ACCELERATION STRATEGIES FOR FIH PROCESS DEVELOPMENT

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There is increasing need for acceleration strategies for FIH process development in order to enable rapid probing of the biology in the clinic. For monoclonal antibodies, platform knowledge can be leveraged to replace process development with platform process verification. However, the therapeutic biologics pipeline is changing, and new modalities do not have an established PD platform approach. An alternate acceleration paradigm is necessary that allows opportunities for process development in addition to time savings. The new Fast-to-Patient strategy addresses these needs by executing the tox campaign early using pools, allowing time for process development. Product quality comparability between clone-derived clinical material and pool-derived material used for toxicology studies is a critical factor for success. Case studies and lessons learned will be discussed. A fundamental understanding of the product attributes, as defined within the Quality Target Product Profile, is a key enabler for acceleration strategies.