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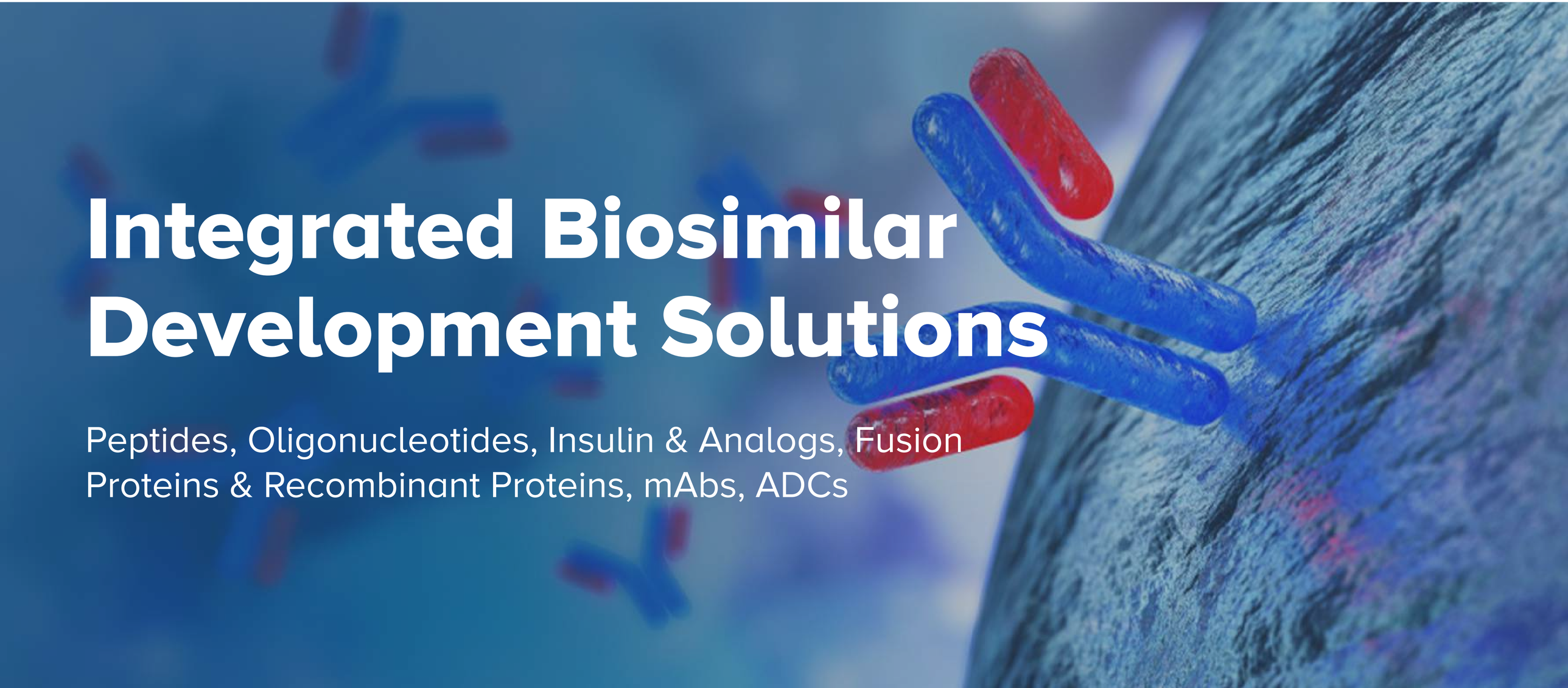
veeda clinical research®

BIONEEDS



Integrated Biosimilar Development Solutions

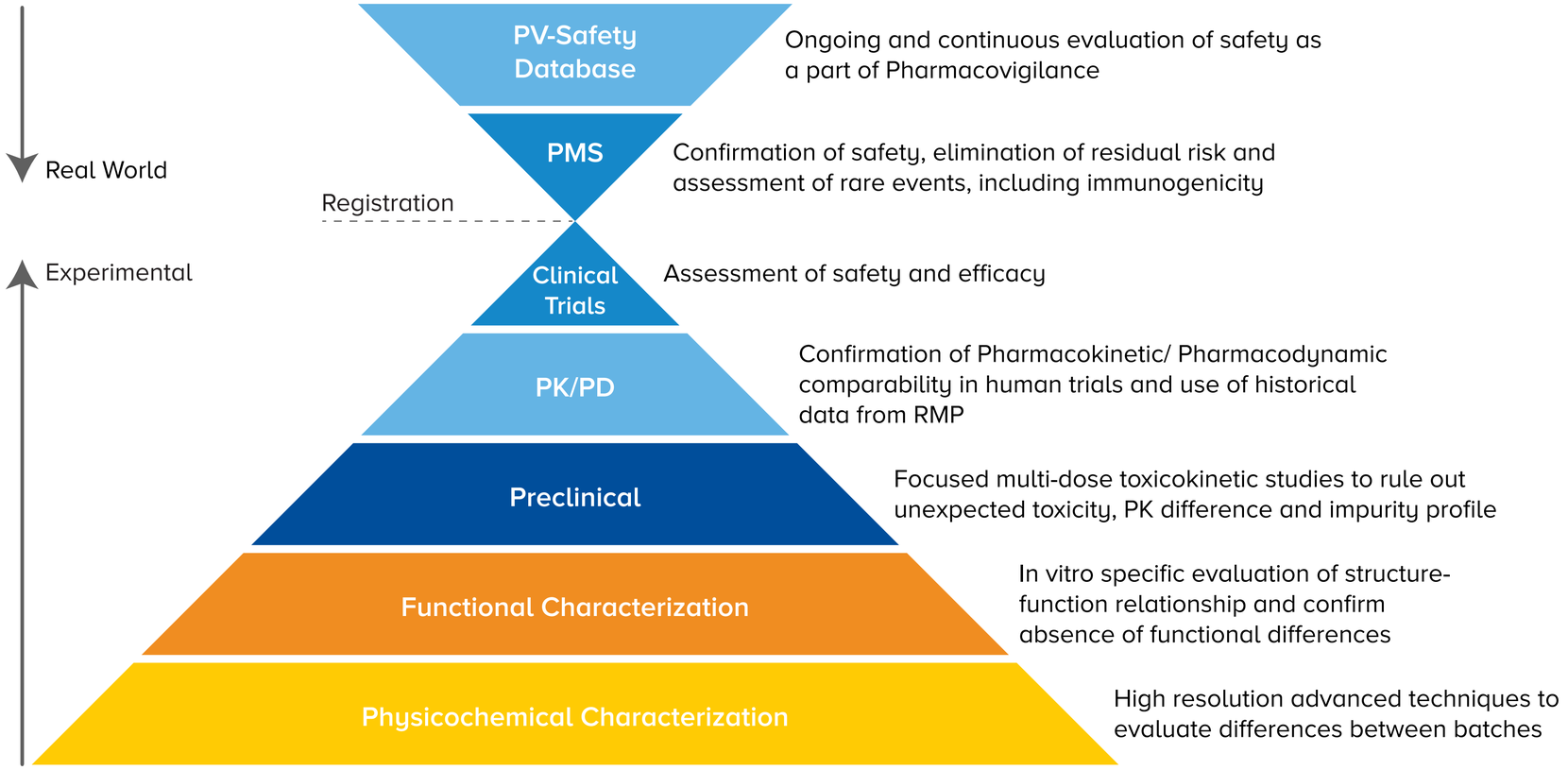
Peptides, Oligonucleotides, Insulin & Analogs, Fusion Proteins & Recombinant Proteins, mAbs, ADCs

In the dynamic landscape of Biosimilar development, ensuring similarity to the Reference Product is crucial. To meet this demand, regulatory bodies advocate for a comprehensive assessment of the "Totality of Evidence." This strategy involves systematically eliminating residual risks from non-clinical to clinical stages, thereby streamlining development timelines and reducing costs.

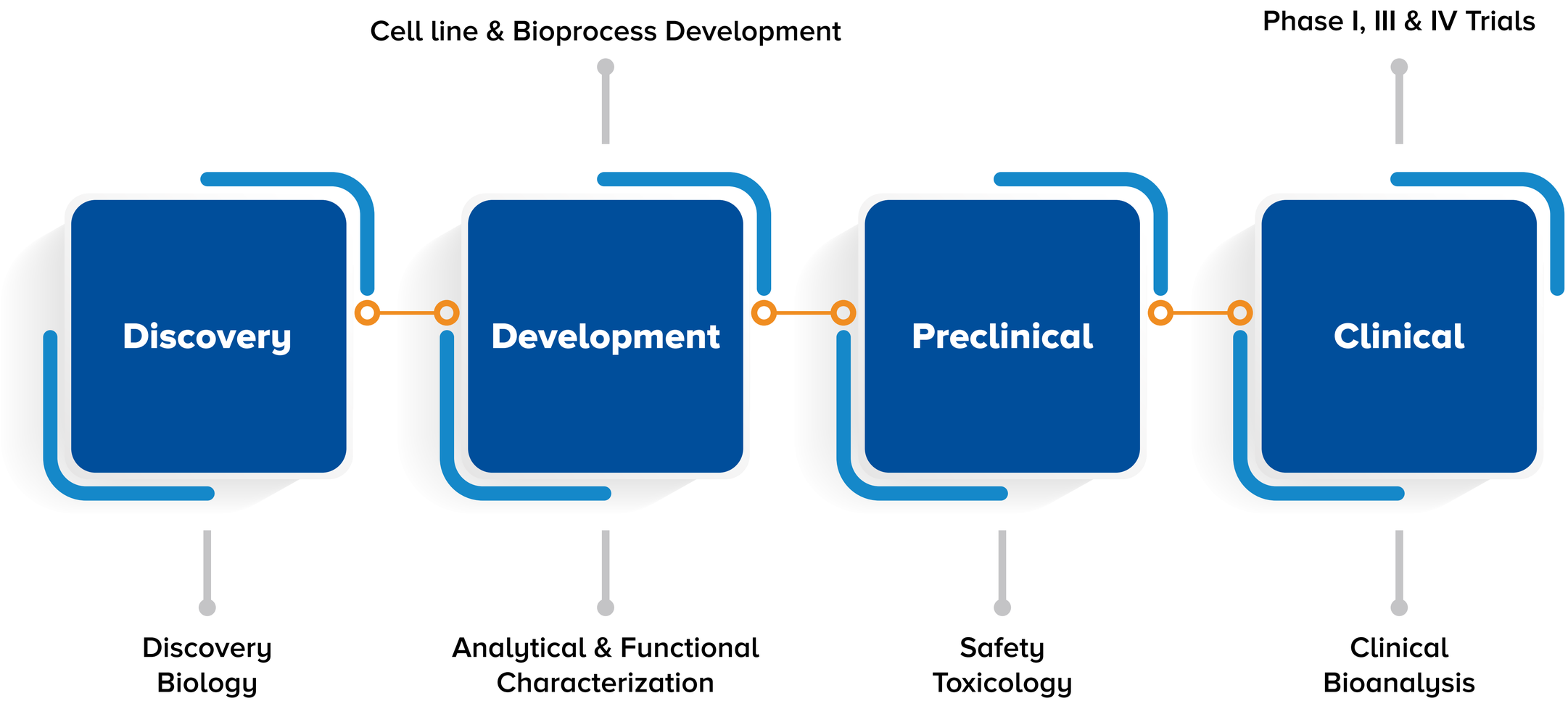
At Veeda Group, we fully support this end-to-end approach, leveraging our expertise to navigate each stage of Biosimilar development efficiently. By integrating data from physicochemical analysis, functional assays, preclinical and clinical trials, we ensure robust evidence of biosimilarity, empowering stakeholders to confidently advance their products to market.

Building Confidence in Biosimilars

Totality of Evidence in Biosimilarity Assessment



Accelerating Biosimilar Development with Scientific Precision



Offering Integrated End-to-End Biosimilar Development Solutions

Discovery Biology

Biochemical and Functional Characterization

- Biochemical activity assays
- Ligand binding assays
- Target Phosphorylation assays (cell-free and cellular)
- cAMP assays
- Proliferation and viability assays
- Apoptosis assays
- Reporter gene assays
- CDC and ADCC assays
- Measurement modes
  - Luminescence
  - HTRF/TRF
  - AlphaScreen®
  - LANCE/DELPHIA
  - Luminex
  - Elispot

Surface Plasmon Resonance

- Association and dissociation kinetics for ligand binding assays
- FcRn, FCγ Binding assays

Flow Cytometry

- Receptor Binding, Cytokine and Immune Cell Profiling
- Biomarker analysis

Immunogenicity Assays for Drug Products Impurities

Offering Integrated End-to-End Biosimilar Development Solutions

Bioprocess Development

Clone/Cell Line Development

- Cloning, expression and purification of recombinant proteins in preferred microbial and mammalian hosts
- Clone screening and selection with high cell density and productivity

Cell Line Characterization (Research Cell Bank)

- Stability
- Purity & Sterility
- Gene/Plasmid copy number

Upstream Process Development & Optimization

- Process development & optimization at 10/30/100 ml scale (DOE)
- Process scale-up at 2 L and 5 L bioreactors
- Harvest clarification

Downstream Process Development & Optimization

- Process development and optimization for purification, viral inactivation and process residue clearance of recombinant proteins using various chromatography strategies
- Filtration (UF/DF) and concentration optimization

Offering Integrated End-to-End Biosimilar Development Solutions

Analytics & Characterization

Physico-Chemical Characterization

- Intact & subunit mass
- Peptide & disulfide mapping, sequencing
- Release glycan (N-/O-linked)
- Post translational modifications & sequence variant
- Product variant analysis
- Molecular heterogeneity by capillary electrophoresis
- Charge variant analysis
- Peptide and oligos characterization

Higher-Order Structure Characterization

- Secondary & tertiary structure
- Protein conformation
- Protein dynamics & stability
- Protein aggregation studies

Process Support and Analytical Services

- Upstream and downstream analytical support (IPQC, FIO, FPC, SAR)
- Process Residuals (HCP, HCD, rProA)
- Method development - RP, SEC, IEX, HILIC, HIC methods
- Impurity identification, enrichment and characterization
- Advanced HOS – NMR & AUC analysis

Offering Integrated End-to-End Biosimilar Development Solutions

Preclinical Assessment

- Acute toxicity studies, sub-chronic and chronic toxicity
- Reproduction & Developmental Toxicity (DART)
- Functional assays including biopotency, bio-identity, pyrogen, and abnormal toxicity assessment, Genotoxicity Studies
- Inhalation toxicity (GLP Inhalation Studies)
- Custom generation of animal sera for Host Cell Protein development services

Test System	Species
Rats	Wistar, Sprague Dawley
Mice	Swiss albino, Balb/C, C-57, CBA/J
Rabbits	New Zealand White
Guinea Pigs	Dunkin Hartley
Dogs	Beagle Dogs (limited approval)
Mini Pigs	Göttingen minipigs (With collaborative partner)
Test Systems for Eco-toxicity	Fish, Honeybee, Earthworm, Daphnia, Alga, Piegon, Fowl, Japanese Quail

Offering Integrated End-to-End Biosimilar Development Solutions

Clinical Trials: Global Presence across USA, EU & Asia-Pacific

- Heathy Volunteers BE Studies (Phase I): Covering PK, PD, Safety, and Immunogenicity
- Phase III Biosimilar Trials: Advancing Biosimilars through Phase III trials, evaluating Safety, Efficacy, and Immunogenicity
- Phase I/III Integrated Studies for Oncology Biosimilars
- Phase IV Studies: PMS Studies & Pharmacovigilance services for Biosimilar

Offering Integrated End-to-End Biosimilar Development Solutions

Clinical Bioanalysis

Pharmacokinetics

- Primary and secondary clinical endpoints
- Quantify PK drug concentrations using sandwich/bridging ligand binding assay formats
- Bio-similarity assessment using One assay approach
- Incurred Sample Reanalysis
- Statistical calculations and report preparation

Immunogenicity Assessment

- Tier based immunogenicity testing
- Advanced sample preparation techniques (ACE, BEAD, SPEAD etc) for improved drug tolerance
- Functional Nab Assays-Cell based/competitive LBA

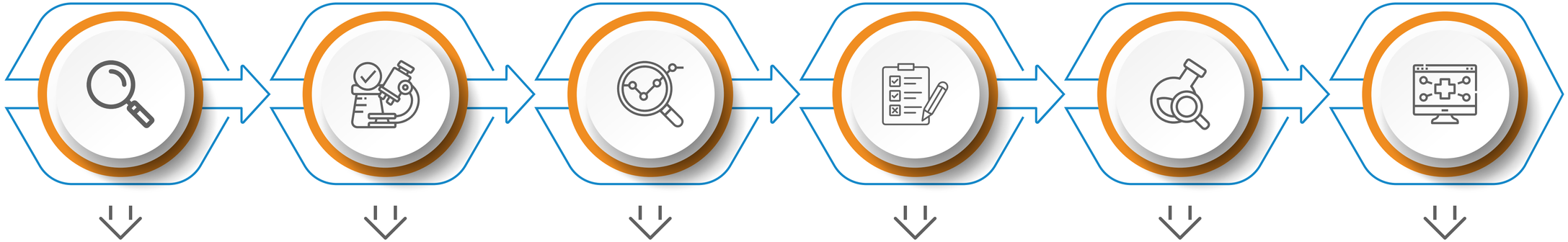
Biomarker/Pharmacodynamics Testing

- Serum PD Biomarker Levels
- Cytokine estimations
- High throughput Multiplex Assays

Critical Reagent Generation and Qualification

- Positive control generation for ADA assays
- Purification and labelling of critical reagents
- Qualification and optimization of critical reagents for assay performance and reproducibility

Our Infrastructure



Discovery Biology

- Tecan SPARK
- Biacore 1S+
- Luminex Intelliplex
- BD FACS Lyric
- Integra Assist Plus
- Agilent Novocyte

Bioprocess Development

- Vi-Cell XR Automated cell counter
- Neon Electroporator
- Single Cell Dispenser
- Cell Imager
- Inverted phase contrast microscope (Olympus)
- BioStat® B Twin (2 L/5 L) Bioreactors
- Biochemical Analyzer
- AKTA pure 150 M

Analytics & Characterization

- Waters Xevo G3 QTof
- Thermo QExactive Orbitrap
- Shimadzu Prominence
- Sciex PA800 Plus
- Postnova AF2000
- Applied Photophysics Chirascan V100
- Bruker Confocheck
- TA nanoDSC
- Anton Paar Litesizer 500

Preclinical Assessment

- Multi-mode reader
- Biacore system FACS System
- BSL-2
- 2D Gel Electrophoresis
- Cell counter
- CO2 incubator

Clinical Trials

- 16 Clinics with 588 Beds across facilities
- 22 Special Care Beds

Clinical Bioanalysis

- BioTek Synergy H1
- MSD Quickplex SQ 120
- Sciex 6500+ with Waters Acquity Premier
- AID vSpot EliSpot
- Integra Assist Plus
- Sample Management Area
- Cell Culture Lab

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Partners in creating a healthier tomorrow