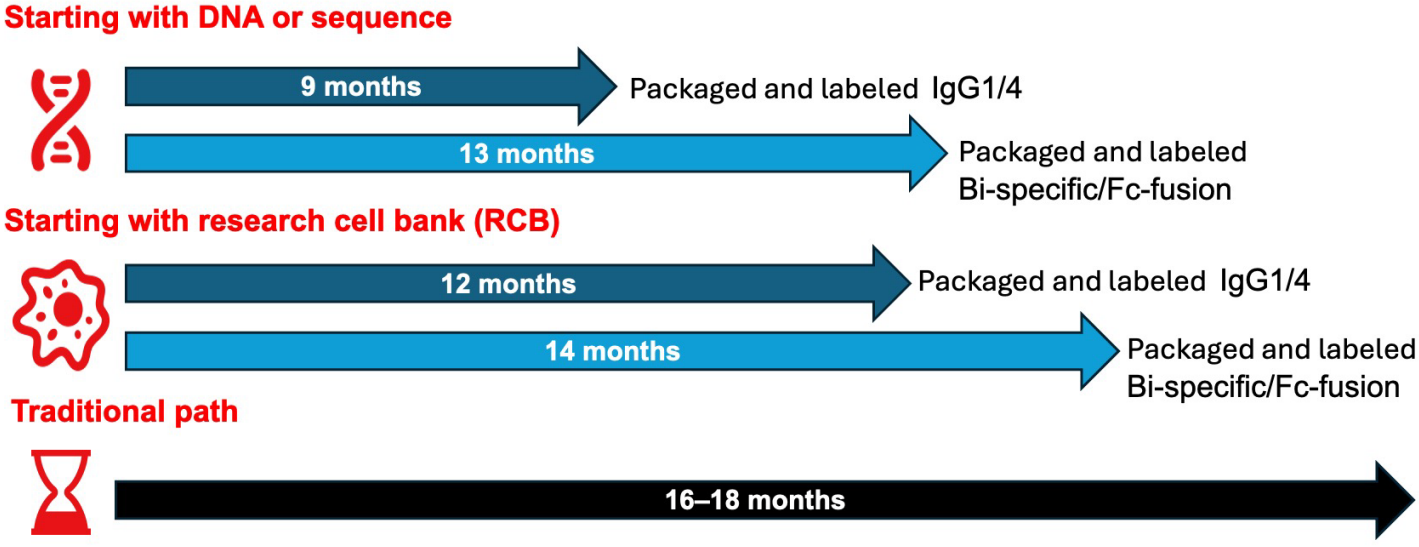
Path to IND for biologics

Reduce time to IND submission and patient dosing **as few as 9 months.*** How much time could we save you?



ThermoFisher SCIENTIFIC

Key factors for compressing timelines on the Path to IND

Utilize artificial intelligence and machine learning (AI/ML) technologies to drive gene optimization and vector construction for increased protein expression.

The CHO-K1 host cell line with transposase technology enhances gene integration and can achieve titers up to 8 g/L. It has been used in over 43 IND/IMPD submissions. High-throughput process development leverages the Beacon™ Optofluidic System to select top-expressing cell clones.

Downstream platform performance for IgG1/4 is confirmed, and process development for Bi-specific/Fc-Fusion molecules is performed using stable pools.

Available platform liquid DS/DP formulation for IgG1/4 up to 50 g/L, with custom formulation development for all modalities below 250 g/L.

Comprehensive analytical testing services help ensure the safety, potency, and purity of your biologics. These include multi-attribute methods (MAM), platform methods, and custom molecule-specific methods to support any modality.

Regulatory document packages (Module 3) are prepared to support your submissions, using templates based on similar projects.

Learn more at patheon.com/PathtoIND or email us at pharmaservices@thermofisher.com

*Terms and conditions: Titer levels provided are estimates based on third-party results and may vary depending on molecule type or other factors. The timeline from DNA to drug product and the start of clinical trials for all Path to IND for biologics options may vary depending on molecule type or other factors and are estimates to be finalized once third-party cell line development dates are available and confirmed. The 9-month timeline involves additional risk.