



## Shanghai Biostatistics Forum (SBF) Special Event, 2019

### 上海生物统计学术论坛

**Date and Time:**

Monday, April 22, 2019, 01:30 PM -- 05:00 PM

**Location:**

Auditorium Building 1, Novartis Campus

No. 4218 Jinke Road, Shanghai

金科路 4218 号, 诺华上海园区, 一号楼大礼堂

**Attendees:**

Open to everyone who is interested.

**Short Course:**

Futility Analyses in Confirmatory Clinical Trials – Methods and Procedures

**Lecturer:**

Paul Gallo, Senior Biometrical Fellow, Statistical Methodology and Consulting, Novartis, US

**Abstract:**

Futility analyses are increasingly utilized in clinical trials. These generally involve interim evaluation of a trial's primary hypothesis to determine if trial success or clinically meaningful effect seems unlikely. Futility analyses can improve resource efficiency by halting trials with ineffective interventions. They also offer ethical advantages by exposing fewer trial participants to ineffective and possibly toxic interventions, and public health advantages in that trial results may be conveyed to the medical community in a more timely fashion. We will describe what futility analyses are, why they are conducted, where and when they should be considered, and how they should be methodologically and operationally implemented. These analyses should be carefully planned during trial design phase, as there are important statistical and operational implications. Challenging questions arise during trial design regarding how futility analyses should be conducted, the statistical scales on which criteria may be expressed, when futility should be assessed, the role of Data Monitoring Committees, and thresholds at which futility may be established. Non-constancy of effect size and other limitations of accruing interim data can raise further challenges. We will describe current practices and recent advancements in methodological approaches of futility analyses with case studies.

**Agenda:**

Time	Item
01:30 PM – 01:40 PM (10 mins)	Introduction and Welcome Remarks
01:40 PM – 03:00 PM (80 mins)	Invited Speaker: Paul Gallo, Senior Biometrical Fellow, Statistical Methodology and Consulting, Novartis, US <i>Short Course: Futility Analyses in Confirmatory Clinical Trials – Methods and Procedures (Part I)</i>
03:00 PM – 03:30 PM (30 mins)	Tea Break
03:30 PM – 04:30 PM (60 mins)	Invited Speaker: Paul Gallo, Senior Biometrical Fellow, Statistical Methodology and Consulting, Novartis, US <i>Short Course: Futility Analyses in Confirmatory Clinical Trials – Methods and Procedures (Part II)</i>
04:30 PM – 04:50 PM (20 mins)	Discussion and Q&A
04:50 PM – 05:00 PM (10 mins)	Closing Remarks



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#### **Registration 会议注册报名:**

请点击如下网页链接进入报名（邮箱注册后，请前往邮箱点击所提供链接，填写详细信息，以完成注册过程 [http://www.ediscchina.org/plugin.php?id=registration\\_sbf:pre\\_register](http://www.ediscchina.org/plugin.php?id=registration_sbf:pre_register)

请在诺华访客中心签到领取访客卡和停车牌，离开时需归还。**诺华园区内不得拍照，参观办公区域需诺华员工陪同。谢谢配合！**如需在诺华园区内午餐，请于4月15日前在线登记，届时会为已注册登记的参会人员提供餐券。用餐时间：12:00-13:00。

#### **参与方式:**

本次学术活动采用现场参与和在线参与两种方式。参会名额有限，人满为止。现场参与请见如下交通说明。在线参与信息将在前一天通过在线报名时所填写的邮箱发至参会者，请及时查收。 \*\*由于网络易受各种因素影响，在线参与效果若不如预期，还请谅解。请尽可能通过现场参会\*\*

#### **Web site and mailing list announcement:**

Zibao Zhang, dMed ([zibao.zhang@dmedglobal.com](mailto:zibao.zhang@dmedglobal.com))

Stanley Wei, Novartis ([zhijun.wei@novartis.com](mailto:zhijun.wei@novartis.com))

#### **Local organizer and contacts:**

Yi Cheng, Novartis ([yi.cheng@novartis.com](mailto:yi.cheng@novartis.com)) (021) 6160 6539



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#### Direction:

1. By Subway: Take Line 13 to Zhongke Road (Exit 5). From there, go straight for about 500 meters to Novartis Campus. (see below map for walking route)  
地铁: 13 号线中科路站 5 号口出地铁站。之后直行约 500 米至园区 (步行路线参见如下地图)



2. By Car/Taxi:
  - From the Inner Ring Road (Longdong Avenue)  
Take the Longdong Avenue exit, turn right and follow Jinke road about 8km southwards. The Novartis Campus is on your right.
  - From the Middle Ring Road  
Take the Jinke road exit, follow Jinke road northwards to the Chuanyang River bridge and make a U-Turn under the bridge. The Novartis Campus is on your right.自驾/出租车  
经内环 (龙东大道): 龙东大道下, 直行至金科路口右转; 南行约 8 公里即可到达上海园区 (道路右侧)。  
经中环: 金科路口下中环高架后北行, 川杨河桥下调头; 园区在道路右侧。