

DRAFT



**2015 BioSafe General Membership Meeting  
May 11-13<sup>th</sup>, 2015  
MedImmune  
Gaithersburg, Maryland**

<b>Monday, May 11<sup>th</sup></b>	
12:00-1:00 PM	Registration
1:00-1:15 PM	<b>Welcome and Introduction</b> David Hutto, Eisai
1:15-1:30 PM	<b>MedImmune Welcome and Introduction</b> Rakesh Dixit, MedImmune
1:30-3:00 PM	<b>Immunotherapy for Cancer: T-cell Targeted mAbs and CAR-T Therapies</b> Chair(s): Patty Ryan, MedImmune
3:00-3:30 PM	Coffee Break
3:30-5:00 PM	<b>Juvenile Toxicity Studies with Biotherapeutics</b> Chair(s): Gerhard Weinbauer, Covance
5:00-5:15 PM	<b>Message from BioSafe Chair</b> Marque Todd, Pfizer
	<b>Open Night</b>

**Tuesday, May 12<sup>th</sup>**

7:30-8:30 AM	Breakfast and Registration
8:30-10:00 AM	<b>Advancing the Contribution of PK, PD and Ig to the Design and Interpretation of Toxicology and Clinical studies</b> Chair(s): Mark Milton, Novartis and Laurie Tsuruda, BioMarin
10:00-10:30 AM	Coffee Break
10:30-12:00 AM	<b>Specialty Biologics</b> Chair(s): Jayanthi Wolf, Merck
12:00-1:00 PM	Lunch
1:00-2:30 PM	<b>Challenges w/ Biotherapeutics Using Non-standard (Alternative) Routes for Delivery</b> Chair(s): Jorg Blumel, Genentech
2:30-3:00 PM	Coffee Break
3:00-5:15 PM	<b>Special Strategic Topics and Programs for Rare Diseases</b> Chair(s): Jim Fikes, Biogen Idec and Lauren Black, CRL
5:30-7:30 PM	<b>Reception at MedImmune</b>

**Wednesday, May 13<sup>th</sup>**

7:30-8:30 AM	Breakfast and Registration	
8:30-9:30 AM	<b>Open Forum</b> Chair(s): Jorg Blumel, Genentech and Patty Ryan, MedImmune	
9:30-10:30 AM	<b>New Pregnancy Labeling</b>	
10:30-11:00 AM	Coffee Break	
11:00-12:30 PM	<b>Carcinogenicity Assessment of Biologics</b> Chair(s): Shawn Heidel, Covance	
12:30-12:45 PM	Closing Remarks and Feedback from General Membership	