Forum for Collaborative HIV Research

Rethinking Clinical Trials Designs for Treatment-Experienced and Treatment-naïve Patients

Introduction

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enhancing & facilitating HIV research

- The Forum for Collaborative HIV Research is a public/private partnership including government agencies, foundations, industry, HIV researchers and clinicians, and the HIV patient/advocacy community.

  Our mission is to facilitate and enhance HIV research.

Special Thanks

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  - Boehringer Ingelheim
  - Gilead
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Special Thanks

- Ben Cheng
- Linda Onaga
- Meagan Lyon
- Meeting Masters:
  - Debbie Cooke
  - Cynthia Capizzo

Agenda Day 1

- Treatment-experienced patients
  - Overviews: History & Evolution/Challenges
  - Recent Clinical Trial Experiences
  - GSS & PSS
  - FDA, EMEA perspectives
  - Specific questions
  - General discussion

Agenda Day 2

- Treatment-naïve patients:
  - Overview: Need for new drugs
  - EMEA, FDA perspectives
  - Specific questions
  - General Discussion

Forum Roundtables

- Plenty of moderated discussion
  - Role of moderators in guiding discussion
- Everyone participates and contributes
- Open, honest, constructive, collaborative dialogue
  - Leave your “hat” at the door, bring your expertise to the roundtable

Introductions

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Roundtable Goals

- Reconsider approaches to drug development
  - Ensure highest level of safety & benefit
  - Maintain new drug pipeline
- Review and discuss issues and challenges in clinical trial designs for treatment-experienced and treatment-naïve patients
  - US and European regulatory processes
- Work toward developing consensus on the best way to study drugs for these patient populations

Specific Objectives

- Definition of patient populations
- Definition of endpoints
- Review study design
  - control arms
  - study duration
- Discuss statistical considerations
- Review best populations for discriminating efficacy with different doses
- Drugs with different mechanisms of action