Immunogenicity guideline – basic description

The importance of a description of possible scenarios / factors that may cause immune reactions towards a biological medicinal product

- Junior assessors in National Agencies not being specialists in immunogenicity

- Also linking to regulatory issues in other chapters/areas of the GL as well, like the Risk Base Approach in Chapter 8

Venke Skibeli, Norwegian Medicines Agency

What is the basic immunogenicity package ?

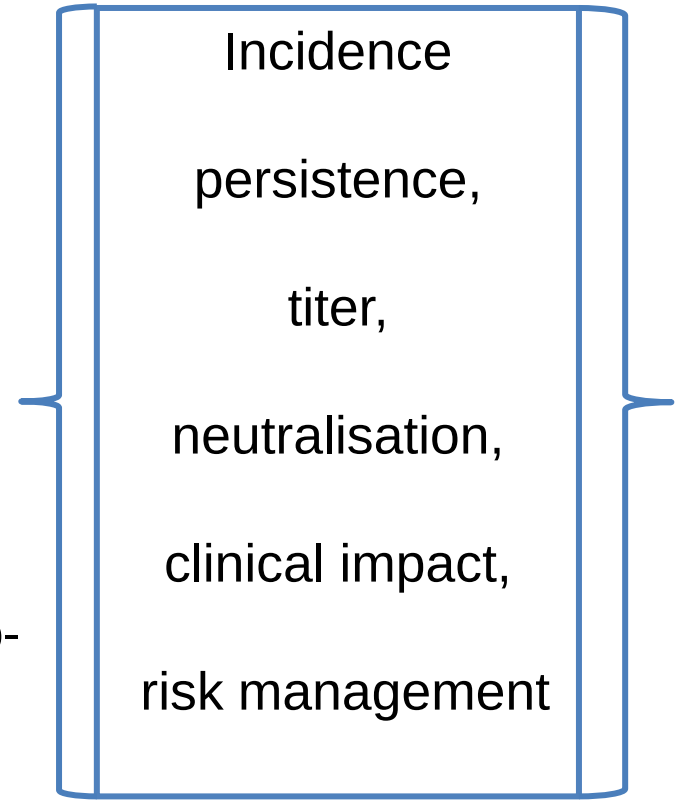
Low risk (e.g. etanercept)

Frequent sampling only at the beginning

Analysis at the end of a trial

Shorter follow up

Routine pharmaco-vigilance (for immuno-genicity)



High risk (e.g. epoetin)

More frequent sampling

Real time analysis

Longer follow up

Cell-based neutralisation assay

Intensified clinical monitoring

Post-marketing immunogenicity study(ies)