager or CRA***
- ***Regulatory***

45

Diversity in Clinical Trials

- Difference in response to medical products has been observed in racially and ethnically distinct subgroups by the US population. Could be related to intrinsic factors (e.g., genetics, metabolism, elimination), extrinsic factors (e.g., diet, environmental exposure, sociocultural)[1]
- Factors that affect risk and likelihood of developing a disease, long-term health outcome and responding to treatment include: age, biological sex, pregnancy status, life experiences, substance use, educational/employment opportunities, adequate sleep, diet, physical activity, pollution, access to health care

46

Diversity in Clinical Trials

- Clinical trials should be inclusive of racial and ethnic minority groups.
- Clinical trials should be inclusive of populations experiencing health disparities, sexual and gender minority groups, socioeconomically disadvantaged populations
- Participants in trials should represent the populations that will use the medical devices

47

Lack of Diversity in Clinical Trials

- FDA summary report of clinical trials between 2015 and 2019 shows that non-Hispanic white populations compose 78 percent of participants enrolled in U.S. trial sites, though they comprise 61 percent of the country's population.[1]
- Majority of women participating in clinical trials in the United States are white women (78 percent between 2015 and 2019). Trials routinely exclude pregnant and lactating individuals.[1]
- 30 vaccine trials from 2011 to 2020 indicated that white participants often are overrepresented, while Black and other minorities tend to be underrepresented.[2]
- Only about 12.1 percent of participants in these vaccine trials were over 65 years of age.[2]

48

Why is there a lack of diversity in clinical trials?[1]

- Mistrust
- Lack of comfort with trial process
- Lack of information about clinical trials
- Time and resource constraints associated with participation
- Lack of awareness about the existence/importance of clinical trials

- For older adults, participation is diminished due to eligibility criteria, concern for toxicity/patient age, transportation limitations, patient knowledge limitations, burden of time with participation

49

49

Diversity in Clinical Trials

- Previous events have contributed to mistrust in clinical research
- U.S. Public Health Service Syphilis Study at Tuskegee between 1932-1972
  - No informed consent conducted outlining study's risks
  - Study population was African American men
  - Withheld penicillin to treat syphilis (available in 1945) to study the disease untreated
  - Resulted in creation of Belmont Report in 1976 which details ethical principles and guidelines to protect research participants
- Members of Havasupai Tribe in Northern Arizona gave DNA samples for diabetes research (early 1990s)
  - Learned samples were used to study ethnic migration, schizophrenia, other genetic markers
  - Not included in informed consent

50

50

Efforts to Improve Diversity in Clinical Trials

- NIH Revitalization Act of 1993 passed to establish guidelines for the inclusion of women and persons from racial & ethnic minority populations in clinical research
- NIH Research Conditions and Disease Categorization Inclusion Statistics Report provides data on participants in NIH studies by race, ethnicity, sex/gender
- NIH updated policy on inclusion of women and people from racial and ethnic minority populations now requiring results of analyses by sex/gender, race, ethnicity be submitted to clinicaltrials.gov
- Now have sexual orientation and gender identity questions as part of health care questionnaires
- Effort to include people with different socioeconomic statuses in trials

51

51

Efforts to Improve Diversity in Clinical Trials

FDA has issued recommendations for enhancing diversity in trials

- Scrutiny regarding eligibility criteria
  - Don't use template eligibility
  - Consider allowing mild organ dysfunction (heart function)
  - As excretory/metabolic pathways, DDI become available, expand eligibility with less exclusions related to conmeds/comorbidities
- Identify drug metabolism/excretion across different populations early in development
- Consider additional testing in women who become pregnant during trial to assess safety in pregnancy
- Make participation less burdensome (virtual visits, health tools at home)
- Engage with patient advocacy groups early on in drug development
- Varying recruitment techniques (social media, social groups)

52

52

Diversity in Clinical Trials

TABLE B-1 Demographics of Participants in Trials Supported by NIH Centers and Institutes

	2013 (%)	2014 (%)	2016 (%)	2017 (%)	2018 (%)
Female	44.3	47.2	54.1	47.0	52.4
American Indian	2.1	1.3	0.8	0.7	1.0
Asian	15.1	17.2	8.4	26.4	7.8
Black/African American	12.2	14.3	10.0	10.8	13.5
Native Hawaiian/Pacific Islander	0.3	0.3	0.6	0.1	0.2
White	52.9	49.5	49.6	49.9	60.0
More than 1 race	1.1	1.1	2.0	1.9	2.3
Unknown race	1.1	1.1	2.0	1.9	2.3
Hispanic	9.8	8.1	10.8	6.7	8.5
Non-Hispanic	86.1	89.6	62.6	81.8	76.2
Unknown ethnicity	4.1	2.3	22.4	9.8	12.0
Sum of all races	84.7	84.8	73.5	91.8	87.2
Sum of all ethnicities	100.0	100.0	95.8	98.3	96.7

Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups.
National Academies of Sciences, Engineering, and Medicine; Policy and Global Affairs; Committee on Women in Science, Engineering, and Medicine; Committee on Improving the Representation of Women and Underrepresented Minorities in Clinical Trials and Research; Bibbins-Domingo K, Helman A, editors.
Washington (DC): National Academies Press (US); 2022 May 17.

53

53

Expanding on Phase I Studies

- First evaluation of a new therapy in humans (FIH)
- Objectives:
  - Identify dose-limiting toxicities (DLT)
  - Identify the maximum tolerated dose (MTD)
  - Assess pharmacokinetics (drug metabolism and clearance)
- Typical starting dose = 1/10th the LD_{10} in mice
- Dose and escalation scheme are a balance between safety and speed
- Eligibility in cancer patients: patients with advanced malignancy refractory to standard therapy or for which no effective therapy exists

54

Standard Dose Escalation Design

- Modified Fibonacci
  - Italian Mathematician and Number Theorist
  - Percent increase in dose decreases as dose levels increase
  - Increase dose by 100%, 67%, 50%, 40%, 33% etc
  - 10mg, 20mg, 33mg, 49mg, 69mg, 92 mg
- 3-6 patients per cohort.
  - If no toxicity in first 3, proceed to the next dose level.
  - If 1 DLT, expand to 6.
  - If >1 DLT out of 3-6, then stop.
  - DLT = Toxicity or toxicities that, due to their severity or their duration, are considered to be unacceptable

55

Maximum Tolerated Dose

- Inconsistently defined. Either:
  - Dose at which ≥ 33% of patients experience unacceptable toxicity (DLT in ≥ 2 of 3, or ≥ 2 of 6) or
  - 1 dose level below that
- MTD = Dose with DLT (in Europe and Japan)
- MTD: 1 level below DLT (in U.S.)
- 6 - 10 patients treated at the recommended Phase II dose (MTD or 1 dose level below)

56

Pharmacokinetics
"what the body does to the drug"

- Mathematical description of the behavior of drug and metabolites
- Provides information on:
  - Absorption (if oral drug)
  - Distribution into compartments
  - Metabolism
  - Excretion
- Variability within and between patients

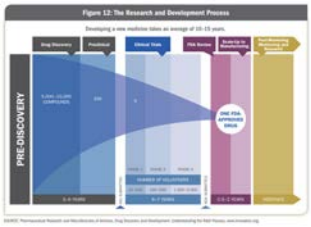
57

Pharmacodynamics
"what the drug does to the body"

- Both toxic and therapeutic response
- Variables to consider
  - Peak effect, time to effect, duration of effect
  - Response, TTP, survival, serum markers

58

Timeline of a new cancer therapy



59

Useful links

- CTCAE version 5:
- https://ctep.cancer.gov/protocoldevelopment/electronic_applications/docs/ctcae_v5_quick_reference_5x7.pdf
- Clinical trials database: www.clinicaltrials.gov
- CTCAE app for your phone: https://apps.apple.com/us/app/ctcae-plus/id1097838147
- Patient friendly material on clinical trials: https://www.nih.gov/health-information/nih-clinical-research-trials-you

60


Resources
National institute on Minority Health and Health Disparities. https://www.nimhd.nih.gov/resources/understanding-health-disparities/diversity-and-inclusion-in-clinical-trials.html
Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs https://www.fda.gov/media/127712/download
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Many slides borrowed from Claire Dees
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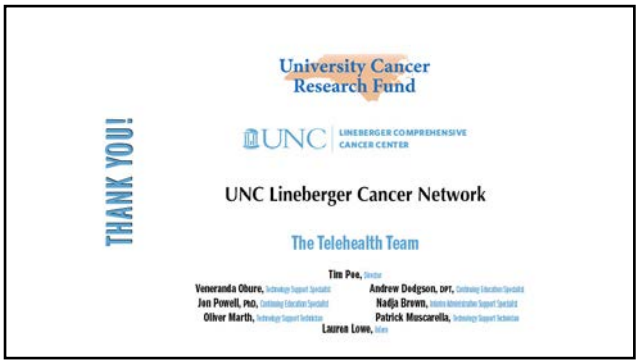
61


Questions/Comments?
Nobody has responded yet.
Hang tight! Responses are coming in.

62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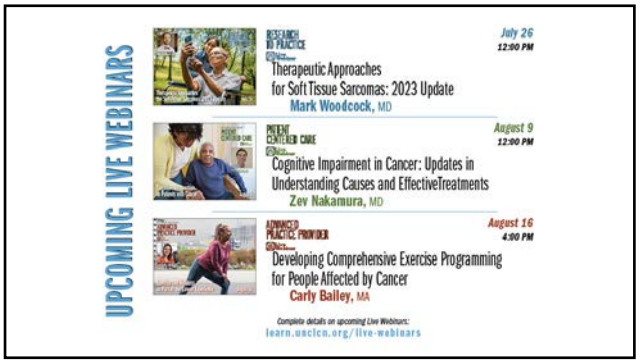
63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August 9
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Cognitive Impairment in Cancer: Updates in Understanding Causes and EffectiveTreatments
Zev Nakamura, MD
ADVANCED PRACTICE PROVIDER
August 16
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