

AMERICAN ASSOCIATION FOR
THE STUDY OF LIVER DISEASES



**Forum for
Collaborative HIV Research**

THE LIVER FORUM #3

SAN FRANCISCO, CA

12 NOVEMBER 2015

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facilitating collaborative research
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John Joseph Sninsky &
Susan Bardsley Sninsky



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STEERING COMMITTEE

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- Co-chairs
 - Gary Burgess, *Conatus*
 - Arun Sanyal, *VCU*
- FDA
 - Lara Dimick, *CDER/DGIEP*
 - Chris Leptak, *CDER/OND*
 - Ruby Mehta, *CDER/DGIEP*
- EMA
 - Elmer Schabel, *BfArM*
- William Baldyga, *Patient Representative*
- Jeff Bornstein, *Biogen Idec*
- Helena Brett-Smith, *BMS*
- Carol Brosgart, *UCSF*
- Laurent Castera, *Hôpital Beaujon*
- Scott Friedman, *Mount Sinai*
- Stephen Harrison, *Brooke Army Med Center*
- Tom Karlsen, *Oslo University*
- Veronica Miller, *HIV Forum*
- Massimo Pinzani, *UCL*
- Detlef Schuppan, *Mainz Uni Med Center/BIDMC*
- David Shapiro, *Intercept*
- Tracy Swan, *Patient Advocate*

FORUM STAFF

*facilitating collaborative research
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- Jeff Kaminski
- Myrna Cozen
- Brenda Rodriguez
- Lauren Smith
- Aileen Artus

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SPECIAL THANKS

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- Informed Horizons, LLC
 - Margie Poole
 - David Poole

THE LIVER FORUM: OVERALL GOALS

*facilitating collaborative research
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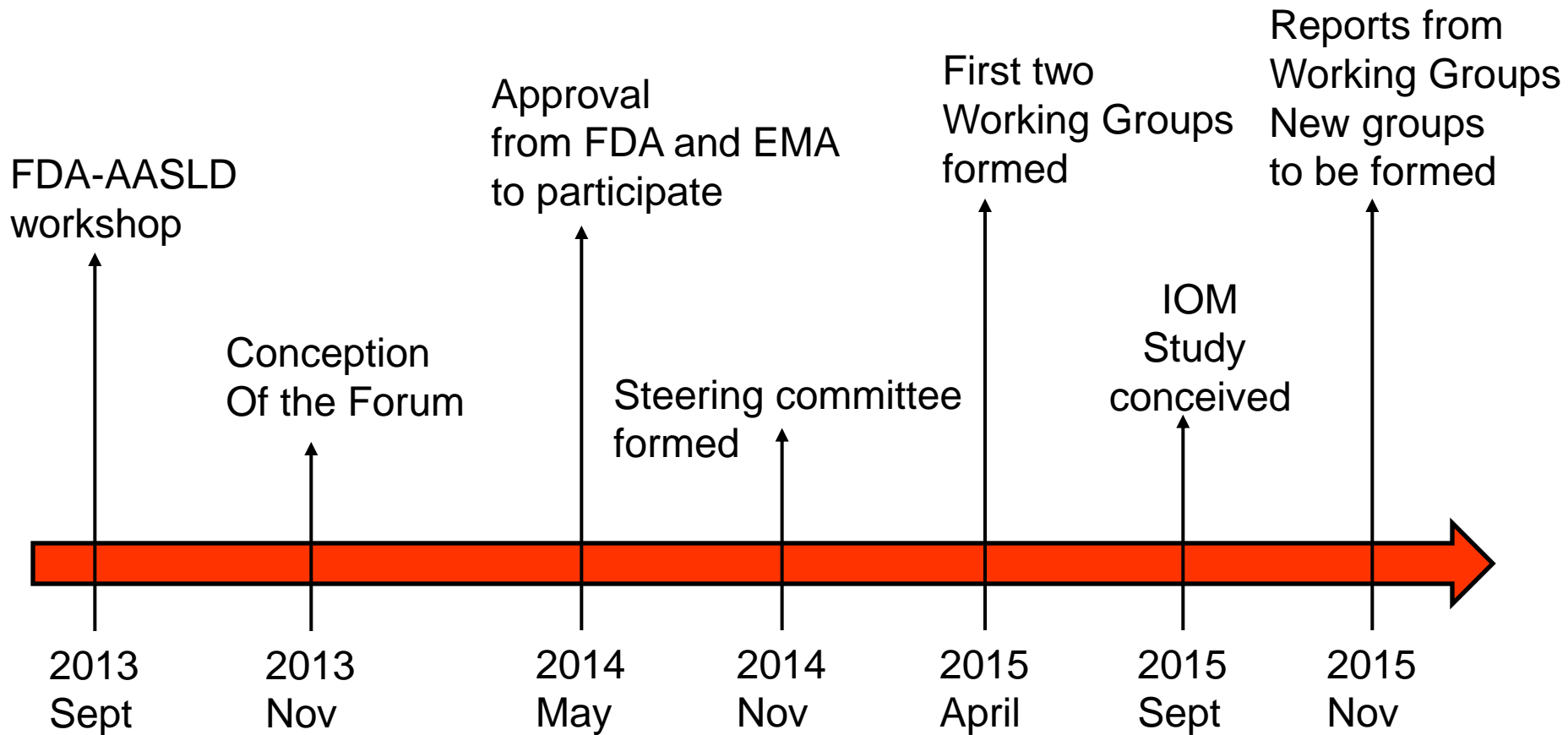
- Independent and neutral venue
 - Ongoing multi-stakeholder dialogue
 - Facilitate more efficient regulatory path for diagnosis and treatment of NASH and fibrosis
- Facilitate best science-based decisions, in real time, regarding efficacy and safety
 - Break down inefficiencies
 - Increase clarity
 - Benefit to the whole field, especially the patient

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The Liver Forum Timeline



AGENDA

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- **SESSION 1: PROJECT OVERVIEW & UPDATES**
 - WELCOME & INTRODUCTIONS
 - LIVER FORUM UPDATES
 - REGULATORY PERSPECTIVES

- **SESSION 2: WORKING GROUP REPORT & DISCUSSION (PART 1)**
 - DISEASE DEFINITIONS WORKING GROUP
 - DISCUSSION

- **SESSION 3: WORKING GROUP REPORT & DISCUSSION (PART 2)**
 - DATA STANDARDIZATION WORKING GROUP
 - DISCUSSION

- **SESSION 4A: NON-INVASIVE DIAGNOSTICS**
 - OVERVIEW: NON-INVASIVE DIAGNOSTICS: STATE OF THE ART

- **SESSION 4B: PANEL DISCUSSION**

- **SESSION 5: ANNOUNCEMENTS & WRAPPING UP**

- **ADJOURN & RECEPTION**

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