



Fourth Open Scientific
European Immunogenicity Platform Symposium

COPENHAGEN 2012
FEB 6 - 8

EIP overview

- Currently 25 members
 - Biopharma companies
 - Service companies
 - Research Institutes
- 4 new members joined in 2011
 - Ferring Pharmaceuticals, Ms. Helen Sjögren
 - H. Lundbeck, Mr. Lars Østergaard Pedersen
 - TNO Pharma, Ms. Babs Fabriek
 - Pieris, Mr. Andreas Hohlbaum



Activity Report

- Working groups
 - Forum for information and strategy exchange
 - ADA Assays:
 - **A fit-for-purpose strategy for the risk-based immunogenicity testing of biotherapeutics: a European industry perspective**
 - Presentation by Cathelijne Kloks
 - Protein characterization
 - Paper published in 2010
 - Cellular Immunogenicity
 - Paper expected in 2012-13



Activity Report

- EMEA Draft Guidelines
 - 'Guideline on similar biological medicinal products containing monoclonal antibodies'
(EMA/CHMP/BMWP/403543/2010)
 - 'Guideline on immunogenicity assessment of monoclonal antibodies intended for in vivo clinical use.'
(EMA//CHMP/BMWP/86289/2010)
 - EIP submitted concerted view on the guidelines in May 2011
 - EIP was invited to the closed EMEA workshop on both guidelines in October 2011
 - Several recommendation of the EIP are being taken into account working toward the final texts of the guidelines.



Activity Report

Biotechnology



SciVerse ScienceDirect 'Top 25 Hottest Articles'
<http://top25.sciencedirect.com>

Top 25 Hottest Articles

SciVerse ScienceDirect also offers a Top 25 Hottest Articles alert report, which lists the articles that have been most downloaded at a journal and subject level. The reports are generated quarterly in order to accurately reflect usage patterns.

Taking

I.C. Büttner, H. Kropshofer, B.M. Reipert, M. Weigert
The Top 5 Hottest Articles for Biologicals for the last quarter of available data were:

- 1. Taking immunogenicity assessment of therapeutic proteins to the next level**
Biologicals, Volume 39, Issue 2, March 2011, Pages 100-109 & Büttner, I.C.; Chamberlain, P.; Chowers, Y.; Ehmann, F.; Greinacher, A.; Jefferis, R.; Kramer, D.; Kropshofer, H.; Lloyd, P.; Lubiniecki, A.; Krause, R.; Mire-Sluis, A.; Platts-Mills, T.; Ragheb, J.A.; Reipert, B.M.; Schellekens, H.; Seitz, R.; Stas, P.; S
- 2. Antivenoms for the treatment of snakebite envenomings: The road ahead • Review article**



2012 conference

- Keynote presentation:
Regulation of T cell-dependent antibody responses by Toll-like receptors, Dr. Tony DeFranco, UCSF (Feb 8)
- EIP Fit-for-purpose Strategy Paper (Feb 7)
 - Cathelijne Kloks
 - Panel discussion with C.Berger, H. Kirby, S. Spindeldreher, D. Kramer
- ARIBISK IMI program (Feb 8)
 - M. Pallardy and D. Sikkema
- Introduction to Immunogenicity (Feb 6)



2012 conference

- Regulatory topics
 - Dr. Robin Thorpe, Dr. Paul Chamberlain, Dr. Gopi Shankar
- Clinical outcome
 - Dr. Denis Mulleman, Dr. Gert Vanassche, Dr. Pauline Van Schouwenburg, Dr. Niels Vande Castele
- Aggregates and Immunogenicity
 - Dr. Roy Jefferis, Dr. John Carpenter, Dr. Christine Bryson, Dr. Grzegorz Kijanka
- Tolerance
 - Dr. Aladair Coles, Dr. David Wraith, Dr. Vera Brinks
- Predictive technologies
 - Dr. Simon Folkerstma, Dr. Matthew Frayne, Dr. Mikkel Harndahl, Dr. Olga Obrezanova
- Assays
 - Dr. Michael Tovey, Dr. Elli Oksanen



However

- Social Event
 - Busses depart at 18:00
 - Fun, Food and Music included
 - Networking and liaising strongly recommended

