BIOSIMILAR CMC ANALYTICAL MASTER FILES & DEVELOPMENT SOLUTIONS

Pre-developed, risk-mitigated biosimilarity assessment, data evaluation, consultation and methodologies

The successful development of a biosimilar presents unique challenges compared to that of an innovator biologic. In particular, one must prove the biosimilar candidate's structural and functional differences do not have a meaningful impact on the clinical safety and efficacy profile already established for the innovator. Comprehensive and rigorous analytical testing to assess biosimilarity is thus the foundation upon which the successful development of a biosimilar begins.

Through experience from more than 150 unique biosimilar programs, we have developed and have plans to expand a portfolio of pre-established analytical methods and data to assess biosimilarity for a number of innovator biologics. Compiled as individual Biosimilar CMC Analytical Master Files, these resources are valuable and unique guides to support your biosimilar program throughout its development and product lifecycle.

CMC Analytical Master Files:

- RoACTEMRA® (tocilizumab) - available
- COSENTYX® (secukinumab) - available
- DARZALEX® (daratumumab) - available
- TECENTRIQ® (atezolizumab) - available
- Eylea® (aflibercept) - available
- Avastin® (bevacizumab) - available
- Humira® (adalimumab) - available
- KEYTRUDA® (pembrolizumab) - available
- OPDIVO® (nivolumab) - available
- IMFINZI® (durvalurnab) - pending
- Yervoy® (ipilimumab) - pending
- Entyvio® (vedolizumab) - pending

Solution Highlights

- Assess biosimilarity sooner with the prospective Biosimilar CMC Analytical Master Files of pre-established methods and preliminary reference data
- Make better decisions with rigorous, comprehensive testing methodologies developed to enable an early and thorough assessment of biosimilarity
- Smarter advancement via a phase-appropriate, molecule management approach with the development and product lifecycle in mind
- Mitigate risks to safety and potency through assessment of pre-identified, high-, medium- and low-risk Critical Quality Attributes (CQAs)

Solution Benefits

- Flexibility: Options wherever your biosimilar is in the development or product lifecycle:
  - Testing solutions
  - Evaluation of your data
  - Consultative insights
  - Access to methods and data
- Time Savings: up to 12 months or more time saved to assess in vitro biosimilarity vs de novo Research & Development
- Increase Probability of Clinical Success: using an early, risk-mitigated approach
- Increase Asset Value: up to 30 percent or more by reaching the market faster and with greater probability of success

COVANCE®
SOLUTIONS MADE REAL®

Biosimilar CMC Analytical Master Files & Development Solutions

Assess Biosimilarity Sooner

With the prospective Biosimilar CMC Analytical Master Files containing pre-established methods and preliminary reference data:

- Pre-identified preliminary CQAs of innovator provide an existing foundation to assess biosimilarity
- Pre-established, qualified methodologies provide a rigorous framework to test the CQAs of your biosimilar candidate right away
- Pre-generated preliminary reference data gives you a head start to assess biosimilarity

Make Better Decisions

Through rigorous and comprehensive testing methodologies developed to enable early and thorough assessment of biosimilarity:

- Increase the probability of your candidate progressing into clinical development with extensive early characterization to establish biosimilarity
- Tailor your program based on a broad spectrum or specific set of regulatory expectations
- Understand protein structure and characteristics relevant to function
- Understand how formulation differences might impact method development, validation and the molecule's attributes

Smarter Advancement

Via a phase-appropriate, molecule management approach with the development and product lifecycle in mind:

- Start using the end in mind with a CMC analytical strategy based on the Target Product Profile and mechanism of action (including secondary mechanism of action – ADCC, CDC)
- Access to qualified methods provides a rigorous early, traceable assessment and rapid progression path to validated status (cGMP standards, ICH requirements)
- Prepare long term for routine, global lot release and stability testing under commercial GMP conditions

Take Advantage of Related Covance Solutions for Biosimilar Development

- Nonclinical: Animal Studies & Bioanalysis (Toxicology, PK/PD, Immunogenicity)
- Clinical: Phase I & III (PK/PD, Immunogenicity, Efficacy)
- Central Labs, Clinical Bioanalysis and Biomarkers, including Companion Diagnostics
- Regulatory Strategy
- Commercial Market Access: Value Communications, Policy Reimbursement, Patient Value and Patient Reported Outcomes

Learn more about our drug development solutions at **www.covance.com**

The Americas +1.888.COVANCE (+1.888.268.2623) +1.609.452.4440
Europe/Africa +00.800.2682.2682 +44.1423.500888
Asia Pacific +800.6568.3000 +65.6.5686588

 SPBPH010-1019

COVANCE®
SOLUTIONS MADE REAL®