

**Brussels I / Sitges III meeting -Third International Workshop  
"Clinical Trial Design: Experimental HCV Drugs for HIV/HCV Coinfected People"**

**Friday 20 November, 2009**

Venue: Radisson SAS EU Hotel, Rue d'Idalie 35, 1050 Brussels

**9:30-9:45 Welcome**

- Wim Vandeveldel – ECAB Chair

**9:45-10:45 Presentation of EMEA guidelines (20 min)**

- Speaker: Dr. Filip Josephson (EMEA)

**FDA perspectives on clinical trial design for new HCV products (20 min)**

- Speaker: Dr. Kimberly Struble (FDA)

**Followed by a general discussion (20 min)**

- Moderator: TBC (Wim Vandeveldel, Joan Tallada , Diego Garcia)

**10:45-11:00 Coffee break**

## EUROPEAN AIDS TREATMENT GROUP

### 11:00-12:00 Update on new anti-Hepatitis C molecules

- Speaker: Tracy Swan (Treatment Action Group, NYC, USA)
- Moderator: TBC (Wim Vandeveldel, Joan Tallada , Diego Garcia)

### 12:00-13:00 Update on resistance to HCV drugs & clinical implications

- Speaker: Dr. Stephane Chevaliez (Department of Virology, Hôpital Henri Mondor, France)
- Moderator: TBC (Wim Vandeveldel, Joan Tallada , Diego Garcia)

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### 13:00-14h30: Lunch at Radisson

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### 14.30-16:00 Roundtable

#### Clinical Trial Design: "Experimental HCV Drugs for HIV/HCV Coinfected People"

- Dr. Bernard Hirschel  
(Division des Maladies infectieuses, unité VIH/SIDA Hôpital Universitaire de Genève)
- Dr. Juergen Rockstroh  
(Department of Internal Medicine I, Bonn University, Bonn, Germany)
- Dr. Massimo Puoti  
(Department of Infectious Diseases, University of Brescia, Italy)
- Dr. Josep Mallolas  
(Infectious Diseases Service, Hospital Clínic, Barcelona, Spain)
  
- Moderator: Tracy Swan and Diego Garcia

This roundtable will feature a dynamic discussion where experts participating will be asked to respond to questions arising from three sources:

- Questions raised during the community pre-meeting the day before

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EATG is also a non profit NGO in Belgium (AISBL)

## EUROPEAN AIDS TREATMENT GROUP

- Questions identified by the moderators as result of the morning sessions
- Questions raised by the audience on the spot.

Typically, questions will address some controversial issues around testing novel HCV drugs in coinfecting populations, for instance:

- Who should be tested first in terms of treatment experience or not, liver disease status, immunological status, other factors? Why?
  - What liver monitoring techniques would you allow or would you prefer to use?
  - Would you allow or encourage use of side-effects palliative interventions?
  - Do you agree with lead-in clinical trial designs? Why?
- Etc.

**16:00-16:15 Coffee Break**

**16:15-18:00 Industry feedback**  
(15 min per company)

**18:00-18:30 Closing remarks**

- Joan Tallada (EATG)