

enhancing and facilitating HIV research



Forum for Collaborative HIV Research



Located in Washington DC, part of the School of Public Health



**Forum for
Collaborative HIV Research**

MEETING OBJECTIVES

**Nina Mani PhD MPH
Forum for Collaborative HIV
Research**



BACKGROUND

- Approval of the two direct acting antivirals (DAAs) is a therapeutic boon for those suffering from chronic hepatitis C viral infection
- Approved DAA + Pegylated interferon/Ribavirin
- Certain patients in particular populations such as those in the historical cohort of bleeding disorder patients
- Complications of long-standing liver disease and interferon intolerance
- Interferon-free DAA combinations



MEETING OBJECTIVES

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- Identification of possible DAA combinations that could be used in this population: Risks and benefits
- Discussion of strategies that could facilitate access, if indicated, to interferon-free DAA combinations: Studies, treatment INDs
- Possible structural and logistical barriers, and ethical concerns: Study sites; outcome reporting; clinical specialties; grants



MEETING FORMAT

- Formal presentations in Session 1
- Followed by moderated discussion :
 - Discussion of questions posed by moderators



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OPEN DISCUSSION

Kenneth Sherman MD, PhD
**University of Cincinnati College of
Medicine**

Veronica Miller PhD
**Forum for Collaborative HIV
Research**



MEETING OBJECTIVES

- Define inclusion/exclusion criteria for the population
Investigational DAAs:
 - DAA characteristics for combination regimens
 - Drug-drug interaction studies
- Types of studies; Reporting requirements;
 - Clinical specialties needed for these trials
- When to start a treatment IND?
 - Where to conduct these trials: HTCs, ACTG, others?
- Other issues: Reimbursement for treating bleeding episodes during combination trials

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