

Fig. 3

Key principles of immunogenicity testing in clinical trials

Evaluation of immunogenicity should be systematic

- Immunogenicity assessment should be part of all clinical trials
- All patients should be tested, not only symptomatic ones
- Sampling should be routine repetitive plus symptom-driven
- Sampling before administration should be included (no or low drug interference)
- Testing should preferably be comparable between trials (standardisation of assay systems(s) allows comparison across indications)
- For chronic treatments 1-year immunogenicity data for MAA required (deviations should be justified)

What antibody testing should reveal:

- Is the antibody response transient or persisting
- Are the antibodies clearing, neutralizing, non-neutralizing

According to Dr. Isabel Büttel, Heidelberg, Oktober 2010