A Team Approach to Ethical Enrollment in Acute Clinical Trials
CTSA Competency Domain #2 “Ethical and Participant Safety Considerations”
and #8 “Communication and Teamwork”
- Multidisciplinary plan for enrolling participants
- Integrate new strategies for interdisciplinary enrollment
- Assign roles in the enrollment process based on discipline

An Update on Advances in Clinical Research on Sport-Related Concussion
CTSA Competency Domain #1 “Scientific Concepts and Research Design”
- Methodological framework for sport-related concussion (SRC) research
- Latest evidence base on acute effects and recovery after SRC
- Review scientific and technological advances

An Update on Zika and Clinical Research - What You Need to Know
CTSA Competency Domain #1 “Scientific Concepts and Research Design”
- History of Zika
- Zika in clinical research

Biosimilars: What Are Their Differences to Biologics In Conducting Clinical Research?
CTSA Competency Domain #1 “Scientific Concepts and Research Design”
- Relationship between biologics and biosimilar drugs
- Regulatory considerations in Clinical Trials
- Benefits of biosimilars

Building a Successful Patient Recruitment Plan & Budget
CTSA Competency Domain #5 “Site and Study Management”
- Adopt Best Practices in patient recruitment.
- Advertising strategies incorporating tradition and social media methods.
- Pros and Cons of using traditional vs. social media methods.

CAPA Isn’t Just a Compliance Tool - Maximizing Site Performance Applying CAPA Principles
CTSA Competency Domain #5 “Site and Study Management”
- Communication techniques for more effective site interactions.
- Applying Root Cause Analysis and CAPA principles to improving site performance
- How to use Root Cause Analysis to prevent, detect, and manage performance problems.
Cloud-Based Clinical Trials - Next Generation of Research

**CTSA Competency Domain #6 “Data Management and Informatics”**
- Confirming cloud software is compliant with FDA 21 CFR Part 11.
- Pros and Cons of Cloud Computing in Clinical Research.
- Understanding data security, QA, and audit trails in the cloud.

**Conditions Impacting Consent for Clinical Research**

**CTSA Competency Domain #2 “Ethical and Participant Safety Considerations”**
- Ethics and necessities of including representative populations in research.
- Evaluating factors that can impact consent.
- Steps to improve diversity in clinical trial participation.

CRAs’ Evolving Role - How to Successfully Elevate Performance in a Transitioning Environment

**CTSA Competency Domain #8 “Communication and Teamwork”**
- Monitors/CRAs performance requirements and qualification
- Development plans for clinical trial Monitors/CRAs
- Qualification and selection of Monitors/CRAs for clinical trial programs

Digital Marketing & Social Media: Understanding the Importance of Sites Using Digital Strategies for Awareness and Enrollment

**CTSA Competency Domain #5 “Site and Study Management”**
- Strategies for working with an IRB on Social Media issues.
- Determining if IRB or Sponsor approval for social media content comes first.
- Identify consumer trends impacting research decisions.
- Determine most important documents to be signed before engaging social media.

Diversity in Clinical Trials Webinar Series - Part I: Planning for Diversity

**CTSA Competency Domain #5 “Site and Study Management”**
- Explain the scientific importance of including diverse women in clinical trials.
- Describe barriers to clinical trial participation for diverse women populations.
- Learn strategies to engage diverse women in clinical trials.

Diverse Women in Clinical Trials Webinar Series - Part II: Recruitment and Retention

**CTSA Competency Domain #5 “Site and Study Management”**
- Identify barriers to recruitment and retention of diverse women populations in clinical trials.
- Use a case study to evaluate barriers to participation in clinical trials.
- Create strategies to increase recruitment and retention of diverse women populations in clinical trials.
eConsent: New FDA/OHRP Final Guidance

*CTSA Competency Domain #3 “Medicines development and regulation”*
- Examples of eConsent approaches.
- eConsent and audit readiness.
- Effect of eConsent on recruitment, retention, and compliance.

FDA BIMO Compliance and Enforcement of Drugs and Devices

*CTSA Competency Domain #3 “Medicines development and regulation”*
- Understand the Biomedical Research monitoring program at FDA.
- Regulatory differences between CDER and CDRH.
- Best practices for FDA inspection.
- Strategies for responding to FDA 483s

How Artificial Intelligence is Revolutionizing Patient Recruitment

*CTSA Competency Domain #6 “Data Management and Informatics”*
- Understanding how Artificial Intelligence selects patients for trials.
- Compare Artificial Intelligence techniques.
- Quantify benefits of Artificial Intelligence vs. conventional methods of recruitment.

How Does the Recent ICH-GCP E6 Update Affect YOU?

*CTSA Competency Domain #3 “Medicines development and regulation”*
- Review update to ICH-GCP E6 (R2) guidelines.
- Identify effect of finalized ICH guideline on clinical trial administration.
- Identify effect of finalized ICH guideline on sponsor oversight of clinical trials.

How Informed are Your Research Participants

*CTSA Competency Domain #2 “Ethical and Participant Safety Considerations”*
- Examine trends related to participant understanding of informed consent.
- Collaborating with your IRB to measure participant understanding of consenting process.
- Interpreting quality metrics regarding site consenting process.

How to Recruit Patients Using Digital & Social Media

*CTSA Competency Domain #2 “Ethical and Participant Safety Considerations”*
- Learn why digital and social media are effective recruitment tools.
- Describe best practices for using digital and social media in clinical research.
- Determine which trials benefit from digital and social media recruitment methods.
- Implement digital and social media recruitment methods.
Improving Communication Skills to Address the Barriers of Informed Consent
**CTSA Competency Domain #2 “Ethical and Participant Safety Considerations” and #8 “Communication and Teamwork”**
- Identify communication techniques that aid in the consent process.
- Learn how information seeking behaviors affect the consent process.
- Assess how participant anxiety can affect communication.

Incorporating the Practice of Pharmacy into Clinical Research
**CTSA Competency Domain #8 “Communication and Teamwork”**
- Understanding the role of the pharmacist in patient care.
- Leveraging the pharmacist role in clinical research.
- Understanding improvements to outcomes, retention, compliance, and study data with greater pharmacist involvement in clinical research.

Investigator-Initiated Sponsored Research: Global Collaborations with Industry and Academia
**CTSA Competency Domain #1 “Scientific Concepts and Research Design”**
- Discuss trends in the biopharmaceutical and medical device industries related to independent medical research.
- Learn how government and academic researchers can request industry support for research projects.
- Learn how ACRP’s special interest group assists independent researchers in requesting industry support.

Making it Work for You. Mobile Health/Patient Engagement from the Research Site Perspective
**CTSA Competency Domain #6 “Data Management and Informatics”**
- Learn how mobile technology can improve study management and participant experience.
- Assess changes to clinical research roles to accommodate technology.
- Strategies for coordinating patient-facing technology.

Medical Cannabis Clinical Trials: What You Thought You Knew... But Didn’t
**CTSA Competency Domain #2 “Ethical and Participant Safety Considerations” and #3 “Medicines development and regulation”**
- Examine the history of medical marijuana (including stigmas).
- Learn about parts and strains of cannabis plants used medically.
- Discuss therapeutic and research applications of medical cannabis.
- Compare regulatory environments for medical cannabis between U.S. and Canada.
- Examine which types of clinical trials are appropriate for cannabis and how to conduct cannabis trials.
Medicare Coverage Analysis for Clinical Research

**CTSA Competency Domain #4 “Clinical Trials Operations” and #3 “Medicines development and regulation”**

- Identify the why and when for performing Medicare Coverage analysis.
- Understand applicable Medicare rules for clinical trials.
- Identify when services or items are covered by Medicare.
- Implementing best practices when conducting a Medicare coverage analysis.

Mentoring: A New Ship on an Uncertain Sea

**CTSA Competency Domain #7 “Leadership and Professionalism”**

- Awareness of professional development needs in clinical research staff.
- Applying training models, tools, and strategies to your specific research program.

One Size Fits All? Not for Small Sponsors and CROs

**CTSA Competency Domain #8 “Communication and Teamwork”**

- Address the challenges small CROs and small Sponsors have when working together.
- Debunk myths related to vendor management and small companies while providing practical solutions to real world problems.
- Examine how informed vendor selection and partnerships benefit both companies.

Patient Navigators in Cancer Clinical Trials

**CTSA Competency Domain #8 “Communication and Teamwork”**

- Understand the rationale of including patient navigators in Cancer trials.
- Best practices related to patient navigators in Cancer trials.
- Examine the role of patient navigator.

Protocol Deviations: Writing, Reviewing, and Reporting. What’s Important and Why?

**CTSA Competency Domain #1 “Scientific Concepts and Research Design”**

- Distinguish between prospective and retrospective protocol deviations.
- Discuss common types of protocol deviations.
- Examine tools for documenting protocol deviations.
- Recommend reporting metrics for proper management and oversight.

Recruiting and Retaining Geriatric Patients: Strategies for Success

**CTSA Competency Domain #2 “Ethical and Participant Safety Considerations”**

- Understand the importance of including geriatric patients in clinical research.
- Discuss challenges of working with geriatric patients in clinical research.
- Examine strategies to facilitate participation and retention of geriatric patients and their caregivers in clinical research.
Simple Tools for Managing Projects

*CTSA Competency Domain #4 “Clinical Trials Operations”*
- Discuss basic project management concepts.
- Apply techniques for organizing tasks and teams.
- Develop templates for project planning, controlling, monitoring, and closing.

Site Visibility: How to Increase Visibility in Your Community to Attract More Potential Trial Subjects

*CTSA Competency Domain #5 “Site and Study Management”*
- Evaluate site visibility.
- Create plan to increase visibility using out-of-the-box strategies.
- Adapt current visibility methods to your specific site.

Taking the Fear Out of an FDA Inspection

*CTSA Competency Domain #3 “Medicines development and regulation”*
- Identify forms and documents related to FDA site inspections.
- Explore strategies for responding to inspection finds.
- Review successful responses to FDA inspections.
- Best practices when responding to FDA warning letters.

The Sawyer Effect: Impacting Recruitment from a Sponsor / CRO Perspective

*CTSA Competency Domain #2 “Ethical and Participant Safety Considerations”*
- Discuss the importance of enrolling expected number of patients.
- Analyze the cause of slow and/or low recruitment from a study and site perspective.
- Understand the effect that sponsors can have on recruitment at the study and site levels.

Tips to Streamline the Ethical Review Process with Multiple IRBs

*CTSA Competency Domain #2 “Ethical and Participant Safety Considerations”*
- Identify common differences in guidelines and structures between IRBs.
- Explore solutions to regulatory challenges that do not compromise research quality.
- Analyze a case study of a single protocol being used with multiple IRBs.

Walk the Talk: Implementing Risk-Based Monitoring

*CTSA Competency Domain #4 “Clinical Trials Operations”*
- Identify project, site, and patient level risks.
- Mitigate risks and performance deficiencies using data analysis.
- Perform a risk analysis to determine if remote monitoring is appropriate during an ongoing study.
When the Doctor is the Subject

CTSA Competency Domain #2 “Ethical and Participant Safety Considerations”

- Gain insight into patient perspective as trial participant.
- Understand the value of diverse participant population in trials.
- Describe the landscape of immunotherapy trials.