



'Perspectives on risked based monitoring'

Program Agenda:

3:00 - 3:30 pm Registration, heavy appetizers

3:30 - 4:30 Ron Carozza, PharmD

4:30 - 5:30 Mike Yasich, PMP

5:30 - 6:00 Dinner Break

6:00 - 7:00 Dema Poppa, PMP

Program Description:

This event will provide a comprehensive discussion of Risk-based Monitoring; the current guidance, the operational challenges surrounding implementing risk-based monitoring as well as the advantages in quality of trial data collection and overall study cost reduction.

Upon completion of this Webinar, attendees should be able to:

- 1. Review key points of the FDAs Guidance on Risk Based Monitoring.
- 2. Describe 3 practical approaches to implementing risk-based monitoring in the practice setting.
- 3. Explain how three key organizations shaped Risk Based Monitoring.
- 4. Examine how risk assessments drive monitoring plan development.
- 5. Identify approaches to focus on Key Risk Indicators (KRIs) and risk analysis.
- 6. Differentiate methods of increasing quality of trial conduct and data collected.

Target Audience:

Clinical Research; Coordinators, Project Managers, Quality Assurance and Compliance and Regulatory Affairs staff.

For additional information contact:

Angela LeClair at angelachein@hotmail.com

Date: November 2, 2016

Time: 3:00 - 7:00 pm

Location:

Fred Hutchinson Cancer Research Center, Pelton Auditorium, 1100 Fairview Ave N. Seattle, WA

Speakers:

Ron Carozza, Pharm D, Mike Yasich, PMP and Dema Poppa, PMP

Registration Cost:

\$15 Chapter Members / \$20 ACRP Members/ \$25 Non-Members

Contact hours: 3 Contact hours have been APPROVED through ACRP. Membership is not required for online registration of contact hours.

To receive contact hours: Purchase the contact hours, sign in at the registration desk, and attend the program. Log on to the ACRP website then "ACRP Learning Portal" to complete the evaluation no later than 30 days following the event and obtain the online certificate.

Contact Hour Cost:

\$0 Chapter Members / \$15 ACRP Members / \$30 Non-Members

Refund Policy: There are no refunds unless the program is cancelled by the chapter before the start of the program.

Level: Medium