

8:00 - 9:00	Breakfast	
9:00 - 9:15	Welcome and Introductions	Ben Cheng
9:15 - 9:35	Overview of Issues with Expanded Access Programs	Valerianna Amorosa
9:35 - 9:45	Prior Expanded Access Programs	Linda Onaga
9:45 - 10:05	Community Perspective	Nelson Vergel Luis Mendao
10:05 - 10:15	Academic Perspective	Joel Gallant
10:15 - 10:25	Private Practice Perspective	Doug Ward
10:25 - 10:35	Payor Perspective	Michael Horberg
10:35 - 10:50	Break	
10:50 - 11:10	Industry Perspective	Karen Manson Randy Tressler
11:10 - 11:40	Regulatory Perspective	Kim Struble Nathalie Morgenstern
11:40 - 1:00	Discussion I	Moderators: Trip Gulick, Ben Cheng Discussants: Rob Camp, Dan Kuritzkes, Randi Leavitt
1:00 - 2:00	Lunch	
2:00 - 3:15	Discussion II	Moderators: Veronica Miller, Ben Cheng Discussants: Pablo Tebas, Fred Schmid, Jeff Murray, Christine Balt
3:15 - 3:30	Wrap up	Ben Cheng

Rethinking the Approach to Expanded Access Programs

Ben Cheng

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The Forum for Collaborative HIV Research is an independent Public-Private Partnership including government agencies, pharmaceutical and diagnostic industries, HIV researchers and clinicians, payors, foundations and the HIV patient advocacy community.

Our mission is to facilitate and enhance HIV research.

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Special Thanks

- Meagan Lyon
- Linda Onaga

- Debbie Cooke - Meeting Masters

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Rethinking the Approach to Expanded Access Programs

- EAPs are a critical component of drug development that provides people with few or no therapeutic options with early access to new therapies
- The number of people participating in EAPs have decreased in recent years
- Goal: how to improve expanded access programs in the future so that it meets the needs of patients, physicians, regulatory agencies and the sponsor

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Issues for Discussion

Need & Access

Are EAPs still necessary in the current treatment landscape?

What patient population has access to drugs through EAPs?

Access to drug during the transition period when the drug is approved for marketing

What are the barriers for patients to access an EAP?

What sites participate in an EAP?

What patient population has access to drugs through EAPs?

How valuable is the information gathered from EAPs?

IRB & Risk:Benefit

What are the IRB issues?

What are the risks?

What are the benefits?

What are the contract and liability issues?

Site Issues

Should there be reimbursement for sites participating in EAPs?

Do EAPs slow enrollment into other clinical trials?