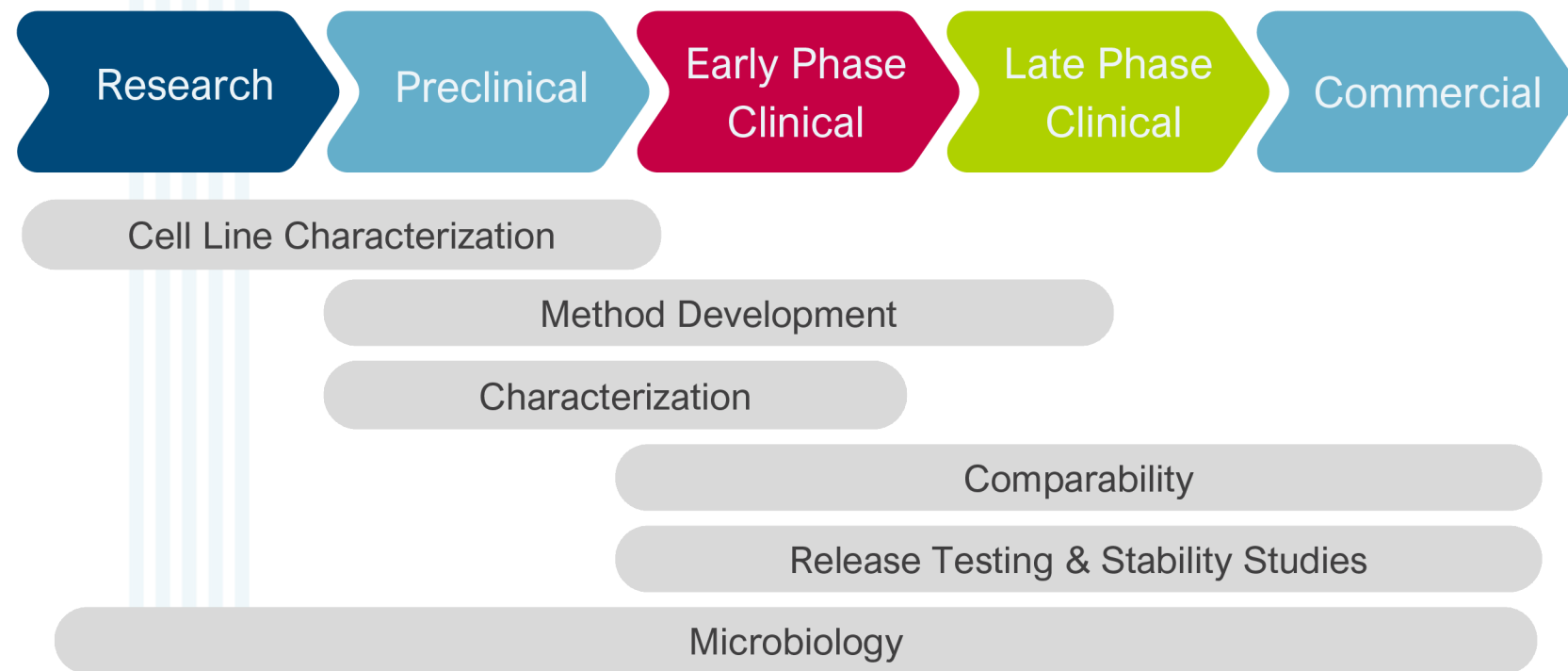


Bring **your innovation** to its destination

Meet every mAb and ADC **challenge** with a Solvias **solution**



Method Development and Validation

- Customizable analytical methods for flexibility and risk reduction.
- Orthogonal approaches for robustness.



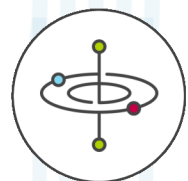
Genetic QC of CHO Cell Lines

- Cell Line Characterization: Ensure correct coding sequence.
- Monoclonality: Assure monoclonal derivation of MCB.
- Genetic Stability: Monitor genetic drift during production.



Biosafety and Microbiology

- Sterile and non-sterile raw materials, cell bank, bulk harvest and product testing.



Stability

- Stability-indicating methods validated for phase-appropriate testing.
- Comprehensive stability testing, including long-term and accelerated studies.



Characterization and Comparability

- Higher Order Structure**
 CD (secondary structure)
 DSC (thermal stability)
 HDX
- Primary Structure**
 PepMap
 AAA (including extinction coefficient)
 N-terminal Sequencing
- Size Heterogeneity**
 SEC or SEC-MALS
 Intact Mass (incl. DAR ratio)
 CE-SDS
 AUC
- Functionality**
 Cell-based Bioassay
 ELISA
 SPR
- Charge Heterogeneity**
 IEX
 cIEF and cIEF-MS
 CZE
- Heterogeneity and PTMs**
 PepMap PTM
 Disulfide Mapping
 Free Thiol
 Carbohydrate Structure (N-/O-Glycans)
 Conjugation Confirmation (site specific)
- Purity**
 SEC
 RPC

■ Dedicated ADC high containment facility

■ Expertise in managing ADC payloads with OELs as low as 5 ng/m³



Release Testing

- Identity**
 Sequence: Pepmap
 Charge: cIEF, CZE, IEX
 Size: SEC, CE-SDS
- Purity**
 Deamidation/Oxidation: gPepMap (UV/MS)
 Charge: cIEF, CZE, IEX
 Size: SEC, CE-SDS
 Toxin: Free Toxin RPC
- Potency**
 Binding ELISA
 Cell-based Bioassay
 SPR
- Impurities & Excipients**
 rProt. A by ELISA
 rHCP by ELISA
 rHC-DNA by qPCR
 Heavy Metals
 Extractables & Leachables
 Tween
 Antifoam
 NA+, Cl-
- Drug Antibody Ratio (DAR)**
 HIC
 LC-MS
- Primary Packaging**
 CCIT
 Appearance of container
- Description**
 pH potentiometry
 Conductivity
 Degree of Coloration
 Turbidity
 Osmolality
 Sub-visible Particles (LO, MFI)
 Visible Particles
- Biosafety and Microbiology**
 Bacterial Endotoxins
 Bioburden
 Sterility