

The Philadelphia Chapter of the American Statistical Association and Wyeth Pharmaceuticals are pleased to present

Adaptive Designs in Drug Development

Friday, October 27, 2006

Wyeth Pharmaceuticals Worldwide Headquarters

500 Arcola Road

Collegeville, PA 19426

Lunch starts at 11:30 AM
Seminars begin at 12:30 PM

Schedule (see abstracts on next page)

11:30 – 12:30	Lunch	
12:30 – 1:15	Adaptive Designs: Terminology and Classification, Adaptive Seamless Phase II/III Designs	Vladimir Dragalin, Wyeth
1:15 – 2:00	Sample Size Reestimation: A Review and Recommendations	Keaven Anderson, Merck
2:00 – 2:20	BREAK	
2:20 – 3:05	Adaptive Dose-Response Studies	Inna Perevozskaya, Merck
3:05 – 3:50	Implementing Adaptive Designs: Logistical and Operational Considerations	Judith A. Quinlan, GlaxoSmithKline
3:50 – 4:45	Discussion	

Registration Instructions

There is no charge for this event, including the lunch. However, pre-registration by Monday October 23 is REQUIRED. No exceptions can be made. The way to register is to reply to the initial email that contained this attachment; an email reply will be sent back to you as confirmation by the end of the following business day (i.e. weekends excluded).

Please note in particular that we only have capacity for 60 attendees. If necessary, a waiting list will be constructed. **If you register, please let us know in advance of the event if you find out later that you cannot attend, so that a slot can be made available to those that may be on the waiting list.** Also when you reply, please let us know if you are attending just the seminars but not lunch.

For more information call or contact Bill Pikounis at bpikouni at cntus dot jnj dot com, 610 240 8498, or Lisa Hickey at hickeyl5 at wyeth dot com, 484 865 1310.

Directions & Instructions on the Day of the Event

Please give yourself plenty of time to arrive, park your car, and make it to the conference center from the directions below, as there is limited visitor parking at the actual conference center building. The main lot is large so some walking will be required when the Conference Center lot is full.

Directions from your origin can be determined from

<http://maps.google.com/maps?q=500+Arcola+Road,+Collegetown,+PA+19426&ie=UTF8&z=15&ll=40.163166,-75.469551&spn=0.013479,0.0421&om=1&iwloc=A>

or using 500 Arcola Road, Collegetown PA 19426 at the destination in your favorite on-line map & directions finder. Once you arrive on the Wyeth campus, here are some more specific directions:

After turning on Arcola Road from Rt. 29, take your first left onto Wyeth Drive. Bear to the right. The Conference Center will be on your right. It has silos like a barn. There is limited visitor parking at the conference center. You can park in any of the spots marked "visitor" in the Conference Center lot or in any spots not marked "reserved" in the main lot adjacent to the Conference Center parking lot.

Abstracts

Adaptive Designs: Terminology and Classification, Adaptive Seamless Phase II/III Designs

Vladimir Dragalin, Wyeth

We give a general definition of adaptive designs, describe their structure, and provide a classification of adaptive designs, mapping them against the drug development process.

Adaptive seamless designs have been considered as one possible way to shorten the time and patient exposure necessary to discover, develop, and demonstrate the benefits of a new drug. We introduce the concept of adaptive designs and describe the current statistical methodologies that relate to adaptive seamless designs. We also describe the decision process involved with seamless designs and present some illustrative examples.

Sample Size Reestimation: A Review and Recommendations

Keaven Anderson, Merck

We focus on sample size reestimation (SSR) for phase III and IV studies. The discussion is relevant to both continuous and binary endpoints even though the basis for SSR might differ for those two cases. We review commonly used approaches to adjust sample size and provide recommendations on how SSR should be implemented to achieve the objectives and maintain the integrity of the trial. The recommendations cover scientific, procedural, and logistic considerations.

Adaptive Dose-Response Studies

Inna Perevozskaya, Merck

Insufficient exploration of the dose response is a shortcoming of clinical drug development, and failure to characterize dosing early is often cited as a key contributor to the high late-stage attrition rate currently faced by the industry. Adaptive methods, for example, make it feasible to design a proof-of-concept study as an adaptive dose-response trial. Efficient learning about the dose response earlier in development will ultimately reduce overall costs and provide better information on dose in the filing package. We present the PhRMA working group's main recommendations regarding adaptive dose-response studies. As background, traditional fixed and adaptive dose-response designs are briefly reviewed. Information on developing a Bayesian adaptive dose design and some monitoring and processing issues are also discussed.

Implementing Adaptive Designs: Logistical and Operational Considerations

Judith A. Quinlan, GlaxoSmithKline

The objective of this presentation is to support a logistical and operational feasibility analysis: given the research question and the environment in which we work, is it appropriate to consider an adaptive design, and are we sufficiently well prepared to deploy successfully?