2022 Travelling Short Course on **Clinical Trials Using Master Protocol and Its Applications**

The NIC-ASA invites you to attend a half day Travelling Course on ***Clinical Trials Using Master Protocol and Its Applications*** **on Friday, May 13, 2022**, to be offered in **virtual format**. Please see below to find more information about the course. Please register by May 9, 2022. We will send out an invitation with access details to all those who register.

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**American Statistical Association 2022 Council of Chapters Traveling Course**

**Organized by: Northeastern Illinois Chapter**

**Course Title: Clinical Trials Using Master Protocol and Its Applications**

**When: Friday, May 13, 2022, 9:00 am – 1:00 pm Central Time**

**Registration**:**$25.** [registration link](https://www.eventbrite.com/e/clinical-trials-using-master-protocol-and-its-applications-tickets-305976372567)

**Instructors**: Jingjing Ye, PhD, Xiaoyun (Nicole) Li , PhD, Chengxing (Cindy) Lu ,PhD

**Course Description**:

As the paradigm of drug development shifts to personalized medicine and targeted therapies, pool of eligible clinical trial patients becomes increasingly smaller and there is a need for rapid learning and confirmation of clinically meaningful treatment effect. Master protocol, including umbrella, basket, and platform trials, promotes innovation in clinical trials and aims at improving efficiency, avoiding duplication and competition, and accelerating the drug development process. Though master protocols used to be primarily sponsored by nonprofit organizations, academic institutes and government agencies mostly in oncology area, there is a growing trend of conducting clinical trials using master protocol in recent years from the pharmaceutical industry in oncology and other therapeutic areas. Regulatory agencies across the globe have issued guidance on master protocols. In 2018, the ASA Biopharmaceutical Section Oncology Scientific Working Group (SWG) was chartered to explore innovative statistics in oncology drug development and a sub-team on master protocol in oncology was formed. In this short course, instructors from the Oncology SWG master protocol sub-team will provide an overview on master protocol, its regulatory landscape, statistical methodologies, special statistical considerations, challenges and opportunities both statistically and operationally. The last part of this short course will include a case study of a COVID platform trial: RECOVERY Trial, with detailed illustrations on how to implement the considerations discussed in the earlier part of the short course. See below the structure of the short course:

Part 1: Overview of master protocol

a. Overview of master protocol: Definitions, Examples

b. Review of Regulatory Landscape: US and Rest-of-World regulatory guidance

c. Practical Considerations

Part 2: Novel statistical methodologies used in master protocol trials, statistical and operational consideration

Part 3: Case Study of a COVID platform trial: RECOVERY Trial

**About the Instructors**:
The instructors have given the short course in Deming Conference 2020 under the same title. Nicole and Cindy are the co-leads of Master Protocol sub-team under the ASA Biopharmaceutical Section Oncology Scientific Working Group (SWG) since 2018. Jingjing, Nicole and Cindy are the current co-leads of Joint DIA-ASA Master Protocol Working Group. The ASA WG manuscript “Practical guide and recommendations for master protocol framework: basket, umbrella and platform trials” is published on Therapeutic Innovation & Regulatory Science.

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