



Northern California Chapter

Secrets to Effective Site Monitoring Visit Follow Up

Speaker: Patty Kasper, founder and owner of P. Kasper & Associates

Wed. Feb. 22, 2012 6:00 – 9:00 PM

BioMarin Pharmaceutical, Inc.

105 Digital Drive

Novato, CA 94949

Directions below

Program Description:

In this interactive presentation, Patty briefly reviews the basic regulatory requirements and guidances for study site monitoring, and describes an example of a monitoring plan. She explains the difference between Notes to File and CAPAs how managers of monitors assess the activities of monitors, and describes the one action that can consistently contribute to more effective management oversight of monitors. Patty provides real-life examples and a group exercise to demonstrate these secrets to effective site visit follow up. Participants will have ample time for questions and to share their own experiences with the group.

Speaker Bio:

Patty Kasper, founder and owner of P. Kasper & Associates since 1995, is a recognized expert in clinical research training and operations. She has experience with Phase 1 through 4 clinical research trials in numerous indications and has directed trials in the US, Canada and Europe. Patty has been on the faculty of the UC Santa Cruz Extension Clinical Trials Design and Management Certificate Program since 1999. She was a former NCC Elected Executive Board member and often contributes as an event ambassador. She holds an MS in Bacteriology and Public Health from Washington State University.

Program Objectives:

1. Identify three site visit follow up monitoring responsibilities to comply with current GCP and guidances
2. Describe four activities that managers of monitors can perform to ensure high quality monitoring
3. List the key components of a Corrective and Preventive Action Plan

Agenda:

6:00 – 7:00 PM Registration, Networking, & Dinner Buffet

7:00 – 7:30 PM President's Welcome, Sponsor recognition, Raffle, Announcements/"OPEN MIC"

7:30 – 9.00 PM Educational Presentation and Q&A

Target Audience:

Clinical Research Professionals

Sponsor Organizations

Study Site Investigators & Coordinators
 Independent Consultants
 Students of Clinical Research
 Academic Medical/Clinical Researchers
 Service Providers/Vendors
 Institutional Review Boards
 Quality Assurance

EVENT REGISTRATION closes Sunday, 19 Feb, 11:59PM PST Register NOW to assure admission; AT EVENT if seats available http://www.acrpnet.org/GetInfoFor/USChapters/NorthernCalifornia/FeaturedEvents.aspx	
NCC ACRP member	Free
ACRP member	\$10
Non-member	\$15
Continuing Education Units: ACRP provides 1.5 CEU for the completion of this educational activity. These credits can be used to meet the certification maintenance requirement (ACRP-2011-CPT-xxx). The California Board of Registered Nursing (Provider Number 11147) approves the ACRP as a provider of continuing nursing education. This activity has been approved for 1.5 contact hours (11147-2011-CPT-xxx).	
NCC ACRP & ACRP member	\$10
Non –member	\$25
Event registration and contact hour purchase information: Membership not required for online registration/CEU purchase. Bring your email confirmation to the event. Please notify Event Manager of cancellation. No refunds or transfers. Walk-in /at the door registration if seats available. CEU purchase not available at the door but may be purchased online up to 7 days after the event. To receive contact hours: Purchase the contact hours, sign in at the registration desk and attend the program. Go to your “My Tests, Evaluations, and Certificates” (TEC) record on the ACRP website to complete the evaluation between 1-30 days following the event and obtain the online certificate. <i>ACRP Online registration/CEU purchase questions: Brannan Meyers: Bmeyers@acrpnnet.org</i> <i>NCC ACRP Event Manager: Lynda Chaplin lyndacarole@comcast.net</i> <i>NCC ACRP Education Committee Chair: Susan Cruikshank sacruikshank@yahoo.com</i>	

Directions to event location:

From San Francisco and South Bay:
 Cross over the Golden Gate Bridge / Hwy 101.
 Continue North towards Santa Rosa/Eureka.
 Exit Ignacio/Bel Marin Keys Blvd. and stay in the middle lane.
 Turn left at the light onto Nave Dr. and keep to the right.
 Make an immediate right onto Ignacio Blvd. and continue straight.
 Ignacio Blvd. becomes Bel Marin Keys Blvd.
 Turn right at the second stoplight onto Digital Dr. BioMarin is located at the end of the street

From the East Bay:
 Cross the San Rafael/Richmond Bridge/580.
 Continue straight onto Hwy 101 North.
 Exit Ignacio/Bel Marin Keys Blvd. and stay in the middle lane.
 Turn left at the light onto Nave Dr. and keep to the right.
 Make an immediate right onto Ignacio Blvd. and continue straight.
 Ignacio Blvd. becomes Bel Marin Keys Blvd.

Turn right at the second stoplight onto Digital Dr. BioMarin is located at the end of the street

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From Sacramento:

Take I-80 West.

Merge onto Hwy 37 and continue West toward San Rafael.

Exit San Rafael/ San Francisco and merge onto Hwy 101 South.

Exit Ignacio/Bel Marin Keys Blvd. Go past the Ignacio Blvd. exit.

Proceed under the overpass to the Bel Marin Keys exit.

Turn right onto Bel Marin Keys Blvd. and travel over the overpass (1 mile).

Turn right at the second stoplight onto Digital Dr. BioMarin is located at the end of the street.

In-kind support provided by

{Peter insert BioMarin logo}

Unrestricted educational grants provided by

{Peter inserts Medtronic, Clinsys, and UCSCX logos}