



**Forum for
Collaborative HIV Research**

HCV DRUG DEVELOPMENT ADVISORY GROUP MEETING #9

**Nov 8, 2012
THE FENWAY
INSTITUTE, BOSTON**

www.hivforum.org



enhancing & facilitating HIV research

FORUM MISSION

- The Forum for Collaborative HIV Research is a public/private partnership including government agencies, industry, HIV researchers and clinicians, payors, foundations and the HIV patient advocacy community
- Our mission is to facilitate and enhance HIV research
- **Apply HIV collaborative model to HCV**



MEMBERS-PARTNERS-COLLABORATORS

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Government Agencies	Academia / Providers	Industry		Community / Advocacy
USA <ul style="list-style-type: none"> • CDC • FDA • HHS/OASH • HRSA • NIH <ul style="list-style-type: none"> - NIAID - NIDA - NIMH - OAR • OGAC • USAID • VA 	<ul style="list-style-type: none"> • ACTG • INSIGHT • Epi / Stats • Immunology • Virology • Women's Health 	HIV <ul style="list-style-type: none"> • Abbott Lab. • Abbott Mol. • Alere • BD • BI • Bio-Rad • BMS • Genentech • Gilead • Illumina • Janssen • Merck • Monogram • Orasure • PacBio • Quest • Quintiles • Roche MS • Tobira • ViiV 	HCV (cont.) <ul style="list-style-type: none"> • Achillion • Biocartis • BI • BMS • DDL • Genentech • Gilead • GSK • Hoffman La Roche • Idenix • Janssen • Merck • Monogram • Novartis • PPD • Quest • Quintiles • Roche MS • Vertex • Virco 	HIV <ul style="list-style-type: none"> • ATAC • CAB-ACTG • CAB-INSIGHT • EATG • NGMAC • TAG
Europe <ul style="list-style-type: none"> • ANRS • EMA 	Foundations <ul style="list-style-type: none"> • BMGF • amfAR • EGPAF 	HCV <ul style="list-style-type: none"> • Abbott Lab. • Abbott Mol. 	HCV <ul style="list-style-type: none"> • HCAB • NATAP • NVHR • PWB+HCV • TAG 	Insurers <ul style="list-style-type: none"> • Kaiser Permanente
	Professional Societies <ul style="list-style-type: none"> • AAN • IAS • HIVMA • IDSA • EASL • AASLD 			



HCV DRUG DEVELOPMENT ADVISORY GROUP (HCV DRAG)

- Neutral, independent platform for dialogue among regulators (US, Europe), industry, professional societies, academia and community representatives in a rapidly evolving field
 - Clinical trial design for HCV DAA's in diverse populations
 - Standardization of nomenclature
 - Consensus on sequence analysis and phenotypic resistance studies
 - Collaborative network among HCV databases
 - Meet educational needs



HCV DRAG: STEERING COMMITTEE

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- Robert Kaufmann
- Patrick Harrington
- Daria Hazuda
- Ira Jacobson
- Donald Jensen
- Filip Josephson
- Ann Kwong
- Jean-Michel Pawlotsky
- Nina Mani
- Veronica Miller
- Isabel Najera
- Stuart Ray
- Kimberly Struble
- Tracy Swan
- Heiner Wedemeyer



PROCESS

- Annual general meetings (x2)
 - EASL conference
 - AASLD conference
- Working group meetings (by phone) as needed
- Special topic meetings as needed



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HCV DRAG WORKING GROUPS

- Sequence Analysis Working Group
- Phenotype Analysis Working Group
- Clinical Trials Working Group
- Definitions/Nomenclature Working Group
- Educational Slide Set Working Group
- Database Working Group



PRODUCTS & PUBLICATIONS

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- Clinically relevant HCV drug resistance mutations figure and tables - *Annals of the Forum for Collaborative HIV Research* 14(3): 1-8, Sep 12, 2012
- *Accepted* online 18 June 2012: Recommendations for standardized nomenclature and definitions of viral response in trials of HCV investigational agents –Special Article in *Hepatology*. DOI: 10.1002/hep.25888
- *Poster*: Consensus recommendations for virologic nomenclature in DAA clinical trials - *Journal of Hepatology* 56 (Suppl 2): S349, April 2012



PRODUCTS & PUBLICATIONS -2

- *Submitted to Clinical Infectious Diseases:*
 - Closing in on the Target: Sustained Virologic Response in Response-Guided Therapy

Manuscripts in process (draft in Program Book)

- Hepatitis C Drug Access for People with Inherited Bleeding Disorders
- **Educational HCV Resistance Slide Set**
 - Updated after each EASL/AASLD conference
 - Published on 5 websites
 - Managed by Erik Lontok



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SUPPORT ACKNOWLEDGMENT

- The Forum receives funding from member pharmaceutical and diagnostic companies