



THE VOICE OF  
UK BIOSCIENCE

**Clinical Development of  
Novel Biological Products**  
24 May 2007  
Central London

- 9:30 – 10:00 Registration**
- 10:00 – 10:05** Opening remarks  
**Dr Lincoln Tsang, Chairman of BIA Regulatory Affairs Advisory Committee, Arnold & Porter**
- 10:05 – 10:45** Keynote presentation: Post TGN1412 challenges of first-in-man clinical studies  
**Professor Sir Gordon Duff, Chairman of Commission on Human Medicines, UK**
- 10:45 – 11:00 Tea/Coffee Break**
- 11:00 – 11:30** Competent Authority perspective: Regulatory approach for assessment of applications for first-in-man trials with novel biological products and interaction with an Expert Advisory Group/CHM  
**Dr Elaine Godfrey, Pharmaceutical Assessor, Clinical Trials Unit, MHRA, UK**
- 11:30 – 12:00** Ethics Committee perspective: Research ethics committees' responsibilities and issues faced post TGN1412  
**Dr Hugh Davies, Ethics Adviser, NRES, UK**
- 12:00 – 12:30 Panel Discussion and Q&A**
- 12:30 – 13:30 Lunch**
- Impact of TGN1412 on clinical development in Europe**
- 13:30 – 14:00** Scientific considerations  
**Dr Sean Harper, Senior VP Global Development and Chief Medical Officer, Amgen, USA**
- 14:00 – 14:30** Industry perspectives in relation to approach for first-in-man clinical trials:  
Big Pharma  
**Dr Mark Levick, VP Clinical Pharmacology and Discovery Medicine, GSK, USA**
- 14:30 – 15:00** Small Biotech  
**Ms Charmian Wells, VP Regulatory Affairs, PanGenetics, UK**
- 15:00 – 15:30 Tea/Coffee Break**
- 15:30 – 16:00** Academic Clinician perspective  
**Dr Richard Begent, Royal Free Hospital, UK**
- 16:00 – 16:30** CRO perspective: Accreditation of Phase I Units  
**Dr Liz Allen, Director of Scientific Affairs, Quintiles**
- 16:30 – 17:00 Panel Discussion and Q&A**
- 17:00 Closing remarks**