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Abstrak

ABSTRAK

Delivery of pharmacological doses of proteins to people has raised concerns of inducing immune responses, especially when the protein is provided in multiple doses over an extended period of time. Immune responses could impact the therapeutic exposure and efficacy of the protein itself. In addition, there have been fears of anaphylaxis or autoimmunity. This review summarizes the available literature regarding the measurement and evaluation of immune responses observed during clinical assessment of recombinant human proteins. Immune responses have ranged from none at all to inactivation and/or accelerated clearance. Presence of antibodies does not necessarily impact therapeutic viability. While responses are related to frequency and route of delivery, there is no clear relationship that enables one to predict the clinical experience.