



Prism Ideas Collaboration Yields New Insights Into IgG Pharmacokinetics in Patients with Primary Immunodeficiencies

Background

A leading pharmaceutical company with an extensive portfolio of biotherapies wanted to investigate novel administration methods for one of its established protein-based supplementation therapies. The company was also keen to understand the efficacy and safety implications of an experimental biologically enhanced dosing strategy currently under investigation by a competitor.

Challenge

The company produced both intravenous (IV) and subcutaneous (SC) preparations of the product; however, the fate of SC-administered therapy was poorly understood. A major challenge facing the client was that of understanding how the bioavailability of the product differed with IV and SC dosing and, in particular, how individual patient characteristics affected the optimal dose required for each patient. A program of clinical trials investigating alternative dosing strategies would have involved considerable expense with no guarantee of a return on investment. The client company approached Prism Ideas to discuss alternative methods by which they could further understand the options for improving the dosing of their product.

Solution

Prism Ideas organised a series of advisory boards with leading academic experts and key opinion leaders in the field of immunodeficiency. The aim of these meetings was to review the available evidence in order to establish the key physiological processes involved in the absorption and distribution of the product when administered by both the IV and SC routes. The meetings led to a consensus 'physiological model' that Prism Ideas, in collaboration with pharmacokinetic (PK) modelling experts, then translated into a robust PK model. This model accurately simulated the pharmacokinetics of the product administered by either route and under a variety of dosing scenarios.

Conclusion

The resulting model gave the client company a greater clinical understanding of the issues involved in the dosing of its product and an insight into the variation in bioavailability seen among individual patients. The model formed a solid base for simulating alternative dosing strategies and also provided the client company with a scientific foundation with which to defend its product from competitor's claims for superior dosing strategies. The work resulted in both a poster and oral presentation at the annual meeting of a leading American congress and will shortly be published as a full article.

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