TT 34: Standardization of bioassays for vaccines

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Background and Aim

- ❑ In contrast to the unwanted immunogenicity field, regulatory papers and recommendations on how to perform and validate assays for wanted immunogenicity of vaccines are not published yet.
- ❑ Aims:
  - ○ Organize break-out session on wanted and unwanted immunogenicity (this conference)
  - ○ Publish White Paper on how to perform and validate assays for the immunogenicity of vaccines

Team Members

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Ongoing Activities and Current Results

- ❑ Organization EBF 2012 break-out session on wanted and unwanted immunogenicity on Thursday 15th from 14.00-15.30h: welcome to join !
- ❑ Current team discussion on White Paper:

<u>Immunogenicity assays for vaccines compared to related assay types:</u>

Ligand-binding assays for PK study	Immunogenicity assays for unwanted immunogenicity	Immunogenicity assays for vaccines
- Quantitative (mass/ international units) - True assay control - Assay: sensitive, accurate, precise, specific.	- Qualitative/ semi-quantitative (titer) - No true assay control - Clinical relevance: Focus on lowest possible detection limit for safety	- Semi-quantitative (titer) - True assay control not always available - Clinical relevance: Focus on correlate of protection

Future Plans

- ❑ Publish White Paper on this topic in 2013:

Key terms: antibody serology assays, validation, correlate of protection, neutralization antibody assays, therapeutic vaccines, regulation.