

Addendum #4 : Experimental Endpoints – Antibodies

Experimental Endpoints of Interest for Antibodies

The following experimental endpoints were used to generate TuneLab™ models and represent the types of data that participating organizations contribute to the federated learning program.

Developability	Endpoint	Data Format
Core	Hydrophobicity/Aggregation (HIC)	Binary classification or retention time
Core	Thermostability (DSF T _m)	Binary classification or T _m (°C)
Core	Non-specific Binding (MSD-NSB)	Binary classification or binding score
Core	Solubility (PEG Precipitation)	Binary classification or mg/mL
Core	Immunogenicity Risk Score	Ensemble score (0-1) or risk category
Core	Deamidation Liability (LC-MS)	Binary classification or site identification
Core	Viscosity at High Concentration	Binary classification or cP at 150 mg/mL

Stability & Formulation	Endpoint	Data Format
Additional	Aggregation by SEC	% monomer over time
Additional	Freeze-Thaw Stability	Aggregate % after 5 cycles
Additional	Shear Stress Stability	Aggregate % post-stress
Additional	pH Stability Range	pH range for <5% aggregate
Additional	Oxidation Susceptibility	% oxidized Met/Trp
Additional	Isomerization Risk	% Asp isomerization
Additional	Fragmentation Propensity	% fragments by CE-SDS
Additional	Charge Heterogeneity	Main peak % by IEX

Binding & Specificity	Endpoint	Data Format
Additional	Species Cross-reactivity	Binary or EC50 ratio
Additional	Epitope Binning	Competition matrix
Additional	Target Specificity Panel	Off-target hits count
Additional	Cell Binding (Flow Cytometry)	EC50 or MFI
Additional	Tissue Cross-reactivity	IHC score panel
Additional	pH-dependent Binding	KD at pH 6.0 vs 7.4

Addendum #4 : Experimental Endpoints – Antibodies

Manufacturing	Endpoint	Data Format
Additional	Expression Yield (Transient)	mg/L in HEK/CHO
Additional	Expression Yield (Stable Pool)	g/L in CHO fed-batch
Additional	Protein A Elution pH	pH for 90% recovery
Additional	Host Cell Protein Clearance	Log reduction value
Additional	DNA Clearance	Log reduction value
Additional	Endotoxin Levels	EU/mg
Additional	Glycosylation Pattern	% fucosylation, galactosylation
Additional	Sialylation Level	% sialylated
Additional	C-terminal Lysine	% K0/K1/K2
Additional	N-terminal Pyroglutamate	% pyroGlu

Functional Activity	Endpoint	Data Format
Non-core	ADCC Activity	EC50 or % max lysis
Non-core	CDC Activity	EC50 or % max lysis
Non-core	ADCP Activity	% phagocytosis
Non-core	FcγR Binding Panel	KD for all FcγRs
Non-core	Clq Binding	KD or relative binding
Non-core	FcRn Binding (pH 6.0/7.4)	KD ratio
Non-core	Neutralization Potency	IC50 or IC50
Non-core	Agonist/Antagonist Activity	EC50/IC50
Non-core	Internalization Rate	t½ or % at timepoints
Non-core	Target Shedding Impact	Activity with shed target

Specialized Format Endpoints	Data Format
Bispecific T-cell Engagement	EC50 cytotoxicity
B Cell Killing (TCE)	EC50 B cell depletion
Cytokine Release (TCE)	pg/mL (IL-2, IL-6, TNF-α, IFN-γ)
Bispecific Dual Binding	KD for both targets
ADC Drug-Antibody Ratio	Average DAR
ADC Linker Stability	% intact over time
ADC Bystander Activity	Killing of antigen-neg cells

Addendum #4 : Experimental Endpoints – Antibodies

Fragment (Fab/scFv) Stability	Tm and aggregation
Nanobody Stability	Tm and aggregation
Fc Fusion Properties	Expression and stability
Antibody-Oligonucleotide Conjugate	Conjugation efficiency

Clinical Translation Endpoints	Data Format
PK Profile (Mouse)	t _{1/2} , CL, Vd
PK Profile (Rat)	t _{1/2} , CL, Vd
PK Profile (Monkey)	t _{1/2} , CL, Vd
Tissue Distribution	Tissue/blood ratios
Tumor Penetration	Tumor/blood ratio
Anti-Drug Antibody Incidence	% positive (preclinical)
In Vivo Efficacy	Tumor growth inhibition
Safety/Tox Findings	NOAEL or findings
Clearance (CL)	mL/hr/kg
Bioavailability (F)	% (SC/IM routes)
Biodistribution	Tissue concentration profiles