

## IMMUNOGENICITY

- Pre-clinical and clinical studies
- Biosimilar studies
- Bridging and direct binding based assays
- Cell based and Ligand binding based neutralization assays
- Isotyping assays
- Supporting confirmation assays
- Anti-PEG assessment

### Dedicated Immunogenicity laboratory

- Method Development
  - Custom drug labeling
  - PC characterization
  - Optimal MRD and drug tolerance
  - ACE and SPEAD adapted methods
  - Pre-validation cut point assessment
- Validation
  - Balanced design
  - Cut point setting
- Sample Analysis
  - In study cut point assessment



Immunologix Scientists and Principal Investigators have demonstrated experience and proficiency with Immunogenicity assays

Dedicated Critical Reagent group prepares and characterizes all conjugates and PCs

Dedicated Sample handling and operations group

