CASE STUDY

Maximizing Drug Tolerance While Maintaining Sensitivity Using Novel Methods

STUDY BACKGROUND

TYPE OF STUDY

Clinical phase anti-drug antibody (ADA) assessment for enzyme replacement therapy for a serious unmet medical need

REGULATORY PARAMETERS

Monitor anti-PEG prevalence and attenuation upon exposure to PEGylated therapeutics

OBJECTIVE

Maximize drug tolerance while maintaining sensitivity

CHALLENGE

PEGylation is used to extend half-lives for many new biologics as well as conventional low molecular drugs, and this potent therapeutic had a very long half-life. Due to environmental exposure, a significant portion of the general population has pre-existing anti-PEG antibodies. In most cases, these antibodies are clinically benign, but there have been occurrences where they play a role in serious adverse reactions upon drug exposure.

For that reason, regulatory agencies are requiring the monitoring of anti-PEG prevalence and attenuation upon exposure to PEGylated therapeutics. In this study, BioAgilytix had to assess the immunogenicity of the PEGlayted therapeutic with an approach that could maximize drug tolerance while maintaining high sensitivity.

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SOLUTION

Unconventional and unique projects like this one pose challenges when it comes to meeting evolving regulatory expectations. Ingenuity was required because the tried and true methods that suffice for the large majority of ADA assessments could not attain the level of sensitivity demanded in this case. It required BioAgilytix to flex its knowledge and the techniques used for other applications in new and innovative ways.

The following areas of expertise were vital to BioAgilytix's overall solution.

- Considerable experience with varied therapeutics and PEG configurations.
- Deep expertise in short chain 5K to long chain branching PEGs.
- Very high proficiency in working with the statistics for dealing with pre-existing antibodies to set appropriate cut points.
- Experience with antibody enrichment and an understanding of the limitations of traditional immunoassay platforms.

Combining research drive and development discipline, BioAgilytix developed a method that leveraged existing technologies in unique ways and ultimately arrived at a regulatory compliant and defendable approach for the client.

OUTCOME

By bringing a novel method from proof of concept to an actual practical solution, BioAgilytix helped the sponsor company meet drug tolerance requirements while maintaining high sensitivity. The method is proving out and providing important data in the project's clinical development phase.

Through its unique solution, BioAgilytix was able to meet regulatory expectations and provide important safety information that, coupled with efficacy data, will likely lead to a new therapeutic drug to address an unmet medical need.

Learn more about our services for large molecule bioanalysis at **www.bioagilytix.com.**

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