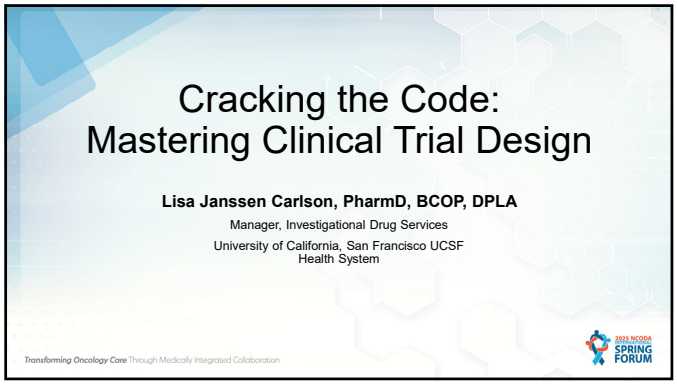
Cracking the Code:
Mastering Clinical Trial Design
Lisa Janssen Carlson, PharmD, BCOP, DPLA
Manager, Investigational Drug Services
University of California, San Francisco UCSF Health System
Transforming Oncology Care Through Medically Integrated Collaboration
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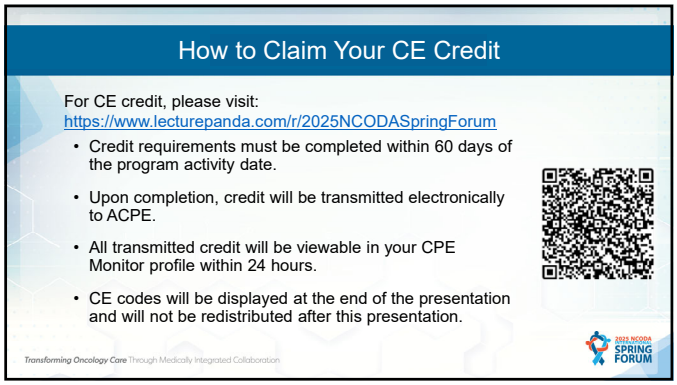
How to Claim Your CE Credit
For CE credit, please visit:
https://www.lecturepanda.com/r/2025NCODASpringForum
• Credit requirements must be completed within 60 days of the program activity date.
• Upon completion, credit will be transmitted electronically to ACPE.
• All transmitted credit will be viewable in your CPE Monitor profile within 24 hours.
• CE codes will be displayed at the end of the presentation and will not be redistributed after this presentation.
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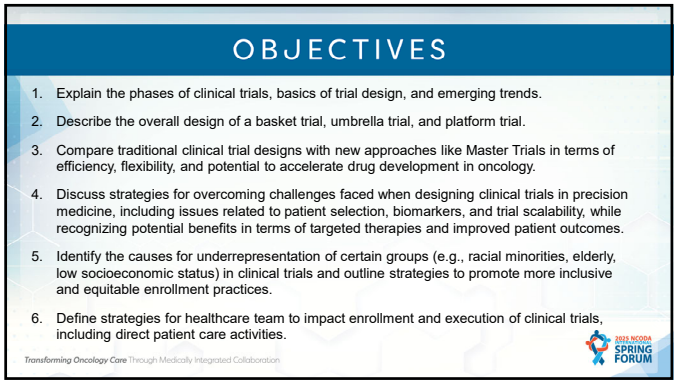
OBJECTIVES
1. Explain the phases of clinical trials, basics of trial design, and emerging trends.
2. Describe the overall design of a basket trial, umbrella trial, and platform trial.
3. Compare traditional clinical trial designs with new approaches like Master Trials in terms of efficiency, flexibility, and potential to accelerate drug development in oncology.
4. Discuss strategies for overcoming challenges faced when designing clinical trials in precision medicine, including issues related to patient selection, biomarkers, and trial scalability, while recognizing potential benefits in terms of targeted therapies and improved patient outcomes.
5. Identify the causes for underrepresentation of certain groups (e.g., racial minorities, elderly, low socioeconomic status) in clinical trials and outline strategies to promote more inclusive and equitable enrollment practices.
6. Define strategies for healthcare team to impact enrollment and execution of clinical trials, including direct patient care activities.
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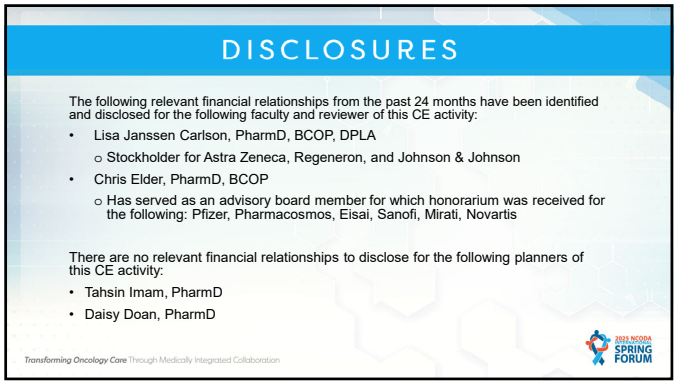
DISCLOSURES
The following relevant financial relationships from the past 24 months have been identified and disclosed for the following faculty and reviewer of this CE activity:
• Lisa Janssen Carlson, PharmD, BCOP, DPLA
o Stockholder for Astra Zeneca, Regeneron, and Johnson & Johnson
• Chris Elder, PharmD, BCOP
o Has served as an advisory board member for which honorarium was received for the following: Pfizer, Pharmacosmos, Eisai, Sanofi, Mirati, Novartis
There are no relevant financial relationships to disclose for the following planners of this CE activity:
• Tahsin Imam, PharmD
• Daisy Doan, PharmD
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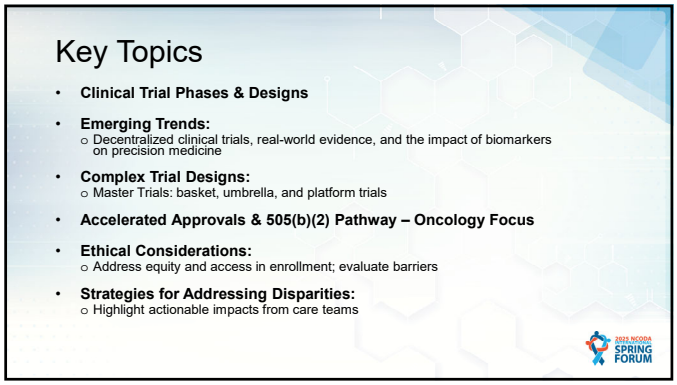
Key Topics
• Clinical Trial Phases & Designs
• Emerging Trends:
o Decentralized clinical trials, real-world evidence, and the impact of biomarkers on precision medicine
• Complex Trial Designs:
o Master Trials: basket, umbrella, and platform trials
• Accelerated Approvals & 505(b)(2) Pathway – Oncology Focus
• Ethical Considerations:
o Address equity and access in enrollment; evaluate barriers
• Strategies for Addressing Disparities:
o Highlight actionable impacts from care teams
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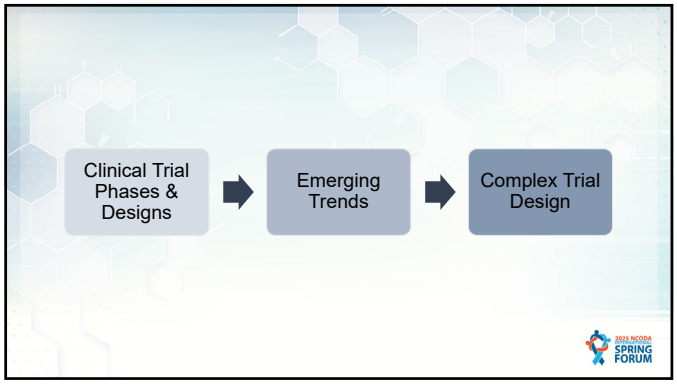
5


Clinical Trial Phases & Designs
Emerging Trends
Complex Trial Design
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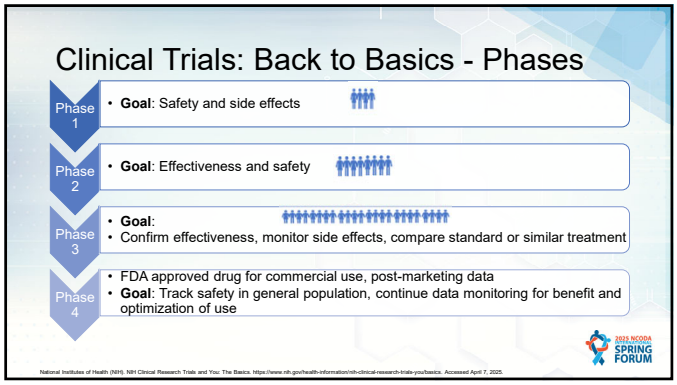
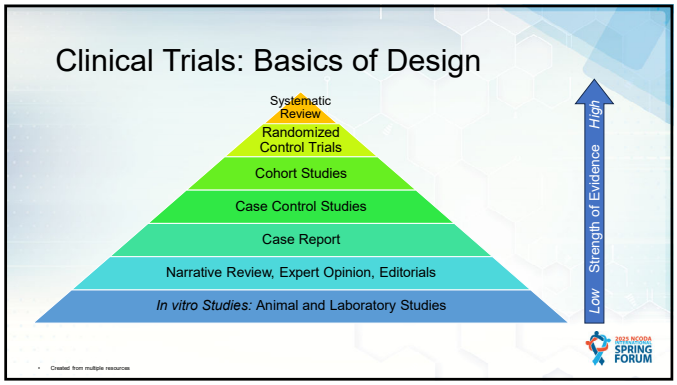
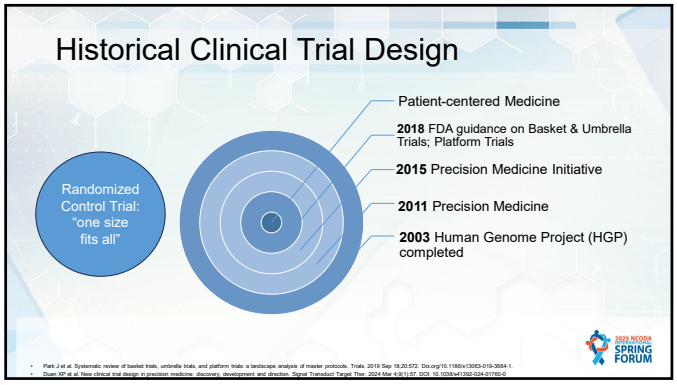

Clinical Trials: Back to Basics - Phases
Phase 1
• Goal: Safety and side effects
Phase 2
• Goal: Effectiveness and safety
Phase 3
• Goal:
• Confirm effectiveness, monitor side effects, compare standard or similar treatment
Phase 4
• FDA approved drug for commercial use, post-marketing data
• Goal: Track safety in general population, continue data monitoring for benefit and optimization of use
National Institutes of Health (NIH). NIH Clinical Research Trials and You: The Basics. https://www.nih.gov/health-information/nih-clinical-research-trials-you/basics. Accessed April 7, 2025.

7


Clinical Trials: Basics of Design
Systematic Review
Randomized Control Trials
Cohort Studies
Case Control Studies
Case Report
Narrative Review, Expert Opinion, Editorials
In vitro Studies: Animal and Laboratory Studies
Low
Strength of Evidence
High
Created from multiple resources

8


Historical Clinical Trial Design
Randomized Control Trial: "one size fits all"
Patient-centered Medicine
2018 FDA guidance on Basket & Umbrella Trials; Platform Trials
2015 Precision Medicine Initiative
2011 Precision Medicine
2003 Human Genome Project (HGP) completed
Park J et al. Systematic review of basket trials, umbrella trials, and platform trials: a landscape analysis of master protocols. Trials. 2019 Sep 18;20:572. Doi.org/10.1186/s13063-019-3664-1.
Duan XP et al. New clinical trial design in precision medicine: discovery, development and direction. Signal Transduct Target Ther. 2024 Mar 4;9(1):57. DOI: 10.1038/s41392-024-01760-0

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Emerging Trends
Biomarker Driven Enrollment
Decentralized Clinical Trials
Remote Participation
Use of Real-World Evidence
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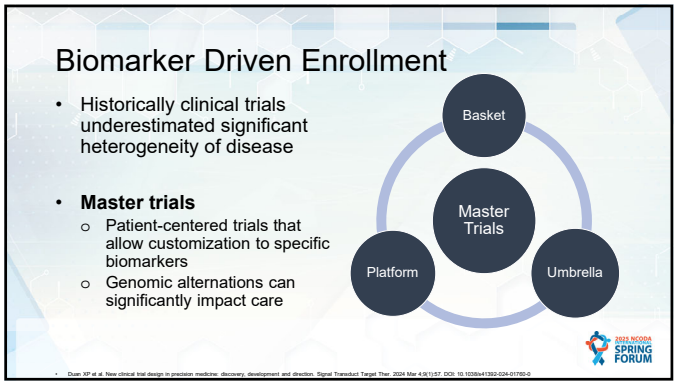
Biomarker Driven Enrollment
Historically clinical trials underestimated significant heterogeneity of disease
Master trials
Patient-centered trials that allow customization to specific biomarkers
Genomic alternations can significantly impact care
Basket
Master Trials
Platform
Umbrella
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Duan XP et al. New clinical trial design in precision medicine: discovery, development and direction. Signal Transduct Target Ther. 2024 Mar 4;9(1):57. DOI: 10.1038/s41392-024-01760-0

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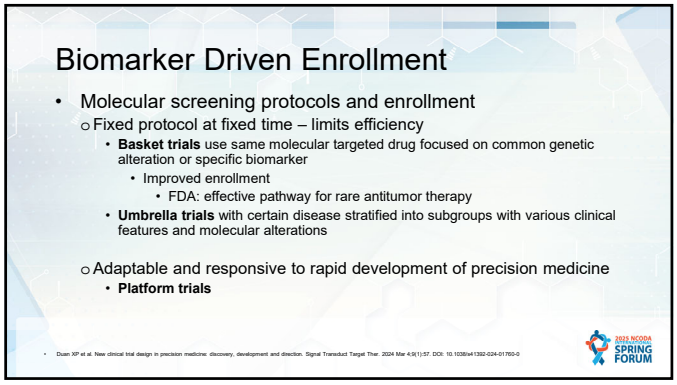
Biomarker Driven Enrollment
Molecular screening protocols and enrollment
Fixed protocol at fixed time – limits efficiency
Basket trials use same molecular targeted drug focused on common genetic alteration or specific biomarker
Improved enrollment
FDA: effective pathway for rare antitumor therapy
Umbrella trials with certain disease stratified into subgroups with various clinical features and molecular alterations
Adaptable and responsive to rapid development of precision medicine
Platform trials
2025 NCODA SPRING FORUM
Duan XP et al. New clinical trial design in precision medicine: discovery, development and direction. Signal Transduct Target Ther. 2024 Mar 4;9(1):57. DOI: 10.1038/s41392-024-01760-0

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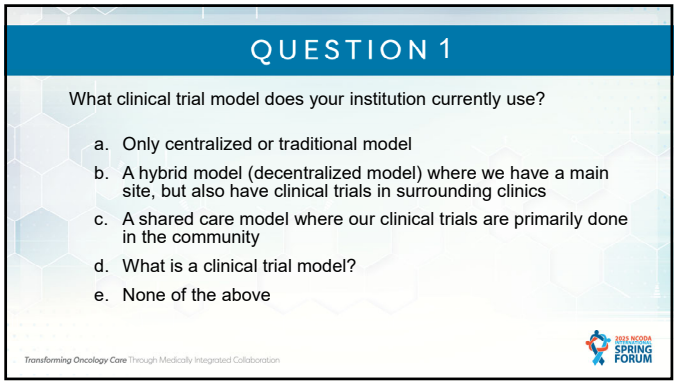
QUESTION 1
What clinical trial model does your institution currently use?
a. Only centralized or traditional model
b. A hybrid model (decentralized model) where we have a main site, but also have clinical trials in surrounding clinics
c. A shared care model where our clinical trials are primarily done in the community
d. What is a clinical trial model?
e. None of the above
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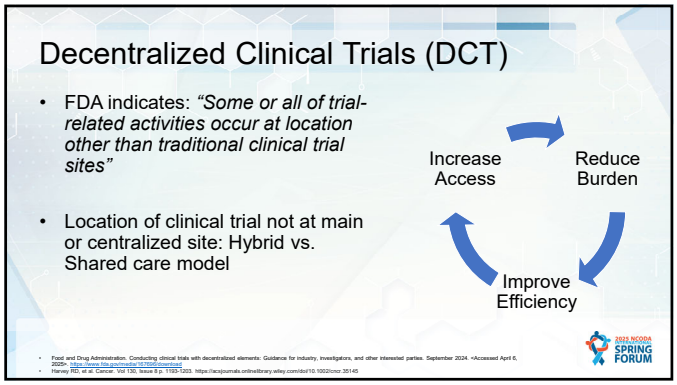
Decentralized Clinical Trials (DCT)
• FDA indicates: "Some or all of trial-related activities occur at location other than traditional clinical trial sites"
• Location of clinical trial not at main or centralized site: Hybrid vs. Shared care model
Increase Access
Reduce Burden
Improve Efficiency
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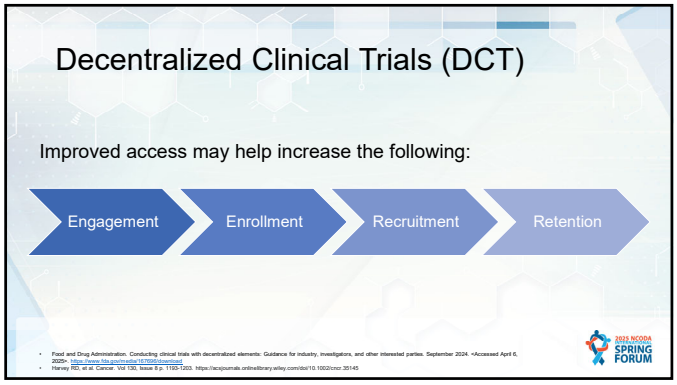
Decentralized Clinical Trials (DCT)
Improved access may help increase the following:
Engagement
Enrollment
Recruitment
Retention
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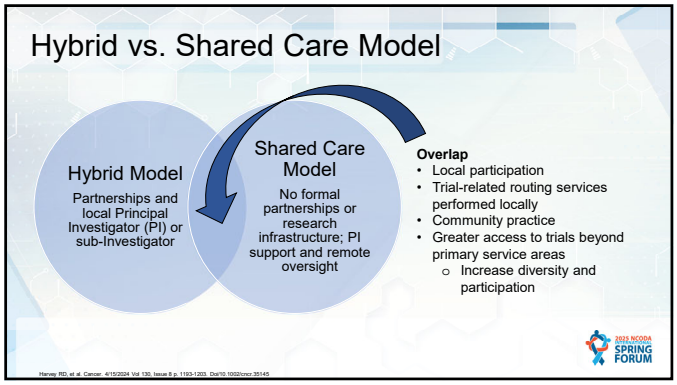
Hybrid vs. Shared Care Model
Hybrid Model
Partnerships and local Principal Investigator (PI) or sub-Investigator
Shared Care Model
No formal partnerships or research infrastructure; PI support and remote oversight
Overlap
• Local participation
• Trial-related routing services performed locally
• Community practice
• Greater access to trials beyond primary service areas
o Increase diversity and participation
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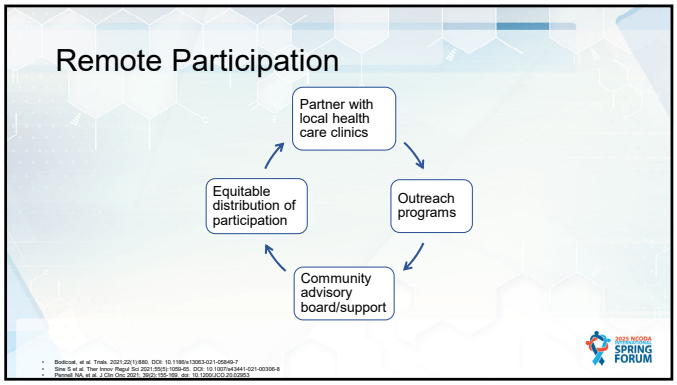
Remote Participation
Partner with local health care clinics
Outreach programs
Community advisory board/support
Equitable distribution of participation
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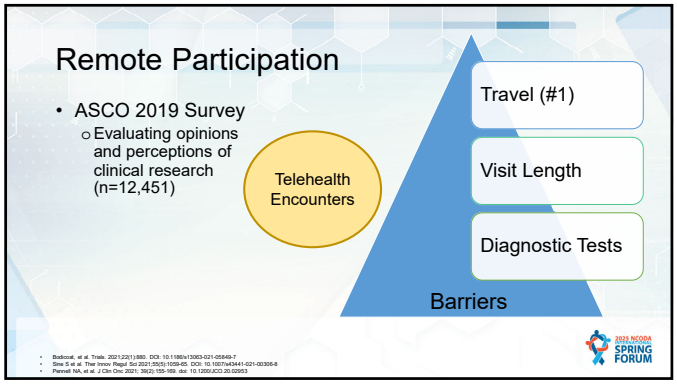
Remote Participation
• ASCO 2019 Survey
o Evaluating opinions and perceptions of clinical research (n=12,451)
Telehealth Encounters
Travel (#1)
Visit Length
Diagnostic Tests
Barriers
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Use of Real-World Evidence

- Utilization of mutation subtypes of enrolled patients must be a balanced approach
  - Overly strict screening → slow enrollment
  - Excessively broad filter → reduce overall effective of treatment
- Many clinical trial have begun enrolling patients based on genetic phenotype or developing standardized biomarker-guided treatment

- Duan ZP et al. Signal Transduction Target Therapy. 2024 Mar 4;9(1):57. doi: 10.1038/s41392-024-01760-0.
- Liu R, et al. Nature. 2021 April ; 592(7855): 629–633. doi:10.1038/s41586-021-03430-5.
- Microsoft Stock Icon

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Use of Real-World Evidence

- Utilization of Artificial Intelligence (AI) has demonstrated strategies to allow more patients to benefit from treatment
  - Broadening restrictive criteria
  - Using data-driven methodology for evaluating eligibility criteria
  - Maintaining safeguards for patient safety
- Enhancing inclusivity may result in more diverse populations better representing real-world populations impacted by disease

	Women	Male	Age >75	White	Black	Other Races/Missing
Original Trial Criteria	44.8%	55.2%	28.3%	70%	9.1%	20.9%
Data-driven Criteria	**46.9%**	53.1%	**28.9%**	**70.2%**	**9.4%**	20.4%

- Duan ZP et al. Signal Transduction Target Therapy. 2024 Mar 4;9(1):57. doi: 10.1038/s41392-024-01760-0.
- Liu R, et al. Nature. 2021 April ; 592(7855): 629–633. doi:10.1038/s41586-021-03430-5.

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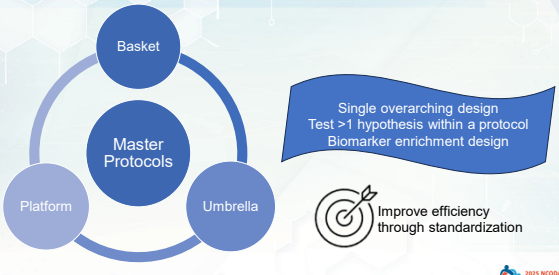
Clinical Trial Designs



Single overarching design
Test >1 hypothesis within a protocol
Biomarker enrichment design

Improve efficiency through standardization

- Park J, et al. Trials. 2019 Sep 18;20:572. doi: 10.1186/s13063-019-3664-1.

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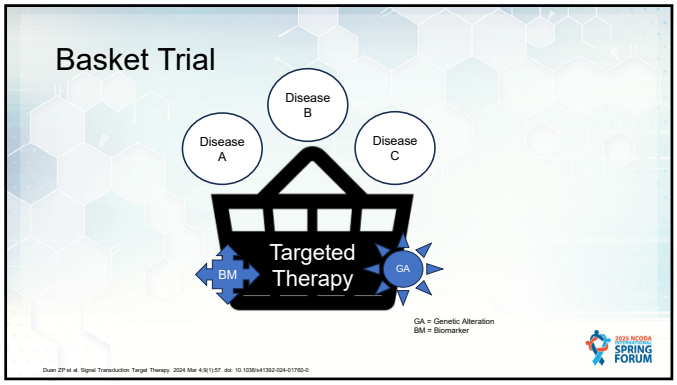
Basket Trial
Disease B
Disease A
Disease C
Targeted Therapy
BM
GA
GA = Genetic Alteration
BM = Biomarker
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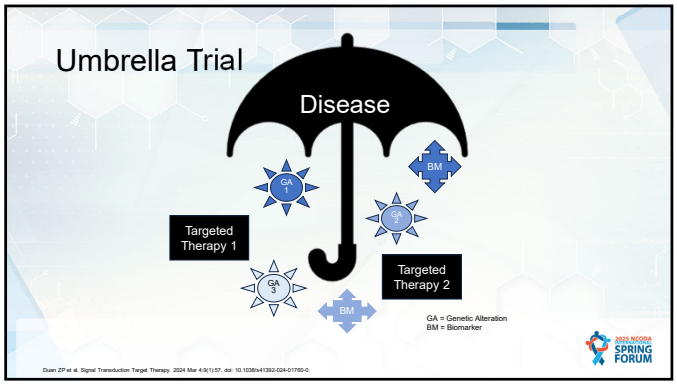
Umbrella Trial
Disease
BM
GA 1
GA 2
GA 3
Targeted Therapy 1
Targeted Therapy 2
BM
GA = Genetic Alteration
BM = Biomarker
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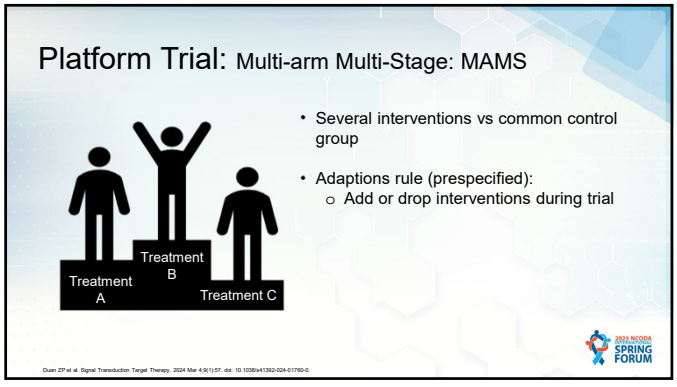
Platform Trial: Multi-arm Multi-Stage: MAMS
Several interventions vs common control group
Adaptions rule (prespecified):
Add or drop interventions during trial
Treatment A
Treatment B
Treatment C
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Platform Trial: I-SPY

- Neoadjuvant and personalized adaptive clinical trial for locally advanced breast cancer
  - Newly diagnosed stage 2 or 3 invasive breast cancer
- Improved treatment regimens for specific breast cancer subtypes
  - Novel drugs in combo with standard chemo
- UCSF consortium study

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- UCSF, University of California San Francisco.
- UCSF. https://ispy2.ucsf.edu/ and clinicaltrials.gov/ct2/show/NCT01042379. Accessed April 9, 2025.

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QUESTION 2

Master trials include basket, umbrella and platform designs: which match correctly reflects the clinical trial design?

a. Platform trials – adaptable, continuous screening
b. Umbrella trials – multiple diseases, one targets
c. Basket trial – multiple targets, one disease
d. Master protocols – evaluates one hypothesis at a time

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Comparing Trial Designs

	Traditional	Master Protocol		
		Basket	Umbrella	Platform
Efficiency	Single disease state	Multiple disease states evaluated at same time	Single disease Multiple populations or targets	Multiple treatments Adapts at interim analysis, continuous screening
Flexibility	Arms are set once study initiated	Evaluation of treatment for multiple diseases	Looking at variety of treatments Patient factors	Add or remove arm
Approval Process	Years to get results for single patient population for specific disease state	Test more than one hypothesis within a protocol Accelerates drug development, especially for oncology		

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Duan ZF et al. Signal Transduction Target Therapy. 2024 Mar 4;9(1):57. doi: 10.1038/s41392-024-01760-0.

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Master Trial Design - Barriers

Master Trial	Barriers
Basket Trial	• Heterogeneity of disease complicates efficacy analysis • Statistical design challenges in pooling or interpreting diverse data • Regulatory hesitancy to approve generalized findings • Weak or unclear biological rationale for cross-indication treatment

- Park J et al. Systematic review of basket trials, umbrella trials, and platform trials: a landscape analysis of master protocols. Trials. 2019 Sep 18;20:572. Doi.org/10.1186/s13063-019-3664-1.
- Duan XP et al. New clinical trial design in precision medicine: discovery, development and direction. Signal Transduct Target Ther. 2024 Mar 4;9(1):57. DOI: 10.1038/s41392-024-01760-0

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Master Trial Design - Barriers

Master Trial	Barriers
Umbrella Trial	• Requires validated biomarkers and rapid testing methods • Screening large numbers of patients is time-consuming and costly • Complex logistics to manage multiple interventions concurrently • Difficult to adapt quickly when standards of care evolve

- Park J et al. Systematic review of basket trials, umbrella trials, and platform trials: a landscape analysis of master protocols. Trials. 2019 Sep 18;20:572. Doi.org/10.1186/s13063-019-3664-1.
- Duan XP et al. New clinical trial design in precision medicine: discovery, development and direction. Signal Transduct Target Ther. 2024 Mar 4;9(1):57. DOI: 10.1038/s41392-024-01760-0

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Master Trial Design - Barriers

Master Trial	Barriers
Platform Trial	• High operational and statistical complexity • Requires advanced infrastructure and ongoing data monitoring • Long-term funding and coordination from multiple sponsors • Frequent protocol amendments may pose regulatory delays

- Park J et al. Systematic review of basket trials, umbrella trials, and platform trials: a landscape analysis of master protocols. Trials. 2019 Sep 18;20:572. Doi.org/10.1186/s13063-019-3664-1.
- Duan XP et al. New clinical trial design in precision medicine: discovery, development and direction. Signal Transduct Target Ther. 2024 Mar 4;9(1):57. DOI: 10.1038/s41392-024-01760-0

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Accelerated Approvals & New Drug Application 505(b)(2) Pathway

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Accelerated Drug Approvals

- Master trials allow for more efficient patient recruitment
  - **Platform**: adaptive randomization, continuous enrollment
- Faster evidence generation using shared infrastructure
  - **Basket**: rapid identification of responsive subgroup across different cancer types, parallel data collection
  - **Umbrella**: replace multiple single-arm studies

Duan XP et al. New clinical trial design in precision medicine: discovery, development and direction. Signal Transduct Target Ther. 2024 Mar 4;9(1):57. DOI: 10.1038/s41392-024-01760-0

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Accelerated Drug Approvals

- Potential for early conditional approval (Platform)
  - Use of surrogate endpoints
    - Response rate
    - Progression-free survival
- Facilitates precision medicine approvals where large randomized control trials are not feasible

Duan XP et al. New clinical trial design in precision medicine: discovery, development and direction. Signal Transduct Target Ther. 2024 Mar 4;9(1):57. DOI: 10.1038/s41392-024-01760-0

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505(b)(2) Pathway: "Hybrid" New Drug Application (NDA)

- NDA that contains full safety and effectiveness reports, but some of the information comes from studies not conducted by or for the applicant
  - Part original, part referenced
- Faster, lower cost verses full NDA
- 3-year market exclusivity

U.S. Food and Drug Administration. Applications Covered by Section 505(b)(2). Published April 27, 2020. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applications-covered-section-505b2. Accessed April 6, 2025.

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505(b)(2) Pathway: "Hybrid" New Drug Application (NDA)

Used for the following:

- New dosage form, route or strength
- New combination of approved drugs
- Already approved drug with a new indication
- Uses a new formulation or delivery method
- Has undergone a change in active ingredient salt or ester
- Seeks repurposing of an existing drug (e.g., for a different condition)

U.S. Food and Drug Administration. Applications Covered by Section 505(b)(2). Published April 27, 2020. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applications-covered-section-505b2. Accessed April 6, 2025.

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FDA Approval Pathways

Feature	505(b)(1) NDA	505(b)(2) NDA	505(j) *ANDA (Generic) (*abbreviated)
Data required	Full new studies	Partial new, partial existing	No new data
Reliance on other sources	No	Yes	Yes (already approved Reference Listed Drug (RLD))
Clinical trials needed	Yes	Sometimes	No (bioequivalence only)
Use cases	New molecular entities	Reformulations, new indications, delivery methods	Generics

U.S. Food and Drug Administration. Applications Covered by Section 505(b)(2). Published April 27, 2020. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applications-covered-section-505b2. Accessed April 6, 2025.

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QUESTION 3

Which statement is false about the FDA New Drug Application (NDA) process 505(b)(2)?

a. Allows for an accelerated approval
b. Can utilize partial data (new or existing) for approval
c. Always requires clinical trials
d. Referred to as a "hybrid" NDA
e. Can be used for new combination of approved drugs

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Ethical Considerations & Strategies for Addressing Disparities In Clinical Trials

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Historical Ethical Concerns

Obermeyer Z, et al. Science 25 Oct 2019 Vol 366, Issue 6464 pp. 447-453 DOI: 10.1126/science.aax2342

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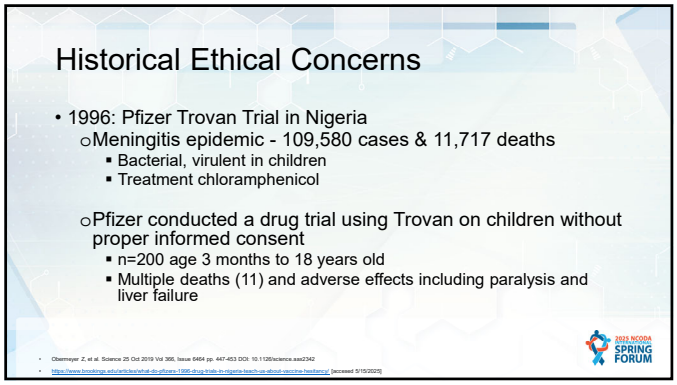
Historical Ethical Concerns
• 1996: Pfizer Trovan Trial in Nigeria
oMeningitis epidemic - 109,580 cases & 11,717 deaths
▪ Bacterial, virulent in children
▪ Treatment chloramphenicol
oPfizer conducted a drug trial using Trovan on children without proper informed consent
▪ n=200 age 3 months to 18 years old
▪ Multiple deaths (11) and adverse effects including paralysis and liver failure
Obermeyer Z, et al. Science 25 Oct 2019 Vol 366, Issue 6464 pp. 447-453 DOI: 10.1126/science.aax2342
https://www.brookings.edu/articles/what-do-pfizers-1996-drug-trials-in-nigeria-teach-us-about-vaccine-hesitancy/ [accessed 5/15/2025]
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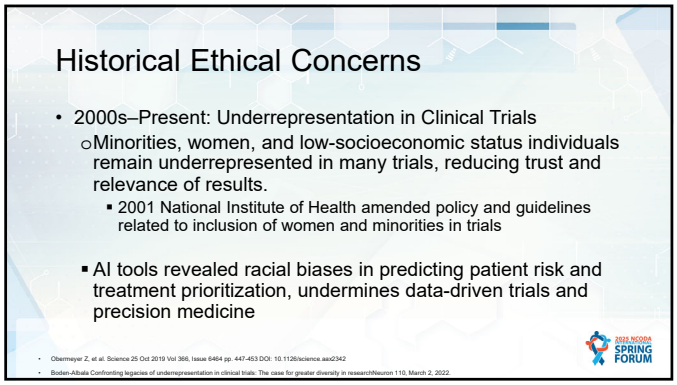
Historical Ethical Concerns
• 2000s–Present: Underrepresentation in Clinical Trials
oMinorities, women, and low-socioeconomic status individuals remain underrepresented in many trials, reducing trust and relevance of results.
▪ 2001 National Institute of Health amended policy and guidelines related to inclusion of women and minorities in trials
▪ AI tools revealed racial biases in predicting patient risk and treatment prioritization, undermines data-driven trials and precision medicine
Obermeyer Z, et al. Science 25 Oct 2019 Vol 366, Issue 6464 pp. 447-453 DOI: 10.1126/science.aax2342
Boden-Albala Confronting legacies of underrepresentation in clinical trials: The case for greater diversity in researchNeuron 110, March 2, 2022.
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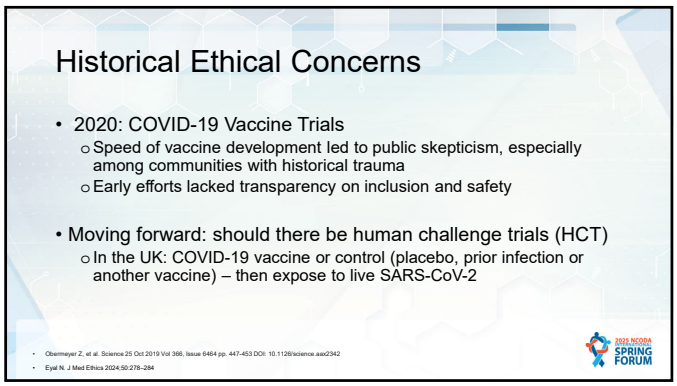
Historical Ethical Concerns
• 2020: COVID-19 Vaccine Trials
o Speed of vaccine development led to public skepticism, especially among communities with historical trauma
o Early efforts lacked transparency on inclusion and safety
• Moving forward: should there be human challenge trials (HCT)
o In the UK: COVID-19 vaccine or control (placebo, prior infection or another vaccine) – then expose to live SARS-CoV-2
Obermeyer Z, et al. Science 25 Oct 2019 Vol 366, Issue 6464 pp. 447-453 DOI: 10.1126/science.aax2342
Eyal N. J Med Ethics 2024;50:278–284
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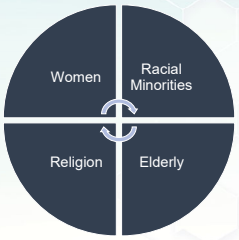
Underrepresentation of Certain Groups



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Ethical Considerations for Oncology

- Accessibility to high quality and safe care should be equitable for all including diverse and underserved populations
- Affordable for patient based on design
- Eligibility criteria not too restrictive & reflects intended population
- Leverage technology
- Overcoming barriers linked to social determinants of health
  - Religion, socioeconomic status, race, healthcare access, etc.

- Hanvey RD, et al. *Cancer*. 2024; 130(8): 1193-1203. doi:10.1002/cncr.35145
- Penned NA, et al. *J Clin Onc* 2021; 39(2):155-169. doi: 10.1200/JCO.20.00983

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Promoting Health Equitability

- Designing inclusive trials that consider cultural, social and economic factors
  - Eligibility criteria design
  - Breaking down barriers:
    - Utilization of local labs, technology (video visits/telehealth)
- Healthcare Practitioners
  - Advocate for patients
  - Implement strategies for removing barriers
  - Centralization of pharmacy services to decentralize clinical trials

Bodicoat, et al. *Trials*. 2021;22(1):880. DOI: 10.1186/s13063-021-05849-7.

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Community Practice

- Patient focused approach
  - Actively evaluating appropriate therapeutic options
    - Genetic and molecular profiles
- To address disparities and access gaps in enrollment enhance engagement and collaboration
- Increase site diversity
  - Ensuring racially and ethnically diverse staff at sites
  - Engaging and supporting healthcare professionals from all backgrounds to serve as principal investigators
    - Create networks and communities to develop skills and expertise

Wright C. Two Straightforward Ways to Improve DEI in Clinical Trials. Published December 27, 2022. https://www.appliedclinicaltrialsonline.com/view/two-straightforward-ways-to-improve-dei-in-clinical-trials. Accessed April 6, 2025.

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Overcoming Barriers in Clinical Trials

Access | Biomarkers | Patient Selection | Technology | Trial Scalability

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Actionable Ways to Promote Enrollment

- Multidisciplinary teams can educate about trials and empower patients with cancer to explore clinical trial as option
- Inclusivity
  - Flexible schedules, minimize patient burden, patient-centric trial design, utilize technology (telemedicine)
- Utilization of pharmacogenomic capabilities in the electronic medical record, work with analytics/informatics

Wright C. Two Straightforward Ways to Improve DEI in Clinical Trials. Published December 27, 2022. https://www.appliedclinicaltrialsonline.com/view/two-straightforward-ways-to-improve-dei-in-clinical-trials. Accessed April 6, 2025.

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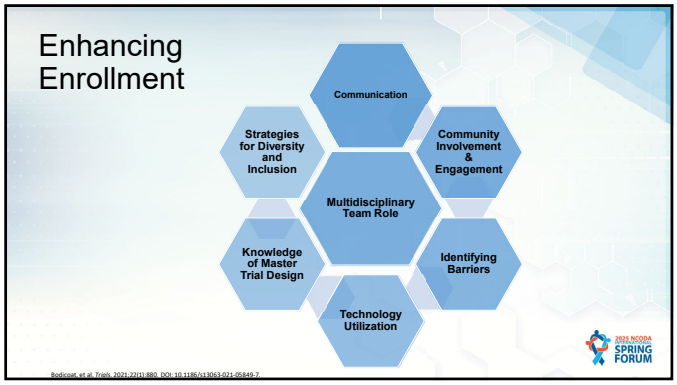
Enhancing Enrollment
Communication
Strategies for Diversity and Inclusion
Community Involvement & Engagement
Multidisciplinary Team Role
Knowledge of Master Trial Design
Identifying Barriers
Technology Utilization
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Bodicoat, et al. Trials. 2021;22(1):880. DOI: 10.1186/s13063-021-05849-7.

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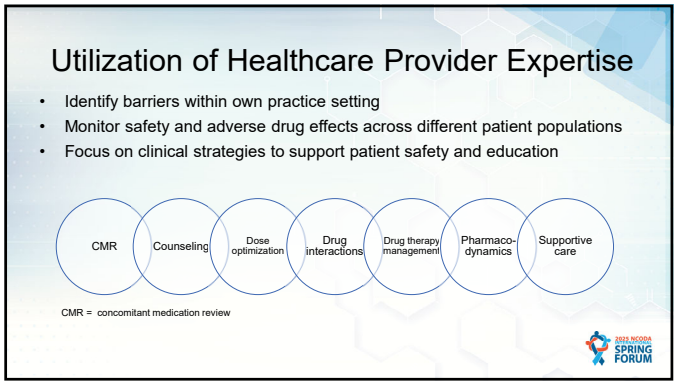
Utilization of Healthcare Provider Expertise
• Identify barriers within own practice setting
• Monitor safety and adverse drug effects across different patient populations
• Focus on clinical strategies to support patient safety and education
CMR
Counseling
Dose optimization
Drug interactions
Drug therapy management
Pharmaco-dynamics
Supportive care
CMR = concomitant medication review
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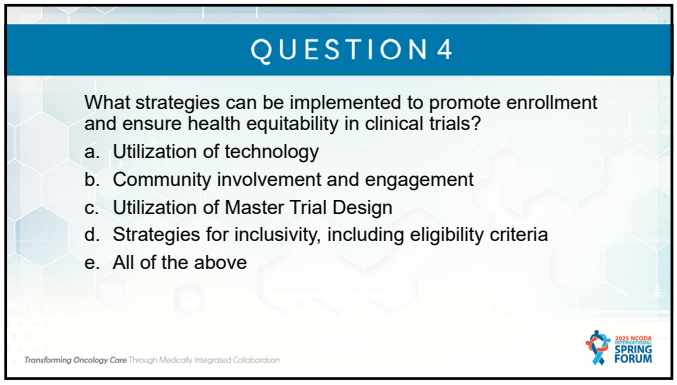
QUESTION 4
What strategies can be implemented to promote enrollment and ensure health equitability in clinical trials?
a. Utilization of technology
b. Community involvement and engagement
c. Utilization of Master Trial Design
d. Strategies for inclusivity, including eligibility criteria
e. All of the above
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SUMMARY

- Master Trial Designs:
  - Enhance reliability and validity through integration of precision medicine
  - Accelerate drug approval processes
- Individualized approach utilizing biomarkers leads to more robust data and better treatment options.
- DCTs expand access and potentially increase enrollment including more diverse patient populations.
- Incorporating real-world evidence and intentional health equity strategies addresses ethical concerns and ensures delivery of high-quality and safe care across diverse populations.
- Multidisciplinary teams play a critical role in enrollment through advocacy, patient engagement, and education, while prioritizing patient safety.

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QUESTION & ANSWER

Cracking the Code: Mastering Clinical Trial Design

Lisa Janssen Carlson, PharmD, BCOP, DPLA
Manager, Investigational Drug Services
University of California, San Francisco UCSF Health System

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CE CODES

Cracking the Code: Mastering Clinical Trial Design

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