

Monday, March 25

9:00AM - 5:00PM

Coverage Analysis Certification™

Forte, in collaboration with Research Matrix, is offering a 2 full-day workshop which is pre-approved for up to 16 hours of continuing education credit through SOCRA and ACRP. The workshop is specifically designed to leverage OnCore functionality to maximize the utility of OnCore billing grids, coverage analyses, and streamlining the budget development process. The workshop also includes an interactive and step-by-step tutorial to address the fundamentals of coverage analysis and workflow engineering decisions related to OnCore financials implementation through the clinical research budgeting and billing continuum. This session is best suited for those who perform or manage coverage analysis, clinical research billing compliance stakeholders, or individuals with interest in OnCore financials and coverage analysis. Attendees will receive tools and checklists adopted by leading academic medical centers, as well as a comprehensive participant guide that will provide step-by-step best practice instructions to create comprehensive billing grids and perform coverage analysis in OnCore. Attendees will also have the opportunity to become Certified Coverage Analysts™ by successfully applying course training in completing practicum assignments that refine both OnCore navigation and coverage analysis skills. The training is led by Bishoy Anastasi, Director of UCLA Office of Clinical Research, Financial Coverage & Activation Teams. Bishoy is highly regarded as a national clinical research subject matter expert, particularly in coverage analysis, research pricing, and clinical research billing & financials. In addition to co-authoring UCLA's coverage analysis and research pricing policies and processes, Bishoy brings over 17 years of clinical research management, contracting, coverage analysis and coordination experience. This two-day workshop has a \$1,495 fee. This fee is separate/additional to the Onsemble Conference registration fee. A group discount of 10% off is offered to organizations that register three or more people for this workshop. Breakfast and lunch will be provided on both days of training as well as a group dinner on Monday.

Financial **CEUs Available**

Tuesday, March 26

9:00AM - 5:00PM

Coverage Analysis Certification™

Financial **CEUs Available**

9:00AM - 5:00PM

Workshop: OnCore 101 Training

This session is designed for those who are new to OnCore (<6 months) and are interested in seeing the great things that can be accomplished using the system. This hands-on workshop will walk trainees through the quick wins and interesting features of OnCore, including task lists, protocol search, Forte Insights dashboards, subject visit management, and sponsor invoicing. Questions will be encouraged!

Adoption & Training

11:30AM - 1:00PM

Lunch

All Attendees

1:00PM - 5:00PM

Workshop: Getting the Most Out of Your Sponsor Relationships

Join Beth Harper as she re-caps lessons learned, and best practices developed and shared throughout the last two decades in a Letterman-style “top 10 list” approach in this interactive workshop. From site empowerment techniques to performance metrics and feasibility optimization to proactive recruitment planning, we’ve covered a lot of ground in prior Onsemble workshops and webinars. Building on Beth’s vast experience and passion for this topic, this session will allow participants to glean the best of the best techniques in one fell swoop. Whether you want to gain greater insights for how sponsors (and CROs) work, address common challenges or generally have more productive working relationships with your sponsors this session is for you.

Adoption & Training **ACRP & CBRN CEUs**

1:00PM - 3:00PM

Workshop: How to Survey Stakeholders to Measure Process Improvement

Administrators and others who implement process improvement changes are often told to survey their stakeholders to determine how satisfied they are and where issues may exist. However, many people do not know how to successfully execute an accurate survey. In this session, Forte’s Director of Analytics, Wendy Tate, will walk you through the development, execution, analysis, and presentation steps of a survey.

Adoption & Training **ACRP & CBRN CEUs**

3:00PM - 5:00PM

Workshop: Forte Solutions Overview: Getting the Most out of Onsemble

Do you want to brush up on your knowledge of Forte products? Could you use a refresher before attending Onsemble sessions? This workshop will provide a foundation in the workflows of the Forte products in order to equip you with the background you need to get the most from subsequent Onsemble sessions. Each 20-minute session will give you a basic overview of the Forte solution to a specific area: Financial Management, Analytics and Reporting, Data Management, and Study Management. Come for a single session or stay for them all!

All Attendees

6:00PM - 8:00PM

Welcome Dinner

Kick off the conference with a welcome dinner on the Vue Lawn. Enjoy networking with your peers while overlooking the Pacific Ocean!

All Attendees

Wednesday, March 27

6:15AM - 7:00AM

Morning Yoga

Start your day off with yoga led by local instructors! Yoga mats, towels, and water will be provided. Please arrive 5-10 minutes prior to the start of the session.

All Attendees

7:30AM - 8:30AM

Breakfast

All Attendees

8:30AM - 9:30AM

Keynote

Join us for the official opening of the 27th Onsemble Conference as Founder and CEO Shree Kalluri will walk through trends in the industry, the evolution of clinical research and Forte's role, and the importance of interconnected systems for the community to ultimately transform clinical research.

All Attendees

9:45AM - 10:45AM

Panel: How Sites, CROs, and Sponsors can Best Partner for Success

During this panel discussion, site, sponsor and CRO representatives will discuss their perspectives on how to make clinical trials more efficient and how to engage the other stakeholders to work together in the most effective way. Topics will include case studies that highlight the methods and value of collaboration across stakeholders, as well as their vision for the leveraging site-centric technology and data at both a study level and a portfolio level to improve clinical trials.

All Attendees **ACRP & CBRN CEUs**

11:00AM - 11:50AM

Leveraging OnCore for Clinical Research Billing Compliance

Clinical research billing is an increasingly complex and regulated process. In this session, Bishoy Anastasi from UCLA will discuss national trends related to billing compliance exposures and opportunities to improve compliance through OnCore. Session attendees will review fundamental regulations governing research billing, discuss key considerations in implementing clinical research billing processes and policy, and best practice approaches to leveraging OnCore to implement effective and compliant clinical research billing.

Financial ACRP & CBRN CEUs

11:00AM - 11:50AM

Improving Your Clinical Trial Staff Onboarding Experience

A comprehensive, interprofessional orientation is essential when creating a safe work environment for new employees. To address this challenge, Rutgers Cancer Institute of New Jersey, an NCI-designated comprehensive cancer, identified the need for improving its onboarding process. Orientation had been occurring in silos, with each department conducting their own onboarding. The center developed a new interprofessional onboarding experience to reduce inefficiencies, improve communication, teamwork, and care outcomes. A team of representatives from Rutgers will outline how the program aims to:

- Identify the barriers of creating an onboarding program.
- Discuss how to create a three-month onboarding program.
- Discuss job-specific orientation checklist.
- Review plans for the program.

General & OnCore Operations ACRP & CBRN CEUs

11:00AM - 11:50AM

Smarter, Not Harder: Leveraging Forte Technologies to Ease Grant Reporting

This session is intended for leadership only. The management of large infrastructure grants (such as the CCSG and CTSA) require methodical reporting and presentation of significant amounts of data. Much of this data is captured in Forte systems during the process of conducting clinical research or for the purpose of reporting to funding agencies. Hear Tesheia Johnson of Yale University discuss how she utilizes the reporting features of OnCore and EVAL as well as Insights dashboards to prepare for presentations and grant reports that highlight program strengths and report required metrics.

Leadership CBRN CEUs

12:00PM - 1:00PM

Lunch

All Attendees

1:00PM - 1:50PM

Lessons Learned Launching a State-Wide Network

To increase access to clinical trials, more and more sites are building their own networks. Hear from at the University of Minnesota on lessons learned when they launched their new state-wide clinical trial network, how they plan to use OnCore and how they are setting their affiliate sites up for success through training and best practices.

General & OnCore Operations **ACRP & CBRN CEUs**

1:00PM - 1:50PM

Best Business Practices for CTO Management

This session is intended for leadership only. At the end of the day, centers need to conduct impactful and compliant research. But how can management implement business practices to streamline operations and increase research productivity? Hear lessons learned and best practices from Nick Fisher, Executive Director of Research and Business Administration at Siteman Cancer Center at Barnes-Jewish Hospital and Washington University School of Medicine.

Leadership **ACRP & CBRN CEUs**

1:00PM - 1:50PM

Recording Clinical Trial Personnel Costs in OnCore

A significant portion of a clinical trial budget is allocated to cover personnel costs. When research staff work across multiple trials, properly identifying the proportion of salary to be recovered from each trial is challenging. While OnCore allows for granular effort tracking on a protocol level, it is not designed to be used for salary recovery. In this session, Renata Panchal will discuss workflows devised by Memorial Sloan Kettering using OnCore calendar functionality to facilitate salary recovery using data already captured by tracking patient visits.

Financial **ACRP & CBRN CEUs**

2:00PM - 2:50PM

A Seat at the Table: The Value of Business Operations

This session is intended for leadership only. The business roles and functions of a centralized Office of Clinical Research (OCR) has not always been well understood within the context of a cancer institute. This is due to its many nuances driven by the requirements within the healthcare environment. In this session, Patricia Black, Manager, Business Operations, Office of Clinical Research at Fox Chase Cancer Center, will share how her team addressed struggles related to significant turnover and an overburdened staff, as well as misconceptions throughout the institution regarding the types of projects best suited for the OCR.

Leadership **ACRP & CBRN CEUs**

2:00PM - 2:50PM

OnCore Financials 101

Are you thinking of implementing Financials in OnCore at your organization? Do you wish you knew more about what OnCore can do to help with your financial workflows? If you answered "yes" to either question, this is the session for you. During this session, Forte's Doug Vosters will be discussing the keys to successful implementation, look through basic financial workflows and take a sneak peek at new and upcoming features of OnCore Financials.

Financial

2:00PM - 2:50PM

Driving Technology Adoption and Preparing End-users for Success

Ensuring a new technology system will be successfully adopted by end users requires a well-planned approach. Kathleen O'Malley, Associate Director of Education and Training at Jefferson Clinical Research Institute and Paul Park, Manager of Clinical Research Systems at City of Hope will discuss robust strategies to drive technology adoption with an emphasis on training practices designed to prepare end users for success. The speakers will discuss first-hand experiences, successes and areas for improvement.

Adoption & Training **ACRP & CBRN CEUs**

3:00PM - 4:30PM

Forte Progress and Plans

Join us for an exciting review of all Forte products and services. James Wurdeman, Forte Chief Product Officer, will cover important products updates and several customers will join to share their stories of using eReg, EVAL, Insights, and Forte Managed Infrastructure at their institution. Orla Mester, SVP of Operations, will provide updates on Business Operations Services, implementation and support.

All Attendees

4:30PM - 5:30PM

Product and Services Happy Hour

Have a question you didn't get to ask at the end of your session, or interested in learning more about Forte solutions? We invite you to stop by to socialize during this happy hour to engage with the experts!

All Attendees

Thursday, March 28

6:15AM - 7:00AM

Morning Yoga

Start your day off with yoga led by local instructors! Yoga mats, towels, and water will be provided. Please arrive 5-10 minutes prior to the start of the session.

All Attendees

7:30AM - 8:30AM

Breakfast

All Attendees

8:30AM - 9:20AM

Managed Infrastructure 101

In this session, Jason Jaszewski, Principal Administrator of Managed Infrastructure at Forte, will outline considerations and answer frequently asked questions regarding moving OnCore to Managed Infrastructure. He will draw from experiences and share best practices from customers that have successfully moved, with a focus on addressing business operations topics.

Technical & Informatics

8:30AM - 9:20AM

EDC Validation from an Institutional Perspective

The process for developing a 21 CFR part 11 validation procedure can be very intense. In this presentation from UNMC/Nebraska Medicine you will learn the steps for creation your institution specific template for part 11 validation, policies, SOPs, testing scripts, and required documentation. Once you have an institution template and policies you can establish your documentation requirements and necessary procedures for Investigator Initiated trials with complete research data integrity.

Regulatory **ACRP & CBRN CEUs**

8:30AM - 9:20AM

Recruiting and Retaining High Performing Staff

This session is intended for leadership only. Would you describe your hiring and retention practices as more ad hoc or systematic? What expectations do you have for high performing staff? What are the biggest gaps when it comes to staff performance and how do you overcome these in your hiring and retention practices? Denise Snyder and Beth Harper will share their insights and best practices in this interactive panel discussion where they'll address these topics and more. Come prepared with your most challenging recruitment and retention challenges to share in the discussion!

Leadership **ACRP & CBRN CEUs**

8:30AM - 9:20AM

Using OnCore to Optimize Study Initiation

Georgetown Lombardi has seen a decrease in their study start up timelines by centralizing ownership of the study start-up process and leveraging OnCore to monitor start-up tasks and efficiently address roadblocks. In this session, Neelam Prabhu and Goga Radakovic of Georgetown University Lombardi Comprehensive Cancer Center will discuss the organizational shifts that took place to centralize the startup process and review the OnCore tools they use to help ensure our study start up stays on schedule.

Study Activation **ACRP & CBRN CEUs**

9:30AM - 10:20AM

OnCore Receivables Interfaces: Sharing Experiences

The OnCore Receivables Interface enables OnCore to work with a General Ledger (GL) system to accurately and efficiently manage sponsor invoicing and payment reconciliation. While the standard interface is brand new and just beginning to be broadly adopted, it was built upon the workflows and experiences from earlier custom receivables interfaces. In this session, panelists from organizations at varying levels of experience with these interfaces will answer questions from the community about their experiences with a focus on the features and workflows that are now supported by the standard OnCore Receivables interface. The questions will explore their motivations for the interface project and key workflow considerations involved along with their experiences working with their GL system team on the project.

Financial

9:30AM - 10:20AM

A Story of Insights: How Michigan Uses Data to Inform Decisions

This session is intended for leadership only. Dashboards are powerful business tools that can connect all levels of the organization from executives to the front-line. Dashboards, which are targeted to the specific needs of the intended constituents, provide visibility to performance against strategies and goals, drive organizational alignment, consolidate disparate data for faster decision making, add accountability, enable continuous improvement, and signal the need for countermeasures and strategic pivots. This session will showcase how the University of Michigan leverages Insights at the leadership level and how it is used to support the institution's goals. Furthermore, learn how the enterprise implementation of OnCore enabled process standards and integration of cross-functional data that drives real-time managerial and operational dashboards, which inform end-to-end process improvement as well as empower individual-level contributors to see the direct impact of their performance on achieving institutional goals.

Leadership

9:30AM - 10:20AM

Encouraging User Adoption & Compliance During New Implementations

Change is challenging and implementing a new CTMS is no exception. The process of moving from legacy systems to a centralized CTMS can require changes to existing workflows, concepts and cultures. While maintenance of strong communication lanes with study teams is a key strategy for overcoming these challenges, there are additional strategies that can be used to drive more efficient study team adoption of the new centralized tool. In this presentation, Harrison Kelner from the Fred Hutchinson Cancer Research Center will highlight three strategies employed during an enterprise implementation of OnCore to promote increased training retention, improved user compliance and positive user experiences.

Adoption & Training ACRP & CBRN CEUs

9:30AM - 10:20AM

Centralizing Intake for Transparency Across Multiple Institutions

In this session, Amanda Childs, Molly Van Rheen, and Christine Ricklefs from the University of Colorado Denver will discuss their centralized intake to study activation process for new research projects and amendments. Their process relies heavily on a centralized submission point, task lists, and custom reports to track over 400 studies in progress at one time. The speakers will outline the development of the process, as well as the results CU Denver has seen since its implementation.

Study Activation ACRP & CBRN CEUs

10:30AM - 11:20AM

Operationalizing Robust, Centralized Financial Management with OnCore

When the University of Michigan implemented OnCore enterprise-wide in 2017, both the Coverage Analysis & Financials consoles factored heavily into standardized workflows, in support of the organizational goal to provide robust, centralized management of clinical trial financials. Since go-live, they've encountered challenges, but have engaged creative solutions and engineered best practices that have helped them make significant strides towards their goal. Senior Business System Analysts Kristen LaVasseur and Mike Lee will highlight some of the hurdles faced, discuss problem-solving processes and examine successes that the UM team has operationalized.

Financial **CBRN CEUs**

10:30AM - 11:20AM

Executing a Successful OnCore Upgrade

In this session, representatives from Forte's Product Support and Systems Administration teams will outline what goes into executing an OnCore upgrade at Forte and at your site. They will walk through a typical upgrade, starting with your initial interest in a new release and ending with a completion of your upgrade in production, sharing best practices each step of the way.

Technical & Informatics

10:30AM - 11:20AM

Improving Operational Efficiencies through Task List Deployment

The Office of Clinical Research (OCR) oversees health-related human subjects clinical research for the University of Florida. Historically, research institutions have had a choice between a centralized and de-centralized approach to managing research projects. Clinical Research Intake Coordinator, Leah Wollitz will discuss the University's centralized approach to project management, the deployment of task lists has provided the Office of Clinical Research improved transparency for customer service, operational efficiencies addressing protocol activation timelines, and quality metrics for appropriate oversight.

Study Activation **ACRP & CBRN CEUs**

10:30AM - 11:20AM

Culture Change and Enterprise Rollout: Beyond OnCore Implementation

The University of Florida completed its enterprise-wide rollout of OnCore within one calendar year, including all health-related human subjects research across the entire campus. A purposeful stakeholder engagement plan was created and evolved throughout the process. Currently, they are transitioning from onboarding new departments and teams to a long-term maintenance strategy that relies heavily on outreach and education to foster continued trust and collaboration between OnCore users and administrators. In this presentation, Associate Director of the Office of Clinical Research Katie Eddleton will focus on both lessons learned during enterprise rollout and how they plan to leverage newly formed relationships to create broader cultural change.

Adoption & Training **ACRP & CBRN CEUs**

11:30AM - 1:00PM

Lunch

All Attendees

1:00PM - 1:50PM

Transitioning to Forte Calendar Services

The process of building protocol calendars can be a huge administrative burden for many research organizations. In this panel discussion led by Mike Neuenfeldt, Services Manager at Forte, speakers will describe the process of transitioning their organization to the use of Forte's Calendar Services as part of their study start up process.

Calendars & Financials

1:00PM - 1:50PM

Inside Forte Release Planning

Ever wonder how Forte prioritizes features and plans software releases? Want to better understand how you can influence the roadmap and have better visibility into Forte release plans? Join Forte's Jon Tack and Shannon Roznoski for a discussion of how Forte prioritizes, scopes, and manages releases, and how Onsemble community input is incorporated into release plans. Jon and Shannon will share Forte's release processes and answer any questions you have.

Technical & Informatics

1:00PM - 1:50PM

Where's Waldo? A Story about Recruitment

This session is intended for leadership only. When discussing enrollment targets with your PI's, how often have you heard "I saw a dozen of those participants last week/month/year"? Do you know how many potential participants are really in your system? In this session, Brian Sevier from UF Health and Mark Marchant from UAB will discuss new (and old) methods for analyzing potential cohorts for recruitment. They will discuss everything from data analytics and business intelligence tools to third-party solutions to help meet your targets.

Leadership **ACRP & CBRN CEUs**

1:00PM - 1:50PM

Task List Optimization to Unlock Study Activation Analysis

Optimizing study activation is always a hot discussion topic throughout the Onsemble Community, with many institutions interested in improving their understanding of activation lifecycles, spot trends and ultimately decrease activation timelines. In this session, Wendy Tate and Jill McKinley of Forte will discuss how to architect task lists for key activation workflows, how to engage stakeholders and build consensus, and how the data can be leveraged and understood via Forte Insights dashboards to support initiatives to improve study activation.

Study Activation **ACRP CEUs**

2:00PM - 2:50PM

Using OnCore Calendars for Budget Negotiations

Have you ever wondered how to develop a draft budget using OnCore? UCLA leverages the OnCore calendar to develop a draft budget by utilizing a custom OnCore export tool. In this session, Principal Coverage Analyst Gevorg Stepanyan will demonstrate their budget draft workflows in OnCore and show how the process can be adopted at your organization.

Financial **CBRN CEUs**

2:00PM - 2:50PM

Utilizing Forte Services to Improve Activation Timelines

This session will feature customers using Forte services, highlighting how the services have improved their activation timelines and reduced the burden on their staff. They will also discuss how they have incorporated these services into their workflows and SOPs. Mike Neuenfeldt, Services Manager at Forte, will also be on hand to answer any pressing questions you have.

Study Activation **CBRN CEUs**

2:00PM - 2:50PM

How we Moved On-Premises Oncore to Forte Managed Infrastructure

In this session, we'll feature a long-time OnCore customer who moved from on-premises to Forte Managed Infrastructure. Rob Schuetz, CTMS Product Manager at the University of Hawaii Cancer Center, will discuss his team's approach to preparing for the move, the lessons learned throughout the project and the benefits the University has seen with Forte Managed Infrastructure.

Technical & Informatics

2:00PM - 2:50PM

Change Management for your OnCore Implementation

Change management isn't all about technology; the human component of change management is also of the utmost importance. Erin Crist and Ann Kreeger from Forte will use this session to speak about the importance of developing a change management strategy for your overall OnCore implementation (even beyond go-live). They will also discuss project structure and roles to manage change, creating a vision for change, how to identify the impact of a rollout and how to pull it all together with a communication plan. They will introduce three phases of change including planning for the implementation, during the change or implementation and after go-live.

Adoption & Training **ACRP & CBRN CEUs**

3:00PM - 3:50PM

Calendar and Billing Optimization

From standardizing initial calendar review process, to implementing Financial Events tracking, MedStar Health Research Institute has utilized OnCore to make their study teams more efficient and optimize billing functions. In this presentation, Director of Clinical Research Revenue Cycle Candice Vance and OnCore Coordinator Allie Moses will describe the challenges they encountered with subject calendars and study billing during the initial OnCore rollout, and the tools and processes they used to address them.

Calendars & Financials **CBRN CEUs**

3:00PM - 3:50PM

Implementing OnCore Intake Processes to Accelerate Activation

In this session, Gina Hawkins and Bishoy Anastasi will outline UCLA's OnCore intake processes leveraging the OnCore API to connect to their IRB system. The process begins with the automatic creation of OnCore study shells and the completion of OnCore annotations. These annotations trigger automatic notifications from our system to kickoff parallel activation

processes with downstream stakeholders such as contracting, coverage analysis, coding and pricing, servicing departments.

Study Activation **CBRN CEUs**

3:00PM - 3:50PM

A Deep Dive into Forte eReg Implementation and Validation

In this session, Forte Director of Product Success Stuart Cotter will outline the implementation, data migration and validation process for Forte's eRegulatory Management System (eReg). He will be joined by eReg customers, who will discuss their experiences implementing eReg at their organizations.

Regulatory

3:00PM - 3:50PM

Reporting for CCSG Competitive Renewal

A Cancer Center Support Grant (CCSG) competitive renewal is an exciting time for a cancer center. OnCore plays a central role in providing information in support of the grant. In this session, Curt Hampton will share experiences and tips related to preparing and presenting information from OnCore for a CCSG competitive renewal at Huntsman Cancer Institute.

Technical & Informatics **CBRN CEUs**

4:00PM - 4:50PM

Make eLearning Engaging with Interactivity

It can sometimes be hard to know whether your training methods are effectively engaging your audience. It's been shown that learners retain more information when they are actively involved in learning, instead of simply watching passively. In this session, Forte's eLearning Developer Tim Spinler will share techniques to liven up eLearning modules with different kinds of interactivity.

Adoption & Training **ACRP & CBRN CEUs**

4:00PM - 4:50PM

Coordinating Multi-Site Trials

Coordinating multisite clinical trials can increase accrual numbers of across a wider geographical area with a more diverse population in a shorter amount of time. These advantages necessitate additional administrative and regulatory oversight through the process. In this session, Kathleen Granlund from University of Michigan Rogel Cancer Center and Susan

Natoli from Duke will talk through best practices and areas for improvement for conducting multi-site clinical trials.

General & OnCore Operations **ACRP & CBRN CEUs**

4:00PM - 4:50PM

Creative Calendar Solutions for Workflow Management

The Calendar Builder Team at the University of Florida's Office of Clinical Research has developed a unique set of tools to counter time and workflow management obstacles. In this session, Ben White and Zach Hudson will address in detail the calendar build decision solutions and how they are currently being implemented, the operational challenges that necessitated the conception of these mechanisms, and how these instruments have been a unique solution for their team.

Calendars & Financials **ACRP & CBRN CEUs**

4:00PM - 4:50PM

The Principal Investigator Credit Score

This session is intended for leadership only. It is well-established that principal investigators are the primary individual responsible for the preparation, conduct, and administration of a research project in compliance with applicable laws and regulations and institutional policy governing research. Yet every scientific review committee, tasked with low-accrual monitoring, have an inordinate volume of trials that are not productive. PI's often argue that their trials should remain open and will improve. University of Arizona Cancer Center has developed an objective PI credit score to help address this challenging dynamic. Chad Adams, UACC Assistant Director of Cancer Clinical Research, will present the scoring system and share results from its use.

Leadership **ACRP & CBRN CEUs**

6:00PM - 10:00PM

Final Night Dinner

Join us for the final night dinner located on the Vue Lawn. Enjoy watching the sunset over the California coastline while enjoying drinks, dinner, and entertainment.

All Attendees

Friday, March 29

7:30AM - 8:30AM

Breakfast

All Attendees

8:30AM - 9:20AM

Part 1: Understanding Regulations

In this session, MaryAnn Kempker and Shannon Roznoski of Forte will provide an overview of 21 CFR Part 11 and discuss the roles both organizations and vendors play during the validation process. These two expert presenters will share ways organizations can work with their vendors to successfully implement a validated system and maintain a compliant status throughout each upgrade.

Regulatory **ACRP & CBRN CEUs**

8:30AM - 9:20AM

More than a Minimum Footprint

In order to improve the quality of clinical research activity, Duke University made an investment in infrastructure, including OnCore. This investment supported reworked business processes to create operational excellence across the institution. The integration with their electronic IRB system was critical to understanding the diverse clinical research activities, including exempt and retrospective research, across departments. This required Duke to implement system-wide workflows, create pathways for heavy and infrequent users, and develop tools for monitoring non-compliance and data completeness. Nearly a year post-go live, Senior Strategic Services Associate Susan Natoli and Project Manager - Office of Research Informatics Christian Stephens will share the challenges and successes of an enterprise-wide adoption of OnCore.

Adoption & Training **ACRP & CBRN CEUs**

8:30AM - 9:20AM

Change Management: Synchronizing New Workflows and Customer Training

In this panel discussion, speakers from The University of Florida's Office of Clinical Research will discuss their experience centralizing processes from the perspective of both core office staff and study teams. They will share their experience with internal workflows that were used for compliance, metrics and research conduct that needed to be redesigned for mapping office processes to the OnCore application. They will also talk about the importance of defining these workflows to not only improve communication throughout their institution, but also implement improved training and education for study teams.

General & OnCore Operations **ACRP & CBRN CEUs**

8:30AM - 9:20AM

Getting Ready for Vendor Payables

Vendor payables is here! Led by Jeff Parks, OnCore Product Manager from Forte, this session will explore the newly created vendor payables module within OnCore, including the intent of

the functionality as well as how to start planning for rolling out this new feature at your organization.

Financial

9:30AM - 10:20AM

Part 2: Application of Regulations to Our Software

Are you about to start the validation process for Forte EDC or eReg? Are you considering purchasing Forte EDC or Forte eReg and not sure what's involved in the validation process? This session, led by Sara Volke, Jordan Smith and MaryAnn Kempker of Forte, will walk through the "Dos and Don'ts" of the validation process, what's involved with validation, what's involved with due diligence and more.

Regulatory **ACRP CEUs**

9:30AM - 10:20AM

Automation of Data Migration and Regression Testing

Migrating large amounts of data by hand is a resource-intensive and error-prone task. Regression testing is often time-consuming and repetitive. Leveraging automation in these scenarios can significantly increase productivity and reduce re-work due to errors. In this session, Oscar Cano will dive into how automation helped the University of Washington, Fred Hutch and the Seattle Cancer Care Alliance successfully implement a shared instance of OnCore against a tight timeline by migrating data for roughly 40,000 subjects and 4,000 protocols. We will also explore potential future uses for automation including regression testing.

Technical & Informatics

9:30AM - 10:20AM

Managing and Using the Minimum Footprint for Long-Term Success

The minimum footprint is core to research operations. But do you know what to do with it once you have it? This session will go over how the minimum footprint is a living document that should guide application support, training, testing, work standards and research metrics. Jill McKinley of Forte will discuss how to manage the document for the long-term to ensure it continues to adapt and adopt research goals.

Adoption & Training **CBRN CEUs**

9:30AM - 10:20AM

Post Award Financials CAN be done with OnCore

When dealing with post-award financials, there are a number of functions that can be achieved using OnCore. This presentation from Seth Richards and Bethany DeFrancesco from Moffitt Cancer Center will focus on their financial processes and the financial database they developed and the reports and queries within it, including but not limited to revenue recognition, billed vs. unbilled accounts receivable, unapplied cash, trial reconciliations, invoice creation and payment application. This presentation will also show some of the analysis reports they have developed to see trends related to the clinical trial finances, staff workloads, sponsors and other useful financial data.

Financial **ACRP & CBRN CEUs**

10:30AM - 11:20AM

Complexities of an All Inclusive Epic Integration

Integrating with Epic involves a number of key considerations from a technological, financial, and organizational perspective. In this session, Marissa Macri from UCHHealth and Christine Ricklefs and Amanda Childs from UCDenver will discuss key considerations for implementing the Epic demographic, RPE and CRPC integrations for all studies, enterprise-wide. This will include how to thoroughly examine your existing portfolio to avoid pitfalls by highlighting Charge Master set up, analysis of specification builds and alignment with EHR data. This panel will discuss how they prepared their end users for the integrations, lessons learned and their established best practices.

Financial **CBRN CEUs**

10:30AM - 11:20AM

Forte Community Resources Panel

When an organization becomes a Forte customer, they join a community that offers a number of resources to help them succeed. In this session, a panel of Forte representatives will show what is available in Onsemble.net, Forte Academy, the Learning Portal, and through the sales and marketing teams.

Adoption & Training

10:30AM - 12:20PM

Change Control (Double Session)

In this workshop, representatives from Forte will discuss the regulatory requirements for change management to meet 21 CFR Part 11, and share the principles of risk-based analysis and how it established the extent of testing. You will have a chance to practice risk-based evaluation of

sample changes and the group will discuss best practices for implementing change management processes.

Regulatory **ACRP & CBRN CEUs**

10:30AM - 11:20AM

Lessons Learned when Migrating Data from Multiple Systems

In this session, Rhodora Garcia of Duke will share how her institution migrated 16,000 protocols, dealing with inconsistent data from multiple source systems along the way. Rhodora will share how Duke set up on their own environment for data migration and ran multiple migration iterations, how they created business rules to clean up data housed in different source systems and how they conducted data validation and utilized Forte audits.

Technical & Informatics **CBRN CEUs**

11:30AM - 1:00PM

Grab and Go Lunch

All Attendees

11:30AM - 12:20PM

Hot Topics

Forte's Jill McKinley will leader a community discussion based on the popular topics on the Onsemble Groups conversations. There will be approximately 10 suggested topics based on the online conversations.

General & OnCore Operations

11:30AM - 12:20PM

Unlocking Analytics with Data Integrity

The phrase "garbage in, garbage out" has become ubiquitous amongst data analysts, primarily in response to questions about how trustworthy and reliable a piece of data analysis may be. Increasing trust in what the analysis is telling you is a key component to being able to rely on reporting. Forte developed the Insights Data Health Analysis process to help customers that were adopting Forte Insights to quickly identify which dashboards they could rely on, and which dashboards were being held back by their OnCore data completeness. Led by Forte Insights Product Manager Blake Taylor and Director of Analytics Wendy Tate, this session will speak to the methods Forte used to create data health analysis, how Forte supports customers in trusting and adopting the analytics tools we provide via Insights and customer use cases of successful health analysis outcomes.

Adoption & Training **CBRN CEUs**